**Qualitative Protocol Development Tool**

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a ‘manual’ for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study’s progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

* Support researchers developing protocols where the sponsor does not already use a template
* Support sponsors wishing to develop template protocols in line with national guidance
* Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you’ve used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

* **This protocol has regard for the HRA guidance and order of content**

**FULL/LONG TITLE OF THE STUDY**

Semi-structured interviews and focus groups to explore the experiences, views, and concerns of both migrant patients and health-service providers around receiving or delivering treatment and care for latent tuberculosis infection (LTBI) and active tuberculosis (TB) at NHS services.

**SHORT STUDY TITLE / ACRONYM**

Analysing experiences of Tuberculosis care

**PROTOCOL VERSION NUMBER AND DATE**

Version 0.6

19/08/20

**RESEARCH REFERENCE NUMBERS**

|  |  |
| --- | --- |
| **IRAS Number:** | 260105 |
| **SPONSORS Number:** | 2019.0056 |
| **FUNDERS Number:** | M775 |

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |
| --- |
| **For and on behalf of the Study Sponsor:** |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name (please print):...................................................................................................... |  |  |
| Position: ...................................................................................................... |  |  |
| **Chief Investigator:** |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):......................................................................................................  |  |  |

#

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# KEY STUDY CONTACTS

|  |  |
| --- | --- |
| Chief Investigator |  |
| Study Co-ordinator |  |
| Sponsor |  |
| Joint-sponsor(s)/co-sponsor(s)  |  |
| Funder(s) |  |
| Key Protocol Contributors |  |
| Committees |  |

**STUDY SUMMARY**

|  |  |
| --- | --- |
| Study Title | Semi-structured interviews and focus groups to explore the experiences, views, and concerns of both migrant patients and health-service providers around receiving or delivering treatment and care for latent tuberculosis infection (LTBI) and active tuberculosis (TB) at NHS services. |
| Internal ref. no. (or short title) | Qualitative analysis of LTBI and TB care experience |
| Study Design | Semi-structured interviews and focus groups |
| Study Participants | * Current and/or past tuberculosis and LTBI patients born outside the UK (migrants)
* Health-service providers involved in LTBI and TB patient care and management.
* Approximately 20 migrant patients with experience of LTBI or TB treatment.
* Approximately 20 health-service providers with experience delivering LTBI or TB treatment to migrant patients.
 |
| Planned Size of Sample (if applicable) | * Approximately 40 individual participants
 |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | 24 months  |
| Research Question/Aim(s) | 1. What are the views, experiences, and concerns of both migrant patients and health-service providers around treatment for LTBI and TB?2. What are their perspectives on what constitutes ‘successful treatment’? 3. Are there specific factors that influence ‘successful’ treatment outcomes?4. What do participants consider targets for novel interventions designed to provide ‘successful’ treatment outcomes? |

**FUNDING AND SUPPORT IN KIND**

|  |  |
| --- | --- |
| **FUNDER(S)**(Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
|  |  |
|  |  |
|  |  |
|  |  |

**ROLE OF STUDY SPONSOR AND FUNDER**

The sponsor and funder have no control over the design, conduct, analysis or interpretation of any data gathered. The Chief Investigator and study team hold the sole responsibility for decision to publish and disseminate results generated by this research.

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

**Study Steering Groups**

Aim: To outline any committees or groups involved in study coordination and conduct.

For each committee/group the protocol should state their roles and responsibilities and degree of independence from Sponsor and Investigators. If not included in the document the protocol should state where the information on the committee/group can be found.

Patient & Public Involvement Group

 Public involvement plays an important role in study design and planning and can help reduce

delays in approvals. Public involvement in study design and study documentation can help with the acceptability of a study to the public which in turn can assist with study set-up and recruitment. Ongoing involvement of the public can help understand blockages to recruitment and the acceptability and relevance of study findings.

For guidance on Patient & Public Involvement follow this link:

http://www.invo.org.uk/find-out-more/information-for-researchers/

**PROTOCOL CONTRIBUTORS**

The sponsor and funders have no role in the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results. The final decision regarding all aspects of the research, as well as the decision to disseminate results lies solely with the research team outlined above.

|  |  |
| --- | --- |
| **KEY WORDS:** | ***Latent Tuberculosis******Tuberculosis******Patient and provider experience******Treatment outcomes******Qualitative study******Migrant*** |

# STUDY FLOW CHART

|  |  |
| --- | --- |
|  | Progress by Month |
|   | 4 | 8 | 12 | 16 | 20 | 24 |
| ***Patient and staff recruitment*** | x | x | x |   |   |   |
| ***Interviews and focus groups*** |  x | x | x | x |   |   |
| ***Transcription of Interviews and focus groups*** |   | x | x | x | x |   |
| ***Coding of individual interview and focus groups data*** |   |   | x | x | x | x  |
| ***Analysis of full data and theory generation*** |   |   |   |   | x |  X |
|  |  |  |  |  |  |  |
|  | x | Recruitment and data collection |  |
|  | x | Data Analysis |  |  |  |
|  | x | Dissemination and submission for publication |

**STUDY PROTOCOL**

# BACKGROUND

Tuberculosis (TB) is one of the top ten causes of death worldwide, and the number one cause of infectious disease-related death, with over 1.6 million deaths attributed to TB in 2017; a further 10 million new cases are estimated to have occurred in 2017.1 Besides the immediate threat of active TB, is that of latent tuberculosis infection (LTBI), which is estimated to be prevalent in around 23% (95% uncertainty interval: 20.4-26.4%) of the entire global population, totalling 1.7 billion people.2 Whilst LTBI itself manifests sub-clinically, and does not cause disease, of those harbouring LTBI approximately 5-10% will go on to reactivate and acquire active TB infection across their lifetime.3

The End TB Strategy adopted by the WHO in 2014, outlining the “Global strategy and targets for tuberculosis prevention, care and control after 2015” represents the most comprehensive and ambitious approach to eradicating TB to date.4 The strategy sets milestones to the end of 2035, the culmination of which is hoped to be a 95% reduction in TB deaths, and 90% reduction in incidence (relative to 2015 levels). The strategy outlines core pillars and key actions, including those designed to address active TB, and to prevent active TB cases through the diagnosis and treatment of LTBI.

Approaches aimed at preventing TB through the management of LTBI are thought to represent an essential component of TB control, particularly in low tuberculosis-incidence countries.4 Low tuberculosis-incidence countries have been the subject of a tailored framework for TB elimination, incorporating and building upon the End TB strategy and are defined as those with a TB notification rate <100 per million population.5 In general, these low-incidence countries represent some of the wealthiest nations on the planet, including many from Europe, and therefore those that are perhaps best equipped to meet TB elimination targets. Despite this, only four of the 31 nations (and 2 territories) that comprise this group are currently meeting the annual decline in TB incidence required to achieve pre-elimination targets by 2035 (<10 notifications per million population), whilst none will achieve elimination.5 The challenges facing low tuberculosis-incidence countries in eliminating TB, like all countries, are complex, dynamic, and multifactorial. However, the key challenges which are particularly pertinent to these countries include: The concentration of TB in vulnerable groups; the increasing importance of progression from LTBI to TB (Vs. transmission); cross-border migration; and securing political commitment to universal healthcare access, and effective TB service planning and delivery.5

One such low tuberculosis-incidence country which exemplifies the situation many of these nations currently find themselves in is the United Kingdom. The UK has relatively few TB cases, with 5,102 incident cases reported in England in 2017.6 However, whilst classified as a low tuberculosis-incidence country, the UK has one of the highest overall incidence rates for TB in Western Europe.7 The UK TB figures are also, unsurprisingly, affected by the key challenges for all low incidence-TB countries outlined previously. The TB in England report 2018 highlights these challenges: Vulnerable populations suffer an inequitable burden of TB, the 10% most deprived individuals in the UK have a TB rate over 7 times higher than that of the 10% least deprived. Furthermore, 13% of TB notifications were among those with a social risk factor (classified as alcohol misuse, drug misuse, homelessness and/or imprisonment). Progression from LTBI to TB is now a major consideration compared to transmission. Indicators of transmission including genotyping clusters, counting of new clusters and rate of TB transmission among children born in the UK, have dropped to their lowest recorded levels.

Cross-border migration, and the influence of migrants on TB numbers also continues to play a substantial role in the UK TB scenario, in 2017, 71% of TB cases were among migrants, defined as individuals born outside the UK, with a notification rate 13 times higher than in the UK-born population, making foreign-born individuals a key demographic in tackling TB in the UK. Underlying the disproportionate numbers of migrants suffering TB are issues surrounding access to care, equity of care, and wider societal and cultural factors. Whilst migrants as a group have come under increasing focus in specific TB control strategies, there has been a lack of clarity in health initiatives globally as to the priorities for improving care – and ultimately treatment outcomes - in these population. Indeed, previous research has shown that equity of care and the appropriate provision of information are considered key facets in providing migrant-focused healthcare, but may currently be neglected.8 Complexities surrounding migrants legal status, for example, in the case of asylum-seekers, can also have a detrimental effect on engagement with healthcare services, and adherence to treatment, and as a consequence negatively impact overall treatment outcomes.9,10

The UK has had comprehensive TB screening and treatment guidelines for many years, whilst those regarding LTBI have been evolving more recently with current UK guidelines being implemented in the last few years.11,12 Screening for LTBI is predominantly focused on pre-entry screening of migrants from high-incidence countries, whilst treatment is offered to any individual testing positive for LTBI. However, whilst LTBI treatment is now routinely offered to those testing positive in the UK, the programmatic management, support for adherence to such treatments, and algorithms to test and treat LTBI are still under question and represent potentially significant research gaps.13 Indeed, how to improve the engagement of migrants in TB and LTBI services and improve the delivery of care/treatment to this group to ensure successful treatment outcomes has yet to be fully elucidated, and therefore represents the target of this study..

# 2 RATIONALE

The proposed research represents a timely and potentially significant contribution to the understanding of LTBI and TB care experience within the United Kingdom. Whilst similarly focused research might traditionally consider one demographic (such as patients, or staff) across one domain (LTBI or TB), our proposed research has a relatively broad scope, in the sense we are documenting the experiences and perspectives of both patients and health service providers across LTBI and TB. Such a holistic consideration of these care pathways will result in a robust piece of research that examines in depth the challenges and triumphs of current TB and LTBI care in the UK, as seen from key stakeholders who include health-service professionals as well as migrants who have been affected by this disease. Research rarely seeks the views of migrant patients, who are a particularly important group in the context of TB elimination in the UK, and so this research will generate direct evidence of migrant patients’ views and experiences.

Whilst standard procedures and approaches to TB care have been in place for some time, there are still a number of challenges regarding reaching elimination in the UK, including delays to treatment initiation, adherence to treatment (particularly among individuals with social risk factors, which may include migrants), and overall treatment completion,6 all of which contribute to projections in which the UK will fail to eliminate TB as part of the End-TB strategy.14 Some current recommendations aimed to achieve ongoing reductions in TB incidence in the UK include the consideration of innovative approaches to improve successful treatment outcomes, particularly among migrant patients who represent the largest demographic with TB.6 This research will specifically explore factors involved in successful treatment outcomes among migrant patients and enable us to better understand the views of both migrant patients and staff on this issue – data which will be used for the development of future interventions that will support TB elimination in the UK.

Whilst LTBI screening and treatment is now increasingly becoming standard procedure, with £10million invested recently in the UK for the testing and treatment of migrants from high-incidence countries,15 little has been done to assess the experiences of migrant patients being increasingly offered LTBI testing and preventative treatment (whom are the predominant demographic targeted by the testing), nor the practitioners delivering such care, and it is unclear how successful treatment uptake and completion is in the UK. Our data will provide much needed information on the views and experiences of patients and NHS staff around ways to improve delivery of care in this area, so as to assess where future efforts could be focused to improve the quality of care, and consequently treatment outcomes.

**3 THEORETICAL FRAMEWORK**

The proposed research will utilise semi-structured interviews and focus groups to explore the experiences of receiving LTBI and TB treatment among migrant patients, the experiences of administering such care among health-service providers, and both groups’ perspectives on what constitutes ‘successful’ treatment.

The topic guides/questionnaires for the interviews and focus groups will be semi-structured, and include open ended prompts. Qualitative methodology is appropriate to the aims of our research, to enable the collection and examination of our participants lived-experiences of the topic under study. Utilising in-depth semi-structured interviews ensures the complexity of the phenomenon we’re examining (i.e individuals’ experiences and perspectives) is respected, especially when working to discover core themes and ideas.16 Similarly, focus groups can act as a powerful method to facilitate discussion between participants who have common experiences, though perhaps differing perspectives, and can lead to the same in-depth understanding of phenomena as interviews.17 Such approaches can then form the basis for further research that can quantitatively assess phenomenon of interest.

In terms of specific methodology and approaches, data collection will be informed by a phenomenological approach.18 The phenomenological approach aims to capture the way in which a phenomenon is experienced by individuals, within its setting and context, and so such an approach aligns with our aims of capturing our participants lived-experiences.19 Whilst there are separate phenomenologically inspired methods and philosophies developed by individuals such as Husserl, Heidegger, Gadamer and Ricoeur, there are often significant overlaps in approaches, and so we don’t aspire to subscribe to one particular phenomenological approach over another.20 Indeed, there are often blurred boundaries and adoption of multiple elements of differing methodologies such as grounded theory and phenomenology in many qualitative studies, and the potential that too rigorously adopting one approach over another may impact rigour.21 Overall, the most important aspect of our approach must be to be clear about the physical methods we have adopted and our means of analysis, and then use our best efforts to implement and evaluate critically our approaches, giving consideration to the different interpretations of the data that could arise throughout the analytical stages of the work.21

As well as examining the phenomena of interest previously described, the finding and recommendation from this research study will support us to develop a novel intervention to improve TB/LTBI treatment outcomes in migrant patients at identified survey sites as a next step. The use of qualitative methodologies, and the focus on the lived-experience of individuals is an established methodology for informing the development of novel healthcare interventions, and is a process used in Experience-Based Co-Design.22 Our use of phenomenological methodologies during this study is also likely to generate data that reflects the public’s interests, therefore increasing the validity and social relevance of the research and any downstream work (such as interventions).23 The use of qualitative methodologies is also appropriate to begin to build networks of individuals (in our case migrant patients and health-service providers) that would contribute to the future co-design of interventions and research, and which is something we are keen to go onto do after this research study.24

# 4 RESEARCH QUESTION/AIM(S)

**4.1** **Objectives**

To understand health-service provider and migrant patient perspective on LTBI and TB treatment – considering what ‘success’ means in the context of treatment, and how these perspectives can inform future interventions designed to improve treatment outcomes – through 4 key questions:

1. What are the views, experiences, and concerns of both migrant patients and health-service providers around treatment for LTBI and TB

2. What are their perspectives on what constitutes ‘successful’ treatment

3. Are there specific factors that influence ‘successful’ treatment outcomes

4. what do participants consider targets for novel interventions designed to provide ‘successful’ treatment outcomes.

**4.2 Outcome**

* Documentation of the views, concerns, and experiences of migrant patients and health-service providers around the treatment of LTBI and TB
* A comparative phenomenological understanding of LTBI and TB treatment from migrant patient and staff perspectives
* The identification of factors that may contribute to ‘successful’ treatment
* Identification of targets for novel interventions designed to improve migrant patient and health-service provider experience, as well as improve treatment outcomes.

# 5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

**Study Design**

This will be a qualitative study utilising in-depth semi-structured interviews and focus groups.

**Data collection**

Data will be collected using a semi-structured topic guide, which has been developed by the chief investigator and research team, and which will be attached to the PIS participants receive to aid in informing their decision. Being a semi-structured qualitative research project, the topic guide itself is not intended to be fully prescriptive/verbatim. The topic guide is intended to show the order in which topics will be explored, and the main questions the research is seeking to answer, but will be somewhat dictated by the responses (e.g. experiences and priorities) of the participants. A separate topic guide will be prepared for use with migrant patients and with health-service providers, though each will cover similar lines of questioning as the other.

Interviews will be conducted by a member of the research team and will be documented through written recordings, and audio recordings (with participants’ permission). Where necessary to facilitate the interview, a translation service will be used (e.g. language line or physical interpreter) in the conducting of interviews. If preferred, participants may also write their responses to the questions in the topic guide, rather than orally.

Focus groups will be facilitated by a member of the research team, with a second member of the research team acting as a scribe to gather written data. Focus groups will also be audio recorded (with the permission of all attending participants).

**Data collection with migrant patients**

Data collection will be carried out individually with migrant patients (e.g. individual interviews or written responses to topic guide if this is preferred). Interviews will be conducted in a private and confidential environment, or via phone depending on the availability and preference of the participant. Translation services (e.g. LanguageLine (NHS translation service) or physical interpreter) will be used if preferred by the participant. With the patients’ consent, all data will be recorded on digital Dictaphones, transcribed and anonymised prior to data analysis.

We are opting to only engage one-on-one with patients due to the personal and potentially sensitive nature of the questions, and the fact it would not be suitable to interview individuals in a group setting – the only exception being if the patient has indicated they would like a chaperone/supportive person present, or if the preference for a translator is indicated.

**Data collection with health-service providers**

Focus groups will be the primary mode of data collection when interacting with health-service providers. However, we will also use one-to-one interviews (in person or by phone) or allow participants to provide written responses to the topic guide depending on the availability and preference of these participants. Health-service providers not captured by the focus groups will be offered one-to-one interviews.

Focus groups will be used with health-service providers as we believe there is less risk to these individuals in disclosing their experiences of their professional environment. We will however make one-to-one interviews available for those that prefer to discuss their professional experiences in a private and confidential setting, and also to be as pragmatic as possible (considerations of staff time and flexibility are important).

The topic guide used will be the same when engaging health-service providers through focus groups, or one-to-one interviews. However, a larger length of time will be allocated to focus groups (~ 2 hours) compared to one-to-one interviews (~ 45-60 mins) to accommodate the larger number of participants.

\*Alternative process for data collection with health-service providers in light of Covid-19

As we already have approval for individual interviews with health-service providers we would like to clarify we will preferentially move to a system of using said individual interviews with this participant group. Any focus groups that might take place in the future would have consideration for social-distancing and maximum room occupancies whilst socially-distancing until such a time that these restrictions cease to be enforced.

**Data Management and Analysis**

Qualitative data will be analysed using phenomenological and/or thematic analysis techniques. Transcription and coding will be performed by members of the research team. Anonymised audio recordings and written accounts/field notes will be transcribed into Word documents, with transcription, coding and analysis being facilitated by NVivo software.

We will de-identify data during the interview process, names will not be recorded or asked for, besides those provided in the signing of consent forms. Where consent forms contain identifiable information, these will be locked in a secure filing cabinet within the department and stored in line with St. George’s University of London Data management requirements. All audio and written recordings will be de-identified and anonymised during transcription. Addresses, phone numbers and email addresses will only be collected as a mean to ensure individual rights of participants are upheld and will be not included on any recording that is sent to transcription/translation services (such as the right to be informed – both about the use of individual participant data, and the final research output). Voice recordings will be transcribed anonymously to written formats, and no audio recording will be released as part of the write-up or dissemination. Where these indirect identifiers are used as part of the analysis process, we will seek to reduce the risk to individuals by presenting findings as generalised group findings.

With regards to storage and transfer, any hand-written notes will be kept in a secure office, within a locked filing unit. Any electronic Word documents will be individually password protected, and only stored on password protected devices (laptop, hard-drive). Audio recording will be via digital Dictaphones and transferred to a password locked device after the interview/focus group, at which point the original recording will be deleted. Transfer of digital files (Word or audio) between research team members will only occur via password protected devices (USB stick/external hard-drive). Where audio recordings require translation or transcription, these audio files will be sent as password protected files via email – the password will be sent in a separate email to the transcription services. These audio files will be redacted to exclude any potentially identifiable information disclosed by the participants at the beginning of the interview (i.e. their migration status, country of birth, professional role).

Access to the ‘raw’ data, including unanalysed transcripts, translated transcripts, transcribed transcripts, or any other file containing identifiable and/or potentially sensitive information will not be authorised beyond the research team, except in instances where a participant has requested access to their personal data, or where access is necessary to translate the data (in particular, audio recordings). In all cases, no personal identifiable information will be included in any transcribed or written data, with the exception of consent forms.

# 6 STUDY SETTING

Participants will be identified and recruited from St. George’s Hospital, Croydon University Hospital and the Imperial College NHS Healthcare Trust (Charing Cross Hospital, Hammersmith Hospital, St Mary’s Hospital) with interviews and focus groups taking place on the ground of St. George’s Hospital, Croydon University Hospital, St. George’s University which adjoins St. George’s Hospital, or named hospitals associated with the Imperial College NHS Healthcare Trust. All interviews and/or focus groups will be confidential and take place within a private room.

Patient interviews will be conducted within a private room within either St George’s Hospital, Croydon University Hospital, Charing Cross Hospital, Hammersmith Hospital, or St Mary’s Hospital or St. George’s University. Similarly, focus groups will be conducted within a suitable private room, capable of holding the expected number of participants at one of the sites.

Using These sites is an appropriate setting as it gives direct access to our populations of interest (TB patients and health-service providers). St. George’s hospital and Croydon University Hospital run dedicated TB clinics and treat the largest number of TB patients in the South-West London region, making them suitable locations for recruitment, and one with which patients and service/providers will be familiar with when it comes to interviews and focus groups. The Imperial College NHS Healthcare Trust also has a substantial TB team working across the three named sites: Charing Cross Hospital, Hammersmith Hospital, and St Mary’s Hospital. As the Imperial College NHS Healthcare Trust TB teams often work across the sites named, it is appropriate to name all three. Incorporating these sites will greatly support recruitment of patients and service providers. Furthermore, by including multiple site from across London, we will be able to recruit a more diverse population which is representative of London as a whole, and therefore our findings are more likely to be generalisable beyond one specific site or setting. St. George’s University provides a suitable site to conduct focus groups and interviews if and where suitable rooms cannot be provided at other sites. The proximity of the university to St George’s Hospital makes it an alternative to that site in many scenarios. The university can also act as a focal point for focus groups with healthcare service provider participants.

**7 SAMPLE AND RECRUITMENT**

**7.1 Eligibility Criteria**

We will specifically seek to recruit migrant patients who have direct experience of, or are currently undergoing, LTBI or TB treatment. We define migrant patient as anyone who is foreign-born These individuals must have, or have had, clinically confirmed LTBI/TB (as ascertained from healthcare staff) and have been or are being treated within the UK.

We are also seeking to engage a range of health-service providers and staff who have experience of monitoring, managing and supporting LTBI/TB treatment. We define health-service providers as any individual working for, or with the NHS in some aspect of TB care, be that delivery of treatment in the clinic, or wider support of individuals with TB through third-sector organisations. This can include: clinicians (Drs, Nurses, Consultants); support workers; outreach workers; and third-sector organisation workers.

**7.1.1 Inclusion criteria**

Patient participants:

* Aged over 18 at the time of recruitment.
* Clinically confirmed LTBI or TB in a migrant patient (defined as an individual who was born outside the UK)
* In receipt of, or having received LTBI or TB treatment in the UK

Service providers/staff:

* Be involved in the delivery of treatment to LTBI and/or TB patients and management of clinical care in migrant patients (e.g. doctors, nurses involved in TB care):
* Otherwise be involved in supporting LTBI/TB treatment and the individuals undertaking these treatments (e.g. voluntary sector workers and support workers specifically supporting LTBI/TB patients).

**7.1.2 Exclusion criteria**

Patient participants:

* No clear evidence of having had clinically confirmed LTBI/TB
* LTBI and/or TB treatment was only received outside the UK
* Individuals who may lack the capacity to consent, as determined by the mental capacity act framework

Service providers/staff:

* Individuals are not involved in delivering, monitoring or managing LTBI/TB treatment, nor supporting individuals in receipt of LTBI/TB treatment.

There will be ***no*** exclusions based on gender, ethnicity, or language.

**7.2 Sampling**

We will use purposive sampling to recruit a diverse sample in relation to demographic and migration experiences, informed by the 2011 census and demographics of the migrant population in the UK. We will also use convenience sampling, in which we accept and recruit any willing participants, provided they meet the inclusion/exclusion criteria, and guided by the need for a diverse and representative sample. This will be achieved through advertising our study to the LTBI/TB teams within the two survey sites, and directly liaising with health-service providers at the two hospital sites through word of mouth and email. We will also encourage snowball sampling among health-service providers and patients, where potential participants are identified by other participants as the data collection takes place. Snowball sampling will also act as a useful mechanism for recruiting potential participants from outside of the immediate departments we are working with, who staff may believe would have an interest in participating, but with whom the research team are unfamiliar (i.e. individual working in third-sector organisations).

Health-service providers, whilst being potential participants, will also help identify and recruit potential migrant patients. This will again be through convenience sampling of migrant patients attending clinics, to whom health-service providers will advertise the study. This method is most suitable as health-service providers are far more familiar with their patients than our research team, and can use their personal and clinical judgement to assess which migrant patients may be interested in participating in the research.

**7.2.1 Size of sample**

We are aiming to recruit approximately 20 migrant patients, and 20 health-service providers. We will therefore recruit approximately 40 individuals in total, though numbers will be guided by saturation. Saturation describes the point at which no new data or insights are being gained from interviews or focus groups and the analysis,25 and so it becomes both methodologically unnecessary to continue recruiting and interviewing individuals.

**7.2.2 Sampling technique**

Participants will be recruited through a mix of purposive, convenience, and snowball sampling of service health-service providers across the survey sites (St. George’s Hospital, Croydon University Hospital, Charing Cross Hospital, Hammersmith Hospital, St Mary’s Hospital), along with patients receiving LTBI/TB treatment at these sites.

The rationale for this is that by utilising multiple sites and recruitment techniques we are more likely to be able to easily recruit sufficient numbers of individuals to make the research robust and valid, and representative of diverse experiences. Hospitals also represent a natural recruitment site as we are interested in health-service providers views and experiences, and the they are also the point of care for individuals with LTBI or TB. Furthermore, we can use the existing infrastructure of hospitals and relationships health-service providers have with patients to facilitate recruitment of migrant-patients to our study. We believe leaning on the personal and clinical judgement of healthcare staff at our chosen sites is also a more appropriate and ethical means to identifying and recruiting migrant patients, on the basis of the interest and capacity of potential participants.

**7.3 Recruitment**

**7.3.1 Sample identification**

Potential health-service provider participants will be identified through interaction between the research team and clinical teams on site at St. George’s Hospital, Croydon University Hospital, Charing Cross Hospital, Hammersmith Hospital and St Mary’s Hospital. We will approach the clinical team collectively and individually to gauge interest in the project, before fully recruiting and consenting individuals who wish to take part. We will also use snowball sampling techniques to identify other potential participants where the research team have not identified all potential participants in any group or individual interactions. The exact form this will take is to attend staff meetings at the sites, or convene a meeting specifically for this purpose ourselves. Through these meetings we will distributing participant information sheets and give an overview of the research/what participating would mean for health-service providers. We will then gather contact details of potential participants who have indicated their willingness to engage. We will also send out an email to the lead clinician for dissemination among the clinical teams, detailing information about the study to the same effect.

Potential migrant patient participants will be identified by the clinical teams responsible for LTBI and TB care at the clinical site. We will liaise with the clinical lead/ a designated research clinician within the department who will identify and contact potential migrant patient participants on behalf of the research team, and provide relevant information materials about the research. The clinical lead can also mediate the arrangements of the subsequent meeting and possible interview between the research team and patient participant where this is preferred by the patient, or the patient may contact the research team directly if they would prefer to elect or decline participation confidentially. No contact details will be disclosed by the clinical lead/researcher. The research team will ask the clinical team to make any initial approaches to potential patient participants and give the potential patient participant a patient information leaflet (translated into key local languages where preferred) and give them sufficient time to read and digest the information before following them up. If interested in participating, the potential participant will be referred onwards to a member of the research team by facilitating a face-to-face meeting with a member of the research team. Meetings with potential participants will be scheduled to coincide with a scheduled appointment, or at a preferred time convenient to the patient.

The research team member will be introduced to the potential participant. The researcher will provide a new (but identical) PIS and go through this with the potential participant verbally, ensure any questions they have are answered, and assess capacity to consent in line with the mental capacity act. The researcher will then arrange a date on which to carry out the interview. On the day of the interview, the researcher will again briefly go through the PIS with the participant and answer any remaining questions they may have, before having the potential participant sign the consent form, before conducting the interview.

To minimise disruption to potential patient participants, we would seek to schedule meeting with the potential patient participants and the interview to coincide with their next scheduled hospital appointment. However, if participants would prefer another time, or date, the research team will accommodate this. Participants will be remunerated for their time and travel expenses associated with attending the interview.

We propose a flat renumeration rate of £20 per migrant patient participant per interview, with interviews predicted to last around 45 minutes to 1 hour.

Reasonable travel expenses will be reimbursed for both migrant patient participants and health-service providers.

**7.3.2 Consent**

Informed consent will be gained through discussion between members of the research team and potential participants. The discussion will be supported by written participant information sheets (PIS), which will be tailored to our two populations (patients & health-service providers). We will use the PIS to detail the nature of the research, our objectives, and any risks involved with participation. The right to decline to participate, or to withdraw consent at any stage of the research will be explicitly stated on both the PIS and in discussion with potential participants. All study information (including information sheets and consent forms) will be explained orally, with support from an interpreter (language line or physical interpreter) where preferred. The opportunity will be given for participants to ask any questions about the scope of the research, or their rights as participants during the consent process.

**Consent for migrant patient participants**

Clinical staff will make initial approaches to potential patient participants, either coinciding with a routine appointment, or direct contact via phone. The clinical staff will provide potential participants with a PIS, translated into the key dominant local language requested where necessary. The clinician will provide a broad, brief outline of the work, aided by the PIS. If the potential patient participant confirms they are interested in participating, the clinician will request permission from the participant for a member of the research team to meet with the potential patient participant coinciding with their next scheduled appointment to carry out the interview. The details of the appointment time will then be passed on to the research team.

When meeting the potential patient participant for interview, our researcher will again provide a PIS (translated where necessary). Our researcher will give an overview of the research, the benefits, and risks of participation, and answer any questions the potential participant may have. An interpreter can be provided if preferred. If after this discussion the potential participant confirms they would like to take part in the research and continue with the interview, they will be asked to sign a consent form. It will be made clear to participants during discussion that the signing of a consent form does not supersede their right to withdraw from the study at any point, including for example, immediately after signing. This marks the point at which informed consent will be deemed to have been acquired. The consent form, also, will be available in the dominant local languages and an interpreter provided where preferred.

At all points during the consent process, the members of the research team will be considering the capacity of individuals to consent in line with the mental capacity act framework. The gap between potential participants being approached by a clinician, and meeting with the researcher and providing fully informed consent will also allow us to check understanding, retention of information, and allow participants to withdraw between meetings (thus demonstrating their free choice to participate if returning and affirming they wish the meeting with our researcher to go ahead).

**Consent for health-service providers**

Potential health-service provider participants will be approached by a member of the research team through staff meetings at the named hospital sites and further contact facilitated by lead clinicians/points of contact at these sites, directing potential participants to the study and providing contact details for the research team where necessary. In the first instance, our researchers will discuss the study with potential participants individually and/or collectively, aided by PIS for each potential participant. Our researcher will answer any questions or queries the potential participants have regarding the study during this initial contact. We will then liaise with the clinical team to arrange a date and time for the focus group and ask for members of the team on site to delineate this information and ask those interested to email a member of the research team to confirm they would like to attend. We will also provide contact details for a member of the research team on the PIS and ask those interested in participating in a one-to-one interview (if preferred to the focus group) to contact the research team directly.

At the beginning of the focus group or interviews, the member of our research team responsible for the session will provide a PIS to each potential participant. The researcher will go through a similar process to the initial contact, by explaining the purpose of the research, the potential benefits and risks and by answering any questions potential participants may have. If the potential health-service provider participants confirm their understanding and desire to participate in the study, they will be asked to sign a consent form. This is the point at which we will consider we have acquired fully informed consent. It will be explicitly stated that their signing of the consent form at no point supersedes their right to withdraw from the study.

\*Amendment to processes due to covid-19

Where phone interviews are being carried out with health-service providers we will email PIS and consent forms in advance and discuss any questions they have over the phone/email prior to the interview. If the participant is happy to participate we would set a date for the interview and we would ask them to sign and email back the consent form before the interview session. Interviewer will then re-confirm consent at the start of the interview and countersign the consent form. A copy of the completed form will be provided to the staff member.

\*Phone Interview and consent with patients - amendment due to Covid-19

In light of the impact of Covid-19 we will use audio-recorded interviews with audio-recorded oral consent as an adapted means of documenting consent with patients where we cannot follow the processes outlined above (In particular, for patients not currently attending in-person clinics).Where necessary an interpreter will be utilised using three-way mobile conference calling.

As normal, clinicians will make the initial approach to patients (in this case over the phone), and where patients indicate they are interested in taking part, a time will be agreed for a member of the research team to contact them to explain the study fully. A PIS and consent form will be mailed to the participant (email or physically)When the researcher contacts the patient they will answer any questions the patient has, and where they agree to take part, a time most convenient for the patient to take part in the interview will be set.

At the beginning of the phone interview proper, the consent form will be read to the patient and their responses audio-recorded. The phone interview would then take place as normal. A duplicate of the audio-recording will be made after the interview but redacting any identifying information and the consent of the patient at the beginning of the recording. This redacted audio file will be transcribed and analysed, whilst the original unedited audio file will form part of the record of consent. All digital files will be securely stored and handled as outlined in further sections of this document.

# 8 ETHICAL AND REGULATORY CONSIDERATIONS

## **8.1 Assessment and management of risk**

We believe that this study is low risk, with a low impact of any risks should these come to pass. Our research team has experience of both qualitative and cross-sectional research with both health service providers and migrant patients, and envisage no issues.

1. *Psychologically or emotionally distressing conversations.* Whilst this study is not aiming to elicit any strong emotional responses, nor explore what could be classically considered acute psychologically damaging experiences (i.e. trauma, war), we do recognise the fact that exploring and discussing experiences around tuberculosis could touch upon what is a challenging and distressing time in participants life (particularly in relation to patients).

We aim to manage this risk through the consent process, clearly explaining to individuals what the study entails and giving ample opportunity to question the process and decline to take part if individuals wish. We also aim to make the interview process as comfortable as possible, and ensure participants know they may stop, take a break, or decide to withdraw from the interview and/or study at any point. The interview will always proceed at the comfort and discretion of the participant. We would also sign-post individuals to an appropriate healthcare professional who could provide further support if it is felt it is needed.

1. *Confidentiality and data protection.* As with all projects of this type there are risks associated with confidentiality. To mitigate and manage this risk, we would inform and reinforce the confidential nature of the discussions with participants, and anonymisation and de-identification of all data in any dissemination material will be guaranteed. There are also issues of confidentiality between participants in focus groups we would hold with service providers/staff. To manage this risk, we would impress upon focus group participants the confidential nature of the discussions. Furthermore, we are also offering one-to-one interviews alongside the focus groups to manage and address the concerns of any potential participants who wouldn’t be comfortable speaking in a group setting.

Data protection issues will be managed through the ascribed plan in section *8.6. Data protection and patient confidentiality.*

**8.2 Research Ethics Committee (REC) and other Regulatory review & reports**

Before the start of the study, ethical approval will be sought from a Research Ethics Committee (REC) within the UK Health Departments Research Ethics Service for the study protocol, informed consent forms, and all other relevant documents.

**Regulatory Review & Compliance**

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](http://www.hra.nhs.uk/resources/after-you-apply/amendments/).

Amendments

Any substantial amendments to the REC application or supporting documents will be submitted via a valid notice to the REC for consideration. Notification will also concurrently be given to the national coordinating function of the NHS R&D office within England, and participating organisations (local sites, and local research team).

The decision for making amendments to the REC application or supporting documents is the sole responsibility of the research team outlined in this application. The decision as to whether amendments are deemed substantial will be taken by the research team in consultation with the local research ethics department at St. George’s University. Where the local research ethics department indicate they believe a change to be substantial, this will be upheld by the research team.

Substantial changes will be communicated to the relevant stakeholders through email correspondence from the research team, and appropriate steps taken to submit amendments by the research team. Amendment history will be tracked through version control of the protocol and supporting documents, substantial changes will be specifically highlighted in subsequent versions of documents that include the amendment.

**8.3 Peer review**

This research study forms part of a larger schedule of research, which was successfully funded by the Rosetrees Trust following a peer-review process for the funding application. Rosetrees Trust utilise a panel of scientific experts to assess proposed research before granting funding, including assessing the feasibility of the proposed research, and critiquing the methods proposed. Rosetrees Trust is independent of the sponsor and academic team involved in the research and are not involved in the study in any way.

**8.4 Patient & Public Involvement**

In developing this research our PPI and stakeholder engagement has taken the form of consulting healthcare service providers at the primary site (St. George’s University Hospital) to gauge interest and support for the research. We also consulted with a wider pool of TB specialist and healthcare staff from the wider area at the South-West London TB cohort review. This included specialists from two of the proposed sites, St. George’s Hospital and Croydon University hospital. The feasibility, acceptability and design of the research have been considered in light of consultation with these groups. Members of the research team also have extensive expertise in qualitative research methodologies, and specifically in involving healthcare staff/service providers.26

We have not directly engaged with patients as an individual group as of yet. This is largely a methodological and pragmatic choice, in that the larger schedule of research in which this individual study sits will employ a substantial component of co-design and stakeholder engagement involving patient and service provider insights. This research, whilst primarily addressing the research questions of interest, and acting as a novel research study in itself, will also act as a mechanism to later guide the co-design process involved in generating an intervention to improve patient outcomes. This research is part of our PPI and stakeholder engagement efforts when viewed in the context of the wider work to be produced.

**8.5 Protocol compliance**

Compliance will be managed through adequate training of all research team members in the full study protocol. The completed and approved protocol, alongside all materials associated with the study will be provided to each member of the research team. A session will be organised amongst the team to reinforce points from the protocol and to ensure members of the team understand the process and need for protocol compliance.

Compliance will be reviewed on a fortnightly basis as a minimum, particularly during the interview and focus group data collection processes, though any deviations from the protocol should be self-reported as soon as possible after the time at which they occurred, which would trigger an internal review of the protocol and need for compliance amongst the team sooner.

Accidental protocol deviations can happen at any time, though these will be adequately documented and archived and reported to the Chief Investigator and Sponsor immediately. Repeated, frequent deviations from the agreed protocol are unacceptable and will require immediate reporting and action, and we accept this could potentially be classified as a serious breach.

###

**8.6 Data protection and patient confidentiality**

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the act’s core principles.27 We will also comply with the General Data Protection Regulations (GDPR).28 Furthermore, the research design has consideration for the UK Policy Framework for Health and Social Care Research which also covers aspects of protection and patient confidentiality.29

We are actively seeking to collect de-identified data from the outset of the research and implement data minimisation as per GDPR. Information that can be used to directly identify participants, particularly names, will only be included as part of the formal signing of consent forms by participants. Exceptions, which could be considered indirect identifiers, are factors such as country of birth and migrant status (for patient participants), and occupation/professional experience (for health-service providers), data which will be acquired outside of the recorded interview and so will not appear on audiotapes being sent to transcription/translation services. Such data collection and processing are directly relevant to our research, in exploring differences in experience between sub-groups of our target population, and in validating we are recruiting the appropriate population, and such data is ultimately collected in the public interest.

Information which could lead to the direct identification of participants, such as addresses, phone numbers and email will only be collected as a means of upholding the individual rights of participants, (such as the right to be informed). At no point is this information to be collected and processed as part of our research question. Any contact information for migrant-patient participants will only be collected upon said participant signing a consent form, and confirming they’d like to be contacted with updates regarding the research in the future, or to be involved in similar research or public engagement effortd going forwards. Before this point contact and meetings with migrant patient participants will be mediated through clinical staff at St. George’s Hospital and Croydon University Hospital.

Collected data relating to individuals will be pseudonymised, using a unique numerical and date reference as the means to identify individual data sets. Such a system will ensure the anonymity of the participants and allow identification of individual data sets should a participant wish to exercise their individual rights (such as access, rectification or erasure).

With regards to storage and transfer, any hand-written notes will be kept in a secure office, within a locked filing unit. Any electronic Word documents will be individually password protected, and only stored on password protected devices (laptop, hard-drive). Audio recording will be via password locked phones, or if by unprotected voice recorders, transferred to a password locked device after the interview/focus group, at which point the original recording will be deleted. Transfer of any files between research team members will only occur via password protected devices (USB stick/external hard-drive). Where audio files require translation access will be provided to translation services via emailing audio files in password protected files, the password will be sent in separate email correspondence. At no point will data be stored on web or cloud-based applications.

Access to the full data set will only be provided to the members of the research team. Individual data sets will be accessible only to the members of the research team and the individual from whom the data were recorded (as per their individual right of access).

Confidentiality will be preserved in transmitting data and publishing results through the de-identification and data minimalization efforts outlined. Results will generally be presented in aggregate format, or where individual excerpts are used to highlight specific themes, no personal or identifiable information will be given as to whom provided the quote.

8.7 Indemnity

St George’s University of London, as the sponsor for this project will assume responsibility for the insurance and/or indemnity related to this project to meet the potential legal liability for harm to participants arising from the management of this research. This will also be in regard to the potential legal liability relating for harm to participants arising from the design of the research.

Arrangements for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participant in the conduct of the research will fall under the purview of the NHS indemnity scheme.

**8.8 Access to the final study dataset**

Access to the final anonymised dataset will be made publicly available in line with open access publication requirements. No personal identifiable information will be included as any part of the publicly available dataset. Individual transcripts and data will be made accessible only to members of the research team, and the individual from whom the data was collected. The final raw dataset will not be released as part of any dissemination plans.

### 9 DISSEMINIATION POLICY

### 9.1 Dissemination policy

Data collected during the interview and focus group process will be co-owned by the research team and individual participants from whom individualised data were derived. Participants reserve the right to withdraw their consent, and therefore any data generated from their participation at any points during the research process but preceding the completion of the final publications and dissemination of material.

Dissemination of the findings of the research will primarily be via open-access peer-reviewed journal and PhD thesis. Findings may also be disseminated through academic conferences, in the form of posters and/or oral presentation. The final decision to publish and disseminate findings lie with the Chief Investigator and research team, and they reserve the sole right to disseminate findings. Any final report/publication will be the property of the research team and sponsors/funders.

The final reports and publications will acknowledge funders and sponsors such as St. Georges’ University, St. Georges Hospital and the Rosetrees Trust.

Participants may request access to the data collected from their individual interactions with the research team at any time. Access to aggregated group results will only be possible upon completion and publication of the final study report, to protect the integrity of the research process. Where they have expressed interest and provided contact information, participants will be informed of the availability of the final study report/publication and directed to/provided copies (in the case of academic journal publications). For those wishing it, we would also provide a lay summary/report to ensure ample accessibility of our participants to the findings, and where necessary have this translated into participants’ dominant language

The study protocol and full study report will be made publicly available upon request to the research team. However, we will not make available the anonymised transcripts or data of any participants, so as to protect their identities and expectations of confidentiality. The only circumstance in which individual level data will be released is in the form of de-identified, anonymised excerpts within the final publication, which is a standard procedure in qualitative research of this type.30 These excerpts will take the form of words, sentences and phrases the participants have provided which exemplify the coding framework and themes generated through the analysis. Such excerpts would generally be no longer than a sentence or two and not linked to any specific patient or staff member.

**9.2 Authorship eligibility guidelines and any intended use of professional writers**

Authorship of the final report/publication will be attributed to the to the research team outlined in the protocol, whom combined, hold the responsibility for the conception and design of the study, the acquisition, analysis and interpretation of data, and the final approval of the report/publication to be disseminated. Individual attributions will be indicated within any final report.

Acknowledgements to include in the final report/publication will include the funders, sponsors and clinical staff/sites and participants whom have facilitated the research.

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### 11. APPENDICIES

**11.1 Appendix 1- Required documentation**

* Research team CV’s
* Patients information sheets (migrant patient participants and health-service providers)
* Consent form
* Topic guides (migrant patient participants and health-service providers)

**11.2** **Appendix 2 – Schedule of Procedures (Example)**

|  |  |
| --- | --- |
| **Procedures** | **Visits (insert visit numbers as appropriate)** |
| **Screening** | **Consenting** | **Data gathering** |
| Approach | 1 |  |  |
| Consent participant |  | 2 |  |
| Interview/Focus groups |  |  | 3 |

**13.3** **Appendix 3 – Amendment History**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol version no.** | **Date issued** | **Author(s) of changes** | **Details of changes made** |
| 1 | 0.2 | 8/3/19 |  | Changes were to address comments proposed by sponsor (SGUL), and to add Imperial College Healthcare Trust as a participatory organisation. |
| 2 | 0.3 | 2/4/19 |  | Changes were to ensure accuracy of language in terms of how we will interact with and protect participants, and our methodological approaches.Slight revision of study titlesRevision of the timeline, to reframe around recruitment and data collection being completed within the 12 months cited, not recruitment, data collection and disseminationRevision of previously suggested quotas on the absolute number of LTBI or TB specific patient participants recruited, to just an absolute suggestion for overall recruitment. |
| 3 | 0.4 | 29/6/18 |  | Amendment to study timeframe recorded in the study protocol graphic on page viii and within the study summary tableAmendment to inclusion criteria, raising age from 16 to 18. |
| 4 | 0.5 | 14/10/19 |  | Amendment to study personnel.Change of Chief Investigator from Dr Laura Nellums to Professor Jon Friedland.  |
| 5 | 0.6 | 17/08/20 |  | Amendment to consent and processes.Use of phone interviews and audio-recorded consent with patients due to Covid-19 impact on ability to conduct in-person interviews.Migrant patient PIS to be updated to 0.5 to reflect changes.\*highlighted yellow in current document |

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.