Reasons for refusal among patients with tuberculosis and their household contacts to participate in an observational cohort study

INTRODUCTION

Reasons for nonparticipation in intervention studies have been explored but less so in observational studies.[1] With increasing focus on TB, it is worthwhile to understand the reasons for nonparticipation in TB research.

METHODS

The data collected for a cohort study conducted in the districts of Puducherry, Villupuram, and Cuddalore (Tamil Nadu) between June 2014 and 2019 under Regional Prospective Observational Research for TB, India, were analyzed. The study protocol was approved by the Institutional Ethics Committees of JIPMER and Boston Medical Center. The study had at least four visits (up to 90 min each) and included the collection of blood, sputum, saliva, urine, and stool samples. Participants were paid Rs. 220/visit (~3 USD). The potential study participants (new smear positive pulmonary TB) from the National Tuberculosis Program were contacted up to three times for setting a meeting at their nearest health center/home. After explaining about the study, participants were given participant information sheet in the local language and were allowed to discuss with their families. Written informed consent was obtained from willing participants. Willing Household contact (HHC's) of the recruited People living with TB (PLWTB) were also enrolled. Reasons for nonparticipation among refusers were recorded (multiple reasons allowed and additional reasons if any were noted). Data were analyzed in STATA version 14 (StataCorp, Texas, USA). The reasons were expressed as percentages. The association between reasons and gender was assessed using the Chi-squared or Fisher's exact test. $P \leq 0.05$ was considered statistically significant.

RESULTS

Of 1612 PLWTB approached, 220 (13.6%) refused to participate (males 13.1% [157/1202] vs. females 15.2% [62/409], $P = 0.285$). Younger individuals were more likely to refuse (age <18 years 23.5% [12/51] vs. ≥18 years 13.3% [208/1353], $P = 0.037$). The common reasons cited for nonparticipation: "Too sick to consent" (36%), "not interested in research" (28%), "concerned about stigma" (19%), "deterred by sample collection (15%), mental impairment (5%), and other reasons (12% comorbid conditions, lack of time, wanting permission, and uncomfortable). A higher proportion of men reported sickness (40% vs. 24%, $P = 0.027$) and uninterest (31% vs. 21%, $P = 0.130$) than women while a greater proportion of women reported stigma (34% vs. 13%, $P = 0.001$) and sample collection (26% vs. 11%, $P = 0.005$).

Among 2149 HHCs approached, 434 (20.2%) refused to participate (males 21.7% [192/883] vs. females 19.1% [242/1266], $P = 0.135$). Older individuals were more likely to refuse (age <18 years 16% [93/580] vs. ≥18 years 21.7% [341/1569], $P = 0.003$). Common reasons cited: Uninterest (53%), stigma (23%), sample collection (16.6%), lack of time (8%), and other reasons (7.4%: mental impairment, sickness, uncomfortable, comorbid conditions, and wanting permission). A higher proportion of women reported stigma as a reason for refusal (27% vs. 18%, $P = 0.019$).

DISCUSSION

From our experience, one-eighth of PLWTB and one-fifth of HHC refused study participation. Severe illness and stigma were reported by one-fifth and one-third of the PLWTB; while about half of the HHCs reported uninterest in research as reasons for refusal and a higher proportion of women reported stigma and sample collection.

Sickness was reported more among men which may be partly because of the higher prevalence of severe TB among them. Lack of interest in research could be due to the absence of direct benefit or misconceptions/fear about research. Ensuring comprehension is an important component of informed consent process and it needs to be focused on. CAB's can improve understanding about

research in the community and positively influence the TB control activities as seen in South Africa.[2] Although a CAB was established only toward the end of our study, the experience has been encouraging.

Since majority of the PLWTB were approached soon after diagnosis (taken ≤ five daily or three intermittent doses of antituberculosis therapy), they may have been apprehensive and concerned about stigma. Enrolment after counselling sessions may help ease the same.

About one-sixth of the PLWTB and HHC's refused because of sample collection. Though the samples collected depend on the study objective, conducting them during patient's routine health-care visit may reduce the inconvenience.

The limitation of our study includes the lack of information regarding pertinent factors such as socioeconomic status and location of the participants and the influence of social desirability.

Some strategies to improve participation:

1. Adopt multi-pronged approach to address TB-related stigma
2. Emphasize on the benefit of the research in the broader community context to the participant
3. Engage a broad variety of community stakeholders through CAB to facilitate community ownership and engagement in research
4. Further research to understand the barriers and facilitating factors for participation in research.

Financial support and sponsorship

This study was financially supported by Government of India's Department of Biotechnology, the Indian Council of Medical Research, and the United States National Institutes of Health, and distributed in part by the U.S. Civilian Research & Development Foundation.

Conflicts of interest

There are no conflicts of interest.

Kalaivani Raghupathy, Selby Knudsen[1], Jerrold Ellner[2,3], Charles Horsburgh[1,2,4,5], Natasha Hochberg[1,2], Padmini Salgame[3], Palanivel Chinnakali, Senbagavalli Prakashbabu, Sonali Sarkar

Department of Preventive and Social Medicine, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India, Departments of [1]Epidemiology, [4]Global Health and [5]Biostatistics, Boston University School of Public Health, [2]Department of Medicine, Boston University School of Medicine, Boston, Massachusetts, [3]Department of Medicine, Rutgers New Jersey Medical School, Newark, New Jersey, United States of America

Address for correspondence: Dr. Senbagavalli Prakashbabu, RePORT India Program Manager, Department of Preventive and Social Medicine, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry - 605 006, India.
E-mail: prco.manuscript@gmail.com

REFERENCES

1. Lamunu D, Chapman KN, Nsubuga P, Muzanyi G, Mulumba Y, Mugerwa MA, *et al*. Reasons for non-participation in an international multicenter trial of a new drug for tuberculosis treatment. Int J Tuberc Lung Dis 2012;16:480-5.
2. Ntshanga SP, Ngcobo PS, Mabaso ML. Establishment of a community advisory board (CAB) for tuberculosis control and research in the Inanda, Ntuzuma and KwaMashu (INK) area of KwaZulu-Natal, South Africa. Health Policy 2010;95:211-5.

Access this article online	
Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.picr_377_20

How to cite this article: Raghupathy K, Knudsen S, Ellner J, Horsburg C, Hochberg N, Salgame P, *et al*. Reasons for refusal among patients with tuberculosis and their household contacts to participate in an observational cohort study. Perspect Clin Res 2021;12:234-5.

Received: 07-12-20, **Revised:** 06-01-21, **Accepted:** 14-01-21, **Published:** 20-09-21.