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BMJ Open

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

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Manuscripts

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

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3 97 **Limitations:**
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- 6 98 • We did not study the sub group of previously treated TB patients in whom levels
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8 99 of food insecurity could be higher due to financial loss caused by repeated
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10 100 episodes of TB.
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13 101 • The study participants were from selected three districts in south India, so
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15 102 generalisability of the findings is limited.
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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

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3 146 living index compared to those with a high standard of living index.(5) Food insecurity
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5 147 is also of greatest significance in households where levels of food insecurity and
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7 148 undernutrition are high at the time of diagnosis. Since food insecurity and under-
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9 149 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite
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11 150 effective treatment.
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15 151 WHO (2013) in its guidelines 'Nutritional care and support for patients with
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17 152 tuberculosis' recommends assessment of food insecurity among TB cases and
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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
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23 155 mitigate costs and improve nutritional status. (10) However, there may be households
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25 156 with more food insecurity that need more food assistance rather than equal assistance
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27 157 to all. In India, studies assessing household food insecurity among TB cases are
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29 158 limited. Therefore, we aimed to determine the level of food insecurity and its
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31 159 associated factors using secondary data from a cohort of pulmonary TB patients in
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33 160 south India.
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3 169 **METHODS**
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6 170 **Study Design**
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9 171 This is a cross sectional analysis of secondary data from a cohort study under
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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)
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16 174 *National tuberculosis program (NTP)*
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19 175 The study covers Puducherry district of Union Territory of Puducherry (population~1.3
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21 176 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5
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23 177 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB
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25 178 diagnostic and treatment services are delivered through the designated microscopy
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27 179 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units
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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
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37 184 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment
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39 185 outcomes of these patients are documented in individual TB treatment card.
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45 186 *RePORT International*
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48 187 Regional Prospective Observational Research in Tuberculosis (RePORT)
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50 188 International represents a consortium of regional cohorts (RePORT India, RePORT
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52 189 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT
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54 190 Indonesia) that are linked through the implementation of a common protocol for data
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56 191 and specimen collection. Objectives and composition of RePORT International are
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58 192 described elsewhere.(15)
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3 193 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate
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5 194 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers
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8 195 University has established a pulmonary TB cohort of adults and children ≥ 6 years and
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10 196 their household contacts to identify biomarkers for risk of TB treatment failure and risk
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12 197 of development of TB in household contacts. TB cases diagnosed under NTP in the
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14 198 three districts (Puducherry, Cuddalore and Villupuram) were included in the cohort
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16 199 since 2014. Only newly diagnosed smear and culture positive pulmonary TB cases
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18 200 were included. Details on tobacco use, alcohol use, household food insecurity, severity
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20 201 of TB (Karnofsky score), diabetes status and HIV status were collected at baseline
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22 202 within seven days of initiation of treatment. Based on Karnofsky score patients were
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24 203 categorized on their functional impairment (scale ranges from 0-100). If the score is
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26 204 low, more severe is the illness.

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

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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

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

17 248 **Ethics Approval**

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20 249 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER
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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
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30 253 analysis was reviewed and approved by Ethics Advisory Group of the International
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32 254 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.

35 255 **Patient and Public Involvement**

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38 256 There was no patient or public involvement.
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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/m²) 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.

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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

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

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

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

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3 337 collection and entry that would have reduced missing data and data errors. Our study
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5 338 included patients identified in the public sector alone and food insecurity levels may
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8 339 be different in patients accessing TB care in the private sector. Since, repeated
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10 340 episodes of TB may be a cause for financial loss leading to food insecurity, the levels
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12 341 could be higher in previously treated TB patients and we did not study this sub group.
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14 342 Being a cross sectional analysis, causal relationships of factors with food insecurity
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16 343 cannot be inferred. The study participants were from selected three districts in south
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18 344 India, so generalisability of the findings is limited.
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24 346 **CONCLUSION**

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28 347 To conclude, household food insecurity was experienced by one in three TB patients
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30 348 and this was twice higher in low income groups. Additional food or cash assistance to
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32 349 food insecure TB patients and household contacts will improve the food insecurity and
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35 350 undernutrition.
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9
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11
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13
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15
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17
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21
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23
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44 381 and Hospital, Puducherry, India; Department of Community Medicine, Velammal
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46 382 Medical College Hospital and Research Institute, Madurai, India; Department of
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48 383 Community Medicine, Yenepoya Medical College, Mangalore, India; Karuna Trust,
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50 384 Bangalore, India and National Institute for Research in Tuberculosis, Chennai, India.
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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) |

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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

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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 |
| 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) |
|--|---------------|----------|----------|---------|

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)

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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 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 | | | | |

| | | | | |
|--------------|-----|------------|----------------|----------------|
| < 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 ¹ | | | |
|---|-------------------------|--------|-----------|-------|
| | 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]

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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

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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.

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3 97 **Limitations:**
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- 6 98 • We did not study the sub group of previously treated TB patients in whom levels
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8 99 of food insecurity could be higher due to financial loss caused by repeated
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10 100 episodes of TB.
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13 101 • The study participants were from selected three districts in south India, so
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15 102 generalizability of the findings is limited.
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46 115 **INTRODUCTION**
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49 116 Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking
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51 117 above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017,
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53 118 there were an estimated 1.3 million TB deaths among HIV-negative people. India
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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
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3 121 Organization (WHO) endorsed the “End TB strategy” in line with the Sustainable
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5 122 Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal
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8 123 with action on poverty, hunger and ensuring healthy lives and well-being of people)
9
10 124 with a common aim to end the global TB epidemic.(1,3)

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13 125 Food security is a state in which “all people at all times have both physical and
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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
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25 131 in patients with active TB can lead to worsening of disease, drug toxicity, drug
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27 132 malabsorption and death or relapse of disease. (5–7)

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32 133 A recent national survey (2016) in Vietnam reported that 22% of households
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34 134 experienced food insecurity during TB treatment, this proportion being as high as 40%
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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
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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
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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-
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50 142 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite
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52 143 effective treatment.
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3 144 WHO (2013) in its guidelines 'Nutritional care and support for patients with
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5 145 tuberculosis' recommends assessment of food insecurity among TB cases and
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7 146 addressing the same with suitable packages including food assistance.(3) Recently,
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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
16 150 to all. In India, studies assessing household food insecurity among TB cases are
17
18 151 limited. Therefore, we aimed to determine the level of food insecurity and its
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20 152 associated factors using secondary data from a cohort of pulmonary TB patients in
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22 153 south India.
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51 162 **METHODS**
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54 163 **Study Design**
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3 164 This is a cross sectional analysis of data from a cohort study under RePORT India
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5 165 Consortium (Regional Prospective Observational Research for Tuberculosis). Details
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7 166 of the study design have been previously reported. (11–14)
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10 167 *National tuberculosis program (NTP)*

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13 168 The study covers Puducherry district of Union Territory of Puducherry (population~1.3
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15 169 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5
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17 170 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB
18
19 171 diagnostic and treatment services are delivered through the designated microscopy
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21 172 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units
22
23 173 (TUs) as nodal points for TB control activities at sub-district level. Sputum smear
24
25 174 microscopy remains the central component of TB diagnosis. Under NTP, both
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27 175 diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of
28
29 176 TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity
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31 177 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment
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33 178 outcomes of these patients are documented in individual TB treatment card.
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39 179 *RePORT International*

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42 180 Regional Prospective Observational Research in Tuberculosis (RePORT)
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44 181 International represents a consortium of regional cohorts (RePORT India, RePORT
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46 182 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT
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48 183 Indonesia) that are linked through the implementation of a common protocol for data
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50 184 and specimen collection. Objectives and composition of RePORT International are
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52 185 described elsewhere.(15)
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57 186 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate
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59 187 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers
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3 188 University has established a pulmonary TB cohort of adults and children ≥ 6 years and
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5 189 their household contacts to identify biomarkers for risk of TB treatment failure and risk
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8 190 of development of TB in household contacts. TB cases diagnosed under NTP in the
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10 191 three districts (Puducherry, Cuddalore and Villupuram) were enrolled in the cohort at
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12 192 the designated microscopy centres and public health centres since 2014. Only newly
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14 193 diagnosed smear and culture positive pulmonary TB cases were included. Details on
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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

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

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

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

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

42 43 231 **Ethics Approval**

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46 232 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER
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48 233 (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center
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50 234 (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was
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52 235 obtained from all participants before enrolment. The study protocol for this secondary
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3 236 analysis was reviewed and approved by Ethics Advisory Group of the International
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5 237 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.
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8 238 **Data sharing document:**
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11 239 Technical appendix, statistical code, and data set will be available upon request from
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13 240 the Corresponding author.
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16 241 **Patient and Public Involvement**
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19 242 There was no patient or public involvement.
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37 248 **RESULTS**
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40 249 Of the 765 individuals included in analysis, the mean (standard deviation) age was 44
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42 250 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases
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44 251 are described in **Table-1**. Of total, 131 (17%) participants did not have any formal
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46 252 education, about 77% were employed and 11% had monthly family income less than
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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
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54 256 <18.5 kg/m²) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or
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56 257 less (require assistance for routine activities) in 29% of patients.
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3 258 Overall, 261 patients had household food insecurity and the proportion was 34.1%
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5 259 (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17
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7 260 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food
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9 261 insecurity are described in **Table-3**. Worry or anxiety about not having enough food
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11 262 was reported in 15% of TB households. In 21% of TB households, eating fewer meals
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13 263 in a day due to lack of enough food was reported.
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18 264 Level of food insecurity in different sub groups is presented in **Table-4**. In adjusted
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20 265 analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95%
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22 266 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were
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24 267 employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of household food insecurity.
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31 271 **DISCUSSION**

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39 272 Our study among newly diagnosed pulmonary TB patients in public sector in south
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41 273 India revealed that about one third of TB patients experienced household food
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43 274 insecurity; about one out of four patients experienced severe food insecurity at the
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45 275 time of diagnosis. Level of food insecurity was high in low income groups, employed
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47 276 and those who had severe illness.
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51 277 Prevalence of food insecurity in the general population of India is also high ranging
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53 278 from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is
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55 279 common as it can be both a cause and consequence of TB. The national level survey
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3 280 from Vietnam (2016) reported 22% of TB patients experienced household food
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5 281 insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)
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8 282 Food insecurity was twice as high in low income TB households (INR<3000) compared
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10 283 to their higher income counterparts. Catastrophic health expenditure, a consequence
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12 284 of TB diagnosis and treatment can lead to worsening of food insecurity in low income
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14 285 groups during the course of the disease.(5) These subgroups need to be provided
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16 286 additional assistance instead of 'equal for all' food or cash assistance benefits. Since
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18 287 income is usually underreported, identifying such target groups may not be an easy
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20 288 task.
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25 289 Food insecurity at the household level is a strong risk factor for progression of latent
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27 290 infection to active TB in household contacts. (9,20) Since, food insecurity measures
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29 291 are applicable to all households, a wider approach of reducing food insecurity targeting
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31 292 all household contacts is needed.
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35 293 In our study, about 60% of the TB patients were underweight. Undernutrition is both
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37 294 an important risk factor for, and a common consequence of TB. In food insecure
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39 295 households, undernutrition could be an intermediary step in the nutritional pathway of
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41 296 food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent
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43 297 in patients with TB and the dietary intake of calories is significantly lower (500-700
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45 298 calories) than recommended. (21) As recommended by WHO, addressing
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47 299 undernutrition through nutritional counselling and support should be considered as
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49 300 part of the standard of care for people with TB. The recently launched "Nikshay Poshan
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51 301 Yojana", a direct benefit transfer scheme by the government of India is a welcome step
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53 302 towards addressing undernutrition. (22) Our study did not include severely ill patients
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55 303 (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates
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3 304 are expected to be high. This may partly explain why our study did not find an
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5 305 association between food insecurity and undernutrition, though previous studies have
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7 306 reported otherwise. (23–26) Also, we have assessed food insecurity at the level of
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9 307 household and body mass index assessed is that of the individual patients. May be
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11 308 the patient's nutrition is maintained at the expense of other family members, so he or
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13 309 she may have had normal BMI. In this study, we couldn't explore details on
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15 310 employment such as type of employment, which could be a risk factor for development
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17 311 of TB and could have influenced the income and thus the ability to purchase food items
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19 312 also.

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

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41 320 Strengths of the study include use of a validated tool (4) for assessing household food
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43 321 insecurity which allows cross country comparisons. We used the data from a
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45 322 prospective cohort study which implemented quality assurance checks for data
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47 323 collection and entry that would have reduced missing data and data errors. Our study
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49 324 included patients identified in the public sector alone and food insecurity levels may
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51 325 be different in patients accessing TB care in the private sector. Since, repeated
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53 326 episodes of TB may be a cause for financial loss leading to food insecurity, the levels
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55 327 could be higher in previously treated TB patients and we did not study this sub group.
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57 328 Being a cross sectional analysis, causal relationships of factors with food insecurity
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3 329 cannot be inferred. The study participants were from selected three districts in south
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5 330 India, so generalisability of the findings is limited.
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10 11 332 **CONCLUSION**

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14 333 To conclude, household food insecurity was experienced by one in three TB patients
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16 334 and this was twice higher in low income groups. Additional food or cash assistance to
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18 335 food insecure TB patients and household contacts will improve the food insecurity and
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21 336 undernutrition.
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37 38 344 **ACKNOWLEDGEMENTS**

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40
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44
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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
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47 **Table 1: Socio-demographic characteristics of individuals with pulmonary**
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49 **tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)**
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| 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) |

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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

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551 **Table 3: Components of household food insecurity among households of**
552 **pulmonary tuberculosis (TB) patients in three districts of South India, 2015-**
553 **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)

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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 ^{II} | | | | |
| < 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 ¹ | | | |
|---|-------------------------|--------|-----------|-------|
| | 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]

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

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

86

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.
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10 98 • The study participants were from selected three districts in south India, so
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12 99 generalizability of the findings is limited.
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15 100 • The model developed for assessing the factors associated with HFI was
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17 101 deficient due to small sample size and unavailability of a few important
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19 102 confounding variables
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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

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3 144 living index compared to those with a high standard of living index.(5) Food insecurity
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5 145 is also of greatest significance in households where levels of food insecurity and
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7 146 undernutrition are high at the time of diagnosis. Since food insecurity and under-
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9 147 nutrition can co-exist, patients with TB are unable to regain a normal weight, despite
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11 148 effective treatment.
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15 149 WHO (2013) in its guidelines 'Nutritional care and support for patients with
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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
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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
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31 157 associated factors using secondary data from a cohort of pulmonary TB patients in
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33 158 south India.
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3 167 **METHODS**
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6 168 **Study Design**
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9 169 This is a cross sectional analysis of data from a cohort study under RePORT India
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11 170 Consortium (Regional Prospective Observational Research for Tuberculosis). Details
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13 171 of the study design have been previously reported. (11–14)
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16 172 *National tuberculosis program (NTP)*
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19 173 The study covers Puducherry district of Union Territory of Puducherry (population~1.3
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21 174 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5
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23 175 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB
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25 176 diagnostic and treatment services are delivered through the designated microscopy
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27 177 centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units
28
29 178 (TUs) as nodal points for TB control activities at sub-district level. Sputum smear
30
31 179 microscopy remains the central component of TB diagnosis. Under NTP, both
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33 180 diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of
34
35 181 TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity
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37 182 details (diabetes, HIV) and medication adherence, follow-up details and TB treatment
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39 183 outcomes of these patients are documented in individual TB treatment card.
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45 184 *RePORT International*
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48 185 Regional Prospective Observational Research in Tuberculosis (RePORT)
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50 186 International represents a consortium of regional cohorts (RePORT India, RePORT
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52 187 Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT
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54 188 Indonesia) that are linked through the implementation of a common protocol for data
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56 189 and specimen collection. Objectives and composition of RePORT International are
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58 190 described elsewhere.(15)
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3 191 One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate
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5 192 Medical Education & Research (JIPMER) Boston Medical Center and Rutgers
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7
8 193 University has established a pulmonary TB cohort of adults and children ≥ 6 years and
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10 194 their household contacts to identify biomarkers for risk of TB treatment failure and risk
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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.

215 Each item is scored on a range of 0 to 3; zero for 'no occurrence' and three for 'often'.

216 The minimum and maximum score for a household are 0 and 27 respectively. The

217 scores were categorized into four levels of household food insecurity: food secure and

218 mild, moderately and severely food insecure (4)-Annexure 1.

219 Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version

220 of AUDIT) (16) was used to assess the alcohol use among participants.

221 **Data extraction, analysis and statistics**

222 Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases

223 excluding two childhood TB cases; the initial 462 cases enrolled were not assessed

224 for household food insecurity because of not having the HFAI scale in the study

225 proforma during initial phase of the project. The HFAI scale was introduced in the

226 revised study proforma after the 462 patients were already enrolled into the project.

227 However, the 462 patients excluded had no difference in the baseline socio-

228 demographic and clinical characteristics compared with those included in the study.

229 Data were extracted from the RePORT India project database for JIPMER site in a de-

230 identified manner and analysed using Stata 12.0 software. The proportion of

231 household food insecurity was summarized as percentage with 95% confidence

232 interval (CI). Possible association of socio-demographic, morbidity related and

233 behavioural characteristics with household food insecurity was assessed using chi-

234 squared test and unadjusted prevalence ratios with 95% CI were calculated. The

235 characteristics with p value less than 0.2 in the univariate model were included in

236 multivariable generalized linear model (binomial function and log link) to derive

237 adjusted prevalence ratios (aPR) with 95% CI. The variables such as marital status,

238 education, residence, number of earners in the household, HIV status, tobacco use,

239 and alcohol use were not included for multivariate analysis.

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3 240 **Ethics Approval**
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6 241 Ethics approval was obtained from the Institutional Ethics Committee of JIPMER
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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
12 244 obtained from all participants before enrolment. The study protocol for this secondary
13
14 245 analysis was reviewed and approved by Ethics Advisory Group of the International
15
16 246 Union Against Tuberculosis and Lung Disease (99/18), Paris, France.
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20 247 **Data sharing document:**
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23 248 Technical appendix, statistical code, and data set will be available upon request from
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25 249 the Corresponding author.
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29 250 **Patient and Public Involvement**
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32 251 There was no patient or public involvement.
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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/m²) 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.

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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

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

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45 329 Several studies support the notion that food insecurity negatively affects treatment
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47 330 adherence. Conditions of food insecurity (lack of adequate food, concern about daily
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49 331 food production) contribute to non-adherence to TB treatment as reported by
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51 332 qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis
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3 333 and linking the patients to food assistance or social security programs is needed. We
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5 334 plan to report the effect of food insecurity on adherence and TB treatment outcomes
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8 335 in a separate paper.
9

10 336 Strengths of the study include use of a validated tool (4) for assessing household food
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12 337 insecurity which allows cross country comparisons. We used the data from a
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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
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19
20 340 a few limitations in the study. Our study included patients identified in the public sector
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22 341 alone and food insecurity levels may be different in patients accessing TB care in the
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24 342 private sector. Since, repeated episodes of TB may be a cause for financial loss
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26 343 leading to food insecurity, the levels could be higher in previously treated TB patients
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28
29 344 and we did not study this sub group. The study participants were from selected three
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31 345 districts in south India, so generalisability of the findings is limited. Being a cross
32
33 346 sectional analysis, causal relationships of factors with food insecurity cannot be
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35 347 inferred. The model we constructed for exploring factors associated with HFI was
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37 348 deficient as a few important confounding variables were included and also, the small
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39 349 sample size (power) was less to perform rational statistical analyses. Thus, the factors
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41 350 associated with the HFI needs to be interpreted in caution considering this major
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43 351 limitation in multivariate analysis.
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51 353 **CONCLUSION**

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54 354 To conclude, household food insecurity was experienced by one in three TB patients
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56 355 and this was twice higher in low income groups. Additional food or cash assistance to
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3 356 food insecure TB patients and household contacts will improve the food insecurity and
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5 357 undernutrition.
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14
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16
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18
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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
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30
31 369 Research, The Union, Paris, France; Department of Preventive and Social Medicine,
32
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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) |

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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

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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 |
| 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) |

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)

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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 ^{II} | | | | |
| < 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^{III}

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 ¹ | | | |
|---|-------------------------|--------|-----------|-------|
| | 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 |
| Introduction | | | |
| 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 |
| Methods | | | |
| 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 |
| Results | | | |

| | | | |
|--------------------------|-----|--|----------------|
| 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 |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 13-14 |
| Limitations | | | |
| 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 |
| Other information | | | |
| 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 |