BE HE@LTHY BE MOBILE

A handbook on how to implement mTB-Tobacco

World Health Organization

ITU

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Contents

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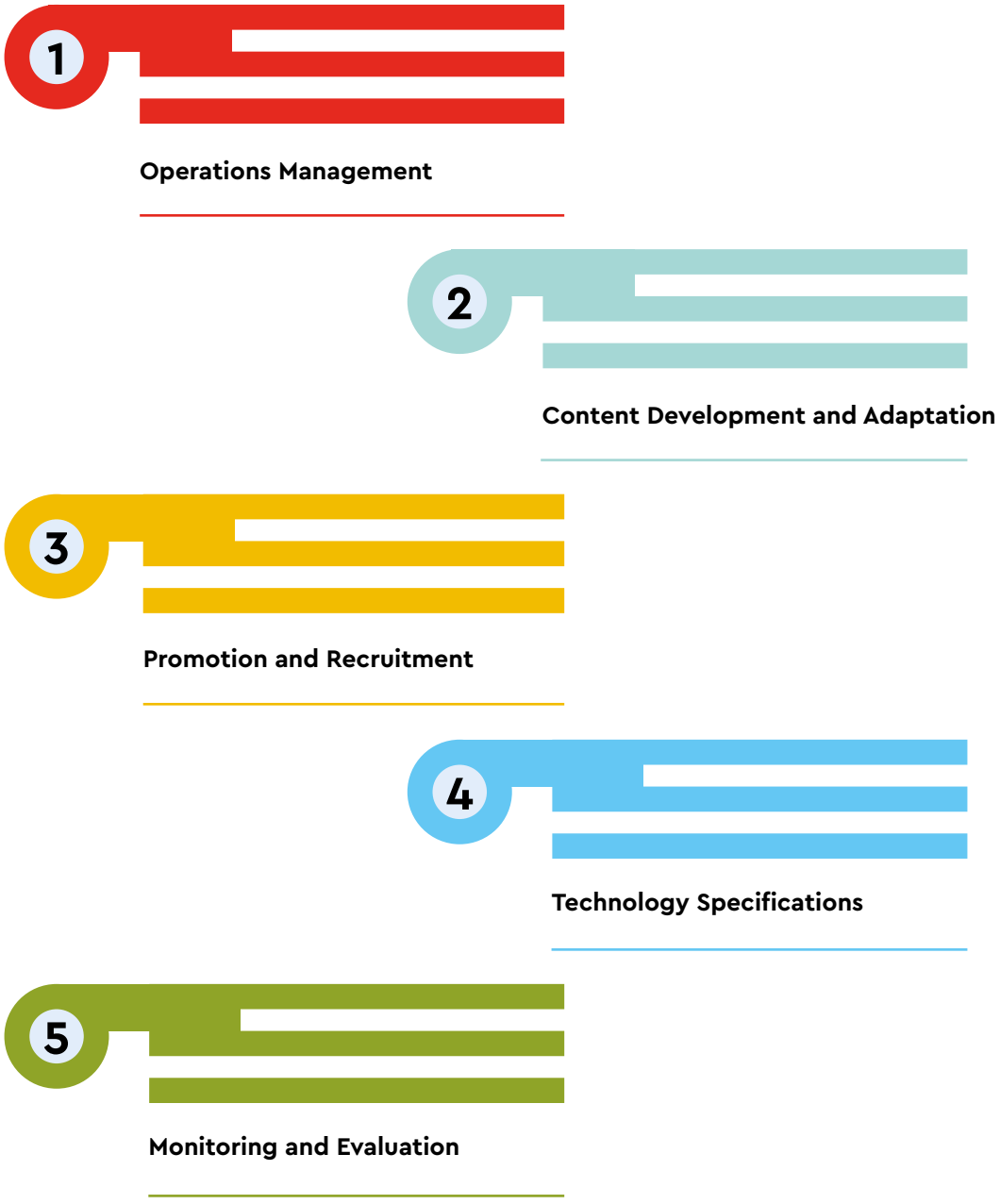
Executive Summary

The Be He@lthy, Be Mobile initiative is a global partnership led by the World Health Organization (WHO) and the International Telecommunication Union (ITU), representing the United Nations agencies for health and information agencies for health and information and communications technologies (ICTs). The initiative was established in direct response to the United Nations General Assembly's call for concerted action towards noncommunicable diseases (NCDs) in 2011. The initiative supports the scale up of mobile health (mHealth) technology within national health systems to help combat NCDs. These include diabetes, cancer, cardiovascular diseases and chronic respiratory diseases. As part of the Be He@lthy, Be Mobile initiative, the mHealth handbooks provide evidence-based and operational guidance to assist countries and governments to implement population-scale mHealth programmes for NCDs.

The central objective of the mHealth for tuberculosis (TB) and tobacco programme, or mTB-Tobacco, is to support TB patients who consume tobacco in quitting tobacco use and guiding them through the journey of recovering from TB. The mTB-Tobacco programme has two distinct areas of intervention. The first tries to instil behaviour change in the patient to quit the habit of tobacco use and the second includes a combination of supportive motivational and informative messages through the period of TB treatment. The overall outcome being that a person is able to both successfully quit tobacco consumption and complete TB treatment.

This document, which is intended for national TB control programmes and organizations responsible for delivering TB control, provides guidance on developing and implementing an mTB-Tobacco programme. The primary focus of the short message service (SMS) content provided here is to inform TB patients who are tobacco users about the hazards of tobacco use and encourage them to quit through text messages for behaviour change. However, the scope of the programme can be expanded to include messages to patients with presumptive TB, TB health-care providers, as well as to deliver content on prevention and compliance to TB patients who do not smoke. These messages are designed to enhance treatment adherence, increase healthy behaviours and reduce potentially harmful behaviours in TB patients in order to improve their health outcomes. The mTB-Tobacco programme will complement routine TB care offered by TB health-care providers, as outlined by the WHO End TB Strategy (1).

THIS HANDBOOK COVERS THE FOLLOWING TOPICS:



This handbook also contains annexes that include considerations for project management and a set of SMS messages to be adapted and used for mTB-Tobacco.

Background

TB and tobacco use are leading global health challenges (2). While global efforts have reduced the TB epidemic in most parts of the world and the prevalence of tobacco use has decreased in many countries, an enormous burden on health remains. In 2017, 1.6 million people died as a result of TB (3). Similarly, from the estimated 1.1 billion smokers in the world (4) around 7 million people died from smoking in 2017 (5). A disproportionate share of the global tobacco burden falls on low- and middle-income countries (LMICs), where the number of smokers is still increasing (4) and where the burden of TB is also concentrated (3).

Moreover, these two epidemics do not operate independently. Tobacco smoking is an established risk factor for being infected with TB, for developing TB and for dying from it (6-8). Compared to those who have never smoked, it is estimated that people who smoke have approximately twice the risk of both TB infection and active disease (9). Smoking is associated with poor TB treatment outcomes, including delayed sputum conversion (10), and greater risk of relapse after initial TB treatment (11,12). Smoking also enhances the risk of TB transmission to others, as TB patients who smoke have a longer period of infectivity and a higher treatment default rate than non-smokers. Studies have consistently found higher prevalence of latent TB infection among smokers compared with non-smokers (13, 14). Additionally, children exposed to environmental tobacco smoke are more likely to acquire TB than those not exposed (15). It is estimated that smoking could cause 40 million excess deaths from TB from 2010-2050 (16, 17).

ADDRESSING THE TB-TOBACCO CO-EPIDEMIC

Adopted by the World Health Assembly in May 2014, the End TB Strategy aims to reduce the number of TB deaths by 90% by 2030 (3). Tobacco use is one of the key barriers to achieving this goal. There are many opportunities to offer cessation support to TB patients through their close and frequent interactions with health-care providers. Furthermore, most TB patients who smoke are highly motivated to stop and can achieve a higher success rate in quitting than other smokers (4). Studies have shown that success rates are higher when health professionals who provide routine TB care offer cessation as part of patients' TB treatment (6). Following cessation, the adverse health effects of smoking in TB patients (e.g. the immunological impairment) start to reverse within six weeks of stopping (7). There is adequate evidence that an integrated approach to TB-tobacco prevention and treatment can be beneficial for preventing both the diseases and confers benefits on the lung health of TB patients who quit smoking (18).

Due to an extraordinary number of TB-infected smokers and their significantly compromised outcomes, tobacco cessation should be considered an integral part of TB treatment plans. However, many TB health-care providers, despite realizing its importance, remain reluctant to offer cessation support to their patients. Barriers to this treatment include doubts about the effectiveness and relevance of cessation interventions, political inertia and social norms (i.e. smoking) within health systems, service providers' workload and their lack of motivation, confidence and capacity to deliver tobacco cessation. Hence,

the movement to integrate tobacco cessation within TB programmes is progressing slowly.

Recognizing the relevance of joint efforts to control the two global epidemics, WHO and the International Union against Tuberculosis and Lung Disease (The Union) published a monograph on TB and tobacco control (19) emphasizing the implementation of tobacco control activities as an integral part of TB case management at primary health-care facilities. One of the key approaches developed as a result of this work was the integration of brief tobacco interventions into the existing Practical Approach to Lung Health (PAL) strategy. The PAL strategy was a key part of the Stop TB strategy that aims to reduce the global burden of TB. It intends to 1) improve the quality of care in patients who seek assistance for respiratory symptoms in primary care settings and 2) improve the efficiency of respiratory service delivery within health systems (20).

In 2014, the WHO Global TB programme, the WHO Department for the Prevention of Noncommunicable Diseases and the European Respiratory Society (ERS) came together to work on digital health (e/mHealth) for TB and tobacco control. The aim of this partnership was to advance global utilization of information and communication technology (ICT) for lung health. In a high-level consultation in 2015, experts in TB -Tobacco control and digital health gathered to discuss the effectiveness of targeted approaches of ICT such as mobile text messaging, among other digital health initiatives (21). The meeting concluded with establishment of a Global Task Force on digital health and TB. The goal of this task force is to advise the Global TB programme of WHO on the promotion of ICT for TB prevention, care and control (22).

THE CASE FOR AN mHEALTH INTERVENTION

Recent advances in mobile telephone technology and its wide accessibility across the globe have created new opportunities to use mobile telephones to create a large public health impact. Worldwide mobile phone use increased dramatically from 1 billion subscriptions in 2002 to over 7 billion in 2015 (23). One-way push mobile text messaging is the simplest technology and the most widely used tool for mHealth. There is now a substantial and growing body of evidence on the use of text messaging in disease management and disease prevention. Reviews of these studies indicate that text messaging can be effective and shows promise for many aspects of health behaviour change and disease management (24-26).

The use of text messaging to support smoking cessation is one application that now has substantial support for its effectiveness. A recent Cochrane systematic review included 12 high-quality randomized controlled trials with six-month cessation measures and concluded that the intervention increased quit rates by 67% (RR of 1.67, 95% CI 1.46 to 1.90; I2 = 59%) (27). Six studies verified quitting biochemically at 6 months and showed an even stronger effect (RR 1.83; 95% CI 1.54 to 2.19). The authors noted that the evidence supports a beneficial impact of mobile phone-based smoking cessation interventions on 6-month cessation outcomes. Some of the studies included purely text messaging interventions from different countries: STOp smoking by Mobile Phone (STOMP) was developed by the University of Auckland and evaluated across New Zealand (28); txt2stop was further developed from STOMP for a United Kingdom population and tested in the largest and highest-quality trial to date (29); and researchers in Australia added text messages as an option to their online quitting coach and as a separate intervention (30). However, one of the major limitations to the evidence to date is that studies have been limited primarily to high-income countries with strong tobacco control policies.

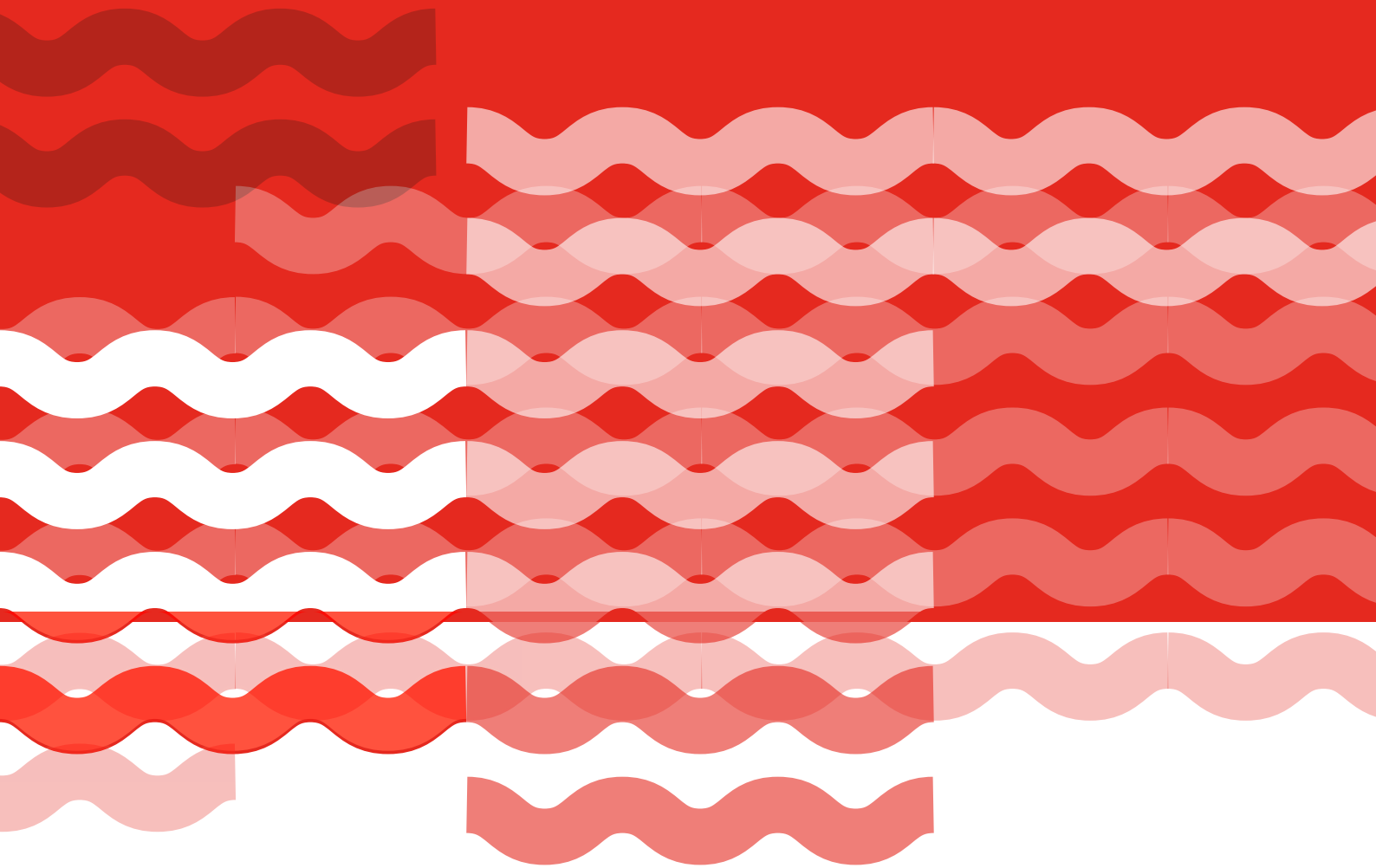
Evidence for use of text messaging in the TB context is more limited, but evidence from randomized controlled trials on mHealth interventions for TB drug adherence indicates that mobile telephones can strengthen compliance with treatment. Supported

by recent study findings, in 2017 WHO recommended SMS among other digital approaches to support TB medication adherence (31,32,33).

In contrast with general smokers, SMS-based cessation messages for TB patients need to be embedded within the wider education and health promotion messages for TB patients. Furthermore, implementation of the messages should be within, and with a good understanding of, routine TB health-care provision. This guidance on mTB-Tobacco therefore takes an inclusive approach to address a range of behaviours and lifestyle factors that determine the success of TB treatment. This approach offers a more holistic and patient-centred approach than one focused on tobacco cessation only.

SECTION 1

OPERATIONS MANAGEMENT



1.1. NEEDS ASSESSMENT

A thorough needs assessment is a crucial step in developing an mTB-Tobacco programme. As with any large-scale intervention, it is essential to understand the context in which the intervention will be delivered. In order for the mTB-Tobacco programme to be effective, SMS messages should match TB patients' motivations and capabilities, address key barriers and be timed to coincide with opportunities to change behaviour. A needs assessment provides a vehicle for consolidating information for planning, identifying gaps in knowledge and helping with decision-making. The needs assessment will provide an understanding of the setting for the operations management teams. Additionally, the assessment will involve visiting, observing and interviewing key informants and stakeholders and documenting existing resources. The data will inform the development and implementation of a national mTB-Tobacco programme and will act as a baseline measure from which the programme can be monitored and evaluated.

A number of questions related to the goals and content of an mTB-Tobacco intervention should be considered as part of a needs assessment:

WHICH BEHAVIOURS ARE THE MAJOR BARRIERS TO IMPROVING PATIENTS' OUTCOMES?

A successful outcome of TB treatment depends on patient-related behaviours such as seeking care, adherence to TB medication, and lifestyle factors such as smoking, diet and alcohol use. TB health-care workers are expected to offer sputum smear examinations and provide results in a timely manner, apply diagnostics adequately, ensure that medicines will be taken, manage drug side-effects and advise on healthy behaviours. If modified, patient-related behaviours can lead to improvements in TB outcomes in the short and medium term and may prevent noncommunicable diseases in the long term. However, the prevalence of these behaviours and lifestyle factors may vary in any given TB population and its different segments.

A good understanding of the most prevalent behaviours would help decisions on the emphasis and frequency of the SMS messages in the mTB-Tobacco programme. Apart from information on adherence to TB treatment and follow-up visits, TB control programmes do not collect behaviour-related data routinely. There may be other ways to access relevant data. Some health services collect socioeconomic and other data in order to provide social support to the most vulnerable patients.

A quick secondary analysis of TB prevalence surveys will provide prevalence of lifestyle factors such as tobacco and alcohol use among TB patients. A literature review may find qualitative research on TB and the use of tobacco and alcohol. A brief TB patient survey can also be conducted in a representative sample of TB facilities to gather such information.

WHICH FACTORS WILL HELP OR HINDER BEHAVIOUR CHANGE?

Once the most prevalent and influential behaviours have been identified among the TB patient population, it will be important to understand the key barriers to, and facilitators of, change in these behaviours. This needs to be explored primarily from the TB patients' perspective using a patient-centered approach. Barriers and facilitators are likely to include:

INTERNAL FACTORS

- poor knowledge
- low risk perception
- myths and misconceptions
- traditional care-seeking practices
- felt stigma
- physical and psychological addiction
- low self-efficacy

EXTERNAL INFLUENCES

- poor economic conditions
- sociocultural norms
- social stigma
- access to good quality health services

A needs assessment will be able to identify the extent to which, and the intensity with which, these barriers and facilitators influence behaviour change in a given context. A quick literature search will identify existing local studies, and an exploratory qualitative study can identify such barriers and facilitators. Such a study would include conducting a set of interviews with TB patients and possibly focus group discussions. The sampling strategy for such a study would need to take account of gender and social groupings within TB populations.

WHICH EVIDENCE-BASED TECHNIQUES CAN CHANGE THESE BEHAVIOURS?

After identifying key behaviours and the most important factors that push these behaviours to change, the next step will be to match these factors with behaviour change techniques that can influence the behaviours.

A taxonomy of behaviour change techniques that are likely to influence target behaviours and their determinants has emerged recently in the literature (34). The idea is to use this taxonomy to identify techniques that are specific to certain behavioural determinants. This desk-based exercise is often facilitated by a health psychologist in a workshop setting with an expert panel. Once a shortlist of techniques is agreed upon, Annex 2 can be used to select SMS messages for cultural and linguistic adaptation.

WHAT ARE TB PATIENTS' DIGITAL MEDIA LITERACY AND HABITS?

As the "digital divide" has declined between different social groupings across the world, there may still be a considerable digital-use divide, reflecting a gap in digital media literacy and digital engagement.

Planning considerations on the technological aspects of mHealth and their population use have already been covered in previous guidance (35). However, given that TB patients often represent the most impoverished sections of the society, due consideration should be given to their digital media literacy and practices. Several tools are now available that can be used on a representative sample to appraise digital media literacy and practices across a range of domains, including operation, navigation, social, creative and mobility. Table 1 lists additional considerations related to the operation and implementation of an mTB-Tobacco programme, which should be included in the needs assessment.

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TABLE 1. THEMES AND CONSIDERATIONS FOR AN mTB-TOBACCO NEEDS ASSESSMENT

THEME	CONSIDERATIONS
TB burden and prevalence of tobacco use	▌Statistics on TB incidence in rural and urban populations by age, gender, income. ▌Statistics on tobacco use by age, gender, type of tobacco, proportion of tobacco users who want to quit or who try to quit annually. ▌High-risk and priority populations, and population segments (Figure 1). ▌Knowledge levels, cultural attitudes, perception of risk, current behaviour and behavioural trends relating to TB and tobacco use in general and affected populations.
State of TB prevention and control programmes	▌Programme objectives, constraints, institutional and human resources, funding. ▌Approaches and algorithms for case-finding, diagnosis, treatment, enhancing adherence and reducing loss to follow-up. ▌Existing or planned synergies with other programmes (e.g. HIV, diabetes). ▌Mass media campaigns and health promotion strategies for TB. ▌Composition of the formal and informal health-care provider network and current priority given to TB. ▌Involvement of nongovernmental, community and patient organizations. ▌Relevant priorities of the government and the health system. ▌Progress towards 100% tobacco-free TB services countrywide. ▌Collection of data on tobacco use; asking about tobacco use; brief advice; cessation support or referral. ▌Rates of tobacco use within national tuberculosis programmes (NTPs) and other providers (e.g. physicians, nurses). ▌Knowledge Attitudes and Practices (KAP) survey or similar about tobacco use and cessation among NTP workers.
State of tobacco cessation services	▌Mapping of services, objectives, constraints, institutional and human resources, funding, political commitment, social acceptance. ▌Approaches and algorithms for advertising/recruitment, interventions, treatment. ▌Existing synergies with other programmes (e.g. TB, NCDs). ▌Existing or planned mTobaccoCessation programme. ▌Mass media campaigns for tobacco control, quitting tobacco use. ▌Current priority given to tobacco control (e.g. MPOWER) (36), especially cessation. ▌Involvement of nongovernmental, community and patient organizations. ▌Relevant priorities of the government and the health system.
State of mobile communications	▌Statistics of use of mobile phones and text messaging; costs to consumers of text messaging, data and calling. ▌Cultural issues relating to the use of mobile phones. ▌Penetration and use of smartphones and mobile Internet access.

	▌Description of the mobile network environment (e.g. the number of network providers, whether they provide "value-added services", including any related to health). ▌Whether unsolicited text messaging (spam) by companies is allowed or occurs. ▌Whether health services use text messaging or smartphone applications. ▌The projected evolution of the mobile telephone market in the near future, particularly with respect to increased penetration of smartphones or semi-smartphones. ▌Regulatory issues such as spam, consent to receive programmes, cost of message transmission, restrictions on the number of messages that can be sent each day. ▌Existing mHealth programmes that could incorporate TB and tobacco messages.
Target group	▌Target populations. ▌Challenges and opportunities within the population. ▌Literacy and language considerations.
Contextual, geographical, cultural and behavioural influences	▌Individual and cultural attitudes to health care and self-management. ▌Determinants and risk factors that influence the incidence of TB. ▌Cultural and social factors that may stop individuals from adopting a healthier lifestyle. ▌Community dynamics and actors that would support successful TB and cessation outcomes. ▌Motivation and incentives for individuals to complete TB treatment, stop tobacco use and alcohol misuse, make homes smokefree, support family and contacts. ▌People who can be considered champions or "trusted advisors", and how to leverage them. ▌Expected interactions of target populations with potential channels in health interventions: SMS, web, app, telephone call, interactive voice response, brochure, face-to-face coaching or consultation. ▌Convenience for the population. ▌Cost (who will pay: the population or the government?)
Stakeholders	▌Relevant agencies, organizations, donors, companies, experts and their potential interest in supporting an mTB-Tobacco programme, including: • National and subnational/regional levels of the NTP, TB experts; • National and subnational/regional levels of tobacco control programme and cessation services, tobacco control experts; • Funders of public health services, of NTP, of cessation services; • Ministry of Health and other relevant government agencies; • Private and other health-care providers working in TB and cessation; • Government agencies responsible for telecommunications and data protection; • Telecommunication companies, mobile network providers and industry bodies or associations; • Any local mobile telephone service providers or companies that provide mHealth services; • Patient associations, community advisory groups, civil society; • Health insurance companies, other private-sector supporters; • Local academic researchers (in public health, TB, tobacco cessation, mHealth).

Promotion	▌Channels through which mTB-Tobacco will be promoted. ▌Promotion and recruitment strategies and approaches. ▌Best communication strategies (text, voice message, or apps). ▌Time frames. ▌Incentives for participation. ▌Access to and availability of health-care services and resources. ▌Access to and availability of mobile technology and services.
Further research	▌Other areas in which further research is required to facilitate a successful pilot or "soft" launch and implementation; operational research.

FIGURE 1. OPTIONS FOR SEGMENTING THE POPULATION WITH TB AND THEIR SUPPORT PERSONS.

PATIENTS WITH PRESUMPTIVE TB	
Smoker/tobacco user	*I'm feeling ill and hear that I might have TB. I've been advised to quit smoking and make my home smokefree.*
Nonsmoker/tobacco user	*I'm feeling ill and hear that I might have TB. I've been advised to make my home smokefree.*
PATIENTS REGISTERED AND ON TREATMENT FOR TB	
Smoker/tobacco user **CORE SEGMENT**	*I want to get cured of TB. I've been advised to quit smoking and make my home smokefree.*
Nonsmoker/tobacco user	*I want to get cured of TB. I've been advised to make my home smokefree.*
FAMILY/FRIENDS OF PATIENTS WITH TB	
Smoker/tobacco user	*My relative/friend has TB. I want to help him/her get cured of TB. I've been advised to quit smoking and make our home/ workplace smokefree.*
Nonsmoker/tobacco user	*My relative/friend has TB. I want to help him/her get cured of TB and quit smoking/tobacco use. I've been advised to make our home/workplace smokefree.*
HEALTH WORKERS CARING FOR PATIENTS WITH TB	
Smoker/tobacco user	*I support patients to get cured of TB. I need to help them quit smoking/tobacco use and I have been advised to quit.*
Nonsmoker/tobacco user	*I support patients to get cured of TB. I need to help them quit smoking/tobacco use.*
COMMUNITY TREATMENT SUPPORTERS OF PATIENTS WITH TB	
Smoker/tobacco user	*I support patients to get cured of TB. I need to help them quit smoking/tobacco use and I have been advised to quit.*
Nonsmoker/tobacco user	*I support patients to get cured of TB. I need to help them quit smoking/tobacco use.*

PLANNING FOR INTEGRATION OF mTB-TOBACCO WITHIN THE NATIONAL TUBERCULOSIS PROGRAMME (NTP)

mTB-Tobacco offers a technological innovation to national tuberculosis programmes (NTPs). It will imply changes, especially for NTPs that have been using the same means to record and communicate information for many years. Some NTPs may need to integrate mTB-Tobacco into systems that rely mainly on paper and face-to-face communication; others may use a mix of paper and electronic formats; some may already be using some digital technology.

For an innovation to be adopted and diffused, the early users need to decide that it improves how things work for them. It will be important to determine how mTB-Tobacco can best be integrated into the existing operations of the NTP and how it could improve outcomes for all involved. To facilitate uptake, it may be useful to consider five characteristics that have been shown to influence the likelihood of adoption of a technological innovation (37). They are: compatibility, relative advantage, level of complexity, triability and observability of results (Table 2).

TABLE 2. FACILITATING IMPLEMENTATION AND UPTAKE OF THE mTB-TOBACCO PROGRAMME WITHIN NATIONAL TUBERCULOSIS PROGRAMMES

Compatibility	Have we adapted mTB-Tobacco to fit well with our NTP goals, objectives, operations and approaches? And those of our communities?
Relative advantage	Will mTB-Tobacco help us to do things better? For instance, will it make it easier to contact patients with results, support, reminders etc? Will it help us make faster progress towards our Stop TB targets (e.g. increase case-finding; minimize concomitant risks and co-morbidities; increase patient adherence to treatment; identify lost-to-follow-up cases)?
Level of complexity	Have we made mTB-Tobacco easy to understand and use? Are there good arrangements for training, support, troubleshooting early on, project management and oversight?
Triability	Can everyone comfortably test out mTB-Tobacco before having to decide whether to adopt it? Is enough time and consultation among all stakeholders planned for the pilots?
Observability of results	How easily and quickly will mTB-Tobacco produce results that people can judge? Have you arranged to present the results in a format that different groups will understand and relate to?

When planning how to integrate the mTB-Tobacco programme into the NTP, it may be useful to review the key elements of an NTP. mTB-Tobacco will need to work within existing strategies, procedures, human resources and activities. For instance, text messages for patients must refer to correct information about where to go, what to do and who to speak to. Messages for health workers must refer to the correct procedures and algorithms. All those involved in the patient pathway should be trained and/or briefed prior to launch of the pilot. mTB-Tobacco must also be incorporated into training and supervision. Additionally, thought should be given to how mTB-Tobacco can enhance existing NTP activities and, conversely, how each activity can promote mTB-Tobacco and make it more effective (Table 3).

TABLE 3. ELEMENTS OF THE NTP FOR CONSIDERATION WHEN PLANNING TO INTEGRATE mTB-TOBACCO

- Overall NTP strategy, objectives
- Strategies such as: community participation, reaching high-risk populations, reaching poor and vulnerable populations, reducing stigma
- Wider network of health-care workers, including laboratory staff, pharmacists, community support workers, private sector, informal providers
- Diagnostic and patient management algorithms
- Medicine prescription and dispensing procedures
- Recording and reporting forms and procedures
- Monitoring and evaluation
- Training
- TB programme supervision
- Operational research
- Health promotion
- Advocacy and social mobilization
- Community involvement
- Media relations

1.2. PROGRAMME LEADERSHIP AND PARTNERSHIPS

To facilitate planning, implementation and monitoring of interventions in the mTB-Tobacco programme, a governance structure and management team should be established, with clear responsibilities and accountability for the programme (Figure 2).

Programme leadership should include:

- an international steering committee for overall direction and guidance;
- an informal expert group, along with WHO and ITU, to advise and support the in-country project team; and
- a national technical advisory group of in-country leaders to manage operations, content development and adaptation, promotion and recruitment, technical specifications, and monitoring and evaluation.

FIGURE 2. PROPOSED STRUCTURE OF AN mTB-TOBACCO MANAGEMENT TEAM

WHO, ITU, and informal expert group:

Group of TB, cessation, and mHealth experts to assist in drafting the handbook and advising on implementation

International mTB-Tobacco steering committee

Representatives from ministries of health and telecommunications, with national and international representatives of WHO and ITU, to decide on the overall direction and agreements

National Technical Advisory Group (National TAG)

Government sectors (including health, telecommunications, business, media, treasury and planning) to set up the legal, technical and financial framework for a sustainable programme. This group will network with a large number of potential partners such as:

▪ the telecommunications and software industries ▪ local telecommunication and mobile network providers ▪ nongovernmental organizations ▪ health professionals ▪ academic and research organizations ▪ health insurance groups ▪ health service providers ▪ civil society groups ▪ opinion leaders ▪ the media and ▪ others as appropriate

National operations, content, promotion, technology, and monitoring and evaluation project leaders (subset of the TAG)

Management of overall programme operations, including needs assessment, workplan, budget and legal aspects	Development and adaptation of the content of the intervention	Management of recruitment, communications, marketing and dissemination	Management of technical aspects of programme development and implementation	Management of the development and implementation of monitoring and evaluation plans

INTERNATIONAL mTB-TOBACCO STEERING COMMITTEE

It is important that collaboration is established between the Ministry of Health and the Ministry of Telecommunications. Both should be represented on the international steering committee. Representatives of WHO and ITU should also be members and should contribute to decision-making in order to maintain the overall coherence of Be He@lthy, Be Mobile and to share lessons between countries. The steering committee will be responsible for presenting the mTB-Tobacco programme to governments and international agencies in order to secure funding for wide scale, sustainable implementation.

WHO, ITU, AND THE INFORMAL EXPERT GROUP

International technical agencies that work on TB and tobacco cessation, such as The Union and the United States National Cancer Institute, can be important in providing technical support. Additionally, a number of university research groups have tested approaches to cessation in TB programmes and have valuable expertise and knowledge to contribute. It is equally important to include stakeholders from international information technology organizations to advise on legal issues, choice of platforms and feasibility, as well as health economists and business development experts to advise on models for sustainability.

NATIONAL TECHNICAL ADVISORY GROUP (NATIONAL TAG)

This group should support, inform and advise the programme through all its stages. It should include persons who can make decisions on funding and planning, those who will be involved in implementing, promoting and evaluating the programme, those who can contribute to the programme's long-term sustainability, and someone who understands or represents the mobile network environment in the country. Regular meetings should be held to share information and updates on progress.

The national TAG will assign roles and responsibilities to various organizations in the different phases of development, adaptation, implementation, evaluation and continuing service provision. The national TAG should encourage discussion on overall programme ownership, funding and contracts or agreements on dealing with technical and other issues. The group will assist the national operations team in making decisions about the target population, type of programme, and programme objectives, design, promotion and evaluation.

For more detail on the roles and questions for consideration by the national TAG, see Annex 1.

NATIONAL OPERATIONS, CONTENT, PROMOTION AND RECRUITMENT, TECHNOLOGY AND MONITORING AND EVALUATION PROJECT LEADERS

These groups include the people who will develop or adapt the programme for cultural relevance and technical accuracy, those who will promote, operationalize and maintain the programme, those who will integrate it into the health system and health promotion services, and those who will evaluate it. This group may include TB and public health specialists, evaluators and statistical experts, health promoters, behaviour change and communications experts and consumer groups. These teams would report to, or be a subset of, the national TAG.

1.3. WORKPLAN DEVELOPMENT

To develop a project workplan, it is useful to have a checklist or template. Table 4 describes the elements of a workplan for use and adaptation by any country intending to implement an mTB-Tobacco programme.

TABLE 4. CONTENT CHECKLIST OF A WORKPLAN FOR AN mTB-TOBACCO PROGRAMME

Background and context

In this section, information from the needs assessment that applies to decisions on the implementation strategy is used.

- ☐ Problem statement: a description of the problem of TB and tobacco use that the programme is intended to address
- ☐ Present situation or context of TB and tobacco use in the country
- ☐ National or government commitment to this project
- ☐ Process used in project identification or formulation, information used and stakeholders involved
- ☐ Relation to previous and current programmes or activities in TB prevention and control, and in tobacco cessation

Operations management

In this section, planning decisions are made, a description of the programme to be implemented is created, and an operations management plan is developed that includes identifying who will be responsible for implementing the project and for ensuring provision of the services.

- ☐ Overall project objective: e.g. "to adapt the mTB-Tobacco programme for the population of X, particularly targeting Y patients, and to implement it as a free national service"
- ☐ How the programme fits into national or regional strategies
- ☐ Strategy for operationalizing and promoting the programme
- ☐ How the initiative will evolve with progress in technology: e.g. will it be extended to other activities of the NTP, will it become an example for other health programmes that wish to incorporate cessation, will it become integrated into a comprehensive mNCD model
- ☐ Roles and responsibilities in the project: project team members, responsibilities for main activities, choice of project team leader
- ☐ Overall description of project management
- ☐ Management committee (if applicable, terms of reference)
- ☐ Accountability for project implementation

Public-private partnership: Every partner has a unique role and all are motivated by the desire to improve health by using technology, is recommended. Some of the important underlying principles to be considered include:

- ☐ A "win–win" philosophy, particularly for a long-term strategy, driven by the government with the private sector and nongovernmental organizations involved in implementation
- ☐ A service free of charge to consumers in order to maximize public health impact (enrolment is very low when consumers have to pay)
- ☐ Consideration of the environmental effects of a mobile network
- ☐ Appropriate contractual arrangements with the best providers
- ☐ Assurance that service provision is sustainable in the long term

Content development and adaptation

In this section, a research driven message refinement process should be implemented.

- ☐ Review of existing programme content and rules of implementation

- ☐ Refinement of content through focus groups and consumer pre-testing, translation, changing the wording, removing and adding new messages, changing the rules in the system, and designing the registration, opt-in and administration functions of the new programme
- ☐ Plan for updating messages

Technology

In this section, decisions are made about the considerations necessary for the infrastructure and rules of the programme.

- ☐ The type of mHealth technology and channels to be used (e.g. SMS, voice, apps)
- ☐ Availability of technology options within the public and/or private sector
- ☐ Process for procurement and adaption of technology
- ☐ Dashboard development and access
- ☐ Procurement of a short code
- ☐ Negotiation with telecom regulators, aggregators and operators for pricing
- ☐ Data security
- ☐ Technology pre-testing and scale-up plans

Promotion and recruitment

In this section, decisions should be made about marketing of and enrolment in the programme.

- ☐ Promotion and recruitment plan (launch, short-term, mid-term and long-term strategies)
- ☐ Recruitment methods (by SMS, Internet, missed calls, third party)
- ☐ Promotion strategy (media, health workforce training, civil society outreach etc.) adapted for various client groups (e.g. by demographics such as urban, rural, age, gender, or income)

Monitoring and evaluation

In this section, decisions should be made about what will be measured by the programme, and with what frequency.

- ☐ Monitoring and evaluation plan based on the mHealth monitoring and evaluation framework
- ☐ Short-term, mid-term and long-term plans
- ☐ Reports and dissemination plans for evaluation, refinement, improvement and service provision

Estimated time frames

Planning: 3–4 months

- ☐ Needs assessment, assuming the information is readily accessible and local researchers are available to inform the national TAG
- ☐ National TAG formation and planning: engaging the right partners, agreeing on the implementation plan, the promotional plan and the evaluation plan. Working groups formed, project leader assigned
- ☐ Behaviour change project team formed
- ☐ Selection of programme and text message content or preparation of new text messages
- ☐ Agreement on programme and technical and transmission specifications

Content adaptation: 4–6 weeks

- ☐ Expert group consultation to review and culturally adapt content
- ☐ Consumer testing of messages before use in focus groups, online surveys, telephone interviews, etc.
- ☐ Modification of messages based on consumer feedback
- ☐ Translation (and back-translation to check for translation accuracy)

Technology adaptation: 4–6 weeks

Development of promotion and recruitment strategy and material: 4–6 weeks

Programme implementation: within 6 months of beginning the planning

Monitoring and Evaluation:

- ☐ Monitoring: should be in real time using agreed indicators
- ☐ Evaluation: beginning at least as a 6-month follow-up of the initial cohort

Budget elements to be considered: (See Annex 3 for budget template)

SECTION 2

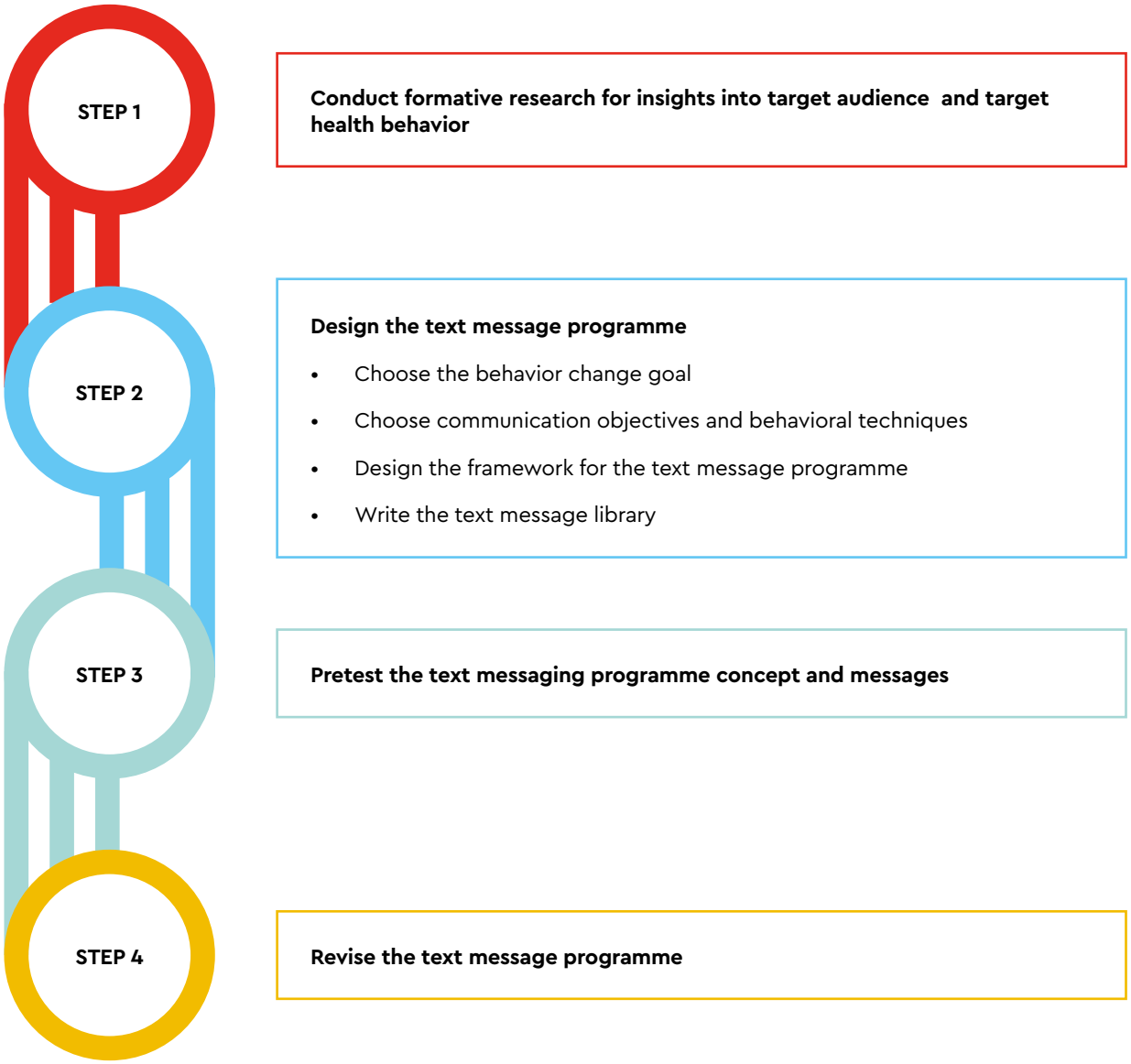
CONTENT DEVELOPMENT AND ADAPTATION

The development and pre-testing of the mTB-Tobacco programme should:

A. be informed by the findings of an mHealth country needs assessment, and
B. follow steps recommended for the development of communication interventions for health behaviour change.

Recently, a consensus has emerged on these steps (38) (see Figure 3), which have been adapted for mTB-Tobacco.

FIGURE 3. DESIGNING A TEXT MESSAGING PROGRAMME



Before the mTB-Tobacco programme can be launched, decisions must be made about the targets, nature and content of the messages (Box 1).

BOX 1.

DECISIONS ON THE TARGETS, NATURE AND CONTENT OF MESSAGES

1. Which population should be targeted: diagnosed TB patients, smokers, presumptive TB cases, patients' family members, health-care providers?
2. Which behaviours should be targeted: treatment adherence, follow-up attendance, smoking, alcohol?
3. Which behaviour change techniques are likely to be relevant and effective here?
4. Which messages should be selected to deliver the above techniques?
5. What should be the source of text messages: doctors, TB DOTS facilitators?
6. What should be the style or tone of text messages: formal, colloquial?
7. At what point should patients be registered to receive text messages?
8. What is the right quantity, frequency and timing of text messages to be sent?
9. Should mTB-Tobacco be interactive (allowing users to send back messages or requests for information)? If yes, to what extent?
10. Should mTB-Tobacco be tailored to a particular audience? If yes, to what extent?
11. How will text messages supplement face-to-face interactions?
12. Should mTB-Tobacco provide web sources and links to social media?

2.1. BEHAVIOUR CHANGE GOALS AND TARGET AUDIENCE

When developing an mTB-Tobacco programme, two key decisions are required - which population(s) and which behaviour(s) should be targeted. To achieve the overarching aim of improving TB treatment outcomes, several potential target groups are possible, as follows:

- patients diagnosed with TB (smokers and/or nonsmokers);
- friends and family members of TB patients;
- health-care workers providing TB care;
- community treatment supporters of patients with TB;
- patients with presumptive TB.

TB patients' own health behaviours – such as treatment adherence, follow-up attendance, smoking and alcohol use – have the biggest influence on their treatment outcomes. However, a change in health professionals' behaviour can also determine whether TB diagnostic and treatment guidelines are adhered to and correct advice is given. Similarly, family members and carers also influence TB outcomes by offering social support to patients, such as by helping

patients to adhere to their treatment and follow-up plans, encouraging them to quit smoking and alcohol, and providing a smokefree living environment. The target audience can also be widened to include all persons presumed to have TB. A TB programme implementing mTB-Tobacco should define the target audience on the basis of specific needs as well as available resources and other practical constraints. Thus, a decision might be made to focus on intervening with patients diagnosed with TB who smoke tobacco and are currently under treatment (for a period of 6-12 months). These patients would receive messages related to both tobacco cessation and TB treatment.

TB treatment success relies on a number of health-related behaviours but it may not be possible to target all of them. While a needs assessment can highlight such behaviours and provide their prevalence among TB patients, the steering committee should prioritize the behaviours for targeting. There are three key considerations in making this decision: 1) the extent to which a particular behaviour determines TB treatment outcomes, 2) the prevalence of this behaviour in the target population, and 3) the degree to which this behaviour is modifiable.

2.2. SELECT BEHAVIOUR CHANGE TECHNIQUES

After the steering committee has agreed on a set of target behaviours, the next task is to agree on the behaviour change techniques required to modify these behaviours. A taxonomy of BCTs likely to influence target behaviours and their determinants has emerged recently in the literature (39). As highlighted in Figure 4, a behaviour change technique that is likely to modify a particular behaviour has to influence the determinant of that behaviour. For instance, in order to help smokers quit, behaviour change techniques should address the trigger(s) that provoke smoking. A needs assessment can help identify specific determinants (barriers and facilitators) to behaviour change. The steering committee can then use the inventory of behaviour change techniques to match against these specific behavioural determinants. The output from this exercise, which can be completed within a steering committee workshop, will be a set of behaviour change techniques that are most likely to be effective in changing target behaviours.

FIGURE 4. SELECTING THE BEHAVIOUR CHANGE TECHNIQUES*

* Adapted from: Hardeman et al. (2005) (39), and Michie et al. (2013) (40).

2.3. DESIGN THE FRAMEWORK OF THE PROGRAMME

A framework for the mTB-Tobacco programme will include the nature and content of the messages, a schedule for timing and frequency, and other logistical considerations.

SELECTING MESSAGES THAT ALIGN TO THE BEHAVIOUR CHANGE TECHNIQUES

Once a set of behaviour change techniques has been chosen, text messages (160 characters maximum) that can deliver these techniques need to be drafted and/or selected from the message library provided in Annex 2. The message library is not exhaustive and it may be desirable to develop additional messages to address target behaviours and their specific determinants. It may also be worthwhile to develop a logic model specific to the mTB-Tobacco programme showing a linear relationship between text messages, behaviour change techniques, target behaviours and their determinants, and health outcomes.

At this stage it is important to select techniques that naturally lend themselves to mobile text messaging. For example, text messaging can provide a prompt or a cue for action (such as a reminder to take TB medicines). Other examples include goal-setting (e.g. deciding on a quit date), self-monitoring (e.g. using a calendar to check off days on which medication has been taken) and providing feedback on behaviour (e.g. sending congratulations on completion of 2 months of TB treatment).

SOURCE AND STYLE OF MESSAGING

Deciding on the source of messaging is important. Messages can come from the programme name (i.e. mTB-Tobacco), or they can come from a real person (e.g. a doctor or TB DOTS facilitator). Within an automated programme, messages can vary between different persons. Some programmes have paired patients or users to act as buddies who send messages to each other. The style of message should suit the source. For instance, a message coming from a doctor should have a professional style. Messages also need to be adjusted to the level of literacy of the target population. There are several web-based tools for checking readability (e.g. Flesch–Kincaid readability tests) although most are based on the English language.

REGISTRATION WITH THE PROGRAMME

The process of registration may vary according to the target audience. In the case of patients diagnosed with TB, the most appropriate time to register them is soon after their diagnosis when their details are entered into a TB register. A TB programme may decide to offer the mTB-Tobacco programme on an opt-out basis, in which patients could be automatically registered to receive text messages unless they explicitly choose not to.

FREQUENCY, QUANTITY AND TIMING OF DIFFERENT MESSAGES

Evidence suggests that a programme with variable frequency and quantity is more effective than one sending out messages constantly. The frequency of text messages within mTB-Tobacco programme should vary according to the trigger of the behaviour, the period that is critical for the target behaviour to change, and important points in TB treatment and follow-ups. Some examples are:

- several messages (5-7) can be sent on the day on which the patient has agreed to quit smoking (with reduced message frequency of one a day or three a week in the following week);
- frequent reminders (2-3 times a day) to take TB medication (desirable in the first few weeks, and then reduced to once a day or less;
- timely text messaging after starting TB medications (to calm fears and encourage treatment continuation when medications harmlessly change the colour of urine to reddish orange); and
- following a month of TB treatment, message reminders of the importance of completing their full treatment course as patients often start feeling better and may stop their treatment unless reminded.

Messages to remind patients to keep to their follow-up appointments and to continue taking medication even after a period of apparent recovery can be scheduled for delivery in the second month. Setting the timing for sending various messages within a particular day is also important. This depends on the content of the message (i.e. what the patient is being asked to do), the patient's daily routine (i.e. whether the patient will have time to consider the message) and the target behaviour (i.e. whether a specific time of day is best for targeting a particular behaviour).

NATURE OF INTERACTION WITH THE PROGRAMME

Another key decision is whether to keep the mTB-Tobacco programme unidirectional or make it bi-directional and interactive. An interactive mHealth programme enhances patient/user engagement but is also more resource- and technology-intensive. An interactive mTB-Tobacco programme can be useful in several ways. A text message asking for a simple Yes/No reply can be a prompt to change behaviour (e.g. have you taken your TB medicines for today? Reply 1 if you have or 2 if you haven't; Are you ready to quit smoking today? Reply 1 if you are or 2 if you aren't). Interaction can also help in tracking behaviours such as smoking, alcohol use and drug adherence and, in response, can provide positive feedback, reinforcement and encouragement to patients.

Actionable replies can be sent in response to specific keywords. For instance, a smoker trying to quit can send certain predefined key words such as "CRAVING" every time he or she has an urge to smoke and can receive an encouraging or informational message in return. An interactive programme can be set to allow some margin of error (spelling or otherwise) on the patient's part. Such two-way communication requires more complex technological specifications and may require additional resources and time to maintain. An additional advantage of interaction is the ability to automate programme evaluation. Survey questions about smoking behaviours and medication adherence can be built in, acting as prompts or data sources for monitoring and evaluation.

TAILORING THE PROGRAMME

Tailored messages are more likely to be read, recalled and perceived as more relevant than generic messages. Consequently, it is important to decide whether to keep mTB-Tobacco as a generic programme (sending all messages to everyone registered) or to tailor it to specific groups or individuals.

At an individual level, messages can be directly addressed to patients by name, and can be sent to fit a particular daily routine (e.g. taking medicines after breakfast around 7:00 AM) or set of events (e.g. forgetting to take medicines during holidays). While an algorithm can be built to fit these situations, such individually tailored programmes are more resource-intensive to develop and need careful thinking and planning.

Tailoring mTB-Tobacco messages to specific patient groups may offer a good compromise. For example, the programme can have a built-in logic to send specific set of messages to different groups based on a few questions at the time of registration (e.g. Do you smoke? Do others smoke in your house? Do you drink alcohol?).

WILL TEXT MESSAGES SUPPLEMENT FACE-TO-FACE INTERACTIONS?

TB patients are likely to receive information about their condition, medications, follow-up routine and other heath behaviours from a doctor and other health professionals working in the TB programme. The mTB-Tobacco messages should complement this information and avoid contradictions. Furthermore, the development of an mTB-Tobacco programme provides a good opportunity for the national TB programmes to review what other information (written or verbal) is provided to their patients. Such an exercise will standardize information and bring it in line with the text messages.

PRIVACY CONCERNS IN RELATION TO TB STIGMA

TB is a stigmatizing condition in many cultures and societies. Consequently, it is important for TB programmes to take concerns about potential breaches of confidential health information very seriously and address them as necessary. mHealth programmes may require that patients' identifiable and sensitive information is recorded and managed at a central data resource. Confidentiality and security of information should be a top priority for the mTB-Tobacco programme. At the time of registration, health professionals can explain to TB patients the steps that have been taken to ensure that their information will be kept secure and confirm that it will not be shared with a third party under any circumstances.

INTEGRATION INTO WEB, SMARTPHONE APPS AND SOCIAL MEDIA

There has been exponential growth in mobile telephone ownership, access to the Internet, smartphones and the use of social media across the globe. There are advantages in linking mTB-Tobacco messages with web content, providing supplementary information in the form of audiovisual content, extra reading material, interactive games and links to social media. Similarly, smartphone applications can provide additional content and opportunities to interact and share materials on social media. Yet integration of mTB-Tobacco into web and smartphone apps needs careful consideration of logistics, access, privacy and finances. Developing effective smartphone apps requires additional programming and technological support. Also, while smartphone apps may appeal to younger and more technologically knowledgeable groups, they may not be effective for all. However, where web or social media campaigns exist on related themes, they may prove useful for promoting the mTB-Tobacco programme.

2.4. MESSAGE CONTENT

This section describes some key topics and functions that the mTB-Tobacco messages could address. These message categories are oriented primarily to a patient on TB treatment who consumes tobacco, using a patient-centred approach through the treatment journey. A detailed library of messages is provided in Annex 2.

MESSAGES TO A PATIENT ON TB TREATMENT WHO USES TOBACCO

1. Information-based

Messages should provide information, answering questions such as: What is TB? What is DOT? For how long must I take the TB medicines? What is the importance of taking TB medicines? Why is it important to adhere to regular treatment? Where do I store/keep my medication? How do I fix a time to take the medication? What is the importance of regular visits to the doctors?

2. Motivational messages on tobacco cessation

Messages should address the harmful effects of tobacco use and why it is important to stop using tobacco at this stage.

3. Emotional support

Messages should address fear of treatment and the emotional ups and downs that are part of the patient's experience. What are the common side-effects of TB medication?

4. Stigma and discrimination

It is essential to address stigma and myths. For example, messages could communicate that: "TB is not spread through spitting or sharing crockery or cutlery. One needs to be exposed to TB droplets in the air for eight hours or more to be at risk of contracting the illness. The idea that TB is easily spread on public transport is a myth."

5. Adherence to treatment

Reminder/reinforcement messages are needed on adherence to treatment in adverse situations (rains, social events, outside the city, when drugs are out of stock) and what to do in an event of a missed visit.

6. Prevention during treatment

What infection control measures I should take as a TB patient? How can I make sure it does not get passed to my family members, children and others in the workplace?

7. Health and nutrition related information

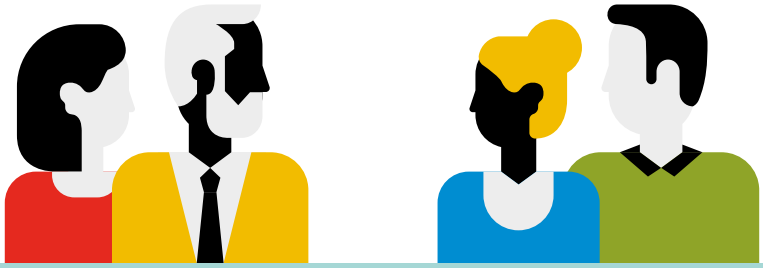
How can I maintain a healthy lifestyle while on TB treatment?

8. Prevention after treatment

At the end of six months once my treatment is completed, what precautions should I be taking? (Messages should discourage starting to use tobacco again. They should emphasize the importance of maintaining a healthy lifestyle, staying fit and being active).

9. Sharing my TB story with others

Messages should encourage friends and family with TB symptoms to get checked and encourage smokers to quit.



MESSAGES TO A PERSON WHO USES TOBACCO AND IS AT RISK OF TB, AND TO ANYONE WHO MIGHT BE AT RISK OF TB BUT IS UNAWARE OF IT

1. Signs and symptoms of TB: What do I do when I have been coughing for more than 2 weeks, I feel exhausted and have night sweats? Why is it important not to ignore these symptoms?

2. Behaviour change for tobacco cessation: Messages should support patients to quit tobacco use.

3. Information on TB: With these symptoms, what should I do first? Where should I go to get tested? What will the test include? Why is my sputum being tested? How long will it take for the test results to come?

4. Prevention: Once I have given my sputum for testing, should I be observing any preventive measures? How long will it take for my results to come?

MESSAGES TO A HEALTH-CARE PROVIDER WHO TREATS TB PATIENTS OR REFERS PATIENTS AT RISK TO TB CLINICS

1. Ask about your TB patients of about their tobacco use status.

2. Advise your TB patients to quit tobacco use.

3. Assess if your TB patients have quit.

4. Assist the TB patients with nicotine replacement therapy (NRT) and additional counselling, and offer to enrol them on this programme.

5. Arrange to see the TB patients after their treatment.

2.5. PRE-TESTING, PILOTING AND REFINING THE mTB-TOBACCO PROGRAMME

Once a plan of the mTB-Tobacco programme has been developed, it should go through iterative stages of pre-testing, piloting and refinement.

PRE-TESTING THE TEXT MESSAGES

The draft text messages should be pre-tested by conducting interviews or focus group discussions with potential users. It is important that such interactions should include representatives from all groups within the target audience. During these interactions, the facilitator/interviewer should explain the purpose and content of mTB-Tobacco to the participants and provide them with the message library, asking them to rate the messages for tone, content, clarity and persuasiveness. Testing should assess message comprehension, language and tone. It is important to consider the literacy level of the target population. Messages that are unclear or inappropriate for the target group should be rewritten either by or with the participants.

PILOT (PLUS ALTERNATIVE VERSIONS OF THE PROGRAMME, IF POSSIBLE)

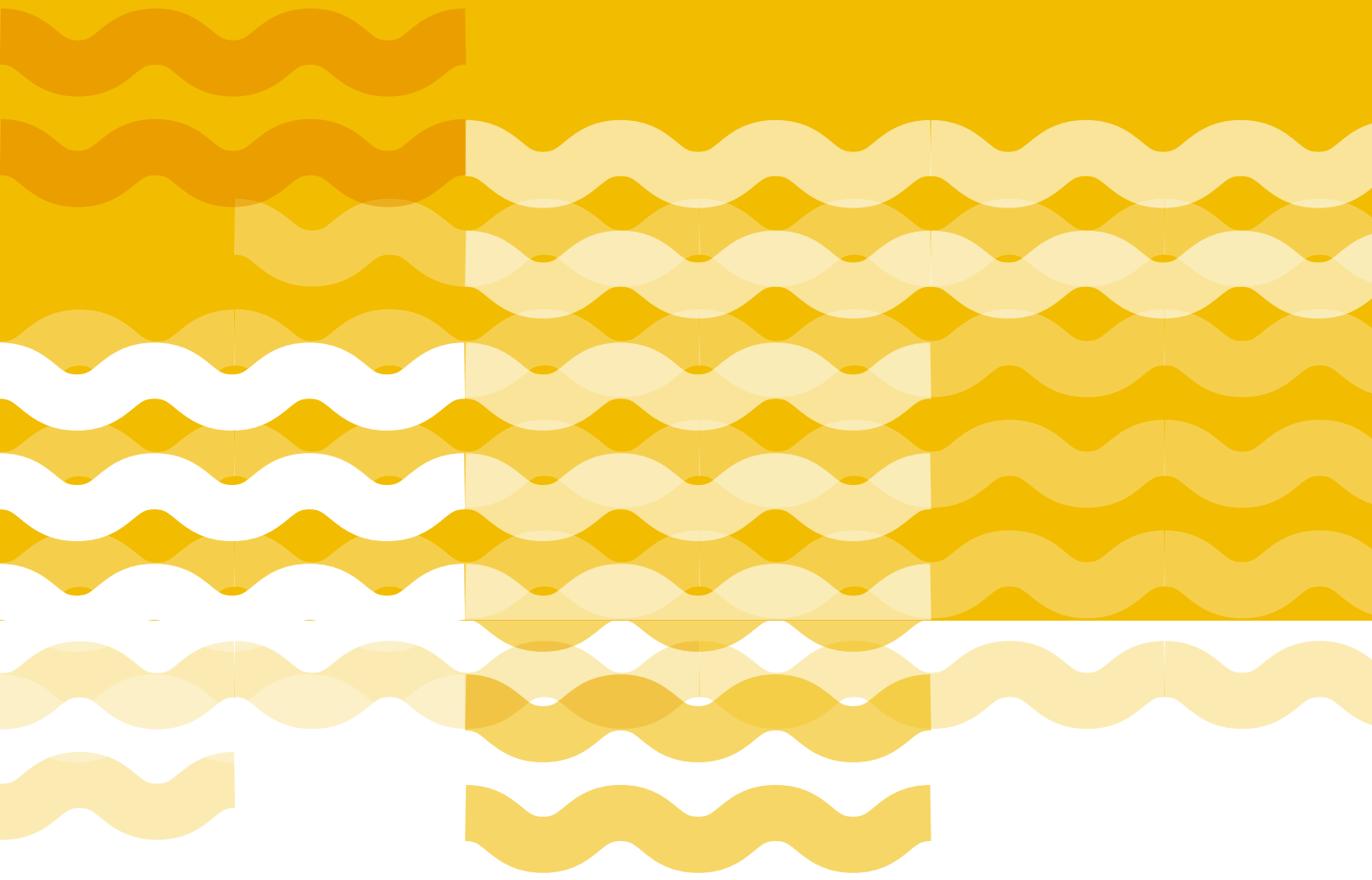
Once the messages have been pre-tested, the mTB-Tobacco programme should be launched as a pilot. The pilot programme should last for 2-4 weeks and should involve some 25-50 users. The pilot should be evaluated using two sets of data: users' self-reported experiences and their real-time engagement with the programme. Users' experiences can be collected either through face-to-face/phone-based interactions or via web-based/internet-based surveys. Key questions should focus on users' experience of taking part in the mTB-Tobacco programme; the clarity, quantity, timing and frequency of messages; what was good about the programme and what was not; completion or non-completion the programme; and any effect on their attitudes or target behaviour(s). Users' real-time engagement can be evaluated using computer records from the programme used for launching mTB-Tobacco. Depending upon the complexity of the programme, these data can provide information on the extent of users' engagement.

REFINE AND OPTIMIZE THE PROGRAMME

Once mTB-Tobacco is pretested and piloted, but before its final launch, the programme should go through a refinement process that addresses all issues highlighted during the pilot. Messages may need to be reviewed and updated on a regular basis. The programme plan should identify someone responsible for maintaining and updating the message library. Having some degree of flexibility and keeping the programme fresh may help to keep the audience engaged. The most common negative feedback from users is that they receive too many messages. While it is not yet clear what the ideal "dose" of messages for mHealth interventions is, user experience is important. A balance should be found between regularly reminding the user about the goals of the programme and sending so many messages that the user becomes annoyed and unsubscribes from the programme.

SECTION 3

PROMOTION AND RECRUITMENT



Promotion and recruitment of the programme is an essential step in implementation. In order to ensure that the mTB-Tobacco programme is effective and reaches the target population, it is important to consider early how information will be disseminated and how users will be recruited. Elements to consider include:

The target audience and the best means of reaching it.

What is the best way to reach patients currently undergoing TB treatment in a timely manner? What promotional materials are needed to reach this population and explain the programme to them?

Who will the public perceive as the "owner" of the programme?

This may depend on how the programme is managed, but it is also important to consider how the programme's brand and identity will be communicated to the public.

Can the programme be linked to existing services or programmes that already have a following?

For instance, there may be an existing national TB campaign or tobacco cessation campaign that could be used as a platform to introduce the mTB-Tobacco programme.

How will people sign up?

For patients under TB treatment, the treatment provider may offer the first opportunity to enrol patients. Other pathways could include enrolment online, by text message, or by telephone.

Is sending unsolicited text messages to TB patients an option?

This may depend on the local regulatory environment for mobile technology, and whether this approach is socially acceptable to the target population. Will the recipients be likely to ignore an unsolicited message?

Will incentives be offered for participation?

Incentives are not a routine feature of text messaging interventions but they have been used in the context of tobacco cessation.

The timing of the promotional campaign.

A "soft launch" may allow for testing key features of the programme before a larger campaign begins.

SECTION 4

TECHNOLOGY SPECIFICATIONS

The following technical aspects of an mHealth programme must be considered by the national TAG from the start, in collaboration with local partners:

- type of mHealth intervention, channels to be used (SMS, voice, apps, see Table 5);
- availability of technology options in the public or private sectors;
- process for procuring and adapting technology;
- procurement of a short code (the 5- or 6-digit unique number used to send and receive SMS to and from mobile phones, "send a message to 123123 to enrol in the programme");
- negotiation with telecommunications regulators, aggregators and operators for pricing;
- dashboard development and access;
- data security;
- review and clearance by appropriate ethics or regulatory bodies; and
- technology pre-testing and scale-up plans.

TABLE 5. EXAMPLES OF TECHNOLOGY OPTIONS

CHANNEL	STRENGTHS	WEAKNESSES
IVR (Interactive Voice Response)	Voice- and phone-enabled access Fast time-to-market Supports natural language Ease of integration	Limited capability and development tools Inability to pause, resume, forward and rewind
SMS	Simple, easy and convenient Cost effective Private communications Fast communications	Some security vulnerabilities Fake SMS (spoofing)
USSD (Unstructured Supplementary Service Data)	Simple and logical Real-time, fast and responsive Inexpensive Interactive navigation	Session-based timeouts Codes more difficult to remember than Common Short Codes
MMS	Direct and personal Messages can be stored and forwarded Interactivity through multi-media	Not compatible with basic phones More expensive than SMS Content adaptation limited by screen size and resolution variations Read and response rates lower than SMS
MOBILE APPLICATION	Self-contained experience Graphics and user-generated content Automatic updates and read content offline Leverages device-native capabilities (camera, GPS) Strong paid model	Fragmentation, need to build for multiple platforms, with time and costs Managing multiple releases Client side changes Need to submit app to some stores for approval

MOBILE WEB	▌More economical than mobile apps ▌Mobile phones and smart phones supported ▌Mobility for content and services ▌Videos and photos	▌Less functionality, unable to use advanced phone features such as camera, global positioning system (GPS) ▌Small display size ▌Low text input and low bandwidth

Mobile communications network environments differ both between and within countries. The specificities for each location should be considered in the planning stage by including technical representatives in TAG membership (such as representatives from telecommunications companies, operators, telecommunication regulatory authorities, government departments responsible for information, communication and technology, cellular associations) or individuals knowledgeable about the communications network in the country, as members of the national TAG. Networks, telecommunications companies or an industry organization can help with setting up the programme and advising on its sustainability. Some providers may consider their support of such a programme as good publicity or as a useful addition to their offers.

In the absence of such support, a programme can be delivered by a contractual arrangement with an "aggregator" or "gateway" company that has established relations with all telecommunications companies and networks.

This can be a cost-effective method for delivering messages to a large number of participants, regardless of their carrier or location, without establishing these interfaces individually. Although the aggregator adds a cost to the programme, this decreases as the scale of the programme increases; using an aggregator can therefore be more cost-effective than attempting these activities "in house", unless capacity and infrastructure already exist.

When thinking about the technical aspects of an mHealth programme, the national TAG may also consider:

- **Partnerships: (see Table 6):** What sort of arrangement with telecommunications companies or the aggregator will best suit long-term implementation of the programme?
- **Communicating messages: (see Table 5):** Should one-way text, voice or interactive messaging (including interactive voice response systems) be used? What are the capacity, cost-effectiveness and reach of the available technologies in the country?
- **Free access:** How can we ensure that the programme is free and available to all consumers regardless of their carrier, network or location?
- **Research:** Who will conduct interviews and through which medium?
- **Data ownership, privacy, security and interoperability with current health systems:** What are the considerations, and how should a central database best be maintained?
- **Contracts:** In establishing contractual arrangements with partners, what are the considerations regarding intellectual property, security and privacy of mobile phone numbers, testing, expectations of involvement in monitoring and evaluation and service agreements? Who will hold the contractual arrangements, and what support will be given for maintenance and any other problems? What lessons can be drawn from previous experiences in other countries?

The national TAG should also consider the detailed logistics and functional plan and finalize the functional specifications. This should be done in collaboration with the technical partners who will build the appropriate systems and interfaces, and test internal and user acceptance. Table 6 provides an overview of the roles of the various stakeholders when determining the logistics of the system.

TABLE 6. ROLES OF STAKEHOLDERS IN SETTING UP mHEALTH TECHNOLOGY

STAKEHOLDER	ROLE
Ministry of Health	Official owner and custodian of the programme, part of the governance body Assess and identify needs, develop and validate content Contract service providers or build in-house infrastructure/ platform Sign cooperation agreements with all operators and/or Service provider Fund or partially fund the programme Can host the mHealth platform/database and own the short code Manage the promotion and marketing campaigns

Telecommunications Ministry **eGovernment entity (if applicable)**	▌Policy making to enable m-services in terms of regulations and policies ▌Fund (partially) the programme, part of the governing body ▌Provide technical expertise to the Ministry of Health ▌Possibly host the platform ▌Facilitate dialogue between Ministry of Health and ICT stakeholders ▌Support the negotiation of preferential prices for m-services
Telecommunication Regulatory Authority	▌Verify eligibility for short code acquisition ▌Allocate short code ▌Facilitate dialogue between Ministry of Health and ICT stakeholders ▌Fund or partially fund the programme
mHealth service providers **(if Ministry of Health or eGov does not have a platform)**	▌Provide SMS management application/platform ▌Manage the platform and run SMS campaigns ▌Provide 24/7 technical support ▌Deals with telecom operators can possibly manage the short code
Telecom operators	▌Deliver SMS to end users ▌Set the cost of SMS and agree on special tarifs with Ministry of Health if possible ▌Facilitate interfacing with service providers and/or local aggregator ▌Support the promotion of the service
Local aggregator	▌Provide interface with all operators and manage relationship and invoicing process ▌Provide reporting on services delivered/failed ▌Possibly own and manage the short code
Data Privacy Commission	▌Set the rules for data protection ▌Enforce the application of data protection regulations ▌Authorize mHealth services providing they respect data privacy ▌Authorize the case of data storage outside of country
WHO and ITU	▌Provide technical expertise and share knoweldge from other countries ▌Help convene stakeholders

SECTION 5

MONITORING AND EVALUATION

Monitoring is the *routine* tracking of an intervention's performance using data collected on a regular and ongoing basis on specified indicators. This information is used to assess the extent to which an intervention is achieving its intended targets on time and on budget.

Evaluation is an *episodic* assessment of either a completed or ongoing programme or intervention, to determine the extent to which its stated objectives were achieved efficiently and effectively.

The aims of both monitoring and evaluation are similar: to provide information to inform decisions, improve outcomes and achieve objectives.

While monitoring routinely gives information on where a project is at any given time relative to respective targets for implementation, an evaluation gives evidence of why targets and outcomes are or are not being achieved or the extent to which changes can be attributed to the intervention. The data to be collected during a project for monitoring should be part of the planning process.

5.1 DEVELOPING A MONITORING AND EVALUATION PLAN

An ongoing process for monitoring and evaluation should be established from the very start of the mTB-Tobacco programme. It is good to be clear from the outset what information is to be collected and for which purposes in order to match the frequency and effort of data collection with its importance and cost. The goals of data collection may include:

- managing the ongoing operation of the programme;
- providing feedback for continuing improvement of the programme;
- reporting to funders on performance and impact to justify further investment;
- providing lessons learned in the implementation of the programme that can be used elsewhere (e.g. for implementing other mHealth programmes).

Wherever possible, data collection can be integrated into the programme while it is being established. This can provide ongoing real-time data for the administration and operation of the programme, and data can also be collated and analysed for monitoring. More expensive independent evaluations can then be scheduled less frequently to answer specific questions about impact. One of the advantages of mHealth interventions is the opportunity to record data on how the programme is used and to ask users about their experiences.

It is helpful if all mHealth interventions use a logic model for monitoring and evaluation. This model can illustrate the presumed relationships between its inputs, outputs, outcomes and impact. An illustrative example of the mHealth logic model is shown in Figure 5. The logic model has been divided into two domains: the person-centered domain and the programme-centered domain, which will allow mid-course adjustments and improvements to be made to the programme.

FIGURE 5. LOGIC MODEL: FRAMEWORK FOR MONITORING AND EVALUATION OF mHEALTH PROGRAMMES AT SCALE

	INPUT	OUTPUT	OUTCOME	IMPACT
PERSON CENTERED DOMAIN	Outgoing messages Incoming messages Surveys, Interviews	Reach and registration Information about the user population Ease of understanding messages	Improved literacy/ knowledge/ outreach Behavior change Return on investment Technology performance	Improved health outcome Improved use of resources
PROGRAM CENTERED DOMAIN	Governance Policy data Resources (Finance, Human resources, ICT architecture Content development Outreach and promotion Data from "Person centered domain"	Coverage of intervention Intervention quality Interoperability	Integration with health systems Improved health literacy Access to intervention	Improved health outcomes (SDG 3) Improved digital capacity (SDG 9) Efficiency & efficacy

5.2 IMPORTANT QUESTIONS IN ONGOING MONITORING AND EVALUATION EFFORTS

1. IS THE PROGRAMME REACHING THE RIGHT PEOPLE?

The programme must be accessible to the entire target population, which should be specified at the start with an estimate of the potential number of persons. Barriers to reaching the right people include: inadequate exposure to programme advertisements, lack of access to the appropriate technology, cost, and cultural or personal perceptions that the programme is not appropriate or is unlikely to be effective. All potential barriers should be considered when designing questions for the evaluation.

Questions for identifying barriers are suggested by the monitoring and evaluation framework:

- What proportion of patients with TB have minimum access to a mobile phone?
- What proportion of each targeted population can read or write in the language used in the text messages?
- What proportion of each targeted population can afford the mHealth programme?

- What proportion of each targeted population is unwilling to engage in mHealth projects for cultural or personal reasons?
- What proportion of each targeted population lives in an area covered by a mobile network?

Once the programme is operational, reports should be made on the number of participants. Information to be reported would include:

- the proportion of the target population who take up the programme;
- the proportion of people at risk with suspected or diagnosed TB in the target population and who take up the programme (by age group, location, ethnicity, income);
- where participants heard about the programme (e.g. mass media, posters, recommended by a professional or service, recommended by family or friends, Internet);
- a questionnaire to compare the knowledge among the participants prior to and post the intervention may be useful.

Objective measures of impact would include:

- tobacco cessation
- changes in TB status or disease progression
- adherence to medication
- TB cases in the household
- comorbidities

Separate scheduled evaluations may be conducted to gather more information. For instance, population-based surveys to determine recognition, awareness and attitudes can help to indicate:

- the effectiveness of mass media and other promotional campaigns in informing people about the programme; and
- the reasons why people with TB have not taken up the programme.

2. ARE WE PROVIDING A HIGH-QUALITY PROGRAMME?

Quality is reflected in several aspects of the programme:

- Is the content of the messages appropriate and helpful?
- Are the messages reliable? (Do they arrive when they are supposed to?)
- Do the registration process and interactive components work as they are advertised?
- Are there are any unexpected technical problems?

Programme metrics could include:

- the number of people who text STOP to stop receiving messages. This can be used as a proxy measure of people who are unhappy with the programme for any reason but may also include people who feel they are fully informed about the risk factors and therefore consider that they no longer need the messages. When presented as a proportion of participants over time, an increasing trend can indicate a problem with the quality of the programme.
- the number of participants using the interactive components of the programme. A very low number may indicate lack of engagement with the programme, which could be due to a perception of poor quality or a lack of understanding of the components.
- administrative reports on the steps in registration. These can be useful for identifying timeliness and any concerns arising during registration (e.g. large numbers who register an interest but fail to complete the full registration process).
- the reliability of message delivery. Aggregator companies can usually report on this, with confirmation of delivery and reports on any technical issues.

- unexpected technical problems. Unscheduled text messages from participants may alert staff to unexpected technical issues.

3. IS THE PROGRAMME HAVING AN IMPACT?

The effectiveness of mTobaccoCessation programmes is usually measured by monitoring whether patients have made serious attempts to quit smoking.

A scheduled evaluation can elicit more detailed feedback from a subsample of participants, such as:

- whether they feel that the programme informed them about the health impact of their smoking and the links to TB;
- which aspects of the programme were helpful;
- what they like and dislike about the programme;
- how the programme could be improved to be more helpful;
- whether they consider that two-way personalized messages are more beneficial than one-way automated messages.

Broader programme metrics could include:

- the proportion of the population reached who complete the programme, whether the user experience was enjoyable and the proportion who changed their behaviour and claim that they will continue to do so; and
- whether the content of the mHealth programme was useful in informing the population, and the extent to which it triggered behaviour change.

4. DOES THE PROGRAMME HAVE ANY NEGATIVE CONSEQUENCES?

Programme administrators should be aware of any negative consequences of the programme. Unexpected consequences may be picked up from incoming text messages. Systems should be set up for early identification of, and response to, predictable issues such as technical problems. Managers might also consider asking about potentially important issues, such as traffic accidents while reading messages on a mobile telephone. Data could be collected by continuous reporting, monitoring (e.g. surveys) and scheduled evaluations that involve all participants or subsamples of populations.

At country level, the appropriate ethical approvals should be sought for an mTB-Tobacco evaluation study. Approval may come from an independent ethics review committee at an academic institution of high standing or another government-approved organization. The documents for approval should be prepared in accordance with the specifications of the agency, with full disclosure of:

- the type of population to be evaluated;
- the survey instrument to be used;
- any compensation for the trial respondents;
- details of the method to be used, including market research design, statistical norms, empirical considerations by country demographics, controls and analysis plan;
- the informed consent form.

Conclusion

This handbook provides guidance for national TB control programmes and organizations responsible for delivering TB control in developing and implementing an mTB-Tobacco programme. The main components of which are: operations management, content development and adaptation, promotion and recruitment, technology specifications and monitoring and evaluation. The content of the mTB-Tobacco programme will complement existing health care services and routine care offered by health care professionals. All content in this handbook is based on WHO guidelines, existing research evidence on effectiveness, content and delivery and expert opinions. The templates showcased here should be considered examples and must be adapted to local context of each participating country.

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ANNEX 1

Purpose, roles and questions of the national technical advisory group (TAG)

The purpose of the national TAG is to:

- assign roles and responsibilities to the various organizations involved in the development, adaptation, implementation, evaluation and ongoing service provision of the programme (this should include discussions on overall programme ownership, funding, contracts or agreements for dealing with technical and other issues);
- agree on the target population(s), type of programme, objectives of the programme, programme design, support for the programme, integration with existing TB and tobacco cessation services and programmes, and the monitoring and evaluation plan;
- support implementation and promotion of the programme;
- make recommendations for ongoing service provision based on evaluation findings.

Initial questions to be considered by the national TAG should include:

- What is the overall purpose and philosophy of the mTB-Tobacco programme? What is the main intention and core intervention: to support TB patients who use tobacco to quit?
- Are there other intentions and optional interventions, such as to enhance care of TB patients, to provide patient information on TB and tobacco cessation, and to provide training and clinical decision-support systems for TB and tobacco care. If so, will these be included from the start or considered only later?
- What is the theoretical basis or mechanism by which the interventions might work? How valid is the relevant behaviour change theory and techniques? How ready are people to change their health or lifestyle behaviours and their use of mobile telephone technology?
- Can existing materials be adapted for the local population and context? Will new materials and strategies have to be developed? Are there any relevant local cultural models of health promotion or successful text or voice campaigns?
- Who are the target audiences? Urban, rural, poor, marginalized? TB patients who have mobile telephones? Who is most likely to benefit from such a programme?
- What are the best ways to apply and promote the programme with the target audiences? How will people be registered, by opting in or by opting out?

- How will the mTB-Tobacco programme fit into the NTP, other TB prevention and care services and other related programmes? Are there lessons to be learned from existing mHealth programmes that are effective and popular?

- Is the programme both effective and cost-effective? Is the evidence strong?

- How will the programme be operationalized? Are there lessons to be learned from the operationalization of mHealth programmes elsewhere, locally or regionally? Who will be responsible and accountable for the programme? What are the roles and responsibilities?

- What is the budget for the programme, including TAG establishment and meetings, message development and refinement, translation and transmission, promotion and enrolment, evaluation of effectiveness and publication?

- Who will pay – the government, the private sector or consumers? Can the programme be free of charge to maximize its public health impact?

- Are there regulatory restrictions, such as for privacy, text message transmission or opting out of the programme?

- Could NTP data be collected through mTB-Tobacco? Could data be collected on rates of tobacco use and cessation?

The national TAG should consider conducting a needs assessment and building an evidence base to answer these questions and determine whether more data or research are required.

ANNEX 2

The mTB-Tobacco Example Messages Library is available upon request.

To request the mTB-Tobacco message library, please contact:

Sameer Pujari at
pujaris@who.int

or Briana Lucido at
lucidob@who.int

ANNEX 3

Example budget breakdown

Activity	Type of expense	Phase component	Product or outcome	Estimated Cost (US$)
FORMULATION, DESIGN AND DEVELOPMENT	CAPITAL (ONE-OFF EXPENSE)	**Operations management**	▌Formative research and successful evidence Review ▌Formation of an informal international experts group ▌Compilation of best practices and lessons learned ▌Assessment of resources/ technology available and mapping to needs assessment	
			▌Engagement with ministries of health, ICT and local stakeholders ▌Identification and formation of a national m-Health for NCD taskforce ▌Consultation meetings of national taskforce	
		Content	▌Country workshop with local and international experts to learn from international experience and finalize project concept and design. ▌Development of a Programme handbook ▌Content development + adaptation + focus group's evaluation for adaptation (to develop culturally appropriate new content prototype for the country (content, level of interaction of SMS, etc.) ▌Focus group meetings to translate content into local languages and modify for cultural acceptability	
		Technology	▌Develop/adapt technical platform/solution ▌Develop database for the country	

Activity	Type of expense	Phase component	Product or outcome	Estimated Cost (US$)
FORMULATION, DESIGN AND DEVELOPMENT	CAPITAL (ONE-OFF EXPENSE)	**Technology**	▌Piloting and deployment at country level - Telecoms provider / SMS gateway integration - Multi-language set-up and user language tracking ▌Application maintenance and fine tuning ▌Platform hosting and maintenance ▌Testing technical platform and messages	
IMPLEMENTATION AND SUPPORT	CAPITAL (ONE-OFF EXPENSE)	**Promotion and recruitment**	▌Promotion, marketing, preparation of materials to recruit participants ▌Strengthen human resource capacity to effectively implement m-Health for NCD projects	
		Operations management	▌Train local partners in project design, platform, SMS database, sampling, results framework and evaluation of results ▌Training in use of mTraining tools	
	OPERATIONAL	**Promotion and recruitment**	▌Marketing ▌Patient communication (telecommunications company) ▌Maintenance of infrastructure	
PROGRAMME MANAGEMENT	OPERATIONAL	**Operations management**	▌Project team (one senior staff, one junior staff and one administrative support) ▌Miscellaneous (e.g. travel, meetings, communication)	
MONITORING AND EVALUATION	CAPITAL (ONE-OFF EXPENSE)	**Monitoring and evaluation**	▌Develop method for data collection and analysis of results, sample size and results framework ▌Adapt global mHealth impact assessment indicators for country ▌Adapt global mHealth impact data collection instrument for country ▌Develop reporting and analysis module for monitoring and evaluation	

Activity	Type of expense	Phase component	Product or outcome	Estimated Cost (US$)
FORMULATION, DESIGN AND DEVELOPMENT	CAPITAL (ONE-OFF EXPENSE)	**Technology**	▌Piloting and deployment at country level - Telecoms provider / SMS gateway integration - Multi-language set-up and user language tracking ▌Application maintenance and fine tuning ▌Platform hosting and maintenance ▌Testing technical platform and messages	
IMPLEMENTATION AND SUPPORT	CAPITAL (ONE-OFF EXPENSE)	**Promotion and recruitment**	▌Promotion, marketing, preparation of materials to recruit participants ▌Strengthen human resource capacity to effectively implement m-Health for NCD projects	
		Operations management	▌Train local partners in project design, platform, SMS database, sampling, results framework and evaluation of results ▌Training in use of mTraining tools	
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PROGRAMME MANAGEMENT	OPERATIONAL	**Operations management**	▌Project team (one senior staff, one junior staff and one administrative support) ▌Miscellaneous (e.g. travel, meetings, communication)	
MONITORING AND EVALUATION	CAPITAL (ONE-OFF EXPENSE)	**Monitoring and evaluation**	▌Develop method for data collection and analysis of results, sample size and results framework ▌Adapt global mHealth impact assessment indicators for country ▌Adapt global mHealth impact data collection instrument for country ▌Develop reporting and analysis module for monitoring and evaluation	

Activity	Type of expense	Phase component	Product or outcome	Estimated Cost (US$)
MONITORING AND EVALUATION	CAPITAL (ONE-OFF EXPENSE)	**Monitoring and evaluation**	▌Develop cost impact assessment model for sustainable financing based on global model	
	OPERATIONAL	**Monitoring and evaluation**	▌Continuous evaluation and assessment ▌Analysis and reporting ▌Results dissemination ▌Continuous adjustments	
	MISCELLANEOUS			
Total operational expenditure (annually recurring)				
Total capital expenditure (one-off)				
TOTAL COST (CAPITAL + OPERATIONAL FOR 1 YEAR)				

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