Abstract S38 Table 1 Biomarker performance of *Mtb*-specific IFN- γ , CXCL10 and CCL2 for ATB diagnosis

Biomarker	Active TB		OD		Sensitivity (95% CI)	Specificity (95% CI)
	True-positive	False-negative	True-negative	False-positive		
QFT-GIT	26	31	28	7	45.6 (32.4 – 59.3)	80.0 (63.1 – 91.6)
IFN- γ	41	13	14	19	75.9 (62.4 – 86.5)	42.4 (25.5 – 60.8)
CXCL10	43	12	14	20	78.2 (65.0 – 88.2)	41.2 (24.7 – 59.3)
CCL2	26	28	15	19	48.1 (34.3 – 62.2)	44.1 (27.2 – 62.1)
IFN- γ +CXCL10	44	10	9	24	81.5 (69.2–89.6)	27.3
IFN- γ +CCL2	43	11	6	27	79.6 (67.1 – 88.2)	18.2
CXCL10+CCL2	44	11	7	27	80	20.6
IFN- γ +CXCL10 + CCL2	45	9	4	29	83.3	12.1

Diagnostic performance for a) QFT-GIT (commercially available IGRA test), b) IFN- γ , c) CXCL10, d) CCL2, e) IFN- γ + CXCL10 combined test, f) IFN- γ + CCL2 combined test, g) CXCL10 + CCL2 combined test, h) IFN- γ + CXCL10 + CCL2 combined test, in patients with ATB and OD (n=92). Combined test algorithm: AND/OR inclusion criteria.

lost specificity (42.9% increase in false positive (FP) results). TNF- α , IL2 and CCL7 had very low raw biomarker concentrations.

In Phase II, based on above results, we analysed IFN- γ , CXCL10 and CCL2 in a further 60 patients (table 1). CXCL10 achieved the highest increase in TP results for ATB diagnosis, with 43 TP compared with 26 TP results for QFT-GIT. MSD-measured IFN- γ detected 41 TP results, while CCL2 only detected 26 TP. All three biomarkers demonstrated >35% loss of specificity compared to QFT-GIT. The QFT-GIT sensitivity and specificity values in our study population were 45.6% and 80% respectively. A 'triple-test' combining IFN- γ , CXCL10 and CCL2 results achieved sensitivity 83.3% and specificity 12.1%.

Conclusion Our study provides a unique and novel gating method for efficiently assessing the diagnostic performance of candidate biomarkers for ATB diagnosis. Our study population was purposely engineered to compare candidate biomarkers to QFT-GIT in a clinically-relevant manner and we hope our study design will aid future, targeted efforts for high-quality biomarker follow-up studies.

REFERENCE

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Please refer to page A188 for declarations of interest related to this abstract.

S39

IS THE TREATMENT OF LATENT TUBERCULOSIS INFECTION AMONGST RECENT MIGRANTS SAFE AND EFFECTIVE IN PRIMARY CARE?

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Introduction The control of latent tuberculosis infection (LTBI) is a key priority in national and global strategies to eliminate tuberculosis (TB). We tested whether a novel community model of care delivered by general practitioners (family physicians) and community pharmacists to treat LTBI amongst recent migrants was effective and safe. Criteria for LTBI testing followed national guidelines.

Methods The CATAPuLT trial (Completion and Acceptability of Treatment Across Primary Care and the community for Latent Tuberculosis) was a pragmatic cluster-randomised, parallel group, superiority trial conducted in 34 general practices in London, UK, comparing LTBI treatment in recent migrants in primary care to secondary care. The primary outcome was treatment completion. Secondary outcomes included treatment adherence, treatment acceptance, adverse events, patient satisfaction, the incidence of active TB and a comparison of costs per case completing treatment.

Results Between September 2016 and May 2019, 7495 patients were offered testing for LTBI, 3624 were tested and 807 returned positive interferon-gamma release assay (IGRA) results. In the primary care arm, 224 were offered and 146 patients accepted treatment. In the secondary care arm, 138 were offered and 130 patients accepted treatment. In primary care, 82.6% of patients accepting LTBI treatment completed it, compared to 86.0% in secondary care. There was no significant difference in treatment completion between the two arms (aOR:0.64, 95%CI:0.31–1.29). There was also no difference in treatment adherence (aOR:0.64, 95%CI:0.32–1.28), drug induced liver injury (DILI) (0.7% vs 2.3%, aOR:0.29, 95%CI:0.03–2.84) or patient satisfaction (aOR:1.80, 95%CI:0.84–3.86). Treatment acceptance was lower in primary care (65.2% vs 94.2%, aOR:0.10, 95%CI:0.03–0.31). The cost per patient completing treatment was lower in primary care with an incremental saving of £315.26.

Conclusions The treatment of LTBI in recent migrants within primary care is effective and safe with lower costs when compared to treatment within secondary care.

Abstract S39 Table 1 Latent tuberculosis infection (LTBI) treatment completion, adherence, acceptance, patient satisfaction and adverse events in the CATAPuLT trial (n=362)

Outcome	Intervention % (N)	Control % (N)	OR (CI)	p	Adjusted OR (CI)	p
Treatment completion						
Treatment completion (missing data imputed)	82.6	86.0	0.70 (0.35-1.38)	0.29	0.64 (0.31-1.29)	0.21
Adherence (Prescription collection and INH urine tests)						
Did not collect prescription	15.6 (19/122)	7.9 (10/127)				
Two or more urine tests negative	0.8 (1/122)	2.4 (3/127)	0.61 (0.31-1.19)	0.15	0.64 (0.32-1.28)	0.21
One negative urine test	7.4 (9/122)	6.3 (8/127)				
All urine tests positive	76.2 (93/122)	83.5 (106/127)				
Treatment acceptance	65.2 (146/224)	94.2 (130/138)	0.10 (0.03-0.31)	<0.001	0.10 (0.03-0.30)	<0.001
Patient satisfaction (score /10)						
7 or lower	3.1 (3/98)	2.5 (3/121)				
8	5.1 (5/98)	8.3 (10/121)	1.84 (0.88-3.87)	0.11	1.80 (0.84-3.86)	0.13
9	14.3 (14/98)	27.3 (33/121)				
10	77.6 (76/98)	62.0 (75/121)				
Serious Adverse Events leading to hospitalisation*	0	0	n/a	n/a	n/a	n/a
Adverse events*						
Drug-induced liver injury (ATS criteria)	0.7 (1/146)	2.3 (3/130)	0.29 (0.03-2.84)	0.29	n/a	n/a

OR: odds ratio, CI: 95% confidence interval *adjusted analyses could not be performed due to the low number of events in each arm

S40

REDUCING NUMBERS, INCREASING COMPLEXITY: AN EVALUATION OF ENHANCED CASE MANAGEMENT IN THE NORTH CENTRAL LONDON TUBERCULOSIS SERVICE 2013 TO 2020

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Background North Central London Tuberculosis (TB) service provides care to patients diagnosed with TB across a large, high-prevalence urban area with complex socio-economic demography. In 2013, a system of categorising patients as requiring Standard or Enhanced Case Management (SCM, ECM) was implemented to identify early those who require additional care, including medication support and social care input. From 01/04/2019 patients were further sub-categorised as ECM 1–3 to better align service support with patient care needs. Here we present an analysis of patients' ECM status and clinical outcome from 2013–2020.

Methods A retrospective service evaluation was conducted by extracting all data from the TB database for patients notified between 01/01/2013 and 31/01/2021. Patients were categorised by ECM status (requiring ECM or not, or ECM category after 01/04/2019) and treatment outcome. Differences in proportions of patients by outcome were analysed using Chi-2 testing.

Results 2,587 patients were included. Numbers of notifications have decreased consistently since 2016 (figure 1), while the proportion requiring ECM has increased. Of 2,422 patients with an outcome registered between 2013 and 2020, 87.4% completed treatment 1.7% died with TB contributing, 2.1% died of other causes, and 8.8% transferred or were lost to follow-up. 2,317 had an ECM status recorded and those requiring ECM were less likely to complete treatment (83.2% vs 91.9%, p=0.03) and more likely to die of TB (2.5% vs 1.5%, p=0.01) or be lost to follow-up (11.8% vs 5.7%, p<0.01).

Of 487 patients notified after 01/04/2019, 248 had been sub-categorised: 22.2% as SCM, and 24.6%, 21.2%, 31.9% as ECM1, ECM2 and ECM3 respectively. Of 237 with an outcome, there was no significant difference in treatment completion or loss to follow-up by SCM or ECM category. Number of deaths was too small to evaluate.