

# KIRIBATI NATIONAL TUBERCULOSIS PROGRAM



# TOWARDS TUBERCULOSIS ELIMINATION IN KIRIBATI

(Revised Project Design and Funding Proposal)

Jointly developed by
the National TB Program, Ministry of Health and Medical Services, Kiribati
and
TB Team, Public Health Division, Secretariat of the Pacific Community

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# Acronyms and abbreviations

ACSM Advocacy, communication and social mobilisation

AIDS Acquired Immune Deficiency Syndrome

ANS Assessment of National Systems

ART Antiretroviral therapy
AUD Australian dollars

AusAID Australian Agency for International Development CCM Global Fund Country Coordination Mechanism

CDW Community DOT Worker
CTN Contact Tracing Nurse

DAC Development Assistance Committee (OECD)

DOTS Directly observed treatment, short-course

DST Drug susceptibility testing

EQAS External quality assurance scheme (laboratory)

EUR Euro

GDF Global Drug Facility
GLC Green Light Committee
GOK Government of Kiribati

HITEC HIV-TB Executive Committee, MHMS

HIV Human immunodeficiency virus

IEC Information, education and communication

IMVS Institute of Medical and Veterinary Sciences (Adelaide, Australia)

IPT Isoniazid preventive therapy
KDP Kiribati Development Plan

KIFHA Kiribati Family Health Association
LFA Local Fund Agent (Global Fund)
M&E Monitoring and evaluation

MDGs Millennium Development Goals

MDR-TB Multi drug resistant TB

MHMS Ministry of Health and Medical Services (Kiribati)

MTR Mid-term review

NCDs Non-communicable diseases
NGO Non-government organisation

NHSP (Kiribati) National Health Strategic Plan

NICC National Implementation Coordinating Committee (QTBECP)

NTP National TB Program

OECD Organisation for Economic Cooperation and Development

PATLAB Pacific TB laboratory (network)
PC Project Coordinator (QTBECP)
PFM Public financial management

PHC Primary health care
PHN Public Health Nurse

PICTs Pacific Island countries and territories

PITC Provider-initiated testing and counselling (for HIV)
PPD Kiribati–Australia Partnership for Development

QAE Quality at entry (AusAID criteria)

QAI Quality at implementation (AusAID criteria)

QC Quality control

QTBECP Quality TB Epidemic Control Project

SDH Social determinants of health

SPC Secretariat of the Pacific Community

SS+ or SS— Sputum smear positive or sputum smear negative

TAG Technical Advisory Group

TB Tuberculosis

TBCC Tuberculosis Control Centre

TBCN TB Community Nurse

TFM Transitional Funding Mechanism (Global Fund)

TORs Terms of reference
USD United States dollar

WHO World Health Organization

XPF Communauté Financière Pacifique franc

# Acknowledgements

This revised design document and funding proposal builds on extensive background work undertaken by Dr Janet O'Connor and the Kiribati National Tuberculosis Program in late 2011, and the new *National Tuberculosis Strategic Plan* developed by NTP Manager Dr Kenneth Tabutoa and NTP staff in 2012.

The design is strongly informed by an in-country planning workshop held in Tarawa in June 2012. The workshop received the strong support of Mr Elliott Ali (Secretary for Health), Dr Teatao Tira (Director of Public Health), Dr Takeieta Kienene (Project Coordinator, QTBECP), Ms Bereka Reiher (NTP Coordinator), Ms Tiero Tetabea (Acting Director, Laboratory Services), other staff of the NTP, and officials from the AusAID Tarawa office; their involvement and contributions are gratefully acknowledged.

The revised design was compiled by Dr Rob Condon (Consultant Public Health Physician) and Ms Kerri Viney (Acting TB Adviser, Public Health Division, SPC). It incorporates a small number of modifications recommended following review by an independent technical expert and final review by MHMS.

# **Project Summary**

Project Title:	Towards TB Elimination in Kiribati
Goal (shared with NTP):	To accelerate scale-up to achieve universal access to prevention, early diagnosis and effective patient-centred treatment for tuberculosis to 2015 and beyond
Mission (Project-specific):	To work with the Kiribati NTP, clinical and public health service providers and technical partners to improve the quality, access and efficiency of preventive, diagnostic and clinical TB services in Kiribati, including by strengthening the TB work force and relevant underlying aspects of the health system
Objectives:	<b>Objective 1</b> – To support universal access to quality TB services, including through active case finding and community mobilisation (aligned with NTP Strategic Plan Objectives 1-4)
	Objective 2 – To support quality laboratory diagnosis and clinical standards (aligned with NTP Strategic Plan Objectives 5 and 6)
	Objective 3 – To support programmatic management of important comorbidities in Kiribati, including TB-HIV, TB-Diabetes and MDR-TB (aligned with NTP Strategic Plan Objective 8)
	Objective 4 – To support planning and management of the NTP and contribute to strengthening related aspects of the health system in Kiribati (aligned with NTP Strategic Plan Objectives 7 and 9)
	Objective 5 – To strengthen TB intervention strategies through evidence-based operational research (aligned with NTP Strategic Plan Objective 9)
Implementing Partners:	National TB Program, MHMS, Republic of Kiribati; and
	TB Team, Disease Surveillance, Research and Control Unit, Public Health Division, SPC
Indicative Dates / Duration:	Transition Phase (3 months): 1 October 2012 – 31 December 2012
	Alignment and Support Phase (up to 3 years):  1 January 2013 – 31 December 2015
	Integration Phase (minimum of 2 years):

1 January 2016 – 31 December 2017

**Budget:** Operations, managem

Operations, management and review: AUD 2,754,812

SPC Management Costs: AUD 192,837

## 1. Introduction

# 1.1 Background and Overview

#### 1.1.1 Emergence and Recognition of the Tuberculosis Epidemic in Kiribati

The National Tuberculosis Program (NTP), the Secretariat of the Pacific Community (SPC) and the World Health Organization (WHO) have all reported that, since 2003, Kiribati has consistently had the highest notification rates of tuberculosis (TB) in the Pacific.<sup>1</sup>

In 2005, the Kiribati Ministry of Health and Medical Services (MHMS) acknowledged that TB transmission had reached a crisis point. The number of reported cases had increased by 40% since the previous year (from 243 cases in 2004 to 337 in 2005), and the first case of multi-drug resistant TB (MDR-TB) had been confirmed. Total notifications peaked at 375 cases in 2006, with a crude notification rate of 399 per 100,000.

Annual TB notification rates at the time were the highest in the entire WHO Western Pacific region, and far exceeded the rates in known high burden countries like Cambodia, China and Vietnam. Among Pacific Island Countries and Territories (PICTs), only the Solomon Islands reported a greater number of cases (but with a lower rate, given its larger population).<sup>2</sup>

#### 1.1.2 Response to the Epidemic

The NTP has intensified TB control efforts since 2005-06, using a strategy based on directly-observed treatment short-course (DOTS; Box 1) and guided by the WHO *Strategic Plan to Stop TB in the Western Pacific Region 2006-10* (Box 2, page 2).<sup>3</sup>

#### **Box 1: Five Key Components of the DOTS Strategy**

- Political commitment with increased and sustained case finding
- 2. Case detection through quality assured bacteriology
- 3. Standardised treatment with supervision and patient support
- 4. An effective drug supply and management system
- A monitoring and evaluation system and impact measurement.

<sup>&</sup>lt;sup>1</sup> SPC (2010) Tuberculosis Surveillance in Pacific Island Countries and Territories

<sup>&</sup>lt;sup>2</sup> This statement excludes Papua New Guinea, which has a much larger population and a generalised HIV epidemic

<sup>&</sup>lt;sup>3</sup> A new WHO Regional Strategy has been developed for the period 2011-15; see Section 3.4

# Box 2: The Six Elements of the WHO Regional Stop TB Strategy, 2006-10

- 1) Pursue high-quality DOTS expansion and enhancement;
- 2) Address TB/HIV, MDR-TB and other challenges
- 3) Contribute to health system strengthening
- 4) Engage all care providers
- 5) Empower people with TB, and communities
- 6) Enable and promote research

Available data (summarised in Section 2) suggest that the epidemic now appears to be coming under control. TB case notification rates have declined by approximately 5% annually since the 2006 peak, and treatment success rates have remained well above regional targets (over 90%).

#### 1.1.3 Donor Funded Support for the National Tuberculosis Program

Enhanced TB control efforts have been jointly funded by the Government of Kiribati (GOK), AusAID and the Global Fund to fight AIDS, Tuberculosis and Malaria ("the Global Fund").

The Global Fund first provided resources for the NTP in 2003 through a regional multi-country project under Round 2.

In 2006, in response to the Government's crisis declaration, Australia provided an additional AUD 2.06 million in bilateral funding support for the NTP. This assistance has been delivered through the Quality TB Epidemic Control Project (QTBECP), which has been implemented by SPC across two phases (Phase 1 from October 2006 to September 2009, and Phase 2 from October 2009 to September 2012).<sup>4</sup>

Current Global Fund support under Round 7 (Phase 2) is for almost USD 0.66 million over three years (July 2010 – June 2013). A modest extension of Global Fund support to December 2014 through a transitional funding mechanism (TFM) of AUD 420,000 under Round 11 has been submitted, and the GOK is awaiting the outcome of this application.

#### 1.1.4 Vulnerability to Premature Cessation of Donor Support

Independent reviews of Phase 1 and Phase 2 of the QTBECP were conducted in June 2009 and August 2011, respectively. (The findings of these reviews are discussed in more detail in Section 4).

Both reviews concluded that achieving adequate control of the TB epidemic in Kiribati (including prevention of the emergence of MDR-TB) is likely to take at least 10 years, and longer to achieve elimination of TB as a public health problem (defined by WHO and the *Stop TB* Partnership as less than 1 case per million population). As donor contributions currently fund around 85% of NTP operational costs, it would be prudent and important to maintain external technical and financial support during most of that time. The imminent conclusion of QTBECP Phase 2 (September 2012) and the likely cessation of Global Fund support relatively soon after that present significant

<sup>&</sup>lt;sup>4</sup> Phase 2 represented a no-cost extension of Phase 1, which had AUD 0.93 million in unexpended budget.

challenges to the NTP maintaining momentum towards controlling the epidemic and eventually eliminating TB (see also budget analysis, Section 8).

### 1.1.5 Development of a New Proposal for Donor Support

To sustain the progress made, a continuation of external funds in the medium term is required. External funding will allow the GOK to consolidate results already achieved and address the long-term sustainability of AusAID / SPC and Global Fund project inputs by seeking to integrate elements of the projects into the national system. Although the GOK has indicated its continuing commitment to the NTP, its own limited budget makes it difficult for the Government alone to ensure implementation of intensified TB control activities of assured quality in the short to medium term.

A proposal for continued post-QTBECP AusAID funding through SPC was therefore developed in late 2011, incorporating many of the findings and recommendations of the mid-term review (MTR) of Phase 2 of the QTBECP.

The new proposal underwent formal appraisal and narrowly failed to meet AusAID's quality at entry (QAE) requirements; re-submission of an amended proposal was strongly recommended.

## 1.2 Purpose

#### 1.2.1 Design Revision and Country Consultation

The present document seeks funding support for a program of assistance that will help Kiribati to implement its new *National Tuberculosis Strategic Plan* (which had not been completed at the time of the original submission) and continue to make progress towards the elimination of TB as a public health problem.

The revised proposal was informed by an in-country planning workshop held in Tarawa on 19-20 June 2012. The workshop was attended by the NTP Manager and staff, the Director of Public Health, AusAID and SPC representatives and, for the introductory sessions, the Secretary for Health.

The revised proposal addresses all of the recommendations of the AusAID QAE assessment, and the recommendations of the MTR of QTBECP Phase 2.

#### 1.2.2 Alignment with the Kiribati National Tuberculosis Strategic Plan

The revised project is now closely aligned with the Kiribati NTP *Strategic Plan*. It seeks to support the NTP to ensure high case detection and treatment success rates (in line with domestic and international targets) by enhancing and expanding high quality TB services and systems, improving the case detection and case management capacity of the NTP, promoting equitable access to TB services in vulnerable communities, further improving laboratory capacity, and strengthening underlying aspects of the health system.

The expected results of this collaborative approach – to which the proposed Project will contribute – will be: 1) an increased case notification rate; 2) an increased case detection rate; 3) sustained high treatment success rates; 4) a reduction in TB prevalence; and 5) a decline in TB incidence.

# 2. The Tuberculosis Epidemic in Kiribati

## 2.1 Regional Context

Despite recent progress, in 2010, Kiribati still reported the second highest number of annual TB case notifications In the Pacific after the Solomon Islands (286 cases; Figure 1), and the second highest TB notification rate (292 cases per 100,000 population) after the Marshall Islands (356 per 100,000).

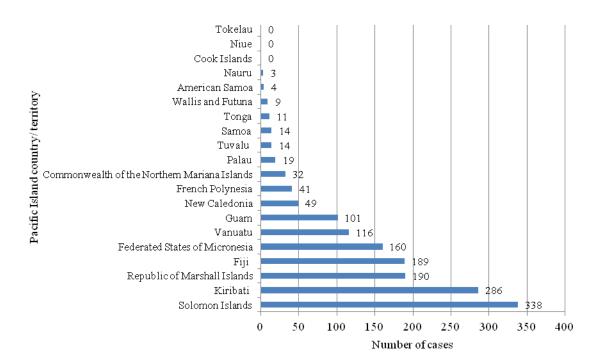


Figure 1: Number of TB cases notified in 2010 in Pacific Island countries and territories

Source: WHO (2011) Global Tuberculosis Control report.

# 2.2 Epidemiological Trends, 2000-2010

Figures 2 and 3 present the long term trend in reported TB mortality, prevalence, case notification and estimated incidence rates per 100,000 in Kiribati during the 11 year period from 2000 to 2010, and Table 1 provides a snapshot of TB surveillance in Kiribati for 2010.

Following the peak in total notifications in 2006, there has been a gradual decline in reported cases and notification rates for all forms of TB, although a slower rate of decline among sputum smear positive (SS+) cases. These data support previous interpretations that Kiribati has reached an early turning point in its TB epidemic (subject to adequate case detection rates; Figure 4); a declining incidence may be partially offset in available data by increased case ascertainment.

Treatment success and case detection rates are high and above *Regional Strategy* and QTBECP targets (Sections 3.4 and 4), and the objectives in the National Health Strategic Plan (NHSP) 2008-11.

Rate per 100,000 population Rateper 100,000 population 

Figure 2: Estimated TB mortality and prevalence rates, Kiribati, 2000–2010

Source: WHO (2011) Global Tuberculosis Control report.

prevalence —mortality

Table 1: TB surveillance data, Kiribati, 2010

Population (2010 Census)	103,371
Number of notified cases	294
Number of notified SS+ cases	116
Notification rate (all forms per 100,000 population)	284
Notification rate (SS+ per 100,000 population)	112
Case detection rate (all forms)	86%
Case detection rate (SS+) ^	_
Treatment success rate (all forms)	92%
Treatment success rate (SS+)	97%
Death rate (all forms)	6%
Default rate (all forms)	1.4%
Smear positivity rate among TB suspects	12%
Proportion of TB suspects screened with 2 or 3 sputum samples	68%

Source: NTP (case data), SPC (rates)

Note: 2009 data are used for the case detection rate, treatment success rate (all forms and SS+), death rate and defaulter rate

<sup>^</sup> WHO is no longer providing the denominator for the sputum smear positive case detection rate, therefore unable to calculate this rate from 2010 onwards. The SS+ case detection rate will not be provided in future reports.

Trends in the notification rate and estimated incidence rate (Figure 3) show that case notification is consistently lower than the estimated incidence for any given year, by a difference of approximately 20%.

600

mother 100

200

2000

2005

2008

2009

2010

incidencerate — notification rate

Figure 3: TB case notification rates and estimated TB incidence rates, Kiribati, 2000-2010

Source: WHO (2011) Global Tuberculosis Control report.

This is also reflected by the estimated case detection rate (%; Figure 4), which was 78% in 2010; this means that up to an estimated 22% of cases in the community may still go undetected.

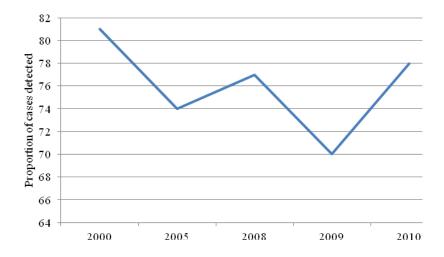
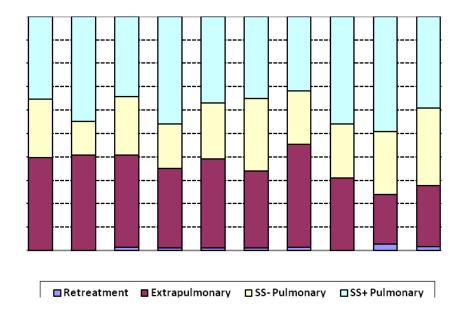


Figure 4: Case detection rate (all forms of TB) (%), Kiribati, 2000–2010

Source: WHO (2011) Global Tuberculosis Control report.

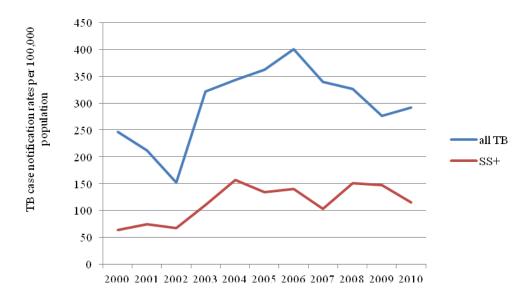
Figure 5 summarises the proportion of cases of TB by type across the 10-year period 2001-10, and Figure 6 compares the notification rate for sputum smear positive pulmonary TB with the all-forms notification rate.

Figure 5: Proportion of notified cases by type of TB, Kiribati, 2001-10



Source: NTP (2009-10 data), SPC (2001-08 data)

Figure 6: Tuberculosis case notification rates (all forms and sputum smear positive), Kiribati, 2000-2010



Source: Kiribati NTP, 2011

The proportion of TB patients who died has increased slightly, from 3% in 2008 to 6% in 2010.

# 2.3 Social Determinants of Health, Hot Spot Communities and Risk

Kiribati has a fragile economy, with a low *per capita* gross domestic product and increasing poverty. Development is constrained by rapid population growth, rapid urbanisation on Tarawa, youth unemployment, and high vulnerability to climate change and external financial influences.

The urban areas of South Tarawa and Betio are the most crowded islands in the country, with almost 50% of the total population (of which more than half reside on Betio). Here, the social determinants of health (SDH) – poverty, population density, housing and ventilation, water supply and sanitation, and standards of nutrition, education and hygiene – are highly conducive to active transmission of TB and other diseases, and contribute to the highest notification rates in Kiribati.

#### 2.3.1 South Tarawa

Of the 294 TB cases that were notified to the NTP in 2010, 227 (77%) resided on South Tarawa (Figure 7) and 67 (23%) in the outer islands.

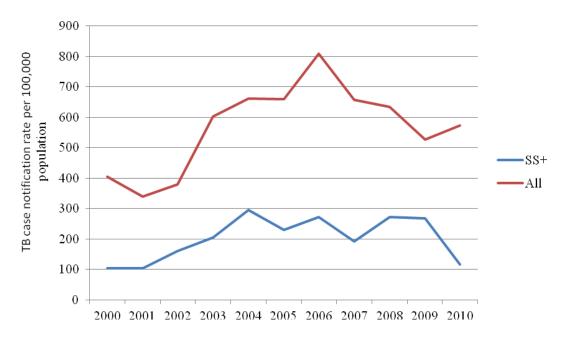


Figure 7: TB case notification rates in South Tarawa, Kiribati: 2000-2010

<sup>5</sup> Preliminary data from the 2010 Census show that the population of Betio has increased by 25% from 12,500 in 2005 to more than 15,700 in 2010 (representing a population density greater than 10,000 people per square km). The overall population of South Tarawa has also jumped 25%, from about 40,000 to just over 50,000.

Source: Kiribati NTP 2011

<sup>&</sup>lt;sup>6</sup> CSDH (2008). Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health. Geneva, World Health Organization

<sup>&</sup>lt;sup>7</sup> Rasanathan K, Sivasankara Kurup A, Jaramillo E, Lönnroth K. The social determinants of health: key to global tuberculosis control. *IntJTLD*, 2011; 15 (Suppl 2): 30-36. Water supply and sanitation are associated with recurrent gastrointestinal infections, and the resulting malnutrition may contribute further to vulnerability to TB.

Of the TB cases reported from South Tarawa, 26% lived in Betio, while 10% were from Bikenibeu West and 8% from Bairiki. The remaining South Tarawa cases were distributed across the atoll, with the villages of Ambo, Antenon, Antebuka, Eita, Banraeaba, Bonriki, Buota and Temwaiku reporting higher than average rates.

Finding TB clusters in relatively poor, crowded and isolated communities is not unusual, particularly in countries like Kiribati with a high background prevalence of TB. However, if allowed to persist, these clusters could potentially function as a steady reservoir of TB infection in the wider community, with the added potential to cause outbreaks. It is therefore incumbent on the NTP and the MHMS to maintain a particular focus on these areas, increasing the case detection rate and maintaining a high treatment success rate in order to accelerate the overall decline TB incidence.

#### 2.3.2 Outer Islands

Figure 8 shows the annual case notification rates reported from the outer islands.

There is also an ongoing risk of introduction of infection through travel between Tarawa and the outer islands and reactivation of latent or previous infection as immunity declines in older age or for other reasons. However, notification rates across all outer islands remain significantly and consistently lower than in South Tarawa.

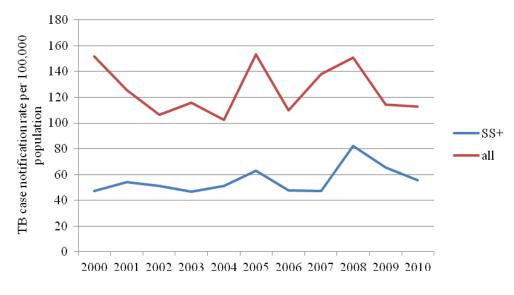


Figure 8: TB case notification rates in the outer islands of Kiribati: 2000–2010

Source: Kiribati NTP 2011

Seven islands in the nearby Gilbert group are consistently reporting cases. These are: Abaiang, North Tarawa, Maiana, Nonouti, Abemama, Makin and Tabiteuea North. Four of these islands were included in the DOTS expansion efforts undertaken as part of QTBECP Phase 2.

Rates of TB in Kiritimati Island are lower than reported elsewhere, with an average of just ten cases per year. However, it is a primary focus of the GOK population resettlement scheme and the rate of TB may rise as population density increases, including as a result of overall population movement

from South Tarawa and higher TB incidence areas in the Gilberts group. Establishing accessible and sustainable TB services in Kiritimati will therefore be important.

#### 2.3.3 Co-Morbidities and Other Risk Factors

Diabetes and HIV infection are co-morbidities that depress immune function and increase the risk of acquiring TB infection; they also influence TB treatment response and outcome. The 2004-05 Kiribati STEPs survey showed that approximately 20% of the adult population had diabetes, and that prevalence increases with age. Around 70% of males and just under 50% of females aged 30-54 years are regular smokers. <sup>8,9,10</sup>

A cumulative total of 55 HIV infections have been reported since 1991, of whom 25 are known to have died; antiretroviral therapy (ART) has been available since 2006.

Forty per cent of total reported TB cases in 2010 were among younger people aged 0–24 years. This suggests ongoing transmission of the disease in the community (rather than any specific vulnerability associated with age).

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<sup>&</sup>lt;sup>8</sup> Jeon CY and Murray MB. Diabetes Mellitus Increases the Risk of Active Tuberculosis: A Systematic Review of 13 Observational Studies. *PLoS Med* 5(7): e152. doi:10.1371/journal.pmed.0050152 (2008).

<sup>&</sup>lt;sup>9</sup> WHO (2004). *Tuberculosis and HIV: A framework to address TB/HIV co-infection in the Western Pacific Region.* Manila, WHO Regional Office for the Western Pacific

<sup>&</sup>lt;sup>10</sup> WHO, MHMS (2009). Kiribati NCD Risk Factors – STEPs Report. Suva, WHO Office for the South Pacific.

# 3. Development Context, Policies and Alignment

# 3.1 Kiribati Development Plan and National Health Strategy

The Kiribati Development Plan (KDP) 2008–2011 was strongly aligned with the Millennium Development Goals (MDGs), and includes health as one of its 6 priority areas.

The current National Health Strategic Plan is also structured around the intended KDP health outcomes and the MDGs. One of the NHSP sub-objectives has been to "reduce the rate of active TB" and the MHMS has supported the full time placement of two senior nurses within the NTP.

Progress towards the health MDGs in Kiribati is hampered by systemic factors including a shortage of skilled health care workers, the age and condition of health infrastructure and teaching facilities, and difficulty meeting the recurrent costs of service delivery. In practice, most of the funded elements of the current NHSP reflect the work plans and budgets of development partners.

A new, fully costed NHSP for 2012-15 is nearing finalisation and is due to be released later this year. Tuberculosis control aligns with Objective 3 of the new NHSP, which addresses communicable disease control.

#### 3.2 AusAID Priorities and Policies

#### 3.2.1 Partnership for Development

AusAID's country strategy and programs are defined by Australia–Kiribati Partnership for Development (PPD). Health is not currently a PPD priority outcome area, but remains a standing agenda item for monitoring during annual Partnership Talks. 12

Although funded through AusAID's bilateral budget, QTBECP has generally been considered a "regional" initiative (as it has been implemented by a regional development partner, SPC, in conjunction with that organisation's role as principal recipient for the multi-country Global Fund TB projects in the Pacific). In practice, however, the Project has been viewed as part of AusAID's portfolio of second-tier PPD support for the health sector in Kiribati, and has been monitored and managed by the AusAID country office in Tarawa.

<sup>&</sup>lt;sup>11</sup> AusAID (2009) *Australia–Kiribati Partnership for Development* [Attachment A – Partnership Priority Outcomes]

<sup>&</sup>lt;sup>12</sup> Tuberculosis is not addressed in detail in the *Concept Paper* that defines Australia's current support for the health sector in Kiribati. Some adjustment of Australia's stated development assistance priorities in Kiribati may be needed to accommodate the status of the proposed new Project as a bilateral (rather than a regional) development assistance activity.

#### 3.2.2 Central AusAID Policies

AusAID's over-arching agency strategy, *An Effective Aid Program for Australia*, <sup>13</sup> and its core agency health policy, *Saving Lives*, <sup>14</sup> both acknowledge the threat posed by TB and MDR-TB in the Asia-Pacific region and beyond.

Both documents commit the Australian aid program to working to halt and reverse infectious disease transmission – including tuberculosis – in line with the MDGs, and to addressing the growing problem of non-communicable diseases (NCD) in the Pacific. Australia will also invest in strengthening health systems to enable partner countries to deliver better services, including by training health workers and improving drug procurement and distribution. Australian support will seek to reduce barriers that prevent people from accessing critical health services and interventions.

The proposed new Project aligns well with the Australian Government's development priorities in the Pacific. It directly targets disease transmission using a combination of enhanced public health approaches, appropriate, innovative technologies and work force capacity development; importantly (given the recognised links between TB infection and diabetes; see Section 2.3.3), it also maintains links with NCD control programs. It will expand work begun under QTBECP on strengthening underlying aspects of the Kiribati health system, including program management, laboratory capacity, and the planning, procurement and distribution of TB and other drugs. Consolidation and integration of active case finding, treatment delivery and other NTP interventions at the community and outer island level will provide critical support for improving access to health services.

The Project will also remain consistent with the overarching objectives and principles of the health elements of the PPD, which notes the importance of providing "support for improved health service delivery ... in cooperation with other development partners".

### 3.3 The New Kiribati National TB Strategic Plan

In 2000, the Government of Kiribati endorsed the WHO *Strategic Plan to Stop TB in the Western Pacific 2006–2010* as the principal guideline for the implementation of the country's TB control strategy: DOTS. <sup>15</sup> This document set the over-arching strategic directions for the NTP, while work plans for the Global Fund projects (also aligned with the WHO regional strategy) provided the detail.

The NTP has just developed a new *National Tuberculosis Strategic Plan*, sub-titled *Acceleration towards TB Elimination*. The time frame for the *Strategic Plan* is the same as for the new NHSP, i.e. 2012-15. It has, as its overall goal:

To accelerate scale-up to achieve universal access to prevention, early diagnosis and effective patient-centred treatment for tuberculosis by 2015

It will do this by ensuring high case detection and treatment success rates in line with international targets, as well as by strengthening underlying elements of the health system.

The new Strategic Plan has 9 objectives – its overall objective structure is summarised in Box 3.

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<sup>&</sup>lt;sup>13</sup> AusAID (2011) An Effective Aid Program for Australia: Making a real difference—Delivering real results

<sup>&</sup>lt;sup>14</sup> AusAID (2011) Saving lives – Improving the health of the world's poor

<sup>&</sup>lt;sup>15</sup> The WHO regional strategy has subsequently been updated; see Section 3.4

As the *Strategic Plan* is still in initial draft form, it remains subject to some further analysis and discussion within the NTP and the MHMS, including agreement on performance indicators; this provides further flexibility and opportunities to ensure alignment of the proposed new Project with it. However, the draft *Strategic Plan* is comprehensive and is strongly informed by the WHO regional strategy (see *Sec*tion 3.4) so major changes are not expected.

Box 3: Structure of Kiribati National TB Strategic Plan 2012–2015 (Draft)		
Goal:	To accelerate scale-up to achieve universal access to prevention, early diagnosis and effective patient-centred treatment for tuberculosis by 2015	
Objective 1:	<b>Social Determinants of Health</b> – Advocating the role of social environmental factors in TB transmission to appropriate authorities and the high risk communities and population	
Objective 2:	Inter-Sectoral-Links – Developing collaboration with MHMS programs, other government departments and NGOs to address factors that increase the risk of developing active TB disease	
Objective 3:	Universal Access – Promoting universal and equitable access to quality and friendly NTP health services	
Objective 4:	Active Case Finding and Referral – Enhancing collaboration with MHMS programs, other government departments and NGOs for active case finding and effective referral mechanisms	
Objective 5:	Clinical and Radiological Capacity – Strengthening clinical and radiological diagnostic capacity	
Objective 6:	<b>Laboratory Capacity</b> – Optimising TB laboratory capacity services to diagnose and monitor treatment of TB cases, including drug-resistant TB, TB-HIV and TB-DM	
Objective 7:	<b>Human Resources</b> – Potentiating NTP human resource capacity through in-country and external training	
Objective 8:	<b>Drugs and Co-Morbidities</b> – Strengthening TB Drug Management system, programmatic managements of MDR-TB, TB-HIV and TB-DM comorbidities and the universal and equitable access to DOT	
Objective 9:	<b>Health Systems and Infrastructure</b> – Strengthening NTP infrastructure and the health systems component that play roles in TB control	

The expected results of implementation of the *Strategic Plan* will be:

- 1) an increased case notification rate;
- 2) an increased case detection rate;
- 3) sustained high treatment success rates;
- 4) a reduction in estimated TB prevalence rate by 50% from 2000 levels (i.e. from 541 to 270 per 100,000) by 2015; and

# 3.4 Alignment with Global and Regional Strategies and Targets

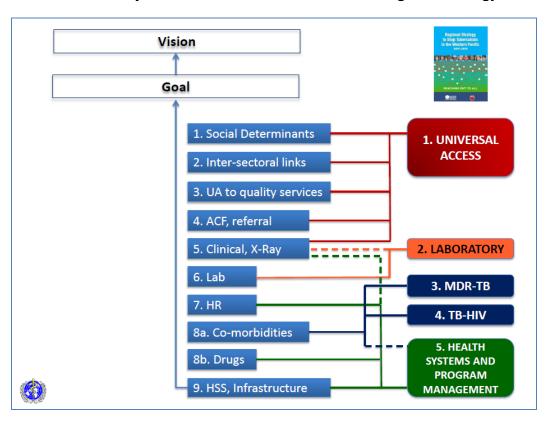
Both the new *National Tuberculosis Strategic Plan* and the proposed Project are aligned to global and regional TB control targets, including the targets in the new WHO regional strategy for 2011-2015, <sup>17</sup> the international Stop TB Partnership targets, <sup>18</sup> and the MDGs.

The alignment of the new *National Tuberculosis Strategic Plan* (Box 3) with the 5 objectives of the WHO *Regional Strategy* is confirmed schematically in Figure 9.

The principal, impact level, global and regional targets for TB control are summarised in Box 4.

By investing in more targeted, more strategic active case finding and effective treatment of those cases, the proposed Project will be able to maintain achievements already made in recent years and increase case detection, and contribute to the achievement of the TB related MDGs.

Figure 9: Program Logic – Alignment of the 9 objectives of the National TB Strategic Plan with the 5 objectives of the WHO Western Pacific Regional Strategy



<sup>&</sup>lt;sup>16</sup> Although not yet formally adopted by the NTP, a reduction in the estimated TB incidence rate by 50% from the peak reported in 2005 (i.e. from 488 to 244 per 100,000) by 2015 has been proposed in the Project performance framework (Appendix 2). Estimates will be based on the annual WHO *Global TB Control* report.

<sup>&</sup>lt;sup>17</sup> World Health Organization Regional Office for the Western Pacific (2010) *Regional Strategy to Stop TB in the Western Pacific Region 2011–2015* 

<sup>&</sup>lt;sup>18</sup> World Health Organization, Stop TB Partnership (2006) *The Stop TB Strategy: Building on and enhancing DOTS to meet the TB-related Millennium Development Goals* 

#### Box 2: International and Regional Goals, Targets and Indicators for TB control

#### **Millennium Development Goals (2015)**

#### Goal 6: Combat HIV/ AIDS, malaria and other diseases

Target 6c. Halt and begin to reverse the incidence of malaria and other major diseases

Indicator 6.9 Incidence, prevalence and death rates associated with TB

Indicator 6.10 Proportion of TB cases detected and cured under DOTS

#### Stop TB Partnership targets (2015 and 2050)

**By 2015:** Reduce TB prevalence and death rates by 50%, relative to the levels in 1990

By 2050: Reduce the global incidence of active TB cases to <1 case per million population per year

#### World Health Organization regional targets (2011-2015)\*

Reduce the prevalence and mortality from all forms of TB by half by 2015, relative to the levels in 2000

Cure rate beyond 85%

Increasing case notification rate as a result of intensified case finding

Country strategy developed for active case finding

100% of MDR-TB patients have access to adequate treatment

# 3.5 Alignment with SPC Strategies

Finally, the proposed Project will support the goal of SPC's *Public Health Division Strategic Plan*, 2010-2014, which is:

To assist Pacific Island countries and territories to achieve improved health outcomes and thereby safeguard and protect the health of Pacific Island people.

The Project also aligns closely with the four main objectives of the Strategic Plan, which are to:

- 1. Reduce the overall impact and burden of disease;
- 2. Contribute towards strengthened national health systems;
- 3. Increase the capacity of PICTs to address the non-health sector determinants of health; and
- 4. Increase the scope, efficiency and impact of interventions.

<sup>\*</sup>A selection of relevant targets is presented in this Box; the complete list of targets is available in the *Regional Strategy to Stop Tuberculosis in the Western Pacific 2011–2015*.

# 4. Lessons Learned from QTBECP

Project funding has supported significant improvements to the NTP infrastructure and TB services across the country; these have been outlined in the annual QTBECP reports to AusAID and the reports of independent reviews of Phase 1 and Phase 2.

Both independent reviews describe how, since 2006, the Project has functioned as an innovative 'pathfinder' project to identify and strengthen appropriate strategies for addressing the TB epidemic in Kiribati – particularly through supporting and strengthening the NTP's implementation of the DOTS strategy.

However, the emergence of MDR-TB remains a potentially destructive and very expensive threat to TB control across the Pacific.<sup>19</sup> The Marshall Islands and Chuuk in the Federated States of Micronesia have both recorded outbreaks of MDR-TB, and sporadic cases have been detected in other PICTs (including Kiribati and, more recently, in Palau and Cook Islands).

# 4.1 Impact of the Project

The Phase 2 review noted that reported TB incidence and prevalence rates had started to decline, and that no further cases of MDR-TB had been detected. Following the peak in total notifications in 2006 (375 cases; crude notification rate 399 per 100,000), there had been a gradual decline in reported cases and notification rates for all forms of TB to 2010 (294 cases; 284 per 100,000), although with a slower rate of decline among sputum smear positive (SS+) cases (which may reflect errors in diagnosis or poor quality of specimens).

The treatment success (92% for all forms of TB, 97% for SS+ pulmonary TB) and case detection rates (86% for all forms) have remained high and above NTP targets; re-treatment cases are uncommon. However – as has also been noted in Section 2 of the present document – some improvement in case detection is still needed (and possible), especially as declines in SS+ cases remain slower than for other forms of TB.

The smear positivity rate among TB suspects has also declined, from 20% in 2008 to 12% in 2010 – close to the WHO recommended proportion of 10% (which suggests better identification and screening of TB suspects).

# 4.2 Enhanced Quality and Capacity of NTP Activities

The QTBECP contributes to the quality and timeliness of diagnosis and treatment of TB at all levels. The completion of the national TB Control Centre (TBCC) and laboratory and the provision of transportation, training and technical support to community TB workers has been particularly

<sup>&</sup>lt;sup>19</sup> A course of standard TB drugs can cost as little as USD 20, while a course of TB drugs for an MDR-TB case can cost USD 5,000 or more. See: WHO (2010) *Drug resistant tuberculosis now at record levels*. Available at: http://www.who.int/mediacentre/news/releases/2010/drug\_resistant\_tb\_20100318/en/index.html

important. (Complementary support has been provided by the Global Fund for 22 community-based and other positions in the expanded NTP; see also *Project Funded Positions*, Section 6.4).

Other than minor errors of quantification, the performance of the TBCC laboratory on external quality assurance schemes (EQAS) for TB microscopy has been close to 100%. The imminent (albeit delayed) establishment of culture facilities in the TB laboratory represents a major step forward in diagnosis and treatment monitoring in Kiribati.

New molecular technologies for TB diagnosis (e.g. procurement of a *GeneXpert* machine) and drug sensitivity testing (DST) will be the next steps for laboratory development, but would be subject to careful policy analysis to guide the evolving National Laboratory Strategy and Plan. This will help to reduce the gap between SS+ and SS- pulmonary TB, which remains wider than expected in a low-HIV environment.

The application of evidence-based diagnosis and treatment protocols and fluctuations in the availability of first-line TB drugs (despite assistance from the Global Drug Facility; GDF) are residual challenges that need to be addressed to consolidate the quality of NTP management and operations.

## 4.3 High-Risk Communities in South Tarawa

Further analysis of South Tarawa NTP data indicates that, in addition to recognised 'hot spots' (Betio, Bairiki, Teaoraereke and Bikenibeu), some intensification of active case finding may be indicated in Antenon and Antebuka, Banraeaba, Ambo, Eita, Temwaiku, Bonriki and Buota.

Given the population and work force constraints on South Tarawa, intensified TB screening in these communities needs to be adequately resourced and done in a way that maximises integration with other areas of community based primary health care (PHC) but is still closely monitored and able to generate sufficient evidence to inform future strategies and health policy. This would involve engagement with Public Health Nurses (PHN) and other community health personnel, and a more active health promotion approach (similar to the more integrated model already practised in the outer islands).

TB screening is in place for higher risk institutional populations (i.e. prisoners, psychiatric patients) but this is in need of periodic evaluation, maintenance and support.

# 4.4 Expanded DOTS Coverage to Outer Islands

In the outer islands, TB treatment and contact tracing are devolved to Nurse Aides at the community level, who work under the supervision of a Medical Assistant based on the island. Overall guidance is provided by Tarawa-based District Nurse Managers, while the project-funded NTP Coordinator and Contact Tracing Nurses provide coaching on quality of care and oversight of outcomes for individual cases and their contacts.

In the Gilberts Group, the latest data suggest a need for some intensification of active case finding in Abemama, Maiama and Makin (in addition to maintaining activities in the identified outer island 'hot spots' of Abaiang, Nonouti, North Tarawa and Tabiteuea North).

# 4.5 Co-Morbidities and Inter-Program Linkages

TB screening is generally integrated into pre-test counselling in the HIV program, and the TB program provides universal access to provider-initiated testing and counselling (PITC) for HIV (with an estimated uptake of 50-70%). However, documentation to assist monitoring the quality and coverage of service provision is lacking in both programs. Awareness of the benefits of isoniazid (IPT) and co-trimoxazole preventive therapy for people living with HIV infection is limited.

The NTP and NCD clinic have continued to promote IPT for diabetic contacts of diagnosed TB cases – but without thorough documentation.

Inter-program meetings to review policies and performance are important to improving the quality of care for patients with co-morbid conditions, but take place very infrequently.

# 4.6 Development Effectiveness

Despite being termed a project, the QTBECP began to follow a more programmatic approach during Phase 2; it now has a more responsive implementation strategy that is closely (and increasing) aligned with NTP priorities, and partially harmonised with the Global Fund Round 7 TB project. This trend will be further supported during the proposed new project.

In relation to the Organisation for Economic Co-operation and Development (OECD) Development Assistance Committee (DAC) assessment criteria and the related AusAID Quality at Implementation (QAI) scoring system, Phase 2 of the Project rated extremely well for relevance and effectiveness and moderately well for efficiency, gender equity and analysis and learning.

Ratings were more modest for sustainability (due to a strong tendency towards substitution for some core NTP responsibilities, with limited absorption of Project functions into Government systems) and monitoring and evaluation (M&E; as reporting had generally been more narrative than analytical; and not based on any reporting criteria or explicit intermediate targets in the log frame or original design).

The Phase 2 review recommended that clear and explicit strategies be developed to integrate donor-funded inputs into the national program as a way of enhancing their sustainability. This would preferably involve integrating activity planning and financial management more closely with the NTP and Government systems, and engaging more strategically with community based PHC and public health services when implementing community aspects of the program.

## 4.7 Conclusions

This proposed new Project follows on from QTBECP Phases 1 and 2, building on all the achievements and lessons of the last 4-5 years.

This will involve a balance between maintaining the momentum and good progress achieved with QTBECP and Global Fund support, improving on the achievements of those projects where possible, then commencing preparation for TB elimination planning as incidence declines and NTP capacity matures.

It will build on the sound TB infrastructure and systems developed under QTBEC Phase 1 and refine the nationwide expansion of TB services created in Phase 2 by enhancing, strengthening and

consolidating activities within the NTP, and by integrating donor-funded planning and management mechanisms and resources with NTP and MHMS structures and systems.

The project will focus on eliminating TB through early case detection using efficient diagnostic tools, effective treatment programs and provision of equitable and accessible TB services to the community, especially the isolated and the poor. TB elimination plans will be an integral part of the project implementation and are expected to continue as part of the NTP longer term plans and activities beyond 2017, towards the global target of TB elimination in 2050.

# 5. Project Design and Theory of Change

This new project will be titled Towards TB Elimination in Kiribati.

Given the declining TB rates in Kiribati since 2006 during QTBEC Phases 1 and 2, the NTP made a conscious decision to move away from the use of the term "QTBECP Phase 3" as the emphasis of the new Project will be different. Instead, and in line with the higher order recommendations of the Phase 2 MTR, a more proactive and forward looking title was chosen to reflect the relevant processes of consolidation and maintenance that will now follow, the commitment of the NTP and MHMS towards the absorption of NTP key services at the end of the proposed 5 years of this Project, and the continuation into the longer term goal of TB elimination.

Towards TB Elimination in Kiribati will be a 5 years and three months project that will support implementation of TB elimination strategies through the consolidation of QTBEC Phases 1 and 2 resources and achievements over approximately the first three years, and the step-wise integration of key elements of the Project to the MHMS over approximately the last two years.

# 5.1 Structure and Program Logic

#### **5.1.1 Vision**

The Vision of the *National Tuberculosis Strategic Plan* is:

#### A TB Free Kiribati Paradise

The Vision tells us what would ideally be achieved, given all the necessary resources to support successful implementation of the *Strategic Plan*. It is shared by the NTP and any partners who support its work, and informs everyone of "**why**" they contribute to the program.

For the purpose of aligning the proposed Project with the national *Strategic Plan*, we have interpreted the meaning of the Vision by expanding and clarifying it as follows:

By 2017, the people of Kiribati, regardless of where they live, have access to and are benefiting from good quality TB prevention, timely and accurate diagnosis, and effective clinical treatment and monitoring that is appropriately integrated into national systems of primary and preventive care.

To achieve this Vision, the NTP will need to maintain high case detection and treatment success rates in line with international targets. Health workers will need to have the right skills, equipment and resources to provide a defined range of services. Those services will be well planned and

efficiently coordinated, and guided by ongoing and regular analysis (i.e. surveillance and operational research). Where services are supported through collaborations with international technical partner agencies, they need to be cost-efficient and sustainable.

#### **5.1.2 Goal**

As noted above, the Goal of the National Tuberculosis Strategic Plan is:

To accelerate scale-up to achieve universal access to prevention, early diagnosis and effective patient-centred treatment for tuberculosis by 2015

The Goal of the NTP *Strategic Plan* will be a collaborative achievement by all partners, and is also adopted as the shared Goal of the proposed Project. However, as the Project will run for two years beyond the *Strategic Plan*, the time frame for the Project Goal is modified as: *to 2015 and beyond*.

#### 5.1.3 Mission

Unlike the Vision or the Goal, the Mission statement helps us to differentiate the Project's contribution to the Vision, and starts to define the Project role and mandate more clearly – i.e.:

- what the Project's core business is,
- who the partners are that the Project works with, and
- how it interacts with those partners

The Mission of the *Towards TB Elimination in Kiribati* project is:

To work with the Kiribati NTP, clinical and public health service providers and technical partners to improve the quality, access and efficiency of diagnostic, clinical and preventive TB services in Kiribati, including by strengthening the TB work force and relevant underlying aspects of the health system

The Mission also starts to define the proposed Project's role and mandate more clearly, and what it can be held accountable for. Together with the Vision, it emphasises improved diagnostic capacity, active case finding in targeted communities and provision of effective treatment through equitable and accessible TB services across the entire country.

In contrast to QTBECP, the new Project will make a gradual shift away from direct support for implementation towards facilitation and capacity support under an integrated annual work plan. The more focused approach of the new Project will complement NTP efforts to reduce the burden of TB, and will provide Kiribati with a good platform from which to commence TB elimination plans.

#### **5.1.4 Objectives**

Rather than directly replicating the 9 objectives of the *National Tuberculosis Strategic Plan*, Project support will contribute to five over-arching functional objectives, each of which addresses one or several objectives of the *Strategic Plan*. This is also better aligned with the Mission statement.

In more detail, the 5 objectives of the Project are:

**Objective 1** – To support universal access to quality TB services, including through active case finding and community mobilisation (aligned with NTP *Strategic Plan* Objectives 1-4)

**Objective 2** – To support quality laboratory diagnosis and clinical standards (aligned with NTP *Strategic Plan* Objectives 5 and 6)

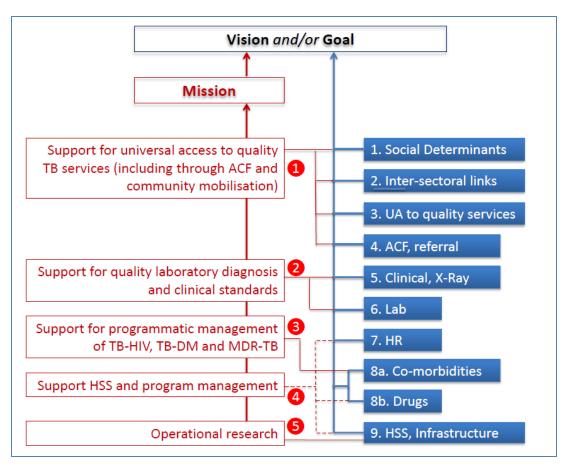
**Objective 3** – To support programmatic management of important co-morbidities in Kiribati, including TB-HIV, TB-Diabetes and MDR-TB (aligned with NTP *Strategic Plan* Objective 8)

**Objective 4** – To support planning and management of the NTP and contribute to strengthening related aspects of the health system in Kiribati (aligned with NTP *Strategic Plan* Objectives 7 and 9)

**Objective 5** – To strengthen TB intervention strategies through evidence-based operational research (aligned with NTP *Strategic Plan* Objective 9)

Alignment of the Project structure with the Strategic Plan is shown diagrammatically in Figure 10.

Figure 10: Program Logic – Alignment of the 5 objectives of the *Towards TB Elimination in Kiribati* Project with the 9 objectives of the *National Tuberculosis Strategic Plan*, and how they contribute (through the Project's Mission) to a shared Goal and Vision



#### 5.2 Duration and Time Line

The Project duration will be 5 years and three months. Based on current TB estimates and trends, the NTP (and independent reviews) anticipate that an additional five years of intensified TB control

efforts and technical and financial assistance will be required to further reduce the TB burden. It will also provide ample time for the gradual transfer and eventual integration of Project elements into the NTP or other areas of the MHMS, depending on resources available and the TB epidemiology at the time.

The 5¼ years of the Project duration will be divided into three distinct phases:

- A *Transitional Phase* of three months (bridging between QTBECP and the new Project)
- An **Alignment and Support Phase** of up to three years ("Phase 1")
- An *Integration Phase* of at least two years ("Phase 2")

The active management of each of the three phases is discussed in more detail in Section 6.5.

It is acknowledged that the proposed duration of the Project is longer than the duration of the NTP *Strategic Plan*. This will ensure continuity of technical and financial support in case of delay in extending or re-developing the *Strategic Plan* or the NHSP beyond their current cycle.

# **5.3 Cross-Cutting Development Themes**

#### **5.3.1 Gender**

Male and female patients currently access NTP services in approximately equal numbers. However, the MTR of QTBECP Phase 2 found a male-to-female ratio of about 1.5:1 among cases across all age groups and a female predominance among cases in older age groups (the latter probably reflecting population structure and the longer life expectancy of women in Kiribati).

The new Project's ACSM strategy and operational research activities will assess possible gender-related risk behaviours or other factors, or poorer access or utilisation of health services by younger adult and middle aged women or older men.

#### **5.3.2 Disability**

Through more efficient case finding and contact tracing, the proposed Project will exercise its major influence over disability through the preservation of better lung function as a result of earlier initiation of treatment. The intensified outreach through improved universal access to preventive and curative, home-based DOTS services (described in detail in Section 6.2.1) will also benefit people with impaired mobility and therefore limited access to fixed health facilities.

The Project will also partner with Te Toamatoa, a non-government organisation (NGO) made up of disabled people from South Tarawa, in community dramas as a vehicle for for health promotion.

#### 5.3.3 Environment

The negative impact of the Project on the environment is likely to be negligible. Clinical staff will use existing systems to dispose of medical waste, and bio-safety systems are already in place in the TB laboratory and for sputum collection in a separate area at the TBCC. Infection control practices will be strengthened through development and dissemination of guidelines for clinical staff; these guidelines will also inform the evolving national laboratory policy and TB laboratory strategic development.

An increase in travel to the outer islands by NTP and community health staff will inevitably increase the direct carbon footprint of the Project. This may be largely off-set by the increased efficiency inherent in diagnosing and treating patients closer to home, i.e. without them needing to be referred to hospital or the TBCC in Tarawa.

#### **5.3.4 Other Cross-Cutting Issues**

Fiduciary risk will be addressed through Project financial management systems (Section 7.3.2).

**HIV infection** and **diabetes** (as an important chronic disease in the Pacific) are AusAID priorities and are prominent areas of focus for the project (Objective 3).

Improved diagnosis and management of paediatric TB will contribute to child protection.

# 6. Project Implementation, Human Resources and Phasing

## 6.1 Integrated Annual Work Plan and Budget

### **6.1.1 The "Four Ones" Principles**

In reviewing options for planning, management and governance, the June 2012 planning workshop for MHMS, the NTP, SPC and AusAID was guided by the principles characterised by UNAIDS as the "Three Ones". <sup>20</sup> The workshop adapted these principles to include a "fourth one" (budget; Box 5).

# Box 5: The "Four Ones" Principles as applied to the Kiribati National Tuberculosis Program

- One agreed National Tuberculosis Strategic Plan that provides the basis for coordinating the work of all partners
- 2. One National TB **Coordinating Authority**, with a broad based multi-sectoral mandate
- One agreed country level Monitoring and Evaluation Framework for the NTP
- One integrated budget and costed work plan, which identifies the activities of all partners and the sources of funding for all activities

<sup>&</sup>lt;sup>20</sup> UNAIDS (2004) "Three Ones" key principles: Coordination of National Responses to HIV/AIDS – Guiding principles for national authorities and their partners

#### 6.1.2 Work Plan Development

Each year, the NTP and SPC (and other partners as appropriate) will collaborate to develop an integrated work plan and budget for all TB activities that will take place under the NTP. (This is a model that has already been piloted for harmonising the QTBECP with the Global Fund Round 7 TB grant to better streamline their activities against the NTP).

The integrated work plan and budget will group activities under each NTP *Strategic Plan* objective (also grouped, as necessary, by area of Project assistance; Figure 10), including identifying the timing of implementation, the cost, and the source of funding.

The first integrated annual work plan and budget (i.e. for 2013) will be developed during the Transitional Phase (i.e. the first three months) of Project implementation, or as soon as the national *Strategic Plan* and the new Project have been endorsed. Should development of the single national work plan be delayed, the Senior NTP/Project Adviser (see Section 6.4) and the SPC TB Adviser may develop a detailed work plan for just the Project and residual Global Fund support as a contingency plan (see *Risk Analysis and Risk Management*, Section 10 and Appendix 3).

# 6.2 Rationale and Indicative Activities for Each Objective

The following discussion describes the principal areas of focus under each Project objective. The phasing of key activity groupings under each Project and NTP *Strategic Plan* objective are presented in more detail in the budget (Appendix 1).

#### **6.2.1 Project Objective 1 - Universal Access**

QTBECP Phases 1 and 2 have made significant contributions to the establishment of a strong foundation for TB control in Kiribati through the development of infrastructure, systems and team capacity during Phase 1, and expansion of TB services to the outer islands in Phase 2.

Objective 1 of the new Project focuses on the further development of universal access to high quality preventive approaches and diagnostic and curative TB services nationwide. It is aligned with Objectives 1-4 of the NTP *Strategic Plan*, which address advocacy for improved social determinants of health, inter-sectoral and inter-program collaboration, access, and active case finding and referral.

Political commitment is crucial to sustain the NTP, including by ensuring adequate human resources to staff the TB laboratory, qualified nurses and doctors to manage the NTP and provide clinical and community TB care and services nationwide, the availability of funds to sustain a continuous supply of TB drugs, and transportation infrastructure to continue timely delivery of TB services to patients and vulnerable groups. The government's anticipated endorsement of the NTP *Strategic Plan* as a key component of the new NHSP underpins the longer term commitment and support.

World TB Day, (March 24) is an annual national event organised by the NTP and its partners on South Tarawa to increase public awareness and to focus political and community leaders' attention on to TB. Education and awareness messages are delivered to the general public and vulnerable community groups during the week leading up to March 24 through different media, such as radio, drama, road floats, singing competitions and public speeches, with the participation of NGO partners such as the Kiribati Red Cross, the Te Toamatoa community dance group (whose members have

already been trained and have performed dramas on TB and other health related themes) and the Kiribati Family Health Association (KIFHA).

Structured advocacy, communication and social mobilisation (ACSM) activities, targeting different population sectors, is an important part of TB control activities. Effective ASCM will aim to decrease stigma, promote equitable access to TB services and increase case detection. The Health Promotion Unit in the MHMS has been working closely with the NTP to produce educational materials, but the Unit has had very little involvement in community outreach activities; it also needs some support to quality-assure and reproduce its information, education and communication (IEC) materials. Partnership between the NTP and NGOs has been quite limited to date, but will be expanded in the new Project to include the partners listed above.

As community-based TB control is progressively implemented, initially on South Tarawa and gradually in the outer islands, provision of comprehensive TB services to patients' door step is desirable. Supervision of TB treatment by trained community based personnel is an important element of community based TB care.

On South Tarawa, the 15 full time Community DOT Workers (CDW) were recruited under QTBEC Phase 1 (see also Section 6.4, *Project Funded Positions*), and will continue to provide supervised TB treatment in patients' homes in South Tarawa. In addition, they will take on an expanded role in the proposed Project: they will be trained to provide TB education and awareness messages to all household members of TB cases whose treatment they supervise, and to carry out active case finding in the household. They will also collect sputum specimens from symptomatic household members (i.e. TB suspects).

Since the extension of TB services to the four selected outer islands with a higher TB burden, (i.e. Abaiang, Nonouti, Tabiteuea North and North Tarawa), Nurse Aides have performed the same functions as the CDWs located on South Tarawa. In the proposed Project, a total of seven outer islands (inclusive of the four that were targeted under QTBEC Phase2) have been identified for intensified TB case finding and NAs will be expected to deliver the same services to TB patients on an incentive basis. In addition, NAs will be trained to conduct basic TB screening using a simple questionnaire in the households they are visiting, and will collect sputum specimens from symptomatic household members to send to the TB laboratory in South Tarawa. The use of NAs in the outer islands ensures the integration of NTP services into the national health system and assures future sustainability of the system. However, the quality of their work needs to be evaluated before this is implemented widely.

The Kiribati NTP has high treatment success rates, a low rate of retreatment cases among smear positive individuals, a low HIV prevalence environment and good laboratory performance, all of which suggest that expanded case finding will be an effective strategy in reducing TB transmission. Hence, the most important focus of this objective will arguably be the intensification of active case finding and making TB services accessible and equitable to vulnerable sectors of the community.

An *active case finding strategy* will be developed during the Transition Phase, and will include the geographic focus principles described in Section 6.3 below. It will particularly target known TB contacts, children, prisoners, the rural population, socially and economically disadvantaged groups in squatter settlements and crowded urban areas (e.g. in Betio), and people living with HIV or diabetes.

Contact tracing will be an important component of the case finding strategy. There are three trained Contact Tracing Nurses (CTNs) on South Tarawa and one on Kiritimati. Their primary role is to conduct TB contact tracing in households of infectious TB cases, where disease transmission may have already taken place. CTNs also supervise Community DOT Workers and conduct supervisory trips to the outer islands, where they will extend their contact tracing activities to include the households of infectious TB cases.

In summary, the principal areas of activity supported through this Project Objective will include:

- Advocacy to political and other leaders on the role of social and environmental factors in TB transmission and orientation on the new NTP Strategic Plan, emphasising the importance of sustained financing for the NTP
- Collaboration with other MHMS programs (in particular, the NCD and child health programs) and other government departments to address factors that increase the risk of developing active TB disease
- Collaboration with NGOs in community education through drama and other activities
- Improved access to and utilisation of TB services through:
  - Strengthening the effectiveness of ACSM activities, including engagement of an ACSM Consultant to support the work of an ACSM Task Force and the MHMS Health Promotion Unit and further develop their skills
  - o Promotion during World TB Day activities
  - o Development or reproduction of IEC materials
  - o Strengthened referral systems to and from outer islands and peripheral clinics
  - Timely and evidence-based monitoring of treatment (i.e. follow up sputum monitoring and clinical review)
- Maintaining support (including refresher training, salaries and transportation) for community-based TB staff on South Tarawa (more detail provided under *Project-Funded Positions*, Section 6.4) to deliver the community-based aspects of each of the 5 elements of the DOTS strategy (Box 1), including by implementing updated active and passive case finding strategies and ensuring good quality sputum specimens for referral
- Maintaining support for Nurse Aides on the outer islands to continue to provide supervision
  of TB patients on treatment and, in consultation with CTNs, to implement screening and
  active case finding among their contacts
- Developing screening programs in higher risk populations (e.g. prisoners, front line health workers)

### 6.2.2 Project Objective 2 - Quality Laboratory Diagnosis and Clinical Standards

Project Objective 2 focuses on further enhancement of the laboratory and radiological diagnostic capacity and clinical treatment knowledge and expertise to assist the NTP to increase case finding and early diagnosis. It is aligned with Objectives 5 and 6 of the NTP *Strategic Plan*, which address clinical and radiological capacity and laboratory capacity, respectively.

In Kiribati, TB is diagnosed by sputum smear microscopy in a dedicated TB laboratory located in the national TBCC; two full-time laboratory staff were recruited under the QTBEC Project Phase 2. The new Project will continue to support the two positions.

Sputum smear microscopy will be maintained as the diagnostic test for TB, so participation in regional EQAS with partner reference laboratories in New Zealand and Australia through the Pacific TB Laboratory (PATLAB) Network is essential. Internal quality control (QC) measures have been implemented and will need to be maintained by the TB Laboratory Supervisor under the oversight of the National Laboratory Manager.

The national TB laboratory must also have up-to-date standard operating procedures, infection control guidelines and QC protocols that are aligned to the national laboratory strategy.

The Kiribati TB laboratory is expected to implement TB culture by the end of 2012. The majority of the equipment needed for TB culture has been procured under QTBECP Phase 2, and two laboratory staff have been trained on TB culture methods at the Institute of Medical and Veterinary Sciences (IMVS) in Adelaide, Australia. Liquid culture and DST will allow better diagnosis of:

- sputum smear negative pulmonary TB,
- drug resistant TB,
- TB among HIV infected adults and children, and
- monitoring of response to treatment for patients with MDR-TB.

Following endorsement by its Strategic and Technical Advisory Group in 2010, WHO has advocated the implementation of an automated nucleic acid amplification test, the *Xpert®* MTB/RIF test (*GeneXpert*; Cepheid, Sunnyvale, CA, USA). The test allows for identification of *Mycobacterium tuberculosis* (i.e. speciation) and detection of resistance to rifampicin, one of the two first line TB drugs that become ineffective in MDR-TB. The test therefore has a potential role in Kiribati in making a definitive diagnosis of TB in suspects who have sputum smear negative pulmonary TB (including in higher risk individuals: re-treatment cases, and in people co-infected with HIV), and in detecting MDR-TB. However, it has no role in monitoring the response to treatment in patients initiated on TB therapy, other than to confirm the emergence of rifampicin resistance in an infection that was previously judged to be sensitive.

Further analysis is needed of the relative cost-effectiveness of molecular diagnosis versus culture and DST in the prevailing epidemiological setting in Kiribati. This will be the subject of the Project's early support for operational research and evidence based policy analysis (described further at Section 6.2.5).

The Project has set aside a dedicated budget to facilitate the adoption of *Genexpert*® MTB/RIF technology in Year 3, subject to the recommendations of the TB laboratory policy analysis.

An alternative remains to further strengthen mycobacterial culture facilities and possibly introduce DST (with the assistance of technical experts from IMVS); a limited number of specimens for molecular diagnosis could then be referred to Fiji, where *Genexpert* facilities are being introduced in three centres in 2012.

Improved laboratory capacity will enhance the quality of TB diagnosis in Kiribati, where there has been a long tradition of initiating trials of TB treatment in individuals – particularly children – with clinically suspicious signs and symptoms but negative sputum microscopy. This Project objective will

complement laboratory strengthening with a program of support for hospital clinicians to improve their diagnostic acumen in the diagnosis of paediatric, sputum negative and extra-pulmonary TB, and to promote IPT in paediatric contacts under 5 years of age.

The introduction of digital radiology will facilitate the introduction of a teleradiology service, whereby electronic chest X-Ray images can be emailed to a participating centre of excellence for a second opinion on hard-to-diagnose cases.

Infection control measures need to be enforced in TB clinics, hospital wards, the TB laboratory, and outpatient and waiting areas in order to prevent cross-infection. Measures include the use of protective masks by health care workers, administrative controls (for example, in waiting areas for people attending outpatient services) and environmental measures such as ventilation systems. The best indicator to assess the quality of infection control is the ratio of the notification rate of TB among health care workers to the notification rate among the general population; this ratio should be around one. <sup>21</sup>

In summary, the principal areas of activity supported through this Project Objective will include:

- Salary support for the TB Laboratory Supervisor and Technician
- Procurement of laboratory reagents and consumables
- The costs of supervisory visits from IMVS to oversee the development of TB culture and possibly the introduction of in-country DST
- The costs of TB culture and first line DST for all retreatment of previously treated cases and others at high risk for MDR-TB (i.e. contacts of an MDR-TB case), and of occasional second line DST, and of HIV testing and confirmation for MDR-TB cases
- Training for laboratory staff (in-country and/or at IMVS in Australia)
- Participation in EQAS activities
- The costs of supervisory outreach by the Laboratory Supervisor to Kiritimati
- Development, production and implementation of infection control guidelines, including availability of N95 masks
- Subject to the recommendations arising from the analysis of the TB laboratory strategy, introduction of *Genexpert* facilities in the Kiribati TB laboratory
- Procurement of digital radiology equipment, and training of radiography staff in its use
- Clinical refresher training and course in the diagnosis and management of sputum negative, suspected pulmonary TB and paediatric TB, including in-country radiology training for clinicians (if feasible, linked opportunistically to a package of broader radiology training for primary care and emergency clinicians)
- Duplication and distribution of WHO guidelines for diagnosis of TB in children

<sup>&</sup>lt;sup>21</sup> World Health Organization, Stop TB Partnership (2006) op cit.

### 6.2.3 Project Objective 3 - Management of MDR-TB and Co-morbidities

MDR-TB was last reported in Kiribati in 2005. Since that time, two cases of rifampicin monoresistant TB have also been reported, one in a person who was co-infected with HIV (who died due to another AIDS-related illness before their TB infection was cured) and one who was cured.

A drug resistance survey conducted in Kiribati during QTBEC Phase 1 as part of a molecular epidemiological study did not find any additional cases of MDR-TB. However, preparedness for a case of MDR-TB remains important for the Kiribati NTP (as it is in Micronesia and the Marshall islands, where MDR-TB outbreaks have occurred); budgetary provision is available through the Project's health systems component (Section 6.2.4).

The best time to take action against MDR-TB is before it becomes a problem. It is far better (and cheaper) to invest in a program to prevent drug resistance occurring than to respond to an MDR-TB case or cluster that has already occurred. Improving the capacity of the NTP to identify and diagnose TB infection and to implement prompt, well-supervised treatment will help to limit the incidence of drug-resistant TB as much as possible. (Systematic screening and testing of TB cases to diagnose drug resistant TB is included as a laboratory function under Project Objective 2. It is estimated that there will be three to four batches annually for the first three years for first line DST among retreatment cases or MDR-TB contacts and suspects; thereafter, the need for DST will likely remain the same).

Collaboration between the TB and HIV programs in Kiribati is relatively loosely structured; reporting and recording of dual interventions, inter-program referrals and other linkages for TB-HIV co-infected individuals has been very inconsistent. However, the NTP has been conducting provider initiated HIV testing and counselling for all confirmed TB cases since mid-2009, with an estimated uptake of 60%.

Studies show that people with diabetes mellitus have a threefold increased risk of acquiring TB. Moreover, clinical experience to date in Kiribati is that TB patients with poorly controlled diabetes have a very poor response to TB treatment, with some remaining sputum smear positive at two months or more and others presenting with relapsed TB after completion of initial treatment.

The Project will help set up a system for screening people with diabetes for TB in the diabetes clinic, and/or if they are a household contacts of an infectious TB case. As part of this inter-program collaboration, isoniazid preventive therapy will be provided for diabetic contacts and for diabetes patients with evidence of TB infection (after ruling out active TB disease).

In summary, the principal areas of activity supported through this Project Objective will include:

- Prevention of MDR-TB through high quality treatment and supervision
- Support for management of any MDR-TB case according to international guidelines, including specialist clinical and diagnostic advice and access to second line drugs
- Establishing inter-program links between the NTP, the HIV program and the NCD program, including scaling up access to IPT for people living with HIV or diabetes, and to ART and cotrimoxazole preventive therapy for people co-infected with HIV and TB
- Maintaining PITC for HIV for eligible individuals
- Scaling up TB screening among people living with HIV

Design and introduction of new registers to facilitate inter-program protocol development,
 patient monitoring and outcome analysis

### 6.2.4 Project Objective 4 - Planning, Management and Health Systems

Stock-outs of first line TB drugs remain a challenge for the Kiribati NTP.

In 2010, the NTP started procurement of fixed dose combination first line TB drugs through the Stop TB Partnership's Global Drug Facility, which should reduce stock-outs and improve patient compliance. However, residual issues still remain, which relate to the drug management system.

The NTP must establish a reliable TB drug management system that links to the MHMS pharmacy procurement system and is aligned to the GDF framework, with technical support from WHO and SPC.

The proposed Project will support procurement of second line TB drugs through the Green Light Committee (GLC, which is hosted and administered by WHO) should a case of MDR-TB be detected. Until the end of the current Global Fund Round 7 TB grant, Kiribati can participate in a pooled procurement mechanism coordinated by the WHO Regional Office in Manila that enables access to quality assured second line TB drugs. The Project will endeavour to maintain those links while covering the cost of the GLC application fee (a one-off payment) and the cost of purchasing the second line drugs, which are beyond the budget of most national Governments.

Various other aspects of the health system will be supported and maintained through the Project, including the NTP health work force (orientation and training), continued supervision and support through the position of a NTP Coordinator, supervisory outreach visits, and strengthening information management systems.

Capacity building and training will be maintained in Phase 1 and 2 as the program must maintain a minimum level of competency and proficiency of among its staff to remain effective.

Currently, all NTP staff plus the TB laboratory staff and a Pharmacy representative attend fortnightly meetings to review and discuss the progress of the NTP; this must continue into the new Project.

Implementation-focused and results-based monitoring and evaluation must be key components of the Project in order to keep track of implementation and to ensure that the intended outcomes and impacts are being achieved. For a long time, the Kiribati NTP has been documenting treatment outcomes for all types of TB. As part of documenting treatment outcomes, SPC and WHO will support the NTP to also monitor and document relevant co morbid conditions to ensure they are treated, in order to minimise adverse impacts on the outcome of treatment.

In addition, an annual program review is proposed at which the achievements, performance and challenges of the previous year are discussed and directions set for the coming year.

In summary, the principal areas of activity supported through this Project Objective will include:

- Training for Pharmacy staff on drug supply management, to ensure a continuous supply of all first line and alternative first line TB drug formulations, including paediatric formulations
- Access to second line TB treatment through the GLC
- Salary support for the NTP Coordinator position, and for the Watchman and Cleaner at the TBCC

- Annual refresher training to all health care workers involved in TB control
- Continued support for fortnightly NTP coordination meetings
- Support for supervisory outreach by the NTP to outer islands
- Technical and logistic support for NTP information and monitoring systems
- Support for an annual program review meeting for NTP staff and selected MHMS
  representatives, with opportunities for staff from selected South Tarawa communities and
  outer island 'hot spots' to also attend
- Some support for maintaining infrastructure (i.e. the TBCC, the Maungan DOTS *maneaba* in Tarawa, the DOTS *bwuia* on Kiritimati)

## 6.2.5 Project Objective 5 - Operational Research

Just over 1% of the Project budget has been reserved for operational research.

Activities currently proposed under this Project Objective include:

- Evaluation of the quality of DOTS currently practised by Nurse Aides on the outer islands
- Follow-up of the TB-Diabetes study conducted under QTBECP
- Evaluation of contact tracing strategies and performance
- Projection of human resources needs of the NTP, including absorption of certain roles into MHMS and/or local government
- Analysis of options for TB laboratory development, and development of a TB laboratory strategy to guide further expansion of laboratory capacity (to include molecular diagnosis or DST)

Each year, the annual program review will update the menu of operational research and aspects of the NTP that need additional data or analysis to enhance their performance. Examples include analysing the reasons for the current wide gap between incidence of smear negative cases and smear positive cases, and exploring the evidence for and against a high level of case finding. This may also entail examining whether smear microscopy is working as well as reported by critically reviewing EQAS processes.

Where relevant, surveys and other operational research projects will disaggregate their data in various ways (e.g. gender, age groups, place of residence or work, and occupational or other risk factor) to inform program development and targeting of interventions.

## 6.3 Active Case Finding Strategy - Geographic Focus

In its *Global tuberculosis control* report (2011), WHO reported sub-optimal case detection rates in Kiribati between 2005 and 2010. This is probably due to a number of factors, including limited access to community level case-finding and TB diagnostic services. Support for active case finding will therefore be a major strategic emphasis of the proposed Project (through Project Objective 1), in support of NTP *Strategic Plan* Objective 4.

An active case finding strategy will be developed prior to the formal commencement of Phase 1 of the Project. This will then be expanded prudently nationwide and intensified, particularly in high risk and socio-economically disadvantaged areas. Expansion of active case finding, combined with TB awareness messages and provision of free and accessible TB services, may be expected to improve engagement with TB services among these communities.

On **South Tarawa**, where close to 80% of current TB cases reside, active case finding will be expanded through a range of activities:

- Contact Tracing Nurses will conduct contact tracing in households of infectious TB cases;
- Community DOTS Workers will be educated to recognise and screen TB suspects in household contacts of TB cases (except in the households of sputum smear positive pulmonary TB cases, who will be covered by CTNs);
- Public Health Nurses will be trained to recognise and screen TB suspects and collect sputum specimens from symptomatic TB suspects during their home visits in the general community;
- TB Community Nurses (TBCNs) will conduct active case finding in high risk population groups, including in the four identified and 8 emerging South Tarawa 'hot spots';
- NGOs (e.g. the Kiribati Red Cross) will be recruited on a short term basis (one or two weeks)
  during national annual festivals and events, such as soccer tournaments and other sporting
  events, to educate people about TB;
- Depending on the availability of resources, contact tracing in work places and schools could occur when there is a reported cluster or new focus of TB infection, or possibly during other health-focused activities.

Active case finding will also be expanded to the **outer islands** through a range of activities, which will focus initially on the four identified and three emerging 'hot spot' islands:

- CTNs will conduct TB contact tracing in households of infectious TB cases
- Nurse Aides will be trained to recognise and screen TB suspects in the households of TB
  cases they are supervising for treatment; they will collect sputum specimens from
  symptomatic suspects and send them to the national TB laboratory in Tarawa
- Other community health staff (e.g. Medical Assistants, Midwives) will also be trained to recognise and screen TB suspects and collect sputum specimens from those who are symptomatic during their home visits in the general community.

As noted above, provision of IPT for those with evidence of TB infection or at-risk contacts of identified infectious cases will be an integral part of active case finding, guided by evidence-based guidelines from WHO and other authorities.

## **6.4 Project-Funded Positions**

### 6.4.1 Current (under QTPECP and Global Fund)

The total number of NTP staff is 35. These positions (all of which are essential to maintaining current NTP services) are summarised in Table 2.

Table 2: Staff working on the Kiribati NTP, by source of funding for position, 2012

Category of Worker	NTP	QTBECP	GF
NTP Manager	1		
NTP Coordinator			1
Project Coordinator		1	
Community TB Nurse	2	2	
Ward TB Nurse	5		
Contact Tracing Nurse			4
Community DOTS Worker			15
Laboratory staff		2	
Ancillary support staff			2
Total:	8	5	22

Only the Manager, two TB community nursing specialists and five TB ward nurses are core MHMS employees.

All other positions (currently 27) working on TB control in Kiribati are funded and engaged through donor supported projects – 22 under the Global Fund (many of whom were initially engaged under QTBECP Phase 1) and 5 under QTBECP Phase 2.

The roles of 7 categories of staff employed by projects and working on the Kiribati NTP are:

**Project Coordinator (PC):** The PC provides overall management and co-ordination of the Project at the country level and ensures that Project implementation is running according to an agreed work plan. The PC works closely with NTP Manager and staff to ensure that the Project supports the NTP and is aligned with NTP priorities and other TB projects in Kiribati.

**NTP Coordinator:** The Coordinator supervises the work of all staff in the NTP, oversees the TB information system, submits Global Fund programmatic reports, conducts supervisory visits to outer islands, conducts on-site training where necessary to staff members, and coordinates the implementation of program activities. She assists the NTP Manager and provides oversight and management of the NTP when the NTP Manager is on leave.

**Contact Tracing Nurses:** CTNs conduct TB contact tracing in households of infectious TB cases. They also supervise CDWs and conduct supervisory visits to selected outer islands.

**Community DOTS Workers:** CDWs provide strict supervision of TB treatment in patients' houses (i.e. directly observed therapy), provide TB education to patients and contacts, and collect sputum specimens from symptomatic household members for follow up. The number of CDWs will need to be reviewed regularly and adjusted (up or down) according to the burden and incidence of TB: a reasonable case load ratio is one CDW per 15 TB cases. The DOT function is a critical element of TB control activities in Kiribati, and high treatment success rates and low rates of drug resistance have been achieved and maintained using CDWs as an integral part of the program.

**TB Community Nurses:** The primary role of the TBCNs is to implement TB control outreach activities to vulnerable populations in the 'hot spots' on South Tarawa. Their role and function may change in the future and will depend on the local TB epidemiology.

**Security Officer:** The Security Officer ensures that the TB Control Centre is safe and secure by conducting patrols of the building.

Cleaner: The Cleaner is responsible for maintaining the cleanliness of the TBCC.

In addition, the *TB Laboratory Supervisor* and one *TB Laboratory Technician* work under the authority of the National Laboratory Manager but with strong functional links to the NTP. Both positions are currently funded by QTBECP.

### **6.4.2 Proposed (under the new Project)**

The limited MHMS budget and Public Service Commission restrictions mean that, in order to maintain NTP services at a level that can meet current and expected levels of demand, the roles of staff currently funded under QTBECP or the Global Fund grant will need to be absorbed during Phase 1 of the new Project, in line with the NTP Human Resources Plan (which will be developed in Year 1).

These roles currently include those of:

- four of the 5 staff who are currently funded by QTBECP two TBCNs and two laboratory staff who will transfer at the beginning of the Transitional Phase of the new Project; and
- the 22 staff who are funded by the Global Fund Round 7 TB grant the NTP Coordinator, four CTNs, 15 CDWs on South Tarawa and the two ancillary staff (the Security Officer and the Cleaner) – who will transfer from 1 July 2013.

The local Project Coordinator position was created under the QTBECP to implement, manage and monitor the Project locally. Under the new Project, this role will be re-designated as *Senior NTP Consultant / Project Adviser*. The Senior Adviser will continue to work closely with the NTP, and many of the more clinical and public health duties and responsibilities will be similar to those of the PC in previous projects. However, unlike the previous projects, there will be two important changes proposed in this Project; a) that the financial and budget responsibilities will be transferred to a Project Accountant, and b) that the day to day implementation of the project will be handed over to the *NTP Co-ordinator*, in line with current MHMS policies regarding project management support for national disease programmes. The Senior Adviser will work closely with the NTP Co-ordinator to provide guidance and oversight of all operational aspects of the project but will also take on clinical and public health duties. The Senior Adviser role will provide advice and support on technical issues related to the Project (including managing the potentially complex, phased absorption of many Project functions into the MHMS during Phase 2) and provide clinical support to the NTP. The Senior Adviser will also assist the NTP Manager to implement and monitor the first *National Tuberculosis Strategic Plan*.

The role of the Senior Adviser will therefore include the following tasks.

- Provide technical support and advice to the NTP regarding the implementation of both the Project and, as necessary, the NTP Strategic Plan
- Assist the NTP Manager and NTP Co-ordinator in the organisation and management of the annual program review and compilation of the annual NTP report

- Participate in and report to the Project governance body, with the NTP Co-ordinator (as described in Section 7)
- Provide support to the NTP Co-ordinator regarding Project-specific reports to SPC's TB Team and the Project governance body on a regular basis (as described in Sections 9 and 10)
- Support the NTP Manager with clinical duties, by assisting in the TB clinics as required.

The role of the NTP Co-ordinator will therefore include the following tasks:

- Manage and co-ordinate the Project according to an agreed work plan, including monitoring progress against an agreed performance framework
- Work with the Project Accountant and the Manager of the MHMS project financial management unit to ensure that financial oversight of the Project and management of fiduciary risk are satisfactory, and that mobilisation of resources and acquittals of expenditure are timely
- Participate in and report to the Project governance body (as described in Section 7)
- Provide Project-specific reports to SPC's TB Team and the Project governance body on a regular basis (as described in Sections 9 and 10)
- Liaise with appropriate government authorities and community leaders to ensure timely implementation of the Project
- Under the direction of the NTP Manager and assisted by the Senior Adviser, organise the annual program review and compilation of the annual NTP report.

If time permits (and subject to MHMS agreement), the Senior Adviser may occasionally be released to provide technical and managerial support to the national tuberculosis programs of other countries in the region in the event of an outbreak or significant performance challenges; separate funding for these tasks will be provided through SPC.

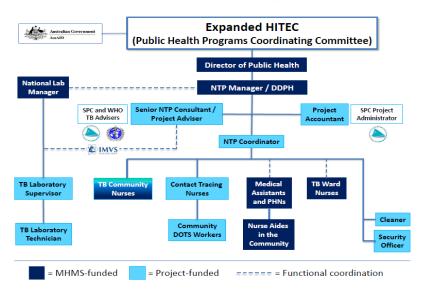
One additional staff member will be recruited under this Project: a **Project Accountant**, who will manage the Project finances. Many of the procedural accounting and book-keeping functions incumbent on the present Project Coordinator role will devolve to the Project Accountant, who will be responsible for the following tasks:

- Manage Project funds at the country level, including disbursements, acquittals and financial monitoring
- Disburse funds to the Project according to an agreed protocol between SPC and the MHMS
- Provide financial reports to SPC's TB Team, the NTP and AusAID on a regular basis (see Section 9.3.2)

It is anticipated that the Project Accountant will be co-located with the MHMS project financial management unit. However, with frequent contact with the Senior Adviser and attendance at fortnightly NTP coordination meetings will be required.

Under the QTBECP, the Project sits alongside the NTP as a parallel organisational structure. Under the new Project, it is proposed that Project-funded positions are integrated more organically into the structure of the NTP, as Figure 11 shows.

Figure 11: Organisational Chart showing MHMS-funded and Project-funded positions within the National TB Program



The *National TB Laboratory Supervisor* is directly responsible for the day-to-day operations of the TB laboratory. The role will essentially continue as per QTBECP, i.e.

- Supervise the laboratory technician(s)
- Collaborate with the NTP to ensure that the TB laboratory fully supports the NTP
- Collaborate with the National Laboratory Manager to ensure that the TB laboratory remains fully consistent with broader national laboratory strategies and policies
- Implement QC activities appropriate to current technologies available in the TB laboratory (microscopy) and those about to be introduced (TB culture)
- Participate in EQAS activities
- Maintain and complete TB laboratory recording and reporting tools
- Collaborate with external technical consultants to improve laboratory operations
- Provide laboratory training

Depending on the findings of the laboratory policy analysis and the evolving TB laboratory strategy, the Laboratory Supervisor's role may need to be adjusted to include the following tasks.

- Implement Xpert®MTB/RIF testing and/or DST
- Implement QC activities appropriate to any newly introduced technologies
- Participate in EQAS activities appropriate to any newly introduced technologies

The roles and responsibilities of **other Project-engaged staff** are expected to remain much the same as under present arrangements, but subject to the requirements of the expanded active case finding and contact tracing strategy.

#### 6.4.3 Terms and Conditions

Detailed *terms of reference* (TORs) for the Senior NTP Consultant / Project Adviser and the NTP Coordinator will be developed by October 2012, i.e. prior to the commencement of the proposed Project.

TORs for all other positions funded through the Project will be finalised at the beginning of the Transitional Phase.

Terms and conditions for Project-funded staff will be aligned with prevailing GOK provisions.

## 6.5 Phasing of Project Support

#### 6.5.1 Transitional Phase

The three-month transitional period from October to December 2012 will enable the Project to align to the GOK fiscal year, which is the calendar year.

The key priorities for the Transition Phase include:

- Development of the first annual integrated work plan and budget, i.e. for 2013;
- Agreement on baselines and indicators for NTP Strategic Plan, especially where those baselines and indicators are shared with the Project's performance framework (Appendix 3);
- Continuation of essential elements of support from QTBECP, including personnel costs for
   5 NTP staff members;
- Confirmation of TORs and job descriptions for all Project-engaged staff working on the NTP;
- Confirmation of core TORs and, if possible, membership of Technical Advisory Group (TAG; see Section 7.6);
- Confirmation of banking and financial management arrangements (see Section 7.3);
- Development of Active Case Finding Strategy, reflecting (where appropriate) available evidence and lessons from comparable countries;<sup>22</sup>
- Commencement of NTP human resources analysis and planning.

## 6.5.2 Phase 1 (Alignment and Support Phase)

Phase 1 proper – the Alignment and Support Phase – will then run for a maximum of 3 years (January 2013 to December 2015).

Key priorities for Phase 1 include:

- Further strengthening of infrastructure and systems developed under QTBEC Phases 1 and 2
  and the Global Fund TB grant, to ensure high quality TB services are available and accessible
  to the community;
- Consolidation and alignment of resources from other projects and the MHMS to further improve the quality of TB services, extend community outreach to vulnerable communities, and support capacity building of staff; and

Eang MT, Satha P, Yadav RP, et al. Early detection of tuberculosis through community-based active case finding in Cambodia. BMC Public Health, 2012; 12: 469-480

<sup>&</sup>lt;sup>22</sup> See, for example:

Akachi Y, Zumla A, Atun R. Investing in Improved Performance of National Tuberculosis Programs Reduces the Tuberculosis Burden: Analysis of 22 High-Burden Countries, 2002–2009. *JID*, 2012; 205: S283-S292.

• Introduction, harmonisation and consolidation of TB services into national health systems and mechanisms (e.g. introduction of DOTS and other core NTP functions to the work of Nurse Aides on the outer islands and PHNs on South Tarawa).

Careful review of progress during the second year of Phase 1 (2014) will inform decisions about whether to transition to Phase 2 a little early (i.e. at the beginning of or during 2015) or, as planned, in late 2015 / early 2016.

### 6.5.3 Phase 2 (Integration Phase)

The principal focus of Phase 2 – the Integration Phase – will be to ensure the maintenance and long term sustainability of Project inputs and the NTP itself.

It will run for a minimum of two years (January 2016 to December 2017); subject to performance and progress with alignment during Phase 2, it may commence earlier but will nevertheless extend to the Project's planned conclusion date.

This process will include the *development a series of integration plans* in the run-up to and during Phase 2 by the Senior NTP/Project Adviser and the NTP Manager (in consultation with SPC and the MHMS) to define and describe the *gradual* transfer and *integration* of Project elements into MHMS systems, including:

- Ownership and responsibility for:
  - Project-funded personnel (i.e. Project-supported NTP positions according to the NTP human resources analysis, projections and development plan – see Section 6.2.5)
  - o Project-funded infrastructure (e.g. Project-funded motor vehicles, the TBCC and adjacent *maneaba*, laboratory equipment, etc)
- Absorption of other NTP functions and recurrent operating costs into the MHMS, including:
  - NTP gradually taking primary responsibility for development of the integrated annual work plan and budget (which should clearly define the roles of participating stakeholders, and must be endorsed by the MHMS and, where relevant, have the agreement of donors)
  - Maintenance and depreciation schedules for large scale infrastructure (e.g. the TBCC and maneaba, which should have been refurbished at MHMS cost during Phase 1 and exchanged with the Project for the existing Maungan DOTS maneaba)
  - TB laboratory functions, including the employment of suitably qualified laboratory technicians and maintaining consumables, equipment maintenance, engagement of technical support, and participation in EQAS
  - o Shipment fees for specimens for DST (and, if relevant under the new TB laboratory strategy, for molecular diagnosis in selected cases), to partner reference laboratories
  - Costs of laboratory consumables
  - Procurement of GeneXpert MTB/RIF (according to laboratory development policy)
- Absorption of selected NTP operating costs and incentive payments into local government, including:
  - Payment of retainers and allowances for CDWs in selected South Tarawa communities, where their services will be retained to manage ongoing treatment and contact tracing, and to support PHNs in active case finding

o Incentive payments for Nurse Aides on the outer islands, who may need to continue to perform tasks similar to the CDWs on South Tarawa

Planning for Phase 2 should begin during Phase 1, as it will require a significant amount of discussion, consultation and agreement.

In the case of Project-funded NTP staff positions, discussion on transfer of staff salaries to the MHMS could commence even earlier – e.g. during the Transitional Phase between the QTBEC Project and Phase 1 of the new Project – to undertake some preparatory thinking about the transfer of some staff to the MHMS earlier than 2017. These discussions will be further guided by an operational research project on the required staff mix within the NTP over the medium- to longer-term.

The Senior NTP/ Project Adviser will be responsible for initiating and coordinating dialogue between the MHMS, the Project and the NTP on these matters.

# 7. Project Governance, Coordination and Management

## 7.1 Responsibility for Implementation

The Project will be jointly implemented by the NTP (under the authority of the MHMS) and the Secretariat of the Pacific Community (whose involvement is described further in Section 7.5.3).

Implementation will be guided by the *National Tuberculosis Strategic Plan*, consistent with the WHO *Regional Strategy to Stop TB in the Western Pacific Region 2011–2015*.

Technical assistance will be provided by SPC, with additional technical support through WHO, the IMVS (for laboratory support) and other experts as appropriate (explained further in Section 7.5.4).

## 7.2 Strategic Oversight and Management

Overall strategic oversight for the Project (including management, technical and financial oversight) should be provided by a single coordination authority that includes representation from MHMS, the NTP, SPC's TB Team (Disease Surveillance, Research and Control Unit, Public Health Division) and, as principal donor, AusAID.

The coordinating body would be responsible for overseeing joint NTP-Project implementation and providing guidance in reaching their stated goal and objectives. From time to time, it may also need to review and approve major changes to the design, management, organisation or Project-funded expenditure.

## 7.2.1 Core Oversight and Management Body - HITEC

Under QTBECP, this role has been taken by a specially-constituted National Implementation Coordinating Committee (NICC).

Under the aligned Project, in line with the "Four Ones" principles, it is proposed that a separate NICC would <u>not</u> be required.

The body that is proposed to assume the strategic oversight role is the HIV-TB Executive Committee (HITEC) of the MHMS, which provides oversight of the Global Fund Country Coordination Mechanism (CCM) and implementation of the Global Fund HIV and TB grants.

HITEC already includes members of the MHMS Senior Executive and key public health decision makers and already works in close collaboration with the Kiribati NTP, who will implement the *Towards TB Elimination in Kiribati* Project.

HITEC currently meets once a quarter and ad hoc as required for emerging issues.

The addition of the new project to their portfolio would be logically aligned with (and probably overlap) their other areas of interest and responsibility.

### 7.2.2 Donor and Technical Partner Participation

During the 5¼ years of the proposed Project, planning and partial transfer of some elements of the Project to the GOK will commence, subject to assurances that the quality of TB control efforts will not be compromised. There will need to be continuing discussions throughout the Project lifecycle between SPC, AusAID and GOK on the funding needed to sustain the necessary intensified TB control efforts beyond this proposed Project period, in order to realise the full benefits from TB control efforts across 10 or more years of donor-funded support.

High level oversight of the project and the NTP should therefore include opportunities for donor and technical partner participation, as it provides an important forum for policy and strategic dialogue.

Although not normally members of HITEC, it is proposed that both AusAID (through the health focal point at its Tarawa office) and the SPC TB technical unit (through the Senior NTP/Project Adviser) are invited to participate in alternate HITEC meetings (i.e. approximately 6-monthly).

As appropriate, the timing of the HITEC Project coordination and management mechanism might be varied slightly to accommodate visits by SPC, WHO or AusAID technical advisers.

## 7.3 Financial Management

### 7.3.1 Current Arrangements under QTBECP and the Global Fund

The QTBECP budget and financial management is currently managed in close association with the TB and Finance Sections in SPC but still stands apart from national or in-country financial management systems.

Global Fund TB resources, on the other hand, are managed directly by an in-country project financial management unit, operating from within the MHMS but through separately earmarked bank accounts. This office also handles Global Fund HIV finances and funds made available through the HIV/STI Response Fund; both of these regional funding programs are mobilised through SPC. It has well established computerised financial management systems and a staff of three (one accountant – a former Secretary of Finance – and two accounts clerks), and both SPC and the Global Fund's Local Fund Agent (LFA) have accredited the unit's systems and capacity as suitable for handling Global Fund resources.

### 7.3.2 Options for Alignment of Financial Management Systems

The MHMS project financial management unit Accountant believes that his team would be capable of absorbing the additional work associated with managing externally funded TB project resources without needing additional staff or risking a slowing of disbursements. Existing processes could be adapted to meet the needs of the new *Towards TB Elimination in Kiribati* Project (or *vice versa*), e.g. generating monthly reports of financial acquittal.

The MTR of QTBECP Phase 2 also strongly recommended channelling project-related funds and financial management through the international projects unit in MHMS, thereby freeing Project staff from routine book-keeping activities but maintaining similar safeguards to those applied to management of Global Fund and Response Fund financial resources.

However, a Pacific Islands Forum peer review and an AusAID Assessment of National Systems (ANS) conducted in the meantime have both recommended a more cautious approach. The AusAID ANS concluded that there is a substantial level of fiduciary risk attached to the use of GOK systems, and that direct placement of Australian Government funds should be restricted to the current limited use of the Kiribati Government Development Fund until such time as a public financial management (PFM) and procurement reform program is well advanced. AusAID has indicated that this cautious approach is not mitigated by SPC's or the Global Fund LFA's accreditation of the processes and standards of the international projects unit in MHMS.

## 7.3.3 Recommended Approach from the Beginning of the new TB Project

MHMS have expressed a keen interest in managing all aspects of the Project (both financial and programmatic) as soon as possible. The compromise approach proposed following the design workshop is to:

- maintain a separate stream of AusAID funding through a dedicated SPC bank account,
- ensure that this bank account is AUD-denominated (to minimise exchange rate losses on conversion from AUD to XPF and back again, and to minimise risks associated with holding AusAID funds in USD- or EUR-denominated accounts),
- maintain a Project-specific, AUD-denominated bank account in Kiribati (e.g. the same bank account in Kiribati created under QTBEC Phase 2),
- place the Project Accountant within the international projects unit in MHMS, where they
  would work in close association with the supervising Accountant of that unit and use
  systems and software that are compatible across programs, and
- use those systems to generate Project-specific financial reports as required.

Project funds would be disbursed by the SPC TB Team to the bank account in Kiribati in accordance with the pace of Project implementation against the integrated NTP budget and work plan and periodic acquittals of expenditure (see also Section 9.3.2).

This approach has the advantage of developing close engagement between the Project Accountant and the MHMS international projects unit. Should PFM and procurement reforms gain AusAID accreditation on subsequent reassessment, the Project will then be well placed to immediately commence a phased integration of elements of Project financial management into the MHMS system in accordance with the principles described above (Section 6.5.3) for Phase 2 integration.

This would also be subject to satisfactory annual external audits of Project finances (which could be undertaken either by an auditor contracted by SPC or by the GOK's Auditor-General's Department).

Subject to the satisfactory assessment and performance of the Project during the Mid Term Review (scheduled for mid-2014, and which will include an assessment of financial management of the Project), MHMS may be able to take on full responsibility for aspects of the Project or, potentially, the whole Project. The Project may then be restructured to take the form of an acquittable cash grant; if recommended by the MTR, separate grants may need to be retained for technical and (if required) accounting/ financial support. However, this will be subject to the MTR team's assessment of the implementation and performance of the Project to date, and will require agreement from AusAID to proceed in this manner.

## 7.4 The Roles of Other Partners in the Project

## 7.4.1 Ministry of Health and Medical Services

The initial arrangement between the MHMS and QTBECP Phase 1, endorsed by the former Health Minister and his Secretary in 2005, stated that the "MOH retains the right to host the project through co-sharing costs of services, such as internet access or providing in-kind contributions to the project through provision of free office space and facilities". This arrangement worked very well during Phase 1 of the Project but changed after the NTP moved into the new national TBCC in 2009.

As described, the MHMS currently supports the NTP through the funding of core NTP staff positions (Table 1 and Figure 11) and the procurement of first line TB drugs through the Global Drug Facility. The *Towards TB Elimination in Kiribati* Project will facilitate smooth transition of Project functions and resources across to the national Government (Section 6.5.3), including developing a human resources plan for the NTP and monitoring the need and disposition of Project funded staff (Sections 6.2.5 and 6.4).

The MHMS will also facilitate and provide overall supervision for the roles of outer island Medical Assistants and Midwives supervising Nurse Aides who are monitoring and supervising DOTS and case finding activities in their communities.

In relation to TB laboratory services, the *National Laboratory Manager* will be responsible for the oversight and management of the TB laboratory in the TBCC. Her role will include the following tasks:

- Complete the National Laboratory Strategic Plan (aligned to the Asia Pacific Strategy for Strengthening Health Laboratory Services, 2010–2015)
- Ensure that the evolving strategy for TB laboratory development is also well aligned with the *National Laboratory Strategic Plan*
- Procure, install and screen (pre-installation) laboratory equipment
- Recruit qualified staff to work in the TB laboratory
- Provide training to national laboratory staff
- Introduce and monitor the application of standard operating procedures and diagnostic
  algorithms in relation to existing technologies (e.g. slide preparation), new technologies (e.g.
  commencement of TB culture) and future technologies (e.g. the introduction of TB DST
  and/or Xpert®MTB/RIF testing)

## 7.4.2 The National TB Program

Within the MHMS, the NTP will be directly responsible for implementation of the *National TB Strategy*, which guides all technical aspects of the Project. In addition to its ongoing TB control work, the NTP will perform the following tasks under the guidance of the NTP Manager:

- Participate in the development of a collaborative work plan that incorporates all TB control activities in the country, including Government and Project funded activities
- Implement Project activities and provide relevant training
- Revise the National TB Strategy and relevant sections of the NHSP beyond 2015

- Ensure that an adequate supply of first line TB drugs is available through the government Pharmacy
- Coordinate external technical assistance
- Maintain TB surveillance and reporting using recording and reporting systems that are aligned to WHO's definitions and requirements
- Provide clinical care for TB patients, TB suspects, TB contacts and others at risk of developing
   TB or co-morbidities
- Collaborate with the Health Promotion Unit and the ACSM consultant to develop a strategy for TB advocacy activities
- Collaborate with other relevant health programmes and groups to increase case detection
- Lead all national TB initiatives

### 7.4.3 Secretariat of the Pacific Community

SPC is the region's multi-sectoral, inter-governmental body and brings a unique capability for technical support, not only for health-related aspects of the Project (through the TB Team in its Public Health Division) but also through linkages with its Human Development Program (addressing gender, youth, and culture), its Statistics for Development Program and its Strategic Engagement Policy and Planning Facility.

SPC's involvement with the existing QTBECP (since 2006) and the Round 2 and Round 7 Global Fund grants (since 2003) give it a profound comparative advantage over other potential implementing partners in relation to the planning and implementation of TB interventions in Kiribati. It has an established relationship with the MHMS (including the in-country project financial management unit) and NTP and with the AusAID country office and, as noted at Section 3.5, its Public Health Division strategic plan is supportive of the directions of the new Project; this also includes close involvement in strategies to address HIV risk and infection and NCDs in the Pacific.

Although SPC does not yet have a country office in Kiribati, the Senior NTP/Project Adviser and, to a certain extent, the NTP Coordinator will be in regular contact with the technical unit in Noumea and can represent SPC on a day-to-day basis.

As principal implementing partner for the new Project, SPC will provide two principal avenues of support:

The SPC **TB Adviser** (TB Team, Noumea) will provide strong support to the Senior NTP/Project Adviser on overall Project management and coordination, including:

- Organising and managing Project implementation and monitoring, including technical, project and financial management
- Helping to develop and then submitting required Project-specific reports to AusAID and SPC
- Providing technical assistance to the Project, in collaboration with other partners.

The SPC **Project Administrator** (TB Team, Noumea) will be responsible for SPC's financial administration of the Project under the guidance of the TB Adviser, and will work closely with the Project Accountant. Other tasks of the Project Administrator include:

- In consultation with the Project Accountant (who will be managing Project disbursement, acquittals and monitoring at the in-country level), developing or refining financial monitoring tools to ensure that that Project requirements are fulfilled
- Ensuring that the Project financial reporting system and tools are compatible with both the SPC reporting system and – eventually – also the MHMS project financial management unit's financial tools
- Assisting in the streamlining of financial systems within the national TB programme

Neither of these two positions is funded out of the Project budget.

### 7.4.4 Other Technical Partners

The Kiribati NTP has had longstanding relationships with other technical partners in the region. Among these, the principal ones are the **Australian Respiratory Council**, the **Institute of Medical and Veterinary Sciences**, the **Pacific Paramedical Training Centre** and the **World Health Organization** (Pacific Division of Technical Support – Western Pacific Region and Kiribati office).

These partners provide technical assistance in the following areas: laboratory strengthening and quality assurance; programmatic management; monitoring and refinement of active case finding strategies; ACSM; capacity building; TB drug procurement; and other areas pertaining to the programmatic management of TB. In addition, as the need arises, the NTP is supported by independent consultants and clinicians in specialist areas such as radiology and other training, research, clinical case assessment, etc.

More recently, the NTP has collaborated with the United States **Centers for Disease Control and Prevention** to promote programmatic research in the area of TB and diabetes.

### **7.4.5 NGOs**

The Kiribati NTP has collaborated with local NGOs for TB related ACSM activities. As described at Section 6.2.1, this collaboration will continue in many aspects of ACSM during the proposed Project.

## 7.5 Technical Advisory Group

It will be critically important to ensure that Project-funded functions are correctly integrated into the NTP, that activities and interventions are based on the best available evidence, and that important risks are being identified and managed in a timely fashion. The Project budget therefore provides for a specific Technical Advisory Group to be engaged annually, either as a stand-alone technical advisory mechanism or as part of an expanded Project and NTP review function.

#### 7.5.1 Composition and Frequency

The TAG would serve as an expert panel not only to the Project but to the overall NTP.

It would bring together specific expertise and experience in the following areas:

- TB control, and clinical diagnosis and management;
- mycobacteriology, laboratory science and laboratory quality management systems;
- health systems, policy, planning and financing;
- data management and M&E; and

• community mobilisation.

Not all of these skill sets might be needed for every TAG visit. However, the right membership of the TAG would most likely ensure that a good breadth of skills could be provided by a small number of individuals anyway.

An expert in TB control programs would be designated as the lead consultant of the TAG, and would ideally be available to participate in all TAG and review missions over the life of the Project.

It is proposed that the TAG be mobilised for up to one week in-country each year.

### 7.5.2 Timing, and Coordination with other Review Activities

The Project design also provides for comprehensive review of the Project and the NTP twice during the 5¼ years: an early MTR would be undertaken around the middle of Year 2, and an end-of-Project review late in Year 4 or, at the latest, early in Year 5 (see Section 9.5).

In the years when formal Project reviews are scheduled, i.e. Years 2 and 4, the scope of the TAG's TORs would be adjusted to ensure an appropriately expanded and strategic focus. Including members of the TAG in the formal review teams (and *vice versa*) will ensure consistency of approaches.

In general, the timing of the TAG visits and the MTR in Years 1-3 would be in the weeks immediately prior to the proposed annual NTP review (Section 9.2); this would allow the SPC TB Adviser – and possibly also the TB focal point in the WHO South Pacific office in Suva – to participate and contribute to the mission. TAG findings would then be presented to the annual review meeting, and any recommendations would be absorbed into the subsequent year's consolidated work plan.

Given the importance of laboratory capacity to the NTP, it is proposed that the annual TAG or MTR visit also aligns with the visit from IMVS, so that the laboratory adviser can participate as a member of the TAG and contribute a laboratory perspective to the TAG's deliberations.

Beginning in Year 4, the annual program review should be managed entirely by the NTP. The end-of-project review team would attend the program review meeting and remain in-country to examine Project-specific achievements, progress with the absorption of Project functions into MHMS, and other activities and risks associated with sustainability.

#### 7.5.3 Terms of Reference

During each visit, the TAG would undertake a concise, practical review of all aspects of service delivery through the NTP, TB epidemiology, programmatic indicators, and the relationship between the Project and GOK systems and other aspects of the operating environment.

A further role for the TAG will be to help interpret the results of operational research and whether (and how) the work of the NTP might need to be reoriented, and to prioritise the future operational research agenda. As noted, the Involvement of IVMS and PATLAB will be critical for guiding the future expansion of laboratory services, which must remain responsive to key challenges and emerging issues for the NTP.

The TAG will provide a concise written report identifying key actions, program adjustments or other recommendations as a result of their visit.

During the Transition Phase, the NTP and SPC (as implementing partners) will jointly develop the core TORs for the TAG for endorsement by the Project's oversight body – the expanded HITEC. Each year, they would negotiate and agree on any additions or adjustments to those TORs that may be needed for individual TAG visits.

During Phase 1, the TAG would be engaged directly by SPC on behalf of the NTP and the Project. Subject to the pace of integration of externally funded mechanisms into the NTP and MHMS and the findings and recommendations of the MTR, contracting arrangements for the TAG may be adjusted in Phase 2 to allow for maturation of GOK procurement, governance and financial management systems.

# 8. Budget and Budget Analysis

### 8.1 Overview

The total budget (excluding SPC management fees of 7%) is AUD 2,754,812 over the five years and three months. The detailed Project budget (Appendix 1) shows anticipated disbursement of funds as time-dependent and output-based to facilitate timely implementation of supported activities as per the integrated NTP work plan and budget.

# 8.2 Budget by Objective and Year

Year-on-year trends in the Project budget and all other sources of NTP funding are shown in Table 3.

Table 3: Funding for the Kiribati NTP, in AUD by source (and, for the new Project, by Objective), 2012-17

Source	2012	2013	2014	2015	2016	2017	Total
MHMS (estimated / projected)	90,000	90,000	90,000	120,000	155,000	180,000	725,000
Global Fund Round 7 Grant	221,817	5,234					227,051
Global Fund Transitional Funding Mechanism		161,385	260,529				421,914
QTBECP	123,995						123,995
Towards TB Elimination in Kiribati Project	159,721	556,614	594,089	573,974	448,770	421,744	8693
% of total Project budget	5.8%	20.2%	21.6%	20.8%	16.3%	15.3%	100%
Objective 1: Universal access	6,331	181,993	228,192	209,937	190,298	199,764	1,016,515
Objective 2: Quality diagnosis and treatment	138,857	138,449	118,089	140,049	75,789	69,689	680,922
Objective 3: Co-morbidities and MDR-TB	0	15,735	11,080	7,075	8,000	3,080	44,970
Objective 4: Planning, management and health system strengthening	488	113,248	131,104	118,103	70,211	44,756	477,909
Objective 5: Operational research	0	35,000	12,500	12,500	12,500	12,500	85,000
Technical Advisory Group and Project reviews	0	14,620	20,072	15,813	14,565	17,103	7346
Project administration	14,045	57,470	73,052	70,497	77,407	74,852	367,323

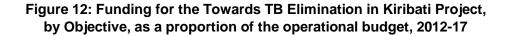
AND TOTAL	595,533	813,233	944,618	693,974	603,770	601,744	4,252,872	
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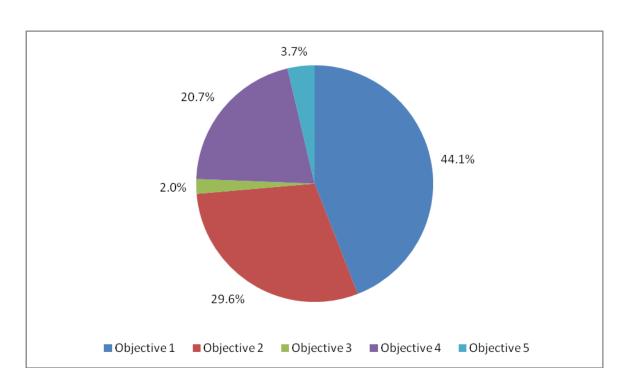
The phasing of Project support is reflected appropriately in the annual budgets, which range from 26.0% of the total budget being provided in 2012-13 (and 68.4% across all of the expected Phase 1) down to 15.3% in 2017 (and 31.6% across all of the expected Phase 2) as the MHMS gradually picks up and funds activities.

## 8.3 Operational Budget by Objective

Figure 12 summarises the breakdown by objective for the operational budget (i.e. Objectives 1-5; AUD 2,303,840) across the whole 5¼ years of the Project.

This reflects the priorities for the Project, which fall under Objectives 1 (universal access to quality services), 2 (strengthening diagnosis and treatment) and 4 (planning, management and health systems).<sup>23</sup>





<sup>&</sup>lt;sup>23</sup> A contingency sum equivalent to 5% of the estimated cost of procurement of goods and internationally-sourced services (including air fares) is incorporated into the operational budget (Objective 4) as a buffer against exchange rate risks and price fluctuations; see Appendix 3, Risk #2.3.

## 8.4 Administration and On-Costs

Project administration (including Senior Adviser and Accountant costs) account for an additional AUD 367,323, and the costs of mobilising an annual Technical Advisory Group (Section 7.6), comprehensive mid-term review or end-of-project review (Section 9.5) are budgeted at AUD 82,173.

SPC's 7% management costs total AUD 192,837 across the entire Project.

## 8.5 Performance-linked and Conditional Funding

A small number of activities are designated in the budget as performance incentives. **Project performance incentives** are contingent on good implementation of an antecedent, linked activity (e.g. completion of a related strategy or plan, or regular meetings of a task force or working group documented) before funding is made available (e.g. to procure particular items, or to attend an international course or training event). **Individual performance incentives** are available to Nurse Aides on completion of a course of treatment for a TB patient and associated contact tracing, and to CDW drivers based on timely and reliable service and ensuring compliance with log books and maintenance schedules.

In addition, where pre-conditions are in place for procurement (i.e. a procurement, depreciation and maintenance plan), the procurement of certain items can be brought forward (for example the procurement of motorbikes and or a CB radio).

Collectively, these items amount to AUD 225,278, or 8.2% of the total Project budget – comprising AUD 165,040 (6.0%) for Project performance and AUD 60,238 (2.2%) for individual incentives.

The annual TAG or MTR mission could be tasked to verify the achievement of Project-linked and individual performance milestones and incentives.

## 8.6 Proportion allocated to M&E

Several activities in addition to the Project reviews will contribute to monitoring, evaluation and performance assessment. These are estimated to comprise 7.6% of the gross Project budget – a proportion that is in the middle of the range recommended by the OECD DAC (5-10%). This reflects the need to closely monitor critical tasks intended to strengthen access to and quality of TB services and to embed many Project-related functions into the NTP during the life of the new Project.

## 8.7 Reprogramming and allocation of cost savings

It is anticipated that throughout the life of the Project there may be some cost savings in certain areas. The most prominent examples of this are the procurement of an *Xpert® MTB/RIF* machine (and the associated consumables) and the procurement of second line TB drugs, in the event of a case of multi-drug resistant TB (which includes associated technical assistance). The reprogramming and re-allocation of these funds (and other savings incurred during the lifetime of the Project) will be subject to review by the HITEC, with a documented decision point about re-allocation of these funds noted in the minutes.

# 9. Project Monitoring, Reporting and Review

## 9.1 Alignment and Principles

Consistent with the "Four Ones" principles, the Project seeks to have a clear, inclusive, integrated monitoring mechanism that is able to demonstrate credible progress in improving NTP outputs and outcomes on a regular basis.

Partners would move to a joint appraisal and reporting system (rather than requiring their own separate arrangements). This would most likely require a blend of:

- Quantitative outcome reporting (against standardised "TB indicators", as is practised under present arrangements between the NTP, SPC and WHO)
- Narrative reporting against agreed performance milestones

Mutual accountability would be an important guiding principle.

It is acknowledged that AusAID and the Global Fund, as principal external donors, would still need:

- separate financial acquittals of the resources they place at the disposal of the GOK to support TB control; and
- diligent, timely and pro-active monitoring and reporting of both inherent and emerging risks.

## 9.2 Annual TB Program Review

In support of a single annual NTP report, it is proposed that a collaborative annual review of the NTP be undertaken.

Costs associated with this review (e.g. bringing key MHMS counterparts to Tarawa from outer island 'hot spots') would be mobilised as necessary through the Project during Phase 1; however, it is envisaged that an annual program review would become institutionalised by MHMS as a regular part of NTP monitoring during Phase 2 of the Project.

## 9.3 Reports Required, and Frequency

This means there will be three levels of regular reporting within the Project:

## 9.3.1 Annual Progress Report for the NTP

The Annual Progress Report for the NTP will be compiled jointly by the NTP Manager, the Senior NTP/Project Adviser and other NTP staff. It will be structured according to the *National TB Strategy* and the integrated annual work plan and budget.

The Annual Progress Report will summarise achievements and challenges at the output, outcome, and impact level, but may include more detail about particular challenges at the activity-based level.

It will draw on routine NTP surveillance data collections (which form the nucleus of the proposed Project performance framework) and the findings and recommendations of the Annual Program

Review. In those years where a TAG or MTR team is mobilised, it should also be informed by the report and recommendations arising from those missions.

It will be shared openly among all partners (MHMS, SPC, WHO, AusAID and technical partners).

### 9.3.2 Monthly Acquittals of Expenditure

A monthly acquittal of expenditure for the period, in accordance with the Project budget, will be prepared by the Project Accountant and SPC Project Administrator in consultation with the NTP Manager, the Senior NTP/Project Adviser and the SPC TB Adviser. For operational context, it will also identify the areas of the integrated NTP work plan and budget that have been supported.

This report will be provided by SPC to the AusAID Kiribati office, and shared with the MHMS via the NTP.

## 9.3.3 Six-Monthly Risk Monitoring, Management and Reporting

A six-monthly report describing general progress against the 5 higher order objective groupings of the Project, including challenges and risks identified in the Risk Management Matrix (Appendix 3) and actions that needed to be taken to mitigate those risks, will be prepared by the Senior NTP/Project Adviser in consultation with the SPC TB Adviser.

This report will be submitted by SPC to the AusAID Kiribati office, and shared with the MHMS via the NTP. It will also constitute an important source document for the annual TAG or MTR mission.

## 9.4 Project-Specific Performance Framework

A Project-specific performance framework – mostly with appropriate indicators, definitions, baselines and targets – is included in Appendix 2.

The format and indicators are closely aligned with the NTP (in most cases, identical) and is also well harmonised the Global Fund Round 7 TB grant work performance framework, with few modifications. Where applicable, the same NTP indicators as are used in the Global Fund performance framework are also used in the Project performance framework to minimise the reporting burden on the NTP Manager and Coordinator and the Senior Adviser.

However, some Project-specific indicators are included in order to focus on the Mission and key objectives of the Project, particularly case detection and laboratory strengthening. For example, the single Project impact indicator – estimated TB incidence rate – is more indicative of the Mission of the Project than the two impact indicators for the Global Fund project and the NTP – estimated TB prevalence rate (as no prevalence survey will be undertaken by the Project) and estimated TB mortality rate (which is difficult to ascertain with confidence, and would have wide confidence intervals in a small country with just over 100,000 population).

A total of 8 Project-specific performance (output or coverage) indicators are included in the performance framework, where they are shaded in blue to differentiate them from core NTP and Global Fund indicators:

1.5 Number of TB advocacy activities conducted in line with the national TB ACSM strategy over a 12 month period

- 1.6 Number and percentage of new smear positive TB patients cured among the new smear positive TB patients registered during a 12 month period
- 2.2 Number and proportion of sputum smear positive TB patients who are also culture positive
- 3.4 Number of TB patients screened for diabetes mellitus
- 3.5 Number of TB/diabetes patients starting treatment for both TB and diabetes and attending regular clinics (in TB and diabetes clinics)
- 4.2 Number of NTP oversight committee (i.e. expanded HITEC) meetings held with documented minutes and action points
- 4.3 Number of quarters when at least 3 months' supply of all first line TB drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) and alternative first line TB drugs (streptomycin) are in stock in both adult and paediatric formulations at the end of the quarter
- 4.4 Number of annual NTP review meetings with documented outcomes, including annual report

These indicators have been selected to reflect Project-specific performance in areas where the Project is providing a high level of support to the NTP to either establish systems (e.g. annual program review, inter-program links) or maintain them (e.g. ACSM, high cure rates), or relate to Project-specific governance processes in a low capacity environment (e.g. HITEC meetings).

The Project performance framework spans the 5 full years of Project implementation, with clear indicator definitions, baselines and targets for each year of the Project. It will be used to guide Project (as well as NTP) monitoring, and will be presented through SPC to the expanded HITEC on a once-yearly basis to assess Project implementation.

## 9.5 Project-Specific Reviews and Reporting

The *Towards TB Elimination in Kiribati* Project will be formally reviewed twice during its five-year lifetime.

#### 9.5.1 Mid-Term Review

An early MTR will be carried out around mid-2014 to ascertain progress with alignment of Project inputs under the single NTP *Strategic Plan* and preparedness for integration of Project functions and financial management.

External independent consultants with appropriate skills in disease control, health systems and financial management (who may also be members of the proposed Technical Advisory Group; see Section 7.5) will be engaged to undertake the MTR.

Provision is made in the budget for a MTR team leader (who may also be the principal consultant on the TAG, and bring skills in TB control and clinical management) plus one additional team member (who may bring skills, for example, in health policy, systems and financing to review the operating and funding environment for the NTP within the MHMS and in the overall GOK context). The alignment of the MTR mission back-to-back with a visit from IMVS would make this – appropriately – the single most comprehensive external review during the life of the Project.

Like the TAG, the timing of the MTR should allow its findings and recommendations to be presented to the annual NTP review.

TORs for the MTR would be agreed among partners including, as principal donor, AusAID. These would be more expansive, more systems- and finance-focused and more forward-looking than those for the intervening TAG visits. Subject to the assessment of the MTR team, some or all of the latter years of the Project's budget may be absorbed into the NTP.

### 9.5.2 End-of-Project Reviews

Subject to the recommendations of the MTR and the pace of integration of Project functions, an *end-of-Project review* will be carried out in the second half of 2016. The purpose of this review will be to guide the final year of Project support, to provide recommendations on TB control in Kiribati beyond the period of Project support, and to document lessons learned from the integration process. It will be conducted jointly by the NTP, external partners and the lead consultant of the TAG.

In addition to the end-of-Project review, SPC will also prepare an *Activity Completion Report*, which will be completed within three months of the end of the Project. The report will comply with relevant AusAID guidelines, and will: a) confirm that the Project has been implemented as planned (or provide reasons for deviations from the plan); b) examine actual achievements against Project objectives; c) provide a full reconciliation and acquittal of all Project funds according to the approved budget; and d) document lessons learned for SPC and the Australian aid program.

# 10. Risk Management

## 10.1 Purpose

The concept of managing risk is an integral part of the accountability requirements for all donor-funded international development activities. Unmanaged risk can compromise the sustainability of Project inputs, and interfere with the efficiency of integration of Project functions into the NTP and MHMS.

A detailed Risk Analysis and Risk Management Plan are included at Appendix 3.

The purpose of the Plan is to provide an outline of how identifiable risks will be monitored throughout the life of the Project, and to provide guidance for documenting those risks and the actions to take when they arise.

The Plan identifies each risk as being one of four types, and classifies them under appropriate subheadings:

- 1. Risks related to Project Design and MHMS / NTP Policy and Planning
- 2. Financing and Financial Risks
- 3. Risks related to Project Implementation
- 4. External Risks

Most foreseeable risks have be rated as "low" or "medium" in terms of their likelihood of occurring and their impact on the Project and/or NTP, suggesting that the Project is appropriately matched to the relatively low capacity operating environment; a small number of risks that have been classified as "high" also reflect the nature and potential ramifications of that operating environment, and will need particular scrutiny. No foreseeable risks have been rated "very high". <sup>24</sup>

The Risk Analysis and Risk Management Plan is intended to be a "living document": emerging risks not yet identified in the Plan may be added in the course of periodic re-analysis, and strategies developed to manage them.

## 10.2 Risk Management Procedure

### 10.2.1 Risk Monitoring by Senior Adviser and SPC

The Senior NTP/Project Adviser, in close consultation with the NTP Manager and the SPC TB Adviser, will be responsible for day-to-day, week-to-week and month-to-month implementation of the Risk Management Plan; this will be a key aspect of their role.

They will be responsible for risk identification, assessment and management. This will take place through continuous monitoring of Project-supported elements of the integrated NTP work plan and

<sup>&</sup>lt;sup>24</sup> The risk rating system is the same as that used by the Australian Aid Program: AusAID (2006) *Risk Management Guide* (Annex 1 to the AusAID Risk Management Policy)

budget and the Project performance framework. It is also expected that the Senior Adviser's local knowledge of the Project and the NTP and responsibility as an implementer will help to identify emerging risks early.

Risk management will involve the whole Project team (and, in most cases, the expanded NTP team); it will include an evaluation of wider contextual factors in relation to the Project work plan, budget and performance framework, as well as NTP- or Project-specific implementation difficulties. Careful attention will be given to the project deliverables, assumptions, constraints and costs.

Risks rated as having only "negligible" or "minor" consequences for the Project or the NTP can be managed locally, while all risks assessed as likely to have "moderate" or "major" consequences will need to be reported immediately to the Chair of HITEC (Secretary for Health or Director of Public Health) and, through him, to SPC and AusAID.

The principle for addressing emerging risk could be avoidance (if appropriate), mitigation, acceptance or transfer.

#### **10.2.2 Documentation**

The Senior Adviser's will be responsible for documenting a risk management log that will become part of the quarterly progress update reports to HITEC (and therefore also the six-monthly reports to SPC and AusAID; see Section 9.3.3).

Two documents – the integrated work plan and budget and the Project performance framework – will aid assessment of risk during the Project, as will the annual NTP reports arising from the annual program reviews, and the independent reviews (mid- and end-of-term reviews).

## **10.2.3 Oversight by HITEC**

Risk assessment and management will be part of the oversight responsibilities of the expanded HITEC.

At its quarterly meetings, HITEC will review progress with implementation of the integrated work plan and budget and relevant Project progress reports (e.g. risk assessment and management) as standing agenda items, which will be documented in meeting minutes.

If required, HITEC can convene an out-of-session meeting to discuss significant developments or problems and to develop a plan to deal with them (including any budgetary implications.

Appendix 1 - Project Budget (see separate Excel file)

# **Appendix 2 - Performance Framework (see separate Excel file)**

**Note**: Targets for the core NTP indicators have been developed and approved by MHMS.

# Appendix 3 - Risk Analysis and Risk Management Plan

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
1. Risks related to Proje	ect Design and M	HMS / NTP Policy and Planni	ing			
1.1 Delayed endorsement and/or major changes to National Tuberculosis Strategic Plan and/or National Health Strategic Plan	Unlikely	Negligible – NTP Strategic Plan is well aligned with WHO Regional Strategy, and applies evidence based, common sense strategies to continued pressure on the TB epidemic in Kiribati; the Project design is also well aligned with these principles and strategies. Delayed endorsement of the Kiribati health and TB Strategies will not delay release of either MHMS or Project resources.	Low	Continued dialogue between SPC and NTP during 2012 regarding finalisation and endorsement of national TB and health <i>Strategic Plans</i> . Inclusion of NTP on agenda of health sector coordination group will provide opportunity for regular high level dialogue among partners on identified priorities within NHSSP; official endorsement of NTP <i>Strategic Plan</i> , advocacy to other partners, and maintaining dialogue with MHMS on a regular basis	MHMS, SPC (Senior Adviser), with some periodic assistance as necessary from AusAID Tarawa	Continuous (but especially during final months of QTBECP and the 3-month Transition Phase, and during bimonthly health sector coordination meetings). Possibility also to address during annual high level consultations between Government of Australia and GOK)
1.2 Distortionary effect of having additional resources human and performance-based incentives) available for NTP and related care, resulting in underemphasis of PHC within overall health program	Unlikely	Minor impact on the project and the NTP, which are focused on TB control and elimination. Project also seeks to support and strengthen PHC services by integrating NTP activities with broader PHC system, via PHNs. (However, the consequences for balance in overall health sector may be	Low	The program will use its NTP-linked governance processes to monitor any possible detrimental effect of its more specialised services support relative to overall PHC, including through regular NTP coordination meetings, HITEC and, at the higher analytic level, the annual program review. Operational research on active case finding network may also be able to examine impact on community	NTP, MHMS, SPC (Program Coordinator), Senior Adviser)	Continuous (but especially during HITEC and program review meetings); to be analysed and documented by Senior Program Adviser in periodic risk management

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
		more significant).		workers' time and activities.		reports

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
1.3 Failure of procurement and supply management of first line TB drugs, resulting in actual or imminent stock-outs	Possible	Major – Would force NTP and possibly its partners to divert MHMS, Project and other resources to expensive, costinefficient, emergency procurement	High	Continuous engagement of Pharmacy with NTP via fortnightly coordination meetings, and continuous monitoring of adequacy of first line drug supply and availability	MHMS (Pharmacist, HITEC), NTP (Manager), SPC (Senior Adviser)	Continuous, and especially after orders have been placed
1.4 Adverse findings of future AusAID fiduciary risk assessment of GOK systems, most likely precluding the placement of Australian Government funds for core budget support	Possible	Moderate – While this would not necessarily impact on the quality of TB control in Kiribati, it would significantly threaten one of the aims of Phase 2 of the Project, i.e. the transfer and integration of some Project management and financial management functions into MHMS.	High	Through the Project Accountant and the Noumea-based Project Coordinator, SPC will continue to work with MHMS (and, in particular, the Project Management Unit Accountant) to ensure strict adherence to established standards of financial management. Annual audits will be conducted of the Project budget and acquittals of expenditure and the MTR will examine progress in relation to financial management and possible fiduciary risks associated with Phase 2.	SPC (Project Accountant and Noumea-based support), MHMS (Project Management Unit), independent auditors; the MTR team will also review preparedness for Phase 2	Continuous, but especially during Years 2 and 3 of the Project, when the performance of Project and financial management systems is becoming clearer; at the of any future AusAID assessment of GOK systems.
1.5 Inability or lack of willingness of MHMS to absorb responsibility for Project-funded positions, infrastructure and maintenance during Integration Phase	Possible	Moderate – Should MHMS not be in a position to assume management and responsibility of Project- funded resources, this will remove an important element of Project sustainability.	High	The design includes the preparation of a medium-to-longer term NTP human resources plan during the final year of the Alignment and Support Phase, as well as transition plans for absorption of infrastructure and development of maintenance and depreciation schedules. This will clearly map out processes for absorption of Project resources, in very close consultation with MHMS.	SPC (Senior Adviser, Program Coordinator) and MHMS; the MTR team will also be tasked with reviewing progress with absorption plans	During Years 2 and 3 of the Project, when work force projections for the longer term are becoming clearer.
1.6 LGUs unable or unwilling to fund allowances for additional community based staff (e.g. CDWs on South Tarawa, or Nurse Aides on	Possible	Minor – Communities with significant residual transmission may be left with inadequate staff to meet DOTS and active case finding needs	Medium	Careful dialogue with LGUs during expansion process into communities, so that they understand that the priority of the Project is to help integrate community level NTP functions into local structures; exploration of possible NGO	NTP, SPC (Program Coordinator)-	During Year 3 of the Project, when integration plans start to be discussed and drafted.

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing			
outer islands) as part of the Integration Phase				links to support ongoing community level management					
2. Financing and Financ	. Financing and Financial Risks								
2.1 Program budget diverted from agreed NTP Strategic Plan priorities, or used to substitute for MHMS investment in TB control	Unlikely, as the annual planning process will maintain oversight of these risks	Moderate – The Project is designed to gradually shift from implementation towards support and facilitation. Use of funds for core MHMS functions (e.g. procurement of first line TB drugs) would significantly compromise progress towards NTP and Project objectives	Medium	The development and careful monitoring of an integrated work plan and budget that captures all inputs and activities under the NTP is designed – in part – to mitigate against this risk. Policy dialogue with MHMS and other partners as necessary at annual program review; and in high level consultations between principal partners (SPC, AusAID) and GOK.	NTP, SPC (Senior Adviser) and MHMS; the MTR team will also be tasked with reviewing risks related to budget fungibility	Ongoing, but especially during annual program review and development of integrated annual work plan and overall (all-sources) NTP budget			
2.2 Failure of Global Fund application for Transitional Funding Mechanism	Unlikely	Moderate – Alternative sources would need to be found for regional salaries (SPC, WHO), supervision and some consumables	Medium	Contingency plan included in Project budget to cover the cost of some supervisory visits. SPC and WHO would need to engage with alternative donors for support for regional positions	SPC (Noumea), WHO (Suva and Manila	Early (during 2012, as results of TFM application should be known soon			
2.3 Negative impact of exchange rate fluctuations on Project budget	Unlikely, as AUD / USD exchange rate likely to remain high during period of Project	Minor – Cost base of incountry expenditure and Program resources sourced from Australia (e.g. consultants, equipment) will remain relatively stable as costed in AUD. Cost of study tours and placements at international destinations, air transport costs (fares, shipping) and cost of some consumable may be adversely affected by changes in exchange rate.	Medium	NTP and SPC will use their own network for sourcing most cost-effective consumables and necessary items of equipment. The Project budget has a 5% contingency sum to cover exchange rate fluctuations and cost variations for the procurement of goods (e.g. equipment, consumables) and international services (consultancies, air fares); any unused windfall savings or contingency funds can be directed back into the program budget and be available for use during later years of the Project. In addition, SPC is exploring the option of using an AUD-denominated bank account so that exchange rate losses are not incurred between AusAID and SPC.	SPC as fund manager, in collaboration with MHMS Project Management Unit	Continuous			

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
2.4 Health budget inadequate to fund all MHMS counterpart contributions	Possible	Minor – Counterpart contributions mainly in the form of personnel (e.g. availability of nursing staff) and in-kind support (e.g. procurement of first line TB drugs and laboratory consumables)	Medium	The Project will minimise recurrent cost burden on the MHMS and NTP by having its own budget for laboratory consumables and accessing second line drugs for any case of MDR-TB. Annual work planning and budgeting process should identify any recurrent cost implications for MHMS.	SPC (Senior Adviser, Noumea- based TB Adviser, IMVS consultants), MHMS (Director of Public Health), NTP	Continuous, but especially during annual program review and development of integrated annual NTP work plan and budget
3. Risks related to Prog	ram Implementa	tion				
3.1 Program unable to identify appropriately qualified and experienced staff to fill Project-funded positions or consultants to undertake Project-funded capacity development tasks	Rare	Major – Potential disruption of capacity development and supervision relationships, and in smooth functioning of relationship with MHMS.	Medium	NTP and SPC already have a stable work force and consultant network who are supportive of the Kiribati NTP. The only new position for the new Project is the Accountant, but this could be filled with a less qualified individual (e.g. a bookkeeper), working under the supervision of the Noumea-based Project Administrator and the Accountant managing the MHMS Projects Management Unit.	SPC (Senior Adviser, Noumea- based staff)	Continuous (but especially during Transition Phase and Year 1)
3.2 Emergence of MDR-TB	Possible	Minor – May cause NTP expansion plans to fall behind schedule as resources are diverted to affected community	Medium	The Project and the NTP Strategic Plan already prioritise management of and response to MDR-TB, including through a Project-funded mechanism to access second line TB drugs. Technical assistance is available via SPC and WHO to help address any cluster or wider transmission of MDR-TB beyond an index case	NTP, SPC, WHO	Continuous
3.3 Failure to negotiate access to molecular diagnosis in Fiji for suspected MDR-TB or persistent sputum-negative cases	Unlikely	Minor– would introduce delays as NTP becomes reliant on alternative diagnostic pathway (e.g. shipping culture specimens to IMVS for DST)	Low	SPC's Laboratory Adviser is based at the Suva campus and has ready access to FIJI MOH and the Daulago Laboratory at Tamavua (where <i>GeneXpert</i> technology will be located). Operational research component will examine feasibility of locating molecular diagnosis capability in Kiribati (at the national TB Laboratory)	SPC (Noumea and Suva), in consultation with NTP and in- country team (Senior Adviser, TB Laboratory Supervisor)	During Year 1 of the Project, then continuous

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
3.4 Reluctance of clinical staff to adopt revised and updated management guidelines, especially for paediatric TB	Possible	Minor impact on Project itself, but some potential impact on NTP outcomes and indicators (which also reflect Project performance) – may be some delay in achieving cure or othr clinical outcomes	Medium	Continued prioritisation of and support for medical staff, including training and orientation on TB management and through clinical case review panel	NTP, with support of Senior Adviser	Continuous (but especially on return of candidates from any regional training for clinicians)
3.5 Large cohort of medical graduates from Cuban system (either returning from overseas or graduating locally) overwhelms NTP with nonstandard approaches to TB diagnosis and treatment	Unlikely	Minor – Health sector and NTP should have enough senior, experienced clinicians to provide mentoring, supervision and case management advice during internship for Cuban graduates (who should also be encouraged to participate in any in-service training through the Project).	Low	Careful dialogue and close collaboration with Cuban Medical Brigade during first program year; to ensure appropriate "reentry" orientation and training in TB as an important local cause of morbidity. Continued engagement with new graduates to develop skills in diagnosis and case management and monitoring, and especially prior to placement in hospitals outside Tarawa	MHMS, NTP	Continuous (but especially during Project Years 2 and 3 when the largest numbers of medical students are expected to graduate)
3.6 Lack (or delay) of biomedical engineering and maintenance services for laboratory equipment	Possible	Moderate – would force NTP to rely on sputum microscopy for diagnosis, with delays in confirmation due to need to ship specimens to Suva or Adelaide	High	Through SPC and regional TB and laboratory networks, Project can exert some pressure for biomedical technical support; careful and thoughtful planning of maintenance schedule through national Laboratory Service. SPC is currently exploring options for technical support for ongoing maintenance of TB laboratory equipment.	SPC, IMVS, national Laboratory Manager and TB Laboratory Supervisor	Continuous (but especially as maintenance milestones for laboratory equipment approach)
3.7 Stock-outs of TB drugs and/or laboratory consumables	Possible	Moderate – potential interruption of diagnosis or treatment pending emergency procurement (at higher cost). If stock-outs prolonged, carries risk of emergence of drug resistance (although this is unlikely).	High	Participation of laboratory and pharmacy representatives in fortnightly NTP coordination meetings, and careful monitoring of stock levels (TB drug stock monitoring is a performance indicator for the Project). WHO to assist with access to reliable supplies of TB drugs, and IMVS to provide training on lab stock control and reliable, cost-effective suppliers	WHO, IMVS, national Pharmacy, national Laboratory Manager and TB Laboratory Supervisor	Continuous via fortnightly NTP meetings (and especially as quarterly milestones for drug supply approach)

Source of Risk	Likelihood	Consequences (Impact on Project)	Risk Assessment	Risk Mitigation Strategy	Responsibility	Timing
4. External Risks						
4.1 Emergence or re- emergence of large scale non-TB outbreak, epidemic or pandemic threat	Possible – outbreaks of dengue and water-borne enteric infections already recorded in Kiribati, and direct links (via shipping and mobile work force) to Asian centres at higher risk of avian influenza	Moderate – Could overwhelm health services, result in social and civil disorder, cause clinical deterioration in TB patients with already compromised lung function, and potentially result in diversion of NTP or Project resources	High	National and regional pandemic and emerging infectious diseases preparedness plans in place, and updated in response to 2009 H1N1 influenza pandemic. NTP, Project and MHMS to work pro-actively with WHO to maintain service provision as much as possible while addressing direct consequences of outbreak or pandemic.	SPC, in close collaboration with MHMS (Director of Public Health) and WHO; and development partners (via sector coordination group)	Continuous
4.2 Global recession or financial crisis	Possible-to-Likely	Moderate – Could result in reduction in purchasing power of AUD-denominated program budget; collapse of GOK and MHMS budgets also possible, with rapid increase in dependence on donor funding – this would compromise the aims of Phase 2 of the Project.	High	Pro-active monitoring of budget position and vulnerability to external shocks during health sector coordination meetings; high level consultations between GOK and AusAID. Stabilisation of Project funds within AUD-denominated bank accounts, which is likely to be more resilient than other currencies.	GOK (through MHMS), SPC, Government of Australia (though AusAID), UNDP and other development partners	Continuous, but with additional emphasis during periods of global financial instability and annual high level consultations
4.3 National fuel (gas) stock-outs	Rare	Minor – Would result in temporary cessation of laboratory activity, requiring deferral of specimen processing or referral offshore; however, overall and longer term impact on the Project and the NTP would be minor	Low	Pro-active monitoring of national fuel stock position via MHMS, who will advocate to Finance and MPWU the importance of maintaining power and fuel supply because of its impact on the health system. IMVS adviser to recommend alternative fuel sources for fixing slides and light sources (e.g. solar or battery powered) for microscopy.	National Laboratory Manager, IMVS and TB Laboratory Supervisor; GOK (through MHMS)	Continuous