Intervening with a Manualised Package to AChieve treatment adherence in people with Tuberculosis

The IMPACT study

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IRAS: 231542

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ISRCTN Study Registration Number:

ISRCTN95243114

Chief Investigator Prof Marc Lipman

PROTOCOL VERSIONS

Version stage	Version no	Version date	Protocol updated & finalised by	Detail the reason(s) for the protocol update
New	5.0	09/03/2020	Marcia Darvell	A new protocol version was requested by our ethics committee before we could commence the RCT study phase. This version contains more specific detail of our manualised intervention contents and how the intervention will be trialled in our study sites: Section 3.3.2 new text specifying the contents of the manualised intervention that have now been developed as a result of the proceeding research phases. Section 3.4.1 minor changes made to text to clarify, new secondary outcome measure added to capture the experience of patients on longer treatment regimens. We will now be using medication monitoring boxes as reminders in some patients and the text has been amended to reflect this. The questionnaires that patients will be asked to fill in is now included in the section 'other' and are accompanied with an appendix of the questionnaires and their timings. Section 3.4.4 and 3.4.5 – the manualised intervention and the way it will be administered in the study are now more clearly explained. Study schedule of visits – these have now been amended and the text clarified to reflect the earlier changes made in 3.3.2 and 3.4.1. The text in 3.4.5 has also been amended to allow for patients who are on longer treatment regimens (eg those with multi-drug resistant TB) Section 3.5.1 – this section has been re-written. When the first protocol was developed we did not know the exact contents of the intervention or how it would be administered, now that we know this, we have changed our process evaluation plan in line with our current knowledge. We have enclosed new process evaluation instruments in Appendix 11and 12 Section 3.6 This section has also been re-written

				with further details of the measures used – ie CSRI and the EQ-5D—5L. Section 4.1.2 – we will now be approaching all patients for inclusion in the study, we will not be using advertising material in the clinics. Section 6.1 – this has been revised to include the new proposed end date of 30 June 2021. New appendices have been added: Appendix 4: new questionnaire booklet containing all questionnaires that will be used in the study. Appendix 6: new TB needs assessment Appendix 7: new flow chart for use by nurses administering the intervention Appendix 8: text from new patient information booklet being trialled in the intervention Appendix 9: new healthcare professionals' training manual explaining how all the intervention should be used in practice. Appendix 10: Schedule of interview timings Appendix 11: Process Evaluation Interview Guide Appendix 12: Process Evaluation Structured Interview Guide
New	4.0	26/08/2019	Marc Lipman Marcia Darvell	Amended Prof Marc Lipman's job title on cover page References to 'cognitive testing' have been changed throughout the document in response to feedback from journal (BMJ Open) expert reviewers of planned published protocol requesting clarity that these were not capacity assessments but testing of particular cognitive questionnaires. 3.1.2 – Critical Review of Quantitative Studies- clarification of study design requested by BMJ

				Open reviewers. The previous version of the protocol conflated treatment completion with non-adherence and this has now been corrected. We limited studies to low incidence high income countries to ensure maximum relevance of the literature to the development of our manualised intervention for the UK pilot study. 3.2.3 and 3.3.5 Cognitive testing section reworded for clarity (i.e. to make it clear that we are not testing patients for cognitive deficits) 3.4 – Piloting the Intervention. New text added in response to BMJ Open reviewer on randomisation, VOT, DOT etc. 3.4.1 Change of study site from Edgware to Whittington 3.4.2 Outcome measures – phrasing clarified throughout 3.4.3.1 Urine testing section removed in response to BMJ Open reviewer comments and further discussion in the study team. 3.4.3.1 Measures of treatment adherence. New text on medication monitoring boxes: we will be using these instead of urine testing, following expert review and further discussions with our research team. These are considered a more effective measure of adherence than urine testing which lacks specificity and is less reliable. 3.4.3.2 Pill count text edited for clarity in relation to 3.4.3.1 3.4.3.3 Section renamed more appropriately for content. Addition of GAD-7 and PHQ-9 questionnaires in response to BMJ Open review and ethics review asking how we would measure patient mental health needs in the pilot study 3.4.4 Study schedule of visits – new detail added, use of Client Service Receipt Inventory (CSRI) - see also new Appendix 8)

				3.4.6 Analysis and Interpretation – section re-written in response to BMJ Open review and with further expert advice from our statistician. Our data analysis is now more explicit and detailed. 3.5.1 Process measures, error corrected in previous protocol, in response to BMJ Open reviewer 3.6 Section re-written. Information added in response to BMJ Open reviewer: further information on cost data being collected and more detail given by health economist 7.1 Recruitment to Pilot Study and Sample Size: BMJ Open reviewer asked us to clarify whether we are approaching all patients or using systematic sampling Appendix 6: reference to excel changed to REDCap, as this is the preferred database.
Previous	3.0	21/08/2018	Marc Lipman Marcia Darvell	NIHR feedback
Previous	2.0	17/05/2018	Marc Lipman	JRO and investigator comments
Previous	1.1	18/04/2018	Colin Campbell Elisha Pickett	JRO and investigator comments
	1.0	2018-01-31	Marc Lipman	Initial version

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the Research Governance Framework 2005 (as amended thereafter), the Trust Data & Information policy, Sponsor and other relevant SOPs and applicable Trust policies and legal frameworks.

Chief Investigator Prof Marc Lipman

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

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:  Date 26/09/2019

Print Name (in full): Marc Lipman

Position: Professor of Medicine and Consultant physician

On behalf of the Study Sponsor:

Signature:..... Date...../...../.....

Print Name (in full):.....

Position:.....

STUDY SUMMARY

Identifiers	
IRAS Number	231542
REC Reference No	REC
Sponsor Reference No	17/0726
Other research reference number(s) (if applicable)	16/88/06 (National Institute for Health Research- NIHR)
Full (Scientific) title	Intervening with a Manualised Package to AChieve treatment adherence in people with Tuberculosis: the IMPACT study.
Health condition(s) or problem(s) studied	Adherence to tuberculosis treatment in vulnerable populations
Study Type i.e. Cohort etc.	Scoping review, qualitative work, pilot cluster randomised controlled trial, process evaluation.
Target sample size	Formative Research: • Interviews with patients (6-8 per site), Interviews with patient's family members/ carers (1-2 per site). Total 30 • Interviews with patients (testing of cognitive tools) (2-4 per site). Total 10 • Interviews with providers (4-6 per site). Total 20 Pilot Stage: • 80 patients on treatment for tuberculosis. Process Evaluation: • 20 interviews with patients 20 interviews with healthcare providers
STUDY TIMELINES	
Study Duration/length	36 months
Expected Start Date	1/01/2018
End of Study definition and anticipated date	31/12/2020

Key Study milestones	Ethical submission and staff recruitment, scoping review and intervention development, pilot study, process evaluation.
FUNDING & OTHER	
Funding	NIHR Health Technology Assessment
Other support	N/A
STORAGE OF SAMPLES (if applicable)	
Human tissue samples	N/A
Data collected / Storage	All records will have a unique identifier. All data will be handled according to current General Data Protection Regulations and Caldecott principles, including anonymisation prior to analysis and publication, as well as storage in password protected files and on secure (NHS) computers within the UCL Respiratory Department. Need-to-know access only will be provided.
KEY STUDY CONTACTS	
Chief Investigator	Professor Marc Lipman Professor of Medicine and Consultant Physician University College London Centre for Respiratory Medicine, The Grove Centre, Royal Free Hospital, Rowland Hill Street, London, NW3 2AG Email: marclipman@nhs.net Tel: 020 7317 7560

Chief Investigator Prof Marc Lipman

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI's role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The CI is responsible for the submission of annual reports, as required. The CI will notify REC of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

PRINCIPAL INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties- this includes the CI of any breaches or incidents related to the study.

Chief Investigator Prof Marc Lipman

KEY WORDS

Adherence, Manualised, Treatment, Tuberculosis

LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRCT	Cluster Randomised Controlled Trial
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
DOT	Directly observed therapy
GAfREC	Governance Arrangement for NHS Research Ethics
GDPR	General Data Protection Regulations
HTA	Human Tissue Authority
IB	Investigator Brochure
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Studies Number
MD	Medical Device
MDR	Multidrug Resistant
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
PAPA	Perceptions and Practicalities Approach
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QMU	Queen Margaret University, Edinburgh
QMUL	Queen Mary University of London
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
TB	Tuberculosis
TMF	Trial Master File
UCL	University College London
UK	United Kingdom
VOT	Video Observed Therapy
AE	Adverse Event

TABLE OF CONTENTS

1. INTRODUCTION AND RATIONALE

Compared to the rest of the UK and Western Europe, England has a major problem with the infectious disease tuberculosis (TB). The large amount of TB in the country has led Public Health England (PHE) and NHS England to develop a national TB control plan [1]. Treatment lasts a long time (at least six months, and even more in people with drug resistant TB). Finding ways to make sure that people are able to take all of their medication as prescribed is one of the plan's priorities. If people miss doses (described as being 'non-adherent or poorly adherent to treatment), their TB can develop resistance to the usual drugs, risking both their health and that of others.

Poor adherence to treatment can occur for a number of reasons. These include someone not knowing much about their disease condition and why they need to take their treatment, side effects from the drugs, or people choosing to stop their treatment as soon as they feel better, rather than taking the entire course. Wider psychological, social, cultural and economic issues, including stigma due to having TB, lack of support from family members or friends, homelessness, drug and alcohol misuse and barriers to good access to NHS services also play a part. Poor adherence to treatment for TB is a key driver of negative patient outcomes and impedes population-level control through increased transmission and development of drug resistance. In the UK, treatment completion and adherence among TB patients is variable.

Patients with multi-drug resistant (MDR) TB, whether acquired through poor treatment adherence or as a primary infection, have particularly poor treatment completion (around 60%, compared to over 85% in people with drug sensitive TB). Vulnerable migrants similarly have a higher risk of poor treatment completion [2]. Although patients without drug resistant TB and no social risk factors are more likely to adhere to their treatment, if they do become non adherent, they can also contribute to ongoing transmission and are at risk of developing drug resistance. Unfortunately, current methods of treatment support are not particularly helpful in identifying these individuals; and do not try to explore the important underlying reasons for non-adherence which may themselves need to be addressed.

The need to ensure that patients adhere to treatment - and finding ways to support them in doing so has been highlighted in the PHE/NHS England collaborative TB strategy [3]. Subsequent NICE guidance noted the lack of robust research in this area [4].

2. RESEARCH QUESTION, AIMS AND OBJECTIVES

2.1. Research Question

Can a manualised package of interventions be developed to help overcome the social and cultural factors that lead to poor adherence to treatment in patients with active tuberculosis?

2.2. Aim

To develop, pilot, and evaluate process and interim outcomes for a manualised intervention package that improves adherence to treatment for TB among NHS patients at risk of poor adherence due to social and cultural factors.

2.3. Objectives

1) Synthesise current knowledge on (a) determinants of adherence to treatment for TB, and (b)

interventions that can support adherence, with particular emphasis on social and cultural barriers. (Scoping Review and Conceptual Framework)

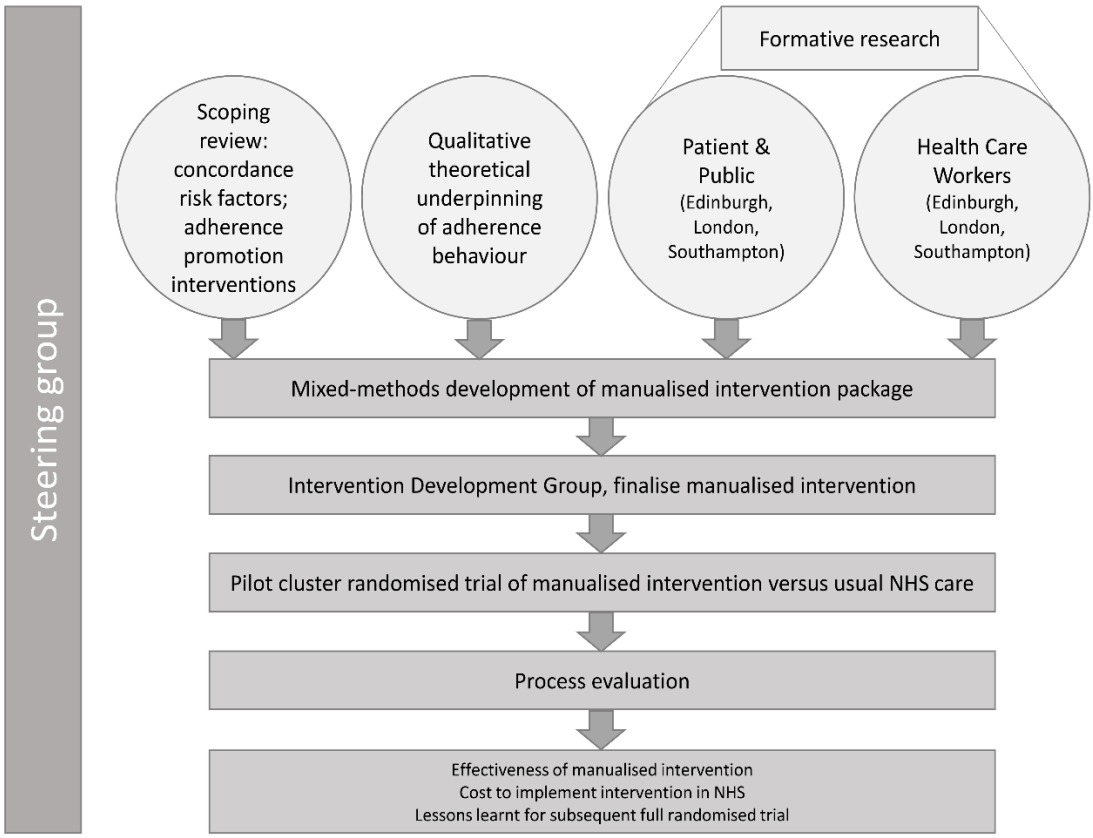
2) Apply a conceptual framework of adherence endorsed by NICE Guidelines and the Perceptions and Practicalities (PAPA) approach (see Appendix 1: PAPA Framework) to elucidate and address the personal, socio-cultural, and health systems context, mechanisms, and pathways of poor adherence among NHS patients with TB. (Formative Research)
3) Develop a manualised intervention package with multiple components that can identify (a) NHS patients most at risk of non-adherence, (b) the salient modifiable barriers; and (c) tailor support mechanisms to meet individual needs by matching appropriate interventions to specific barriers, as recommended by NICE. (Development of Intervention)
4) Pilot the intervention package in people at risk of poor adherence to define how the components work in combination and separately. (Pilot Study)
5) Evaluate the process of implementation of this intervention through describing the challenges and facilitators in delivering the package as intended (fidelity, reach) and assessing the impact of the intervention through evaluation of adherence indicators. (Process Evaluation)
6) Use the findings of the pilot to assess the costs of delivering the manualised intervention in an NHS setting, and to guide development of a proposal for a full randomised controlled trial (RCT). (Cost Analysis and Future Work)

3. STUDY DESIGN

This section is presented in six sub-sections, reflecting the six objectives: i) Scoping Review and Conceptual Framework; ii) Formative Research; iii) Development of Intervention; iv) Pilot Study; v) Process Evaluation; vi) Cost Analysis and Future Work.

Although these components are described separately below, the research activities for each will overlap, and some will run concurrently (Appendix 2: Gantt chart). This study uses a mixed methods approach, with different methods employed in each of the study components. For example, behavioural science methods will be used to understand the determinants of acceptability and adherence in the pilot study, the scoping review will inform the development of the manual and a cluster randomized design will be used to pilot the intervention. The full programme of work and relationships between subsections is shown in Figure 1.

Figure 1- Components of the IMPACT study



3.1. Scoping Review and Conceptual Framework (i)

3.1.1. Scoping Review

The scoping review of relevant literature on 'adherence to TB treatment' will inform a conceptual framework for the project methods and approach. The review will investigate the following research questions:

1. What personal, social, cultural, health systems-related, and structural factors affect individuals' ability to adhere to TB treatment?
2. What kinds of intervention have been developed to address the multiple levels (personal, social, cultural, system and structural) at which barriers to adherence may operate?
3. What is the evidence for the successful impact of interventions to address barriers to adherence to treatment for TB?

To address these three questions, researchers at QMU (Queen Margaret University, Edinburgh) and UCL will conduct three separate reviews that will enable the following outputs:

1. A narrative synthesis of findings from *qualitative* studies examining the personal, social, cultural, health systems-related and structural factors affecting adherence to treatment for TB (led by QMU, Edinburgh)
2. A critical review of *quantitative* studies examining the personal, social, cultural, health systems-

related and structural factors affecting adherence to treatment for TB (led by University College London, UCL)
3. A critical review of studies that have examined the effectiveness of interventions to improve adherence in people taking treatment for TB (led by UCL).

Together, these three reviews will enable us to conduct a critical interpretive synthesis of findings from qualitative and quantitative studies examining the assumptions and mechanisms of effect underlying interventions to improve adherence to treatment for TB (QMU and UCL).

Scoping Review of qualitative studies examining the personal, social, cultural, health systems-related, and structural factors affecting adherence to treatment for TB.

We adopt a recent definition of a scoping review as "a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge" [5]. We will follow six stages in conducting the scoping review [6]:

1. Clarify and link the purpose and research question (s).
2. Identify relevant studies, using the following inclusion and exclusion criteria

   Inclusion criteria:

   i. studies that examine reasons for adherence and non-adherence to treatment for TB from the perspectives of children, adult patients, care givers, or health care providers AND studies that evaluate interventions to support adherence to treatment for TB
   ii. studies from any discipline or theoretical tradition that uses qualitative methods, including papers that used both qualitative and quantitative methods and reported qualitative findings

   Exclusion criteria:

   i. studies that exclusively use quantitative methods to examine reasons for adherence/non-adherence to TB treatment AND/OR studies that evaluate uptake of interventions to support adherence to TB treatment
   ii. studies published in languages other than English

3. Use an iterative team approach (QMU team) to select studies, refine the search strategy, and review articles for inclusion.
4. Extract and chart data based on a collectively agreed data-charting form that includes variables relevant to the research question(s). Charting will be iterative; the first 5-10 studies included will be done independently by two researchers (from QMU) to check consistency in the approach.
5. Analyse the studies in three stages including: a descriptive bibliometric summary, a qualitative analysis of the key themes emerging from the studies as pertinent to the research question(s), and a critical interpretive synthesis [7].
6. Report results and implications of scoping review for development of the manualized

intervention; and consult with the Intervention Development Group to incorporate any further issues or suggestions.

Critical review of quantitative studies to synthesise evidence on the personal, social, cultural, health systems-related and structural factors affecting adherence to treatment for TB

Inclusion criteria:

i. empirical cross-sectional, case-control, or cohort studies
ii. studies reporting information on individuals with active TB
iii. studies presenting data on treatment adherence and how this relates to other factors
iv. Studies undertaken in low incidence, high income, settings
v. Exclusion criteria:
vi. studies that exclusively use qualitative methods to examine reasons for adherence/non-adherence to treatment for TB
vii. studies published in languages other than English

Exposure: The primary exposures of interest are the risk factors that may influence adherence. Thus, studies reporting on patient demographics, knowledge and attitudes, characteristics of TB disease, social characteristics of patients and comorbidities will be included in the review. As will studies looking at health systems and environmental factors.

Outcome: Studies will be included in the review if the primary outcome is adherence. Adherence will be determined by for example self-reporting through attendance at follow-up appointments, collecting prescriptions from clinics, pill counts and pharmacy reports, electronic devices (such as Medication Event Monitoring System caps), urine inspection, testing for drug levels and directly observed therapy attendance or video-observed therapy sessions.

Selection process: For the initial screening stage, two reviewers will select articles by screening the title and abstract to assess whether they fulfil the study eligibility criteria. Two reviewers will conduct abstract selection and critical appraisal of the full-text articles. Reasons for rejection of articles during both the initial screening and at the full-text screening process will be noted and any discrepancies discussed.

Data extraction: Data extraction will be systematized using a pre-defined standardised template.

Critical review of studies that have examined the effectiveness of interventions to improve adherence in people taking treatment for TB

We will build on existing systematic reviews of interventions, including studies that assess the effectiveness of a strategy or intervention aimed at improving adherence, such as the provision and delivery of information and/or education; enablers and/or incentives; social support; case management approaches; and studies of modifiable determinants of treatment adherence.

The comparator will either be usual care or an alternative intervention.

Population: Adults, young people and children who have or are suspected to have TB, regardless of drug sensitivity.

Outcome: Treatment adherence. Adherence will be determined by for example self-reporting through attendance at follow-up appointments, collecting prescriptions from clinics, pill counts and pharmacy reports, electronic devices (such as Medication Event Monitoring System caps), urine inspection, testing for drug levels and directly observed therapy attendance or video-observed therapy sessions.

Selection process: For the initial screening stage, two reviewers will select articles by screening the title and abstract to assess whether they fulfil the study eligibility criteria. Two reviewers will conduct abstract selection and critical appraisal of the full-text articles. Reasons for rejection of articles during both the initial screening and at the full-text screening process will be noted and any discrepancies discussed.

Data extraction: Data extraction will be systematized using a pre-defined standardised template.

Applicability: Are the findings relevant to patients treated within the NHS?

For the two critical reviews, a random sample of 10% of references will be screened independently by two reviewers at UCL, and differences resolved by consensus. Screening will occur of titles initially, followed by abstracts and then full texts. The degree of concordance will be assessed and, if above 95%, the remaining references will be screened by one reviewer alone. Levels of concordance will be assessed and differences resolved by consensus and the involvement of other members of the research team, all of which will be fully documented.

3.1.2. Search Strategies

Development of search strategies for the three reviews will be created with advice from expert Information and Library Support from QMU and UCL. The initial strategy will be developed in MEDLINE (Ovid Interface), and then adapted for other databases.

Scoping review for qualitative literature: MEDLINE, EMBAS, ECINAHL, PsychInfo, Assia, Web of Science, Scopus, Open Grey, Google Scholar and, Cochrane databases. Our draft search strategy will combine MeSH and free text terms (including term explosion) for the following: tuberculosis AND (adherence OR compliance OR concordance) AND treatment AND (qualitative OR ethnograph* OR anthropolog* OR sociol* OR phenomenol* OR narrative).

Critical review for quantitative literature: CINAHL, MEDLINE, PsycINFO, Assia, Web of Science, Scopus, Open Grey, Cochrane databases and Google Scholar. We will use combined MeSH and free text terms (including term explosion) for the following search strategy: tuberculosis, patient acceptance of health care, adherence, non-adherence, concordance, directly observed therapy.

Critical review of interventions to support adherence: MEDLINE, EMBAS, ECINAHL, PsychInfo, Assia, Web of Science, Scopus, Open Grey, Google Scholar and, Cochrane databases. Our draft search strategy will combine MeSH and free text terms (including term explosion) for TB; interventions (education, information dissemination, social support, incentives, case management, enablers, directly observed therapy (DOT), video observed therapy (VOT), reminders, e-health, m-health); and treatment outcomes/adherence.

A filter for human studies will be applied. No filters for study type will be applied for TB studies. We will remove editorials, news items and letters. Searches will be performed only for English Language articles.

3.1.3. Database Development

Reference databases will be created in EndNote or equivalent, where records will also be manually and electronically de-duplicated. Screening and extraction will occur in a Microsoft Access database to ensure that all retrieved references are fully tracked.

3.1.4. Quality assessment

Studies will be quality assessed and data extracted into pre-designed databases by the respective reviewers (QMU, UCL) and using the appropriate tools in the NICE methods manual for each study design. Differences between the reviewers will be resolved by consensus.

Scoping reviews do not conventionally undertake quality assessments [8, 9]; however, we will develop a matrix following guidelines for quality assessment of qualitative research papers and apply this to selected studies in order to exclude studies that do not meet an acceptable standard for methodological criteria. This will use the PRISMA 2 guidance [10].

For the review of quantitative studies and the effectiveness of interventions to support adherence, assessment of risk of bias of individual studies and outcomes will be conducted by two reviewers independently and will subsequently be discussed with a third researcher for arbitration if needed. Cross-study assessment of strength of evidence for particular risk factors affecting adherence will use the AMSTAR 2 critical appraisal tool [11]. Specifically, differential outcome measurement in exposed and unexposed cohort populations, incomplete follow-up, failure to control for confounding, difference in measurement of exposure, and selection of exposed and unexposed in cohort studies from different populations will be examined. We will test each outcome for risks of bias, inconsistency, indirectness, imprecision, publication bias and any additional domains deemed appropriate. We will prioritise direct objective measures of adherence, which are less prone to reporting bias.

3.1.5. Synthesis and development of conceptual framework

Outputs from the scoping review of qualitative studies will include a descriptive bibliometric summary, and a qualitative analysis of the key themes emerging from the studies that are relevant to the research question(s). The review of quantitative studies will report adherence measures during treatment for TB for the interventions identified within the search. Interventions that have demonstrated efficacy will be presented within evidence tables. These will be arranged and divided according to different treatment durations and regimens. Inconsistency on identified risk factors across instruments of assessment, and for different time periods (initiation phase of treatment and/or continuation phase and/or throughout treatment) will be reported separately. Sub-analyses to assess whether treatment regimens are predictors of non-adherence will be performed. A narrative synthesis of the studies will be compiled, including a consideration of the socio-economic context in which included interventions were implemented and where other critical factors were present, such as drug resistance profiles of the study population.

The findings from the three reviews will be used to build on the NICE-approved PAPA-based approach (see Appendix 1: PAPA Framework) to improving adherence support by:

- Identifying potentially modifiable determinants of adherence-related motivation and ability which have not been identified from the PAPA theoretical model which is based on research on

adherence across a range of conditions that includes other infectious diseases.
- Identifying personal, social, cultural, health systems-related, and structural factors that interact with individual-level determinants (motivation and ability) to influence adherence directly or indirectly.

These steps will allow us to map the relationships, pathways, and mechanisms of effect between these factors and adherence outcomes for TB patients on treatment, including when specific interventions to support adherence are employed.

We will present the outputs of these reviews and the initial emergent framework development in an accessible and visual format. This, together with the findings from the formative work, will be provided to the patient and professionals from the Manualised Intervention Development Group to elicit comment and discuss the application of the framework to support the study methodology and the main output of this work programme (see Section 3.3).

As described above, a further output from the review of both qualitative and quantitative studies will include a critical interpretive synthesis[7] examining the theoretical assumptions and proposed mechanisms of effect underlying interventions adopted to support individuals' adherence to treatment in high, low, and middle-income care settings. This method provides critical interrogation of the ways in which the literature has constructed the problematics of 'poor adherence', the nature of assumptions on which it draws, and what has influenced the choice of proposed strategies.

3.2. Formative Research (ii)

Building on the conceptual framework developed in the first phase, the formative research will use qualitative methods to elicit TB patients' experiences of starting and staying on treatment, and health providers' views on the barriers and facilitators for TB treatment adherence. We will also interview, with patient consent, carers and family members involved with patients who are receiving or have received treatment for TB.

3.2.1. Patients and Carers/Family members

Adults who are currently taking or recently completed treatment will be identified by the local TB service and asked to take part in the study. The patient group will be enriched with people who have been poorly-adherent to treatment, though we will also include patients who report full adherence, so that we can capture what led them to take treatment as prescribed. With patient consent, family members and/or carers will also be approached and asked to take part. The participants will receive travel costs and refreshments during the interviews. These will be in line with INVOLVE guidance. The eligibility criteria for participants are described in Section 4.2.

3.2.2. Health and Social Care Providers

Health and social care workers from both primary and secondary care settings will be directly approached by researchers and invited to take part in the formative work. The TB nurse is often the patient's case manager and hence can develop strong bonds with their patients. We will therefore ensure we include TB nurses at each study site. The providers will receive travel costs and refreshments during the interviews. The eligibility criteria for participants are described in Section 4.2.

3.2.3. Formative Research Methods

Three different methods of data collection will be used (Table 1):

1. **In-depth interviews** with patients and where possible, their caregivers, i.e. family or other significant members of their social networks who provide care or support
2. **Cognitive testing of outcome questionnaires** on medication beliefs (BMQ-S) and illness perceptions (brief IPQ) with a purposive selection of patients representing key vulnerable populations
3. **Semi-structured interviews** with health providers responsible for TB care (doctors, nurses, social workers, DOT providers, managers and administrators)

The purposive sampling approach will allow us to capture the social and demographic population groups who are more likely to be non-adherent. Based on previous experience plus the scoping review, a qualitative sampling framework covering important socio-demographic characteristics (such as age, sex, ethnicity, socio-economic status) relevant to access and adherence to treatment for TB will be used to ensure our sample represents the range of patient experiences.

3.2.4. In-depth Interviews

Using a Topic Guide (see Appendix 3: Patient Interview Topic Guide), interviews will be conducted with patients. They will focus on issues of systemic barriers to accessing health care, experience of illness and treatment-seeking trajectory, social support, and any relevant cultural factors influencing TB treatment literacy and medicine-taking. Where possible, and with patient consent, a family member or other social contact close to the index case will be invited to be interviewed separately.

The issues discussed within the interview may result in the participants talking about personal subjects. We will endeavour to ensure that this information remains confidential, and only used to develop an understanding of their experience of healthcare, tuberculosis and treatment. We will inform them of this when they are first approached about the study. However, we will also let them know that we have a duty of care to safeguard adults and children, which includes acting appropriately if we are given information that suggests that an adult or child is at risk of harm.

Given the in-depth nature and length of interviews, we estimate that 6-8 patient interviews per site, plus an additional 1-2 family members or carers per site (estimated total therefore 30 interviews across participating sites), is both feasible and adequate.

3.2.5. Cognitive Testing

To ensure that the validated questionnaires used in the pilot study [assessing patient perceptions and practicalities affecting adherence to medication for TB (Beliefs about Medicines Questionnaire [12] [BMQ-Specific for TB], and perceptions of TB as an illness (Brief Illness Perception Questionnaire [13] (see Appendix 4) are accessible and acceptable to patients, we will conduct brief interviews to check whether they make sense and are suitable for use with 10 patients. In this short interview, questionnaires will be presented to patients. We will then use brief cognitive testing with reactive verbal probing by asking patients to 'think aloud' as they complete the questionnaire. For example we will explore the ease of completion of the questionnaires: identifying any difficulties in understanding or answering the questions, as well as whether they miss key patient-relevant issues.

This standard process for piloting questionnaires which assess patients' views and perspectives allows us to make small adjustments to improve the acceptability of the questionnaires without compromising the validity and reliability of the measures.

3.2.6. Semi-structured Interviews

These will be performed with health care providers, and will focus on their own perception of their patients' understanding of TB and its treatment. By asking providers to recall specific examples, and encouraging reflexivity, the interviews will enable comprehensive mapping of patient pathways to identify systems-related enablers and barriers during the diagnostic and treatment trajectory that may impact upon adherence. We will interview 4-6 providers at each site, aiming for a total of 20.

Table 1– Populations, methods, sampling and recruitment of patients and providers taking part in manualised intervention formative research

Method/population	Sampling strategy/sample	Recruitment/site	Areas of inquiry
In-depth interviews with patients/carers/family members	Purposive selection of patients, on treatment or recently completed, enriched from ethnic or societal groups at risk of low adherence. Carers/relatives of patients. Sample: 6-8 patients & 1-2 family members /carers per site (total - 30)	Edinburgh London Barts London Royal Free Southampton	Self-perception; personal beliefs and practices related to medicine-taking. Health literacy and health-seeking behaviour; social support; cultural norms around health-seeking behaviour; financial and other structural barriers
Cognitive testing (interview and questionnaire review) with patients	Purposive selection of patients, on treatment or recently completed with poor adherence. Sample: 2-4 per site (total - 10)	Edinburgh London Barts London Royal Free Southampton	Self-perception; personal beliefs and practices related to medicine-taking
Semi-structured interviews with providers	Purposive selection. Sample: 4-6 per site (total - 20)	Edinburgh London Barts London Royal Free Southampton	Providers' perceptions of factors affecting patient understanding of TB and treatment; service delivery model including staffing, organisation of care and communication

3.2.7. Data analysis

Interviews will be recorded (with participant's permission) and transcribed verbatim. Interviews are expected to last 45-60 minutes. Where appropriate, translations services (face-to-face, and by telephone if appropriate) will be used to support people whose first language is not English.

The research elements exploring social and cultural factors influencing adherence as well as providers' perceptions will be conducted by Dr. Kielmann and team at the Institute for Global Health and Development, Queen Margaret University. Interview transcriptions will be subjected to a thematic analysis [14] to identify the key concepts and themes, in line with the information obtained from the scoping review. It will adopt a phenomenological approach that privileges subjective, lived experience of illness and a grounded theory approach to the data analysis. Data on health systems issues gained through mapping of patient pathways will be structured so as to lend itself to visual display, for example, through flow-charts and decision-making trees.

Personal factors that may be relevant to adherence, and so could input into the development of the manualised intervention, will be identified through cognitive testing of the BMQ and BMQ-TB performed by Professor Horne and team at the Centre for Behavioural Medicine, University College London. Methods will use framework analysis following the PAPA approach [15]. This is to identify additional themes relating to perceptions and practicalities driving adherence/nonadherence that are not adequately represented in the validated questions in section 3.2.5 (and Appendices 4 & 5). Cognitive testing will also sense-check any changes we make to the questionnaires. We do not expect this to be an issue, given their successful use as in vulnerable populations with infection [16].

The data generated through qualitative data collection methods comprises textual and visual data (e.g. diagrams or maps). Assigning unique identifier codes to all data files, with the coding manual available to relevant co-investigators (Dr Kielmann at the QMU and Professor Horne at UCL), will ensure anonymity of all data sources. All hard copies of the data will be kept in a central, secure, and locked location. All data files will be appropriately labelled, with a documented list of relevant abbreviations, inclusive of the site of data collection (Edinburgh, London, Southampton), the type of data (Map; Field Notes; In-depth Interviews, with type of informant; etc.), date data collected, person responsible for data (initials of original data collector and data transcribed, as relevant). Data files will be organised into relevant sub-folders and folders. All data files will be password protected. All data files will be backed-up in a secure data location.

Audio data will be transcribed by professional transcribers, following an agreed protocol for all transcriptions, to ensure uniformity across sites and across transcribers. All transcriptions will be stored as Word or Excel files, both easily uploaded to software for qualitative data analysis (e.g. NVivo or ATLAS.ti). Textual data in the form of documents and field notes will be stored as Word of PDF documents, again easily uploaded for analysis in software for qualitative data analysis (e.g. NVivo or ATLAS.ti). Visual data collected manually on patient pathways and the organisation of care, will be captured electronically via REDCap. All data systems and data handling procedures for capturing, transferring, analysing and storing the study data will be developed and tested to verify their ability to preserve participant confidentiality. The Chief Investigator will have overall responsibility for data transfer and storage.

Data analysis will be performed at QMU and UCL. Anonymised and/or aggregated results will be received by the research teams, with anonymised information being transformed as required to

produce the manualised intervention (see Appendix 6: Management and Data Flow Charts).

The patient interviews and patient pathway mapping data will enrich and substantiate findings from the scoping review, identify context- and population-specific enablers and barriers in vulnerable groups. This data will enable us to apply the draft conceptual framework and tailor its application to the specific population, taking into account the context, processes, and mechanisms of effect that help to elucidate reasons for poor adherence, and can suggest pragmatic, feasible and sustainable interventions to support adherence within an NHS context.

3.3. Development of Manualised Intervention (iii)

The development of the manualised intervention will utilise the evidence from literature obtained through the scoping and critical reviews plus the formative research applied within the conceptual framework. The resulting intervention will aim to support adherence by targeting both psychosocial and structural barriers to adherence. The results of the formative research, and its synthesis within a dynamic conceptual framework for understanding barriers to TB treatment adherence in vulnerable groups, will help identify the optimal parameters for a prototype manualised intervention that can be presented to a panel: the Intervention Development Group (IDG).

3.3.1. Intervention Development Group

The panel will be convened in Year 2 of the study, at the end of the formative research and before the pilot study commences. The IDG will include:

- patients (in particular the homeless, ethnic minorities, migrants new to the UK, and patients with drug resistant TB)
- family members/significant others of affected persons
- members of the public
- health care professionals (from both primary and secondary care)
- other professionals who work with patients/communities affected by TB.

The group will be supported by TB Alert and Find&Treat (as described in Section 8, Patient and Public involvement), as well as by North Central and North East London TB services (clinical support and expertise), the TB Nurses Network (clinical nursing support and expertise) and UCLPartners TB Clinical Research Network (to ensure generalisability to diverse patient populations and stakeholders). It will contain representatives from Edinburgh and Southampton. This will enable a co-production approach to ensure that the intervention is pragmatic, can be delivered within the context of existing care pathways and is of benefit to service users and those who are likely to access the intervention.

The IDG will meet to develop the manual based on information from the reviews, and formative research, as well as materials developed for promoting informed choice addressing perceptual and practical barriers to adherence developed for use in other diseases [17,18].

Members of the group will be remunerated for their time, and travel costs. They will also receive support and payment for any further time spent preparing for the meeting.

A further meeting will take place for the IDG to agree and feedback on the final output from the first meeting. The IDG will also have the opportunity to review the manualised intervention in practice during

the cluster randomized trial pilot. This will be to determine whether the intervention performs as expected and would be suitable for a larger definitive study.

3.3.2. Manual contents

The manualised intervention consists of a:

- TB needs assessment - TNA (see Appendix 6)
- A series of linked actions to the TB needs assessment, tailored appropriately for the patient
- A brief intervention session structure flow chart (one side of A4) to help the health practitioner deliver each intervention session tailored to the patient's needs (see Appendix 7)
- Two patient videos (links below)

  (https://vimeo.com/391469608/f0c7b1ca96)

  https://vimeo.com/391470015/08ac0b7d6c

- Patient information booklet and medication diary (see Appendix 8).

An accompanying Healthcare Professionals' Training Manual (see Appendix 9) explains how the different components should be administered in the pilot study and helps healthcare professionals to clearly navigate their way through the delivery of the intervention. Based on the formative work, it addresses three areas that may lead to poor adherence, namely personal (including psychological) factors, the impact of the social and cultural environment, and health systems level barriers and failures.

To be adopted successfully into existing care pathways, our intervention is succinct, as it is intended to be delivered by nurses and health workers as part of routine care.

It is intended to be completed at each routine clinical consultation. The first use of the intervention will be prior to the person starting anti-TB treatment at baseline. The next will be after two weeks of therapy – by which point the adverse effects of anti-TB medication may have become in themselves a barrier to adherence. It will be translated into three of the commonest languages spoken by TB patients (based on information from staff at the local sites regarding specific language needs).

The assessment will be done on a hand -held tablet device (eg an iPad), allowing ease of use and immediate data collection. Printed copies will also be available for patients who prefer this method, or to account for any IT failure.

The menu of supportive measures includes:

Intervention components (given to all patients in the intervention: a new TB needs assessment (TNA) to replace risk assessments currently undertaken in standard care [reference APPENDIX], two animated videos and an interactive patient booklet and additional nurse led phone calls. The TNA will identify patients that require additional measures to improve adherence and will suggest actions that can be taken to help patients with identified social, structural or psychosocial needs. The booklet and animated videos will aim to prevent and address doubts about the personal need for continued treatment by offering a convincing story setting out the rationale and ongoing need for medication, addressing concerns about potential adverse effects and consequences of treatment, and what to do if such events

occur. For example, the participant will be informed that it is possible to change treatment to alternatives [19]. The intervention will also include additional nurse follow-up phone calls at weeks 1 and 6, to help support all patients and provide an additional channel for any concerns to be addressed.

Adherence support tools: These tools will be offered to patients with an identified need for additional support measures in the TNA: These may include VOT, DOT, reminders through electronic monitoring boxes, dosette boxes, incentives e.g. travel vouchers.

3.4. Piloting the intervention (iv)

Once the intervention is developed, proof-of-concept is required within the real world. This pilot study will use a Cluster Randomised Controlled Trial (CRCT) design comparing the manualised intervention to the usual standard of care in four clinics treating TB. (see Section 3.4.4 for further details on the different arms of the study).

The Pilot Study will enable a process evaluation to be performed using a structure, process and outcome evaluation model. The study also mimics the likely design of the subsequent definitive trial, on a smaller scale, and therefore informs the feasibility of that trial.

3.4.1. Setting and Population

The setting of the pilot study will be hospital and community sites where TB patients are currently supported to complete treatment**.** We will work with four large TB clinics in East and North London, two sites from within Barts Health NHS Trust (Mile End and Newham clinics) and two from within the North Central London TB Network (Royal Free London NHS Foundation Trust, Hampstead site and the Whittington Hospital) each of which treat in excess of 60 TB patients per annum. The clinics manage a broad mix of patients, representative of the national demographic picture of contemporary TB. This includes established and newly arrived migrants, the homeless, those with mental and physical co-morbidities, people who misuse drugs or alcohol, and the immunosuppressed (through associated illness, including HIV, or medication). The clinics are also regional referral centres for MDR TB. Within each Trust we shall allocate one clinic to the intervention and one to standard of care, ensuring balance between study arms. Piloting the intervention in this way in four sites, each of which has its own TB nursing and administrative team, yet are within two large Trusts, strikes a balance between performing a much larger and more expensive pilot at several financially distinct, and potentially geographically remote sites, and having minimal cross-contamination when running the pilot.

Section 4.3 sets out the eligibility criteria for the study, We will try to ensure that we recruit migrants newly arrived in the UK, people whose first language is not English, women who are pregnant, people with a mental health disorder, people taking immunosuppressive therapy or known to have immunodeficiency, those with a previous history of treatment for TB, or poor-adherence with anti-TB medication, and people with a current or previous history of drug or alcohol misuse.

3.4.2. Outcome Measures

Primary outcome

1. Treatment adherence:

Adherence (percentage of prescribed doses taken) assessed at six months from the start of treatment.

2. Secondary outcomes

1) Percent consenting to the study
2) Adherence at treatment completion (if longer than 6 months) in patients who require a longer course of treatment.
3) Completeness of data for measures of adherence
4) Completeness of data for health economic evaluation (i.e. resource use and quality of life)
5) Proportion of patients withdrawing during the study and the reasons why. Proportion of patients identified as needing adherence support in intervention arm
6) Proportion of patients offered adherence support and accepting it in the intervention arm
7) Documentation of which adherence-promoting activities have been implemented among patients both in the standard of care and intervention arm, and when.
8) Detailed treatment implementation information:

    a. Proportion of patients completing treatment
    b. proportion of patients who have completed treatment by 12 months or at study completion (whichever is the earlier)

9) Patterns of adherence (implementation and discontinuation)
10) Process variables – adherence-related perceptions and practicalities (assessed using validated questionnaires – with adaptations if necessary – see above).
11) Impact of manualised intervention on adherence for the duration of treatment.

3.4.3. Measures of patient outcome and wellbeing

Our primary measure of adherence will be data obtained from medication monitoring boxes. Other measures will also be used and compared with this. These will include pill counts (the remaining medication in the box at the end of each month) and also patient-reported adherence, where we will ask patients to estimate how many doses they have missed in the last month In the case of VOT or DOT methods being used, a record of missed does will be kept.

Medication monitoring boxes

Medication monitoring boxes (where a patient's medication is placed inside a plastic box with a digital insert that monitors box opening) provide the most detailed data possible on adherence to treatment within all current technologies [20]. Data are available on whether a patient has taken every single dose of their medication in the required time frame, through date and time stamping of each time the box is opened. This detailed temporal recording also allows for falsified dose-taking (where patients open the box multiple times in a day) to be cleaned from the dataset. Critically, dose-by-dose data from a reliable digital source provides substantially more detailed information on the impact of interventions to improve adherence than measures using less frequent eg monthly summaries (such as pill counts, or

self-report) [21]. Medication monitoring boxes can also act as reminder systems for patients and this will be offered to some patients as an adherence support tool option where indicated during the TNA session

Pill counts

Each month, patients will bring their medication monitor boxes to the clinic to be refilled. The research nurse will count the number of pills in the box when the patient returns it, at the same time as downloading its data. These data on the number of pills remaining can then be compared to the adherence data recorded by the box, to check for sources of error.

In the case of Directly Observed or Video Observed Therapy methods being used, a record of missed doses will be kept. Patients who do not bring their medication with them when they are reviewed, will be reminded for future visits by phone call or text to bring their medication with them.

Other

Patient-reported drug administration, and - if the patient is receiving either DOT or VOT- objective evidence of taking medication [22] will be validated against the other adherence measures and the quality of each assessed. We will additionally collect whether clinic attendance occurs as planned.

Participants will also complete a range of self-reported questionnaires across their participation (see Appendix 10 schedule of questionnaires diagram). Measures include perceptions of illness (Brief Illness Perceptions Questionnaire) and beliefs about medicines (BMQ-specific and BMQ-general), depressive and anxious symptomatology (Patient Health Questionnaire 4-item), quality of life (EQ-5D-5L), service use (Client Service Receipt Inventory), self-reported adherence (Medication Adherence Report Scale), side effect experience (Side Effect Experience Questionnaire), and intervention feedback (for intervention arm participants only).

The questionnaire sessions will map onto follow up/intervention session (baseline, 2 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months) but patients who are on treatment for longer than 6 months will also repeat questionnaires at treatment completion or 12 months (whichever comes first).

3.4.4. Study Arms

Manualised intervention

The patient's case manager (usually the clinic TB nurse) will administer the TB needs assessment in partnership and consultation with the patient to identify whether personal, socio-cultural and/or systems risk factors are present that suggest likely poor adherence with treatment. If these are identified, then the relevant measures outlined in the manualised intervention that may mitigate these will be reviewed and implemented with the agreement of the participant. As outlined in the manual, this may include additional adherence support tools (e.g. DOT, VOT, medication box reminders) or other linked support actions (e.g. referrals to services, travel vouchers, scripted conversations to address beliefs etc). All participants will watch two three-minute animated videos and receive an interactive patient booklet (developed during the production of the manualised intervention). These tools are designed to increase patient's motivation to take their treatment, by providing a rationale for the necessity of their TB treatment and decrease their concerns.

The intervention also offers tips and resources to increase patients' ability to take treatment. Throughout the study, potential barriers to adherence will be assessed and addressed using the TB needs assessment. This includes applying changes to adherence support where required, and providing other linked actions when necessary. As part of the intervention, patients will also receive two phone calls from the HCP delivering the intervention, at week 1 and week 6 of treatment. The timing of these calls aims to address treatment initiation and treatment maintenance respectively. The week 1 phone call addresses any beliefs that may be barriers to adherence identified in the TB needs assessment completed at baseline. The week 6 questionnaire focuses on highlighting the importance of treatment completion to the patient, even in the absence of symptoms.

Standard care for TB

The national adoption of approaches such as cohort review [25] to TB management means that all patients have case managers, and at the start of treatment are assessed for a set of risk factors felt to be associated with likely poor-adherence. These focus generally on areas such as homelessness, drug and alcohol misuse, previous incarceration and mental health issues rather than other psycho-social factors such as what having TB means to the person, or whether they feel that they really need to take treatment. If a risk factor is identified then the patient will be offered the relevant support available in the clinic. All patients will be followed throughout their treatment by their case manager; and if concerns regarding adherence are identified, further support measures will be implemented in line with clinic practice. Although a process evaluation will be performed during the pilot study (see below), the researchers will not intervene to provide advice or to suggest a change in practice in either arm, should they identify a problem. The exception to this would be if the Study Steering Committee had concerns about study conduct or outcome and wished to stop the trial.

Study schedule of visits

Study subjects will be seen at weeks 0, 2, 4, 8, 12, 16, 20 and 24 (earliest date of treatment completion). Should patients in the intervention arm require ongoing treatment after 6 months, they will continue to be treated using the 6 month follow-up interventions session structure. This includes reviewing adherence, completing the TB needs assessment to highlight any new barriers to address, and addressing any other concerns as appropriate.

At each consultation, the TB Needs Assessment will be performed which includes a review of adherence.

Patients will complete self-report questionnaire with the assistance of the research nurse at each study visit. The research nurse will also refill the patient's medication box, and count any remaining pills.

3.4.5. Follow up

Most patients who do not have clinically important drug resistant disease receive six months of treatment and they will be followed for the duration of the pilot study . Although patients with extensive or drug resistant disease (who can require therapy for anything between nine and 24 months) may not have all of their treatment captured within the pilot, (depending on time of entry into the study) the maximal time of 12 months that a participant could be within the study enables us to obtain some data on patients with complex TB. The maximal duration of time that a participant remains within the study depends on their planned treatment duration (minimum 6 months), and when during the pilot study that they are recruited. Patients will continue to receive the 6 month follow-up intervention structure

if they continue on treatment for 6 months (up to a maximum of 12 months). After this time, they would then return to standard care if they have not finished treatment for TB by the end of the study. Patient's adherence data will also be followed up monthly if they continue on treatment for over 6 months. Patients who continue on treatment past 6 months will also complete a battery of questionnaires at treatment completion or 12 months (whichever is earlier). Given the study sites, we do not believe this will adversely affect the quality of care provided.

3.4.6. Analysis and interpretation

Where possible, univariable analyses will be undertaken to compare each outcome measure listed between study arms (intervention and control). For the primary outcome (adherence) the mean percentage value will be reported by arm (intervention and control) and histograms used to describe the distribution of values by study arm. Binary secondary outcomes will be reported by the proportion of individuals achieving this within each arm. The need to adjust for clustering by site and clinical care provider will be assessed using the cluster summary method (a t-test to compare the cluster means or proportions [as appropriate, two values per arm] between arms). An assessment of the balance in baseline characteristics between the study arms will also be conducted. If randomisation has failed to evenly distribute key characteristics (e.g. age, sex, ethnicity, or other factors identified as important during the scoping reviews), then the cluster means or proportions will be adjusted for these differences before applying the t-test. This two-stage approach to analysis is described by Hayes and Moulton [27]. We recognise that adherence data may be highly skewed and thus require compensatory analytical approaches.

The analysis of the first three of our secondary outcomes will address the feasibility of a definitive trial following a similar design to the pilot. Analysis of secondary outcomes 4 to 6 addresses the intervention, and complements the process evaluation (see below). Analysis of the primary outcome and final secondary outcomes around treatment adherence provides initial information - given the modest sample size - concerning the effectiveness of the intervention, and may assist the sample size calculation for the definitive trial. They can also offer an alert in the unlikely event that the intervention is harmful.

3.5. Process evaluation (v)

The process evaluation will consist of a description of the process of intervention implementation and normal standard NHS care. It will assess how the well the manualised intervention achieves its intended aim compared to standard care.

We will consider:

1) The fidelity of the intervention as delivered in practice, in comparison to how it was designed and envisaged
2) The reach of the intervention (the proportion of the target group receiving it)
3) The barriers to facilitating implementation of the intervention and how these can be addressed
4) The pre-existing factors that facilitated implementation.

3.5.1. Process measures

Process measures for each element of the package have been developed and will be used to assess success. Areas that will be evaluated include acceptability, uptake, and perceived utility of the various intervention elements, as well as fidelity to recommended usage, and change in practice. We will work

with patients and health care providers (HCP) separately, and at all four London sites. We will interview 12–20 participants (3–5 at each study site, hence 6–10 from each arm); and if possible 8–12 HCPs (2–3 at each site). Participants will be selected for inclusion in the process evaluation from each site using purposeful sampling of clinic lists of all enrolled participants at that site, to enable us to reflect the demographic spread of patients. Reasonable expenses incurred by participants will be reimbursed. These include transportation and refreshments to reflect the additional estimated 30 minutes in taking part in the process evaluation. Wherever possible, interviews with participants will be conducted at the same time as a regular clinic visit, minimising inconvenience to participants and additional travel.

Data collection methods:

1. **Evaluation of intervention delivery** will entail review of routine data sources including clinic lists, TB treatment register as well as project instruments, in particular the adherence risk assessment tools and records of intensified adherence support delivery.
2. **Development of narrative description of process of intervention implementation and maintenance**, through qualitative research methods. This will focus on understanding the key obstacles and facilitators to delivery of the package and the participants' experiences of the intervention. One-to-two brief, structured interviews will be conducted with HCPs involved in patient care and follow-up (see Appendix 11 for example interview guide), focused primarily on issues around the delivery of 1) the TB needs assessment and 2) the interactive booklet, as well as other parts of the intervention process. Semi-structured observation (1-2 consultations per participant for selected participants) will be used to document HCP communication and care practices at different stages of participants' trajectories through care. Brief, semi-structured interviews will be conducted with selected participants after 2–4 weeks of treatment and at the end of treatment to understand their perceptions of the information, care, and support received (see Appendix 12 for example observation checklist)
3. **Quantitative assessment of adherence-related perceptions** (using the Necessity Concerns Framework) and practicalities within intervention and control groups

3.6. Cost –Effectiveness Analysis

This will be performed in collaboration with Health Economists at the Research Department of Primary Care and Population Health, University College London. The overall aim is to collect data to assess the feasibility of calculating the incremental cost per quality-adjusted life-year (QALY) gained of using a manualised intervention compared to standard of care to improve adherence to TB treatment. A full analysis would be performed in a future large RCT.

We will collect health and social care resource use data using the modified Client Service Receipt Inventory [28] (see Appendix 4) to assess the feasibility of generating cost information from an NHS and Personal Social Services perspective, controlling for baseline values. This will include information on the various methods used across both arms to promote adherence to TB treatment to allow the costs for these types of activities to also be estimated. Costs associated with the intervention, including how much staff time is required, will be captured from nurses and other health care professionals who are involved in delivering the intervention. Resource use and other data relating to costs will be collected from participants at baseline, and at 2, 4 and 6 months, asking each time for the previous 2 months' resource use. We will also capture participants' out-of-pocket costs, as missed opportunities to control TB have cost implications not only for the NHS, but also for patients and associated members of the public.

We will collect EQ-5D-5L responses (see Appendix 4) from participants at baseline, 2, 4 and 6 months, to allow us to assess the feasibility of generating quality of life scores that can be used to calculate numbers of quality-adjusted life-years (QALYs) per participant in each arm, using area under the curve methods and controlling for baseline values. This will allow us to assess the feasibility of performing a full cost-effectiveness analysis in a future large RCT.

3.7. Future Work

After the pilot study and process evaluation have been completed, a final intervention package will be designed for use in a definitive RCT of the manualised package of interventions. The design of this final package will be based on the results of process evaluation and the experience gained during the piloting of the intervention, modifying the definitive trial design and/or data collection accordingly.

We plan to summarise data from the potential full RCT into a format that commissioners can use as the basis for subsequent decisions on investments to improve adherence to treatment for TB. In particular, this will draw on existing studies such as National Institute for Health Research (NIHR) RP-PG-0407-10340: Improving the management and control of tuberculosis among hard to reach groups (TB REACH), which includes a comparison of DOT and VOT, and other cost analysis as part of NIHR and Department of Health funded work.

4. ELIGIBILITY CRITERIA

The study will recruit participants during the Formative Stage (iii) and Pilot Study (iv).

4.1. Recruitment to Formative Study (ii) and Pilot Study (iv)

4.1.1. Formative Study (ii)

It is planned to enrol approximately 60 participants into the Formative Research Study, this will include a mixture of both patients with a current or previous history of TB, their family members and carers, and Healthcare workers managing TB cases (i.e. TB nurse or case manager; Table 1).

4.1.2. Pilot study

It is planned to enroll 80 participants starting treatment for TB into the Pilot Study.

Patients with possible TB attending the four TB clinic study sites will be informed about the trial. Those who are diagnosed subsequently with active TB (approximately 1 in 4 of new referrals) and are eligible for the study will be approached with further information, and asked if they would like to take part. To ensure that the study participants are truly representative of the clinic population, a record of those patients who do not wish to take part will be kept in the screening log. This will contain routinely collected data such as age and sex. It will not enable patients to be identified through deductive disclosure.

4.2. Eligibility criteria - Formative Study (iii)

4.2.1. Subjects with TB, their family members and carers

Inclusion criteria:

i. Age ≥ 18 years
ii. Able to provide Informed Consent
iii. People who are suspected to have or have previously had TB. Family members/carers of consented participants will also be approached and consented (where possible)

Exclusion criteria:

i. Unable to give informed consent

4.2.2. Health providers

Inclusion criteria

i. Age ≥18 years
ii. Able to provide informed consent
iii. Healthcare professionals who are involved in TB management and care

Exclusion criteria

i. Unable to give informed consent

4.3. Eligibility Criteria - Pilot Study (iv)

Inclusion criteria

i. Age ≥18 years
ii. Able to provide informed consent
iii. Being started on treatment for TB affecting any part of the body

Exclusion criteria

i. Patients already on treatment for TB at the point they attend the TB services in the study
ii. If the patient is not expected to live for the duration of the study (that is a minimum of six months from starting treatment)

4.4. Eligibility Criteria - Evaluation Study (v)

Inclusion criteria

i. Age ≥18 years
ii. Able to provide informed consent
iii. Started on treatment for TB at one of the four London sites OR a staff member treating patients at one of the four London sites

Exclusion criteria

i. Unable to give informed consent

4.5. Randomisation procedures

Randomisation occurs at the clinic level prior to the pilot trial. Within each of the two selected NHS trusts one clinic will be allocated at random to the intervention and one to standard of care. This allocation will be conducted through random computerized permutation using Stata 15 software.

4.6. Unblinding

The study will not require unblinding procedures.

5. CONSENT

5.1. Informed Consent

A member of the patient's clinical care team (independent of the research team) will first approach the patient about the study. If the participant indicates that they are happy to consider taking part then an appropriately trained member of the research team, as designated on the delegation log, will go through the written information sheet with the patient which will explain the research and the level of participation/commitment required. The researcher will discuss the consent process and provide the opportunity for the participant to ask any questions. Once the potential participant has confirmed that they have enough information about the study they will be given adequate time to decide whether or not they wish to participate.

Participants who decide that they wish to take part in the study will then provide written informed consent by signing and dating the study consent form, which will be witnessed and dated by a member of the research team with delegated responsibility to do so. Written informed consent will always be obtained prior to study specific procedures/investigations.

The original signed consent form will be retained in the clinical notes, with a copy in the Investigator Site File and a copy provided to the participant. The participant will specifically consent to their GP being informed of their participation in the study. The right to refuse to participate without giving reasons will be respected.

5.2. Withdrawal procedure

Participants have the right to withdraw from the study at any time for any reason, and without giving a reason. The investigator also has the right to withdraw patients from the study if s/he judges this to be in the patient's best interests. Unnecessary withdrawal of patients should however be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

There are two withdrawal options:

1. Withdrawing completely (i.e. withdrawal from both the study and provision of follow-up data)
2. Withdrawing partially (i.e. withdrawal from full study procedures but continuing to provide

partial follow-up data by attending clinic and completing questionnaires).

Consent will be sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants will be asked if they would be happy for the reason for the decision to withdraw to be recorded.

6. SCHEDULE

6.1. Start and duration

Study will commence January 2018. Total duration is 36 months. The different components will run as required to achieve completion by 31 December 2020 (see Appendix 2: Gantt chart).

7. STATISTICAL METHODS

7.1. Recruitment to pilot study and sample size

Eligible participants will be approached at all four sites and the nature of the pilot study will be explained. Over a 6 month period, we will recruit 80 consenting subjects (20 at each site). Depending on where they receive their treatment they will be offered either the manualised intervention or standard care when starting treatment for TB.

Patients attending the four TB clinics taking part in the study will be informed about the study by their clinical care team. All patients who agree to take part in the study will either be allocated to the intervention, or the control group who will receive standard care. To ensure that the study participants are truly representative of the clinic population and to allow us to calculate the proportion of people who have agreed to take part, a record will be kept of those patients who do not wish to take part. This will contain routinely collected data.

Using as a stringent measure of complexity in UK patients the requirement for Directly Observed anti-TB Therapy within the clinic populations seen at the two sites, we estimate that around 33% of patients will have a risk factor for non-adherence. Taking this as a minimum (as the manualised intervention is likely to be more sensitive than current risk assessments), we would expect that at least 26 patients will be identified as requiring adherence support. This sample size allows us to measure consent for more than 100 individuals, data completeness for adherence and treatment outcomes for 80 individuals, data on acceptability and feasibility of the intervention package for 40 individuals, and data on acceptability and feasibility of adherence support for at least 26 individuals (13 receiving the manualised intervention and 13 standard care).

We will use the first 80 participants to determine feasibility and define measures that may improve participation and recruitment. It is not planned to recruit more patients to the pilot study as this may bring with it extra costs. We will not rely on this phase of the trial for hypothesis testing - as at this point the results obtained will be unpowered. The effect size will not be looked at formally and no explicit conclusions will be drawn.

8. PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patients and the public will be actively involved in the following:

- Design of the research
- Management of the research (e.g. steering / advisory group)
- Developing participant information resources
- Contributing to the reporting of the research
- Dissemination of research findings

This study was prepared in conjunction with TB Alert and Find&Treat. TB Alert is the UK's national TB charity, whose focus is on making sure people with TB are promptly diagnosed and supported appropriately during treatment. Find&Treat work alongside the NHS and third sector services as a specialist TB outreach team. They support vulnerable communities including the homeless, drug or alcohol misusers, disadvantaged migrants and ex-prisoners. Working collaboratively, we have ensured that our proposal focuses on the needs of people who may find it difficult to adhere to TB treatment for a range of social and other factors. Also, a charity representative and a former patient who is a member of the TB Action Group (patient advocate group facilitated by TB Alert) contributed to the qualitative study design and provided input into the planned development of the manualised intervention, as well as the pilot study.

There will be full PPI involvement during the development of the intervention, including issues around the approach to participants, production of the ethics application and supporting material such as information sheets. There will be PPI stakeholder representatives on the Study Steering Committee, drawn from TB Alert and former TB patients. The PPI representatives will contribute to the final report, ensuring that this represents the views of the forum and records their involvement in the project. Finally, we will work with our PPI Study Steering Committee members and stakeholder charities to ensure that there is effective translation and dissemination of the evidence generated from the study into formats accessible to the community.

9. FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCL Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via the Local Clinical Research Network, North Thames.

This work was supported by the National Institute for Health Research (NIHR) Health Technology Assessment Programme, UK grant number 16/88/06. The views expressed are those of the author(s) and not necessarily those of the National Health Service, UK, the NIHR or the Department of Health and Social Care.

10. DATA HANDLING AND MANAGEMENT

10.1. Data Protection and Confidentiality

All data will be handled in accordance with the General Data Protection Regulations (GDPR).

All participants will be given a unique study numbers. Case Report Forms (CRFs) used will not bear the participant name or contain any identifiable data.

The interviews will be recorded and transcribed. Qualitative data recordings (staff and patient interviews) will be transcribed and translated; observation notes will be extracted from the forms. All data will be anonymised through the use of culturally appropriate pseudonyms, and through removal of any personal or familial references not immediately relevant to the interview content.

Staff will be bound by existing confidentiality agreements through their employment at UCL. The study will be fully compliant with Caldicott principles and the General Data Protection Regulations. Any published output will not allow identification of any participant through deductive disclosure.

The study information at UCL (traceable only with codes) will be stored in a locked offices of the clinical or research teams, stored in password protected files (electronic) or locked filing cabinet (paper). Only members of clinical research team will have access. Data will be collected and stored according to current General Data Protection Regulations. All study documents, including data collection forms, will be stored in a secure location. Data flow for the formative research and pilot cluster randomised trial are shown in Appendix 6.

Personal data relating to participants will be stored under a unique patient identifier and would therefore uphold confidentiality. Those on the participant direct care team and Principal Investigator will have access to the participant personal data. So too will members of the research team who have direct contact with the people taking part in the study. This will occur once consent has been obtained.

In compliance with the requirement of the funders and conditions stipulated by UCL, anonymised data sets will be retained for at least 5 years.

11. PEER AND REGULATORY REVIEW

11.1. Ethics and Research Governance

The study will be reviewed by an Independent Research Ethics Committee and the Health Research Authority. All study data will be held in accordance with NHS data protection principles including the use of secure password protected systems. UCL will be the nominated sponsor.

The study will be reviewed by an Independent Research Ethics Committee (NHS Research Ethics Committee). Study amendments, will be submitted by the CI to the sponsor. Trial related essential documents will be assessed by the sponsor and submitted in writing to the appropriate REC, Regulatory Authority and Trust Research & Development (R&D) for approval prior to implementation.

Before the site can enrol patients into the trial, the investigator at site or designee must apply for NHS permission from their Trust Research & Development (R&D) Department.

The CI will supply the Sponsor with a final report of the clinical trial, which will then be submitted to the MHRA and REC within one year of the end of the trial.

11.2. Internal Review

The study has been peer reviewed in accordance with the requirements outlined by UCL and was reviewed externally as part of the NIHR peer review mechanism. The Sponsor has accepted these reviews as adequate evidence of peer review.

12. RECORDING AND REPORTING OF EVENTS AND INCIDENTS

12.1. Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved
Serious Adverse Event (SAE).	Any adverse event that: results in death, is life-threatening* requires hospitalisation or prolongation of existing hospitalisation** results in persistent or significant disability or incapacity or consists of a congenital anomaly or birth defect

*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.

12.2. Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

12.2.1. Severity

The generic categories below are given for use as a guide.

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

12.2.2. Causality

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form.

The following categories will be used to define the causality of the adverse event:

Category	Definition
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events)
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition)
Not related	There is no evidence of any causal relationship
Not Assessable	Unable to assess on information available

12.2.3. Expectedness

Category	Definition
Expected	An adverse event which is consistent with the information about the procedure listed in the Investigator Brochure, SPC, manual of Operation (amend as appropriate) **or clearly defined in this protocol**
Unexpected	An adverse event which is not consistent with the information about the procedure listed in the manual of operation (or other – amend as appropriate)* **or clearly defined in this protocol**

* this includes listed events that are more frequently reported or more severe than previously reported

12.3. Recording adverse events

Choose most appropriate sentence(s):

All adverse events will be recorded in the medical records in the first instance.

12.4. Procedures for recording and reporting Serious Adverse Events

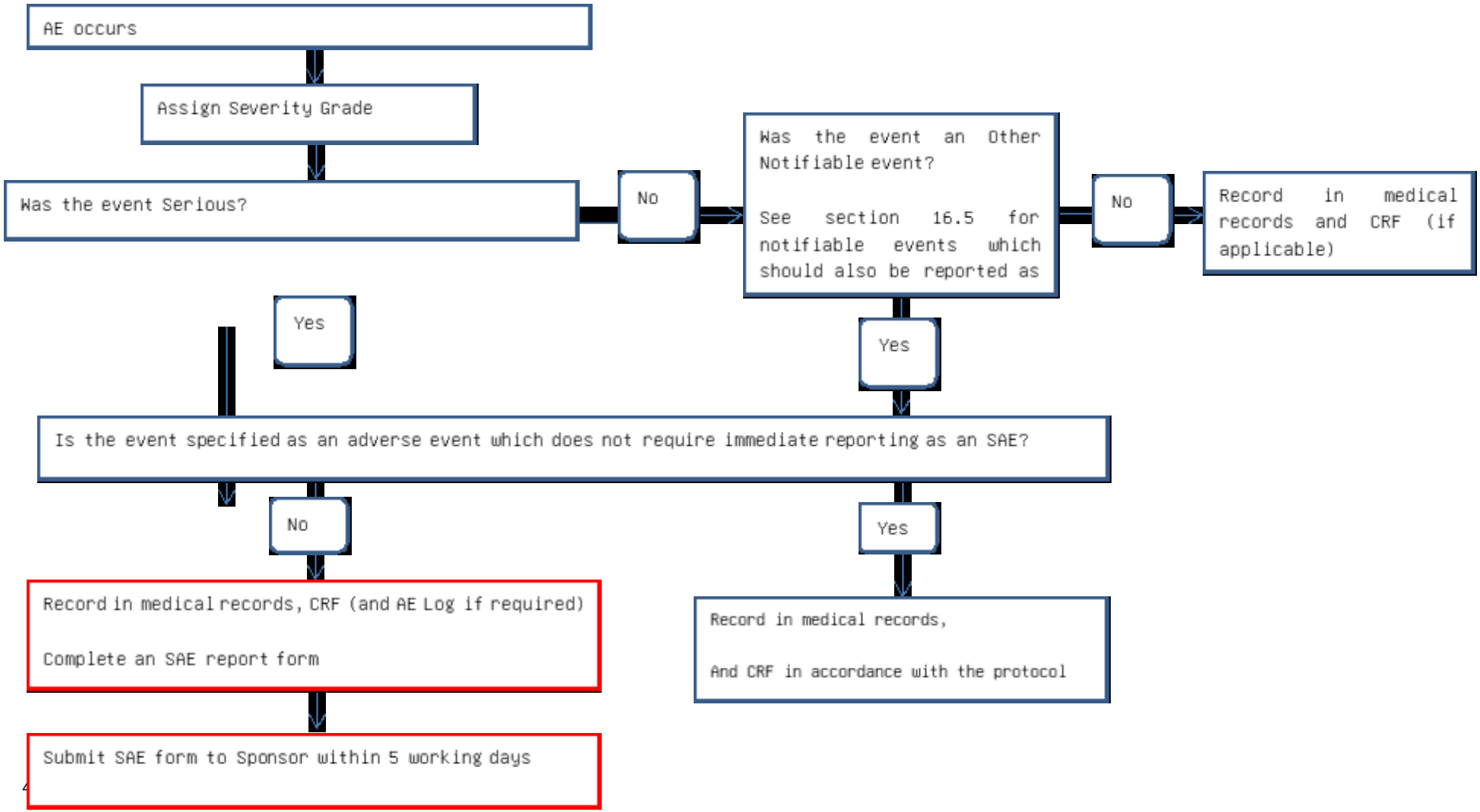
All serious adverse events will be recorded in the medical records and the CRF, and the sponsor's AE log (the sponsors AE log is used to collate SAEs and AEs so that the CI can review all in one place for trend analysis. If this data will be collated on a database throughout the study, from which a line listing of the SAEs can be extracted for review, an AE log will not be required).

All SAEs (except those specified in section 16.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Health Research Authority within 15 days.

Completed forms for unexpected SAES must be sent within 5 working days of becoming aware of the event to the Sponsor
Email forms to Research-incidents@ucl.ac.uk (if sponsored by UCL)

Figure 2- flow chart for SAE reporting



12.4.1. Serious Adverse Events that do not require reporting

All SAE will be reported.

12.5. Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

12.6. Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree:

1) the safety or physical or mental integrity of the participants of the study; or
2) the scientific value of the study.

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

12.7. Trust incidents and near misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

1) It is an accident or other incident which results in injury or ill health.
2) It is contrary to specified or expected standard of patient care or service.
3) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
4) It puts the Trust in an adverse position with potential loss of reputation.
5) It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.

A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

1) It is an accident or other incident which results in injury or ill health.
2) It is contrary to specified or expected standard of patient care or service.
3) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
4) It puts the Trust in an adverse position with potential loss of reputation.
5) It puts Trust property or assets in an adverse position or at risk of loss or damage.

13. MONITORING AND AUDITING

The CI will ensure there are adequate quality and number of monitoring activities conducted by the

study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The CI will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

14. INTELLECTUAL PROPERTY

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL confidential information or infringement of UCL IPR.

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

15. ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The CI confirms that he/she will archive the study master file at Royal Free Hospital for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The PI at each participating site agrees to archive his/her respective site's study documents for at least 5 years and in line with all relevant legal and statutory requirements.

16. PUBLICATION AND DISSEMINATION POLICY

A comprehensive report will be prepared. This will include recommendations regarding the manualised intervention and any subsequent evaluation required. The report will summarise findings particularly relevant to UK TB control policy. In addition to a formal report to the HTA, the research will be disseminated through peer reviewed publications, conference presentations and engagement with policy makers, patients and the public (via local clinical networks, community-based programmes working with at-risk for TB populations and voluntary sector agencies).

It is expected that there will be at least three research publications arising from this work: these include the results of the scoping review, the manualised intervention and the formative research that went into its development, and the pilot study and process evaluation. We also plan to publish the study protocol.

This work was supported by the National Institute for Health Research (NIHR) Health Technology Assessment Programme, UK grant number 16/88/06. The views expressed are those of the author(s) and not necessarily those of the National Health Service, UK, the NIHR or the Department of Health and Social Care.

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18. APPENDICES

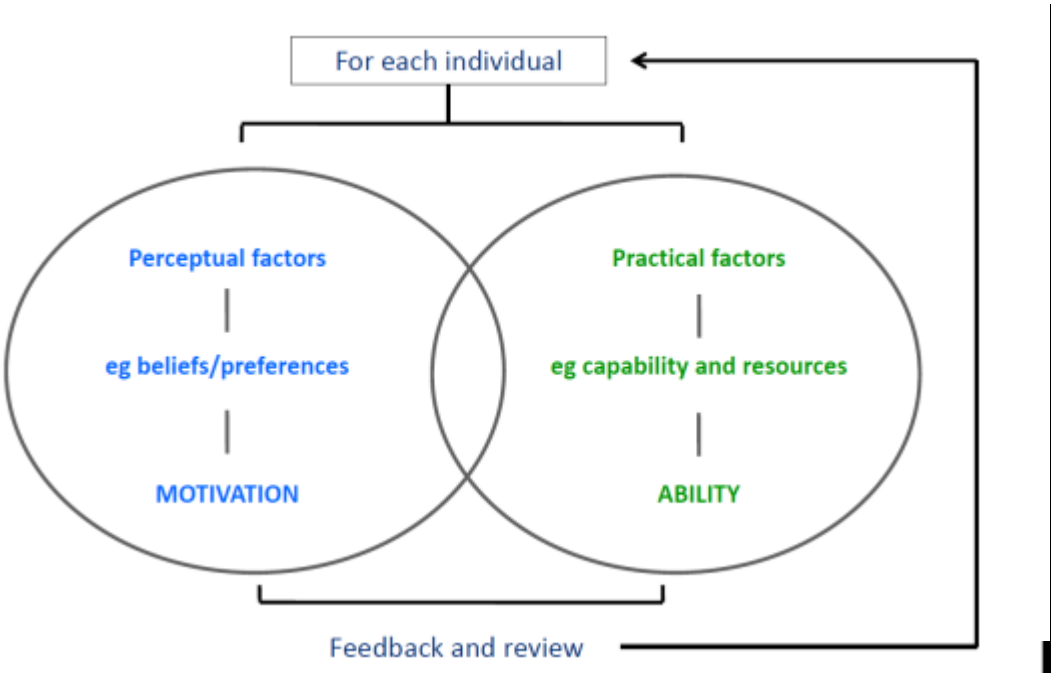
APPENDIX 1: PAPA Framework

Applying NICE medicines adherence guidelines: the Perceptions and Practicalities Approach

The PAPA is based on the recognition that non-adherence is best understood as a variable behaviour, rather than a trait characteristic. Adherence varies not just between individuals but within the same individual over time and across treatment: in other words, most of us are non-adherent some of the time. Adherence/non-adherence is determined by the unique interaction of each individual with the illness and treatment. Poor adherence can arise for many reasons, though these may be grouped under two broad classifications: “can’t” and “don’t want to”. Non-adherence may be both intentional and unintentional in the same individual. Unintentional non-adherence occurs when the patient wants to take the medicine but is prevented from doing so by barriers beyond their control, such as poor recall or comprehension of instructions, difficulties in administering the treatment, simply forgetting or because they cannot afford it. Conversely non-adherence may be intentional when the patient decides not to follow the treatment recommendations. Adherence/non-adherence is a product of motivation and ability.

The NICE Medicines Adherence Guidelines recommend that support be tailored to meet the needs of the individual by addressing both the perceptions e.g. personal beliefs about the illness, treatment, and self-efficacy and practicalities e.g. capability, resources and opportunity influencing the motivation and ability to start and continue with treatment[29]. This can be summarised as a `Perceptions and Practicalities Approach (Figure 1).

Figure 1 Perception and Practicalities model applied to adherence to treatment for TB.

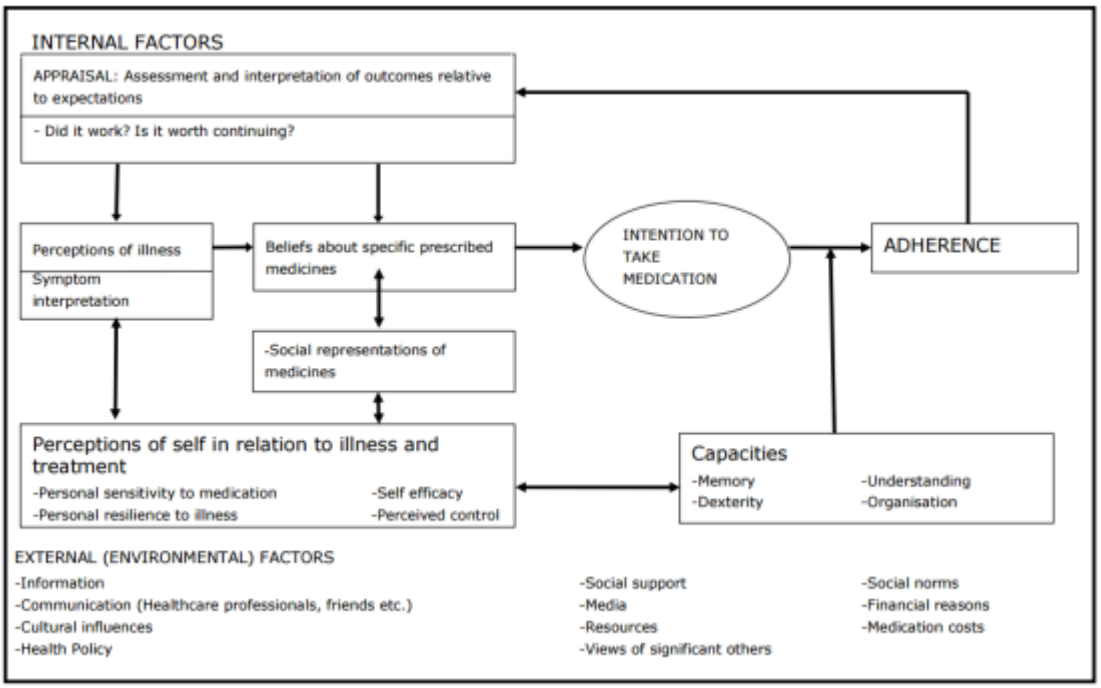


The PAPA explains the limited efficacy of interventions to improve adherence through information provision or 'education'. In order for something to change behaviour, it must be consistent with or change our patients' underlying beliefs.

We have previously used these principles to develop a simple, cost-effective, intervention to support adherence to new medicines prescribed for long-term conditions, delivered by telephone call with a community pharmacist, that resulted in higher adherence and more positive perceptions of treatment (higher Necessity, lower Concerns) plus fewer medication–related problems (18). This study was the basis for the NHS New Medicines Service.

It is important to recognise that the perceptions and practicalities influencing adherence will be affected by a wide range of external factors including the social and cultural environment and the healthcare system (of which communication with healthcare professionals is a component) - as illustrated in Figure 2.

Figure 2 Perceptions and Practicalities Approach conceptual map of determinants of adherence (taken from Horne *et al* 2005, Reference 8)



APPENDIX 2: GANNT Chart

Period	Pre-study	Year 1				Year 2				Year 3			
Month	-4	3	6	9	12	15	18	21	24	27	30	33	36
Ethics and staff													
• Ethics approval													
• Staff recruitment			★			★							
Scoping Review and Intervention Development													
• Literature search and data extraction													
• Synthesis and analysis													
• Formative Work													
• Development of manualised intervention							★						
• Intervention Development Group													
Pilot Study													
• Preparation													
• Recruitment										★			
• Follow up & data collection													
• Statistical analysis													★
• Health economic feasibility analysis													★
Process Evaluation													
Progress report and final report					★				★				★
Publications and dissemination													
Plan definitive study													

APPENDIX 3: Formative Research Patient Interview Topic Guide

Thank you for agreeing to be interviewed. We are interviewing individuals who are currently or recently have been on TB treatment in order to understand their pathways to care, and the issues they may face while being on treatment. We are conducting interviews with both health providers and patients attending this facility, as well as doing some observations to better understand how patients like yourself experience care in this facility. The questions we will ask you today are focused on your TB care journey, with particular emphasis on how things have been for you since starting on treatment. We value your reflections on your own experience and your thoughts on what, if anything, is needed to improve your care here. As already mentioned in the information sheet and consent form, the interview will take approximately 1 hour of your time. Please do feel free to ask any questions now or during the interview itself.

Patient profile

- Please tell me a little bit about yourself and your situation (probes can include place of origin/residence, length of residence in current location, employment/occupation)
- Do you have any family here? Can you tell me a bit about them?
- How is your health at the moment? How do you feel?
- What kinds of health issues have you faced in the past? How about your family?
- What has been your experience of seeking health care in this city? (probe regarding experience of NHS if from outside the country)
- What have you found positive during with this experience? What have you found negative? (probe on access, transport, ease of finding services)

Pathways to TB treatment and care

- Tell me about when you first started feeling symptoms that led you to seek care? OR
- When were you first screened for TB? Can you recall the experience? (tell me more about it, what were the circumstances?)
- What happened next? How were you diagnosed?
- Did you talk to family or friends about this diagnosis?
- Tell me about when you started coming to this clinic for your treatment (probe for original first impressions, ease of access, general feelings at the time)
- Is there a typical time of day you prefer to visit the clinic? How long does it take you to travel here?
- Do you have to spend money to come to clinic?
- How long are you normally in the clinic? (probe on how much time out of the day is required to receive treatment)
- Are there disadvantages to having to come to the clinic? Advantages?

Treatment adherence issues

Perceptions and practicalities affecting adherence

- What does TB mean to you? (probe: what did you know about TB before you found out you had the disease? What do you associate the condition with now?)
- Going back to when you were diagnosed, tell me more about how you were informed. (probe on who did this, in which facility, how long did they take to explain the diagnosis and treatment?)
- What do you think about the TB treatment you have been prescribed?
- How important do you think it is for you to follow the prescription?
- How have you felt on this treatment? (*probe on different stages of treatment*)
- Do you have any concerns about the treatment?
- What makes it easy/difficult to stay on treatment? (*probe on social/environmental challenges*)

Social support

- How do you cope with your illness on a daily basis?
- When you are sick, is there anyone in particular who looks after you/supports you?
- If yes – who is this person? How do they support you? (*probe: psychological, social, financial*)
- Are there members of the family or other social contacts who know about your illness? If so, have you been able to talk to them?
- Has there been anyone who helps you stay on track in terms of your treatment?
- If so, how do they help you?
- How often do you see family? What about friends? Has anything changed since you were diagnosed with TB?
- Do you feel that anything has changed for you in terms of your social life since being on TB treatment?
- Do you know other people on treatment? If yes, do you discuss how you feel with them?

[*question to identify social contact interviewee*] Is there a family member or someone who you are close to whom we could interview? We would like to gain their understanding of the issues in supporting you whilst on treatment. We would be very grateful for the opportunity to speak to them.

Structural and health systems issues

- Tell me more about your daily visits for treatment. How many staff members would you say you come in contact with each time? For how long with each?
- Do you ever feel you need more/less time with clinic staff?
- How do you feel you are treated when you come in (probe on whether it is a personable or welcoming experience? (*probe on patient/staff rapport if any*)
- Do you find it easy to get around the clinic?
- Can you give me any examples of a situation that would make it difficult for you to visit the clinic for your treatment (*traffic, work, illness*)? What would you do in this case? (*probe on whether they inform the clinic or if clinic contacts them first*)
- In what ways does the clinic support your treatment currently? What are they doing to help you stay on treatment?

- What could be done to improve your experience of treatment?
- What are your perceptions of the ways staff interact with you or other patients? Do you feel there is strong communication? Do you feel sufficiently supported? (*probe on communication content, language issues, staff communication style, is it sufficient, easy to reach out to staff members if necessary*)
- Can you recall any instances where you felt that the clinic staff was unavailable to you?
- How important do you think it is to be in regular contact with your treatment team?

Perspectives on Intervention

- Finally, are there any lessons gained from your experience of being on TB treatment that you could share with others who are starting treatment?
- Can you think of anything more that you would have liked to know or would have been helpful to have been explained to you when you were diagnosed?
- What could be improved in the service to support people like you on treatment?
- What could be done differently in this clinic? (probe: access, opening hours, finding one's way through clinic, communication, care)

APPENDIX 4: Questionnaire booklet

IMPACT questionnaire booklet

Baseline

[Brief Illness Perception Questionnaire; Brief IPQ]

Your views ABOUT TB

For the following questions, please circle the number that best matches your views:

How much does TB affect your life?										
0 No affect at all	1	2	3	4	5	6	7	8	9	10 Severely affects my life
How long do you think TB will continue?										
0 A very short time	1	2	3	4	5	6	7	8	9	10 Forever
How much control do you feel you have over TB?										
0 Absolutely no control	1	2	3	4	5	6	7	8	9	10 Extreme amount of control
How much do you think treatment can help TB?										
0 Not at all	1	2	3	4	5	6	7	8	9	10 Extremely helpful
How much do you experience symptoms from TB?										
0 No symptoms at all	1	2	3	4	5	6	7	8	9	10 Many severe symptoms
How concerned are you about TB?										
0 Not at all concerned	1	2	3	4	5	6	7	8	9	10 Extremely concerned

How well do you feel you understand TB? 0 1 2 3 4 5 6 7 8 9 10 Don't Understand understand very clearly at all
How much does TB affect you emotionally? (E.g. does it make you angry, scared, upset or depressed?) 0 1 2 3 4 5 6 7 8 9 10 Not at Extremely all affected affected emotionally emotionally
How concerned are you about passing TB onto others? 0 1 2 3 4 5 6 7 8 9 10 Not Extremely at all concerned concerned

[Beliefs about Medicines Questionnaire-specific, baseline version; BMQ-S baseline version]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about TB Medicines
- These are statements other people have made about their TB Medicines.

There are no right or wrong answers

We are interested in your personal views

Please show how much you agree or disagree with them by ticking a box:

	Views about TB Medicines	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
N1	My health will depend on TB medicines					
C1	Having to take TB medicines worries me					
N2	My life will be impossible without TB medicines					
C2	The long-term effects of TB medicines are a worry for me					
N3	Without TB medicines I would be very ill					
C3	TB medicines are a mystery to me					
	TB treatment will have a negative effect on how I see myself					
N4	My health in the future will depend on TB medicines					
C4	Having to take TB medicines will disrupt my life					
C5	Becoming too dependent on TB medicines will be a concern for me					
N5	TB medicines will cure me of TB					
C6	TB medicines will give me unpleasant side effects					
C7	Using TB medicines will be embarrassing					
N6R	Missing TB medicines for a day won't matter in the long run					
C8R	I am unlikely to get a bad side effect from TB medicines					
C11	I am concerned that I will have to take too many pills each day					
C12	Having to take TB medicines doesn't bother me at all					
	Having to take TB treatment will affect the way others see me					

[Beliefs about Medicines Questionnaire-general, BMQ-G; Perceived Sensitivity to Medicines Scale, PSM]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- These are statements that other people have made about medicines in general.

There are no right and wrong answers.

We are interested in your personal views

Please show how much you agree or disagree with them by ticking the appropriate box:

	Views about MEDICINES IN GENERAL	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
BG1	Doctors use too many medicines					
BG2	People who take medicines should stop their treatment for a while every now and again					
BG9	Medicines help many people to live better lives					
BG3	Most medicines are addictive					
BG4	Natural remedies are safer than medicines					
BG11	In most cases the benefits of medicines outweigh the risks					
BG10	In the future medicines will be developed to cure most diseases					
BG6	Most medicines are poisons					
BG5	Medicines do more harm than good					
BG12	Medicines help many people to live longer					
BG7	Doctors place too much trust on medicines					
BG8	If doctors had more time with patients they would prescribe fewer medicines					
PSM1	My body is very sensitive to medicines					

PSM2	My body over-reacts to medicines.					
PSM3	I usually have stronger reactions to medicines than most people					
PSM4	I have had a bad reaction to medicines in the past.					
PSM5	Even very small amounts of medicine can upset my body.					

[Patient Health Questionniare-4 item, PhQ-4]

PHQ-4

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Little interest or pleasure in doing things	0	1	2	3
4. Feeling down, depressed, or hopeless	0	1	2	3

[EQ-5D-5L]

Health questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

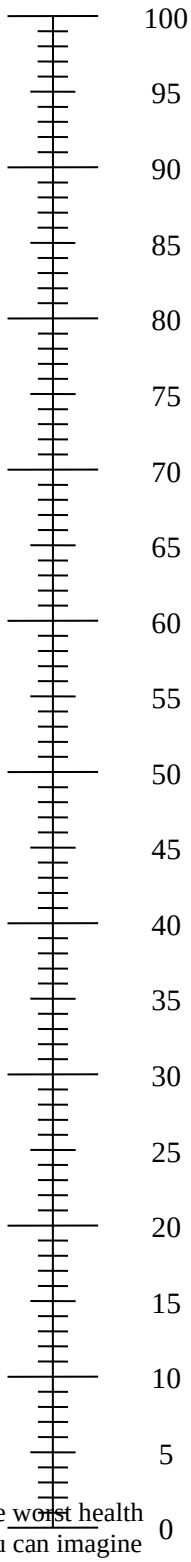
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

The best health you can imagine



The worst health you can imagine

YOUR HEALTH TODAY = ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

[Client Service Receipt Inventory; CSRI]

Patient Resource Use Questionnaire

TB Nurse and Support Service - have you had any of the following contact with the healthcare team in the last 2 months? (PLEASE DO NOT INCLUDE VISITS SPECIFICALLY FOR THE IMPACT STUDY)		
Visited TB nurse at the clinic	Yes Number of times _____	No
TB nurse visited you at home	Yes Number of times _____	No
Spoke to TB nurse on the phone	Yes Number of times	No

	_____	
Visited a social worker at their office or in clinic	Yes	No
	Number of times	
	_____	
Social worker visited you at home	Yes	No
	Number of times	
	_____	
Spoke to a social worker on the phone	Yes	No
	Number of times	
	_____	
Visited a support worker at the clinic	Yes	No
	Number of times	
	_____	
Support worker visited you at home	Yes	No
	Number of times	
	_____	
Spoke to a support worker on the phone	Yes	No
	Number of times	
	_____	

Hospital outpatient appointments		
Have you had any hospital outpatient	Yes	No

appointments in the last 2 months other than the TB service?

Oncology (cancer services)	Yes No Number of times _____
Kidney services	Yes No Number of times _____
Liver services	Yes No Number of times _____
Gastroenterology	Yes No Number of times _____
Rheumatology	Yes No Number of times _____
Psychiatry	Yes No Number of times _____
Other specialist outpatient appointments	Yes No Number of times: **1** **2** **3** Please give the details of the first of these visits: Please give the details of the second of these visits:

Please give the details of the third of these visits:

Hospital outpatient procedures.

In the last 2 months have you had any of the following outpatient medical procedures for your TB (other than any asked about in the previous section)?

X ray — Yes / No

Number of x rays

_____

CT scan — Yes / No

Number of CT scans

_____

Ultrasound — Yes / No

Number of ultrasounds

_____

Biopsy — Yes / No

If yes, site of biopsy:

Gland (lymph node)

Number of gland (lymph node) biopsies

_____

Skin

Number of skin biopsies

_____

Lung

Number of lung biopsies

_____

Gut	Number of gut biopsies _____
Back	Number of back biopsies _____
Other	Number of other biopsies (not listed above) _____ Please list type of biopsies:
Have you had any other outpatient tests?	Yes No Number of tests **1** **2** **3** Please give details of the first one of these tests: Please give details of the second one of these tests: Please give details of the third one of these tests:

Hospital admissions and visits to A&E /casualty	
Have you been admitted to hospital or been seen in accident and emergency in the last 2 months?	Yes No
Been to accident and emergency (casualty)	Yes No Number of times _____
Admitted to hospital after visiting A&E	Yes No

(emergency hospital admission)

Number of times

1 **2** **3**

Duration of first visit (in days)

_____

Reason(s) for stay:

_____

Duration of second stay (in days)

_____

Reason(s) for stay:

_____

Duration of third stay (in days)

_____

Reason(s) for stay:

_____

Planned ("elective") hospital admission Yes No

Duration of stay (in days)

_____

	Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____
Overnight hospital stay in intensive care/high dependency	Yes No Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____

Primary care visits - have you had any visits to primary care (i.e. services connected with your GP surgery) in the last 2 months?	
GP visit at the surgery	Yes No Number of times _____

GP visited you at home	Yes Number of times _____	No
Spoke to GP on the phone	Yes Number of times _____	No
Saw practice nurse at the surgery	Yes Number of times _____	No
Spoke to practice nurse on the phone	Yes Number of times _____	No
Saw or spoke to mental health nurse (or community psychiatric nurse)	Yes Number of times _____	No
Attended individual NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes Number of times _____	No
Attended group NHS mental health therapy session (with someone other then a mental	Yes	No

health nurse or

psychiatrist)

Number of times

_____

Saw a non-nhs counsellor or therapist	Yes	No
How much did you pay per visit?	Under £5 £6-10 £11-20 £21-30 £31-40 £41-50 Over £50? Number of times	

_____

Have you used any of the following healthcare support measures in the last 2 months?

Have you used Directly Observed Therapy (DOT) for your TB?	Yes	No
How often do you use this during the week?	Every day Five times a week Three times a week	
When did you start using DOT?		
Have you used Video Observed Therapy (VOT) for your TB?	Yes	No
How often do you use it during the week?	Every day Five times a week Three times a week	
When did you start using VOT?		
Have you had any referrals to a housing	Yes	No

service for housing problems?

Number of times

_____

Have you had any referrals to an immigration service for immigration concerns? Yes No

Number of times

_____

Have you had any referrals to an alcohol service for alcohol problems? Yes No

Number of times

_____

Have you had any referrals to a drug service for drug problems? Yes No

Number of times

_____

Have you had any referrals to a mental health service for mental health problems? Yes No

Number of times

_____

Out of pocket costs (eg parking costs, travel to hospital etc)

In the last 2 months have you had to spend any of your own (or your family's) money on treatment or other things related to your TB (eg transport to appointments)	Yes	No

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Or approximate total cost:
Approximate cost per time:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

IMPACT questionnaire booklet

2 week follow-up

[Brief Illness Perception Questionnaire; Brief IPQ]

Your views ABOUT TB

For the following questions, please circle the number that best matches your views:

How much does TB affect your life?										
0 No affect at all	1	2	3	4	5	6	7	8	9	10 Severely affects my life
How long do you think TB will continue?										
0 A very short time	1	2	3	4	5	6	7	8	9	10 Forever
How much control do you feel you have over TB?										
0 Absolutely no control	1	2	3	4	5	6	7	8	9	10 Extreme amount of control
How much do you think treatment can help TB?										
0 Not at all	1	2	3	4	5	6	7	8	9	10 Extremely helpful

How much do you experience symptoms from TB?										
0	1	2	3	4	5	6	7	8	9	10
No symptoms at all										Many severe symptoms
How concerned are you about TB?										
0	1	2	3	4	5	6	7	8	9	10
Not at all concerned										Extremely concerned
How well do you feel you understand TB?										
0	1	2	3	4	5	6	7	8	9	10
Don't understand at all										Understand very clearly
How much does TB affect you emotionally? (E.g. does it make you angry, scared, upset or depressed?)										
0	1	2	3	4	5	6	7	8	9	10
Not at all affected emotionally										Extremely affected emotionally
How concerned are you about passing TB onto others?										
0	1	2	3	4	5	6	7	8	9	10
Not at all concerned										Extremely concerned

[Beliefs about Medicines Questionnaire-specific, BMQ-S; Medicine Practicalities scale, MPracS]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about TB Medicines.
- These are statements other people have made about their TB Medicines.

There are no right or wrong answers

We are interested in your personal views

Please show how much you agree or disagree with them by ticking a box:

	Views about TB Medicines	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
N1	My health, at present, depends on TB medicines					
C1	Having to take TB medicines worries me					
N2	My life would be impossible without TB medicines					
C2	I sometimes worry about the long-term effects of TB medicines					
N3	Without TB medicines I would be very ill					
C3	TB medicines are a mystery to me					
	TB treatment has a negative effect on how I see myself					
N4	My health in the future will depend on TB medicines					
C4	TB medicines disrupt my life					
C5	I sometimes worry about becoming too dependent on TB medicines					
N5	TB medicines will cure me of TB					
C6	TB medicines give me unpleasant side effects					
C7	Using TB medicines is embarrassing					
N6R	Missing TB medicines for a day won't matter in the long run					
C8R	I am unlikely to get a bad side effect from TB medicines					
C9	Taking TB medicines has been much worse than expected					
C10R	I have received enough information about TB medicines					
C11	I have to take too many pills each day					
C12	Having to take TB medicines makes me stressed					
	TB treatment has a negative effect on how others see me					
	I am sometimes too busy to take TB medicines					
	It is difficult to remember to take TB medicines					
	TB medicines are very difficult to swallow					

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

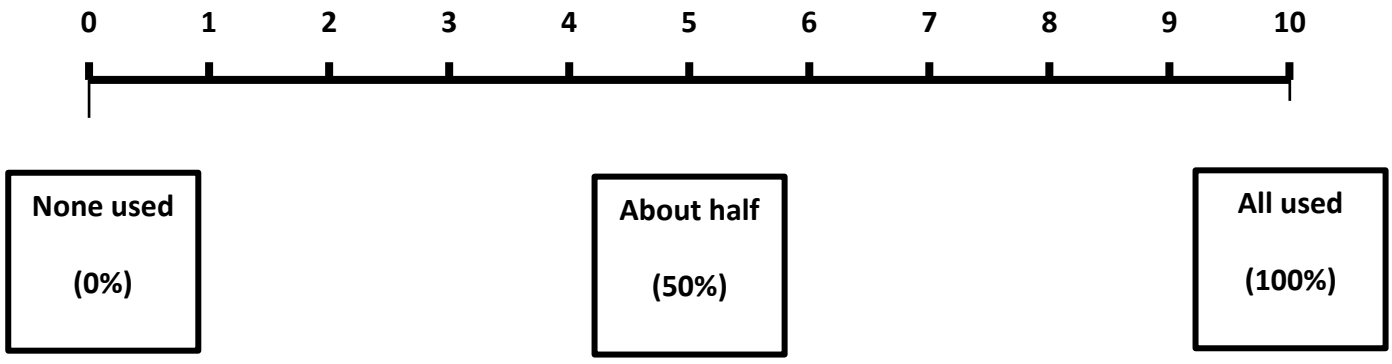
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

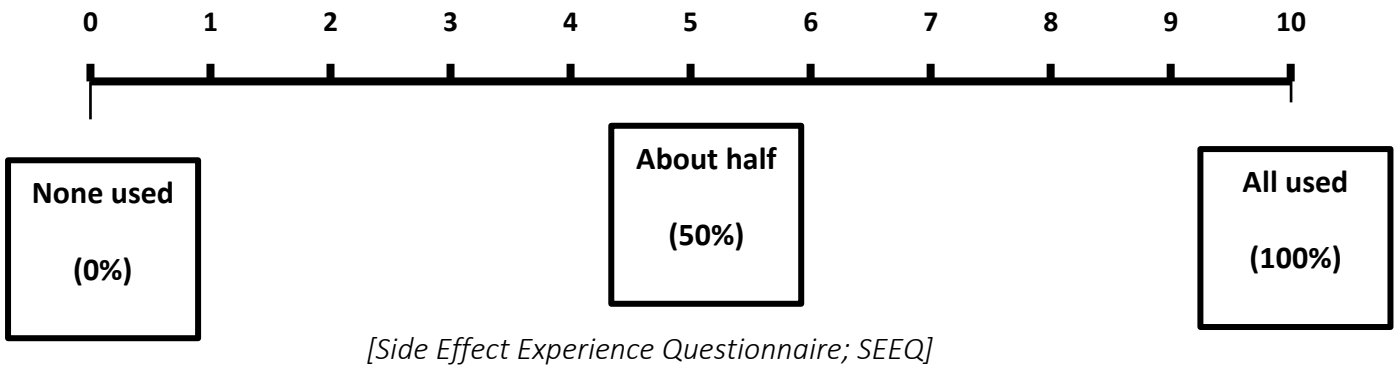
For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

© Professor Rob Horne

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

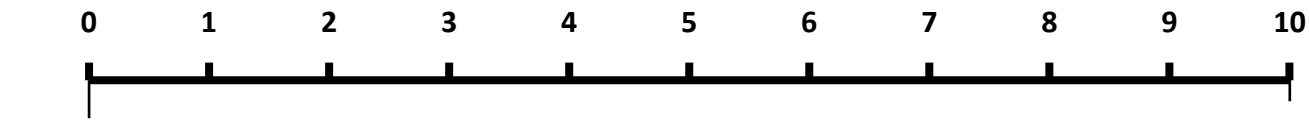
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?

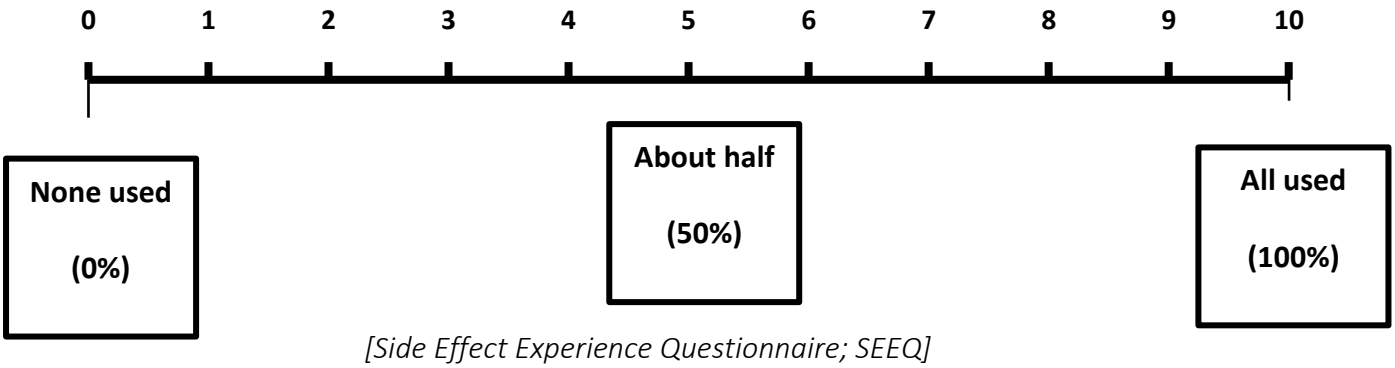


None used (0%)

About half (50%)

All used (100%)

Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

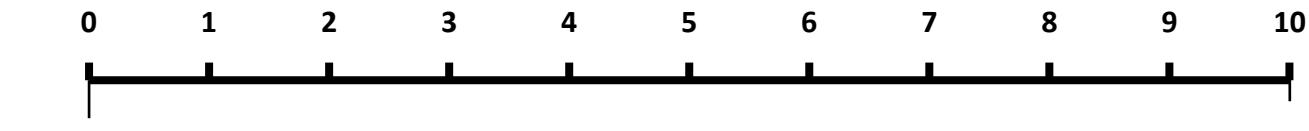
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



None used

(0%)

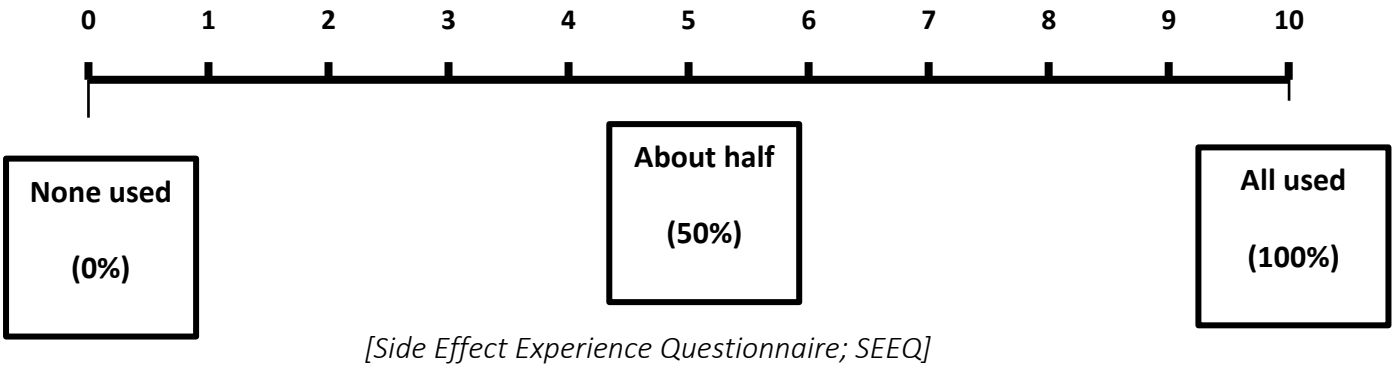
About half

(50%)

All used

(100%)

Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[EQ-5D-5L]

Health questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

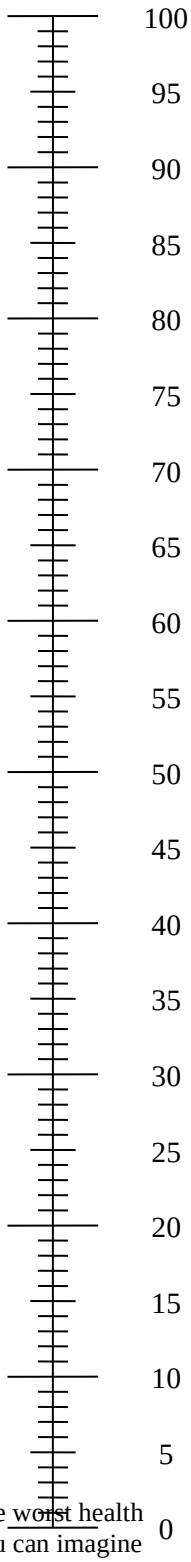
I am slightly anxious or depressed ❑

I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

The best health you can imagine



The worst health you can imagine

YOUR HEALTH TODAY = ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

[Client Service Receipt Inventory; CSRI]

Patient Resource Use Questionnaire

TB Nurse and Support Service - have you had any of the following contact with the healthcare team in the last 2 months? (PLEASE DO NOT INCLUDE VISITS SPECIFICALLY FOR THE IMPACT STUDY)		
Visited TB nurse at the clinic	Yes Number of times _____	No
TB nurse visited you at home	Yes Number of times _____	No
Spoke to TB nurse on the phone	Yes Number of times	No

	_____	
Visited a social worker at their office or in clinic	Yes Number of times _____	No
Social worker visited you at home	Yes Number of times _____	No
Spoke to a social worker on the phone	Yes Number of times _____	No
Visited a support worker at the clinic	Yes Number of times _____	No
Support worker visited you at home	Yes Number of times _____	No
Spoke to a support worker on the phone	Yes Number of times _____	No

Hospital outpatient appointments		
Have you had any hospital outpatient	Yes	No

appointments in the last 2 months other than the TB service?

Oncology (cancer services)	Yes No Number of times _____
Kidney services	Yes No Number of times _____
Liver services	Yes No Number of times _____
Gastroenterology	Yes No Number of times _____
Rheumatology	Yes No Number of times _____
Psychiatry	Yes No Number of times _____
Other specialist outpatient appointments	Yes No Number of times: **1** **2** **3** Please give the details of the first of these visits: Please give the details of the second of these visits:

Please give the details of the third of these visits:

Hospital outpatient procedures.

In the last 2 months have you had any of the following outpatient medical procedures for your TB (other than any asked about in the previous section)?

X ray — Yes / No

Number of x rays

_____

CT scan — Yes / No

Number of CT scans

_____

Ultrasound — Yes / No

Number of ultrasounds

_____

Biopsy — Yes / No

If yes, site of biopsy:

Gland (lymph node)

Number of gland (lymph node) biopsies

_____

Skin

Number of skin biopsies

_____

Lung

Number of lung biopsies

_____

Gut	Number of gut biopsies _____
Back	Number of back biopsies _____
Other	Number of other biopsies (not listed above) _____ Please list type of biopsies:
Have you had any other outpatient tests?	Yes No Number of tests **1** **2** **3** Please give details of the first one of these tests: Please give details of the second one of these tests: Please give details of the third one of these tests:

Hospital admissions and visits to A&E /casualty	
Have you been admitted to hospital or been seen in accident and emergency in the last 2 months?	Yes No
Been to accident and emergency (casualty)	Yes No Number of times _____
Admitted to hospital after visiting A&E	Yes No

(emergency hospital admission)

Number of times

1 **2** **3**

Duration of first visit (in days)

_____

Reason(s) for stay:

_____

Duration of second stay (in days)

_____

Reason(s) for stay:

_____

Duration of third stay (in days)

_____

Reason(s) for stay:

_____

Planned ("elective") hospital admission Yes No

Duration of stay (in days)

_____

	Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____
Overnight hospital stay in intensive care/high dependency	Yes No Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____

Primary care visits - have you had any visits to primary care (i.e. services connected with your GP surgery) in the last 2 months?	
GP visit at the surgery	Yes No Number of times _____

GP visited you at home	Yes Number of times _____	No
Spoke to GP on the phone	Yes Number of times _____	No
Saw practice nurse at the surgery	Yes Number of times _____	No
Spoke to practice nurse on the phone	Yes Number of times _____	No
Saw or spoke to mental health nurse (or community psychiatric nurse)	Yes Number of times _____	No
Attended individual NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes Number of times _____	No
Attended group NHS mental health therapy session (with someone other then a mental	Yes	No

health nurse or

psychiatrist)

Number of times

_____

Saw a non-nhs counsellor or therapist	Yes	No
How much did you pay per visit?	Under £5 £6-10 £11-20 £21-30 £31-40 £41-50 Over £50? Number of times	

_____

Have you used any of the following healthcare support measures in the last 2 months?

Have you used Directly Observed Therapy (DOT) for your TB?	Yes	No
How often do you use this during the week?	Every day Five times a week Three times a week	
When did you start using DOT?		
Have you used Video Observed Therapy (VOT) for your TB?	Yes	No
How often do you use it during the week?	Every day Five times a week Three times a week	
When did you start using VOT?		
Have you had any referrals to a housing	Yes	No

service for housing problems?

Number of times

_____

Have you had any referrals to an immigration service for immigration concerns?	Yes	No

Number of times

_____

Have you had any referrals to an alcohol service for alcohol problems?	Yes	No

Number of times

_____

Have you had any referrals to a drug service for drug problems?	Yes	No

Number of times

_____

Have you had any referrals to a mental health service for mental health problems?	Yes	No

Number of times

_____

Out of pocket costs (eg parking costs, travel to hospital etc)

In the last 2 months have you had to spend any of your own (or your family's) money on treatment or other things related to your TB (eg transport to appointments)	Yes	No

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Or approximate total cost:
Approximate cost per time:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

IMPACT questionnaire booklet

3 month follow-up

[Brief Illness Perception Questionnaire; Brief IPQ]

Your views ABOUT TB

For the following questions, please circle the number that best matches your views:

How much does TB affect your life?										
0 No affect at all	1	2	3	4	5	6	7	8	9	10 Severely affects my life
How long do you think TB will continue?										
0 A very short time	1	2	3	4	5	6	7	8	9	10 Forever
How much control do you feel you have over TB?										
0 Absolutely no control	1	2	3	4	5	6	7	8	9	10 Extreme amount of control
How much do you think treatment can help TB?										
0 Not at all	1	2	3	4	5	6	7	8	9	10 Extremely helpful
How much do you experience symptoms from TB?										
0 No symptoms at all	1	2	3	4	5	6	7	8	9	10 Many severe symptoms
How concerned are you about TB?										
0 Not at all concerned	1	2	3	4	5	6	7	8	9	10 Extremely concerned

How well do you feel you understand TB?
0 1 2 3 4 5 6 7 8 9 10 Don't understand understand very clearly at all
How much does TB affect you emotionally? (E.g. does it make you angry, scared, upset or depressed?)
0 1 2 3 4 5 6 7 8 9 10 Not at Extremely all affected affected emotionally emotionally
How concerned are you about passing TB onto others?
0 1 2 3 4 5 6 7 8 9 10 Not Extremely at all concerned concerned

[Beliefs about Medicines Questionnaire-specific, BMQ-S; Medicine Practicalities scale, MPracS]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about TB Medicines.
- These are statements other people have made about their TB Medicines.

There are no right or wrong answers

We are interested in your personal views

Please show how much you agree or disagree with them by ticking a box:

	Views about TB Medicines	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
N1	My health, at present, depends on TB medicines					
C1	Having to take TB medicines worries me					
N2	My life would be impossible without TB medicines					
C2	I sometimes worry about the long-term effects of TB medicines					
N3	Without TB medicines I would be very ill					

C3	TB medicines are a mystery to me					
	TB treatment has a negative effect on how I see myself					
N4	My health in the future will depend on TB medicines					
C4	TB medicines disrupt my life					
C5	I sometimes worry about becoming too dependent on TB medicines					
N5	TB medicines will cure me of TB					
C6	TB medicines give me unpleasant side effects					
C7	Using TB medicines is embarrassing					
N6R	Missing TB medicines for a day won't matter in the long run					
C8R	I am unlikely to get a bad side effect from TB medicines					
C9	Taking TB medicines has been much worse than expected					
C10R	I have received enough information about TB medicines					
C11	I have to take too many pills each day					
C12	Having to take TB medicines makes me stressed					
	TB treatment has a negative effect on how others see me					
	I am sometimes **too busy** to take TB medicines					
	It is difficult to **remember** to take TB medicines					
	TB medicines are very difficult to **swallow**					

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

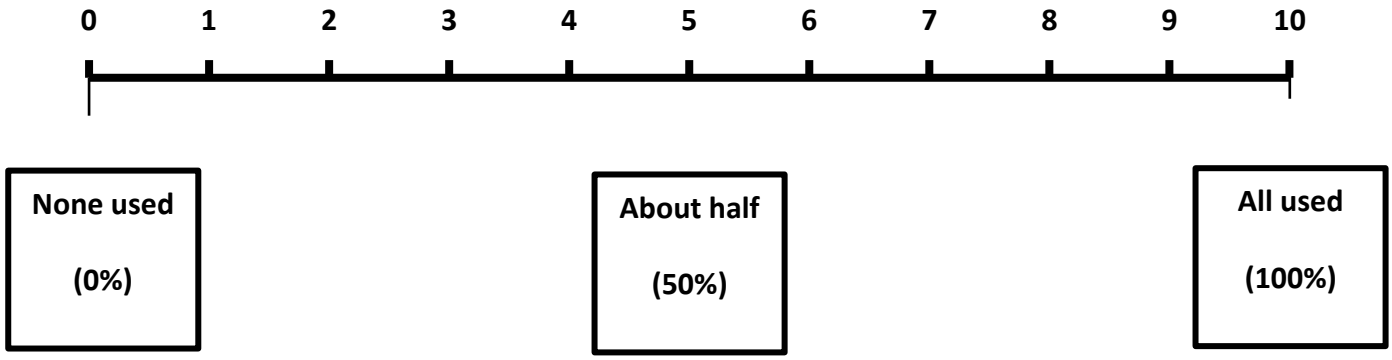
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

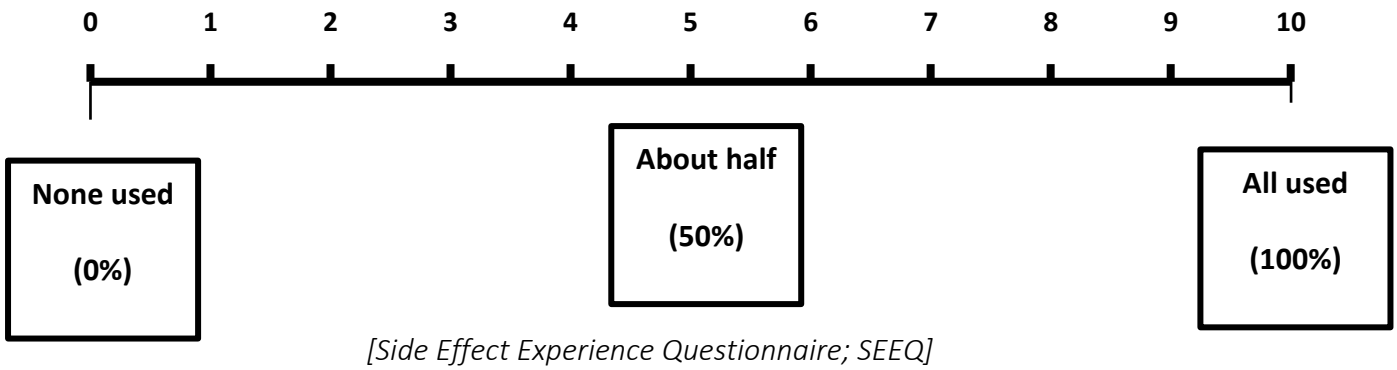
For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

IMPACT questionnaire booklet

4 month follow-up

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

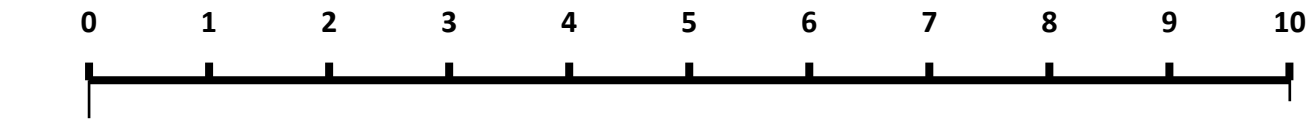
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



None used

(0%)

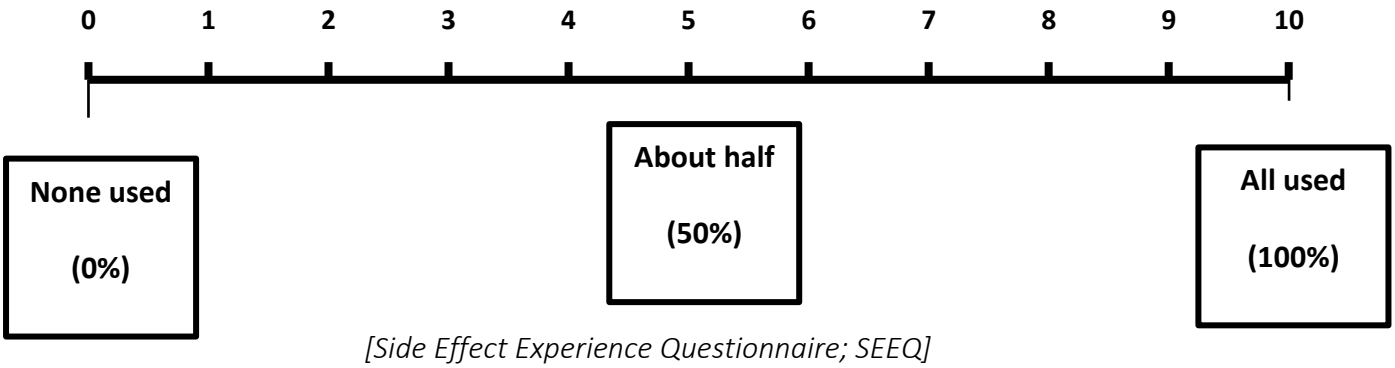
About half

(50%)

All used

(100%)

Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[EQ-5D-5L]

Health questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

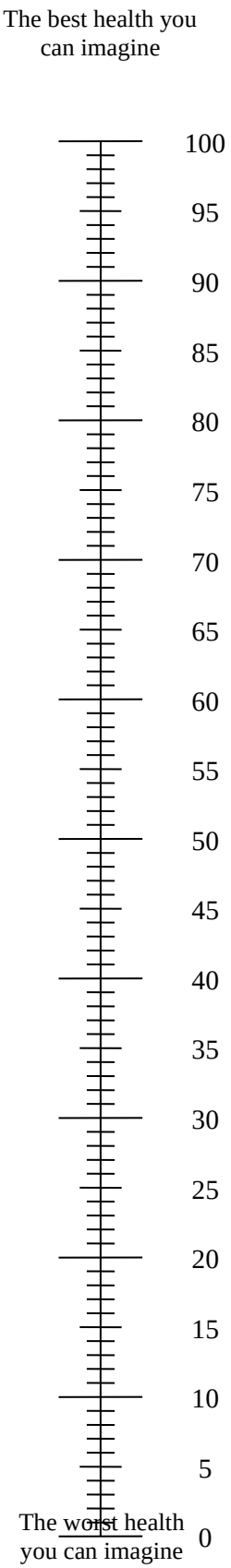
I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

YOUR HEALTH TODAY = ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.



[Client Service Receipt Inventory; CSRI]

Patient Resource Use Questionnaire

TB Nurse and Support Service - have you had any of the following contact with the healthcare team in the last 2 months? (PLEASE DO NOT INCLUDE VISITS SPECIFICALLY FOR THE IMPACT STUDY)		
Visited TB nurse at the clinic	Yes Number of times _____	No
TB nurse visited you at home	Yes Number of times _____	No
Spoke to TB nurse on the phone	Yes Number of times	No

	_____	
Visited a social worker at their office or in clinic	Yes Number of times _____	No
Social worker visited you at home	Yes Number of times _____	No
Spoke to a social worker on the phone	Yes Number of times _____	No
Visited a support worker at the clinic	Yes Number of times _____	No
Support worker visited you at home	Yes Number of times _____	No
Spoke to a support worker on the phone	Yes Number of times _____	No

Hospital outpatient appointments		
Have you had any hospital outpatient	Yes	No

appointments in the last 2 months other than the TB service?

Oncology (cancer services)	Yes No Number of times _____
Kidney services	Yes No Number of times _____
Liver services	Yes No Number of times _____
Gastroenterology	Yes No Number of times _____
Rheumatology	Yes No Number of times _____
Psychiatry	Yes No Number of times _____
Other specialist outpatient appointments	Yes No Number of times: **1** **2** **3** Please give the details of the first of these visits: Please give the details of the second of these visits:

Please give the details of the third of these visits:

Hospital outpatient procedures.

In the last 2 months have you had any of the following outpatient medical procedures for your TB (other than any asked about in the previous section)?

X ray — Yes / No

Number of x rays

_____

CT scan — Yes / No

Number of CT scans

_____

Ultrasound — Yes / No

Number of ultrasounds

_____

Biopsy — Yes / No

If yes, site of biopsy:

Gland (lymph node)

Number of gland (lymph node) biopsies

_____

Skin

Number of skin biopsies

_____

Lung

Number of lung biopsies

_____

Gut	Number of gut biopsies _____
Back	Number of back biopsies _____
Other	Number of other biopsies (not listed above) _____ Please list type of biopsies:
Have you had any other outpatient tests?	Yes No Number of tests **1** **2** **3** Please give details of the first one of these tests: Please give details of the second one of these tests: Please give details of the third one of these tests:

Hospital admissions and visits to A&E /casualty

Have you been admitted to hospital or been seen in accident and emergency in the last 2 months?	Yes No
Been to accident and emergency (casualty)	Yes No Number of times _____
Admitted to hospital after visiting A&E	Yes No

(emergency hospital admission)

Number of times

1 **2** **3**

Duration of first visit (in days)

_____

Reason(s) for stay:

_____

Duration of second stay (in days)

_____

Reason(s) for stay:

_____

Duration of third stay (in days)

_____

Reason(s) for stay:

_____

Planned ("elective") hospital admission Yes No

Duration of stay (in days)

_____

	Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____
Overnight hospital stay in intensive care/high dependency	Yes No Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____

Primary care visits - have you had any visits to primary care (i.e. services connected with your GP surgery) in the last 2 months?	
GP visit at the surgery	Yes No Number of times _____

GP visited you at home	Yes Number of times _____	No
Spoke to GP on the phone	Yes Number of times _____	No
Saw practice nurse at the surgery	Yes Number of times _____	No
Spoke to practice nurse on the phone	Yes Number of times _____	No
Saw or spoke to mental health nurse (or community psychiatric nurse)	Yes Number of times _____	No
Attended individual NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes Number of times _____	No
Attended group NHS mental health therapy session (with someone other then a mental	Yes	No

health nurse or

psychiatrist)

Number of times

_____

Saw a non-nhs counsellor or therapist	Yes	No
How much did you pay per visit?	Under £5 £6-10 £11-20 £21-30 £31-40 £41-50 Over £50? Number of times	

_____

Have you used any of the following healthcare support measures in the last 2 months?

Have you used Directly Observed Therapy (DOT) for your TB?	Yes	No
How often do you use this during the week?	Every day Five times a week Three times a week	
When did you start using DOT?		
Have you used Video Observed Therapy (VOT) for your TB?	Yes	No
How often do you use it during the week?	Every day Five times a week Three times a week	
When did you start using VOT?		
Have you had any referrals to a housing	Yes	No

service for housing problems?

Number of times

_____

Have you had any referrals to an immigration service for immigration concerns? Yes No

Number of times

_____

Have you had any referrals to an alcohol service for alcohol problems? Yes No

Number of times

_____

Have you had any referrals to a drug service for drug problems? Yes No

Number of times

_____

Have you had any referrals to a mental health service for mental health problems? Yes No

Number of times

_____

Out of pocket costs (eg parking costs, travel to hospital etc)

In the last 2 months have you had to spend any of your own (or your family's) money on treatment or other things related to your TB (eg transport to appointments)	Yes	No

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Or approximate total cost:
Approximate cost per time:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

IMPACT questionnaire booklet

5 month follow-up

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

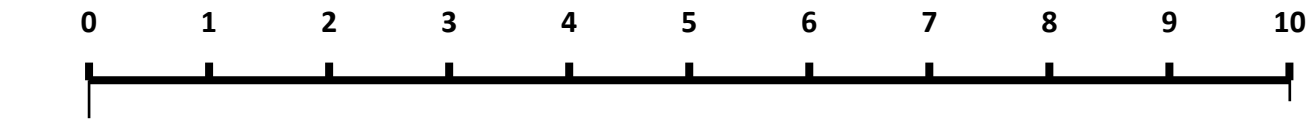
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?

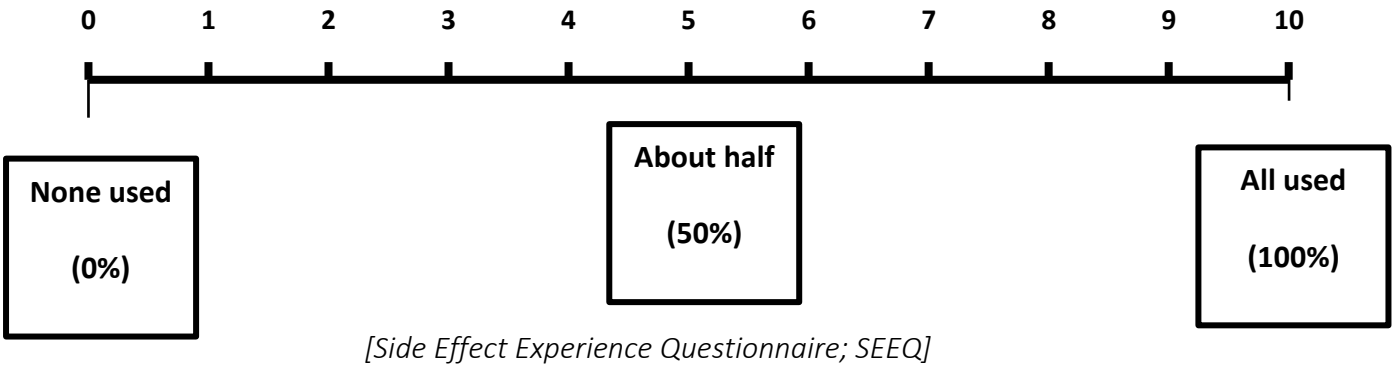


None used (0%)

About half (50%)

All used (100%)

Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[Brief Illness Perception Questionnaire; Brief IPQ]

Your views ABOUT TB

For the following questions, please circle the number that best matches your views:

How much does TB affect your life?										
0 No affect at all	1	2	3	4	5	6	7	8	9	10 Severely affects my life
How long do you think TB will continue?										
0 A very short time	1	2	3	4	5	6	7	8	9	10 Forever
How much control do you feel you have over TB?										
0 Absolutely no control	1	2	3	4	5	6	7	8	9	10 Extreme amount of control
How much do you think treatment can help TB?										
0 Not at all	1	2	3	4	5	6	7	8	9	10 Extremely helpful
How much do you experience symptoms from TB?										
0 No symptoms at all	1	2	3	4	5	6	7	8	9	10 Many severe symptoms
How concerned are you about TB?										
0 Not at all concerned	1	2	3	4	5	6	7	8	9	10 Extremely concerned

How well do you feel you understand TB?
0 1 2 3 4 5 6 7 8 9 10 Don't understand understand very clearly at all
How much does TB affect you emotionally? (E.g. does it make you angry, scared, upset or depressed?)
0 1 2 3 4 5 6 7 8 9 10 Not at Extremely all affected affected emotionally emotionally
How concerned are you about passing TB onto others?
0 1 2 3 4 5 6 7 8 9 10 Not Extremely at all concerned concerned

[Beliefs about Medicines Questionnaire-specific, BMQ-S; Medicine Practicalities scale, MPracS]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about TB Medicines.
- These are statements other people have made about their TB Medicines.

There are no right or wrong answers

We are interested in your personal views

Please show how much you agree or disagree with them by ticking a box:

	Views about TB Medicines	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
N1	My health, at present, depends on TB medicines					
C1	Having to take TB medicines worries me					
N2	My life would be impossible without TB medicines					
C2	I sometimes worry about the long-term effects of TB medicines					
N3	Without TB medicines I would be very ill					

C3	TB medicines are a mystery to me					
	TB treatment has a negative effect on how I see myself					
N4	My health in the future will depend on TB medicines					
C4	TB medicines disrupt my life					
C5	I sometimes worry about becoming too dependent on TB medicines					
N5	TB medicines will cure me of TB					
C6	TB medicines give me unpleasant side effects					
C7	Using TB medicines is embarrassing					
N6R	Missing TB medicines for a day won't matter in the long run					
C8R	I am unlikely to get a bad side effect from TB medicines					
C9	Taking TB medicines has been much worse than expected					
C10R	I have received enough information about TB medicines					
C11	I have to take too many pills each day					
C12	Having to take TB medicines makes me stressed					
	TB treatment has a negative effect on how others see me					
	I am sometimes too busy to take TB medicines					
	It is difficult to remember to take TB medicines					
	TB medicines are very difficult to swallow					

[Beliefs about Medicines Questionnaire-general, BMQ-G; Perceived Sensitivity to Medicines Scale, PSM]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- These are statements that other people have made about medicines in general.

There are no right and wrong answers.

We are interested in your personal views

Please show how much you agree or disagree with them by ticking the appropriate box:

	Views about MEDICINES IN GENERAL	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
BG1	Doctors use too many medicines					
BG2	People who take medicines should stop their treatment for a while every now and again					
BG9	Medicines help many people to live better lives					
BG3	Most medicines are addictive					
BG4	Natural remedies are safer than medicines					
BG11	In most cases the benefits of medicines outweigh the risks					
BG10	In the future medicines will be developed to cure most diseases					
BG6	Most medicines are poisons					
BG5	Medicines do more harm than good					
BG12	Medicines help many people to live longer					
BG7	Doctors place too much trust on medicines					
BG8	If doctors had more time with patients they would prescribe fewer medicines					
PSM1	My body is very sensitive to medicines					
PSM2	My body over-reacts to medicines.					
PSM3	I usually have stronger reactions to medicines than most people					
PSM4	I have had a bad reaction to medicines in the past.					
PSM5	Even very small amounts of medicine can upset my body.					

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

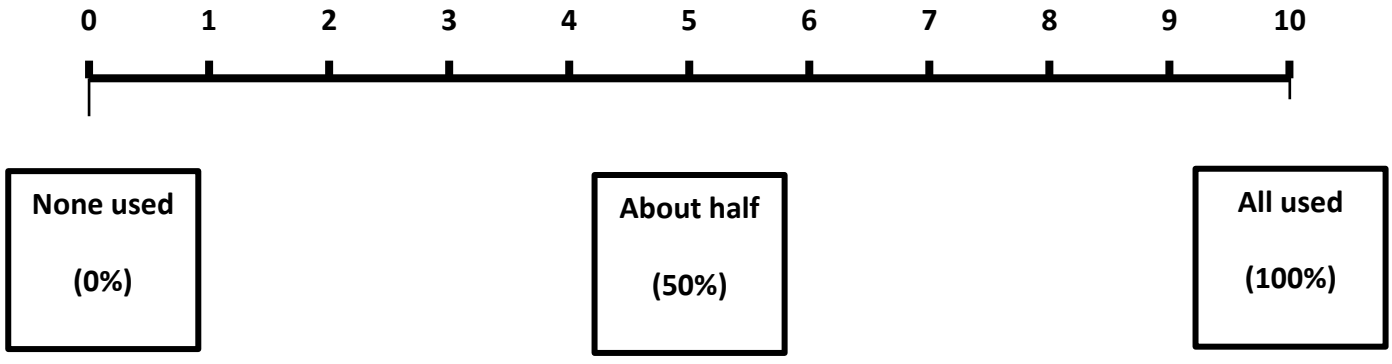
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

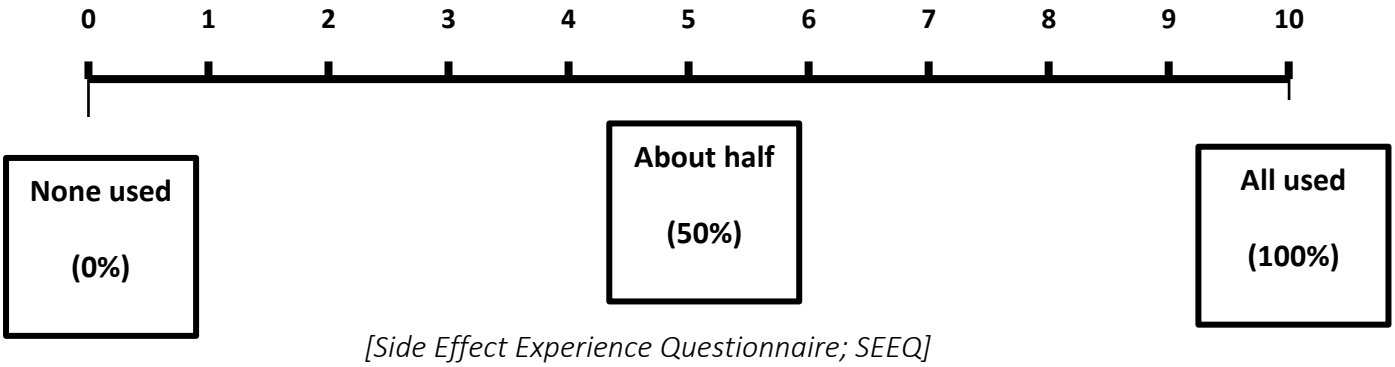
For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

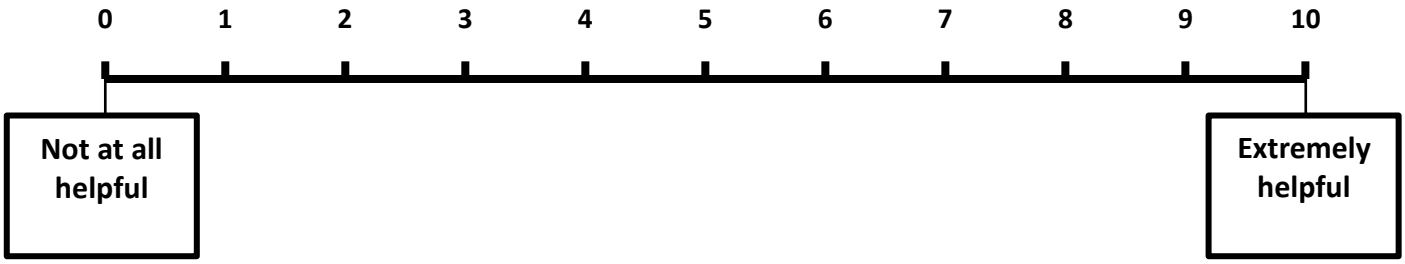
Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

Intervention feedback

Please rate how helpful you found each item by marking an X on each line:

Needs assessment

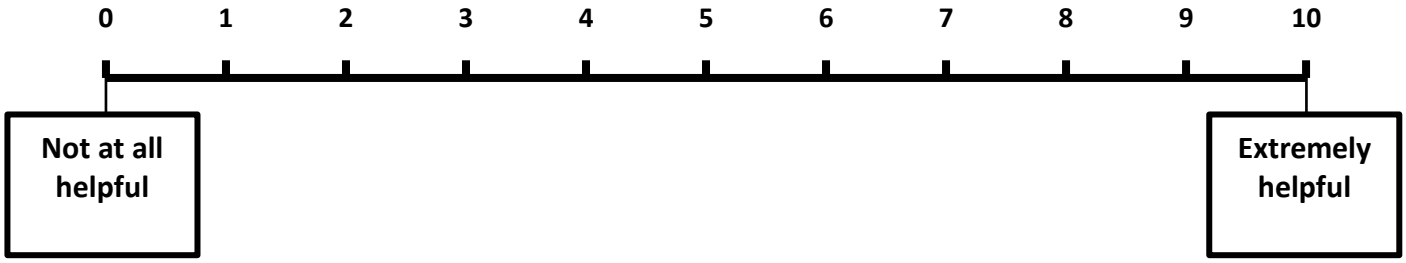
How helpful did you find the needs assessment that the nurse did at the beginning of each session?



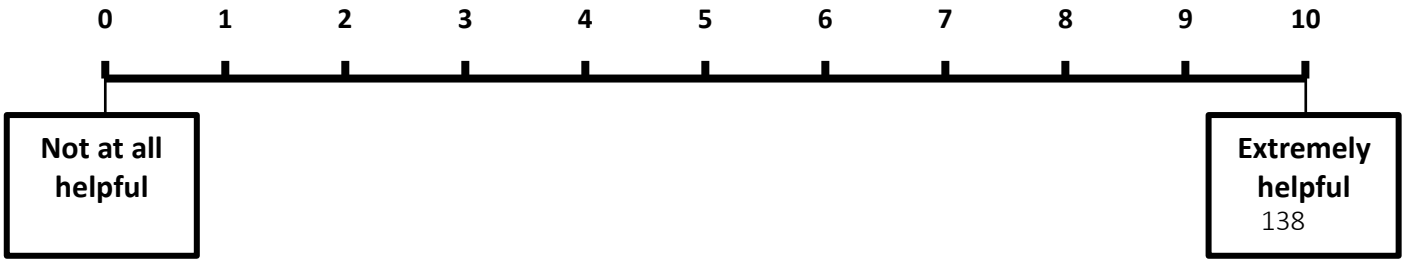
*Do you have any comments about the **needs assessment?** Was there anything that could be changed or improved?*

Patient booklet

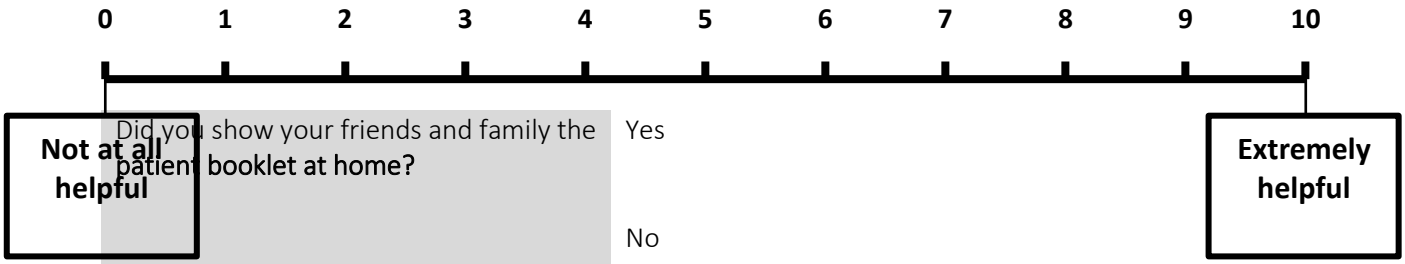
Overall, how helpful did you find the patient booklet?



How helpful did you find the medication diary?



How helpful did you find the creating a medication plan?



Did you show your friends and family the patient booklet at home?

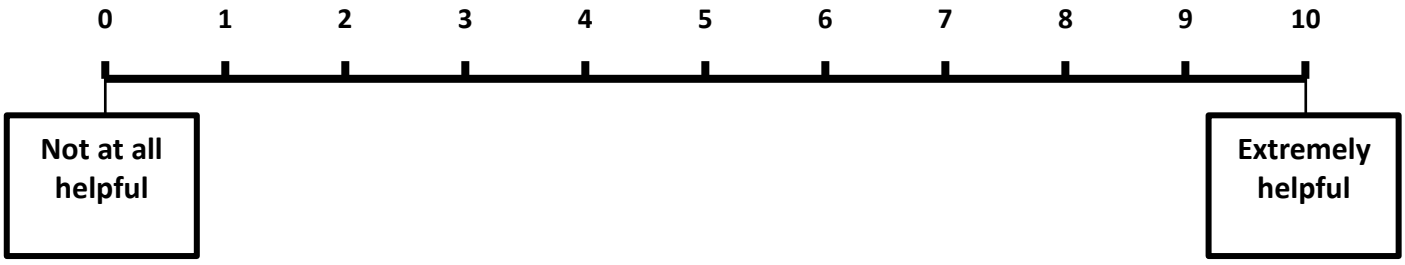
Yes

No

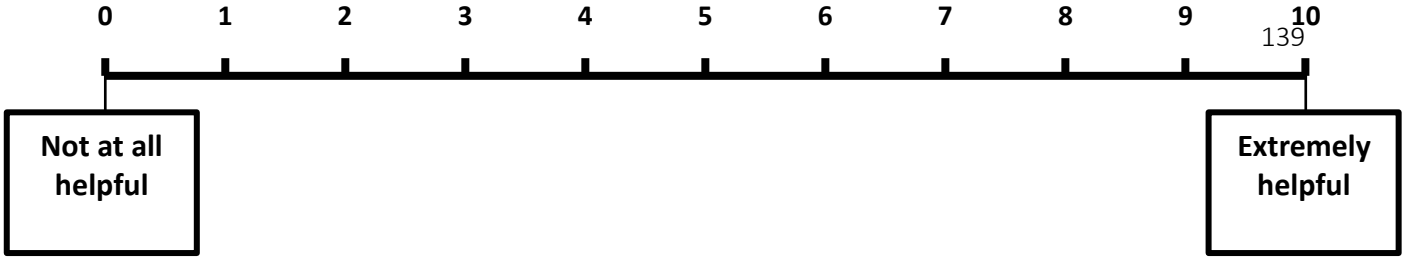
*Do you have any comments about the **patient booklet?** Was there anything that could be changed or improved?*

Phone calls

How helpful did you find the phone call from the nurse at Week 1 of your treatment?



How helpful did you find the phone call from the nurse at Week 6 of your treatment?



*Do you have any comments about the **nurses' phone calls?** Was there anything that could be changed or improved?*

Videos

How helpful did you find the **videos you watched with the nurse?**

Please tick or write your answer for the following questions:

Did you watch the videos at home in your **own time**?	Yes	If yes, how many times did you watch the videos? _____
	No	
Did you show the videos to **others**?	Yes	If yes, how many times did you watch the

videos with others?

_____

No

*Do you have any comments about the **videos?** Was there anything that could be changed or improved?*

[Patient Health Questionniare-4 item, PhQ-4]

PHQ-4

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Little interest or pleasure in doing things	0	1	2	3
4. Feeling down, depressed, or hopeless	0	1	2	3

[EQ-5D-5L]

Health questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

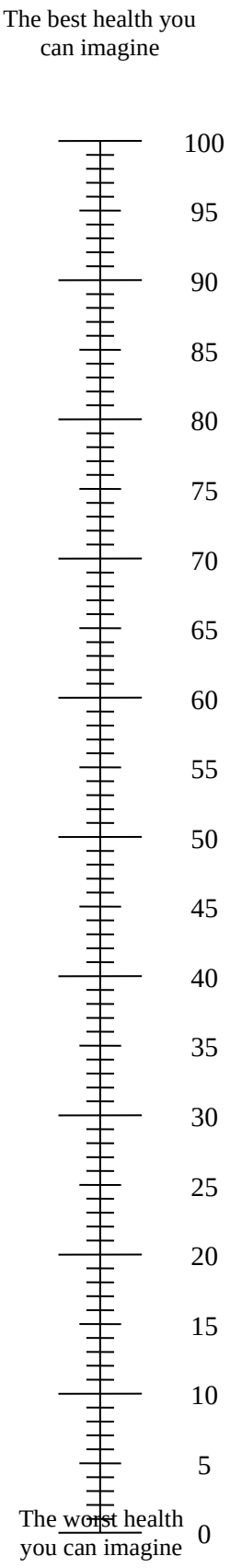
PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑



YOUR HEALTH TODAY = ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

[Client Service Receipt Inventory; CSRI]

Patient Resource Use Questionnaire

TB Nurse and Support Service - have you had any of the following contact with the healthcare team in the last 2 months? (PLEASE DO NOT INCLUDE VISITS SPECIFICALLY FOR THE IMPACT STUDY)		
Visited TB nurse at the clinic	Yes Number of times _____	No

TB nurse visited you at home	Yes Number of times _____	No
Spoke to TB nurse on the phone	Yes Number of times _____	No
Visited a social worker at their office or in clinic	Yes Number of times _____	No
Social worker visited you at home	Yes Number of times _____	No
Spoke to a social worker on the phone	Yes Number of times _____	No
Visited a support worker at the clinic	Yes Number of times _____	No
Support worker visited you at home	Yes Number of times _____	No
Spoke to a support worker on the phone	Yes Number of times _____	No

Hospital outpatient appointments		
Have you had any hospital outpatient appointments in the last 2 months other than the TB service?	Yes	No
Oncology (cancer services)	Yes Number of times _____	No
Kidney services	Yes Number of times _____	No
Liver services	Yes Number of times _____	No
Gastroenterology	Yes Number of times _____	No
Rheumatology	Yes Number of times _____	No
Psychiatry	Yes Number of times _____	No

Other specialist outpatient appointments	Yes No Number of times: **1** **2** **3** Please give the details of the first of these visits: Please give the details of the second of these visits: Please give the details of the third of these visits:

Hospital outpatient procedures.

In the last 2 months have you had any of the following outpatient medical procedures for your TB (other than any asked about in the previous section)?

X ray	Yes No Number of x rays _____
CT scan	Yes No Number of CT scans _____
Ultrasound	Yes No Number of ultrasounds _____
Biopsy If yes, site of biopsy:	Yes No
Gland (lymph node)	Number of gland (lymph node) biopsies _____
Skin	Number of skin biopsies

	_____
Lung	Number of lung biopsies
	_____
Gut	Number of gut biopsies
	_____
Back	Number of back biopsies
	_____
Other	Number of other biopsies (not listed above)
	_____
	Please list type of biopsies:
Have you had any other outpatient tests?	Yes No Number of tests **1** **2** **3** Please give details of the first one of these tests: Please give details of the second one of these tests: Please give details of the third one of these tests:

Hospital admissions and visits to A&E /casualty	
Have you been admitted to hospital or been seen in accident and emergency in the last 2 months?	Yes No

Been to accident and emergency (casualty)	Yes No Number of times _____
Admitted to hospital after visiting A&E (emergency hospital admission)	Yes No Number of times **1 2 3** Duration of first visit (in days) _____ Reason(s) for stay: _____ Duration of second stay (in days) _____ Reason(s) for stay: _____ Duration of third stay (in days) _____ Reason(s) for stay: _____

Planned ("elective") hospital admission	Yes No Duration of stay (in days) _____ Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____
Overnight hospital stay in intensive care/high dependency	Yes No Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____

Primary care visits - have you had any visits to primary care (i.e. services connected with your GP surgery) in the last 2 months?

GP visit at the surgery	Yes Number of times _____	No
GP visited you at home	Yes Number of times _____	No
Spoke to GP on the phone	Yes Number of times _____	No
Saw practice nurse at the surgery	Yes Number of times _____	No
Spoke to practice nurse on the phone	Yes Number of times _____	No
Saw or spoke to mental health nurse (or community psychiatric nurse)	Yes Number of times _____	No
Attended individual NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes	No

	Number of times _____	
Attended group NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes	No
	Number of times _____	
Saw a non-nhs counsellor or therapist	Yes	No
How much did you pay per visit?	Under £5 £6-10 £11-20 £21-30 £31-40 £41-50 Over £50? Number of times _____	

Have you used any of the following healthcare support measures in the last 2 months?		
Have you used Directly Observed Therapy (DOT) for your TB?	Yes	No
How often do you use this during the week?	Every day Five times a week Three times a week	
When did you start using DOT?		
Have you used Video Observed Therapy (VOT) for your TB?	Yes	No

How often do you use it during the week?

Every day

Five times a week

Three times a week

When did you start using VOT?

Have you had any referrals to a housing service for housing problems?

Yes No

Number of times

_____

Have you had any referrals to an immigration service for immigration concerns?

Yes No

Number of times

_____

Have you had any referrals to an alcohol service for alcohol problems?

Yes No

Number of times

_____

Have you had any referrals to a drug service for drug problems?

Yes No

Number of times

_____

Have you had any referrals to a mental health service for mental health problems?

Yes No

Number of times

_____

Out of pocket costs (eg parking costs, travel to hospital etc)

In the last 2 months have you had to spend any of your own (or your family's) money on treatment or other things related to your TB (eg transport to appointments)	Yes	No

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Or approximate total cost:
Approximate cost per time:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

IMPACT questionnaire booklet

Treatment completion or 12 month questionnaire [only for patients continuing treatment past 6 months]

[Brief Illness Perception Questionnaire; Brief IPQ]

Your views ABOUT TB

For the following questions, please circle the number that best matches your views:

How much does TB affect your life?										
0 No affect at all	1	2	3	4	5	6	7	8	9	10 Severely affects my life
How long do you think TB will continue?										
0 A very short time	1	2	3	4	5	6	7	8	9	10 Forever
How much control do you feel you have over TB?										
0 Absolutely no control	1	2	3	4	5	6	7	8	9	10 Extreme amount of control
How much do you think treatment can help TB?										
0 Not at all	1	2	3	4	5	6	7	8	9	10 Extremely helpful
How much do you experience symptoms from TB?										
0 No symptoms at all	1	2	3	4	5	6	7	8	9	10 Many severe symptoms
How concerned are you about TB?										
0 Not at all concerned	1	2	3	4	5	6	7	8	9	10 Extremely concerned

How well do you feel you understand TB? 0 1 2 3 4 5 6 7 8 9 10 Don't understand understand very clearly at all
How much does TB affect you emotionally? (E.g. does it make you angry, scared, upset or depressed?) 0 1 2 3 4 5 6 7 8 9 10 Not at Extremely all affected affected emotionally emotionally
How concerned are you about passing TB onto others? 0 1 2 3 4 5 6 7 8 9 10 Not Extremely at all concerned concerned

[Beliefs about Medicines Questionnaire-specific, BMQ-S; Medicine Practicalities scale, MPracS]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- We would like to ask you about your personal views about TB Medicines.
- These are statements other people have made about their TB Medicines.

There are no right or wrong answers

We are interested in your personal views

Please show how much you agree or disagree with them by ticking a box:

	Views about TB Medicines	**Strongly Agree**	**Agree**	**Uncertain**	**Disagree**	**Strongly Disagree**
N1	My health, at present, depends on TB medicines					
C1	Having to take TB medicines worries me					
N2	My life would be impossible without TB medicines					
C2	I sometimes worry about the long-term effects of TB medicines					
N3	Without TB medicines I would be very ill					

C3	TB medicines are a mystery to me					
	TB treatment has a negative effect on how I see myself					
N4	My health in the future will depend on TB medicines					
C4	TB medicines disrupt my life					
C5	I sometimes worry about becoming too dependent on TB medicines					
N5	TB medicines will cure me of TB					
C6	TB medicines give me unpleasant side effects					
C7	Using TB medicines is embarrassing					
N6R	Missing TB medicines for a day won't matter in the long run					
C8R	I am unlikely to get a bad side effect from TB medicines					
C9	Taking TB medicines has been much worse than expected					
C10R	I have received enough information about TB medicines					
C11	I have to take too many pills each day					
C12	Having to take TB medicines makes me stressed					
	TB treatment has a negative effect on how others see me					
	I am sometimes too busy to take TB medicines					
	It is difficult to remember to take TB medicines					
	TB medicines are very difficult to swallow					

[Beliefs about Medicines Questionnaire-general, BMQ-G; Perceived Sensitivity to Medicines Scale, PSM]

Your views about

TB MEDICINES PRESCRIBED FOR YOU

- These are statements that other people have made about medicines in general.

There are no right and wrong answers.

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Please show how much you agree or disagree with them by ticking the appropriate box:

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BG2	People who take medicines should stop their treatment for a while every now and again					
BG9	Medicines help many people to live better lives					
BG3	Most medicines are addictive					
BG4	Natural remedies are safer than medicines					
BG11	In most cases the benefits of medicines outweigh the risks					
BG10	In the future medicines will be developed to cure most diseases					
BG6	Most medicines are poisons					
BG5	Medicines do more harm than good					
BG12	Medicines help many people to live longer					
BG7	Doctors place too much trust on medicines					
BG8	If doctors had more time with patients they would prescribe fewer medicines					
PSM1	My body is very sensitive to medicines					
PSM2	My body over-reacts to medicines.					
PSM3	I usually have stronger reactions to medicines than most people					
PSM4	I have had a bad reaction to medicines in the past.					
PSM5	Even very small amounts of medicine can upset my body.					

[Medication Adherence Report Scale; MARS-5]

Questions about using

YOUR MEDICINES

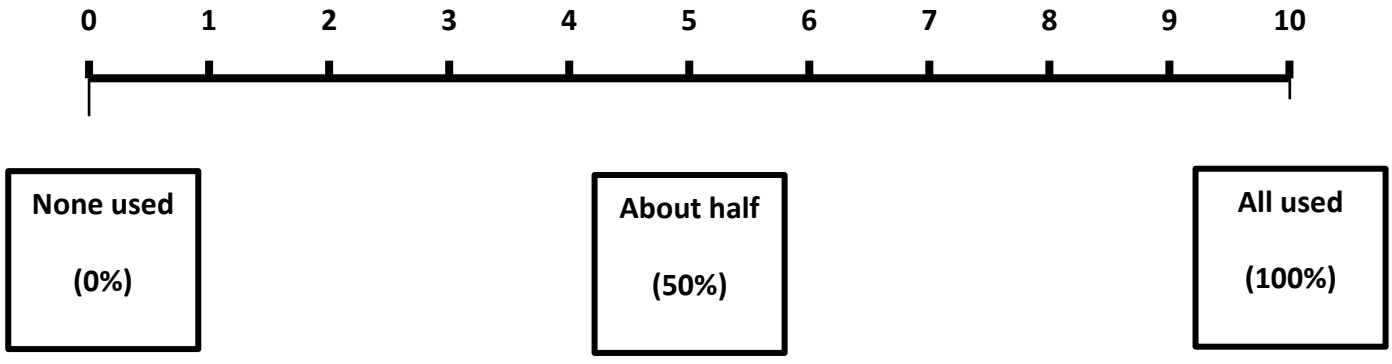
- Many people use medicines in their own way.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you used your medicines over the last few months

Here are some ways in which people have said that they use their medicines

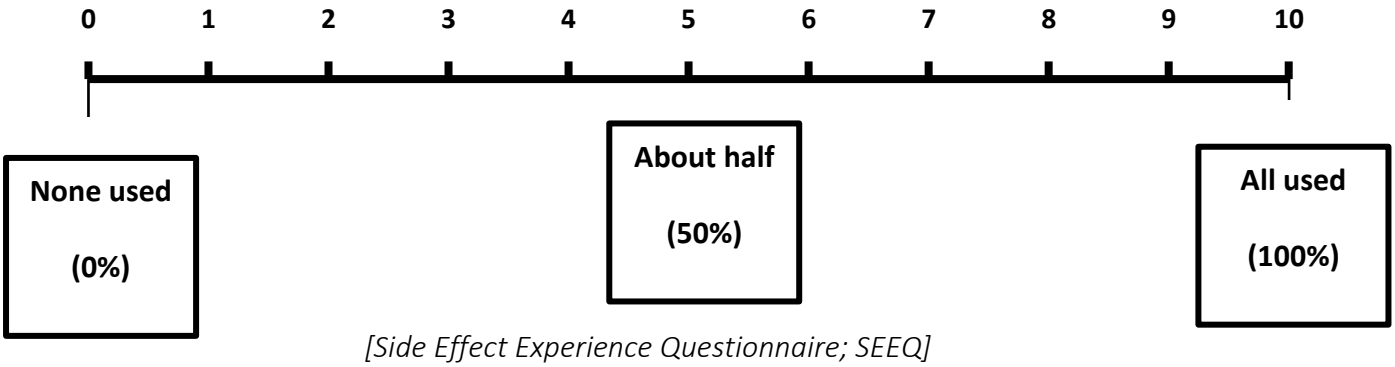
For each of the statements, please tick the box which best applies to you:

	How you used your medicines	Always	Often	Sometimes	Rarely	Never
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

Over the last **WEEK** how much of your medicine have you used?



Over the last MONTH how much of your medicine have you used?



[Side Effect Experience Questionnaire; SEEQ]

Your experience of

MEDICATION SIDE-EFFECTS

Please circle yes or no for each item to say if you are experiencing that symptom as a side effect of your TB medicine:

Are you currently experiencing this symptom as a side-effect of your TB medicine?		
Headache	**Yes**	**No**
Fatigue	**Yes**	**No**
Stomach upsets	**Yes**	**No**
Nausea (feeling sick)	**Yes**	**No**
Vomiting	**Yes**	**No**
Diarrhoea	**Yes**	**No**
Chills or fever	**Yes**	**No**
Dizziness	**Yes**	**No**
Joint pain	**Yes**	**No**
Skin rashes and itchiness	**Yes**	**No**
Pins and needles in the fingers or toes	**Yes**	**No**
Bodily fluids turn orange	**Yes**	**No**
Yellowing of the skin or eyes	**Yes**	**No**
Visual disturbances (blurry vision)	**Yes**	**No**
Red and peeling skin on lips or inside mouth	**Yes**	**No**

[Patient Health Questionniare-4 item, PhQ-4]

PHQ-4

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Little interest or pleasure in doing things	0	1	2	3
4. Feeling down, depressed, or hopeless	0	1	2	3

[EQ-5D-5L]

Health questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

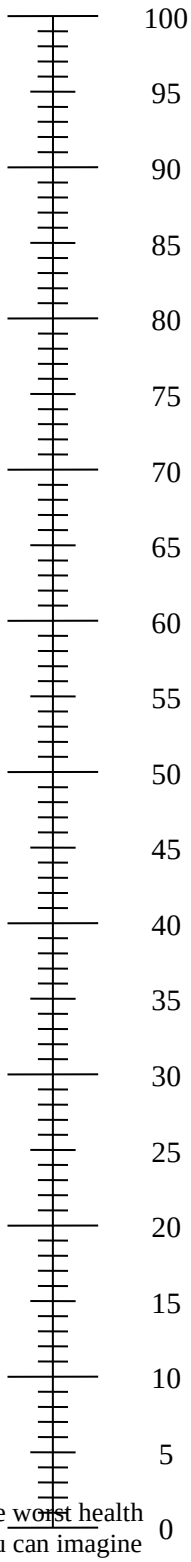
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

The best health you can imagine



The worst health you can imagine

YOUR HEALTH TODAY = ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

[Client Service Receipt Inventory; CSRI]

Patient Resource Use Questionnaire

TB Nurse and Support Service - have you had any of the following contact with the healthcare team in the last 2 months? (PLEASE DO NOT INCLUDE VISITS SPECIFICALLY FOR THE IMPACT STUDY)		
Visited TB nurse at the clinic	Yes Number of times _____	No

TB nurse visited you at home	Yes Number of times _____	No
Spoke to TB nurse on the phone	Yes Number of times _____	No
Visited a social worker at their office or in clinic	Yes Number of times _____	No
Social worker visited you at home	Yes Number of times _____	No
Spoke to a social worker on the phone	Yes Number of times _____	No
Visited a support worker at the clinic	Yes Number of times _____	No
Support worker visited you at home	Yes Number of times _____	No
Spoke to a support worker on the phone	Yes Number of times _____	No

Hospital outpatient appointments		
Have you had any hospital outpatient appointments in the last 2 months other than the TB service?	Yes	No
Oncology (cancer services)	Yes Number of times _____	No
Kidney services	Yes Number of times _____	No
Liver services	Yes Number of times _____	No
Gastroenterology	Yes Number of times _____	No
Rheumatology	Yes Number of times _____	No
Psychiatry	Yes Number of times _____	No

Other specialist outpatient appointments	Yes No Number of times: **1** **2** **3** Please give the details of the first of these visits: Please give the details of the second of these visits: Please give the details of the third of these visits:

Hospital outpatient procedures.

In the last 2 months have you had any of the following outpatient medical procedures for your TB (other than any asked about in the previous section)?

X ray	Yes No Number of x rays _____
CT scan	Yes No Number of CT scans _____
Ultrasound	Yes No Number of ultrasounds _____
Biopsy If yes, site of biopsy:	Yes No
Gland (lymph node)	Number of gland (lymph node) biopsies _____
Skin	Number of skin biopsies

_____

Lung — Number of lung biopsies

_____

Gut — Number of gut biopsies

_____

Back — Number of back biopsies

_____

Other — Number of other biopsies (not listed above)

_____

Please list type of biopsies:

Have you had any other outpatient tests? — Yes No

Number of tests

1 **2** **3**

Please give details of the first one of these tests:

Please give details of the second one of these tests:

Please give details of the third one of these tests:

Hospital admissions and visits to A&E /casualty

Have you been admitted to hospital or been seen in accident and emergency in the last 2 months? — Yes No

Been to accident and emergency (casualty)	Yes No Number of times _____
Admitted to hospital after visiting A&E (emergency hospital admission)	Yes No Number of times **1 2 3** Duration of first visit (in days) _____ Reason(s) for stay: _____ Duration of second stay (in days) _____ Reason(s) for stay: _____ Duration of third stay (in days) _____ Reason(s) for stay: _____

Planned ("elective") hospital admission	Yes Duration of stay (in days) _____ Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____	No
Overnight hospital stay in intensive care/high dependency	Yes Number of times _____ Duration of stay (in days) _____ Reason(s) for stay: _____	No

Primary care visits - have you had any visits to primary care (i.e. services connected with your GP surgery) in the last 2 months?

GP visit at the surgery	Yes Number of times _____	No
GP visited you at home	Yes Number of times _____	No
Spoke to GP on the phone	Yes Number of times _____	No
Saw practice nurse at the surgery	Yes Number of times _____	No
Spoke to practice nurse on the phone	Yes Number of times _____	No
Saw or spoke to mental health nurse (or community psychiatric nurse)	Yes Number of times _____	No
Attended individual NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes	No

	Number of times _____	
Attended group NHS mental health therapy session (with someone other then a mental health nurse or psychiatrist)	Yes	No
	Number of times _____	
Saw a non-nhs counsellor or therapist	Yes	No
How much did you pay per visit?	Under £5 £6-10 £11-20 £21-30 £31-40 £41-50 Over £50? Number of times _____	

Have you used any of the following healthcare support measures in the last 2 months?		
Have you used Directly Observed Therapy (DOT) for your TB?	Yes	No
How often do you use this during the week?	Every day Five times a week Three times a week	
When did you start using DOT?		
Have you used Video Observed Therapy (VOT) for your TB?	Yes	No

How often do you use it during the week?

Every day

Five times a week

Three times a week

When did you start using VOT?

Have you had any referrals to a housing service for housing problems?

Yes No

Number of times

_____

Have you had any referrals to an immigration service for immigration concerns?

Yes No

Number of times

_____

Have you had any referrals to an alcohol service for alcohol problems?

Yes No

Number of times

_____

Have you had any referrals to a drug service for drug problems?

Yes No

Number of times

_____

Have you had any referrals to a mental health service for mental health problems?

Yes No

Number of times

_____

Out of pocket costs (eg parking costs, travel to hospital etc)

In the last 2 months have you had to spend any of your own (or your family's) money on treatment or other things related to your TB (eg transport to appointments)	Yes	No

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Or approximate total cost:
Approximate cost per time:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

Item:

Number of times:
Approximate cost per time:
Or approximate total cost:

APPENDIX 5: Data Management and Data Flow Charts

Case Report Forms

Participants at the study sites will be assigned a study number and paper Case Report Forms (CRFs) will be completed at the study sites, anonymised and stored according to General Data Protection Regulations (GDPR) and the University and Trust Information Governance procedures.

Only study number will be entered onto the CRF; patient-identifiable data will be kept separately on the enrolment log and filed in the Site File at the site.

The completed CRFs will be signed off by the Principal Investigator at the site. Trial specific documents held at site will be stored in a secure location and access will be restricted and limited to nominated research staff recorded on the delegation log.

The CRF has been designed to record all study data in a standardised fashion and in the format and order required by the study protocol. This has been reviewed by the sponsor and approved by the Chief Investigator and Statistician

Data will then be entered on to the eCRF for the Pilot and Evaluation phases of the study (a password protected REDCapdatabase), the anonymised data will then be analysed by the research team.

The excel database will:

- be password protected with user accounts specific for staff trained to use the database as per the delegation log.
- be single data entry with validation checks and source data verification against the data in the database.
- e ability to add queries to the electronic dataset to assist with follow-up of missing data or other issues.
- record a full audit log of all changes to data
- maintain an audit trail of any change or correction to the case report form or the electronic database. Data will be generated, recorded and reported in compliance with the protocol and with Good Clinical Practice. Free text variables will also be allowed to describe, for example, deviations from protocol.

All stored CRFs will be kept in a secure environment at UCL and in the sites. This will include a locked filing cabinet in a locked room, only accessible by authorised personnel. The key to the participant code list will be kept separately to these documents, in a secure location at the site.

The eCRF will only be accessed by staff authorised to do so on the delegation log, at each site. The Principal Investigator at each study site will be responsible for data security at each study site and the Chief Investigator will have overall responsibility to ensure that all data is stored and processed in accordance with General Data Protection Regulations and UCL Information Governance. Only

anonymised aggregated research outputs (i.e. analysed data in the form of research papers, reports and statistical analyses) will be shared between study sites.

Security

Data security will be maintained through the use of password protection at computer and database levels for nominated staff only, recorded on the delegation log by the CI.

This database will be held on a secure drive on a NHS server. All data will be stored in accordance with General Data Protection Regulations and the UCL information security policy and trust information governance policies. The drives are backed up regularly, allowing data retrieval in the event of data loss.

Data Archiving

Archiving of data will be authorised by the sponsor following submission of the end study report. The CI is responsible for the secure archiving of all essential trial documents at the coordinating centre and the trial database as per UCL policy. These will be archived for a minimum of 15 years after the end of the study.

The PI or their delegate at the site is responsible for the secure archiving of essential site trial documents as per local trust policy arrangements. Destruction of any essential documents will require authorisation from the sponsor.

Figure 1 Data flow for Formative Research

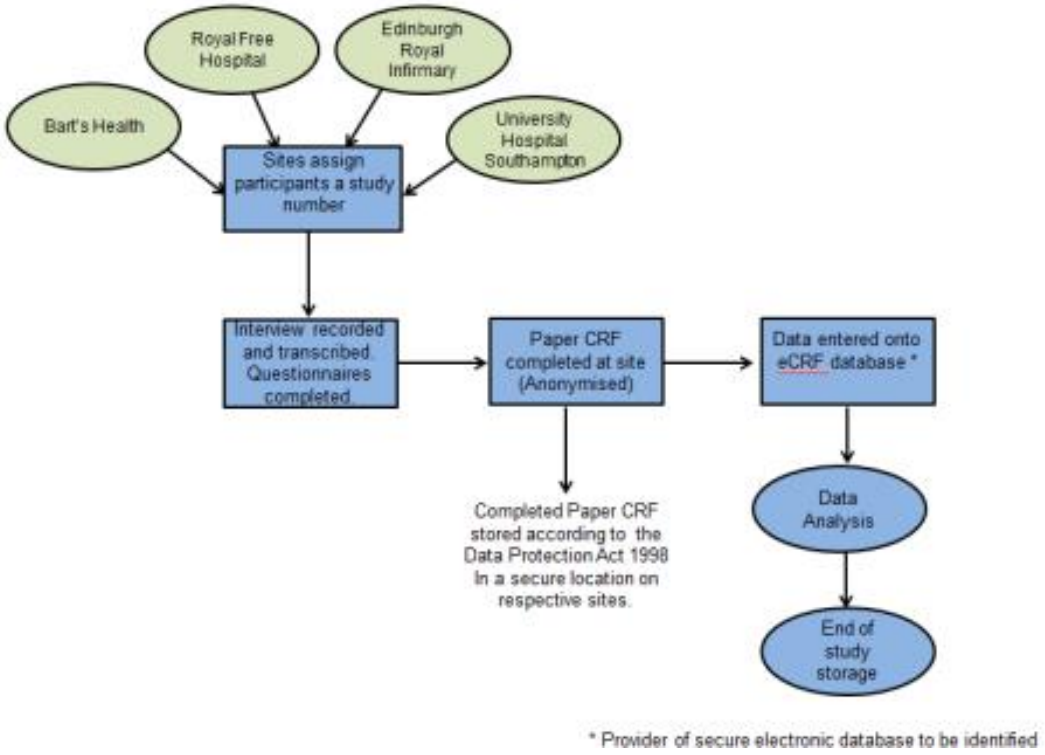
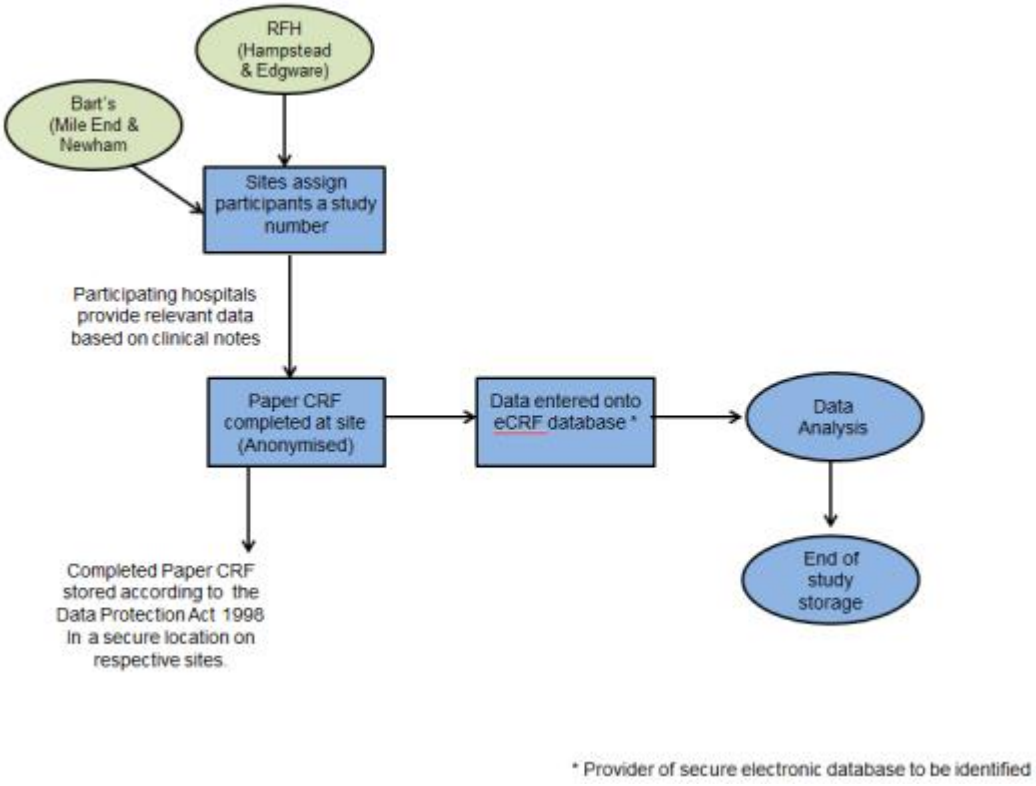


Figure 2 Data flow for Randomised Cluster Control Trial



APPENDIX 6: TB Needs Assessment Baseline and Follow-up

Confidential

TNA Baseline

Please complete the survey below.

Thank you!

Patient ID Number	_____
Demographic	
Older Age (65+)	◯ Yes ◯ No
Child, adolescent or young adult (up to age 25)	◯ Yes ◯ No (Up to 25)
Medical factors	
Previous TB treatment or diagnosis (including latent TB)	◯ Yes ◯ No ◯ Don't know
Co-morbidities	◯ None ◯ Chronic renal disease ◯ Chronic liver disease ◯ Diabetes ◯ HIV ◯ Chemotherapy ◯ Transplant ◯ Other
Other, please specify	_____
Unable to manage their current co-morbidities (eg medicines management or following health advice)	◯ Yes ◯ No
Complex TB type (extensive pulmonary, CNS or Disseminated)	◯ Yes ◯ No
Known drug resistance	◯ Yes ◯ No
Patient has a history of missed previous appointments with the TB service or for another chronic condition	◯ Yes ◯ No ◯ N/a or unknown
Previous non-adherence to TB treatment or treatment for a chronic condition	◯ Yes ◯ No ◯ N/a or Unknown

Practical/Communication Factors	
Patient has a physical barrier to taking medication (eg difficulty swallowing pills, opening tablets)	◯ Yes ◯ No
Patient is too ill or frail to administer treatment themselves	◯ Yes ◯ No
Patient is unable to travel to clinic independently (eg due to mobility issue or other mental health/health issue)	◯ Yes ◯ No
Patient is unable to pay costs for travel to clinic	◯ Yes ◯ No
Needs interpreter (unable to communicate in English)	◯ Yes ◯ No
Language	_____
Sensory Impairment (eg visual impairment, hearing Impairment, other sensory issues)	◯ Yes ◯ No
If yes, please specify	◯ Visual impairment ◯ Hearing Impairment ◯ Other sensory issues
Cognitive or memory disorder (eg autism, dementia, learning disability)	◯ Yes ◯ No

Structural Factors	
Patient has financial concerns (eg unemployment, insecure employment status, reliance on welfare benefits, no recourse to public funds etc)	◯ Yes ◯ No
Urgent housing problem (no fixed abode)	◯ Yes ◯ No
If no fixed abode, do they have recourse to public funds (eg access to welfare benefits)?	◯ Yes ◯ No
Other housing problem (eg concerns about covering rent, 'sofa surfing', history of homelessness in past 5 years or other unstable housing issue)	◯ Yes ◯ No
Immigration concerns (ie worries about right to stay in the UK)	◯ Yes ◯ No
History of prison in last 5 years	◯ Yes ◯ No

Psychosocial factors	
Current alcohol problem (affects person's daily functioning)	◯ Yes ◯ No
Current drug problem (affects person's daily functioning)	◯ Yes ◯ No
History of mental health problems (Anxiety disorder Depressive disorder, Personality disorder, Psychosis)	◯ Yes ◯ No
Patient/nurse has current concerns about the patient's mental health	◯ Yes ◯ No
Lack of treatment support OUTSIDE THE MEDICAL TEAM (ie people who can support the patient during their treatment)	◯ Yes ◯ No
Named support person details	◯ Spouse ◯ Parent ◯ Sibling ◯ Other family member ◯ Friend ◯ Other
Patient has doubts about need for treatment or their diagnosis	◯ Yes ◯ No ◯ Declined to say
Patient is worried about the response from their family/community to their TB diagnosis	◯ Yes ◯ No ◯ Declined to say
Patient is worried about storing medicines/taking medicines in front of others	◯ Yes ◯ No ◯ Declined to say
Patient is worried about remembering to take treatment	◯ Yes ◯ No ◯ Declined to say

TNA Follow Up

Please complete the survey below.

Thank you!

Patient ID Number	_____
Patient has missed any recent visits with the TB service?	◯ Yes ◯ No ◯ N/a or unknown
Medical factors	
Non adherence identified (Pill Count, Self Report, Patient booklet, Urine testing, Patient does not understand medication regimen)	◯ Yes ◯ No
Any new co-morbidities	◯ Yes ◯ No
New Co-morbidity Type	◯ None ◯ Chronic renal disease ◯ Chronic liver disease ◯ Diabetes ◯ HIV ◯ Chemotherapy ◯ Transplant ◯ Other
Other, please specify	_____
New indications of complex TB (extensive pulmonary, CNS or Disseminated)	◯ Yes ◯ No
New diagnosis of drug resistance	◯ Yes ◯ No
Slow sputum culture conversion (culture still positive >2 months after treatment started for drug sensitive TB)	◯ Yes ◯ No
Clinical deterioration (eg symptom increase, worsening chest x-ray, paradoxical reaction to treatment)	◯ Yes ◯ No

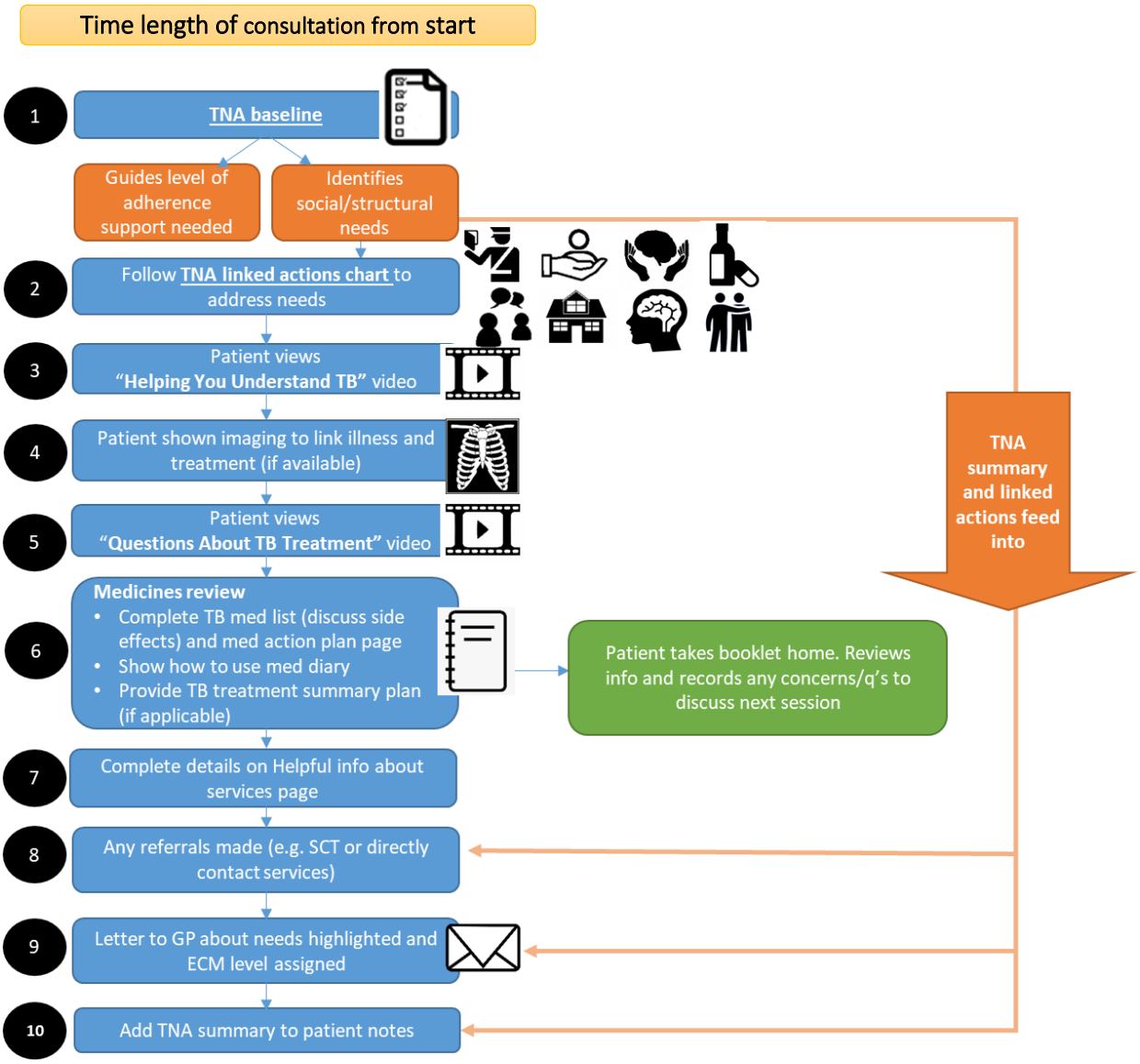
Practical/Communication Factors	
Any changes to physical barriers in taking medication since last visit (eg difficulty swallowing pills, opening tablets, symptoms burden, frailty)?	◯ Yes ◯ No
Patient is now too ill or frail to administer treatment themselves since last visit	◯ Yes ◯ No

Structural factors	
Patient has new financial concerns (eg changes to employment status, welfare benefits etc) since last visit	◯ Yes ◯ No
Patient is now unable to travel to clinic independently	◯ Yes ◯ No
Patient is now unable to pay costs for travel to clinic	◯ Yes ◯ No
New urgent housing problem (no fixed abode)	◯ Yes ◯ No
New other type of housing problem since last visit- no immediate action (eg concerns about covering rent week to week, unstable housing etc)	◯ Yes ◯ No
New immigration concerns since last visit	◯ Yes ◯ No

Psychosocial factors	
New alcohol problem (affecting person's daily functioning)	◯ Yes ◯ No
New drug problem (affecting person's daily functioning)	◯ Yes ◯ No
Patient/nurse has new concerns about changes in mental health since last visit	◯ Yes ◯ No
Patient reports changes/increased isolation from family and friends since last visit	◯ Yes ◯ No
Named support person is no longer providing support to the patient	◯ Yes ◯ No
Patient has new or ongoing doubts about need for treatment or diagnosis since last visit	◯ Yes ◯ No ◯ Declined to say
Patient has new or ongoing worries about the response from their family/community to their TB diagnosis	◯ Yes ◯ No ◯ Declined to say

Patient has new or ongoing worries about remembering to take their treatment	◯ Yes ◯ No
Patient has new or ongoing worries about storing medicines/taking medicines in front of others	◯ Yes ◯ No ◯ Declined to say
Patient has experienced severe side effects that are affecting their daily functioning since their last visit?	◯ Yes ◯ No
Patient become anxious/overly concerned about developing side effects since their last visit	◯ Yes ◯ No

APPENDIX 7: Intervention Session Structure Baseline



APPENDIX 8: Patient Information Booklet (text to be designed and printed)

IMPACT

Patient Booklet

How this booklet can help you

This booklet is designed to help you through your TB treatment. This booklet has three sections:

Section 1: Information about TB and TB treatment

This section has helpful information about TB and its treatment. It explains why TB treatment is needed and answers common treatment concerns, such as how to manage **side effects** and what you can expect during your care. There are also links to videos which you can watch and share with others.

Section 2: Living with TB

This section gives tips on how to talk to others about TB and has advice on coping with TB and managing treatment.

Section 3: My TB Medicines

This section includes a list of your medicines, and a space to create a plan for taking them. It also has a diary to help you keep track of your treatment and record any issues.

How to use this booklet

This booklet is for *you*. It is designed so you can read the different parts as you need them. There are also spaces to write down your thoughts, questions, and concerns about TB and treatment wherever you see this sign.

You can then choose whether you want to share these with your TB team.

There is a list at the back of the booklet of new words you may hear during your care. These words are highlighted in bold through the booklet.

Please bring this booklet with you whenever you visit a member of your TB team (a nurse, a doctor, a pharmacist, or other health professional). Your TB team can then discuss your questions and concerns, and check how you are doing with your treatment.

Don't be afraid to ask…

Sometimes, people worry about asking questions as they don't want to bother their TB team. The TB team are there to support you. Sharing how you feel means they can help you manage your treatment.

Friends and Family

We encourage you to involve your friends and family in your care, and share this booklet with them if you wish. They are welcome to come along with you to the TB clinic so they can learn more about TB and treatment.

What this booklet contains

Section 1:

Information about

TB and TB treatment

About TB

What is TB?

- TB is an infection caused by **bacteria.** It can lead to long-term damage to the body.
- TB is usually found in the lungs (**pulmonary TB**), but it can affect any part of the body (**extra-pulmonary TB**).
- Once inside the body, the number of TB bacteria can increase. These can also spread to other parts of the body. As this happens, you may feel more unwell.
- **Symptoms** of TB might include coughing, tiredness, losing weight, sweats, and fevers.
- Some people can develop pain or swellings in the neck or other parts of the body where TB is causing disease

Video link

Please watch the video you saw in clinic with the nurse again here. Showing this to family and friends may also be helpful.

How did I get TB?

- Anyone can get TB!
- TB is found all over the world, including here in the UK.
- TB is passed from person to person through the air. If someone with TB in the lungs coughs or sneezes, the bacteria can get into the air. Other people may then breathe in the bacteria and become infected.
- You can become unwell years after coming into contact with TB. This makes it hard to know when you may have caught it

See page XX for new words you may hear during your treatment.

How will TB affect me and others?

- TB is a very serious infection. Without treatment, people can die from TB.
- The number of TB bacteria in your body will increase, they can cause damage, and can spread to other parts of the body. This will make you will feel more and more unwell.
- If your TB is in the lungs, it may be **infectious -** meaning you can pass TB on to others (page XX has tips on how to reduce the risk of passing on TB)

How long will I have TB?

- TB disease can be lifelong if it is not treated correctly.
- However, with the right treatment, TB can be cured after 6 months of medicines.

Your TB treatment

What can I do about TB?

- The good news is that TB can be cured.
- You will need to take a number of different medicines called **antibiotics** which work together to kill the TB **bacteria** and allow your body to recover.
- These medicines must be taken every day for the full length of treatment.

Why do I need to take TB treatment daily?

- TB is a hard bacteria to kill.
- Each day your body needs a certain amount of medicines to gradually reduce the TB bacteria until it is cured.
- Over time you will feel better and you won't be able to pass TB on to others.

Before TB treatment	During TB treatment	After TB treatment

Remember!

- **Feeling better before you've finished all of your medicines does not mean your TB is cured.**
- You may not have **symptoms** but the TB is still in your body.
- Stopping your medicines too soon means the number of TB bacteria can increase again, making you feel unwell. You may also be at risk of passing TB on to others.
- Also, if you don't take your medicines regularly, TB may become **resistant**. This means that the medicines stop working against the bacteria in your body.
- You will then need different medicines for much longer that often have more **side effects**

You can cure TB by taking your medicines every day for the full length of treatment

Questions about TB treatment

It is normal to have worries when starting a new treatment.

This section discusses common concerns people may have when they start taking TB medicines.

Video link

Please watch the video you saw in clinic with the nurse again here. Showing this to family and friends may also be helpful.

Why do I need so many pills?

TB is a serious infection that can be difficult to treat. Using a single **antibiotic** medicine alone is not effective, and so you need to take several together to get rid of TB.

Why do TB medicines need to be taken for so long?

TB is a tough **bacteria**. To kill it and stop it coming back, you need medicines every day for at least 6 months.

Taking medicines every day will gradually reduce the TB bacteria until you're cured.

Remember, if you stop your medicines early, TB bacteria can return and you could become very unwell.

Do TB medicines cause side effects?

Most patients will not have **side effects** during their treatment.

However, TB is a serious infection, so TB medicines must be powerful.

Sometimes, this causes unwanted effects. For example, some people may feel sick or get a rash on their body from taking TB medicines. Although these side effects can make

Write anything you would like to ask your TB team next time you see them in the space below:

My concerns about TB treatment

Managing side effects

As with any medicines, **side effects** can be experienced from TB treatment.

However, these do not usually cause long term problems, and most patients will not have side effects during their treatment

Some patients may have these side effects:

- feeling sick and/or feeling tired
- body fluids (e.g. tears, urine, saliva) turning orangey-red
- other medicines that are being taken including contraception (e.g. the pill, implants) having a reduced effect
- vomiting and diarrhoea
- pins and needles in the fingers or toes
- rashes and itch

Red bodily fluids?

The TB medicine Rifampicin is red. It can make bodily fluids like urine an orangey-red colour.

This might look shocking but it is completely normal. It is a harmless sign that the medicine is being flushed out of your body after it has done its job.

Very rare side effects to be aware of:

- yellowing of the eyes or skin (jaundice)
- blurred vision or changes in how you see colours
- red and peeling skin
- flu-like **symptoms** (chills, fever, dizziness, or joint pain).

If you experience any symptoms from your medicines, please tell your TB team who can advise and support you

Please use your medication diary to record how you feel when you take your medicines (see page XX)

Remember:

- Most side effects are temporary and disappear as the body gets used to the medicines.
- Your TB team will check for any side effects and help you to manage these.
- If side effects don't improve, your TB team can use other medicines to treat TB that might suit you better.

How can I make my treatment as easy as possible?

Busy lives can make taking your medicines difficult.

This section provides some helpful tips that can **make treatment easier for you**:

Make treatment a routine

Most people find that treatment is easier once they have a routine:

- Try taking your TB medicines at the same time every day (e.g. in the morning before breakfast).
- Link taking your TB medicines with another regular activity (e.g. take them before having a shower in the morning).
- Create a medication plan that works best for you (see page XX).
- Use your medication diary (page XX) to record when you take your TB medicines and to see your progress

Use reminders

Reminders such as alarms on your phone or notes left around the house can be useful.

Try keeping your medicines somewhere you will see them when it is time to take them. E.g. next to your toothbrush or on your bedside table, so you see them in the morning.

Plan ahead

Changes in life and our routines are normal. Speak to your TB team if you need to make changes to the time that you take your medicines.

If you ever plan on being away from home, let your TB Team know. They can make sure that you have enough medicines to take with you and last you during this time.

If any religious festivals or community events might affect your ability to take your medicines, talk to your TB team.

Have a look at the "If I forget plan" on page XX. This tells you what to do if you forget to take your

Support from others

Support from family or friends can be really helpful. They can remind you to take your treatment and also help you manage your medicines. Some people find that talking to community or religious leaders and groups can also be a helpful source of support.

Who you tell about TB is your decision. We encourage you to involve your friends and family for support if you wish. They are welcome to come with you to the TB clinic to learn more.

Extra support from your TB team

Sometimes people need extra support with taking their treatment.

The TB team can offer this in a number of ways. They may suggest extra visits at home, or using your phone to record when you take your medicines. Your TB team will discuss these options and help you decide what is best for you.

Each time they see you, the TB team will ask how things are going and check if there are other services that may be helpful to support your treatment.

If you miss any appointments, don't worry – please get in touch. You are always welcome at your TB

If you ever experience difficulties with taking your treatment, ***always talk to your TB team***.

They are there to support you and make treatment as easy for you as possible.

Each person's experience of TB is different, so each treatment journey may be different too.

The following gives you an idea of what to expect from your TB treatment:

START

- Standard TB treatment is 6 months, though some people may need treatment for longer.
- You will usually be asked to start taking 4 different **antibiotic** medicines. Starting treatment with this many medicines means your TB will be treated faster.

Treatment starts

- If you have **infectious** TB, you may need to reduce contact with others for the first few weeks while your treatment starts to work. Your TB team will discuss this with you.
- Page XX has tips on how to reduce the risk of passing TB on to others.

Week 2

- By now, you may start feeling better. The TB team may also tell you that your TB is no longer infectious.
- **Beware – feeling better does not mean your TB is cured.** TB is still in your body, even if you don't feel any **symptoms**.
- The only way to cure your TB is to take treatment every day until finished.

BEWARE – don't stop treatment

2 months

- If you have been taking your medicines every day, your TB team may ask you to take fewer tablets each day until the end of treatment.
- Completing the entire course of treatment will make sure your TB is cured.

Fewer tablets

Keep taking your medicines

Stay in touch with your TB team

Write down or tell your TB team if you have any concerns

BEWARE – don't stop treatment

6 months

FINISH

- At 6 months, most people will finish treatment and have a final appointment with the TB team.
- **For some people, treatment may take longer.**
- Remember - it is highly unlikely that TB will come back if you have taken your medicines every day for the full length of treatment.
- In the future, if you are worried that your TB has returned you can contact your TB team for advice.

Having an idea of what to expect from your TB journey can make you feel more confident.

It's important to remember that each day is progress towards curing TB.

Write anything you would like to ask your TB team next time you see them in the space below:

My questions, thoughts, concerns about this section…..

Section 2:

Living with TB

Talking to others about TB

People can be scared or worried when they hear that someone has TB.

A lot of these concerns are caused by having the wrong information.

To help others understand TB, here are some useful facts:

TB FACTS!

1. TB is a treatable condition that can be fully cured
2. TB is an infection that anyone can catch, even in wealthy countries
3. Some types of **extra-pulmonary TB** are <u>not</u> **infectious**
4. Many people with infectious TB do not pass it on to others
5. TB is not passed on as easily as a cold or flu
6. TB is not usually passed through touch or sharing household items
7. TB is not passed between family members through genes

Video links

Showing friends and family these videos can help them understand TB

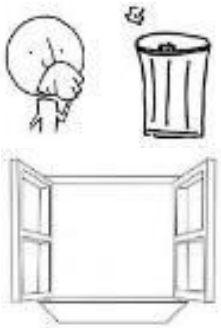
https://tinyurl.com/impactvid1

Will TB affect my ability to work?

- If your TB is *not* infectious and you feel well enough to work, then you can keep doing so.
- If your TB is infectious, you may need time off work, just for the first few weeks of treatment.
- With your help, your TB team may test workmates who are at risk of TB. Your confidentiality is important and your name will not be given out.

- If you are unable to work because your TB is infectious or you feel too unwell, you may be able to receive sick pay:
    - Visit the TB Alert link below. The "employment rights and sick pay" section at the bottom of the webpage tells you about services you may benefit from.

tinyurl.com/tbalertrights



If I have infectious TB…

…how can I reduce the risk of passing TB to others?

- If you have infectious TB, taking your TB medicines every day is the BEST way to reduce the chance of passing TB to others.
- If you are coughing, cover your mouth with a tissue. Throw it in the bin and wash your hands.
- Open doors and windows where possible. Good ventilation helps clear TB **bacteria** from the air.
- It is safe to hug, kiss, shake hands, and share food, cutlery, toilet seats, and other household items

…what does this mean for those around me?

- If you have infectious TB, you may need to reduce contact with others for the first few weeks of your treatment. Your TB team will discuss this with you.
- The TB team may ask you about **close contacts** (people who you spend a lot of time with), to check if they may need treatment. This is called **contact tracing**.

Coping with TB

Being diagnosed with an illness can be difficult.

Feeling unwell for a while may mean that some parts of your life change, so feeling down can be normal.

If your mood is low or you are struggling to manage, there is information about helpful services on page XX.

Remember, you can always discuss any issues with your TB team or GP.

Here are some things to remember if you feel low during your treatment:

Feeling unwell with TB is temporary

- Most people start feeling better after taking treatment for a few weeks.
- Finishing treatment will mean you can get back to doing the things that are important to you.

Treatment is a journey

- Each day you take your treatment you are closer to curing TB.
- Mark this off in your medication diary (page XX) to help you stay on track and see your progress.
- Celebrate goals along the way:
    - After 2 weeks you should start feeling better and your TB may no longer be **infectious**.
    - After 2 months, you may take fewer tablets each day until the end of treatment.

You aren't alone

Patient stories can be helpful to learn what to expect and see how others managed their treatment.

Reach out to other patients in the UK on this forum hosted by TB alert:

tinyurl.com/tbalertforum

Try and find activities that you can still enjoy

- Feeling unwell might mean having to stop some activities for a while, but try to make time for those you can still enjoy and look forward to.
- Keep up with the things you like doing, such as reading, watching your favourite TV shows, or simply going for a short walk to get some fresh air.
- Still doing activities you enjoy can take your mind off your illness and help you to feel better.

- Spend time with friends and family. If your TB is infectious and you need to reduce contact, stay connected through social media and phone calls.

Be kind to yourself

- You are doing your best to manage a difficult treatment. It is normal that sometimes this can seem tough.
- You can always discuss any difficulties with your TB team. They can help you manage these or point direct you to other services that can help.

Feeling stressed? Practise relaxation

The charity Mind has some helpful tips and exercises on their website

tinyurl.com/mindukrelax

Remember why you want to get better

- Think about your "Reasons for completing TB treatment" (page XX).
- This might be for yourself and to get back to your normal life, back to your work, or for your friends and family.

Write anything you would like to ask your TB team next time you see them in the space below:

My questions, thoughts, concerns about this section.....

Section 3:

My TB medicines

My list of TB medicines

My list of TB medicines

My list of TB medicines

My medication action plan

My reasons for completing TB treatment:

The best time for me to take my TB medicines:

AM

PM

How I will remember to take my medicines (what I will do before/after):

Where I will keep my medicines:

If I forget my medicines:

…AND I REMEMBER ON THE SAME DAY:

- Take your medicines.
- Follow the usual instructions e.g. 1 hour before or 2 hours after food.

…AND I DON'T REMEMBER UNTIL THE NEXT DAY - DO NOT TAKE A DOUBLE DOSE:

- Record that you missed your medicines the day before in your medication diary (page XX).

If you have any concerns, contact your TB team

My medication and symptom diary – months 1 to 2

Week 1	DAY 1 START DATE: ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 2	DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 3	DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week	DAY 1 ☐	DAY 2 ☐	DA ☐	D ☐	D ☐	D ☐	☐	Did you have any side effects or difficulties with your treatment?
Week 5	DAY 1 START DATE: ☐	D ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 6	DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 7	DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
	☐		☐	☐	☐	☐	☐	

If your treatment is twice a day, mark your first dose with a line like this / and use another \ when you take your second dose to make an X

Week 8	DAY 1	DAY 2 ☐	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?

My medication and symptom diary – months 3 to 4

Week 9	START DATE:	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 10		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 11		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week		DAY 1	DAY 2	D	D	D	D		Did you have any side effects or difficulties with your treatment?
Week 13	START DATE:	DAY 1	D	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 14		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 15		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?

If your treatment is twice a day, mark your first dose with a line like this / and use another \ when you take your second dose to make an X

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 16		☐						

My medication and symptom diary – months 5 to 6

Week 17	START DATE:	DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 18		DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 19		DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week		DAY 1 ☐	DAY 2 ☐	D ☐	D ☐	D ☐	D ☐	☐	Did you have any side effects or difficulties with your treatment?
Week 21	START DATE:	DAY 1 ☐	D ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 22		DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
Week 23		DAY 1 ☐	DAY 2 ☐	DAY 3 ☐	DAY 4 ☐	DAY 5 ☐	DAY 6 ☐	DAY 7 ☐	Did you have any side effects or difficulties with your treatment?
		☐		☐	☐	☐	☐	☐	

If your treatment is twice a day, mark your first dose with a line like this / and use another \ when you take your second dose to make an X

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Did you have any side effects or difficulties with your treatment?
Week 24		☐						

Helpful information about services

Your TB case manager:	Your TB case manager phone number:
Your TB clinic:	Your TB clinic contact phone number:
Out of hours help: If you have concerns outside of normal working hours (Monday to Friday 9am to 5pm) please contact your GP or go to your local accident and emergency clinic.	

Information about your rights (housing, benefits, and sick pay)
Charity support
TB patient forum

Housing services

Help with housing, benefits, immigration
Drug and Alcohol services

NHS transport services
Mental health helpline

Words you may hear during your treatment

Active TB: When TB bacteria are causing symptoms and making you feel unwell.

Antibiotics: Medicines that get rid of bacteria. Antibiotic medicines are used to treat TB.

Bacteria: A type of germ. TB is caused by a type of bacteria called a mycobacteria.

Contact tracing: A process used by the TB service to check whether any of your close contacts (people who you spend a lot of time with) have been in contact with TB.

Directly-observed therapy (DOT): A form of treatment where a person takes their medicines with support from the TB team. This can be done at home, in a community meeting place, or at the TB clinic. This can be helpful for keeping track of medicines.

Dosette box: A medication organiser or compartment where TB medicines are separated and labelled with each day of the week. This can be helpful for keeping track of medicines.

Drug resistance: When a medicine is no longer effective at killing TB bacteria. It is possible to catch drug-resistant TB, but it can also develop from not taking treatment correctly. Treatment for drug resistance is longer and often has more side effects.

Extra-pulmonary TB: TB in a part of the body other than the lungs.

Infectious (or contagious): When TB can be passed on to others. Usually, only pulmonary (lung) TB is infectious. Most people will stop being infectious once treatment has killed enough bacteria.

Isolation: Reducing contact with others and time spent in public places to lower the chance of passing on TB. The TB team will let the person know if isolation is needed.

Latent TB: This means the person has a TB infection but does not have symptoms and cannot pass it on to others. Latent TB can be treated to prevent it from developing into active TB.

Mono-resistant TB: When TB bacteria become resistant to <u>one</u> of the important medicines used to treat TB. This is more difficult to treat and requires more medicines to be taken for longer.

Multi-drug resistant TB (MDR-TB): When TB bacteria become resistant to <u>two</u> of the important medicines used to treat TB. This is more difficult to treat and requires more medicines to be taken for longer.

Needs assessment: A checklist of items the nurse will ask to see whether any aspects of a person's life may affect their ability to take TB treatment.

Pulmonary TB: TB in the lungs.

Side effects: The unwanted or unintended effects of medicines as they work inside the body.

Symptom: A physical or mental sign of a condition or disease. Symptoms of TB can include coughing,

tiredness, losing weight, sweats and fevers, or pain and swellings of the infected area (in extra-pulmonary TB).

TB case manager: A member of the TB team who is responsible for helping manage a persons' treatment. This is likely to be a nurse in the local TB team.

Video-observed therapy (VOT): Where a person records and sends a video clip of themselves taking their medicines using a smartphone. This can be helpful for keeping track of medicines.

We hope this booklet is useful for you.

Please let your TB team know if you have comments or questions about any sections of the booklet.

Thank you for participating in this study.

Funding acknowledgments, NIHR disclaimed and study logos to add

APPENDIX 9: Healthcare Professional Training Manual

IMPACT

HCP Delivery Manual

About this manual

This manual is a guide to delivering the IMPACT intervention to improve adherence in patients taking treatment for tuberculosis (TB).

The purpose of the IMPACT intervention is to support patients with their treatment and overcoming potential barriers to adherence. The intervention is based on formative research conducted as part of the IMPACT study and frameworks for understanding adherence behaviour. This includes evidence from literature reviews and interviews with patients and health care professionals (HCPs), which has been mapped to adherence theories.

The manual is laid out in three sections. The first part includes diagrams describing intervention processes. This includes Intervention Session Structure diagrams and Intervention and Standard Care Delivery diagrams, which will be helpful references for intervention delivery. The second section describes the purpose of each intervention component and how to deliver it. Finally, the Intervention Delivery section provides a step-by-step guide to delivering each part of the intervention.

This intervention is underpinned by a theoretical framework for understanding how patients' interact with their treatment - the Perceptions and Practicalities Approach (Horne, Cooper, Wileman, & Chan, 2019; Horne et al., 2005). This framework for adherence has been used extensively in health settings and informed the *NICE Medicines Adherence Guidelines*. The framework suggests that two components are essential for treatment adherence- a patient's *motivation* and their *ability* to take treatment. The framework suggests that non-adherence occurs because the patient either 1) cannot take their treatment correctly (ability) or 2) because they do not want to take their treatment (motivation). The IMPACT intervention is designed to improve motivation by providing patients' with a common sense rationale for the necessity of treatment, decreasing their treatment concerns, and increasing their ability to take treatment by providing practical tools to support adherence. The PAPA framework uses an individualised approach by identifying and addressing each patient's perceptual and practical barriers to adherence.

The intervention includes face-to-face sessions delivered during standard care appointments. The intervention sessions at baseline and Week 2 have the most content to cover. The follow-up sessions (from Months 1 to 6) are intended to identify any adherence issues or new barriers to adherence that may occur across treatment, and to address any concerns that may develop.

The intervention also includes two phone calls at Weeks 1 and 6 of treatment. These times were specifically chosen to target treatment initiation and treatment maintenance respectively.

We recommend that HCPs delivering the intervention familiarise themselves with all parts of the manual prior to intervention delivery. The manual is intended to be used as a guide and reference tool throughout intervention delivery.

How does the IMPACT intervention fit with standard care?

The IMPACT intervention is designed to complement standard care procedures for treating patients with TB. It is not designed to replace standard care but instead to provide standardised forms of risk assessment, support, and information delivery to patients.

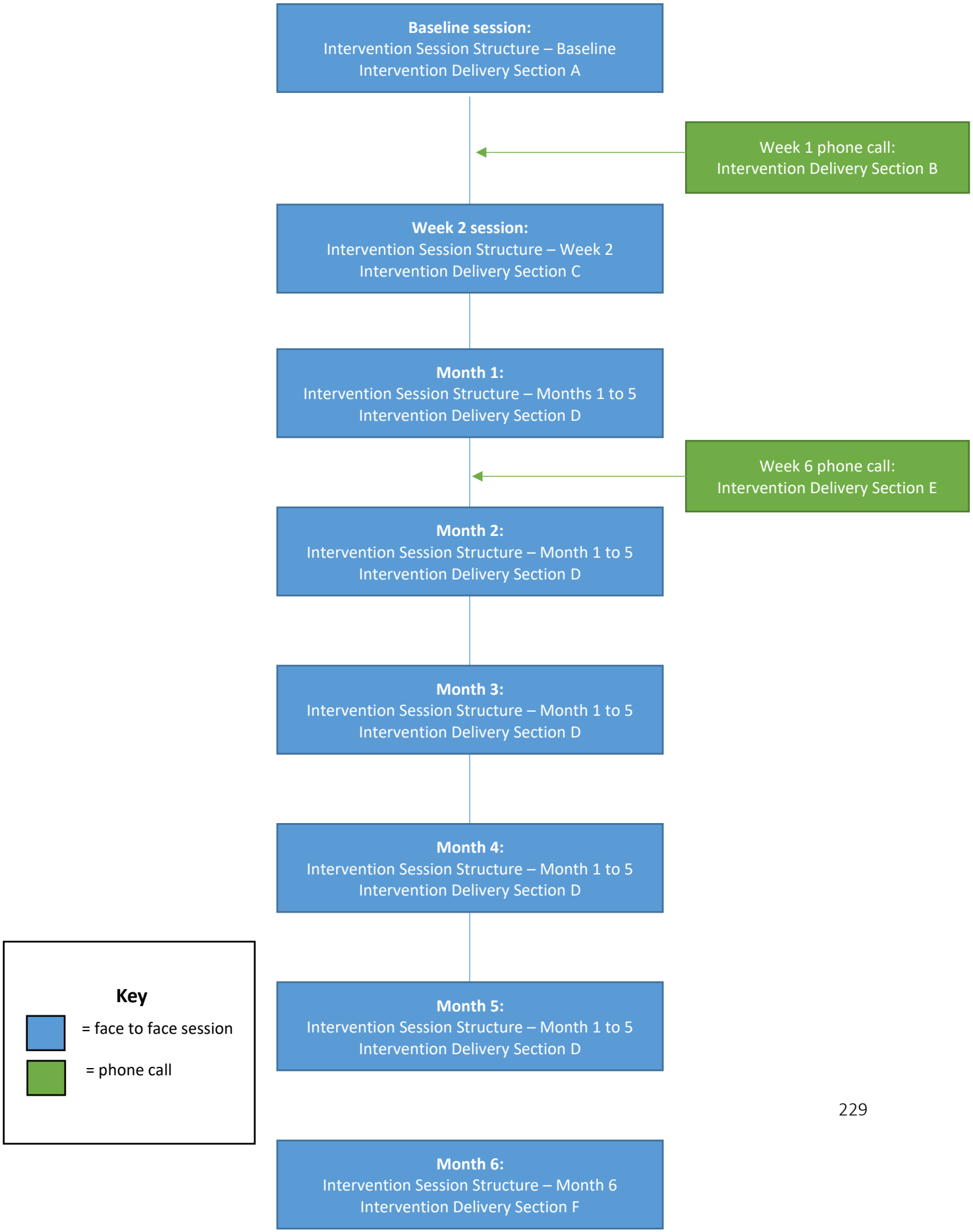
The intervention includes using a new tool to assess and identify patient needs and barriers which may influence patient adherence (the TB Needs Assessment). A standardised approach is used to address highlighted barriers and provide adherence support tools to patients as needed.

It also includes the delivery of standardised information about TB and TB treatment, using patient videos and an interactive patient booklet.

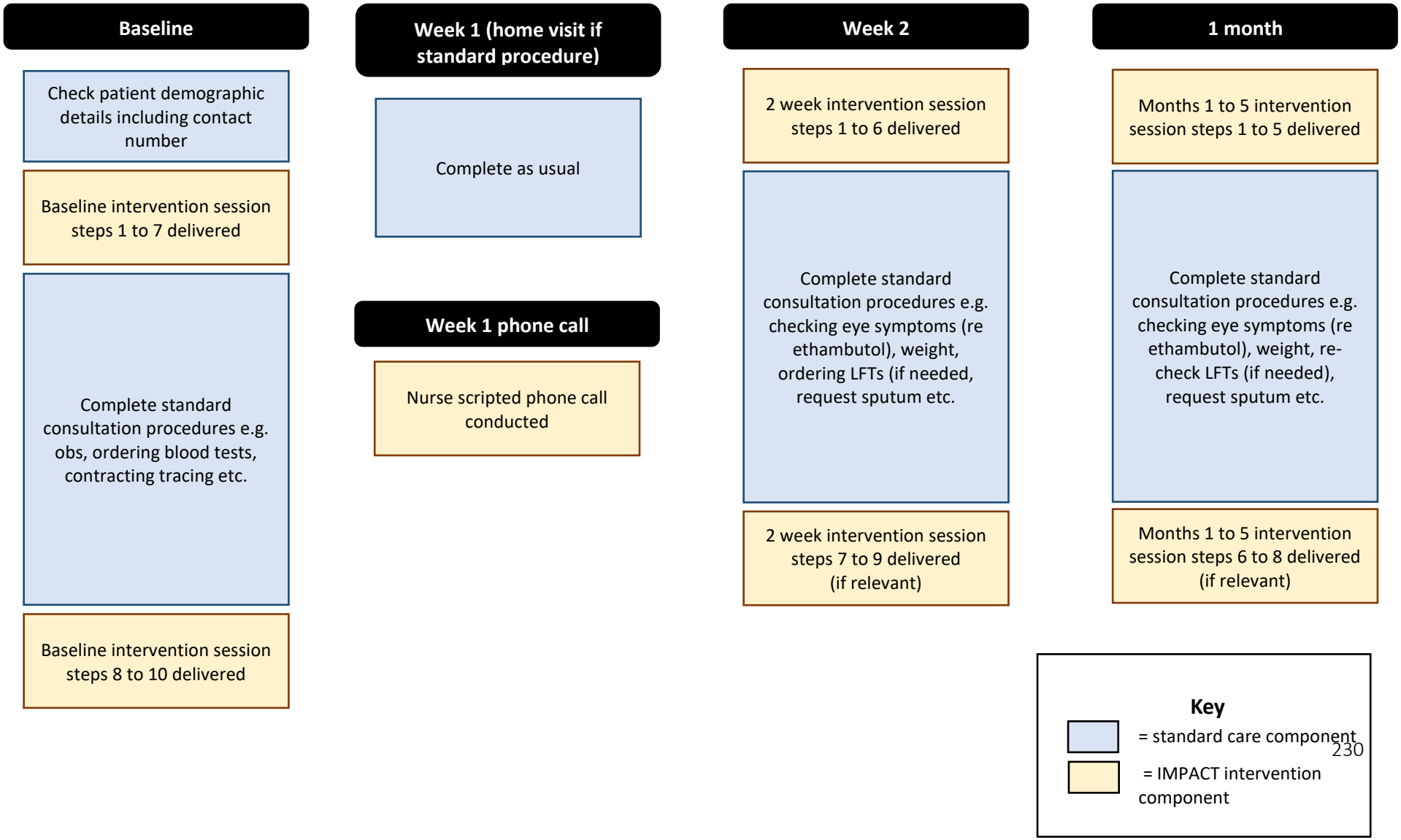
The Intervention and Standard Care Delivery diagrams (pg. 5 to 6) provide clear guidance on how standard care procedures can be conducted around the delivery of the intervention. HCPs should still use local procedures and services where necessary. Appendix 1 (pg. 42) describes parts of standard care that the IMPACT intervention may replace based on an example care pathway.

Face-to-face intervention sessions are delivered during normal standard care touch points. The content of these sessions differs based on the time point of delivery. It is important to familiarise yourself with the Intervention Session Structure guides (pg. 7 to 10) to ensure relevant content is delivered at each time point. The Intervention Delivery section of the manual (pg. 16 to 40) provides more detailed information about how to conduct each session.

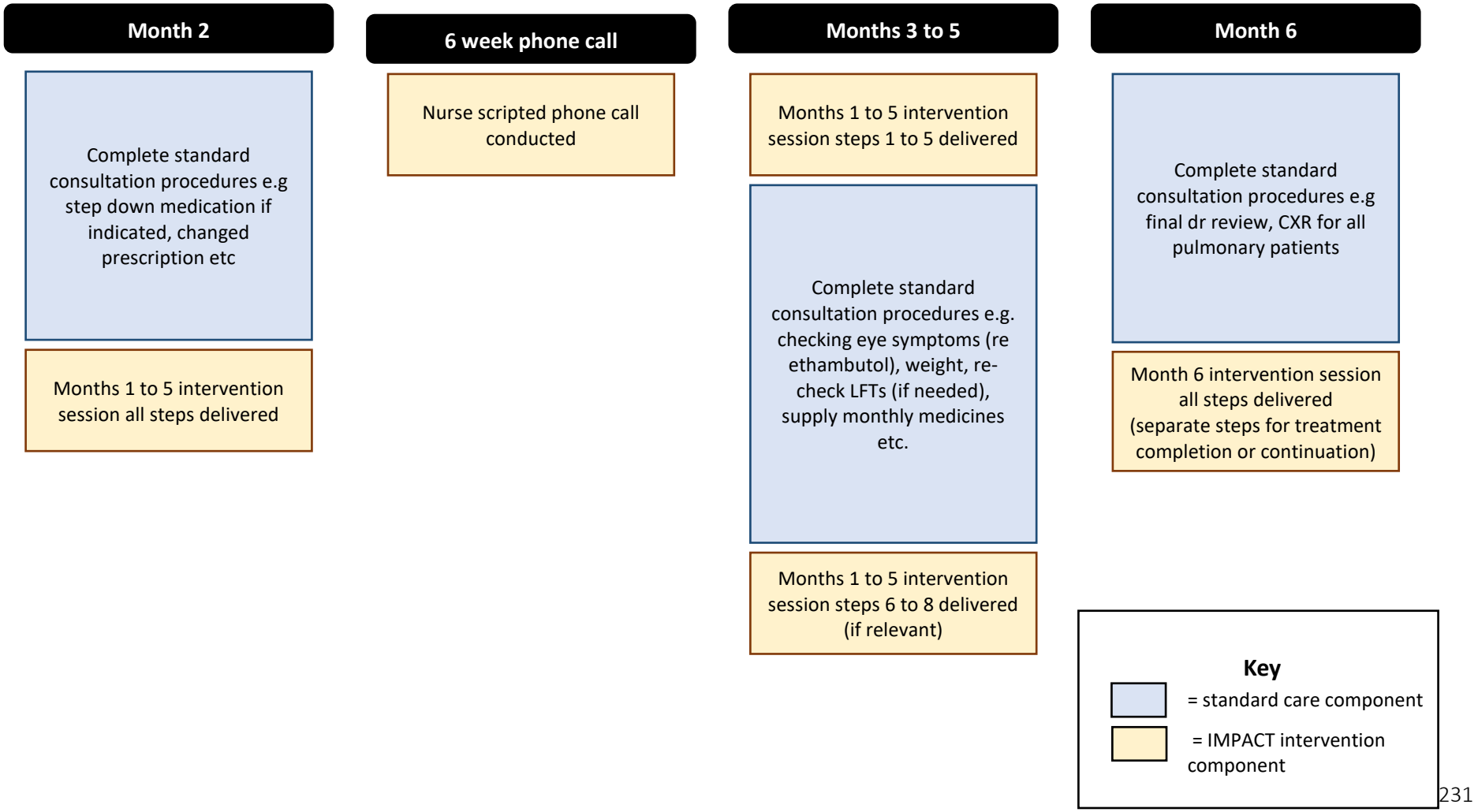
Overview of IMPACT intervention and resources



Intervention and Standard Care Delivery – Baseline to 1 Month

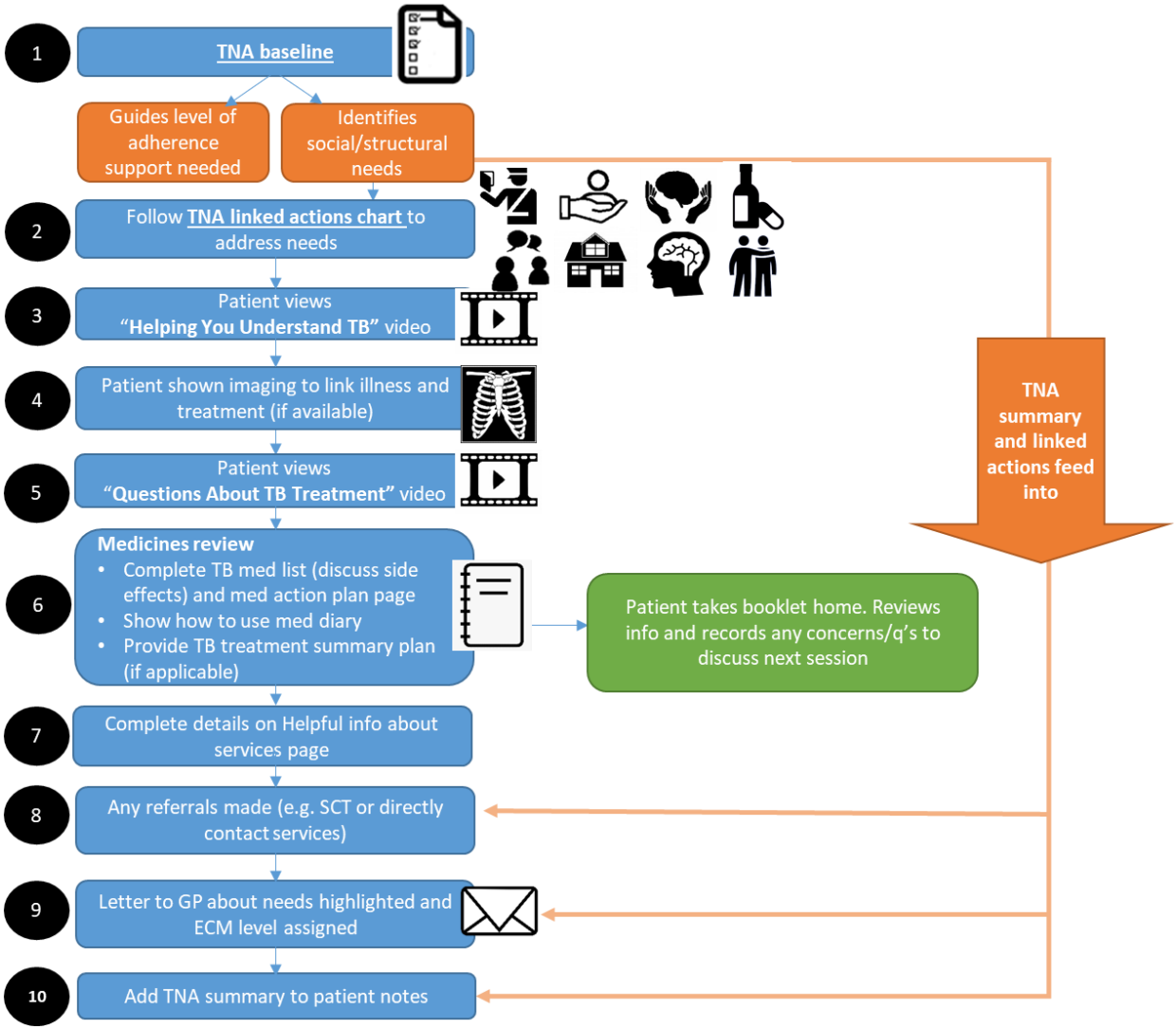


Intervention and Standard Care Delivery – Month 2 to Month 6



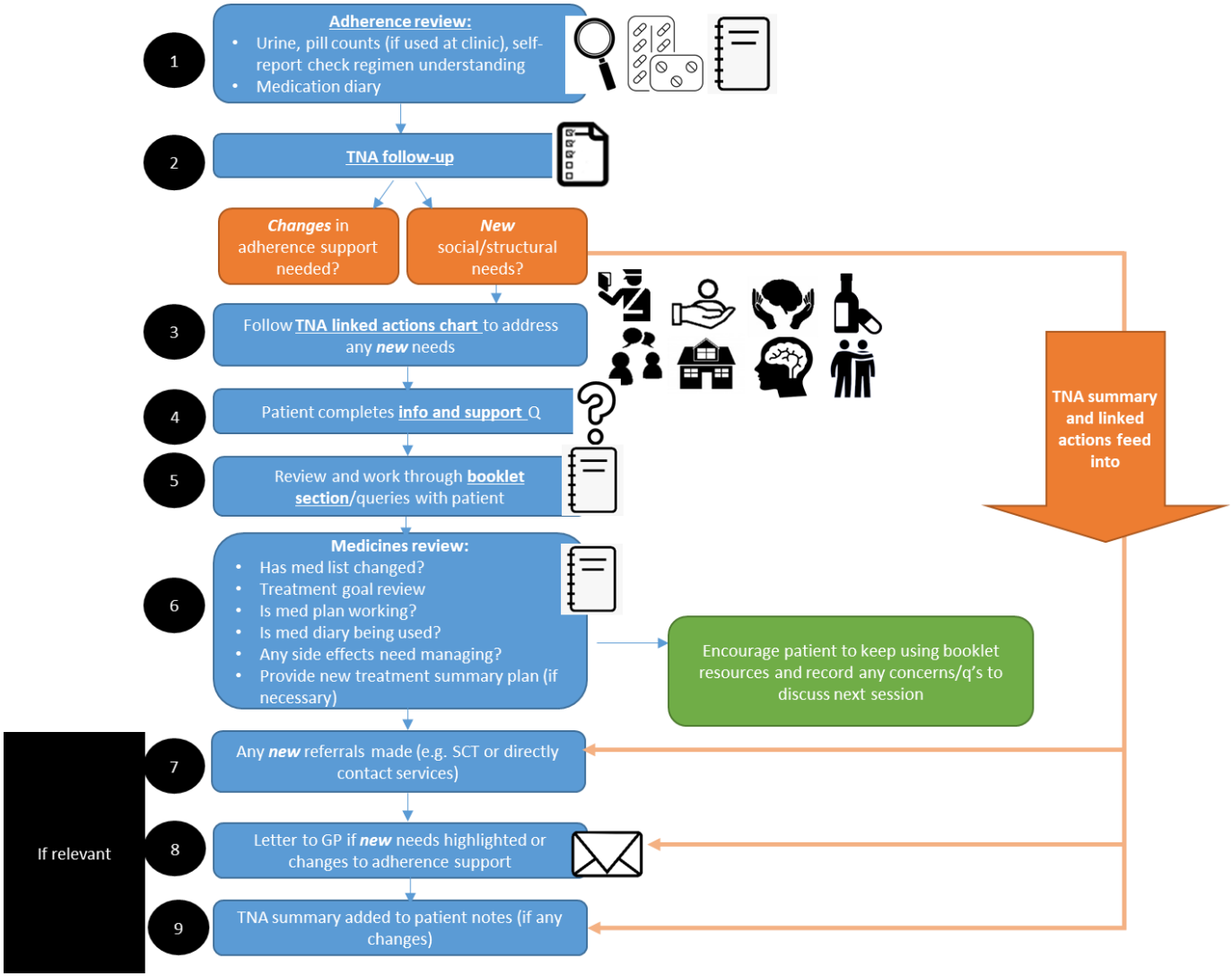
Intervention Session Structure – Baseline

Time length of consultation from start

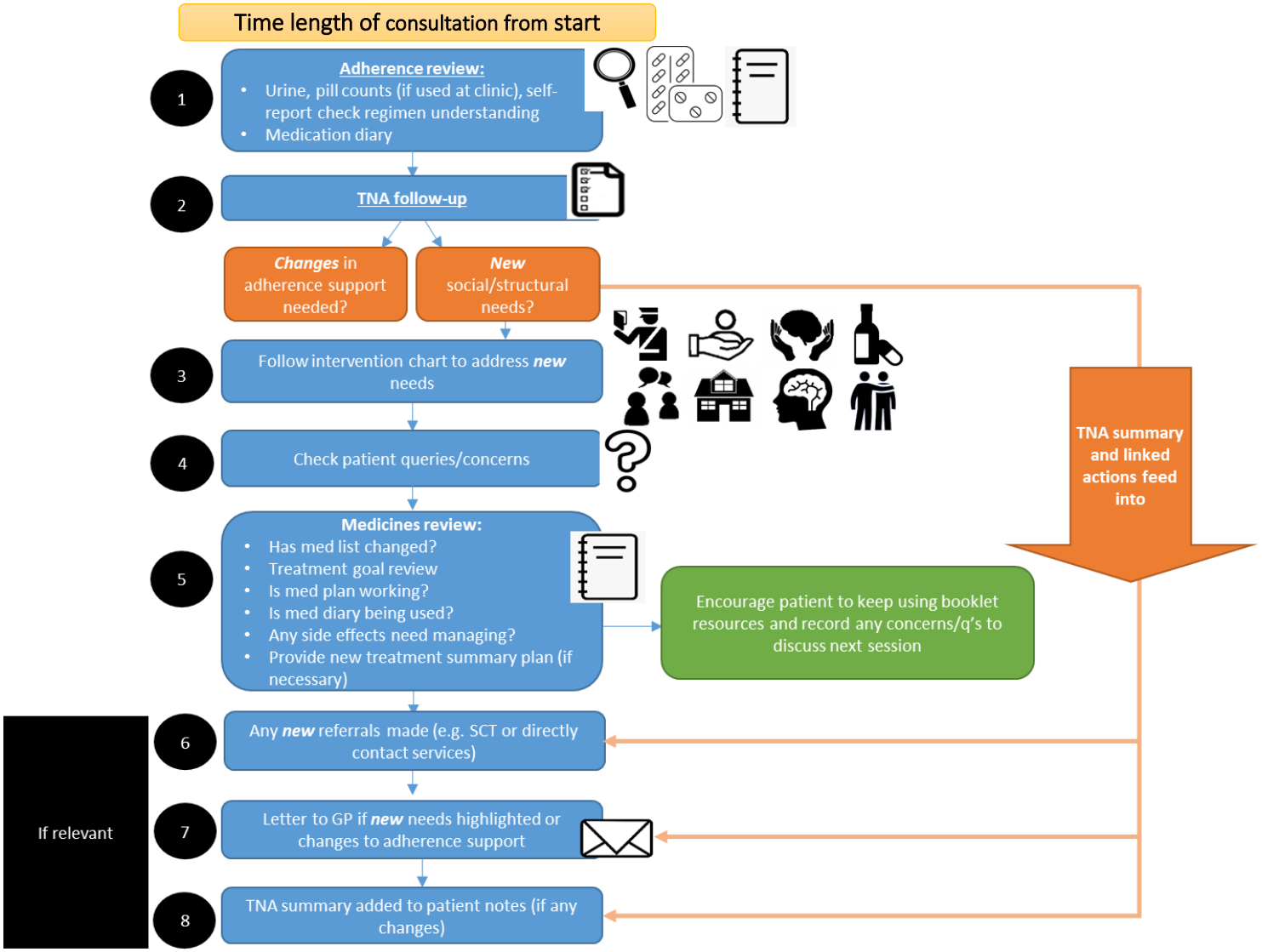

1
TNA baseline
Guides level of adherence support needed
Identifies social/structural needs
2
Follow TNA linked actions chart to address needs
3
Patient views "Helping You Understand TB" video
4
Patient shown imaging to link illness and treatment (if available)
5
Patient views "Questions About TB Treatment" video
6
Medicines review
• Complete TB med list (discuss side effects) and med action plan page
• Show how to use med diary
• Provide TB treatment summary plan (if applicable)
Patient takes booklet home. Reviews info and records any concerns/q's to discuss next session
7
Complete details on Helpful info about services page
8
Any referrals made (e.g. SCT or directly contact services)
9
Letter to GP about needs highlighted and ECM level assigned
10
Add TNA summary to patient notes
TNA summary and linked actions feed into

Intervention Session Structure– Week 2

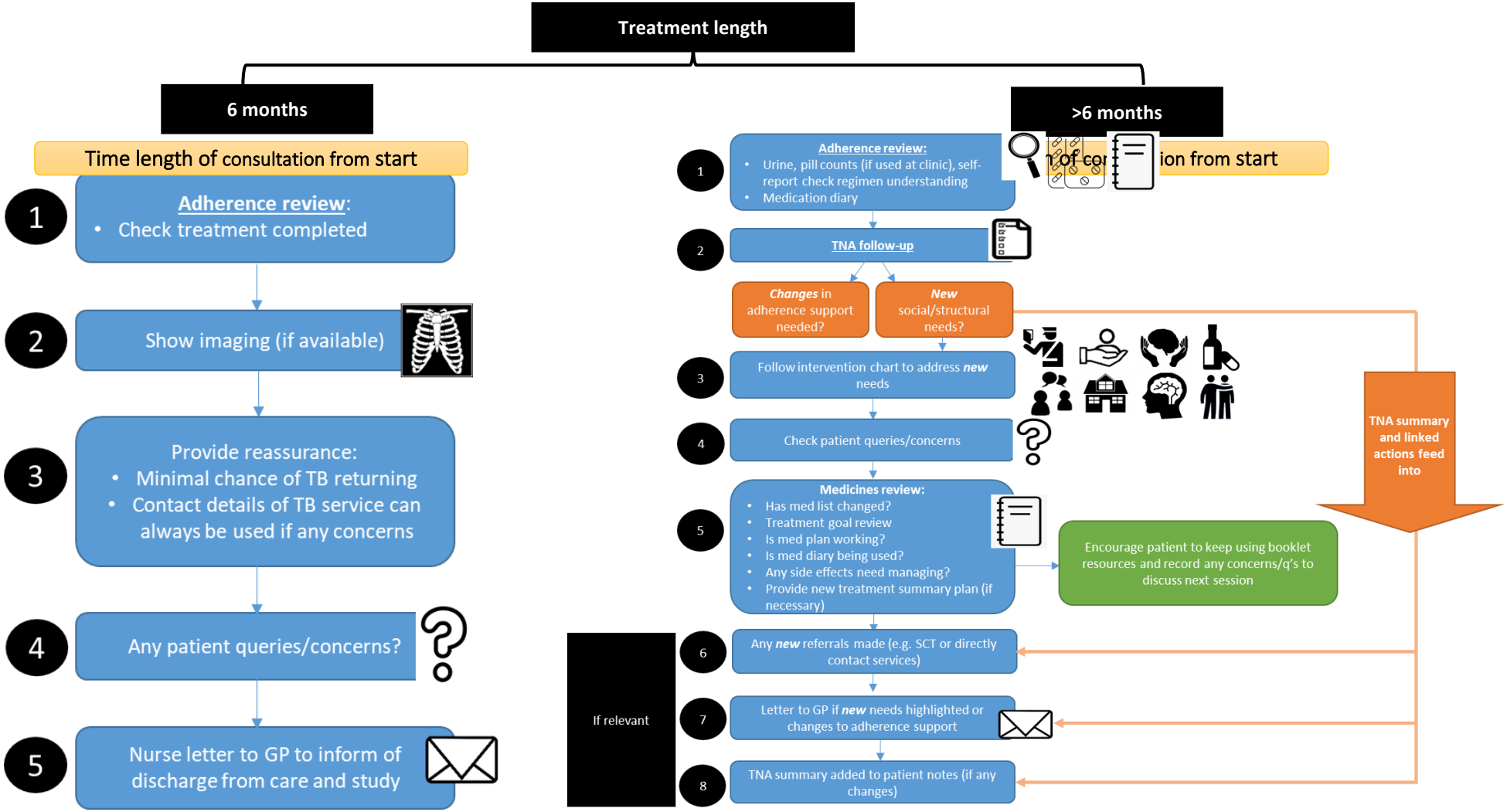
Time length of consultation from start


1
Adherence review:
Urine, pill counts (if used at clinic), self-report check regimen understanding
Medication diary
2
TNA follow-up
Changes in adherence support needed?
New social/structural needs?
3
Follow TNA linked actions chart to address any new needs
4
Patient completes info and support Q
5
Review and work through booklet section/queries with patient
6
Medicines review:
Has med list changed?
Treatment goal review
Is med plan working?
Is med diary being used?
Any side effects need managing?
Provide new treatment summary plan (if necessary)
Encourage patient to keep using booklet resources and record any concerns/q's to discuss next session
TNA summary and linked actions feed into
If relevant
7
Any new referrals made (e.g. SCT or directly contact services)
8
Letter to GP if new needs highlighted or changes to adherence support
9
TNA summary added to patient notes (if any changes)

Intervention Session Structure- Months 1 to 5


Time length of consultation from start
1
Adherence review:
• Urine, pill counts (if used at clinic), self-report check regimen understanding
• Medication diary
2
TNA follow-up
Changes in adherence support needed?
New social/structural needs?
3
Follow intervention chart to address new needs
4
Check patient queries/concerns
5
Medicines review:
• Has med list changed?
• Treatment goal review
• Is med plan working?
• Is med diary being used?
• Is med diary being used?
• Any side effects need managing?
• Provide new treatment summary plan (if necessary)
Encourage patient to keep using booklet resources and record any concerns/q's to discuss next session
TNA summary and linked actions feed into
If relevant
6
Any new referrals made (e.g. SCT or directly contact services)
7
Letter to GP if new needs highlighted or changes to adherence support
8
TNA summary added to patient notes (if any changes)

Intervention Session Structure – Month 6



TB Needs Assessment (TNA)

The TB Needs Assessment (TNA) is administered at each intervention session. The TNA replaces the "psychosocial risk assessment" section of the current risk assessment form used by your service. This section does therefore not need to be completed again with intervention patients. However, it is important that the rest of the standard care risk assessment form is completed outside of the intervention, during the consultation.

The TNA provides a comprehensive assessment of known barriers to adherence. This includes structural barriers such as homelessness and low income, but also psychosocial factors including beliefs about treatment. The TNA therefore extends the current risk assessment by asking about a wider range of factors that may affect adherence. There is a baseline version and a follow-up version. The TNA is completed at each follow-up session to allow any new barriers to be identified and addressed accordingly. The follow-up TNA is shorter and includes additional items relating to side effects.

The TNA is delivered using a computer tablet and the software REDCap [Instructions on how to access TNA on REDCap to be added]. The TNA has a range of items to be covered. Any barriers identified indicate a need for additional adherence support. Levels of additional adherence support include DOT, VOT, medication box reminders or a Dosette box. In addition, some items may have additional linked actions (see pg. 19 to 21). Some follow-up items simply provide useful information for patient notes.

The TNA items should be used to guide conversation to collect information about barriers that may affect adherence. Not all items are designed to be asked like questions, but are instead topics that need to be covered. Patient self-report may therefore not be needed to answer all items. HCPs with experience of the standard care risk assessment may choose to interview patients using the method they feel most comfortable with. Appendix 2 (pg. 46) provides a guide to conducting the TNA, including an explanation of the purpose of each item and suggested methods/questions to elicit relevant information. All staff, including those experienced in TB care, should familiarise themselves with this guide, as there are TNA items that are not in the current standard care risk assessments. Specifically, this includes the items assessing patient beliefs about TB and treatment. The section from the guide about how to assess beliefs is repeated here below (the full list of TNA items can be found in Appendix 2, page 46):

<u>Guide to administering TB Needs Assessment items assessing beliefs about TB and Treatment:</u>

Patient has doubts about their need for treatment or their diagnosis: Ticking yes indicates need for additional adherence support. This is the first item that aims to understand the patient's beliefs about their TB and TB treatment. Having a lack of perceived need for treatment is an important barrier to adherence (as there is no psychological 'fit' between the illness and treatment).

[Example questions to elicit information]: "How do you feel about your TB diagnosis?" "How do you feel about your TB treatment?" "Do you feel that you need treatment to get better?"

Patient is worried about the response from their family/community to their TB diagnosis: Ticking yes indicates need for additional adherence support. This is the second belief item. This item aims to

highlight the presence of stigma about TB that may affect adherence to treatment.

[Example question to elicit information]: "How do you feel about talking to your friends and family about TB?"

Patient is worried about storing medicines/taking medicines in front of others: Ticking yes indicates need for additional adherence support. This is the third belief item. This item aims to highlight the presence of stigma specifically about taking TB treatment or storing medicines. This is likely to be more apparent for patients from communities where stigma about TB is present.

[Example question to elicit information]: "We will talk about your medicines shortly. How do you feel about taking your TB medicines? Do you have any worries about where/when you can take these?" "Can you help me understand how you might take your medicine?"

Patient is worried about remembering to take treatment: Ticking yes indicates need for additional adherence support. This is the fourth belief item. This item aims to highlight where the patient has practical concerns about their ability to remember treatment. *Note.* Patients may have previously identified non-adherence in the earlier item. If so, it may be particularly important to reflect this back to the patient in case this was a factor affecting their previous non-adherence.

[Example question to elicit information]: "It can be quite normal to forget to take medicines – is this something that worries you? "Do you feel concerned about being able to remember to take your TB medicines each day?"

[Follow-up TNA only]

Patient has become anxious/overly concerned about developing side effects since their last visit: Ticking yes may indicate need for additional adherence support. Concerns about side effects can be an important barrier to treatment non-adherence. This item aims to understand if patients concerns about side effects are making them not want to take their treatment. This item will likely to be answered in conjunction with the item above experience of side effects.

[Example question to elicit information]: "How are you feeling on this medicine?" "Is this affecting your ability to take your treatment?"

Using TNA output

After completing the TNA, a summary of highlighted needs will be produced. This informs both whether the patient needs additional adherence support, and whether any TNA Linked Actions need to be delivered (see pg. 20 & 21). These procedures are explained in the Baseline Intervention Delivery section (pg. 19 to 26). Instructions on how to complete the follow-up TNA are provided in the Week 2 Intervention Delivery section (pg. 34 and 35).

The TNA output should be included in the letter to the GP or social care team where relevant. The TNA output should also be added to patient notes (in paper or electronic format) at baseline. TNA output should also be added at follow-up if there are any new barriers highlighted [instructions on how to obtain TNA summary and add to documents to be added here].

Information and support questionnaire –Week 2 only

The Information and Support questionnaire (ISQ) gives patients an opportunity to highlight topics they would like further information about during the Week 2 session. The ISQ items are based on questions and concerns that other patients have about TB and treatment. Highlighting this to the patient before delivering the questionnaire should help normalise concerns and make patients feel more comfortable with asking their own questions.

Each item on the ISQ links to a section of the patient booklet as seen below in Table 1. The HCP delivering the intervention uses this section of the booklet to guide discussion with the patient around this topic. The ISQ is administered using REDCap on the computer tablet [instructions on accessing ISQ on REDCap to be added]. The Week 2 Intervention Delivery Section has further information about administering the ISQ (pg. 35 to 36).

Table 1. Information and Support Questionnaire items and linked patient booklet topics.

Information and Support Questionnaire item:	*Booklet topic:*
Why I need TB treatment	*About TB and Your TB treatment*
How to manage any side effects of TB treatment	*Concerns about TB treatment*
How I can make taking my treatment easier	*How can I make my TB treatment as easy as possible?*
What to expect during my TB treatment	*What to expect from my TB treatment*
How my TB may affect others	*Talking to others about TB*
Talking to my family or friends about TB	*Talking to others about TB*
If TB affects my ability to work	*Talking to others about TB*
Where I can access extra support from other TB patients	*Coping with TB*
How to cope with my TB diagnosis and wellbeing through treatment	*Coping with TB*

Videos

Two videos are shown to patients during the baseline session. These are played using the computer tablet [instructions on how to access videos using computer tablet needed]. The Intervention Session Structure – Baseline diagram (pg. 7) shows when the videos should be delivered in the session. The patient booklet includes links for patients to access the videos online at home. Patients are also asked if they would like to receive a text or email link [need to add instructions on how to send this link to patient].

The videos are designed to target patient perceptions' of TB and TB treatment by answering questions

mapped to the theoretical framework of the intervention. The content is designed to highlight the necessity of TB treatment, address potential treatment concerns, and provide practical tips to make treatment easier. The first video "Helping You Understand Tuberculosis" talks about TB as an illness (e.g. what is TB? How did I get TB? What can I do about it?) and provides patients with a rationale for the necessity of initiating and completing their TB treatment. The second video "Questions About TB Treatment" answers common concerns that patients have about taking TB treatment, including concerns about side effects. The purpose of these videos is to provide standardised education for patients that increases their motivation to take their treatment.

Patient imaging

If available, patients can be shown imaging of their TB site to help explain the link between illness and treatment at baseline and the Month 6 session (if treatment is complete). Instructions on how this should be delivered are given below in the Intervention Delivery sections for these time points (for baseline session, see pg. 26; for Month 6 session see pg. 39).

Patient booklet

Patients receive a booklet during the baseline session. The patient booklet is designed to be a guide for the patient's TB treatment. The first section provides information about TB and TB treatment, including addressing common concerns, providing expectations for TB treatment, and practical advice on how to make treatment easier. The second section addresses emotional and social consequences of TB, including tips on how to cope during treatment and how to talk to others about TB. The third section has resources to help the patient manage their treatment, including a list of their TB regimen with instructions for each medicine, a space to create a treatment goal and medication plan, as well as a medication and symptom diary to help track adherence and any side effects experienced. The booklet also contains contact information for helpful services and a glossary of terms that the patient may hear during their treatment.

The patient is asked to bring their booklet to each session and any appointments with the TB service. If a patient forgets to bring their booklet, the session structure should be followed as much as possible. The HCP delivering the intervention can use the master copy where appropriate.

The booklet is designed to be interactive, both for the patient and the HCP delivering the intervention. The HCP can refer to and use sections of the booklet throughout the intervention sessions. The patient should use the medication resources in the booklet, but they can also record their thoughts, concerns, and questions throughout where indicated. The HCP can then check the patient booklet for any questions to discuss at each session from Week 2 onwards.

HCPs delivering the intervention should familiarise themselves with the patient booklet so they are aware of the information inside. This will allow them to refer to the booklet throughout treatment and signpost patients to information sections accordingly.

Patients can be sent an electronic copy of the patient booklet [insert instructions here].

Treatment summary plan

A TB Treatment Summary Plan should be created and completed for all patients who are receiving any level of additional adherence support, which is any patient who has a barrier identified on the TNA. The purpose of the treatment summary plan is to provide patients with information about the barriers that were identified for them and how these will be addressed, so that patients feel more involved in the steps taken to support them with their care.

Example plans are provided in Appendix 6 (pg. 67). There are two versions based on whether or not there is a social care team in service. There are also separate forms for use at baseline versus any follow-up sessions. Follow-up treatment summary plans only need to be provided if there are changes as indicated from the TNA at any follow-up session. Complete the summary plan by ticking any barriers specific to your patient and selecting their treatment plan (additional adherence support) from the boxes at the bottom of the checklist. This is a loose document but patients may wish to keep it with their patient booklet.

Note. For barriers where travel vouchers are given as part of the linked action, this information needs to be filled in by the HCP delivering the intervention in the box titled “any other help:”.

Phone calls

Phone calls are made to the patient at Weeks 1 and 6 of the intervention. The Week 1 phone call targets treatment initiation – ensuring the patient was able to start their treatment correctly. It is also an opportunity to follow up on the beliefs and concerns highlighted in the baseline TNA.

The Week 6 phone call targets treatment maintenance – ensuring the patient is still adhering to their treatment. We know that adherence can reduce as the patient becomes less symptomatic. Many patients associate treatment necessity with symptom experience (therefore, no symptoms=no treatment needed). This phone call aims to provide positive affirmation of the progress made to date, and to highlight the need for consistent adherence and the consequences of stopping treatment early.

Intervention Delivery

Overview

The Intervention Session Checklists in Appendix 3 (pg. 53 to 62) detail each step of the intervention that needs to be delivered for each session. The session checklists should be used to check off each component as it is delivered, and to note down any issues (e.g. reason why an intervention step was unable to be delivered). It is also important to remember to time the length of each of your consultations with the patient using the stopwatch provided with your intervention materials. This will be from the time the patient enters the room until they leave (including intervention tasks and standard care). Record the timed session length on the Intervention Session Checklists.

Complete the Intervention Session Checklists for each patient in hard copy. Please ensure that these are handed over to the research nurse securely – this data is used to evaluate how well the intervention components can be delivered within services and where there are issues.

Section A: Baseline session

Welcome the patient into the clinic room and greet as normal. Explain:

"Today we will discuss tuberculosis and the treatment you will need to take. I will cover some information but also give you lots to take home so that you can look at this in your own time. Then we can talk about any specific questions you might have next time we speak."

As outlined on the Intervention and Standard Care Delivery diagram (pg. 5 and 6), you may wish to collect demographic details as you normally would before delivering any intervention material.

TB Needs Assessment (TNA)

The baseline TNA is completed at the beginning of session. *Note.* Details provided by the patient during the completion of the TNA may be relevant to completing their medical notes for standard care (e.g. mental health history, drug use etc). It may therefore be useful to have patient notes open at the same time, so information can also be recorded there simultaneously.

Explain the purpose of the TNA:

"Before we start talking about tuberculosis, I'm going to ask you some questions to learn more about you. These questions help us to understand if there are ways we can provide extra support to you during your TB treatment. Don't be alarmed by any of these questions. We ask everyone starting TB treatment the same things and your answers remain confidential with the TB team."

Complete the TNA with the patient. The TNA is a checklist of items that need to be covered. The Intervention Components section (pg. 11 and 12) and Appendix 2 (pg. 46) has further details. The TNA should be delivered as a guided conversation. Therefore, if it feels more fluid or comfortable to ask items in a different order, feel free to do so as long as no items are missed.

REDCap will provide a summary of any TNA items identified for each patient. If no barriers are highlighted, you can move on to delivering Video 1. If any barriers are highlighted, there are two follow-up steps to be completed– 1) assigning level of additional adherence support and 2) following the TNA Linked Actions chart for specific barriers.

1) Explaining additional adherence support options

Additional adherence support options are offered in a hierarchy, depicted in Figure 1:

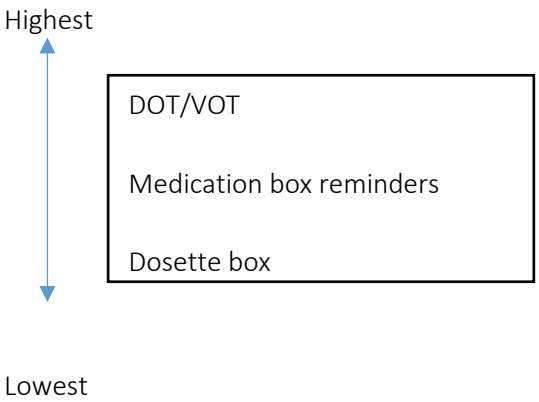


Figure 1. Hierarchy of additional adherence support options

Explain the additional adherence support options to patients as you would in standard care. Below is an example script:

"*Some patients need additional help and support when taking their treatment. We can offer this to you through the TB service in a number of different ways.*

The first options are what we call DOT and VOT. DOT is where someone from the TB team meets you to give you your medicines and watch you take these. This can be done at home, in the community, or at the clinic. This is helpful to make sure your medicine is taken each day.

With VOT, the V stands for video. The idea is the same, but instead of someone watching you take your medicines, you record a video of yourself taking your medicine and send this to the clinic staff each day. They might then remind you if you miss your medication.

As well as DOT and VOT, we can also offer reminders. The box you will keep your medicines in can be set to have an alarm if your medicines haven't been taken each day.

Lastly, we can also give you a medicine organiser called a Dosette box. This fits inside your box and

separates your medicines so you can see exactly what pills need to be taken each day. So your Monday pills would be in one section, your Tuesday pills in another and so on…. It also means you can easily check that you've taken your tablets for that day."

Note. If a patient has barriers that would normally result in you initiating them directly on DOT/VOT (e.g. a patient with multiple barriers or extreme needs), you can more strongly direct the patient to this option– for example *"To support you with your treatment, we will watch you take this – we can do that in one of two ways [describe DOT or VOT]".* Then you can allow the patient to choose between DOT or VOT. If they refuse both you can offer the other adherence support options available.

Note. As indicated on Table 2 and 3, some items on the TNA indicate additional adherence support but you will need to explore the individual patient's situation to determine which support option will be most appropriate (e.g. do they have a carer or family member who can help them to administer VOT or would home DOT be more suitable?). More information on gathering this information for relevant items is provided in Appendix 2 (pg. 46).

With other patients, after explaining the adherence support options, ask them which level of support they would like:

"So the options are taking your treatment with someone from the clinic (DOT), videoing yourself taking your medicines (VOT), reminders from your medicines box, or the medication organiser.

Throughout your treatment the level of support your need may change, however at the start of treatment we recommend that DOT or VOT are the most helpful way to support you. Does this sound like something that would work for you?"

IF YES TO DOT/VOT:

"Would you prefer using DOT or VOT?" [Follow patient response]

"We can start using DOT/VOT and see how this works for you. Each time we see each other, I will check in and we can make any changes if needed."

IF NO TO DOT/VOT:

"The next option we would offer is having reminders from your medicine box. Does this sound like something you would be willing to try?" [Follow patient response]

IF YES TO REMINDERS:

"We can start using reminders and see how this goes. Each time we see each other I will check in and we can make any changes if needed."

IF NO TO REMINDERS:

"Does the medication organiser inside your box sound like something that you would want to try?"

IF YES TO DOSETTE:

"We can start using the medication organiser and see how this goes. Each time we see each other I will check in and we can make any changes if needed."

IF NO TO DOSETTE:

"We really recommend using one of these strategies. Do you think we could try one and see how this works for the first few weeks?"

[See if patient changes mind. If not, follow procedures for refusal of adherence support as in standard practice]

Note. The HCP can suggest a combination of these options if they feel these would add further support for the patient e.g. VOT plus reminders or Dosette.

At the end of the baseline session, any level of additional adherence support given should be arranged appropriately and discussed with the research nurse. Standard care procedures for arranging DOT/VOT in your practice should be followed. The research nurse will need to know the patients' additional adherence support plan so they set this up appropriately (e.g. set reminders for the box, put Dosettes inside the box, or check who will keep medicines in the case of DOT).

If the patient is going on to DOT, the HCP delivering the intervention will need to organise who will keep the medicines box, just as they would need to consider who will keep the patients' medicines in standard care. For example, the community worker delivering DOT may need to have the patient's medicines box.

2) TNA Linked Actions

The TNA Linked Actions Tables (see Tables 2 and 3 below) highlight how each barrier on the TNA should be addressed. Some barriers will only indicate additional adherence support, however others have an additional step or steps to be completed. There are two versions of the chart as actions will differ based on whether services have a social care team present in service. When following the TNA linked actions chart, any usual local protocols to support patients should be incorporated e.g. ollalo, completing housing assessments where available, linking to any locally used charities or services (not just those listed in the patient booklet). The TNA linked actions should not replace any usual procedures undertaken to address these barriers. If there is no social care team in service, it is important that the HCP delivering the intervention makes referrals for urgent housing problems, drug and alcohol issues and current mental health concerns as demonstrated in Table 3. With issues where the linked action it signposting, it is at the HCP's discretion whether or not they make a referral or just signpost information to patients so they can self-refer. For urgent housing concerns, if the HCP delivering the intervention is unsure of the patient's status regarding recourse to public funds, guidance can be found on the NPRF [www.nrpfnetwork.org.uk] and GOV.UK Migrant Health Guide [https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide] websites. As in standard care, make sure you have the patients' permission before making any referrals to services on their behalf.

Table 2. TNA Linked Actions Chart [Social care team in service]

TNA item	Linked action(s)		
Demographics			
Older Age (65+)	Additional adherence support		
Child, adolescent, young adult	Additional adherence support		
Medical factors			
Previous TB Rx or diagnosis	Additional adherence support		
Unable to manage co-morbidities	Additional adherence support		
Complex TB type	Additional adherence support		
Known drug resistance	Additional adherence support		
Hx missed appointments	Additional adherence support		
Previous non-adherence	Additional adherence support		
Practical/communication factors			
Physical barrier (swallowing or dexterity)	Additional adherence support	Explore options available in your service (e.g. syrup or pill glide aids, Dosette)	
Too ill/frail to administer treatment	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Unable to travel to clinic independently	Additional adherence support	Signpost to NHS transport	
Unable to pay for costs for travel to clinic	Additional Adherence support	Signpost booklet info on reimbursement if available, use local protocols	Travel voucher
Needs interpreter	Additional adherence support	Follow local protocols, book interpreter where possible	
Sensory impairment	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Cognitive or memory disorder	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Structural factors			
Financial concerns	Additional adherence support	SCT referral	Travel voucher
Urgent housing problem	Additional adherence support	SCT referral	Travel voucher
Other housing problem	Additional adherence support	SCT referral	
Immigration concerns	Additional adherence support	Reassure treatment is free in UK	SCT referral
Prison Hx last 5 years	Additional adherence support		
Current alcohol problem	Additional adherence support	SCT referral	
Current drug problem	Additional adherence support	SCT referral	
Hx of mental health problem	Additional adherence support	Signpost to IAPT self-referral	
Current mental health concerns	Additional adherence support	SCT referral	
Lack of social support	Additional adherence support	Signpost to TB alert forum	
Doubts about need for treatment	Additional adherence support	Scripted conversation	
Worried about family/ community response	Additional adherence support	Scripted conversation	
Worried about storing/ taking meds	Additional adherence support	Scripted conversation	
Worried about remembering meds	Additional adherence support	Scripted conversation	
Follow-up only			
Severe side effects experienced	Additional adherence support	Address using standard care procedures	
Worried about side effects	Additional adherence support	Scripted conversation	

Table 3. TNA Linked Actions Chart [No social care team in service]

TNA item	Linked action(s)		
Demographics			
Older Age (65+)	Additional adherence support		
Child, adolescent, young adult	Additional adherence support		
Medical factors			
Previous TB Rx or diagnosis	Additional adherence support		
Unable to manage co-morbidities	Additional adherence support		
Complex TB type	Additional adherence support		
Known drug resistance	Additional adherence support		
Hx missed appointments	Additional adherence support		
Previous non-adherence	Additional adherence support		
Practical/communication factors			
Physical barrier (swallowing or dexterity)	Additional adherence support	Explore options available in your service (e.g. syrup or pill glide aids, Dosette)	
Too ill/frail to administer treatment	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Unable to travel to clinic independently	Additional adherence support	Signpost to NHS transport	
Unable to pay for costs for travel to clinic	Additional Adherence support	Signpost booklet info on reimbursement if available, use local protocols	Travel voucher
Needs interpreter	Additional adherence support	Follow local protocols, book interpreter where possible	
Sensory impairment	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Cognitive or memory disorder	Additional adherence support (explore support available (e.g. carers or family) to inform additional adherence support choice)		
Structural factors			
Financial concerns	Additional adherence support	Signpost to booklet services (CAB & TB alert)	Travel voucher
Urgent housing problem			
Recourse to public funds	Additional adherence support	Make appointment with local council housing officer	Travel voucher
No recourse to public funds	Additional adherence support	Complete full housing assessment, use local protocols	Travel voucher
Other housing problem	Additional adherence support	Signpost to booklet services (CAB, TB alert, shelter)	
Immigration concerns	Additional adherence support	Reassure treatment is free in the UK	Signpost to booklet services (CAB, local immigration services)
Prison Hx last 5 years	Additional adherence support		
Current alcohol problem	Additional adherence support	Make appointment with local D&A services	
Current drug problem	Additional adherence support	Make appointment with local D&A services	
Hx of mental health problem	Additional adherence support	Signpost to IAPT self-referral	
Current mental health concerns	Additional adherence support	Complete IAPT referral	
Lack of social support	Additional adherence support	Signpost to TB alert forum	
Doubts about need for treatment	Additional adherence support	Scripted conversation	
Worried about family/ community response	Additional adherence support	Scripted conversation	
Worried about storing/ taking meds	Additional adherence support	Scripted conversation	
Worried about remembering meds	Additional adherence support	Scripted conversation	
Follow-up only			
Severe side effects experienced	Additional adherence support	Address using standard care procedures	
Worried about side effects	Additional adherence support	Scripted conversation	

For items that have additional linked actions, suggested wording for addressing these barriers with the patient is provided below in Table 4. If any medication beliefs are highlighted these are addressed using scripted conversations also provided below (*Note*. Concerns about side effects is only in follow-up TNA):

Table 4. Addressing TNA Linked Actions with patient

Barrier highlighted	Site differences	Script to address
Physical barrier to med taking	All services	[Explore issue with patient –swallowing] *"We can offer you liquids instead of tablets for some of your medicines."* [If available within your service] *"We can offer you something called pill glide which makes it easier to swallow your medicines."* [Explore issue with patient –dexterity] *"We can offer you a Dosette box. This is a medication organiser that fits inside your medication box, but it also means you don't need to pop the pills out of their strips. This should make it easier to take your medicines."*
Patient unable to travel to clinic independently	All services	[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. There are details about how to contact the NHS transport service to find out if you are eligible for transport support."*
Patient unable to pay for costs to travel to clinic	All services	[If reimbursement office is available at the patients' site, show them the patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. It includes the details of the hospital reimbursement office where you may be able to claim travel costs back if you're eligible.* *We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers]
Needs interpreter	All services	[Use interpreter/language line to explain] *"We have asked to have an interpreter available for your appointments. We will do our best to make sure we address your language needs."*
	Social Care Team (SCT) in service	*"At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can help you with accessing support through your treatment. Is it okay for me to do that?*
Financial concerns		*We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers]

Urgent housing problem (homelessness)	No SCT in service	[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. Your local Citizen's Advice Bureau can give you helpful advice and information about benefits you may be entitled to. The charity TB Alert also has helpful information on their website.* *We will keep checking in to see if anything changes throughout your treatment and if you need any further help.*
	SCT in service	*We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers] *"At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can look at options to support you with finding housing during your treatment. Is it okay for me to do that?*
	No SCT in service (has recourse to public funds)	*We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers] *"I can call your local council housing officer at the end of our session today to see if we can arrange an appointment for you. Is it okay for me to do that?*
	No SCT in service (*no* recourse to public funds)	*We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers] *"I can [complete a housing assessment/follow other local protocols] at the end of the appointment to help support you with finding housing during your treatment. Is it okay for me to that?*
Other housing concern	SCT in service	*We can also offer you some travel vouchers to help support you to get to your next clinic appointment."* [provide vouchers] *"At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can help support you with your housing concerns. Is it okay for me to do that?"*

	No SCT in service	[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. Your local Citizen's Advice Bureau can give you information about your housing rights. There are also charities like TB Alert and Shelter who have helpful information on their websites. We will also keep checking in to see if anything changes throughout your treatment and if you need any extra help."*
	SCT in service	*"Treatment for TB is free in the UK, regardless of your immigration status. Our priority is to get you better. At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can help you with accessing support with your immigration concerns. Is it okay for me to do that?"*
Immigration concerns		[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. The immigration services listed here may also be able to help you."*
	No SCT in service	*Treatment for TB is free in the UK, regardless of your immigration status. Our priority is to get you better.*
		[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information which includes immigration services that may be able to help you."*
Current alcohol or drug problem	SCT in service	*"At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can help you access support through your treatment. Is it okay for me to do that?"*
	No SCT in service	*"At the end of our appointment today, I can call your local drug and alcohol services to arrange an appointment for you to get some support. Is it okay for me to do that?"*
History of mental health problem	All services	[Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. There are details of your local psychological services. You can refer yourself into these services at any time, or we can help you with this. If you have any concerns during your treatment you can always contact our TB team or your GP."*
Current mental health concerns	SCT in service	*"At the end of our appointment today, I can refer you to [SCT member] from the social care team in our service. They can help you with accessing support through your treatment. Is it okay for me to do that?"*

	No SCT in service	*"At the end of our appointment today, I can refer you to local psychological support services. Is it okay for me to do that?*
Lack of social support outside the medical team	All services	*It can take some time to get an appointment so in the meantime if you have any concerns, please always contact our TB team or your GP."* [Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session. For now, I want to show you this list of helpful information. Here is a link to a patient forum managed by the charity TB Alert, where patients can post questions about TB and treatment and interact with each other. It may be helpful for you to look at this during your treatment. You also always have the support of our TB team. If you ever have any concerns – please let us know."*
Doubts about need for treatment	All services	[Ask patient]: *"Can you please tell me more about why you feel you don't need TB treatment?"* [Validate as appropriate, e.g.]: *"I can understand why you may think that."* [Explain]*:* *"The TB team have found evidence of TB disease in your body. TB is a serious illness. It can make you feel unwell. But even if you don't feel unwell right now, it doesn't mean it is not there.* *But, the good news is that TB can be completely cured with the right treatment.* *So, TB treatment is really important because, without it, you will not get better.* *The sooner you start treatment, the sooner you will get rid of TB.* *We will watch a video soon that will explain more about why treatment is necessary for you."*

Worried about family/community response	All services	[Ask patient]: *"Can you please tell me more about why you feel worried about talking to your family/others about TB?"* [Validate as appropriate, e.g.]: *"I understand why you might feel that way. Other patients have this concern too.* [Explain]: *"There is a lot of misinformation about TB. People can be scared of TB because they don't understand how TB is spread and that it can't be treated."* [If the patient has extra-pulmonary TB]: *"For example, your TB infection is outside the lungs, so it cannot be passed on to others."* *"That is why we've worked with TB experts and people who have been treated for TB to make some videos that give you the right information about TB and TB treatment. We will watch these later."* [Show patient booklet] "*We also produced this booklet. It is yours to keep. We will look at it again later in our session."* [Turn to Talking to others about TB section] *"There is lots of information about TB and TB treatment in here. It may be helpful to share this with your family/friends so they can learn more about TB.* *It is up to you who you tell about TB. Having family and friends to support you with your treatment can be really helpful. You are welcome to bring anyone to your next appointment with the TB team. This can be helpful as we can discuss any concerns they might have together."*
Worried about storing/taking meds	All services	Ask patient]: *"Can you please tell me more about why you're worried about storing your medicines/taking them in front of others"?* [Validate as appropriate, see above examples] [Explain]: *"You will see that TB medicines look like medicines for lots of different*

illnesses. Other people would not know the difference unless you decided to tell them.

We will create a plan for taking your medicines later in our session today. You can decide when and where to take your medicines so you feel comfortable doing so.

Sometimes, people are scared because they do not have the correct facts about how TB is spread and that it can be treated."

[If the patient has extra-pulmonary TB*]: "For example, your TB infection is outside the lungs, so it cannot be passed on to others."*

"That is why we've worked with TB experts and people who have been treated for TB to make some videos that give you the right information about TB and TB treatment. We will watch these later."

[Show patient booklet] "*We've also made this booklet. It is yours to keep. We will look at it again later in our session."*

[Turn to Talking to others about TB section] *"There is lots of information about TB and TB treatment in here. It may be helpful to share this with your family/friends so they can learn more about TB.*

It is up to you who you tell about TB. Having family and friends to support you with your treatment can be really helpful. You are welcome to bring anyone to your next appointment with the TB team. This can be helpful as we can discuss any concerns they might have together."

Worried about remembering meds	All services	[Ask patient]: *"Can you please tell me more about why you're worried about remembering your medicines?"* [Validate as appropriate, e.g.]: *"Fitting medicines into your life can be difficult."* [Explain]: *"As we discussed, using* [adherence support patient is receiving e.g. DOT, medication reminders etc] *will help you to take your treatment. Today we will also make a plan for when it is best for you to take your medicines, and give you tips on how to get into a routine. Remember, if you ever have issues with remembering your medicines, you can always contact the TB team. They can see if there is additional support to help you with this."*

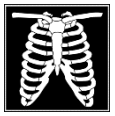
Video 1

Next the patient should watch the first video called "Helping You Understand Tuberculosis". This video addresses perceptions of TB as an illness but also the necessity of TB treatment by explaining the consequences of discontinuing treatment early.

Introduce the video to the patient: "*Now we are going to watch a short video to help you understand TB and TB treatment. If anything is unclear or you have any questions we can talk about these afterwards or you can ask me to stop the video as we watch it*."

After playing the video, ask the patient if they have any questions. Answer these appropriately. Let the patient know if these questions will be addressed in the second video or in the booklet.

Reviewing imaging



Check if there is any available imaging for the patient. If there is, you can choose to show this to the patient. Imaging can be helpful to link TB disease to treatment. For example, if you have the chest x-ray of a pulmonary patient available that shows disease, share this with the patient and explain to them that as explained in the video, this shows the TB bacteria in their body. It is important to link the problem to the solution, or in other words, to link the evidence of disease (from imaging) to the importance of TB treatment. Explain to patients that taking their TB treatment every day for their full course will get rid of the bacteria until it is all gone.

If no image is available or this does not appear helpful then you can choose not the share this with the patient.

Video 2

Show the patient the second video "Questions About TB Treatment". This video normalises and addresses common concerns that patients have when they begin TB treatment.

Introduce the video to the patient: *"We are going to watch another short video now. This video talks about common concerns some patients have when they start TB treatment. Once again, if anything is unclear or you have any questions, let me know."*

After playing the video, ask the patient if they have any questions. Answer these appropriately. Let the patient know if these questions will be addressed within the booklet.

Explain to the patient that re-watching the videos in their own time and sharing these with family and friends could be really useful. Ask the patient if they would like to receive links to the videos by text or email. Send these using their preferred method. Appendix 5 has a text or email template for sending this information (pg. 66).

Patient booklet

Overview

Provide the patient booklet.

Explain to patient (if they have not already been shown the booklet through the TNA linked actions section]: "*This booklet is yours to keep. It has information and resources to help support you through your TB treatment*."

[Turn to What is inside this booklet page]: "*This booklet has helpful information about TB and TB treatment that you can look at yourself or share with others. It also has links to the videos we just watched so you watch these at home.*

There is a lot of information in this booklet. It isn't meant to be read all at once. It is designed so that you can read the sections that are helpful to you when you need them. Spend time looking at the booklet at home. There is space inside for you to write down questions and thoughts you have as you go through it. You might think of questions you want to ask the TB team while you are at home, and it isn't always easy to remember these when you are at the clinic. If you write these down in your booklet and bring this to your appointments, then we can make sure we discuss your questions. Please bring your booklet with you every time you come to the clinic to see a member of the TB team."

Ask the patient if they would an electronic copy of the booklet emailed to them (instructions provided on pg. 14). A template message for sending the booklet is provided in Appendix 5 (pg. 66).

"Now let's talk about your TB medicines."

My medicines section

Turn to the My TB medicines section. This section has resources to help make taking treatment easier. These include clear information about the patient's medication regimen and how to take their medicines correctly ("My list of TB medicines"), a place to create a treatment goal and routine for taking medicines daily ("My medication action plan"), and a diary to record adherence and any side effects experienced ("My medication and symptom diary). Details are provided below on how to introduce and/or complete each of these resources with the patient in the baseline session:

My list of TB medicines

This is a place to list the patient's medication regimen. Use the medicine sticker labels provided. Each sticker represents a medicine. Some labels will need specific dose information to be added (i.e. medicines where dose is dependent on the patient's weight).

[Explain to patient]: "*This page will have your list of TB medicines. These labels have instructions about how each of your medicines should be taken*."

Ask the patient whether they think taking their medicines at morning or night would work best for them. Based on this, position the medicine labels at the top (morning) or bottom (evening) of the page.

The subsequent blank "My list of TB medicines" pages are provided so that new lists can be made when any changes in medicines or doses occur throughout treatment.

[Explain to patient]: "*These are your current medicines. If things change we will make a new list*".

Make sure the patient understands their regimen instructions. You could ask them to repeat this back to you.

Ensure that any relevant medication side effects are discussed with the patient as per standard care.

My medication action plan

Next, help the patient complete the "My medication action plan" page. The patient can write this themselves or you can help them with this.

First, help the patient create a treatment goal/reasons for completing TB treatment.

[Explain to patient]: "*Taking treatment for a long time can be challenging. It is helpful to remember why you want to get better to motivate you to keep going. Try think of reasons that are personal to you*."

[Example questions to prompt the patient]: *"Is your TB currently stopping you from doing anything?", "Why do you want to get rid of TB?" "What would getting rid of TB mean for you?"*

Right down any reasons the patient provides in the box. If the patient cannot think of a reason, you could suggest "getting better from TB" as a treatment goal.

Next, help the patient develop their medication action plan. First, ask about and record the time of day

that works best for the patient to take their medicines.

[Explain to patient]: "*As the video said, it can be helpful to link taking your medicines with another activity to help this become part of your daily routine. For example you could take your medicines after a shower, or after brushing your teeth.*

What do you do normally at this time of day that we could tie taking your medicines with?"

Listen to the patient's response and record it in this section. The more specific the plan is, the more helpful it will be for the patient. This is the same for deciding where medicines are kept.

[Explain to patient]: *"It can be helpful to keep your medicines somewhere so you see them at the time of day you need to take them. Where can you keep your medicines to help with this?"*

[Listen to patient response and record in this section e.g.]: "*So let's write in the box, you will keep your medicines in your bathroom next to your toothbrush, so you see them when you brush your teeth.*"

Note. Where medicines are stored will not be relevant for patients on DOT (unless they are self-managing their medicines). However, you may be able to link the time they will meet their DOT worker with another activity if this is relevant/helpful.

Next, run through the "If I forget" plan.

[Explain to patient]: "*Life can get busy and sometimes, and you may forget to take your medicines on time. If this ever happens, the If I forget plan down here in red tells you what to do.*

So if you forget your medicines and realise on the same day – take your medicines as you usually would following your usual instructions.

If you forget your medicines and don't realise until the next day, don't take yesterday's medicines – this would be a double dose. Instead, record that you missed yesterday's medicines in your diary (I'll show you how to do this in a moment), and take your medicines for today only. If you are ever unsure what to do, it is always best to call our TB team so we can help."

My medication and symptom diary

The medication and symptom diary helps patients keep track of their medicines but also has space to record any side effects. The HCP can then follow-up on adherence and side effects during the patient's next appointment. The medication and symptom diary is therefore a useful tool for both the patient and HCP. It is therefore really important to encourage the patient to utilise this resource.

[Explain to patient]: "*This is your medication and symptom diary. This is a really useful tool. On the left side, you can mark off when you take your medicines each day, just like a calendar. This is helpful to keep track of your medicines. It also means we can see if there are particular days where you are having issues remembering your medicines so we can try and find ways to help.*

On the right side there is space for you to write down how you feel when you take your medicines. Did you feel unwell or was there anything that concerned you after taking your medicines? This is helpful

because when we ask you how you've been at clinic, it isn't always easy to remember back to how you were when you were at home. Filling this out each day means that we can make sure we cover any issues during your next appointment."

If the patient is on a once daily regimen, they can mark off their calendar using an 'X' or ✓.

If the patient is on a twice daily regimen, refer them to the thought bubble on the diary pages. This suggests using two lines to mark when each dose is taken that day (to form an 'X').

If the patient is on a three times daily regimen, they could also use the 'X' idea to mark their first two doses, and then put a circle around this for the third dose e.g. ⊗

Ask the patient if they have any questions about how to complete the My medicines section of the booklet. Address these appropriately.

My TB treatment summary plan

A baseline treatment summary plan (see Appendix 6, pg. 66) should be completed for any patients receiving additional adherence support. Explain to the patient that this is for their records so they know the plan that you have made together to support them with their TB treatment. You can talk this through with the patient as you complete it to reiterate your plans as well as their additional adherence support. Remember to record if travel vouchers were given in the appropriate boxes if applicable for that patient (see pg. 14 for more information).

Helpful information about services section:

Show the patient the Helpful information about services section. This is a list of local services that may be helpful for them during their treatment.

[Explain to patient]: "*Here is a list of helpful services you may need during your treatment. Things change over time so it's helpful to know that this information is here in case you need it*. *We will always check in each time we see you as well to ask about how things are going."*

Add your contact details to the top box. Explain to the patient the availability of the service during working hours and what to do outside of this.

This completes steps 1 to 7 of the baseline session.

[Explain to patient]: "*We've covered a lot of information today. I want you to take time to look at your booklet at home. Feel free to watch the videos again if you wish. Write down any questions or concerns that you have in your booklet and bring this next time so we can talk about these. Start using your diary too and write down any difficulties you have. Remember to bring the booklet with you next time*."

Time for phone calls: The final action that should take place before continuing on to other standard consultation procedures at baseline is to ask the patient the best time to call them at home. This is for the Week 1 and Week 6 intervention phone calls. Let the patient know you about these times planned phone calls, but that it is also helpful to know when is best to reach them for any other contact needed.

Check that you have their correct contact phone number.

Service referrals

After delivering other standard care parts of the consultation (see Intervention and Standard Care Delivery diagram pg. 5 and 6), any follow-up referrals based on the TNA Linked Actions should be made. Complete referrals to any services using local procedures. This includes social care referrals if relevant for your service. Include the summary TNA output in your referral (instructions on how to do this can be found in the Intervention Components TNA section on pg. 12).

If no SCT is present in your service, referrals to services as highlighted through the TNA Linked Actions should be completed. E.g. referrals to IAPT, drug and alcohol services, housing assessments or local council housing officers.

Letter to GP

Relevant information from the TNA summary and regarding the patient's treatment plan (any adherence support) should be included in a letter to the GP. This can be incorporated into letters completed as part of standard care. Appendix 4 provides an example letter template demonstrating the information relevant from the intervention that should be included (pg. 62).

Patient notes

The output TNA summary should be added to patient notes, as this provides an important summary of barriers to adherence. As per standard care, also be sure to record any additional adherence support and the patient's care plan in their notes.

Section B: Week 1 phone call

The Week 1 phone call aims to provide support during treatment initiation. This call should take place as close to day 7 from the baseline session as possible. The purpose of the call is to check the patient has initiated treatment and to further address any beliefs identified in the baseline TNA that may be barriers to adherence. Make sure the baseline TNA output is available to you before completing the call. *Note.* Standard procedures and resources should be used (e.g. languageline) for patients who require interpretive services.

Begin the call by greeting the patient. Ask how they are, check treatment has been initiated and if any problems have occurred.

If problems have occurred or adherence issues are present, address these appropriately.

[Next, normalise concerns to the patient]: "*It is understandable that you may have concerns about TB treatment. Patients often have concerns when they start TB treatment. But, the TB team are here to help you get through treatment and back to feeling better. The booklet and videos we looked at in your*

last appointment explain the importance of your TB treatment and have tips to help you manage and stick with your treatment."

[Provide positive affirmation on progress]: "*The early weeks of treatment are often the most difficult for patients. You've done really well in starting treatment and taking your medicines so far."*

[Address beliefs identified on baseline TNA]: "*When we met last week, we talked about how you were feeling about TB and treatment. I want to check how you're doing now that you've started".*

Table 5. Scripts for addressing TNA beliefs

Doubts about need for treatment:	
"*Last week, you didn't seem convinced that you needed TB treatment – how do you feel now*?"	
[Validate patient's response]	
Patient now feels treatment necessary:	*"It is great that you understand how important your TB medicines are. Completing the full course of treatment is the only way to get rid of TB.*
Patient still has lack of treatment necessity beliefs:	*"Remember as we discussed, just because you can't see or feel TB it doesn't mean it isn't there. If you leave TB untreated, it will continue to make you ill and you will not get better. The only way to stop this is to take your TB medicines every day."*
	[If patient is infectious]*: "Remember that without medicines, you're also at risk of passing your TB infection on to others."*
	"Is there anything we can do to help with taking your medicines?" [Address as appropriate – e.g. if you have concerns about patient adherence, could consider a home visit if patient not already on DOT]
"*Remember, the TB team are always here to support you and we want to get you through your treatment. You can contact us at any time with any questions or concerns."*	

Worries about family/community response:	
"*Last week, you were concerned about talking to others about TB – how do you feel now?"*	
[Validate patient's response]	
Patient no longer worried about talking to others about TB:	*"That's good to hear. The more your friends/family understand TB, the more supportive they can be during treatment."*
	"Have you shown your friends/family the patient booklet or the videos?"
	[If no]: "*They may find these helpful to learn more. Remember, they are also welcome to come to your appointments and ask any questions they may have."*

[If yes]: *"Remember, they are also welcome to come to your appointments and ask any questions they may have."*

Patient **still worried** about talking to others about TB:

"*Often family/friends are scared of TB because they don't have the correct facts. I think it would be helpful to bring your friends/family to your next clinic appointment if you would feel comfortable with that. They can tell me their concerns and we can discuss these so they better understand TB."*

"Is there anything we can do to help with taking your medicines?" [Address as appropriate – e.g. if you have concerns about patient adherence, could consider a home visit if patient not already on DOT]

"*Remember, the TB team are always here to support you and we want to get you through your treatment. You can contact us at any time with any questions or concerns."*

Worries about storing/taking meds:

"*Last week you were worried about storing your TB medicines/taking your TB medicines in front of others - how are you feeling about this now?"*

[Validate patient's response]

Patient no longer worried about storing meds/taking in front of others:

"That is good to hear. Remember, you decide who you want to tell about your TB treatment and how to fit taking your treatment into your life. You are always welcome to bring family/friends to the clinic to learn more about TB if this would be helpful."

Patient **still worried** about storing meds/taking them in front of others:

"Now you have your TB medicines, you will see that these look like medicines for lots of different illnesses. Other people would not know the difference unless you decided to tell them.

Remember, you decide who want to tell about your TB treatment and how to fit taking your treatment into your life.

You are always welcome to bring family/friends to the clinic to learn more about TB if this would be helpful. That way I can help address any questions or concerns they might have."

"Is there anything we can do to help with taking your medicines?" [Address as appropriate – e.g. if you have concerns about patient adherence, could consider a home visit if patient not already on DOT]

"Remember, the TB team are always here to support you with your treatment. You can contact us at any time with any questions or concerns."

Worries about remembering meds:

"Last week you mentioned worries about being able to remember your medicines – how are you feeling about this now?"

[Validate patient's response]

Patient no longer worried about remembering medicines:	"*It's good to hear that you're doing well. We will check again at your next appointment, but If you have any issues before then, let our TB team know*."
Patient **still worried** about remembering medicines:	"*Sticking to a new medicine routine can take time."*
	[Ask about current routine. Suggest appropriate changes to time or habit. Suggest reminders (if not already using), e.g. visual cues for medicines, linking treatment to another behaviour, alarms, peer support if available]
	"Is there anything we can do to help with taking your medicines?" [Address as appropriate – e.g. if you have concerns about patient adherence, could consider a home visit if patient not already on DOT]

"*Remember, the TB team are always here to support you and we want to get you through your treatment. You can contact us at any time with any questions or concerns."*

[Ask the patient if they have any questions. End the call by reminding them of next appointment]:

"*Well done on getting through your first week. We will see each other next week at clinic and check how you are doing. If you have any issues before then, please get in touch with the TB team*".

Section C: Week 2 session

Overview

The Week 2 session structure differs from the previous baseline session and later follow-up sessions. It is important to familiarise yourself with the different session outlines. Parts of the Week 2 session involve the patient booklet. If the patient does not bring their booklet, continue with the interventions steps as much as possible. For example, the master copy can be used to discuss topics relevant to the Information and Support Questionnaire. You can also ask the patient to self-report their adherence and any side effects experienced, and report on whether their medication plan is working. If the patient has lost their booklet at Week 2, the HCP delivering the intervention should print out the My TB Medicines section so that the patient can continue to use the patient diary and complete their medication action plan again.

At Week 2, if the patient does not have their booklet check if they have lost this or have just forgotten to bring it today. Remind them to search for this and bring it along to their next session if they find it. In the meantime, patients can also be emailed a PDF copy of the booklet which may be helpful for them.

The HCP delivering the intervention can also print off any additional booklet information sections (booklet Sections 1 and 2) they think the patient would find useful.

Adherence review

The Week 2 session begins with an adherence review. This can be completed using any resources normally used in clinic (e.g. urine tests, pill counts). In addition you may want to check the medication diary or ask the patient to self-report their adherence.

Adherence can also be reviewed by checking the patient's understanding of their regimen. Ask the patient which tablets they take and how many they take each day.

It is helpful to first normalise non-adherence:

[Example normalisation statement]: *"Any information you can give us about your treatment and any difficulties is really useful. It means we can see how treatment is working for you, and if there is anything extra than we can do to support you.*

Many patients come across some issues when taking their treatment. Particularly, when they first start. Have there been any days where you didn't take your medicine as planned? What happened?"

Any non-adherence should be highlighted on the follow-up TNA as explained below.

Follow-up TNA

From Week 2 onwards, the patient completes the follow-up TNA. The follow-up TNA is shorter and focuses on identifying new barriers that may affect adherence. It is important to re-familiarise yourself with the patient's response to their baseline TNA, and any previous barriers that were highlighted [insert instructions on how to access through computer tablet]. The first item on the follow-up TNA asks about any non-adherence demonstrated. There are also additional items about side effects, which may have become an issue since starting treatment. A guide on how to ask items at follow-up can be seen in Appendix 2 (pg. 49 to 51).

[Explain to patient]: *"I'm going to ask you some questions similar to those we talked through in our first session. We want to see if anything has changed for you since we last saw each other."*

Complete the follow-up TNA. After asking all items, there are three follow-up steps to complete:

1) Consider stepping up additional adherence support

   If new barriers are highlighted at follow-up, consider stepping up the patient's level of additional adherence support where appropriate. This may be relevant for barriers such as demonstrated non-adherence, changes in living arrangements, deterioration of mental health, and others. This may be less relevant for other items e.g. worries about side effects may not necessarily need an increased level of adherence support, but should be addressed through the linked TNA action (highlighted below).

The hierarchy of additional adherence support options can be seen in Figure 1 (pg. 17). If the patient is already on DOT/VOT, follow any usual standard care procedures available to increase support e.g. additional visits/contact. If the patient is being stepped up from reminders or a Dosette, explain DOT/VOT to them using the information on pg. 16 to 19.

2) TNA Linked Actions

Any new barriers highlighted should be addressed using the TNA Linked Actions and same instructions provided in the Baseline Intervention Delivery section (pg. 19 to 26). From Week 2 onwards, worries about side effects may be a new belief highlighted. Usual procedures should be used for managing any experienced side effects (this can be completed during the medication review as per intervention step 6 (see pg. 36)). If worries about side effects are highlighted, these should be addressed using the following script:

Item	Site differences	Script to address
Worries about side effects [FOLLOW-UP ONLY]	All services	[Ask patient]: *"Can you please tell me more about your worries about side effects?"* [Validate as appropriate, e.g.]: *"Worries about side effects are common for many patients."* [Explain]: *"Any medical treatment can cause side effects. It is important to know that most patients will not get side effects. Our TB team will monitor you closely and help manage any side effects that do happen."* [Show patient booklet] *"This booklet is yours to keep. We will look at it again later in our session."* [Turn to Managing Side Effects section]*: "This section talks about how to manage any side effects. The most important thing to remember is that if you are ever concerned about how you are feeling, you can always contact the TB team. We are there to support you through your treatment."*

3) Check previous linked actions status

Check the status of any relevant TNA Linked Actions from the previously completed TNA (e.g. ask if the patient has been contacted by the SCT. If the HCP delivering the intervention has made referrals

to services on the patient's behalf (e.g. housing, D&A, psychological support), ask the patient if they have been contacted by these services/had appointments made. Follow-up where necessary.

Information and Support questionnaire

At 2 week session only, the Information and Support questionnaire (ISQ) should be delivered using the computer tablet via REDCap (see pg. 12 to 14 for instructions).

Read the instructions aloud at the top of the questionnaire. The patient can complete the ISQ themselves or with assistance from the HCP delivering the intervention.

[If patient selects more than 2 topics, ask]: "*What are the two topics that you would most like information about today?"*

Go to the sections of the booklet linked with these topics and summarise the information (see Table 1, pg, 13) for these topics. Ask the patient if they still have any specific questions about each section and respond accordingly.

For any additional topics that you are not able to cover during your session, show the patient where they can find these sections in the booklet. Encourage the patient to review these sections at home, and write down any questions that can be addressed in the next session.

Questions and Concerns

At each follow-up session, ask the patient if they have any other specific questions or concerns they would like to discuss.

If the patient has their booklet, check if they've written down any questions or concerns on the "My thoughts" pages throughout the book. Address these appropriately. Revisit any information in the patient booklet or re-watch the videos if you feel that this will help address the patients' concern.

Medicines review

At each follow-up session, the patient's medicines should be reviewed using the My TB medicines section of the patient booklet. *Note.* Use the master copy to guide discussion if the patient has not brought their booklet. As stated above, If the patient has lost their booklet and it is not possible to give them a replacement booklet, the HCP delivering the intervention should print out the My TB Medicines section so that the patient can continue to use the patient diary and complete their medication action plan again.

My list of TB medicines

Firstly, check if there are any changes to the patient's regimen since you last saw them. If so, use the medication labels to make a new list on a blank My list of TB medicines page. Use a pen to cross out the previous list and explain to the patient that this is no longer correct. Make sure the patient understands

any new instructions for their medicines – this includes explaining any side effects to new medicines as per standard care.

My medication action plan

If the patient has their booklet, reflect on their reason for completing treatment.

[Examples to discuss]: "*Remember why you want to get better. Last time, you said this was to [talk about patient's reasons]. Is there anything you want to change or add to this section now*?"

Address appropriately.

Provide positive affirmation to patient: "*You are doing well to manage your TB treatment. TB medicines can be complicated and the beginning of any treatment can be challenging. Remember how well you are doing. Each day you are a step closer to getting rid of TB*."

Check the patient's medication action plan. Is this working for them? Do any new medicines or instructions mean this needs to be altered? *Note.* This can be done via self-report if the patient has forgotten their booklet. This is particularly important if non-adherence has been identified. Non-adherence may be a result of the plan not working. Make changes as appropriate. If any updating is needed, use blank white labels to cover sections on the page and write new instructions.

If non-adherence was identified, check what the patient did. Did they follow the If I forget plan? Make sure they are familiar with what to do and they know to always call the TB team if they have any questions.

My medication and symptom diary

If the patient has their booklet, look if they have been using these resources. Encourage them to continue doing so. Remind them that ticking off each time they take their medicines can help them feel one step closer to completing treatment. *Note.* Ask the patient to self-report any issues if they have not brought their booklet.

If the patient hasn't been using the diary, encourage them to do so. Explain that this is a helpful way to keep track of taking their medicines and record any issues.

See if the patient has filled out anything in the difficulties/side effects section. Enquire about these and address any side effects as appropriate using standard management procedures. *Note.* If the patient has not brought their booklet, ask them to self-report any issues and address appropriately.

Encourage the patient to keep using these resources and to record any concerns and questions on the relevant pages, so that these can be discussed next time you see each other.

My TB treatment summary plan

Complete a follow-up treatment summary plan if there were any changes/new barriers identified on

the follow-up TNA (see Appendix 6, pg. 66).

New referrals

Complete any new referrals needed as indicated by the follow-up TNA.

Letter to GP

From Week 2 onwards, include any information about changes in barriers to adherence or levels of adherence support in the letter to the GP. This information can be included in the letter sent as part of standard care. An example of how to word this is given in Appendix 4 (pg. 63). This should include the TNA follow-up summary and any important information regarding referrals or changes in additional adherence support.

Patient notes

The TNA summary output can be added to the patient notes if new barriers are highlighted or if there are any changes to additional adherence support (instructions on how to do this are provided on pg. 12).

Section D: Month 1 to Month 5 sessions

Overview

All intervention sessions from Months 1 to 5 follow the same format (see Intervention Session Structure diagram pg. 9). This includes the adherence review, TNA follow-up (including associated follow-up steps), checking patient questions and concerns, medicines review, and following up with any referrals as necessary. Changes in additional adherence support level or new barriers highlighted should be addressed by new referrals, including providing the TNA summary in a letter to the GP and in patient notes. The instructions for completing these components can be followed as described in the Week 2 session. When completing the follow-up TNA, be sure to always re-familiarise yourself with previous responses and barriers highlighted, so that any changes and new issues can be easily identified.

At 1 month, if the patient does not have their booklet and this is still lost, then you may provide them with a replacement booklet, if resources are available. *Note.* There are limited additional booklets available in each service. Replacements can therefore only be provided where possible and a patient should only ever receive a maximum of one replacement booklet. If a replacement is not possible, patients can be emailed a PDF copy of the booklet which may be helpful for them (see pg. 27). The HCP delivering the intervention can also print off any booklet sections they think the patient would find useful. The My TB Medicines sections should always be available to patients so they can complete the diary and have the medication action plan, so re-print this section for any patient who does not have this with them.

Continuation phase of treatment

At Month 2, most patients will move into the continuation phase of their treatment as per standard care. The patient's "My TB medicines list" will therefore need updating. Provide the patient with positive affiliation for achieving this milestone and remind them how well they are doing. Any new barriers highlighted through the TNA or changes in level of adherence support should be included in a letter to the GP, the same as in previous sessions.

Reducing level of additional adherence support

When checking adherence at each session, it may become apparent that the level of adherence support the patient has been receiving is no longer necessary. For example, a patient who is consistently adhering well may no longer need the level of touch provided by DOT/VOT. The decision to reduce adherence support is to be made at the discretion of the HCP delivering the intervention, as per standard care, and should be only be done so where the HCP feels confident that the patient can now self-manage treatment.

Section E: Week 6 phone call

At Week 6 from baseline, the second phone call to the patient should be made. This call aims to reiterate the importance of treatment maintenance, given that many patients may be less symptomatic at this stage.

[Greet patient. Check how they are doing. Address any issues appropriately]

[Provide positive affirmation of progress]: "*I want to thank you for sticking with your medicines. Taking treatment for any illness can be really challenging. It is important to remember how well you are doing with managing a difficult treatment. Remember, each day is a step closer to getting rid of TB. Keep marking this off in your calendar so you can see the progress you are making.*"

[Ask patient how they feel now compared to baseline. Acknowledge where there is improvement]

[If patient is still symptomatic, explain]: "*You've made great progress with your treatment. Although it may not always feel like it, each time you take your medicines you are reducing the amount of TB in your body. This will make you feel better over time as it continues to cure your TB. Do you feel like you have any issues with taking your medicines?*"

[Address appropriately. Consider further support options if necessary].

[If patient is feeling better, explain importance of treatment maintenance]: "*It's great that you are feeling better. This is good news - it means that the treatment you are taking is working.*

It may seem strange that you still need medicines when you feel better, but TB is different to other illnesses. Feeling better does not mean your TB is cured. We know that it takes at least 6 months to cure TB. Remember, if you stop taking your medicines early this would reverse all your hard work. The TB bacteria could start to increase again, making you feel unwell, and also at risk of passing TB on to others.

Sticking with your medicines, just as you have been for the past 6 weeks, means you will recover from TB."

[Ask if patient has any questions. End call by reminding them of next clinic appointment].

Section F: Month 6 session

This is the final intervention session for the study. As seen in the Intervention Session Structure Diagram (see pg. 10), the content of this session differs depending on the patients' treatment length.

Patients who are completing treatment at Month 6 session

Adherence review

As depicted on the left-hand side of the Intervention Session Structure diagram – Month 6 (pg. 10), the patient should have a final adherence review to check that they have completed their treatment. Follow standard care procedures for this.

Imaging

If available, this is a good opportunity to compare the patient's baseline imaging with current imaging. This allows the patient to see the improvement from their treatment. It may provide reassurance for patients who are worried about TB not being cured. Explain and use imaging with patients appropriately.

Providing reassurance

This is an important step of the final session. We know that some patients continue to worry about TB returning or spreading when they see symptoms in themselves or others.

[Ask the patient]: "*How are you feeling now that you have been cleared*?"

[Listen and validate the patient's response]

[Explain to the patient]: "*Now that you have completed treatment, your TB infection has gone. That means there is no TB bacteria in your body. The chance that you would get TB again is really low. The best thing you can do to keep yourself well is to keep up a healthy lifestyle.*

If you do ever have worries or concerns about TB, get in touch with us here at the TB service. You are always welcome at the clinic and we will be happy to help where we can."

Questions and concerns

Ask the patient if they have final questions about their TB and address these appropriately. Deliver anything else as part of standard care for completing treatment.

Letter to GP

Complete a letter to the GP using the template in the Appendix 4 (pg. 64).

Patients whose treatment is longer than 6 months

Patients whose treatment lasts longer than 6 months may stay in the study up until 12 months or treatment completion (whichever happens first). For these patients, continue using the session structure provided on the right-hand side of the Intervention Session Structure – Month 6 diagram (page 10). This session structure follows the same format as the standard follow-up sessions described from Months 1 to 5 (on page 9). If the patient completes their treatment before the 12 month maximum date, deliver the completing treatment session structure for their final session (see left side of Intervention Session Structure – Month 6 diagram, pg. 10).

If patients are continuing on treatment after the maximum 12 months of study participation, they will be discharged from the study and treated using standard care procedures. The HCP delivering the intervention can choose to continue using the resources/structure from the IMPACT intervention for those standard care sessions if they wish (follow the Intervention Session Structure – Months 1 to 5 diagram on pg. 9, details on pg. 37 to 38), although these patients will no longer be followed up as part of the study.

References

Horne, R., Cooper, V., Wileman, V., & Chan, A. (2019). Supporting Adherence to Medicines for Long-Term Conditions: A Perceptions and Practicalities Approach Based on an Extended Common-Sense Model. *European Psychologist*, Vol. 24, pp. 82–96. https://doi.org/10.1027/1016-9040/a000353

Horne, R., Weinman, J., Barber, N., Elliot, R., Morgan, M., & Cribb, A. (2005). *Concordance, adherence and compliance in medicine taking: Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO)*. London, UK.

Appendix 1: IMPACT intervention components and standard care using an example care pathway

Note: Below is an example of a nurse led follow-up pathway for patients receiving treatment for active TB (based on the North Central London model). It is not intended to be a prescriptive or exhaustive description of standard care but rather a guide to how the study intervention might interact with components of standard care where they are applied. The right-hand column of the table shows where parts of the IMPACT intervention can replace parts of this pathway. The IMPACT intervention does not replace standard care, and it is important that standard care procedures that are not covered in the intervention are still delivered. The Intervention and Standard Care Delivery diagrams provide detail of how the intervention can fit into standard care (see pg. 5 and 6).

Visit	TB Nurse actions in standard care	Action: ✓ (TBC as standard care) X (IMPACT intervention component replaces)
1 (day 0) treatment start	• Check patient demographic details including contact number	✓
	• Risk assessment – treatment plan, consider DOT	X TB Needs assessment
	• Check TB medication – explain regimen	X completed as part of "My TB medicines" section of patient booklet
	• Explain potential side effects: o discoloured urine/body fluids o skin rash, itching or jaundice o nausea/vomiting o peripheral neuropathy o interaction with other medication including contraceptive pill (advise alternative) o dietary restrictions.	✓
	• Check weight	✓
	• Check baseline LFT's NAD before commencing treatment	✓
	• Eye assessment for patient on Ethambutol – Ishihara/schnellen test and document record of warning patient to stop treatment and contact us if visual symptoms occur	✓
	• Provide patient information leaflet	X IMPACT patient booklet provided and discussed
	• Provide name and contact number of case manager and TB clinic	X Provided in "Helpful information about services" section of patient booklet

	• Contact tracing assessment	✓
	• Commence cohort review documentation	✓
	• Admin to notify on LTBR	✓
	• Consider patient eligibility for research studies	✓
Day 7 (community home visit)	• Assess patient environment and identify further contacts – arrange screening appointment while on site at patients home where possible	✓
	• Consider commencing contact tracing in the community	✓
	• Symptom check	✓
	• Assess side effects and take action as appropriate	✓
	• Adherence discussion/tablet identification	✓
Day 14	• Weight – check dosage correct and take appropriate action	✓
	• Symptom check	X completed as part of "My TB medicines" section review in patient booklet
	• Assess side effects of treatment, Record that eye symptoms specifically enquired about if on ethambutol	X completed as part of "My TB medicines" section review in patient booklet ✓ eye symptoms need to be recorded in patient notes
	• Check adherence (tablet count/urine check)	X completed as part of adherence review
	• Re – check LFT's only is background liver disease/previous LFT's significantly abnormal/pt for anti TNF	✓
	• Bloods: request vitamin D level, HbA1c, hepatitis B surface antigen, hepatitis C antibody screen, HIV if not previously offered and done	✓
	• Request x3 sputum samples for AFB's if patient still expectorating	✓
	• Check microbiology results	✓
	• Complete risk assessment as necessary	X follow-up TNA completed at every follow-up appointment
	• Follow-up on identification/appointing of contacts details/progress	✓
	• Confirm patient understands action to take if unwell (i.e. contact clinic/GP/A&E)	✓
	• Complete electronic record/generate letter	✓ (GP letter is completed if

		there are changes to record at follow-up)
1 month	• Weight – check dosage correct	✓
	• Symptom check	X completed as part of "My TB medicines" section review in booklet
	• Assess side effects of treatment. Record that eye symptoms specifically enquired about if on ethambutol	X completed as part of "My TB medicines" section review in booklet ✓ eye symptoms need to be recorded in patient notes
	• Inform patients of bloods results from last appointment e.g. HIV/Hep B/Hep C/Vit D	✓
	• Re-check LFT's if indicated	✓
	• Request sputum for AFB's in patients with pulmonary TB if still expectorating	✓
	• Check microbiology results	✓
	• Check adherence (tablet count/urine check)	X completed as part of adherence review
	• Complete electronic record/generate letter, include BBV and vitamin D results depending on local procedure	✓ (GP letter is completed if there are changes to record at follow-up)
Month 2	• Step down medication if indicated	✓
	• Dr to write up 4 month prescription or as per locally agreed protocol	✓
Month 3	• Weight – check dosage correct. Discuss with Dr if amendment required	✓
	• Symptom check	X completed as part of "My TB medicines" section review in booklet
	• Assess side effects of treatment. Record that eye symptoms specifically enquired about if on ethambutol	X completed as part of "My TB medicines" section review in booklet ✓ eye symptoms need to be recorded in patient notes
	• Re check LFT's if previous results abnormal	✓
	• Check microbiology results	✓
	• Check adherence (tablet count/urine check)	X completed as part of adherence review
	• Supply 1 month TB medication	✓
	• Complete electronic record/generate letter	✓ (GP letter is completed if there are changes to record at follow-up)

Month 4	• Weight – check dosage correct. Discuss with Dr if amendment required	✓
	• Symptom check	X completed as part of "My TB medicines" section review in booklet
	• Assess side effects of treatment. Record that eye symptoms specifically enquired about if on ethambutol	X completed as part of "My TB medicines" section review in booklet ✓ eye symptoms need to be recorded in patient notes
	• Re check LFT's if previous results abnormal	✓
	• Check microbiology results	✓
	• Check adherence (tablet count/urine check)	X completed as part of adherence review
	• Supply 1 month TB medication	✓
	• Complete electronic record/generate letter	✓ (GP letter is completed if there are changes to record at follow-up)
Month 5	• Weight – check dosage correct. Discuss with Dr if amendment required	✓
	• Symptom check	X completed as part of "My TB medicines" section review in booklet
	• Assess side effects of treatment. Record that eye symptoms specifically enquired about if on ethambutol	X completed as part of "My TB medicines" section review in booklet ✓ eye symptoms need to be recorded in patient notes
	• Re check LFT's if previous results abnormal	✓
	• Check adherence (tablet count/urine check)	X completed as part of adherence review
	• Supply 1 month TB medication	✓
	• Complete electronic record/generate letter	✓ (GP letter is completed if there are changes to record at follow-up)
Month 6	• Final review by dr	✓
	• CXR for all pulmonary TB patients	✓

Appendix 2. Guide to items on the TNA

Baseline

Demographics

Older Age (65+): Patients' with older age are consider more high need. Ticking yes to this item indicates need for additional adherence support. This information will most likely be gathered from medical notes but can confirm with patient.

Child, adolescent, or young adult (up to age 25): Younger patients' are more high need. Ticking this item indicates need for additional adherence support. This information will most likely be gathered from medical notes but can confirm with patient. The up to 25 limit is so that young adults can also be included here who may not be adolescents but who's age and lifestyle may indicate a need for additional adherence support.

Medical factors

Previous TB treatment or diagnosis (including latent TB): Ticking yes indicates need for additional adherence support. This information will most likely be gathered from medical notes but can confirm with patient (particularly if they are from overseas).

Co-morbidities: Selecting a co-morbidity does not in itself indicate need for additional adherence support (see next item). This does allow this information to be collected and used in notes and letters where relevant. This information will most likely be gathered from medical notes but can confirm with patient (particularly if they are from overseas).

Unable to manage their current co-morbidities (e.g. medicines management or following health advice): Ticking yes indicates need for additional adherence support. Some of this information may be gathered from medical notes but will probably need to ask the patient to self-report.

[Example questions to elicit information]: "It can be hard managing medicines for conditions, particularly if they have specific instructions to follow. How do you find managing your medicines for your condition? Do you ever have any issues/trouble storing these and making sure you take them as needed?

"Tell me about how you find following advice (e.g. lifestyle, diet) for managing your condition. Have you ever had problems with this?"

Complex TB type (extensive pulmonary, CNS, or disseminated): Ticking yes to this item indicates need for additional adherence support. This information will be gathered from medical notes.

Known drug resistance: Ticking yes to this item indicates need for additional adherence support. This information will be gathered from medical notes.

Patient has a history of missed previous appointments with the TB service or for another chronic condition: Ticking yes to this item indicates need for additional adherence support. This information

may be gathered from medical notes or known already (if TB service has had trouble getting hold of the patient), although patient self-report may also be required.

[Example questions to elicit information]: "Have you ever had any issues with attending clinic appointments for [name co-morbidity if known]?" "Have you managed to get to your appointments okay?" [If applicable, explore reasons for any issues]

Previous non-adherence to TB treatment or treatment for a chronic condition: Ticking yes to this item indicates need for additional adherence support. This information may be included in medical notes (particularly if previous TB) or known already by TB service, but self-report from patient may also be required. *Note.* There may be some overlap here and information already gathered to answer this from the "unable to manage current co-morbidities" item.

[Example questions to elicit information]: "It's really common for people to find it hard to remember to take their medicines. How did you/do you find taking your medicines for [insert co-morbidity]" "Have you ever had problems/issues in being able to take your medicines every day/as needed for [name of co-morbidity]?" "Is this something that happened to you regularly?"

Practical/communication factors

Patient has physical barrier to taking medication (e.g. difficult swallowing pills, opening tablets): Ticking yes to this item indicates need for additional adherence support. Information relevant to answer this item may be included in medical notes otherwise you may need the patient to self-report. *Note.* Dexterity issues likely to be most relevant to older patients – may not be necessary

[Example questions to elicit information]: How do you find taking tablets?" "Do you have any problems with swallowing tablets?" "Do you have any problems with being able to open pills bottles?"

Patient is too ill or frail to administer treatment themselves: Ticking yes to this item indicates need for additional adherence support. Information relevant to answer this item will most likely be gained a judgement of the patient's physical symptoms. *Note.* Fragility will likely to be most relevant to older patients. If you would like to ask the patient to self-report how they feel:

[Example question to elicit information]: "Do you feel able/well enough to be able to take your TB treatment without help from someone else?"

Patient is unable to travel to clinic independently (e.g. due to mobility issue or other mental health/health issue): Ticking yes to this item indicates need for additional adherence support. Information relevant to answer this item may be in the patients' notes or apparent from meeting the patient. Patient self-report may also be necessary. As well as mobility/access issues, patients may also need assistance to get to clinic if they have other cognitive, health or mental health issues. Some of this information may be gathered from medical notes but will probably need to ask the patient to self-report. It will also be important to determine the level of support available to the patient, as this should influence the type of additional adherence support that will be most appropriate for this patient (e.g. do they have a carer or family member who can help them to use VOT or would home DOT be more suitable?).

[Example questions to elicit information]: [Example question to elicit information]: "We will need to see

you on a monthly basis – how did you get here today? Are you going to be okay to come back to the TB clinic for each visit?" "Does someone usually help you with getting around and to other appointments?" "Do you have support available at home?"

Patient is unable to pay costs for travel to clinic: Ticking yes indicates need for additional adherence support. This item will need to be gathered by patient self-report, although this may already be indicated from the financial concerns item.

[Example question to elicit information]: "We will need to see you on a monthly basis – How did you get here today? Are you going to be okay to come back to the TB clinic for each visit?"

Needs interpreter (unable to communicate in English): Ticking yes to this item indicates need for additional adherence support. Information relevant to answer this item may be in the patients' notes or apparent from meeting the patient.

Sensory impairment (e.g. visual impairment, hearing impairment, other sensory issues): Ticking yes to this item indicates need for additional adherence support. Information relevant to answer this item may be in the patients' notes or apparent from meeting the patient. Otherwise, you may need the patient to self-report It will also be important to determine the level of support available to the patient, as this should influence the type of additional adherence support that will be most appropriate for this patient (e.g. do they have a carer or family member who can help them to use VOT or would home DOT be more suitable?).

[Example question to elicit information]: "Do you have any issues with eyesight or hearing?" [If so, investigate further to see if this affects their ability to take treatment]. "Does someone usually help you with getting around and to other appointments?" "Do you have support available at home?"

Cognitive or memory disorder (e.g. autism, dementia, learning disability): Ticking yes to this item indicates need for additional adherence support. It will also be important to determine the level of support available to the patient, as this should influence the type of additional adherence support that will be most appropriate for this patient (e.g. do they have a carer or family member who can help them to use VOT or would home DOT be more suitable?). Information relevant to answer this item may be in the patients' notes or apparent from meeting the patient. If this is unclear and self-report is needed an example question is below:

[Example question to elicit information]: "Have you ever been diagnosed with any problems with memory or learning?" [If yes] "Does someone usually help you with getting around and to other appointments?" "Do you have support available at home?"

Structural factors

Patient has financial concerns (e.g. unemployment, insecure employment status, reliance on welfare benefits etc): Ticking yes indicates need for additional adherence support. Some of this information may be gathered from medical notes but will probably need to ask the patient to self-report.

[Example questions to elicit information]: "Do you have any concerns about being able to support

yourself financially? Do you have stable employment? Are you receiving welfare benefits?"

Urgent housing problem (no fixed abode): Ticking yes indicates need for additional adherence support. Information to help determine if the patient has recourse to public funds can be found at the following websites [www.nrpfnetwork.org.uk and [https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide]. This item may be known before the patient comes in (e.g. if referred from find and treat, or from gathering patients details). This information may also need collecting/confirming by patient self-report (there may have been indications of hardship from the financial concerns item).

[Example question to elicit information]: "Where are you living at the moment? Who are you living with?" "Do you have a stable place of living at the moment?"

Other housing problem (e.g. concerns about covering rent, 'sofa surfing', history of homelessness in past 5 years or other unstable housing issue): Ticking yes indicates need for additional adherence support. This item will need to be gathered by patient self-report, although there may have been indications from the financial concerns item. *Note*. If the patient highlighted financial concerns you may want to ask them specifically about concerns with covering rent.

[Example question to elicit information]: "Where are living at the moment? Who are you living with? "Have you ever had any problems with having a stable place of living in the past?" [If patient has highlighted financial concerns]: "Have you ever had concerns about covering rent?"

Immigration concerns (i.e. worries about right to stay in the UK): Ticking yes indicates need for additional adherence support. Collecting demographic information as per standard care at the beginning of the consultation should mean a patient's place of birth and time spent in UK may already be known. This item may also need to be answered by patient self-report. *Note*. The question only needs to be asked to patients who are not a UK citizen. It may be helpful to begin by asking the patient how long they have been in the UK.

[Example questions to elicit information]: "How long have you been living in the UK for?" "Do you have any concerns about immigration and right to stay in the UK?"

History of prison in last 5 years: Ticking yes indicates need for additional adherence support. This item will need to be gathered by patient self-report, unless the information is already known.

[Example question to elicit information]: "Have you ever spent time in prison or detention centres?" "Do you have any history of imprisonment during the past 5 years?"

Psychosocial Factors

Current alcohol problem (affects person's daily functioning): Ticking yes indicates need for additional adherence support. This item will need to be gathered by patient self-report, unless the information is already known/in patient notes.

[Example question to elicit information]: "Alcohol and drugs can interact with TB medicines, so it is important for us to know if you use these. Do you drink alcohol to a level that affects your day to day life, for example your ability to look after yourself or work?"

Current drug problem (affects person's daily functioning): Ticking yes indicates need for additional adherence support. This item will need to be gathered by patient self-report, unless the information is already known/in patient notes. *Note*. Drugs can include illegal, recreational or prescription.

[Example question to elicit information]: "Do you take any drugs to a level that it affects your day to day life, for example your ability to look after yourself or work?" [Follow-up questions: "What drugs? How often do you take these?"]

History of mental health problems (anxiety disorder, depressive disorder, personality disorder, psychosis): Ticking yes indicates need for additional adherence support. This item may be in the patient notes but self-report may be needed otherwise.

[Example question to elicit information]: "Have ever been diagnosed or treated for any mental health problems?"

Patient or nurse has current concerns about patients' mental health: Ticking yes indicates need for additional adherence support. This item may be answered from the nurse's judgement of the patient's mental health, but you can also ask patient's to self-report any concerns.

[Example question to elicit information]: "How are you feeling at the moment?" "Do you have any current worries about your mental health?"

Lack of treatment support OUTSIDE OF THE MEDICAL TEAM (i.e. people who can support the patient during their treatment): Ticking yes indicates need for additional adherence support. This item will need to be answered by patient self-report. We want to know whether or not the person is lacking in potential social support through their treatment.

[Example question to elicit information]: "Do you have someone in your life like a family member or friend, who can support you during your treatment? By support we mean they can be around, come to clinic appointments if you need them to and generally check in to see how are doing."

Patient has doubts about their need for treatment or their diagnosis: Ticking yes indicates need for additional adherence support. This is the first item that aims to understand the patient's beliefs about their TB and TB treatment. Having a lack of perceived need for treatment is an important barrier to adherence (as there is no psychological 'fit' between the illness and treatment).

[Example questions to elicit information]: "How do you feel about your TB diagnosis?" "How do you feel about your TB treatment?" "Do you feel that you need treatment to get better?"

Patient is worried about the response from their family/community to their TB diagnosis: Ticking yes indicates need for additional adherence support. This is the second belief item. This item aims to highlight the presence of stigma about TB that may affect adherence to treatment.

[Example question to elicit information]: "How do you feel about talking to your friends and family about TB?"

Patient is worried about storing medicines/taking medicines in front of others: Ticking yes indicates need for additional adherence support. This is the third belief item. This item aims to highlight the

presence of stigma specifically about taking TB treatment or storing medicines. This is likely to be more apparent for patients from communities where stigma about TB is present.

[Example question to elicit information]: "We will talk about your medicines shortly. How do you feel about taking your TB medicines? Do you have any worries about where/when you can take these?" "Can you help me understand how you might take your medicine?"

Patient is worried about remembering to take treatment: Ticking yes indicates need for additional adherence support. This is the fourth belief item. This item aims to highlight where the patient has practical concerns about their ability to remember treatment. *Note.* Patients may have previously identified non-adherence in the earlier item. If so, it may be particularly important to reflect this back to the patient in case this was a factor affecting their previous non-adherence.

[Example question to elicit information]: "It can be quite normal to forget to take medicines – is this something that worries you? "Do you feel concerned about being able to remember to take your TB medicines each day?"

Follow-up

The follow-up TNA assesses if there are any new barriers affecting treatment adherence. The items should be completed as explained below. For some items, ticking yes indicates a need to consider stepping up the patient's level of adherence support (where possible). For other items, this may be less appropriate. *Note.* As indicated, for some items the same questions/method can be used to obtain this information as in the baseline TNA, but will have to be worded to ask about change instead e.g. "do you have any new issues with alcohol that are affecting your day-to-day life?"

Medical Factors

Non-adherence identified: Ticking yes indicates need for additional adherence support. This information is gathered from the adherence review conducted at the beginning of each follow-up appointment.

New co-morbidities: same as Baseline TNA.

New drug resistance: same as Baseline TNA.

Slow sputum conversion: Ticking yes to this item indicates need for additional adherence support. This information will be gathered from medical notes.

Clinical deterioration: Ticking yes to this item indicates need for additional adherence support. This information will be gathered from medical notes.

Practical/Communication Factors

Changes to physical barriers: same as Baseline TNA.

Patient now too ill or frail to administer treatment themselves: same as Baseline TNA.

Structural Factors

Patient has new financial concerns: same as Baseline TNA.

Patient is now unable to travel to clinic independently: same as Baseline TNA.

Patient is now unable to pay costs for travel to clinic: same as Baseline TNA.

New urgent housing problem: same as Baseline TNA.

New other housing problem: same as Baseline TNA.

New immigration concerns: same as Baseline TNA.

Psychosocial Factors

New alcohol problem: same as Baseline TNA.

New drug problem: same as Baseline TNA

Patient/nurse has new concerns about changes in mental health: same as Baseline TNA

Patient reports changes/increased isolation from family and friends: Ticking yes indicates need for additional adherence support. This item is to understand if the patient is receiving support for their friends and family.

[Example question to elicit information]: "Have you been able to talk to your friends and family about your TB?" "Are they able to offer you support?"

Named support person is no longer providing support to the patient: Ticking yes indicates need for additional adherence support. Ask the patient if they are still receiving support from the person they named in their baseline TNA.

[Example question to elicit information]: "Last time we spoke you said that [insert name] was able to support you during your treatment. Are they still able to do that?"

Patient has new or ongoing doubts about need for treatment or diagnosis: Ticking yes (particularly with new concerns) indicates need for additional adherence support. This question can be asked similar to baseline:

[Example questions to elicit information]: "How are you feeling now about your TB diagnosis?" "How are you feeling now about your TB treatment?" "Do you feel that you need treatment to get better?"

Patient has new or ongoing worries about the response from their family/community to their TB diagnosis: Ticking yes (particularly with new concerns) may indicate need for additional adherence support. This question can be asked similar to baseline:

[Example questions to elicit information]: "Have you been able to talk to your friends and family about

TB?”

Patient has new or ongoing worries about remembering to take their treatment: Ticking yes (particularly with new concerns) may indicate need for additional adherence support. This may be a particular issue for patients who have demonstrated signs of non-adherence to treatment. This question can be asked similar to baseline:

[Example question to elicit information]: “It can be quite normal to forget to take medicines – is this something that has worried you? “Have you been concerned about remembering to take your TB medicines each day?” “Have you had issues remembering to take your treatment each day?”

Patient has new or ongoing worries about storing medicines/taking medicines in front of others: Ticking yes (particularly with new concerns) may indicate need for additional adherence support. This question can be asked similar to baseline:

[Example question to elicit information]: “How have you felt about taking your TB medicines? Have you had any worries about where/when you can take these?”

Patient has experienced severe side effects affecting their daily functioning since last visit: Ticking yes may indicate need for additional adherence support. Asking a broad question and following up more specifically, as suggested below, may be most helpful.

[Example question to elicit information]: “How are you feeling on this medicine?” “Is anything affecting your ability to take your treatment?”

Patient has become anxious/overly concerned about developing side effects since their last visit: Ticking yes may indicate need for additional adherence support. Concerns about side effects can be an important barrier to treatment non-adherence. This item aims to understand if patients concerns about side effects are making them not want to take their treatment. This item will likely to be answered in conjunction with the item above by asking the suggested questions.

Appendix 3: Intervention Session Checklists

BASELINE intervention checklist		
Participant number:		
Session length: _____ minutes		
Baseline TNA Completed	Yes ☐	No ☐
Did TNA indicate need for additional adherence support?	Yes ☐	No ☐
Description of additional adherence support	DOT ☐ VOT ☐ Box reminders w ☐ Dosette box ☐ No additional adherence support ☐	
"TNA Linked Actions" delivered	Yes ☐ N/a ☐	No ☐
Intervention Video 1 shown	Yes ☐	No ☐
Patient imaging shown (if relevant)	Yes ☐ N/a ☐	No ☐
Intervention Video 2 shown	Yes ☐	No ☐
Patient booklet given	Yes ☐	No ☐
Medicines list created and medicines described (including any relevant side effects)	Yes ☐	No ☐
Treatment goal created	Yes ☐	No ☐
Medication plan created	Yes ☐	No ☐
Patient shown how to use medication and symptoms diary	Yes ☐	No ☐
Any referrals made following TNA Linked Actions (e.g. to SCT or direct contact to services)	Yes ☐ N/a ☐	No ☐
Letter sent to GP	Yes ☐	No ☐
TNA summary in patients notes	Yes ☐	No ☐

Any alterations to intervention steps delivered:
Other comments/observations on intervention session delivery:

WEEK 2 FOLLOW-UP intervention checklist		
Participant number:		
Session length: _____ minutes		
Adherence reviewed	Yes ☐	No ☐
Tools used to review adherence	patient self-reported ☐ pill count ☐ urine test ☐ medication diary ☐ patient unable to describe medication regimen ☐	
Follow-up TNA Completed	Yes ☐	No ☐
Level of adherence support reassessed	Yes ☐	No ☐
Changes to level of adherence support based on TNA results	*No change to adherence support* ☐ Changed to DOT ☐ Changed to VOT ☐ Changed to box reminders ☐ Changed to Dosette box ☐	
Info and support Q completed	Yes ☐	No ☐
Any sections of the manual reviewed following info and support Q answers?	*No topics selected* ☐ About TB and Your TB treatment ☐ Concerns about TB ☐ How can I make my TB treatment as easy as possible? ☐ Talking to others about TB ☐ Coping with TB ☐	
Patient given opportunity to ask additional questions?	Yes ☐	No ☐

Medicines list reviewed and any changes made/discussed with patient	Yes ☐	No ☐
Reviewed patient treatment goal	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Medication plan reviewed and any changes made/discussed with patient	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Reviewed medication & symptom diary with patient	Yes ☐	No ☐
Reviewed/managed any side effects experienced?	Yes ☐ N/a ☐	No ☐
Any *new* referrals made following TNA Linked Actions (e.g. to SCT or direct contact to services) **or** previous referral status checked?	Yes ☐ N/a ☐	No ☐
Letter sent to GP (if new linked actions or changes to level of adherence support)	Yes ☐ N/a ☐	No ☐
TNA summary in patient notes	Yes ☐	No ☐
Any alterations to intervention steps delivered:		
Other comments/observations on intervention session delivery:		

MONTH 1 TO MONTH 5 FOLLOW-UP intervention checklist		
Participant number:		
Session length: _____ minutes		
Adherence reviewed	Yes ☐	No ☐
Tools used to review adherence	patient self-reported ☐ pill count ☐ urine test ☐ medication diary ☐ patient unable to describe medication regimen ☐	
Follow-up TNA Completed	Yes ☐	No ☐
Level of adherence support reassessed	Yes ☐	No ☐
Changes to level of adherence support based on TNA results	*No change to level of adherence support* ☐ Changed to DOT ☐ Changed to VOT ☐ Changed to box reminders ☐ Changed to Dosette box ☐	
Patient given opportunity to ask additional questions?	Yes ☐	No ☐
Medicines list reviewed and any changes made/discussed with patient	Yes ☐	No ☐
Reviewed patient treatment goal	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Medication plan reviewed and any changes made/discussed with patient	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Reviewed medication & symptom diary with patient	Yes ☐	No ☐
Reviewed/managed any side effects experienced?	Yes ☐	No ☐

	N/a ☐	
Any *new* referrals made following TNA Linked Actions (e.g. to SCT or direct contact to services) **or** previous referral status checked?	Yes ☐ N/a ☐	No ☐
Letter sent to GP (if new linked actions or changes to level of adherence support)	Yes ☐ N/a ☐	No ☐
TNA summary in patient notes	Yes ☐	No ☐
Any alterations to intervention steps delivered:		
Other comments/observations on intervention session delivery:		

MONTH 6 FOLLOW-UP intervention checklist Treatment finished at Month 6		
Participant number:		
Session length: _____ minutes		
Adherence reviewed (checking treatment complete)	Yes ☐	No ☐
Show imaging compared to diagnosis (if available)	Yes ☐ N/a ☐	No ☐
Provide reassurance	Yes ☐	No ☐
Provided patient opportunity to ask any questions and answered appropriately	Yes ☐	No ☐
Letter to GP to inform of discharge from care and study	Yes ☐	No ☐
Any alterations to intervention steps delivered:		
Other comments/observations on intervention session delivery:		

MONTH 6 FOLLOW-UP intervention checklist Treatment continuing after 6 months		
Participant number:		
Session length: _____ minutes		
Adherence reviewed	Yes ☐	No ☐
Tools used to review adherence	patient self-reported ☐ pill count ☐ urine test ☐ medication diary ☐ patient unable to describe medication regimen ☐	
Follow-up TNA Completed	Yes ☐	No ☐
Level of adherence support reassessed	Yes ☐	No ☐
Changes to level of adherence support based on TNA results	*No change to level of adherence support* ☐ Changed to DOT ☐ Changed to VOT ☐ Changed to box reminders ☐ Changed to Dosette box ☐	
Patient given opportunity to ask additional questions?	Yes ☐	No ☐
Medicines list reviewed and any changes made/discussed with patient	Yes ☐	No ☐
Reviewed patient treatment goal	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Medication plan reviewed and any changes made/discussed with patient	Yes ☐	No ☐ Not possible (no patient booklet) ☐
Reviewed medication & symptom diary with patient	Yes ☐	No ☐

Reviewed/managed any side effects experienced?	Yes ☐ N/a ☐	No ☐
Any *new* referrals made following TNA Linked Actions (e.g. to SCT or direct contact to services) **or** previous referral status checked?	Yes ☐ N/a ☐	No ☐
Letter sent to GP (if new linked actions or changes to level of adherence support)	Yes ☐ N/a ☐	No ☐
TNA summary in patient notes	Yes ☐	No ☐
Any alterations to intervention steps delivered:		
Other comments/observations on intervention session delivery:		

WEEK 1 PHONE CALL intervention checklist		
Participant number:		
Asked patient if they started treatment/any issues addressed?	Yes ☐	No ☐
Provided positive affirmation of progress	Yes ☐	No ☐
Any beliefs items in the baseline TNA addressed using scripted conversations?	Yes ☐	No ☐
Beliefs items covered	Denial ☐ Worries about talking to friends/family about TB ☐ Worries about storing medicines ☐ Worries about remembering medicines ☐	
Other comments/observations on phone call delivery:		

WEEK 6 PHONE CALL intervention checklist		
Participant number:		
Provided positive affirmation of progress	Yes ☐	No ☐
Any issues with treatment maintenance checked and addressed appropriately	Yes ☐	No ☐
Acknowledge/elicit symptom improvement since baseline	Yes ☐ N/a ☐	No ☐
Provide treatment maintenance script	Yes ☐	No ☐
Other comments/observations on phone call delivery:		

Appendix 4: Letter to GP example templates

Baseline sessions

[Date]

Private & Confidential

[GP name]

[Address line 1]

[Address line 2]

[Address line 3]

[Postcode]

Project title: Intervening with a Manualised Package to AChieve Treatment adherence in people with Tuberculosis: the IMPACT study.

IRAS ID: 231542

Re: [Name of participant]

Dear Dr. [Name of doctor]

As outlined in a previous letter sent, your patient, [Name of participant], is a participant in the IMPACT Study.

[If no adherence support required or barriers present]: As part of the intervention, your patient underwent an enhanced needs assessment to identify potential needs and barriers to adherence for tuberculosis (TB) treatment. No needs were currently highlighted. Your patient is receiving standard, self-administered TB treatment.

[If adherence support required or barriers present]: As part of the intervention, your patient underwent an enhanced needs assessment to identify potential needs and barriers to adherence for tuberculosis (TB) treatment. The following needs were highlighted for your patient:

[Insert Baseline TNA summary]

[If SCT in service and referral made]: A referral has been made to the social care team within our TB service to address these needs.

[No SCT in service, referrals made by HCP]: Our team has contacted relevant services to make referrals on behalf of the patient.

Your patient is receiving additional adherence support for their TB medicines, which includes [provide details of level of adherence support].

We wanted to inform you of this to enhance joint-up care for the patient. You may wish to follow-up on how their treatment is going when you next see them.

Yours sincerely,

[name of HCP delivering intervention]

Follow-up sessions

[Date]

Private & Confidential

[GP name]

[Address line 1]

[Address line 2]

[Address line 3]

[Postcode]

Project title: Intervening with a Manualised Package to AChieve Treatment adherence in people with Tuberculosis: the IMPACT study.

IRAS ID: 231542

Re: [Name of participant]

Dear Dr. [Name of doctor]

As outlined in a previous letter sent, your patient, [Name of participant], is a participant in the IMPACT Study.

As part of the intervention, your patient completes a repeated needs assessment to identify any changes in potential needs and barriers to adherence for tuberculosis (TB) treatment. The following new barriers were highlighted for your patient:

[Insert Follow-up TNA summary]

[SCT in service and relevant]: A referral has been made to the social care team within our TB service to

address these needs.

[No SCT, referrals made by HCP]: Our team has contacted relevant services to make referrals on behalf of the patient.

Your patient is receiving additional adherence support for their TB medicines, which includes [Provide details of level of adherence support].

We wanted to inform you of the changes to these needs to enhance joint-up care for the patient. You may wish to follow-up on whether they have contacted or been contacted by some of these services.

Yours sincerely,

[name of HCP delivering intervention]

Month 6 session

[Date]

Private & Confidential

[GP name]

[Address line 1]

[Address line 2]

[Address line 3]

[Postcode]

Project title: Intervening with a Manualised Package to AChieve Treatment adherence in people with Tuberculosis: the IMPACT study.

IRAS ID: 231542

Re: [Name of participant]

Dear Dr. [Name of doctor]

As outlined in a previous letter sent, your patient, [Name of participant], was a participant in the IMPACT Study. The intervention lasts for 6 months so your patient's participation in the study is now complete.

[Finish letter here if patient's treatment is complete]

[If patient is continuing on treatment but no new barriers are identified]: [Name of participants]'s TB treatment will continue for [insert estimate length] with standard care. Any interactions with you about [name of participant] will be as part of usual care.

[If patient is continuing on treatment and new barriers are identified]: As part of the intervention, your patient completed a needs assessment to identify any potential needs and barriers to treatment non-adherence at each intervention session. This was conducted at the final intervention session and the following new barriers were highlighted for your patient:

[Insert Follow-up TNA summary]

[SCT in service and relevant]: A referral has been made to the social care team within our TB service to address these needs.

[No SCT, referrals made by HCP]: Our team has contacted relevant services to make referrals on behalf of the patient.

Your patient is receiving additional adherence support for their TB medicines, which includes [Provide details of level of adherence support].

We wanted to inform you of the changes to these needs to enhance joint-up care for the patient. [Name of participants]'s TB treatment will continue for [insert estimate length] with standard care. Any interactions with you about [name of participant] will be as part of usual care.

Yours sincerely,

[name of HCP delivering intervention]

Appendix 5: Text/Email template for sending video link and patient booklet.

[Video Link]

Hi there, here is the link to the videos you watched in your session with the nurse today.

Video 1: tinyurl.com/impactvid1

Video 2: tinyurl.com/impactvid2

Many thanks,

The IMPACT Study team

[Patient booklet]

Hi there, here is the link to an electronic version of the booklet we gave you in your session with the nurse today.

[insert link]

Many thanks,

The IMPACT Study team

Appendix 6: My TB Treatment Summary plan templates

My TB treatment summary- Baseline session (Week 0) Date:

Things that might affect my TB treatment:	(✓)	To help support me with my treatment:		
Difficult with swallowing or opening medicines		See my plan below	The TB team has given me options to make taking my treatment easier (e.g. with swallowing or opening tablets)	
I'm unable to get to clinic independently		See my plan below	My booklet has contact information for NHS transport to see if I can get support	My TB team will explore ways in which to get me to my TB appointments
I need help with costs for travel to clinic		See my plan below	My booklet has information on where I might be able to reimbursed for travel costs	Any other help available:
I need an interpreter		See my plan below	An interpreter will be booked for me at each appointment where possible	
I have financial concerns		See my plan below	The social care team in my TB service will get in contact with me	Any other help available:
I have an urgent housing problem		See my plan below	The social care team in my TB service will get in contact with me	Any other help available:
I have another (non-urgent) housing problem		See my plan below	The social care team in my TB service will get in contact with me	
I have concerns about immigration		See my plan below	The TB service have told me that treatment is free in UK	The social care team in my TB service will get in contact with me
I have a current alcohol/drug problem		See my plan below	The social care team in my TB service will get in contact with me	
I have a history of mental health issues		See my plan below	The TB service have shown me where I can make a self-referral to psychological support services if needed (or they can help me)	
I have a current mental health concern		See my plan below	The social care team in my TB service will get in contact with me	
My only support is from the TB team		See my plan below	The TB service have told me about the TB Alert patient forum where I can talk to other patients with TB (details in my booklet)	
I'm worried about talking to my friends/family about TB		The TB team has encouraged me to show my family/friends the booklet and videos and to bring them along to our next session		
My TB Treatment plan:				**(✓)**
I will film myself taking my medicines on my phone and send this to the team (VOT)				
Someone from the TB team will watch me take my medicines (DOT)				

I will have reminders to take treatment on my medication box

I will have a medication organiser inside my medication box

My TB treatment summary- Follow-up session

Treatment week: Date:

Things that might affect my TB treatment:	(✓)	To help support me with my treatment:		
I'm now unable to swallow, open or take my medicines myself		See my plan below	The TB team has given me options to make taking my treatment easier (e.g. with swallowing or opening tablets)	
I have new financial concerns		See my plan below	The social care team in my TB service will get in contact with me	Any other help available:
I need help with paying for the cost of travel		See my plan below	My booklet has information on where I might be able to reimbursed for travel costs	Any other help available:
I need help with travelling to the clinic independently		See my plan below	My booklet has contact information for NHS transport to see if I can get support	My TB team will explore ways in which to get me to my TB appointments
I have a new urgent housing problem		See my plan below	The social care team in my TB service will get in contact with me	Any other help available:
I have a new, other (non-urgent) housing problem		See my plan below	The social care team in my TB service will get in contact with me	
I have new concerns about immigration		See my plan below	The TB service have told me that treatment is free in UK	The social care team in my TB service will get in contact with me
I have a new alcohol/drug problem		See my plan below	The social care team in my TB service will get in contact with me	
I have a current mental health concern		See my plan below	The social care team in my TB service will get in contact with me	
I'm worried about talking to my friends/family about TB		The TB team has encouraged me to show my family/friends the booklet and videos and to bring them along to our next session		
I've experienced severe side effects of treatment		See my plan below	I should contact my TB team if I have any concerns about side effects	My TB team have changed my medication. The details have been explained to me and are in my booklet
My TB Treatment plan:				(✓)

I will film myself taking my medicines on my phone and send this to the team (VOT)

Someone from the TB team will watch me take my medicines (DOT)

I will have reminders to take treatment on my medication box

I will have a medication organiser inside my medication box

My TB treatment summary- Baseline session (Week 0) [NO SCT] Date:

Things that might affect my TB treatment:	(✓)	To help support me with my treatment:		
Difficulty with swallowing or opening medicines		See my plan below	The TB team has given me options to make taking my treatment easier (e.g. with swallowing or opening tablets)	
I need help with travelling to the clinic independently		See my plan below	My booklet has contact information for NHS transport to see if I can get support	My TB team will explore ways in which to get me to my TB appointments
I need help with costs for travel to clinic		See my plan below	My booklet has information on where I might be able to reimbursed for travel costs	Any other help available:
I need an interpreter		See my plan below	An interpreter will be booked for me at each appointment where possible	
I have financial concerns		See my plan below	My booklet has contact details for Citizen's Advice Bureau and TB Alert who can provide more information	Any other help available:
I have an urgent housing problem		See my plan below	My TB team will refer me to local services who can help support me with finding housing	Any other help available:
I have another (non-urgent) housing problem		See my plan below	My booklet has information for useful services who can provide more information (Citizen's advice, TB Alert, and Shelter)	
I have concerns about immigration		See my plan below	The TB service have told me that treatment is free in UK	My booklet has contact details for local immigration services
I have a current alcohol/drug problem		See my plan below	My TB team will make an appointment for me with local services	
I have a history of mental health issues		See my plan below	The TB service have shown me where I can make a self-referral to psychological support services if needed (or they can help me)	
I have a current mental health concern		See my plan below	My TB team will make an appointment for me with local services	
My only support is from the TB team		See my plan below	The TB service have told me about the TB Alert patient forum where I can talk to other patients with TB (details in my booklet)	

I'm worried about talking to my friends/family about TB		The TB team has encouraged me to show my family/friends the booklet and videos and to bring them along to our next session	

My TB Treatment plan:	(✓)
I will film myself taking my medicines on my phone and send this to the team (VOT)	
Someone from the TB team will watch me take my medicines (DOT)	
I will have reminders to take treatment on my medication box	
I will have a medication organiser inside my medication box	

<u>My TB treatment summary-</u> Follow-up session [NO SCT]

Treatment week: Date:

Things that might affect my TB treatment:	(✓)	To help support me with my treatment:		
I'm now unable to swallow, open or take my medicines myself		See my plan below	The TB team has given me options to make taking my treatment easier (e.g. with swallowing or opening tablets)	
I have new financial concerns		See my plan below	My booklet has contact details for Citizen's Advice Bureau and TB Alert who can provide more information	Any other help available:
I need help with paying for the cost of travel		See my plan below	My booklet has information on where I might be able to reimbursed for travel costs	Any other help available:
I need help with travelling to the clinic independently		See my plan below	My booklet has contact information for NHS transport to see if I can get support	My TB team will explore ways in which to get me to my TB appointments
I have a new urgent housing problem		See my plan below	My TB team will refer me to local services who can help support me with finding housing	Any other help available:
I have a new, other (non-urgent) housing problem		See my plan below	My booklet has information for useful services who can provide more information (Citizen's advice, TB alter, and Shelter)	
I have new concerns about immigration		See my plan below	The TB service have told me that treatment is free in UK	My booklet has contact details for local immigration services
I have a new alcohol/drug problem		See my plan below	My TB team will make an appointment for me with local services	
I have a current mental health concern		See my plan below	My TB team will make an appointment for me with local services	
I'm worried about talking to my		The TB team has encouraged me to show my family/friends the booklet and videos and to bring them along to our next session		

friends/family about TB				
I've experienced severe side effects of treatment		See my plan below	I should contact my TB team if I have any concerns about side effects	My TB team have changed my medication. The details have been explained to me and are in my booklet

My TB Treatment plan:	(✓)
I will film myself taking my medicines on my phone and send this to the team (VOT)	
Someone from the TB team will watch me take my medicines (DOT)	
I will have reminders to take treatment on my medication box	
I will have a medication organiser inside my medication box	

APPENDIX 10: Schedule of interviews

IMPACT study – Timings for RN sessions

Baseline		*Wk 2*		*1m*		*2m*		*3m*		*4m*		*5m*		*6m*	
Brief IPQ	5	Brief IPQ	5	MARS	5	MARS	5	Brief IPQ	5	MARS	5	MARS	5	Brief IPQ	5
BMQ-S baseline	10	BMQ-S follow-up	12	SEEQ	5	SEEQ	5	BMQ-S follow-up	12	SEEQ	5	SEEQ	5	BMQ-S follow-up	12
BMQ-G	10	MARS	5			EQ-5D-5L	10	MARS	5	EQ-5D-5L	10			BMQ-G	10
PHQ4	5	SEEQ	5			CSRI	20	SEEQ	5	CSRI	20			MARS	5
EQ-5D-5L	10													SEEQ	5
CSRI	20													Intervention feedback	10
														PHQ4	5
														EQ-5D-5L	10
														CSRI	20
TOTAL	60	TOTAL	27	TOTAL	10	TOTAL	40	TOTAL	27	TOTAL	40	TOTAL	10	TOTAL	82

APPENDIX 11: Process Evaluation Interview Guide (intervention and standard care)

Participant & HCP interviews | v2.0 | 06 March 2020

Participant interview #1: ~2 weeks after treatment start

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 1: Introduction				
1.	**Have there been any problems with your care so far?**	Dropdown	0, No | 1, Yes	0 >> Section 2
	1. Please document (briefly) what the problems were/are	Text		
	2. Have these problems been resolved?	Dropdown	0, Not at all | 1, Yes, some of them/partially | 2, Yes, all completely resolved | 99, Don't know	
Section 2: TB Needs Assessment (TNA)				
1.	**During your 'first' appointment, did the nurse conduct a 'risk assessment' or 'needs assessment' to see if you needed extra support?**	Dropdown	0, No | 1, Yes	
	1. Was the purpose of the needs assessment explained to you?	Dropdown	0, No | 1, Yes	
	1. Did you understand the explanation?	Dropdown	0, Not at all | 1, Yes, a little bit | 2, Yes, most of it | 3, Yes, completely	
	2. Had you previously considered yourself someone who might need extra support with taking medication?	Dropdown	0, No | 1, Yes	
	3. Did the assessment process change your perceptions of your own needs?	Dropdown	0, No | 1, Yes	
	1. Can you explain how?	Text		
	4. Were there any questions asked that you were not comfortable answering?	Dropdown	0, No | 1, Yes	
	1. Which areas?	Multi-choice (select all that apply)	**List of areas explored by risk assessment/TNA**	
	2. Do you mind saying why?	Dropdown	1, I was embarrassed | 2, I did not trust the nurse | 3, It did not feel appropriate | 4, It was nothing to do with my health/TB | 5, I don't like to talk about it | 96, Other, specify | 99, Don't know	
	1. Other, specify	Text		
2.	**Do you know if you were assessed as needing any**	Dropdown	0, No | 1, Yes | 9, Don't know	0/9 >> Q3

Q#	Question	Type of field	Options (if applicable)	Skip logic
	extra support?			
	1. If you were assessed as needing extra support with taking your TB medicines, what was this supposed to be?	Dropdown	*List types of ECM*	
	1. [If 2.1=Yes] Did they nurse explain why this extra support might be helpful for you?	Dropdown	0, No | 1, Yes | 9, Don't know	0>>2.1.2
	1. [If 2.1.1=Yes] What did they say?	Text		
	2. Did you or the nurse (to your knowledge) initiate the additional support (e.g., start directly observed therapy?)	Dropdown	0, No | 1, Yes | 9, Don't know	
	3. Have you received any of the extra support so far?	Dropdown	0, No | 1, Yes | 9, Don't know	
	4. Do you think you do actually need/would like some extra support?	Dropdown	0, No | 1, Yes | 9, Don't know	0 >>> 2.2
	1. What would this support be?	Text		
	2. Did the nurse [ask you to contact/make a referral] to [an external team/the social care team]	Dropdown	0, No | 1, Yes | 9, Don't know	0 >> Q3
	1 If the nurse made a referral, have you been in touch with the [social care/external team]?	Dropdown	0, No | 1, Yes	
	2. If the nurse asked you to contact an external team, have you done this yet?	Dropdown	0, No | 1, Yes	
	1. If not, why?	Text	1, Not had time | 2, Didn't think it was important | 3, Forgot | 4, Don't know how | 96, Other specify	
	1. Other, specify	Text		
3.	**Since starting treatment, have you had a repeat risk assessment/needs assessment?**	Dropdown	0, No | 1, Yes	0 >> Section 3
	1. How many repeat assessments have you had?	Numeric		
	2. If so, do you think this was useful?	Dropdown	0, No | 1, Yes | 9, Don't know	
	1. Why do you think it was/was not useful?	Text		
	3. Had anything changed?	Dropdown	0, No | 1, Yes | 9, Don't know	
	1. What has changed?	Text		
Section 3: Information videos				
1.	**During the first appointment, were you shown the information videos?**	Dropdown	0, No | 1, Yes	0 >> Section 4
	1. After watching the first video ("TB and me") in the consultation:			
	1. Did you have any questions?	Dropdown	0, No | 1, Yes	0 >> 1.2
	1. Did you ask these questions?	Dropdown	0, No | 1, Yes	0 >> 1.2
	1. Why not?	Dropdown	1, Felt like it was wasting time | 2, Didn't think the nurse would know| 3, Didn't feel comfortable asking | 96, Other specify	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	1 Other, specify	Text		
	2. To whom did you ask these questions?	Dropdown	1, Your nurse, during the consultation | 2, Your nurse at another time | 3, Another nurse | 4, One of the TB doctors | 5, My GP | 6, Family member or friend | 96, Other, specify	
	1 Other, specify	Text		
	3. Was s/he able to answer to your satisfaction?	Dropdown	0, No, not at all | 1, Yes, partially | 2, Yes, completely	
2.	After watching the second video ("Concerns about TB treatment"):			
	1. Did you have any questions?	Dropdown	0, No | 1, Yes	0 >> 1.3
	1. Did you ask these questions?	Dropdown	0, No | 1, Yes	0 >> 1.3
	1. Why not?	Dropdown	1, Felt like it was wasting time | 2, Didn't think the nurse would know| 3, Didn't feel comfortable asking | 96, Other specify	
	1 Other, specify	Text		
	2. To whom did you ask these questions?	Dropdown	1, Your nurse, during the consultation | 2, Your nurse at another time | 3, Another nurse | 4, One of the TB doctors | 5, My GP | 6, Family member or friend | 96, Other, specify	
	1 Other, specify	Text		
	3. Was s/he able to answer to your satisfaction?	Dropdown	0, No, not at all | 1, Yes, partially | 2, Yes, completely	
3.	Is there anything you would change about either of the videos? *(Prompt re: tone, language, images, scope, detail, length)*	Dropdown	0, No | 1, Yes	0 >> 1.4
	1. What would you change?	Text		
4.	Between the first consultation and today:			
	1. Have you watched the video/s again at home?	Dropdown	0, No | 1, Yes	1 >> 1.4.1.2
	1. If no, did you try to watch the video/s again at home?	Dropdown	0, No | 1, Yes	
	2. If watched or tried to watch, did you encounter any difficulties trying to watch the video/s	Dropdown	0, No | 1, Yes	0 >> 1.4.2
	1. What was/were the difficulties?	Multi-choice (choose all that apply)	1, Do not have access to a relevant device | 2, Device/s were not working | 3, No access to the internet | 4. Content would not work	
	2. Please give more details/list other reasons	Text		

Q#	Question	Type of field	Options (if applicable)	Skip logic
	2. Have you shown the videos to any friends or family members?	Dropdown	0, No | 1, Yes	1 >> 1.4.2.2
	1. If no, why not?	Dropdown	1, Felt like a waste of time | 2, Didn't think they would be interested | 3, Didn't feel comfortable talking about it | 4, Didn't have any one to show it to | 96, Other specify	
	1. Other, specify	Text		
	2. If yes, who did you show it to?	Dropdown	1, Parent | 2, Sibling | 3, Partner/spouse | 4, Other family member | 5, Friend | 96, other, specify	
	1. Other, specify	Text		
Section 4: Interactive booklet				
1.	**During the first visit, were you given any written material (e.g., information leaflets, an interactive booklet)?**	Dropdown	0, No | 1, Yes – standard NHS leaflets | 2, Yes – interactive booklet	
	1. What is your understanding of what the [leaflet/booklet] is meant to do?	Text		
	2. During the first visit, did the nurse go through parts of the [leaflet/booklet] with you?	Dropdown	0, No | 1, Yes	
	3. During the first visit, did you create a 'medication action plan' together with the nurse?	Dropdown	0, No | 1, Yes	Show if Q1=2
	1. Did you already have a regular routine, or did you have to create a routine to take your medication?	Dropdown	1, Already had a routine | 2, Had to create a routine	
	2. Did having the plan make any difference to you in establishing/following a routine?	Dropdown	0, No | 1, Yes	
	4. During the first visit, did you set a 'treatment goal'?	Dropdown	0, No | 1, Yes	Show if Q1=2
	1. If you had any problems with this, please describe them.	Text		
	5. During the first visit, did the nurse go through a 'medication & symptom diary' with you?	Dropdown	0, No | 1, Yes	Show if Q1=2
	1. If you had any problems with this, please describe them.	Text		
	2. Are you still using this diary?	Dropdown	0, No | 1, Yes	
Section 5: Final comments				
1.	**Do you have any additional comments about the TB needs assessment/risk assessment, the videos (if applicable), or the written material with which you were provided (if applicable)?**	Dropdown	0, No | 1, Yes	0 >> END
	1. Please record your comments here	Text		
END OF PARTICIPANT INTERVIEW #1				

Participant interview #2: ~3 months after treatment start

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 1: Introduction				
1.	**Have there been any problems with your care so far?**	Dropdown	0, No | 1, Yes	0 >> Section 2
	1. Please document (briefly) what the problems were/are	Text		
	2. Have these problems been resolved?	Dropdown	0, Not at all | 1, Yes, some of them/partially | 2, Yes, all completely resolved | 99, Don't know	
Section 2: TNA				
1	**Since starting treatment, have you had a repeat risk assessment/needs assessment?**	Dropdown	0, No | 1, Yes	0 >> Section 3
	1. How many repeat assessments have you had?	Numeric		
	2. If so, do you think this was useful?	Dropdown	0, No | 1, Yes | 9, Don't know	
	1. Why do you think it was/was not useful?	Text		
	3. Had anything changed?	Dropdown	0, No | 1, Yes | 9, Don't know	
	1. What has changed?	Text		
Section 3: Information videos				
1.	**During the first appointment, were you shown the information videos?**	Dropdown	0, No | 1, Yes	0 >> Section 4
2.	**Between the first consultation and today have you watched the video/s again at home?**	Dropdown	0, No | 1, Yes	1 >> 2.1.2
	1. If no, did you try to watch the video/s again at home?	Dropdown	0, No | 1, Yes	
	2. If watched or tried to watch, did you encounter any difficulties trying to watch the video/s	Dropdown	0, No | 1, Yes	0 >> 4.2
	1. What was/were the difficulties?	Multi-choice (choose all that apply)	1, Do not have access to a relevant device | 2, Device/s were not working | 3, No access to the internet | 4. Content would not work	
	2. Please give more details/list other reasons	Text		
	3. Have you shown the videos to any friends or family members?	Dropdown	0, No | 1, Yes	
	1. If no, why not?	Dropdown	1, Felt like a waste of time | 2, Didn't think they would be interested | 3, Didn't feel comfortable talking about it | 4, Didn't have any one to show it to | 96, Other specify	
	1. Other, specify	Text		
	2. If yes, who did you show it to?	Dropdown	1, Parent | 2, Sibling | 3, Partner/spouse | 4, Other family member | 5, Friend | 96, other, specify	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	1. Other, specify	Text		
Section 4: Interactive booklet				
1.	**During the first visit, were you given an interactive booklet?**	Dropdown	0, No | 1, Yes – standard NHS leaflets | 2, Yes – interactive booklet	0 >> Section 5
2.	**Since you started treatment, have you looked again at any of the information in the booklet?**			
3.	**Since you started treatment, have you sought any extra help following the links or telephone numbers in the booklet?**			
	1. If so, which ones?			
4.	**Since you started treatment, has your nurse reviewed your 'medication action plan'?**			
	1. Have any changes been made to your plan?			
5.	**Since you started treatment, have you been using the medication and symptom diary?**			
	1. Is it making a difference to how you manage your treatment (and how)?	Dropdown	0, No difference | 1, Yes, it has made it better | 2, Yes, it has made it worse	0 >> 5.2
	1. Please give details, if possible.			
	2. Has your nurse reviewed the medication diary again?	Dropdown	0, No | 1, Yes	
	3. How could the medication diary be improved?	Text		
6.	**Since you started treatment, have you used the booklet to write down your questions or concerns**			
	1. Have you shared these with your nurse?			
	2. How useful has this been as a way of thinking about your TB/treatment?	Dropdown	0, Not at all useful | 1, Somewhat useful | 2, Very useful | 9, Don't know	1/2 >> 6.2.1
	1. Please give details, if possible	Text		
	3. Has this made a difference to your relationship with your nurse?	Dropdown	0, No difference | 1, Yes it has improved our relationship| 2, Yes, it has made our relationship worse| 9, Don't know	1/2 >> 6.3.1
	1. Please give details, if possible	Text		
7.	**Since you started treatment, have you used the information in the booklet to explain TB/treatment to your friends/family?**	Dropdown	0, No | 1, Yes	
	1. Has this made a difference to your communication with friends/family?	Dropdown	0, No difference | 1, Yes, it has made communication better | 2, Yes, it has made communication worse | 9, Don't know	
	1. Please give details, if possible	Text		
8.	**Has being on TB treatment made any changes to your (close) relationships?**	Dropdown	0, No | 1, Yes	
	1. Has the booklet made any difference in how you have managed this?	Dropdown	0, No | 1, Yes	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	1. Please give details, if possible	Text		
9.	If the information in the booklet had been provided electronically (e.g., within a mobile phone app), how would that have been?	Dropdown	0, No difference | 1, It would have been better | 2, It would have been worse | 9, Don't know	
	1. Please dive details, if you can	Text		
Section 5: Final comments				
1.	Do you have any additional comments about the TB needs assessment/risk assessment, the videos, or the interactive booklet?	Dropdown	0, No | 1, Yes	0 >> END
	1. Please record your comments here	Text		
END OF PARTICIPANT INTERVIEW #2				

HCP interview guides

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 1: TB Needs Assessment (TNA)				
1.	**With how many patients have you used the TNA so far?**	Numeric		If <2, stop interview?
	1. Roughly how long does the TNA take to administer (in minutes)?	Numeric		
	2. Have you been using the TNA as 'prescribed'?	Dropdown	0, No | 1, Yes	
	1. If not, please say which parts you have changed?	Text		
2.	**Do you like the new TNA?**	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, I like it a lot	
	1. Please say what you like/don't like about it.	Text		
	2. Regarding the time it takes to administer the TNA, do you think it:	Dropdown	0, Takes about the right time | 1, Takes a little too long | 2, Takes far too long	
	3. Regarding the language used in the TNA, do you think:	Dropdown	0, It is fine as it is | 1, A few things need to change | 2, A lot of things need to change	0 >> 2.4
	1. Please give details, if you can.	Text		
	4. Have you had any issues using the TNA on the tablet?	Dropdown	0, No | 1, Yes	0 >> 2.5
	1. Please give details, if you can.	Text		
	5. Compared with the standard 'risk assessment', do how do you think the TNA performs in detecting those who need ECM?	Dropdown	0, Much the same | 1, It is worse than the standard risk assessment | 2, It is better than the standard risk assessment	
3.	**How useful has it been to have a summary of the TNA to guide your choice of ECM?**	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
4.	**How often have you used the 'TNA summary' to make decisions about the use/type of ECM?**	Dropdown	0, Never | 1, Most of the time | 2, Every time	
5.	**Were there any occasions where you ignored the TNA summary (either using ECM when not recommended, or not using when it was recommended)?**	Dropdown	0, No | 1, Yes	0 >> Q6
	1. Please give details, if you can.	Text		
6.	**How useful have been the 'links to services/referrals' recommendations provided at the end of the TNA?**	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
7.	**How often do you think you have completed *all* the actions suggested by the TNA summary?**	Dropdown	0, Never | 1, Most of the time | 2, Every time	
8.	**How appropriate do you think are the recommendations made by the TNA summary?**	Dropdown	0, Not at all appropriate | 1, Somewhat appropriate | 2, Entirely appropriate	2 >> Q9
	1. Please give details, if you can.	Dropdown		
9.	**How could the TNA be improved?**	Text		

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 2. Information videos				
1.	How have the videos been integrated into your 'baseline' consultation?	Dropdown	0, Not at all integrated | 1, Somewhat integrated | 2, Completely integrated	
2.	Roughly how long does it take to show both videos and answer any questions they generate (in minutes)?	Numeric		
3.	How useful have the videos been for conveying information to patients?	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
4.	How useful have the videos been for saving you time in explaining things?	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
5.	Regarding the language used in the videos, do you think:	Dropdown	0, It is fine as it is | 1, A few things need to change | 2, A lot of things need to change	0 >> Q6
	1. Please give details, if you can.	Text		
6.	Regarding the images used in the videos, do you think:	Dropdown	0, They are fine as they are | 1, A few things need to change | 2, A lot of things need to change	0 >> Q7
	1. Please give details, if you can.	Text		
7.	Have you encountered any technological difficulties when trying to play the videos during consultations?	Dropdown	0, No | 1, Yes	0 >> Q8
	1. Please give details, if you can.			
8.	Please list the three most common questions asked by your patients after they watched the videos.	*Descriptive*		
	1. Question 1	Text		
	2. Question 2	Text		
	3. Question 3	Text		
9.	Have any patients given you feedback about the videos themselves?	Dropdown	0, No | 1, Yes	0 >> Q10
	1. Please give details, if you can.	Text		
10.	Is there anything else you would change about the videos?	Dropdown	0, No | 1, Yes	0 >> Q11
	1. Please give details, if you can.	Text		
11.	If you could, would you continue using the videos after the study has ended?	Dropdown	0, No | 1, Yes, for some patients | 2, Yes, for all patients	
Section 3: Interactive booklet				
1.	Do you like the interactive booklet?	Dropdown	0, Not at all | 1, Yes, parts of it | 2, Yes, all of it	
2.	How has the booklet been integrated into your 'baseline' consultation?	Dropdown	0, Not at all integrated | 1, Somewhat integrated | 2, Completely integrated	
3.	During the 'baseline' consultation, roughly how long does it take to complete the following	*Descriptive*		

Q#	Question	Type of field	Options (if applicable)	Skip logic
	activities:			
	1. Create medicines list	Numeric		
	2. Set treatment goal	Numeric		
	3. Create medication action plan	Numeric		
	4. Review medication & symptom diary	Numeric		
4.	**How useful do you think the following parts of the booklet are:**	*Descriptive*		
	1. Medicines list	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	2. Treatment goal	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	3. Medication action plan	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	4. Medication & symptom diary	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
5.	**After the first consultation, how often do patients use the booklet as a way to enhance communication?**	Dropdown	0, Not at all | 1, Used occasionally | 2, Used consistently	
6.	**How useful do you think the booklet is in:**	*Descriptive*		
	1. Creating a structure for consultation	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	2. Improving communication and/or building the relationship between patient and provider	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	3. Including family/friends	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	4. Reducing stigma	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	5. Identifying and/or managing side-effects	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
	6. Identifying and/or managing mental health issues	Dropdown	0, Not useful at all | 1, Somewhat useful | 2, Very useful	
7.	**Have any patients given you feedback about the booklet?**	Dropdown	0, No | 1, Yes	0 >> Q8
	1. Please give details, if you can	Text		
8.	**Is there anything you would change about the booklet?**	Dropdown	0, No | 1, Yes	0 >> Q9
	1. Please give details, if you can	Text		
9.	**If you could, would you continue using the booklet after the study has ended?**	Dropdown	0, No | 1, Yes	

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 4: Final comments				
1.	Do you have any additional comments about the TNA, the videos, or the interactive booklet?	Dropdown	0, No | 1, Yes	0 >> END
	1. Please record your comments here.	Text		
END OF INTERVIEW				

APPENDIX 12: Process Evaluation Structured Observation Guide

IMPACT: Process evaluation

Structured observations | Intervention sites | Version 2.0 | 06 March 2020

1. Baseline consultation [intervention sites]

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 1: Meta-data				
1	**Date of consultation**	Date/time		
2.	**HCP study ID**	Text		
3.	**Participant study ID**	Text		
4.	**Observer initials**	Text		
5.	**Type of consultation (baseline visit or follow-up)?**	Drop-down	1, Baseline consultation | 2, Follow-up	1 >> Proceed 2 >> Skip to 'Follow-up' instrument
Baseline section 2: Setting				
1.	**What kind of room did the consultation take place in?**	Drop-down	1, Standard clinic room (containing sink, examination bed, etc.) | 2, "Day" or "Family" room (i.e., non-clinical) | 96, Other, specify	96 >> 1.1
	1. If other, specify	Text		
	2. Additional comments around the potential effect/s of the space on the consultation	Text		Always shown
2.	**What time did the consultation start?**	Date/time		
3.	**What time did the consultation end?**	Date/time		
4.	**Please describe the mood of the nurse at the start of the consultation?**	Text		
5.	**Please describe the mood of the participant at the start of the consultation?**	Text		
6.	**Was the participant accompanied by a non-HCP?**	Dropdown	0, No | 1, Yes	0 >> 7
	1. How many other people?	Numeric		
	2. What was the relationship of person 1 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.2.1
	1. Other, specify	Text		
	3. What was the relationship of person 2 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.3.1
	1. Other, specify	Text		

Q#	Question	Type of field	Options (if applicable)	Skip logic
	4. What was the relationship of person 3 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.4.1
	1. Other, specify	Text		
7.	**Was the participant accompanied by an HCP?**	Dropdown	0, No | 1, Yes	0 >> 8
	1. What cadre was the other HCP?		1, Another nurse | 2, Social care/ outreach worker | 3, Advocate | 4, External translator| 96, Other, specify | 99, Don't know	96 >> 7.1.1
	1. Other, specify	Text		
8.	**Was the consultation conducted in English?**	Dropdown	0, No | 1, Yes	0 >> 8.1
	1. If no, who translated?	Dropdown	1, Non-HCP accompanying the participant | 2, Advocate | 3, External translator | 4, Language line | 96, Other specify	96 >> 8.1.1
	1. Other, specify	Text		
9.	**Had the diagnosis been delivered on the same day as the consultation (e.g., earlier in the day)?**	Dropdown	0, No | 1, Yes, by the doctor | 2, Yes, by the same nurse | 3, Yes, by a different nurse | 99, Don't know	
	1. Did the patient seem accepting of their diagnosis?	Dropdown	0, No | 1, Yes	Always shown
	2 Did the patient express any negative emotions about their diagnosis?	Dropdown	0, No | 1, Yes	Always shown
	3. Please document any further observations about the participant's reaction to their diagnosis, particularly if this changed or evolved during the consultation	Text		Always shown
Baseline section 3: TB needs assessment (TNA)				
1.	**How involved was the participant in the assessment of their own needs?** *Try to answer this question with consideration of the patient's facial expressions, body language, the amount of eye contact between patient & HCP, and the number of clarification questions asked/interest shown.*	Dropdown	1, Participant provided minimal responses to the HCP's questions | 2, Participant provided moderate responses (i.e., some issues in obtaining information/participant only provided additional information when probed) | 3, Participant provided detailed responses (was forthcoming with information/TNA completed with ease) | 96, Other, specify | 99, Don't know	96 >> 1.1
	1. Other, specify	Text		
2.	**If the participant was accompanied by a non-HCP, were they involved in the TNA?**	Dropdown	0, Not accompanied | 1, Accompanied, but not involved | 2, Involved a little [*definition*] | 3, Very involved [*definition*] | 96, Other, specify	96 >> 2.1
	1. Other, specify	Text		
3.	**How long did it take to conduct the TNA (in minutes)**	Numeric		
4.	**Based on your knowledge of the TNA, did the HCP**	Dropdown	1, Complete tool administered as	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	go through the entire tool with the participant, or were some areas/questions skipped over or modified?		written| 2, Tool not used as written | 99, Don't know	
	1. If Q4=2, please describe how the delivery of the tool differed from how it was written	Text		
5.	**Did the HCP ask any follow-up questions during or after using the TNA (for example, did they ask for more detail about a specific issue that was identified by the TNA)?**	Dropdown	0, No | 1, Yes	
	1. Please give additional details, if possible.	Text		Always shown
6.	**Please document any additional observations or comments about the delivery of the TNA.**	Text		
Baseline section 4: Information videos & imaging				
1.	**Was the participant shown any videos during the consultation?**	Dropdown	0, No | 1, Yes	0 >> Section 5
2.	**At what point in the consultation were the video/s shown?**	Dropdown	1, Before the TNA/risk assessment had been administered | 2, After the TNA but before the interactive booklet was introduced | 3, After the interactive booklet was introduced | 96, Other, specify	96 >> 2.1
	1. Other, specify	Text		
3.	**Was the participant shown the "Helping you understand tuberculosis" video?**	Dropdown	0, No | 1, Yes	1 >> 3.1
	1. Did the participant watch the video/s and seem to follow its content?	Dropdown	0, No | 1, Yes, somewhat| 2, Yes, they were completely focused on it	
4.	**Was the participant shown the "Questions about TB treatment" video?**	Dropdown	0, No | 1, Yes	1 >> 4.1
	1. Did the participant watch the video/s and seem to follow its content?	Dropdown	0, No | 1, Yes, somewhat| 2, Yes, they were completely focused on it	
5.	**After showing the video/s, did the HCP prompt to check if the participant had any questions?**	Dropdown	0, No | 1, Yes	
6.	**Did the participant ask the HCP any questions after watching the videos?**	Dropdown	0, No | 1, Yes	1 >> 6.1
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
7.	**If the participant was accompanied by a non-HCP, did they have any questions for the HCP after watching the videos?**	Dropdown	0, No | 1, Yes	1 >> 7.1
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
8.	**How long did it take to show the videos and answer any questions they generated?** (in minutes)	Numeric		
9.	**Please document any additional observations or comments about the delivery of the information videos.**	Text		

Q#	Question	Type of field	Options (if applicable)	Skip logic
10.	**Was the participant shown any of their imaging?**	Dropdown	0, No | 1, Yes	0 >> Section 5
	1. Did the participant ask the HCP any questions about the imaging?	Dropdown	0, No | 1, Yes	
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	2. Please provide additional details about the review of imaging, if needed	Text		
Baseline section 5: Interactive booklet				
1.	**Did the HCP give the participant the interactive booklet?**	Dropdown	0, No | 1, Yes	0 >> Section 6
2.	**At what point in the consultation was the interactive booklet given to the participant?**	Dropdown	1, Before the TNA/risk assessment had been administered | 2, After the TNA/risk assessment but before the information videos were shown | 3, After the information videos were shown | 96, Other, specify	96 >> 2.1
	1. Other, specify	Text		
3.	**Was the participant helped to create a 'medicines list' using the interactive booklet?**	Dropdown	0, No | 1, Yes	0 >> Q4
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about this part of the booklet?	Dropdown	0, No | 1, Yes	0 >> 3.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. Did the HCP use the pre-made stickers?	Dropdown	0, No | 1, Yes	
	4. Was there any discussion around relevant side effects?	Dropdown	0, No | 1, Yes	
	5. How long did it take to create the medicines list and answer any questions generated (in minutes)	Numeric		
	6. Please provide more details if needed.	Text		
4.	**Was the participant helped to create a 'treatment goal'?**	Dropdown	0, No | 1, Yes	0 >> Q5
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the treatment goal?	Dropdown	0, No | 1, Yes	0 >> 4.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. How long did it take to create the treatment goal and answer any questions generated (in minutes)	Numeric		
	4. Please provide more details if needed.	Text		
5.	**Was the participant helped to create a 'medication plan'?**	Dropdown	0, No | 1, Yes	0 >> Q6

Q#	Question	Type of field	Options (if applicable)	Skip logic
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the medication plan?	Dropdown	0, No | 1, Yes	0 >> 5.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. How long did it take to create the medication plan and answer any questions generated (in minutes)	Numeric		
	4. Please provide more details if needed.	Text		
6.	**Was the participant shown how to use the 'medication & symptom diary'?**	Dropdown	0, No | 1, Yes	0 >> Q7
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the medication & symptom diary?	Dropdown	0, No | 1, Yes	0 >> 6.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. Was the participant helped to create an 'If I forget' plan?	Dropdown	0, No | 1, Yes	
	4. How long did it take to go through the medication & symptom diary and answer any questions generated (in minutes	Numeric		
	5. Please provide more details if needed.	Text		
7.	**Was the participant shown the 'list of helpful services' page of the interactive booklet?**	Dropdown	0, No | 1, Yes	
8.	**If the participant was accompanied by a non-HCP, did that person have any questions for the HCP regarding the interactive booklet?**	Dropdown	0, No | 1, Yes | 7, N/A (not accompanied by non-HCP)	0/7 >> Q9
	1. To which part of the booklet did the question/s relate?	Multi-choice (select all that apply)	1, Medicine list | 2, Treatment goal | 3, Medication plan | 4, Medication & symptom diary | 96, Other, specify	96 >> 8.1.1
	1. Other, specify	Text		
	2. Was the HCP able to answer the question/s to their satisfaction?	Dropdown	0, No | 1, Yes	
	3. Please provide more details if needed.	Text		
9.	**Please document any additional observations or comments about the delivery of the interactive booklet.**	Text		
Baseline section 6: Final comments				
1.	**Please document any additional observations or comments not captured in previous sections.**	Text		
End of baseline instrument				

2. Follow-up consultation [intervention sites]

Q#	Question	Type of field	Options (if applicable)	Skip logic
Follow-up section 2: Setting				
1.	**What kind of room did the consultation take place in?**	Drop-down	1, Standard clinic room (containing sink, examination bed, etc.) | 2, "Day" or "Family" room (i.e., non-clinical) | 96, Other, specify	96 >> 1.1
	1. If other, specify	Text		
	2. Additional comments around the potential effect/s of the space on the consultation	Text		Always shown
2.	**What time did the consultation start?**	Date/time		
3.	**What time did the consultation end?**	Date/time		
4.	**Please describe the mood of the nurse at the start of the consultation?**	Text		
5.	**Please describe the mood of the participant at the start of the consultation?**	Text		
6.	**Was the participant accompanied by a non-HCP?**	Dropdown	0, No | 1, Yes	0 >> 7 1 >> 6.1
	1. How many other people?	Numeric		
	2. What was the relationship of person 1 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.2.1
	1. Other, specify	Text		
	3. What was the relationship of person 2 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.3.1
	1. Other, specify	Text		
	4. What was the relationship of person 3 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.4.1
	1. Other, specify	Text		
7.	**Was the participant accompanied by an HCP?**	Dropdown	0, No | 1, Yes	0 >> 8 1 >> 7.1
	1. What cadre was the other HCP?		1, Another nurse | 2, Social care/ outreach worker | 3, Advocate | 4, External translator| 96, Other, specify | 99, Don't know	96 >> 7.1.1
	1. Other, specify	Text		
8.	**Was the consultation conducted in English?**	Dropdown	0, No | 1, Yes	0 >> 8.1
	1. If no, who translated?	Dropdown	1, Non-HCP accompanying the participant | 2, Advocate | 3, External translator | 4, Language line | 96, Other specify	96 >> 8.1.1
	1. Other, specify	Text		
Follow-up section 3: Adherence review & TNA				
1.	**Was the participant's adherence reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q2
	1. Which tools were used to review the	Multi-choice	1, Self-report | 2, Pill count | 3,	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	participant's adherence?	(select all that apply)	Urine test | 4, Medication diary | 96, Other specify	
	1. Other, specify	Text		
	2. Please record additional details about the adherence review if needed.	Text		
2.	**Was a follow-up TNA completed?**	Dropdown	0, No | 1, Yes	0 >> Q9
3.	**How involved was the participant in the assessment of their own needs?** *Try to answer this question with consideration of the patient's facial expressions, body language, the amount of eye contact between patient & HCP, and the number of clarification questions asked/interest shown.*	Dropdown	1, Participant provided minimal responses to the HCP's questions | 2, Participant provided moderate responses (i.e., some issues in obtaining information/participant only provided additional information when probed) | 3, Participant provided detailed responses (was forthcoming with information/TNA completed with ease) | 96, Other, specify | 99, Don't know	96 >> 3.1
	1. Other, specify	Text		
4.	**If the participant was accompanied by a non-HCP, were they involved in the TNA?**	Dropdown	0, Not accompanied | 1, Accompanied, but not involved | 2, Involved a little [*definition*] | 3, Very involved [*definition*] | 96, Other, specify	96 >> 4.1
	1. Other, specify	Text		
5.	**How long did it take to conduct the TNA (in minutes)**	Numeric		
6.	**Based on your knowledge of the TNA, did the HCP go through the entire tool with the participant, or were some areas/questions skipped over or modified?**	Dropdown	1, Complete tool administered as written| 2, Tool not used as written | 99, Don't know	2 >> 6.1
	1. If Q4=2, please describe how the delivery of the tool differed from how it was written	Text		
7.	**Did the HCP ask any follow-up questions during or after using the TNA (for example, did they ask for more detail about a specific issue that was identified by the TNA)?**	Dropdown	0, No | 1, Yes	
	1. Please give additional details, if possible.	Text		Always shown
8.	**Please document any additional observations or comments about the delivery of the TNA.**	Text		
9.	**Was the participant assessed to need a change in the level of adherence support?**	Dropdown	0, No | 1, Yes | 9, Don't know	0/9 >> Section 4
	1. Was this discussed with the participant?	Dropdown	0, No | 1, Yes	0 >> 9.2
	1. Did the participant agree to the change in adherence support?	Dropdown	0, No | 1, Yes	
	2. Please give additional details of the discussion, if possible *(particularly if the participant was reluctant to change)*	Text		

Q#	Question	Type of field	Options (if applicable)	Skip logic
Follow-up section 4: Interactive booklet				
1.	**Did the participant bring their interactive booklet with them?**	Dropdown	0, No | 1, Yes	0 >> Q6
2.	**Was the medicines list reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q3
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the medicines list?	Dropdown	0, No | 1, Yes	0 >> 2.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. How long did it take to review the medicines list and answer any questions generated (in minutes)?	Numeric		
	4. Please provide more details if needed.	Text		
3.	**Was the treatment goal reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q3
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the treatment goal?	Dropdown	0, No | 1, Yes	0 >> 3.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. How long did it take to review the treatment goal and answer any questions generated (in minutes)	Numeric		
	4. Please provide more details if needed.	Text		
4.	**Was the 'medication plan' reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q5
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the medication plan?	Dropdown	0, No | 1, Yes	0 >> 4.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	3. Were any changes made to the medication plan?	Dropdown	0, No | 1, Yes | 9, Don't know	
	4. How long did it take to review the medication plan and answer any questions generated (in minutes)?	Numeric		
	5. Please provide more details if needed.	Text		
5.	**Was the medication & symptom diary reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q6
	1. Did the participant seem to engage with this process?	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
	2. Did the participant have any questions about the medication & symptom diary?	Dropdown	0, No | 1, Yes	0 >> 5.3
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	

Q#	Question	Type of field	Options (if applicable)	Skip logic
	4. How long did it take to go through the medication & symptom diary and answer any questions generated (in minutes)?	Numeric		
	5. Please provide more details if needed.	Text		
6.	**Was the participant asked about side effects?**	Dropdown	0, No | 1, Yes	
7.	**If the participant was accompanied by a non-HCP, did that person have any questions for the HCP regarding the interactive booklet?**	Dropdown	0, No | 1, Yes | 7, N/A (not accompanied by non-HCP)	0/7 >> Q8
	1. To which part of the booklet did the question/s relate?	Multi-choice (select all that apply)	1, Medicine list | 2, Treatment goal | 3, Medication plan | 4, Medication & symptom diary | 96, Other, specify	96 >> 7.1.1
	1. Other, specify	Text		
	2. Was the HCP able to answer the question/s to their satisfaction?	Dropdown	0, No | 1, Yes	
	3. Please provide more details if needed.	Text		
8.	**Please record any additional observations or comments about the review of the interactive booklet.**	Text		
Follow-up section 5: Final comments				
1.	**Please document any additional observations or comments not captured in previous sections.**	Text		
End of follow-up instrument				

1. Baseline consultation [control sites]

Q#	Question	Type of field	Options (if applicable)	Skip logic
Section 1: Meta-data				
1	**Date of consultation**	Date/time		
2.	**HCP study ID**	Text		
3.	**Participant study ID**	Text		
4.	**Observer initials**	Text		
5.	**Type of consultation (baseline visit or follow-up)?**	Drop-down	1, Baseline consultation | 2, Follow-up	1 >> Proceed 2 >> Skip to 'Follow-up' instrument
Baseline section 2: Setting				
1.	**What kind of room did the consultation take place**	Drop-down	1, Standard clinic room (containing	96 >> 1.1

Q#	Question	Type of field	Options (if applicable)	Skip logic
	in?		sink, examination bed, etc.) | 2, "Day" or "Family" room (i.e., non-clinical) | 96, Other, specify	
	1. If other, specify	Text		
	2. Additional comments around the potential effect/s of the space on the consultation	Text		Always shown
2.	**What time did the consultation start?**	Date/time		
3.	**What time did the consultation end?**	Date/time		
4.	**Please describe the mood of the nurse at the start of the consultation?**	Text		
5.	**Please describe the mood of the participant at the start of the consultation?**	Text		
6.	**Was the participant accompanied by a non-HCP?**	Dropdown	0, No | 1, Yes	0 >> 7 1 >> 6.1
	1. How many other people?	Numeric		
	2. What was the relationship of person 1 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.2.1
	1. Other, specify	Text		
	3. What was the relationship of person 2 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.3.1
	1. Other, specify	Text		
	4. What was the relationship of person 3 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.4.1
	1. Other, specify	Text		
7.	**Was the participant accompanied by an HCP?**	Dropdown	0, No | 1, Yes	0 >> 8 1 >> 7.1
	1. What cadre was the other HCP?		1, Another nurse | 2, Social care/ outreach worker | 3, Advocate | 4, External translator| 96, Other, specify | 99, Don't know	96 >> 7.1.1
	1. Other, specify	Text		
8.	**Was the consultation conducted in English?**	Dropdown	0, No | 1, Yes	0 >> 8.1
	1. If no, who translated?	Dropdown	1, Non-HCP accompanying the participant | 2, Advocate | 3, External translator | 4, Language line | 96, Other specify	96 >> 8.1.1
	1. Other, specify	Text		
9.	**Had the diagnosis been delivered on the same day as the consultation (e.g., earlier in the day)?**	Dropdown	0, No | 1, Yes, by the doctor | 2, Yes, by the same nurse | 3, Yes, by a different nurse | 99, Don't know	
	1. Did the patient seem accepting of their diagnosis?	Dropdown	0, No | 1, Yes	Always shown
	2 Did the patient express any negative emotions about their diagnosis?	Dropdown	0, No | 1, Yes	Always shown
	3. Please document any further observations about the participant's reaction to their	Text		Always shown

Q#	Question	Type of field	Options (if applicable)	Skip logic
	diagnosis, particularly if this changed or evolved during the consultation			
Baseline section 3: Risk assessment				
1.	**How involved was the participant in the assessment of their own risk?** *Try to answer this question with consideration of the patient's facial expressions, body language, the amount of eye contact between patient & HCP, and the number of clarification questions asked/interest shown.*	Dropdown	1, Participant provided minimal responses to the HCP's questions | 2, Participant provided moderate responses (i.e., some issues in obtaining information/participant only provided additional information when probed) | 3, Participant provided detailed responses (was forthcoming with information/risk assessment completed with ease) | 96, Other, specify | 99, Don't know	96 >> 1.1
	1. Other, specify	Text		
2.	**If the participant was accompanied by a non-HCP, were they involved in the risk assessment?**	Dropdown	0, Not accompanied | 1, Accompanied, but not involved | 2, Involved a little [*definition*] | 3, Very involved [*definition*] | 96, Other, specify	96 >> 2.1
	1. Other, specify	Text		
3.	**How long did it take to conduct the risk assessment (in minutes)**	Numeric		
4.	**Did the HCP ask any follow-up questions during or after conducting the risk assessment (for example, did they ask for more detail about a specific issue that was identified by the assessment)?**	Dropdown	0, No | 1, Yes	
	1. Please give additional details, if possible.	Text		Always shown
5.	**Please document any additional observations or comments about the delivery of the TNA.**	Text		
Baseline section 4: imaging				
1.	**Was the participant shown any of their imaging?**	Dropdown	0, No | 1, Yes	0 >> Section 5
	1. Did the participant ask the HCP any questions about the imaging?	Dropdown	0, No | 1, Yes	0 >> 1.2
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	2. Please give more details about the review of imaging, if needed	Text		
Baseline section 5: Written material				
1.	**Was the participant provided with any written material?**	Dropdown	0, No | 1, Yes	0 >> Section 6
	1. During the consultation, did the HCP go through some of the written material with the participant +/- someone accompanying the participant?	Dropdown	0, No | 1, Yes	

Q#	Question	Type of field	Options (if applicable)	Skip logic
2.	**Did the participant seem to engage with the written material?**	Dropdown	0, No | 1, Yes, somewhat | 2, Yes, they seemed fully engaged	
3.	**Did the participant have any questions about the written material??**	Dropdown	0, No | 1, Yes	0 >> Q4
	1. Were the questions answered to the participant's satisfaction?	Dropdown	0, No | 1, Yes	
	2. How long did it take to go through the written material and answer any questions generated (in minutes)?	Numeric		
	3. Please provide more details if needed.	Text		
4.	**If the participant was accompanied by a non-HCP, did that person have any questions for the HCP regarding the written material?**	Dropdown	0, No | 1, Yes | 7, N/A (not accompanied by non-HCP)	0/7 >> Q5
	1. Was the HCP able to answer the question/s to their satisfaction?	Dropdown	0, No | 1, Yes	
	2. Please provide more details if needed.	Text		
5.	**Please document any additional observations or comments about the introduction & review of the written material**	Text		
Baseline section 6: Final comments				
1.	**Please document any additional observations or comments not captured in previous sections.**	Text		
End of baseline instrument				

2. Follow-up consultation [control sites]

Q#	Question	Type of field	Options (if applicable)	Skip logic
Follow-up section 2: Setting				
1.	**What kind of room did the consultation take place in?**	Drop-down	1, Standard clinic room (containing sink, examination bed, etc.) | 2, "Day" or "Family" room (i.e., non-clinical) | 96, Other, specify	96 >> 1.1
	1. If other, specify	Text		
	2. Additional comments around the potential effect/s of the space on the consultation	Text		Always shown
2.	**What time did the consultation start?**	Date/time		
3.	**What time did the consultation end?**	Date/time		
4.	**Please describe the mood of the nurse at the start of the consultation?**	Text		
5.	**Please describe the mood of the participant at the start of the consultation?**	Text		
6.	**Was the participant accompanied by a non-HCP?**	Dropdown	0, No | 1, Yes	0 >> 7
	1. How many other people?	Numeric		
	2. What was the relationship of person 1 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.2.1
	1. Other, specify	Text		
	3. What was the relationship of person 2 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.3.1
	1. Other, specify	Text		
	4. What was the relationship of person 3 to the participant?	Dropdown	1, Spouse/partner | 2, Parent | 3, Child | 4, Other family | 5, Friend | 96, Other, specify | 99, Don't know	96 >> 6.4.1
	1. Other, specify	Text		
7.	**Was the participant accompanied by an HCP?**	Dropdown	0, No | 1, Yes	0 >> 8 1 >> 7.1
	1. What cadre was the other HCP?		1, Another nurse | 2, Social care/ outreach worker | 3, Advocate | 4, External translator| 96, Other, specify | 99, Don't know	96 >> 7.1.1
	1. Other, specify	Text		
8.	**Was the consultation conducted in English?**	Dropdown	0, No | 1, Yes	0 >> 8.1
	1. If no, who translated?	Dropdown	1, Non-HCP accompanying the participant | 2, Advocate | 3, External translator | 4, Language line | 96, Other specify	96 >> 8.1.1
	1. Other, specify	Text		
Follow-up section 3: Adherence review				
1.	**Was the participant's adherence reviewed?**	Dropdown	0, No | 1, Yes	0 >> Q2
	1. Which tools were used to review the participant's adherence?	Multi-choice (select all that	1, Self-report | 2, Pill count | 3, Urine test | 96, Other specify	

Q#	Question	Type of field	Options (if applicable)	Skip logic
		apply)		
	1. Other, specify	Text		
	2. Please record additional details about the adherence review if needed.	Text		
2.	**Was the participant assessed to need a change in the level of adherence support?**	Dropdown	0, No | 1, Yes | 9, Don't know	0/9 >> Section 4
	1. Was this discussed with the participant?	Dropdown	0, No | 1, Yes	0 >> Section 4
	1. Did the participant agree to the change in adherence support?	Dropdown	0, No | 1, Yes	
	2. Please give additional details of the discussion, if possible *(particularly if the participant was reluctant to change)*	Text		
Follow-up section 4: Other				
1.	**Was the participant asked about side effects?**	Dropdown	0, No | 1, Yes	
2.	**If the participant was accompanied by a non-HCP, did that person have any questions for the HCP?**	Dropdown	0, No | 1, Yes | 7, N/A (not accompanied by non-HCP)	0/7 >> Q8
	1. Was the HCP able to answer the question/s to their satisfaction?	Dropdown	0, No | 1, Yes	
	2. Please provide more details if needed.	Text		
8.	**Please record any additional observations or comments about the review of side-effects or about interactions with accompanying non-HCP**	Text		
Follow-up section 5: Final comments				
1.	**Please document any additional observations or comments not captured in previous sections.**	Text		
End of follow-up instrument				