**Title of the article:** A survey of knowledge and variables influencing perceptions about Clinical Research: a cross sectional study from Mumbai

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**ABSTRACT**

**Objective**:

The clinical research in India has been besieged by controversies. While studies have addressed other stakeholders, few have addressed the patient. The present study was conducted to assess extent of awareness and understanding about the nature and conduct of clinical research amongst people of Mumbai.

**Methods**:

*Ethics*: Institutional Ethics Committee approval was taken [EC/OA-12/15] and written informed consent was obtained from the participants.

*Study Design and setting*: A prospective cross sectional study conducted across the city of Mumbai.

*Study Participants:* Adults who were residents of Mumbai were enrolled.

*Intervention:* A pre-validated and published 48-item questionnaire based on six themes, *viz.* awareness & participation, Voluntariness and autonomy, compensation, confidentiality, safety and involvement in clinical research was administered.

*Outcomes:* Assessment of perception based on 06 themes and association of variables like age, gender, socioeconomic class and education on this perception.

Descriptive statistics along with Chi square test/Chi square test for trend and crude Odds Ratio (cOR) were assessed.

**Results**:

Of the 453 participants approached, 400(age 32 (18-96)] consented. Only 210/400 (52.5%) were aware of clinical research. Almost half [194/400 (48.5%)] said they needed permission for participation. 226/400 (56.5%) were aware of their rights whereas only 111/400 (27.75 %) felt that clinical trial participants were adequately compensated. A majority [309/400 (77.25%)] endorsed involvement of public in research. The socioeconomic class influenced awareness of clinical research (p<0.00001; r2=0.495) as did the age (p<0.0001; r2=0.82). Men were less likely to need permission to participate relative to women [cOR(95% C.I)2.47 [1.6, 3.6] (p<0.00001)]. Those who had heard of clinical research were twice more willing to participate [cOR (95% C.I) 1.72 [1.2, 2.6]; p=0.008]

**Conclusions:**

Increasing awareness about clinical research will help improve patient engagement in research. There is a greater need to improve awareness especially about safety, compensation and confidentiality in clinical research.

**Trial Registry and Registration details**: Clinical Trial Registry of India [CTRI/2017/07/009066].

**Key Words:** Clinical Research, Public awareness, Compensation, Confidentiality, Patient safety

**INTRODUCTION**

India has emerged as one of the key destinations for the conduct of Clinical Research [CR] over the last decade [1]. A slew of regulatory changes were introduced in the country in recent times to foster growth of CR and protect patient rights. These include the mandatory registration of ethics committees (ECs), specification of conditions required for conduct of clinical trials, defining the quantum of compensation for trial related injuries. [2]

Very limited data is available on how the public perceives CR in India. Previous reports which assessed public awareness and attitude towards CR in India found that people lack adequate understanding about compensation for adverse outcomes and safety of the participants enrolled in trials [3, 4, 5, 6]. Similarly, a meta-analysis of 7 studies including 03 from India found that an overwhelming 64 % denied participation in research owing to reasons like mistrust of trial organization, concerns about safety and efficacy and breach of confidentiality [7]. Studies have shown that creating awareness, changes attitude towards clinical trials, enrolment and the benefits of participation [8]. Also, a well-informed public is always in a better position to safeguard their rights.

Understanding the existing perceptions and knowledge about CR among people is crucial for designing better awareness programs. Mumbai, a cosmopolitan city in India is home to people from diverse cultural backgrounds, ethnicities and religions. Also, a large number of clinical trial sites are located in Mumbai [9]. Despite this, there is no data on the public attitudes and perceptions towards research in Mumbai.

Thus, the present study was conducted with the primary objective ofevaluating public knowledge and perceptions about clinical research in the city. A secondary objective was to study the association of variables such as age, gender and socioeconomic class with these perceptions.

**METHODS**

*Ethics:* The Institutional Ethics Committee of Seth GS Medical College and KEM Hospital approved this study [EC/OA-12/15] and written informed consent was obtained from the participants.

*Study Design*: This was a cross sectional study.

*Study site and Duration*: The study was conducted across diverse locations representing the 24 administrative wards in Mumbai between June 2015 and October 2016.

*Study instrument*: A 48 item pre-validated and published questionnaire comprising of open ended, multiple choice and binary response questions developed by Tal Burt *et al* [4] was used after obtaining permission from the original author. The questionnaire was translated into two regional languages namely Marathi and Hindi by a study team member. The translation authentication was performed by the respective subject experts and ethics committee approval for the authenticated copies was sought and obtained. [The original English language questionnaire is enclosed as a supplementary appendix 1].

*Sample size and sampling*: The sample size of 400 participants for the study was calculated using Yamane equation [10]. As per this equation, a 95% confidence level and a precision of 5% are assumed for the equation given below:

n=N/1+N (e)2

n is the sample size, N is the population size and e is the level of precision. Assuming a precision of 5%, and considering a population size of more than 1,00,000, we obtained the sample size of 400.

The study team members screened the potential participants from across the 24 administrative wards of Mumbai by visiting residences in the respective ward area of the city. In each ward, the study team members visited public places like railway stations, bus stands, Jogger’s park and colleges. They also visited residential buildings in the wards including slum areas but through acquaintances since many residential complexes declined permission. The individuals visiting our hospital outpatient departments from the different parts of the city were also invited to participate in the survey. Those above 18 years of age and who provided written, informed consent and confirmed their willingness to answer the study questionnaire were enrolled in the study. There were no other eligibility criteria.

*Study procedure*: The questionnaire was self-administered and each participant was given adequate time to answer it in the presence of a study team member who resolved any difficulties in understanding. Per the format of the questionnaire, after each participant had answered the question ‘Have you heard about clinical research?’ a standard definition and explanation about clinical research was provided to each participant by the study team members. The remaining questions were administered post this explanation. Demographic details for the language, monthly income, gender, education, occupation and age were collected for each participant. Socioeconomic class of the study participants was assessed using the modified Kuppuswamy scale 2015[10]. This scale classifies participants into upper, upper middle, lower middle, upper lower and lower classes.

**Outcome measures:**

Responses given to the six themes of the questionnaire formed the primary outcome. As each theme had a main question with a binary response, this response was expressed as a proportion. Based on the response to the main question, we evaluated association of that response with variables such as age, gender, socioeconomic class [with education being part of socioeconomic class].

*Statistical analysis:*

Data was analysed using both descriptive and inferential statistics. Quantitative data [age] was expressed as median [range]. Qualitative data [gender, language, socioeconomic class and education] are expressed as proportions. Association between the response to the main question [in all six themes] with age, gender and socioeconomic class was analysed using the chi-square for trend and the strength of this association was expressed as crude odds ratio [cOR] along with 95% Confidence Intervals [CIs]. All analyses were performed at 5% significance using Graphpad Instat 5.0.

**RESULTS**

A total of 453 participants were screened and counselled out of which 400 participants agreed to participate (Figure 1: Flowchart for screening of participants).

The demographic details of these 400 is given in Table 1.

*Age*: Only 353 [88.25%] participants had mentioned their age and majority [168, 47.59%] were between the age group 18-30 years. *Gender*: More than 50% of the participants were male. *Socioeconomic class as per the Kuppuswamy* *scale*: Three Hundred and Eighty Three [95.75%] participants had mentioned information pertaining to their socioeconomic class and more than 60% belonged to the upper middle class. *Language*: More than 50% were Marathi speakers. *Education as per Kuppuswamy scale*: Three Hundred and Ninety Seven [99.25%] had mentioned their education and 191/400 [48.1%] were either graduates, post graduates or had a professional degree.

**Table 1**: Demographics of the study participants as per socioeconomic class, education and language

|  |  |  |
| --- | --- | --- |
| **Variables** | **Number (n)** | **Percentage (%)** |
| **Age *(N= 353 )*** |  |  |
| 18-30 | 168 | 47.59 |
| 31-50 | 147 | 41.64 |
| Above 50 | 38 | 10.76 |
|  |  |  |
| **Gender *(N=400 )*** |  |  |
| Males | 233 | 58.25 |
| Females | 167 | 41.75 |
|  |  |  |
| ***Socioeconomic class (N= 383)*** |  |  |
| Upper Middle Class | 262 | 68.40 |
| Upper Class | 47 | 13.31 |
| Upper Lower Class | 56 | 15.86 |
| Lower Middle Class | 15 | 4.2 |
| Lower Class | 3 | 0.84 |
|  |  |  |
| ***Language (N=398 )*** |  |  |
| Marathi | 225 | 56.53 |
| Hindi | 101 | 25.37 |
| Gujrati | 28 | 7.03 |
| Sindhi | 10 | 2.51 |
| English | 6 | 1.5 |
| Other | 28 | 7.14 |
|  |  |  |
| ***Education (N=397)*** |  |  |
| Professional | 28 | 41.05 |
| Graduate or Post Graduate | 163 | 7.05 |
| Intermediate | 73 | 18.38 |
| High School Certificate | 76 | 19.14 |
| Middle School Certificate | 38 | 9.57 |
| Primary School Education | 19 | 4.7 |

**Overall response with respect to the six themes****[Table 2]**

*Awareness* and *participation:* Two hundred and ten of 400 [52.5%] had heard about clinical research. Doctors [46, 21.90%] and media [17, 8.09%] were listed as the main source of knowledge about Clinical Research. Although only 35/400 [8.8%] had actually participated in research, a majority [238/400, 59.5%] were willing to participate and endorsed public involvement in clinical research [310/400, 77.5%]. Interestingly, a majority [99/190,52.10%] of those who had not heard about clinical research were also willing to participate. *Voluntariness and* *Autonomy*: An overwhelming number of participants [359, 89.8] felt that participation in clinical trials is voluntary. However, nearly half [196, 48.5] said they would need permission from a family member or their family physician to participate in research. *Confidentiality*: More than 80% felt that confidentiality in clinical research is important while only 60% actually believed that confidentiality in clinical trials is adequately protected. *Compensation*: About 45% (180/400) were not aware about compensation for adverse outcomes during study conduct. *Safety*: More than 50% of the participants felt that researchers ensure safety of research participants *Importance of Clinical Research*: Over 80% felt that conducting trials was important.

**Table 2**: Response based on themes

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** | **Themes and related questions** | **Response** | **Percentage [%]** |
| 1 | **Awareness and participation** | |  |
|  | Have you heard about clinical research? | 210/400 | 52.5 |
|  | From whom did you hear about clinical research? | Doctor- 46/210 | 21.9 |
| Media – 37/210 | 17.6 |
| Internet – 17/210 | 8.09 |
| Relatives – 18/210 | 8.5 |
| Friends – 17/210 | 8.09 |
| Colleagues- 10/210 | 4.76 |
| Other sources like company training, school etc -24/210 | 11.42 |
| Multiple sources- 41/210 | 52 |
|  | Are you willing to participate in clinical trials? | Yes- 238/400 [59.5%] | 59.5 |
|  | If yes, what type of study would you like to participate? | Non interventional – 101/238 | 42.43 |
| Low risk observational studies like single blood draw- 28/238  Multiple visit interventional study- 30/238  Multiple types of studies – 75/238 | 11.76  12.60  31.51 |
|  | If No, can you state a reason | Concern about safety- 57/157  Lack of time – 30/157  Lack of trust – 13/157 | 36.30  19.10  8.29 |
|  | **Voluntariness and autonomy** | |  |
|  | Participation in research is entirely voluntary | True- 359/400 | 89.8 |
| Would you have to take permission from someone else in order to participate in research? | Yes-196/400 | 49 |
| If yes who would it be?  Do you know anyone who was coerced to participate in research? | Family members -139/196  Yes -15/ 400 | 70.91  3.7 |
|  | **Confidentiality** | |  |
|  | Confidentiality is a matter of importance to research participants | Yes- 324/400 | 81 |
|  | Confidentiality of research participants is adequately protected. | Yes- 272/400 | 68 |
|  | **Compensation** | |  |
|  | Participants in clinical research get adequate compensation for any adverse outcomes | Not aware – 180/400  No- 103/400  Yes – 112/400  Not answered -05/400 | 45  25.75  28  1.25 |
|  | **Safety** | |  |
|  | Human Participants in clinical research are treated like experimental animals (‘human Guinea Pigs’) | 64/400 | 16 |
|  | Researchers make sure research is safe for participants. | 223/400 | 55.8 |
|  | **Importance of Clinical Research** | |  |
|  | Clinical research benefits society | 342/400 | 85.5 |
|  | Clinical research is essential step in developing new treatments | 373/400 | 93.3 |
|  | The most important reason for developing new treatments is the advancement of science. | 368/400 | 92 |

**Associations within the themes[Table 3]:**

A few associations were found 1) Awareness with willingness - those who were aware of CR were approximately twice more willing to participate relative to those who were not aware of CR. 2) Autonomy and willingness - Those who had autonomy were twice as likely to participate relative to those who did not 3) Gender and autonomy- Women were twice more likely to need permission to participate relative to men.

**Table 3**: Associations within the themes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Number of participants** | | **cOR (95 % C.I)** |
| Associations |  |  | |  |
|  | **Awareness** | **Willing** | **Not willing** |  |
| Awareness with willingness to participate | **yes** | 138 | 72 | 1.725 [1.15-2.57] |
| **No** | 100 | 90 |
|  | **Autonomy** | **Willing** | **Not Willing** |  |
| Autonomy to participate with willingness to participate | No | 142 | 63 | 2.372[1.58-3.57] |
| Yes | 95 | 100 |
|  |  | **No autonomy to participate** | **Autonomy to participate** |  |
| Gender and autonomy to participate | Women (n=167) | 103 | 64 | 2.5[1.61-3.64] |
| Men(n=233) | 92 | 141 |

**Association of variables on the six themes**

*Socioeconomic class*

Socioeconomic class was associated with awareness (lower awareness in lower socio economic classes relative to other classes. (p<0.00001), willingness to participate (decrease in willingness to participate among lower class; p=0.012), voluntariness (A large number required permission to participate in lower classes; p=0.041) and understanding of confidentiality (higher in upper classes) among study participants [p<0.05]. Figure 2 - Association of socioeconomic class with the themes).

*Age*

Age was seen to be associated with awareness [reduction with rising age; p=0.00006], willingness [reluctance to participate with rising age; p=0.0004)] and confidentiality [Older individuals less concerned about confidentiality, p=0.009].

*Education*

Education was also associated with a participant’s willingness to participate [willingness being higher with greater education p<0.0001], need for permission [less educated needed permission; p=0.001], belief about confidentiality [more highly educated felt that confidentiality is important; p<0.0001], belief about safety [individuals with higher education had better perception about safety; p=0.006 and lesser feeling about being treated like an experimental animals; p<0.0001] (Figure 3: Association of education on the themes related to clinical research).

**DISCUSSION**

We conducted a cross-sectional study among lay people in various administrative wards of the city of Mumbai and found that a majority (more than 50%) individuals were aware of clinical research and as many as 60% were willing to participate in the research. We found an association between awareness and participation in that those who had heard about clinical research were more willing to participate. Older participants were less aware about clinical research as were those from the lower socioeconomic class and those with lower education.

The extent of awareness seen by us [52%] was much higher than in the study by Burt *et al*. [2013] in Delhi and Joshi et al [2013] in Pune where awareness was only 26% and 25 % respectively among the population sampled [5] This variation was seen despite the fact that all three surveys were done in urban cities of India with similar literacy levels and a large number of young people (Mean age(±SD): 32 (±12) in our study Vs 39.6 (±16.6) in Burt *et al* Vs 39(±14) in Joshi *et al*). The extent of awareness reported in the studies conducted in Delhi and Pune as well as our study in Mumbai are expressed in proportions without confidence intervals. This makes it difficult to discern whether this is true difference as the overlap in confidence intervals cannot be assessed.

Physicians were stated as being the main source of knowledge about CR by most participants (21.9%) in our study. In the Pune study, similarly, 72% participants knew about CR through physicians [4]. The greater willingness to participate in research among our participants was associated with low risk and non-interventional studies. This was similar to a study by Decosta *et al* (2015) conducted in rural North India which found that participants preferred CR involving interview-based and low risk studies that had a single blood sample collection [11]. Another study by Thaker SJ *et al* (2015) which assessed the reasons for consent refusal in CR had identified ‘*concerns about the risk*’ as one among the several factors influencing the decision to participate [12]. Concerns about the risks in a study is an important parameter that appears to influence willingness to participate in CR.

Individuals who were aware of CR were more willing to participate in CR as per our study. This finding was corroborated by the findings from the “Haris interactive” survey conducted in a High-Income Country [13] (United States of America) in 2001 where it was seen that, the majority (75%) of interviewed participants would have enrolled in a trial had they been made aware of it [8].

An overwhelming number (89.8%) of individuals believed that participation in CR is voluntary yet, very few had the freedom to participate without consulting a family member or a physician. The ‘*need to seek permission’* before participating in a clinical trial reflects the social fabric of the country where decision-making process of an individual is invariably a “joint” decision of the individual with his/her family or even community. [14] Studies from various developing settings indicate that the decision of the females to participate in CR was especially guided by their spouse or a family member often the mother in law for married women [15]. The low recruitment of women in CR with a high dropout is a reflection of this limited autonomy in women [16].

The willingness to participate was better among individuals from upper socioeconomic class, as well as younger and individuals with a higher education. One of the reasons suggested by Unger *et* *al* for less willingness among lower income groups is the concern about excess expenditure which might be incurred during participation. [17] Our observation however differs from a study conducted by Chu *et al* in the urban and rural areas of South Korea who found no correlation between age, gender, socioeconomic class and education on the willingness to participate [18]. Social systems have the ability to impact an individual’s attitude, knowledge and decision-making regarding participating in clinical research [19] and therefore perceptions may vary depending on the setting of the CR.

We found that most of the participants (68%) believed that confidentiality of research participants is adequately protected by researchers. This reflects the confidence that people have in the treating physician, which leads them to believe that the physician will safeguard his/her interests including his/her data. The belief in physicians among Indian patients is further corroborated by a study conducted by Doshi MS *et al* in India that assessed the reasons that motivate participants to consent for non-therapeutic trials in India and found that 88% considered participation solely on the physician’s request [20]

We observed that a majority (55%) of the participants perceived that research was safe for participants and this observation is similar to a study conducted in Mexico by Gonzalez-Saldivar *et al* in which they found 68.95% of the individuals who had not participated in trials felt ‘*protected in case of a serious adverse event related to the experimental drugs*’ [21]

India has been through tumultuous times in CR in the recent past (since 2011) [22] leading to a slew of regulatory changes [23,24]. In our study, we found that 45 % of the participants participants were not very well aware of compensation for adverse research related events and 25.7% believed that compensation is not given in clinical research. This is surprising considering the regulatory requirement of providing compensation for research related injury as well as the wide publicity this issue has had in the recent past in India [25]

An overwhelming number of participants in our study emphasized upon the importance of clinical research with 93 % stating that ‘*Clinical Research was important in the development of new treatment*’ and 92 % believed that through development of new treatments there is advancement of science. This observation is similar to the findings from a qualitative study conducted in Ghana, where participants believed that trial studies are needed to determine efficacy and to ‘come out with new knowledge on whether the drugs were suitable for human beings to use’ [26].

Our study is limited by the fact that it is cross-sectional in nature and therefore inferences about causality cannot be truly drawn. At best inferences can be made about possible associations. The interactions between the independent variables were not looked at in a multivariate analysis. Additionally, the census data for education and income of the city of Mumbai was not available in the public domain at the time of study conduct and therefore the classification as per Kuppuswamy scale for socioeconomic class was used. The distribution of the participants with respect to socioeconomic class may not represent the actual census data for the city of Mumbai. Also, due to the operational challenges faced while approaching participants from different administrative wards like denial of permission by some residential societies, refusal by participants due to lack of time the participants who agreed when approached were ultimately enrolled and thus there is some amount of selection bias in the study

In summary, our study showed that potential participants in Mumbai were aware of CR and also largely aware of their rights as research participants. However, they were less aware of the new regulations including compensation for trial related injuries and safety of trial participants in CR. The study provides baseline awareness about CR in the city and the need for improving awareness that could translate into better participation in CR. Awareness programs about CR will help promote patient engagement in trials beyond mere participation and consolidate their position as stakeholders in clinical research.

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**COMPETING INTERESTS**

Authors have no competing interest to state.

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**Supplementary Files**

A copy of the questionnaire, informed consent form and study protocol are enclosed as supplementary files 1,2 & 3 respectively.

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