ARTICLES

Listening to the voices of the general public in India on biomedical research – an exploratory study

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Abstract

Medical research, from clinical trials to novel research on stored samples, is growing rapidly in India. Ethical regulations largely reflect standard international guidelines and the norms of "good clinical practice". Through in-depth interviews, this study aimed to explore the perceptions, motivations and concerns of the public with respect to participation in clinical trials and biobanking-related research. It was found that the expectation of therapeutic benefit reflects "therapeutic misconception" and this, along with a poor understanding of research, leads to favourable participation in clinical trials. A relatively low level of awareness and knowledge of health matters and research (health literacy), along with the differences in the power of the doctor and the participant, lead to an unquestioning trust in the physician or the institution conducting the research. "Informed consent" is thought to protect the interests of the researcher and the institution rather than the participants' rights. Biobanking research was very new to the participants and relatively unknown. Thus, it has not yet filtered into the public consciousness. As a result, the perceptions of the general public do not appear to be sufficiently evolved.

Introduction

Healthcare practice and the ethics of research in India may be different from what we find in western countries (1) due to the influence of sociocultural factors, such as poor literacy, traditional social groupings, the power dynamics between physician and patient, inadequate access to healthcare, and deep-rooted cultural, traditional and religious beliefs (2). Given this scenario, the involvement of the public in ethical deliberations is a central bioethical concern (3). The argument for a lack of discourse is that the public has limited knowledge of healthcare practice and the ethics of research, especially in the area of science and technology (4).

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In India, the studies conducted on public opinion or public perceptions regarding research have primarily involved participants in clinical trials, and have aimed to understand their decision-making regarding participation (5,6). However, other studies have shown that work with non-participants leads to a wider and a more nuanced understanding of the ethical processes linked to research (7,8).

The collection of human biological samples (blood/tissues), their storage in "biobanks" and subsequent research on them have been spurred on by advances in the storage of samples, an understanding of the human genome, high-throughput laboratory assays, improved processing and management of data, and extensive collaborative, international research (9–12). The ethical issues related to biobanking research range from broad consent to confidentiality in genetic research, ownership issues and benefit-sharing (13–16).

We do not know what the Indian public thinks about biobank-related research and their participation in it (17). This qualitative exploratory study aims to:

1. Understand public perceptions regarding biomedical and biobanking research and their ethical concerns
2. Gain insights into how the rights of research participants are protected
3. Explore ways of promoting ethical practices in biomedical research so as to protect the public's interests and help them to trust the research process.

Methods

Study setting and participants

The study was conducted in Bangalore in the south Indian state of Karnataka. Purposive sampling was done to obtain respondents from a wide age range; engaged in a variety of occupations; belonging to both genders; and with or without a chronic disease, such as diabetes or cancer. Seven participants were known to the researcher (first author) and were contacted over the telephone to fix a meeting. The names of the other participants were suggested by personal and professional contacts in the Department of Oncology and Endocrinology at the medical college where the authors are working. Sampling was stopped at 14 participants as "information saturation" had been reached.

Study design

In-depth interviews were chosen as the method of data collection as this method is particularly useful in understanding the reasons and beliefs underlying people's responses and practices. The first author, who is a postgraduate in social work, the member of an ethics committee, as well as a member of the Human Research Protection Programme, has many years of experience in qualitative research. It was she who conducted in-depth interviews with 10 of the 14 participants. These were primarily in English, the language of choice of the participants. She was present while a research assistant more fluent with the local language, Kannada (also known to the researcher/first author), and familiar with interview techniques, conducted the remaining four in-depth interviews.

Participants willing to spare an hour were interviewed at a location of their choice.

Data collection instrument

The data collection tool had two parts. A structured questionnaire sought information on the sociodemographic details, any history of previous participation in research and the healthcare provider accessed by the participant. The second part was a semi-structured interview guide, using two hypothetical case vignettes with broad questions and structured probes. Vignette 1 was about participating in a vaccine trial and Vignette 2 about contributing a blood and tissue sample for biobanking research. Each vignette followed an unfolding design which was explained to the participants as a real-life situation, putting them into the hypothetical context of the case. [The interview guide with the vignettes is available with the first author.]

The interview guide was pilot-tested, finalised, and then administered over January and February 2014. All interviews were recorded using a digital voice recorder and transcribed by two external agencies. One of these transcribed the English interviews and the other, the Kannada interviews. All the transcribed data were in English. In addition, field notes were made by the interviewers and added to the transcripts.

Data analysis

The interviewers first reviewed the transcripts. They simultaneously listened to the audio recordings and read the transcripts to check for the accuracy and completeness of the content and translation. The first author, who was the principal investigator, re-read each transcript and the field notes, and prepared a coding tree with broad conceptual codes and sub-codes. Coding was done manually. Coding and interpretation of the data was an iterative process. The method of assigning codes was primarily inductive and this was defined as more data were analysed (18). The process was guided by the principles of grounded theory and the "constant comparison" method of coding (19).The themes which emerged from the analysis were *a priori* (predetermined while developing the instrument) to some extent, but also *de novo* (participant-generated) (20). The themes have been discussed under the results, as well as in the concluding paragraphs.

Ethics clearance

The study was approved by the Institutional Ethics Committee of St John's National Academy of Health Sciences (IERB Ref No.86/2013). The purpose of and procedures employed by the study were explained to illiterate subjects verbally and audio recorded. All participants learnt about the purpose of the research and the researcher's personal goals from the information sheet accompanying the consent form. Written informed consent was obtained from all participants. Six people contacted to participate in the study refused, some because of lack of time and others because of uncertainty regarding their knowledge of the subject. Study IDs were used to maintain anonymity.

Results

Participants' characteristics

There were 14 participants in all (18–73 years of age; 6 female). Table 1 provides the occupation, education, and family income profile of the participants. Most of them were from the higher socioeconomic strata. Seven had a family member connected with a hospital or the medical profession. Five had a history of a chronic medical condition (hypertension, diabetes, cancer) which may have required hospitalisation in the preceding six months. Though six respondents stated that they had not been involved in research earlier, it emerged later that one had participated in a nutritional supplement study, one in an interview-based study and one in a clinical trial which he thought was a "scheme" (70-year-old male, Participant 13).

Table 1
Occupation and socioeconomic profile of the participants

Occupation	Who	Education[a]	Monthly family income[b]
College students	Participants 3, 9	4, 4	5, 5
Housewives	Participants 1, 14	5, 3	5, 1
School, college teachers	Participants 2, 11, 12	6, 6, 5	5, 5, 5
Business persons/ professionals	Participants 4, 7, 8	5, 5, 5	5, 5, 5
Domestic workers/ cleaners	Participants 5, 6	2, 1	2, 2
Retired	Participants 10, 13	5, 2	4, 1

[a]***Education**: 1=primary, 2=middle school, 3=high school, 4=pre-university, 5=diploma/degree, 6=postgraduate and above.*

[b]***Monthly family income**: 1=<Rs 8019, 2=Rs 8020–12,019, 3=Rs 12,020 –16,019, 4=Rs 16,020–32,049, 5=>Rs 32,050.*

Perceptions of research

The respondents had varying ideas about research. The non-English speaking participants had not heard the word "research" and were not familiar with the words for it in

the local language – "*adhyayana*", which means "study", and "*praayoga*", which means "experiment". In general, those who knew of "research" perceived it as in-depth study required for progress in any field to improve the quality of life. Biomedical research was considered important and there were a lot of positive expectations linked to it. This is illustrated by the following quotes: "it makes life better"; "deaths have reduced because of medical research"; and "... cures for cancer and other new things will come out". A negative aspect of research mentioned by the respondents was the unethical practices related to research participants, eg "using people as guinea pigs" and "inhumane treatment". As for researchers, mention was made of "fudging of data or fudging of results", "plain profiteering" and "scams". Apart from one person who spoke about a recent vaccine trial involving a tribal community and the deaths of some of the young girls who were study subjects, none of the others supported their views by citing any research incident, either historical or recent. Television and the newspapers were the participants' main sources of information on research.

Vignette 1 - Willingness to participate in a hypothetical vaccine trial

With respect to the willingness to participate in a hypothetical vaccine trial, the respondents fell into three categories – those who would never take part in a trial, those who were unsure about whether or not to participate and those who were willing to participate.

Most respondents belonged to the "unsure" category. Their doubts were related to the absence of sufficient information, a fear of harm and side-effects, and the need for a second opinion. What they wanted, first and foremost, was more information, primarily on the possible side-effects and to a lesser extent, on why such a vaccine was needed and why the existing treatment was not sufficient. These respondents belonged mainly to the higher socioeconomic strata. They had a better understanding of research and were more discerning with regard to their health-related decision-making.

The few respondents who were clear that they would never take part in a trial were sceptical about research and the need for new vaccines, and had doubts about the motives of the doctor.

> - *"As long as it's under research and not proven, I will not take part."* (37-year-old male, Participant 7),
>
> - *"This is all a marketing gimmick. I don't want to be taken advantage of."* (50-year-old male, Participant 8)

The few who were immediately willing to participate happened to be women. They had a poor understanding of research and appeared to be driven by altruism: "… nice to help out" (36-year-old female, Participant 5). Therapeutic misconception was the explanation in other cases:

> - *"I want to get well. If the doctor says I need it, I must take it. I need to look after my children."* (28-year-old female, Participant 14).

Process of decision-making and influencing factors

1. *Asking questions*: The category of respondents who were willing to participate and a few others would not have any questions to ask of the doctor prior to participating in the hypothetical trial. They were the less educated respondents, who were either patients undergoing treatment in the hospital for a terminal or chronic illness and/or who did not know the meaning of research. They appeared to have limited autonomy in terms of their choices and decision-making. They lacked sufficient information, yet were unwilling to seek clarifications. This speaks of the power and authority structures between researchers and participants, especially those coming from a lower socioeconomic/educational background, as reflected in the lack of desire to challenge the doctor's authority.

   > - *"The doctor knows best. I will not ask questions, it might insult him. Must follow what MBBS says."* (Participant 13)

2. *Role of information*: Some of those who were doubtful would consider joining the study if they were given convincing replies.

3. *Role of the treating or family physician*: An important factor that affected the willingness to participate in a trial was the influence of the family doctor or the regular treating physician. As one participant said,

   > - *"Because he is a family physician, one would trust his judgment. I think there would be a sense of trust and I would participate. I mean if I don't, I question his judgment. Then there is a question of why is he my family physician?"* (24-year-old male, Participant 4).

   According to another,

   > - *"Our belief is with someone we know, who is next to our house. He will give a prescription slip, we will buy and take it (the medicine)."* (22-year-old male, Participant 6)

4. *Role of the family or another doctor*: While decision-making was claimed to be autonomous, consultations with others, such as family members and a second doctor, were considered necessary.

   > - *"I'd make the decision on my own.... maybe I would consult my GP."* (40-year-old female, Participant 1)

5. *Role of community*: Before reaching the decision-making stage, the participants considered it empowering to hold discussions with the wider community from which other participants were expected to come forward. The level of questioning (the researcher) would also increase when they were in a group.

   > - *"Better if they tell us in front of everyone. Then we can discuss. They can ask us all together. Then there's no problem. Even when my mother has to decide something, she consults the neighbours."* (Participant 6)

Consent – the perceived meaning and implication

To nearly all respondents, "to consent" meant "to agree" and they did this by signing. They also felt that it was good

Table 2
Perceptions of the implication of "giving consent"

Themes (*de novo*)	Data
Waiving of signatory's right to prosecute	*"Giving my consent is to agree, and to waive my right to ever trying to prosecute him (short laugh) if something went wrong."* (24-year-old male, Participant 4)
Responsibility of consequences on me (the subject)	*"I'm aware of what I am getting into and I am responsible in case anything goes wrong."* (37-year-old male, Participant 7) *"If there were any consequences stated, then by signing I agreed to having them...so... if something happens to me, they know that I signed willingly."* (18-year-old female, Participant 3)
Responsibility of consequences on the doctor/ protects me (the subject)	*"They will ask to sign, I will sign. They will look after us after signing the form."* (28-year-old female, Participant 14)
Protects doctor/ researcher/ institution (*n*=11)	*"I feel it's generally…more biased towards safeguarding the company. It is a disclaimer, allows a company to say that you are responsible for your actions."* (21-year-old male, Participant 9) *"It helps the doctors, not me certainly, because I am consenting to this."* (50-year-old male, Participant 8)

to have such a process. Table 2 presents the range of views regarding consent under different themes. Noticeably, most felt that signing the consent form gave more protection to the doctor/ researcher and hospital than themselves. Thus, while the needs of the researcher are fulfilled by the signing of an informed consent form, the perception of the public regarding this raises several questions – Is it a legal formality? Do they see withdrawal of consent as a truly viable option? How binding do they think consent is?

Protecting the participants' rights through an empowering "consent" process

To reverse the notion that the consent form primarily protects the interests of the researcher, an idea which emerged from a few initial respondents, and got vigorous support from subsequent respondents , was to get an undertaking signed by the doctor/researcher. The undertaking would not only explain the details of the procedures, but also provide a guarantee of prompt medical attention in case of adverse events. The aim would be to give the participants a clear idea of the responsibility of the researcher and clarify the researcher's position on potential harm during the study.

Respondents who were educated and from the higher socioeconomic strata suggested that participants in trials must thoroughly understand the information given in the form, and think over their decision carefully before signing,

> - *"Make sure you read it and understand as much as you can …about what is being done."* (Participant 4)
>
> - *"People should know why they are signing, to what they are consenting, what are the implications of the consent."* (Participant 1)

The participants were not aware of the role of ethics committees in protecting the interests of research participants or in addressing violations of their rights. One person raised the need for a neutral patient-centred group in the hospital to do this job. He said, "Need to have a group manned by honest people who should guide the patient to explain the benefits, the harm, what will happen to your family if you die" (73-year-old male, Participant 10). Does this suggest that an institutional ethics committee (IEC) could play a wider role, beyond its regulatory functions, to cover the protection of participants? Is there a need for more proactive dissemination of the role of the IEC and human research protection committees (where they exist) to potential research participants, beyond a cursory mention in the consent form?

The respondents were not familiar with the rules or regulations on biomedical research and expressed a sense of hopelessness with respect to cases of medical negligence or violations of the rights of research participants. The main causes of this were: (i) the difference in the power equation between doctors and participants, (ii) the fact that it would be too late to change things once the damage has been done, and (iii) a lack of knowledge of the procedures for resolution, or the fact that they were too long drawn out. These feelings are illustrated by quotes such as, "We are small and they are powerful," and, "There is nothing we can do, the damage is already done."

The participants unanimously agreed that all patients or all those taking part in research must be made aware of their rights, who they can approach to lodge a complaint, and what steps they can take. Given that the information on who to approach and how to make a complaint is stated in a consent form, the important issue here is the extent to which this information is internalised during the consent process. Addressing this might make "informed consent" an empowering process that addresses the power imbalance between researcher and participant. It is a matter of concern that the consent form could well be an instrument which further enhances the power imbalance, particularly when the participants are illiterate and/or poor. Considering that the participants were less likely to question their treating physician during the enrolment and consenting process due to the greater degree of trust between them, the question arises as to whether the treating physician should be involved at all in the consent process.

Money matters – free vaccine, payment to participants and incentives to researchers

Perceptions of the ethics of monetary transactions in research were dealt with at three levels: the product, the participant and the researcher.

Product: Educated participants from higher socioeconomic backgrounds felt that the product needed to be free so as to serve as a motivation for participating; to make participation easier for the "common man"; and as a logical requirement for something that was under research and hence not on sale.

> - *"It must be free. It's then a win-win situation for both."* (18-year-old female, Participant 3)

"Free" meant "inferior" to some, mainly from the lower socioeconomic strata. This seems to stem from a lower level of trust and results in less trust as well.

> - *"Free is dangerous", "If they say free, I won't trust it. … there will be something in there, right? Something will come from it, that's the fear."* (Participant 6)
>
> - *"If free, then the medicine might have less power, less quality. If it is free treatment, then they might not care so much. As in government hospitals, they will treat us carelessly."* (Participant 14)

In addition, if a participant perceived of the research as therapeutic, expecting it to lead to a recovery from illness, there was a definite willingness to pay in order to make the researcher feel responsible for "good treatment".

> - *"When they are taking money they will make sure they will give us service, but in government hospitals anyway they are not taking money. Therefore, they will give some medicine and injection and send us away."* (Participant 14)
>
> - *"If it is good for me, then I will have to pay."* (Participant 5)

The costs were not a deciding factor for their participation. Investigators need to explain to participants that integral to the process of research is the concept of "non-payment" for something experimental within a research study. It is clearly unethical for a participant to pay for something experimental. In the absence of the understanding that research products or procedures had to be free, the notion of "free" investigations or treatment could constitute coercion to participate.

Participants: Paying for participation, just like receiving the test product free, was considered anathema by the category of people who did not have a good understanding of research and had a higher therapeutic misconception.

Some felt that payment was their right or their due. They described it as "appreciation for taking part" and "a necessity if the rules say so", and said it was "required to compensate for the risk or inconvenience".

Payment was also considered an incentive: "A cash incentive would really help a lot … considering I'm a student right now" (21-year-old male, Participant 9). Others saw it as a means of holding on to the participant, maybe for the purpose of compliance, follow-up, and so on: "It will also ensure the participant is accountable." (Participant 9)

In the eyes of a few sceptics, payment denoted being bought up by the sponsor or institution, which meant that the sponsor/institution no longer had a responsibility towards the participants, who possibly became more vulnerable.

Researchers: The difference in opinion on the main ethical issue regarding payment to the researcher appeared to be one of "degree". Those participants whose major reason for participation in research was altruism expected the doctor/researcher to have the same attitude and thus, felt that payment was not acceptable.

> - *"Never, it's bad! They should not take money from companies. It should be part of their service."* (Participant 5)
>
> - *"I think if the doctor is already being paid, I don't see why he should be paid more for us going voluntarily and participating in the study. I wouldn't do it then..."* (Participant 3)

Some felt that it was reasonable and "fair" for the researcher to be paid.

> - *"The company or the agency that is promoting it (the research) has to pay. It is absolutely fine; I mean they (researchers) have put in their hard work."* (Participant 7)

The quantum of payment needed to be "reasonable", otherwise it would be "an unethical push beyond a tipping point". The participants would feel uncomfortable about the motives of the doctor/researcher if the incentives and payment were high: "The focus of the doctor would be more on the payment than the patient."(Participant 14)

Payment in terms of "recognition" and "a name" through publications and rewards were also mentioned.

There was a categorical rejection of the idea of doctors being paid per patient as "it defeated the very purpose of research" and made the research "unethical". The doctor /researcher was expected to stand up against such pressures.

> - *"It's definitely not okay, and the doctor should put his foot down and refuse it. It's like the doctor is being given a cut."* (Participant1).
>
> - *"In the field of medicine, that doesn't really make sense. For the doctors … they shouldn't be paid on the number of patients, especially when it comes to research. They shouldn't experiment on more and more number of people…it shouldn't be on that number basis."* (Participant 7)

So do participants expect to know if researchers are being paid to conduct the research? Some felt it was "better to know upfront". Another participant said that "the process will be transparent". It was felt that knowing the truth would ensure a positive, trustful approach to the study. "It would be more ethical to have it disclosed and I would feel happier. I would say it's quite positive if it was disclosed." (54-year-old male, Participant 2)

Sharing of benefits

The concept of the sharing of benefits after a successful research study, especially one that has commercial returns, was new to the participants. Those who had not had a proper idea of the meaning of research and were from the lower economic strata understood the idea of companies making profits through the manufacture of the drugs, but were not clear about the concept of the sharing of benefits or profits. To those who were decided that they would not participate in the trial, this issue was irrelevant.

In the view of the few who responded, the following two approaches could be used for meaningful benefit-sharing.

(a) A community development approach: "Because the returns in the pharma industry are huge, they really need to contribute back. I think the best thing is to give back to the medical field. Try and facilitate or provide low-cost healthcare for the underprivileged because India is a country where there is a huge absence of quality healthcare for people who cannot afford it..." (Participant 1)

(b) A participant-focused approach: "When things were unsure we agreed to take part in the study, so if it turns out well and it is benefiting other people, then probably they should do something … I think in any way that would make anyone happy. Just to appreciate what we did for the other people..." (Participant 3)

Vignette 2 – Biobanking research: from no concerns to some concerns

Willingness to contribute a biological sample

To begin with, nearly all the participants readily agreed to have their blood and tissue samples stored for future research once their diagnostic tests had been carried out. The primary reason was that it was "anyway a waste for me", the tissue was already outside the body and hence, there would be no harm to the body. The participants expressed curiosity about whether biological samples were stored routinely, but said that it did not matter to them if the practice was helping others.

As this area was probed further, some doubts and concerns were raised. The concerns included questions such as: who was conducting the research, where it would be conducted and what the research was about. By now, half of those who had agreed to participate were asking such questions: "My only doubt is what they will do by taking it…" (Participant 6), and "I will be concerned if the place is not known; I will trust only a known place" (Participant 9). Trust in the individual and the institution could thus be important factors in determining people's willingness to participate in this form of research.

Consent – needed or not needed

Gradually, there was a shift in perception from not wanting to be asked for their consent (for something that was considered a "waste" and to be of no apparent risk or harm), to feeling the need for it in situations in which the person/institution was not known and trustworthy, preferring to be given some information on the research.

> - *"It would be nice to know … the more transparent they are, the more you tend to repose faith in them."* (Participant 1)

A few participants, who could not be sure of the intention of the researcher, were in favour of detailed and specific informed consent. They did not wish to be taken for granted and wanted the researcher/sponsor to be accountable to them. E-mail was suggested as a means of seeking this detailed consent.

> - *"We should be told … the details of who is supporting the research, why it is being done, because something general like 'good cause' is relative. They can send an e-mail and I will say Yes or No if I am convinced. They cannot take it for granted."* (Participant 4)

Another suggestion was that the option of detailed or general consent be given to the sample contributor at the time of the initial consent.

Biobanking and genetic research

The participants displayed considerable excitement about and a positive response to the possibility of conducting genetic research on a contributed sample. About half of them stated that they had some degree of familiarity with the broad area, while others had little or no knowledge.

Of the respondents who knew about genetic research, most had more positive expectations from genetic research than concerns, both of which they found difficult to articulate in specific terms (Table 3). They did, however, voice some definite concerns, including those related to the misuse of samples, ethical dilemmas related to preventative medical action (eg, a mastectomy performed on a US actress on the basis of a genetic marker she was carrying), commercial exploitation, the manipulation of nature, and eugenics. The participants felt that engaging in a discussion on these issues had been an eye-opener and made them more circumspect about giving blanket consent. "They should inform us if they are doing genetic research. It will make them a little accountable ... Otherwise, they feel they can do anything." (59-year-old female, Participant 11) This again seems to indicate that a little awareness makes participants more discerning and sceptical, and reduces the tendency to trust blindly.

Table 3
Perceptions of potential benefits of and concerns related to genetic research

Benefits	Concerns
Generally good: They are doing these things for the good of society. It will be good; it may help children in the future. It may be useful; it could be good for us. Specific benefit: It can prevent diseases.	Misuse / harm Things could go wrong and there could be misuse of the research. If it is not for the preservation of health, then it is not to be done. As long as it is not harming people, it is all right. Eugenics There is a thin line between research for treatment and trying to create maybe physically better people or trying to play around with nature. It is all right as long as it is not going to change the way people are. Commercial exploitation by selling, they must not exploit the patient in any way.

Use of clinical data and medical records in biobanking research

The utilisation of hospital records and the individual's clinical data for sample-linked research was perceived of as non-controversial, as long as these were being used for beneficial purposes and confidentiality was maintained.

> - *"If something can be learnt from that, then good."* (Participant 10)
> - *"No issues, if helpful for the research."* (Participant 1)

Some, however, preferred it if they were informed about why their medical data was required and felt that it should be used only after they had been informed. The legal position, that medical records are the private possession of the individual, in the custody of and held in trust by the institution housing them, was not mentioned at all.

Confidentiality was considered important by all, with the exception of one participant. This participant felt strongly that only those who had something to hide would be concerned about confidentiality and that this was not the case with the "majority of people in India". The use and disclosure of the details of one's illness and medical history, though without the mention of one's name and personal identifiers, were considered acceptable. A few respondents were in favour of "restricted disclosure", ie disclosure to only those concerned with the research. There was some fear of possible stigmatisation from the disclosure of illness-related information to people outside the medical circle. "I'll feel bad if friends get to know. They won't meet me anymore." (Participant 14)

A member of the younger generation was concerned about the challenges of technology and the security of electronic information: "Confidentiality means not to be tracked. But in today's age, they can hack and find out anything if they want to…" (Participant 9)

The participants were asked for their responses on the question of if anonymisation were seen as the best way of maintaining confidentiality and one of its consequences was the inability to contact them to share the individual findings. Interestingly, some respondents preferred the option of being contactable, especially in the case of genetic research.

Ways to ensure public trust in medical research

The participants made some rich and varied suggestions with regard to improving and ensuring public trust in medical research. These were:

1. Greater transparency, honesty and disclosure are required on the part of the researcher/doctor.
2. The commercial interests of researchers or research sponsors should not be at the expense of people/patients and ethics.
3. Research should be better monitored.
4. The doctors involved in research should provide better healthcare and treatment, especially in the case of medical complications occurring during the study.
5. Discussions should be held not just with individuals, but with significant others (family physicians, family, community).
6. The researchers should communicate with the participants and express their appreciation of the latter at the end of the study.
7. Research needs to be demystified for the public and good research should be given greater publicity.

The themes have been elaborated upon in Table 4.

Comparing perceptions of the two forms of research – biomedical interventional and biobanking research

It was rather difficult to compare the two types of research, not only because the procedures and implications of each are very different, but also because the participants' level of familiarity with the two types varied.

In the case of both types of research, participants who had a greater knowledge and awareness of the functioning of hospitals and research had a better idea of the risks and more doubts. They felt a greater need to question, and were more hesitant or discerning when it came to participating in research. Individual circumstances, such as socioeconomic background, level of education, health status and awareness regarding research, emerged as important factors that influenced perceptions. Trust was associated with positive experiences, ie confidence arising from what has previously gone well.

While both types of research have their own implications, those of biobanking became apparent to most people only after discussion, once they had developed a better understanding of the issues linked to this type of research. This confirms the role of knowledge and awareness in helping people make informed choices. Informed consent with detailed information at the time of a particular study, instead of a blanket or broad consent, was considered essential by those who were sceptical about research and the motives of researchers and did not want to be taken for granted. On the other hand, therapeutic misconception and the power imbalance between doctor and patient played a more pronounced role especially among those from the vulnerable category of the chronically or terminally ill and/or those of a lower socioeconomic status, making them more amenable to participating in a clinical trial.

Conclusion

This study has yielded several lessons on the perceptions of the public with regard to participation in medical research studies.

One category of subjects consists of the "believers/followers", who have great trust in the doctor, are accepting of what the doctor says, do not have a great need to seek details

Table 4
Perceptions of ways to ensure public trust in medical research

Suggestions on particular themes	Specific views
Greater transparency and honesty and more disclosure by the researcher/doctor	*"The trust from the subject's side will grow with more transparency from the organisational side. If everything about the economics and all other things are told to you upfront, at one time ,then you can understand and digest what is being said then the trust will automatically grow."* (Participant 2) *"Honesty, this is the only thing which will help, in the long run. You have to talk in the vernacular of that particular area and the truthfulness of the people conducting the trial should be there. Then people will be more comfortable. The ethics committee should be doing that part …They should be honest in every respect. The compensation they all are getting should be declared openly."* (Participant 10)
Commercial interests not at the expense of people/ patients and ethics	*"Profit is important but don't do it mercilessly at the cost of people. People should not be treated like goats and sheep for the sake of a company's profits. The interest of the patient should be foremost."* (Participant 1) *"When it comes to the medical field, ….it's somebody's health in your hands, somebody's life in your hands. So I think ethics is a very integral part of it. You cannot detach the ethics from the practice. So it is very important for me that the doctor I go to is ethical and not purely commercial."* (Participant 11)
Better monitoring of research	*"..I would hope that there would be an independent authority that would oversee the research that is being done. Because it would be more helpful for the participants to know that we are not fighting individually. And if we do have a problem, we know that it is not just our problem – there is an authority. I guess also an independent body would make the research more credible. …. I think a large independent body could be beneficial."* (Participant 4) *"There should be a health ethics body, but they should have teeth and they should have integrity, to be able to resist pressures and to be able to punish wrongdoers. It could be a quasi-government body with a mix of private individuals and other institutions; it would have to be a mixed body. It should have ordinary lay citizens as well."* (Participant 1) *"… There are professional ethics for any profession. For a field like medicine, definitely ethics are to be followed. So long as this is ensured, we are fine."* (Participant 7)
Better healthcare and treatment by doctors	*"By giving good treatment, the doctor is trusted. We will have confidence in them and will trust them."* (Participant 8) *"I don't think doctors should be running after money. Their main thing should be to take care of a patient and make sure they are okay rather than how much money they will get from the particular thing they are doing."* (Participant 3)
Discussions not just with individuals but at the community/group level	*"Better if they tell us in front of everyone. Then we can discuss. They can ask us all together. Then there's no problem. Even when my mother has to decide something, she will consult with the neighbours. We won't ask just one person; we will confirm with at least 2–3 people."* (Participant 6)
Communication and appreciation at the end of the study	*"Some sort of appreciation at the end of the study, which will help."* (Participant 3)
Demystifying research and publicising good research for the public	*"Like now, people are donating their organs or the organs of dead relatives all because they feel it is going to be for something good. Hence, they are willing to go through all the trauma … Publicity has to be built up around these positive things."* (Participant 2) *"I guess if the whole idea of research was brought into public view – not all air-conditioned rooms with key card access, sliding doors, people with masks and lab coats, all fancy futuristic things and Spiderman-like outcomes – it will help people to relate to research."* (Participant 4)

(whether about the product, payments or the impact of the research on themselves), are highly dependent on the medical system for decision-making, are comfortable with a paternalistic relationship with the doctor, and overall, have limited autonomy. The lack of knowledge or awareness of research among these subjects may lead them to expect only a therapeutic encounter with a doctor, rather than an uncertain outcome with potential risk ("therapeutic misconception") (21).

Another category of subjects is that of the "doubters/fence-sitters". These have limited information on research, health and medicine, but consider knowledge to be empowering and hence, seek information that will enable them to make decisions. Such persons will question, be discerning and make informed decisions. They may turn cynical too. They may also become blind "believers" if the physician/ researcher/institution has credibility, is known to them and is "trustworthy" in their eyes. Thus, they are willing to accept "blanket" or "broad" consent in research-related situations, including in biobanking research. "Convincing answers" from the doctor/researcher and an openness and transparency in disclosure, especially in terms of payments to researchers, the purpose of the research and the expected outcome, reduce these subjects' perception of risk.

The third category is that of the "sceptic/cynic", who is sceptical about the outcomes of research, raises questions about the motives of the doctor/researcher, has a relatively greater mistrust of the doctor and the healthcare system, and feels that both research based on clinical trials and biobanking research entail quite a high degree of risk. These subjects strongly feel that informed consent is tipped against the patient/participant and more protective of the doctor. They would always require detailed information on a study and never accept a blanket or broad consent.

***Perceptions about the "researcher"*:** Some people look upon the researcher as a paternalistic figure whose decisions are

in the best interest of the client. Others feel that researchers have the requisite knowledge, and expect them to inform the participants about the research, treat them with respect and be accountable. The subjects feel that it is "fair" to pay the researcher, but it is questionable if the payment is "too much", beyond a "tipping point". The disclosure of the amount paid to the researcher for conducting the study, as well as of payment per patient, is considered desirable in the spirit of transparency and trust. Mutual altruism is considered ideal. The concept of a doctor also being a researcher, when the encounter is primarily therapeutic, is difficult for people to comprehend.

Perceptions about "research": Essentially, research is seen as something which is good, but which can lead to the exploitation of people. The lack of knowledge of research makes the patient/participant somewhat vulnerable. It reduces the effectiveness of the informed consent process, and the participants' lack of comprehension of the risks and benefits of the research gives rise to misconceptions about whether the research outcomes are the established or newly proven therapy. The challenge before the medical fraternity is how to translate the word "research" into the local language and then handle the repercussions of an improvement in the understanding of research, ie more questioning and greater willingness to participate (22,23). This is the present situation with respect to biobanking research and similar situations could arise in the case of new technologies and forms of research as well. Such a situation would be perpetuated if people continue not to know enough to make informed decisions, and if there are no guidelines or they are in a nascent form.

Role of ethics committees: From the point of view of the public or prospective participants, there is a clear need for a body that can protect their interest and to which they have recourse. At present, the name and contact information of the IEC on informed consent forms has not been observed (though this is beyond the scope of the study). It seems desirable that ethics committees move beyond their "institutional" role to a more "public" role, whereby potential participants are informed not only about the existence of IECs, but also about their roles, responsibilities and commitment to participants. Regular monitoring of the research process onsite and frequent interactions with participants are also an important responsibility.

Moving forward

A limitation of the study was its small sample size. The study has, however, considerably expanded our understanding of people's perceptions of research in India, and this can serve as a basis for more focused enquiry into the area. A fair number of the participants were from a higher socioeconomic group and hence, were possibly more articulate and able to voice independent views than the average member of the general public. Although the perceptions of the participants appear to be grounded in their educational levels, economic categories and previous familiarity with research, further research using mixed methods is required to draw firm conclusions. The value of heeding the opinions of the public on the ethical functioning of service providers, researchers and other people in power has been widely established in disciplines such as medical sociology, political science, anthropology and other humanities. Public deliberation has led to a bottom-up demand for standards to be met, the formulation of people-centric regulations and policies, and methods to ensure that they are followed (24–26). There is a need to work further on "public deliberation" as a research method in the development of regulations in the context of biobanking research.

The concepts of "health literacy" and "health-related locus of control" seem to be relevant when attempting to understand the empowerment of human participants in research (27,28). This needs to be explored further in the context of health-related decision-making and research participation among the three categories of people that emerged from this study.

In conclusion, in a heterogeneous, complex society like India's, an ongoing engagement with the members of the public is required to understand their diverse views and dilemmas, and to engage them in the formulation of relevant policy and in the consequent debates on ethical matters.

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Access to controlled medicines for palliative care in India: gains and challenges

SUNITA VS BANDEWAR

"It is critical to provide attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity."

—UN Committee on Economic, Social and Cultural Rights

"The failure to ensure access to controlled medications for pain and suffering threatens the fundamental rights to health and to protection against cruel, inhuman and degrading treatment."

—UN Special Rapporteurs on Health and Torture

Abstract

It was in the early 1990s that an appeal was made, both in India and globally, for access to palliative care to be treated as a human rights issue. Over the past few years, India has witnessed robust advocacy efforts which push for the consideration of palliative care and pain management as a human right. Central to this paper is India's Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985: its genesis, its critique, and the amendments aimed at enhancing access to the NDPS for medical care and research. I refer to the advocacy efforts in India, particularly the most recent ones, which led to the amendments to the NDPS Act, 1985 in February 2014; and the contribution of the global and local human rights discourse on palliative care to these efforts. This I situate in the overall status of palliative care in India. Towards the end, I briefly set out the agenda that should be pursued in the coming years to enhance access to controlled medicines for pain management and palliative care.

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Introduction

In the early 1990s, an appeal was made, both in India and globally (1), that access to palliative care (PC) must be treated as a human rights issue. Among other things, access to controlled medicines, that is, narcotic drugs and psychotropic substances (NDPS), remains central to the realisation of the human right to PC. Access to NDPS is often regulated and controlled around the world, including India, to contain their (ab)use for non-medical and harmful purposes. Over the past few years, India has witnessed robust advocacy efforts aimed at changing the situation and ensuring that PC and pain management are recognised as a human right.