Name of document: Procedures for the prevention and management of Tuberculosis

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Executive Lead: Dr Sarah Taylor

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- Infection Control Team
- Consultant Physicians
- Child Health Team
- Control of Infection Committee

Date | Version | Group | Reason | Outcome
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12.14 | 3.0 | ICT | Comment | Flowchart included (isolation decisions for staff, p5)

Examples of reasons for presenting to the group:
- Professional input required re: content (PI)
- Professional opinion on content (PO)
- General comments/suggestions (C/S)
- For information only (FIO)

Examples of outcomes following meeting:
- Significant changes to content required – refer to Executive Lead for guidance (SC)
- To amend content & re-submit to group (AC&R)
- For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
- Recommend proceeding to next stage (PRO)
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<tr>
<td>July 2012</td>
<td>Section on epidemiology updated and changes to notification procedures</td>
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<td>Update of diagnostic procedures</td>
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<td>July 2012</td>
<td>Chapter on Contact tracing completely revised in line with <em>Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland 2009</em></td>
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<td>Chapter on management revised in line with <em>Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland 2009</em></td>
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<td>Adherence Risk Assessment tool added</td>
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<td>July 2012</td>
<td>Section on audit added</td>
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<tr>
<td>July 2012</td>
<td>Removed copies of lab form and ESMI form from Appendices</td>
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<tr>
<td>July 2012</td>
<td>Added links to other sources of information for professionals and patients to appendices (Appendices 1 and 4)</td>
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<td>Added local documentation for BCG Vaccination and Mantoux testing (Appendix 5)</td>
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<td>Revised local documentation for contact tracing (Appendix 6)</td>
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<td>Revised Useful Contact Appendix (Appendix 7)</td>
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<td>All Appendices fully revised and updated</td>
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Shetland NHS Board

Procedures for the Prevention and Management of Tuberculosis

Approved by: ICT May 2015
Review Date: May 2018
Isolation decisions for staff when patients admitted to Gilbert Bain Hospital with suspected respiratory Tuberculosis

Patient admitted via GP or Accident and Emergency with respiratory TB

Admit to a single room on Ward 3

Sputum smear positive? (1 or more from 3 samples)

Yes

No

Risk for MDR TB?

Yes

No

Negative pressure room mandatory* so transfer based on clinical decision

Negative pressure room mandatory* so transfer based on clinical decision

Single room on Ward 3 with restrictions

Treatment of patients with infectious MDRTB should be carried out only in hospitals with adequate isolation facilities, and therapy must be undertaken only by specialist physicians. For Shetland patients, this necessitates being transferred to Edinburgh. Patients with suspected infectious MDRTB who are admitted to Gilbert Bain Hospital Hospital via their GP or A&E should be admitted to the single room (with separate adjoining room) in Ward 3.
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A. BACKGROUND

Tuberculosis (TB) is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. The organism is related to a number of different bacteria which together are called the Mycobacterium tuberculosis complex. It typically affects the lungs (pulmonary TB) but can affect other sites as well (extra-pulmonary TB). The disease is spread in the air when people who are sick with pulmonary TB expel bacteria, for example by coughing. In general, a relatively small proportion of people infected with *M. tuberculosis* will go on to develop TB disease; however, the probability of developing TB is much higher among people infected with the human immune-deficiency virus (HIV). TB is also more common among men than women, and affects mostly adults in the economically productive age groups; around two-thirds of cases are estimated to occur among people aged 15–59 years. Tuberculosis (TB) is a global issue and it is estimated that TB continues to kill approximately 1.2-1.5 million people worldwide each year.

TB can be active or latent. Active TB is when the person is symptomatic and infectious; it becomes a slowly progressive disease which is likely to be fatal if left untreated. An initial TB infection may also become a latent TB infection, where the infected person feels completely well while the bacteria remain alive but dormant in their body. A latent TB infection may become active later in life if, for example, the person’s immune system is weakened (by age, other diseases or medical treatments). In this case, it progresses to the active TB disease.

Treatment for TB requires a course of a combination of antibiotics, which a patient must take for at least six months. *M. tuberculosis* can become resistant to these antibiotics this is known as multi-drug resistant TB (MDR-TB). More recently, some TB bacteria have developed many more antibiotic resistances; this is known as extensively drug resistant TB (XDR-TB) and is extremely difficult to treat. Co-infection with TB and HIV is a particular issue, as the two conditions interact leading to poorer outcomes. Treatment becomes very complicated, with several different drugs required.

1 Changes to Version 1.0 of these procedures

The first version of this document was produced in 2008. This revised version incorporates two recent Scottish documents and guidance from the Chief Medical Officer:

- *Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland* (based on the NICE guidelines used in England) which was published by Health Protection Scotland in 2009.¹

The main changes to these procedures as a result are:

- Update of the epidemiology to reflect the rising incidence of TB in Scotland.
- Changes to notification procedures
- Update on diagnostic methods
- Changes to contact tracing and screening procedures
Changes to guidance on management
Changes to new entrant screening procedures
Introduction of audit
Updation of local documentation for contact tracing
Update of local documentation for Mantoux testing and BCG Vaccination
Emphasis on multidisciplinary team approaches for TB prevention and control amongst high risk groups, specifically new entrants and people with alcohol problems, and promotion of neonatal BCG vaccination.

This procedure includes a local update in line with the TB Action Plan Annual Report which set out recommendations covering four broad areas:
• effective laboratory services and diagnostic tools;
• effective clinical services;
• effective surveillance;
• effective public health services.
## 2 WHO definitions

<table>
<thead>
<tr>
<th>Definite TB case</th>
<th>A patient with <em>Mycobacterium tuberculosis</em> complex identified from a clinical specimen, either by culture or by a newer method such as molecular line probe assay. In countries that lack laboratory capacity to routinely identify <em>M. tuberculosis</em>, a pulmonary case with one or more initial sputum specimens positive for acid-fast bacilli (AFB) is also considered to be a ‘definite’ case, provided that there is functional external quality assurance (EQA) with blind rechecking.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB case</td>
<td>A definite case of TB (defined above) or one in which a health worker (clinician or other medical practitioner) has diagnosed TB and decided to treat the patient with a full course of TB treatment.</td>
</tr>
<tr>
<td>Pulmonary Tuberculosis</td>
<td>Pulmonary (or respiratory) tuberculosis is a TB infection involving the lung parenchyma. For contact tracing purposes, pulmonary TB is divided into:</td>
</tr>
<tr>
<td></td>
<td><strong>Smear positive:</strong> A patient with one or more initial sputum smear examinations (direct smear microscopy) AFB-positive; or one sputum examination AFB+ and radiographic abnormalities consistent with active pulmonary TB as determined by a clinician. Smear-positive cases are the most infectious and thus of the highest priority from a public health perspective.</td>
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<td><strong>Smear negative:</strong> A patient with pulmonary TB not meeting the above criteria for smear-positive disease. Diagnostic criteria should include: at least two sputum smear examinations negative for AFB; radiographic abnormalities consistent with active pulmonary TB; no response to a course of broad-spectrum antibiotics (except in a patient for whom there is laboratory confirmation or strong clinical evidence of HIV infection); and a decision by a clinician to treat with a full course of anti-TB chemotherapy. A patient with positive culture but negative AFB sputum examinations is also a smear-negative case of pulmonary TB.</td>
</tr>
<tr>
<td>Non-pulmonary or extra-pulmonary Tuberculosis</td>
<td>Non-pulmonary (or non-respiratory) tuberculosis is a TB infection of any other part of the body, provided there is also no TB infection of the lungs as described above. Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extrapulmonary disease, followed by a decision by a clinician to treat with a full course of anti-TB chemotherapy. A patient in whom both pulmonary and extrapulmonary TB has been diagnosed should be classified as a pulmonary case.</td>
</tr>
<tr>
<td>Multi-drug resistant TB (MDR-TB)</td>
<td>TB that is resistant to two first-line drugs: isoniazid and rifampicin.</td>
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3 Epidemiology

3.1 Epidemiology of tuberculosis in Shetland

Although many Shetlanders will remember their parents and neighbours being affected by TB, it is now an infrequent infection. This reflects the situation in the rest of Scotland (See Section 2.2). In 1948 in Shetland there were 24 new cases of TB notified, 187 people were known to be suffering from TB, and there were 16 deaths due to TB. At that time TB patients were treated in the Zetland County Sanatorium. Over the past 20 years there have been only one or two cases of TB each year in Shetland, (except for 1994, when there was an outbreak on a ship.)

Table 2 Tuberculosis Notifications in Shetland 1993-2012

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<th>Year</th>
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<tr>
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<td>4</td>
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<tr>
<td>2014</td>
<td>1</td>
</tr>
</tbody>
</table>

3.2 Epidemiology of tuberculosis in Scotland

In the 1850s tuberculosis was one of the most common causes of death in Scotland with a recorded mortality rate of about 400 per 100,000 in 1850. Notification of TB became statutory in 1914 and, as with mortality rates, notification rates fell progressively apart from
the documented increased rates as a result of both world wars. The early 1950s saw the establishment of effective chemotherapy for tuberculosis and an acceleration of the rate of decline of mortality and notifications from tuberculosis in Scotland. This decline continued until the mid 1980s, when it plateaued. Scotland then had a relatively low and stable incidence of TB, unlike other parts of the UK and Europe where it had been increasing. However, the numbers of cases in Scotland started to increase in 2005, although still at lower levels than other parts of the UK. Although the rates in the past two years have dropped, there is a mean increasing 5 year trend from 7.8 per 100,000 in 2008, to 8.8 per 100,000 in 2012.³

3.3 Scale of the problem

National surveillance data on tuberculosis provide information on the numbers, distribution and characteristics of tuberculosis cases, drug resistance patterns and treatment outcomes. Tuberculosis surveillance was introduced in Scotland in 2000 through the Enhanced Surveillance of Mycobacterial Infections (ESMI) scheme. The most recent figures reported below are for 2012.⁴

In 2012 the ESMI scheme received 408 provisional notifications of tuberculosis, an incidence of 7.7 cases per 100,000. This was an decrease of 8.9% in the number of cases and a decrease of 9.4% in the annual incidence compared with 2011. This represents a continued decrease in numbers of TB cases since 2010 although it is not possible to tell if this is the start of a downward trend.

In 2012, as previous years, around half the cases (198) were from Glasgow and surrounding areas (16.3 cases per 100,000 population).

The highest incidence continued to be observed in males aged 25-34 years (16.9 cases per 100,000 population). The rate of tuberculosis among children under five years of age (an indicator of recent tuberculosis transmission) decreased from 4.4 per 100,000 (11 children) in 2011 to 1.4 cases per 100,000 (4 children) in 2012 suggesting that transmission in Scotland may be declining.

The proportion of tuberculosis cases born outside the UK was 56.2% in 2012 continuing the upward trend observed since 2000. Over 60% non-UK born cases reported to ESMI originated from India and Pakistan, which have high incidences of tuberculosis.

28.6% of tuberculosis cases reported in 2012 had a known risk factor, with 18 individuals having more than one risk factor. Alcohol misuse, immunosuppression, working in healthcare, being a refugee or homeless continue to be the most commonly reported risk factors in Scotland.
Detailed analysis of this data is available in the HPS annual report of ESMI data published in September 2014

### 3.4 Worldwide epidemiology

TB is a major global health problem. In 1993, the World Health Organisation (WHO) declared TB a global public health emergency, at a time when an estimated 7-8 million cases and 1.3-1.6 million deaths occurred each year.

In 2012, an estimated 8.6 million people developed TB and 1.3 million died from the disease (including 320 000 deaths among HIV-positive people). An estimated 1.1 million (13%) of the 8.6 million people who developed TB in 2012 were HIV-positive. About 75% of these cases were in the African Region. Globally in 2012, an estimated 450 000 people developed MDR-TB and there were an estimated 170 000 deaths from MDR-TB.

The majority of cases worldwide in 2012 were in the South-East Asia (29%), African (27%) and Western Pacific (19%) regions. India and China alone accounted for 26% and 12% of total cases, respectively. The TB incidence rate at country level ranges substantially, with around 1000 or more cases per 100 000 people in South Africa and Swaziland, and fewer than 10 per 100 000 population in parts of the Americas, several countries in Western Europe, Japan, Australia and New Zealand.

The WHO has set targets for tackling TB worldwide. The 2015 global targets for reductions in disease burden are that TB incidence should be falling and that prevalence and death rates should be halved compared with their levels in 1990. The Stop TB Strategy was launched in 2006 as an enhancement of the preceding DOTS strategy. The other components of the Stop TB Strategy highlight the need to address the challenge of drug-resistant TB and the co-epidemics of TB and HIV; the importance of engaging all care providers in TB care and control, and of them contributing to strengthening health systems: the role of communities and people with TB; and the role of research in developing new diagnostics, drugs and vaccines.

Globally by 2012, the TB mortality rate had been reduced by 45% since 1990 and so we are on track to reduce the target to reduce deaths by 50% by 2015. However, although
the level of active TB disease in the community (prevalence) has fallen by 37% globally since 1990, the target of a 50% reduction by 2015 is not expected to be achieved.

### 3.5 High risk groups in Shetland?

In Shetland the numbers of individuals diagnosed with tuberculosis is small. High risk individuals within the population are identified via new entrant screening, ante-natally or through routine services. An identified gap locally is linking the multi-disciplinary team approach for migrants and new entrant screening from high risk countries, those identified as problem alcohol drinkers and neonatal BCG uptake through the auditing of local services.
B. SURVEILLANCE

4 Surveillance

4.1 Surveillance mechanisms

Surveillance consists of the continuing scrutiny of the occurrence and spread of a disease to enable and inform public health action which is appropriate, timely and effective.

At a local level, surveillance is important to identify potential sources and outbreaks of tuberculosis, and to allow adequate contact tracing. It is also valuable in establishing the level of immunity and BCG vaccine uptake in a community. In addition, good surveillance allows valuable resources to be coordinated properly.

At a national level, surveillance is particularly important in identifying trends which are not obvious in smaller populations, such as Shetland. Problems can be identified in particular sub groups of the population, such as the elderly or particular ethnic groups. The emergence of antibiotic-resistant tuberculosis strains can also be monitored. Surveillance data are also important in formulating national policies.

The current paper-based enhanced surveillance system for TB provides detailed retrospective information on cases. This system is no longer fit for purpose and not in line with international best practice. Scotland requires a surveillance system that provides real time functionality and that can link to case and, liaise with other relevant networks and cluster management.

A pilot of the current PHE surveillance system has been carried out in NHS Lothian but PHE is developing an updated system expected to be ready in 2015. The national TB surveillance and SHPIMS groups are exploring the options to include a TB functionality in the SHPIMS system. The TB surveillance group has already submitted a paper to the Scottish Government Public Health Portfolio Management Group. This submission will be updated in light of the development of SHPIMS and the PHE system.

4.2 Notifications

Doctors have a compulsory duty to notify all forms of tuberculosis (pulmonary and extra-pulmonary) under the Public Health Etc. (Scotland) Act 2008. The doctor making or suspecting the diagnosis is legally responsible for notification. **Suspected cases must be notified early on the basis of clinical suspicion rather than waiting for laboratory confirmation. A decision to commence treatment for TB should trigger notification.**

All suspected and/or confirmed cases of pulmonary and non-pulmonary TB must be notified by the clinician to the Public Health Department within three days via Scottish Care Information (SCI) Gateway.

Currently TB is subject to enhanced surveillance in Scotland through the Enhanced Surveillance of Mycobacterial Infections Scheme (ESMI) so in addition ESMI forms A, B and C must be completed and signed off by the clinician.¹

---

¹ The TB Action Plan for Scotland notes that this scheme is now out of date, and a new surveillance system as noted above is being considered.
4.3 Laboratory Reporting

At present only 50-60% of cases nationally are confirmed bacteriologically. This is often because no samples (or inappropriate samples) are sent to the laboratory. It is important that clinicians are encouraged to send fresh samples of tissue, body fluids etc., and to liaise closely with laboratory staff, so that as many cases as possible are confirmed bacteriologically.

All specimens from patients with suspected TB in Shetland are sent by the Gilbert Bain laboratory to Aberdeen Microbiology laboratory for microscopy. The Aberdeen laboratory then sends the specimens to the Scottish Mycobacteria Reference Laboratory (SMRL) in Edinburgh for culture, identification and sensitivity testing.

4.4 The Scottish Mycobacteria Reference Laboratory

The SMRL undertakes the identification (including molecular characterization) and susceptibility testing of all mycobacterial isolates in Scotland, both for clinical management and for epidemiological purposes. The laboratory reports all identification results weekly to Health Protection Scotland (HPS), and provides regular epidemiological information as requested, and in the SMRL Annual Report. By means of a confidential reporting system, the laboratory is able to keep statistics of HIV-associated mycobacterial infections.

Cultures sent to the laboratory for testing should be accompanied by the relevant form, duly completed (A copy is included for information (not copying) in Appendix 1). As much information as possible should be given, and is welcomed. The form can be obtained from SMRL, and SMRL must be informed by fax or telephone before cultures or specimens are sent.

The SMRL is able to provide a laboratory resource for joint clinical / laboratory and epidemiological studies, and provides advice on the laboratory diagnosis and antimicrobial therapy of TB (see Section 5). Advice is always available on Control of Infection aspects of TB.

4.5 Enhanced Surveillance of Mycobacterial Infections (ESMI) in Scotland

Scotland began enhanced TB surveillance in January 2000. This incorporates the European minimum data set, and allows continuous monitoring of numbers of cases, types of disease, and geographical distribution. It is administered by HPS under strict confidentiality conditions.

Notifications should be made using the ESMI form A (a copy is included for information as an appendix). These can be obtained by telephoning the Department of Public Health. Copies of the form should not be used, as they are produced in triplicate, and numbered. Written confirmation using ESMI form A must follow verbal notification as soon as possible. ESMI form B will be sent by the Public Health Specialist to the appropriate clinician once culture has been confirmed by the SMRL or 3 months after commencing treatment, whichever is sooner. ESMI form C will be sent to the clinician in charge of the patient’s care by HPS or the Public Health Specialist for completion 1 year after diagnosis. Copies of all these forms will be sent to Health Protection Scotland by the Public Health Department.
HPS produces an annual report on TB in Scotland using ESMI data, which is circulated to all Public Health Departments, clinicians and laboratories participating in the scheme. The data is also available to participating agencies at all times for ad hoc enquiries.

4.6 Dissemination of Information for Action

A single case of TB requires rapid public health action, in liaison with clinicians and laboratories, which is consistent with best practice; national surveillance of TB informs the strategic approach to the problem, identifies important trends in patterns of infection in the community, and allows tracking of cases across health board boundaries. There is a need for a clear and consistent flow of timely information between the key players to ensure that opportunities for health gain at a local and national level are not lost.
B. PREVENTION, DIAGNOSIS AND MANAGEMENT

5 Tuberculin Testing; IGRA testing and Vaccination

5.1 The rationale behind tuberculin testing

After first infection with tubercle bacilli, the body’s responses include development of hypersensitivity (allergy) to tuberculoproteins and also specific cell-mediated immunity. Subsequent contacts with tubercle bacilli incite a rapid response from primed lymphocytes. These collect around the site of invasion and produce tissue changes which inhibit the growth and dissemination of bacilli, and also destroy them.

While allergy and immunity develop together they are separate entities. The allergic element is demonstrable by the tuberculin test, which indicates whether or not the individual is hypersensitive. A patient not infected by tubercle bacilli in the past gives a negative response, or at the most a trivial non-specific one. With certain provisos (detailed below) an individual previously infected gives a positive result. The degree of hypersensitivity does not necessarily correlate with the extent of the subject’s immunity.

The tuberculin test can be of great value not only in diagnosis but also in epidemiological work, including the selection of subjects for BCG vaccination.

A tuberculin skin test must be carried out before BCG vaccination. The only exception to this rule is infants and children under the age of six years as described below. The test assesses the individuals’ sensitivity to tuberculin protein; a positive test implies past infection or past successful immunisation and such people should not be given BCG. Those with a strongly positive test may have active disease and must be referred to the TB Clinic in Aberdeen for further investigation and treatment as appropriate.

5.2 The tuberculin skin test

BCG may be given to infants and children under six years of age without prior tuberculin skin testing provided that:
- There are no general contraindications as detailed in the Green Book
- There is no history of residence or prolonged stay (>1 month) in a country with a TB incidence of 40/100,000 or greater
- There is no history of close contact with a known case of tuberculosis

Individuals older than six years of age should have tuberculin skin testing (TST) prior to vaccination to check for the presence of cell mediated immunity. If the skin test is positive this means that the individual has been previously exposed to mycobacterium, from previous infection (which may have been asymptomatic) or from previous BCG vaccination. False negatives can occur temporarily following viral infections such as measles or chickenpox which suppress the cell-mediated immune response and even after MMR vaccination.

There are two tuberculin skin tests: Mantoux and Heaf tests.\(^i\)

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\(^i\) The Heaf test is not now routinely used in UK because the necessary reagents and equipment are no longer available. It involves multiple intradermal inoculations and the result is usually ‘read’ after 5-7 days.
5.2.1 Mantoux test

Only the Mantoux test is now recommended for general use. It is essential that the correct method is used to ensure standardisation, and hence correct interpretation. The Mantoux is technically difficult to administer and read, but it is sensitive in expert hands and training in the correct procedures is essential.

The Mantoux test involves injecting tuberculin purified protein derivative (PPD) injected into the skin to assess an individual’s sensitivity to tuberculin protein. The greater the reaction, the more likely it is that an individual is infected or has active TB disease. The Mantoux test should be administered intradermally (sometimes referred to as intracutaneous administration) normally on the flexor surface of the left forearm at the junction of the upper third with the lower two-thirds.

The results should be read 48 to 72 hours after the test is taken, but a valid reading can usually be obtained up to 96 hours later. The transverse diameter of the area of induration at the injection site is measured with a ruler and the result recorded in millimetres. As several factors affect interpretation of the test, the size of the induration should be recorded and NOT just as a negative or positive result. The area of erythema is irrelevant.

There is some variability in the time at which the test develops its maximum response. The majority of tuberculin-sensitive subjects will be positive at the recommended time of reading. A few, however, may have their maximum response just before or after the standard time.

The interpretation of results is shown below.

<table>
<thead>
<tr>
<th>Diameter of induration</th>
<th>Positivity</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 6mm</td>
<td>Negative – no significant hypersensitivity to tuberculin protein</td>
<td>Previously unvaccinated individuals may be given BCG provided there are no contraindications</td>
</tr>
<tr>
<td>6mm or greater, but less than 15mm</td>
<td>Positive – hypersensitive to tuberculin protein</td>
<td>Should not be given BCG.* May be due to previous TB infection or BCG or exposure to non-tuberculous mycobacteria</td>
</tr>
<tr>
<td>15mm and above</td>
<td>Strongly positive – strongly hypersensitive to tuberculin protein</td>
<td>Suggests tuberculosis infection or disease. Should be referred for further investigation and supervision (which may include preventive chemotherapy)</td>
</tr>
</tbody>
</table>

*When Mantoux tests are being performed as part of an immunisation programme, no further action is required for people with a reaction in this range. In other contexts (e.g. new immigrant screening, contact-tracing programmes), where the subject has not previously been vaccinated with BCG, and taking account of the precise size of the reaction and the circumstances of the case, referral to a chest clinic may be indicated for further investigation.
5.2.2 Factors affecting the result of the tuberculin test

The reaction to tuberculin protein may be suppressed by the following:

- glandular fever
- viral infections in general, including those of the upper respiratory tract
- live viral vaccines (tuberculin testing should not be carried out within four weeks of having received a live viral vaccine)
- sarcoidosis
- corticosteroid therapy
- immunosuppression due to disease or treatment, including HIV infection.

Subjects who have a negative test but who may have had an upper respiratory tract or other viral infection at the time of testing or at the time of reading should be re-tested two to three weeks after clinical recovery before being given BCG. If a second tuberculin test is necessary it should be carried out on the other arm: repeat testing at one site may alter the reactivity either by hypo- or more often hyper-sensitising the skin, and a changed response may reflect local changes in skin sensitivity only.

If BCG is given to an individual who is positive on Mantoux testing, serious complications are unusual but a rapid Mantoux type of response may develop at the site of inoculation within 2-3 days of vaccination.

5.2.3 Storage and Use of Purified Protein Derivative (PPD)

The Mantoux test uses Purified Protein Derivative, which is obtained from Pharmacy in the Gilbert Bain Hospital. This is a heat-treated product derived from mycobacteria. All PPD must be stored between 2°C and 8°C (never frozen) and protected from light. Once an ampoule is opened its contents must be used within one hour and not retained beyond that session. PPD should be used within 30 minutes of being put in a syringe.

PPD is available as 2TU/0.1ml (for routine screening) and 10TU/0.1ml (for clinical diagnostic purposes)

5.2.4 Training

Staff in Shetland may attend training in Aberdeen with the Specialist TB nurse. This includes the opportunity to attend TB screening clinics for overseas students to gain experience.
5.3 IGRA TESTING

The recommendations for the use of Interferon Gamma Release Assays (IGRA) in this procedure are made on the basis of available evidence of the utility of the test and its cost in relation to tuberculin skin testing (TST). It is likely that further evidence will come to light as there is more experience with these tests and we recognise that the cost is likely to fall over time. There are several practical advantages to using IGRA and further review will be required to ensure that recommendations on the use of IGRA remain up to date. A review of the use of IGRA across Scotland will help provide evidence to inform future revisions of this guidance.

Interferon-Gamma Release Assays (IGRA) can aid in the swift diagnoses of Mycobacterium tuberculosis infection. NICE and HPA have published updated guidance on the IGRA test. Whilst work being considered by the Scottish Health Protection Network to inform guidelines on the use of IGRA in Scotland, Shetland patients undergoing IGRA testing will be done in consultation with NHS Grampian.

5.4 Vaccination

5.4.1 Bacillus Calmette-Guerin (BCG) Vaccine

BCG vaccine contains a live attenuated strain derived from Mycobacterium bovis. The vaccine gives good protection against M. tuberculosis; In British children, efficacy has been shown to be greater than 70%, with protection lasting for at least 15 years. It appears to be more effective at preventing TB meningitis in children, than pulmonary TB. There is little evidence regarding its use in adults over 16 years old. It is therefore no longer recommended in adults unless there are special occupational, ethnic or travel risks.

BCG vaccine was introduced for general use in Scotland in 1953. A national vaccination programme was started, aiming to vaccinate all children before they left school at the age of 13. This programme ran until 2004. Uptake was reasonably high, for example in 2002 89% of the target group in Shetland were vaccinated. In addition 8.6% were already tuberculin positive from either previous immunization or natural immunity, and therefore exempt from vaccination. This brought the total up to 97.6% coverage.

The programme was reviewed in the light of analysis of ESMI data by age and risk groups and in 2005 the UK vaccination programme changed from a population based programme to a selective programme, with only children and adults in specific high risk groups being offered the vaccination.

Adverse reactions to BCG vaccine are rare if attention is paid to the proper selection of subjects and to the techniques for both testing and vaccinating. **Staff administering BCG vaccinations therefore need specific training in the technique.** It is recommended that the BCG vaccine should be administered intradermally. At present in Shetland, BCGs are given by a small number of staff in the Child Health Department and Occupational Health Department along with some hospital doctors and GPs who are confident in the technique.

5.4.2 Groups recommended for BCG vaccination (UK guidelines)

In Britain routine vaccination for teenagers at school was discontinued with a new targeted BCG programme brought in from 1\textsuperscript{st} September of that year. \textsuperscript{4}
Immunisation should now be offered to:

- All infants (aged 0-12 months) living in areas of the UK where the incidence of TB is 40/100,000 or greater.
- All infants (aged 0-12 months) with a parent or grandparent who was born in a country where the incidence of TB is 40/100,000 or greater.
- Previously unvaccinated children aged one to five years with a parent or grandparent who was born in a country where the incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities and can normally be vaccinated without tuberculin testing.
- Previously unvaccinated tuberculin-negative children aged from six to under 16 years of age with a parent or grandparent who was born in a country where the incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities, tuberculin-tested and vaccinated if negative.
- Previously unvaccinated tuberculin-negative contacts of cases of respiratory TB.
- Previously unvaccinated, tuberculin-negative new entrants under 16 years of age who were born in or have lived for at least three months in a country with an annual TB incidence of 40/100,000 or greater.

Certain occupational groups are more likely to be exposed to TB than the general population.

Individuals at occupational risk:

- Healthcare workers who will have contact with patients or clinical material.
- Laboratory staff who will have contact with patients, clinical materials or derived isolates
- Veterinary and staff such as abattoir workers who handle animal species known to be susceptible to TB eg simians.
- Prison staff working directly with inmates.
- Staff of care homes for the elderly.
- Staff of hostels for homeless people and facilities for accommodating refugees and asylum seekers.

Unvaccinated, tuberculin-negative individuals aged under 35 years in these occupations are recommended to receive BCG. There are no data on the protection afforded by BCG in those over the age of 35 years.

Recommendations for Travellers

Some travellers are at risk of exposure when going to countries where the disease is still common (e.g. with rates above 40/100,000 population). The current rates of infection (from WHO) are described in the country records when BCG vaccination is 'sometimes advised'.
BCG is recommended for tuberculin-negative travellers under 16 years of age who will be living or working with local people for a prolonged period of time (three months or more) in areas with an annual TB incidence of 40/100,000 or greater. Following individual risk assessment, vaccination may also be considered for travellers who may be at risk through their occupation abroad eg individuals working in a healthcare setting (see UK occupational risks above).

**The option of tuberculin skin testing before and after travel**
Sometimes, if BCG is contraindicated or the traveller presents too late for vaccination, a TST can be performed before departure and can be rechecked 1-2 months after return to detect those that have been exposed while abroad. Anti-tuberculosis therapy can then be considered. However it must be remembered that the test itself can stimulate latent cell mediated immunity and for 4-8 weeks after a TST, a further test may transiently become positive which does not necessarily mean exposure has occurred.

### 5.4.3 Contra-indications for BCG
The vaccine should not be given to:

- those who have already had a BCG vaccination
- those with a past history of TB
- those with an induration of 6mm or more following Mantoux (SSI) tuberculin skin testing
- those who have had a confirmed anaphylactic reaction to a component of the vaccine
- neonates in a household where an active TB case is suspected or confirmed
- people who are immunocompromised by virtue of disease or treatment, e.g.:
  - patients receiving corticosteroid or other immunosuppressive treatment, including general radiation. Inhaled steroids are not a contraindication
  - those suffering from a malignant condition such as lymphoma, leukaemia, Hodgkin’s disease or other tumour of the reticuloendothelial system.

BCG is contraindicated in symptomatic HIV-positive individuals. In countries such as the UK where the risk of TB is low, it is recommended that BCG is also withheld from all those known to be or suspected to be HIV positive, regardless of clinical status. Where vaccination is indicated, for example infants born to HIV-positive mothers, this can be administered after two appropriately timed negative postnatal PCR tests for HIV infection (see Chapter 6 Contraindications and special considerations).

### 5.4.4 The BCG vaccine
The vaccine is a freeze-dried powder for suspension for injection. BCG Vaccine SSI is supplied in a glass vial containing the equivalent of 10 adult or 20 infant doses, fitted with a bromobutyl rubber stopper which does not contain latex. The unreconstituted vaccine and its diluent should be stored in the original packaging at +2°C to +8°C and protected from light.

The powder must be reconstituted with 1ml of the diluted Sauton SSI diluent which is supplied separately, and then used immediately. Unused reconstituted vaccine should be
discarded after four hours. The vaccine is usable for up to four hours at room temperature after reconstitution.

5.4.5 Administration of BCG vaccine

In all cases, BCG vaccine must be administered strictly intradermally, normally into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle (just above the middle of the left upper arm – the left arm is recommended by WHO). Sites higher on the arm, and particularly the tip of the shoulder, are more likely to lead to keloid formation and should be avoided. Jet injectors and multiple puncture devices should not be used. The dosage is 0.05ml for infants under 12 months, and 0.1ml for children aged over 12 months and adults.

No further immunisation should be given in the arm used for BCG immunisation for at least three months because of the risk of regional lymphadenitis. The subject must always be advised of the normal reaction to the injection and about caring for the vaccination site.

BCG should ideally be given at the same time as other live vaccines such as MMR. If live vaccines cannot be administered simultaneously, a four-week interval is recommended.

5.4.6 Immunisation reaction and care of the immunisation site

The expected reaction to successful BCG vaccination, seen in 90 to 95% of recipients, is induration at the injection site followed by a local lesion which starts as a papule two or more weeks after vaccination. It may ulcerate and then slowly subside over several weeks or months to heal, leaving a small, flat scar. It may also include enlargement of a regional lymph node to less than 1cm.

It is not necessary to protect the site from becoming wet during washing and bathing. The ulcer should be encouraged to dry, and abrasion (by tight clothes, for example) should be avoided. Should any oozing occur, a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (e.g. to permit swimming), an impervious dressing may be used but it should be applied only for a short period as it may delay healing and cause a larger scar.

Further observation after routine vaccination with BCG is not necessary, other than as part of monitoring of the quality of the programme, nor is further tuberculin testing recommended.

5.4.7 Adverse reactions

Severe injection site reactions, large, local discharging ulcers, abscesses and keloid scarring are most commonly caused by faulty injection technique, excessive dosage or vaccinating individuals who are tuberculin positive. It is essential that all health professionals are properly trained in all aspects of the process involved in tuberculin skin tests and BCG vaccination.

Other adverse reactions to the vaccine include headache, fever and enlargement of a regional lymph node to greater than 1cm and which may ulcerate.

Allergic reactions (including anaphylactic reactions), more severe local reactions such as abscess formation, and disseminated BCG complications (such as osteitis or osteomyelitis) are rare.
5.4.8 Management of adverse reactions

Individuals with severe local reactions (ulceration greater than 1cm, caseous lesions, abscesses or drainage at the injection site) or with regional suppurative lymphadenitis with draining sinuses following BCG vaccination should be referred to a chest physician or paediatrician for investigation and management.

An adherent, suppurating or fistulated lymph node may be incised and drained, and left to heal. There is little evidence to support the use of either locally instilled anti-mycobacterial agents or systemic treatment of patients with severe persistent lesions.

Disseminated BCG infection should be referred to a chest physician or paediatrician for specialist advice and will normally require systemic anti-TB treatment following current guidance for managing *M. bovis* infection.
6 Diagnosis and Laboratory Facilities

6.1 Clinical Diagnosis
The key step in the clinical diagnosis of TB is for the clinician to be aware of, and consider this possibility. As a result of the substantial decline in TB over several decades, doctors have become less experienced with this disease. Most cases of TB present with respiratory disease, but clinicians need to be alert to atypical presentations which are more common in certain ethnic groups, the young, elderly and immuno-suppressed.

The diagnosis may be suggested by persistent cough, purulent sputum production, haemoptysis, weight loss, fever or night sweats. The early identification and treatment of smear positive cases is the most important single measure in controlling tuberculosis. Therefore the clinical suspicion of pulmonary TB should be immediately followed by the following appropriate investigations:

- **Chest X-ray:** The presence of cavitating lesions will certainly support the clinical diagnosis. Clinicians need to be alert to the more unusual radiological presentations, such as diffuse infiltration, miliary disease, and pleuropertidocardial disease. This is particularly important in Shetland where there is no on-site reporting of x-rays, so diagnosis may be delayed unless clinicians are alert. A chest x-ray should be organized within 2 working days.

- **Sputum Examination:** At least 3 good sputum specimens collected over three consecutive days should be sent to the Gilbert Bain laboratory with the appropriate clinical information.

Normally only those with positive sputum smears or discharging tuberculous sinuses (rare), are likely to be infectious. For immuno-compromised patients and contacts the situation is different. (See Section 18).

6.2 Laboratory Diagnosis
Sputum microscopy is done by Aberdeen Microbiology laboratory. The Gilbert Bain laboratory sends all suspected TB specimens directly to them. Any sputum positive results will be reported to the Gilbert Bain laboratory, the requesting clinician and Public Health. Notification should be made and contact tracing initiated on the basis of a smear positive result, and not delayed until the laboratory has confirmed the diagnosis by culture.

Diagnosis should be confirmed by culture wherever possible. All specimens received by the Aberdeen laboratory will be sent to the Scottish Mycobacterium Reference Laboratory (SMRL) in Edinburgh for culture.

**Microscopy Positive:** is where Acid Fast Bacilli (AFB) are visible after staining the sample with Auramine stain (new cases then confirmed by Ziehl-Neelsen stain). If present this demonstrates the presence of Mycobacteria.

**Microscopy Negative:** is where Acid Fast bacilli (AFB) are not visible after staining the sample with Auramine stain.

**Culture:** all samples will be cultured in a liquid culture for up to 6 weeks in a MIGIT automated system and 12 weeks on a solid medium looking for a growth of acid fast bacilli in order that the Mycobacteria may be typed and drug sensitivities confirmed.
The laboratory will issue a report of any positive sputum specimens. Final culture results are sent back from SMRL to the laboratory at the Gilbert Bain. Copies of the final culture results are sent to

- Department of Public Health
- The relevant Consultant in Thoracic Medicine
- The patient’s G.P.

All smear-positive or culture positive cases must be assumed to be TB and reported accordingly by the laboratory to the DPH and Health Protection Scotland. Provisional results can be amended if necessary when identification results are available (usually within 2-3 weeks of receipt of cultures by SMRL).

6.2.1 Rapid diagnostic techniques

Including PCR, may enable the early categorisation of patients into TB or non-TB mycobacteria (atypical) categories. ‘PCR’ should be written on the microbiology request form along with clinical details. The specimen should be sent to the Gilbert Bain laboratory, which in turn will forward it to the SMRL, Edinburgh. This has the potential to obviate the need for contact tracing and screening in non-TB cases. This is recommended when drug resistance is suspected or a large contact screening exercise is planned i.e. a school or care home, and should be organized in conjunction with Public Health.
7 Notification

Both respiratory and non-respiratory TB are statutorily notifiable. The doctor suspecting the diagnosis is responsible for notifying the Director of Public Health (DPH). When cases are brought to the attention of the DPH via reports from the laboratory, or other sources, the DPH is responsible for notification. Information from the following sources should be directed, both informally and formally to the Department of Public Health without delay, so that appropriate action can be taken.

- **Clinicians:** where a hospital clinician or GP suspects TB, even if not confirmed bacteriologically, this information should be passed immediately to the Department of Public Health. The clinician is statutorily required to notify via SCI Gateway, but should also give as many other details as possible.

- **Hospital Laboratory Staff:** As soon as mycobacterial infection is suspected, sufficient information should be passed to the DPH, so that further details of the patient's condition and whereabouts can be obtained. This is particularly important when organisms are seen on direct staining of a sputum smear.

- **Hospital Pathologists:** The Shetland pathology service is in Aberdeen. If they suspect TB from a pathology specimen of a patient residing in Shetland, they should contact Shetland DPH by telephone, and via the notification form.

For statutory purposes “Respiratory” TB refers to disease affecting the lung parenchyma, tracheo-bronchial tree or pleura, larynx or upper respiratory tract; “Non-Respiratory” includes any other body site.

The Department of Public Health notifies all known and suspected cases of TB to Health Protection Scotland at the end of every week. Where further evidence (e.g. from bacteriology or post mortem specimens) suggests the diagnosis has been erroneous or that the infection has been caused by an atypical mycobacterium, then this information is passed on so that the records can be corrected centrally. **It is much better to notify a case of TB and subsequently denotify it, than not to notify a case which is clinically likely to be TB.**

**Patients given chemoprophylaxis should NOT be notified via the statutory scheme.** This rule applies where chemoprophylaxis is given either for protection (as in the case of children), or where a strongly positive tuberculin reaction suggests infection in the absence of clinical illness or radiological changes. A record should be kept, however by the prescribing physician and the DPH informed for case finding purposes. A clinical decision to treat a patient (as opposed to chemoprophylaxis) requires that the patient be notified. Recurrence of active disease following an apparently successful course of treatment should be re-notified as a fresh contact-tracing exercise may be required.
8 Treatment and Compliance

8.1 Treatment of active (respiratory) TB

Hospital admission is often not necessary but may be indicated for medical or social reasons. All cases should be supervised by (or in collaboration with) a Consultant in Thoracic Medicine in Aberdeen. GP involvement in follow up must only be as part of shared care with that Consultant.

If smear positive patients are being managed in hospital, or other institutions, they should be in isolation for a minimum of 2 weeks with effective therapy. It is recommended that patients with infectious TB should not be in the same ward as immuno-compromised patients, therefore all infectious TB patients requiring hospital admission should be transferred to Aberdeen as there may be immune-suppressed patients on the Gilbert Bain Hospital medical ward. After 2 weeks therapy patients can be deemed non-infectious, even if they remain smear positive, since the bacilli in the sputum are assumed to be dead. (The evidence for this is limited however). This does not apply to patients with HIV and multi - drug resistant cases. (see Sections 9 and 19) Infection control precautions are dealt with in Section 17.

Scottish Guidance (based on NICE)

1. Once a diagnosis of active TB is made, the clinician responsible for care should refer the person with TB to a physician with training in, and experience of, the specialised care of people with TB. TB in children should be managed either by a paediatrician with experience and training in the treatment of TB, or by a general paediatrician with advice from a specialised physician. If these arrangements are not possible, advice should be sought from more specialised colleagues throughout the treatment period.

2. A daily 6-month, four-drug initial regimen (6 months of isoniazid and rifampicin supplemented in the first 2 months with pyrazinamide and ethambutol) should be used to treat active respiratory TB in:
   - adults not known to be HIV-positive
   - adults who are HIV-positive
   - children.

This regimen is referred to as ‘standard recommended regimen’ in this guideline and is outlined in the current British National Formulary (BNF) or BNF for children (BNF-C)

3. Where possible fixed dose combination tablets should be used as part of any TB treatment regime

4. There are two main approaches for administering the regime either daily or thrice weekly dosing. The doses for each approach are different and are listed in the current BNF and BNF-C
8.2 Non-compliance with treatment

The WHO recommends the use of DOT (directly observed therapy) for all patients, to ensure compliance. BTS guidelines state this should be used ‘for those at risk of non-adherence’. The clinicians involved must make a judgment on an individual patient basis regarding how much supervision they require, and have the resources to offer the level they think is needed. In Shetland this will mean GPs, health visitors and district nurses providing the supervision.

All patients should have a risk assessment for adherence to treatment and DOT should be considered for patients who have adverse factors on their risk assessment, in particular:

- street- or shelter-dwelling homeless people with active TB
- patients with likely poor adherence, in particular those who
- have a history of non-adherence.

Use of directly observed therapy (DOT) is not usually necessary in the management of most cases of active TB.

Clinicians who are planning to start a patient on a course of DOT should consider ways to mitigate the environmental, financial and psychosocial factors that may reduce adherence, including stability of accommodation and transport. The setting, observer and frequency of treatment should be arranged to be most practicable for the person with TB. The person with TB and his or her assigned key worker should be involved in deciding these arrangements. DOT should also be supported by frequent contact with the key worker. In appropriate circumstances, the key worker may transfer responsibility for certain tasks (e.g. administering drugs) to a member of the patients’ family or primary care team, for example a health visitor or district nurse.

When supervised therapy is proving ineffective, there is Public Health Law, which can be used to arrange the compulsory detention of a patient in hospital. (Section 54 of the Public Health (Scotland) Act 1897) This should only be considered if the patient is posing a serious risk of infection to others. It can only be used for patients with infectious TB of the respiratory tract, and cannot be used for compulsory treatment. This should only be considered in conjunction with the DPH, and legal advice.
9 Multi-drug Resistant Tuberculosis

The term multi-drug resistant tuberculosis (MDRTB) is generally applied to strains which are resistant to both rifampicin and isoniazid, but many strains are also resistant to other anti-mycobacterial agents. Drug resistant TB strains usually arise from poor clinical management and/or poor compliance with standard treatment regimes. They can then be passed from person to person, so that subsequent infections simply reflect the mechanism of spread of TB.

Guidance on the management of HIV associated and MDRTB has been produced by the Interdepartmental Working Group. (See Appendix 5)

9.1 Epidemiology

MDRTB is presently uncommon in the UK. However there have been some hospital outbreaks in England, and sporadic cases in Scotland. Most outbreaks arise in the setting of HIV co-infection, because HIV infected patients are more likely to progress to active disease than an immuno-competent individual exposed to the same bacilli. However, infection in HIV negative patients accounts for nearly all Scottish MDRTB cases to date.

MDRTB is not more virulent or more infectious than other forms of TB, but the consequences of acquiring disease are much more serious because of the complexities and duration of the required treatment regimens. Prevention of the emergence of MDRTB, by following National Treatment guidelines, is therefore important. However it is inevitable some cases will be acquired abroad, and therefore strict infection control procedures must be followed to limit its spread in this country.

9.2 Risk Factors

Clinicians should be alert to the risk factors for MDRTB. These include;

- Previous drug treatment for TB
- Contact with a known case of MDRTB
- HIV infected
- Failure of clinical response on treatment
- Prolonged sputum smear or culture positive while on treatment (smear positive at 2 months, or culture positive at 3 months)
- Foreign born person from a country with a high incidence of MDR TB\(^\text{iii}\) (>10% of TB cases MDR TB).
- Travel or residence (3 months or more) in a country or setting with high incidence of MDR TB

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\(^{iii}\) Countries with a high incidence of MDR TB are available from the [http://www.who.int](http://www.who.int) and searching for MDR TB country data. The WHO 2013 MDR TB and XDR TB world report is available at [http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf?ua=1](http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf?ua=1)
9.3 Management Decisions

Patients with MDRTB, regardless of HIV status may be managed as outpatients if this does not put others at risk and suitable arrangements can be made for supervising therapy. Home contacts should be screened urgently, and new contacts avoided until the patient is non-infectious. Some patients will require hospital treatment for medical or social reasons (e.g. they live in a hostel).

Nosocomial transmission of MDRTB has been documented in healthcare settings in which immuno-compromised patients are treated. The greatest danger arises when a patient with unrecognised TB is nursed or subjected to cough-inducing procedures on an open ward. Therefore it is important that cases of MDRTB are recognized promptly, and referred to Edinburgh Western General Hospital, which has appropriate negative pressure isolation facilities. Treatment of patients with infectious MDRTB should be carried out only in hospitals with adequate isolation facilities, and therapy must be undertaken only by specialist physicians. For Shetland patients, this necessitates being transferred to Edinburgh.

Patients with suspected infectious MDRTB who are admitted to Gilbert Bain Hospital hospital via their GP or A&E should be admitted to the single room (with separate adjoining room) in Ward 3. Care should be carried out in this room until the patient is found to be non-infectious or non-resistant, and ideally until cultures are negative, or transferred as above.

9.4 Staff Protection

To prevent spread to health care staff who may work with the patient prior to or during their transfer, all such staff should be adequately immunized. (See Section 16) Staff who have close or prolonged contact should wear dust / mist masks meeting the 1992 Personal Protective equipment regulations. Visitors or relatives accompanying the patient should be restricted to those who have had contact prior to the admission, and they should wear face masks. Masks can be obtained from the emergency planning cupboard, or the A&E department in the Gilbert Bain Hospital. Face masks are not necessary for those with casual or brief contact.

9.5 Transfer Procedures

The Scottish Ambulance Service will transport these patients from one hospital to another by air ambulance and road. The ambulance crews must be made aware of the following:

- the possible diagnosis, this alerts staff to follow the appropriate standard operating procedure
- the patient being transferred should wear a face mask for the duration of the journey - a surgical mask is satisfactory for this
- it is the responsibility of the transferring medical team to discuss any precautions the crew needs to take prior to transfer with the ambulance crew

9.6 Laboratory Diagnosis

Clinical specimens should be submitted to SMRL without delay in a suspected case of MDRTB. Molecular tests for identification of *Mycobacterium tuberculosis* and rifampicin resistance are strongly recommended.
9.7 Treatment
Treatment will be decided by the Thoracic Medicine Consultant, in liaison with SMRL. Treatment will involve at least 3 drugs, to be taken for a minimum of 9 months after becoming culture negative. All treatment should be fully supervised, with DOT, (unless there are exceptional circumstances). If admitted to hospital, the patient should not be discharged until secure arrangements have been made with the appropriate Primary Care Team for continuing treatment supervision. Public Health should also be aware of the discharge.

Follow up should include regular sputum examination and annual chest x-rays for up to 5 years. (Life-long for HIV-infected patients). Follow up should be done by the TB specialist, who will liaise with the GP.

Chemoprophylaxis regimes should also be decided by the TB specialist.

9.8 Respiratory Isolation
Cases should remain in negative pressure isolation in Edinburgh at least until three smear negative sputum specimens are obtained over a 14 day period, and there has been at least 14 days of compliance with, and tolerance of, the drug regimen. The patient should also show clinical signs of improving. Ideally they should stay until the cultures are negative.

The decision to discharge should involve Edinburgh Hospital Infection Control Team, Microbiologist, and Shetland DPH. All the arrangements necessary for continuing treatment supervision, follow up, and social support must be in place.

9.9 Surveillance
Drug susceptibility can only be monitored if all isolates and specimens are processed by SMRL. ESMI also collects data on resistance. The laboratory should inform the DPH immediately by telephone on discovery of a case of MDRTB. The DPH should then inform the Scottish Department of Health and HPS. For patients first diagnosed outside Scotland, the person who establishes first medical contact with the patient should inform the other appropriate agencies, especially the SMRL.
10 Contact Tracing and Management

Contact tracing is crucial to preventing TB transmission. Overall, a low proportion of contacts go on to develop active TB disease, with most developing disease within the first year after exposure. The maximal risk is in household contacts where 1 in 3 contacts have a risk of being infected with TB with a 10% lifetime risk of developing active TB (if HIV negative). A further proportion will develop latent TB infection.

1.8.1 Contact tracing: human to human transmission

Once a person has been diagnosed with active TB (i.e. commenced on anti-tuberculosis treatment), the diagnosing physician should inform relevant colleagues (i.e. CPHM / TB nurse and infection control nurse) within 24 hours so that the need for contact tracing can be assessed without delay. Whilst a written notification is required, contact tracing should not be delayed until written notification is made.

Screening should be offered to the household contacts of any person with active TB, irrespective of the site of infection. Household contacts are defined as those who share a bedroom, kitchen, bathroom or sitting room with the index case. All contacts should be screened within 6 weeks.

High risk contacts (such as children, those who are symptomatic, and where the index case has a long history of infection) should be screened within 7 days.

For contacts screened within 6 weeks of most recent contact with a case, they should have standard testing for latent TB for those aged 35 or younger.

However to reflect the clinical circumstance (for example someone initially tested a few weeks after their exposure) it may be necessary to repeat such tests at the end of the six weeks after their exposure.

There should also be consideration of BCG or treatment for latent TB infection once active TB has been excluded.

10.1 Procedure for tracing contacts

Contact tracing includes registering the index case and details of the illness, particularly the duration and degree of infectivity. Those at risk must then be contacted, the need for attendance should be explained and possible fears and anxieties explored. Follow up must be made as easy as possible to ensure attendance. Contact tracing must include monitoring attendance so that appropriate action can be taken if a contact fails to attend. Accurate and up to date records should be kept of all cases and their contacts.

Contact tracing is the responsibility of the Public Health Department. The tracer in Shetland will usually be the Public Health Nurse. The tracer will compile a list of contacts to be screened for each index case. These contacts will then be informed that they have been in contact with an infective case of TB and that screening and follow up may be necessary. A draft letter for casual contacts is given in Appendix 6. It is important that GPs are aware of the contact tracing guidelines, so that they can give appropriate advice and reassurance to their patients.

This section gives guidance for most contact tracing situations. For special situations it is necessary to refer to other sections for more specific advice;

- section 14.4 for contacts of animal TB,
- section 15.2 for contact tracing in an occupational setting,
● section 16.5 for contact tracing in a hospital ward setting.

10.2 Public Health On-call Action
If the case is a healthworker, teacher or other individual in contact with particularly susceptible individuals, consult the Incident (Outbreak) Control Plan. (Section 10) However action can usually wait until the next day.

10.3 Close and Casual Contacts
Patients with pulmonary disease spread TB by live bacilli in their sputum. Their infectivity depends on the frequency and intensity of sputum droplet dispersal (by coughing, sneezing, speaking, singing or laughing), and the number of bacteria in their sputum. A contact’s risk of infection therefore depends on their being physically close to the case for a significant length of time. Contacts should therefore be divided into close and casual contacts.

- Close contacts These are members of the same household, who share a kitchen, and very close associates such as boyfriend/girlfriend or frequent visitors to the home. Occasionally contacts from other places, like work, or the pub, may be judged to be close contacts if they have had at least 8 hours cumulative contact at conversational distance. However, if the index case is thought to be highly infectious as evidenced by transmission to more than 10% of close contacts the threshold for close contacts should be lowered. All close contacts should be screened regardless of the sputum status of the index case.

- Casual Contacts These include most occupational contacts. If the index case is smear negative the contacts do not need to be examined. If the index case is smear positive, casual contacts need only be examined if they are unusually susceptible e.g. young children and immuno-compromised individuals, or if the index case is thought to be highly infectious.

Screening contacts of patients with non-pulmonary disease is not recommended, unless the patient is thought to have been recently infected. (e.g a child, or HIV infected individual, or a case with erythema nodosum or meningitis). If this is the case, contact tracing may identify a source.

BTS recommends contact tracing for the period of time which the patient has had respiratory symptoms for, or if that is not known, for 3 months preceding the first positive sputum smear or culture. If cases are found during this time period, contact tracing should be extended back in time, a month at a time, until there is a month with no contact infections found.

Decisions on which contacts should be classified as close or casual will be made by the tracer, in discussion with the DPH and Consultant responsible for the index case. Box 1 summarises the questions that need to be asked to inform contact tracing.
Box 1 How to assess the likelihood of transmission of TB

1 How infectious is the source case?
- Sputum smear positive: Infectious to any close contact
- Smear negative, culture positive: possibly infectious to highly susceptible contacts
- 3 sputum samples negative: not infectious
- 2 weeks appropriate treatment: not infectious
- Non-pulmonary disease: not infectious
- Children: less infectious than adults

2 How great is the exposure?
- Exposure to coughing, sneezing, singing, more than 5 minutes conversation
- Prolonged multiple indoor exposure usually needed to infect contacts
- Brief contact: low risk
- Outdoor contact: very low risk
- Aerosols may persist after case leaves the room
- Dishes, laundry etc. not infectious

3 How susceptible is the contact?
- Neonates: very high risk
- Age under 3 years: high risk
- BCG reduces risk by 50 – 80% in developed countries
- Immuno-suppressed at very high risk, including AIDS, lymphoma, leukaemia, cancer chemotherapy, and taking more than 15mg oral prednisolone per day.
- Severe malnutrition (e.g. post gastrectomy): increased risk
- Silicosis and drug abuse: increased risk
- Diabetics and those with chronic renal failure have increased risk of reactivation of latent disease

10.4 Aircraft Travellers:
If the case has been in an aircraft in the previous 3 months,
- for over 8 hours flight,
- is smear positive
- and was coughing at the time
Then it is the responsibility of the DPH to inform HPS, who will initiate further contact tracing.

People with known or suspected *infectious* TB should not travel on public aircraft. This means any transfers of such patients must be by air ambulance.

10.5 Examination of Contacts

The investigation of contacts will involve some or all of the following actions.

*Table 5 The people involved in contact tracing actions in Shetland.*

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Whose Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess BCG status</td>
<td>Contact Tracer (Public Health Specialist)</td>
</tr>
<tr>
<td>Mantoux Testing</td>
<td>Through Public/Child Health Departments</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>Tracer to liaise with GP. Report by ARI</td>
</tr>
<tr>
<td>Clinical Examination</td>
<td>Tracer to liaise with GP</td>
</tr>
<tr>
<td>Advise and Inform Patient. Give Leaflet and card in Appendix 7.</td>
<td>Tracer and GP</td>
</tr>
<tr>
<td>Give BCG</td>
<td>Tracer (liaise with Child Health +/- or GP)</td>
</tr>
<tr>
<td>Chemoprophylaxis</td>
<td>Tracer to ask GP to refer to Thoracic Medicine Consultant, ARI</td>
</tr>
<tr>
<td>Further Investigation and Treatment</td>
<td>Tracer to ensure GP refers to Thoracic Medicine Consultant, ARI</td>
</tr>
</tbody>
</table>

The following Flow Diagrams set out the screening protocol for contacts of Pulmonary TB cases as described in the Scottish Guidance 2009.

Note that if the index case is smear positive, close contacts who have not had BCG vaccination and who have a negative Mantoux test should ideally be retested six weeks after last contact to allow for tuberculin conversion. If *retesting is not practicable*, BCG vaccination should be given after the first negative Mantoux test; chemoprophylaxis may also be given to children under 2 years of age.

In HIV infected individuals, and others who are immuno-compromised, a chest x-ray is essential because prior BCG and Mantoux tests cannot be relied upon in any age group. See section 18 for further details.

All contacts being discharged should be given the leaflet in Appendix 7, which details the symptoms of TB.

The following protocols should all be used in conjunction with table 5.
Testing and treating asymptomatic household and other close contacts of all cases of active TB

For children aged between 4 weeks and 2 years old who are contacts of people with sputum smear-positive TB, use the algorithm below.

Previous BCG vaccination cannot be accepted as evidence of immunity in HIV-infected patients.

People advised to have treatment for latent TB infection, but who decline, should have 'inform and advise' information reinforced and chest X-ray follow-up at 3 and 12 months.

If Interferon gamma test is not available presume the result is positive. The next steps involve clinical review and a chest X-Ray at which the risk for TB will be assessed.

Testing and treating asymptomatic children older than 4 weeks but younger than two years who are contacts of people with sputum smear – positive TB

10.6 Vaccination and Chemoprophylaxis

10.6.1 Vaccination

Should only be offered to previously unvaccinated, persistently Mantoux test 0-5mm contacts under the age of 16 (18 in the Grampian protocol). This is because there is a lack of data about whether BCG is effective if given in adults, and because once the index case is treated, risk of infection is low.

10.6.2 Chemoprophylaxis

May be given to some contacts with strongly positive Mantoux reactions, but no clinical or radiological evidence of tuberculous disease. It usually involves either 6 months isoniazid, or 3 months rifampicin and isoniazid. The risk of developing disease after infection depends on BCG status, HIV status, and how recent the infection is. Youth implies recent infection, as well as an increased risk of serious forms of the disease (e.g. meningitis). Therefore it is recommended the following contacts are referred to a Thoracic Medicine Consultant in ARI for chemoprophylaxis.

10.7 Follow up and Compliance

Most disease in contacts is found at the initial examination. Those without findings of disease on initial screening should be informed by the contact tracer, or GP, of the symptoms of TB, given the leaflet about these symptoms (copy in Appendix 7) and told to report them to their GP if they occur during the next year. The GP should be informed by the contact tracer that their patient has had contact with TB, and of the action / advice they have received.

Routine chest x-rays at 3 and 12 month follow up is now only recommended for those who are eligible for chemoprophylaxis, but did not receive it. These should be organised by the tracer in liaison with the GP.

If a contact fails to attend for follow up within one month of the initial approach, he or she should be sent a reminder. If they fail to attend for a second time, they should be visited in order to elucidate any worries or problems they have. If in spite of this visit they fail to attend, the tracer should discuss the contact with the DPH, and a decision will be made when to cease attempting follow-up. When this decision is made the tracer should document this in the contact tracing notes, and inform the GP.
11 Incident (Outbreak) Plan for TB
The investigation of an outbreak of TB involves a description of the situation, its nature and timing, where and from whom the cases might have acquired the disease and the characteristics of the affected people. Information about source and spread may allow instigation of prompt and effective investigation and management. Management of a TB outbreak in Shetland would be co-ordinated by an Incident Management Team (TB outbreak). An IMT would also be called to manage the response to single cases of particular importance (e.g. multi-drug resistance or a health care worker). But in general two or more apparently related cases constitute an outbreak until proved otherwise; in the current section, major outbreaks and “incidents” require similar or identical actions. Further issues relating specifically to hospitals and residential homes are dealt with in sections 16 & 17.

11.1 Guiding Principles
The objectives of incident management are:
- To recognise a major incident
- To define its important epidemiological characteristics and aetiology
- To prevent its further spread and recurrence
- To maintain satisfactory communications with appropriate external agencies and the public.

The DPH in Shetland has the overall responsibility for the investigation and control of a TB outbreak or incident.

11.2 Identification and initial response
Cases of TB may come to the attention of GPs, hospital clinicians, Environmental Health Officers, or laboratory staff. They should inform the DPH as soon as they have a suspected case. If an outbreak occurs in a care home or day care facility the officer in charge should inform the client’s GP and the responsible manager in the Social Work Department. It is the duty of the GP to notify the DPH, although the care home manager may do so informally.

The DPH maintains routine surveillance of infectious diseases in the community and will make the preliminary investigations and consultations to determine whether or not there is an outbreak, the extent of such an outbreak, and the urgency with which any subsequent investigation is carried out.

When informed of one or more cases of TB the DPH (or other appropriate member of the Infection Control Team) will undertake an initial risk assessment looking at:
- Whether there is a significant risk to the public health
- Scale of the problem
- Severity of the problem
- Possible cause of incident or outbreak
- Initial actions to be taken and why.
Box 2 Definition of a TB Outbreak or Incident

A TB outbreak or incident can be defined as one of the following:

two or more cases of the TB, either clinical diagnosis or laboratory confirmation, linked in person, place or time (an outbreak)
a situation when the observed number of cases of TB unaccountable exceeds the expected number (an outbreak)
a single case of TB with major public health implications (e.g. a health care worker) where action is necessary to investigate and prevent ongoing exposure (an incident)

11.3 Initial Action

The DPH will take initial action depending on the results of the initial risk assessment. For TB, the options are summarised in the following table;

<table>
<thead>
<tr>
<th></th>
<th>Initial Action to be taken by the DPH / CPHM when a case of TB is diagnosed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Single case of TB</td>
</tr>
<tr>
<td></td>
<td>Follow procedures in section 9 (contact tracing)</td>
</tr>
<tr>
<td>2</td>
<td>Possible TB incident or outbreak</td>
</tr>
<tr>
<td></td>
<td>DPH to seek advice and discuss with relevant colleagues e.g. microbiologist, physician, infection control nurse, occupational health. Need to decide on any further investigations, immediate control measures and whether or not to call an IMT. The decisions made, and reasons for the decisions must be recorded.</td>
</tr>
<tr>
<td></td>
<td>Example of a possible outbreak is 2 cases of TB in Shetland that do not appear to be linked.</td>
</tr>
<tr>
<td>3</td>
<td>Definite TB incident or outbreak</td>
</tr>
<tr>
<td></td>
<td>Call IMT (TB outbreak) and institute immediate control measures if necessary</td>
</tr>
<tr>
<td></td>
<td>Example of a definite outbreak is 2 cases of TB in a school.</td>
</tr>
</tbody>
</table>

11.4 Incident Management Team

An incident management team is a multi-disciplinary, multi-agency group with responsibility for investigating an outbreak or incident and implementing control measures.

The DPH will decide if and when to call an IMT (TB outbreak) in discussion with relevant colleagues e.g. microbiologist, physician, infection control nurse, occupational health. The DPH will co-ordinate and lead the investigation and control of the incident.

11.4.1 Core (Essential) Membership

The IMT should not be too large (e.g. approx 10). Representatives from agencies not based in Shetland may be part of the IMT via telephone or video link.
Table 7 Core Membership of the IMT (TB Outbreak) in Shetland

<table>
<thead>
<tr>
<th>National Guidance</th>
<th>Shetland IMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPHM</td>
<td>DPH (in their absence, CPHM)</td>
</tr>
<tr>
<td>Appropriate Physicians</td>
<td>Local Consultant Physician(s) and / or Community Paediatrician</td>
</tr>
<tr>
<td></td>
<td>Consultant in Thoracic Medicine from Aberdeen (Grampian University Hospitals Trust)</td>
</tr>
<tr>
<td></td>
<td>GP(s) if appropriate</td>
</tr>
<tr>
<td>Consultant Microbiologist</td>
<td>Consultant Microbiologist</td>
</tr>
<tr>
<td>Tuberculosis Liaison Nurse</td>
<td>Public Health Nurse (could link with TB nurse in Grampian if appropriate)</td>
</tr>
<tr>
<td>Infection Control Nurse</td>
<td>Hospital Infection Control Nurse if appropriate</td>
</tr>
<tr>
<td>Representative of Health Board Management</td>
<td>DPH</td>
</tr>
<tr>
<td></td>
<td>If necessary, the Director of Clinical Services</td>
</tr>
<tr>
<td>Administrative support</td>
<td>Public Health Secretary</td>
</tr>
<tr>
<td>Press Officer</td>
<td>Corporate Services Manager or representative</td>
</tr>
</tbody>
</table>

Other organisations or individuals who may be members of the IMT if appropriate:
- Other members of Infection Control Team
- Other members of Child Health Department, School Nurse
- Community Health Partnership representative
- Environmental Health Department
- Emergency Planning Officer
- Health Protection Scotland
- Scottish Mycobacteria Reference Laboratory
- Divisional Veterinary Manager (based at Inverurie)
- Scottish Government Health Directorates
- Other NHS Boards if the incident / outbreak crosses boundaries

11.4.2 Objectives of the IMT (TB Outbreak)
- To investigate the source and cause of the outbreak / incident
- To agree on the implementation of any measures necessary to control the outbreak / incident
- To monitor the effectiveness of control measures
• To provide information to GPs, patients, patients’ contacts, the general public, the media and appropriate staff
• To liaise with appropriate health bodies, local authority and other statutory services
• To evaluate the overall work of controlling the outbreak, co-ordinate the investigation and implement the lessons learnt

11.4.3 IMT Meetings
Meetings will be chaired by the DPH and administrative support will be provided by the Public Health Department.

IMT meetings will usually be held at Brevik House (Shetland NHS Board) or other appropriate accommodation arranged through the Public Health Department. It is not always necessary or feasible for representatives of agencies based on the mainland to physically travel to Shetland. Telephone and videoconferencing should be used where appropriate to minimise delay in managing the incident. Videoconferencing facilities are available in Brevik House and a number of other places within Shetland NHS Board including Primary Care practices. However it will be necessary to ensure that members of the IMT based in Shetland have access to the technical experience to use these facilities.

11.4.4 Resources
Members of the IMT should have the authority to mobilise resources as required for the management of the outbreak.

The Emergency Planning Officer can assist with logistical arrangements (such as facilities for mass screening).

There is limited availability of equipment, supplies and drugs on Shetland and these may need to be sourced from elsewhere.

Manpower
For clinical manpower, Shetland Health Board has mutual support arrangements with neighbouring Health Boards. To enlist such support, the DPH would contact Grampian Health Board, in the first instance. HPS may also be requested to provide additional public health support, particularly for epidemiological investigation. The Emergency Planning Officer and the Environmental Health Department can provide further support if appropriate.

11.4.5 Record Keeping
Detailed recording of all aspects of the outbreak or incident and its management must be carried out. Individual members of the IMT will keep personal daily logs of their activities, including details of information received, conversations held and meetings attended. All meetings of the IMT should be carefully minuted. Actions agreed and by whom should be clearly defined. Minutes and actions should be issued promptly and reviewed at the next IMT meeting. All documentation, including computer-generated information, must be retained. Regular back-ups of electronically stored material should be made.

11.4.6 Accountability and Reporting
The IMT is accountable through the DPH to Shetland NHS. Any TB outbreak or incident will be reported to the Shetland NHS Board via the Control of Infection Committee. The Committee reports via the Clinical Governance Co-ordinating Group to the Clinical
Governance Committee of the Board. The Control of Infection Committee Annual Report is published on the intranet.

Following control of the outbreak and completion of all investigations, a debriefing meeting of the IMT will be held and a report compiled and distributed to the organisations represented on the IMT and other agencies including HPS and Scottish Government.

### 11.4.7 IMT Support Group

If the situation develops into a very large-scale incident or one with considerable national interest, the IMT may become subject to outside pressures which could distract from the core task of managing the incident. Such pressures could include sustained enquiries from the public, media and politicians. Very large incidents could lead to secondary impacts on a range of services such as healthcare and social care and may lead to increased expenditure and relocation of money from existing budgets. In such an incident, the Chair of the IMT (i.e. the DPH) should discuss the setting up of an IMT Support Group with the Shetland NHS Board Chief Executive and Senior Management Team.

Where there is political interest, the IMTSG should provide the focal point of contact with the Scottish Government and for briefing Executive Officials and local and national politicians. It should also advise the Chief Medical Officer and Scottish Government Officials on the need to deploy further resources if incident management arrangements are overwhelmed.

The IMTSG should normally consist of representatives of senior management of the agencies involved in the IMT. It will normally be led by the Shetland NHS Board Chief Executive or other Senior Manager and the DPH will be a member of the group.
11.5 Investigation

11.5.1 Epidemiological study

Working hypothesis

The epidemiological information already available from the initial case(s) should be used to generate a working hypothesis. The hypothesis should explain the most likely source, site and time of infection.

Case definition

A simple definition of a case should be agreed. The initial case definition should be broad enough to include all those who could reasonably be part of the outbreak. The definition may be modified later.

Contacts also need to be defined for the purposes of contact tracing, investigation and appropriate management. Care is needed in how cases and contacts are defined in media and public messages as there could be confusion between the two. It is particularly important to ensure a consistent case / contact definition if more than one NHS Board is involved.

<table>
<thead>
<tr>
<th>Box 3 Suggested Case-definition for use in an outbreak(^8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Confirmed:</strong> Culture or PCR positive with clinically compatible disease</td>
</tr>
<tr>
<td><strong>Probable:</strong> Demonstration of acid-fast bacilli with clinically compatible disease</td>
</tr>
<tr>
<td><strong>Clinical:</strong> Clinical diagnosis leading to initiation of antituberculous therapy</td>
</tr>
</tbody>
</table>

11.5.2 Case finding and contact tracing

Other people with TB (cases) and people exposed to TB (contacts) need to be identified. Methods of case finding and contact tracing will vary depending on the circumstances of the outbreak or incident. It may be more difficult to trace contacts and identify TB cases that are linked to an outbreak within the community than in a more defined situation such as a residential home. However, as the community in Shetland is small and there are usually very few cases of TB (generally one or two a year) linking cases to an outbreak should not be a big problem. Molecular typing may help in assessing whether cases are linked: this would be carried out by the Scottish Mycobacteria Reference Laboratory.

11.5.3 Data analysis

The information collected above should then be analysed to produce

- epidemic curve
- range of incubation periods
- incidence rates within exposed population (if denominator is known, otherwise whole population)
- description of the range of symptoms and severity

The analysis may be carried out manually or using a computer package such as EPI INFO.
11.5.4 **Microbiological investigation**

The Consultant Microbiologist should be alerted as early as possible in the investigation of an outbreak. For Shetland, the Microbiologist is based in Aberdeen. The Microbiologist will be a member of the IMT (by videolink if necessary).

The role of the Microbiologist is to:

- advise on the appropriate clinical specimens, including sampling, transportation and storage
- arrange for relevant microbiological investigations on samples
- liaise with relevant reference laboratory and arrange for further identification and/or typing of isolates
- advise on further sampling in the light of initial results
- report and interpret results of microbiological analysis

Sputum microscopy is done by Aberdeen Microbiology laboratory. The Gilbert Bain laboratory sends all suspected TB specimens directly to them. Any sputum positive results will be reported to the Gilbert Bain laboratory, clinician and Public Health Department. Diagnosis should be confirmed by culture wherever possible. All specimens received by the Aberdeen laboratory will be sent to the Scottish Mycobacterium Reference Laboratory (SMRL) in Edinburgh for culture.

In the event of an outbreak, it may be appropriate to use rapid diagnostic techniques such as PCR which are performed at the reference laboratory. This would be on the advice of the Microbiologist.

11.5 **Control Measures**

11.5.1 **Measures to prevent further exposure**

The main method of preventing further exposure of the population to TB is to treat cases and screen and treat contacts as appropriate. The principles of screening and treatment are the same as for a single case, although the numbers involved will be higher.

Cases should be (section 7):

- isolated if appropriate
- treated as appropriate

Contacts should be (section 9):

- identified
- screened
- managed as appropriate

Guidance on the tracing and screening of contacts in particular situations is contained in Part D of this document:

- Hospital - section 16
- Residential homes – section 17
11.5.5 Bovine TB
There is the possibility of an outbreak of TB from drinking infected milk, although this is now highly unlikely given modern pasturisation methods and the system for the control of TB in cattle. In this situation, the Environmental Health Department would be involved in the IMT and the management of the outbreak would need to refer to both the TB plan and the Foodborne Outbreak Plan. Bovine TB is discussed in section 14.

11.5.6 Patient care measures
The main issue for Shetland in the event of a TB outbreak or incident would be the resources and manpower required to manage the incident. Although infectious cases would be transferred to Aberdeen for initial treatment, there may be non-infectious cases that have to be managed at the Gilbert Bain Hospital or in the community. It may be necessary to institute the Board’s Major Emergency Procedures if there are a large number of cases or if the outbreak is within the hospital.

Screening and management of a large number of contacts will have significant resource implications. Wherever possible, screening should be undertaken in an appropriate central location (e.g. in the school for a school outbreak, or at the local community hall) to make the most effective use of resources and manpower. Appropriate healthcare staff from both Primary and Secondary Care would be required to help with mass screening, and vaccination if necessary.

The Emergency Planning Officer would be able to assist with the logistical aspects of mass screening; and the Environmental Health Department may also be able to assist with (non-clinical) manpower.

11.6 Communication
The Shetland Public Health Incident (Outbreak) Plan will contain a detailed communications strategy. This is a summary of the relevant points for a TB outbreak or incident.

Risk communication is an essential part of the process of managing any public health incident or outbreak. This process should be based on a presumption in favour of openness. However, care must be taken to avoid creating undue public anxiety. Decisions on risk communication must be recorded. Decisions not to communicate about actual or potential risks to the public health, even when these are uncertain, should be justified and recorded.
11.7 Intra and inter agency communication

Notification of the occurrence or likely occurrence of the incident of outbreak should be made to the key agencies involved in managing the incident before the first IMT meeting. Information should be regularly updated. IMT member organisations will generally communicate through the IMT meetings and related communications. The DPH will inform the Chief Executive of Shetland NHS Board of any incident or outbreak and keep them and the Senior Management Team regularly updated. The DPH will inform HPS, Scottish Government and other NHS Boards if necessary of an incident or outbreak.

Communication will be by telephone, e-mail and fax as appropriate. A contact list (including out of hours arrangements) is included in this document.

Where deaths have, or are suspected to have, arisen as part of the outbreak or incident, the Procurator Fiscal should be informed and subsequently briefed if appropriate.

11.7.1 Communication with healthcare professionals

The CHCP, individual GPs and the Medical Director for Shetland NHS Board will be alerted at an early stage by the DPH. Communication will be via telephone, e-mail or fax as appropriate. Out of hours, communication will be by telephone.

11.7.2 Communication with the general public

To help allay any unnecessary anxiety, communications should be made as early as possible in the management of the incident. Communication with the general public is in addition to the communication with individuals who are potential cases or contacts. All communications will be agreed by the IMT before issue. There are a number of possible methods which may be appropriate in Shetland; the method(s) chosen will depend on the nature and scale of the outbreak or incident.

- Face to face communication with affected individuals or groups (e.g. a public meeting)
- Information in the form of statements, press releases, interviews, briefings and advertisements for the local media (see below)
- Leaflet and fact sheets
- Establishment of a helpline - probably only possible if extra manpower was available to staff the helpline
- Briefing of key members of the community such as councillors, community councils, MSP, headteachers

11.7.3 Communication with the media

The IMT will agree on a single spokesperson; this will normally be the DPH.

The IMT will also agree on who will liaise with the media and organise arrangements for press briefings, interviews etc.

All press releases, newspaper articles and advertisements will be agreed by the IMT before issue.

All press releases will be copied to the press offices of all organisations represented on the IMT, HPS, Government and other relevant agencies.
11.8 IMT debriefing and report

Following control of the outbreak and completion of all investigations, a debriefing meeting of the IMT will be held with the following objectives:

- To review the experiences of all participants involved in the management of the incident
- To identify shortfalls and particular operational difficulties encountered
- To revise the incident (outbreak) plan if necessary
- To recommend appropriate actions required to prevent a further outbreak

11.8.1 Incident / Outbreak Report

The IMT will compile an incident / outbreak report for distribution to the organisations represented on the IMT and other agencies including HPS and Scottish Government. The report will be presented to Shetland NHS Board’s Control of Infection Committee, Senior Management Team and the Board. It is the responsibility of the DPH to ensure the report is completed.

The following aspects should be covered in the report:

- Cause of the outbreak
- Investigation of the outbreak and results
- Control measures including risk communication
- Conclusions and lessons learnt
- Any recommendations

A template for an IMT report will be included in the Shetland Public Health Incident (Outbreak) Plan.

Based on the results of the incident investigation, risk assessment and debriefing, the IMT should formulate targeted recommendations. The Chair of the IMT (the DPH) should ensure that the report and specifically the section dealing with the recommendations is communicated to the targeted organisation.
C. SPECIAL SITUATIONS

12 Homeless persons, travelling people, hostel residents and vulnerable groups

12.1 People of no fixed abode
There are very few, if any, people living rough in Shetland, most of the homeless living in hostel accommodation. TB is a well-established and important health problem for those who are homeless, this group having a much higher incidence of TB than the general population. Despite this such cases are likely to be rare in Shetland. All Shetland homeless people are registered with a GP.

12.2 Travelling People
The high mobility of this group can make treatment particularly problematic. Educational interventions and explaining the importance of contact tracing and treatment may be effective, and liaison between health boards is essential when patients move on during the therapeutic period. Shetland DPH, and GPs are ready to cooperate should this situation arise.

12.3 Hostels and equivalent establishments

12.3.1 Residents:
There are no long-term hostel residents in Shetland, so TB screening is not required. However, the diagnosis should always be borne in mind when a resident develops, or has a change in respiratory symptoms, particularly if they have slept rough in the past. Hostel staff should be aware of likely signs, symptoms and presentations of TB, and of the appropriate points of contact (GP and Public Health) for action.
Hostel residents each live in single units, so no special criteria for contact tracing are applicable. The usual guidelines should be followed.

12.3.2 Staff
Hostel staff should be BCG vaccinated if necessary as a routine occupational health measure on taking up the post (see Section 15). Where staff have been in contact with a smear positive case, they should be assessed for degree of exposure and thereafter managed as set out in Section 9.

12.4 Vulnerable Groups

12.4.1 Individuals who consume Excess Alcohol:
Alcohol misuse is a recognised risk factor for TB and previous work has sought to investigate this association in Scotland. HPS are working on guidance to identify further areas for intervention and support, and support the sharing of good practice and initiatives across Scotland.
13 Migrants and New Entrants

13.1 Migrants

New entrant case finding is a priority in *A TB Action Plan for Scotland*\(^2\). The incidence of TB in many migrant groups in the UK is high, and the highest rates of disease occur within five years of first entry to the UK. The incidence of TB varies within countries, and some countries have a higher incidence of drug resistant strains, so monitoring and surveillance are important. Although Shetland receives only small numbers of migrants each year, it is nonetheless important to be aware of this important health risk in this population.

Previously all migrants (or other entrants, e.g. students, planning to stay in the country for 6 months or more) from countries with a high incidence of disease have been screened. In Shetland this included au-pairs and teenagers coming on the Global Classroom Exchange Programme. This UK programme to screen migrants for active TB at the port of entry is being replaced by quality assured pre-entry screening. However, this will not identify latent TB infection (LTBI) which studies indicate could account for up to three out of four new cases in the UK\(^4\).

The incidence of 40 per 100,000 population per year is suggested as a reasonable level above which TB may be considered high. (Appendix 3 - Up to date information can be obtained from WHO websites regarding individual countries. Alternatively contact the Public Health Department).

Screening not only allowed the identification of cases, but also allows chemoprophylaxis and BCGs to be given to those who may benefit from them. When potential cases were identified at port of entry, forms issued to Shetland Health Board by the Port Health Control Unit, ensured follow-up was done. See Table 12 for the criteria for completing the forms while pre-entry screening is not yet available.

*Table 12: Port Health Forms issued following referral for medical examination by the Immigration Service*

<table>
<thead>
<tr>
<th>Form Port 101 (white)</th>
<th>Form Port 102 (blue)</th>
<th>Form 103 (yellow)</th>
</tr>
</thead>
<tbody>
<tr>
<td>is used where the entrant appears to be in satisfactory health and where medical examination and chest x-ray have been completed either at Port Health Control Unit, or in the country of origin. Further investigation will depend on ethnic susceptibility to diseases such as TB. They should be helped to register with a GP.</td>
<td>is used when the medical examination is incomplete or is inconclusive in providing evidence of satisfactory health. Public Health will contact the entrant as soon as possible to ensure completion of the examination and other arrangements as above.</td>
<td>is used where the medical examination points to significant disease that may endanger the public health. Where appropriate the chest x-ray will be enclosed. The entrant will have undertaken to report to the DPH on arrival (and is required to do so under the Immigration Act 1971). Public Health should arrange a visit as a priority. Follow up will be monitored and the DPH is asked to return part C of the form to the Scottish Government within the time stated.</td>
</tr>
</tbody>
</table>
It should be noted that chest x-ray alone is an insensitive screening method, and a normal chest x-ray presented by the immigrant may not be recent, or even be theirs.

At present the arrangement for ports informing health boards of new arrivals cannot be relied upon, so additional methods for identifying those at risk are required. In Shetland this primarily involves GPs and schools being alert to new people registering on their lists. In addition new entrants such as au-pairs and students do not need Port Health Forms, so it is important GPs and schools are alert to their need for screening, and inform Public Health when such entrants register.

DPH should ensure that the full protocol has been applied if not carried out at port of entry. In practice this will be done by the Public Health Specialist, or Primary Care Staff. This should include a health status interview including current symptoms, previous TB and BCG. Mantoux testing should be limited to those without a BCG scar. Screening and Mantoux testing should be carried out in the home or at a health centre convenient to the immigrant.

**National Guidance for New Entrant Screening:**

The national guidance says that new entrants should have a CXR done if they have not had one recently. If it is abnormal they are referred to the TB service. If it is normal and they are either under 16; or aged 16-35 and from a highest risk country* then they should have a Mantoux test.

**NHS Grampian Policy**

The NHS Grampian policy differs from national guidance. This does not include the initial chest x ray and says that if aged over 35 they should receive information and advice. If aged 16-35 and from a highest risk country* they should have a Mantoux test.

The Shetland procedures follow national guidance.

*Sub-Sharan Africa or a country with an incidence of > 500/100000

The protocol for screening new-entrants is summarized in flow diagram 4 below.
Screening of New Entrants from High Risk Countries

1. Chest x-ray taken recently?
   - Yes
   - No

2. Age <11 or possibly pregnant?
   - Yes
   - No

3. Chest X-Ray
   - Abnormal?
     - Yes
     - No

4. Selected group?*
   - Yes
   - No

5. Had BCG?
   - Yes
   - No

6. Mantoux test
   - Mantoux ≥ 15mm?
     - Yes
     - No

7. Interferon –gamma test
   - +ve or not available
     - Consider Chest x-ray
   - -ve
     - No action

8. TB Clinic – for chemoprophylaxis, selected groups*

*Selected groups: aged under 16 or aged 16-35 and from Sub-Saharan Africa or a country with an incidence of > 500/100,000
13.2 People travelling or moving abroad from Shetland

GPs should ask patients about their BCG status, when consulted for travel advice or immunisations. BCG is recommended for tuberculin-negative travellers under 16 years of age who will be living or working with local people for a prolonged period of time (three months or more) in areas with an annual TB incidence of 40/100,000 or greater.

Following individual risk assessment, vaccination may also be considered for travellers who may be at risk through their occupation abroad eg individuals working in a healthcare setting (see UK occupational risks above).

Shetland residents in this group should be assessed for the presence of a BCG scar by their GP before departure. If there is no evidence of a BCG scar, and a Mantoux test is negative, they should be offered BCG. This can be done by the GP, or arranged through Public Health. If the skin test is strongly positive or positive without evidence of BCG scar, they should have a chest x-ray. Otherwise no action is needed. Travellers should be advised to report any suspicious symptoms, with their travel history on their return. **There is no role for repeating BCG vaccination in those who are known to have received it in the past.**

Long-haul flights of over 8 hours in close proximity to a smear positive case of TB may constitute close contact, and should be managed accordingly.
14 Institutions

14.1 Colleges
The screening protocol for immigrants should be followed for all students coming from high-incidence countries for more than 6 months. Colleges and schools in Shetland should cooperate by making sure the DPH is aware of any such students, so that appropriate screening can be arranged.

14.2 Factories and other work settings
Generally the delivery of an advisory letter and contact card (Appendix 6) to each individual is sufficient following discovery of a case. Occasionally work settings (such as the cases on a ship in Shetland in 1994) may produce close contacts, and they should receive the standard screening for close contacts. If a high number of contacts are found to be infected (>10%), screening should be extended to those judged to be at the next level of risk.
15 Animal TB

15.1 Mycobacterium bovis infection in humans
Human infection with *M. Bovis* is uncommon. Since 1986 this organism has comprised only 2% of all TB notifications in Scotland. None of the cases was reported as directly attributable to an animal source, most representing reactivation of existing infections.

15.2 *M. bovis* in cattle
Cattle TB is becoming more common in the UK, particularly in parts of England. Udder infection is rare and spread between cattle is mainly by the respiratory route. Cattle herds are tested routinely. Animals giving a positive reaction to the tuberculin test are slaughtered and a post-mortem examination is carried out. In all cases the origin of the infection is investigated and the movements of potentially infected cattle on or off the farm are traced.

15.3 Liaison between medical, veterinary and other agencies
The Divisional Veterinary Manager of the State Veterinary Service, (based in Inverurie), should inform the DPH if any human cases of bovine TB are suspected as an origin, or consequence of cattle TB cases. The DPH should also be notified if there are several positive reactions or visible lesions at post mortem. Similar arrangements should apply to animals with lesions detected at routine meat inspection in the abattoir. Similarly the Divisional Veterinary Manager should routinely be informed of any human cases of *M. Bovis*, by the DPH.

Where any human case has a possible occupational origin, the DPH should inform the employer of their responsibility to report the case to the Employment Medical Advisory Service (EMAS), and also may advise the EMAS informally about the case.

While the responsibility to deal with milk from an infected dairy herd lies with the local authority, the DPH should confirm with the Environmental Health Department that arrangements for heat treatment of the milk are satisfactory.

15.4 Guidelines for screening humans
Where studies of human contacts of cattle have been undertaken little evidence of transmission – as judged by Heaf testing –and no clinical disease has been found. Only those who have direct exposure to an animal with pulmonary lesions or raw milk from an animal with udder lesions should be screened.
### Table 13 Investigation of contacts of M. Bovis infected cattle

<table>
<thead>
<tr>
<th>Animal Reactor Type</th>
<th>Action by DPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactors with no visible lesions and culture negative</td>
<td>No screening required</td>
</tr>
<tr>
<td>All other reactors i.e. culture positive (uncommon) and/or those with visible lesions</td>
<td>Screen those in contact with animals Screen staff and other people living on the farm</td>
</tr>
<tr>
<td>Reactors with proven or possible udder infection</td>
<td>Screen those who may have consumed raw milk</td>
</tr>
<tr>
<td>Abattoir cases with visible lesions</td>
<td>Discuss with Divisional Veterinary Manager to assess risk.</td>
</tr>
</tbody>
</table>

See flow chart 5 for the screening protocol. (The responsibilities of the Contact Tracer, GP and Consultant in Thoracic Medicine are the same as detailed in Section 9, Table 5).
Screening Protocol for Human Contacts of Animals with TB

Direct exposure (animal with pulmonary lesions/raw milk from animal with udder lesions)

Had BCG, proven by scar or documented neonatal BCG

- Age <16
  - Mantoux 6 wks post exposure
    - ≥ 6mm: GP to organise CXR & clinical examination
    - 0-5mm: GP to organise CXR & clinical examination
      - Normal: Discharge
      - Abnormal: Refer to Thoracic Medicine Consultant for chemoprophylaxis
    - Abnormal: Refer to Consultant for investigation
    - Normal: Discharge
  - ≤ 6mm: GP to organise CXR & clinical examination
    - Normal: Discharge
    - Abnormal: Give BCG if <16
      - Age 16+:
        - Normal: Discharge
        - Abnormal: Give BCG
      - Age <16:
        - Normal: Discharge
        - Abnormal: Refer to Consultant for chemoprophylaxis

No BCG

- Age 16+
  - Mantoux 6 weeks post exposure
    - ≥ 6mm: GP to organise CXR & clinical examination
    - 0-5mm: GP to organise CXR
      - Normal: Discharge
      - Abnormal: Give BCG if <16
        - Age 16+:
          - Normal: Discharge
          - Abnormal: Refer to Consultant for chemoprophylaxis
        - Age <16:
          - Normal: Discharge
          - Abnormal: Refer to Consultant for chemoprophylaxis

Age <16
- Mantoux 6 weeks post exposure
  - ≥ 6mm: GP to organise CXR
    - Normal: Discharge
    - Abnormal: Give BCG
  - 0-5mm: GP to organise CXR
    - Normal: Discharge
    - Abnormal: Give BCG

Age 16+
- Mantoux 6 weeks post exposure
  - ≥ 6mm: GP to organise CXR
    - Normal: Discharge
    - Abnormal: Give BCG
  - 0-5mm: GP to organise CXR
    - Normal: Discharge
    - Abnormal: Give BCG
16 Occupational Risk

Where there is a known occupational risk, such as in the Health Service, the Control of Substances Hazardous to Health Regulations 1994 (COSHH) require potential occupational exposures to be assessed and controlled, and where necessary the introduction of health surveillance for exposed workers. There is also a duty on employers to provide information and training to their staff to reduce the risk. If an employee contracts TB as a result of his or her occupation, then the employer has a duty to report this under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). It is also considered to be a Prescribed Disease if contracted in the work setting.

16.1 Screening and Vaccination

16.1.1 Personnel requiring screening

The following staff should be screened as summarized in 17.1.2.

Healthcare workers

- Doctors
- Nurses
- Professions Allied to Medicine
- Others in direct regular contact with patients or specimens (e.g. laboratory staff, mortuary staff, porters)

This includes all part-time, externally contracted and non-NHS staff. Screening for all Health Board and Sodexho staff is done by the Department of Occupational Health in Brevik House.

Local Authority Workers

- Mortuary workers
- Care staff in residential homes and hostels
- Social workers dealing with children and people with HIV infection
- Environmental Health Officers with regular or prolonged patient contact

Occupational health services are provided by NHS Occupational Health Service.

Voluntary Sector Workers

- Those working with people with HIV infection
- Those working with minority ethnic groups
- Those working with homeless people

Others

These include those working with animals:

- Veterinary staff
- Farmers
- Agricultural workers and students
• **Oil workers** who are transferring to work abroad. They are referred by Sullom Voe Occupational Health to their GP in Shetland for travel advice, including TB screening/vaccination. GPs should follow the advice for travellers (see Section 12.2). GPs should also be aware of the increased risk of TB in Oil Workers on their lists who have returned from abroad.

Note that routine pre-employment screening for those working with children, e.g. **school teachers** is no longer required. They should be aware of the need to report suspicious symptoms.

**HIV infected healthcare staff** should not care for patients with infectious TB, due to the risk of becoming infected themselves, and then spreading the infection. They should also understand their duty to report any symptoms of TB immediately. In the UK, it is **not** recommended that they are offered BCG. Routine screening for HIV is not appropriate before giving BCG vaccination to new staff, but questions to determine whether the individual has a high risk of being immuno-compromised should be asked, and HIV testing offered if appropriate.

### 16.1.2 Screening protocol

All workers at occupational risk should be advised of the importance of reporting symptoms suggestive of TB to their own GP and their Occupational Health service. Contact tracing may be indicated where there has been a known exposure to TB, at the discretion of the clinician and DPH.

Routine screening of new employees should be done by Occupational Health in accordance with the following protocol;
Screening Protocol for Staff who may be at Occupational Risk of TB

Pre-employment questionnaire

Suspicious symptoms

Medical examination & CXR

Abnormal

Refer to Consultant in Thoracic Medicine for investigation

No suspicious symptoms

Working with patients or specimens

Normal

No

No Action

Yes

BCG Scar or documented evidence or clear and reliable history?

Yes

Mantoux*

No

0-5mm

Inform & advise Re potential symptoms

≥ 5mm

Give BCG

*Mantoux test may be repeated in older persons to detect a boosted reaction and avoid unnecessary BCG vaccination.
Although there is little evidence for the efficacy of BCG in adults, because health-care workers face potentially continuous exposure to TB, those who are previously unvaccinated, with Mantoux <6mm should be offered BCG. Should they refuse this offer the risks should be explained and the refusal documented. The importance of reporting any suspicious symptoms should be re-emphasized. If an individual does receive BCG, there is now no need to inspect the site after vaccination (although Occupational Health may want to inspect the scar for audit purposes); repeat the Mantoux test, or revaccinate, according to the BTS 2000 guidelines.

There is evidence that strongly positive reactions in health-care staff are common and do not indicate clinical disease. A chest x-ray should only be requested if there are symptoms, or a history of contact with TB on careful enquiry. If a chest x-ray is abnormal they should be referred to a Thoracic Medicine Consultant in ARI.

Individuals with grades 2-4 reactions, who are asymptomatic should be advised they have encountered the tuberculous bacillus in the past and do not require BCG. They too should be advised to report any suspicious symptoms promptly.

New employees from high-incidence countries (check WHO websites, or ask Public Health for up-to-date information about which countries have an incidence of TB >40 per 100,000) should be screened as set out under Section 12 on immigrants.

16.2 Contact Tracing

Healthcare staff who have been in close contact with a smear positive case will be assessed according to the contact screening protocol, 9) by the Contact Tracer (Public Health staff). If they are considered immune, from previous exposure or BCG, they should be issued with a contact card (Appendix 7) to remind them of the risk and to report relevant symptoms. It is expected that staff working routinely with TB patients or specimens will have been given BCG pre-emptively.
17 Control of Infection in Hospitals

17.1 Advice and communication
Advice on day-to-day Control of Infection issues relating to individual patients with tuberculosis can be obtained from Shetland Control of Infection Manual; HPS Model Polices (respiratory precautions) and the Infection Control Nurse, and can be supplemented by advice from SMRL.

17.2 Non-Pulmonary TB
Adults with non-pulmonary TB can be nursed on a general ward, although aerosol generating procedures, such as abscess or wound irrigation may necessitate isolation.

17.3 Pulmonary TB

17.3.1 Isolation / Transfer
Staff, patients and visitors are all at risk of infection from smear-positive cases. Smear positive cases, and patients with clinical or radiological evidence suggestive of pulmonary TB should be considered infectious and isolated. They should be considered infectious until they have completed 14 days of treatment or until they have had 3 consecutive negative smears, over at least 14 days. BTS and Interdepartmental guidelines state that if there are immuno-compromised patients on a ward, infectious TB patients should be nursed in a negative pressure room. Since there is always the possibility of there being immuno-compromised patients on ward 3, all patients with infectious TB must be transferred to Aberdeen if they require hospital treatment. Once the patient is not infectious they may be transferred back to the Gilbert Bain, (although treatment should continue to be supervised by the Consultant in Aberdeen). The criteria for deeming a patient no longer infectious should be applied strictly, since there may be immuno-compromised patients in the GBH, and evidence for the 14 days treatment rule is not strong.

Table 14 Transfer criteria for patients with TB

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Infectious</th>
<th>Potentially infectious</th>
<th>Non-infectious or extra-pulmonary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug sensitive disease</td>
<td>Transfer to ARI</td>
<td>Transfer to ARI</td>
<td>Nurse on open ward, but transfer to ARI may be required for specialist treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDR TB</td>
<td>Transfer to Edinburgh Western General for Negative Pressure room isolation</td>
<td>Transfer to Edinburgh WGH for Negative Pressure room isolation</td>
<td>Requires single room isolation only, but transfer to ARI may be required for specialist treatment</td>
</tr>
</tbody>
</table>
17.4 Control of Infection in the Gilbert Bain Hospital

Although all infectious patients should be transferred, bad weather may mean this cannot happen immediately. If the patient is admitted to GBH they should be nursed in a single room, on a ward without immuno-compromised patients if possible. The following advice should also be observed.

- While the patient is in single room isolation visitors should be restricted to those with prior substantial exposure.
- Children with TB and their visitors should be segregated from the rest of the ward until the visitors have been screened to exclude them as the source of the infection. Only those who have already been in contact with the patient before diagnosis should be permitted to visit while the patient is considered infectious.
- Marked crockery and separate washing up facilities are unnecessary, and no special precautions are needed for books, etc.
- Linen should be sent in red alginate bags to the laundry. (Refer to Linen Procedures)
- The door of the side room should remain shut to prevent nosocomical spread to other rooms.
- Patients should be taught to cover both nose and mouth with a tissue whenever they cough or sneeze. The risk of aerosol contamination is reduced if patients are encouraged to expectorate into tissues. Those with sputum positive disease and a cough and are unable to co-operate with this practice should wear a mask to prevent aerosol droplet spread when being transported through other patient areas. A surgical mask is acceptable (BTS, 2000).
- Sputum and other respiratory specimens should be sent in plastic bags and labelled “biohazard”. The laboratory has guidelines for handling these specimens, and will send them on, unopened to ARI.
- Disposal of infected material, such as tissues, should be by incineration, so should be securely disposed of in orange bags. (Refer to Clinical Waste Disposal Procedures)
- Fumigation of rooms which have housed TB patients is unnecessary. A fresh solution of general purpose detergent and hot water should be used for general environmental cleaning in isolation rooms and following termination of isolation. (Refer to local Procedures for cleaning of Isolation Rooms)
- Laying out procedures: these should be carried out by the carer/undertaker or relatives (under supervision) wearing gloves and aprons.
- “Danger of Infection” precautions: the body should be placed in a shroud (or the person’s own clothes) and then in a secured body bag. The identity labels and “Notification of death” labels should be attached in such a way that they may be read through the body bag. “Notification of death” and “Danger of infection” labels should be attached discreetly to the outside of the bag. Neither label should state the diagnosis (which is confidential information), only the type of precautions required.
Once the body bag is sealed there is no further need for protective clothing for those handling the body.

- Viewing of the deceased by relatives and friends: those who wish to view the body should do so as soon as possible after death. They should be told that there is a risk of infection and should be advised to refrain from kissing or hugging the body.

- Any staff who attend the patient in a routine manner are not at special risk. Such staff are casual contacts and can be reassured and reminded of the possible symptoms of TB to report. Barrier nursing and gowns are unnecessary. However because of the more serious consequences of infection, those attending confirmed or suspected infectious MDRTB patients should use dust / mist-fume masks meeting the 1992 Personal Protective Equipment (EC Directive) Regulations. For further details of working with MDRTB patients see Section 8.
17.5 Contact Tracing

If an individual on an open ward is diagnosed as having infectious TB, the risk of other patients being infected is likely to be small. Decisions about appropriate action should be taken by Public Health Nurse and DPH in conjunction with the hospital clinicians, and will take into account the degree of infectivity, the duration before the infectious individual was isolated, the proximity of contact, and whether other patients were unusually susceptible to infection. The DPH will do a risk assessment, and will use the Incident (Outbreak) Plan if necessary.

- In general patients in the same bay should be regarded as close contacts only if the index case was coughing and in the same bay for over 8 hours before being isolated. If this is not the case, it is sufficient to document the exposure, inform the GP and patient. (See model letters in Appendix 6)

- If the length of stay of the index case was for more than a day or two, and the other patients are known to be more than usually susceptible to infection, such patients should have their risk assessed even if they were not in the same bay.

- Where the index case is shown to have MDRTB more stringent contact tracing may be necessary.

- Similarly if the investigation of household contacts of the index case has an unusually high yield, a repeat risk assessment should be done.

- Staff who have undertaken mouth to mouth resuscitation without appropriate protection, prolonged care of a High Dependency patient, or repeated chest physiotherapy on a patient with undiagnosed TB should be managed as close contacts.

For guidance for immuno-compromised patients (e.g. patients or visitors with HIV) with TB see Section 18.
18 Elderly patients and care/residential homes

The aim of this section is to ensure that all reasonable steps are taken to protect residents and staff from TB acquired or treated in residential homes. It contains guidance on organisational and management issues which should be considered in prevention of further cases, and has been laid out with a view to circulation of copies to managers of local care homes.

18.1 Monitoring and reporting
A record (e.g. a log book) should be kept at the care home to record information on residents with suspected and confirmed infections; arrangements for this must protect patient confidentiality. Prompt notification and reporting of TB cases enables investigation and control measures to be instituted rapidly, and is essential for the monitoring of infection. Cases must be notified by the attending physician (usually the GP) to the Director of Public Health (DPH) of the Health Board. A notification form and advice on local arrangements is available from the DPH. It is recommended that the manager of the home should also report such cases immediately to the DPH by telephone. (The DPH or on-call Public Health consultant is always contactable via Gilbert Bain switchboard, 01595 743000)

18.2 Control of Outbreaks (see Section 10)
An outbreak may be defined as 2 or more cases of the same infection associated in time and place. As soon as an outbreak of TB is suspected within a home, the person in charge must immediately contact the DPH by telephone. The DPH will:

• Decide whether there is a true outbreak and will initiate and coordinate any necessary action using the local Incident (Outbreak) Control Plan.

• Advise the person in charge of any immediate actions necessary to control the outbreak; these may include isolation of patients, and/or stopping admissions and transfers for a period of time.

18.3 Occupational Health
In the context of overall infection control, each home should have appropriate policies for the protection of staff through vaccination, training and compliance with Health and Safety legislation. Such policies should apply to all agency and locum staff, and to those on short-term contracts. Each new member of staff should complete a pre-employment health questionnaire and give information about previous illness and symptoms. Evidence of previous BCG immunisation (presence of the characteristic pale, flat circular BCG scar on the upper arm or thigh) should be sought, the results recorded and any action taken as advised by the Occupational Health Physician/Advisor.

Infection Control Policies should be available to ensure that residents are protected from staff with TB. Such policies should clearly set out the responsibilities of staff members to report episodes of illness to their manager. When necessary, staff may have to be excluded from work until they have recovered or results of specimens are available; as homes vary in terms of the vulnerability of their residents to infection, policies may differ between homes and advice should be sought from the home’s Occupational Health Advisor, or the Department of Public Health.
18.4 Last Offices for an infected person
The precautions used for handling infectious residents do not stop with the person’s death. The body of a person who has been suffering from an infectious disease may remain infectious to those that handle it. The following guidance should be adhered to:

- **Laying out procedures:** these should be carried out by the carer/undertaker or relatives (under supervision) wearing gloves and aprons.

- **“Danger of Infection” precautions:** the body should be placed in a shroud (or the person’s own clothes) and then in a secured body bag. The identity labels and “Notification of death” labels should be attached in such a way that they may be read through the body bag. “Notification of death” and “Danger of infection” labels should be attached discreetly to the outside of the bag. Neither label should state the diagnosis (which is confidential information), only the type of precautions required. Once the body bag is sealed there is no further need for protective clothing for those handling the body.

- **Viewing of the deceased by relatives and friends:** those who wish to view the body should do so as soon as possible after death. They should be told that there is a risk of infection and should be advised to refrain from kissing or hugging the body.

18.5 Control of Infection Precautions
TB in the elderly usually results from reactivation of previously healed tuberculosis infection. The original infection might have occurred years before and passed unnoticed. New residents should have any past history of TB recorded, and symptoms suggestive of TB in any resident should be investigated promptly. All staff should be aware of the symptoms of TB (e.g. chronic cough, perhaps with blood stained sputum, weight loss, night sweats) and immediately report suspicious symptoms in themselves or residents. Table 15 illustrates the precautions required for control of TB infection in care homes.
Table 15 Control of Infection precautions

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Code</th>
<th>Duration of application of precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory (sputum smear positive)</td>
<td>3</td>
<td>Until 2 weeks of treatment are completed. Seek advice from DPH on management of contacts.</td>
</tr>
<tr>
<td>Respiratory (sputum smear negative)</td>
<td>1</td>
<td>Nil required</td>
</tr>
<tr>
<td>Genito-urinary</td>
<td>2</td>
<td>Until recovered. Apron &amp; gloves must be worn when handling urine</td>
</tr>
<tr>
<td>Abscess</td>
<td>2</td>
<td>Gloves or a no-touch technique must be used when dealing with secretions or discharges from the affected area</td>
</tr>
<tr>
<td>Lymph nodes</td>
<td>2</td>
<td>Gloves or a no-touch technique must be used when dealing with secretions or discharges from the affected area</td>
</tr>
<tr>
<td>Meningitis</td>
<td>-</td>
<td>Cases normally admitted to hospital. Seek advice from DPH on management of contacts</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>Gloves or a no-touch technique must be used when dealing with secretions or discharges from the affected area</td>
</tr>
</tbody>
</table>

Code 1: No extra precautions necessary

Code 2: Residents may mix freely but consider treating linen as infected

Code 3: Single room isolation; no social mixing with other residents; separate eating arrangements; treat linen as infected.

Homes need to be aware of the physical, social and psychological effects of Code 3 isolation. There is a need for verbal and written information explaining the need for precautions being taken.
19 HIV Infected and immuno-compromised patients

It is essential to be aware of the risk of TB for immuno-compromised patients. In such patients TB infection can progress rapidly to disease. TB is an established AIDS indicator disease, and HIV is a recognised risk factor for TB. In the UK to date, however, overlap between the two diseases has been small.

Further technical details of requirements for hospitals dealing with HIV-infected patients are available in the Interdepartmental Working Group document (See Appendix 5).

19.1 Definition of immuno-compromised

Immuno-compromised patients include HIV infected and transplant patients, patients with leukaemia and lymphoma, and patients receiving immunosuppressive drugs, including the equivalent of 15mg of prednisolone daily.9

19.2 Screening

Screening for TB infection in HIV infected and other immuno-compromised individuals should include a chest x-ray. Evidence of a BCG scar is not sufficient to discount active infection and Mantoux testing results in high false negative rates. Notification rates for TB are consistently lower in HIV seropositive cases than in those known or thought to be HIV negative. All suspected cases should be notified even if later denotification is required. (e.g. if the disease is found to be due to an atypical mycobacteria). In contact tracing, the patient’s consent to divulging the dual infection where appropriate should be sought, as the contacts may also be HIV seropositive.

19.3 Diagnosis

Diagnosis of TB in immuno-compromised patients may be difficult. Clinical presentation may be atypical and TB may mimic, or co-exist with other opportunistic infections such as Pneumocystis carinii or atypical mycobacteria (usually M. avium). In this patient group a higher proportion of culture positive sputum samples are smear negative than in the general population, there may be no reaction to tuberculin testing, and chest x-rays may have a non-characteristic appearance. Advice on molecular typing is available from the SMRL.

19.4 Specialised hospital management facilities and infection control

It is particularly important that cases of TB in the immuno-compromised are managed by specialist physicians with access to appropriate isolation facilities. Therefore all such patients in Shetland should be transferred to Aberdeen.

Immuno-compromised staff and visitors should not be in contact with potentially infectious TB patients. If such a visitor insists on entering the room of the patient, they should be advised to wear a mask.

19.5 Treatment

Discharge from isolation should be arranged carefully with the DPH and GP, so that DOT supervision will continue. Treatment is the same as in immuno-competent individuals, as they have similar responses to treatment.

Lifelong chemoprophylaxis with isoniazid following completion of TB treatment is no longer recommended, as its efficacy in preventing recurrence is unproven, and it encourages resistance to develop.
Preventive chemoprophylaxis in HIV infected individuals who have evidence suggesting past tuberculous infection, but no evidence of active disease, may be considered. However if compliance is judged likely to be poor, it may do more harm than good, if isoniazid resistant strains are thereby encouraged. Such decisions should be made by specialists.

19.6 Drug Resistant TB
HIV infection is a risk factor for MDRTB. DOT is recommended, and lifetime follow up should include at least annual radiography. Follow-up arrangements will be made by the Thoracic Medicine Consultant, in liaison with the GP.
20 Other Aspects

20.1 Education and training
There have been significant worldwide changes in the incidence, presentation and management of TB over the past few years. There is a professional obligation on medical and nursing staff, particularly those directly involved with Mantoux testing, BCG, DOT, TB cases or contacts, to maintain their skills and be aware of recent advances. Opportunities for further training will be made available through Grampian courses and training days. Further information can be obtained from the Public Health Nurse.

There is a statutory obligation on employers to ensure training on Health and Safety.

Training in infection control is a regular feature in the education programme for nurses and junior doctors.

20.2 Audit
The local procedures for information flow, contact tracing and management of sporadic cases and for outbreaks are amenable to simple audit and should be the subject of regular review by those involved. The enhanced surveillance scheme also facilitates this process. Target setting is an essential component of the audit cycle, in order that outcomes are measurable. The following targets are in line with the Grampian targets, as some of them involve referral to Grampian services.

Targets set are:

- 100% case notification
- 100% of patients will commence treatment within one week of diagnosis
- 100% notification within three working days of diagnosis/decision to treat (verbal if not written)
- 100% of patients will complete treatment
- 100% of paediatric patients will be managed jointly between paediatrician and consultant in thoracic medicine
- 100% of close contacts of smear positive patients will have screening arranged within 2 weeks of identification
- 10% of all school age children receiving BCG will be recalled for BCG scar inspection

Specific MDT audit such as of contact tracing, with voluntary groups and new entrants, primary care and problem alcohol users through AADP are detailed in the NHS Shetland Control of Infection Committee Workplan.
20.3 Research
Epidemiological research is facilitated by the enhanced surveillance scheme and it is important Shetland cooperates fully with this. Other important areas of research include drug resistance, molecular epidemiology, and methods of delivering treatment to poor compliers.

20.4 Resources
Due to the small number of cases locally, the control and surveillance of TB is usually resourced using the existing Public Health Department staff, and Primary Care staff. Specialist care is provided by Grampian. In the event of an outbreak or major contact tracing exercise being necessary, it will be necessary to request outside help in order to provide sufficient staff, and other resources.
21 References


9 Definition from Interdepartmental Working Group guidelines and Communicable Disease Handbook