A TB Action Plan for Scotland

The Scottish Government

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Foreword

Tuberculosis is an ancient disease that has been with mankind for centuries, probably millennia. Towards the end of the last century, it was commonly accepted that tuberculosis was a conquered disease, an infection of the old world which was well controlled by modern medicines and good clinical practice. In particular the work of Scottish physician Sir John Crofton played a significant part in the steps taken to control TB during this period. However we now know that our optimism that TB had been conquered was ill-founded. Tuberculosis has not survived for so long with mankind to be so easily eliminated.

The introduction to this Action Plan reports that tuberculosis continues to kill an estimated 1.8 million people worldwide each year. Many of these deaths continue to be in developing countries where access to vaccines, antibiotics and health care can be limited. But it is wrong to assume that these parts of the world are the only places where tuberculosis can devastate lives. In the developed world tuberculosis continues to have a strong grip, particularly amongst those with other social and health related problems. Drug resistant strains of the disease are emerging and need to be carefully managed and the continued prevalence of HIV can lead to significant complications for those co-infected with tuberculosis. In a rapidly changing world with increased movement of people wealthier countries no longer have the luxury of thinking tuberculosis is not a problem. Tuberculosis is an issue of global concern affecting every country. It is also naïve and simplistic to think that tuberculosis is a problem whose cause is immigration alone.

In recent years Scotland has had a relatively low and stable incidence of tuberculosis. Compared with other parts of the UK and Europe the disease has not been a significant problem. However, the recent epidemiological evidence suggests that the picture may be changing. While tuberculosis is still at lower levels than elsewhere in the UK, the numbers of cases we are now seeing are suggestive of an increasing incidence. We need to act now to reverse this trend in Scotland.

At the highest level, the intention of this Action Plan is to ensure that Scotland provides the best quality clinical, laboratory and public health services in relation to tuberculosis, and that these are underpinned by the best possible surveillance and epidemiology. Our ambition is not just to stabilise the incidence of tuberculosis in Scotland. We want to go further. We want to significantly reduce the burden of ill-health caused by this serious disease. I believe the recommendations that are contained within this Plan provide a firm steer on what is needed. I have accepted these recommendations and the NHS Boards and other partners, including the Scottish Government, now need to deliver them.

I am grateful to all those who gave their time to the Working Group or Sub-Groups that developed this Action Plan. This commitment to improving services across the country, and the shared ambition to significantly reduce the impact of tuberculosis on the people of Scotland, reflects the very best that the NHS can be. It carries on the very good work that Sir John Crofton took forward in Scotland half a century ago.

Shona Robison
Minister for Public Health and Sport

About this document

This document details the recommendations of the TB Action Plan Working Group. These recommendations have been accepted by Government.

Sections 2-6 of this report summarise the issues considered by the Working Group and Subgroups and detail the recommendations that have been made as a result. Annex C summarises all of the recommendations made and also provides details on which organisation(s) will be primarily responsible for delivery in each case and expected timescales for commencement/completion as appropriate.

The TB Action Plan is primarily intended for those involved in the delivery of TB related services in Scotland. Accordingly the content and many of the recommendations of sections 2-6 are technical or relate to NHS structures and practices.

Section 1, the Introduction and Background section, is intended as an introduction to the topic for the lay-person or the non-TB specialist.

1. Introduction and Background

Tuberculosis

1.1 Tuberculosis (TB) is a global issue and it is estimated that TB continues to kill approximately 1.8 million people worldwide each year.

1.2 TB is a disease caused by infection with a bacterium called *Mycobacterium tuberculosis*. The organism is related to a number of different bacteria which together are called the *Mycobacterium tuberculosis* complex.

1.3 TB commonly infects people's lungs and respiratory tracts and in these cases it is known as pulmonary or respiratory TB. However, TB can infect almost any part of the body as non-pulmonary or non-respiratory TB.

- **Pulmonary (or respiratory) tuberculosis** is a TB infection of the lungs themselves, or of the bronchi or trachea (the windpipes) or of the larynx (the voice box)
- **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.

1.4 The symptoms of TB vary, depending on which part of the body is infected. General symptoms include fever, night sweats, weight loss, loss of appetite and lethargy. Pulmonary TB usually causes a persistent, severe cough with sputum which may have blood in it. Non-pulmonary TB causes symptoms which are related to the organ infected. For example TB of the glands may cause swelling in the neck and a discharge.

1.5 TB infection can be **latent** or **active**. The symptoms of latent and active TB are summarised in Table 1 below. A person with active TB may spread TB infection to others, usually has a positive tuberculin skin test (see 1.11 below) or positive TB blood test, and may have an abnormal chest x-ray or positive sputum smear or culture.

TABLE 1: Latent and Active TB

Latent TB	Active TB
A person has: • No symptoms of TB • Does not feel unwell • Cannot spread TB to others • Usually has a positive skin test or TB blood test • Has a normal chest x-ray and sputum test • May convert to active TB later in life if individual's immune system declines	Symptoms *may* include: • A bad cough that lasts 3 weeks or longer • Pain in the chest • Coughing up blood or sputum • Weakness or fatigue • Weight loss • No appetite • Chills • Fever • Sweating at night

1.6 When a person is infected with TB, they may simply get better, recovering from the infection. However, in some cases the initial infection can progress to become active TB disease and in these

cases it usually 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, already described.

1.7 **Treatment** for TB requires a course of a combination of four antibiotics, which a patient must take for at least six months. Because of the particular drugs involved, which tend to be used only for TB, some doctors and nurses specialise in treating TB and work together as a team to look after TB patients.

1.8 The bacteria which cause TB can develop **resistance to the drugs** used to treat the condition. For this reason, it is very important that every patient completes their full course of TB treatment. If the bacteria develop resistance to the antibiotics the disease becomes much more difficult to treat. There has been an increasing risk of TB bacteria developing resistance to the main antibiotics used to treat the disease. 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. Treatment of drug-resistant TB also takes much longer than non-drug resistant TB and is also significantly more expensive.

1.9 When HIV and TB disease occur together they interact and treatment becomes very complicated, with several different drugs required. Those with such 'co-infection' may have a poorer outcome unless both conditions are identified early and treatment is very closely supervised.

1.10 Currently, the only available **vaccine** against TB is the Bacillus Calmette-Guerin (BCG) vaccine. The BCG vaccine contains live bacteria that have been modified to be safe. Studies of the effectiveness of the BCG vaccine have given widely varying results, but meta-analyses have shown the vaccine to be 70 to 80% effective against the most severe forms of TB, such as TB meningitis in children. The vaccine is less effective at preventing respiratory disease, which is the more common form in adults. Protection has been shown to last for 10 to 15 years. There are few data on the protection afforded by BCG vaccine when it is given to adults aged 16 and over, and virtually no data for persons aged 35 years or over. For more information on the BCG vaccine see the Department of Health publication *Immunisation Against Infectious Disease* (the 'Green Book') which is available in electronic format at the following link: http://www.dh.gov.uk/en/Publichealth/Immunisation/Greenbook/index.htm.

1.11 The **tuberculin skin test** is a diagnostic tool for TB. It helps to determine if someone has an immune response to the bacterium that causes TB. The skin test is administered and then read 2-3 days later. Administration involves injecting a small amount of tuberculin protein into the skin with a needle and syringe. A person who has been exposed to TB bacteria previously, who currently has TB, or who has had a BCG vaccination in the past, will normally mount an immune response in the skin containing the tuberculin bacterial proteins. If the test is positive, further investigation may be necessary.

1.12 New diagnostic tests for TB have recently been developed called Interferon Gamma Release Assays (IGRAs). These are discussed further in section 2.

A Global Issue

1.13 Tuberculosis occurs across the world, although the World Health Organisation (WHO) estimates that 95% of TB cases now occur in developing countries. The effective treatments for TB described above have been available since the 1940s and many countries have made great progress in controlling the disease. However, despite the availability of effective drugs TB remains one of the leading causes of human illness and premature death in the world. The WHO Global Tuberculosis Control 2010 report

(http://whqlibdoc.who.int/publications/2010/9789241564069_eng.pdf) indicates that there were an estimated 14 million people living with TB in 2009 (see Table 1, page 5 of the 2010 report).

1.14 In 1991 the World Health Assembly recognised that TB was a major global public health problem and adopted a resolution calling for increased efforts to control TB. In 2000, The United Nations adopted the Millennium Development Goals (MDG). MDG 6 defines the objectives of halting and starting to reverse the incidence of several major diseases including TB by 2015. This has increased the need for work to control TB. On 23 May 2007 the World Health Organisation adopted a resolution (WHA60.19 – (World Health Assembly)) calling for all Member States to develop and implement long-term plans for tuberculosis prevention and control in line with the Global Plan to Stop TB 2006–2015. Although there has been a small decline in worldwide incidence of TB, the reductions in incidence are not likely to meet the WHO target of halving the prevalence and mortality as a result of TB from 2006 to 2015.

1.15 The WHO has developed a new six point "Stop TB" Strategy (http://www.stoptb.org) addressing the key challenges facing TB. Its goal is to dramatically reduce the global burden of TB by 2015 by ensuring all TB patients, including for example, those co-infected with HIV and those with drug-resistant TB, benefit from universal access to high-quality diagnosis and patient-centred treatment. The strategy also supports the development of new and effective tools to prevent, detect and treat TB. The six points of the Stop TB Strategy include:

1. Pursue high-quality Directly Observed Therapy expansion and enhancement (see http://www.who.int/tb/dots/en/ for more information on Directly Observed Therapy)
2. Address TB-HIV, MDR-TB and the needs of poor and vulnerable populations
3. Contribute to health system strengthening based on primary health care
4. Engage all care providers
5. Empower people with TB, and communities though partnership
6. Enable and promote research

1.16 While TB has been declining globally in recent years, it is actually increasing in Europe. Accordingly the European Centre for Disease Control (ECDC) has a programme of work to tackle TB under its *Framework action Plan to fight TB in the EU. (*Available in electronic format at the following link*:* http://www.ecdc.europa.eu/en/publications/Publications/0803_SPR_TB_Action_plan.pdf).The programme aims to support Member States in TB prevention and control and thus reach the long-term goal of reducing and ultimately eliminating TB in the EU. The WHO defines "elimination" as an incidence of less than 1 per million population per year. It also intends to create a reference point for EU Member States that provides relevant expertise and information about trends in the epidemiology of TB, about emerging threats related to TB and about scientific advances in the field.

1.17 The Scottish Government takes seriously the WHO resolution and the work of the ECDC to tackle TB and recognises the impact of the global TB burden on the Scottish population. The Scottish Government has also made a commitment to *Health is Global*, a UK Government strategy in respect of global health priorities (published 30 September 2008 and available electronically at the following link: http://www.dh.gov.uk/en/Publichealth/Immunisation/Greenbook/index.htm). and TB is identified in this. Scotland is committed to global action on TB

The Scottish Dimension

1.18 The impact of this global public health threat is very much felt in Scotland. The development of drug resistance due to inadequate treatment and higher prevalence of disease in certain countries (due to poor detection and high levels of HIV in the population) has a significant impact on the UK and Scotland. While in the recent past the number of TB cases in Scotland has been largely stable,

epidemiological data from the last 4 years suggests that this picture is changing (see Figure 1 below) We are therefore seeing an increase in cases that mirrors the picture in some other parts of Europe (Sweden, Ireland). This presents a number of challenges for the NHS in Scotland.

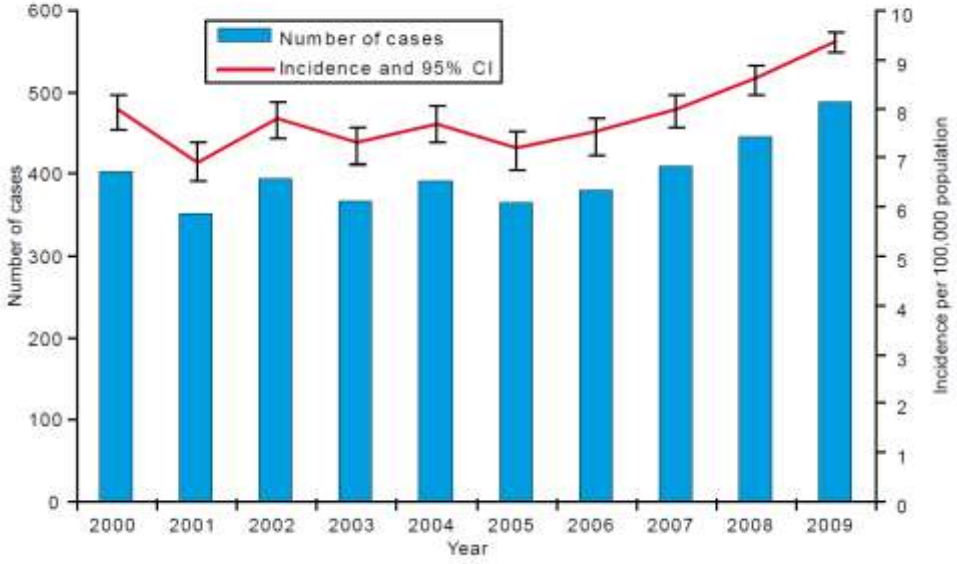
1.19 Cases of tuberculosis are currently recorded in Scotland using two different systems. The first is a system of "notification" of infectious diseases. This notification system has been in place since 1976 and simply records whether a patient with tuberculosis has pulmonary or non-pulmonary disease. The second system is the Enhanced Surveillance of Mycobacterial Infections (ESMI) system which has been operating since 2000. This system records much more information about tuberculosis cases, including details of their diagnosis, treatment and how well they have recovered. The detailed information on tuberculosis in Scotland is based on the ESMI data.

1.20 Scotland has had a continuing increase in the numbers of tuberculosis cases and the incidence of TB since 2005 (see Figure 1, below).The incidence in Scotland was lower than that of the whole of the UK population in 2009: 9.4 per 100,000 population in Scotland compared with 14.6 cases per 100,000 population across the UK. However, the incidence in Scotland is rising and is catching up with the rest of the UK. The 487 cases reported in 2009 were an increase of 8.8% in the incidence compared with 2008.

1.21 Historically, Scottish TB incidence has been higher in Glasgow and its surrounding area. In 2009, Greater Glasgow and Clyde notified 235 TB cases (48% of Scotland's total, an incidence of 19.6 per 100,000 of the population). Lothian had 78 cases and Grampian had 52 (incidences of 9.4 and 9.5 per 100,000 respectively).

1.22 In 2009 TB was more common amongst males, with 298 cases representing 61% of TB cases. The age group which had the most TB cases was aged 25-34 years, while TB was least common amongst those aged 5-14 years. The rate of TB among children aged under five years has remained stable at 3.1 cases per 100,000. This is important as infections in this age group do not occur from reactivation of latent TB infections, so this implies recent infection with TB. The fact that this figure has remained constant therefore suggests that transmission of TB within the population is continuing in Scotland.

FIGURE 1: Numbers of tuberculosis cases and incidence in Scotland, 2000-2009*



*Data for 2007-2009 are provisional and may be subject to change

1.23 The main risk factor for TB infection in Scotland is being non-UK born. In 2009, 53% of TB cases in Scotland were described as White Caucasian, while those of Pakistani or Indian origin accounted for 15% each and Black Africans represented 8%. 47% of those whose place of birth was known, were born outside the UK. Patients who were born in the UK had a higher average age when they were diagnosed (53 years) than those who had been born abroad (34 years). Of those born abroad, 31% were born in India and 28% were born in Pakistan while Nigeria and Nepal each accounted for 4% of these cases. 74% of those who were born abroad had entered the UK two or more years before they were diagnosed with TB and 38% had entered five or more years earlier. It is not fully understood why individuals develop TB more than 2 years after arriving in the UK but this could also be related to either latent infection on entry to the UK, infection once within the UK or perhaps frequent travel abroad.

1.24 Aside from place of birth, the other main risk factor for TB is problem alcohol use. The incidence of TB is also influenced by – and associated with – adverse social circumstances such as poverty, poor nutrition, reduced access to healthcare, homelessness, problem drug use and imprisonment (although TB is not a significant problem in Scottish prisons, with very few cases in the last ten years).

Current Policy

1.25 In Scotland, the most recent national and strategic document that set out policy on TB was *The Control of Tuberculosis in Scotland*, published by the Scottish Office Department of Health in 1998 (available in electronic format at: http://www.scotland.gov.uk/Resource/Doc/158121/0042779.pdf). This document has been supplemented by CMO letters and other instructions since it was published.

1.26 In March 2009 the Scottish Health Protection Network published *Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland*, (available at: http://www.documents.hps.scot.nhs.uk/about-hps/hpn/tuberculosis-guidelines.pdf) which was adapted from the similar publication by the National Institute of Clinical Excellence (NICE) in England. This document provided updated guidance to professionals on clinical approaches to management of TB and effectively superseded the 1998 Scottish Office document.

1.27 Given the changing epidemiology within Scotland and other developments across the UK and globally this TB Action Plan provides an opportunity to build on and support the implementation of the existing Scottish Health Protection Network guidance.

An Action Plan for Scotland

1.28 Recognising these commitments and developments, in 2008, the Minister for Public Health and Sport requested the Scottish Government and Health Protection Scotland to develop a TB Action Plan for Scotland. The aim of this Action Plan is to identify where current practices and services could be improved or enhanced, with the long term goal of a reduction of TB incidence in Scotland.

1.29 A Working Group, chaired by a Senior Medical Officer from the Scottish Government, was convened to take forward this work. To support the Working Group, four topic specific Subgroups were convened, each of which was tasked with reviewing evidence and experience in respect of one or more of the key areas of work for the Action Plan. Subgroups provided their conclusions to the Working Group which then consolidated the Subgroup recommendations into this Action Plan.

Membership of all groups is attached at Annex A and B.

Themes

1.30 As requested by the Minister for Public Health and Sport, the Working Group agreed to provide recommendations for actions specifically covering the following themes:

- **Effective laboratory services and diagnostic tools** – consideration of the best models of service for Scotland in terms of laboratory diagnostic services for TB.
- **Effective clinical services** in the broad sense – considering issues around identification, management and treatment of TB; around models of care; and best use of resources locally and nationally. It was also agreed that this strand of work would also consider associated issues such as drug resistant TB and co-infection issues (HIV).
- **Effective surveillance** – assessment of current surveillance systems and the need for/options for improvement.
- **Effective public health services** – considering issues around population level approaches to tackling TB, including contact tracing; detecting TB in risk groups; approaches to vaccination, and awareness raising.

1.31 In delivering this work, the Working Group and sub-groups considered recent evidence and experience including, but not limited to:

- Surveillance information in Scotland showing an upwards trend in incidence of TB in Scotland;
- A lack of knowledge around the current effectiveness and application of the selective vaccination programme and the need to reinforce professional practice to ensure the programme is effective;
- The results of a stocktake of TB services within Scotland carried out by Health Protection Scotland as part of the Action Plan development process.
- Some evidence of varying levels of clinical performance and practice in Scotland in respect of TB;
- Recent TB related public health incidents;
- The guidance document, *Clinical Diagnosis and Management of TB and Measures for its prevention in Scotland;*
- *Tuberculosis in the UK*, the Health Protection Agency annual report on tuberculosis; and
- The experience elsewhere in the UK, particularly in respect of *Stopping Tuberculosis in England*, the Department of Health action plan on TB, published in October 2004.
- Evidence and action plans for Europe (ECDC's *Framework action Plan to fight TB in the EU*) and the World (WHO's *Stop TB Strategy*)

The Healthcare Quality Strategy for NHSScotland

1.32 The Scottish Government published its Healthcare Quality Strategy on 10 May 2010 (available at http://www.scotland.gov.uk/Topics/Health/NHS-Scotland/NHSQuality). The Strategy sets out the Scottish Government's vision for health and health care in Scotland and, in particular, three Quality Ambitions that provide a focus for all activity.

1.33 In developing the TB Action Plan and finalising recommendations the Working Group has kept the key themes of the Quality Strategy in mind, in particular the three Quality Ambitions. These are central to what this Action Plan is seeking to achieve. Specifically:

- Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision-making

- There will be no avoidable injury or harm to people from healthcare they receive, and an appropriate, clean and safe environment will be provided for the delivery of healthcare services at all times
- The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated.

1.34 The recommendations contained within this Action Plan seek to reduce the future number of people developing TB and improve delivery of services to those affected by TB in Scotland in line with these ambitions.

2. Laboratory Services and Diagnostic Tools

Introduction

2.1 Laboratory services and the diagnostic tools laboratories use play a key role in the assessment, management and treatment of patients with TB. Currently across Scotland, nine mainly larger laboratories provide a microscopy and culture service for mycobacteria and at least four smaller laboratories provide a microscopy service only. Seven of the larger laboratories use traditional solid media only, two use liquid only and two a combination of both solid and liquid. Current Scottish Guidance and the Health Protection Agency (HPA) recommend use of both liquid and solid media for mycobacterial culture diagnosis. Laboratories which do not directly provide culture services often perform microscopy only for mycobacteria on clinical samples and send these to culturing labs. Microscopy and culture services are generally available in Scotland 5 days a week. HPA and the US Centre for Disease Control (CDC) CDC recommendations are for these facilities to be available 6 days a week.

2.2 The Scottish Mycobacteria Reference Laboratory (SMRL) is a key clinical and laboratory service, which also reviews new technological developments, helping to underpin the management of TB in Scotland. The SMRL receives specimens for direct molecular detection of *Mycobacterium tuberculosis* complex and the detection of drug resistance, rapid culture and cultures for identification, sensitivity testing and molecular typing (mycobacterial interspersed repetitive unit - variable number tandem repeat (MIRU-VNTR); 'fingerprinting'). The SMRL, which also reviews new technological developments, helping to underpin the management of TB in Scotland.

2.3 Technology is advancing and a number of new diagnostic tools are available now, with more likely to become available in the near future. There is a need to consider the value of these on an ongoing basis, learning from experience elsewhere in the UK, EU and globally.

2.4 The detection of active TB is the key priority for TB services. The detection of latent TB is developing technologically, but remains a lower priority than active TB.

2.5 The Laboratory Services and Diagnostic Tools sub-group considered these issues and provided advice to the TB Action Plan Working Group.

Key Issues

Microbial culture

2.6 Currently, predominant Scottish practice is for laboratories to culture mycobacterial samples on traditional solid culture media. Newer liquid culture techniques can reduce the time to obtaining a positive result by as much as 50%, and this offers significant benefit to clinicians, patient care and public health. However it is important to note that solid culture media, while slower, can provide greater sensitivity for some strains and species of mycobacteria, allowing more comprehensive diagnosis of *Mycobacterium tuberculosis* complex infection as well as non tuberculosis mycobacteria.

2.7 Current Scottish Health Protection Network (March 2009) and NICE (2006) guidance, is that clinical samples should be cultured by liquid and solid methods, bearing in mind that laboratories need a certain level of throughput to maintain quality control. The Working Group considers that it is now legitimate to move to the adoption of liquid culture techniques and that **at a minimum all specimens should now be cultured in liquid media as this reduces by more than half the time to result from 27 to 13 days as compared with solid culture**. Precious samples (e.g. CSF, biopsies, lymph nodes) and those requiring incubation at other than 36^0C such as skin biopsies and abscesses should receive

solid culture in addition to liquid culture. **Specimens should not be cultured on solid media alone**. Beyond this, solid culture, although ideal for maximal sensitivity, is less critical, particularly in a financially constrained environment, as the cost effectiveness of using both techniques has not been demonstrated. This will be reviewed in time.

Quality assurance

2.8 In line with the Quality Strategy, TB diagnostic services in Scotland should be high quality and efficient. To ensure that this is the case robust quality assurance mechanisms – which currently exist – should be adopted as standard practice. Specifically, **all laboratories carrying out mycobacterial microscopy and culture should be Clinical Pathology Accreditation (CPA) accredited, have specific quality systems and undertake appropriate External and Internal Quality Assurance.**

Laboratory service availability

2.9 Most mycobacterial diagnostic services in Scotland are currently provided 5 days a week. Health Protection Agency and CDC recommendations are for these facilities to be available 6 days a week. It is our view that 5 days per week is an adequate minimum. Current guidance is that the acute clinical and public health management should not be delayed by awaiting laboratory confirmation e.g. microscopy results. **The Scottish Government will support a 5 day minimum service, pending more evidence becoming available about potential implications of service increase to six days in terms of cost and quality. This will be reviewed in time**.

Optimisation of laboratory services

2.10 In line with the above comments about service provision, it is legitimate to consider the number of laboratories across Scotland that currently provide TB bacteriological diagnosis. The Quality Strategy has set us the ambition of reducing unnecessary duplication and improving efficiency while at the same time ensuring best quality services.

2.11 The Laboratory Services Subgroup researched evidence on optimal 'size' of laboratories for primary specimen processing but found that the only available guidance on numbers of specimens processed comes from the USA. The CDC National Plan recommendations (2005) indicates that culturing less than around 1500 specimens per annum in a low incidence area raises concerns about staff proficiency and that these concerns are addressed when more than 2340 specimens annually were examined. The American Thoracic Society and CDC recommendations are that for microscopy alone numbers of more than 20/week (1040 per annum) should be performed. (discussed in: Murray PR et al Editors, Manual of Clinical Microbiology 9th Edition 2007 Vol 1 Ch 36 P361. American Society of Microbiology Press, 2007 Washington).

2.12 Clearly there is a relationship between numbers of specimens and staff competency. Adequate specimen throughput for microscopy and culture is important and this too can strengthen the case that the centralisation of services into a smaller number of higher throughput laboratories would promote best quality practice and performance.

2.13 In line with the Quality Strategy and the commitment to reducing unnecessary duplication, **the Scottish Government will support work through the Scottish Microbiology Forum to consider the centralisation of Scottish mycobacterial diagnostic services into a smaller number of laboratories with higher throughput and defined quality standards in laboratories in Scotland.**

Future Developments

2.14 There are a range of new developments around diagnostic tools. Importantly the Interferon Gamma Release Assays (IGRAs) are currently under review by NICE. IGRAs are whole-blood tests that can aid in the diagnosis of *Mycobacterium tuberculosis* infection, measuring a person's immune reactivity to the bacterium. The value of the IGRA tests are that they are not confounded (i.e. are more *specific* than skin testing) by previous BCG vaccination and have a role in diagnosis of latent TB infection They can however be very misleading if used in the diagnosis of active TB infection and in their current format should not be used for this purpose. They may sometimes be more sensitive than skin testing, but longitudinal data is lacking at present. IGRAs may have significant benefits for the diagnosis of latent TB infection, improving the clinical care and contact tracing exercises. New IGRA guidance is being released by NICE and **this work should be considered by the Scottish Health Protection Network when available to inform guidelines on use of IGRA in Scotland.**

2.15 **The Working Group also notes that while IGRAs may in time to be shown to be more sensitive and specific than skin tests (which generally require more than one clinic visit by the patient) in the diagnosis of latent TB infection, these tests are expensive and their introduction should be managed in the most cost effective way.**

2.16 More generally molecular and other diagnostic tools are evolving and there needs to be ongoing review of these new technologies. As with IGRA the **Scottish Government should ensure a mechanism exists for the appropriate Scottish body to assess these developments on an ongoing basis to ensure the best quality and most efficient diagnostic tools are available in Scotland**. This may be best achieved though a Scottish Health Technology assessment.

2.17 The SMRL provides a valuable reference service as well as being a source of clinical and laboratory advice for mycobacterial issues. In addition it provides the national fingerprinting service (MIRU-VNTR, see 2.2 above). Fingerprinting can enable clusters of infection to be identified earlier than would be possible through traditional means, through a strain typing database, facilitating more effective control. This requires close collaboration with Consultants in Public Health Medicine (also known as Consultants in Health Protection), Health Protection Scotland, and other parts of the UK, through the Health Protection Agency. **The Working Group recommends that Health Protection Scotland and SMRL should establish a group to develop a clear strategy for the systematic use of molecular typing of *M. tuberculosis* complex in Scotland.**

3. Clinical Services

Introduction

3.1 Clinical services relate to the treatment, care and management at an individual level of those infected with TB. This relates to the critical role of TB clinicians (whatever clinical speciality) and TB specialist nurses but also to those who contribute to the management of patients through associated services.

3.2 Clinical care of patients with TB can increasingly involve management of complex issues such as treatment of drug resistant strains of the bacteria or clinical care for those co-infected with HIV or with other serious co-morbidities.

3.3 The Scottish Health Protection Network guidance *Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control in Scotland,* published in 2009, underpins approaches to clinical management of TB patients in Scotland. The document is available at: http://www.documents.hps.scot.nhs.uk/about-hps/hpn/tuberculosis-guidelines.pdf

3.4 The Clinical Services Subgroup considered a range of current issues in respect of treatment, care and management of patients, and provided advice to the TB Action Plan Working Group.

Key Issues

Strategic Planning

3.5 The incidence of TB varies across Scotland. In NHS Boards that have fewer cases of TB there has to date often been less of a clear focus on TB, both clinically and organisationally, than has occurred in some of the larger cosmopolitan Boards. However, it is vital to ensure that the quality of care that is delivered is of a high standard throughout Scotland, irrespective of the size of the Board or the number of TB cases seen per annum. Agreed systems and structures should be in place in all Boards, with an emphasis on multidisciplinary team-working, quality, audit, and shared TB learning on local, regional and national basis.

3.6 The Working Group felt strongly that **TB should be a Board priority for those areas in Scotland with the highest incidence of cases**. **Other Boards with lower incidence of TB should however also review their response to TB in line with recommendations in this report.**

Improving clinical management

3.7 A key aim of this Action Plan is to improve the consistency and quality of care for TB patients across Scotland, removing inappropriate variation as far as possible in line with the Quality Strategy. Informal TB networks exist in most Boards, but the Clinical Services Subgroup agreed that a more formal multidisciplinary approach – of the kind that has been shown to be very successful in other complex clinical areas, such as cancer care – should now be universally adopted by TB services in Scotland. Several Boards have already successfully introduced a multidisciplinary approach to TB care. This approach recognises that TB is a complex, multi-dimensional condition and that care of patients needs to take account of a range of clinical, social, occupational and other needs to ensure the best clinical outcomes.

3.8 Multidisciplinary approaches involve regular scheduled meetings to review every TB patient being treated. Meetings review the clinical and public health management of TB patients and so have a wider focus than traditional x-ray review meetings. Multidisciplinary team membership includes, as a minimum, every clinician treating TB in the geographic area covered by the team (including infectious disease, paediatric and respiratory specialists); every TB nurse in the area; public health nurses involved in caring for TB patients; Consultants in Public Health Medicine with TB lead; microbiologists and pharmacists.

3.9 The multidisciplinary team has a local leadership role, being responsible for developing local protocols based on national guidance, for supporting clinical audit of treatment, contact tracing activities, and for monitoring local morbidity and mortality. Multidisciplinary teams also have a role in promoting and supporting local continuing professional development (CPD) in respect of TB to ensure staff involved in patient care have up-to-date knowledge and skills.

3.10 GPs have a key role in the early detection and treatment of TB and a primary care representative should be a member of local multidisciplinary teams.

3.11 The view of the TB Action Plan Working Group is that the multidisciplinary team model of clinical care should be adopted across Scotland. In practice this means that **no TB patient should be treated by a single consultant without the involvement or oversight of a multidisciplinary team. Evidence shows that treatment of TB should be initiated by a specialist and supervision of management should be as part of an multidisciplinary team, including primary care**.

3.12 **GPs and primary care teams (including pharmacists) have a crucial role in the early detection of TB and, in collaboration with others, the overall care and treatment of their patients.**

3.13 **All TB patients in Scotland should have their care plans reviewed by a TB multidisciplinary team. In patients with suspected TB, initiation of anti-TB therapy should be discussed with a TB specialist to ensure optimal investigation and management.**

3.14 For those NHS Boards with a high incidence of TB it would be expected that multidisciplinary teams could be limited to NHS Board geographic areas. However, in Boards with lower TB incidences it may be more beneficial for two or more Boards to come together to form a single multidisciplinary team covering their areas. This would ensure sufficient clinical throughput for the maintenance of expertise.

Sharing Best Practice

3.15 The role of multidisciplinary teams can promote and ensure best quality care within the geographic area of that team. However there is a recognised need for professionals from different parts of the country to come together to share best practice, to jointly undertake training and development, and to inform future policy. **The Scottish Government should ensure that a national network of multidisciplinary team staff/leads is supported and facilitated.**

3.16 **Recognising the key role of TB Nurses, the Scottish Government should also ensure that the national TB Nurses Network is supported and facilitated.**

3.17 To ensure that clinicians from across Scotland working in the field of TB have the opportunity to meet and discuss issues, **the Scottish Government should ensure an annual national meeting of all health professionals involved in treatment and management of the disease is funded and facilitated**. This should include all clinical staff (including from the multidisciplinary team and TB Nurses networks) as well as public health leads.

Access to Negative Pressure Facilities

3.18 The Health Protection Network guidance on the management of TB, published in 2009 (see paragraph 3.3), states that there should be adequate arrangements in place for provision of suitable negative-pressure rooms for all NHS Board areas for treating respiratory and suspected respiratory TB. This is partly in the context of the challenges posed by immunocompromised patients in all areas of hospitals and the increasing incidences of multi-drug resistant TB for infection control

3.19 The TB Action Plan Working Group supports this guidance. To this end, **every NHS Board should have documented arrangements in place to ensure access to negative pressure facilities where these are required. Individual circumstances may make this challenging but at a minimum single rooms should be used where required for the period that any patient would be considered to be infectious.**

3.20 **Patients with MDR/XDR-TB should be managed in negative pressure facilities with en-suite facilities without exception. All patients with suspected MDR/XDR-TB, should be managed in a negative pressure room with en-suite facilities pending microbiological results.**

3.21 **These arrangements should be understood by all relevant staff involved in patient management and should, for example, form a core part of multidisciplinary team operational documentation.**

3.22 The above recommendations do not mean that every NHS Board is required to have their own facilities, but rather that they should have ready access to such facilities elsewhere in the country if required.

TB and HIV/AIDS

3.23 The relationship between TB and HIV infections is an important one. TB is an AIDS defining condition and there is significant incidence of TB and HIV co-infection in other parts of the world. According to the World Health Organisation 5% of all TB cases globally have co-infection with HIV.

3.24 Co-infection does occur within Scotland with associated clinical implications for both conditions. Early recognition of HIV infection in TB infected patients is important as initiation of anti-HIV therapy during the course of TB therapy has been shown to reduce mortality. There are also important treatment-limiting and potentially life-threatening drug interactions which need to be anticipated in co-infected patients. In order to ensure best possible clinical outcomes for patients concerned it is vital that both conditions are diagnosed as quickly as possible.

3.25 The Chief Executive of the NHS in Scotland issued guidance in 2007 asking that all TB patients (amongst others) should be screened for HIV. (Chief Executive Letter 15(2007) http://www.sehd.scot.nhs.uk/mels/CEL2007_15.pdf). We know from the stocktake of services undertaken by Health Protection Scotland that less than half of NHS Boards offer and advise HIV screening for all TB cases. **The TB Action Plan Working Group recommends that this existing guidance should be implemented routinely across Scotland, and health professionals should be reminded of this guidance. Moreover multidisciplinary teams should ensure that HIV screening has been carried out during patient reviews.**

3.26 **Patients co-infected with HIV and TB should be directly managed by a physician with expertise in the management of both conditions. Ideally this should be an adult or paediatric trained infectious diseases physician.**

3.27 **At the same time, Health Protection Scotland will initiate a population based study (an anonymised data linkage exercise) to improve our evidence base around dual TB/HIV infection and associated risk factors in Scotland. This work will commence in 2011.**

National guidelines for TB control

3.28 As detailed in paragraph 3.3 above the Scottish Health Protection Network published guidance in March 2009 on the clinical management of patients with TB. The view of the Action Plan Working Group is that these guidelines should not be a static document. Given the public health importance of TB in Scotland and globally, and recent epidemiological trends, our ambitions are such that we should constantly ensure we are operating on the basis of the most up to date evidence and experience. **National guidelines should therefore be reviewed for Scotland at a minimum of every 3 years. The Scottish Health Protection Network should lead these reviews.**

Drug Resistant TB

3.29 Reports have indicated that multi-drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB) are becoming more common in some foreign countries. These include countries in the former Soviet Union and parts of Asia and Africa. The Scottish Health Protection Network TB guidance (see paragraph 3.3) recommends that the risk of MDR-TB or XDR-TB must be assessed for every TB patient at diagnosis. The Working Group supports this guidance.

3.30 This assessment should include TB exposure in high risk countries, as well as previous, possibly failed, TB treatment. As stated in paragraph 3.21 patients with suspected MDR/XDR-TB should be managed in a negative pressure room with en-suite facilities, pending microbiological results.

The Public Health (Scotland) Act 2008

3.31 The Public Health (Scotland) Act 2008 has enabled NHS Boards to respond more actively in cases (fortunately relatively uncommon) where an individual with active TB and known to be infectious fails to comply with treatment and presents a significant public health risk to others in the community. "Competent persons", with defined qualifications and experience, designated by the NHS Boards are able to use powers available within the Act. These include the ability to restrict or exclude an individual from places or activities which put others at significant risk. It also includes the power to detain and individual in hospital. The use of such powers must always be justified within the law by a Competent Person acting on behalf of the NHS Board.

4. Surveillance

Introduction

4.1 Accurate, timely and efficient surveillance of TB cases is a vital foundation for good quality disease prevention and control. Without up-to-date and accurate information on the burden of disease and the epidemiology of TB cases it would become increasingly difficult to target services and provision to those most in need and thus prevent further cases of the infection. The Surveillance Subgroup reviewed the current surveillance of TB in Scotland and provided advice to the TB Action Plan Working Group on areas for action.

Key Issues

TB Surveillance

4.2 Tuberculosis surveillance was introduced in Scotland in 2000 through the Enhanced Surveillance of Mycobacterial Infections (ESMI) scheme. This scheme is still in existence and has operated largely unchanged since its introduction. The scheme is paper based and slow, data only becomes available retrospectively and its completeness is likely to be affected by the extent to which clinicians locally are aware of and comply with the scheme

4.3 **The TB Action Plan Working Group considers that ESMI is now out of date –** and any replacement system should provide real time information for the clinical management of cases and for contact tracing. The Working Group believe that **an updated and dynamic surveillance system that provides real time functionality and that is efficient and easy to use, would significantly improve TB services across Scotland, and should be introduced as soon as possible.**

4.4 There are several potential solutions, including considering existing off-the-shelf solutions or designing a new TB surveillance system for Scotland. However in the course of preparing the TB Action Plan for Scotland it became clear that a web-based Enhanced Tuberculosis Surveillance system (ETS), which was designed by the Health Protection Agency in England for their own surveillance purposes has already been implemented in England. Given the potential value of adopting an existing and proven surveillance system that would allow data be collected in a format consistent with other parts of the UK and link with TB reference laboratory results, the Working Group felt that the Scottish Government and Health Protection Scotland should **establish a group involving NHS Board representatives as soon as possible to actively consider adopting a compatible version of ETS.**

4.5 In the meantime, the Working Group felt that there is scope to improve the timeliness and completeness of the existing ESMI scheme. **Multidisciplinary teams locally should routinely feedback local ESMI surveillance to local clinicians and audit the completeness and timeliness of the return of surveillance data using the current paper-based ESMI system.**

Evaluation of TB control across Scotland

4.6 The surveillance of drug resistance and treatment outcome monitoring are essential tools for the evaluation of TB control. Surveillance data from ESMI and its eventual replacement should be used for TB service evaluation both nationally and locally.

4.7 At the **National Level** HPS should continue to report annually to the Scottish Government (copied to NHS Boards) on TB. This report should include a section describing Scotland's performance on the

specific ECDC indicators (See the ECDC Progressing towards TB Elimination document: http://www.ecdc.europa.eu/en/publications/Publications/101111_SPR_Progressing_towards_TB_elimination.pdf):

- Information on local epidemiology of TB, trends, vulnerable populations
- Treatment success rates nationally and by health boards
- Drug resistance rates
- Mortality data
- Percentage of cases lost to follow up and reasons why

4.8 At the **Local Level**, each NHS Board TB service/multidisciplinary team should report annually on TB prevention and control activities. These reports should be sent to their local Clinical Governance Committee and copied to Health Protection Scotland. Local clinicians should be made aware of this report. The report should include:

- Information on local epidemiology of TB, trends, vulnerable populations
- Treatment success rates locally
- Mortality data
- Percentage of cases lost to follow up and reasons why
- Contact tracing uptake and outcomes
- Timeliness of service delivery
- HIV testing uptake
- Drug resistance rates
- Summary data on Incidents and outbreaks data
- Audit of compliance with recommendations in this document and those from the Health Protection Network 2009 guidance.

4.9 The WHO has set targets of a 90% cure rate for sensitive TB and >75% cure rate for drug resistant TB by 2015. These targets reflect the aspirations of the Scottish Government to deliver world class TB control and local services should be planned, delivered and monitored in a such a way as to support achievement of these targets.

Examples of objectives for a local TB service adapted from Global Plan to Stop TB 2011–2015, WHO 2010 (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf)

- **Objective 1**: Ensure early diagnosis of all TB cases (increase percentage of cases seen within two weeks of first presentation to NHS, decrease percentage of cases with delayed diagnosis over 12 weeks from symptom onset)

- **Objective 2**: Ensure high quality treatment of all diagnosed cases of TB (increase percentage of cases on four drug regime, increase percentage of cases completing treatment within 12 months, maintain /increase percentage of cases with laboratory culture confirmation, drug resistance monitoring)

[continued over…]

- **Objective 3**: Strengthen monitoring and evaluation including measurement of the impact of the service on the burden of disease (numbers of cases, trends in TB rate in UK born & non UK born, deaths from TB, number of cases in children aged under 5 years, trends in cases amongst vulnerable groups, percentage uptake of HIV testing amongst cases, incident and outbreaks, MIRU data on clusters, drug resistance monitoring data)

- **Objective 4**: Strengthen human resources for TB control (availability of TB specialist nurses, resources for directly observed therapy, training for TB specialist nurses, clinicians microbiologists, multidisciplinary meetings per annum, local professional awareness events held)

- **Objective 5**: Ensure appropriate TB control through contact tracing and management of incidents and outbreaks (contact tracing timeliness, contact screening uptake and outcomes, review of incidents & outbreaks)

5. Public Health Services

Introduction

5.1 TB is a disease of significant public health importance. It is a communicable disease that if undiagnosed and unchecked can spread amongst populations and, particularly, amongst those whose are vulnerable or have other serious conditions such as HIV. While TB is not necessarily a disease that will spread very easily from person to person, the potential for transmission remains and there is a sufficient cultural memory of TB that the risk of transmission can in itself cause fear and alarm. Concerns around drug-resistant strains of the disease also support the need to limit the spread of disease wherever possible. The role of public health services in reducing TB transmission at a population level and in responding to TB incidents is therefore crucial. These issues were considered by the Public Health Services Subgroup.

Key issues

Contact Tracing

5.2 Contact tracing is a key public health approach to minimising the spread of TB in the population. When a patient with TB is identified, public health teams undertake work to trace all close contacts of that case and to assess and if necessary test them for infection. Although only a low proportion of these contacts of TB patients go on to develop active TB disease, this work can reduce the potential for further community spread of the infection. Contact tracing can be a laborious and resource intensive exercise, particularly in the case of individuals with many social contacts or whose contact history is not clearly understood.

5.3 The 2009 Scottish Health Protection Network guidance document provides detailed guidance on approaches to contact tracing in a range of settings, including at schools, and in community care, as well as amongst travellers on aircraft. In order to ensure contact tracing approaches across the country are as effective as possible and consistent with guidance **Multidisciplinary teams locally should be responsible for auditing contact tracing actions to ensure that they follow national guidance** (http://www.documents.hps.scot.nhs.uk/about-hps/hpn/tuberculosis-guidelines.pdf).

New Entrant Screening

5.4 Current national policy on port health states that Immigration Control staff risk-assess new entrants to the United Kingdom who arrive through ports. Those coming from high-risk countries and intending to stay in the United Kingdom for more than 6 months, and all refugees and asylum seekers, should be referred to Port Health Control Units (PHCU).

5.5 NHS Board Consultants in Public Health Medicine are notified of medical examinations by port health units (including chest X-ray status) via standard procedures. Consultants in Public Health Medicine are expected to arrange appropriate follow-up, usually by passing the information on to local NHS tuberculosis services.

5.6 In the past few years there has been a rapid increase in the number of referrals from Immigration Control. The Health Protection Agency's *Tuberculosis in the UK 2010* annual report, published in October 2010 (available in electronic format on the Health Protection Agency website at: http://www.hpa.org.uk/Publications/InfectiousDiseases/Tuberculosis/1011TuberculosisintheUK/), found

the majority (79%) of non-UK born patients were diagnosed with active TB two or more years after arrival in the UK. There is currently substantial debate about the value of port entry screening for TB.

5.7 It is not fully understood why individuals develop TB more than two years following entry to the UK but this could also be related to either latent infection on entry to the UK, infection once within the UK or perhaps frequent travel abroad. However surveillance information in Scotland clearly indicates the value in ensuring such individuals are appropriately screened for TB infection. One of the key recommendations in the Health Protection Agency report on screening is that identification and treatment of latent tuberculosis infection should be strengthened amongst groups at high risk of TB.

5.8 The Working Group recommends that **multidisciplinary teams should explore locally how best to identify new entrants within their own areas and to implement local systems of case-finding for latent TB infection in these entrants. NHS Boards should be encouraged to emphasize the importance of case-finding TB in new and recent entrants.** The Working Group in particularly highlights the potential benefit of TB multidisciplinary teams linking with local inequalities groups and teams. All NHS Boards will have well established groups, and in some cases, dedicated teams that promote equality and diversity. This work is set in the context of the Scottish Government policy of "Fair for All". These groups may be able help to raise awareness of TB in ethnic groups and provide advice to multidisciplinary teams on how to better engage with those in varied ethnic populations.

5.9 In Scotland the 2009 Scottish Health Protection Network guidance (see paragraph 3.3) advised that new entrants should be identified for screening from, for example, new registrations with primary care. To ensure screening/case finding can be as effective as possible, it is important that migrants (including temporary workers) are positively supported to register with local GPs**.** This work should recognise that new entrants to countries can present particular challenges for health services, not least difficulties in respect of language/cultural barriers. **Therefore multidisciplinary teams should work with statutory and voluntary groups that have regular contact with new entrants to support them registering with GPs**.

5.10 **Primary care staff should identify and refer those individuals known to be at risk of TB and NHS Boards should ensure that primary care staff are able to assess new entrants and refer as appropriate (for chest x-ray, to a local skin test/interferon gamma clinic, or a TB clinic) in line with National Guidance.**

5.11 **Multidisciplinary teams locally should ensure the provision of adequate language translation facilities to support case-finding by staff.**

5.12 It should be recognised that these actions will increase demand on public health and clinical services.

<u>Detecting TB in high risk groups</u>

5.13 It is a recognised fact that certain population sub-groups are at higher risk of TB than others. Individuals from other parts of the world, including the Indian sub-continent, sub-Saharan Africa and China, and some parts of Eastern Europe, are more likely to be at risk of being infected. Likewise those from deprived areas, with serious alcohol or drug related problems, or with certain other co-morbidities are equally likely to be at greater risk.

5.14 This is an important area and the TB Action Plan Working Group recognises the importance of ensuring equitable treatment to all members of society in line with the Quality Strategy.

5.15 The main risk factor for TB infection in Scotland, excluding place of birth, is problem alcohol use. However incidence of TB is influenced by – and associated with – other social risk factors as well. These include poor nutrition, poor access to healthcare, homelessness, problem drug use and imprisonment. It is of note that some of these groups are almost hidden within the community and unlikely to register with GPs to access primary care. They may present late and adhere poorly to treatment, increasing the risk of spread of TB and emerging drug resistance. TB is one of a number of disease that contributes to the continuing inequality in health experienced by those living in deprived communities relative to those in affluent communities.

5.16 A stocktake of TB services within Scotland carried out by Health Protection Scotland for the TB Action Plan highlighted that of those Boards that responded to the stocktake, five do not undertake work to detect TB in populations that are at higher risk of being infected.

5.17 The Working Group is aware of the NICE initiative to develop guidance on the public health programme aimed at reducing the transmission of TB among hard-to-reach groups. NICE defines hard to reach groups as:

> *Children, young people and adults whose social circumstances or lifestyle, or those of their parents or carers, make it difficult to:*
>
> - *recognise the clinical onset of tuberculosis*
> - *access diagnostic and treatment services*
> - *self-administer treatment (or, in the case of children and young people, have treatment administered by a parent or carer)*
> - *attend regular appointments for clinical follow-up.*

5.18 Scotland has contributed to the development of this guidance. **The Working Group recommends that the Scottish Health Protection Network review the output of this work when it is published (expected March 2011) to consider its applicability in Scotland.**

5.19 In the meantime, and while this work is progressing, **multidisciplinary teams/local services should be aware of those groups in their area which are most difficult to reach and should design approaches to better reach them.** This work should include discussions with local partners such as addiction services about approaches to raise awareness of TB amongst hard-to-reach groups in their area.

5.20 Because of importance of problem alcohol use as a risk factor, **multidisciplinary teams/local services should engage with primary care teams to highlight the increased risk of TB amongst problem alcohol users. Multidisciplinary teams should also link with the local Alcohol and Drug Partnerships to raise awareness of the increased risk of TB in those with problem alcohol and drug use.**

Vaccination

5.21 Scottish BCG policy follows national guidelines of the Joint Committee on Vaccination and Immunisation (JCVI). Current policy is as set out in the Department of Health's *Immunisation against infectious disease* (the 'Green Book', which is available in electronic format at: (http://www.dh.gov.uk/en/Publichealth/Immunisation/Greenbook/index.htm). These recommendations are set out in the box on page 25.

The JCVI recommends immunisation for the groups listed below (unless BCG immunisation has been previously carried out or the tuberculin skin test is positive or there are contra-indications):

- all infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater*
- all infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual 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 annual 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 annual incidence of TB is 40/100,000 or greater.
- previously unvaccinated tuberculin-negative individuals under 16 years of age who are contacts of cases of TB
- previously unvaccinated, tuberculin-negative individuals under 16 years of age who were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater.

In addition, unvaccinated, tuberculin-negative individuals aged under 35 years in the following occupations are recommended to receive BCG:

- healthcare workers who will have contact with patients or clinical materials (both NHS and non-NHS facilities)
- 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, e.g. simians
- prison staff working directly with prisoners
- staff of care homes for the elderly
- staff of hostels for homeless people and facilities accommodating refugees and asylum seekers.

Newborn BCG Services in Scotland

5.22 The Information Services Division (ISD) Child Health Information Team recently reviewed BCG immunisation data recording on the Scottish Immunisation and Recall System (SIRS). SIRS facilitates the automated identification of babies requiring BCG immunisation through the recording of details about the country of birth of baby's parents and grandparents. Ideally these details would be recorded on the "Pregnancy Record" part of the Scottish Woman Held Maternity Record (SWHMR) and an alert indicated on the relevant field of the Neonatal section of the SWHMR. There would, however, need to be some modification to SWHMR to allow the country of birth of parents and grandparents to be adequately recorded. Details of vaccination should also be entered into this part of the SWHMR. Unfortunately, the

SWHMR is paper-based in most parts of Scotland, so the information cannot be forwarded electronically to SIRS. Information could also be entered into the clinical section of the Scottish Birth Record (SBR), for those NHS Boards which use this facility. The SBR would need to be modified to allow recording of country of birth of parents and grandparents, and it does not yet have an electronic link to SIRS so data has to be printed off and re-entered. If the details are not recorded at birth they should be recorded at the 10 day visit by the health visitor and passed on to SIRS. It is thought that currently these details are being recorded at the 10 day visit rather than during pregnancy or at birth. Where the new born baby has been immunised details should also be entered onto SIRS. The system identifies from the entered fields the child's TB risk status based on TB incidence of reference data. NHS Boards have local arrangements for calling children requiring BCG immunisation to clinics. The results from a recent ISD study showed that there was considerable variation amongst Boards for TB risk status not recorded on SIRS (a range 3-15%). The recording of parents/grandparents country of birth not recorded by NHS Board is also variable (range 3-40%).

BCG Services for Older Children

5.23 According to current JCVI advice, previously unvaccinated older children with specific risk factors for TB who would formerly have been offered BCG through the schools' programme should be identified at suitable opportunities, and tested and vaccinated if appropriate. The school catch up campaign across Scotland was completed in 2007. It is unclear how many Boards still continue to use the Child Health Systems Programme (CHSP) BCG screening questionnaire to systematically identify schoolchildren who may be at risk. Some Boards have developed their own questionnaires while other Boards identify children at birth.

Improving BCG Services

5.24 The Working Group believes that the national focus for improvement in BCG services should be on newborns where BCG immunisation is most effective. The Public Health Services Subgroup provided a number of key points for Boards to consider to promote improvements in new born BCG vaccination, specifically:

- A new born baby within identified risk groups should have the same chance of BCG immunisation wherever that baby is born/lives within Scotland.
- A robust audit system is key to successful implementation of neonate vaccination and Boards/multidisciplinary teams should ensure that they audit neonatal BCG immunisation on a regular basis.
- Boards should ensure that BCG services are co-ordinated and monitored. One option for doing this would be to nominate a lead within Board Health Protection Teams to undertake his role

5.25 The Action Plan Working Group therefore recommends **that NHS Boards should review roles and responsibilities for neonatal BCG immunisation in their locality to re-examine current operational plans, in light of the above.**

5.26 At the national level, it is recognised that development of existing IT systems can support and promote BCG vaccination. The Scottish Government and Health Protection Scotland should **explore the additional work required to develop the SIRS childhood vaccination call/recall system to enable Boards to record data in an effective manner**. Work should also be done to **explore the required developments to link the Scottish Birth Record with SIRS**.

5.27 **Health Protection Scotland should examine whether the existing CHSP school system BCG screening questionnaire for identifying children at risk is still appropriate.**

5.28 **In future, Health Protection Scotland should undertake a more detailed review of Board BCG audit activities so that best practice is shared across Scotland.**

Occupational Health: Clearance and Vaccination

5.29 Healthcare professionals can be at increased risk of exposure to TB and are currently recommended for BCG vaccination under national vaccination policy. The Scottish Government published guidance on health clearance of healthcare workers for TB and blood borne viruses in May 2008 (see:http://www.scotland.gov.uk/Publications/2008/04/25104624/0). This guidance sets out the requirements for screening of new healthcare workers (which can include existing healthcare workers moving to new posts or carrying out certain types of procedure for the first time) for TB. This guidance includes the requirement that:

- Employees new to the NHS who will be working with patients or clinical specimens should not start work until they have completed a TB screen or health check, or documentary evidence is provided of such screening having taken place within the preceding 12 months.

5.30 This guidance was based on existing guidance from NICE and JCVI and reflects a UK expert opinion. It may not fully reflect the different epidemiological picture in Scotland compared with some parts of England. The document does acknowledge that not all healthcare workers are at an equal risk of TB. There are likely to be categories of healthcare workers who are at particular risk of TB, and this should be part of the clinical risk assessment when the use of BCG is being considered for a healthcare worker over 35 years of age (given that there is no data on the protection afforded by BCG vaccine when it is given to adults aged 35 years or over).

5.31 Anecdotal reporting is that occupational health professionals do not necessarily agree that this universal approach is proportionate in Scotland, particularly in cases where it is clear there is a low risk of TB. Work is currently underway by the Senior Occupational Physicians Group in conjunction with NHS QIS to examine performance across Scotland in occupational health departments against the health clearance guidance. The value of this work is supported by the Action Plan Working Group who agreed that any recommendations to change current guidance should await the outcome of the survey.

5.32 The Action Plan Working Group therefore recommends that, in light of the above considerations **the Scottish Government should establish a process to review the TB elements of the 2008 health clearance guidance document** http://www.scotland.gov.uk/Publications/2008/04/25104624/0). **This review should take account of the audit of performance against the existing guidance that is already under way by the Senior Occupational Physicians Group. Any review should seek to ensure that subsequent guidance takes a risk-based approach.**

6. Monitoring and Ensuring Progress

6.1 The Scottish Government has established the TB Action Plan as means of delivering on its ambition to reduce the incidence of the disease in Scotland through high quality clinical, laboratory and public health services underpinned by the highest quality surveillance available and at a time when a number of factors are increasing the number of cases in Scotland. The recommendations within this Action Plan are testing and demanding and commitment and drive is required to ensure progress is maintained and outcomes are achieved.

6.2 The Working Group recommends that an **Action Plan Monitoring Group should be established by the Scottish Government to monitor progress against recommendations and to provide advice to Ministers, NHS Boards or other delivery partners to ensure the ambition of this Action Plan is achieved.**

6.3 **This group should meet at least annually and should have a small membership so as to be as effective as possible.** It should chaired by a Senior Medical Officer of the Scottish Government and suggested membership, in addition to Government officials, should include (at a minimum):

- Health Protection Scotland
- A representative of the Consultants in Public Health Medicine
- A representative of Infectious Disease Consultants
- A representative of Respiratory Medicine Consultants
- A representative of the TB Nurses Group
- At least one NHS Board multidisciplinary team lead

6.4 **The group should establish key performance indicators (KPIs) for the recommendations within the Action Plan where appropriate, to enable measurement of progress.**

6.5 **The group should report annually to Ministers on overall progress in delivery of the Action Plan, or by exception in the case of particular problems.**

6.6 **The group should provide a report on progress to the national annual meeting of TB clinicians/nurses.**

6.7 It will be a function of the group to consider the continued relevance of recommendations in future years, to review progress and to provide advice to Ministers on future policy on TB management in Scotland.

Annex A

Membership of Working Group

Name	Organisation(s)/Role
Dr Malcolm McWhirter (Chair)	Senior Medical officer, Scottish Government
Dr Ibrahim Abubakar	Consultant Epidemiologist, Health Protection Agency
Dr Oliver Blatchford	Consultant Epidemiologist, Health Protection Scotland
Mr Gareth Brown	Health Protection Team, Scottish Government
Dr Mark Cotton	Consultant in Respiratory Medicine, NHS Greater Glasgow & Clyde; Representative of British Thoracic Society
Ms Susan Duthie	TB Specialist Nurse, NHS Grampian
Dr Laura Jones	Consultant Paediatrician in Immunology and Infectious Diseases, NHS Lothian Representative of Royal College of Paediatrics and Child Health
Dr Ian Laurenson	Consultant Microbiologist & Director of the Scottish Mycobacterial Reference Laboratory, NHS Lothian
Dr Alistair Leckie	Director of Occupational Health & Safety Advisory Services, NHS Fife Special advisor to the CMO on occupational health
Dr Mini Mishra	Primary and Community Care Directorate, Scottish Government
Dr Tim Patterson	Consultant in Public Health Medicine, NHS Borders
Dr R. Andrew Seaton	Infectious Disease Consultant, NHS Greater Glasgow and Clyde Representative of the Scottish Infectious Diseases Physicians Group
Dr Janet Stevenson	Consultant in Public Health Medicine, NHS Lothian
Mrs Rona Watters	Health Protection Team, Scottish Government

Membership of Sub-groups

Name	Organisation(s)/Role
Laboratory Services and Diagnostic Tools	
Dr Oliver Blatchford	Consultant Epidemiologist, Health Protection Scotland
Ms Susan Duthie	TB Specialist Nurse, NHS Grampian
Mr Gordon Hepburn	Chief Biomedical Scientist, Medical Microbiology, Aberdeen Royal Infirmary, NHS Grampian
Dr Laura Jones	Consultant Paediatrician in Immunology and Infectious Diseases, NHS Lothian Representative of Royal College of Paediatrics and Child Health
Dr Ian Laurenson (Chair)	Consultant Microbiologist & Director of the Scottish Mycobacterial Reference Laboratory, NHS Lothian
Professor Alistair Leonard	Consultant Microbiologist, NHS Greater Glasgow and Clyde
Dr Michael Lockhart	Consultant Microbiologist, NHS Tayside
Dr R Andrew Seaton	Infectious Disease Consultant, NHS Greater Glasgow and Clyde Representative of the Scottish Infectious Diseases Physicians Group

Clinical Services	
Dr Oliver Blatchford (Chair)	Consultant Epidemiologist, Health Protection Scotland
Dr Mark Cotton	Consultant in Respiratory Medicine, NHS Greater Glasgow & Clyde; Representative of British Thoracic Society
Ms Susan Duthie	TB Specialist Nurse, NHS Grampian
Dr Adam Hill	Consultant Chest Physician and Honorary Senior Lecturer, NHS Lothian
Dr Laura Jones	Consultant Paediatrician in Immunology and Infectious Diseases, NHS Lothian Representative of Royal College of Paediatrics and Child Health
Dr Nick Kennedy	Consultant Physician, NHS Lanarkshire
Ms Eisin McDonald	Epidemiologist (Respiratory and Immunisation), Health Protection Scotland
Ms Ceri McSparron	TB Specialist Nurse, NHS Lothian
Mr Mike Mandelbaum	Chief Executive, TB Alert
Dr R Andrew Seaton	Infectious Disease Consultant, NHS Greater Glasgow and Clyde Representative of the Scottish Infectious Diseases Physicians Group

Surveillance	
Dr Ibrahim Abubakar	Consultant Epidemiologist, Health Protection Agency
Dr Oliver Blatchford	Consultant Epidemiologist, Health Protection Scotland
Dr Mark Cotton	Consultant in Respiratory Medicine, NHS Greater Glasgow & Clyde; Representative of British Thoracic Society
Ms Susan Duthie	TB Specialist Nurse, NHS Grampian
Dr Chris Faldon	Health Protection Nurse Specialist, NHS Borders
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Dr Ian Laurenson	Consultant Microbiologist & Director of the Scottish Mycobacterial Reference Laboratory, NHS Lothian

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Annex C

Table of Recommendations

Issue	Number	Recommended Action	Responsibility	Timescale
Laboratory Services and Diagnostic Tools				
Culturing TB bacteria (bacteriological diagnosis)	1	At a minimum all specimens should now be cultured in liquid media as this reduces by more than half the time to result from 27 to 13 days as compared with solid culture Precious samples (e.g. CSF, biopsies, lymph nodes) and those requiring incubation at other than 36^0C such as skin biopsies and abscesses should receive solid culture in addition to liquid culture. Specimens should not be cultured on solid media alone.	NHS Laboratories	Immediately
Laboratory quality assurance	2	All laboratories carrying out mycobacterial microscopy and culture should be Clinical Pathology Accreditation (CPA) accredited, have specific quality systems and undertake appropriate External and Internal Quality Assurance.	NHS Laboratories	Immediately
Laboratory service availability	3	The Scottish Government will support a 5 day minimum service, pending more evidence becoming available about potential implications of service increase to six days in terms of cost and quality. This will be reviewed in time.	Scottish Government	Immediately
Optimisation of laboratory services	4	In line with the Quality Strategy and the commitment to reducing unnecessary duplication, the Scottish Government will support work through the Scottish Microbiology Forum to consider the centralisation of Scottish mycobacterial diagnostic services into a smaller number of laboratories with higher throughput and defined quality standards in laboratories in Scotland	Scottish Microbiology Forum (with Scottish Government Support)	By end 2011.

Future Developments	5a	The IGRA test is currently under review by NICE and is due to be published in March 2011. This work should be considered by the Scottish Health Protection Network when available to inform guidelines on use of IGRA in Scotland. The Working Group also notes that while IGRAs may in time to be shown to be more sensitive and specific than skin tests (which generally require more than one clinic visit by the patient) in the diagnosis of latent TB infection, the tests themselves are expensive and their introduction should be managed in the most cost effective way.	Scottish Health Protection Network	Work to commence once NICE publishes (due March).
	5b	Scottish Government should ensure a mechanism exists for the appropriate Scottish body to assess these developments on an ongoing basis to ensure the best quality and most efficient diagnostic tools are available in Scotland.	Scottish Government	Mechanism discussed and agreed by end 2011.
	5c	The Working Group recommends that Health Protection Scotland and SMRL should establish a group to develop a clear strategy for the systematic use of molecular typing of *M. tuberculosis* complex in Scotland.	HPS and SMRL	Group to be established by end 2011
Clinical Services				
Strategic Planning	6	TB should be a Board priority for those areas in Scotland with the highest incidence of cases. Other Boards with lower incidence of TB should however also review their response to TB in line with recommendations in this report.	NHS Boards	Immediately

Improving clinical management	7a 7b	No TB patient should be treated by a single consultant without the involvement or oversight of a multidisciplinary team. Evidence shows that treatment of TB should be initiated by a specialist and supervision of management should be as part of an multidisciplinary team, including primary care. GPs and primary care teams (including pharmacists) have a crucial role in the early detection of TB and, in collaboration with others, the overall care and treatment of their patients. All TB patients in Scotland should have their care plans reviewed by a TB multidisciplinary team. In patients with suspected TB, initiation of anti-TB therapy should be discussed with a TB specialist to ensure optimal investigation and management.	NHS Boards	Multidisciplinary teams and associated protocols should be in place by end 2011.
Sharing best practice	8a 8b 8c	The Scottish Government should ensure that a national network of multidisciplinary team staff/leads is supported and facilitated. Recognising the key role of TB Nurses, the Scottish Government should ensure that the national TB Nurses Network is supported and facilitated. To ensure that clinicians from across Scotland working in the field of TB have the opportunity to meet and discuss issues, the Scottish Government should ensure an annual national meeting of all health professionals involved in treatment and management of the disease is funded and facilitated	Scottish Government	Network established in 2011 Arrangements for supporting the Network should be put in place immediately. First meeting to take place in 2011 and annually thereafter

Access to negative pressure facilities	9a 9b 9c	NHS Board should have documented arrangements in place to ensure access to negative pressure facilities where these are required. Individual circumstances may make this challenging but at a minimum single rooms should be used where required for the period that any patient would be considered to be infectious. Patients with MDR/XDR TB should be managed in negative pressure facilities with en-suite facilities without exception. All patients with suspected MDR/XDR TB, pending microbiological results should be managed in a negative pressure room with en-suite facilities. These arrangements should be understood by all relevant staff involved in patient management and should, for example, form a core part of multidisciplinary team operational documentation.	NHS Boards/ multidisciplinary teams	Documented arrangement in place by end 2011
Tuberculosis and HIV/AIDS	10a 10b 10c	Existing guidance on HIV screening of TB patients should be implemented routinely across Scotland, and health professionals should be reminded of this guidance. Moreover multidisciplinary teams should ensure that HIV screening has been carried out during patient reviews. Patients co-infected with HIV and TB should be directly managed by a physician with expertise in the management of both conditions. Ideally this should be an adult or paediatric trained infectious diseases physician. Health Protection Scotland will initiate a population based study (an anonymised data linkage exercise) to improve our evidence base around dual TB/HIV infection and associated risk factors in Scotland. This work will commence in 2011	NHS Boards/ Multidisciplinary teams Health Protection Scotland	Immediately Commence in 2011
National guidelines for TB control	11	National guidelines should therefore be reviewed for Scotland at a minimum of every 3 years. The Scottish Health Protection Network should lead the reviews.	Scottish Health Protection Network	Ongoing

Surveillance				
Good quality, efficient and effective surveillance of TB	12	An updated and dynamic surveillance system that provides real time functionality and that is efficient and easy to use, would significantly improve TB services across Scotland, and should be introduced as soon as possible. As a first step Scottish Government and Health Protection Scotland should establish a group involving NHS Board representatives as soon as possible to actively consider adopting a compatible version of ETS	Scottish Government, Health Protection Scotland and NHS Boards	Group should be established immediately and timescales for work agreed before the end of 2011.
Improving ESMI as an interim measure	13	Multidisciplinary teams locally should routinely feedback local ESMI surveillance to local clinicians and audit the completeness and timeliness of the return of surveillance data using the current paper-based ESMI system.	Multidisciplinary teams.	Annually
Improving TB service evaluation at national and local level	14a 14b	HPS should continue to report annually to the Scottish Government (copied to NHS Boards) on TB. This report should include a section describing Scotland's performance on the specific ECDC indicators Each NHS Board TB service/MDT should report annually on TB prevention and control activities. These reports should be sent to their local Clinical Governance Committee and copied to Health Protection Scotland. Local clinicians should be made aware of this report	Health Protection Scotland NHS Boards/ Multidisciplinary teams	Annually
Public Health Services				
Contact Tracing	15	Multidisciplinary teams locally should be responsible for auditing contact tracing actions to ensure that they follow national guidance. (http://www.documents.hps.scot.nhs.uk/about-hps/hpn/tuberculosis-guidelines.pdf)	Multidisciplinary teams	Ongoing

New Entrant Screening	16a	Multidisciplinary teams should explore locally how best to identify new entrants within their own areas and to implement local systems of case-finding for latent TB infection in these entrants. NHS Boards should be encouraged to emphasize the importance of case-finding TB in new and recent entrants.	Multidisciplinary teams	By March 2012
	16b	Multidisciplinary teams should work with statutory and voluntary groups that have regular contact with new entrants to support them registering with GPs.	NHS Board/ Multidisciplinary teams	Ongoing
	16c	Primary care staff should identify and refer those individuals known to be at risk of TB and NHS Boards should ensure that primary care staff are able to assess new entrants and refer as appropriate (for chest x-ray, to a local skin test/interferon gamma clinic, or a TB clinic) in line with National Guidance.	Primary Care staff	By March 2012
	16d	Multidisciplinary teams locally should ensure the provision of adequate language translation facilities to support case-finding by staff	NHS Boards/ Multidisciplinary teams	By March 2012
Detecting TB in high risk groups	17a	Scottish Health Protection Network should review the output of the NICE initiative to develop guidance aimed at reducing the transmission of TB among hard-to-reach groups when it is published, and to consider its applicability in Scotland.	Scottish Health Protection Network	When NICE report is available (expected March 2011)
	17b	In the meantime, multidisciplinary teams/local services should be aware of those groups in their area which are most difficult to reach and should design approaches to better reach them	Multidisciplinary teams	By March 2012
	17c	Multidisciplinary teams/local services should engage with primary care teams to highlight the increased risk of TB amongst problem alcohol users. Multidisciplinary teams should also link with the local Alcohol and Drug Partnerships to raise awareness of the increased risk of TB in those with problem alcohol and drug use.	Multidisciplinary teams	By March 2012

Vaccination	18a	NHS Boards should review roles and responsibilities for neonatal BCG immunisation in their locality to re-examine current operational plans	NHS Boards	By end 2011
	18b	The Scottish Government and Health Protection Scotland should explore the additional work required to develop the SIRS childhood vaccination call/recall system to enable Boards to record data in an effective manner. Scottish Government and Health Protection Scotland should also explore the required developments to link the Scottish Birth Record with SIRS.	Scottish Government/Health Protection Scotland	By end 2011
	18c	Health Protection Scotland should examine whether the existing CHSP school system BCG screening questionnaire for identifying children at risk is still appropriate.	Health Protection Scotland	By end 2011
	18d	In future, Health Protection Scotland should undertake a more detailed review of Board BCG audit activities so that best practice is shared across Scotland.	Health Protection Scotland	Ongoing
Health clearance and vaccination of those at occupational risk	19	The Scottish Government should establish a process to review the TB elements of the 2008 health clearance guidance document http://www.scotland.gov.uk/Publications/2008/04/25104624/0). This review should take account of the audit of performance against the existing guidance that is already under way by the Senior Occupational Physicians Group. Any review should seek to ensure that subsequent guidance takes a risk-based approach	Scottish Government	Process established by end 2011

Monitoring and Ensuring Progress				
Monitoring Progress	20a	An Action Plan Monitoring Group should be established by the Scottish Government, to monitor progress against recommendations and to provide advice to Ministers, NHS Boards or other delivery partners to ensure the ambition of this Action Plan is achieved.	Scottish Government	
	20b	This group should meet at least annually and should have a small membership so as to be as effective as possible	Action Plan Monitoring Group	
	20c	The group should establish key performance indicators (KPIs) for the recommendations within the Action Plan where appropriate, to enable measurement of progress.	Action Plan Monitoring Group	
	20d	The group should report annually to Ministers on overall progress in delivery of the Action Plan, or by exception in the case of particular problems.	Action Plan Monitoring Group	
	20e	The group should provide a report on progress to the national annual meeting of TB clinicians/nurses.	Action Plan Monitoring Group	

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