

# Experience of participating in community-based clinical trials from rural Maharashtra: Analysis of over 4000 participant feedback forms

## INTRODUCTION

Community engagement includes processes for receiving feedback from the community regarding the ethical conduct of clinical studies. Lack of community participation can lead to mistrust, nonadherence, or nonretention in large-scale community-based studies.<sup>[1]</sup> National guidelines highlight the importance of community engagement in clinical research.<sup>[2]</sup>

Feedback received from the clinical trial participants is a method for community engagement that can offer valuable inputs on study conduct, quality of implementation, and needs of the community.<sup>[3,4]</sup> This can provide valuable information on perspective of the participants, reasons for study participation in the research, and possible measures to prevent dropouts. This also demonstrates respect toward the community members and engages them in research participation.<sup>[5]</sup> Collection of participation feedback from all research participants has been mandated as per the National Accreditation Board for Hospitals and Healthcare Providers (NABH) requirements for the Institutional Ethics Committee (IEC) accreditation.<sup>[6]</sup>

There are scarce literature from India on feedback of community members about the participation in the research studies. Literature on this subject is largely restricted to studies conducted in developed countries.<sup>[3,4,7]</sup> The present paper analyses the feedback of approximately 4000 participants or parents of participants residing in a rural area of Pune district who participated in the vaccine clinical trials conducted at Vadu Rural Health Program of KEM Hospital Research Centre, Pune.

## METHODS

Vadu Rural Health Program is a community-based research department of KEM Hospital Research Centre, Pune, involved in conduct of community-based large-scale vaccine clinical trials.<sup>[8]</sup> Most of these studies are conducted in healthy children and volunteers residing in the rural and semi-urban areas of Shirur and Haveli blocks of Pune district.

This is a retrospective analysis of 4618 feedback forms collected during regulatory vaccine clinical trials conducted in healthy adults and children from the year 2016 to 2023 (5 adult and 10 pediatric studies). All studies were approved by the KEMHRC EC, and informed written consent was taken in all the studies. The feedback forms were collected as a part of regular end-of-study process for all the studies as per the NABH and IEC policy, hence separate approval was not needed.

The feedback was collected at the end of participation, and the form involved questions about sources of information, reasons for study participation, and overall feedback about the study conduct. The collected information from the participants was translated from local language to English and was entered into an Excel sheet for descriptive analysis.

## RESULTS

For majority of the participants (72.67%), the primary source of information about the upcoming study was prestudy home visits conducted by the study team. The prestudy home visits were done by the field research assistants to inform the potential participants about an upcoming study and invite them for study participation. Village-level community meetings formed the next best source of information for the local community (18.02%). Information by government health staff, Accredited Social Health Activist/Auxiliary Nurse & Midwife (ASHA/ANM) or family physicians was reported to be helpful by 6.65% and 2.19% of respondents, respectively. Health-care benefits to participants (38.5%), health awareness and counseling (25.2%), and supportive study staff (26.8%) were the commonest reasons for participation. Access to new treatment and a desire to contribute for research were reported as reasons for participation by 6%–7% of participants. In addition, 90% of respondents reported their experience as satisfactory or very satisfactory, and 95% reported that they will recommend it to others.

## DISCUSSION

Our experience of collection of participant feedback from approximately 4000 participants of nationally important

vaccine studies from rural Maharashtra provides important learning on “what has worked.” In large community-based studies, it is challenging to disseminate study-related information to all potential study participants. The results show that prestudy home visits and village-level meetings form the major sources of information to the participants. This has been reported earlier to be an effective strategy for community engagement.<sup>[9]</sup>

The feedback also provides an insight that interaction with government officials and local practitioners can be further strengthened. Provision of medical care or health-care benefits to the study participants was the most common reason for participation in vaccine studies, followed by counseling and supportive nature of the staff. Personal benefit has been reported to be an important reason for research participation along with altruism and trust in global literature.<sup>[3]</sup> It was reassuring to know that financial compensation was not found to be a major reason for participation and thus provides evidence that the reimbursement provided to the study participants for clinic visits was not inducing them to participate.

The feedback forms along with other methods of community engagement have helped to build trust with the local community and enabled high retention and compliance in community-based studies in rural Pune. Although the analysis is related to experience on participation in vaccine clinical trials, the lessons learned are relevant for all community-based interventional studies.

## CONCLUSION

The study shows that participant feedback in community based studies is an important tool to provide insights into the study implementation and expectations of the community from a clinical research project.

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## Conflicts of interest

There are no conflicts of interest.

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