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British Thoracic Society

NHS

A Case Management Tool for TB Prevention, Care and Control in the UK

CLINICAL PROFESSIONAL RESOURCE

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Contents

Purpose of this document

This is a practical manual for any clinical or non-clinical professional involved in the case management of suspected and confirmed TB cases. It aims to:

- *promote standardisation of protocols and procedures*
- *ensure accountability for delivery*
- *establish clear performance measures through cohort review.*

The manual is consistent with existing guidance for professionals working in the field of TB in the UK which provide a sound framework for clinical management and commissioning (see NICE's 2016 guideline on preventing, diagnosing and managing active and latent TB in adults, young people and children).

The RCN's 2012 case management tool, ***Tuberculosis Case Management and Cohort Review*** *was developed by an expert working group set up in March 2009 by the Department of Health, and included representation from the following organisations and groups:*

British Thoracic Society, Royal College of Nursing, Health Protection Agency, National Treatment Agency, Find & Treat and the London TB Workforce. This 2019 manual is an updated edition.

The authors and editors would value any feedback you have about the publication. Please contact **publications.feedback@rcn.org.uk**

1. Case management

1.1 What is TB case management?

Case management is the comprehensive follow-up of a suspected or confirmed TB case (Dorsinville, 1998). Case management requires a collaborative multidisciplinary team (MDT) approach. Case management should commence as soon as possible after a suspected case has been identified. Please refer to Appendix 4 (standard case management flowchart).

Where a risk/ needs assessment demonstrates that the patient has clinically and/or socially complex needs, an enhanced level of case management should be provided. Enhanced case management (ECM) commences from suspicion of disease and may include directly observed treatment (DOT), monitoring drug levels, hepatotoxicity, and/or a package of supportive care tailored to a patient's needs which should be available in both high and low incidence areas. The service should include all socially and/or clinically complex patients, including those who are vulnerable (older people), those in denial of diagnosis, and those where there is interruption to TB treatment. ECM must be available to TB patients and they may be referred to (or collaboratively managed alongside) a local specialist centre where necessary.

Column title	Column title
Diagnostic work-up	*Initial interview, include clinical history and order relevant investigations.*
Start of treatment	*Seen by TB physician and case manager, initiate contact investigations, supply one month of medication (see Appendix 1: Form 3). Patient to be notified on the National TB surveillance system.*
One week	*Make contact with patient either by telephone or home visit (clinically assess patient and the environment and complete contact list within five working days). Visiting the patient in their own environment enhances the assessment of their needs and contact identifying.*
Two weeks	*Seen by case manager as an outpatient or in the community.*
One month	*Seen by case manager as an outpatient or in the community and ensure patient has an adequate supply of medication. Supply further medication, ensure sufficient supply until next review.*
Two months	*Seen by TB physician and case manager, switch from initiation to continuation regimen, provide one month of medication. Confirmation of drug sensitivity or record that no drug sensitivity yet available (to be reviewed regularly until either culture negative or sensitivities documented).*
Three months	*As for month one.*
Four months	*As for month one.*
Five months	*As for month one.*
Six months	*Seen by TB physician and case manager, treatment completion confirmed by the clinical team and outcome reported on the TB surveillance system.*

1.2 Referral process and pathway

TB services must be accessible to and within primary, community, secondary and integrated care health providers, and allied agencies in the community. An essential part of the role of the TB MDT is to promote awareness of TB among local health and social care professionals and to ensure that all suspected cases of TB are rapidly referred for investigations. Routes of presentation and referral will vary according to the local case mix and populations and should be monitored to inform targeted awareness raising and active case finding activities. The most common routes by which patients access TB services include:

- *primary care referrals – general practitioners and practice nurses*
- *other hospital medical specialties (paediatrics, human immunodeficiency virus (HIV), renal, diabetes/endocrinology, immunology, rheumatology and ear nose and throat specialties)*
- *emergency departments*
- *active case finding – contact investigations, new entrant screening and under-served populations (USP)*
- *microbiology, histopathology and radiology*
- *clinical teams working with local USP groups*
- *open access service/s or walk-in clinics.*

Diagnosis of TB can be confirmed rapidly, for example, by polymerase chain reaction or nucleic acid amplification test, which also provides a useful indication of some forms of drug resistance. TB services should be accessible through one designated referral number and contact address. Triaging all referrals through the TB specialist nursing/medical staff promotes appropriate level of case management and ensures that relevant investigations necessary to inform clinical decision making are completed and results are available prior to seeing a physician specialising in TB.

1.3 Standard case management (SCM)

Standard TB case management is co-ordinated by a named case manager who assesses patients as being non-clinically/socially complex, able to self administer their anti-TB treatment and able to present for their monthly follow-up in a hospital or community setting. The case manager carries out a risk assessment at the beginning of treatment (and reviewed during treatment) to determine if the patient requires enhanced case management (ECM). If not ECM then SCM for drug sensitive, non-complicated TB can be structured as follows in the table below (also see Appendix 4).

A standard review questionnaire/form to assist SCM may be used as shown in Appendix 1 (Form 2a).

Where the patient is not seen by the case manager initially, the nurse should handover to the designated case manager at the earliest opportunity. Due to local service configurations

and pathways, the patient may not see the case manager on all occasions, but another team member. In all cases, there should be an introduction to the other team member and formal handover.

For examples of samples of case management forms/documents see Appendix 1 (Forms 1 and 2 include the important information that needs to be collected/obtained).

1.4 Enhanced case management (ECM)

The named case manager co-ordinates ECM and works alongside a specialist multidisciplinary TB team to provide expert clinical and psychosocial care, and where appropriate ensures effective engagement with the client group in the community. The case manager carries out a risk assessment at the beginning of treatment to determine if the patient requires ECM. This assessment should be reviewed throughout the course of treatment.

ECM should be provided for all clinically and socially complex cases (including vulnerable patients) with suspected TB to reduce the risk of patients disengaging with services prior to confirmation of diagnosis. In addition to the standard services and expertise within a multidisciplinary TB team. TB services providing ECM can provide access to:

- *expert management for clinically complex cases – including spinal, central nervous system disease, HIV co-infection, significant other co-morbidities and multi-drug resistant disease*
- *negative pressure facilities appropriate for prolonged isolation*
- *skilled outreach and advocacy workers able to draw effectively on the services of allied agencies to address a patient's language, advocacy, housing, addiction, welfare benefits and other social care needs*
- *flexible clinic opening hours, appointment systems and community DOT options.*

A hub and spoke model, with all TB services providing SCM and onward referral to specialist centres able to provide ECM will ensure that all TB patients can access a level of care commensurate with their needs.

Some TB services apply different levels of ECM when reporting the case at cohort review to reflect the degree of support required by each patient. The level is documented at the initial assessment but may be altered during the patient's treatment course if required.

Examples of the ECM levels are as follows:

- *ECM 0: used for patients who require the standard level of input to successfully complete the course of treatment*
- *ECM 1: meets criteria for level 1 ECM, for example, fortnightly visits, children with TB, dual*

diagnosis taking antiretroviral treatment

- *ECM 2: meets criteria for level 2 ECM, for example, weekly visits, complex side effects, DNA clinic/home visits, single drug resistance*
- *ECM 3: meets criteria for level 3 ECM, for example, requires DOT, homeless issues, more than one drug resistance, complex contact tracing, children who require social service involvement (Tucker A et al., 2017)*

Due to the duration of treatment, and support to parents/families/children the British Association for Paediatric TB suggests that all children require ECM 1 or 2 as a minimum. Further guidance for adult-trained nurses caring for children may be found in Getting it Right for Children (RCN, 2017).

1.5 Who provides TB case management?

SCM and ECM will usually be provided by a specialist TB nurse or (in low-incidence areas) a nurse with responsibilities which include TB.

Dependent upon the patient's circumstances and needs, case management can also be provided by appropriately trained and supported non-clinical members of the TB multidisciplinary team.

There is a guide for TB nurse competencies – Tuberculosis Nurse Competency Framework for TB Prevention and Control (2017).

1.6 When does case management begin?

Case management should commence as soon as possible from the first presentation for all suspected cases to ensure a timely diagnosis.

Sometimes the patient's route to diagnosis will be via microbiology or another medical specialty. If so, first contact with TB services may be shortly prior to, or after start of, TB treatment and a named case manager should be appointed on the same day the patient becomes known to the TB service. A named case manager should follow

up all suspected cases who fail to attend an out- patient appointment (See 6.4 RTS activities – suspected cases).

1.7 What are the responsibilities of the TB case manager?

The case manager ensures that diagnostic investigations are completed, outcomes documented, an appropriate treatment regimen is monitored and completed, and contacts are identified, evaluated and treated. This requires:

- *ensuring that relevant clinical investigations are completed and acted on (see 6.0 Managing lost to follow-up (LFU) and return to service (RTS) activities)*
- *risk/needs assessment prior to commencement of a planned course of treatment to identify cases that require ECM (including DOT/VOT) from start of treatment (see 3.1 Delivering TB treatment)*
- *All TB cases are required legally to be notified within three working days: statutory notification. It is the responsibility of the case manager to ensure that the patient has been notified and that subsequent information is entered into the database as the patient progresses through treatment*
- *providing patient education and advocacy*
- *arranging screening and contact investigation in accordance with NICE guidance (2016) and documenting outcomes to contact investigations*
- *deciding and agreeing on a care plan and co-ordinating care with allied providers, where appropriate, with the aim of addressing any psychosocial barriers to treatment adherence and ensuring completion of the prescribed treatment regimen*
- *ensuring treatment delivery, including supervision of DOT /VOT and attendance for clinical assessment and follow-up care*
- *ensuring all new cases are notified and their contacts outcomes recorded and presented at cohort review.*

1.8 Ratio of suspected, active and latent TB cases to case managers

Previous guidance from the Joint Tuberculosis Committee of the British Thoracic Society recommended a ratio of one WTE TB nurse specialist to 40 notifications in London (equivalent to any high prevalence urban centre) and one to 50 notifications outside of London (equivalent to any low prevalence area), based on the number of new cases reported from a TB service in any given year.

It is necessary to factor in the demands of case managing all suspected cases and the additional complexity of managing socially and clinically complex cases requiring ECM.

As TB services vary in terms of rates, geography, complexity for workforce capacity and skill mix, TB services should ensure that their local contract/ service level agreement includes the case manager to patient ratio, appropriate in order to achieve positive outcomes for both active and latent cases.

When looking at the case manager to patient ratio the following points should be taken under consideration:

1.0 WTE nurse	1.0 WTE nurse	0.5 WTE nurse
30 actives cases on SCM and 20 LTBI cases on SCM **Or** *Active cases = 1:40 SCM* **Or** *LTBI cases = 1:80*	*20 active cases on SCM and 10 ECM level 3* **Or** *Active cases = 1:20 ECM*	*20 active cases* **Or** *40 LTBI cases*

- *number of patients requiring SCM*
- *number of patients requiring ECM*
- *number of patients that require DOT/VOT and type/level of resources for effective delivery*
- *drug resistant cases (these require DOT/ VOT, are clinically and/or socially complex, and require treatment duration for up to 20 months)*
- *number and size of incidents and outbreaks (the frequency and complexity of these will vary from area to area, therefore resources and time requiring for capacity and capability to manage these must be considered)*
- *having the appropriate staff skill mix is key for tasks such as social care/outreach support (DOT)*
- *services should have designated and adequate administrative staff to support both case management and incident/outbreak management. Administrative and clerical staff should also form part of the teams*
- *job plans need to take into account cohort review meetings, including preparation time, training and awareness sessions.*

As a standard, it is proposed that staffing levels for all TB services should be based on one WTE TB case manager per 40 notifications at any time or annually requiring SCM. LTBI cases on treatment should be counted as a half notification.

Where patients are receiving ECM and there are no alternatives, such as support staff (support workers, etc.) then the ECM case should be counted as two notifications. LTBI cases requiring ECM should be counted as one notification.

In practice this would mean that a TB service providing care to 80 non-complex, 20 socially or clinically complex cases and 80 LTBI cases at any time or per annum would need a total of 4.0 WTE TB case managers, plus designated administrative and clerical staff and social care/ outreach staff.

Example below: (for high incidence areas)

This proposed staffing ratio does not include essential administrative staff, health

advocates, interpreters and other outreach staff working alongside a TB MDT. It is vital that administrative staff are considered an essential part of the TB team.

2. The initial interview and assessment

This should take place on first presentation to the TB service or as soon as possible for all suspected or confirmed active TB patients and patients commencing preventive treatment for LTBI. The interview should be conducted by the named case manager and undertaken in either a clinical or community setting, depending on the patient's individual circumstances. If the patient is diagnosed with TB whilst an inpatient in hospital, plans for follow-up care upon discharge must be initiated in conjunction with the inpatient team and not on the day before discharge. This will require early liaison with the inpatient nursing and medical teams (plus awareness on their part that they must contact the TB team when a patient is admitted or diagnosed with TB).

The aim of the initial interview between the case manager and any suspected or confirmed TB patient is to:

1. *establish a trusting relationship*
2. *educate and support the patient by using motivational interviewing techniques*
3. *identify and assess physical and psychosocial care needs, and potential barriers to completion of diagnostic investigations and treatment*
4. *initiate contact investigation as appropriate.*

Current NICE guidance (2016) provides information on clinical assessment, including potential drug interactions, which will not be covered in this manual. In addition to clinical assessment, the initial interview should be structured to cover the following key issues.

2.1 Education

Assess the patient's knowledge and misconceptions about TB, determine the most appropriate education intervention and provide appropriate literature/information. For patients who are about to commence treatment (for either active or latent TB) the educational content should include:

- *TB transmission and pathogenesis*
- *preventing TB*
- *distinguishing infection from disease*
- *how drug resistance develops*
- *length of treatment needed for latent versus active and for sensitive versus drug-resistant TB*
- *standard TB medications, including names, dosages, actions and adverse effects (including possible drug interactions). It is important that the case manager explains the interactions of drugs, especially if interactions are likely. Guidance for those on antiretrovirals can be found at: www.hiv-druginteractions.org*
- *level of treatment support that can be expected*
- *show medication and how to take medication*

- *promote ECM including DOT as required*
- *explain contact investigation process*
- *gather a list of contacts and explain the importance of the information/screening to the index case (see Form 3, Appendix 1)*
- *empower the patient's role in contact tracing process.*

2.2 Locating information

It is vital to obtain and document comprehensive information and agree with the patient on the best mode of communication (for example, mobile phone, home/work number, email address, significant other, parent, carer details). Identify an individual who will always know where to find the patient and determine if the patient plans to remain in accessible proximity to the TB service for the duration of treatment.

It is also important to obtain contact details of patients who are likely to return to their country of origin, (email and/or address in home country will be appropriate) so that planned transfer of care can be facilitated to ensure they continue

to receive appropriate treatment and support by their local TB service. For patients with complex social needs, locating information should include details of other involved agencies and consent should be obtained from the patient to contact these agencies (see 2.5 Consent).

2.3 Assess psycho-social needs and potential barriers to completion of diagnostic investigations and treatment (see TB Treatment 3.4: Who should be offered DOT?)

This assessment should be tailored to the individual patient's needs. TB patients presenting with complex social needs, such as homelessness and/or substance misuse, no recourse to public funds will require detailed MDT assessment to ensure that an appropriate plan of care can be implemented. Issues to address in the initial assessment include:

- *housing needs and living situation*
- *mental capacity, emotional capacity and cognitive status (via referral to a mental health team and social worker as necessary)*
- *stigma associated with TB*
- *language and literacy barriers*
- *cultural and religious beliefs that may impact on acceptance of diagnosis and adherence*
- *substance misuse*

- *access, mobility and transportation*
- *employment and income source, including entitlement to benefits*
- *family/social support and dynamics*
- *legal or immigration issues.*

2.4 Contact investigations

Explain to the patient why it is important that contacts be identified and evaluated as soon as possible. Enquire about all household contacts, not only who they live with but visitors to the household and other contacts outside the household who they spend a lot of time with. Obtain names, demographic details, contact information, exposure history and any factors for increased risk of TB disease (see 7.0 Implementing contact investigations and form 3 of Appendix 1).

Patients should be informed about the possibility of home visits and the TB service initiating 'return to service' activities if treatment is interrupted. Patients do not need to provide separate permission for this as this is part of the treatment package and the action is not only in their own interest but also in the interest of their contacts and the general public. For further guidance see NICE's Tuberculosis: contact tracing and testing pathway (NICE, 2016).

2.5 Consent

Obtaining informed consent is a matter of good practice. For example, the patient consent should be an agreement with the case manager to follow-up care and that personal information about them may be shared with other agencies and with other professionals.

Case managers should explain to patients that providing their consent to share information will help them receive the care and support they need. Consent lasts as long as co-ordinated interagency services are required. Individuals have the right to withdraw consent at any time after they have given it. If consent has not been sought, or sought and withheld, then advice from the local health protection team should be obtained where information sharing is deemed necessary in order to prevent serious harm to a child or adult and/or to provide urgent medical treatment (see Appendix 12: Simple guide to information sharing).

3. Anti-TB treatment

3.1 Delivering anti-treatment

TB treatment can be either self-administered or directly observed. The most important factor affecting TB treatment outcomes is the patient's ability to adhere to and complete a prescribed course of treatment (Fox, 1958 and 1962; Addington, 1979) and whether they receive the additional support required in a timely manner. Adherence refers to the extent to which a patient follows the instructions given for prescribed treatment. Low adherence with any prescribed treatment is common, with typical adherence rates estimated to be about 50% (Haynes et al., 2008). Non-adherence to TB treatment results in onward transmission, ill health, severe morbidity, preventable death, and the emergence of drug-resistant strains.

3.2 What is self-administered treatment (SAT)?

The patient takes responsibility to self- administer their medication, with the minimum support of the case manager. Adherence for patients administrating their own treatment should be promoted by providing medication in a conveniently packaged with delivery of medication to patients in the community where appropriate. Patients undergoing SAT should be monitored regularly (minimum monthly, see Appendix 4 Standard Case Management – flow chart) either in the community or clinic setting.

Monitoring for adherence to SAT

- *Discuss any perceived adverse effects or problems tolerating the medication as prescribed (See Appendix 11: Drug therapy adverse effects requiring clinical action).*
- *Tablet count.*
- *Urine test (if available) – commercially available test strips for isoniazid or rifampicin (butanol) are a simple tool for monitoring adherence. If no commercial tests are available, a visual check for discolouration may be performed if soon after ingestion.*
- *Counselling on the importance of treatment continuity and completion.*
- *Re-supply medications from the TB service (only one month should be given to ensure early identification of non-attendance and pill counts) and check arrangements for future prescriptions and clinical follow-up appointments.*

3.3 What is directly observed treatment (DOT)?

DOT includes watching the patient swallow the prescribed medication, documenting this on a clear log/chart of observations and checking for adverse effects. DOT is a daily process and not thrice weekly (WHO, 2017).

DOT is part of a patient-centred enhanced case management approach and includes:

- *support to encourage attendance of medical appointments*

- *ongoing patient education*
- *offering incentives and/or enablers*
- *assisting with transport*
- *connecting patients with social services and other specialist support agencies as appropriate.*

TB services should aim to ensure that all TB patients who are likely to benefit from

treatment observation receive either DOT or Video Observed Treatment (VOT). All DOT appointments should be logged (see Appendix 1: Form 4), including if parents/carers are being supported by providing DOT.

DOT significantly increases completion rates; it is shown to reduce the rate of drug resistance and relapse when compared with self-administered therapy (Weis et al., 1994; Wilkinson, 1994).

If SAT is the only option for drug delivery, the drugs must be taken daily (Canadian Thoracic Society's TB Committee, 2017).

3.4 What is Video Observed Treatment (VOT)?

DOT can be challenging to deliver and inconvenient for patients and resource intense for TB services and can result in high levels of patient refusal to agree to this level of treatment supervision. A UK multicentre randomised controlled trial demonstrated VOT to be more effective, more acceptable and cheaper than either clinic or community based DOT. The World Health Organization (WHO) recommends that VOT can replace DOT when the video communication technology is available and can be appropriately organised and operated by health care providers and patients. VOT can reduce patient and TB services burden without sacrificing any of the benefits of traditional methods of monitoring TB medication adherence.

VOT should be provided on a secure NHS approved digital platform by an expert provider who can quality assure the service. VOT typically uses affordable smartphones or tablet computers provided to the patient, along with a data plan.

Patients are trained to film themselves taking every dose of their medication using an approved smart phone application which securely uploads videos to a cloud platform. Videos are then viewed by a trained observer who verifies that the medication has been taken as prescribed and responds to any issues reported by the patient, including side effects, and liaises directly with the case manager as necessary.

3.5 Who should be offered DOT/VOT?

The long duration of TB treatment requires sustained commitment by both patients and TB services to ensure success. While demographic factors such as age, sex, ethnicity, education and socio-economic status are not accurate predictors of adherence, psychiatric illness, substance abuse (alcohol and drug) and homelessness do typically predict non-adherence

(Dorsinville, 1998). The best predictor of non-adherence is a previous history of non-adherence to TB treatment.

DOT or VOT should be considered for all TB patients with active disease since it is difficult to predict with any certainty who will comply with treatment (Fox, 1958 and 1962). TB case managers should undertake a risk assessment to identify whether the person should have DOT or VOT from the start of treatment, for all children aged under 16, people who request it and those who:

1. *do not (or have not in the past) adhere/d to treatment*
2. *have been treated previously for TB*
3. *have a history of homelessness, drug or alcohol misuse*
4. *are currently or have previously been in prison*
5. *have a major psychiatric, memory or cognitive disorder*
6. *are in denial of the TB diagnosis*
7. *have mono, poly or multi-resistance TB*
8. *are too ill or frail to administer the treatment themselves.*
9. *have clinically complex disease eg, TB meningitis*
10. *young adults over the age of 18, where their main focus may not be their health*
11. *are children or young people with current or previous safeguarding concerns*
12. *all children should be considered for DOT/ VOT, and if the above factors apply to either the child or young person themselves, or to their parent or other caregiver. Wherever practically possible DOT/VOT should be initiated at the start of TB treatment as patients who are switched to observed treatment can see this as a punitive measure and there is less chance of successfully completing treatment. Both the DOT/VOT provider and case manager treating should reinforce the value of supporting the patient through treatment observation.*

Treatment of the following patients not initially on DOT/VOT should be switched to DOT/VOT if any of the following occur without clear clinical reasons:

- *slow sputum culture conversion (culture still positive >2 months after treatment started for fully sensitive cases)**
- *slow clinical improvement or clinical deterioration while on TB therapy (worsening chest x-ray)*
- *noted being non-adherent to treatment.*

** Note: in practice this may only be apparent after several weeks and reinforces the need to obtain regular sputum samples if the patient still has a productive cough.*

In addition, patients who experience adverse effects after taking the medication may be reluctant to self-medicate and should receive close supervision, including those on latent TB therapy.

All patients receiving DOT/VOT should sign a contract that clearly states the agreed timing and location for DOT, and include the potential public health implications of not taking TB treatment as prescribed. This agreement must be in a language understood by the patient and should be included in their medical/nursing records. (A sample of this is provided in Appendix 2).

Where resources for providing DOT/VOT are limited, providers should still assess the need for treatment observation using the characteristics listed above and work with local commissioners, clinical TB networks and health protection staff to demonstrate the need for additional TB case management and DOT/VOT resources.

3.6 Who should observe DOT?

WHO recommends DOT should be administered by trained health-care workers or lay providers over DOT administered by family members. In the UK, DOT can be provided by a trained nurse, health care professional, outreach worker or with the consent of the patient a lay person who is supported and trained by the TB case manager. The process involves observing a prescribed dose swallowed by the patient and documentation of that observation.

Potential DOT observers

- *Nurses.*
- *Outreach support workers.*
- *Staff working in homeless hostels (key workers).*
- *Pharmacists.*
- *Teachers/school nurses/first aid workers or welfare officers.*
- *Staff working with prisoners and ex- offenders.*
- *Staff working with clients who are dependent on drugs or alcohol.*
- *Staff working with people with major psychiatric/memory or cognitive disorders.*
- *Occupational health staff.*
- *Trained individuals from voluntary sectors.*
- *Primary health care staff.*
- *Foster carers or care home workers.*

It is not usually recommended that family members, other than parents of young children, be responsible for watching TB patients take their medication, as they are not typically neutral or objective about the patient's health. With a high level of community support from the named case manager and/or other relevant health professional, eg, paediatric community nursing team, a parent or guardian can be best placed to supervise the treatment of children and younger adults living in a household setting. VOT can be an effective option to promote adherence for

children and young people (see 3.7).

3.7 Where should DOT be provided?

WHO recommends community or home-based DOT over health facility-based DOT. In practice, treatment should be arranged to be most practicable for the patient, provided the location is convenient and safe for both patient and provider (DOT worker). If not at home, then when agreeing the DOT location DOT workers should consider issues associated with accessibility and economic resources (incentives, enablers, travel costs, employment disruptions), other treatments currently underway (HIV, methadone maintenance) and their locations, and possible social stigma associated with having TB.

Community or home-based DOT can be provided more efficiently by establishing partnerships with allied health and social care services. TB services providing DOT to patients willing to be treated on an outpatient basis should consider flexible or extended opening hours.

3.8 How frequently should DOT be provided?

The effectiveness of anti-TB medication is dependent on adherence to the prescribed therapy; convenient dosing schedules are an important means to improve patient adherence. Treatment should be given daily for both treatment phases.

It is not recommended that patients with drug- susceptible pulmonary TB use thrice-weekly dosing in the intensive and continuation phases of therapy – daily dosing should remain as the recommended dosing frequency (WHO, 2017).

It is common practice to request patients taking daily DOT, to self-administer at the weekend.

However, if every weekend dose is omitted then the patient would be taking only around 71% of the prescribed treatment. Where this is a concern that doses are being omitted, VOT should be considered or DOT through alternative providers.

Where clinical management is complicated by the concurrent treatment of other morbidities, such as HIV or opiate use, then expert guidance should be sought (see Appendix 10: Methadone and anti-TB treatment containing rifamycins).

Providing DOT for patients who are prescribed complex drug regimens that include intravenous, intramuscular or more than one daily dose is a major challenge and highly resource intensive and disruptive to patients' lives.

VOT is an effective alternative to DOT for patients who require multiple daily dosing. Where it is not possible to provide VOT, TB services should aim to provide home care in collaboration with other community health providers.

3.9 How long should DOT/VOT be continued?

Ideally, all patients commenced on DOT should complete the planned treatment course with DOT/VOT. All patients receiving DOT should successfully complete at least the initiation phase of treatment before any consideration is givento reducing the level of treatment supervision. Where patients have demonstrated good adherence, and treatment is well tolerated, it may be appropriate to step down from DOT/VOT to SAT, with regular review in the continuation phase.

3.10 How should patients who will not agree to DOT/ VOT be managed?

From practice there are often two main reasons for DOT refusal which are that patients feel they can self-medicate and DOT interferes with their schedule and life style. In most cases these

factors can be overcome by providing education, support and ensuring the arrangements for DOT are as convenient as possible for the patient.

While patients falling into recommended categories for DOT have the right to refuse DOT, the provider must stress the potential public health implications of not taking anti- TB treatment. The case manager must offer alternative tools, such as VOT.

Sputum smear positive and/or drug-resistant patients who present a clear threat to public health and refuse DOT/VOT, should be reported to the local TB lead and the local health protection team. These people will work with the case manager to involve the patient in a multidisciplinary/ agency case conference to address DOT/VOT need. All patients who refuse DOT/VOT should receive a high level of community support from their named case manager, including weekly adherence checks.

3.11 How should latent tuberculosis infection (LTBI) treatment be provided?

LTBI treatment requires people, who are otherwise well, to complete either three months of rifampicin/isoniazid or six months or isoniazid alone of daily medication. Research has shown that adherence is even more difficult than in cases for full treatment of active TB disease and that no one strategy has been found to be successful for improving adherence to treatment for LTBI (Hirsch-Moverman et al., 2008). Shorter courses of LTBI treatment (Trajman et al., 2010) and offering patients the choice of medication regimen (Rennie et al., 2007) are associated with improved adherence to LTBI treatment. Weekly treatment with rifapentine and high-dose isoniazid may make observation of treatment for LTBI more practicable, but this is a limited option given the current difficulties obtaining Rifapentine. Patients about to commence preventive treatment should be risk assessed for factors likely to complicate adherence as for patients with active TB (WHO, 2015).

DOT for LTBI results in higher completion rates (White, 2003; Gourevitch, 1998) and should be considered for children following a risk assessment and any patients with additional risk factors (WHO, 2015).

3.12 Advice for home isolation

The duration of treatment required to render patients non-infectious varies between individuals and remains largely unknown (Iseman, 1997). In the absence of drug resistance and extensive cavitatory disease, patients with pulmonary and/or laryngeal TB are usually considered not infectious after two weeks of treatment. Advice from the treating clinician should be sought.

Isolation advice to patient includes:

- *stay at home unless you need medical care*
- *put off all non-emergency appointments (dentist, hairdresser, etc.) until you are no longer contagious/infectious*
- *inform any medical practitioner that you may need to see, that you have TB*
- *people who you already have had contact with or live with during the infectious period will be investigated as contacts. Avoid contact/spending time with new people until declared as being non-infectious*
- *you can go outside but avoid public transport*
- *do not go to school, work or any other public place until you have been informed that you are no longer infectious to others.*

See Home isolation policy in Appendix 6.

4. Promoting adherence

DOT works best as part of a range of supportive measures tailored to the individual needs of each patient. A package of care should include: education, counselling, incentives, enablers and psychosocial care to address housing, substance misuse and other problems likely to impede adherence.

4.1 Incentives and enablers

Incentives and enablers are measures to help a patient overcome barriers and improve adherence. There is international expert consensus that the use of incentives and enablers can improve case detection and treatment success. Good evidence exists for incentives and enablers to increase adherence with DOT (Fujiwara, Larkin and Frieden, 1997; Davidson, Schluger and Feldman, 2000; Bock et al., 2001). Service commissioners should recognise the role that incentives and enablers can play in TB control and ensure that they are readily available to patients.

4.2 What are incentives?

Incentives are small rewards, eg, travel expenses, etc. that encourage patients with suspected and/or confirmed TB to attend for community TB screening, outpatient follow-up and DOT appointments. Incentives must be something that meets the patient's interests and needs. Providers should be creative and tailor incentives to the individual and make a clear written agreement on what is expected, what will be received, where and when. Incentives are usually used on an ongoing basis – weekly, monthly, or when key milestones in investigations or treatment are reached. Use incentives to motivate, not coerce. Services should work with food banks, charities, commissioners and local authorities to obtain incentives or provide a budget to provide patient support funds.

4.3 What are enablers?

Enablers help overcome barriers to completing investigations and anti-TB treatment. Examples of barriers that are likely to impact on outcomes include: transport, housing, nutrition and immigration status. Assistance with transport is crucial for some patients who may not have the means to cover these costs. For TB patients on treatment, the importance of housing cannot be understated. In some areas, local agreements between commissioners and local authority housing officers are in place to ensure that patients with TB can access accommodation and successfully complete treatment.

4.4 When should incentives/enablers be used?

A thorough individualised needs/risk assessment should identify barriers to care and any potential adherence problems and ensure that enablers are used appropriately.

4.5 Accommodation

A safe and supportive environment is essential to recovery and prerequisite to anti-TB treatment. All patients with TB should have their housing circumstances systematically assessed.

Patients who are homeless need rapid access to accommodation eg, hostels and supported housing projects. TB services should forge links with local homeless services in order to:

- *harness expertise within the homeless sector*
- *help engage and manage patients with such challenges*
- *promote rapid referral*
- *support treatment continuity and recovery.*

All acute hospitals should have formal admission and discharge policies for people who are homeless, especially those with TB (Department for Communities and Local Government, 2006; Public Health England, 2017).

5. Managing non-adherence

5.1 What is non-adherence?

- *SAT patients are considered non-adherent after two consecutive missed outpatient appointments, or have not been available for a community/home consultation, after the initial non-attendance, irrespective of the amount of medication that they potentially hold.*
- *DOT patients are on daily treatment and are considered non-adherent after missing three daily doses.*

All episodes of non-adherence must be documented and action initiated by the case manager (in consultation with the multidisciplinary team) to address any potential barriers to treatment continuity.

5.2 Managing non-adherence for active TB patients on SAT

Case managers have no objective means of verifying that SAT patients are taking their medication. As such they should be highly alert and responsive to potential indicators of non-adherence.

Indicators of non-adherence

- *Missed appointments.*
- *Delayed clinical improvement (including failure to regain weight) or clinical deterioration while on TB treatment.*
- *Slow sputum conversion.*
- *Inability to verify correct doses of medication.*
- *Discrepancies in tablet counts.*
- *Poor or non-acceptance of TB diagnosis.*
- *Adverse effects as these make patients reluctant to self-medicate.*
- *Unanswered attempts at communication with patient via the TB service*
- *Failed urine checks.*

The named case manager should phone the patient via telephone within one working day of a missed appointment:

- *if the patient is estimated to have enough medication to last until the new appointment date, and they can confirm by phone that they are taking the medication and are not experiencing side effects, then a new appointment should be made to see the patient within five working days or sooner if the patient does not have enough medication*
- *if the patient is not contactable by telephone, then a home/community visit should be*

made and a new appointment delivered to the patient within three working days of the first missed outpatient appointment. A standard letter reiterating the importance of treatment completion, in a language understandable to the patient should be hand delivered

- *if the patient cannot be contacted or does not attend the new appointment, the case manager must inform the treating physician and continue to attempt to contact the patient with repeat telephone calls and home/community visits*
- *if the patient has not been in contact within 10 working days of the first missed appointment, then the patient is defined as lost to follow-up (LFU). The case manager should convene a case conference (see 6.0 on Managing LFU and RTS activities)*
- *where specialist street/community outreach teams are available, such as Find & Treat in London, case managers should contact these services and initiate RTS activities for LFU patients ie, those not contacted within 10 working days of the first missed appointment*
- *other professionals involved in the patient's care should be contacted, including the GP and in the case of pre-school children, the health visitor, and for older children, the school nurse*
- *in children and young people, consideration should be given to the need for a safeguarding referral or contacting the child through their school (bearing in mind confidentiality).*

5.3 Managing non-adherence for active TB patients on DOT

The role of observing the patient take their medication is sometimes devolved by the case manager to another responsible person. However the case manager remains ultimately responsible for monitoring adherence and ensuring that any potential barriers to treatment continuity are addressed. This includes the following points.

- *Case managers should attempt to contact patients who miss a DOT appointment on the same day or within one working day.*
    - *Where DOT is devolved by the case manager, the person observing the patient should inform the case manager on the day of a missed DOT appointment.*
    - *The case manager should attempt to contact the patient via telephone on the same day, or within one working day of a missed DOT appointment.*
- *If the phone call is unsuccessful or if a phone number is unavailable for the patient, the case manager should ensure that a home/community visit is undertaken within one working day of the missed DOT appointment/visit. A standard letter, reiterating the importance of treatment completion, in a language understandable to the patient, should be hand delivered to the contact address.*
    - *If the patient cannot be contacted within five working days of the first missed appointment, then the case manager must inform the treating physician and continue to attempt to contact the patient with repeat telephone calls and home/community visits.*
    - *Patients on DOT who cannot be contacted within 10 working days of the first missed DOT*

appointment are defined as LFU. The case manager should initiate local RTS activities for LFU patients.

5.4 Managing non-adherence during preventative treatment/LTBI

Preventive treatment is not 100% effective even when completed and carries the risk of adverse effects. As such, the potential patient and public health benefit of preventive treatment will vary. All individuals who agree to take preventive treatment will require case management, including regular clinical review. Where appropriate, this will include DOT of preventive treatment (see 3.4 Who should be offered DOT?).

In young children who are household contacts, HIV co-infected individuals and persons receiving anti TNF-alpha treatment, the benefits of preventative treatment are clear and service providers should aim to encourage and document a high rate of uptake and achieve a high rate of treatment completion (85%) among these groups (see 6.3 Return to service (RTS)).

Patients or their legal guardians who elect not to start preventive treatment, or who stop treatment prior to completion, should be given written information and advice on the risks and symptoms of TB, including the TB service/clinic contact details should they wish to seek advice on treatment in the future and their GP should be informed in writing (NICE, 2016).

5.5 Measures to support and enable patients to take TB treatment

The following health and social interventions may contribute to improved anti-TB treatment continuity. To ensure a consistent and appropriate use of public health powers, health service providers considering an application to detain a patient with TB should demonstrate that alternative interventions to support and engage the patient has been tried, exhausted and failed.

Patients or their legal guardians who elect not to start preventive treatment, or who stop treatment prior to completion, should be given written information and advice on the risks and symptoms of TB, including the TB service/clinic contact details should they wish to seek advice on treatment in the future and their GP should be informed in writing (NICE, 2016). Case managers must discuss with the treating paediatrician and if concerns of risks remain, liaise with the safeguarding/child protection team.

Measures may include the following:

1. *provide a flexible, open access one-stop TB service. Rigid clinic/long waiting times, multiple appointments in different locations and with different providers alienate patients*
2. *case management should include a comprehensive needs assessment to inform a plan of care and identify factors known to complicate TB treatment*
3. *counselling, education and support in the patient's first language*

4. *involving peer groups to ensure that the appropriate approach is used*
5. *access to accommodation suitable for recovery and appropriate to the patient's level of need*
6. *Referral to allied services relevant to un- met health and social care needs eg, drugs, alcohol, mental health, welfare benefits, refugee advocacy and advice services*
7. *a patient/provider contract to undergo anti-TB treatment, accept counselling and to take anti-TB treatment supervised by one or more specified person/s*
8. *DOT from treatment onset provided in:*
    - *a hospital/TB outpatient clinic or other health facility*
    - *the patient's home environment*
    - *in a methadone maintenance programme*
    - *or other community/institutional setting.*
9. *provide non-cash incentives/enablers eg,*
    - *travel assistance*
    - *food vouchers/access to food bank*
    - *other non-cash assistance.*
10. *provide cash incentives/enablers*
11. *offer respite through voluntary admission into acute care, intermediate care or a secure medical and psychosocial unit where available*
12. *ensure that children take the most suitable formulation of medication. Many children can swallow tablets and may find these preferable to liquids. Children can be taught to swallow tablets using a 'pill school approach' (CHIVA, 2009). Also see: Appendix 5: Tips for giving medication to children, and the Children's HIV Association has additional helpful resources.*

6. Managing lost to follow-up (LFU) and return to service (RTS) activities

6.1 Lost to follow-up (LFU) – definition, principle and purpose

- *Patients on SAT who cannot be contacted within 10 working days of the first missed outpatient appointment are defined as LFU*
- *Patient on DOT who cannot be contacted within 10 working days of the first missed DOT appointment is defined as LFU*

The principle of defining LFU is to identify confirmed (diagnosed) cases of active TB, LTBI treatment cases and suspected cases of active TB who could potentially harm either themselves or others by not completing prescribed treatment or relevant investigations.

The purpose of defining LFU is to trigger RTS action following missed doses of medication and/ or missed follow-up appointments.

6.2 Return to service (RTS)

Tracing individuals who have interrupted treatment to encourage treatment completion is an essential element of effective TB treatment and effective TB control. RTS will include internal review and action by the local TB service and specialist outreach teams, where available.

The aim of RTS is to ensure that patients on treatment with active TB, LTBI treatment cases, or suspected cases who are at high risk of active TB disease, are rapidly re-engaged with treatment services and opportunities are not missed to prevent TB treatment non-adherence and delay diagnosis.

Patients who are LFU should be discussed at MDT/case review meetings involving multidisciplinary staff with specialised expertise. Based on case by case situation, as impacts on patient's health and/or public health, a case conference should be convened by a delegated representative of the local authority/ director of public health department office.

Administration of the case conference, including the recording of meeting notes/minutes, should be the responsibility of the local authority and/ or public health department, although the meeting can be chaired by a senior specialist from another organisation, such as a consultant in communicable disease control (CCDC) or a consultant in health protection from the local health protection team.

Specialist expert representation at the case conference will be required from a range of statutory and voluntary services/organisations, depending on the particular circumstances of the

case. These could include services to address:

- *TB case management, for example, case manager/TB specialist nurse, TB physician, microbiologist*
- *housing, for example, local authority, commissioner/s, voluntary sector*
- *drug and alcohol dependence, for example, key worker*
- *mental health*
- *sexual health and HIV*
- *financial support and social benefits, for example, commissioner, Citizens Advice Bureau, Department of Work and Pensions*
- *safeguarding (adult and child) – social services/child protection*
- *crime and justice, for example, police/ probation*
- *immigration, for example, UK Visas and Immigration Representative*
- *animal/pets, for example, local authority – animal health, environmental health*
- *ambulance service.*

A referral should also be made to specialist outreach teams, in areas where these are available.

6.3 Prioritising RTS activities – active cases

TB services should prioritise locating and re- engaging the following patients with active TB.

1. *Those who have not been contactable for 10 working days of the first missed outpatient appointment or DOT appointment/visit.*
2. *Any patient with MDR-TB with current positive microbiology (smear or culture), regardless of the site of their disease.*
3. *Newly diagnosed patients, or reactivated patients, who have had AFB (acid-fast bacilli) positive sputum smears with no documentation of conversion to negative within the last nine months.*
4. *Any child younger than 16 years of age with less than six months of treatment (including preventive treatment: three months or less if prescribed three months of rifampicin/*

isoniazid: chemoprophylaxis), regardless of site of disease.*

5. *Any patient who is HIV-positive with current sputum AFB-negative smears, but whose culture has not converted to negative.*
6. *MDR-TB patients with negative microbiology (smear and culture) who have received less than 18 months of therapy.*
7. *Patients with single drug-resistant TB who remain culture positive.*
8. *Patients with drug-sensitive TB who have negative smears but remain culture positive.*
9. *Patients with drug-sensitive TB who have negative smears and have received less than six months of treatment.*
10. *Patients with drug-resistance extra- pulmonary TB.*

** All case managers should be trained and aware of potential safeguarding/child protection issues when managing both active disease and preventive treatment in persons under 16 years of age.*

6.4 RTS activities – suspected cases

All patients with suspected TB referred to TB services for diagnostic investigations should have a named case manager appointed to ensure a timely diagnostic conclusion is reached and reported. The following suspected cases should be managed as per: Section: '5.2 Managing non- adherence for active TB patients on SAT.'

1. *Any medically assessed person with signs or symptoms compatible with active pulmonary TB.*
2. *Any child (<16 years of age) who has been medically assessed and referred for investigations.*

All other suspected cases who fail to attend an outpatient appointment should be followed up as per contacts of pulmonary smear negative and all non-pulmonary cases (see 7.42).

6.5 RTS – Process and management

Where a local decision is made to initiate RTS activities, the case manager takes responsibility

for informing the local authority public health department with a view to considering the need for a case conference. The local health protection team should also be informed. This should be done within ten working days of the patient becoming LFU. It is essential to provide as much information as possible so the patient can be identified on databases and signposted in relevant local services. If the patient is known to be homeless the case manager must inform the specialist street outreach teams (where available).

As a minimum, case managers should provide the RTS team with:

1. *patient's full name, date of birth and any aliases used*
2. *usual/last address (for patients who have no forwarding address, this should include details of places where the patient was sleeping or hanging out)*
3. *next of kin, names of person(s) known to the patient and contact addresses*
4. *contact details, such as telephone/mobile phone numbers*
5. *date/place first presented and date/place last seen*
6. *date last verified dose of medication*
7. *clinical information including the route of presentation, symptoms, site of disease, risk of sputum smear positivity, drug resistance and total amount of the prescribed regimen taken. Co-morbidities, for example, HIV, Hepatitis B and C status. Plus whether using other medication (which may interact with anti-TB treatment eg, antiretrovirals)*
8. *any previous history of TB and adherence*
9. *details of any mental health problems*
10. *allied agencies involved including details of DOT observer where devolved to allied professionals*
11. *social factors and history including immigration status (date of arrival in the UK), homelessness, drug and alcohol misuse and prison history*
12. *GP or other health provider known to the patient.*

The case manager should contribute to the MDT meeting with the RTS team and provide details of all efforts and interventions made to facilitate completion of investigations and adherence to prescribed TB treatment. Case managers should be directly involved in developing and implementing relocation plans. The RTS team should not consider legal intervention until all reasonable efforts to assist the patient in completing planned investigations and the entire course of TB treatment have failed.

7. Implementing contact investigations

Contact investigations are a cornerstone of TB control because they detect new TB cases, assist in the identification of the source case/other index cases and prevent future cases (Mohle-Boetani and Flood, 2002). Internationally, there are standard definitions for the type, duration, closeness, and time period of exposure to an active TB case that warrant investigation; there are no standard criteria for expanding investigations beyond the most frequent contacts to include those with less frequent exposure, and there are no standard procedures for identifying, screening and tracking contacts (Reichler et al., 2002). A risk assessment-based approach is recommended, where the need to screen contacts is prioritised on: the infectiousness of the index case, the intensity of exposure, and the susceptibility of contacts (Erkens et al., 2010).

The named case manager takes responsibility to ensure that contacts are identified, investigated and appropriately managed and the outcomes of contact investigations are reported through a cohort review. Contact investigations should not be delayed until notification.

The named case manager should compile a comprehensive list of exposed individuals for all newly diagnosed TB cases (see sample form 3, as Appendix 1). This process begins during the initial interview but an accurate assessment of who should be included as a contact – based on the risk of onward transmission is best undertaken in the patient's home or usual community setting. TB services that are clinic based should undertake a risk assessment at the patient's home and within five working days of the initial interview, especially where the above information is required or needs to be confirmed. For further information, see NICE's contact tracing and testing pathway (2017).

7.1 How should contact investigations be organised and prioritised?

Contact investigations should first assess those persons most likely to be infected. This will depend on the duration of exposure, the degree of infectiousness of the index case, environment and proximity of contact and susceptibility of the contact. Usually, it takes many hours or days to transmit an infectious dose, but casual exposures may lead to transmission if the case is sufficiently infectious and the environmental air conditions are favourable, or if the contact is at high risk of infection (Golub et al., 2001; Nardell and Fennelly, 2006).

Household and other close contacts of pulmonary and laryngeal TB cases, and symptomatic individuals, should be screened immediately and again at six weeks. This provides an important opportunity to demonstrate conversion caused by recent infection. Given that only a proportion of contacts return for a second screening after six weeks, the local MDTs may decide to screen asymptomatic and immunocompetent contacts of pulmonary smear negative and extra-pulmonary cases only once and this should occur six weeks after any potential exposure. Vulnerable contacts including immunocompromised and young children (<2 years) and any contacts reporting symptoms should not have screening deferred.

In practice, an objective duration of exposure is useful to determine which contacts should be screened first and to limit the number of contacts who need to be identified. The 'eight-hour cumulative exposure rule' is generally used as a very rough rule of thumb to guide contact investigations. However a lower threshold may be indicated for the screening of contacts who

Contacts with increased risk of infection and progression

The following list of groups is useful to identify high-risk contacts to be assessed for screening (Rieder, 1999).

- *Pre-school children (under the age of five).*
- *Immunocompromised eg, HIV, lymphoma, leukaemia, cancer chemotherapy, anti-TNF alpha treatment.*
- *Diabetes.*
- *Surgical history of solid organ transplantation, jejuno-ileal bypass, gastrectomy.*
- *Chronic renal failure or on haemodialysis.*
- *Silicosis.*

are more susceptible to TB. Household contacts are invariably those most likely to have been exposed but for infectious cases it is necessary to screen all close contacts (NICE, 2016).

Concentric circle approach to contact investigations

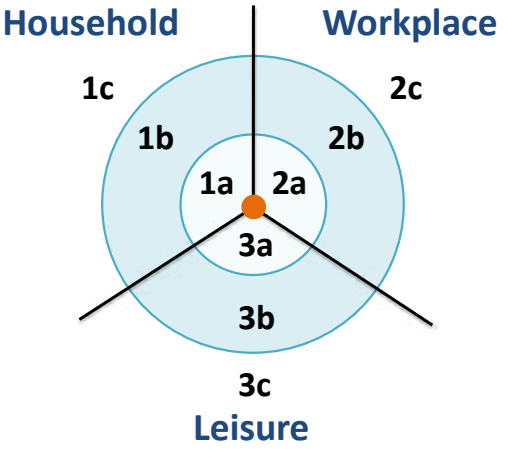
The 'stone in the pond' principle provides a method of organising and prioritising contacts in order of intensity of exposure and risk of being infected (Veen, 1992). The following concentric

Definition of household contacts and close contacts

- **Household contacts of pulmonary and laryngeal TB**
  Persons from the same household (those who share a bedroom, kitchen, bathroom or sitting room with the index case).
- **Close contacts of infectious TB cases**
  Persons exposed for eight or more hours to the TB patient during the infectious period, with a high degree of infectiousness based on one or more of the following factors:*
  - *AFB pulmonary TB, sputum positive on direct smear*
  - *extensive pulmonary disease, including cavitory disease on radiology*
  - *laryngeal TB (Sultan et al., 1960; Riley et al., 1962)*
  - *productive/frequent cough.*

* **Infectious period:** *The time during which a person with active pulmonary/laryngeal TB disease is potentially infectious to others. Where there is a reliable history of onset of a cough /hoarseness of voice, contact investigation should extend back to the date of symptom onset. If the date of onset of cough is unknown or unreliable, then the inclusion period for contact investigations is defined as beginning three months before the start of anti-TB treatment. This period can be readjusted on a case-by-case basis according to epidemiological findings and clinical considerations.*

figure provides a useful way of organising a contact investigation (Etkind and Veen, 2006). Please note – 'workplace' can also be an educational setting.



Household contacts of pulmonary and laryngeal TB

1a: Close contacts: *Persons from the same household (those who share a bedroom, kitchen, bathroom or sitting room with the index case).*

1b: *Persons potentially exposed in the household setting for less than eight hours during the infectious period.*

1c: *Contact investigations are occasionally expanded to wider family/household networks in the rare event of secondary cases, or a greater than expected number of positive tuberculin skin test (TST) or interferon gamma release assays (IGRA) results among 1b contacts. 1c investigations can occur due to undetected source cases and require input from local health protection teams.*

Workplace/school contacts of infectious cases

Incidents/outbreaks are managed in partnership with TB teams and health protection teams (informed by individualised exposure risk assessment):

2a: *persons exposed to infectious cases in the workplace or school for >8 hours during the infectious period*

2b: *persons exposed to infectious cases in the workplace or school for < 8 hours during the infectious period*

2c: *on the advice of local health protection teams, workplace/education setting contact*

investigations can be expanded and in the rare event of secondary cases or a greater than expected number of positive TST or IGRA results among 2b contacts. 2c investigations can occur due to undetected source cases.

Leisure contacts of infectious cases (informed by individualised exposure risk assessment)

These commonly include social networks around pubs, clubs, sporting activities, etc:

3a: *persons exposed to infectious cases for >8 hours during the infectious period*

3b: *persons exposed to infectious cases for <8 hours during the infectious period*

3c: *on the advice of local health protection teams, investigations of leisure contacts can be expanded in the rare event of secondary cases or a greater than expected number of positive TST or IGRA results among 3b contacts. 3c investigations can occur due to undetected source cases.*

A log of daily activities or social network is suggested to be recorded by the Index case, where it is likely that a number of contacts may be identified, or if the case is known to have social networks. This may allow identification of additional contacts. More than one sheet (up to one week of logs) may be needed to identify close contacts (see Appendix 3).

7.2 Which contacts should be assessed first?

The first contacts should include all:

- *close contacts of infectious TB cases (smear and culture confirmed cases)*
- *household contacts of person with active pulmonary and laryngeal TB.*

For further guidance, see NICE's (2017) contact tracing and testing pathway.

Potential duration of infectiousness and the environment where exposure took place also needs to be assessed. The regular routine MDT meeting should be used to agree which contacts to include in the first ring for all:

- *newly diagnosed patients found to have AFBs on direct smear microscopy, with or without cavitary disease, who report a cough for longer than 12 weeks before start of treatment*
- *infectious patients who have been resident or employed in a congregate setting (for example, a prison, homeless shelter, hospital, nursing home, school, college) during the infectious period*
- *infectious patients who have spent eight or more hours with work colleagues, in a confined and poorly ventilated setting during the infectious period.*

Where it is decided to include more than 10 non- household contacts in the first ring then expert advice from the local health protection team should be sought.

7.3 When should contact investigations be expanded beyond household and close contacts?

Where evidence of transmission between the index case and contacts (active or latent case and/or more that 10%) in the first concentric ring can be demonstrated, then contact investigations should be expanded to include persons who have less than eight hours exposure – especially those contacts at high risk of developing TB once infected.

Assessing the probability that transmission has occurred is not straightforward.

Epidemiologically-linked secondary cases, and documented TST or IGRA conversions among household contacts and close contacts of infectious cases, provide good evidence that recent transmission is likely to have occurred and a justification to expand contact investigations.

The occurrence of clusters of cases identified using WGS (whole genome sequencing) in either temporal or geographical proximity of one another, can inform the expansion of contact investigations outside of the household setting. TB MDTs and local health protection teams should meet regularly to ensure that WGS data is used in a timely and co-ordinated way to inform expanded contact and outbreak investigations.

The occurrence of secondary cases and positive TST and IGRA test results among exposed children (<16 of age) is likely to reflect recent transmission. Interpreting the results of TST and IGRA testing among adult contacts is complicated by the fact that, in the absence of documented conversion, it is not possible to differentiate between recent and remote infection. The proportion of persons with positive test results will vary considerably according to the age and previous exposure risk of those tested. This must be taken into consideration when assessing whether or not the proportion of contacts tested who have positive TST or IGRA results is greater than expected eg, when screening a local population with possible remote LTBI born in high-incidence countries).

Contact investigations should be expanded beyond household contacts and close contacts of infectious cases if one or more of the following is demonstrated:

- *epidemiologically-linked secondary cases*
- *documented TST or IGRA conversions*
- *the proportion of contacts tested who have positive TST or IGRA results is greater than expected*
- *clusters of cases with indistinguishable WGS (on the advice of local health protection teams).*

7.4 How should contacts who do not attend (DNA) be managed?

Contacts of pulmonary and laryngeal smear-positive cases

- **1st missed out-patient appointment**
  - *Review information provided, in case of any child/vulnerable adult safeguarding issues have been overlooked.*
  - *Important to consider home visit for vulnerable contacts.*
  - *Repeat appointment for next outpatient clinic (within five working days).*
  - *Assign a case manager and contact the contact by telephone within one working day to explain in an appropriate language the importance of attendance.*
  - *Check if their details and address are the same.*
  - *Ask them what will help them to attend for screening, what are the barriers and attempt to address these barriers.*
  - *If patient has moved out of the area, following discussion with them refer the contact to their most accessible local TB service.*
  - *Document in the contact's and index case's notes.*

- **2nd missed outpatient appointment**
  - *Repeat appointment for next outpatient clinic (within five working days).*
  - *Case manager undertakes a home/ community visit.*
  - *Hand deliver letter, explaining the importance of attending.*
  - *Based on the local service set-up, if possible offer home screening or other convenient clinic.*
  - *Document in the contact's and index case's notes.*

- **3rd missed outpatient appointment**
  - *Discharge with advice of risk and symptoms of TB, service contact details.*
  - *Record outcome for cohort review.*
  - *Send second letter to contact.*
  - *Copy of second letter sent to GP (and previous letters).*
  - *Copy of letters placed in contact's notes.*
  - *If index case is being treated elsewhere, send the same letter to the referring TB service.*

Contacts of pulmonary-smear negative

- **1st missed outpatient appointment**
  - *Repeat appointment for next outpatient clinic (within five working days).*
  - *Case manager contacts the contact by telephone within one working day to explain the importance of attendance, in an appropriate language.*
  - *Check if their details and address remain the same.*
  - *If contact has moved out of the area refer the contact to an accessible local TB service.*
  - *Document in the contact's and index and case's notes.*

- **2nd missed outpatient appointment**
- *Discharge, with advice of risks and symptoms of TB.*
  - *Record outcome for cohort review.*
  - *Send second letter to contact.*
  - *Copy of second letter sent to GP.*
  - *Copy of GP letter in contact's notes.*
  - *If index case is being treated elsewhere, send the same letter to the referring TB service.*

7.5 How should child (aged 16 years and <16 years of age) contacts, who are not brought in for screening be managed?

The risk of developing TB disease after infection in children aged under five, and especially in infants, is as high as 40% (Nice, 2016, Grzybowski, Barnett and Styblo, 1975; Miller, Seal and Taylor, 1963) and disease can develop within weeks of infection (Comstock, Livesay and Woolpert, 1974). All child contacts who are not brought to their appointments should be discussed at the MDT meeting involving the paediatrician and, where appropriate, with safeguarding/child protection teams.

Failure to investigate and clinically assess children who have been potentially exposed to TB raises issues around safeguarding of children. All frontline staff engaged in the management of TB including case managers should have received the relevant child safeguarding training. They should have close contact with the paediatrician and the local health protection team to discuss non-attendances before discharge planning.

7.6 Contacts of extra-pulmonary cases

There is variance across the United Kingdom in screening of contacts of extra-pulmonary cases with NICE (2016) recommending screening contacts of pulmonary and laryngeal TB. However, experience shows that following a risk assessment of individual cases of extra- pulmonary TB, latent TB cases are diagnosed.

It is therefore suggested that TB services/clinics undertake a risk assessment to identify contacts where there is the potential to identify latent TB cases.

7.7 How should timeliness, completeness and yield of contact investigations be reported?

(See 8.4: Contact investigation outcome indicators)

7.8 Source case investigations

The diagnosis of TB in a child <16 years of age should initiate a source case investigation to evaluate all persons (adults and children) who have had close or household contact with the paediatric index case. All close or household contact in the one year prior to the time that the paediatric case was diagnosed should be located. The source case investigation aims to identify the individual with active TB disease who may have infected the child and any other high-risk contacts who may have been infected in the same setting.

The source case is most commonly an adult in the home, a frequent visitor or an adult with whom the child spends significant periods of time such as a relative, nursery worker, childminder or teacher.

Sometimes the paediatric index patient is potentially infectious (ie, strongly AFB positive on gastric lavage or sputum, cavitary disease or positive respiratory cultures). This should initiate a contact investigation to identify any secondary cases (See 7.1 How should contact investigations be organised and prioritised?).

7.9 Contacts of homeless and socially complex cases

Contact investigations around cases of TB among homeless and socially complex cases are particularly challenging and often fail to identify contacts using routine investigation methods because:

- *socially complex cases are unable or unwilling to divulge potential contacts*
- *index cases can have extended and complex social networks*
- *identified contacts are difficult to locate and motivate to attend for screening*
- *results of investigations for LTBI are difficult to interpret due to a high background rate of infection.*

Determining when a contact investigation becomes a targeted screening exercise can be difficult (de Vries and van Hest, 2006). A proposed alternative approach is active case finding on possible sites or locations of exposure, such as homeless hostels. NICE (2016) recommends screening homeless people for active pulmonary TB using digital chest radiography but this will not detect latent infection. NICE also stresses the importance of regular education about TB, and referral pathways to primary care colleagues, social workers and voluntary workers who work with homeless people. Expert advice is available from local health protection units and from Find & Treat in London.

7.10 Whole genome sequencing (WGS)

Where there is strong evidence of TB transmission, WGS can help TB services and public health specialists enhance contact tracing and screening activities on cases eg, tackling TB clusters by identifying sub-groups of individuals linked to previously unidentified congregate settings.

8. Communication and monitoring

8.1 Routine MDT/case review meetings

The TB service MDT should meet regularly, based on the incidence rate. This may be either weekly or monthly to discuss and plan care for:

- *all newly diagnosed TB cases*
- *all suspected TB cases who have not attended their appointments*
- *children who were not brought to their appointments*
- *all other socially and/or clinically complex cases*
- *Contact/source case investigations (including incident and outbreak investigations).*

The MDT meeting provides an opportunity to co-ordinate care across the different professional disciplines and ensure timely and appropriate action. MDT meetings must be attended by the physician, possibly the paediatrician (to discuss children) and the case managers overseeing the care of the patients. Attendance from allied service professionals contributing to the care of patients under ECM should be routine.

8.2 What is a cohort review?

A cohort review is a systematic quarterly review of the management of every case of TB for treatment completion, contact investigations and their outcomes. The 'cohort' is a group of cases counted over a specific time, usually three months.

Details on the management and outcomes of each case are reviewed in a group setting. The case manager presents the cases for which they are responsible, giving the opportunity to bring up problems, challenges and difficulties, plus revealing service strengths, weaknesses and training requirements for staff and successes in management.

A cohort review is an essential method of programme evaluation and provides a multidisciplinary forum to review the management of each case and their contacts to ensure accountability at all levels of the service, whilst also linking to local, regional and national targets.

While TB services differ in both TB epidemiology and service provision, the principles of systematic review and accountability that are central to the cohort review are applicable to any setting.

Objectives of the cohort review process are to:

- *ensure the implementation of comprehensive case management procedures for all patients with TB*
- *improve promptness of appropriate interventions*
- *maintain reliability of data on the national and local TB surveillance systems/registers*

- *provide immediate analysis of treatment outcomes and contact investigation efforts, measured against previous cohorts*
- *assess efforts compared to local, regional and national TB control targets*
- *identify, track and follow up on important case management issues*
- *provide ongoing training and education for staff*
- *provide staff with a forum for open discussion*
- *identify, praise and share good practice.*

8.3 How to organise a cohort review

All TB clinical networks or local TB service administrative sectors should undertake a cohort review of every active case of TB diagnosed during a given quarter of the year. The review should be scheduled for each TB team approximately six months after the close of each quarter (so cases are presented six to nine months after starting treatment). The cohort process is enhanced if it is attended by all members of the TB service, multidisciplinary staff and other key allied professionals.

Cohort review meetings should be chaired by a person external to the local TB services, such as a lead physician or nurse from another area, or a consultant in communicable disease (TB). At the meeting, case managers present standardised information on each case, including information on contact investigations. Where there has been contact tracing investigation as part of an incident/outbreak eg, workplace or an education setting, the information should be presented on a cohort review incident form (sample form in Appendix 8).

The chair and medical reviewer are responsible for raising questions about the management of each case and ensuring standards of care were adhered to and creating opportunities to share good practice.

Immediately following the case presentations, the epidemiologist will calculate and give a preliminary presentation on each geographical area/service, the completion data for treatment and contact investigation outcomes at the time of cohort. Updated completion data on cases and contacts presented at previous cohort reviews will also be provided to local staff. Issues or problems that arise during cohort review are systematically documented/logged and followed up. The logged/ actions items are then reviewed at the next cohort review. Where actions require follow up, the chair or the lead co-ordinator of the cohort review takes responsibility for following these in a timely manner. An example of a template to log actions is in Appendix 7.

8.4 Performance standards: What information should be collected?

In order to assess progress, targets must be set for particular indicators, which can be measured at each review. These indicators will be measured using data in the TB surveillance system and presented on the day by the epidemiologist.

Indicators may be set locally/regionally by an expert group. The cohort review group may include:

- *TB case manager*
- *TB physician (adult/paediatric)*
- *TB outreach/support workers*
- *epidemiologist*
- *public health*
- *data analyst.*

Good practice examples of outcome indicators for both case management and contact investigation are given below.

Case management outcome indicators

1. *100% of TB patients assessed as requiring DOT will be offered DOT.*
2. *100% of TB patients will be offered HIV testing.*
3. *At least 85% of TB cases will successfully complete a recommended treatment regimen within 365 days. Treatment outcomes will be reported separately for the following categories of patients:*
    a. *patients receiving DOT from treatment onset*
    b. *patients who have had AFB-positive sputum.*
4. *Less than 5% Of TB cases will be LFU at time of cohort review.*

Contact investigation outcome indicators

1. *Among pulmonary sputum smear positive cases:*

   a. *at least 95% will have one or more (minimum 5) contacts identified (providing there is evidence that a full assessment in the community has been carried out; some may not have expected number of contacts)*

   b. *at least 80% will have five or more contacts identified (see above 1a).*

2. *At least 90% of contacts of smear-positive cases will receive clinical evaluation.*

3. *At least 85% of contacts with LTBI, who are started on treatment, will successfully complete.*

4. *At least 80% of pulmonary TB cases will be confirmed by culture (European Centre for Disease Prevention and Control, 2014).*

Appendices

Appendix 1: Sample case management forms

Suspected TB case (Form: 1)

Form 1: Suspected TB Case (complete for every person referred for TB investigations). Clinic:

Hospital number: | Case manager: | Date referred to TB service: / / | Date 1st seen by TB service: / /

Last name: | First name: | Other names(AKA): | Designation:

Sex: M☐ F☐ | DOB: / / | Ethnicity: | Religion: | Country of birth: | Date/ Year of entry in the UK:

NHS no. | Occupation/ school details: | 1st language: | Needs interpreter: Yes ☐ No ☐

Address (usual place of residence or 'where can be found')

Telephone:

Next of kin/ parental responsibility (name and contact details)

GP details (if registered)

Health Visitor:

School Nurse:

Other: (e.g. Clinic, RIO,CHAIN, HCU, MXU)

Route of presentation [AUDIT B]
1st seen by HCP / /

- ☐ Primary care (GP) [AUDIT A]
- ☐ Primary care (other)
- ☐ Secondary care
- ☐ TB Service
- ☐ Occupational Health
- ☐ A&E
- ☐ MXU
- ☐ Prison screening
- ☐ Self referral

Reason for referral

- ☐ Symptomatic
- ☐ TB contact screening
- ☐ New entrant screening
- ☐ Transferred In TB Rx
- ☐ Anti TNF treatment
- ☐ BCG Vaccination
- ☐ Other (comments)

Symptoms [AUDIT B]
Date onset / /

- ☐ Weight loss (weight:)
- ☐ Lethargy
- ☐ Night sweats
- ☐ Fever
- ☐ Cough (dry)
- ☐ Cough (productive)
- ☐ Haemoptysis
- ☐ Dyspnoea
- ☐ Lymphadenopathy
- ☐ None
- ☐ Other (comments)

TB contact (index case details)

LTBR/name
Hospital number
Relationship to index case
Site of disease
PT sputum smear
PT culture
Date diagnosed

Initial assessment
* = enhanced case management to diagnosis (Dx) [AUDIT C]

- ☐ Previous TB diagnosis (year:)* (where: for how long:)
- ☐ Previous TB prophylaxis (year:)
- ☐ Previous TB screening (year: where:)
- ☐ Known TB contact (see box below)
- ☐ Current problem drug user*
- ☐ Problem drug use in last 5 years*
- ☐ Problem drug use > 5 years ago
- ☐ Alcohol misuse*
- ☐ Pregnant/ post partum
- ☐ Currently homeless*
- ☐ Homeless in the last 5 years*
- ☐ Homeless > 5 years ago
- ☐ Currently in prison*
- ☐ Prison in the last 5 years*
- ☐ Prison > 5 years ago
- ☐ Mental health history*
- ☐ BCG history
- ☐ BCG scar seen
- ☐ Recent travel to high risk area
- ☐ Immigration concerns

Notes - other TB risk factors and issues that may complicate diagnosis

Does this case require enhanced case management to diagnosis(any*)? Yes ☐ No ☐

TB Investigations :	Date	Results	Medical history/ medication/ screening summary
☐ CXR	/ /	☐ CXR NAD	
☐ Sputum 1: [AUDIT B] Smear: Culture:	/ /	☐ CXR consistent with active TB	
☐ Sputum 2: [AUDIT B] Smear: Culture:	/ /	☐ CXR suggestive 'Old TB'	
☐ Sputum 3: [AUDIT B] Smear: Culture:	/ /	☐ CXR abnormal (not TB)	
☐ Sputum (PCR)	/ /	☐ Sputum PCR +ive (any specimen)	
☐ Induced or BAL	/ /	☐ Other culture +ive (e.g. pleural fluid)	
☐ FNA - Site:	/ /	Site:	
☐ Biopsy - Site:	/ /	☐ Histopathology suggestive of TB	
☐ QFT/T Spot	/ /	☐ QFT+/T Spot positive	
☐ CT	/ /	☐ Blood tests normal	
	/ /	☐ Blood tests abnormal (comments)	

Appendix 1: Sample case management forms

Suspected TB case (Form: 1)

☐ Routine Blood Tests ☐ Other (comments) / /

Mantoux (1) **Date:** / / Live vaccine past 4/52 **Yes** ☐ **No** ☐

Batch Nr: _____ Expiry Date: _____

Signature: _____

Induration: _____ mm Site: _____

Read by: (signature) _____ Date: / /

Mantoux (2) **Date:** / / Live vaccine past 4/52 **Yes** ☐ **No** ☐

Batch Nr: _____ Expiry Date: _____

Signature: _____

Induration: _____ mm Site: _____

Read by: (signature) _____ Date: / /

Cont. Notes **Name:** **Hospital number:**

Recall for further investigations Date / /

BCG **Date:** / /

Site: _____

Batch Nr: _____ Expiry Date: _____

Signature: _____

Diagnostic outcome Date / /	**Action**	**Audit**
☐ **1** No evidence of active TB	**1** Inform and advise - discharge	**A** Seen within 2 weeks of referral [if GP suspected pul.TB] **Yes** ☐ **No** ☐
☐ **2** Not TB Atypical - REFERRED	**2** Where referred? [detail in comments]	**B** All sputum smear results within 1 working day **Yes** ☐ **No** ☐
☐ **3** Active TB - TREAT	**3** Complete FORM 2: Initiate Rx [AUDIT E]	**C** Initial assessment completed **Yes** ☐ **No** ☐
☐ **4** Latent TB - TREAT	**4** Complete FORM 2: Initiate Rx	**D** Referred to Find & Treat if : **Yes** ☐ **No** ☐
☐ **5** Latent TB – Not treated/declined	**5** Inform, advise and arrange follow up	High risk (see *) or LFU pre-diagnosis of AFB+ TB contact
☐ **6** LFU prior to diagnostic decision	Detail plan in comments	**E** (Calculate in days for **Active TB cases only** – see definitions sheet)
☐ BCG to be given	6 Refer to Find & Treat: Action / Info [AUDIT D]	1) Patient delay _____ days
		2) Health Service delay _____ days
		3) Total delay _____ days

Initial assessment by (Name): _____ **Date:** _____

Signature: _____ **Designation:** _____

Appendix 1: Sample case management forms

Active TB treatment (Form: 2)

Form 2: TB Treatment (complete at commencing TB treatment for active disease OR latent infection) clinic:

NHS no: | Hospital no: | Case manager: | Consultant:

Last name: | Other names: | NTBS no: | DOB: / /

Address (Usual place of residence or "where can be found") | GP details

Telephone

Diagnosis (tick all known at Rx start)

☐ **Active Pulmonary TB**
Smear: (date: / /) ☐ positive ☐ negative ☐ not done ☐ unknown
Culture: (date: / /) ☐ positive ☐ negative ☐ not done ☐ unknown

☐ **Active Extra-Pulmonary TB**
Smear: (date: / /) ☐ positive ☐ negative ☐ not done ☐ unknown
Culture: (date: / /) ☐ positive ☐ negative ☐ not done ☐ unknown

☐ **Latent TB infection**
☐ recent exposure known
☐ recent exposure unknown

Site of disease (tick any for Active TB cases)
☐ Pulmonary
☐ Lymph node
☐ CNS
☐ Bone
☐ Spinal
☐ Miliary
☐ Other (below)

Drug resistance risk factors (AUDIT G)
☐ Previous TB treatment (year:) (where: for how long:)
☐ Contact of known resistant case
☐ Problem drug use (ever)
☐ Problem alcohol use (ever)
☐ Imprisonment (ever)

Drug sensitivity (tick any as known)
☐ Fully sensitive
☐ Isoniazid resistant
☐ Rifampicin resistant
☐ Ethambutol resistant
☐ Pyrazinamide resistant
☐ Other

Weight (kg) (at Rx start) :
BMI:

LFT's (Baseline) Normal ☐ Abnormal ☐ Not done ☐

Snellen: aided/unaided
Left _____ Right _____

Other relevant clinical issues

Visual acuity Date tested: / /
NAD ☐ Not done ☐ No ETH ☐ Abnormal ☐
Referred to eye clinic **Yes** ☐ **No** ☐

Ishihara:

Planned treatment regimen start: / / | **Planned date continuation phase:** / / | **Estimate treatment completion:** / /

Actual Treatment start: / / | **Continuation phase date:** / / | **Treatment completion date:** / /

☐ 2 (RHZE) 4 (RH) – Standard short course Rx
☐ 2 (RZSE) 7 (RE) – Isoniazid res. known at start
☐ 2 (RZE) 10 (RE) – Isoniazid res. known after start
☐ 2 (RHZE) 10 (RH) – Central Nervous System
☐ 6 (Isoniazid) – Latent TB
☐ 3 (Rifinah) – Latent TB
☐ 6 (Rifampicin) – Latent TB
☐ Pyridoxine

Other TB/regular medication:

Possible drug interactions:

OPD F/U appointments arranged and given to patient? **Yes** ☐ **No** ☐

Medical factors (tick any)

☐ known HIV +ve (HAART Yes☐ No☐)
☐ offered HIV test (Audit A)
☐ not offered HIV test
☐ refused HIV test
☐ tested HIV negative this Rx episode
☐ tested HIV positive this Rx episode
☐ chronic liver disease
☐ Chronic renal failure / haemodialysis
☐ opiate dependency
☐ alcohol dependency
☐ Hepatitis B +ve (test this episode Yes☐ No☐)
☐ Hepatitis C +ve (test this episode Yes☐ No☐)
☐ TNF-alpha treatment planned
☐ Diabetes
☐ Long-term corticosteroid therapy
☐ Low BMI (<20 =1, <18.5=2)
☐ Pregnant / postpartum at time of diagnosis
☐ Possible drug interactions
☐ Drug Allergies
☐ Other prescribed/ non prescribed medication

Psychosocial assessment:		Agencies known to/ referred to:
Housing (current situation)	☐ Urgent housing problem (NFA) give details ☐ Housing problem(no immediate action) give details ☐ No housing problem	Housing officer:
Immigration concerns	**Yes** ☐ **No** ☐ details	Immigration support worker:
History of imprisonment in past 5 yrs	**Yes** ☐ **No** ☐ details	Probation officer:
Substance misuse	Is the client scripted for methadone **Yes** ☐ **No** ☐ details Alcohol **Yes** ☐ **No** ☐ details Illicit drug **Yes** ☐ **No** ☐ details	Drug / alcohol worker:
Mental health	Give details including diagnosis	CPN/ CMHT
Communication	Needs interpreter **Yes** ☐ **No** ☐ Language: Sensory impairment **Yes** ☐ **No** ☐	
Financial (income/ benefits)	Nil income ☐ On benefits ☐ Other(SS/NASS) ☐ Employed ☐	
Mobility problem	**Yes** ☐ **No** ☐	
Access & Transport	Needs help with transport **Yes** ☐ **No** ☐ If yes : **Provision** ☐ **Finance** ☐	
Directly Observed Therapy (DOT)	offered **Yes** ☐ **No** ☐ if **No, reason**_____ if **Refused, reason** _____	

Other info: health beliefs, history of non-adherence (any medical treatment) lack of social/ family support or any other complicating factors

Any other places of regular contact (social services, probation services, drop-in centres, church groups, mosque, temple, etc)

Treatment delivery & support (at Rx start)						Audit	
☐	DOT offered	☐	DOT (Clinic)	☐	Dossette box	**F** Offered HIV test (all >16 not already known +ve)	**Yes** ☐ **No** ☐
☐	DOT refused	☐	DOT (Community)	☐	Self Admin (SAT) (weekly review)	**G** Assessed for risk of drug resistance	**Yes** ☐ **No** ☐
☐	DOT not poss.	☐	DOT other Commence DOT form.	☐	Self Admin (SAT) (monthly review)	**H** DOT from onset if at risk	**Yes** ☐ **No** ☐
				☐	Self Admin (SAT) other (detail PTO)		

Initial assessment by (Name): _____ **Date:** _____

Signature: _____ **Designation:** _____

Lone worker visit assessment done
Yes ☐ **No** ☐ date: / /
Home/ community assessment done
Yes ☐ **No** ☐ date: / /

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Appendix 1: Sample case management forms

TB patient review record (Form: 2a)

Form 2a: TB patient review record. Clinic:

NHS no. | Hospital No: | Case manager: | Consultant:

Last name: | Other names: | NTBS no: | Diagnosis:

DOB: / / | Estimated date change to dual therapy : / / | Weeks on TB/LTBI treatment: | Estimated treatment completion date: / /

Treatment start date: / /

Nurse OPA ☐ Case worker OPA ☐ Medical OPA ☐ | Venue: OPD/Ward ☐ Home visit ☐ | Date next follow-up: / /

Interpreter used No ☐ Yes ☐ Language: ID code:

Symptoms & Progress

Appetite, weight loss, fever, coughing, night sweats, lethargy, feeling better: Request sputum No ☐ Yes ☐

Side effects: (nausea/vomiting, rash, itchy skin, joint pain) | Weight: Kg Increase ☐ Decrease ☐

Liver function test: Previous: / / Normal ☐ Abnormal ☐ | Checked today : Yes ☐ No, not due/ indicated ☐

Visual disturbances (Ethambutol) N/a ☐ No ☐ Yes ☐ If yes, has vision screen been undertaken? ☐ Comments (if applicable):

Medication: Self Administered: No ☐ Yes ☐ DOT : No ☐ Yes ☐ | Frequency: Daily ☐ 3 x weekly ☐

Adherence

Self reported: Doses missed? No ☐ Yes ☐ If yes, No. of doses missed: _____ More than 85% of doses taken? Yes ☐ No ☐

Percentage of doses taken: _____ Reason for non-adherence: _____

Tablet identification: Correct ☐ Incorrect ☐ Tablet count: Correct ☐ Incorrect ☐ Did not bring ☐

Butanol/other urine test in use N/a ☐ Positive ☐ Negative ☐ Not done ☐ (state reason) _____

Adherence Plan: | Continue/ resume Self Admin Therapy (SAT) Yes ☐ No ☐ | DOT offered : Yes ☐ No ☐ | Switched to DOT: No ☐ (Please comment overleaf) Yes ☐ Date: / / (initiate Form 4/5 DOT Form)

Recommended BBV screening: HIV outcome documented ☐ Hepatitis outcome documented ☐ Rpt. offered required? Yes ☐ No ☐

Prescription: Repeated on time ☐ Repeated late ☐ comment:

TB Medication:

Length of supply given: (in days)

Due date next prescription: / /

Px Rifinah: _____ Px Ethambutol: _____ Px Vit D: _____

Px Rifampicin: _____ Px Pyrazinamide: _____ Px Other: _____

Px Isoniazid: _____ Px Pyridoxine : _____ Px Other: _____

Px Rifater : _____ Px Rifabutin: _____ Px Other: _____

Other medication (Non-/Prescribed)

Px _____ Px _____ Px _____

Px _____ Px _____ Px _____

Px _____ Px _____ Px _____

If any new medication since last visit, drug interactions/contra-indications discussed: N/a ☐ Yes ☐ Comment:			
Women of childbearing age reminded regarding reduced efficacy of oral/implant contraception by taking *Rifampicin*? Yes ☐ N/a ☐			
Contact tracing:	**Complete** ☐ **Incomplete** ☐ New contacts identified **No** ☐ **Yes** ☐ comments (incl. date referred):		
Assessment date	Assessor ; Name:	Designation:	Signature

Name	**Hospital no.**	
Form 2: Notes relevant to follow-up. *including update on medical factors/psychosocial assessment recorded on Form2		
Date/time	**Comments/ Actions:**	**Signature/ Designation:**

Appendix 1: Sample case management forms

TB contact investigation/risk assessment (Form: 3)

(If a workplace/educational setting is involved then a referral to local public health should be made.)

Form 3:TB Contact/Source case investigation (complete for all patients starting TB treatment).clinic:

Clinic no:	Case manager:	Consultant:	Date start treatment: / /
Index case Last name:	Other names:	NTBS no:	DOB: / /

Define investigation:

☐ identify secondary cases ☐ household ☐ identify source case(s) AND secondary cases
☐ contact investigation in institutional setting (* **refer HPU**) ☐ community investigations
Date referred to HPU ___/___/___ Details of education/ work place: _____
Referred to: _____
HPU ref No _____

Date 1st assessed: / /	Assessed by:	Where assessed?

Infectivity risk assessment - factors specific to index case

☐ PTB sputum smear +ve
☐ PTB sputum smear -ve
☐ laryngeal TB
☐ cavitation on CXR
☐ sputum culture +ve
☐ bronchial washings smear +ve
☐ induced sputum smear +ve
☐ sputum PCR +ve
☐ cough on presentation
☐ MDR-TB

Est. Period of infectivity _____ (days)
Last date school/work _____

Overall infectivity risk assessed as –
☐ High (PTB smear +ve +/- cavitation)
Number AFB seen: _____
☐ Medium (PTB culture +ve & cough)
☐ Low (PTB culture –ve/ extra-pulmonary)

Environmental risk assessment – code by setting and level of exposure (e.g. 1a)

☐ household (family)
☐ shared household (tenants)
☐ lives alone
☐ prison *
☐ homeless hostel *
☐ health care setting *
☐ school (5-16 years) *
☐ school (<5 years) *
☐ congregate drug use (eg crack, khat)*
☐ pub /club *
☐ other setting (detail in comments)

diagram

Exposure risk assessment – (# children < 5 years of age, immuno-compromising illness, immuno-suppressing treatment)

Name: _____ Address: _____ Tel: _____ GP _____ Hospital No _____	DOB: _____ Sex: M☐ F☐ Relationship to index: _____ Date last contact: _____ Contact risk code _____ Date referred: _____ Date screened: _____	Outcome: _____
Name: _____ Address: _____ Tel: _____ GP _____ Hospital No _____	DOB: _____ Sex: M☐ F☐ Relationship to index: _____ Date last contact: _____ Contact risk code _____ Date referred: _____ Date screened: _____	Outcome: _____

Contact list continuation. **Index case- name** **Hosp. No.**

Name: _____ Address: _____ Tel: _____ GP _____ Hospital No _____	DOB: _____ Sex: M☐ F☐ Relationship to index: _____ Date last contact: _____ Contact risk code _____ Date referred: _____ Date screened: _____	Outcome: _____

Name: Address: Tel: GP Hospital No	DOB: Sex: M☐ F☐ Relationship to index: Date last contact: Contact risk code Date referred: Date screened:	Outcome:
Name: Address: Tel: GP Hospital No	DOB: Sex: M☐ F☐ Relationship to index: Date last contact: Contact risk code Date referred: Date screened:	Outcome:
Name: Address: Tel: GP Hospital No	DOB: Sex: M☐ F☐ Relationship to index: Date last contact: Contact risk code Date referred: Date screened:	Outcome:
Name: Address: Tel: GP Hospital No	DOB: Sex: M☐ F☐ Relationship to index: Date last contact: Contact risk code Date referred: Date screened:	Outcome:

Comments:	**Audit**
** Initiate FORM 1 for all contacts	**Total no. of contacts identified:** **I** No. contacts screened **J** No. non-attendees **K** No. contacts Mantoux / IGT +ve **L** No. contacts commenced on preventive Rx **M** No. contacts commenced on TB Rx **N** All high risk contacts seen within 2 weeks **Yes** ☐ **No** ☐

Initial assessment by (Name): ______ **Date:** ______
Signature: ______ **Designation:** ______

Audit:

- *How many contacts identified?*
- *How many contacts completed screening?*
- *How many contacts received treatment for LTBI?*
- *How many completed treatment for LTBI?*
- *How many <2 years of age received chemoprophylaxis?*

Appendix 1: Sample case management forms

DOT chart/log (Form: 4)

Form 4: DOT/VOT (complete this form for every person commencing DOT TB treatment for active/ latent disease) clinic:

	Hospital no:	Case manager:	Consultant:	Assessment Date : / /
Last name:	Other names:		DOB: / /	NTBS no:
Treatment key: given/ DNA/ self ad.	DOT treatment start: / /	Estimated date change to dual therapy: / /	Estimated treatment completion date: / /	

TB Medication: (dosage)	Rifater Dose: Frequency:	Rifinah Dose: Frequency:	Rifampicin Dose: Frequency:	Isoniazid Dose: Frequency:	Pyrazinamide Dose: Frequency:	Ethambutol Dose: Frequency:	Pyridoxine Dose: Frequency:	Other	Dosage date: / / Signature/ designation:	
Month:									**HCW Sig.**	**Patient Sig.**
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										

Month _____ Year _____
Doses observed: _____
Doses self administered _____
Doses missed: _____
Observed doses taken (%) _____

Action: _____

Date: ___/___/___ Signature: _____ Name: _____ Designation: _____

Appendix 1: Sample case management forms

MDR DOT/VOT (Form: 5)

Form 5: MDR DOT/VOT (complete this form for every person commencing MDR DOT/VOT TB treatment for active disease) clinic;

NHS no.	Hospital no:	Case manager:	Consultant:	Assessment Date: / /
Last name:	Other names:		NTBS no:	DOB: / /
Treatment key: **given/ DNA/ self ad.**	DOT treatment start: / /	Estimated date change to therapy: / /		Estimated treatment completion date: / /

TB Medication:	Dose:	Dose:	Dose:	Dose:	Dose:	Dose:	Dose:		Dosage date: / / Signature/designation:	
Date/time: (dd/mm/yy - hh:min)	Frequency:	Frequency:	Frequency:	Frequency:	Frequency:	Frequency:	Frequency:		**HCW Sig.**	**Patient Sig.**

Month _____ Year _____
Doses observed: _____
Doses self administered _____
Doses missed: _____
Observed doses taken (%) _____

Action: _____

Date: ___/___/____ Signature: _____ Name: _____ Designation: _____

Appendix 2: Sample contract for directly observed therapy (DOT) in the community

Whittington Health NHS

Date:	**Between:** **TB clinic:**	**And:** **Patient's name** **DOB**
Patient section:		
It has been explained to me that the most effective way to treat tuberculosis (TB) is by providing medication to the patient and having a trained supervisor observe the ingestion of all oral TB medication.		
Therefore I *(patient name)*		agree to the following:
1. Will take my TB medication/treatment under direct observation and I will keep all my DOT appointments. 2. I will look after my TB medication and store in an appropriate place 3. If for any reason I cannot keep my appointment, I will contact the DOT worker to reschedule a visit. 4. I will inform my DOT worker and/or case manager in advance of any planned holiday or other events including, if my address or telephone number changes. 5. Understand that if the DOT worker is unable to make contact with me, they may contact my next of kin and/or key worker. 6. I agree to attend DOT visits at the mutually agreed upon place and time.		
Agreed place:	At *(time)*	**On** *(date)*
7. If I cannot attend I will contact:	**DOT worker:** (contact details)	
	TB case manager: (contact details)	
8. If at any time I have any questions, concerns, suggestions or complaints regarding any aspect of my care I will tell:	**Name/title:**	
	Phone number:	
9. I understand that if I miss any DOT TB medication the treatment period may be extended to ensure that I receive a full course of TB medication.		

10. I understand that I will continue to be seen in the TB clinic at least once a month for continued review and will attend these appointments.	
Staff section: Case manager	I *(case manager)* Have assessed and agreed with the patient that that they will benefit from DOT and I have assessed them as able to manage their own medication in the presence of a DOT worker.
1. I will ensure that *(patient)* is seen by me or in my absence by a colleague at least once a month. 2. I will ensure that the patient will receive their medication supply on a weekly, twice weekly or monthly basis. 3. I will ensure that *(patient)* has my contact details and can call to discuss any concerns about their treatment/disease/medication.	
DOT worker:	I *(DOT worker)*
Agree to the following: 1. I will attend the DOT appointments at the time and place specified. 2. I will inform patient of any changes to my schedule in good time. 3. If for unforeseen reasons I cannot keep my appointment, or I am delayed, the patient will be notified as soon as possible and other arrangements made by the DOT supervisor. 4. I will ensure that any questions and concerns that are raised by the patient will be fed back immediately to the case manager and answered within 48 hours.	
Signature of patient	
Signature of DOT worker	
Signature of case manager	

Appendix 3: Sample social/network questionnaire

(All questions refer to a six-month period preceding TB diagnosis or evaluation as a contact)

NHS
Birmingham Chest Clinic
Part of University Hospitals Birmingham NHS Foundation Trust

1. During day time (6am to 5pm), where are three places you usually spend time with other people indoors?		
Place:	*Location: (street address and city/town)*	*Main activity/purpose:*

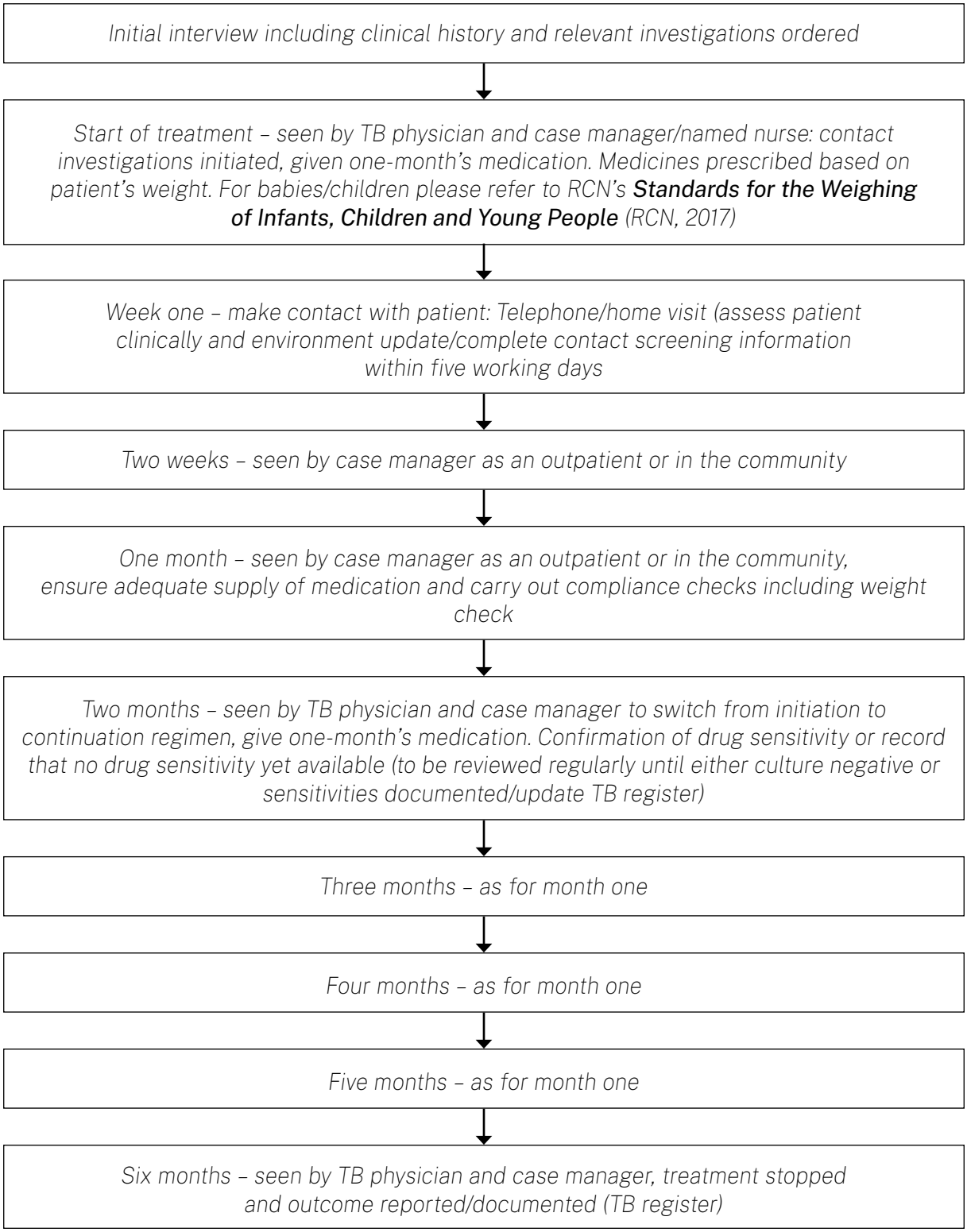
2. During the evening (5 to 10pm), where are three places you usually spend time with other people indoors?		
Place:	*Location: (street address and city/town)*	*Main activity/purpose:*

3. During the night (10pm to 6 am), where are three places you usually spend time with other people indoors?		
Place:	*Location: (street address and city/town)*	*Main activity/purpose:*

Time spent conducting this interview		
Date 1:	*Time start:* *(circle) am/pm*	*Time start:* *(circle) am/pm*
Date 2:	*Time start:* *(circle) am/pm*	*Time start:* *(circle) am/pm*
Date 3:	*Time start:* *(circle) am/pm*	*Time start:* *(circle) am/pm*

Activity codes	
1 = Eat **2 = Sleep** **3 = Job** **4 = School** **5 = Socialise**	**6 = Drink** **7 = Share drugs** **8 = Exercise** **9 = Unknown** **10= Other (state)**

Appendix 4: Standard case management – flow chart



Appendix 5: Tips for giving medication to children

Age	Strategy
Infant	· *Offer medication when child is hungry* · *Crush and mix medication with age-appropriate fluids or foods* · *Offer special bib when giving Rifampin*
Toddlers: **1 – 3 years**	· *Use distraction* · *Expect difficulties* · *Be persistent and consistent* · *Give simple explanations* · *Offer incentives for each dose*
Pre-schoolers: **3 – 5 years**	· *Give simple explanations* · *Allow some negotiation for the method of taking medicine* · *Offer medicine when child is rested* · *Offer lots of praise* · *Offer incentive for each dose* · *Be persistent and consistent*
School: **5 – 12 years**	· *Provide simple explanation* · *Allow negotiation for method of taking pills (eg, pills whole or crushed, with water or juice)* · *May be able to swallow pills – offer tips – capsules versus tablets (see Figures 1 and 2)* · *Offer praise and incentives*
Adolescent: **12 – 18 years**	· *Involve adolescent in decision making* · *Should be able to swallow pills* · *Offer tips – capsules versus tablets (see Figures 1 and 2)* · *Allow flexible method of taking pill* · *Offer praise and incentives* · *May be interested in longer-term incentives (eg, gift, certificate to a store or favourite food spot) instead of small item with each dose*

Centre for Disease Control (2011) Direct Observed Therapy: Manual for Tuberculosis Programmes in British Columbia.

Appendix 6: Home isolation policy

TB Service

Home isolation

A patient guide and practical advice on how to prevent the spread of tuberculosis (TB)

What is TB?

TB in the lungs and throat is a serious infectious illness. TB is spread from person to person through the air when you cough, talk loudly, sneeze, laugh or sing.

TB can affect other areas of the body but only TB in the lungs and throat is infectious.

What is home isolation?

This is when you are required to stay at home and limit your activities to prevent the spread of infectious TB. This means avoiding enclosed public spaces and other areas where lots of people gather.

How long will I need to be in home isolation?

At least 2 weeks but it might be longer. Your nurse / doctor will tell you when you can stop home isolation.

How do I protect people around me at home?

✓ It is ok for you to continue living with the same people as before your TB diagnosis. They will be automatically contacted by your nurse for TB screening tests.

× Do not have new visitors to your home.

× Stay away from people who have a greater risk of catching TB, e.g. young children and people with a weak immune system.

Please note: TB is not spread by sharing plates, cups or utensils, or on clothing, linen or furniture. It cannot be spread through using a toilet or by touch, such as shaking hands.

Reference details to be added by the patient information manager

p1

How to protect the people around me in the community?

You should stay at home but you can go outside for a walk, avoiding crowded areas.

- ✓ **Keep your TB appointments.**
- ✓ **Reschedule other routine appointments, e.g. the dentist and other medical appointments. If you think the appointment is urgent, you should phone them in advance to discuss.**
- ✖ **Avoid public transport.**
- ✖ **Stay off work, school / college.**
- ✖ **Do not go to enclosed public places such as shops, cinemas, restaurants, gyms and libraries.**
- ✖ **Do not go to places of worship, e.g. mosque, church, temple.**
- ✖ **Do not attend community and family gatherings**

If you need a letter from the hospital for work, school / college to explain your absence please ask your nurse or doctor.

If you require emergency care, make sure you tell the ambulance team and hospital that you are being treated for TB.

Tips for coping with home isolation

Home isolation can be difficult but it is necessary to prevent the spread of TB. Remember this is temporary and as long as you take your medicines properly you will return to normal life soon.

✓ Try to have a routine.

✓ Go out for a walk.

✓ Keep in contact with family and friends by telephone or email.

Reference details to be added by the patient information manager

p2

What are my responsibilities?

✓ Comply with home isolation.

✓ Cover your mouth and nose with a tissue when you cough or sneeze, and put this in the bin after every use.

✓ Take your medicines as instructed and attend your TB appointments.

Who can I contact for more information?

TB service

What kind of support can I get?

The charity TB Alert provides information and support for people with TB through the website www.thetruthabouttb.org You can also receive support from someone who has had TB - to find out more go to www.tbalert.org/ patient-support or call 01273 234 029.

How do I make a comment about my treatment?

We aim to provide the best possible service and staff will be happy to answer any questions you may have. However, if your experience of our services does not meet your expectations and you would like to speak to someone other than staff caring for you, please contact

The team are able to listen to your concerns, suggestions or queries and are often able to help sort out problems on behalf of patients.

Alternatively, you may wish to write to us on the following address:

Reference details to be added by the patient information manager

p3

BACK TO CONTENTS

Appendix 7: Sample cohort review action log

Name of trust/TB service/clinic:

Action log no:	TB surveillance registration no:	Case manager:	Issue:	Action by whom:	Action by when (deadline date):	Action completed: Yes/No	Theme Identified/ recommendations:
1.		*Name of case manager*	*Example: delay in diagnosis*	*Name of case manager or TB physician*	*Two weeks*	*Yes*	*Example:* *data/training and education/ organisational or system issues.*
2.			*Example: patient declined DOT*	*Case manager*	*Next cohort review*	*Ongoing*	*Use alternative tools: offer, VOT, community DOT*
3.							
4.							
5.							

Appendix 8: Cohort review incident reporting form

TB COHORT REVIEW – Presentation form for incidents

TB service: **Quarter:** **Year:**

INDEX CASE

Name of case manager:	**Name of CCDC:**	**Name of consultant:**

National TB surveillance no:		*Location of incident:*	
Date incident notified to PH:		*HPZone no:*	
Total no. contacts identified:		*Of which:*	*(adult)* *(child)*
Date environmental risk assessment done:		*Date incident meeting held:*	
Date of screening:		*Screening location:*	
Date incident closed:			

Contact screening

	Contacts screened by clinic	**Contacts referred elsewhere**	**Total contacts**
Identified:	*(adult)* *(child)*	*(adult)* *(child)*	
Assessed:	*(adult)* *(child)*	*(adult)* *(child)*	
Still under investigation:	*(adult)* *(child)*	*(adult)* *(child)*	
No. with active disease (state TB surveillance registration no:	*(adult)* *(child)*	*(adult)* *(child)*	
No. with LTBI:	*(adult)* *(child)*	*(adult)* *(child)*	
No. started LTBI treatment:	*(adult)* *(child)*	*(adult)* *(child)*	
No. completed LTBI treatment:	*(adult)* *(child)*	*(adult)* *(child)*	
Adverse reaction:			
Discontinued LTBI treatment due to: *Death:*			
Moved:			
Refused:			
Was any contact a previous TB case? If so, please state TB surveillance registration no:	*(adult)* *(child)*	*(adult)* *(child)*	

Discussion

Appendix 9: Outreach and safe practice

Source: Information adapted from Find & Treat Outreach Safety Protocol developed by Joe Hall (TB Social Worker) and Al Story (Clinical Lead)

Community outreach is an essential activity for frontline staff working in TB control. It is important that workers who undertake home visits and outreach in the community feel safe when carrying out their duties.

Statistics show that there is a very low risk of attacks on outreach staff. Common sense, a raised awareness of potentially difficult

situations and taking simple precautions will reduce any potential risk even further. It is important that all staff complete relevant in- house training, such as courses in personal safety or dealing with difficult, dangerous and disturbing behaviour.

Safe practice procedures should be followed when ***preparing****,* ***during*** *and at the* ***end*** *of any home visits or community outreach activities.*

Under no circumstances should workers compromise their safety.

If you feel unsafe at any point remove yourself from the situation.

1. Before

1.1 Before carrying out a home visit to a [unknown] patient, it is important to gather as much information as possible about the patient and the location you are visiting. Useful sources include: the referrer, GP, discharge co-ordinators, colleagues, and other allied agencies. Use this information to assess any potential risks. Points you should consider include:

- *patient's background – is there a risk of aggression/violence due to alcohol/drug use or mental ill health?*
- *nature of visit – could the visit cause the patient serious distress or potentially incite extreme behaviour?*
- *location/type of accommodation – is it a flat, bedsit or hostel in an at-risk area? It may be appropriate to arrange to meet patients who live in shared accommodation, such as squats, in a neutral location – perhaps a GP practice, community centre or café.*

1.2 If planning to visit a patient in the community for the first time, it is often useful to do a joint visit with a professional already known to the person (ie, drug worker, community psychiatric nurse (CPN), housing key-worker).

1.3 Any staff undertaking community outreach activities should have a mobile telephone provided by their employer. It is your responsibility to ensure that your telephone is charged and functioning and that your contact number is known to your manager, team members and other relevant co- workers. You must carry your identity card with you at all times when undertaking outreach in the community.

1.4 Always keep a diary record of any planned visits, preferably in a shared calendar that can be viewed by your team. Always inform a team member shortly before you enter a property

that is not known to you. Estimate the time that the visit will take and tell your team member to expect a call from you in a specified number of minutes AND to call you if they do not receive your call.

1.5 Make every effort to inform the patient that you are planning to visit them prior to the visit. This may not be appropriate for patients who are deliberately evading services. In this instance, advice from the local health protection unit or specialist outreach service should be sought.

2. During

2.1 As you approach the location, assess the situation to determine if anything is unusual or if anything makes you feel uneasy. Do not enter areas or properties if you have any doubts or concerns.

2.2 If any person answering the door gives you cause for concern (e.g. they appear very intoxicated, high or aggressive in nature) do not enter and/or if appropriate speak with the person on the doorstep. It is not usually appropriate to disclose the purpose of your visit to an unknown third party. Be tactful; show your identity card and request to speak with, or find out the whereabouts of the person you are trying to contact. If you are unsure, you should withdraw immediately from the area and inform your line manager, document findings in notes and, where appropriate, complete an incident report form.

3. After

3.1 Check in with your manager, team members or other relevant co-workers at the end of the visit. Make specific arrangements to check in if the visit is likely to continue after normal hours.

3.2 Document the visit, including the time of arrival and departure, according to local practice.

3.3 Regularly review procedures for outreach in MDT meetings and update information on patients whenever there is a change in circumstances or new information obtained from external agency.

Remember – your personal safety is paramount.

Appendix 10: Methadone and anti-tuberculosis treatment containing rifamycins

Principles

Serum methadone levels can be markedly reduced by rifampicin (rifampin) and withdrawal symptoms have occurred in some patients. Methadone levels in the plasma can fall by up to 50% if on rifampicin. Rifabutin appears to interact similarly, but to a lesser extent.

There will need to be a concomitant increase in methadone dose to counterbalance the effect of anti-TB drugs (especially rifampicin). There are no good pharmacokinetic data to have an absolute titration for this interaction. Some have recommended merely doubling the dose of methadone, but most titrate this gradually (eg, by 10% per time) with the help of drug dependency units.

There is consensus about ensuring that methadone is only given if on DOT and the taking of rifampicin is established and linked given the risk of overdosing if rifampicin is not taken.

(a) Rifampicin (Rifampin)

The observation that former diamorphine (heroin) addicts taking methadone complained of withdrawal symptoms when given rifampicin, prompted a study[2] in 30 patients taking methadone. Withdrawal symptoms developed in 21 of the 30 patients within one to 33 days of starting rifampicin 600 to 900 mg daily and isoniazid daily. In 6 of the 7 patients most severely affected, the symptoms developed within one week, and their plasma methadone levels fell by 33 to 68%. Of 56 other patients taking methadone with other anti-TB treatment (which included isoniazid but not rifampicin), none developed withdrawal symptoms.[2-4] Other cases of this interaction have been reported.[5-9] Some patients needed two- to threefold increases in their methadone dose while taking rifampicin, in order to control the withdrawal symptoms.[6,7,9]

Mechanism

Rifampicin is a potent enzyme inducer, which increases the activity of the intestinal and liver cytochrome P450 isoenzymes concerned with the metabolism of methadone, resulting in a marked decrease in its levels.[10] In 4 patients in the study cited, the urinary excretion of the major metabolite of methadone rose by 150%.[2] In addition there is considerable interindividual variability in the blood concentration of methadone given the variability of CYP enzymes.[11] Rifabutin has only a mild enzyme-inducing effect and therefore the effects are not as great.

Importance and management

The interaction between methadone and rifampicin is established, adequately documented and of clinical importance. The incidence is high: two-thirds (21) of the narcotic-dependent patients in one study[2] developed this interaction, 14 of whom were able to continue treatment. Withdrawal symptoms may develop within 24 hours. The analgesic effects of methadone would also be expected to be reduced. Concurrent use need not be avoided, but the effects should be monitored and appropriate methadone dose increases (as much as two to threefold) made where necessary.[11]

In practice increases of 10 mg can be made every 72 hours on introduction of TB treatment. Once TB treatment is discontinued the doses may be slowly reduced over 2–3 weeks which is the period the liver enzymes can remain in an induced state for.

Rifabutin appears to interact to a much lesser extent than rifampicin, so that fewer, if any, patients are likely to need a methadone dose increase.

(b) Rifabutin

A study in 24 HIV-positive patients taking methadone found that rifabutin 300 mg daily for 13 days had only minimal effects on the pharmacokinetics of methadone. However, 75% of the patients reported at least one mild symptom of methadone withdrawal, but this was not enough for any of them to withdraw from the study. Only three of them asked for and received an increase in their methadone dose. The authors offered the opinion that over-reporting of withdrawal symptoms was likely to be due to the warnings that the patients had received.[1]

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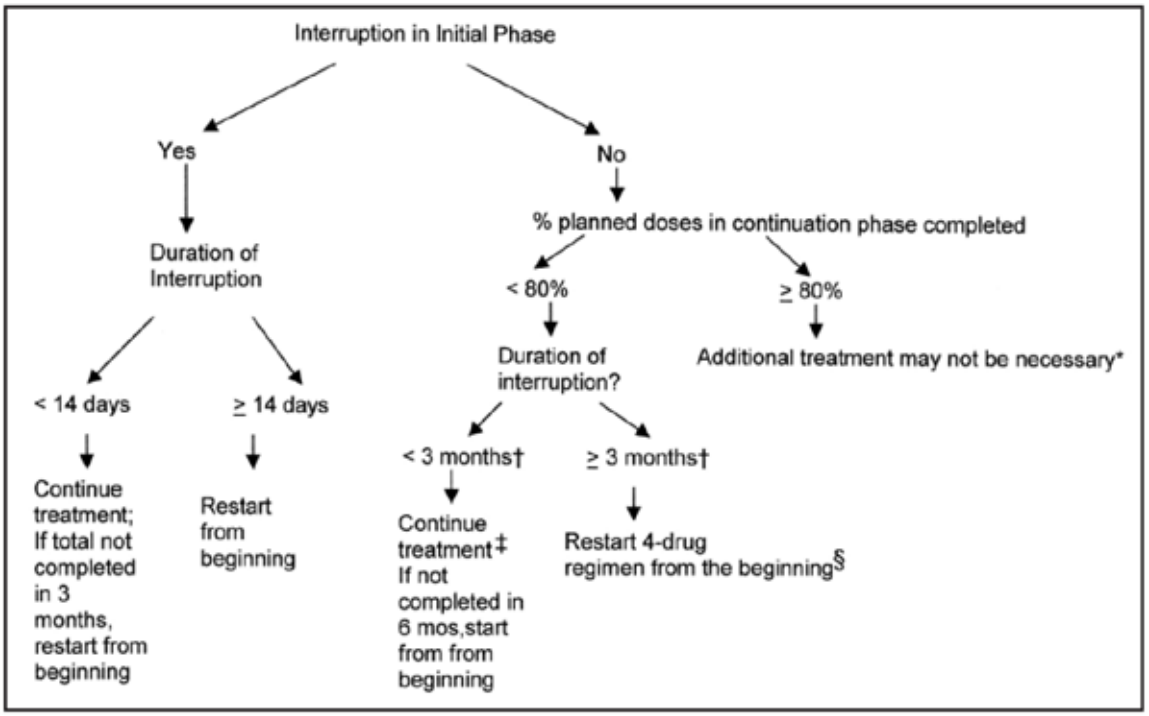
Appendix 11: Managing treatment interruptions

There are no controlled studies evaluating regimens addressing this clinical situation. The recommendations from the American Thoracic Society (ATS) are empiric and based on best perceived practice. The figure below outlines the ATS suggested protocol:

Figure: Managing treatment interruptions



*Patients who were initially AFB smear-positive should receive additional therapy.
†Recheck smears and cultures (if positive, check drug susceptibility results). Start DOT if not already being used.
‡If repeat culture is positive, restart four-drug regimen while waiting for drug susceptibility results. If repeat culture is negative, continue therapy to complete regimen within 9 months of original start date.
§If repeat culture is positive, continue four-drug regimen while waiting for drug susceptibility results. If repeat culture is negative, consider stopping therapy if patient has received a total of 9 months of therapy.

The principles guiding an approach are based on:

- *when the interruption occurred is a key arbiter – ie, initiation or continuation phase – initiation phase breaks are more crucial (given that there are likely to be more viable organisms and therefore may warrant a more robust restart)*
- *the length of the lapse in treatment is important but the regime reintroduced is dependent on when the break occurred (eg, restart all four drugs if the break is more than two weeks at induction phase and three months at continuation phase)*
- *always attempt to obtain samples in any break of treatment to guide sensitivity – any positive cultures mean that full treatment has to be completely restarted (ie, ignore all previous dosing)*
- *account for the potential for immunosuppressive states (eg, HIV) where rapid replication may occur despite short interruptions in treatment – ie, consider full retreatment even if below the standard time criteria*

- *a 'full' course of therapy (completion of treatment) is determined more accurately by the total number of doses taken, not solely by the duration of therapy (eg, six-month daily regimen given seven days/week – should consist of at least 182 doses of INH and RIF, and 56 doses of PZA) – aim to get a minimum of six months of drug doses over a maximum of nine months*
- *if the patient has completed > 80% of the planned course, cessation of treatment can be considered but only in initial smear negative and non-cavitory cases.*

"The following approach (summarized in Figure Managing treatment interruptions), modified from the New York City Bureau of ***Tuberculosis Control Clinical Policies and Protocols (22), is presented as an example. If the interruption occurs during the initial phase of treatment and the lapse is 14 days or more in duration, treatment should be restarted from the beginning. However, if the lapse is less than 14 days, the treatment regimen should be continued. In either instance the total number of doses targeted for the initial phase should be given. If the interruption in treatment occurs during the continuation phase after the patient has received more than 80% of the planned total continuation phase doses given by DOT, further treatment may not be necessary if the patient's sputum was AFB smear negative on initial presentation. However, for patients who were smear positive initially, continued treatment to complete the planned total number of doses is warranted. If the patient has received less than 80% of the planned total doses and the lapse is 3 months or more in duration, treatment should be restarted from the beginning. If the lapse is less than 3 months in duration, treatment should be continued to complete a full course. At the time the patient is returned to treatment sputum cultures should be obtained and repeat drug susceptibility testing performed. If the cultures are still positive, the treatment regimen should be restarted. If sputum cultures are negative the patient could be treated as having culture-negative tuberculosis and given an additional 4 months of combination chemotherapy. Regardless of the timing and duration of the interruption, DOT should be used. If the patient was already being managed with DOT, additional measures will be necessary to ensure completion of therapy. Consultation with an expert is recommended to assist in managing treatment interruptions."***

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Appendix 12: Drug therapy – adverse effects requiring clinical action

As is true with all medications TB treatment can cause adverse effects in some patients. This section covers the important adverse effects to standard TB treatment and is aimed at non-clinical professionals, carers of TB patients and persons who have been trained to act as DOT observers.

Named case managers should provide all TB patients and their carers, including DOT observers, with education and information leaflets on the commonly reported adverse effects to TB treatment.

Patients and their carers, including DOT observers, should report any of the following adverse effects on the same day to the named case manager who will inform the treating physician, who can provide advice on whether to continue or stop the treatment and make arrangements for the patients to be reviewed urgently (ideally within one working day).

1. *Trouble breathing* – **stop treatment and seek urgent medical help**.
2. *Yellow skin or eyes, or very dark-coloured urine* – **stop treatment and seek urgent medical help**.
3. *Stomach pain, nausea, or vomiting.*
4. *Any eye problems: vision changes, blurring, colour blindness, trouble seeing, or eye pain.*
5. *Pain or swelling in the face or joints.*
6. *Numbness, pain, or tingling in hands or feet.*
7. *Skin rash, severe itching, or hives.*
8. *Headache or dizziness.*
9. *Fever or chills.*
10. *Unusual tiredness or loss of appetite.*

Appendix 13: Simple guide to information sharing

Information sharing with consent

If you have the person's consent, then it is ok to share personal information about them with other health and social care professionals. Obtaining explicit consent for information sharing is best practice in most situations but it is not always possible.

The seven golden rules* for information sharing

If you are considering sharing information with other health and social care professionals and you do not have the person's consent, and there is not an information sharing protocol in place to govern an exchange of information, follow the golden rules to ensure that you strike the correct balance between protecting people's privacy, protecting the public and ensuring that fellow practitioners have the information they need to deliver services.

1. **Remember that the Data Protection Act is (General Data Protection Regulation) not a barrier to sharing information** *but provides a framework to ensure that personal information about living persons is shared appropriately.*
2. **Be open and honest** *with the person from the outset about why, what, how and with whom information will, or could be shared, and seek their agreement, unless it is unsafe or inappropriate to do so.*
3. **Seek advice** *if you are in any doubt, without disclosing the identity of the person where possible.*
4. **Share with consent where appropriate** *and, where possible, respect the wishes of those who do not consent to share confidential information. You may still share information without consent if, in your judgement, that lack of consent can be overridden in the public interest. You will need to base your judgement on the facts of the case.*
5. **Consider safety and wellbeing:** *Base your information-sharing decisions on considerations of the safety and wellbeing of the person and others who may be affected by their actions.*
6. **Necessary, proportionate, relevant, accurate, timely and secure:** *Ensure that the information you share is necessary for the purpose for which you are sharing it, is shared only with those people who need to have it, is accurate and up-to-date, is shared in a timely fashion, and is shared securely.*
7. **Keep a record** *of your decision and the reasons for it – whether it is to share information or not. If you decide to share, then record what you have shared, with whom and for what purpose*

** Copied from Information Sharing: Guidance for Practitioners and Managers, Department for Children, Schools and Families, and Communities and Local Government.*

www.governornet.co.uk/linkAttachments/ Information%20sharing%20guidance%20for%20 practitioners%20and%20managers.pdf

Glossary

Case management – *Case management is the comprehensive follow-up of a suspected or confirmed TB case. It requires a collaborative, multidisciplinary approach. Case management should commence as soon as possible after a suspected case has been identified to ensure a timely diagnostic conclusion.*

Case manager – *Standard and enhanced case management is overseen by a designated case manager who will usually be a specialist TB nurse or (in low-incidence areas) a nurse with responsibilities which include TB. Dependent upon the patient's particular circumstances and needs, case management can also be provided by appropriately trained and supported social care members of the TB multidisciplinary team.*

Children: family-centred approaches and safeguarding – *As a field of nursing where children, young people and adults are included in the caseload, it is vital that family-centred approaches are adopted and support is sought, where necessary, from paediatric specialist physicians, nurses, and local and national safeguarding policies are strictly adhered to. TB nurses may well be visiting people's homes, either where a child is the patient or where children are present, it is important to consider what level of safeguarding training is required. Additional competencies relating to children and young people have been produced by the RCN (2012). Also see* ***Getting it Right for Children and Young People*** *(RCN, 2017).*

Directly observed therapy (DOT) – *A trained health professional, or responsible lay person supported by a trained health professional, provides the prescribed medication and observes the patient swallowing every dose.*

Enablers – *Methods of helping someone to overcome barriers to completing diagnostic investigations and TB treatment. Examples of barriers that may need to be overcome include: transport, housing, nutrition and immigration status.*

Enhanced case management (ECM) – *Enhanced case management commences as soon as TB is suspected. It may include in conjunction with a package of supportive care tailored to the patient's needs. It is provided when a patient has clinically and/or socially complex needs, including when language is a barrier and, despite having interpretation services available, the patient is unable to adhere to treatment and/or understand the advice provided. In most cases ECM will start from the case is identified or if the patient's circumstances change. ECM may be justified where a contact investigation process requires collaborative management, such as safeguarding, and/or there has been an incident or outbreak.*

Hazardous and harmful alcohol use – *Hazardous drinking is a repeated pattern of drinking that increases the risk of physical or psychological problems. Harmful drinking is defined by the presence of these problems.*

High incidence – *High incidence includes any country or area with a TB incidence of more than 40 per 100,000 population per year, as listed by the countries on the World Health Organization site, for country data look up the incidence* **www. who.int/tb/country/data/profiles/en** *and for each UK district visit the country's public health/health protection site.*

High-risk drug use (HRDU) – *formerly called problem drug use (PDU) which was defined as injecting drug use or regular and/or long-term use of opiates (later revised to opioids), cocaine and/or amphetamines. The term was revised to HRDU in part due to changing patterns of drug use such as heavy cannabis use and heavy stimulants use without the presence of opioids*

use and users of new drugs (novel psychoactive substances). High-risk drug use is defined as 'recurrent use of psychoactive substances (excluding alcohol, tobacco and caffeine) by high-risk pattern (eg intensively) and/or by high-risk routes of administration in the last 12 months that is causing actual harms (negative consequences) to the person (including dependence, but also other health, psychological or social problems) or is placing the person at a high probability/risk of suffering such harms'.

Homelessness (or housing problems) – *incorporates the issue of overcrowded and substandard accommodation and goes beyond statutorily homelessness. People with one or more of the following should be considered homeless.*

- *Share an enclosed air space (for non- occupational reasons) with individuals at high risk of undetected active pulmonary TB (persons with a history of rough sleeping, hostel residence or substance misuse).*
- *Without the means to securely store prescribed medication.*
- *Without private space in which to take their TB treatment.*
- *Without secure accommodation in which to rest and recuperate in safety and dignity for the full duration of planned treatment.*

Incentives – *Small rewards, for example, food and phone vouchers that encourage/motivate patients with both suspected and confirmed TB to attend for community TB screening, out-patient follow-up and concordance with DOT appointments.*

Index case – *The first case of TB, this maybe within the household or in another defined group that comes to the attention of the health care investigator.*

Lost to follow-up (LFU) – *TB patients are defined as lost to follow-up if they have not completed a planned course of TB treatment and cannot be contacted within 10 working days of their first missed:*

- *outpatient or community (home visit) appointment – those on self-administering treatment (SAT) plan*
- *DOT appointment.*

Multidisciplinary/multiagency TB team (MDT) – *A team of professionals with skills that can meet the needs of patients particularly those with very complex physical and psychosocial issues (complex cases), which meets regularly to plan, implement and evaluate care pathways for patients. Specific members should be able to convene in order to discuss new notifications, deal with urgent issues (missed appointments and complex cases). Examples of members include:*

- *TB lead physician*
- *TB nurse(s) (case manager(s)*
- *outreach and social care staff*
- *peer support and/or advocacy*
- *anyone else who is involved in the patient's management plan, for example, a health visitor,*

school nurse, local housing representative, or other community health teams.

Non-adherence – *Self-administered treatment (SAT) patients are considered non-adherent after two consecutive missed outpatient appointments, irrespective of the amount of medication that they potentially hold and with efforts by the case manager to make contact with the patient.*

DOT/VOT patients, usually on daily therapy, are considered non-adherent after missing three daily doses over two consecutive weeks.

Outbreak investigation – *An epidemiological investigation into the occurrence of disease in a population to identify transmission sources and prevent additional cases, or example, two or more linked cases.*

Peers – *Members of the affected communities who may have experience of TB. Peers are in the best position to help deliver health strategies to their peer group. They may be recruited and supported to communicate health messages, assist with contact investigations/screening, or offer support to individuals during investigation and treatment.*

Return to service (RTS) – *The process of locating LFU suspected and confirmed TB cases and re-engaging them with diagnostic and treatment services. RTS activities are arranged locally by TB MDTs in collaboration with health protection staff or specialist outreach teams where available (such as Find & Treat in London). The TB MDT should make a decision whether or not to initiate RTS activities within five working days for any:*

- *patient on TB treatment where there has been no contact for 10 working days of their first missed appointment*
- *medically assessed person with signs or symptoms compatible with active pulmonary TB who has not attended for planned investigations*
- *child (aged 16 years and under 16 of age) who has been medically assessed and referred but has not attended for planned investigations.*

Self-administered treatment (SAT) – *A patient who administers, collects and organise their own TB medication, with the support of a case manager.*

Substance misuse – *Substance misuse is defined as intoxication by/or regular excessive consumption of dependence on psychoactive substances, leading to social, psychological, physical or legal problems. It includes problematic use of both legal and illegal drugs.*

Underserved population (USP) – *defined as individuals whose social circumstances, language, culture or lifestyle (or those of their parents or carers) make it difficult to recognise the clinical onset of TB, access diagnostic and treatment services, self-administer treatment (or, in the case of children and young people, have treatment administered by a parent or carer); or attend regular appointments for clinical follow-up.Such groups may include:*

- *asylum seekers, refugees, undocumented migrants and those in immigration detention*
- *individuals in contact with the criminal justice system (CJS) (custodial settings like prisons, immigration removal centres, children and young people's secure estate etc.)*
- *individuals with drug or alcohol misuse, including those in contact with drug and/or alcohol*

treatment services

- *individuals with mental health needs or learning difficulties*
- *homeless people*
- *adults, young people and children whose social circumstances, language, culture or lifestyle, or those of their parents or carers make it difficult to:*
- *recognise the clinical onset of TB*
- *access diagnostic and treatment services*
- *self-administer treatment (or in the case of children and young people, have treatment administered by a parent or carer)*
- *attend regular appointments for clinical follow-up.*

Further information on underserved populations has been produced by Public Health England (2017), ***Tackling tuberculosis in underserved populations. A resource for TB control boards and their partners.***

Video observed therapy (VOT) – *patients are trained to film themselves taking every dose of their medication using a secure NHS approved smart phone application and cloud platform. The videos are then viewed by a trained observer who verifies that the medication has been taken as prescribed and responds to any issues reported by the patient, including side effects, and liaises directly with the patient's case manager as necessary. The objective for VOT in TB is to reduce patient and provider burden without sacrificing any of the benefits of traditional methods of monitoring TB medication adherence.*

Whole genome sequencing (WGS) – *In England, WGS is replacing Multilocus Sequence Type Variable-Number Tandem Repeat (MIRU- VNTR), as the routinely used system to type TB isolates. Compared to MIRU-VNTR, WGS provides greater detail on the genetic relatedness of different TB strains. This new technology has great potential to improve the effectiveness of contact tracing activities, by helping TB nurses and public health specialists to focus contact tracing and screening activities on cases where there is strong evidence of TB transmission. For example, in the Midlands where WGS has been used routinely in the diagnosis of TB since 2016, WGS data has helped public health teams to tackle longstanding TB clusters by identifying sub-groups of individuals linked to previously unidentified congregate settings.*

There is an ongoing programme of work at Public Health England to translate the data generated from WGS into practical tools for clinicians and TB nurses to support contact tracing activities. This includes work to visualise TB clusters over time linked to geographical location, considerations around information governance and disclosure of patient identifiable information and challenges associated with the integration of WGS data with existing sources of epidemiological data.

Social networking interviews/questionnaires can also aid information gathering, by identifying links or an unidentified setting (see Appendix 3 for sample form).

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Royal College of Nursing – Information on tuberculosis with links to further guidance and resources www.rcn.org.uk/clinical-topics/public-health/ tuberculosis

TB Alert, The truth about TB. Online resource about all aspects of TB, available at: www. thetruthabouttb.org

TB Drug Monographs – supports the monitoring and safe use of anti-tuberculosis drugs and second line treatment of multidrug resistant tuberculosis. drugmonographs.co.uk

Travel health Pro – Information on medical tourism (travelling for treatment) http://travelhealthpro.org.uk/factsheet/59/ medical-tourism-travelling-for-treatment

World Health Organization Tuberculosis country profiles, available at: www.who.int/tb/country/ data/profiles/en/

RCN quality assurance

Publication

This is an RCN practice guidance. Practice guidance are evidence-based consensus documents, used to guide decisions about appropriate care of an individual, family or population in a specific context.

Description

Guidance for clinical and non-clinical staff involved in the management and care of TB patients. This RCN publication focuses on case management (standard and enhanced), to include responsibilities, what the initial interview encompasses, delivery of TB treatment and promoting adherence.

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