

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Prevalence of household food insecurity and its associated factors in tuberculosis patients in south India: A cross sectional analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033798
Article Type:	Original research
Date Submitted by the Author:	12-Sep-2019
Complete List of Authors:	<p>Ayiraveetil, Reshma; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Sarkar, Sonali; JIPMER, Preventive and Social Medicine; JIPMER, Preventive and Social Medicine Chinnakali, Palanivel; Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Department of Preventive and Social Medicine Jeyashree, Kathiresan; Velammal Medical College Hospital and Research Institute, Vijayageetha, Mathavaswami; Jawaharlal Institute for Postgraduate Medical Education and Research, Department of Preventive and Social Medicine Thekkur, Pruthu; International Union Against Tuberculosis and Lung Disease, Centre for Operational Research; The Union South-East Asia Office, Centre for Operational Research Lakshminarayanan, Subitha; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Knudsen, Selby; 7. Boston Medical Center, Boston, Massachusetts, United States of America, Department of Infectious Diseases Hochberg, Natasha; Boston University School of Medicine, Section of Infectious Diseases, Department of Medicine; 6. Boston University School of Public Health, Boston, Massachusetts, United States of America, Department of Epidemiology Horsburgh, C ; Boston University Ellner, Jerrold; 8. Rutgers University, New Jersey, US, Department of Medicine, Roy, Gautam; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine</p>
Keywords:	Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

SCHOLARONE™  
Manuscripts

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1 **TITLE**  
4

5  
6 2 Prevalence of household food insecurity and its associated factors in tuberculosis  
7  
8 3 patients in south India: A cross sectional analysis  
9

10  
11 4 **MANUSCRIPT TYPE:** Research Article  
12

13  
14 5 **SHORT RUNNING TITLE**  
15

16 6 Household Food insecurity in TB patients  
17

18  
19 7 **AUTHORS**  
20

21  
22 8 Ayiraveetil Reshma,<sup>1</sup> Sonali Sarkar,<sup>1</sup> Palanivel Chinnakali,<sup>1</sup> Kathiresan Jeyashree,<sup>2</sup>  
23  
24 9 Mathavaswami Vijayageetha,<sup>1</sup> Pruthu Thekkur,<sup>3,4</sup> Subitha Lakshminarayanan,<sup>1</sup> Selby  
25  
26 10 Knudsen,<sup>7</sup> Natasha S. Hochberg,<sup>5,6,7</sup> C. Robert Horsburgh,<sup>5,6</sup> Jerrold Ellner,<sup>6</sup> Gautam  
27  
28 11 Roy,<sup>1</sup>  
29

30  
31  
32 12 1. Department of Preventive and Social Medicine, Jawaharlal Institute of  
33  
34 13 Postgraduate Medical Education and Research (JIPMER), Puducherry, India.  
35

36 14 2. Department of Community Medicine, Velammal Medical College, Madurai,  
37  
38 15 Tamilnadu.  
39

40  
41 16 3. Centre for Operational Research, International Union Against Tuberculosis and  
42  
43 17 Lung Disease (The Union), Paris, France  
44

45 18 4. The Union, South East Asia Office, New Delhi, India.  
46

47  
48 19 5. Section of Infectious Diseases, Department of Medicine, Boston University  
49  
50 20 School of Medicine, Boston, Massachusetts, United States of America  
51

52 21 6. Boston University School of Public Health, Boston, Massachusetts, United  
53  
54 22 States of America  
55

56  
57 23 7. Boston Medical Center, Boston, Massachusetts, United States of America  
58

59 24 8. Department of Medicine, Rutgers University, New Jersey, US  
60

1  
2  
3 25 **WORD COUNT**  
4

5 26 **Abstract :299**  
6

7  
8 27 **Text: 2329 (excluding summary, references, tables and figures)**  
9

10 28 **NUMBER OF TABLES: 4+1 (Supplementary file)**  
11

12 29 **NUMBER OF FIGURES: nil**  
13

14 30 **NUMBER OF REFERENCES: 29**  
15

16  
17 31 **AUTHOR FOR CORRESPONDENCE**  
18

19 32 Dr. Sonali Sarkar  
20

21 33 Additional Professor & Head  
22

23 34 Department of Preventive and Social Medicine, JIPMER  
24

25 35 E-mail: [sarkarsonaligh@gmail.com](mailto:sarkarsonaligh@gmail.com)  
26

27 36 Phone: (+91) 9442174663  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 50 **ABSTRACT**

### 51 **Objectives**

52 Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe  
53 foods or inability to acquire foods in socially acceptable ways'. A major proportion of  
54 Tuberculosis (TB) cases of resource-poor settings experience food insecurity, which  
55 impacts treatment adherence and outcomes. We aimed to determine prevalence of  
56 household food insecurity and its associated factors in tuberculosis (TB) patients.

### 57 **Design**

58 This is a cross sectional analysis of secondary data from a cohort study.

### 59 **Setting**

60 National Tuberculosis Program (NTP) in three districts of south India.

### 61 **Participants**

62 All newly diagnosed pulmonary TB cases (both smear and culture positive) of the  
63 cohort enrolled from October 2015 to October 2018.

### 64 **Primary Outcome Measures**

65 The proportion of baseline household food insecurity assessed using a validated  
66 household food insecurity access scale was summarized as percentage with 95%  
67 confidence interval (CI). Possible association of socio-demographic, morbidity and  
68 behavioural characteristics with household food insecurity was assessed using chi-  
69 squared test, unadjusted prevalence ratios with 95% CI were calculated. The  
70 characteristics with p value less than 0.2 in the univariate model were included in  
71 multivariable generalized linear model (binomial function and log link) to derive  
72 adjusted prevalence ratios (aPR) with 95% CI.

## 73 **Result**

74 Of total 765 patients, 261 had household food insecurity and the prevalence was  
75 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in  
76 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. TB patients who had  
77 monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score  
78 of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95%  
79 1.0-2.0) had higher prevalence of household food insecurity.

## 80 **Conclusions**

81 High level of food insecurity was seen in households of TB cases. Additional food or  
82 cash assistance for this sub-group might improve food insecurity and thereby  
83 nutritional status.

## 84 **Key Words**

85 Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

## 87 **Article Summary**

### 88 **Strengths:**

- 89 • Use of a validated tool for assessing household food insecurity which allows  
90 cross country comparisons.
- 91 • We used the data from a prospective cohort study which implemented quality  
92 assurance checks for data collection, entry and completeness that would have  
93 reduced missing data and data errors.
- 94 • Our study included patients identified in the public sector alone and food  
95 insecurity levels may be different in patients accessing TB care in the private  
96 sector.



1  
2  
3 97 **Limitations:**  
4  
5

- 6 98 • We did not study the sub group of previously treated TB patients in whom levels  
7  
8 99 of food insecurity could be higher due to financial loss caused by repeated  
9  
10 100 episodes of TB.  
11  
12  
13 101 • The study participants were from selected three districts in south India, so  
14  
15 102 generalisability of the findings is limited.  
16  
17  
18  
19 103  
20  
21 104  
22  
23 105  
24  
25 106  
26  
27 107  
28  
29 108  
30  
31 109  
32  
33 110  
34  
35 111  
36  
37 112  
38  
39 113  
40  
41 114  
42  
43 115  
44  
45 116  
46  
47 117  
48  
49 118  
50  
51 119  
52  
53 120  
54  
55 121  
56  
57  
58  
59  
60

## 122 INTRODUCTION

123 Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking  
124 above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017,  
125 there were an estimated 1.3 million TB deaths among HIV-negative people. India  
126 contributes roughly 25% of global incident TB cases and there were an estimated  
127 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health  
128 Organization (WHO) endorsed the “End TB strategy” in line with the Sustainable  
129 Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal  
130 with action on poverty, hunger and ensuring healthy lives and well-being of people)  
131 with a common aim to end the global TB epidemic.(1,3)

132 Food security is a state in which “all people at all times have both physical and  
133 economic access to sufficient food to meet their dietary needs for a productive and  
134 healthy life”.(4) Catastrophic health expenditure is a common consequence of TB  
135 diagnosis, treatment and care which can lead to impoverishment and in turn food  
136 insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional  
137 relationship with TB; both cause TB and could be consequences of TB. Undernutrition  
138 in patients with active TB can lead to worsening of disease, drug toxicity, drug  
139 malabsorption and death or relapse of disease. (5–7)

140 A recent national survey (2016) in Vietnam reported that 22% of households  
141 experienced food insecurity during TB treatment, this proportion being as high as 40%  
142 among the poorest wealth quintiles.(8) Food insecurity at the household level is  
143 common in India and is a strong risk factor for progression of latent infection to active  
144 TB in household contacts.(9) TB in India affects poor families and communities  
145 disproportionately, with a fourfold higher prevalence in those with a low standard of

1  
2  
3 146 living index compared to those with a high standard of living index.(5) Food insecurity  
4  
5 147 is also of greatest significance in households where levels of food insecurity and  
6  
7 148 undernutrition are high at the time of diagnosis. Since food insecurity and under-  
8  
9 149 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite  
10  
11 150 effective treatment.  
12  
13  
14

15 151 WHO (2013) in its guidelines 'Nutritional care and support for patients with  
16  
17 152 tuberculosis' recommends assessment of food insecurity among TB cases and  
18  
19 153 addressing the same with suitable packages including food assistance.(3) Recently,  
20  
21 154 Government of India has launched a cash assistance scheme for all TB cases to  
22  
23 155 mitigate costs and improve nutritional status. (10) However, there may be households  
24  
25 156 with more food insecurity that need more food assistance rather than equal assistance  
26  
27 157 to all. In India, studies assessing household food insecurity among TB cases are  
28  
29 158 limited. Therefore, we aimed to determine the level of food insecurity and its  
30  
31 159 associated factors using secondary data from a cohort of pulmonary TB patients in  
32  
33 160 south India.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 169 **METHODS**  
4  
5

6 170 **Study Design**  
7  
8

9 171 This is a cross sectional analysis of secondary data from a cohort study under  
10  
11 172 RePORT India Consortium (Regional Prospective Observational Research for  
12  
13 173 Tuberculosis). Details of the study design have been previously reported. (11–14)  
14  
15

16 174 *National tuberculosis program (NTP)*  
17  
18

19 175 The study covers Puducherry district of Union Territory of Puducherry (population~1.3  
20  
21 176 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5  
22  
23 177 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB  
24  
25 178 diagnostic and treatment services are delivered through the designated microscopy  
26  
27 179 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units  
28  
29 180 (TUs) as nodal points for TB control activities at sub-district level. Sputum smear  
30  
31 181 microscopy remains the central component of TB diagnosis. Under NTP, both  
32  
33 182 diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of  
34  
35 183 TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity  
36  
37 184 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment  
38  
39 185 outcomes of these patients are documented in individual TB treatment card.  
40  
41  
42  
43  
44

45 186 *RePORT International*  
46  
47

48 187 Regional Prospective Observational Research in Tuberculosis (RePORT)  
49  
50 188 International represents a consortium of regional cohorts (RePORT India, RePORT  
51  
52 189 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT  
53  
54 190 Indonesia) that are linked through the implementation of a common protocol for data  
55  
56 191 and specimen collection. Objectives and composition of RePORT International are  
57  
58 192 described elsewhere.(15)  
59  
60

1  
2  
3 193 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate  
4  
5 194 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers  
6  
7  
8 195 University has established a pulmonary TB cohort of adults and children  $\geq 6$  years and  
9  
10 196 their household contacts to identify biomarkers for risk of TB treatment failure and risk  
11  
12 197 of development of TB in household contacts. TB cases diagnosed under NTP in the  
13  
14 198 three districts (Puducherry, Cuddalore and Villupuram) were included in the cohort  
15  
16 199 since 2014. Only newly diagnosed smear and culture positive pulmonary TB cases  
17  
18 200 were included. Details on tobacco use, alcohol use, household food insecurity, severity  
19  
20 201 of TB (Karnofsky score), diabetes status and HIV status were collected at baseline  
21  
22 202 within seven days of initiation of treatment. Based on Karnofsky score patients were  
23  
24 203 categorized on their functional impairment (scale ranges from 0-100). If the score is  
25  
26 204 low, more severe is the illness.

27  
28  
29  
30  
31 205 All the above information was recorded in project specific case report forms (CRFs)  
32  
33 206 and these CRFs were scanned and transferred to data coordinating centre at Boston  
34  
35 207 Medical Centre with Verity TeleForm Information Capture System software V10.8  
36  
37 208 (Sunnyvale, CA, USA), and read and uploaded into a Microsoft Access (Seattle, WA,  
38  
39 209 USA) database. All the filled-in CRFs were checked for completeness by a supervisor  
40  
41 210 on daily basis and periodically by the data manager.

### 211 **Study population**

212 For this analysis, we included all TB cases of the cohort enrolled from October 2015  
213 to October 2018. Multi drug resistant and extremely drug resistant TB cases at  
214 diagnosis were excluded.

215

216

## 217 **Study tool**

218 Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food  
219 insecurity in the households in the past 30 days. The scale consists of nine items  
220 grouped under three domains: 1) anxiety or uncertainty about the household food  
221 supply 2) Insufficient Quality and 3) Insufficient food intake and its physical  
222 consequences (4). The respondent is first asked an occurrence question, whether the  
223 condition in the question happened at all in the past four weeks (yes or no). If the  
224 respondent answers “yes” to an occurrence question, a frequency-of-occurrence  
225 question is asked to determine whether the condition happened rarely (once or twice),  
226 sometimes (three to ten times) or often (more than ten times) in the past four weeks.  
227 Each item is scored on a range of 0 to 3; zero for ‘no occurrence’ and three for ‘often’.  
228 The minimum and maximum score for a household are 0 and 27 respectively. The  
229 scores were categorized into four levels of household food insecurity: food secure and  
230 mild, moderately and severely food insecure (4)-Annexure 1.

231 Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version  
232 of AUDIT) (16) was used to assess the alcohol use among participants.

## 233 **Data extraction, analysis and statistics**

234 Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases  
235 excluding two childhood TB cases; the initial 462 cases enrolled were not assessed  
236 for household food insecurity and were excluded. Data were extracted from the  
237 RePORT India project database for JIPMER site in a de-identified manner and  
238 analysed using Stata 12.0 software. The proportion of household food insecurity was  
239 summarized as percentage with 95% confidence interval (CI). Possible association of  
240 socio-demographic, morbidity related and behavioural characteristics with household  
241 food insecurity was assessed using chi-squared test and unadjusted prevalence ratios

1  
2  
3 242 with 95% CI were calculated. The characteristics with p value less than 0.2 in the  
4  
5 243 univariate model were included in multivariable generalized linear model (binomial  
6  
7  
8 244 function and log link) to derive adjusted prevalence ratios(aPR) with 95% CI. The  
9  
10 245 variables such as marital status, education, residence, number of earners in the  
11  
12 246 household, HIV status, tobacco use, and alcohol use were not included for multivariate  
13  
14  
15 247 analysis.

### 17 248 **Ethics Approval**

19  
20 249 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER  
21  
22  
23 250 (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center  
24  
25 251 (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was  
26  
27 252 obtained from all participants before enrolment. The study protocol for this secondary  
28  
29  
30 253 analysis was reviewed and approved by Ethics Advisory Group of the International  
31  
32 254 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.

### 35 255 **Patient and Public Involvement**

36  
37  
38 256 There was no patient or public involvement.  
39  
40  
41 257  
42  
43  
44 258  
45  
46  
47 259  
48  
49  
50 260  
51  
52  
53 261  
54  
55  
56 262  
57  
58  
59 263  
60

## 264 RESULTS

265 Of the 765 individuals included in analysis, the mean (standard deviation) age was 44  
266 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases  
267 are described in **Table-1**. Of total, 131 (17%) participants did not have any formal  
268 education, about 77% were employed and 11% had monthly family income less than  
269 INR 3000 (~USD 43). Behavioural and disease related characteristics are described  
270 in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30%  
271 were current tobacco users. Of total, 470 (61%) were underweight (body mass index  
272 <18.5 kg/m<sup>2</sup>) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or  
273 less (require assistance for routine activities) in 29% of patients.

274 Overall, 261 patients had household food insecurity and the prevalence was 34.1%  
275 (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17  
276 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food  
277 insecurity are described in **Table-3**. Worry or anxiety about not having enough food  
278 was reported in 15% of TB households. In 21% of TB households, eating fewer meals  
279 in a day due to lack of enough food was reported.

280 Prevalence of food insecurity in different sub groups is presented in **Table-4**. In  
281 adjusted analysis, TB cases who had monthly family income less than INR 3000 (aPR  
282 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those  
283 who were employed (aPR 1.4; 95% 1.0-2.0) had higher prevalence of household food  
284 insecurity.

285

286

287



## 288 **DISCUSSION**

289 Our study among newly diagnosed pulmonary TB patients in public sector in south  
290 India revealed that about one third of TB patients experienced household food  
291 insecurity; about one out of four patients experienced severe food insecurity at the  
292 time of diagnosis. Prevalence of food insecurity was high in low income groups,  
293 employed and those who had severe illness.

294 Prevalence of food insecurity in the general population of India is also high ranging  
295 from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is  
296 common as it can be both a cause and consequence of TB. The national level survey  
297 from Vietnam (2016) reported 22% of TB patients experienced household food  
298 insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)

299 Food insecurity was twice as high in low income TB households (INR<3000) compared  
300 to their higher income counterparts. Catastrophic health expenditure, a consequence  
301 of TB diagnosis and treatment can lead to worsening of food insecurity in low income  
302 groups during the course of the disease.(5) These subgroups need to be provided  
303 additional assistance instead of 'equal for all' food or cash assistance benefits. Since  
304 income is usually underreported, identifying such target groups may not be an easy  
305 task.

306 Food insecurity at the household level is a strong risk factor for progression of latent  
307 infection to active TB in household contacts. (9,20) Since, food insecurity measures  
308 are applicable to all households, a wider approach of reducing food insecurity targeting  
309 all household contacts is needed.

310 In our study, about 60% of the TB patients were underweight. Undernutrition is both  
311 an important risk factor for, and a common consequence of TB. In food insecure

1  
2  
3 312 households, undernutrition could be an intermediary step in the nutritional pathway of  
4  
5 313 food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent  
6  
7 314 in patients with TB and the dietary intake of calories is significantly lower (500-700  
8  
9 315 calories) than recommended. (21) As recommended by WHO, addressing  
10  
11 316 undernutrition through nutritional counselling and support should be considered as  
12  
13 317 part of the standard of care for people with TB. The recently launched “Nikshay Poshan  
14  
15 318 Yojana”, a direct benefit transfer scheme by the government of India is a welcome step  
16  
17 319 towards addressing undernutrition. (22) Our study did not include severely ill patients  
18  
19 320 (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates  
20  
21 321 are expected to be high. This may partly explain why our study did not find an  
22  
23 322 association between food insecurity and undernutrition, though previous studies have  
24  
25 323 reported otherwise. (23–26) Also, we have assessed food insecurity at the level of  
26  
27 324 household and body mass index assessed is that of the individual patients. May be  
28  
29 325 the patient’s nutrition is maintained at the expense of other family members, so he or  
30  
31 326 she may have had normal BMI.

32  
33  
34  
35  
36  
37  
38 327 Several studies support the notion that food insecurity negatively affects treatment  
39  
40 328 adherence. Conditions of food insecurity (lack of adequate food, concern about daily  
41  
42 329 food production) contribute to non-adherence to TB treatment as reported by  
43  
44 330 qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis  
45  
46 331 and linking the patients to food assistance or social security programs is needed. We  
47  
48 332 plan to report the effect of food insecurity on adherence and TB treatment outcomes  
49  
50 333 in a separate paper.

51  
52  
53  
54  
55 334 Strengths of the study include use of a validated tool (4) for assessing household food  
56  
57 335 insecurity which allows cross country comparisons. We used the data from a  
58  
59 336 prospective cohort study which implemented quality assurance checks for data

1  
2  
3 337 collection and entry that would have reduced missing data and data errors. Our study  
4  
5 338 included patients identified in the public sector alone and food insecurity levels may  
6  
7  
8 339 be different in patients accessing TB care in the private sector. Since, repeated  
9  
10 340 episodes of TB may be a cause for financial loss leading to food insecurity, the levels  
11  
12 341 could be higher in previously treated TB patients and we did not study this sub group.  
13  
14 342 Being a cross sectional analysis, causal relationships of factors with food insecurity  
15  
16 343 cannot be inferred. The study participants were from selected three districts in south  
17  
18 344 India, so generalisability of the findings is limited.  
19  
20  
21  
22  
23  
24  
25  
26  
27

345

## 346 **CONCLUSION**

28 347 To conclude, household food insecurity was experienced by one in three TB patients  
29  
30 348 and this was twice higher in low income groups. Additional food or cash assistance to  
31  
32 349 food insecure TB patients and household contacts will improve the food insecurity and  
33  
34  
35 350 undernutrition.  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

351

352

353

354

355

356

357

358

359

360

1  
2  
3 361 **ACKNOWLEDGEMENTS**  
4

5  
6 362 This cross-sectional analysis was conducted through the Structured  
7  
8 363 Operational Research and Training Initiative (SORT IT), a global partnership led by  
9  
10 364 the Special Programme for Research and Training in Tropical Diseases at the World  
11  
12 365 Health Organization (WHO/TDR). The model is based on a course developed jointly  
13  
14 366 by the International Union Against Tuberculosis and Lung Disease (The Union) and  
15  
16 367 Médecins sans Frontières (MSF/Doctors Without Borders). The specific SORT IT  
17  
18 368 programme which resulted in this publication was jointly developed and implemented  
19  
20 369 by: The Union South-East Asia Office, New Delhi, India; the Centre for Operational  
21  
22 370 Research, The Union, Paris, France; Department of Preventive and Social Medicine,  
23  
24 371 Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry,  
25  
26 372 India; Department of Community Medicine and School of Public Health, Postgraduate  
27  
28 373 Institute of Medical Education and Research, Chandigarh, India; Department of  
29  
30 374 Community Medicine, All India Institute of Medical Sciences, Nagpur, India; Dr.  
31  
32 375 Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical  
33  
34 376 Sciences, New Delhi, India; Department of Community Medicine, Pondicherry Institute  
35  
36 377 of Medical Science, Puducherry, India; Department of Community Medicine, Kalpana  
37  
38 378 Chawla Medical College, Karnal, India; National Centre of Excellence and Advance  
39  
40 379 Research on Anaemia Control, All India Institute of Medical Sciences, New Delhi,  
41  
42 380 India; Department of Community Medicine, Sri Manakula Vinayagar Medical College  
43  
44 381 and Hospital, Puducherry, India; Department of Community Medicine, Velammal  
45  
46 382 Medical College Hospital and Research Institute, Madurai, India; Department of  
47  
48 383 Community Medicine, Yenepoya Medical College, Mangalore, India; Karuna Trust,  
49  
50 384 Bangalore, India and National Institute for Research in Tuberculosis, Chennai, India.  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 385 Authors would like to thank the funders, the index cases, their families, and the  
4  
5 386 staff that worked on the RePORT India project. We also acknowledge the contribution  
6  
7 387 of the Data Coordinating Center at Boston Medical Center, US.  
8  
9

## 10 388 **FUNDING**

11  
12  
13 389 The training programme, within which this paper was developed, and the open access  
14  
15 390 publication costs were funded by the Department for International Development  
16  
17 391 (DFID), UK and La Fondation Veuve Emile Metz-Tesch (Luxembourg). The RePORT  
18  
19 392 India project has been funded in whole or in part with Federal funds from the  
20  
21 393 Government of India's (GOI) Department of Biotechnology (DBT), the Indian Council  
22  
23 394 of Medical Research (ICMR), the United States National Institutes of Health (NIH),  
24  
25 395 National Institute of Allergy and Infectious Diseases (NIAID), Office of AIDS Research  
26  
27 396 (OAR), and distributed in part by Civilian Research and Development Foundation  
28  
29 397 (CRDF) Global. The contents of this publication are solely the responsibility of the  
30  
31 398 authors and do not represent the official views of the DBT, the ICMR, the NIH, or  
32  
33 399 CRDF Global. The funders had no role in study design, data collection and analysis,  
34  
35 400 decision to publish, or preparation of the manuscript.  
36  
37  
38  
39  
40  
41

## 42 401 **COMPETING INTERESTS**

43  
44  
45 402 The authors have declared that no competing interests exist.  
46  
47

## 48 403 **CONTRIBUTION OF AUTHORS**

49  
50  
51 404 **RA:** Principal Investigator (PI), conception/ design of the protocol, data capture,  
52  
53 405 development of data capture tool, data analysis / interpretation, drafting / critically  
54  
55 406 reviewing the paper, giving approval for the final version to be published  
56  
57

58 407 **SS:** Acquisition of data, conception/ design of the protocol, revision of manuscript,  
59  
60 408 critically reviewing the paper, giving approval for the final version to be published

1  
2  
3 409 **PC:** Conception/Design of the protocol, development of data capture tool, data  
4  
5 410 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
6  
7 411 final version to be published  
8  
9

10 412 **JK:** Conception/Design of the protocol, development of data capture tool, data  
11  
12 413 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
13  
14 414 final version to be published  
15  
16

17 415 **VM:** Data analysis and interpretation, critically reviewing the paper, giving approval for  
18  
19 416 the final version to be published  
20  
21

22 417 **PTK:** Conception, data analysis, revision of manuscript, critically reviewing the paper,  
23  
24 418 giving approval for the final version to be published  
25  
26

27 419 **SL:** Conception, Project management, critically reviewing the manuscript, giving  
28  
29 420 approval for the final version to be published  
30  
31

32 421 **SK:** Data curation and management, reviewing the manuscript, giving approval for the  
33  
34 422 final version to be published  
35  
36

37 423 **NH:** Project administration and supervision, critically reviewing and editing the  
38  
39 424 manuscript, giving approval for the final version to be published  
40  
41

42 425 **CRH:** Critically reviewing and editing the manuscript, giving approval for the final  
43  
44 426 version to be published  
45  
46

47 427 **JE:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
48  
49 428 version to be published  
50  
51

52 429 **GR:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
53  
54 430 version to be published.  
55  
56

57 431  
58  
59  
60 433

434 **REFERENCES**

- 435 1. World Health Organization. END TB Global Tuberculosis Report 2017. Geneva;  
436 2017. 147 p.
- 437 2. Central TB Division. TB India-Annual Report 2017. India TB Rep [Internet].  
438 2017;1–173. [https://tbcindia.gov.in/WriteReadData/TB India 2017.pdf](https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf)
- 439 3. World Health Organization. WHO Guideline : Nutritional care and support for  
440 patient with tuberculosis. World Heal Organ (2013) WHO Guidel Nutr care  
441 Support patient with Tuberc 9. [http://doi.org/ISBN 978 92 4 150641 0](http://doi.org/ISBN%20978%2092%204%20150641%200). 2013;9.
- 442 4. Coates J, Swindale a, Bilinsky P. Household Food Insecurity Access Scale  
443 (HFAS) for measurement of food access: indicator guide. Washington, DC Food  
444 Nutr Tech .... 2007;(August):Version 3.
- 445 5. Central TB Division. Guidance Document: Nutritional care and support for  
446 patients with Tuberculosis in India. 2017;107.  
447 [http://www.tbcindia.nic.in/WriteReadData/Guidance Document - Nutritional  
448 Care %26 Support for TB patients in India.pdf](http://www.tbcindia.nic.in/WriteReadData/Guidance%20Document%20-%20Nutritional%20Care%20Support%20for%20TB%20patients%20in%20India.pdf)
- 449 6. Bhargava A, Benedetti A, Oxlade O et al. Undernutrition and the incidence of  
450 tuberculosis in India: National and subnational estimates of the population-  
451 attributable fraction related to undernutrition. *Natl Med J India*. 2014;27(3):128–  
452 33.
- 453 7. Sinha Pranay, Davis Juliana, Saag LW et al. Undernutrition and Tuberculosis:  
454 Public Health Implications. *J Infect Dis*. 2019; 219(9):1356–63.
- 455 8. Nhung N V., Hoa NB, Anh NT et al. Measuring catastrophic costs due to  
456 tuberculosis in Viet Nam. *Int J Tuberc Lung Dis*. 2018;22(9):983–90.  
457 <http://www.ingentaconnect.com/content/10.5588/ijtld.17.0859>
- 458 9. Jubulis J, Kinikar A, Ithape M et al. Modifiable risk factors associated with

- 1  
2  
3 459 tuberculosis disease in children in Pune, India. *Int J Tuberc Lung Dis.*  
4  
5 460 2014;18(2):198–204. A  
6  
7  
8 461 10. Central TB Division. National Strategic Plan for Tuberculosis Elimination 2017-  
9  
10 462 2025. *Dir Gen Heal Serv Minist Heal Fam Welf.* 2017;(March):110–108.  
11  
12 463 11. Van Ness SE, Chandra A, Sarkar S et al. Predictors of delayed care seeking for  
13  
14 464 tuberculosis in southern India: An observational study. *BMC Infect Dis.*  
15  
16 465 2017;17(1):1–9.  
17  
18  
19 466 12. N.S. Hochberg, S. Sarkar, C.R. Horsburgh et al. Comorbidities in pulmonary  
20  
21 467 tuberculosis cases in Puducherry and Tamil Nadu, India: Opportunities for  
22  
23 468 intervention. *PLoS One.* 2017;12(8):e0183195.  
24  
25  
26 469 13. Hoyt KJ, Sarkar S, White L et al. Effect of malnutrition on radiographic findings  
27  
28 470 and mycobacterial burden in pulmonary tuberculosis. *PLoS One.* 2019;14(3):1–  
29  
30 471 11.  
31  
32  
33 472 14. Leong S, Zhao Y, Joseph NM et al. Existing blood transcriptional classifiers  
34  
35 473 accurately discriminate active tuberculosis from latent infection in individuals  
36  
37 474 from south India. *Tuberculosis* . 2018;109(August 2017):41–51.  
38  
39 475 <https://doi.org/10.1016/j.tube.2018.01.002>  
40  
41  
42 476 15. Hamilton CD, Swaminathan S, Christopher DJ et al. RePORT International:  
43  
44 477 Advancing Tuberculosis Biomarker Research Through Global Collaboration.  
45  
46 478 *Clin Infect Dis.* 2015;61(Suppl 3):S155–9.  
47  
48  
49 479 16. Babor TF, Saunders JCH-BJB, Monteiro MG. The Alcohol Use Disorder  
50  
51 480 Identification Test. Guidelines for Use in Primary Care. World Heal Organ  
52  
53 481 Geneva. 2015;(2):1–41.  
54  
55  
56 482 17. Chinnakali P, Upadhyay RP, Shokeen D et al. Prevalence of household-level  
57  
58 483 food insecurity and its determinants in an urban resettlement colony in North  
59  
60



- 1  
2  
3 484 India. *J Heal Popul Nutr*. 2014;32(2):227–36.
- 4  
5 485 18. Joshi A, Arora A, Amadi-Mgbenka C et al. Burden of household food insecurity  
6  
7 in urban slum settings. *PLoS One*. 2019;14(4):1–24.
- 8 486  
9  
10 487 19. Jayasuriya NA, Nayanathara L, Iddamalgoda N et al. Food Security and  
11  
12 488 Nutrition among the Tuberculosis infected patients. A case study among the  
13  
14 489 patients screened at Chest Clinic of Medical Research Institute of Colombo, Sri  
15  
16 Lanka. *World Food Programme: Food security analysis(VAM)*.2014 August.
- 17 490  
18  
19 491 20. Bloem MW, Saadeh R. The role of nutrition and food insecurity in HIV and  
20  
21 492 tuberculosis infections and the implications for interventions in resource-limited  
22  
23 493 settings. *Foreword. Food Nutr Bull*. 2010;31(4):S289-91.  
24  
25 <http://www.ncbi.nlm.nih.gov/pubmed/21214034>
- 26 494  
27  
28 495 21. Swaminathan S, Padmapriyadarsini C, Sukumar B et al. Nutritional Status of  
29  
30 496 Persons with HIV Infection, Persons with HIV Infection and Tuberculosis, and  
31  
32 497 HIV-Negative Individuals from Southern India. *Clin Infect Dis*. 2008;46(6):946–  
33  
34 498 9.
- 35  
36  
37 499 22. Yadav S, Atif M, Rawal G. Nikshay Poshan Yojana- Another step to eliminate  
38  
39 500 TB from India. *IP Indian J Immunol Respir Med*. 2018;3(2):28–9.
- 40  
41  
42 501 23. Gupta KB, Gupta R, Atreja A et al. Tuberculosis and nutrition. *Lung india*.  
43  
44 502 2015;26(1):9–16.
- 45  
46  
47 503 24. Park HO, Kim SH, Moon SH et al. Association between body mass index and  
48  
49 504 sputum culture conversion among South Korean patients with multidrug  
50  
51 505 resistant tuberculosis in a tuberculosis referral hospital. *Infect Chemother*.  
52  
53 506 2016;48(4):317–23.
- 54  
55  
56 507 25. Lönnroth K, Williams BG, Stadlin S et al. Alcohol use as a risk factor for  
57  
58 508 tuberculosis - A systematic review. *BMC Public Health*. 2008;8.
- 59  
60

- 1  
2  
3 509 26. Podewils LJ, Holtz T, Riekstina V et al. Impact of malnutrition on clinical  
4  
5 510 presentation, clinical course, and mortality in MDR-TB patients. *Epidemiol*  
6  
7 511 *Infect.* 2011;139(1):113–20.
- 8  
9  
10 512 27. Mekonnen HS, Azagew AW. Non-adherence to anti-tuberculosis treatment,  
11  
12 513 reasons and associated factors among TB patients attending at Gondar town  
13  
14 514 health centers, Northwest Ethiopia 11 *Medical and Health Sciences* 1103  
15  
16 515 *Clinical Sciences* 11 *Medical and Health Sciences* 1117 *Public Hea. BMC Res*  
17  
18 516 *Notes.* 2018;11(1):1–8. <https://doi.org/10.1186/s13104-018-3789-4>
- 19  
20  
21 517 28. Munro SA, Lewin SA, Smith HJ et al. Patient adherence to tuberculosis  
22  
23 518 treatment: A systematic review of qualitative research. *PLoS Med.*  
24  
25 519 2007;4(7):1230–45.
- 26  
27  
28 520 29. Diefenbach-Elstob T, Plummer D, Dowi R et al. The social determinants of  
29  
30 521 tuberculosis treatment adherence in a remote region of Papua New Guinea.  
31  
32 522 *BMC Public Health.* 2017;17(1):1–12. [http://dx.doi.org/10.1186/s12889-016-](http://dx.doi.org/10.1186/s12889-016-3935-7)  
33  
34 523 3935-7
- 35  
36  
37 524  
38  
39 525  
40  
41 526  
42  
43 527  
44  
45 528  
46  
47 529  
48  
49 530  
50  
51 531  
52  
53 532  
54  
55  
56  
57  
58  
59  
60

533 **Table 1: Socio-demographic characteristics of individuals with pulmonary**  
 534 **tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)**

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)
60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)
Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)

>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)
Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

535

536

537

538

539

540

541

542

543

544

545

546 **Table 2: Morbidity and behavioural characteristics of individuals with pulmonary**  
 547 **tuberculosis (TB) in three districts of South India, 2015-2018(N=765)**

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)
Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)
Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)

Never	394 (51.5)
-------	------------

548 \*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were  
549 reported by the participants

550 † Alcohol use- Alcohol use was measured for the past one year

551 ‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

552

553

554

555

556

557

558

559

560

561

562

563

564

565

566

567

568 **Table 3: Components of household food insecurity among households of**  
 569 **pulmonary tuberculosis (TB) patients in three districts of South India, 2015-**  
 570 **2018. (N=765)**

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
<b>I. Worry or anxiety about food</b>				
1.worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
<b>II. Insufficient Quality of Food</b>				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
<b>III. Insufficient Quantity of Food</b>				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)
7. There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)

9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)
--	---------------	----------	----------	---------

571 \*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past

572 four weeks), 3 = Often (more than ten times in the past four weeks)

573

574

575

576

577

578

579

580

581

582

583

584

585

586

587

588

For peer review only



589 **Table 4: Association of socio-demographic, morbidity, and behavioural**  
 590 **characteristics with household food insecurity among individuals with**  
 591 **pulmonary TB in Puducherry, N= 765**

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				
15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.91.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)
Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)

5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residence				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-
Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)
≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index				

< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-
Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

592 \*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale

593 (HFIAS) for Measurement of Food Access-FANTAIII

594 †PR- Prevalence ratio

595 ‡ CI-Confidence Interval

596 § Adjusted for characteristics with p-value<0.2 in the univariate model

597 || Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

## ANNEXURE 1

## Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence <sup>1</sup>			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1. worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7. There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				

9. Any household member go a whole day and night without eating anything because there was not enough food

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

### HFIA category

- 1 = Food Secure
- HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
- HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
- HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
- HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

# BMJ Open

## Household food insecurity among pulmonary tuberculosis patients and its associated factors in south India: A cross-sectional analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033798.R1
Article Type:	Original research
Date Submitted by the Author:	12-Nov-2019
Complete List of Authors:	<p>Ayiraveetil, Reshma; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Sarkar, Sonali; JIPMER, Preventive and Social Medicine; JIPMER, Preventive and Social Medicine Chinnakali, Palanivel; Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Department of Preventive and Social Medicine Jeyashree, Kathiresan; Velammal Medical College Hospital and Research Institute, Vijayageetha, Mathavaswami; Jawaharlal Institute for Postgraduate Medical Education and Research, Department of Preventive and Social Medicine Thekkur, Pruthu; International Union Against Tuberculosis and Lung Disease, Centre for Operational Research; The Union South-East Asia Office, Centre for Operational Research Lakshminarayanan, Subitha; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Knudsen, Selby; 7. Boston Medical Center, Boston, Massachusetts, United States of America, Department of Infectious Diseases Hochberg, Natasha; Boston University School of Medicine, Section of Infectious Diseases, Department of Medicine; 6. Boston University School of Public Health, Boston, Massachusetts, United States of America, Department of Epidemiology Horsburgh, C ; Boston University Ellner, Jerrold; 8. Rutgers University, New Jersey, US, Department of Medicine, Roy, Gautam; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine</p>
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Epidemiology, Health services research, Infectious diseases, Public health
Keywords:	Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.



**1 TITLE**

2 Household food insecurity among pulmonary tuberculosis patients and its associated  
3 factors in south India: A cross sectional analysis

4 **MANUSCRIPT TYPE:** Research Article

**5 SHORT RUNNING TITLE**

6 Household Food insecurity in TB patients

**7 AUTHORS**

8 Ayiraveetil Reshma,<sup>1</sup> Sonali Sarkar,<sup>1</sup> Palanivel Chinnakali,<sup>1</sup> Kathiresan Jeyashree,<sup>2</sup>  
9 Mathavaswami Vijayageetha,<sup>1</sup> Pruthu Thekkur,<sup>3,4</sup> Subitha Lakshminarayanan,<sup>1</sup> Selby  
10 Knudsen,<sup>7</sup> Natasha S. Hochberg,<sup>5,6,7</sup> C. Robert Horsburgh,<sup>5,6</sup> Jerrold Ellner,<sup>6</sup> Gautam  
11 Roy,<sup>1</sup>

12 1. Department of Preventive and Social Medicine, Jawaharlal Institute of  
13 Postgraduate Medical Education and Research (JIPMER), Puducherry, India.

14 2. Department of Community Medicine, Velammal Medical College, Madurai,  
15 Tamilnadu.

16 3. Centre for Operational Research, International Union Against Tuberculosis and  
17 Lung Disease (The Union), Paris, France

18 4. The Union, South East Asia Office, New Delhi, India.

19 5. Section of Infectious Diseases, Department of Medicine, Boston University  
20 School of Medicine, Boston, Massachusetts, United States of America

21 6. Boston University School of Public Health, Boston, Massachusetts, United  
22 States of America

23 7. Boston Medical Center, Boston, Massachusetts, United States of America

24 8. Department of Medicine, Rutgers University, New Jersey, US

1  
2  
3 25 **WORD COUNT**  
4

5 26 **Abstract :299**  
6

7  
8 27 **Text: 2273 (excluding summary, references, tables and figures)**  
9

10 28 **NUMBER OF TABLES: 4+1 (Supplementary file)**  
11

12 29 **NUMBER OF FIGURES: nil**  
13

14 30 **NUMBER OF REFERENCES: 29**  
15

16  
17 31 **AUTHOR FOR CORRESPONDENCE**  
18

19 32 Dr. Sonali Sarkar  
20

21 33 Additional Professor & Head  
22

23 34 Department of Preventive and Social Medicine, JIPMER  
24

25 35 E-mail: [sarkarsonaligh@gmail.com](mailto:sarkarsonaligh@gmail.com)  
26

27 36 Phone: (+91) 9442174663  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 50 **ABSTRACT**

### 51 **Objectives**

52 Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe  
53 foods or inability to acquire foods in socially acceptable ways'. Majority of Tuberculosis  
54 (TB) cases of resource-poor settings experience food insecurity, which impacts  
55 treatment adherence and outcomes. We aimed to determine level of household food  
56 insecurity (HFI) and its associated factors in pulmonary tuberculosis (TB) patients.

### 57 **Design**

58 This is a cross sectional analysis of data from an ongoing cohort study.

### 59 **Setting**

60 National Tuberculosis Program (NTP) in three districts of south India.

### 61 **Participants**

62 All newly diagnosed pulmonary TB cases of the cohort enrolled from National  
63 Tuberculosis Program at the Designated Microscopy Centres (DMCs) and Primary  
64 Health Centres (PHCs) from October 2015 to October 2018.

### 65 **Primary Outcome Measures**

66 The proportion of baseline HFI assessed using a validated household food insecurity  
67 access scale was summarized as percentage with 95% confidence interval (CI).  
68 Possible association of socio-demographic, morbidity and behavioural characteristics  
69 with HFI was assessed using chi-squared test, unadjusted prevalence ratios with 95%  
70 CI were calculated. The characteristics with p value less than 0.2 in the univariate  
71 model were included in multivariable generalized linear model (binomial function, log  
72 link) to derive adjusted prevalence ratios (aPR) with 95% CI.

## 73 **Result**

74 Of total 765 patients, 261 had HFI and the proportion was 34.1% (95% CI 30.8-37.6%).  
75 Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177  
76 (23.1%) TB cases respectively. TB patients who had monthly family income less than  
77 INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-  
78 1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of  
79 HFI.

## 80 **Conclusions**

81 High level of food insecurity was seen in households of TB cases. Additional food or  
82 cash assistance for this subgroup might improve food insecurity and thereby nutritional  
83 status.

## 84 **Key Words**

85 Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

## 87 **Article Summary**

### 88 **Strengths:**

- 89 • Use of a validated tool for assessing household food insecurity which allows  
90 cross country comparisons.
- 91 • We used the data from a prospective cohort study which implemented quality  
92 assurance checks for data collection, entry and completeness that would have  
93 reduced missing data and data errors.
- 94 • Our study included patients identified in the public sector alone and food  
95 insecurity levels may be different in patients accessing TB care in the private  
96 sector.

1  
2  
3 97 **Limitations:**  
4  
5

- 6 98 • We did not study the sub group of previously treated TB patients in whom levels  
7  
8 99 of food insecurity could be higher due to financial loss caused by repeated  
9  
10 100 episodes of TB.  
11  
12  
13 101 • The study participants were from selected three districts in south India, so  
14  
15 102 generalizability of the findings is limited.  
16  
17  
18  
19 103  
20  
21 104  
22  
23 105  
24  
25 106  
26  
27 107  
28  
29 108  
30  
31 109  
32  
33 110  
34  
35 111  
36  
37 112  
38  
39 113  
40  
41 114  
42  
43  
44  
45

46 115 **INTRODUCTION**  
47  
48

49 116 Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking  
50  
51 117 above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017,  
52  
53 118 there were an estimated 1.3 million TB deaths among HIV-negative people. India  
54  
55 119 contributes roughly 25% of global incident TB cases and there were an estimated  
56  
57 120 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health  
58  
59  
60

1  
2  
3 121 Organization (WHO) endorsed the “End TB strategy” in line with the Sustainable  
4  
5 122 Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal  
6  
7 123 with action on poverty, hunger and ensuring healthy lives and well-being of people)  
8  
9  
10 124 with a common aim to end the global TB epidemic.(1,3)  
11  
12

13 125 Food security is a state in which “all people at all times have both physical and  
14  
15 126 economic access to sufficient food to meet their dietary needs for a productive and  
16  
17 127 healthy life”.(4) Catastrophic health expenditure is a common consequence of TB  
18  
19 128 diagnosis, treatment and care which can lead to impoverishment and in turn food  
20  
21 129 insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional  
22  
23 130 relationship with TB; both cause TB and could be consequences of TB. Undernutrition  
24  
25 131 in patients with active TB can lead to worsening of disease, drug toxicity, drug  
26  
27 132 malabsorption and death or relapse of disease. (5–7)  
28  
29  
30  
31

32 133 A recent national survey (2016) in Vietnam reported that 22% of households  
33  
34 134 experienced food insecurity during TB treatment, this proportion being as high as 40%  
35  
36 135 among the poorest wealth quintiles.(8) Food insecurity at the household level is  
37  
38 136 common in India and is a strong risk factor for progression of latent infection to active  
39  
40 137 TB in household contacts.(9) TB in India affects poor families and communities  
41  
42 138 disproportionately, with a fourfold higher prevalence in those with a low standard of  
43  
44 139 living index compared to those with a high standard of living index.(5) Food insecurity  
45  
46 140 is also of greatest significance in households where levels of food insecurity and  
47  
48 141 undernutrition are high at the time of diagnosis. Since food insecurity and under-  
49  
50 142 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite  
51  
52 143 effective treatment.  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 144 WHO (2013) in its guidelines 'Nutritional care and support for patients with  
4  
5 145 tuberculosis' recommends assessment of food insecurity among TB cases and  
6  
7 146 addressing the same with suitable packages including food assistance.(3) Recently,  
8  
9  
10 147 Government of India has launched a cash assistance scheme for all TB cases to  
11  
12 148 mitigate costs and improve nutritional status. (10) However, there may be households  
13  
14 149 with more food insecurity that need more food assistance rather than equal assistance  
15  
16  
17 150 to all. In India, studies assessing household food insecurity among TB cases are  
18  
19 151 limited. Therefore, we aimed to determine the level of food insecurity and its  
20  
21 152 associated factors using secondary data from a cohort of pulmonary TB patients in  
22  
23  
24 153 south India.  
25  
26  
27 154  
28  
29  
30 155  
31  
32  
33 156  
34  
35  
36 157  
37  
38  
39 158  
40  
41  
42 159  
43  
44  
45 160  
46  
47  
48 161  
49  
50  
51 162 **METHODS**  
52  
53  
54 163 **Study Design**  
55  
56  
57  
58  
59  
60

1  
2  
3 164 This is a cross sectional analysis of data from a cohort study under RePORT India  
4  
5 165 Consortium (Regional Prospective Observational Research for Tuberculosis). Details  
6  
7 166 of the study design have been previously reported. (11–14)  
8  
9

10  
11 167 *National tuberculosis program (NTP)*  
12

13  
14 168 The study covers Puducherry district of Union Territory of Puducherry (population~1.3  
15  
16 169 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5  
17  
18 170 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB  
19  
20 171 diagnostic and treatment services are delivered through the designated microscopy  
21  
22 172 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units  
23  
24 173 (TUs) as nodal points for TB control activities at sub-district level. Sputum smear  
25  
26 174 microscopy remains the central component of TB diagnosis. Under NTP, both  
27  
28 175 diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of  
29  
30 176 TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity  
31  
32 177 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment  
33  
34 178 outcomes of these patients are documented in individual TB treatment card.  
35  
36  
37  
38

39  
40 179 *RePORT International*  
41

42  
43 180 Regional Prospective Observational Research in Tuberculosis (RePORT)  
44  
45 181 International represents a consortium of regional cohorts (RePORT India, RePORT  
46  
47 182 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT  
48  
49 183 Indonesia) that are linked through the implementation of a common protocol for data  
50  
51 184 and specimen collection. Objectives and composition of RePORT International are  
52  
53 185 described elsewhere.(15)  
54  
55

56  
57 186 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate  
58  
59 187 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers  
60



1  
2  
3 188 University has established a pulmonary TB cohort of adults and children  $\geq 6$  years and  
4  
5 189 their household contacts to identify biomarkers for risk of TB treatment failure and risk  
6  
7  
8 190 of development of TB in household contacts. TB cases diagnosed under NTP in the  
9  
10 191 three districts (Puducherry, Cuddalore and Villupuram) were enrolled in the cohort at  
11  
12 192 the designated microscopy centres and public health centres since 2014. Only newly  
13  
14 193 diagnosed smear and culture positive pulmonary TB cases were included. Details on  
15  
16  
17 194 data collection and procedures were previously reported (11-14).

### 195 **Study population**

196 For this analysis, we included all TB cases of the cohort enrolled from October 2015  
197 to October 2018. Multi drug resistant and extremely drug resistant TB cases at  
198 diagnosis were excluded.

### 200 **Study tool**

201 Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food  
202 insecurity in the households in the past 30 days. The scale consists of nine items  
203 grouped under three domains: 1) anxiety or uncertainty about the household food  
204 supply 2) Insufficient Quality and 3) Insufficient food intake and its physical  
205 consequences (4). The respondent is first asked an occurrence question, whether the  
206 condition in the question happened at all in the past four weeks (yes or no). If the  
207 respondent answers “yes” to an occurrence question, a frequency-of-occurrence  
208 question is asked to determine whether the condition happened rarely (once or twice),  
209 sometimes (three to ten times) or often (more than ten times) in the past four weeks.  
210 Each item is scored on a range of 0 to 3; zero for ‘no occurrence’ and three for ‘often’.  
211 The minimum and maximum score for a household are 0 and 27 respectively. The

1  
2  
3 212 scores were categorized into four levels of household food insecurity: food secure and  
4  
5 213 mild, moderately and severely food insecure (4)-Annexure 1.

6  
7  
8 214 Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version  
9  
10 215 of AUDIT) (16) was used to assess the alcohol use among participants.

### 11 12 216 **Data extraction, analysis and statistics**

13  
14  
15 217 Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases  
16  
17 218 excluding two childhood TB cases; the initial 462 cases enrolled were not assessed  
18  
19 219 for household food insecurity and were excluded. Data were extracted from the  
20  
21 220 RePORT India project database for JIPMER site in a de-identified manner and  
22  
23 221 analysed using Stata 12.0 software. The proportion of household food insecurity was  
24  
25 222 summarized as percentage with 95% confidence interval (CI). Possible association of  
26  
27 223 socio-demographic, morbidity related and behavioural characteristics with household  
28  
29 224 food insecurity was assessed using chi-squared test and unadjusted prevalence ratios  
30  
31 225 with 95% CI were calculated. The characteristics with p value less than 0.2 in the  
32  
33 226 univariate model were included in multivariable generalized linear model (binomial  
34  
35 227 function and log link) to derive adjusted prevalence ratios(aPR) with 95% CI. The  
36  
37 228 variables such as marital status, education, residence, number of earners in the  
38  
39 229 household, HIV status, tobacco use, and alcohol use were not included for multivariate  
40  
41 230 analysis.

### 42 43 44 45 46 47 48 231 **Ethics Approval**

49  
50  
51 232 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER  
52  
53 233 (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center  
54  
55 234 (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was  
56  
57 235 obtained from all participants before enrolment. The study protocol for this secondary  
58  
59  
60

1  
2  
3 236 analysis was reviewed and approved by Ethics Advisory Group of the International  
4  
5 237 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.  
6  
7

8 238 **Data sharing document:**  
9

10  
11 239 Technical appendix, statistical code, and data set will be available upon request from  
12  
13 240 the Corresponding author.  
14  
15

16 241 **Patient and Public Involvement**  
17

18  
19 242 There was no patient or public involvement.  
20  
21  
22  
23 243  
24  
25  
26 244  
27  
28  
29 245  
30  
31  
32 246  
33  
34  
35 247  
36

37 248 **RESULTS**  
38

39  
40 249 Of the 765 individuals included in analysis, the mean (standard deviation) age was 44  
41  
42 250 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases  
43  
44 251 are described in **Table-1**. Of total, 131 (17%) participants did not have any formal  
45  
46 252 education, about 77% were employed and 11% had monthly family income less than  
47  
48 253 INR 3000 (~USD 43). Behavioural and disease related characteristics are described  
49  
50 254 in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30%  
51  
52 255 were current tobacco users. Of total, 470 (61%) were underweight (body mass index  
53  
54 256 <18.5 kg/m<sup>2</sup>) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or  
55  
56 257 less (require assistance for routine activities) in 29% of patients.  
57  
58  
59  
60

1  
2  
3 258 Overall, 261 patients had household food insecurity and the proportion was 34.1%  
4  
5 259 (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17  
6  
7 260 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food  
8  
9 261 insecurity are described in **Table-3**. Worry or anxiety about not having enough food  
10  
11 262 was reported in 15% of TB households. In 21% of TB households, eating fewer meals  
12  
13 263 in a day due to lack of enough food was reported.  
14  
15  
16

17  
18 264 Level of food insecurity in different sub groups is presented in **Table-4**. In adjusted  
19  
20 265 analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95%  
21  
22 266 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were  
23  
24 267 employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of household food insecurity.  
25  
26  
27

28 268

29 269

30 270

## 31 271 **DISCUSSION**

32  
33  
34  
35  
36  
37  
38  
39 272 Our study among newly diagnosed pulmonary TB patients in public sector in south  
40  
41 273 India revealed that about one third of TB patients experienced household food  
42  
43 274 insecurity; about one out of four patients experienced severe food insecurity at the  
44  
45 275 time of diagnosis. Level of food insecurity was high in low income groups, employed  
46  
47 276 and those who had severe illness.  
48  
49

50  
51 277 Prevalence of food insecurity in the general population of India is also high ranging  
52  
53 278 from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is  
54  
55 279 common as it can be both a cause and consequence of TB. The national level survey  
56  
57  
58  
59  
60

1  
2  
3 280 from Vietnam (2016) reported 22% of TB patients experienced household food  
4  
5 281 insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)  
6  
7

8 282 Food insecurity was twice as high in low income TB households (INR<3000) compared  
9  
10 283 to their higher income counterparts. Catastrophic health expenditure, a consequence  
11  
12 284 of TB diagnosis and treatment can lead to worsening of food insecurity in low income  
13  
14 285 groups during the course of the disease.(5) These subgroups need to be provided  
15  
16 286 additional assistance instead of 'equal for all' food or cash assistance benefits. Since  
17  
18 287 income is usually underreported, identifying such target groups may not be an easy  
19  
20 288 task.  
21  
22  
23

24  
25 289 Food insecurity at the household level is a strong risk factor for progression of latent  
26  
27 290 infection to active TB in household contacts. (9,20) Since, food insecurity measures  
28  
29 291 are applicable to all households, a wider approach of reducing food insecurity targeting  
30  
31 292 all household contacts is needed.  
32  
33  
34

35 293 In our study, about 60% of the TB patients were underweight. Undernutrition is both  
36  
37 294 an important risk factor for, and a common consequence of TB. In food insecure  
38  
39 295 households, undernutrition could be an intermediary step in the nutritional pathway of  
40  
41 296 food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent  
42  
43 297 in patients with TB and the dietary intake of calories is significantly lower (500-700  
44  
45 298 calories) than recommended. (21) As recommended by WHO, addressing  
46  
47 299 undernutrition through nutritional counselling and support should be considered as  
48  
49 300 part of the standard of care for people with TB. The recently launched "Nikshay Poshan  
50  
51 301 Yojana", a direct benefit transfer scheme by the government of India is a welcome step  
52  
53 302 towards addressing undernutrition. (22) Our study did not include severely ill patients  
54  
55 303 (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates  
56  
57  
58  
59  
60

1  
2  
3 304 are expected to be high. This may partly explain why our study did not find an  
4  
5 305 association between food insecurity and undernutrition, though previous studies have  
6  
7 306 reported otherwise. (23–26) Also, we have assessed food insecurity at the level of  
8  
9 307 household and body mass index assessed is that of the individual patients. May be  
10  
11 308 the patient's nutrition is maintained at the expense of other family members, so he or  
12  
13 309 she may have had normal BMI. In this study, we couldn't explore details on  
14  
15 310 employment such as type of employment, which could be a risk factor for development  
16  
17 311 of TB and could have influenced the income and thus the ability to purchase food items  
18  
19 312 also.

20  
21  
22  
23  
24 313 Several studies support the notion that food insecurity negatively affects treatment  
25  
26 314 adherence. Conditions of food insecurity (lack of adequate food, concern about daily  
27  
28 315 food production) contribute to non-adherence to TB treatment as reported by  
29  
30 316 qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis  
31  
32 317 and linking the patients to food assistance or social security programs is needed. We  
33  
34 318 plan to report the effect of food insecurity on adherence and TB treatment outcomes  
35  
36 319 in a separate paper.

37  
38  
39  
40  
41 320 Strengths of the study include use of a validated tool (4) for assessing household food  
42  
43 321 insecurity which allows cross country comparisons. We used the data from a  
44  
45 322 prospective cohort study which implemented quality assurance checks for data  
46  
47 323 collection and entry that would have reduced missing data and data errors. Our study  
48  
49 324 included patients identified in the public sector alone and food insecurity levels may  
50  
51 325 be different in patients accessing TB care in the private sector. Since, repeated  
52  
53 326 episodes of TB may be a cause for financial loss leading to food insecurity, the levels  
54  
55 327 could be higher in previously treated TB patients and we did not study this sub group.  
56  
57 328 Being a cross sectional analysis, causal relationships of factors with food insecurity

1  
2  
3 329 cannot be inferred. The study participants were from selected three districts in south  
4  
5 330 India, so generalisability of the findings is limited.  
6  
7  
8  
9 331

## 10 11 332 **CONCLUSION**

12  
13  
14 333 To conclude, household food insecurity was experienced by one in three TB patients  
15  
16 334 and this was twice higher in low income groups. Additional food or cash assistance to  
17  
18 335 food insecure TB patients and household contacts will improve the food insecurity and  
19  
20  
21 336 undernutrition.  
22  
23

24 337

25  
26 338

27  
28 339

29  
30 340

31  
32 341

33  
34 342

35  
36 343

## 37 38 344 **ACKNOWLEDGEMENTS**

39  
40  
41 345 This cross-sectional analysis was conducted through the Structured  
42  
43 346 Operational Research and Training Initiative (SORT IT), a global partnership led by  
44  
45 347 the Special Programme for Research and Training in Tropical Diseases at the World  
46  
47 348 Health Organization (WHO/TDR). The model is based on a course developed jointly  
48  
49 349 by the International Union Against Tuberculosis and Lung Disease (The Union) and  
50  
51 350 Médecins sans Frontières (MSF/Doctors Without Borders). The specific SORT IT  
52  
53 351 programme which resulted in this publication was jointly developed and implemented  
54  
55 352 by: The Union South-East Asia Office, New Delhi, India; the Centre for Operational  
56  
57  
58  
59  
60

1  
2  
3 353 Research, The Union, Paris, France; Department of Preventive and Social Medicine,  
4  
5 354 Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry,  
6  
7 355 India; Department of Community Medicine and School of Public Health, Postgraduate  
8  
9 356 Institute of Medical Education and Research, Chandigarh, India; Department of  
10  
11 357 Community Medicine, All India Institute of Medical Sciences, Nagpur, India; Dr.  
12  
13 358 Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical  
14  
15 359 Sciences, New Delhi, India; Department of Community Medicine, Pondicherry Institute  
16  
17 360 of Medical Science, Puducherry, India; Department of Community Medicine, Kalpana  
18  
19 361 Chawla Medical College, Karnal, India; National Centre of Excellence and Advance  
20  
21 362 Research on Anaemia Control, All India Institute of Medical Sciences, New Delhi,  
22  
23 363 India; Department of Community Medicine, Sri Manakula Vinayagar Medical College  
24  
25 364 and Hospital, Puducherry, India; Department of Community Medicine, Velammal  
26  
27 365 Medical College Hospital and Research Institute, Madurai, India; Department of  
28  
29 366 Community Medicine, Yenepoya Medical College, Mangalore, India; Karuna Trust,  
30  
31 367 Bangalore, India and National Institute for Research in Tuberculosis, Chennai, India.  
32  
33  
34  
35  
36  
37

38 368 Authors would like to thank the funders, the index cases, their families, and the  
39  
40 369 staff that worked on the RePORT India project. We also acknowledge the contribution  
41  
42 370 of the Data Coordinating Center at Boston Medical Center, US.  
43  
44  
45

## 371 **FUNDING**

372 The training programme, within which this paper was developed, and the open access  
373 publication costs were funded by the Department for International Development  
374 (DFID), UK and La Fondation Veuve Emile Metz-Tesch (Luxembourg). The RePORT  
375 India project has been funded in whole or in part with Federal funds from the  
376 Government of India's (GOI) Department of Biotechnology (DBT), the Indian Council  
377  
378  
379  
380



1  
2  
3 377 of Medical Research (ICMR),the United States National Institutes of Health (NIH),  
4  
5 378 National Institute of Allergy and Infectious Diseases (NIAID), Office of AIDS Research  
6  
7  
8 379 (OAR), and distributed in part by Civilian Research and Development Foundation  
9  
10 380 (CRDF) Global. The contents of this publication are solely the responsibility of the  
11  
12 381 authors and do not represent the official views of the DBT, the ICMR, the NIH, or  
13  
14 382 CRDF Global. The funders had no role in study design, data collection and analysis,  
15  
16  
17 383 decision to publish, or preparation of the manuscript.  
18  
19

## 20 384 **COMPETING INTERESTS**

21  
22  
23 385 The authors have declared that no competing interests exist.  
24  
25

## 26 386 **CONTRIBUTION OF AUTHORS**

27  
28  
29 387 **RA:** Principal Investigator (PI), conception/ design of the protocol, data capture,  
30  
31 388 development of data capture tool, data analysis / interpretation, drafting / critically  
32  
33 389 reviewing the paper, giving approval for the final version to be published  
34

35  
36 390 **SS:** Acquisition of data, conception/ design of the protocol, revision of manuscript,  
37  
38 391 critically reviewing the paper, giving approval for the final version to be published  
39

40  
41 392 **PC:** Conception/Design of the protocol, development of data capture tool, data  
42  
43 393 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
44  
45 394 final version to be published  
46

47 395 **JK:** Conception/Design of the protocol, development of data capture tool, data  
48  
49 396 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
50  
51 397 final version to be published  
52

53  
54 398 **VM:** Data analysis and interpretation, critically reviewing the paper, giving approval for  
55  
56 399 the final version to be published  
57  
58  
59  
60

1  
2  
3 400 **PTK:** Conception, data analysis, revision of manuscript, critically reviewing the paper,  
4  
5 401 giving approval for the final version to be published  
6

7 402 **SL:** Conception, Project management, critically reviewing the manuscript, giving  
8  
9 403 approval for the final version to be published  
10

11 404 **SK:** Data curation and management, reviewing the manuscript, giving approval for the  
12  
13 405 final version to be published  
14

15 406 **NH:** Project administration and supervision, critically reviewing and editing the  
16  
17 407 manuscript, giving approval for the final version to be published  
18

19 408 **CRH:** Critically reviewing and editing the manuscript, giving approval for the final  
20  
21 409 version to be published  
22

23 410 **JE:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
24  
25 411 version to be published  
26

27 412 **GR:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
28  
29 413 version to be published.  
30

31 414

32 415

33 416

34 417

## 35 418 **REFERENCES**

36 419 1. World Health Organization. END TB Global Tuberculosis Report 2017. Geneva;  
37  
38 420 2017. 147 p.

39 421 2. Central TB Division. TB India-Annual Report 2017. India TB Rep [Internet].  
40  
41 422 2017;1–173. [https://tbcindia.gov.in/WriteReadData/TB India 2017.pdf](https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf)

42 423 3. World Health Organization. WHO Guideline : Nutritional care and support for  
43  
44 424 patient with tuberculosis. World Heal Organ (2013) WHO Guidel Nutr care  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 424 Support patient with Tuberc 9. [http://doi.org/ISBN 978 92 4 150641 0](http://doi.org/ISBN%20978%2092%204%20150641%200). 2013;9.  
4  
5 425 4. Coates J, Swindale a, Bilinsky P. Household Food Insecurity Access Scale  
6 (HFAS) for measurement of food access: indicator guide. Washington, DC Food  
7  
8 426  
9  
10 427 Nutr Tech .... 2007;(August):Version 3.  
11  
12 428 5. Central TB Division. Guidance Document: Nutritional care and support for  
13 patients with Tuberculosis in India. 2017;107.  
14  
15 429  
16  
17 430 [http://www.tbcindia.nic.in/WriteReadData/Guidance Document - Nutritional](http://www.tbcindia.nic.in/WriteReadData/Guidance%20Document%20-%20Nutritional%20Care%20Support%20for%20TB%20patients%20in%20India.pdf)  
18  
19 431 Care %26 Support for TB patients in India.pdf  
20  
21 432 6. Bhargava A, Benedetti A, Oxlade O et al. Undernutrition and the incidence of  
22 tuberculosis in India: National and subnational estimates of the population-  
23 attributable fraction related to undernutrition. Natl Med J India. 2014;27(3):128–  
24 433  
25  
26 434  
27  
28 435 33.  
29  
30 436 7. Sinha Pranay, Davis Juliana, Saag LW et al. Undernutrition and Tuberculosis:  
31 Public Health Implications. J Infect Dis. 2019; 219(9):1356–63.  
32  
33 437  
34  
35 438 8. Nhung N V., Hoa NB, Anh NT et al. Measuring catastrophic costs due to  
36 tuberculosis in Viet Nam. Int J Tuberc Lung Dis. 2018;22(9):983–90.  
37  
38 439  
39  
40 440 <http://www.ingentaconnect.com/content/10.5588/ijtld.17.0859>  
41  
42 441 9. Jubulis J, Kinikar A, Ithape M et al. Modifiable risk factors associated with  
43 tuberculosis disease in children in Pune, India. Int J Tuberc Lung Dis.  
44  
45 442  
46  
47 443 2014;18(2):198–204. A  
48  
49 444 10. Central TB Division. National Strategic Plan for Tuberculosis Elimination 2017-  
50 2025. Dir Gen Heal Serv Minist Heal Fam Welf. 2017;(March):110–108.  
51  
52 445  
53  
54 446 11. Van Ness SE, Chandra A, Sarkar S et al. Predictors of delayed care seeking for  
55 tuberculosis in southern India: An observational study. BMC Infect Dis.  
56  
57 447  
58  
59 448 2017;17(1):1–9.  
60

- 1  
2  
3 449 12. N.S. Hochberg, S. Sarkar, C.R. Horsburgh et al. Comorbidities in pulmonary  
4  
5 450 tuberculosis cases in Puducherry and Tamil Nadu, India: Opportunities for  
6  
7 451 intervention. PLoS One. 2017;12(8):e0183195.  
8  
9  
10 452 13. Hoyt KJ, Sarkar S, White L et al. Effect of malnutrition on radiographic findings  
11  
12 453 and mycobacterial burden in pulmonary tuberculosis. PLoS One. 2019;14(3):1–  
13  
14 454 11.  
15  
16 455 14. Leong S, Zhao Y, Joseph NM et al. Existing blood transcriptional classifiers  
17  
18 456 accurately discriminate active tuberculosis from latent infection in individuals  
19  
20 457 from south India. Tuberculosis . 2018;109(August 2017):41–51.  
21  
22 458 <https://doi.org/10.1016/j.tube.2018.01.002>  
23  
24 459 15. Hamilton CD, Swaminathan S, Christopher DJ et al. RePORT International:  
25  
26 460 Advancing Tuberculosis Biomarker Research Through Global Collaboration.  
27  
28 461 Clin Infect Dis. 2015;61(Suppl 3):S155–9.  
29  
30 462 16. Babor TF, Saunders JCH-BJB, Monteiro MG. The Alcohol Use Disorder  
31  
32 463 Identification Test. Guidelines for Use in Primary Care. World Heal Organ  
33  
34 464 Geneva. 2015;(2):1–41.  
35  
36 465 17. Chinnakali P, Upadhyay RP, Shokeen D et al. Prevalence of household-level  
37  
38 466 food insecurity and its determinants in an urban resettlement colony in North  
39  
40 467 India. J Heal Popul Nutr. 2014;32(2):227–36.  
41  
42 468 18. Joshi A, Arora A, Amadi-Mgbenka C et al. Burden of household food insecurity  
43  
44 469 in urban slum settings. PLoS One. 2019;14(4):1–24.  
45  
46 470 19. Jayasuriya NA, Nayanathara L, Iddamalgoda N et al. Food Security and  
47  
48 471 Nutrition among the Tuberculosis infected patients. A case study among the  
49  
50 472 patients screened at Chest Clinic of Medical Research Institute of Colombo, Sri  
51  
52 473 Lanka. World Food Programme: Food security analysis(VAM).2014 August.  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 474 20. Bloem MW, Saadeh R. The role of nutrition and food insecurity in HIV and  
4  
5 475 tuberculosis infections and the implications for interventions in resource-limited  
6  
7 476 settings. Foreword. Food Nutr Bull. 2010;31(4):S289-91.  
8  
9 477 <http://www.ncbi.nlm.nih.gov/pubmed/21214034>  
10  
11  
12 478 21. Swaminathan S, Padmapriyadarsini C, Sukumar B et al. Nutritional Status of  
13  
14 479 Persons with HIV Infection, Persons with HIV Infection and Tuberculosis, and  
15  
16 480 HIV-Negative Individuals from Southern India. Clin Infect Dis. 2008;46(6):946–  
17  
18 481 9.  
19  
20  
21 482 22. Yadav S, Atif M, Rawal G. Nikshay Poshan Yojana- Another step to eliminate  
22  
23 483 TB from India. IP Indian J Immunol Respir Med. 2018;3(2):28–9.  
24  
25  
26 484 23. Gupta KB, Gupta R, Atreja A et al. Tuberculosis and nutrition. Lung india.  
27  
28 485 2015;26(1):9–16.  
29  
30  
31 486 24. Park HO, Kim SH, Moon SH et al. Association between body mass index and  
32  
33 487 sputum culture conversion among South Korean patients with multidrug  
34  
35 488 resistant tuberculosis in a tuberculosis referral hospital. Infect Chemother.  
36  
37 489 2016;48(4):317–23.  
38  
39  
40 490 25. Lönnroth K, Williams BG, Stadlin S et al. Alcohol use as a risk factor for  
41  
42 491 tuberculosis - A systematic review. BMC Public Health. 2008;8.  
43  
44  
45 492 26. Podewils LJ, Holtz T, Riekstina V et al. Impact of malnutrition on clinical  
46  
47 493 presentation, clinical course, and mortality in MDR-TB patients. Epidemiol  
48  
49 494 Infect. 2011;139(1):113–20.  
50  
51  
52 495 27. Mekonnen HS, Azagew AW. Non-adherence to anti-tuberculosis treatment,  
53  
54 496 reasons and associated factors among TB patients attending at Gondar town  
55  
56 497 health centers, Northwest Ethiopia 11 Medical and Health Sciences 1103  
57  
58 498 Clinical Sciences 11 Medical and Health Sciences 1117 Public Hea. BMC Res  
59  
60

- 1  
2  
3 499 Notes. 2018;11(1):1–8. <https://doi.org/10.1186/s13104-018-3789-4>
- 4  
5 500 28. Munro SA, Lewin SA, Smith HJ et al. Patient adherence to tuberculosis  
6 501 treatment: A systematic review of qualitative research. PLoS Med.  
7  
8 502 2007;4(7):1230–45.
- 9  
10 503 29. Diefenbach-Elstob T, Plummer D, Dowi R et al. The social determinants of  
11 504 tuberculosis treatment adherence in a remote region of Papua New Guinea.  
12  
13 505 BMC Public Health. 2017;17(1):1–12. [http://dx.doi.org/10.1186/s12889-016-](http://dx.doi.org/10.1186/s12889-016-3935-7)  
14  
15 506 3935-7  
16  
17 507  
18  
19 508  
20  
21 509  
22  
23 510  
24  
25 511  
26  
27 512  
28  
29 513  
30  
31 514  
32  
33 515  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

47 **Table 1: Socio-demographic characteristics of individuals with pulmonary**  
48 **tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)**  
49  
50

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)

60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)
Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)
>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)

Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

518

519

520

521

522

523

524

525

526

527

528

**Table 2: Morbidity and behavioural characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018(N=765)**

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)



Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)
Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)
Never	394 (51.5)

531 \*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were  
 532 reported by the participants

533 † Alcohol use- Alcohol use was measured for the past one year

534 ‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

535

536

1  
2  
3 537  
4  
5  
6 538  
7  
8  
9 539  
10  
11  
12 540  
13  
14  
15 541  
16  
17  
18 542  
19  
20  
21 543  
22  
23  
24 544  
25  
26  
27 545  
28  
29  
30 546  
31  
32  
33 547  
34  
35  
36 548  
37  
38  
39 549  
40  
41  
42 550  
43  
44  
45 551  
46  
47 552  
48  
49 553  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Table 3: Components of household food insecurity among households of pulmonary tuberculosis (TB) patients in three districts of South India, 2015-2018. (N=765)**

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				

1.worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)
7. There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)
9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)

554 \*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past  
 555 four weeks), 3 = Often (more than ten times in the past four weeks)

556

557

1  
2  
3 558  
4  
5  
6 559  
7  
8  
9 560  
10  
11  
12 561  
13  
14  
15 562  
16  
17  
18 563  
19  
20  
21 564  
22  
23  
24 565  
25  
26  
27 566  
28  
29  
30 567  
31  
32  
33 568  
34  
35  
36 569  
37  
38  
39 570  
40  
41  
42 571  
43  
44  
45 572  
46  
47 573  
48  
49 574  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Table 4: Association of socio-demographic, morbidity, and behavioural characteristics with household food insecurity among individuals with pulmonary TB in Puducherry, N= 765**

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				

15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.9-1.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)
Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)
5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residencell				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-

Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)
≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index <sup>II</sup>				
< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-

Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

575 \*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale

576 (HFIAS) for Measurement of Food Access-FANTAIII

577 †PR- Prevalence ratio

578 ‡ CI-Confidence Interval

579 § Adjusted for characteristics with p-value<0.2 in the univariate model

580 || Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

For peer review only

## ANNEXURE 1

## Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence <sup>1</sup>			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1. worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7. There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				



9. Any household member go a whole day and night without eating anything because there was not enough food

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

### HFIA category

- 1 = Food Secure
- HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
- HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
- HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
- HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

# BMJ Open

## Household food insecurity among pulmonary tuberculosis patients and its associated factors in south India: A cross-sectional analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033798.R2
Article Type:	Original research
Date Submitted by the Author:	01-Feb-2020
Complete List of Authors:	<p>Ayiraveetil, Reshma; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Sarkar, Sonali; JIPMER, Preventive and Social Medicine; JIPMER, Preventive and Social Medicine Chinnakali, Palanivel; Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Department of Preventive and Social Medicine Jeyashree, Kathiresan; Velammal Medical College Hospital and Research Institute, Vijayageetha, Mathavaswami; Jawaharlal Institute for Postgraduate Medical Education and Research, Department of Preventive and Social Medicine Thekkur, Pruthu; International Union Against Tuberculosis and Lung Disease, Centre for Operational Research; The Union South-East Asia Office, Centre for Operational Research Lakshminarayanan, Subitha; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine Knudsen, Selby; 7. Boston Medical Center, Boston, Massachusetts, United States of America, Department of Infectious Diseases Hochberg, Natasha; Boston University School of Medicine, Section of Infectious Diseases, Department of Medicine; 6. Boston University School of Public Health, Boston, Massachusetts, United States of America, Department of Epidemiology Horsburgh, C ; Boston University Ellner, Jerrold; 8. Rutgers University, New Jersey, US, Department of Medicine, Roy, Gautam; Jawaharlal Institute of Post Graduate Medical Education and Research, Department of Preventive and Social Medicine</p>
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Epidemiology, Health services research, Infectious diseases, Public health
Keywords:	Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1 **TITLE**  
4  
5

6 2 Household food insecurity among pulmonary tuberculosis patients and its associated  
7  
8 3 factors in south India: A cross sectional analysis  
9

10  
11 4 **MANUSCRIPT TYPE:** Research Article  
12  
13

14 5 **SHORT RUNNING TITLE**  
15

16 6 Household Food insecurity in TB patients  
17  
18

19 7 **AUTHORS**  
20  
21

22 8 Ayiraveetil Reshma,<sup>1</sup> Sonali Sarkar,<sup>1</sup> Palanivel Chinnakali,<sup>1</sup> Kathiresan Jeyashree,<sup>2</sup>  
23  
24 9 Mathavaswami Vijayageetha,<sup>1</sup> Pruthu Thekkur,<sup>3,4</sup> Subitha Lakshminarayanan,<sup>1</sup> Selby  
25  
26 10 Knudsen,<sup>7</sup> Natasha S. Hochberg,<sup>5,6,7</sup> C. Robert Horsburgh,<sup>5,6</sup> Jerrold Ellner,<sup>6</sup> Gautam  
27  
28 11 Roy,<sup>1</sup>  
29  
30

31  
32 12 1. Department of Preventive and Social Medicine, Jawaharlal Institute of  
33  
34 13 Postgraduate Medical Education and Research (JIPMER), Puducherry, India.  
35

36 14 2. Department of Community Medicine, Velammal Medical College, Madurai,  
37  
38 15 Tamilnadu.  
39

40  
41 16 3. Centre for Operational Research, International Union Against Tuberculosis and  
42  
43 17 Lung Disease (The Union), Paris, France  
44

45 18 4. The Union, South East Asia Office, New Delhi, India.  
46

47  
48 19 5. Section of Infectious Diseases, Department of Medicine, Boston University  
49  
50 20 School of Medicine, Boston, Massachusetts, United States of America  
51

52 21 6. Boston University School of Public Health, Boston, Massachusetts, United  
53  
54 22 States of America  
55

56  
57 23 7. Boston Medical Center, Boston, Massachusetts, United States of America  
58

59 24 8. Department of Medicine, Rutgers University, New Jersey, US  
60

1  
2  
3 25 **WORD COUNT**  
4

5 26 **Abstract :299**  
6

7  
8 27 **Text: 2462 (excluding summary, references, tables and figures)**  
9

10 28 **NUMBER OF TABLES: 4+1 (Supplementary file)**  
11

12 29 **NUMBER OF FIGURES: nil**  
13

14 30 **NUMBER OF REFERENCES: 29**  
15

16  
17 31 **AUTHOR FOR CORRESPONDENCE**  
18

19 32 Dr. Sonali Sarkar  
20

21 33 Additional Professor & Head  
22

23 34 Department of Preventive and Social Medicine, JIPMER  
24

25 35 E-mail: [sarkarsonaligh@gmail.com](mailto:sarkarsonaligh@gmail.com)  
26

27 36 Phone: (+91) 9442174663  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 50 **ABSTRACT**

### 51 **Objectives**

52 Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe  
53 foods or inability to acquire foods in socially acceptable ways'. Majority of Tuberculosis  
54 (TB) cases of resource-poor settings experience food insecurity, which impacts  
55 treatment adherence and outcomes. We aimed to determine level of household food  
56 insecurity (HFI) and its associated factors in pulmonary tuberculosis (TB) patients.

### 57 **Design**

58 This is a cross sectional analysis of data from an ongoing cohort study.

### 59 **Setting**

60 National Tuberculosis Program (NTP) in three districts of south India.

### 61 **Participants**

62 All newly diagnosed pulmonary TB cases of the cohort enrolled from National  
63 Tuberculosis Program at the Designated Microscopy Centres (DMCs) and Primary  
64 Health Centres (PHCs) from October 2015 to October 2018.

### 65 **Primary Outcome Measures**

66 The proportion of baseline HFI assessed using a validated household food insecurity  
67 access scale was summarized as percentage with 95% confidence interval (CI).  
68 Possible association of socio-demographic, morbidity and behavioural characteristics  
69 with HFI was assessed using chi-squared test, unadjusted prevalence ratios with 95%  
70 CI were calculated. The characteristics with p value less than 0.2 in the univariate  
71 model were included in multivariable generalized linear model (binomial function, log  
72 link) to derive adjusted prevalence ratios (aPR) with 95% CI.

## 73 **Result**

74 Of total 765 patients, 261 had HFI and the proportion was 34.1% (95% CI 30.8-37.6%).

75 Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177

76 (23.1%) TB cases respectively. TB patients who had monthly family income less than

77 INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-

78 1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) were independently

79 associated with HFI.

## 80 **Conclusions**

81 High level of food insecurity was seen in households of TB cases. Additional food or

82 cash assistance for this subgroup might improve food insecurity and thereby nutritional

83 status.

## 84 **Key Words**

85 Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

## 87 **Article Summary**

### 88 **Strengths:**

- 89 • Use of a validated tool for assessing household food insecurity which allows  
90 cross country comparisons.
- 91 • We used the data from a prospective cohort study which implemented quality  
92 assurance checks for data collection, entry and completeness that would have  
93 reduced missing data and data errors.

### 94 **Limitations:**



- 1  
2  
3 95 • We did not study the sub group of previously treated TB patients in whom levels  
4  
5 96 of food insecurity could be higher due to financial loss caused by repeated  
6  
7 97 episodes of TB.  
8  
9  
10 98 • The study participants were from selected three districts in south India, so  
11  
12 99 generalizability of the findings is limited.  
13  
14  
15 100 • The model developed for assessing the factors associated with HFI was  
16  
17 101 deficient due to small sample size and unavailability of a few important  
18  
19 102 confounding variables  
20  
21  
22 103  
23  
24 104  
25  
26 105  
27  
28 106  
29  
30 107  
31  
32 108  
33  
34 109  
35  
36 110  
37  
38 111  
39  
40 112  
41  
42 113  
43  
44 114  
45  
46 115  
47  
48 116  
49  
50 117  
51  
52 118  
53  
54 119  
55  
56  
57  
58  
59  
60

## 120 INTRODUCTION

121 Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking  
122 above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017,  
123 there were an estimated 1.3 million TB deaths among HIV-negative people. India  
124 contributes roughly 25% of global incident TB cases and there were an estimated  
125 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health  
126 Organization (WHO) endorsed the “End TB strategy” in line with the Sustainable  
127 Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal  
128 with action on poverty, hunger and ensuring healthy lives and well-being of people)  
129 with a common aim to end the global TB epidemic.(1,3)

130 Food security is a state in which “all people at all times have both physical and  
131 economic access to sufficient food to meet their dietary needs for a productive and  
132 healthy life”.(4) Catastrophic health expenditure is a common consequence of TB  
133 diagnosis, treatment and care which can lead to impoverishment and in turn food  
134 insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional  
135 relationship with TB; both cause TB and could be consequences of TB. Undernutrition  
136 in patients with active TB can lead to worsening of disease, drug toxicity, drug  
137 malabsorption and death or relapse of disease. (5–7)

138 A recent national survey (2016) in Vietnam reported that 22% of households  
139 experienced food insecurity during TB treatment, this proportion being as high as 40%  
140 among the poorest wealth quintiles.(8) Food insecurity at the household level is  
141 common in India and is a strong risk factor for progression of latent infection to active  
142 TB in household contacts.(9) TB in India affects poor families and communities  
143 disproportionately, with a fourfold higher prevalence in those with a low standard of

1  
2  
3 144 living index compared to those with a high standard of living index.(5) Food insecurity  
4  
5 145 is also of greatest significance in households where levels of food insecurity and  
6  
7 146 undernutrition are high at the time of diagnosis. Since food insecurity and under-  
8  
9 147 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite  
10  
11 148 effective treatment.  
12  
13  
14

15 149 WHO (2013) in its guidelines 'Nutritional care and support for patients with  
16  
17 150 tuberculosis' recommends assessment of food insecurity among TB cases and  
18  
19 151 addressing the same with suitable packages including food assistance.(3) Recently,  
20  
21 152 Government of India has launched a cash assistance scheme for all TB cases to  
22  
23 153 mitigate costs and improve nutritional status. (10) However, there may be households  
24  
25 154 with more food insecurity that need more food assistance rather than equal assistance  
26  
27 155 to all. In India, studies assessing household food insecurity among TB cases are  
28  
29 156 limited. Therefore, we aimed to determine the level of food insecurity and its  
30  
31 157 associated factors using secondary data from a cohort of pulmonary TB patients in  
32  
33 158 south India.  
34  
35  
36  
37  
38

39 159

40  
41  
42 160

43  
44  
45 161

46  
47  
48 162

49  
50  
51 163

52  
53  
54 164

55  
56  
57 165

58  
59  
60 166

## 167 **METHODS**

### 168 **Study Design**

169 This is a cross sectional analysis of data from a cohort study under RePORT India  
170 Consortium (Regional Prospective Observational Research for Tuberculosis). Details  
171 of the study design have been previously reported. (11–14)

#### 172 *National tuberculosis program (NTP)*

173 The study covers Puducherry district of Union Territory of Puducherry (population~1.3  
174 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5  
175 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB  
176 diagnostic and treatment services are delivered through the designated microscopy  
177 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units  
178 (TUs) as nodal points for TB control activities at sub-district level. Sputum smear  
179 microscopy remains the central component of TB diagnosis. Under NTP, both  
180 diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of  
181 TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity  
182 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment  
183 outcomes of these patients are documented in individual TB treatment card.

#### 184 *RePORT International*

185 Regional Prospective Observational Research in Tuberculosis (RePORT)  
186 International represents a consortium of regional cohorts (RePORT India, RePORT  
187 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT  
188 Indonesia) that are linked through the implementation of a common protocol for data  
189 and specimen collection. Objectives and composition of RePORT International are  
190 described elsewhere.(15)

1  
2  
3 191 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate  
4  
5 192 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers  
6  
7  
8 193 University has established a pulmonary TB cohort of adults and children  $\geq 6$  years and  
9  
10 194 their household contacts to identify biomarkers for risk of TB treatment failure and risk  
11  
12 195 of development of TB in household contacts. TB cases diagnosed under NTP in the  
13  
14 196 three districts (Puducherry, Cuddalore and Villupuram) were enrolled in the cohort at  
15  
16 197 the designated microscopy centres and public health centres since 2014. Only newly  
17  
18 198 diagnosed smear and culture positive pulmonary TB cases were included. Details on  
19  
20 199 data collection and procedures were previously reported (11-14).

## 200 **Study population**

201 For this analysis, we included all TB cases of the cohort enrolled from October 2015  
202 to October 2018. Multi drug resistant and extremely drug resistant TB cases at  
203 diagnosis were excluded.

## 205 **Study tool**

206 Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food  
207 insecurity in the households in the past 30 days. The scale consists of nine items  
208 grouped under three domains: 1) anxiety or uncertainty about the household food  
209 supply 2) Insufficient Quality and 3) Insufficient food intake and its physical  
210 consequences (4). The respondent is first asked an occurrence question, whether the  
211 condition in the question happened at all in the past four weeks (yes or no). If the  
212 respondent answers "yes" to an occurrence question, a frequency-of-occurrence  
213 question is asked to determine whether the condition happened rarely (once or twice),  
214 sometimes (three to ten times) or often (more than ten times) in the past four weeks.

1  
2  
3 215 Each item is scored on a range of 0 to 3; zero for 'no occurrence' and three for 'often'.  
4  
5 216 The minimum and maximum score for a household are 0 and 27 respectively. The  
6  
7  
8 217 scores were categorized into four levels of household food insecurity: food secure and  
9  
10 218 mild, moderately and severely food insecure (4)-Annexure 1.

11  
12 219 Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version  
13  
14  
15 220 of AUDIT) (16) was used to assess the alcohol use among participants.

### 16 17 221 **Data extraction, analysis and statistics**

18  
19  
20 222 Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases  
21  
22 223 excluding two childhood TB cases; the initial 462 cases enrolled were not assessed  
23  
24 224 for household food insecurity because of not having the HFAI scale in the study  
25  
26  
27 225 proforma during initial phase of the project. The HFAI scale was introduced in the  
28  
29 226 revised study proforma after the 462 patients were already enrolled into the project.  
30  
31 227 However, the 462 patients excluded had no difference in the baseline socio-  
32  
33 228 demographic and clinical characteristics compared with those included in the study.

34  
35  
36  
37 229 Data were extracted from the RePORT India project database for JIPMER site in a de-  
38  
39 230 identified manner and analysed using Stata 12.0 software. The proportion of  
40  
41 231 household food insecurity was summarized as percentage with 95% confidence  
42  
43 232 interval (CI). Possible association of socio-demographic, morbidity related and  
44  
45 233 behavioural characteristics with household food insecurity was assessed using chi-  
46  
47 234 squared test and unadjusted prevalence ratios with 95% CI were calculated. The  
48  
49 235 characteristics with p value less than 0.2 in the univariate model were included in  
50  
51 236 multivariable generalized linear model (binomial function and log link) to derive  
52  
53 237 adjusted prevalence ratios (aPR) with 95% CI. The variables such as marital status,  
54  
55 238 education, residence, number of earners in the household, HIV status, tobacco use,  
56  
57  
58  
59 239 and alcohol use were not included for multivariate analysis.

1  
2  
3 **240 Ethics Approval**  
4  
5

6 241 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER  
7  
8 242 (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center  
9  
10 243 (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was  
11  
12  
13 244 obtained from all participants before enrolment. The study protocol for this secondary  
14  
15 245 analysis was reviewed and approved by Ethics Advisory Group of the International  
16  
17 246 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.  
18  
19

20  
21 **247 Data sharing document:**  
22

23 248 Technical appendix, statistical code, and data set will be available upon request from  
24  
25  
26 249 the Corresponding author.  
27  
28

29 **250 Patient and Public Involvement**  
30  
31

32 251 There was no patient or public involvement.  
33  
34  
35 252  
36  
37 253  
38  
39  
40 254  
41  
42  
43 255  
44  
45  
46 256  
47  
48  
49 257  
50  
51  
52 258  
53  
54  
55 259  
56  
57  
58 260  
59  
60

## 261 RESULTS

262 Of the 765 individuals included in analysis, the mean (standard deviation) age was 44  
263 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases  
264 are described in **Table-1**. Of total, 131 (17%) participants did not have any formal  
265 education, about 77% were employed and 11% had monthly family income less than  
266 INR 3000 (~USD 43). Behavioural and disease related characteristics are described  
267 in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30%  
268 were current tobacco users. Of total, 470 (61%) were underweight (body mass index  
269 <18.5 kg/m<sup>2</sup>) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or  
270 less (require assistance for routine activities) in 29% of patients.

271 Overall, 261 patients had household food insecurity and the proportion was 34.1%  
272 (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17  
273 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food  
274 insecurity are described in **Table-3**. Worry or anxiety about not having enough food  
275 was reported in 15% of TB households. In 21% of TB households, eating fewer meals  
276 in a day due to lack of enough food was reported.

277 Level of food insecurity in different sub groups is presented in **Table-4**. In adjusted  
278 analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95%  
279 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were  
280 employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of household food insecurity.

281

282

283



## 284 DISCUSSION

285 Our study among newly diagnosed pulmonary TB patients in public sector in south  
286 India revealed that about one third of TB patients experienced household food  
287 insecurity; about one out of four patients experienced severe food insecurity at the  
288 time of diagnosis. Level of food insecurity was high in low income groups, employed  
289 and those who had severe illness.

290 Prevalence of food insecurity in the general population of India is also high ranging  
291 from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is  
292 common as it can be both a cause and consequence of TB. The national level survey  
293 from Vietnam (2016) reported 22% of TB patients experienced household food  
294 insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)

295 Food insecurity was twice as high in low income TB households (INR<3000) compared  
296 to their higher income counterparts. Catastrophic health expenditure, a consequence  
297 of TB diagnosis and treatment can lead to worsening of food insecurity in low income  
298 groups during the course of the disease.(5) These subgroups need to be provided  
299 additional assistance instead of 'equal for all' food or cash assistance benefits. Since  
300 income is usually underreported, identifying such target groups may not be an easy  
301 task.

302 Food insecurity at the household level is a strong risk factor for progression of latent  
303 infection to active TB in household contacts. (9,20) Since, food insecurity measures  
304 are applicable to all households, a wider approach of reducing food insecurity targeting  
305 all household contacts is needed.

306 In our study, about 60% of the TB patients were underweight. Undernutrition is both  
307 an important risk factor for, and a common consequence of TB. In food insecure

1  
2  
3 308 households, undernutrition could be an intermediary step in the nutritional pathway of  
4  
5 309 food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent  
6  
7 310 in patients with TB and the dietary intake of calories is significantly lower (500-700  
8  
9 311 calories) than recommended. (21) As recommended by WHO, addressing  
10  
11 312 undernutrition through nutritional counselling and support should be considered as  
12  
13 313 part of the standard of care for people with TB. The recently launched “Nikshay Poshan  
14  
15 314 Yojana”, a direct benefit transfer scheme by the government of India is a welcome step  
16  
17 315 towards addressing undernutrition. (22) Our study did not include severely ill patients  
18  
19 316 (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates  
20  
21 317 are expected to be high. This may partly explain why our study did not find an  
22  
23 318 association between food insecurity and undernutrition, though previous studies have  
24  
25 319 reported otherwise. (23–26) Also, we have assessed food insecurity at the level of  
26  
27 320 household and body mass index assessed is that of the individual patients. May be  
28  
29 321 the patient’s nutrition is maintained at the expense of other family members, so he or  
30  
31 322 she may have had normal BMI. However, the temporality of the BMI, HFI and weight  
32  
33 323 loss could not be established due to cross-sectional nature of this study and we also  
34  
35 324 failed to account for sequence of these events during analysis. Thus, we fail to strongly  
36  
37 325 comment on the causal pathways of association between HFI, BMI and weight loss.  
38  
39 326 Also, we couldn’t explore details on employment such as type of employment, which  
40  
41 327 could be a risk factor for development of TB and could have influenced the income  
42  
43 328 and thus the ability to purchase food items also.

44  
45 329 Several studies support the notion that food insecurity negatively affects treatment  
46  
47 330 adherence. Conditions of food insecurity (lack of adequate food, concern about daily  
48  
49 331 food production) contribute to non-adherence to TB treatment as reported by  
50  
51 332 qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 333 and linking the patients to food assistance or social security programs is needed. We  
4  
5 334 plan to report the effect of food insecurity on adherence and TB treatment outcomes  
6  
7  
8 335 in a separate paper.  
9

10 336 Strengths of the study include use of a validated tool (4) for assessing household food  
11  
12 337 insecurity which allows cross country comparisons. We used the data from a  
13  
14  
15 338 prospective cohort study which implemented quality assurance checks for data  
16  
17 339 collection and entry that would have reduced missing data and data errors. There were  
18  
19  
20 340 a few limitations in the study. Our study included patients identified in the public sector  
21  
22 341 alone and food insecurity levels may be different in patients accessing TB care in the  
23  
24 342 private sector. Since, repeated episodes of TB may be a cause for financial loss  
25  
26 343 leading to food insecurity, the levels could be higher in previously treated TB patients  
27  
28 344 and we did not study this sub group. The study participants were from selected three  
29  
30 345 districts in south India, so generalisability of the findings is limited. Being a cross  
31  
32 346 sectional analysis, causal relationships of factors with food insecurity cannot be  
33  
34 347 inferred. The model we constructed for exploring factors associated with HFI was  
35  
36 348 deficient as a few important confounding variables were included and also, the small  
37  
38 349 sample size (power) was less to perform rational statistical analyses. Thus, the factors  
39  
40 350 associated with the HFI needs to be interpreted in caution considering this major  
41  
42  
43 351 limitation in multivariate analysis.  
44  
45  
46  
47  
48  
49

50  
51 352

## 51 353 **CONCLUSION**

52  
53  
54 354 To conclude, household food insecurity was experienced by one in three TB patients  
55  
56 355 and this was twice higher in low income groups. Additional food or cash assistance to  
57  
58  
59  
60

1  
2  
3 356 food insecure TB patients and household contacts will improve the food insecurity and  
4  
5 357 undernutrition.  
6  
7  
8  
9 358  
10  
11 359

## 12 13 360 **ACKNOWLEDGEMENTS**

14  
15 361 This cross-sectional analysis was conducted through the Structured  
16  
17 362 Operational Research and Training Initiative (SORT IT), a global partnership led by  
18  
19 363 the Special Programme for Research and Training in Tropical Diseases at the World  
20  
21 364 Health Organization (WHO/TDR). The model is based on a course developed jointly  
22  
23 365 by the International Union Against Tuberculosis and Lung Disease (The Union) and  
24  
25 366 Médecins sans Frontières (MSF/Doctors Without Borders). The specific SORT IT  
26  
27 367 programme which resulted in this publication was jointly developed and implemented  
28  
29 368 by: The Union South-East Asia Office, New Delhi, India; the Centre for Operational  
30  
31 369 Research, The Union, Paris, France; Department of Preventive and Social Medicine,  
32  
33 370 Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry,  
34  
35 371 India; Department of Community Medicine and School of Public Health, Postgraduate  
36  
37 372 Institute of Medical Education and Research, Chandigarh, India; Department of  
38  
39 373 Community Medicine, All India Institute of Medical Sciences, Nagpur, India; Dr.  
40  
41 374 Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical  
42  
43 375 Sciences, New Delhi, India; Department of Community Medicine, Pondicherry Institute  
44  
45 376 of Medical Science, Puducherry, India; Department of Community Medicine, Kalpana  
46  
47 377 Chawla Medical College, Karnal, India; National Centre of Excellence and Advance  
48  
49 378 Research on Anaemia Control, All India Institute of Medical Sciences, New Delhi,  
50  
51 379 India; Department of Community Medicine, Sri Manakula Vinayagar Medical College  
52  
53 380 and Hospital, Puducherry, India; Department of Community Medicine, Velammal  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 381 Medical College Hospital and Research Institute, Madurai, India; Department of  
4  
5 382 Community Medicine, Yenepoya Medical College, Mangalore, India; Karuna Trust,  
6  
7  
8 383 Bangalore, India and National Institute for Research in Tuberculosis, Chennai, India.  
9

10  
11 384 Authors would like to thank the funders, the index cases, their families, and the  
12  
13 385 staff that worked on the RePORT India project. We also acknowledge the contribution  
14  
15 386 of the Data Coordinating Center at Boston Medical Center, US.  
16

## 17 18 387 **FUNDING**

19  
20  
21 388 The training programme, within which this paper was developed, and the open access  
22  
23 389 publication costs were funded by the Department for International Development  
24  
25 390 (DFID), UK and La Fondation Veuve Emile Metz-Tesch (Luxembourg). The RePORT  
26  
27  
28 391 India project has been funded in whole or in part with Federal funds from the  
29  
30 392 Government of India's (GOI) Department of Biotechnology (DBT), the Indian Council  
31  
32 393 of Medical Research (ICMR), the United States National Institutes of Health (NIH),  
33  
34 394 National Institute of Allergy and Infectious Diseases (NIAID), Office of AIDS Research  
35  
36 395 (OAR), and distributed in part by Civilian Research and Development Foundation  
37  
38 396 (CRDF) Global. The contents of this publication are solely the responsibility of the  
39  
40 397 authors and do not represent the official views of the DBT, the ICMR, the NIH, or  
41  
42 398 CRDF Global. The funders had no role in study design, data collection and analysis,  
43  
44 399 decision to publish, or preparation of the manuscript.  
45  
46  
47

## 48 49 400 **COMPETING INTERESTS**

50  
51  
52 401 The authors have declared that no competing interests exist.  
53  
54

## 55 402 **CONTRIBUTION OF AUTHORS**

1  
2  
3 403 **RA:** Principal Investigator (PI), conception/ design of the protocol, data capture,  
4  
5 404 development of data capture tool, data analysis / interpretation, drafting / critically  
6  
7 405 reviewing the paper, giving approval for the final version to be published  
8  
9  
10 406 **SS:** Acquisition of data, conception/ design of the protocol, revision of manuscript,  
11  
12 407 critically reviewing the paper, giving approval for the final version to be published  
13  
14 408 **PC:** Conception/Design of the protocol, development of data capture tool, data  
15  
16 409 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
17  
18 410 final version to be published  
19  
20  
21 411 **JK:** Conception/Design of the protocol, development of data capture tool, data  
22  
23 412 analysis/ Interpretation, drafting/critically reviewing the paper, giving approval for the  
24  
25 413 final version to be published  
26  
27  
28 414 **VM:** Data analysis and interpretation, critically reviewing the paper, giving approval for  
29  
30 415 the final version to be published  
31  
32  
33 416 **PTK:** Conception, data analysis, revision of manuscript, critically reviewing the paper,  
34  
35 417 giving approval for the final version to be published  
36  
37  
38 418 **SL:** Conception, Project management, critically reviewing the manuscript, giving  
39  
40 419 approval for the final version to be published  
41  
42  
43 420 **SK:** Data curation and management, reviewing the manuscript, giving approval for the  
44  
45 421 final version to be published  
46  
47  
48 422 **NH:** Project administration and supervision, critically reviewing and editing the  
49  
50 423 manuscript, giving approval for the final version to be published  
51  
52 424 **CRH:** Critically reviewing and editing the manuscript, giving approval for the final  
53  
54 425 version to be published  
55  
56 426 **JE:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
57  
58 427 version to be published  
59  
60

1  
2  
3 428 **GR:** Acquisition of data, critically reviewing the manuscript, giving approval for the final  
4  
5 429 version to be published.  
6  
7

8 430  
9

10 431  
11  
12

13 432  
14  
15

16 433 **REFERENCES**  
17

18  
19 434 1. World Health Organization. END TB Global Tuberculosis Report 2017. Geneva;  
20  
21 435 2017. 147 p.  
22

23 436 2. Central TB Division. TB India-Annual Report 2017. India TB Rep [Internet].  
24  
25 437 2017;1–173. [https://tbcindia.gov.in/WriteReadData/TB India 2017.pdf](https://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf)  
26  
27

28 438 3. World Health Organization. WHO Guideline : Nutritional care and support for  
29  
30 439 patient with tuberculosis. World Heal Organ (2013) WHO Guidel Nutr care  
31  
32 440 Support patient with Tuberc 9. [http://doi.org/ISBN 978 92 4 150641 0](http://doi.org/ISBN%20978%2092%204%20150641%200). 2013;9.  
33  
34

35 441 4. Coates J, Swindale a, Bilinsky P. Household Food Insecurity Access Scale  
36  
37 442 (HFIAS) for measurement of food access: indicator guide. Washington, DC Food  
38  
39 443 Nutr Tech .... 2007;(August):Version 3.  
40  
41

42 444 5. Central TB Division. Guidance Document: Nutritional care and support for  
43  
44 445 patients with Tuberculosis in India. 2017;107.  
45  
46 446 [http://www.tbcindia.nic.in/WriteReadData/Guidance Document - Nutritional](http://www.tbcindia.nic.in/WriteReadData/Guidance%20Document%20-%20Nutritional%20Care%20Support%20for%20TB%20patients%20in%20India.pdf)  
47  
48 447 Care %26 Support for TB patients in India.pdf  
49  
50

51 448 6. Bhargava A, Benedetti A, Oxlade O et al. Undernutrition and the incidence of  
52  
53 449 tuberculosis in India: National and subnational estimates of the population-  
54  
55 450 attributable fraction related to undernutrition. Natl Med J India. 2014;27(3):128–  
56  
57 451 33.  
58  
59  
60

- 1  
2  
3 452 7. Sinha Pranay, Davis Juliana, Saag LW et al. Undernutrition and Tuberculosis:  
4  
5 453 Public Health Implications. *J Infect Dis.* 2019; 219(9):1356–63.  
6  
7  
8 454 8. Nhung N V., Hoa NB, Anh NT et al. Measuring catastrophic costs due to  
9  
10 455 tuberculosis in Viet Nam. *Int J Tuberc Lung Dis.* 2018;22(9):983–90.  
11  
12 456 <http://www.ingentaconnect.com/content/10.5588/ijtld.17.0859>  
13  
14  
15 457 9. Jubulis J, Kinikar A, Ithape M et al. Modifiable risk factors associated with  
16  
17 458 tuberculosis disease in children in Pune, India. *Int J Tuberc Lung Dis.*  
18  
19 459 2014;18(2):198–204. A  
20  
21 460 10. Central TB Division. National Strategic Plan for Tuberculosis Elimination 2017-  
22  
23 461 2025. *Dir Gen Heal Serv Minist Heal Fam Welf.* 2017;(March):110–108.  
24  
25  
26 462 11. Van Ness SE, Chandra A, Sarkar S et al. Predictors of delayed care seeking for  
27  
28 463 tuberculosis in southern India: An observational study. *BMC Infect Dis.*  
29  
30 464 2017;17(1):1–9.  
31  
32  
33 465 12. N.S. Hochberg, S. Sarkar, C.R. Horsburgh et al. Comorbidities in pulmonary  
34  
35 466 tuberculosis cases in Puducherry and Tamil Nadu, India: Opportunities for  
36  
37 467 intervention. *PLoS One.* 2017;12(8):e0183195.  
38  
39  
40 468 13. Hoyt KJ, Sarkar S, White L et al. Effect of malnutrition on radiographic findings  
41  
42 469 and mycobacterial burden in pulmonary tuberculosis. *PLoS One.* 2019;14(3):1–  
43  
44 470 11.  
45  
46  
47 471 14. Leong S, Zhao Y, Joseph NM et al. Existing blood transcriptional classifiers  
48  
49 472 accurately discriminate active tuberculosis from latent infection in individuals  
50  
51 473 from south India. *Tuberculosis* . 2018;109(August 2017):41–51.  
52  
53 474 <https://doi.org/10.1016/j.tube.2018.01.002>  
54  
55  
56 475 15. Hamilton CD, Swaminathan S, Christopher DJ et al. RePORT International:  
57  
58 476 Advancing Tuberculosis Biomarker Research Through Global Collaboration.  
59  
60



- 1  
2  
3 477 Clin Infect Dis. 2015;61(Suppl 3):S155–9.  
4  
5 478 16. Babor TF, Saunders JCH-BJB, Monteiro MG. The Alcohol Use Disorder  
6  
7 Identification Test. Guidelines for Use in Primary Care. World Heal Organ  
8 479 Geneva. 2015;(2):1–41.  
9  
10 480  
11  
12 481 17. Chinnakali P, Upadhyay RP, Shokeen D et al. Prevalence of household-level  
13  
14 food insecurity and its determinants in an urban resettlement colony in North  
15 482 India. J Heal Popul Nutr. 2014;32(2):227–36.  
16  
17 483  
18  
19 484 18. Joshi A, Arora A, Amadi-Mgbenka C et al. Burden of household food insecurity  
20  
21 in urban slum settings. PLoS One. 2019;14(4):1–24.  
22 485  
23  
24 486 19. Jayasuriya NA, Nayanathara L, Iddamalgoda N et al. Food Security and  
25  
26 Nutrition among the Tuberculosis infected patients. A case study among the  
27 487 patients screened at Chest Clinic of Medical Research Institute of Colombo, Sri  
28 488 Lanka. World Food Programme: Food security analysis(VAM).2014 August.  
29  
30 489  
31  
32 490 20. Bloem MW, Saadeh R. The role of nutrition and food insecurity in HIV and  
33  
34 tuberculosis infections and the implications for interventions in resource-limited  
35 491 settings. Foreword. Food Nutr Bull. 2010;31(4):S289-91.  
36  
37 492  
38 493 <http://www.ncbi.nlm.nih.gov/pubmed/21214034>  
39  
40 494 21. Swaminathan S, Padmapriyadarsini C, Sukumar B et al. Nutritional Status of  
41  
42 Persons with HIV Infection, Persons with HIV Infection and Tuberculosis, and  
43 495 HIV-Negative Individuals from Southern India. Clin Infect Dis. 2008;46(6):946–  
44 496 9.  
45  
46 497  
47  
48 498 22. Yadav S, Atif M, Rawal G. Nikshay Poshan Yojana- Another step to eliminate  
49  
50 TB from India. IP Indian J Immunol Respir Med. 2018;3(2):28–9.  
51 499  
52  
53 500 23. Gupta KB, Gupta R, Atreja A et al. Tuberculosis and nutrition. Lung india.  
54  
55 2015;26(1):9–16.  
56 501  
57  
58  
59  
60

- 1  
2  
3 502 24. Park HO, Kim SH, Moon SH et al. Association between body mass index and  
4  
5 503 sputum culture conversion among South Korean patients with multidrug  
6  
7 504 resistant tuberculosis in a tuberculosis referral hospital. *Infect Chemother.*  
8  
9 505 2016;48(4):317–23.  
10  
11  
12 506 25. Lönnroth K, Williams BG, Stadlin S et al. Alcohol use as a risk factor for  
13  
14 507 tuberculosis - A systematic review. *BMC Public Health.* 2008;8.  
15  
16  
17 508 26. Podewils LJ, Holtz T, Riekstina V et al. Impact of malnutrition on clinical  
18  
19 509 presentation, clinical course, and mortality in MDR-TB patients. *Epidemiol*  
20  
21 510 *Infect.* 2011;139(1):113–20.  
22  
23  
24 511 27. Mekonnen HS, Azagew AW. Non-adherence to anti-tuberculosis treatment,  
25  
26 512 reasons and associated factors among TB patients attending at Gondar town  
27  
28 513 health centers, Northwest Ethiopia 11 Medical and Health Sciences 1103  
29  
30 514 Clinical Sciences 11 Medical and Health Sciences 1117 Public Hea. *BMC Res*  
31  
32 515 *Notes.* 2018;11(1):1–8. <https://doi.org/10.1186/s13104-018-3789-4>  
33  
34  
35 516 28. Munro SA, Lewin SA, Smith HJ et al. Patient adherence to tuberculosis  
36  
37 517 treatment: A systematic review of qualitative research. *PLoS Med.*  
38  
39 518 2007;4(7):1230–45.  
40  
41  
42 519 29. Diefenbach-Elstob T, Plummer D, Dowi R et al. The social determinants of  
43  
44 520 tuberculosis treatment adherence in a remote region of Papua New Guinea.  
45  
46 521 *BMC Public Health.* 2017;17(1):1–12. [http://dx.doi.org/10.1186/s12889-016-](http://dx.doi.org/10.1186/s12889-016-3935-7)  
47  
48 522 3935-7  
49  
50  
51 523  
52  
53 524  
54  
55  
56 525  
57  
58  
59 526  
60

527

528

529

530

531

**Table 1: Socio-demographic characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)**

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)
60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)

Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)
>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)
Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

534

535

536

537

538

539

540

541

542

543

544

545 **Table 2: Morbidity and behavioural characteristics of individuals with pulmonary**546 **tuberculosis (TB) in three districts of South India, 2015-2018(N=765)**

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)
Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)

Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)
Never	394 (51.5)

547 \*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were  
 548 reported by the participants

549 † Alcohol use- Alcohol use was measured for the past one year

550 ‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

551

552

553

554

555

556

557

558

559

560

561

562

563

564

565

566

567 **Table 3: Components of household food insecurity among households of**  
 568 **pulmonary tuberculosis (TB) patients in three districts of South India, 2015-**  
 569 **2018. (N=765)**

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
<b>I. Worry or anxiety about food</b>				
1. worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
<b>II. Insufficient Quality of Food</b>				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
<b>III. Insufficient Quantity of Food</b>				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)

7. There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)
9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)

570 \*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past

571 four weeks), 3 = Often (more than ten times in the past four weeks)

572

573

574

575

576

577

578

579

580

581

582

583

584



585

586

587

**Table 4: Association of socio-demographic, morbidity, and behavioural characteristics with household food insecurity among individuals with pulmonary TB in Puducherry, N= 765**

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				
15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.91-1.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)

Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)
5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residence cell				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-
Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)

≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index <sup>II</sup>				
< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-
Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

591 \*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale

592 (HFIA) for Measurement of Food Access-FANTA<sup>III</sup>

593 †PR- Prevalence ratio

594 ‡ CI-Confidence Interval

595 § Adjusted for characteristics with p-value<0.2 in the univariate model

596 || Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

## ANNEXURE 1

## Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence <sup>1</sup>			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1. worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7. There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				

9. Any household member go a whole day and night without eating anything because there was not enough food

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

### HFIA category

- 1 = Food Secure
- HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
- HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
- HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
- HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

## STROBE Statement for Quantitative Part (cohort) of Study

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3,4
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8-9
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	9
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	9-11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10
		(b) Describe any methods used to examine subgroups and interactions	10
		(c) Explain how missing data were addressed	10
		(d) If applicable, explain how loss to follow-up was addressed	Not applicable
		(e) Describe any sensitivity analyses	Not applicable
<b>Results</b>			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12
		(b) Give reasons for non-participation at each stage	12
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12
		(b) Indicate number of participants with missing data for each variable of interest	12
		(c) Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	Report numbers of outcome events or summary measures over time	12
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(b) Report category boundaries when continuous variables were categorized	12
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	13-14
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	4-5, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	5
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17