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FACTORS INFLUENCING PARENTAL WILLINGNESS FOR THEIR BABY'S PARTICIPATION IN VACCINE CLINICAL TRIALS

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ABSTRACT

The study was planned to determine factors influencing parental decisions to permit their baby, to participate or not, in randomized vaccine clinical trials with the aim of improving recruitment in vaccine clinical trials.
This was prospective cross sectional non interventional study. Study population consisted of parents (n=125) of babies aged 6-8 weeks, A questionnaire was used which covered the basic demographic information and reasons for parents' willingness for their baby to participate or not into clinical trials.
The demographic characteristics of participating babies which were in favour of clinical trial participation were i.e. female child & successive birth order. Establishing trust with parents, counselling both parents, explaining study in detail as regards to risk/benefits, valuing their time, emerge to be the key factors for increasing participation of babies in vaccine clinical trial.

INTRODUCTION:

India is increasingly recognized as a site for clinical research due to its large population and growing research capabilities. Although there is an extensive literature evaluating the factors promoting and precluding participation in clinical trials among various populations, studies in Indian population are limited. Data is also scarce about factors deciding parental willingness to participate their 6-8 weeks young babies in vaccine clinical trials.

Studies have shown that parents balance risks and benefits when deciding about trial participation for their child. [1,2] Perceived benefits by parents include the offer of hope, better care of their child, the opportunity to access new treatments, trust in healthcare professionals and health information and helping others. Perceived barriers include potential side effects, being randomized to ineffective treatments, mistrust of the healthcare system and the inconvenience for visits etc.[3]

We planned this study to determine factors influencing parental decisions to permit their baby, to participate or not, in randomized vaccine clinical trials with the aim of improving recruitment in vaccine clinical trials.

MATERIAL & METHODS:

This was prospective cross sectional non interventional study, which was carried out in the pediatric clinical research unit of a tertiary care multispecialty teaching hospital in Pune. The study was conducted over one year period from March 2017 to Feb 2018, when enrollment of babies aged 6-8 weeks old in 2 consecutive vaccine trials was going on in the pediatric clinical research unit.

The study was initiated after approval from Institutional Ethics committee. Study population consisted of parents (n=125) of babies aged 6-8 weeks, who were offered the option of participation in the vaccine trial.

The parents were informed of this study in detail after they had decided their baby's participation or not, in the ongoing vaccine trial. Parent information sheet of this study was given to parents. Parents of babies who were not eligible for clinical trial participation & illiterate parents were excluded from our study.

After obtaining written informed consent from parents, they (mother /father) were asked to fill up the study questionnaire form. Instructions for completion of study questionnaire were given & any queries while filling it were answered, so as to get the correct response.

Self-made questionnaire was used which covered the basic demographic information and reasons for parents' willingness for their baby to participate or not into clinical trials. The study questionnaire consisted of four sections: 1) information of parent who had signed the informed consent form i.e. name, age, gender, education, income & contact details, 2) baby's information i.e. age, gender, birth order, illnesses etc. 3) reasons for willingness for child's study participation, which had 17 responses/ items & 4) reasons for refusal of participation in vaccine trial, which had 16 responses/ items. In section no. 3 & 4, parents were asked to tick the appropriate response/s or write their reason for baby's participation/non participation in detail, if they had any other reason than mentioned in the study questionnaire. The filled questionnaire form was collected back, reviewed and checked for its completeness. Care was taken to maintain confidentiality & anonymity of the participating parents.

Statistical analysis was done by SPSS version 25.0. For Quantitative variables we computed descriptive statistics & Qualitative variable's analysis was done by using chi-square test with 95% C.I. & level of significance of 0.05.

OBSERVATIONS & RESULTS:

The parents of infants aged 6-8 weeks old, (n=125) were counseled for their baby's participation in 2 consecutive randomized vaccine clinical trials, conducted at our clinical research site. They were given study questionnaire after obtaining their consent for study participation.

Total 125 parents participated in this study. The parent's age was between 19 to 41 years. Majority (70.4%) parents were 21 to 30 years old. Mothers outnumbered fathers in study participation i.e. 87/125 (69.6%). Regarding parent's education it was noted that 17(13.6%) had done post graduation, 48(38.4%)were graduate, 30(24%) were educated till higher Secondary level, 29(23.2%) were of secondary level & only one parent had primary level education.

Out of 125 babies, 68(54.4%) were females & 57(45.6%) were male babies. Majority babies were first born (74, 59.2 %), followed by babies of second birth order (45-36%) & only 6 (4.8 %) babies were of third birth order.

Though study proforma asked regarding income, majority mothers did not know it, so was not included in analysis, but where available, it was of low to middle socioeconomic group.

Out of 125 parents, 65(52%) participated their baby in the ongoing clinical trial whereas 60(48%) did not. 23of 38 (60.5%) fathers consented for baby's participation but only 42 of 87(48.3%) mothers gave consent for baby's participation. Parental age did not show any significant influence on willingness for trial participation.

Parents who showed willingness for participation, 47.3% were first born babies, 60% were second born babies & 66.67%were third born. 60.3 % were female babies & 42.1% were male babies.

Table 1:Association of Gender of the baby and Participation in Clinical trial

Gender of Baby	Participation in Clinical trial		Total	p-value	Chi-square value
	Yes	No			
Female	41	27	68	0.043	4.110
Male	24	33	57		
Total	65	60	125		

Parental responses are as shown in the tables below

TABLE 2:

Sr No	Reasons for child's study participation	No of Preferences	Percentages (%)
1	Potential health benefit	45	69.23
2	Better treatment on participation	37	56.92
3	Follow up care given	23	35.38
4	Free treatment given	17	26.15
5	Faith in Doctor/hospital	40	61.54
6	Doctor's influence	19	29.23
7	Contribution to research	25	38.46
8	Will benefit other children in future	41	63.08
9	Benefits outweigh the risks	11	16.92
10	Better option than not getting that particular treatment/vaccine	9	13.85
11	ICF has explained the study well & think it is suitable for my child	23	35.38
12	Previous experience of trial participation	8	12.31
13	Curiosity, will like to give a try	7	10.77
14	Referred by someone to the study	4	6.15
15	Heard from someone regarding this study	2	3.08
16	Payment for participation	2	3.08
17	Other	2	3.08

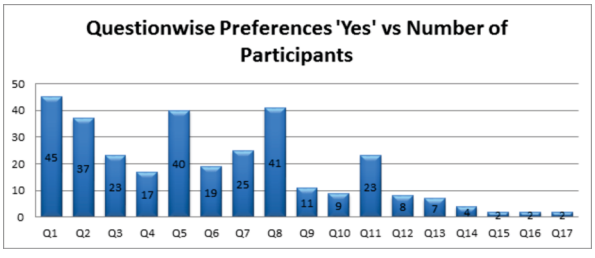
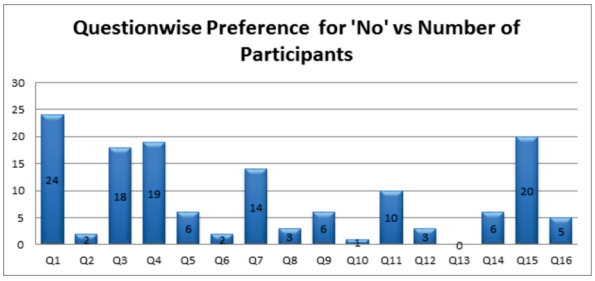


TABLE 3:

Sr No	Reasons for child's non participation in the study	No of Preferences	Percentages (%)
1	Not willing	24	40.00
2	Fear of being treated as genie pigs	2	3.33
3	Inconvenience to come for study visits	18	30.00
4	No time for study procedures	19	31.67
5	Not willing to complete forms	6	10.00
6	Idea of randomization not acceptable (if applicable)	2	3.33
7	Belief that standard treatment of care is better	14	23.33
8	Not wiling for study procedures	3	5.00
9	Fear of side effects & death	6	10.00
10	Previous bad experience of clinical trial	1	1.67
11	Family member's denial	10	16.67
12	Blood withdrawal during study	3	5.00
13	No direct benefit to the child	0	0.00
14	May harm the child	6	10.00
15	More risks than benefits	20	33.33
16	Other	5	8.33



DISCUSSION:

This study was carried out to find out various factors influencing parents' decisions to permit their 6-8 week old baby, to participate or not, in randomized vaccine clinical trials.

In our study just over half of the parents (52 %) were willing to participate their baby in clinical trials, which was similar to studies done earlier by Qiuhuan Kong [3]& Nimbalkar[4] & their colleagues, but higher participation rate of 64.5% (100/155) is reported by Madhu Gupta & colleagues [5].

There are varied views about correlation of parent's age & education with decision to enroll their baby in the study, but we did not find any correlation in this study.

We observed that when both parents visited outpatient department (OPD), for their baby's vaccination , the enrolment in the clinical trial was more(60.5%) in contrast only 48.3 % mothers permitted their baby's participation, when they were alone. Though the difference was not statistically significant, we propose that explaining study to both parents especially baby's father, may help in enhanced recruitment. Similar finding is also reported by Madhu Gupta & collegues[5] that the decision to participate / not in the study, in most of the cases, was found to be taken jointly by both parents, however fathers were found to give final approval.

There was significant gender bias noted in our study, i.e. for girl child, 60.3 % parents consented for clinical trial participation, whereas for male child only 42.1 % agreed for participation as seen in table 1. Thus it shows that parents are more likely to give consent for participation in clinical trial, for a girl child (p value of 0.043). This was a peculiar finding as gender preferences are not reported in other countries as in India.

Parents who showed willingness for participation, 47.3% were first born babies whereas 60% were second born babies. Of 6 babies who were of third birth order, 3 males & 3 females, parents consented for all 3 female babies whereas only for 1 male child, thus 66.67% parents of third order babies consented for participation and gender bias for participation was also seen. Thus it shows that parental willingness for trial participation increases with successive birth order.

Parents who have enrolled their babies in the vaccine clinical trial, the most common reason, mentioned by majority of parents

(90.77%) was faith in doctor/hospital & doctor's influence. This emphasizes the fact that good rapport with the patients does increase clinical trial participation, which is similar to various previous studies. [1,2,3,4,6,7,8,9,10,11]

Another commonly seen response was 'Potential health benefit to baby' which was reported by 69.23% parents in this study, whereas higher percentage is reported by Akalzili [9] (92.9 %), Robert Jacobson[10](90%), Jatin Y. Shah [12](100%) & their colleagues. Altruistic motivation was the next common reason for participation, which was also noted by many previous authors. [1,4,10,11,13,14,15]

'Free treatment given' was seen as an incentive for participation in few earlier studies [1,2,3,9,12] but in this study even though the parents were from low to middle income group, only 3.08 % parents considered it as motivational factor for their baby's participation.

The response of most of the parents (40.0%), who did not consent for their baby's participation in the vaccine trial was 'Not willing' and they had not given any other reason for unwillingness. Family member's denial for baby's non participation was seen in (16.67%) in this study , indicating influence of family members in our society.

No time for study procedures and inconvenience involved in coming for study visits were important reasons for non participation as reported by 61.67% of the parents, similar to reports of other authors. [10,16] 33% parents denied participation due to perception of 'More risks than benefits' in this study which is also seen in studies done by Caldwel [1] and Nimbalkar[4] & their colleagues.

Non participation due to 'Blood withdrawal during study', 'Not willing for study procedures', 'Idea of randomization not acceptable', 'Fear of being treated as genie pigs' was reported by very few parents. (3-4%)

None of the parents marked response- 'No direct benefit to the child', depicts that though they realized that the child will be benefited by participation in the vaccine clinical trial, but did not participate due to some or the other reasons.

CONCLUSION

Thus our study shows that the demographic characteristics of participating babies which were in favor of clinical trial participation were i.e. female child & successive birth order. Involvement of father has positive impact on trial participation and discussing with family members also may help .

Faith in doctor/hospital & doctor's influence, potential health benefit & altruistic motivation were the most common parental reasons for baby's enrolment in the clinical trials. Whereas unwillingness, perceival of more risks than benefits, no time for study procedures, & inconvenience to come for study visits were the main reasons for non study participation of their baby in vaccine randomized clinical trial.

So establishing trust with parents, counseling both parents, explaining study in detail as regards to risk/benefits, valuing their time, emerge to be the key factors for increasing participation of babies in vaccine clinical trial.

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