Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Guidelines for the delivery of Directly Observed Therapy in the community to persons with TB disease

Document reference number	Version 1.0 February 2013	Document developed by	TB DOT subgroup of HSE TB Control Group
Revision number	1.0	Document approved by	Assistant National Director of ISD-Health Protection
Approval date	22/11/2012	Responsibility for implementation	
Revision date	November 2015	Responsibility for review and audit	

Contents

1. Glossary of Terms and Definitions

Active Tuberculosis (TB) - Human tuberculosis is caused by infection with bacteria of the Mycobacterium tuberculosis complex (*M. tuberculosis*, *M. bovis*, *M. africanum*). The organism may infect any part of the body. However, the majority of cases involve the respiratory system (National TB Advisory Committee, 2010). Active TB is characterised by symptoms of weight loss, cough, night sweats and fever.

Bacille Calmette-Guerin (BCG) vaccination - vaccine derived by in-vitro attenuation of the bovine tubercle bacillus between the years 1908 and 1918 in France. The clinical efficacy of a vaccine is measured in terms of the percentage reduction in disease among vaccinated individuals that is attributed to vaccination i.e. the proportion of those vaccinated who gain protective immunity from the vaccine. BCG vaccine does not give 100% protection but it does protect against the more serious forms of the disease e.g. TB meningitis and miliary tuberculosis with protection lasting approximately 15 years (National TB Advisory Committee, 2010).

DOT - Direct observed therapy. DOT refers to the supervision of a patient taking a correctly prescribed dose of TB medication and swallowing the medication.

Key Worker /DOT Provider - The key worker will be actively involved in the supervision of DOT and should actively monitor and ensure adherence (National TB Advisory Committee, 2010). Measures should be mutually acceptable to the patient and the key worker who is acceptable and accountable to the patient and to the health system.

Extensively Drug Resistant Tuberculosis (XDR-TB) - resistance to at least isoniazid and rifampicin (i.e. MDR-TB), plus resistance to any fluoroquinolone, and any one of the second line anti-TB injectable drugs (capreomycin, amikacin or kanamycin). (National TB Advisory Committee, 2010)

Latent TB infection- A person with latent TB infection (LTBI) usually has a positive tuberculin skin test (mantoux /TST) or interferon gamma (IGRA) test but has no physical findings of TB disease and the chest X-ray is normal or only reveals evidence of healed infection e.g. granulomas or calcification in the lung, hilar nodes or both. Persons with LTBI are asymptomatic and are not infectious (National TB Advisory Committee, 2010).

MOH
Medical Officer of Health

Multi-Drug Resistant Tuberculosis (MDR-TB)
MDR-TB is a specific form of TB which is resistant to at least isoniazid and rifampicin, two of the main first line drugs used in the treatment of TB. MDR-TB therefore is much more difficult to treat, takes longer to treat with second line drugs (which are more expensive and have more side-effects) and the outcome is not always successful. Treatment is directed by a consultant respiratory physician/consultant in infectious disease with appropriate training in the management and treatment of TB and should be in line with the International Standards for TB Care (i.e. given for two years). (National TB Advisory Committee, 2010) MDR -TB may require IV infusions in addition to oral medications.

2. Background

It is acknowledged that directly observed therapy (DOT) is an internationally proven method recommended by the World Health Organization (WHO) to prevent the spread of tuberculosis in the community by providing infected persons with the support necessary for effective treatment to ensure a rapid and lasting cure.

2.1 What is DOT

Direct Observation of Therapy (DOT) means a trained healthcare worker or other designated individual (excluding family member and friends) observes the patient diagnosed with TB swallow the prescribed medication over the course of their treatment. This ensures that a patient diagnosed with TB takes the correct drugs and correct dose at the correct times. It is important that DOT is acceptable to the patient and to ensure that key workers are aware of their accountability and adhere to practice in relation to confidentiality.

2.2 Rationale for DOT

It can be difficult to predict who will take medications as directed and who will not. Persons from all backgrounds, gender and ethnicities and of all age groups can have problems taking medications directly. Each patient with a diagnosis of TB should be assessed to determine the likelihood of adherence with treatment. DOT should be prescribed for all patients with suspected or confirmed TB who demonstrate that they may be incapable, unreliable or unwilling to take TB drugs. DOT also reduces the risk of drug resistance, relapse and reactivation of TB disease and mortality from TB. In addition, it also helps prevent TB spreading to others. DOT helps identify problems which might interrupt treatment and allows the healthcare worker (HCW) to monitor the patient regularly for side effects and response to anti-tuberculous therapy.

A multidisciplinary team approach is critical for the effective implementation of DOT

The benefits of adopting a patient-centred case management approach include:

a) Explaining the rationale for and benefits of DOT to the patient
b) Ensuring patients attend medical appointments
c) Providing ongoing patient education
d) Offering incentives and/or enablers (see p. 6)
e) Connecting patients with social services or transportation as required

2.3 Universal versus Selective DOT

Selective DOT means providing DOT only to clients who are considered to be non-compliant or at high risk of non- or those with a history of resistance to prescribed medications for the treatment of TB (Section 2.4). Universal DOT describes the policy where DOT is used for treating all patients with TB.

Two studies by Ormerod et al show that selective DOT may be used successfully with at least 90% of patients completing treatment (no culture done at the end of treatment) or being cured (negative culture at the end of treatment) (Ormerod et al, 1998; 2002). Based on this evidence, the DOT subgroup has agreed that selective DOT is the best option for Ireland taking into consideration evidence from the aforementioned research and the current resources available for implementation.

2.4 Target Groups for Selective DOT

Clients who are deemed to be non compliant or those who have a history of resistance to prescribed medication for the treatment of TB are referred by a hospital clinician for DOT in the community.

2.4.1 Groups of patients where DOT is the best option include:

- Patients with suspected or proven drug-resistant TB requiring second line treatment e.g. MDR-TB, XDR-TB
- Patients receiving intermittent therapy
- Patients with a history of recurrence or relapse
- Patient with a history of treatment failure
- Persons in correctional facilities (prisons)
- Persons co-infected with HIV (if deemed appropriate following the clinician's assessment)
- Patients with poor understanding of TB diagnosis or non-acceptance of diagnosis.

2.4.2 Patients at high risk of non-adherence include:

- Homeless or unstably housed persons
- Persons who suffer from substance misuse (alcohol and/or illicit drugs)
- Persons who are unable to take medications due to mental, emotional or physical disability
- Persons with a history of non-adherence

2.5 Promoting adherence

2.5.1 Incentives and Enablers

Incentives and enablers (see definitions below) are tools to assist in the patient's adherence to TB medication, but DO NOT replace building a therapeutic relationship based on trust and mutual respect.

- **An incentive** is a reward for desired behaviour
- **An enabler** is an intervention to assist the patient in completing therapy. It helps patients overcome barriers to treatment.

2.6 Advantages of DOT

- It ensures that the patient is supported to successfully complete the full course of medication
- The patient is closely monitored for side effects of medications and supported to work through the side effects appropriately
- The patient is encouraged and supported to complete regular check-ups e.g. bloods, chest X-ray etc.
- A trust relationship develops between the Key worker/ DOT provider and the patient which reduces fear about TB and its treatment
- Increases the patient's comfort level so that he/she can ask questions
- Improves the patient's quality of health care as key worker/DOT provider can be an important link to other community and social resources for the patient
- Reduces the possibility of TB becoming resistant to the medication

2.7 Perceived disadvantages of DOT

- It is time consuming and labour intensive
- Some patients may find that it undermines their independence
- It can be perceived by the patient as demeaning or punitive

It is important to explain the benefits of DOT to each patient and to stress the fact that DOT is not punitive rather it is a way of helping the patient remember to take their medication so that they get better quicker and do not infect others.

2.8 How can a Key Worker/DOT provider build rapport and trust?

- Identify patient concerns
- Protect confidentiality
- Communicate clearly
- Avoid criticising the patient's behaviour
- Respectfully offer helpful suggestions for change
- Be on time and be consistent
- Be flexible with the time and place for DOT administration
- Adopt and reflect a non-judgemental attitude

2.9 Key Worker/DOT provider

The key worker/DOT provider (nurse or agreed person who is deemed responsible and suitably trained) co-ordinates an agreed process of DOT with the client. Where possible, the key worker/DOT provider is usually a nurse. However, this role can be extended to include other healthcare professionals e.g. pharmacists, GP practice nurse. When the role of key worker/DOT provider is extended to non-healthcare professionals, suitable training and information should be provided.

3. Guideline Statement

3.1 The Health Service Executive (HSE) is committed to implementing and promoting measures to ensure the effective and safe management of clients referred for Directly Observed Therapy (DOT).

3.2 It is the policy of the HSE that healthcare professionals who have undertaken required education and training are facilitated to implement and promote the safe and effective management of persons referred for DOT in Primary Care.

4. Purpose

This guideline promotes best practice, and must always be used in conjunction with professional judgement. The purpose of this guideline is to:

4.1 Outline the specific requirements indicated in the care of the client referred for the management of tuberculosis utilising DOT safely and within their scope of practice.

4.2 Act as a framework to enable local development and revision of procedures/guidelines by healthcare workers regarding the management of clients referred for Directly Observed Therapy (DOT).

4.3 Provide a standardised framework for healthcare professionals to exercise clinical judgement within the domains of professional accountability.

5. Scope

5.1 This guideline applies to all healthcare staff including referring clinicians, senior medical officers (SMO's), specialists in public health medicine, public health nursing staff members and other care workers e.g. GPs, pharmacists, practice nurses involved in the management of DOT.

5.2 Each professional is accountable both legally and professionally for their own practice.

6. Roles and Responsibilities

All TB patients are the responsibility of the treating physician until their treatment has been successfully completed.

6.1 Referring physician

It is the responsibility of the referring physician to:

- Explain to the patient at the outset the rationale and the need for DOT in their specific case
- Confirm the patient's willingness to comply with DOT
- Request DOT by completing the referral form and forwarding to the DPHN including prescription(s) (initial and subsequent). A copy of the DOT referral form should be forwarded to the local department of public health.
- Advise when mask-wearing is necessary
- Inform the key worker/ DOT provider when there is a change of medication
- Meet with patients who miss DOT doses to discuss problems with adherence
- Call and chair case-conferences as needed for non-compliant patients
- Facilitate hospital admission for patients who are unable / unwilling to comply with DOT and for whom self-medication in the community is deemed inappropriate
- Assist with the education and training of DOT providers.

6.2 Director of Public Health Nursing

It is the responsibility of the Director of Public Health Nursing to:

- To ensure that all staff within the Public Health Nursing Services are aware of this policy and that effective communication systems are in place to disseminate this policy document
- To provide the necessary resources and supports to ensure adherence to the policy.
- To ensure that appropriate personal protective equipment (PPE) is available as required by staff undertaking DOT.
- To have robust governance structures in place to monitor and audit practice and ensure patient safety
- To ensure systems are in place, to facilitate education and training with regard to the management of DOT and use of PPE.

- To ensure that risk management policies and procedures are in place for reporting all adverse events, incidents, near misses and adverse drug events

6.3 Assistant Director of Public Health Nursing

It is the responsibility of the Assistant Director of Public Health Nursing to:

- To ensure that all staff within the Public Health Nursing Services involved in the management of clients with DOT are aware of the policy and the significance of adhering to the principles contained within
- To ensure that communication and governance structures are operational at Primary Care level
- To maintain a signature sheet detailing that this policy document is read and understood
- To facilitate evaluation and audit of the policy

6.4 Staff supervising DOT administration

It is the responsibility of the staff supervising DOT administration to:

- To be accountable for their practice; it is the responsibility of each key worker/DOT provider to be familiar with the main pharmacological actions, the usual dose, storage and stability of medication and frequency, route of administration and potential side effects and incompatibilities of the drugs in the management of clients referred for DOT (Appendix 1). This includes appropriate observation of the patient i.e. observing them take their medications.
- Report any difficulties/failures to the treating physician or Public Health
- To ensure they take appropriate steps to develop and maintain competence with regard to the management of clients referred for DOT.
- To ensure that they have read and understand the contents of the policy and have signed to that effect
- To adhere to all related policies, procedures, guidelines and protocols including risk management structures for their area
- To maintain appropriate documentation

6.5 Public Health Department

The role of the Public Health Department is outlined as follows:

Strategic:

- To assist in developing, through Regional Collaborative TB Committees, strategies to improve patient adherence

- To participate in the education and training of health professionals/key worker/DOT provider (staff supervising DOT)

Specific Cases:

Department of Public Health (Director of Public Health) receives copy of each DOT Referral Request Form (Appendix 2)

- Supportive role (advisory) to supervising key worker/DOT provider if required especially in relation to complex cases

- Alerting the treating consultant physician / treating clinical team if they become aware of concerns re case adherence with DOT

- Collaboration with treating consultant physician in convening DOT case conferences where necessary (chaired by treating consultant physician). It is essential that the DPHN, key worker/ DOT provider and the patient's GP participate in the case conference and the pharmacist, when appropriate.

- Where a patient on DOT is non-compliant with treatment and resistant to any intervention in the community under Section 38 of the Health Act (1947), the MOH may order the detention and isolation of an infectious person until that person is no longer a probable source of infection. **Note***: this legislation is currently under review*.

7. Management of DOT process

7.1 Referral Pathway

- A referral form is completed by the prescribing clinician. This should be printed to ensure legibility.

- This is forwarded with the prescription (printed to ensure legibility) to the relevant Director of Public Health Nursing (DPHN) and cc'd to the Director of Public Health and to the patient's GP OR as per local arrangements

- DPHN forwards the referral form and prescription to the Asst DPHN. The Asst DPHN then contacts the Public Health Specialist by telephone as per local arrangements. The Asst DPHN communicates the referral to the key worker/DOT provider.

- Any changes in medication must be notified in a timely manner by the prescribing hospital clinician to the client and to the DPHN, DPH and attending GP. The DPHN should then advise the key worker/DOT provider.

7.2 Procedure

The key worker/DOT provider (nurse or agreed person who is deemed responsible) co-ordinates an agreed process of DOT with the client.

This involves:

-
- Ensuring that the medication has been obtained by the client prior to the visit
- Confirming the identity of the client at the time of the first visit
- Observing the client's condition and recording relevant information
- Verifying that the drugs to be taken are as prescribed
- The DOT provider must observe the patient to ensure that the medication has been swallowed
- Document this in clients' records which includes initialling the time and date that medications were taken
- Report any observed side effects of medications as soon as possible to the referring clinician, GP, DPH and line manager as appropriate

The "five rights" of medication administration should be applied for each patient/service user encounter. These are outlined as follows:

a) The right medication
b) The right patient/service user
c) The right dosage
d) The right form
e) The right time

7.2.1 **Non -adherence**– ***Where the key worker/DOT provider is unable to access the client for two consecutive appointments and the client is not contactable, the key worker/DOT provider must inform their line manager. The hospital clinician and DPH must also be informed.***

7.2.2 Missing Doses

Correction for treatment interruptions depends on the timing of such interruptions i.e. whether they occur in the initiation phase or continuation phase of therapy. The physician in charge of the case will decide and advise on the appropriate course to be followed.

7.2.3 Case Conferences

A case conference is a multidisciplinary review for individual TB cases when difficulties arise with DOT administration. Any difficulties arising with DOT administration should be discussed with the treating physician who may then decide to call a case conference. The treating physician will chair the case conference supported by public health.

7.2.4 Safety and Home Visiting

See HSE document on Lone working policy and guidelines available at http://www.hse.ie/eng/staff/Resources/hrppg/Lone_Working_Policy_and_Guidelines.html

Document and report all incidents to the DPHN.

7.3 Documentation

The administration of a medicinal product and the patient/service-user response should be accurately documented according to local policy.

8. Revision and Audit

8.1.1 The policy should be reviewed two years for the date effective. The National TB Control Group is responsible for further review. Revision of this document must be considered if new evidence that impacts on this policy emerges in advance of the two year period.

8.1.2 **Audit tool:** An audit tool which may include feedback from patients/service users should be developed locally to evaluate local processes and procedures.

8.1.3 Services employing DOT should undertake regular audit. The lead on this activity should be by local agreement.

9. Production/Consultation Trail

This document was first drafted and circulated for peer review in July 2012 and was amended following these reviews. Consultation by colleagues was sought and the document further amended accordingly. The authors developed this version of the document on 13th February 2013.

10. References/Bibliography

National TB Advisory Committee (2010) Guidelines on the Prevention and Control of Tuberculosis in Ireland. Dublin: Health Protection Surveillance Centre.

Directly observed therapy (DOT) for tuberculosis. New Zealand Ministry of Health available at: http://www.moh.govt.nz

Frieden TR, Sbarbaro JA. Promoting adherence to treatment for tuberculosis: the importance of direct observation (2007). Bulletin of the World Health Organization May; 85(5):407-9

Ormerod LP, Horsfield N, Green RM. Tuberculosis treatment outcome monitoring. : Blackburn 1988-2000 (2002). Int J Tuberc Lung Dis 6:662-665.

Ormerod LP, Zwarenstein M, Schoeman JH, Vundule C, Lombard CJ, Tatley M. (1999) Randomised controlled trial of self-supervised and directly observed treatment for tuberculosis. Thorax 54 (2); 542-545

11. Suggested Reading

Chaulk PC, Kazandjan VA (1998) Directly observed therapy for treatment completion of pulmonary tuberculosis. JAMA, 279(12): 943-948

Directly observed therapy (DOT) (June 2011). Manual for tuberculosis programs in British Columbia. Available at: http://www.bccdc.ca/NR/rdonlyres/68E9243A-3CCE-41E1-AA32-FBF41B5AB2D2/0/TB_DOTManual_June2011_Compressed.pdf

Farmer T. (2005). Factors influencing adherence to tuberculosis directly observed therapy: a review of the literature; prepared for Toronto Public Health. Available at: http://www.toronto.ca/health/tb_prevention/pdf/literature_nov2005.pdf

Floyd K, Wilkinson D, Gilks C. (1997). Comparison of cost-effectiveness of directly observed therapy (DOT) and conventionally delivered treatment for tuberculosis: experience from rural South Africa. British Medical Journal 315: 1407-11.

Moonan PK, Quitugua TN, Pogoda JM, Woo, G, Drewyer G, Sahbazian B, Dunbar D, Jost KC, Wallace C, Weis SE (2011). Does directly observed therapy (DOT) reduce drug resistant tuberculosis. BMC Public Health 11:19

WHO Patient Charter available at: http://www.who.int/tb/people_and_communities/patients_charter/en/

12. List of Appendices:

Appendix I	Doses of Primary Medications used in the treatment of TB
Appendix II	DOT referral form
Appendix III	Degree of infectiousness of the patient
Appendix IV	Letter to Regional Director of Operations from Assistant National Director, ISD-Health Protection re DOT
Appendix V	Membership of Working Group
Appendix VI	List of Stakeholders involved in Peer Review Group
Appendix VII	DOT recording form

Appendix I: Doses of Primary Medications used in the treatment of TB (p1/2)

Drug *Mode of action*	Route of administration	Daily dose [max]	3 Times a week dose [max]	2 Times a week dose [max]	Major adverse reactions*
Isoniazid *Bactericidal*	Oral/ Intramuscular	Children: 5-10mg/kg[1] Adults: 5mg/kg [300mg]	Children: 20mg/kg Adults: 10mg/kg (range 8-12mg/kg) [900mg]	Children: 20mg/kg Adults: 15mg/kg (range 13-17mg/kg) [900mg]	Hepatic enzyme elevations, hepatitis, rash, peripheral neuropathy, CNS effects, increased phenytoin levels, possible interaction with disulfiram
Rifampicin *Bactericidal*	Oral/ Intravenous	Children: 10-20mg/kg[2] Adults: 600mg (range 8-12mg/kg) [600mg]	Children: 10-20mg/kg Adults: 600mg (range 8-12mg/kg) [600mg]	Children: 10-20mg/kg Adults: 600mg (range 8-12mg/kg) [600mg]	Hepatic enzyme elevations, hepatitis, rash, fever, thrombocytopaenia, influenza-like syndrome, reduced levels of many drugs (including methadone, warfarin, hormonal forms of contraception, oral hypoglycaemic agents, theophylline, dapsone, ketoconazole, PIs, and NNRTIs)
Pyrazinamide *Bacteriostatic*	Oral	Children: 25mg/kg (range 20-30mg/kg) Adults: 25mg/kg (range 20-30mg/kg) [2.0g for adults and children	Children: 35mg/kg (range 30-40mg/kg) Adults: 35mg/kg (range 30-40mg/kg) [3.0g for adults and children	Children: 50mg/kg (range 40-60mg/kg) Adults: 50mg/kg (range 40-60mg/kg) [3.5g for adults and children	Gastrointestinal (GI) upset, hepatotoxicity, hyperuricaemia, gout (rarely), arthalgias, rash
Ethambutol *Bacteriostatic*	Oral	Children: 20mg/kg (range 15-25mg/kg) [1.5g] Adults: 15-25mg/kg [2.0g]	Children: 30mg/kg (range 25-35mg/kg) Adults: 30mg/kg (range 25-35mg/kg) [2.8g]	Children: 40-50mg/kg [2.5g] Adults: 45mg/kg (range 40-50mg/kg) [3.6g]	Decreased red-green colour discrimination, decreased visual acuity, skin rash
Streptomycin *Bactericidal*	Intramuscular/ Intravenous	Children: 15-30mg/kg Adults: 15mg/kg [1.0g]	Children: 15mg/kg Adults: 15mg/kg [1.0g]	Children: 15mg/kg Adults: 15mg/kg [1.0g]	Auditory toxicity, renal toxicity, hypokalaemia, hypomagnesaemia

Appendix I: Doses of Primary Medications used in the treatment of TB (p2/2)

Drug	Recommended regular monitoring	Comments
Isoniazid	- Monthly clinical evaluation - Liver function tests[3]	- Vitamin B_6 (pyridoxine) 10mg/day may decrease peripheral neuritis and CNS effects and should be used in patients who are abusing alcohol, pregnant, breastfeeding infants on isoniazid, malnourished, or who have HIV infection, cancer, chronic renal or liver disease, diabetes, or pre-existing peripheral neuropathy - Aluminium-containing antacids reduce absorption - Drug interactions with several agents
Rifampicin	- Monthly clinical evaluation - Complete blood cell count including platelets and liver function tests as indicated[3]	- Orange discolouration may occur in contact lenses and body secretions such as tears and urine - Patients receiving methadone will need their methadone dosage increased, by an average of 50%, to avoid opioid withdrawal - Interaction with many drugs leads to decreased levels of the co-administered drug - May make glucose control more difficult in people with diabetes. - Contraindicated for patients taking most PIs and NNRTIs - Patients should be advised to use barrier contraceptives while on rifampicin
Pyrazinamide	- Monthly clinical evaluation - Liver function tests as indicated[3]	- May complicate management of diabetes mellitus - Hyperuricaemia can be used as indicator of compliance - Treat increased uric acid only if symptomatic - Allopurinol increases level of pyrazinamide by inhibiting xanthine oxidase resulting in failure of allopurinol to lower serum uric acid
Ethambutol	- Monthly clinical evaluation - Check colour vision and visual acuity monthly	- Optic neuritis may be unilateral; check each eye separately. If possible avoid in children too young to undergo vision testing. - If patient develops visual complaints, refer for prompt ophthalmologic evaluation. May need to discontinue ethambutol while awaiting evaluation.
Streptomycin	- Monthly clinical evaluation - Audiometry, renal function, electrolytes, including magnesium	- Ultrasound and warm compresses to injection site may reduce pain and induration

[1]World Health Organization (WHO), International Union against TB and Lung Disease (IUATLD), and British Thoracic Society (BTS) recommend 5mg/kg in children; Centers for Disease Control and Prevention (CDC), American Thoracic Society (ATS), Infectious Disease Society of America (IDSA) and the American Academy of Paediatrics (AAP) recommend 10-20mg/kg
[2]WHO, IUATLD, and BTS recommend 10mg/kg in children; CDC/ATS and the AAP recommend 10-20mg/kg
[3]Liver function tests are indicated if baseline is abnormal or patient has risk factors for toxicity

Reproduced with kind permission from *Tuberculosis, Clinical Policies and Protocols*. New York City Department of Health and Mental Hygiene (2008). Available at www.nyc.gov/html/doh/downloads/pdf/tb/tb-protocol.pdf

PI= Protease inhibitors
NNRTI= Non-Nucleoside Reverse Transcriptase Inhibitors

Appendix II: DOT referral form[1]

TO DIRECTOR OF PUBLIC HEALTH NURSING
Fax number: _____
Phone number:_____

Consultant name
Consultant address line 1
Consultant address line 2
Consultant address line 3
Consultant contact number

REFERRAL REQUEST FOR DIRECTLY OBSERVED THERAPY
TUBERCULOSIS MEDICATION

Name: _____ DOB: _____

Home Address: _____ Current Address (If different) _____

_____ _____

_____ _____

_____ _____

Contact number: _____
Hospital: _____ Chart number: _____
GP name: _____ GP contact number: _____
Diagnosis: _____
Date of commencement of TB therapy

Most recent sputum smear: Date:_____ Result:_____
Case currently infectious? Yes No
Mask wearing recommended ? Yes No If, YES, for how long? _____

Reason(s) for DOT request:

Poor/Non-adherence	Yes	No	
MDR-TB	Yes	No	
TB relapse	Yes	No	
Homeless	Yes	No	
Other	Yes	No	Please specify _____

Date of next OPD appointment: _____

Prescription attached/faxed? Yes No

Signed:_____ Date: _____
Referring physician

CC Department of Public Health **Yes** **No**

For further details, please see Appendix 9 (p171) of Guidelines on the Prevention and Control of Tuberculosis in Ireland, 2010. Available at: http://www.hpsc.ie/hpsc/A-Z/VaccinePreventable/TuberculosisTB/Guidance/

[1] The above form is a sample form and may need to be adapted for local use

Appendix III: Degree of infectiousness of the patient

Adapted from the *Guidelines on the Prevention and Control of Tuberculosis in Ireland, 2010* (HPSC) (Chapter 6)-available at www.hpsc.ie

Degree of infectiousness

• It is accepted that a patient who is sputum smear positive or bronchial lavage (BAL) positive is infectious and should be treated as such. However, any patient who has symptoms or signs suggestive of pulmonary TB should be regarded as infectious and treated as such until evidence to the contrary (three properly performed negative sputum smears) have been found.

• Compliant patients, sensitive to appropriate anti-TB treatment are generally deemed non-infectious after 2 weeks of treatment. AFB positive sputum results may continue to be reported due to the persistence of inactive killed organisms which are not infectious.

• A patient who is sputum smear negative can attend a health centre for DOT/DOTS but should be restricted from any contact with immunocompromised patients.

• Some patients who are infectious can remain at home in the household that has already been exposed, as it has been shown that the risk of additional transmission of infection in this setting is extremely low. Exposure duration of less than eight hours is generally considered not to be significant. (National TB Advisory Committee, 2010)

• The use of an FFP2 mask by staff/carers is recommended only when caring for patients with suspected or known infectious TB . FFP3 masks are recommended for the care of patient with suspected or confirmed infectious MDR-TB or XDR-TB.

Appendix IV: Letter to Regional Director of Operations from Assistant National Director of Health Protection re DOT

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Office Health Protection
Health Service Executive
31/33 Catherine Street
Limerick

Tel: (061) 483347
Fax: (061) 464205

8th. January 2010

To / Regional Director of Operations, HSE.

Re: TB Patients and Directly Observed Therapy (DOT) in the Community

Dear Colleague,

TB is still a major health risk in Ireland and our own indigenous problem has been exacerbated by the arrival of immigrants from areas of much higher incidence. There were 465 cases of TB notified in Ireland in 2006 (crude notification rate 11.0/100,000), slightly higher than the rates reported between 2000 and 2005. Provisional figures for 2007 are in turn slightly higher than 2006 *[Report on the Epidemiology of TB in Ireland 2006. HPSC Oct 2008]*.

Compliance with treatment is central to establishing good cure rates for TB and for preventing the problem of drug resistance. Whenever a treating physician identifies that a TB case is poorly compliant with treatment, or is likely to become so, Directly Observed Therapy (DOT) is generally recommended. DOT is a major element of our national programme of TB control. Suboptimal care of TB patients has implications not only for the patient but also for the wider community. The arrangements for setting up and providing DOT are working in some areas, there have been difficulties in others with regard to the provision of DOT for TB patients in the community.

Various Health Acts and SI's have indicated that the provision of health care to people with an infectious disease is an universal entitlement.

I would be grateful if you could remind the relevant staff in your area a high priority is given to ensuring that staff are available to provide this service. It is essential that the role of our Public Health Nurse colleagues in TB control be acknowledged and that they be reminded of how crucial their role is in providing DOT in the community.

I would be grateful for your assistance in this. I would also appreciate your confirmation that community provision of DOT will receive ongoing priority. Should you, or Directors of Public Health Nursing, require any clarification on this issue, I am assured that the local Departments of Public Health will be happy to assist.

Yours sincerely,

DR. KEVIN KELLEHER
ASSIST. NATIONAL DIRECTOR FOR POPULATION HEALTH – HEALTH PROTECTION

cc. Each Director of Public Health

Appendix V: Membership of Working Group

Name	Area of Work
DR. Heidi Pelly (Chair)	Specialist in Public Health Medicine, HSE West (Galway, Mayo and Roscommon)
Dr. Joan O Donnell (secretary from September 2011 to March 2012)	Specialist in Public Health Medicine, HPSC
Carmel Buckley	Representing the Office of Nursing & Midwifery Services
Marie Gleeson	Child Heath/ Immunisation Co-ordinator DML
Dr. Margaret O Sullivan	Specialist in Public Health Medicine, HSE South (Cork and Kerry)
Carmel Fallon (secretary from March 2012)	Infection Prevention and Control Nurse, Department of Public Health HSE West (Galway, Mayo and Roscommon)
Ger O Connor	Public Health Nurse, HSE East
Marianne Healy	Director of Public Health Nursing, HSE East
Dr. Terry O Connor	representing the Irish Thoracic Society
Dr. Mary Scully	Specialist in Public Health Medicine, HSE East

Appendix VI: List of Stakeholders Involved in Peer Review

Name	Title	Location

Appendix VII: DOT Recording Form[2]

Patient Surname:		**Forename:**		**DOB**	
Address					
Contact Numbers:					
Consultant					

Medications	**Name**	**Dose**	**Frequency**

Please observe above named taking listed medications and sign opposite appropriate date

Day	**Date and Time Morning (AM)**	**Date and Time Evening (PM)**	**Notes**	**Signature**
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				

[2] The above form is a sample form and may need to be adapted for local use