Latent tuberculosis screening of recent migrants attending language classes: a cohort study and cost analysis

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Summary :

Setting: A key recommendation of the National TB Strategy for England is testing and treatment of latent Tuberculosis infection (LTBI) among new migrants. Programmatic testing is based in primary care; however, this may be inaccessible to some individuals. Current strategies therefore could be complemented with screening in other settings.

Objective: To investigate the feasibility and effectiveness of LTBI screening in a community college.

Design: We performed a cohort study, based on observational data collected during and after the pilot project. Eligible language students from high TB incidence countries were consented and tested with a single-step Interferon Gamma Release Assay (IGRA) and enrolled in the cohort. We used single and multivariable analyses to estimate effectiveness of LTBI screening and to explore effectiveness in different sub-groups.

Results: Screening uptake was 75% and the treatment completion rate was 85%. 71/440 students (16%) were LTBI positive and two had active TB. There was an association of positivity with age and TB incidence in the country of origin. We included costs from a UK National Health Service perspective. Three potential TB incidence thresholds met our cost effectiveness criteria for screening: countries with incidences of more than 40, more than 100 and more than 200 per 100,000 plus students from sub-Saharan Africa.

Conclusion: We found that LTBI screening can be offered effectively in a community college setting, and could be a feasible complement to primary care-based programmes in low-incidence countries.

Keywords:

Tuberculosis; latent TB screening; community college; recent migrants

Background

Latent TB infection (LTBI) screening of new immigrants from countries with a high incidence of TB is an effective and cost effective way to identify eligible individuals for preventive treatment and thereby prevent subsequent cases of active disease[1-3]. The UK National Institute for Health and Care Excellence (NICE) and the World Health Organization (WHO) both recommend a targeted screening approach to individuals at highest risk of reactivation[4,5]. In England, more than 72% of TB cases are notified amongst the non-UK born population and most of these cases (86%) arise more than two years after entry to the UK and are likely due to reactivation of LTBI[6]. The Collaborative TB Strategy for England 2015-2020[7] therefore emphasises recent immigrant LTBI screening in primary care as a key intervention. However, primary care registration of recent immigrants in the UK can be low[8]. There is an on-going debate about how to best implement LTBI screening, including the benefits and costs of different settings and screening thresholds. While there is evidence supporting the use of community venues and schools for health outreach or opportunistic screening programmes for other diseases[e.g. 9,10] and for screening for active TB[11] the evidence for the effectiveness of LTBI screening in such venues is more limited.

The aim of this study is to evaluate an outreach programme targeted to recent immigrants enrolled in English for Speakers of Other Languages (ESOL) courses at a Birmingham community college. We describe the results of this screening pilot to investigate the feasibility and estimate the effectiveness, costs and costs per case prevented of LTBI screening in this community college setting. We also identify factors associated with a positive IGRA test and explore the effects of screening different sub-groups of students to inform and optimise screening strategies for community college settings.

Methods

We carried out a cohort study, based on observational data collected during and after the ESOL pilot. Data were used to describe the pilot and estimate its effectiveness and determine service costs. We then determined costs of different screening strategies (based on TB incidence, age and years since entry into the UK) to identify the cost per positive IGRA and the percent of positives in the whole cohort identified at these thresholds. The data used in the study was anonymised and was collected as part of a Public Health service review, so ethics approval was not required.

1. Outreach programme

Information sessions were held at two sites offering ESOL classes (English for Students of Other Languages) over four days in February and March 2014. ESOL classes are often taken to fulfil requirements for enrolling into higher education or for citizenship in the UK. Enrolling in ESOL courses is voluntary.

Two third-sector organisations were involved and provided information on TB, the screening programme and general health messages such as encouraging GP registration.

Two LTBI screening sessions were delivered on campus by the TB service team together with Public Health England (PHE). Students who tested positive for LTBI or had any symptoms suggestive of TB were referred to a specialist TB clinic for investigation and treatment. LTBI screening was offered using a commercially-available Interferon Gamma Releasing Assay (IGRA). Students in the UK need to be registered with a general practitioner (GP) to access the healthcare system. Where they were not registered, they were assisted with the process.

2. Clinical pathway

The patient pathway is shown in Fig 1. Screening was done initially by questionnaire that asked about symptoms of active disease, previous TB treatment and TB contacts. Eligible students had IGRA tests (QuantiferonTB Gold InTube®, Qiagen – samples processed by Synlab). GPs of students

were sent results and information letters. Students who were IGRA positive were contacted by letter and invited to attend a TB clinic at the Birmingham Chest Clinic. Records were kept of attendance, tests performed and outcomes.

Students who tested IGRA positive were started on a standard 3 month course of a combination of 300mg isoniazid and 600 mg rifampicin, with appropriate adjustments for persons under 50 kg. All patients were seen at the start of treatment by a TB nurse. They were then seen or phoned monthly for the duration of treatment. Patients having difficulties with treatment were contacted by their TB nurse and seen more often, either weekly or daily. All patients were seen by a physician at the start and end of treatment. Students who were suspected to have active disease attended the TB clinic for investigation and treatment.

The patient pathway was used to assess the economic aspects of the study (Fig 1).

Literature review

We performed a literature review in February 2015 to identify papers reporting LTBI progression and the positive predictive values (PPV) of IGRA tests. Relevant papers with the terms Tuberculosis, TB infection, TB disease ,''QuantiFERON'' , ''Elispot'' ,''T-SPOT'', ''interferon gamma assay'', IGRA, reactivation and progression were identified in Medline [1966-Feb 2015]. Forty-two papers were identified and five retained which addressed the research question. Because of the limited follow up time of our study, we estimated progression and treatment efficacy based on this literature evidence. A more detailed description is provided in appendix 1.

Data analysis

We described the demographics, clinical characteristics and outcomes of the cohort, including age, sex, TB incidence in the country of origin and year since UK entry. The association between a positive

IGRA test and these individual risk factors were tested in a univariable and multivariable logistic regression. All analyses were carried out with Excel 2010 (Microsoft Corporation) and Stata (v13, STATACorp 2013).

Economic investigation

A simplified decision tree was built to estimate the programme costs (Figure 1). Costs were determined from a UK National Health System (NHS) perspective. Costs are taken from NHS 2014 tariffs, and represent costs directly billable to commissioning services.

The cost per prevented case is estimated using a two year time frame to reflect early savings for the health system. However, this is likely to underestimate overall savings, as benefits accrue over a longer period. The costs per case include all screening and treatment costs and no discounting was applied.

Figure 1. Model decision tree

Results

Demographics of cohort

Table 1: Description of cohort

Results

The demographics of the participants are given in Table 1. A total of 588 eligible students were present on campus during the recruitment sessions. Of these, 440 took up the invitation for screening, an uptake of close to 75% (Table 2). The median time since entry was four years. 71/440 (16.1%) tested IGRA positive. Fifty-three individuals initiated LTBI treatment, and 45 (85%) of these completed treatment (table 2).

The screening exercise also identified two cases of active TB (2.8% of the IGRA+ cohort).

Table 2. Programme outcomes

Explanatory factors for IGRA positivity in this cohort

We analysed potential explanatory factors for IGRA positivity and in uni- and multivariable analysis. We found an association between IGRA positivity and age as well as TB incidence in the country of origin (Table 3). We did not find a significant association with sex or time since entry into the UK.

Table 3: Single and multiple variable analyses

Cost estimates

Cost per active case avoided

To evaluate costs at different screening thresholds, we compared subgroups by age, TB incidence in the country of origin and years since entry (Table 4). The results were ranked by decreasing efficacy

(as defined as the proportion of IGRA positive identified at that threshold / all IGRA positive results in the cohort). Thresholds that were both more expensive and less effective were discarded. The incremental costs of the remaining subgroups were calculated as the ratio of the difference in cost to the difference in number of cases avoided relative to the next most effective model. Models with a higher incremental cost but lower effectiveness were also removed (Table 4). The results were compared with those when screening all participants.

Table 4. Cost and effectiveness of screening at different thresholds

For our calculations we assumed a treatment completion of 90% among IGRA positive and efficacy of treatment of 70% with a reactivation rate of 10% over 24 months [12,13]. Three models remained after applying the above criteria: countries with incidences of more than 40, more than 100 and more than 200 per 100,000 plus students from sub-Saharan Africa (Table 5). Of these, the most favoured option relative to the "screen all" scenario (with an estimated incremental cost of £27,602.85 per case avoided) was to use a TB incidence threshold in the country of origin of 100 per 100,000 (+sub-Saharan Africa). This option identified 80.9% of IGRA+ results with an average cost of £17,845.61 per positive IGRA and an incremental cost of £25,521 / case avoided.

Table 5. Model outcomes

Sensitivity analysis

To investigate the sensitivity of the model to differences in reactivation and efficacy assumptions, we tested a range of values, separately varying treatment efficacy from 65-80% [13] and reactivation rates from 5%-14.8% (see methods for discussion of values chosen). The overall costs (and cost per case) varied based on the values tested; however, the retained thresholds remained the same for all values examined (data not shown). Figure 2 shows the sensitivity of the model for whole cohort.

Figure 2. Sensitivity analysis to changes in key variables

DISCUSSION

This study analysed the feasibility of a systematic latent TB screening project among ESOL students attending a community college in Birmingham, a region of the UK that has the highest incidence of TB outside London. We demonstrated that the project was feasible to implement and detected a 16% LTBI positivity with an 85% treatment completion rate. A number of screening scenarios were similarly effective within the cost parameters tested; however the most favoured cut-off was that of 100 per 100,000 in the country of origin (plus Sub-Saharan Africa). This option identified 80.9% of IGRA positive results with an average cost of £17,845.61 and an incremental cost of £25,521 per case avoided. This is consistent with the findings of Pareek et al. [1] who report that that screening migrants from countries with a TB incidence of 150 per 100,000 was similarly cost effective and captures the majority of LTBI cases.

Two cases of active TB were identified and treated, thereby achieving immediate-term health gains through treatment and interruption of onward transmission. Also, using the values of reactivation and treatment efficacy described, we estimated that this initiative is likely to have avoided a further two cases of active TB over 2 years.

A review of cost effectiveness of LTBI screening in migrants from high incidence countries [22] found that in eight of nine economic evaluations, screening of recent immigrants was cost effective, although different assumptions, incidence thresholds and screening strategies were used. It is not possible to directly compare the costs across different studies, as here the costs were limited to directly billable costs to the UK National Health Service within a pilot study. However, the finding that screening strategies targeting recent immigrants in various settings can be feasible and effective at different screening thresholds in this and in other published studies supports the further use of screening in college settings.

We also observed benefits beyond the identification of latent TB and prevention of future cases. These included raised awareness, increased primary care registrations and provision of other health information and screening services, such as for blood-borne viruses and sexual health.

There is evidence in the literature to support the use of community venues and schools for health outreach or opportunistic screening programmes [9,10].In a systematic review, Jamil et al. [14] showed that educational venues are feasible settings for identifying and treating students for chlamydia, and that classroom-based interventions seemed to have higher identification and treatment completion rates. In the UK, the national Chlamydia screening programme has successfully implemented screening in various school and college settings.

Educational settings have been used successfully for screening other infectious diseases, such as HIV [15] and for smoking cessation initiatives [10]. Colleges also have been used for screening for active TB although there is less literature on LTBI screening initiatives in such venues. Our study shows that educational venues can be appropriate for screening of recent immigrants. Such a setting could be used as a complement to other, primary care-based screening strategies.

Our small cohort study provides useful lessons for the development of screening in similar UK and European settings. The study benefited from an almost complete follow-up including all treatment and follow up costs. In addition, the uptake and completion rates were high. However, the study is based on observational data from a single centre. Although this limits the generalisability of our observations, our findings are consistent with previous studies. Our estimates are based on number of assumptions, in particular about LTBI reactivation rates and the effectiveness of treatment. However, we applied a plausible range of these variables to the sensitivity analysis and doing so did not significantly alter our conclusions. The differences in assumptions that are made in economic models limit the ability to directly compare absolute values across studies but our findings fall in the range of values reported elsewhere [2,16].

Conclusions: Our study demonstrates that LTBI screening in community colleges can be feasible and effective, particularly if implemented at appropriate screening thresholds and may therefore have a role in conjunction with primary care settings within the national TB screening programme.

List of abbreviations

TB Tuberculosis; LTBI Latent TB infection; IGRA Interferon gamma release assay; GP General practitioner

Competing interests

DZ is head of TB screening for PHE and lead the national programme; HM is the Acting Health Protection Deputy Director for PHE and the TB sponsor lead for Public Health West Midlands but has no other conflict of interest.

Authors' contributions

MU carried out the analysis and produced the first draft of the paper. DZ had the idea, contributed to writing and acted as sponsor. RG and VA were involved in designing, implementing and analysing the intervention. MD contributed to the design and implementation of the pilot and the clinical management of the cohort. KD coordinated the implementation of the pilot; HK contributed to the gathering of data and HK, YA and PH contributed to the design and implementation. HM contributed to funding applications and the design of the pilot. CLW contributed to the design, implementation and initial evaluation. All authors have reviewed and commented on the paper.

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Appendix 1. Assumptions in estimating TB progression and efficacy of prophylaxis

We performed a literature review in February 2015 to identify papers reporting LTBI progression and the positive predictive values (PPV) of IGRA tests. Relevant papers with the We searched Pubmed and the grey literature and hand-searched reference lists of identified articles. The search was limited to English language publications, and used any combination of the terms Tuberculosis, TB infection, TB disease ,''QuantiFERON'' , ''Elispot'' ,''T-SPOT'', ''interferon gamma assay'', IGRA, reactivation and progression. We excluded papers that did not report a positive predictive value or reactivation/progression rate, or studies in HIV infected cohorts as well as studies without LTBI prophylaxis. Forty-two papers were identified and five retained which addressed the research question. Because of the limited follow up time of our study, we estimated progression and treatment efficacy based on this literature evidence.

Rate of reactivation: Very few studies directly addressed the question of rates of progression to active disease if IGRA+ (i.e. the positive predictive values, PPV). Diel et al. [12] performed a meta-analysis of published studies. Four studies met the inclusion/exclusion criteria, two of which were in an HIV+ cohort. The reported PPVs for TB progression ranged from 2.8%-14.3% over 24 months. However, if the results were limited to those using commercial IGRAs as the primary predictive test, the range is 8.3-14.6%. One paper [17] tested progression in patients who were TST+ before IGRA, giving a different prior probability in that cohort relative to other cohorts where this dual testing strategy was not done.

Diel et al.[18] published a larger meta-analysis reporting a pooled PPV of 2.7% over all studies, with a range of 0%-17%. PPVs for progression in studies using commercially available tests rose to 6.8%; studies examining healthy untreated contacts including those from high risk groups gave a pooled PPV of 8.5%. These results are slightly lower than the PPV discussed above.

Rangaka et al.[19], in a detailed meta-analysis, included 8 of 16 studies in which it was not clear whether prophylaxis was given or did not report HIV status, making the pooled values difficult to interpret.

Given the heterogeneity in the study populations and methods used, and the dependence of PPV on LTBI prevalence in the population tested, we chose a pragmatic value between the pooled PPVs reported in [18] and the range of PPVs from the two meta-analyses [12,18], taken as 5%-14.6%, with a mean of 10%. However, this value needs to be taken with caution, given the uncertainties discussed here, and the lower rates reported in some other studies [e.g. 19,20].

Efficacy of treatment: In the results of a large placebo-controlled trial, efficacy in those subsets with close to full compliance was ~70%; this value is close to that of the Cochrane systematic review (60% efficacy) over all completion rates and types of cohort identified[13,21]. We thus used the higher value of 70% efficacy and explored a range of plausible values from 65-80% in a sensitivity analysis.

Tables

Table 6: Description of cohort

Demographics		
	Whole cohort (%)	**IGRA+ individuals (%)**
Age	**N=440**	**N=71**
15-20	122 (27.8%)	9 (12.6%)
21-25	65 (14.8%)	11 (15.5%)
26-30	122 (27.8%)	24 (33.8%)
31-35	130 (29.6%)	26 (36.6%)
Unknown	1 (0.2%)	1 (1.4%)
All	440	71
Sex		
Male	196 (44.5%)	31 (43.7%)
Female	234 (53.2%)	38 (53.5%)
not recorded	10 (2.3%)	2 (2.8%)
TB incidence per 100,000 in country of origin		
<40	102 (23.2%)	6 (8.5%)
40-150	165 (37.5%)	33 (46.5%)
>150	172 (39.1%)	29 (40.8%)
>150 plus SSA	269 (61.3%)	52 (73.2%)
unknown	3 (0.7%)	3 (4.2%)
Years since entry into UK (N=380)		**(N=59)**
<=5	291 (76.6%)	43 (60.6%)
>5	89 (23.4%)	16 (22.5%)

Table 2. Programme outcomes

Group	No.	%
Number of eligible students	544	100.0%
Eligible students screened (uptake)	440	80.9%
IGRA positivity	71	16.1%
IGRA positive with treatment start	53	74.6%
Did not start treatment	18	25.4%
Not started on treatment: non-attendence	5	9.4%
Not started on treatment: pregnancy	7	13.2%
Not started on treatment: active TB	2	3.8%
Not started on treatment: previous LTBI	2	3.8%
Not started on treatment: previous TB	2	3.8%
Completed LTBI treatment	45	84.9%
Not completed treatment- defaulted	3	5.7%
Not completed treatment- Toxicity	5	9.4%

Table 3. Single and multivariable analyses of risk of IGRA positivity amongst tested student cohort

	Univariable			Multivariable		
	RR	**p**	**95% CI**	**RR**	**p**	**95% CI**
TB incidence (base= <40/100,000)						
40-100	3.09	0.01	1.31-7.28	3.52	0.01	1.40-8.88
100-200	3.45	0.01	1.39-8.54	3.62	0.01	1.37- 9.58
200-300	2.63	0.03	1.09-6.33	2.72	0.05	1.01-7.30
>300	6.54	0.00	2.32-18.44	8.38	0.00	2.70-25.98
age group (base = 15-20 yrs)						
21-25	2.09	0.09	0.89-4.87	2.21	0.10	0.86-5.70
26-30	2.67	0.01	1.29-5.50	3.39	0.00	1.50-7.68
30-35	2.61	0.01	1.27-5.36	3.31	0.00	1.47-7.44
Years since entry	1.23	0.44	0.73-2.07	0.79	0.40	0.47-1.36
Sex (Female)	1.07	0.76	0.69-1.66	1.09	0.71	0.68-1.75

Table 4. Cost and Effectiveness of screening at different thresholds

Cutoff	Cost per IGRA+	% of all IGRA+ detected at this level
TB incidence in country of origin		
all	£19,234.08	100.0
300+	£71,702.83	7.4
***300+SSA**	£16,603.12	63.2
200+	£36,438.19	35.3
200+SSA	£17,486.94	75.0
100+	£21,809.68	55.9
100+SSA	£17,845.61	80.9
40+	£22,428.31	91.2
40+SSA	£18,454.40	91.2
Age		
15-20	£62,073.07	12.7
21-25	£20,055.32	14.1
26-30	£21,050.78	32.4
31-35	£35,041.90	36.6
Years since entry into UK		
<=5	£17,587.02	72.9
>5	£42,589.29	27.1

Table 5. Model outcomes

Cutoff	Total cost of programme	Average cost/IGRA positive	Incremental cost	Estimated number of cases avoided	% of all IGRA+ results identified
All	£117,401.55	£19,234.08	£27,602.85	2.10	100.0
>=40+SSA	£103,042.00	£18,454.40	£26,247.11	1.58	91.2
>=100+SSA	£92,422.42	£17,845.61	£25,521.41	1.18	80.9
>=200+SSA	£86,521.87	£17,486.94	Baseline	1.95	75.0