Memorandum on leprosy 2012

on behalf of the Panel of Leprosy Opinion
## Contents

Preface ......................................................................................................................... 2

Leprosy update – what is new in this Memorandum? .................................................. 2

1.0 Introduction ............................................................................................................. 3

2.0 Natural history of leprosy infection ....................................................................... 3

3.0 Global epidemiology .............................................................................................. 5

4.0 Epidemiology of leprosy in England and Wales .................................................... 6

5.0 Presentation of leprosy ......................................................................................... 7

6.0 Diagnosis .............................................................................................................. 9

7.0 Notification and national surveillance .................................................................. 10

8.0 Patient management ............................................................................................ 11

9.0 Complications ...................................................................................................... 14

10.0 Admission to hospital ...................................................................................... 14

11.0 Prevention and control in the United Kingdom .................................................. 15

12.0 Useful websites .................................................................................................. 16

Bibliography ............................................................................................................. 17

Appendices ............................................................................................................... 19

1 The Panel of Leprosy Opinion .................................................................................. 19

2 Notes for completing neurological assessment ...................................................... 20

3 Neurological assessment form ................................................................................ 22

4 Microscopic examination of skin slit smears, and diagnostic skin biopsy for leprosy 23

5 Reference laboratories for testing of specimens .................................................... 24

6 Contact details for Consultant Advisors in Leprosy, National Leprosy Centres and Consultant Epidemiologists ......................... 25

7 Surveillance questionnaire .................................................................................... 26

8 Abbreviations ........................................................................................................ 27
Preface

This document has been produced by Public Health England (PHE) on behalf of the Panel of Leprosy Opinion. The memorandum is based on best available evidence and expert advice from the Panel of Leprosy Opinion.

Leprosy update–what is new in this memorandum?

This memorandum aims to be a concise but comprehensive update on the previous Memorandum published in 1997. It is a didactic consensus document based on best international practice, but does not attempt to assign grades to the evidence base supporting statements made or the strength of the recommendations. Key changes since that document include:

- Updated current global epidemiology of leprosy and tables summarising the epidemiology of leprosy notifications in England and Wales over the past four decades
- An update on clinical features, diagnosis and clinical and public health aspects of management
- Current thoughts on classification of the different clinical presentations of leprosy
- Details of the presentations and management of leprosy reactions, the importance of which is increasingly recognised, including the need for ongoing specialist input
- Clear messages for general and specialist clinicians and public health practitioners on their roles and responsibilities
- Updated lists and contact details of British specialists who should be contacted for advice on clinical, diagnostic and public health aspects of management of all patients
- Clinical record charts for individual patient management, courtesy of the Hospital for Tropical Diseases, London
- Bibliography including key general references on leprosy and a compendium of historical and more recent publications relating to leprosy in the UK
- Websites of use to patients, physicians and others interested in all aspects of leprosy
1.0 Introduction

1.1 Leprosy is an uncommon disease in England and Wales, yet it remains an important disease globally with 250,000 cases diagnosed annually. Its importance lies in the need for early diagnosis and expert treatment and support, both for those with active disease and for those who are physically, psychologically, or socially affected by it.

1.2 The objectives of this memorandum are to provide information to both clinicians and consultants in communicable disease control (CCDCs) involved in notifying and managing a case of leprosy. The memorandum draws on the best available evidence together with the specialist knowledge of the Panel of Leprosy Opinion. The full membership and a description of the remit of the panel are given at Appendix 1.

1.3 Contact details are also provided for: Consultant Advisors in Leprosy with experience in the treatment and prevention of leprosy; the Tuberculosis Surveillance Section of Public Health England (PHE) in London which manages notifications of leprosy and provides advice on public health action; Consultant Epidemiologists at PHE; national leprosy referral centres in England and Wales; and reference laboratories performing diagnostic tests for leprosy.

2.0 Natural history of leprosy infection

2.1 Leprosy is a curable chronic infectious disease caused by the acid-fast bacillus *Mycobacterium leprae*. It mainly affects the cooler parts of the body such as the skin, respiratory mucosa and superficial nerves.

2.2 Initial infection is asymptomatic. The disease progresses slowly and has an incubation period ranging from 2 to 12 years. Most people infected with the organism are thought not to develop clinical disease but the exact proportion is not known. Once symptoms appear, the disease progresses, usually insidiously but sometimes rapidly. In females, pregnancy may precipitate clinical leprosy.

2.3 The type of disease which develops reflects the degree to which the host is able to mount a cell-mediated immune response. Types of disease may be classified according to the Ridley-Jopling classification, which is based on skin lesion type and bacterial load:

- *Tuberculoid leprosy* (TT): Patients have a vigorous cell-mediated immune response. This results in well-demarcated lesions containing few bacilli and surrounded by lymphocytes.

- *Lepromatous leprosy* (LL): Patients do not develop effective cell-mediated immunity. Lesions are diffusely infiltrated with macrophages in which bacteria multiply in large numbers. Antibodies are produced, often in large quantities, but are ineffective in killing the bacilli.

- *Borderline leprosy*: This category covers the spectrum between the two extremes described above. Patients have some cell-mediated immune response, multiple lesions and unstable immunity. Borderline leprosy can be further classified according to the category it most resembles:
  - *Borderline tuberculoid*       (BT)
  - *Borderline (mid-borderline)* (BB)
  - *Borderline lepromatous*       (BL)
2.4 The World Health Organization (WHO) has introduced a simplified field-based classification. Disease may be either described as paucibacillary (between one and five lesions) or multibacillary (greater than five lesions).

Figure 1 below illustrates the different classifications and features of leprosy, and their correlation with the "Bacteriological Index", which is a measure of the number of leprosy bacilli seen in stained material obtained from slit skin smears.

**Figure 1: Classifications and features of Leprosy**

<table>
<thead>
<tr>
<th>WHO Classification</th>
<th>Paucibacillary (PB)</th>
<th>Multibacillary (MB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriological Index(^1)</td>
<td>0</td>
<td>0-1+</td>
</tr>
<tr>
<td>Type of leprosy</td>
<td>Polar Tuberculoid</td>
<td>Borderline</td>
</tr>
<tr>
<td>Ridley-Jopling Classification</td>
<td>TT</td>
<td>BT</td>
</tr>
<tr>
<td>Skin lesions</td>
<td>Increasing number of skin lesions</td>
<td></td>
</tr>
<tr>
<td>Nerve lesions</td>
<td>Increasing number of enlarged nerves &amp; nerve involvement</td>
<td></td>
</tr>
<tr>
<td>Stability</td>
<td>Stable</td>
<td>Unstable – may develop reactions and new nerve damage</td>
</tr>
</tbody>
</table>

2.5 Pure neural leprosy may be any type of leprosy.

2.6 If detected early, however, and treated with multidrug therapy (MDT), the disease may be cured and will not lead to disabilities.

2.7 Infectivity

2.7.1 Leprosy is infectious when viable leprosy bacilli are shed by an untreated patient and infect a susceptible contact; the degree of infectivity depends on the concentration of leprosy bacilli in the body, and this inversely reflects the degree of the host cell-mediated immune response.

2.7.2 Patients with tuberculoid or borderline tuberculoid leprosy are probably not infectious. Leprosy bacilli in the tissues are extremely scanty, most are degenerate and non-viable, and are intra-cellular.

\(^1\) Calculated by counting six to eight stained smears under the 100 x oil immersion lens.

1+ At least 1 bacillus in every 100 fields.
2+ At least 1 bacillus in every 10 fields.
3+ At least 1 bacillus in every field.
4+ At least 10 bacilli in every field.
5+ At least 100 bacilli in every field.
6+ At least 1000 bacilli in every field.
2.7.3 In lepromatous and borderline-lepromatous leprosy, however, bacilli are numerous and present in many organs. In the lepromatous form, many millions of viable bacilli from the nasal mucosa are discharged daily from the upper respiratory tract and may remain viable for hours or days after leaving the body. Although the mode of transmission has still not been conclusively proven, droplet infection is thought to be the likeliest means of spread of the disease.

2.7.4 Nonetheless, in endemic countries only about 5% of spouses of lepromatous patients develop clinical leprosy. As a result, infection control precautions are rarely indicated.

2.7.5 Treatment with standard WHO MDT rapidly reduces the number of viable bacilli in the nasal discharge. Within a few days of starting treatment virtually all the bacilli are dead and the patient may be considered no longer infectious.

2.7.6 Patients with untreated leprosy do not need special isolation precautions if they require admission to health care settings and staff do not need to wear personal protective equipment (masks etc.) for prevention of airborne infections when attending to patients in clinics or on the ward. Standard precautions for prevention of contact-related infection (gloves, impermeable aprons etc.) should be employed when dealing with patients who have open skin lesions, or when performing procedures such as skin biopsy or slit skin smears.

2.7.7 Type 1 and Type 2 immune-mediated reactions can occur in almost one third of patients with multibacillary disease during and after MDT. Leprosy reactions should be managed by a Consultant Advisor in Leprosy, and are discussed in sections 9.1 to 9.3. The development of a reaction does not mean that the MDT treatment is failing or that the patient has become infectious. MDT should not be stopped when reactions occur.

3.0 Global epidemiology

3.1 Leprosy occurs throughout the tropics and sub-tropics and is still present in some parts of southern Europe, the Middle East and North Africa. Countries with the greatest numbers of new cases detected in 2010 included India, Indonesia and Brazil. Pockets of high endemicity remain in some areas of Angola, Central African Republic, Democratic Republic of Congo, Madagascar, Mozambique, Nepal, and the United Republic of Tanzania.

3.2 The introduction of MDT for leprosy in 1982 along with neonatal vaccination BCG vaccination to prevent tuberculosis, has contributed to a very substantial reduction in the prevalence of leprosy. At the beginning of 2008, the registered prevalence of leprosy was 212,802 cases, compared to 5.2 million in 1985.

3.3 Nonetheless, the global number of incident cases has shown only a modest decline over recent years (2006-2009) when compared with previous years (Table 1).

3.4 The number of new cases should be interpreted with caution. Changes in the classification of leprosy, as developed by the WHO, have resulted in data which are inconsistent with previous classification systems. Furthermore, systems for registration of cases differ between countries.
Table 1: Trends in detection of new cases of leprosy by WHO region, 2003-09

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
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<tbody>
<tr>
<td>African</td>
<td>47006</td>
<td>46918</td>
<td>45179</td>
<td>34480</td>
<td>34468</td>
<td>29814</td>
<td>28935</td>
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<tr>
<td>Americas</td>
<td>52435</td>
<td>52662</td>
<td>41952</td>
<td>47612</td>
<td>42135</td>
<td>41891</td>
<td>40474</td>
</tr>
<tr>
<td>South-East Asia</td>
<td>405147</td>
<td>298603</td>
<td>201635</td>
<td>174118</td>
<td>171576</td>
<td>167505</td>
<td>166115</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>3940</td>
<td>3392</td>
<td>3133</td>
<td>3261</td>
<td>4091</td>
<td>3938</td>
<td>4029</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>6190</td>
<td>6216</td>
<td>7137</td>
<td>6190</td>
<td>5863</td>
<td>5899</td>
<td>5243</td>
</tr>
<tr>
<td>Total</td>
<td>514718</td>
<td>407791</td>
<td>299036</td>
<td>265661</td>
<td>258133</td>
<td>249007</td>
<td>244796</td>
</tr>
</tbody>
</table>

*No reports were received from the European region
Source: WHO Weekly Epidemiological Record: Global Leprosy Situation, 2010

4.0 Epidemiology of leprosy in England and Wales

4.1 In 1951, leprosy became a notifiable disease in England and Wales. At that time, a confidential register of all cases was established. Currently, a National Leprosy Surveillance Database is maintained by the Tuberculosis Surveillance Section of Public Health England, London.

4.2 The incidence of leprosy has fallen substantially over time in the UK. In the UK, 373 cases were notified between 1951-1960, compared to 129 between 2001 and 2010. The total number of cases notified since the inception of the register until the end of 2010 was 1533 (Table 2).

4.3 There have been no definite indigenously acquired cases reported since 1954. Prior to that, the last indigenously acquired case was reported in 1925. Of cases notified in England and Wales between 1981 and 2010, 64.5% were male and 62.7% were aged 15 to 44 years. The highest proportion of cases were from South Asia (59.9%), especially India, Sri Lanka, and Bangladesh, and then from Brazil and Nigeria. However, patients had acquired infection in 44 other countries, emphasizing the need to consider the diagnosis of leprosy in travellers/migrants from all continents. Under-reporting is likely, as the rarity of the disease leads to low awareness of its clinical presentation and diagnosis, but the extent of this is unknown. Patients often present many years after arriving in Britain from an endemic area, so a diagnosis of leprosy may not be considered.

Table 2: New cases of leprosy in residents of England and Wales reported to the Central Register of Leprosy, 1951-2010

<table>
<thead>
<tr>
<th>Period</th>
<th>Total no. Notifications (All types of leprosy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1951 – 60</td>
<td>373</td>
</tr>
<tr>
<td>1961 – 70</td>
<td>464</td>
</tr>
<tr>
<td>1971 – 80</td>
<td>277</td>
</tr>
<tr>
<td>1981 – 90</td>
<td>173</td>
</tr>
<tr>
<td>1991 – 2000</td>
<td>117</td>
</tr>
<tr>
<td>2001 – 2010</td>
<td>129</td>
</tr>
<tr>
<td>Total</td>
<td>1533</td>
</tr>
</tbody>
</table>

*Not known=Patients for whom year of diagnosis is not recorded.
Source: TB Surveillance Section, PHE, London, as at 30 March 2012
5.0 Presentation of leprosy

5.1 Box 1 on page 11 summarises features in a patient which may indicate a diagnosis of leprosy. The possibility of leprosy should be borne in mind when a person has come from, or spent some time in, an endemic area (e.g., India, Indonesia, Brazil, Angola, Brazil, Central African Republic, Democratic Republic of Congo, Madagascar, Mozambique, Nepal, and the United Republic of Tanzania) and presents with:

5.1.1 A chronic, non-itchy patch in the skin which does not resemble a known condition or has not responded to treatment.

A diminished cutaneous sensitivity (to light touch, pain or temperature) within an area of hypopigmentation. If there is complete anaesthesia in the skin lesion, leprosy is the leading differential diagnosis.

Widespread maculation or infiltration of the skin and persistent papules or nodules which can occur in lepromatous leprosy.

5.1.2 Signs of damage to one or more peripheral nerve trunks (particularly the ulnar, median, common peroneal or posterior tibial), pain in a peripheral nerve, usually accompanied by one or more skin lesions, and/or thickened nerves or other neurological symptoms that do not fit into a well-recognised pattern.

5.1.3 An ulcer on the sole of the foot.

5.1.4 Leprosy may also present in spontaneous reaction, with new skin lesions, previously flat skin lesions which suddenly become erythematous or raised, or neuritis, or other sudden changes in symptoms.

5.2 Less common presentations of leprosy include one or more of the following:

- Arthritis
- Erythema nodosum leprosum
- Orchitis
- Acute uveitis (very rare)

5.3 Common misdiagnoses rather than a true diagnosis of leprosy are:

- Diabetes
- Other causes of neuropathy e.g. vitamin B₁₂ deficiency
- Erysipelas
- Lupus vulgaris (cutaneous tuberculosis)
- Sarcoïd
- Vasculitis

5.4 Grade 1 disability is defined as a loss of feeling in the palm of the hand and/or the sole of the foot. Grade 2 disability is defined as visible damage to the hands such as wounds, claw hand, loss of tissue and/or visible damage to the foot such as wounds, loss of tissue or foot drop.
5.5 If the patient suspects the diagnosis there may be accompanying depression and anxiety.

5.6 Most patients are referred initially to a dermatologist, neurologist or rheumatologist.

5.7 A granulomatous skin or peripheral nerve lesion in an Asian or African patient should be considered leprosy until proven otherwise.

5.8 Appendices 2 and 3 contain forms and notes for completing a neurological assessment.

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**Box 1. LEPROSY - DIAGNOSIS**

1. **Patient who has resided in a leprosy endemic area (India, Indonesia, Brazil, Angola, Brazil, Central African Republic, Democratic Republic of Congo, Madagascar, Mozambique, Nepal, and the United Republic of Tanzania)**

2. **Clinical features:**
   
   i. **Skin lesion(s):**
      
      - chronic non-itchy patch with or without hypopigmentation (macular, annular or occasionally a plaque)
      - altered sensation (to light touch, temperature and/or pain)
      - widespread maculation and/or infiltration with or without papules or nodules;
   
   ii. **Peripheral nerve trunk damage and/or pain:**
   
   iii. **Thickened peripheral nerves;**
   
   iv. **Ulceration on sole of foot;**
   
   v. **If presenting in reaction:**
      
      - acute erythema and oedema of skin lesions
      - sudden change in previously flat skin lesions
      - neuritis
      - other sudden change in symptoms
   
   vi. **Less commonly:**
      
      - erythema nodosum with or without fever
      - hoarseness
      - arthritis
      - orchitis
      - acute uveitis (very rare)

3. **Microscopy shows acid--fast bacilli (slit skin smears from skin lesions or ear lobes).**

4. **Histological findings consistent with leprosy (skin biopsy or in some cases, peripheral nerve biopsy).**
6.0 Diagnosis

6.1 Diagnosis depends on the clinical signs, the finding of acid-fast bacilli on microscopy and/or appropriate histological appearances (Box 1).

6.2 The Consultant Advisors in Leprosy will advise doctors on any problems concerning diagnosis, potential infectivity and management of all patients with suspected leprosy and their close contacts. A consultation with the Consultant Advisors in Leprosy also gives the best opportunity for appropriate smears and/or biopsies to be taken. The diagnosis should be confirmed microscopically or histologically in every case (Box 2).

6.3 Details of microscopic examination of skin and of the recommended procedure for diagnostic skin biopsy are contained in Appendix 4. Slit skin smears (for microscopy) should only be taken by a Consultant Advisor in Leprosy or their delegate and sent to either the Hospital for Tropical Diseases in London or the Liverpool School of Tropical Medicine (Appendix 5). Finding acid-fast bacilli in such specimens confirms the diagnosis and gives an indication of the potential infectivity of the patient. Culture of specimens is not performed.

6.4 Skin biopsies should be of a depth to include some subcutaneous fat and should be examined by an expert. The histopathological picture may be characteristic and pathognomonic even when bacilli cannot be demonstrated. Specimens may be sent to the histopathology laboratory in St Thomas’s Hospital, London (Appendix 5).

6.5 In rare cases where the only clinical sign is a thickened peripheral nerve with associated loss of nerve function (neural leprosy), the Consultant Advisor in Leprosy will advise whether a nerve biopsy is indicated.

6.6 The lepromin skin test is of no value in diagnosis. There is no serological test that provides a reliable diagnosis across the leprosy spectrum.

**Box 2. LEPROSY - THE ROLE OF THE CLINICIAN**

1. **Maintain an index of suspicion for leprosy.**

2. **Discuss every case with a Consultant Advisor in Leprosy before slit skin smears and/or biopsies are taken. Refer the patient to one of the national leprosy centres (Appendix 6).**

3. **Ensure any slit skin smears of skin lesions are taken by a Consultant Advisor in Leprosy or their delegate. Diagnostic skin biopsies should be taken according to the protocol in Appendix 4. Specimens for microscopy and for histological examination should be sent to reference laboratories with appropriate expertise (Appendix 5).**

4. **Notify any newly diagnosed cases of leprosy, cases with relapse, cases of leprosy new to the UK and on MDT and cases of leprosy new to the UK, diagnosed abroad and not on MDT (section 7.1) to the proper officer of the local authority in which the patient resides (in confidence).**

5. **Discuss the management of household contacts with the CCDC, Consultant Epidemiologist at PHE in Colindale, and Consultant Advisor in Leprosy if necessary (Appendix 6).**
7.0 Notification and national surveillance

7.1 Leprosy is one of 31 statutorily notifiable diseases under the Health Protection (Notification) Regulations 2010. These regulations only apply to England. Leprosy is included in the list of notifiable diseases to help ensure prompt detection and treatment, and to allow epidemiological monitoring and surveillance. Doctors (registered medical practitioners) are required to notify any newly diagnosed cases of leprosy, cases with relapse, cases of leprosy new to the UK and on MDT or cases of leprosy new to the UK, diagnosed abroad and not on MDT, to the proper officer of the local authority in which the patient resides. Local authorities are required to notify PHE of such notifications.

Where the proper officer of the local authority is a PHE consultant in communicable disease control (CCDC) from the local Health Protection Team (HPT), this duty is automatically effected. Where the proper officer is a local authority employee, the local authority should notify the CCDC at the local HPT. The CCDC should then notify the Tuberculosis Surveillance Section of the Respiratory Diseases Department, Public Health England, 61 Colindale Avenue, London, NW9 5EQ. Doctors should refer all suspected or confirmed cases to one of the national leprosy centres (Appendix 6) where the case can be reviewed by a Consultant Advisor in Leprosy.

While Leprosy is not notifiable in Northern Ireland, all confirmed or suspected cases should be reported to the Public Health Agency Duty Room and managed in accordance with advice from the Consultant Leprosy Advisor (Public Health Agency is 12–22 Linenhall Street, Belfast BT2 8BS, Duty Room Telephone 02890553997 or 02890553994).

7.2 Notification of leprosy serves many purposes. It ensures that cases are managed by a Consultant Advisor in Leprosy. The CCDC will also discuss with the Consultant Advisor in Leprosy and PHE lead Consultant Epidemiologist, the management of any close contacts, so that any necessary contact tracing is performed, with due regard to the stigma and sensitivities attached to this disease. CCDCs should keep a strictly confidential record of persons suffering from leprosy in the area covered by their HPT. In addition, by reporting the case to the national centre, this ensures that the national surveillance system can be used to monitor the key indicators required by the WHO. These indicators include: the number of new cases, the new case detection rate, and the rate of new cases with grade 2 disabilities.

Box 3 summarises the actions for a CCDC when they are notified of a case of leprosy.

Box 3. LEPROSY - THE ROLE OF THE CCDC

1. Ensure the patient is being managed by, or in conjunction with, a Consultant Advisor in Leprosy.
2. Ensure contact tracing is carried out and discuss the management of household contacts with the relevant Consultant Epidemiologist at PHE Tuberculosis Surveillance Section, Colindale, and Consultant Advisor in Leprosy as appropriate.
3. Ensure the national surveillance questionnaire is completed and sent to PHE Tuberculosis Surveillance Section in order to comply with international reporting obligations and for the purposes of national surveillance.
7.3 As part of leprosy notification, each patient is allotted a unique identifier and details such as address, type of leprosy and the state of the disease are entered onto the National Leprosy Surveillance Database. After two years patient-identifiable data is split from clinical and socio-demographic information to be stored separately. Following this, only numbered records with clinical and socio-demographic data remain. This is consistent with the approach taken with a number of other conditions where patient identifying information is only needed for public health purposes at the time of initial reporting.

7.4 Patients on MDT who have been referred to a Consultant Advisor in Leprosy prior to January 2012 do not need to be notified. Cases newly arrived to the UK and on active MDT for leprosy and cases of leprosy new to the UK, diagnosed abroad and not on MDT, should be notified to ensure appropriate referral to a Consultant Advisor in Leprosy, and to ensure public health action is taken, if relevant.

7.5 The diagnosing clinician is responsible for notifying a case. The leprosy surveillance questionnaire may be provided by the local HPT on notifying the case. In practice, it may be agreed that the Consultant Advisor in Leprosy completes the surveillance questionnaire (Appendix 7). A link to the questionnaire is provided here: www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317136551813

7.6 It is helpful if the type of leprosy from which the patient is suffering is indicated when the patient is first notified, even if this is only a provisional classification based on the clinical findings. The CCDC should subsequently be informed of the definitive classification as soon as further information becomes available (usually from histopathological examination). The classification used should be either the Ridley-Jopling or WHO classifications described in section 2.3.

7.7 The PHE Tuberculosis Surveillance Section should be forwarded the questionnaire by the HPT. The questionnaire is entered onto the confidential National Leprosy Surveillance Database. This will also allow PHE to comply with international reporting obligations to the WHO. The personal identifiable information for a case will be removed from the database two years after notification.

7.8 All cases are notified confidentially. Discrimination against patients notified with the disease has not been identified in practice as a consequence of the reporting process.

7.9 There is no link between notification of a leprosy case and the exercise of powers available to local authorities or a Justice of the Peace under the Health Protection (Local Authority Powers) Regulations 2010, or the Health Protection (Part 2A Orders) Regulations 2010. Neither is notification grounds for isolation, detainment, or deportation from the UK.

7.10 Leprosy case notification does not prevent UK advocacy on the human rights and freedom of leprosy patients. The Leprosy Panel supports the aims of the UN resolution 62/215 adopted by the General Assembly in December 2010 “Elimination of discrimination against persons affected by leprosy and their family members”.

8.0 Management of the patient

8.1 It is recommended that whenever possible, patients are transferred to the care of a Consultant Advisor in Leprosy.

8.2 Management includes: specific chemotherapy; detecting and treating recent nerve damage with steroids; patient education about the disease and its treatment in order to encourage compliance and to lessen the stigma; patient education on the care of anaesthetic hands or feet; treating any immunological reactions that may arise and any sequelae from the anaesthesia; and the appropriate examination of close contacts. These aspects are discussed in more detail in the following sections.
8.3 Drug therapy

8.3.1 The WHO now recommends one of two standard multidrug regimens:

*For paucibacillary patients:*
- Rifampicin 600 mg monthly, supervised using directly observed therapy (DOT), plus
- Dapsone 1-2 mg/kg per day, unsupervised (a large adult receives 100 mg daily, a small adult 50 mg daily, and children pro rata doses based on their weight)

*For multibacillary patients:*
- Rifampicin 600 mg monthly, supervised using DOT, plus
- Clofazimine 300 mg monthly, supervised using DOT, given with the rifampicin, plus
- Clofazimine 50 mg daily, unsupervised, plus
- Dapsone 100 mg daily, unsupervised

8.3.2 A blister pack should be used for all patients receiving MDT for multibacillary leprosy.

8.3.3 In the UK the type of regimen that a patient receives is determined by combining their Ridley-Jopling classification, skin smear result and biopsy findings. Paucibacillary treatment is given for 6 months to TT and BT patients with negative slit skin smears. Multibacillary treatment is given to smear positive BT, BL and LL patients for 12 months. Patients with an initial bacterial index above 4 need 24 months of treatment.

8.3.4 Clofazimine may cause the development of a ‘sun tan pigmentation’ due to increased melanin production, especially in areas of the body exposed to daylight, and also increased dryness and mild ichthyosis of the skin of the legs and in anaesthetic areas. If clofazimine is not tolerated, newer drug treatments are available and should be discussed with a Consultant Advisor in Leprosy.

8.3.5 Improvement after starting treatment is often detectable within 7-14 days.

8.4 Supervision during treatment

8.4.1 Patients need regular supervision and encouragement both to ensure that they take the treatment as prescribed and attend for follow-up regularly, and to detect any incipient reactions, including neuritis or early damage to anaesthetic hands or feet. Patients may also need advice or help with social problems, housing and employment. A patient who has developed irreversible weakness of a hand or foot, or lagophthalmos, may require reconstructive surgery.

8.5 Length of drug treatment and follow-up

8.5.1 Patients with paucibacillary disease can stop treatment after 6 months treatment with the WHO regimen. Although the skin lesions may still appear active, the inflammation is due to immunological recognition of antigens from dead leprosy bacilli and not due to the activity of viable bacilli. With time, the erythema fades whether or not treatment is prolonged. Patients receiving steroids for the treatment of an immunological reaction do not need to extend MDT for longer.
8.5.2 Immunological reactions may occur for many years after treatment. Patients must be educated about this at the time of completing chemotherapy and told to come back immediately should there be a problem. Otherwise they should be seen annually for at least 2 years after starting chemotherapy.

8.5.3 Patients with multibacillary leprosy should take MDT for at least one year. Treatment may be continued for longer than 12 months based on the assessment of the Consultant Advisor in Leprosy.

8.5.4 All multibacillary patients should be reviewed at least once a year by a doctor experienced in leprosy, both during and for 5 years after completing chemotherapy. These follow-ups should include a full clinical neurological assessment and annual bacteriological examination of skin smears for the first two years, and subsequently as necessary. New skin and nerve lesions occurring after MDT are most likely to be reactions and should be investigated appropriately in consultation with a Consultant Advisor in Leprosy, and will usually need skin biopsy.

8.5.5 Dead leprosy bacilli may be detected in decreasing numbers for over 5 years in multibacillary patients after commencement of treatment, and immunological reactions may occur for at least as long.

8.6 Relapse
8.6.1 Relapse rates following standard MDT are very low: of the order of 1 per 100 person years, and not over 3 per 100 person years.

8.6.2 In paucibacillary leprosy, it is often difficult to distinguish between a late immunological reaction and an early relapse. If suspicious lesions are detected or there is evidence of deteriorating nerve function, either during or after the period of surveillance, it is recommended that the patient is urgently referred to a Consultant Advisor in Leprosy.

8.6.3 When any multibacillary patient who has completed treatment with standard WHO MDT shows clinical and/or bacteriological signs of relapse, it is recommended that a biopsy is performed and the patient reviewed by a Consultant Advisor in Leprosy.

8.7 Drug resistance
8.7.1 The WHO introduced MDT because of the rising incidence of both primary and secondary dapsone resistances. Since its introduction, no new drug resistances have emerged during treatment.

8.8 Nerve damage at diagnosis
8.8.1 Between 30-60% of patients will have nerve damage at diagnosis. It is important that new nerve damage should be checked for because new nerve damage is more likely to improve with steroid treatment.

8.8.2 Nerve damage is detected by testing the motor function of the small muscles of the eyes, hands and feet and testing sensory function in the areas supplied by the ulnar, median and posterior tibial nerves. A Consultant Advisor in Leprosy should carry out this investigation. Appendix 2 shows the muscles and nerves that should be tested and the sensory points to be assessed. Sensation should be tested using Semmes Weinstein monofilaments (obtainable from The Hospital for Tropical Diseases). Nerve function should be tested every month to detect new loss.

8.8.3 If nerve function loss has been present for less than six months, a 24 week course of steroids should be started.
9.0 Complications

9.1 Reactions

9.1.1 Reactions are immune mediated complications of leprosy that can occur before, during or after treatment. There are three types of reaction:

*Type 1:* Erythema and oedema of skin lesions and/or acute neuritis.

*Neuritis:* Acute loss of peripheral nerve function.

*Type 2:* Erythema nodosum leprosum (ENL). Crops of tender erythematous skin lesions accompanied by systemic manifestations such as fever, malaise, neuritis, bone pain, orchitis, or iritis.

9.1.2 If a patient develops signs of a reaction, they should immediately contact the Consultant Advisor in Leprosy to be seen within 24 hours.

9.1.3 Most reactions require rapid treatment with corticosteroids to prevent nerve damage. Thalidomide may be needed to control erythema nodosum leprosum.

9.1.4 Nerve function should be monitored monthly during MDT to detect any new nerve damage. Patients with nerve damage at diagnosis are at highest risk of developing new nerve damage. The peak time for this is during the first three months of MDT.

9.2 Management of complications secondary to nerve damage

9.2.1 Education of patients with motor or sensory deficits helps to prevent much of the damage which results from unappreciated trauma. Patients with anaesthetic feet must wear well-fitting shoes with an appropriate microcellular rubber insole. Judicious physiotherapy helps to maintain muscle power and preserve useful function. Regular chiropody reduces the likelihood of ulceration developing in an anaesthetic foot. Patients must be told to report immediately any new symptoms, especially pain, weakness or altered sensation, bruising or the appearance of a new ulcer.

9.2.2 Established deformities of hands, feet or face resulting from peripheral nerve damage may require specialised care including splints, prostheses and reconstructive surgery with suitable pre- and post-operative physiotherapy. The help of an orthopaedic surgeon skilled in reconstructive surgery in leprosy should be enlisted; the Consultant Advisor in Leprosy at the Hospital for Tropical Diseases will advise practitioners if necessary.

9.2.3 Patients suffering from lepromatous or borderline-lepromatous leprosy are at risk of developing an iridocyclitis often of insidious and painless onset. These patients should be examined regularly by an ophthalmologist.

10.0 Admission to hospital

10.1 Most patients with newly diagnosed leprosy can be treated as out-patients without danger to themselves or others.

10.2 Hospital admission may also be indicated for medical or other reasons, including the management of immunological reactions, the care of plantar ulcers or burns or secondary infections, and for reconstructive surgery.
10.3 Any intercurrent surgical intervention, accident or other form of stress may precipitate an immunological reaction.

10.4 Section 2.12 describes infection control precautions required in hospital or health care settings.

11.0 Prevention and control of leprosy in the United Kingdom

11.1 The most important measures in the control of leprosy are to identify cases as early as possible and to ensure that adequate treatment is taken for the required period of time.

11.2 Examination of contacts

11.2.1 Close (i.e. household) contacts of all patients with leprosy should be traced and examined by a Consultant Advisor in Leprosy as they may have had a common exposure. Household contacts of patients with lepromatous leprosy are also examined because of their exposure to infection from the index case. Children are at increased risk.

11.2.2 The whole skin should be examined in a good light by a Consultant Advisor in Leprosy or their delegate. Changes in the skin may appear at any time from two to five years after exposure.

11.3 BCG

11.3.1 Several well-designed trials show that BCG enhances any natural resistance to infection with the leprosy bacillus. For this reason, any child or young adult under 16 years who has been a household contact of a patient with leprosy should be offered BCG if they have not already had it.

11.4 Chemoprophylaxis

11.4.1 Single dose rifampicin for chemoprophylaxis may be considered in certain circumstances for contacts of a case with multibacillary leprosy. Advice should be sought from the Consultant Advisor in Leprosy.

11.5 Control

11.5.1 Responsibility for the control of leprosy rests with the local CCDC. The CCDC should liaise with the consultant in charge of the patient, and if necessary take advice on the public health aspects of management from the Consultant Advisor in Leprosy and Consultant Epidemiologist at PHE, Tuberculosis Surveillance Section, Colindale. Box 3 summarises the role of the CCDC in the prevention and control of leprosy.

11.6 Health education

11.6.1 Misunderstandings and irrational fears about leprosy are common in the community. The following facts about leprosy may be useful in talking to patients and their relatives:

Leprosy is a curable disease caused by an easily identifiable bacterium.

It is rare to catch leprosy from another member of the family (the last reported case in the United Kingdom was in 1954).

If leprosy is treated early and properly, disabilities can usually be prevented; treatment must be taken as prescribed and any difficulty with treatment reported to the doctor.
Leprosy is slow to develop and takes a considerable time to treat.

Leprosy affects different people in different ways. After the start of treatment, reactions to dead bacilli can occur and cause inflammation, which may need special treatment. Any new symptoms or concerns should be reported to the doctor immediately without waiting for the next planned appointment.

If loss of sensation or deformities in the skin have occurred, much can be done to prevent further damage. The patient (and his/her relatives) should be taught how to care for their skin, hands or feet to protect them and should be referred to a physiotherapist skilled in the management of paralytic deformities and anaesthetic limbs or an orthopaedic surgeon with similar skills.

Patients with leprosy can normally live at home, continue normal family life, work, attend hospital out-patients or be admitted to a general hospital without danger to others.

12.0 Useful websites

The International Federation of Anti-Leprosy Associations

www.ilep.org.uk/
www.ilep.org.uk/library-resources/ilep-publications/english/
www.leprosy-information.org/

The Leprosy Mission

www.leprosymission.org.uk/
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Available at: [www.hpa.org.uk/cdph/issues/CDPHvol2/no2/surv.pdf](http://www.hpa.org.uk/cdph/issues/CDPHvol2/no2/surv.pdf) [Accessed 22 June 2012]


Appendix 1

The Panel of Leprosy Opinion

The membership of the Panel of Leprosy Opinion is described below. The Panel of Leprosy Opinion meets once every 2 years to: consider the local and global epidemiology of leprosy; consider changes in drug treatment, diagnostic and treatment services in the light of new research; discuss potential areas for future research; and raise awareness among relevant specialties e.g. dermatology and neurology, through teaching and training. The panel formally reports to the PHE Respiratory Infections Programme Board.

Membership of Panel of Leprosy opinion:

Professor Diana Lockwood, Consultant Leprologist and Consultant Advisor in Leprosy, Hospital of Tropical Diseases and London School of Tropical Medicine and Hygiene

Dr Nick Beeching, Consultant Advisor in Leprosy, Liverpool School of Tropical Medicine and Royal Liverpool University Hospital

Dr Christopher Ellis, Consultant Advisor in Leprosy, Birmingham Heartlands Hospital

Dr Steve Walker, Consultant Dermatologist, London School of Tropical Medicine and Hygiene

Dr Hadi Manji, Consultant Neurologist, The National Hospital for Neurology and Neurosurgery, London and the Ipswich Hospital

Dr Mark Bailey, Consultant in Infectious Diseases, Birmingham Heartlands Hospital

Professor Neil French, Consultant in Infectious Diseases, Royal Liverpool University Hospital and University of Liverpool


Dr Simon Cathcart, Consultant in Health Protection, North East & North Central Health Protection Team, London

Patient representative: Mary Tyler, English foreign language editor,
maryktyler@btinternet.com
Appendix 2

Notes for Completing Leprosy Neurological Assessment

1. Nerve palpation
   - Note thickening and tenderness
   - Ulnar, Median, Radial Cutaneous, Lateral Popiteal, Posterior Tibial

2. Nerve function
   Use MRC Grading System:

   **Muscle Assessment**

   **Modified 5-point MRC scale for muscle strength scoring**

<table>
<thead>
<tr>
<th>Hands and feet</th>
<th>MRC grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full ROM(^1), full resistance</td>
<td>5</td>
</tr>
<tr>
<td>Full ROM(^1), reduced resistance</td>
<td>4</td>
</tr>
<tr>
<td>Full ROM(^1), no resistance</td>
<td>3</td>
</tr>
<tr>
<td>Reduced ROM(^1), some joint movement</td>
<td>2</td>
</tr>
<tr>
<td>Flicker only</td>
<td>1</td>
</tr>
<tr>
<td>Full paralysis</td>
<td>0</td>
</tr>
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</table>

\(^1\)ROM: range of movement
\(^2\)In addition, eyelid gap in mm is measured and recorded

**Movements and muscles tested**

<table>
<thead>
<tr>
<th>Nerve</th>
<th>Movement</th>
<th>Muscle / muscle group</th>
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</thead>
<tbody>
<tr>
<td>Ulnar</td>
<td>Little finger abduction</td>
<td>Abductor digiti minimi</td>
</tr>
<tr>
<td>Ulnar</td>
<td>Index finger abduction</td>
<td>1st dorsal interosseos</td>
</tr>
<tr>
<td>Median</td>
<td>Thumb abduction</td>
<td>Abductor pollicis brevis</td>
</tr>
<tr>
<td>Radial</td>
<td>Wrist extension</td>
<td>Wrist extensors</td>
</tr>
<tr>
<td>Lateral popliteal</td>
<td>Foot dorsiflexion</td>
<td>Foot dorsiflexors</td>
</tr>
<tr>
<td>Lateral popliteal</td>
<td>Extension big toe</td>
<td>Extensor hallucis longus</td>
</tr>
<tr>
<td>Lateral popliteal</td>
<td>Toe fanning</td>
<td>Intrinsic muscles of the foot</td>
</tr>
<tr>
<td>Facial</td>
<td>Closes eyes (strong and gentle closure tested)</td>
<td>Orbicularis oculi</td>
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</tbody>
</table>
Sensory Testing

Use the nylon monofilaments on the marked sites on hands and feet

<table>
<thead>
<tr>
<th>Nylon colour</th>
<th>Approx. force</th>
<th>Interpretation</th>
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</thead>
<tbody>
<tr>
<td>Green</td>
<td>(0.05 gm)</td>
<td>Sensation within normal limits for the hand and foot</td>
</tr>
<tr>
<td>Blue</td>
<td>(0.2 gm)</td>
<td>Diminished light touch sensation in the hand with difficulty in the fine tactile discrimination. Within normal limits for the foot</td>
</tr>
<tr>
<td>Purple</td>
<td>(2.0 gm)</td>
<td>Diminished protective sensation in the hand but sufficient to prevent injury. Gross tactile discrimination, shape and temperature discrimination are difficult</td>
</tr>
<tr>
<td>Dark Red</td>
<td>(4.0 gm)</td>
<td>Loss of protective sensation for the hand, in some cases for the foot. Hands particularly vulnerable to injuries. Usually, loss of temperature discrimination</td>
</tr>
<tr>
<td>Orange</td>
<td>(10.0 gm)</td>
<td>Definite loss of protective sensation for the foot. Continues to feel deep pressure and pain in both hands and feet</td>
</tr>
<tr>
<td>Bright Red</td>
<td>(300.0 gm)</td>
<td>Able to feel deep pressure and pain</td>
</tr>
<tr>
<td>No response</td>
<td>(.....)</td>
<td>Loss of deep pressure sensation. Usually does not feel pain. Proprioceptive sensation persists</td>
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Complete Disability Record

C = clawed
= wound or open crack
= shortening level
# Appendix 3

## Neurological Assessment Form

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<thead>
<tr>
<th>Date</th>
<th>ADM</th>
<th>IDI</th>
<th>APB</th>
<th>DF</th>
<th>EHL</th>
<th>TF</th>
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<th>APB</th>
<th>DF</th>
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*Withdrawn August 2023*
Appendix 4

Microscopic Examination of Smears and Slit Skin Smears, and Diagnostic Skin Biopsy for Leprosy

1. Microscopic examination of slit skin smears:

   Smears are taken from the active edge of from one to four skin lesions, and from the earlobes.

   Slit skin smears should only be taken by a person experienced in the technique. Neuropathic ulcers of the extremities do not shed leprosy bacilli, although viable bacilli may be present in the discharges from ulcerating lesions of the proximal skin in untreated multibacillary leprosy.

2. Diagnostic skin biopsy

   The recommended procedure for skin biopsy for leprosy diagnosis is as follows:

   i. Select a representative lesion (if necessary two lesions) and take the biopsy from the most active part; normal skin need not be included. In tuberculoid (paucibacillary) leprosy, the biopsy should be from the active edge of the lesion.

   ii. The incision should be about 1.5cm x 0.5cm. Cut vertically down to the subcutaneous fat and include some fat. Alternatively, a 5mm or 6mm punch biopsy may be used.

   iii. Excise the specimen with care and place it in ordinary 10% formal saline (buffered or unbuffered). Record the biopsy site on the label of the bottle.
## Reference Laboratories for Testing of Specimens

<table>
<thead>
<tr>
<th>Reference Laboratory</th>
<th>Tests Performed</th>
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<tbody>
<tr>
<td>Hospital for Tropical Diseases</td>
<td>Microscopy of slit skin smears (Dept. of Microbiology)</td>
</tr>
<tr>
<td>University College London Hospital</td>
<td></td>
</tr>
<tr>
<td>Mortimer Market Centre</td>
<td></td>
</tr>
<tr>
<td>Capper Street</td>
<td></td>
</tr>
<tr>
<td>London</td>
<td></td>
</tr>
<tr>
<td>WC1E 6JB</td>
<td></td>
</tr>
<tr>
<td>Tel: 0845 155 5000</td>
<td></td>
</tr>
<tr>
<td>Liverpool School of Tropical Medicine</td>
<td>Microscopy of slit skin smears.</td>
</tr>
<tr>
<td>Pembroke Place</td>
<td></td>
</tr>
<tr>
<td>Liverpool</td>
<td></td>
</tr>
<tr>
<td>Merseyside</td>
<td></td>
</tr>
<tr>
<td>L3 5QA</td>
<td></td>
</tr>
<tr>
<td>Tel: 0151 705 3220</td>
<td></td>
</tr>
<tr>
<td>Histopathology Laboratory</td>
<td>Histopathological review (Dr Ula Mahadeva)</td>
</tr>
<tr>
<td>St Thomas’s Hospital</td>
<td></td>
</tr>
<tr>
<td>Lambeth Palace Road</td>
<td></td>
</tr>
<tr>
<td>London</td>
<td></td>
</tr>
<tr>
<td>SE1 7EH</td>
<td></td>
</tr>
<tr>
<td>Tel: 0207 188 2934</td>
<td></td>
</tr>
<tr>
<td>Email: <a href="mailto:Ula.Mahadeva@gstt.nhs.uk">Ula.Mahadeva@gstt.nhs.uk</a></td>
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Appendix 6

Contact Details of Consultant Advisors in Leprosy, National Leprosy Centres and Consultant Epidemiologists

<table>
<thead>
<tr>
<th>Consultant Advisor in Leprosy</th>
<th>Address of National Leprosy Centre</th>
<th>Telephone/Email/Fax</th>
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</thead>
<tbody>
<tr>
<td>Professor Diana Lockwood</td>
<td>Hospital for Tropical Diseases Mortimer Market Centre Capper Street London WC1E 6JB</td>
<td>Tel: 0203 456 7890 Ext. 75972 Fax: 0203 447 9761 Email: <a href="mailto:Diana.Lockwood@lshtm.ac.uk">Diana.Lockwood@lshtm.ac.uk</a></td>
</tr>
<tr>
<td>Dr Nick Beeching</td>
<td>Tropical and Infectious Disease Unit Royal Liverpool University Hospital Liverpool L7 8XP</td>
<td>Tel: 0151 706 3835 Email: <a href="mailto:Nicholas.Beeching@rlbuht.nhs.uk">Nicholas.Beeching@rlbuht.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Christopher J. Ellis</td>
<td>Birmingham Heartlands Hospital Bordesley Green East Birmingham B9 5SS</td>
<td>Tel: 0121 424 0358 Email: <a href="mailto:christopher.ellis@heartofengland.nhs.uk">christopher.ellis@heartofengland.nhs.uk</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultant Advisor in Leprosy</th>
<th>Address of National Leprosy Centre</th>
<th>Telephone/Email/Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor John Watson</td>
<td>61 Colindale Avenue Colindale London NW9 5EQ</td>
<td>Tel: 020 8327 7481 Email: <a href="mailto:John.Watson@phe.gov.uk">John.Watson@phe.gov.uk</a></td>
</tr>
<tr>
<td>Professor Ibrahim Abubakar</td>
<td>As above</td>
<td>Tel: 020 8327 7144 Email: <a href="mailto:Ibrahim.Abubakar@phe.gov.uk">Ibrahim.Abubakar@phe.gov.uk</a></td>
</tr>
<tr>
<td>TB Section at PHE</td>
<td>As above</td>
<td>Tel: 020 8327 6427 Email: <a href="mailto:tbsection@phe.gov.uk">tbsection@phe.gov.uk</a></td>
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Appendix 7

IN STRICT MEDICAL CONFIDENCE
PHE Colindale
QUESTIONNAIRE FOR LEPROSY CASES

Please mark the appropriate space with an "X", or write in the space provided.

Last name: NHS No:
First name: Local Authority:
Date of Birth: Consultant:
Address: Hospital:

1. Diagnosis of Leprosy (please mark appropriate space)
   New diagnosis of leprosy in the UK __ Relapse ___
   New to the UK but already on treatment ___
   New to UK, diagnosed abroad, but not on treatment ___

2. Sex:

3. Ethnic Group: (please mark appropriate space)
   White __ Indian __ Chinese ___
   Black Caribbean __ Pakistani __ Mixed/Other ___
   Black African __ Bangladeshi __ Not known ___
   Black other ___

4. Country of Birth:

5. Year of entry to the UK:

6. Country of acquisition (give details):

7. Date symptoms started: ......... 5. Date of diagnosis: .........

8. Type of Leprosy: (please mark appropriate space)
   Lepromatous __ Tuberculoid ___
   Borderline lepromatous __ Indeterminate ___
   Mid-borderline __ Neural ___
   Borderline tuberculoid __ Other or not known ___
   Multi-bacillary __ Pauci-bacillary ___

9. Does the patient have grade 2 disabilities due to leprosy? Yes __ No ___

10. Is the patient already on MDT? Yes __ No ___

11. Has contact tracing been performed? Yes __ No ___

12. Has the patient been referred to a Consultant Advisor in Leprosy Yes __ No ___

Name of doctor completing form: ...........................................................................................................
Address for Correspondence: ...................................................................................................................
........................................................................................................ Date ___/___/___

Please return to: Respiratory Department, Public Health England, 61 Colindale Ave, London NW9 5EQ or email to: tbsection@phe.gov.uk

For HPS Colindale use: Date Entered _____/_____/____ Initials _____

Withdrawn August 2023
Appendix 8

Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BB</td>
<td>Borderline leprosy</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacille Calmette Guerin</td>
</tr>
<tr>
<td>BI</td>
<td>Bacterial Index</td>
</tr>
<tr>
<td>BL</td>
<td>Borderline lepromatous leprosy</td>
</tr>
<tr>
<td>BT</td>
<td>Borderline tuberculoid leprosy</td>
</tr>
<tr>
<td>CCDC</td>
<td>Consultant in Communicable Disease Control</td>
</tr>
<tr>
<td>DOT</td>
<td>Directly Observed Therapy</td>
</tr>
<tr>
<td>ENL</td>
<td>Erythema Nodosum Leprosum</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>HPT</td>
<td>Health Protection Team</td>
</tr>
<tr>
<td>HTD</td>
<td>Hospital for Tropical Diseases</td>
</tr>
<tr>
<td>LL</td>
<td>Lepromatous leprosy</td>
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<tr>
<td>MDT</td>
<td>Multidrug therapy</td>
</tr>
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<td>TT</td>
<td>Tuberculoid leprosy</td>
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<tr>
<td>UK</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Withdrawn August 2023