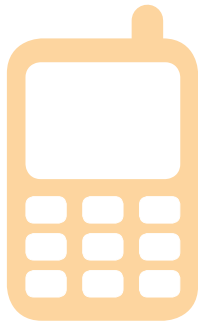# Electronic recording and reporting for tuberculosis care and control

World Health Organization

Electronic recording and reporting for tuberculosis care and control

World Health Organization

Contents

Acknowledgements

Abbreviations

CSV	comma-separated values
DOTS	the internationally recommended strategy for TB control until 2006, and the first component and foundation of its successor, the Stop TB Strategy
DR-TB	drug-resistant tuberculosis
DST	drug susceptibility testing
GIS	geographic information system
HIV	human immunodeficiency virus
HMN	Health Metrics Network
IT	information technology
KNCV	KNCV Tuberculosis Foundation
MDR-TB	multidrug-resistant tuberculosis
MoH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
NTP	national TB control programme (or equivalent)
PDA	personal digital assistant
RFP	request for proposals
SOP	standard operating procedure
TB	tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
XML	extensible markup language

Introduction

Recording and reporting of data is a fundamental component of care of patients with tuberculosis (TB) and control of the disease. Data recording and reporting is necessary to monitor trends in the TB epidemic at global, national and subnational levels; to monitor progress in the treatment of individual patients and groups (cohorts) of patients and ensure continuity of care when patients are referred between health-care facilities; and to plan, raise funds for, implement and evaluate programmatic efforts to control TB, including forecasting the numbers of cases and the associated requirements for staffing, medicines and laboratory supplies; and analysing treatment outcomes. When high-quality data are available, successes can be documented and corrective actions taken to address problems that are identified.

Recording and reporting data about people who have TB symptoms and those who are diagnosed with TB is, nonetheless, a data-intensive process. Treatment regimens span many months (or years in some cases), and patients need to take anti-TB drugs at least a few times a week and often daily. Compliance with treatment must be recorded regularly (daily for drug-resistant treatment and weekly for drug-sensitive treatment). The results of laboratory tests are needed for the microbiological diagnosis of TB; to determine the susceptibility of *Mycobacterium tuberculosis* isolates to anti-TB drugs; to monitor patient response to medication; and to determine cure or failure of treatment.

There is a strong tradition of recording and reporting in TB care and control. Building on the success of national model programmes established in southern and east Africa in the 1980s,[1] a standardized system for *paper-based* recording and reporting of the number of cases diagnosed with TB and their treatment outcomes was rolled out worldwide from the mid-1990s as one of the five elements of the World Health Organization's (WHO) DOTS strategy. DOTS – the internationally recommended strategy for TB control until 2006 – remains the first component and foundation of its successor, the Stop TB Strategy.[2] This paper-based system includes TB treatment cards that record information about the patient's history of treatment; TB registers in which data for all cases within a particular health-care facility are documented; quarterly reporting forms for sending summaries of aggregated data on notifications and treatment outcomes for all cases within a particular geographical area to higher administrative levels (up to national level); and well-understood supervision and quality control processes. Within a decade, more than 99% of the world's TB cases were being recorded and reported in countries that had adopted the WHO-

[1] Murray CJ, Styblo K, Rouillon A. Tuberculosis in developing countries: burden, intervention and cost. *Bulletin of the International Union against Tuberculosis and Lung Disease*, 1990, 65:6–24.
[2] Raviglione MC, Uplekar MW. WHO's new Stop TB Strategy. *Lancet*, 2006, 367:952–955.

recommended recording and reporting system.[1,2] Today, TB data are comparable across many thousands of treatment facilities worldwide, and WHO is able to report on the global TB epidemic and progress in TB care and control using the resulting standard datasets that countries report to WHO each year.[3]

The move to electronic recording and reporting systems

Since the mid-1990s, there have been transformational changes in information technologies and communication networks. According to the International Telecommunications Union, the number of Internet users reached an estimated 2 billion people by the end of 2010 (numbers doubled between 2005 and 2010) and the number of subscriptions to mobile phones reached 5.3 billion.[4] Most health-care workers in even the poorest countries are familiar with mobile phone technologies and many use them regularly in their daily lives. The spread of mobile and web-based technologies is dramatically reducing the barriers to implementing electronic systems that existed until the very recent past.

In this context, it is not surprising that there is growing use of and interest in electronic recording and reporting of TB data.

There are various potential benefits to be realized when TB data are captured and stored electronically, compared with paper-based reporting systems. The immediate benefits include:

Data quality. Transcription of data from one paper-based record to another is prone to error and there is no built-in mechanism for identifying and correcting mistakes. In an electronic system, validation checks can be an integral part of recording and reporting; for example, warnings may be generated when implausible or inconsistent values are entered, prompting the person entering the data to check and (if appropriate) correct information.

Workload. Aggregation and analysis of data and their reporting to higher administrative levels are tedious and labour-intensive tasks in paper-based systems. This problem grows rapidly as the number of patients being treated or the number of treatment centres increases. Electronic systems can reduce the workload involved by automating some of the tasks; for example, by generating report summaries and pre-specified checks for data completeness and validity;

Data access. Paper-based systems rely on quarterly reports of aggregated data. Data on individual cases or patients are thus not readily available above the level of a health facility. When electronic records are available, they can be transferred to and shared with anyone, whatever their location. This means that at national

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[1] *Global tuberculosis control: a short update to the 2009 report*. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.426).

[2] *Revised TB recording and reporting forms and registers – version 2006*. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.373; also available at http://www.who.int/tb/dots/r_and_r_forms/). The most recent WHO recommendations on recording and reporting for drug-resistant TB specifically were published in 2008 and 2011. See (i) *Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update, 2008*. Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.402) and (ii) *Multidrug-resistant tuberculosis (MDR-TB) indicators. A minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programmes*. Geneva, World Health Organization, 2011 (WHO/HTM/TB/2010.11).

[3] *Global tuberculosis control: WHO report 2011*. Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.16).

[4] *The world in 2010: ICT facts and figures*. Geneva, International Telecommunication Union (available at http://www.itu.int/ITU-D/ict/material/FactsFigures2010.pdf).

level, for example, a much richer quantity of data become available for analysis, interpretation and use.

Timeliness of information. Paper-based records take time to aggregate and transfer to higher levels of the system. Electronic systems can automate the aggregation process and save time and effort as well as reduce the possibility of errors in generating aggregate reports. In some electronic systems, when coupled with an electronic communications network such as a national web-based system, data can be made available instantly, in real time, and to many more people.

Flexibility. It is difficult to modify paper-based systems when recording and reporting requirements are updated. New printed materials such as forms, registers and reporting templates need to be developed, printed and distributed and older versions of printed materials removed from circulation. This can be a slow process. For example, five years after international recording and reporting guidelines were updated to include HIV status in TB registers and reports, many countries with paper-based systems were still unable to accurately report on treatment outcomes disaggregated by HIV status.[1] In contrast, with careful planning and the right skills, well-designed electronic systems can be modified relatively quickly.

Data analysis and reporting. When data are available in well-structured and well-managed electronic format, they can be imported into powerful statistical packages for analysis and research, and into geographic information systems (GIS) for mapping and spatial analysis and research. When data are stored electronically, it is also possible to automate the production of standard outputs and reports for use at different levels of the system (for example, at national, district and health-facility levels). Annual reports at the national level become much easier to produce and disseminate.

Managing complex data. The complexity of data has increased in recent years, especially with greater attention to diagnosis and treatment of drug-resistant TB. Data complexity is easier to manage in an electronic system, provided adequate data management procedures and staff are available. For example, an electronic system facilitates monitoring of drug dosages, changes of treatment regimen and assessment of treatment outcomes (outcomes for multidrug-resistant TB (MDR-TB) treatment are easy to compute electronically, but are very easy to get wrong using manual calculations).

Delivering more data more quickly and easily, with better quality and in an accessible format that allows a more thorough analysis are the potential benefits of adopting electronic systems for recording and reporting. If these "immediate" benefits are fully realized, other "bigger picture" benefits could result. Benefits could include better patient care, better programme management and better monitoring of trends in the TB epidemic nationally, regionally or locally. For example, staff could be alerted automatically using up-to-date information about treatment compliance or clinic visits so that they could take action to prevent a patient from defaulting from treatment; purchase of drugs and laboratory supplies could be based on close to real-time information, avoiding potential stock-outs; linking to other national health-management information systems such as those for HIV provides decision-

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[1] *Global tuberculosis control: WHO report 2011*. Geneva, World Health Organization, 2011 (WHO/HTM/ TB/2011.16).

makers with a richer picture of the health situation; linking to other local information systems such as laboratory and pharmacy systems makes key patient data available to clinicians; it could become easier for non-NTP care providers to notify TB cases. These benefits have already been realized and documented in many countries around the world and some examples are highlighted in this guide.

About this guide

While the potential advantages of electronic recording and reporting are considerable, so too are the potential pitfalls. Adopting electronic recording and reporting is not simply about choosing a piece of software: it is also about changing how people work. It may be difficult to even know where to start, especially in countries with no previous experience of introducing an electronic system for recording and reporting of TB data: what are the critical questions to ask? what are my options? what is recommended among the range of choices available? where can I go for expert advice and support? Without any guidance, it is easy to make mistakes, and those mistakes may cost considerable time, energy and money.

As interest in electronic recording and reporting for TB care and control has grown substantially, so too has the demand for clear guidance on how to select, design, implement and maintain such systems. However, while agencies such as WHO, the United States Centers for Disease Control and Prevention (CDC), the KNCV Tuberculosis Foundation (KNCV) and Management Sciences for Health (MSH) have helped several countries to introduce electronic recording and reporting (often with a specific focus on MDR-TB) and have convened meetings to facilitate sharing of experience among countries that have implemented such systems, there has been no published guidance on the subject.

This guide aims to fill that gap by providing practical advice for countries planning to introduce electronic recording and reporting systems, or to enhance existing systems. It is intended for the following groups of people, who are likely to be involved in the design and implementation of electronic recording and reporting systems for TB care and control:

- national TB control programme (NTP) managers and their staff, including district TB control officers, who are considering a switch from paper-based systems to electronic recording and reporting systems;
- procurement officers, legal officers, project managers and software developers who are working with NTP managers to commission an electronic recording and reporting system;
- health information system managers who are in charge of developing and implementing a strategy for electronic recording and reporting and eHealth[1] projects;
- consultants and technical agencies who are asked to support the development and implementation of information and communication technology for electronic recording and reporting systems.

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[1] Defined by WHO as the use of information and communication technologies in support of health and health-related fields, including health-care services, health surveillance, health literature and health education.

The guide responds to a clear mandate vested in WHO by the World Health Assembly. In 2005, the Health Assembly urged Member States to promote eHealth services and requested WHO to support Member States by disseminating best practices and guidelines.[1] More recently, and more specific to TB, the Health Assembly has promoted the strengthening of "health information and surveillance systems to ensure detection and monitoring of the epidemiological profile of multidrug-resistant and extensively drug-resistant tuberculosis and monitor achievement in its prevention and control" through both country and WHO action.[2]

The guide is structured in four major chapters.

Chapter 1 defines 10 critical questions that need to be asked and answered when considering the adoption of an electronic recording and reporting system and at the design stage (that is, before commissioning the implementation of a system). These identify the general scope of the system. Understanding and answering these questions does not require a high level of expertise in information technology (IT), but the answers are essential for the IT experts who will design and implement the system. The importance of each question is explained, the options to be considered are described and recommended approaches provided.

Chapter 2 defines 18 more detailed questions about the desired capabilities of the system, the resources that will be needed and the technical (IT-related) infrastructure that need to be asked and addressed at the design stage. The importance of each question is explained, the options to be considered are described, and recommended approaches are provided. With the exception of some of the infrastructure questions, understanding and answering these questions does not require a high level of IT expertise, but the answers are essential for the IT experts who will design and implement the system.

Chapter 3 explains how to set about commissioning an electronic system that meets the standards defined by answers to the questions posed in Chapter 1 and Chapter 2.

Chapter 4 provides guidance on implementing an electronic system, drawing on recent experience.

Throughout these chapters, country examples are provided to illustrate what the questions, options and recommendations mean in practice.

The guide also includes an Annex and is accompanied by a web appendix. The **Annex** explains the process that was used to develop the guide. The **web appendix** (http://www.who.int/tb/publications/electronic_recording_reporting/) contains complementary material and is a living resource to which new material will be added as it becomes available. For example, the web appendix includes links to WHO guidelines on TB recording and reporting, and in future will showcase particular systems (for example using videos and examples of outputs).

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[1] Resolution WHA58.28. *eHealth*. In: Fifty-eighth World Health Assembly, Geneva, 16–25 May 2005, Resolutions and decisions; annexes. Geneva, World Health Organization, 2005 (WHA58/2005/ REC/1):108–110. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf

[2] Resolution WHA62.15 *Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis*. In: Sixty-second World Health Assembly, Geneva, 18–22 May 2009, Resolutions and decisions; annexes. Geneva, World Health Organization, 2009 (WHA62/2009/REC/1):25–29. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA62-REC1/WHA62_REC1-en.pdf

Identifying general requirements

This chapter identifies 10 questions that need to be considered to define broad needs when planning to adopt electronic recording and reporting for TB care and control.

- **Organization:**
  - Is there a functioning TB recording and reporting system in place?
  - Who needs to provide overall oversight and participate in decision-making related to the adoption, design and implementation of an electronic recording and reporting system for TB?
- **Scope:**
  - What are the primary objectives of building an electronic recording and reporting system for TB care and control?
  - Who are the users and beneficiaries of the system?
  - Which patients will the system cover?
  - Which locations will the system cover?
  - Will the system be a stand-alone system or will it be integrated with other electronic systems?
  - What elements of paper-based recording and reporting should be maintained?
  - Is the basic unit of recording clinical data a patient, a case or a group of cases?
  - What data items need to be captured?

The importance of each question is explained, the options to be considered are described and recommended approaches are provided.

Understanding and answering these questions does not require a high level of IT expertise, but the answers are essential for the IT experts who will design and implement the system.

This initial activity may be time-consuming, but it will save time and resources in the long term. Together with the results of Chapter 2, it will help NTPs to develop clearly structured and justified proposals that can also provide a foundation for resource mobilization.

A. Organization

1.1 Is there a functioning TB recording and reporting system in place?
Rationale

When planning for a new electronic system, it is important to know the foundations upon which it will be built and to determine if there are any critical conditions that have to be met before even considering building a system.

Implementing an electronic system may expose weaknesses in the existing TB programme's recording and reporting culture, and these weaknesses need to be addressed before embarking on implementing an electronic system.

Recommendations

■ WHO-recommended case definitions and standards for recording and reporting of TB cases[1,2,3,4,5] should already be in place, either on paper or on a combination of paper and electronic systems.
■ National guidelines for TB care and control should already be in use in the country and should comply with updated, internationally-recommended norms.
■ Staff involved in TB care should already be familiar with the basic data items that need to be recorded and with established reporting and data monitoring procedures.

1.2 Who needs to provide overall oversight and participate in decision-making related to the adoption, design and implementation of an electronic recording and reporting system for TB?
Rationale

Introducing a new electronic system has long and far-reaching implications for the way people and organizations work. It affects many people, not just those who interact directly with an information system. The decision is therefore a strategic one and needs to be taken with involvement and support of a wide range of stakeholders.

Forming a decision-making body with representation from multiple stakeholders is an important step. The decision-makers need to understand the objectives of a new system, know what resources are available, understand existing working methods within TB treatment programmes (in both public and private sectors if relevant), be

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[1] *Revised TB recording and reporting forms and registers – version 2006*. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.373; also available at http://www.who.int/tb/dots/r_and_r_forms/).

[2] *Treatment of Tuberculosis: guidelines for national programmes*, 4th ed. Geneva, World Health Organization 2010:57–59 (WHO/HTM/TB/2009.420; also available at http://www.who.int/tb/publications/tb_treatmentguidelines/).

[3] *Multidrug-resistant tuberculosis (MDR-TB) indicators: a minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programmes*. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2010.11; also available at http://www.who.int/tb/challenges/mdr/programmatic_guidelines_for_mdrtb/).

[4] *Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update, 2008*. Geneva, World Health Organization, 2008:219–235 (WHO/HTM/TB/2008.402; also available at http://www.who.int/tb/challenges/mdr/programmatic_guidelines_for_mdrtb/).

[5] *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT and TB/HIV: standardized minimum data set and illustrative tools*. Geneva, UNAIDS, UNICEF and the Global Fund to Fight AIDS, Tuberculosis and Malaria, 2010 (also available at http://www.who.int/hiv/pub/imai/three_patient_monitor/).

aware of relevant infectious disease treatment programmes and reporting systems, and know about information-system regulations in the country.

Note that this decision-making body is not the same as those that will be needed during the development and implementation phases when more specialized tasks will be undertaken, such as user acceptance testing.

Recommendation

Establish a body with the appropriate competence, authority and with an adequate representation of all key stakeholders.

Country-wide systems. A national electronic system for TB needs to fit within a national framework for disease surveillance and for health information management. Key decision-makers, or sponsors, will be those within the national ministry of health responsible for public health. Health programmes other than TB (such as HIV) will need to be involved.

The decision-making body could take the form of a steering committee[1] with representatives from some or all of the following sectors:

- users and beneficiaries (including staff and patients) of the electronic recording and reporting system (**Section 1.4**);
- ministries responsible for health, disease surveillance and health information systems;
- tuberculosis control (e.g. NTP) at different administrative levels, including experts in managing the care of patients with TB and drug-resistant TB (DR-TB), plus representatives of staff who would have to use the system;
- TB care providers outside the NTP, such as private sector practitioners;
- health information technology specialists;
- laboratory networks;
- pharmacies or dispensaries;
- legal experts and IT experts knowledgeable about regulations and standards (including identification and confidentiality) governing information systems in the country;
- external agencies providing technical or financial support.

Local systems. Establish a steering committee with representatives from users and beneficiaries of the system (**Section 1.4**). Here it will be important to consider the input from the body responsible for managing an existing national TB surveillance system.

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[1] This body is referred to as the *Project Board* in PRINCE2 (http://www.prince-officialsite.com/) which is a formal approach to project management.

B. Scope

1.3 **What are the primary objectives of building an electronic recording and reporting system for TB care and control?**

Rationale

This is a fundamental and strategic decision that will determine the nature, design, content and complexity of the system to be commissioned. All subsequent decisions should accord with the primary objectives of the system.

Options

The primary objectives of an electronic system can range from a national to a local focus, for example:

- ■ **Improving surveillance and public health.** Examples include improving the coverage, quality and timeliness of data available to decision-makers on TB patients and their treatment outcomes, improving monitoring of trends in TB disease burden or enabling rapid responses to emerging problems.
- ■ **Improving programme and resource management at health-care facilities, subnationally and nationally.** For example, preventing drug stock-outs (**Box 1.1**) or relieving clinical staff from the burden of reporting.
- ■ **Improving clinical care of individual patients.** For example, improving day-to-day management of patient care at facility level (**Box 1.2**) or facilitating referrals from non-NTP providers.

Detailed goals and indicators can be associated with these primary objectives (see also **Section 4.5**).

Individual systems may span more than one of these areas; a detailed patient management system could feed data into a more general national surveillance system. Hierarchical systems are made up of multiple locally-focused systems whose data are combined at subnational or national levels.

Much of the focus in this document is on national systems for surveillance and management (which is the focus of the WHO Global Task Force on TB Impact Measurement[1]), but this does not detract from the importance of local electronic systems that support the delivery of diagnostic and treatment services for patients and that are able to feed data into national surveillance systems.

Recommendation

Clearly define the primary objectives of the proposed system.

1.4 **Who are the users and beneficiaries of the system?**

Rationale

The identification of users and intended beneficiaries of the system is closely linked to the objectives discussed in **Section 1.3**. It helps to identify which groups to consult and to involve during both the planning and implementation phases. Introducing an electronic system will change how some people have to work and may result in

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[1] http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/

Box 1.1

Electronic platform helps to prevent second-line anti-TB drug stock-outs in Brazil

The web-based e-TB Manager[a] system for programmatic management of drug-susceptible and drug-resistant TB was introduced in Brazil in 2004. It integrates case management, medicine control and epidemiological surveillance into a single platform.

The medicines module uses automated functions for calculating quantities to order, management of drug distribution, tracking inventories with expiry dates and documenting overall consumption quantities. This allows the national TB program (NTP) to avoid drug stock-outs over a specified time period. Unexpected delays in procurement are managed centrally by distributing adequate security (buffer) stock and matching the exact needs of each treatment centre with the number of patients enrolled for treatment, as recorded in the system.

The ability to monitor and manage second-line anti-TB drug supplies centrally using a web-based system in a continental-size country such as Brazil has made it possible to overcome many of the problems typically faced in second-line drug management.

FIGURE 1.1 **Drug supply management is a primary objective of the e-TB Manager system in Brazil** (source: MSH)

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[a] e-TB Manager was developed by MSH and introduced in Brazil in partnership with the Ministry of Health and the Helio Fraga TB Reference Centre.

changes to existing roles and responsibilities, and in the creation of new ones. Such changes need careful planning and management, so it is crucial to identify and involve all those affected.

Recommendations

■ Identify points at which the system will be used, for example:
  ● people entering data directly, at local level;
  ● people using the data directly while interacting with the system, such as a treatment supporter looking up a patient's address to plan a home visit, or a requesting physician receiving laboratory results;

Box 1.2

Electronic platform enables real-time monitoring of directly-observed treatment in the community

The Indus Hospital in Pakistan introduced a mobile-phone-based electronic system for recording and reporting of MDR-TB DOT (directly-observed treatment) data. The community-based programme involves treatment supporters visiting the homes of MDR-TB patients to perform DOT. Each treatment supporter is given a mobile phone containing software that allows them to enter DOT data electronically. These data can then be uploaded to the hospital's patient database in real-time over the phone network or, where mobile network connectivity may be unreliable, completed electronic forms can be stored on the phone and then bulk uploaded when connectivity is available. This method also allows real-time monitoring of treatment supporters to ensure that patients are being visited every day.

- people viewing or receiving reports (including graphs or maps) generated by the system, such as a data manager reviewing notification trends during the previous quarter, a pharmacy manager reviewing projected stock levels, or a programme manager at national level retrieving standard performance management reports;
- people extracting data from the system to conduct their own analyses using statistical or geographical information software;
- people viewing or using reports released into the public domain.

■ Identify all groups that will interact directly with the system by entering or retrieving data, and all groups that will benefit from the outputs of the system and who therefore have an incentive to use it. Examples of such groups include:
- Local (or facility) level:
  - clinical staff such physicians, nurses, medical assistants
  - patients
  - relatives or carers of patients
  - treatment supporters (**Box 1.2**),
  - administrative staff such as receptionists, dedicated data entry clerks
  - laboratory staff
  - pharmacy staff
- Subnational, national or international level:
  - district and regional TB managers
  - NTP management staff
  - ministry of health
  - funders of TB treatment programmes
  - national and international surveillance programmes
  - researchers
  - the general public (**Figure 1.2**)

FIGURE 1.2 **The NTP in the Netherlands makes aggregated reports, graphs and maps based on the collected data available to everyone via a public website** (source: http://www.tbc-online.nl)
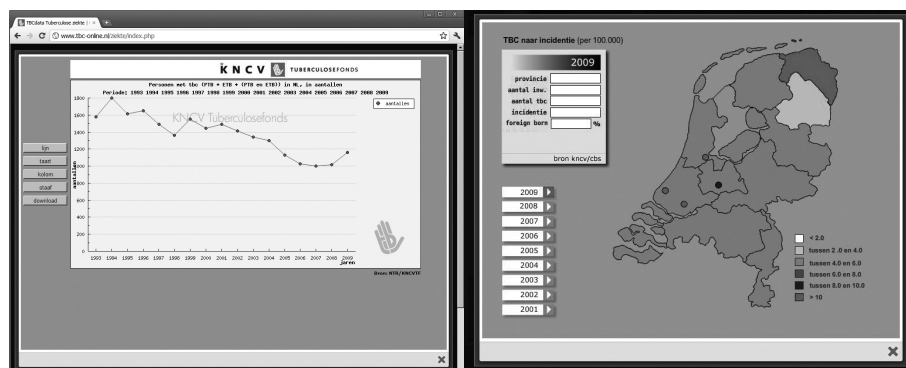
1.5 Which patients will the system cover?

Rationale

Many systems are constructed around the WHO-recommended district TB register, which provides a framework for registering individual data for TB patients requiring treatment.

Any system specification will need to define the intended scope, as this will influence the choice of aspects such as data sets, data flows, types of users, screens, outputs and work flows. Unforeseen changes to scope (and indeed to primary objectives) introduced after development and roll-out have begun could have a major impact on implementation of a system resulting in delays and increased costs. So system scope needs to be clear at the outset. This includes defining types of patients from which the system will be capturing information, which could also include patients who do not have active TB (for example, people with suspected TB), those with latent TB infection, people in known risk categories or contacts of confirmed cases.

Extending the remit of a system beyond TB patients increases the data entry and data management workload, so the benefits of doing so needs to be weighed against the additional costs.

Options

The system could include:

1. all diagnosed TB patients;
2. only a subset of TB patients, such as MDR-TB patients;
3. initially only a sub-set of patients and will be expanded at a later stage to cover all TB patients;

or

4. links to different systems covering different sub-groups of TB patients so that all TB patients are eventually covered for surveillance nationally.

In addition, TB suspects, patients screened for TB (regardless of result), sometimes systematically for occupational health purposes, or because of their HIV status, or contacts of TB patients could also be considered for inclusion in the system.

Recommendations

- Aim for coverage of all notifiable TB patients, microbiologically or clinically diagnosed, drug-susceptible or drug-resistant, based on national policies and case definitions.
- If this is not possible:
  - explain why coverage will not be universal, for example because certain settings have very specific or complex needs outside the primary aim of the system and operate under difficult conditions;
  - outline conditions or a timeline for if and when the system could be extended to include all TB patients;
  - make sure system specifications do not prevent future expansion to other case types.
- Establish a clear rationale if patients other than notifiable TB cases are to be included in the system.

1.6 Which locations will the system cover?

Rationale

The specific needs and conditions that exist in different settings may influence the decision on coverage. For example, the administrative structure in a country or the remoteness and lack of infrastructure of some of its regions may make it difficult to achieve nationwide coverage immediately or in the near future. On the other hand, the system could be built with the intention of including health-care providers who are not traditionally engaged with, or report data to, NTPs, such as hospitals or private general practitioners.

Options

The system could include:

1. all locations and all providers of TB diagnostic and care service (both public and private) in the country
2. only a subset of locations, defined by these categories:
   a. **Geographic location:** such as principal urban areas or specific districts within a country
   b. **Type of facility:** such as treatment centres, laboratories, pharmacies, hospitals, regional or national administrative offices (**Figure 1.3**)
   c. **Sector:** such as public treatment facilities, the private sector (**Box 1.3**), refugee camps, military establishments or prisons.

or

3. initially only a sub-set of locations and will be expanded at a later date to cover all locations in the country that provide TB diagnostic and care services.

Recommendations

- Aim for nationwide surveillance of all TB patients, either through nationwide coverage of a single system or via integration of information from multiple systems in the country.
- If this is not possible, describe why coverage will not be universal, and outline conditions or a timeline for if and when electronic recording and reporting could be extended to include all TB patients in the country.

FIGURE 1.3 **This shows the facilities using Romania's web-based system, which is based at the National TB Surveillance Unit. MDR-TB units and special facilities such as prisons also use the system. Hospitals are not shown because they do not use the system**
(source: Romania National TB Programme)
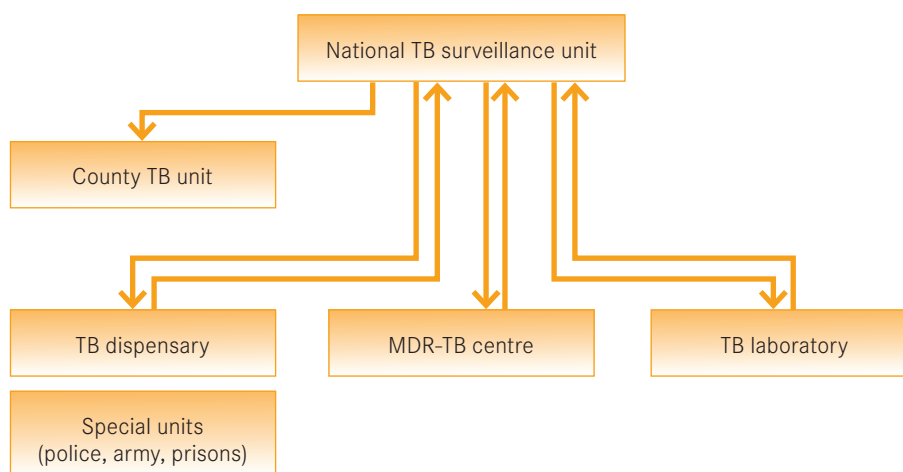
Box 1.3

Creating an opportunity to engage with the private sector

The Indus Hospital in Karachi, Pakistan, treats a large number of MDR-TB patients. It built an electronic system to help manage the complexity inherent in managing these patients.

In January 2011 it extended its electronic TB recording and reporting system to implement an incentive scheme to reward private doctors and community health workers for identifying and referring TB suspects, confirming TB cases and for ensuring TB patients successfully complete treatment. Family doctors and community health workers report their activities electronically using a mobile phone interface to the Indus Hospital system. Payments ('conditional cash transfers') are made via mobile banking facilities directly to the doctor or community heath worker's mobile phone.

The Indus Hospital reported a doubling of TB case notifications after launching the scheme.[a] Many of these cases would never have been notified in the past and their disease and treatment in the private sector would have remained unknown to the NTP.

[a]   http://www.stoptb.org/news/stories/2011/ns11_039.asp

1.7 **Will the system be a stand-alone system or will it be integrated with other electronic systems?**

Rationale

Electronic systems rarely exist in isolation. Knowing the broader information landscape helps to identify the key stakeholders who need to be involved when strategic decisions are made (as discussed in **Section 1.2**) and is an important factor when developing specifications for a new system. A number of systems which include elements of TB recording and reporting may already exist. These may have been built with a different primary objective, such as vital registration (especially mortality), HIV, pharmacy or laboratory data management (especially results of drug–susceptibility testing). Data from such systems may need to be made available within the TB recording and reporting system.[1]

Other examples of differentiation could be by sector (TB patients registered in a health insurer's system), or by funder (TB projects supported by a particular agency).

Options

The system could be built:

1. with mechanisms to send and/or to receive data from other systems; this is known as *interoperability* and is often made possible through the adoption of agreed data protocols and standards,
2. as a module or extension of an existing broader electronic system such as a national infectious disease surveillance system, or an electronic patient record system (**Box 1.4**, **Figure 2.1** and **Box 4.3**),

or

3. with no interaction or data exchange with any other electronic system.

Recommendations

■ Take a "whole system view" by mapping all existing paper and electronic systems that are relevant to TB care and control. This is especially important if TB services are fragmented with multiple service providers playing different roles.

■ Find out if the ministry of health (or its equivalent) has defined a national framework (such as an *Enterprise Architecture*[2]) for building and integrating health information systems, information systems requirements and an associated data dictionary, a set of commonly used and agreed terms (controlled vocabularies), or a national indicator repository into which the new system must fit.

■ Integrate systems whenever feasible[3] making sure that the benefits of doing so are clearly defined and that they are consistent with the primary objectives of the

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[1] See also *Framework and standards for country health information systems*, 2nd ed. Geneva, World Health Organization, 2008 (also available at http://www.who.int/healthmetrics/documents/framework/).

[2] An Enterprise Architecture defines the key elements and relationships in an organization (or a health information system), the methods for designing health information systems in terms of a well defined set of building blocks, including showing how the building blocks fit together and how the communication between the building blocks can be achieved. See *The Case for a National Health Information System Architecture; a Missing Link to Guiding National Development and Implementation* http://www.who.int/healthmetrics/tools/1HMN_Architecture_for_National_HIS_20080620.pdf via http://www.who.int/healthmetrics/tools/

[3] Such as TB and HIV. See *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT and TB/HIV: standardized minimum data set and illustrative tools* http://www.who.int/hiv/pub/imai/three_patient_monitor/

Box 1.4

The development of web-based surveillance of TB in China

The public health emergency caused by the SARS outbreak in 2003 highlighted the lack of actionable public health information and prompted the government to develop a real-time web-based Infectious Disease Reporting System (IDRS). The system was launched in 2004 for 37 notifiable infectious diseases, including TB. A case-based TB Information Management System, using the same web platform and linked to the IDRS, was launched in 2005. This replaced the previous paper-based TB quarterly reports.

By the end of 2010 the IDRS was used by over 68 000 health care facilities nationwide, including 97% of hospitals at county level and above and 82% of township-level clinics and around 25 000 new cases of infectious diseases are reported each day. Many of these facilities operate outside the NTP and in the past had not been notifying its TB cases to the NTP.

A total of 965 000 new and relapse TB cases were notified in 2009, accounting for 17% of the 5.8 million cases notified worldwide. This is up from 454 000 cases notified in 2000 and illustrates the scale of the system's achievement in dramatically improving TB notification rates.

FIGURE 1.4 **Depicts the dramatic rise in TB case notifications in China beginning in 2003, the first year where data were collected using the IDRS** (source: WHO global TB database)
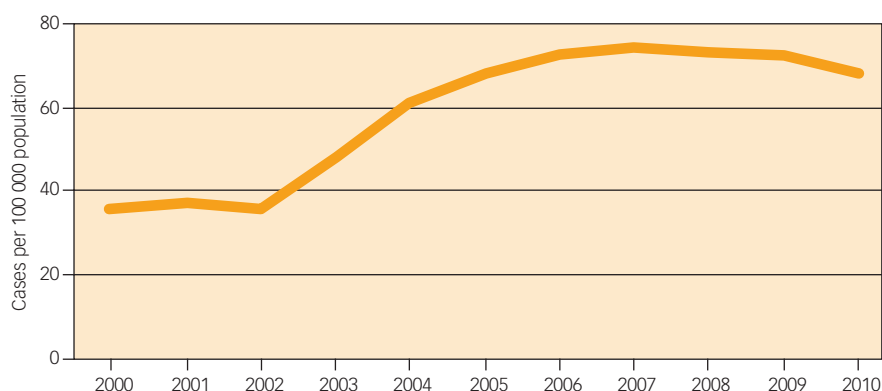
system as defined when answering **Section 1.3**. Factors to consider when deciding whether the benefits are justified by the effort needed to integrate systems include:

- available funding
- human resources
- IT infrastructure such as communications networks
- extent of the TB epidemic
- existence of other epidemics and associated systems
- health information policies within the country
- existence of data and systems standards for interoperability and data exchange

■ Identify which data items are essential ("non-negotiable") and which are desirable but optional for integration.

1.8 What elements of paper-based recording and reporting should be maintained?

Rationale

An electronic system usually needs to interact with paper-based records at different stages. There is often a hybrid of paper and electronic patient records, for example detailed patient clinical data held on paper, with a subset recorded electronically and then routine TB reports produced electronically (see **Figure 1.5** for another example). There may also be legal requirements for certain documents to be kept on paper.

It is unlikely that the ultimate goal would be to have a completely paperless system of recording and reporting for TB patients countrywide.

Standardized paper-based registers, forms and report templates have been long-standing features in DOTS and the Stop TB Strategy. TB control staff are familiar with their use. The robustness of these tools for record-keeping is largely attributable to the efforts spent over many years on using common case definitions and recording similar variables rather than the fact that data are collected on paper.

FIGURE 1.5 **TB case information in Georgia is collected at district level on paper forms. These are sent to regional level by regular mail where they are recorded electronically** (source: MEDES, France)
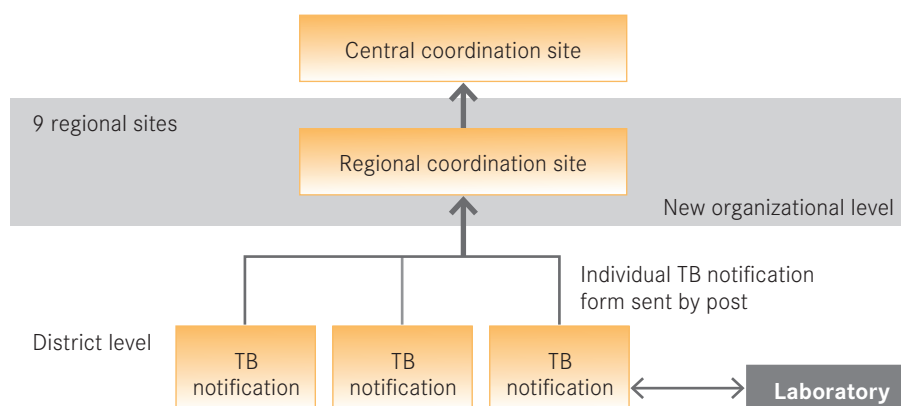
Options

Table 1.1 lists documents commonly used in TB control programmes and identifies which of these could be transferred to an electronic recording and reporting system. There are various types of recording documents to consider, for example:

- ■ **core patient details:** such as patient records and registers which form the basis of TB surveillance
- ■ **records of events:** such as treatment cards
- ■ **communications or messages:** such as notifications, referrals or requests for investigations which could be partially or wholly generated by an electronic system, either in digital or in printed format. Whether these documents are used digitally depends on whether related systems such as laboratory or pharmacy systems exist and can receive and act upon electronic messages(see also **Section 1.7**).

Table 1.1

Documents used in TB control

	Could be transferred to an electronic system?
Patient records	
Patient identification card	Possibly (2)
TB treatment card (including DR-TB treatment card)	Possibly (1)
Clinical records for TB patients	Possibly (1)
TB patient appointment card	Possibly (2)
Discharge letters from facilities	Possibly (2)
Patient registers	
Register of TB suspects	Yes
Register of TB contacts	Yes
District TB register	Possibly (3)
Laboratory registers (results for sputum smear, culture, drug susceptibility testing or Xpert MTB/RIF)	Possibly (3)
Patient referral	
Patient notification	Yes
Patient referral for TB care or specialist services	Possibly (1)
Request for investigations (radiology, smear, culture, DST, Xpert)	Possibly (4)
Drug prescriptions	Possibly (4)
Management of drugs and supplies	
Drugs and devices order form	Possibly (4)
Laboratory supplies order form	Possibly (4)
Drug stocks register	Yes
Laboratory supply register	Yes
Reports	
Managerial and operational reports	
Stocks of drugs	Yes
Stocks of laboratory supplies	Yes
Programme performance, supervision checklists, activity report	Yes
Routine reports	
Case detection	Yes
Sputum conversion	Yes
Treatment outcome and TB/HIV activities	Yes
MDR-TB indicators	Yes

(1) Only if electronic recording and reporting is routinely used for case management and recovery of electronic records is reliable at the point of care; if records are home-based then keeping to paper format is recommended.
(2) Only if electronic recording and reporting is routinely used for case management and patients can store appointment details, for example on their mobile phones.
(3) Only if electronic records are reliably available where the register is kept.
(4) Only if integrated systems exist between the requesting centre and the other services.

Print-outs from electronic systems may still be necessary, for example the patient identification card could be generated by an electronic system and printed. Alternatively, regulations in a country may require that paper records are kept and that electronic data can only be captured from paper records.

Recommendations

■ Check legal requirements to identify which documents have to be kept on paper.
■ Refer to **Table 1.1** when deciding which elements of TB recording and reporting are to be kept on paper.
■ Do not put the well-being and efficient management of TB patients at risk through a drive to completely eliminate paper recording and reporting.
■ Parallel runs using paper and electronic systems may be necessary during initial system roll out, but plan to restrict this to a limited testing period and to avoid a long-standing "pilot-project".

1.9 Is the basic unit of recording clinical data a patient, a case or a group of cases?

Rationale

The type of clinical information entered into the system has a direct bearing on the types of outputs it can generate. When the focus of the system is individual patients then a greater variety of reports can be produced compared to when the focus is simply the total number of cases seen by a facility in a given time period.

The system may also hold other data such as those related to programme activities, laboratory supplies, budgets or human resources where the unit of measurement will differ. This section focuses on patient-specific information.

Options

The basic unit of recording could be:

1. **Individual data** at the point of data entry.

or

2. **Aggregated totals only** at the point of data entry. Aggregated data are typically found in reports where the numbers of cases are the focus and individual details are not important; aggregated totals are not usually found at the point of data entry (**Box 1.5**).

The advantages of storing individual data include:

■ records can be used during clinical management of patients;
■ records of every encounter with a patient result in a detailed longitudinal profile for each TB case and enable case- or patient-based analyses (for example, mapping the location of new TB cases);
■ variables of interest can be added over time, such as risk factors like smoking status or the presence of diabetes, which can then be used to create new types of aggregated and dis-aggregated reports;
■ data quality checks can be implemented, for example identifying duplicate entries or identifying implausible data combinations such as pregnant men;
■ links can be made to records in other databases to retrieve additional information such as DST results from a laboratory information system;

Box 1.5

Phasing in of case-based recording and reporting in Viet Nam

The Vietnamese TB surveillance system (*VITIMES*) is being developed by the NTP, MoH and local IT companies in three distinct phases. The first phase provided district-level aggregated data entry. The second phase, under development in 2011, will provide district-level case-based data collection. The third phase will add other disease notifications to the system.

■ up-to-date drug management forecasts can be calculated and consumption monitored based on patients' real data, and these can be aggregated at any level of the supply chain.

Individual data could be stored as:

1. **Patient-based records:** this is where a *patient* (an individual person rather than a TB case) is the basic unit of recording. If there is a reliable, nationally-unique identifier for all or at least an appreciable proportion of TB patients when they present for care, such as an ID card number or social security number,[1] then records can truly be patient-based. If coverage of the system is national then the system could be built to recognize relapsed TB patients automatically using records of their earlier TB episodes; the patients' previous treatment history would be known accurately.

   Transfers between treatment units could be handled smoothly: the receiving unit will have access to the patient's details and overall the system will be able to calculate treatment outcome rates accurately. Moreover, if a national patient identifier is in use it can identify or prevent duplicate entries and make data exchange with other information systems much easier.

or

2. **Case-based records:** this is where a case of TB, and associated care and treatment information is recorded. There will typically be a case identifier held in the system to link various items of information related to the TB case, and this identifier may be confined to a limited part of the system (such as a treatment facility). This makes it difficult or impossible to identify previous treatment episodes automatically, particularly if the patient had been treated at a different facility.

A unique national patient ID is often not available, so a compromise could be to hold the detailed patient-based records at local or sub-national level and only key variables in case-based records at the national level. Alternatively, records may be matched at a higher level to identify duplicate patient records and corrected identifiers exported back down to lower levels.

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[1] At the time of writing, the Unique Identification Authority of India was implementing a project called Aadhaar to issue all residents of India a unique 12-digit identification number, with biometric data such as fingerprints and Iris scans used to validate identities
http://uidai.gov.in/aadhaar-technology.html

Another less useful option could be to hold the detailed patient-based records at local or sub-national level and only aggregated data at the national level, but this would limit the ability to detect duplicates or to link records of transferred patients.

Recommendations

- The ideal system would use patient-based records at the point of data entry using a **unique national personal identifier** that is also used by other information systems.
- If unique national personal identifiers are not available, but recognized and well-managed **sub-national or local** patient identifiers are in available (such as a hospital number), use patient-based records at the point of data entry.
- If patient-based records are not feasible then use case-based records at the point of data entry whenever possible.
- A system based on aggregated data at point of data entry will not offer the full benefits of electronic recording and reporting, and is not encouraged.

1.10 What data items need to be captured?
Rationale

System developers need to know about all data that will be held in the system. This will include a core set of variables needed to satisfy the minimal reporting requirements as per WHO recommendations. This includes the variables needed to calculate or generate indicators based on existing indicator definitions (including how they are calculated).

Recommendations

- Specify all data to be held in the system, including (see also **Figure 1.6**):
  - Data items for **programme management and TB surveillance at sub-national, national and international levels**, such as those needed to produce WHO-recommended reports. Some data items captured for patient and programme management at local level can feed into this level.
  - Data items for **patient management at local level**, such as address, HIV status, co-morbidities, treatment details and laboratory results. See **Table 1.2** below for some suggested patient management data items.
  - Data items for **programme management at local level**, such as staffing or activities. Some of these data items may only be needed at the local level whilst others may feed into the sub-national or national levels.
  - Data items for **work flow management and system administration**, such as names of health care facilities or names and roles of users. These will depend in large part on the technical solution selected and may not be easily defined beforehand.
  - Data items for **system monitoring and audit**, such as access logs and time stamps. These are usually captured automatically.

Note that some data items will not be immediately obvious until decisions have been made about workflows and data management processes (see **Chapter 2**).

- Develop a *data dictionary* and keep it up-to-date. This documents data items in terms of variable names, definitions, data formats, allowed values, codes and

FIGURE 1.6 **Screen shot of a user's home page in the e-TB Manager system showing the four main functional areas and associated data available** (source: MSH, Brazil)

categories. Identify relationships between data items (for example a patient has a name, but can be cared for by multiple treatment facilities).

- Identify the level (local, sub-national, national) at which each data item is needed.
- Include all data items needed to calculate or generate the currently-recommended core set of indicators (see footnotes on page 7) plus any needed for country-specific indicators based on existing indicator definitions (including how they are calculated).
- Identify which of the possible data items are absolutely essential to fulfil the objectives of the system and which items are desirable but optional. There is always a trade-off to be considered: additional data items increase the burden and associated costs of data entry. Bear in mind that the main purpose of the system is to manage day-to-day operations rather than to conduct research.
- If a new system is to replace an existing electronic system, identify the data items to migrate from the old to the new system. Migrating data can be difficult and time-consuming and it has to be done carefully and accurately, so it needs to be planned for at the very beginning of the project.
- It may be worth considering data items that may be needed in the near future, or other types of data that have become possible with recent technological advances, such as GPS coordinates or digital x-ray images. A realistic and practical list is more useful than an aspirational one because there are usually cost and compatibility implications when data items are added or modified (for example analysing trends over time becomes more difficult).

For example, in 2010 WHO endorsed the use of Xpert MTB/RIF as a diagnostic tool and, as this guide was being prepared (2011), WHO is reviewing TB case definitions and parameters for reporting. Electronic recording and reporting would also need to provide, among laboratory methods, options for registration of Xpert MTB/RIF results for confirmation of TB and resistance to rifampicin.

Table 1.2

Data items for patient registration and management at local level[a]

Geographical data	Region, district, facility, facility sector (such as *public*, *private*,...), facility type (such as *treatment centre*, *pharmacy*, *laboratory*, *prison*,...)
Identification and demographic data	Unique patient or case ID,[b] other patient IDs (e.g. related register numbers), name, address, telephone numbers, date of birth, sex, origin (such as *national*, *foreign*,...), criteria for assigning origin (such as *birth place*, *citizenship*,...), risk group (such as *prisoner*, *slum dweller*,...).
Clinical data	Date of first contact with health services, date of TB diagnosis, site of TB disease, previous anti-TB treatment (before current episode), HIV test, HIV test date, HIV status, is the TB patient receiving antiretroviral therapy?, is the TB patient receiving co-trimoxazole preventative therapy?, other important risk indicators and co-morbidities (such as *smoker*, *diabetic*,...).
Bacteriology data	Bacteriological confirmation, method (such as *smear*, *culture*,...), reason (such as *diagnostic*, *follow up*,...), date sample collected, date result determined.
Drug susceptibility data	Method (such as *solid media*, *liquid culture*,...), drugs to which resistance was tested (such as *rifampicin*, *isoniazid*, ...), date sample collected, date result determined, result (such as *susceptible*, *resistant*,...).
Treatment (summary) data	Date of start of treatment, treatment regimen (such as *first line*, ...), intermediate treatment result (such as *conversion*, *died*, *defaulted*,...), final treatment result (such as *cured*, *completed*,...), date of end of treatment.
Treatment (details) data	Drug taken, dose, date, observed.

[a] Note that this is not a formal data dictionary, nor is it a comprehensive data model as it does not specify all possible data items nor how these data items relate to each other. The data model for a *patient-based* system will be different to the data model for a *case-based* system.

[b] *Patient-based* systems use a unique patient ID whereas *case-based* systems use a unique case ID that may also be facility-specific.

Identifying detailed requirements

This chapter identifies 18 questions that need to be considered to define detailed requirements once the broad scope has been identified (see **Chapter 1**).

- **Capabilities**
  - Who enters data, where and when will data be entered, and how do data flow within the system?
  - What data quality assurance processes are required?
  - How is feedback provided to system users?
  - What standard outputs, reports and other analyses are required?
  - What are the data entry screen or interface requirements?
  - How will data confidentiality and security be ensured?
- **Resources**
  - What staffing is required?
  - What user support is needed?
  - What technical support is needed?
  - What level of service availability, response times and contingency planning is required?
  - What funding is required for both start-up and routine operations?
  - How long will electronic data be retained and will they be archived?
- **Infrastructure**
  - How is the electronic recording and reporting software made available to users?
  - What devices will users need to use the system?
  - What database software is required?
  - Where will the servers be located?
  - What communications networks are needed?
  - What are the electrical power needs?

The importance of each question is explained, the options to be considered are described and recommended approaches are provided. With the exception of some of the infrastructure questions, understanding and answering these questions does not require a high level of IT expertise, but the answers are essential for the IT experts who will design and implement the system. Case studies at the end of the chapter show how two countries have addressed these questions.

This initial activity may be time-consuming, but it will save time and resources in the long term. Together with the results of **Chapter 1**, it will help NTPs to develop clearly structured and justified proposals that can also provide a foundation for resource mobilization.

A. Capabilities[1]

2.1 Who enters data, where and when will data be entered, and how do data flow within the system?

Rationale

System designers need to understand the various processes and activities involved in TB care and how data flow within the system, including where data come from, who enters them, where they are entered, when they are entered and how often. System designers also need to understand the roles and responsibilities of users as they interact with the system and as data flows through the system, to know about approval and checking procedures.

Data may be generated in one place but only entered into a system at a later stage. For instance, a patient may be detected with TB and started on treatment in a rural health facility but only registered in an electronic system when paper documents reach the designated data entry point. The source documents may be registers (laboratory, pharmacy, cases) or the patient's medical notes, such as the TB treatment card or requests for sputum smear microscopy tests.

There may be more than one data entry point, for instance at health facilities and at laboratories. This is expected in particular for patients with drug-resistant TB where drug regimens are more complicated and in whom monitoring is more intensive and prolonged. Information may need to be retrieved from other health-information systems such as pharmacies or vital registration systems.

The administrative structure of a country plays an important role in workflows, particularly when data flow from local up to national levels. Each administrative level may, for example, implement its own checks as it consolidates its data before making them available higher up the chain.

The nature of data flow is also important. If a primary objective of the system is to provide real-time, up-to-date information at the national level, then data must be consolidated immediately at the national level and delays reduced to a minimum. This would preclude adopting a system that is based on subnational units sending their data to the national level at predefined, but long intervals such as monthly or quarterly.

It is also useful to estimate the size of data sets to be transferred, the number of transfers (for example, the number of treatment facilities sending data to district level each day, and the size of each delivery) and the workload placed upon staff. This allows system designers to plan for adequate data transfer capacity and for programme managers to plan for adequate human resources.

Options for documentation

The answers to questions **2.1** to **2.4** could be documented or illustrated in the form of *user stories* or *use case*s. User stories are short informal phrases about what a user tries to achieve in a particular situation; use cases describe in detail all interactions between users and the system, and include both inputs and outputs.[2] These help

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[1] The expression *Functional requirements* is often used to describe system capabilities; that is, what a system is to accomplish and how it is supposed to behave.
[2] http://en.wikipedia.org/wiki/User_story and http://en.wikipedia.org/wiki/Use_case

systems analysts and software developers to understand how the system is to be used and how users expect it to behave.

Another useful way of describing system behaviour is to illustrate how a patient "moves" through the system as they progress through various diagnostic and treatment phases.

Recommendations

■ Describe all the situations and activities in which data are entered into the system. For example:
  ● Directly, without the use of paper records:
  interactions with patients (e.g. consultations, supervision of medication)
  digital output of diagnostic systems (e.g. digital x-ray, GeneXpert instruments)
  ● Recording of data found in paper documents, such as:
    – TB treatment cards, or equivalent medical records of treatment
    – Laboratory request forms
    – Laboratory results received on paper forms
    – X-ray results received on paper and film
    – Patient transfers between treatment facilities
■ Describe who will need to enter data, and the workload involved. For example:
  ● examining physician
  ● nurse
  ● medical assistant
  ● community health worker
  ● administrative staff
  ● laboratory technician
  ● pharmacist
  ● patient or relative/guardian of patient.
■ Describe where, when and how often data will be entered. For example:
  ● during or immediately after consultation;
  ● during or immediately after supervision of medication;
  ● in the health care facility administrative office at specific regular intervals such as end of the working day, end of the week or end of the month;
  ● immediately after microscopy result is established;
  ● when patients are transferred from one treatment centre to another.
■ Aim for immediate data capture at source when it is generated, for example at facility level.
■ Identify and describe any data flows, for example:
  ● Data sets to be received from external systems, such as patient management systems, electronic health records, laboratory systems, pharmacy systems, other public service providers such as prisons and harm reduction services, and private service providers.
  ● Data sets to be sent to external systems such as electronic medical records, administration, finance, pharmacy (electronic subscriptions), laboratory (electronic test requests).
  ● Data sets to be sent from treatment facilities to higher administrative levels, such as treatment records or treatment outcomes sent to district level.

FIGURE 2.1 **Simplified overview of data flows in China's web-based system showing the two-way and real-time exchange of data between the Infectious Disease Reporting System and the more specialized TB Information Management System**
(source: Chinese Center for Disease Control and Prevention)
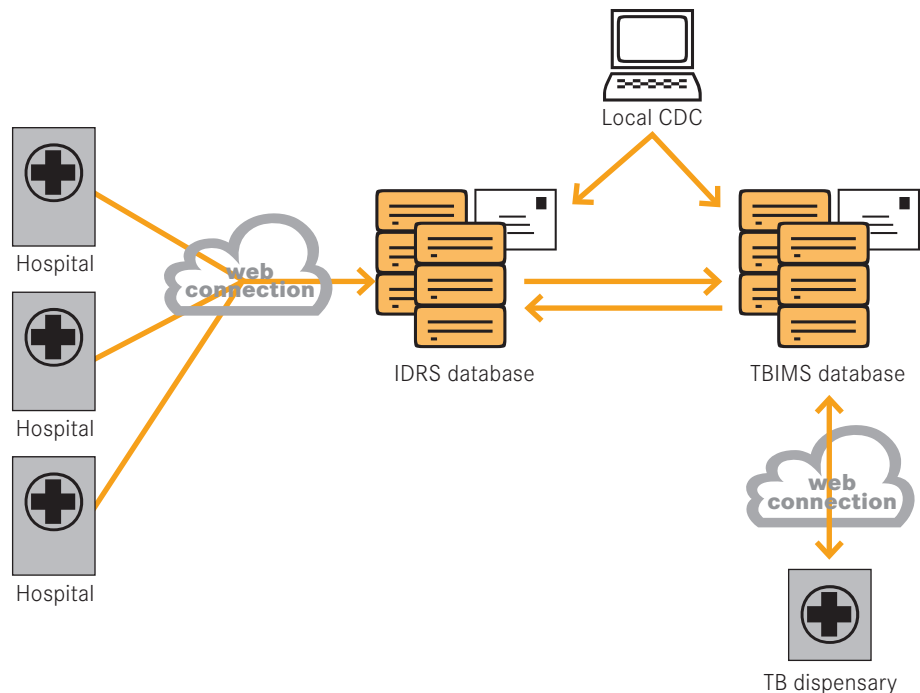
- Data sets exchanged between treatment facilities, for example when patients are transferred.
- Data sets to be received from mobile input devices (if not instantaneous).

■ Develop a diagram that gives an overview of data flows (**Figure 2.1** shows a simplified example). This is especially useful when data are combined in stages, such as when subnational levels maintain separate databases and then send their data to a separate national database. Working with systems analysts will allow for more detailed diagrams to be developed, showing how data move through elements of the system and how they are transformed as they move.

■ Describe how often data would need to be integrated at subnational or national level, for example:
  - in real-time (facilities connected directly to a national or subnational database);
  - at fixed-time intervals, such as hourly or daily.

■ Aim for real-time data transmission or consolidation wherever possible, or with the minimum amount of delay if real-time operations are not possible at particular locations. Therefore, use digital networks (such as the Internet or cellular phone networks) to transmit or consolidate data. Only transfer data physically using digital media such as memory sticks or CD-ROMs if networks are not available or are unreliable.

■ Aim for automatic integration or importation of data generated by other electronic systems (such as laboratory systems) without manual data re-entry.

2.2 What data quality assurance processes are required?
Rationale

Checking and approval processes are familiar in paper-based recording environments. For example, district supervisors regularly visit treatment facilities to cross-check laboratory registers and TB patient registers. Moving to an electronic system may mean replacing the existing processes of checks and balances with new ones. These will need to be fully described: the people involved, their responsibilities in the process, when they take place, how they happen, and what happens to records at each stage.

The concept of *data governance* is useful. It means thinking about the people, processes and information technology required to ensure that data can be trusted.[1] It is about putting people in charge of fixing and preventing problems with data and establishing clear responsibilities for data quality.

Options

Data quality assurance processes can be integrated into all levels of the system. Some countries may add extra emphasis to these by, for example:

■ Creating a national data management unit responsible for establishing and monitoring data quality procedures. Local or subnational data managers could also be considered.
■ Adopting systematic approaches to quality management such as those required for ISO9001[2] certification (**Box 2.1**).

Box 2.1

Developing a quality management system in the UK

The Health Protection Agency in the UK has been developing a quality management system under which the electronic TB surveillance system, amongst others, will operate. It is working towards ISO9001 certification of its quality management system. Key principles include:

● Commitment of senior management

● Audits and evaluation

● Comprehensive record-keeping to allow tracing of problems

● Customer-driven, allowing for complaints and feedback

● Documented development process and including tests for quality and user satisfaction

● Mechanisms for implementing quality improvement

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[1] http://en.wikipedia.org/wiki/Data_governance
[2] http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/quality_management.htm

FIGURE 2.2 **Part of a screen shot showing real-time validity checking at the time of data entry. The user is prevented from entering an invalid combination of dates and the error is explained, allowing the user to correct the date before it can be saved**
(source: Health Protection Agency, UK)

Clinical Details

Date of onset of symptoms | **Date first presented** | **Date of diagnosis**

01/03/2010 | | 03/02/2010

Date of diagnosis year cannot be before date of onset of symptoms. Please amend.

Recommendations

■ Consider how those responsible for data entry actually use the data. If they rely on the data for their work, they will be looking at the data regularly and will spot errors and have an incentive to correct them. If data entry is simply a one-way process for data entry clerks, other feedback mechanisms will be needed such as real-time data validation checks.

■ Define real-time data validation checks at the point of data entry, such as:
  ● enforcing data types (for example numeric fields cannot accept text);
  ● defining mandatory fields (such as a patient's name and sex) without which a record cannot be saved;
  ● defining plausible ranges for numeric variables;
  ● enforcing valid options for categories by using drop-down lists or tick boxes instead of entering free text;
  ● checking valid formats for some fields such as identifiers;
  ● defining hierarchies such as districts within a region;
  ● defining "skip" or conditional fields (for example, do not ask about drug regimens if a patient has not started treatment yet);
  ● checking for implausible or illogical combinations (for example, a male patient cannot be pregnant; date of diagnosis cannot be before date of symptoms onset) (**Figure 2.2**);
  ● deriving or calculating fields rather than requiring data entry (for example, if date of birth is known there is no need to enter the age of a patient, or if patient address is known the local authority is automatically derived).

■ Define system-generated deadlines and prompts such as alerting users to treatment outcome records that are due but have not been entered into the system yet so that these can be followed up to ensure data are entered without too much delay.

■ Define regular data validation algorithms to be run by designated staff at different levels (for example, data managers at national or subnational levels) and to be run at well-defined stages or frequencies with well-defined follow-up or clean-up

processes, and with full documentation of the results. Define algorithms to look for:

- missing items (**Figure 2.3** and **Figure 2.4**);
- inconsistent data (**Figure 2.4**);
- suspected duplicate records;
- misclassified cases (such as new cases recorded as re-treatment cases);
- unusual trends in key indicators such as notification rates;
- unusual distribution of key indicators and identifying outliers;
- assessing completeness or under-reporting (for example, using record linkage or inventory studies linking records to those in other electronic systems such as laboratory systems, mortality databases or HIV registers).

■ Define a specific type of unusual trend detection process to be run on a fixed, frequent schedule: an *outbreak detection algorithm*. This identifies unusual clusters of cases (geographically and/or temporally) and procedures for immediate investigation. It is useful to display any unusual trend using graphs and/or maps.

FIGURE 2.3   **A data quality monitoring report in China's TB Information Management System used to identify extent of delays in receipt of data** (source: Chinese Center for Disease Control and Prevention)

FIGURE 2.4   **Part of a screen shot from the e-TB Manager system showing a menu of missing data and data inconsistency reports, and the number of records identified by each report** (source: MSH, Brazil)

■ Establish external data checks involving supervisory visits to local facilities.

■ Agree record completeness targets, particularly for core data items such as age, sex, geographical location and type of case (for example, "these variables are complete for at least 95% of notified patients") and monitor the system to ensure these targets are met.

■ Define regular checks against samples of original paper documents, if relevant.

■ Ensure adequate resources will be available to carry out data quality activities: train staff so that all are aware of their roles and responsibilities; develop clear standard operating procedures (SOPs) for the various data quality processes. This helps to ensure uniformity of data quality mechanisms across all facilities using the system, especially when complemented by clear, up-to-date definitions of all terms and expressions used within the system. Some activities are specialized and time-consuming, so planning and budgeting for these staff is important (see also **Sections 2.7** and **2.11**).

■ Do not use double-data entry. It adds a considerable data entry burden, is only intended to prevent transcription errors, and is not necessary if the recommendations in this section are implemented and if data are in constant use. Remember that this is a system for day-to-day operations, not a system for research.

2.3 How is feedback provided to system users?

Rationale

An electronic recording and reporting system gains better acceptance if it helps and informs all those who use it, not just those at the national level viewing aggregated outputs. It is important to enable those tasked with data entry to have a direct stake in, and an incentive to ensure, the accuracy of the data they enter.

Recommendations

■ Make data entry an element of engaging users in an interactive system. Ensure data entry is not just a mandatory chore. If staff need to use the data they enter to carry out their daily tasks, data entry is no longer a passive, one-way process.

■ Think about who enters data: do they also need to use data in their work, for example to inform their decisions? Will they be adversely affected if data they see in the system are inaccurate? Will their work be made easier if they can correct data that are wrong? In other words, is there a feedback loop for those entering data so that data entry is not a passive, one-way activity? The analyses needed for workflows (**Section 2.1**), data quality processes (**Section 2.2**) and standard reports (**Section 2.4**) could identify feedback, such as:

● prompting users to act upon the data in the system, such as tracing missing data (**Figure 2.5**) or contacting patients who have not attended a clinic;

● making reports on standard performance indicators, such as case notifications, treatment outcomes or data completeness rates, available to all users so that staff within individual health-care units or districts can compare their performance with those of others regionally or nationally. This encourages two-way communications and shows staff how their work fits into a larger picture.

● higher administrative levels informing lower levels about data problems to be

FIGURE 2.5   **A user's home page in the England and Wales TB surveillance system. Alerts highlight pending data that have not been received so that this particular user can follow up to ensure all expected data are received** (source: Health Protection Agency, UK)
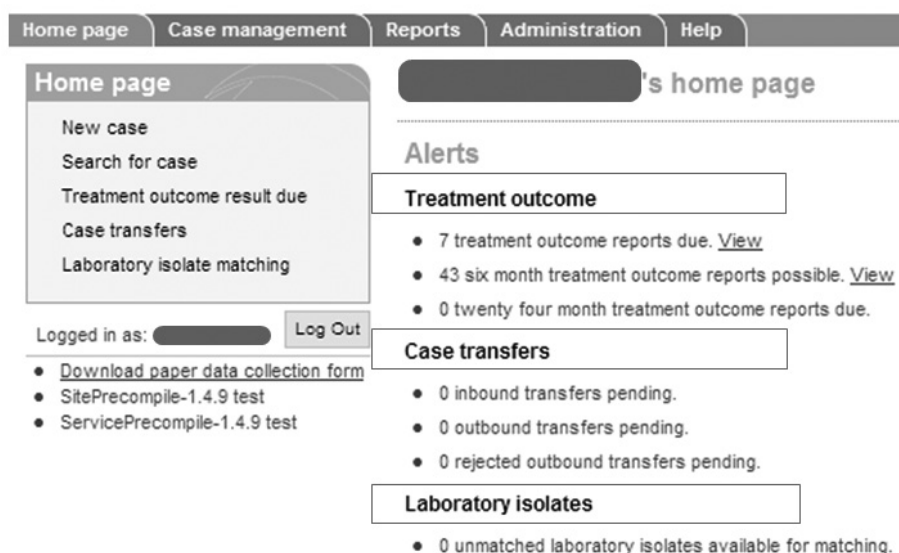
corrected, for example if higher administrative levels detect duplicated patient records.

2.4   What standard outputs, reports and other analyses are required?

Rationale

A core function of an electronic recording and reporting system is to show users accurate, timely and useful information upon which they can take meaningful decisions. Useful and actionable outputs transform a system from a passive repository of data into an engaging and interactive work tool.

Automatically producing standard reports allows more staff at all levels to understand what is happening and reduces the need for individual, detailed analyses to be conducted. However, staff will need training to understand and interpret system outputs, and how best to act upon them (see also **Section 2.8** which discusses training needs).

There are two key types of outputs to consider: **operational**, which are concerned with the daily activities of running a TB treatment programme, and **surveillance**, which are concerned with epidemiological analyses and trends (examples are shown in **Table 2.1**).

Options

Outputs such as alerts could be generated automatically based on triggering events or on a predefined frequency, such as daily or weekly. Outputs could also be generated on demand, such as when a manager needs to know the number of patients seen in a clinic during the previous week.

Table 2.1

Examples of operational and surveillance reports available within China's TB Information Management System (source: Chinese Center for Disease Control and Prevention)

Category	Examples of reports
Case detection	Notification of various types of pulmonary TB, patient source and suspect examination
Treatment and management	Sputum conversion, cohort outcomes, systematic management
NTP activity	Funding, training, supervision, health education
Drug	Quarterly drugs expenditure
Laboratory	Blind re-check of sputum smear results
Others	Basic information on TB dispensaries, human resources

Operational outputs can be tied to specific workflows for users, such as reminders, follow-ups and deadlines. Examples of actionable operational outputs include:

■ an SMS alert sent to a patient so that they do not miss their appointment;
■ identifying potential treatment defaulters so that they can be traced;
■ alerts for when sputum examinations need to be done for a patient according to the standard treatment guidelines;
■ tracking drug usage, expenditure (**Figure 2.6**) and stocks, and forecasting usage to prevent stock-outs;
■ data quality algorithms (as mentioned in **Section 2.2**) to identify and correct faulty data.

Surveillance or epidemiological reports are often based on the standard set of indicators that WHO recommends for TB case-finding, sputum conversion and treatment outcomes (**Figure 2.7** and **Figure 2.8**). Such reports (including tables, graphs or maps) can be generated routinely with minimum effort and with little risk

FIGURE 2.6   **Drug usage and expenditure report automatically generated by the Indus Hospital system** (source: Interactive Research for Development, Pakistan)

OpenMRS

Home | MDR TB

Another calculation

Drug Usage Calculation for **TUBERCULOSIS TREATMENT DRUGS** for **All patients in system (221 patients)** from **01/01/2008** to **31/12/2008 (365 days)**

Medication		Average Daily Usage	Total Quantity Required	Price per unit		Cost for this drug
Amikacin (Am)	AMIKACIN mg	67.1	24500.0 x $	0.5	=	$12250
Cycloserine (Cs)	CYCLOSERINE mg	75.3	27500.0 x $	0.75	=	$20625
Ethambutol (E)	ETHAMBUTOL mg	667.3	243600.0 x $		=	$0
Ethionamide (Eto)	ETHIONAMIDE mg	323.9	118250.0 x $		=	$0
Kanamycin (Km)	KANAMYCIN mg	367.8	134250.0 x $		=	$0
Ofloxacin (Ofx)	OFLOXACIN mg	1126.5	411200.0 x $		=	$0
P-aminosalyicylic acid (PAS)	P-AMINOSALICYLIC ACID mg	7320.5	2672000.0 x $	0.33	=	$881760
Rifampicin (R)	RIFAMPICIN mg	461.5	168450.0 x $		=	$0
					Total cost:	$914635

FIGURE 2.7 **Standard MDR-TB treatment outcomes report generated automatically by e-TB Manager based on filters chosen by the user** (source: http://etbmanager.org)

Treatment result of confirmed DR-TB patients starting 2nd line treatment - WHO form 7

Type of patient	On treatment	Transferring to another unit	Treatment completed	Failed	Defaulted	Died	Total
New	6	1	2	1	2		12
Previously treated with both first- and second-line drugs	12	1	3	2	4	3	25
Previously treated with first-line drugs only							0
Total	18	2	5	3	6	3	37

FIGURE 2.8 **Menu of reports based around standard surveillance indicators available in the web-based WEB-TBS surveillance system used by some countries in the Eastern Mediterranean region** (source: WHO Eastern Mediterranean Regional Office)

FIGURE 2.9   **The Indus Hospital MDR-TB system stores GPS-encoded locations of patients in its database and can display these data in a map** (source: Interactive Research for Development, Pakistan, not real patient data)

of computation errors, in contrast to the labour-intensive process needed to produce them when data are not recorded electronically.

Data in the system may be summarized in different ways in addition to the standard WHO format. For example:

■ The output may be in the form of tables or graphs

■ Geographic Information System (GIS) functions or web-based mapping services could produce maps showing where patient live by using data captured via GPS-enabled portable devices or by encoding patient addresses (**Figure 2.9**).

■ Displaying trends in notifications graphically using charts or maps is especially useful as it can identify unusual changes or spikes over time or in particular areas (**Figure 2.10**). Well-trained staff presented with good data visualization are often better than mathematical algorithms at identifying unusual patterns. This visualization is particularly important for detecting outbreaks, as discussed earlier, although staff such as surveillance officers will need training in analysis and interpretation of the data and the course of action to take, such as undertaking detailed cross-checking of data.

■ Performing analyses such as two-by-two tables or logistic regression for risk factors.

■ It may not be necessary for the core TB recording and reporting software modules to provide charting and visualization capabilities. Anonymous data could be exposed in a standard format (such as CSV or XML files[1]) without compromising the security or confidentiality of the data to be used by external software, such as statistical analysis packages, GIS, spreadsheets or data visualization software.

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[1]   CSV = comma-separated values; XML = extensible markup language.

FIGURE 2.10 **A set of time series of TB patient notifications by case type (new smear positive, new smear negative, etc., plus total) shows an unusual spike in total new pulmonary cases in a particular year. The graphs show that this is due to a sudden large number of cases recorded as "new pulmonary smear unknown or not done". Highlighting this visually can prompt staff to go back to the source records to fix the problem**
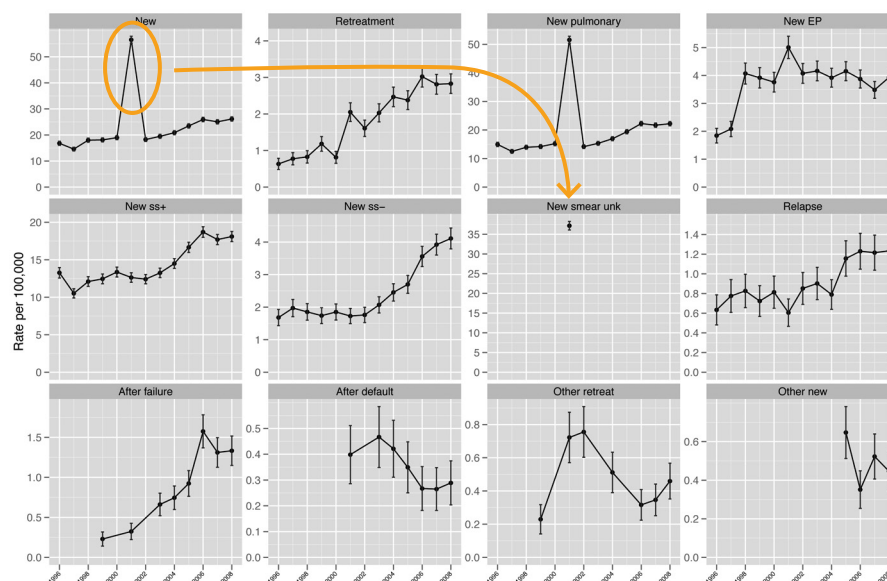
■ It may not be necessary for the core TB recording and reporting software modules to produce specialized reports that are only needed occasionally by a small number of people. These could be produced by external software packages once anonymous data have been exported to them.

Recommendations

■ Identify the audience for each output or report. Will the report be in the public domain or only available to users with appropriate access credentials? Which types of users (administrators, clinicians, laboratory technicians, surveillance officers, TB programme managers, etc.)? Which level in the hierarchy (local, district, regional, national)? Think about the needs of these different types of users. For example, a district programme manager would want to know about all patients transferred in or out of their treatment facilities, whereas regional-level staff may only be interested in transfers in or out of their region and not be concerned about transfers between facilities in a given district.

■ Define outputs needed for each type of user and at each level (local, district, national), with a particular emphasis on *actionable* outputs; that is, useful, understandable and timely information upon which action can be taken.[1]

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[1] The significance of having useful information is emphasised in the introduction (pages 1–4) of *Framework and Standards for Country Health Information Systems – Second Edition*. Geneva, World Health Organization 2008. http://www.who.int/healthmetrics/documents/framework/

■ Make sure the system will be able to generate standard indicators of programme performance with which NTPs are already familiar, such as quarterly cohort analysis.

■ Make sure visual displays such as graphs or maps of spacial and temporal trends and of potential outbreaks can be created, either within the system or by using external software such as statistical, visualization or GIS packages.

■ Train relevant staff to understand system outputs and know how to act upon those outputs.

■ Enable authorized users to conduct customized analyses or to produce customized reports, either within the system or by using external software.

■ Keep the data dictionary up-to-date to allow those conducting analyses to understand the data they are using.

2.5 What are the data entry screen or interface requirements?
Rationale

System designers need to understand how best to design the system's screens.

Recommendations

■ Discuss rough sketches of screens with systems analysts, developers and users to reach a joint understanding about what is expected of the system.

■ Display screens in a language with which staff are familiar. If more than one language is available, allow users to choose which language they want on their screens.

■ Use date or time formats with which staff are familiar, including provision for any non-Gregorian calendars.

■ Choose screen layouts that are compatible with or similar to standard paper–based TB recording and reporting forms, and compatible with electronic systems with which staff are familiar.

■ Test and refine interfaces to ensure optimum usability and user-friendliness.

2.6 How will data confidentiality and security be ensured?
Rationale

TB recording and reporting systems hold sensitive personal data on patients. Many countries will have laws on how confidential or personal data should be stored and accessed, for example by restricting access to sensitive personal information to those directly involved in a patient's care. There are various aspects of a system's operations where data confidentiality could be compromised, such as:

■ access to screens and reports;

■ physical access to data files;

■ data transmission via public networks or using portable media devices such as memory sticks, which can be lost or stolen.

Options

Techniques to consider include:

■ Role-based access to data: users of the system get access on a need-to-know and need-to-use basis. This identifies:

a. which data items, screens and reports a user is allowed to see;

b. which data items a user is allowed to add, edit or delete;

c. for which set of patients the access rights above are defined.

For example, someone working at a TB treatment centre could be prevented from seeing any patient who is being treated at a different centre. Someone working at the regional level could be allowed to see, but not modify, patient records from all treatment centres in that region, but not be allowed to see any patient records from other regions. Someone working at the national level could be prevented from modifying individual patient records, and could be prevented from seeing a patient's HIV status, or even prevented from seeing any personal data.

■ Training users in the importance of confidentiality and having them make a formal commitment by signing a document describing what they may and may not do with the data held in the system.

■ Keeping automated detailed logs showing details of all user interactions with the system, including logging in, viewing and modifying data so that there are clear audit trails and that security breaches can be traced.

■ Excluding access to personal data for those not directly involved in patient care.

■ Preventing direct access to physical data files so that the only access users have to the data is via screens and reports.

■ Physical security such as locking server rooms.

■ Secure data transmission methods to prevent others from seeing data sent from one computer to another by using data encryption across public networks (such as https[1]), by using a *Virtual Private Network* (VPN) across public networks or by using private networks.

■ Data encryption of physical media such as memory sticks.

Recommendations

■ Identify all legal requirements regarding data confidentiality.

■ For access to screens and reports, implement role-based access permissions combined with individual user accounts.

■ Restrict access to physical data files: these are best held on a server with no direct end-user access and not on a shared hard drive so that the only access users have to the data is via screens and reports.

■ Restrict access for users not directly involved in patient care to anonymous data only. Care should be taken that individuals cannot be identified through using the other variables in the data, for example through a combination of age, sex and location.

■ Ensure physical security (protection against theft) of all devices that store patient data.

■ Use secure data encryption methods whenever possible to prevent others from seeing data transmitted between computers.

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[1] Hypertext Transfer Protocol Secure. This allows web browsers to communicate with web servers securely and is commonly used with web-based commercial services such as banking.

B. Resources

2.7 What staffing is required?

Rationale

Staff at local, district and national levels will need to interact with various components of an electronic recording and reporting system. Some roles such as data entry, data management, data analysis or IT systems management may be new and require new skills. There will be an extra workload for some staff, especially for data entry. This change needs to be managed carefully.

An electronic recording and reporting system cannot function without adequately trained people (**Box 2.2**). It is crucial to identify the human resources needed to run the system and what skills they will need. This may depend on the solutions proposed by suppliers, but it is useful to describe any restrictions on staff tasked with managing or maintaining the system; for example, number, budget restrictions, location (can staff work remotely or do they need to be on site), security clearance, confidentiality agreements.

Options

In addition to the staff needed to develop and roll out a new system, there may be others who are needed, for example:

- to fulfil new roles, such as surveillance or monitoring and evaluation officers;
- to engage private and public non-NTP providers in using the electronic system;
- to establish a data management unit with staff dedicated to data management. The tasks of the unit could include:
  - managing and validating all national TB surveillance data for national monitoring, reporting and research;
  - defining procedures and protocols for all data management activities;
  - defining, maintaining and making available all indicator definitions;

Box 2.2

Staffing requirements in South Africa

An electronic recording and reporting system for TB (ETR.net) was introduced in South Africa in 2004. It incorporates data on notifications, patient medications, laboratory analyses and treatment outcomes. By mid-2011, there were close to 400 sites at district and sub-district levels entering data into ETR.net in all parts of the country, although not all facilities managing TB cases are included. Around 400 000 individual case records are added annually.

ETR.net is based on proprietary software and needs an in-country external agent for maintenance and development in addition to two full time equivalents employed by the TB control programme for day-to-day maintenance. There have been challenges using the system, for example because of limited capacity to do data analysis and, in some locations, lack of human resources to manage the data in the system. The workload of TB coordinators when using the system varies substantially but is largely due to differences in patient case loads.

- providing and maintaining the tools, and training staff at subnational level, to send notified TB patient details from subnational levels to national level;
- maintaining database and system security and integrity, including taking backups and developing disaster recovery plans;
- preparing and maintaining data files for monitoring, reporting and research;
- coordinating related activities with external partners;
- reporting on data management activities to the NTP manager.

Recommendations

- Identify roles required at each level for operating the system (such as data entry, data management, user support, IT support, project management), the terms of reference, skills required and number of staff needed. This includes both short-term (development and roll-out phases) and long-term needs.
- Develop a human resources plan with contingency for turnover to ensure the long-term sustainability of the electronic recording and reporting system.

2.8 What user support is needed?

Rationale

Users of the system will need help while they develop new skills and familiarize themselves with a new way of working, new work flows, and new roles and responsibilities.

The system may, for example, create new situations that did not exist before, such as timely identification of clusters of cases. Staff will need to know how to act upon the data presented in these new situations.

Options

Support mechanisms to consider include:

- training;
- providing "how to" guides or easy-to-follow SOPs;
- providing help desk or hotline services with defined response times;
- providing a web-based discussion forum (this proved to be a valuable resource when the NTP of Romania first launched its system);
- sharing experience with and learning from users in other countries that have moved from paper-based to electronic recording and reporting.

Some support activities could be done in-house using existing resources and some could be provided by external suppliers.

Recommendations

- Describe the level of help and support required for all types of users, and the source of support (whether in-house or outsourced to external suppliers). Some users will have very specific roles and tasks and therefore have different support needs, so consider how these various subgroups can be supported.
- Ensure staff are adequately trained in using their part of the system.
- Provide written material such as SOPs.
- Provide interactive help facilities such as a help desk or hotline with clearly defined and agreed response times, or a web-based user support forum.

2.9   **What technical support is needed?**
       Rationale

The technical infrastructure used by the system, such as PCs, printers, laptops, tablets, mobile phones, servers, network routers, power supply units, will need to be managed and any problems will need to be fixed quickly to ensure smooth operation of the electronic system.

Software maintenance is crucial. Bugs, changing requirements (such as the incorporation of new data items or reporting requirements) and availability of new techniques are in the nature of information technology and mean that any software deployed will change over time.

Options

A variety of **software licensing models** exist which define:

- who owns the software;
- who has the right to modify the software;
- the fees that should be paid for the software (for example, some suppliers will charge for each software copy that has been installed on a device, while others may provide *site licences* allowing any number of installations on devices owned and hosted by the software customer.)

Open source software allows programmers to change and adapt software and to fix bugs without needing the permission of the original software developers. This work is often done collaboratively, so that the software evolves as a result of the work of a community of programmers. Some of these programmers may already live and work in the country, so engaging them helps to build local programming capacity and reduces the reliance on specialists from abroad.

The choice of software licence can have a long-term impact on the development and evolution of a system (**Box 2.3**).

For more on software licensing schemes, see section 4.6.1 of the Health Metrics Network draft guide on procurement and acquisition for health information systems.[1]

Box 2.3

Software ownership and lack of resources to fund upgrades

Romania engaged a local company to build its web-based TB recording and reporting system which was launched in 2005. The system is being successfully used nationwide. However, it has been difficult to engage the original software developers to upgrade the system and to fix bugs due to NTP budget restrictions: the NTP's agreement with the original software developers did not include software maintenance and upgrades because the cost of such provision exceeded the available project budget at that time. The company has retained ownership of the source code and the NTP does not have the right to contract alternative software developers to modify the software.

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[1]   http://wiki.healthmetricsnetwork.info/wiki-kigali/lib/exe/fetch.php?media=background:hmn_ procurement_guide:hmn_procurement_guide_v5.2.doc

Box 2.4

Open source software allows development of local expertise

Medes, a French non-profit organisation, developed the TB surveillance system in Georgia using a software platform which it developed and which it then made available as *open source software*.[a] This opens up the possibility for Georgian companies to take over maintenance and further development the TB surveillance system which would reduce dependence on Medes and help to foster local expertise. In 2011, for example, a Georgian company began developing a system to send laboratory results from the laboratory information system to the TB surveillance system.

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[a] http://code.google.com/p/imogene/

A number of options may be available when deciding **who will be responsible for software maintenance**:

1. limited to the supplier: some suppliers may place restrictions through their software licences preventing others from having access to, or from modifying their programs (also called *source code*). If software suppliers do not allow access to source code, one way to guard against the risk of having unsupported software if the supplier goes out of business is for the supplier to place the source code in *escrow*;[1]
2. outsourced to other programmers, if this is permitted by the supplier; *or*
3. programmers within the NTP or ministry of health.

Options may also be available when deciding from where to get the **programming expertise** needed to maintain the system, for example:

1. local software companies (**Box 2.4**);
2. local programmers;
3. open source development communities; *or*
4. foreign experts.

Recommendations

■ Keep the system operational and fit for purpose by planning and budgeting for:
  ● **system administration** (such as regular backing up, network configuration, user account management or rolling out the system to a new TB treatment facility);
  ● **hardware maintenance**;
  ● **fixing software bugs**;
  ● developing **new functionality** in the software, such as adding new modules for specific patient groups, to support new activities, to provide new outputs

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[1] Escrow is where the source code is held by a third party who will release the source code if certain pre-defined conditions arise, such as bankruptcy of the solution provider. See for example http://www.ncc.co.uk/article/?articleref=500005

(for example graphing or mapping capabilities) or building links to other health information systems (see **Section 1.7**).

■ Establish mechanisms with those responsible for software maintenance to capture and manage bug reports and requests for new functionality:

● Define feedback channels (for example via a button in the software or a dedicated email address, or even via supervision visits or management meetings) for users to report bugs or to submit suggestions.

● Decide how information about reported bugs and suggested enhancements will be shared, and with whom.

● Agree how decisions to accept and implement or to reject suggested enhancements are made.

● Ensure that those responsible for software maintenance have well-defined and transparent procedures to log, track and act upon reported bugs, for example through the use of dedicated bug tracking software.

● Define severity scales and response times desired for each type of request, for example what length of delay is acceptable before a critical bug is fixed.

● Ensure that maintenance budgets include provision for bug-fixing and software upgrades.

● Check that software licences do not prevent the desired level of bug-fixing and software upgrading. Where funding is limited, ensure that there is at least provision or an agreement with the software suppliers to fix serious bugs that may not have arisen during the initial roll-out of the system.

● Ensure that up-to-date technical documentation of the system will be available and be maintained, particularly if programmers other than the original software developers will maintain and/or enhance the system.

2.10 What level of service availability, response times and contingency planning is required?

Rationale

Electronic systems may become integral part of work processes. This dependency carries the obvious risk that work may grind to a halt when there is a system outage. It is important to consider the consequences of system unavailability and to plan how people can continue to work during periods of system downtime.

Poorly-built or configured systems that cannot cope with the requested volume of work can be almost as bad as system downtime, with long delays between key presses and screen responses.

Options

There may be a choice in how to continue working when the electronic system is not available:

1. Use paper recording while the system is down and consider how and when data are entered electronically once the system is available again.

or

2. Some systems allow users to work offline when networks or remote servers are down; data are then uploaded to servers when they are available again.

Recommendations

■ Specify desired response times (for example, new page displayed in less than 3 seconds or report generated in less than 10 seconds).

■ Develop a business continuity plan that describes what to do if there is a major failure (such as extended periods of power cuts or more severe events such as a fire where servers are located); how daily work can be conducted; if an alternative electronic system would be put in place; if paper-based recording could be used as a temporary solution; how all data could be extracted and used to move to a new software solution.

■ Define and implement a regular backup schedule (for example, daily) and a regular backup-testing schedule (for example, quarterly) to ensure backups can correctly restore both the electronic recording and reporting software and its data.

■ Establish service level agreements with solution providers if the system servers are hosted at a professional data centre, and not hosted within NTP facilities. Service level agreements specify system *uptime* (for example 99.9% uptime during a calendar year, which is about 9 hours of system unavailability or *downtime* in a calendar year).

2.11 What funding is required for both start-up and routine operations?
Rationale

Funding needs careful consideration and long-term thinking to ensure that the system is sustainable beyond the initial implementation phase. A draft budget will need to be developed based on all the choices made (as covered in **Chapters 1** and **2**) so that funding can be secured. The budget needs to describe projected annual running costs in addition to start-up costs.

Recommendations

■ Develop a long-term budget identifying all possible costs and calculate a total cost of ownership (see **Box 2.5** and, for more details, see **Chapter 3**). It will be a challenge to develop an accurate budget, but it is necessary to identify all possible costs, both fixed and variable, that need to be covered if the system is introduced and the timescale over which they are needed, which include:

● capital costs: hardware such as input devices, servers, printers, power supply units, air conditioning, network routers and firewalls;

● hardware maintenance and replacement schedules;

● initial software development and ongoing software maintenance and upgrades, including long-term support (see also **Section 2.9** and **Box 2.5**);

● software licences, including any needed for operating systems, security and anti-virus systems in addition to any licences for the recording and reporting system itself (see **Chapter 3**). Note that if the software is in use in other areas of government, there may be a *site licence* allowing multiple installations of the software, eliminating the need to purchase additional licences;

● project management (especially during implementation and roll-out);

● procurement processes and legal fees;

● staffing, especially for data entry, data management, user support and system maintenance;

Box 2.5

Guidance material on funding for health information systems

The Health Metrics Network has developed a number of tools to help with assessing costs and sourcing funds for health information systems. These include:

- a detailed list of tasks that need to be considered in order to calculate the total cost of ownership of a proposed health information system. See http://wiki.healthmetricsnetwork.info/wiki-kigali/lib/exe/fetch.php?media=background:hmn_procurement_guide:annexa_tco.doc (or access it via the web annex at http://www.who.int/tb/publications/electronic_recording_reporting/)

- guidance and tools to support country applications to the Global Fund. See http://www.who.int/healthmetrics/tools/gfapplication/

- training;
- service costs (for example, power usage, Internet access, network usage, mobile network subscription charges and SIM cards);
- consumables such as paper and ink for printers;
- any specific additional costs (for example, conditional cash transfers for private general practitioners who refer TB patients to the NTP).
- Develop a long-term funding plan for the project as a whole to guarantee the sustainability of the system, including start-up costs, annual running costs and sources of funding. A gap analysis would be useful to identify where and when potential financial shortfalls occur. A long-term funding plan such as this can be used to approach potential funders to raise the necessary funds for implementation.

2.12 How long will electronic data be retained and will they be archived?
Rationale

TB recording and reporting systems are built for the long term. When large numbers of patient records are anticipated, such as in countries with a high TB burden, it is useful to have a policy on how long electronic records will be kept in the system.

There may already be well-defined mechanisms for the retention and archiving of paper-based records. It is important to define specific mechanisms for the retention and archiving of electronic records.

Some countries may have legal requirements for electronic data storage or archiving, and for how long those records are to be kept.

Options

Types of records that could be archived (each type could have a different retention policy):

- patient records;
- system access logs and audit trails;
- reports (e.g. aggregated notifications and treatment outcomes).

Retention policy for patient records:

1. Keep all records indefinitely.
2. Retain basic patient identification information such as IDs, name, sex and date of birth, and a summary of TB treatment episodes; but archive extra details after a defined period has elapsed since the last encounter in the system (for example, 10 years after the end of the most recent TB treatment episode).

or

3. Archive patient records entirely after a defined period has elapsed since the last encounter in the system.

Type of archives:

1. Electronic

or

2. Print records and archive the printouts, and delete the electronic records. This method could be costly and hard to maintain.

Recommendations

Plan for the long term and define retention policies for different types of data as listed above. If detailed electronic records are not to be kept indefinitely, specify secure archiving and retrieval processes while ensuring that system functionality (such as automatically identifying patients with a previous history of TB treatment) is not compromised and that all legal requirements regarding data retention in the country are fulfilled.

C. Infrastructure

2.13 How is the electronic recording and reporting software made available to users?

Rationale

Maintaining and upgrading software is inevitable: bugs are identified that need to be fixed, requirements change, for example if new case definitions are adopted. The logistics involved in rolling out updated versions of the application software to all users depend on the type of software chosen and, if not considered carefully, can result in a slow, costly and complicated process.

Licensing fees could also be associated with where application software is installed, so the type of user software chosen also has a bearing on cost (see also **Section 2.9** on technical support).

Options

1. Users have access to the system via **standard web browsers** such as Internet Explorer, Firefox, Chrome or Safari, which are now available on most web-enabled devices. The electronic recording and reporting system itself resides on a remote web server and not on users' devices.

   Advantages. All users have access to the same system and database. Updates and bug fixes are easy to roll out because they are applied to servers only and do not need to be applied to each user's device. User support is much easier and there are no dependencies on the specific configurations of users' devices. Server and data security and management can be carried out by dedicated professional teams.

   Disadvantages. There is a single point of failure: if servers are down or Internet connections are disrupted, the system is inaccessible. The web-based system may not work properly using old or non-standard-compliant browsers.

or

2. Users have access to the system via **dedicated application software that needs to be installed on each user's device** such as their PC or mobile phone. This is sometimes called *client software* and is becoming increasingly known as an *app* on mobile devices. The data may be stored remotely, but can often also be stored locally on each user's device. Client software can be quite complex, carrying out all data-related activities; however, it is also possible to have lightweight client software that provides a simple interface to the main application and data hosted on a remote server. Alternatively, client software can work with local copies of data and then synchronize at a later stage with a database hosted on a remote server.

   Advantages. The system can be used in the absence of network connections.

   Disadvantages. (on non-networked PCs in particular). Logistic difficulties in installing, testing, bug-fixing and upgrading software (for example, the addition of new data items) on all users' machines (particularly in remote areas of large countries), in supporting users (help desk) and diagnosing problems, and in handling the variety of PC configurations likely to be found, such as different

versions of operating systems, library files, peripherals, memory and hard drives. When there is a large number of client installations on PCs with no Internet access, it is highly likely after a few years that different, sometimes incompatible, versions exist on different PCs, making support and upgrading extremely difficult. It is also difficult to guarantee security of data when distributed over a large number of locally-managed PCs.

Recommendations

■ When Internet connections are available and reliable, use a web-based system with a standard browser interface (not requiring additional *plug-ins* or custom additions) or a lightweight *client* (such as an *app*) on networked devices, which can be easily updated, and which preferably does not require devices to have specific versions of an operating system.

■ When Internet connections are available and reliable, avoid heavyweight *client software*, especially those that have multiple dependencies (such as needing specific versions of an operating system or the presence of certain library or system files), unless updates can be rolled out easily over the web.

2.14 What devices will users need to use the system?
Rationale

With the increasing familiarity and use of portable devices such as mobile phones and tablet computers, desktop computers are no longer the only option for entering or retrieving electronic data. The spread of mobile phone networks to many remote rural areas means that mobile networks offer a viable and affordable mode of data connectivity (**Figure 2.11**).

FIGURE 2.11 **Both PC web browsers and mobile phones can be used with Georgia's TB surveillance system** (source: MEDES, France)
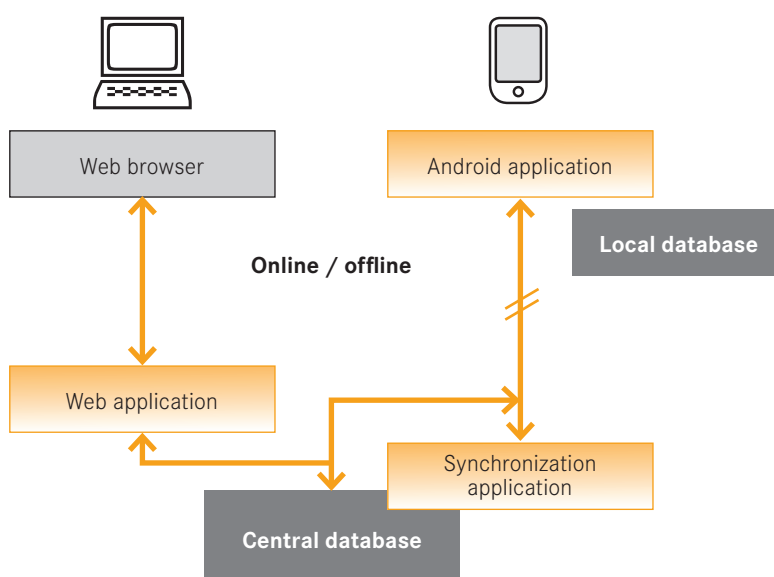
Box 2.6

Examples of using Personal Digital Assistants as input devices

A. Kenya

Data collection at district level takes place via small mobile computing devices called personal digital assistants (PDAs). District TB coordinators input health facility level data and send the data up to provincial/county level for aggregation and then inclusion in national aggregates. PDAs were being rolled out to more regions during 2011, although an evaluation has resulted in a decision to switch to using Android[a]-based tablet computers instead.

B. India

Using PDAs for TB data management was piloted in India in 2004. Users appreciated the benefits but the project also highlighted the challenges such as replicating changes in the data collection forms to the PDAs, customization of PDAs for each TB unit, the need for a central coordination and support team and commitment from the programme management team for implementation.

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[a] http://source.android.com/

Options

Types of devices:

- Interactive devices in which users can type in information or commands and can receive information from a central database:
  - fixed-location, such as desktop PCs
  - mobile, such as laptops, tablet computers, personal digital assistants (**Box 2.6**) and mobile phones.
- Electronic data capture only:
  - digital cameras
  - bar code scanners
  - digital x-ray devices
  - laboratory equipment, such as GeneXpert instruments
  - biometric sensors (such as fingerprint or iris scanners).

Recommendations

When deciding which devices to use, take the following aspects into account:

- **long-term sustainability:** hardware costs (initial and replacement, along with the required hardware replacement schedule – for example every three years), connectivity costs (such as SIM cards and payment plans for mobile devices), availability, maintenance and upgrade requirements;
- **location and security:** where do the devices have to be used (for example at a treatment facility or at patients' homes) and how can the risks of theft be minimized?
- **usability:** size and types of interfaces (text, graphics) that can be displayed;
- **connectivity:** does the device need to be connected to a network? Does the device provide access to web-based systems or is it restricted to using local (client) software (see also **Section 2.13**)?

- **reliability** and care needed when using the devices;
- **power needs** and, where relevant, battery life;
- **single- or multi-purpose:** can the devices be used for other activities?
- **type of data that can be entered**, for example GPS-enabled mobile devices that can also provide location coordinates;
- **operating systems that are supported:** are technical staff who are responsible for maintaining or configuring devices familiar with the operating system? Windows, for example, when not properly protected is prone to virus attacks making the device unusable and unsafe.

2.15 What database software is required?

Rationale

Data must be stored securely and reliably using a system that can store the amount projected to be needed in the long term and that can add, edit and retrieve data quickly enough for the expected growth in volume of requests.

Recommendations

- Use a robust, industry-standard, well-proven and scalable relational database management system providing standard functionality such as:
  - multiple tables of data with enforced relationships between them, such as patient demographic details and patient TB treatment;
  - *referential integrity*; that is, ensuring there are no broken links between data tables, for example making sure there is always a patient demographic record associated with each laboratory result;
  - allowing many users to have simultaneous access;
  - efficient and standard data definition and querying language, such as *Structured Query language* (SQL);
  - enforcing standard data types such as text, integer, float, date;
  - adding user-defined views, functions and stored procedures;
  - Unicode support to handle non-Roman scripts;
  - error-trapping so that if one part of a complex data change operation fails, the database reverts back to its state before the change was attempted;[1]
  - efficient indexing of tables and views for fast data retrieval;
  - sufficient storage capacity to hold expected data items for the defined retention period and to support the expected rate of data addition and retrieval operations;
  - robust role-based access permissions;
  - backup facilities (both full and incremental);
  - transaction logging;
  - administrative tools to manage all of the above.

Examples of such relational database management systems include (but are not limited to): Ingres, MySQL, Oracle, PostgreSQL and SQL-Server.

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[1] In the technical jargon, this means that database transactions are compliant with *ACID* principles of atomicity, consistency, isolation and durability.

■ Databases designed for small-scale personal use on a desktop, such as Epidata or Microsoft Access, are not recommended for large-scale multi-user national or subnational systems. They could be used as part of client software running on desktops in remote locations with no Internet access, but care is needed to prevent users from accessing or modifying data files directly rather than through the recording and reporting software interface.

■ Spreadsheets such as Excel are not relational databases and are not appropriate for data storage and data management.

2.16 Where will the servers be located?
Rationale

Servers are computers that hold an application's software and/or data and provide controlled access to these. Web servers provide access via web sites: users are not able to see the web server's software nor to navigate its filing system. Database servers provide data to applications without users needing direct access to database tables or queries and without having direct access to its data files. Web-based recording and reporting systems need both types of server. When properly configured and professionally managed, servers provide a secure environment in which to run information systems used by large numbers of people.

This approach is *scalable*: it is relatively easy to add more users to the system. Techniques exist to add additional servers when one server is not able to respond quickly to all the requests made of it. Such *load balancing* results in better response times so that users do not have to wait too long for the system to show new screens or reports. Servers are usually located (*hosted*) in secure, controlled environments, well away from where their users are found.

Options

Servers can be hosted by various entities such as:

1. commercial hosting providers
2. the NTP at national or subnational levels
3. ministry of health
4. research institutes

or

5. universities.

If the chosen solution is based on subnational levels maintaining separate databases that feed data to a national database, then hosting arrangements need to be considered for each of the databases used in this federated structure.

Cloud computing services are gaining momentum at the time of writing. Providers of these services manage their own servers and give clients access to software applications and/or data without clients needing to know which servers are being used, and without clients being allocated specific servers. Web-based e-mail services are an example of this. Commercial services (also known as *Software as a Service* and *on-demand software*) exist and these can be paid for by subscription fees based on some measure of usage (such as the number of users or the number of records edited, etc.).

Recommendations

■ Whenever possible, aim to host the electronic recording and reporting system's databases on database servers.

■ Identify any legal and institutional requirements for hosting. For example,
  ● is it acceptable for the entire application and/or its data be hosted remotely by a commercial hosting service?
  ● does the application have to be hosted by a specific agency?
  ● is it acceptable for the servers to be located in a foreign country?

■ If the software and/or database is to be hosted outside the NTP, describe clearly the conditions of data security, confidentiality and ownership of software and data hosted on remote servers, and ensure that all data hosted remotely can be retrieved and downloaded by the NTP.

2.17 What communications networks are needed?

Rationale

The electronic recording and reporting system collects data locally but needs to consolidate data nationally. Electronic networks are usually the most efficient way to transfer data, so identifying which networks can handle data communications is important.

Options

Possible networks to use include:

1. local area networks, such as when transferring data within hospital facilities;
2. the Internet (via cable, Wi-Fi or satellite);
3. landline telephone networks;

or

4. mobile (cellular) telephone networks.

Recommendations

■ Aim for real-time data transmission or consolidation wherever possible, or with the minimum amount of delay if real-time operations are not possible at particular locations. Use digital networks such as the Internet or mobile phone networks for data transmission or consolidation, ensuring that these can support data encryption, for example by using the https protocol or *virtual private networks* (see **Section 2.6**).

■ Only transfer data physically using digital media such as memory sticks or CD-ROMs if networks are not available or are unreliable (see also **Section 2.1**).

■ Check whether there are any legal or practical restrictions on using public networks such as the Internet or mobile phone networks.

■ Check if there are any bandwidth limitations, and time or cost restrictions.

■ Assess the volume of data to be transported between different parts of the system and assess the bandwidth and suitability of existing and planned communications infrastructure to carry those data. This needs to be done for all levels in the system (such as facility-level and central server level).

2.18 **What are the electrical power needs?**

Rationale

Potential software developers or system suppliers need to be aware of any problems, limitations, special features or particular requirements regarding power supply that would affect how hardware and software will be deployed and managed.

Recommendations

- Identify the quality and availability of electrical power at all the sites that will be using the recording and reporting system, and consider how power requirements for all components of the system can be satisfied, including:
  - data entry devices such as PCs or mobile phones;
  - printers;
  - database and web servers;
  - communication devices such as network routers;
  - cooling devices such as air conditioners in server rooms;
- Use *uninterruptible power supplies* (UPS) to maintain power to vital equipment such as servers, especially if power outages are common, and to allow those servers to be shut down safely when power outages are prolonged.
- Use surge protectors to protect all electronic devices, especially if power outages or fluctuations are common.

D. Case studies

2.19 Key characteristics of an established system in China and of a system under development in Kenya

These are *very brief descriptions* based on the key questions outlined in chapters 1 and 2. Full technical details are beyond the scope of these case studies.

A. China

The TB Information Management System (TBIMS), launched in 2005, is a web-based, case-based electronic reporting and recording system used by all TB dispensaries in China. It is linked to the nationwide Infectious Disease Reporting System (IDRS) and data about TB cases are exchanged between the two systems in real time.

1. GENERAL REQUIREMENTS	
ORGANISATION	
1.1 Is there a functioning TB recording and reporting system in place?	Yes, following WHO-recommended case definitions and standards. National guidelines for TB care and control are in use and staff involved in TB care are familiar with the basic data items.
1.2 Who needs to provide overall oversight and participate in decision-making related to the adoption, design and implementation of an electronic recording and reporting system for TB?	A decision-making body was formed led by the National Centre for TB control and prevention at the Chinese Center for Disease Control and Prevention (China CDC), with representatives of: staff who would have to use the system (such as administrative staff in TB facilities and TB control staff at different administrative levels); experts in TB and drug-resistant TB care; ministries responsible for health, disease surveillance and health information systems; legal experts and information technology experts with knowledge of the regulations and standards (including identification and confidentiality) governing information systems in the country.
SCOPE	
1.3 What are the primary objectives of building an electronic recording and reporting system for TB care and control?	**Improving surveillance and public health:** improving the coverage, quality and timeliness of data available to decision-makers; monitoring of trends in TB disease burden; enabling rapid responses to emerging problems.
	Improving programme and resource management at health-care facilities: reducing the reporting burden on staff; engaging and motivating staff who can act on live data, such as outbreak containment, identifying and preventing potential treatment defaults or contact tracing; improving analysis and planning at country and global level.
	Improving clinical care of individual patients: providing fast access to accurate, integrated patient data such as previous treatment history, latest laboratory results or current treatment compliance; better identification of patients requiring special treatment, such as HIV-positive TB patients or patients with drug-resistant forms of TB.
1.4 Who are the users and beneficiaries of the system?	**At the local level:** physicians, township supervisors, dedicated data entry clerks, laboratory staff, TB dispensary staff.
	At the subnational, national or international levels: district and regional TB managers, national TB programme management staff, ministry of health, national and international surveillance programmes.
	About 10 000 staff in TB dispensaries and designated hospitals use TBIMS directly. TBIMS exchanges TB case data with the Infectious Disease Reporting System (IDRS) in real time. IDRS is available at all health facilities and has around 68 000 users, so staff at public hospitals report on, and track the status of, TB cases.

1.5	Which patients will the system cover?	All diagnosed TB patients (including MDR-TB patients), plus tuberculous pleurisy patients.
		About 1 million patients are added each year.
1.6	Which locations will the system cover?	**Geographic areas:** the whole country.
		Facilities: all TB dispensaries (NTP TB treatment centres and TB laboratories) and all NTP administrative offices.
		Sector: all public sector TB treatment facilities.
		About 3 000 TB dispensaries and designated hospitals use TBIMS.
1.7	Will the system be a stand-alone system or will it be integrated with other electronic systems?	The system is not stand-alone. It sends and receives data with the IDRS in real time, so TB cases reported initially to IDRS are managed by TBIMS.
		There is a national framework for building and integrating health information systems.
1.8	What elements of paper-based recording and reporting should be maintained?	Both paper and electronic forms are used for district TB registers, laboratory results registers and patient notification. All other forms (clinical records such as TB treatment cards and discharge letters, registers of contacts and TB suspects, referrals, requests for investigations, prescriptions, drugs and laboratory supplies order forms) remain paper-based.
		Managerial, operational and routine reports are generated electronically and printouts are stored for backup.
1.9	Is the basic unit of recording clinical data a patient, a case or a group of cases?	Data at the point of entry are case-based records. The unique record identifier is the *notification number*.
1.10	What data items need to be captured?	Data held about individual TB patients include demographic details, clinical data (e.g. date of TB diagnosis, TB site, co-morbidities, previous treatment history), bacteriological data (e.g. sputum smear and culture results), drug susceptibility testing results and treatment outcomes.
		Data items, definitions, formats, allowed values and codes are documented in a data dictionary that is kept up to date.

2. DETAILED REQUIREMENTS

CAPABILITIES

2.1	Who enters data, where and when will data be entered, and how do data flow within the system?	Staff in all TB dispensaries at province, prefecture and county levels enter data using TBIMS. The patient-related data should be entered within 24 hours. NTP activity reports are entered within 5 days.
		Staff in public hospitals can enter data about TB cases using IDRS, which should also be done within 24 hours. This information is transferred to TBIMS in real time.
		All data are entered in real time into the central database located in China CDC.
2.2	What data quality assurance processes are required?	Real-time data validation checks at the point of data entry; supervisory site visits; establishing and monitoring record completeness targets; adequate number of trained staff available to carry out quality assurance processes; standard operating procedures have been developed and staff are trained to follow them.
2.3	How is feedback provided to system users?	**Staff involved in data entry:** use data found in the system for other tasks; are prompted to act (e.g. tracing missing data or contacting potential treatment defaulters); have access to reports on standard performance indicators so that their performance can be compared with others at regional or national levels.
		Staff at higher administrative levels inform those at lower levels about data problems.

2.4	What standard outputs, reports and other analyses are required?	Standard reports are defined, each with a known audience, for example national quarterly analysis reports are disseminated to all TB dispensaries at provincial level; standard indicators of programme performance (such as quarterly reports on treatment outcomes) can be generated; staff are trained to understand system outputs and how to act upon them; trained staff can conduct customized analyses or produce customized reports; data can be exported to external software such as statistical, visualization or GIS packages for analysis or to create graphs and maps; a data dictionary is available and kept up-to-date.
2.5	What are the data entry screen or interface requirements?	Chinese is used in all screens and reports.
2.6	How will data confidentiality and security be ensured?	The system is accessed using individual, not general, user accounts (usernames and passwords); role-based permissions define which data items, screens and reports different types of users can see and which data items they can modify; data storage devices are protected against theft; secure data encryption methods are used when data are transferred between computers or across the web (the system is accessed using a Virtual Private Network); user interactions are logged in audit trails.

RESOURCES		
2.7	What staffing is required?	A long-term human resources plan is in place to ensure long-term sustainability and a data management unit has been established with dedicated data management staff.
		Staff operating the system fulfil the following roles:
		National level: data management, user support and project management.
		Provincial and prefecture level: data entry, data management, user support and project management.
		County level: data entry, data management and project management.
2.8	What user support is needed?	Training (adapted to various user roles) is conducted; written and easily-accessible standard operating procedures are available; a help desk or hotline (via telephone or email) is available, as is a web-based discussion forum.
2.9	What technical support is needed?	The budget includes provision for system administration, hardware maintenance, fixing software bugs and software enhancements. There is a feedback mechanism for users to submit bug reports and to suggest enhancements. There is a mechanism to prioritise bugs and change requests, with defined severity scales and agreed response times. Technical documentation is available and kept up-to-date.
		The software is run under a commercial licence, with the supplier responsible for software maintenance.
2.10	What level of service availability, response times and contingency planning is required?	System response times have been defined (e.g. for network bandwidth of 24 Kbps: • at least 90% of response times for data entry are under 10 seconds; • at least 90% of response times for batch queries are under 15 seconds; • at least 60% of response times for report generation are under 60 seconds and at least 90% are under 120 seconds.)
		Backups are made on a regular schedule.
2.11	What funding is required for both start-up and routine operations?	There is a long-term funding plan and a long-term budget which includes provision for hardware maintenance and replacement, software maintenance (bug fixing, enhancements) and training. Human resources are covered by a separate plan.
		The annual software maintenance cost (carried out by a software company) is about USD 20 000.
2.12	How long will electronic data be retained and will they be archived?	At present all records are kept on the system. Records may be archived in the future.

INFRASTRUCTURE	
2.13 How is the electronic recording and reporting software made available to users?	It is a web-based system with access via standard web browsers.
2.14 What devices will users need to use the system?	Desktop PCs and laptops.
2.15 What database software is required?	The system uses Oracle database software.
2.16 Where will the servers be located?	At China CDC facilities.
2.17 What communications networks are needed?	Internet: via cables and wi-fi.
	Data are integrated into the national database in real time.
2.18 What are the electrical power needs?	Power from the national electricity grid is used for all components of the system (PCs, phones, printers, servers, network routers, air conditioning etc.). Uninterruptible power supply units and surge protectors are used.

B. Kenya

The TB recording and reporting system is currently paper-based at the health facility level, with quarterly reports aggregated manually at subnational and national levels. An electronic system based on district TB coordinators collecting case-based information from health facilities using Personal Digital Assistants (PDAs) or tablet computers began to be rolled out in 2009, but at the time of writing not all districts had made the transition. A national web-based system is being planned. (See also **Box 4.1**)

1. GENERAL REQUIREMENTS	
ORGANISATION	
1.1 Is there a functioning TB recording and reporting system in place?	Yes, there is a paper-based system following WHO-recommended case definitions and standards.
1.2 Who needs to provide overall oversight and participate in decision-making related to the adoption, design and implementation of an electronic recording and reporting system for TB?	A steering committee (technical working group) was formed at the national level with a key focal person to take the lead. The committee reports on progress and consensus to a policy making organ of the ministry of health. The steering committee includes representatives of: staff who would have to use the system (such as administrative staff in TB facilities and TB control staff at different administrative levels); experts in TB and drug-resistant TB care; ministries responsible for health, disease surveillance and health information systems; health information technology specialists; external agencies providing technical or financial support; training institutions; non-governmental organizations and the pharmaceutical sector.
SCOPE	
1.3 What are the primary objectives of building an electronic recording and reporting system for TB care and control?	**Improving surveillance and public health:** improving the coverage, quality and timeliness of data available to decision-makers; monitoring of trends in TB disease burden; enabling rapid responses to emerging problems; improving pharmacovigilance; enabling research; improving governance and accountability.
	Improving programme and resource management at health-care facilities: reducing the reporting burden on staff; engaging and motivating staff who can act on live data, such as outbreak containment, identifying and preventing potential treatment defaults or contact tracing; improving drug supply management and preventing drug stock-outs; improving analysis and planning at country and global level.

1.4	Who are the users and beneficiaries of the system?	**At the local level:** physicians, nurses, medical assistants, dedicated data entry clerks, pharmacy staff.
		At the subnational, national or international levels: district and regional TB managers, national TB programme management staff, ministry of health, funders of TB treatment programmes, national and international surveillance programmes, researchers.
		Around 300 users are initially expected to use the system.
1.5	Which patients will the system cover?	All diagnosed TB patients.
		About 100 000 patients will be added each year.
1.6	Which locations will the system cover?	**Geographic areas:** the whole country. All districts in the 215 TB control zones will use the system and all sites with web access will be able to view their data and reports.
		Facilities: all NTP TB treatment centres and administrative offices, all hospitals, all TB laboratories (via links to the laboratory information system).
		Sector: all public sector TB treatment facilities, all private sector TB treatment facilities, all prisons, all military establishments.
1.7	Will the system be a stand-alone system or will it be integrated with other electronic systems?	The system will not be stand-alone. It will exchange data with a laboratory information system. In the long term, the TB system will be integrated into the Ministry of Health's Health Information System which is also under development.
		There is a national framework for building and integrating health information systems.
1.8	What elements of paper-based recording and reporting should be maintained?	The proposed system will use electronic forms for district TB registers, patient notification, drug stocks register and laboratory supply register. All other forms (clinical records such as TB treatment cards and discharge letters, registers of contacts and TB suspects, laboratory results registers, referrals, requests for investigations, prescriptions, drugs and laboratory supplies order forms) will remain paper-based.
		Reports on drug stocks, laboratory supplies and treatment outcomes will be electronic while programme performance, case detection and sputum conversion reports will remain paper-based.
1.9	Is the basic unit of recording clinical data a patient, a case or a group of cases?	Case-based data will be entered into the interim PDA/tablet-based system. The final web-based system aims to collect patient-based data, although the unique national patient identifier has yet to be determined because national IDs are only issued to people upon reaching 18 years of age.
1.10	What data items need to be captured?	Data held about **individual TB patients** include demographic details, clinical data (e.g. date of TB diagnosis, TB site, co-morbidities), bacteriological data (e.g. sputum smear and culture results), drug susceptibility testing results, detailed treatment data (e.g. drugs, dosage, dates) and treatment outcomes.
		Data items, definitions, formats, allowed values and codes will be documented in a data dictionary that is kept up to date.

2. DETAILED REQUIREMENTS

CAPABILITIES

2.1	Who enters data, where and when will data be entered, and how do data flow within the system?	For the interim solution, district TB coordinators will enter case-based information from TB treatment facilities into a mobile device (tablet or PDA) during monthly supervisory visits to health care facilities. They later download the data onto local computers. Case-based data are sent quarterly to subnational (provincial) level electronically, where reports can be generated. Case-based data are then submitted to the national level.
		In the final web-based solution, case-based information could be entered at TB treatment facilities or by district TB coordinators. Case-based data are transmitted to the central server in real time, or after a short delay, depending on available network connectivity. There will also be modules for financial management and for pharmacies to capture consumption data.
		Information about sputum samples submitted for culture and drug sensitivity testing, and their test results will be exchanged with the laboratory information system.
2.2	What data quality assurance processes are required?	Real-time data validation checks at the point of data entry; automated deadlines and alerts; data validation algorithms run at regular intervals; supervisory site visits; establishing and monitoring record completeness targets; regular checks against samples of original paper documents; adequate number of trained staff will be available to carry out quality assurance processes; standard operating procedures will be developed and staff will be trained to follow them.
2.3	How is feedback provided to system users?	**Staff involved in data entry:** use data found in the system for other tasks; are prompted to act (e.g. tracing missing data or contacting potential treatment defaulters); have access to reports on standard performance indicators so that their performance can be compared with others at regional or national levels.
		Staff at higher administrative levels inform those at lower levels about data problems.
2.4	What standard outputs, reports and other analyses are required?	Outputs upon which action can be taken are defined for each type of user; standard reports are defined, each with a known audience; standard indicators of programme performance (such as quarterly reports on treatment outcomes) can be generated; visual displays (graphs or maps), including trends over time, can be created within the system; staff are trained to understand system outputs and how to act upon them; trained staff can conduct customized analyses or produce customized reports; data can be exported to external software such as statistical, visualization or GIS packages for analysis or to create graphs and maps; a data dictionary will be available and kept up-to-date.
2.5	What are the data entry screen or interface requirements?	All screens and reports will be in English.
2.6	How will data confidentiality and security be ensured?	The system will be accessed using individual, not general, user accounts (usernames and passwords); role-based permissions will define which data items, screens and reports different types of users can see and which data items they can modify; users will not have direct access to the data files; users not directly involved in patient care will be restricted to viewing anonymous data; data storage devices will be protected against theft; secure data encryption methods will be used when data are transferred between computers or across the web; user interactions will be logged in audit trails.

RESOURCES	
2.7 What staffing is required?	A long-term human resources plan is being developed to ensure long-term sustainability and a data management unit has been established with dedicated data management staff. The roles and responsibilities of staff required to operate the system at each level will be defined in the plan.
2.8 What user support is needed?	Training (adapted to various user roles) will be offered, along with a help desk or hotline (via telephone or email).
2.9 What technical support is needed?	The budget will include provision for system administration, hardware maintenance and software enhancements. There will be a feedback mechanism for users to submit bug reports and to suggest enhancements. There will be a mechanism to prioritise bugs and change requests, with defined severity scales and agreed response times, and a mechanism to manage and share information about bugs and change requests. Technical documentation will be available and kept up-to-date.
	Open source software will be used, with internal programmers responsible for software maintenance. They will use bug-tracking software.
2.10 What level of service availability, response times and contingency planning is required?	A business continuity plan is being developed which will describe what to do if there is a major system failure. There will be regular schedules for backups and for checking backups.
2.11 What funding is required for both start-up and routine operations?	There is a long-term budget which includes provision for capital costs, hardware maintenance and replacement, initial software development, software maintenance (bug fixing, enhancements), operating system and anti-virus licences, project management, staffing (including data entry, data management, user support), training and service costs (e.g. electricity, internet, mobile network subscriptions).
2.12 How long will electronic data be retained and will they be archived?	Patient records will be archived after a defined period has elapsed.
INFRASTRUCTURE	
2.13 How is the electronic recording and reporting software made available to users?	It will have two components: 1. A web-based system with access via standard web browsers. 2. Dedicated offline software installed on a user's device (such as a tablet computer) that can synchronize with the remote server when network connections become available.
2.14 What devices will users need to use the system?	Desktop PCs, laptops, tablet computers, personal digital assistants, digital cameras and barcode readers (the latter to be used mainly at the TB reference laboratory to read sample data).
2.15 What database software is required?	The main server will use MySQL database software. Tablet devices will use SQLite.
2.16 Where will the servers be located?	The main server will be hosted by the NTP but will also be mirrored to a server hosted by the Ministry of Health.
2.17 What communications networks are needed?	Internet (cables and wi-fi) and the mobile phone network.
	Data will be consolidated in real time into the national database, except when network connections are not available in which case data can be held on local tablet devices and uploaded to the national system when connections become available again.
2.18 What are the electrical power needs?	Power from the national electricity grid is used for all components of the system (PCs, phones, printers, servers, network routers, air conditioning etc.). Uninterruptible power supply units and surge protectors are used and spare batteries for tablet computers are available.

Selecting a solution

This chapter describes the procurement process for purchasing an electronic health information system. It gives a brief outline of solicitation, selection, negotiation and contracting, and gives pointers to more detailed documentation developed by the Health Metrics Network. It is aimed at those without any specialist expertise to understand the key issues to be considered during these phases, to make informed choices about the available options, and to work with specialists such as procurement officers, legal officers, project managers and software developers to ensure that the most appropriate solution is commissioned.

3.1 Looking for a solution

Once requirements have been defined (**Chapters 1** and **2**), the next step is to find an appropriate solution. It is likely that software already exists that provides most, if not all, of the technical requirements, but you may decide that you are looking for more than software delivery; for example, you may want a solution that provides and installs the necessary hardware and that provides the staff to administer the system.

The types of software solutions to think about include:

■ developing a new system ("custom development");

■ using or modifying existing software. This can be either a complete package or could be made up of individual software modules that are integrated to create the desired solution. *Open-source* components (see **Section 2.9**) are often focussed on achieving specialized tasks, and need to be combined with others in order to create a functional system (**Box 3.1**).

Software that needs to run on a server can either be hosted within the organization's IT infrastructure or can be outsourced to an external professional hosting organization.

Box 3.1

Integrating open-source components

The Indus Hospital in Pakistan used local programmers to create its system by adapting and integrating two *open-source* components: the OpenMRS[a] medical record system, and the OpenXData[b] data collection platform, which was used to develop data collection forms that can be used on cellular phones.

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[a] http://openmrs.org/
[b] http://www.openxdata.org/

The people who will carry out the work also need to be identified. Possible options are:

■ in-house staff (existing staff or those recruited specifically for the task);
■ individual freelance contractors;
■ commercial entities;
■ non-commercial entities (such as international agencies engaged in supporting TB control programmes).

The work includes various tasks, and different people could be used for different tasks. Tasks include defining requirements; software design, development, testing, support and upgrading; hardware procurement, installation, maintenance and upgrading; training; and system administration. All of these tasks need to be worked out (see **Chapter 4**).

3.2 Procurement

The Health Metrics Network (HMN)[1] has been developing guidance material on procurement of health information systems.[2]

These documents provide a wealth of detailed practical guidance. What follows is a very short summary of those documents. Readers are advised to consult the latest version of HMN's documents for full details (**Box 3.2**).

There may well be laws in place in your country that determine how you need to go about engaging the services of individuals or organizations. This will usually take the form of a bidding process by providers – such as competitive tender – following a "request for proposals" (RFP). This is required especially if the cost is projected to be above a certain threshold, to ensure an open and transparent procurement process.

HMN describes an RFP as "a document used to solicit bids for a project, goods, or services, whether it is a health information system, equipment procurement, or a feasibility study" and it "lays out the requirements, evaluation criteria, and evaluation process". In other words, it goes well beyond documenting the functional and operational requirements of the desired electronic system. It needs to be carefully drafted to ensure that the software delivered meets the needs of the users. HMN has produced a pro forma RFP document that you can use to develop your own RFP (**Box 3.3**) and also a document[3] listing in detail the various tasks that need to be considered in order to calculate the total cost of ownership of a proposed solution.

3.3 Choosing the solution

There will be a number of bidders competing for the work. HMN's documentation gives advice on how to assess the bids and provides a scoring sheet to help identify the best proposal (price is not the only consideration). The documentation also gives advice on contracts, and contract negotiation and pricing.

Conducting a competitive tender can be complicated and time-consuming. It will

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[1] http://www.who.int/healthmetrics/
[2] Draft versions are available at
http://wiki.healthmetricsnetwork.info/wiki-kigali/doku.php?id=background_documentation and also on the web annex at http://www.who.int/tb/publications/electronic_recording_reporting/
[3] http://wiki.healthmetricsnetwork.info/wiki-kigali/lib/exe/fetch.php?media=background:hmn_procurement_guide:annexa_tco.doc

Box 3.2

The Health Metrics Network (HMN)'s major keys to success for procuring health information systems[a]

HMN describes the greatest challenge throughout procurement as the "long-term sustainability of the Health Information System" and lists the following **major keys to success**:

- View technology as an integral part of a larger system, supported by adequate policies, funding, communication, and skilled leaders and staff.
- Create a long-term strategic plan for health information systems and technology.
- Maintain control of the purchasing process – demand good customer service.
- Understand the true and total cost of ownership – not just the cost of computers or software.
- Carefully match existing resources with the pace of implementation to allow for a sustained, incremental approach.
- Build local capacity to fully utilize the technology.

During procurement:
- Understand your country's holistic health information system needs, and buy a solution that addresses those needs.
- Buy what works best; expect vendors to prove their worth.
- Prepare contracts taking into consideration problems that will arise 5–10 years from now.
- Use [the HMN guide] to inform yourself throughout the complex process in which you are now engaging.

HMN emphasizes in its document that "organizational and not ICT (information and communication technology) needs drive the process" and to view software procurement as a **long-term engagement**.

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[a] http://wiki.healthmetricsnetwork.info/wiki-kigali/lib/exe/fetch.php?media=background:hmn_procurement_guide:hmn_procurement_guide_v5.2.doc

usually need the expertise of specialists such as procurement officers within your country or Ministry of Health, especially as countries have their own rules about procurement that have to be followed.

When deciding on a solution, it is useful to hear the experience of others who have used or who are using a proposed solution. Find out who has used a particular system (such as an NTP) or worked with a particular supplier and contact them for more information. Ask to talk to managers or users, or both. If your budget allows, consider visiting in person to see how it works, or ask for a remote demonstration over the web[1] so that they can show you some aspects of their system and you can see their screens while they talk you through them. Remember to ask about the issues discussed in **Chapter 2** such as data quality assurance, training, staffing, resources, and technical and user support.

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[1] This is possible using services such as GoToMeeting, Skype or WebEx.

Box 3.3

Table of content in HMN's template RFP[a]

Section 1 – Instruction to bidders
Contains 30 subsections such as schedule of events, enquiries, examination of bids, contract negotiation, and payment terms and schedule.

Section 2 – Current situation at MoH
Contains 5 subsections including current IT situation.

Section 3 – Scope of work
Contains 9 subsections such as critical success factors, modules to be implemented, project scope and data conversion.

Section 4 – Proposal format
Appendix A – Financial proposal cost sheets
Appendix B – Functional requirements
       Patient management
       Disease surveillance
       Registries module
       Administration module
       Additional modules
Appendix C – Data requirements
Appendix D – Reporting requirements
Appendix E – Operational requirements
Appendix F – Security requirements
Appendix G – Performance requirements
Appendix H – Business requirements
Appendix I – Legal and regulatory requirements
Appendix J – Technical requirements
Appendix K – General requirements
Appendix L – Training requirements
Appendix M – Maintenance and support
Appendix N – Forms
Appendix O – Non-disclosure agreement
Appendix P – MoH Law, bylaws and regulations

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[a] http://wiki.healthmetricsnetwork.info/wiki-kigali/lib/exe/fetch.php?media=background:hmn_procurement_guide:annexb2_sample_his_rfp.doc

3.4 Finalizing the agreement

Once a decision has been made, you need to negotiate prices, and set up and sign contracts with the provider(s). Non-commercial providers such as nongovernmental organizations (NGOs), international agencies or universities may prefer a memorandum of understanding. In all cases, fees and services to be provided need to be stated clearly, including licence fees, escrow arrangements (if applicable), hardware costs, installation fees, warranties, service-level agreements and long-term support. Full details are beyond the scope of this document, and this is where you will need procurement and legal specialists to guide the process.

Implementing an electronic recording and reporting system

This chapter discusses practical aspects to consider once the choice of an electronic recording and reporting system has been made. It includes examples of system development from various countries. Descriptions of factors for success and lessons learnt from implementing an electronic recording and reporting system are also provided.

4.1 The general implementation phases

The previous chapters focused on analysis, needs assessment and selection of an electronic recording and reporting system. This chapter addresses how to implement such a system. While conditions will vary across settings, there are some common themes relevant to all settings and systems. This chapter draws on the experience of countries and of technical agencies such as Management Sciences for Health (MSH) and KNCV Tuberculosis Foundation (KNCV) in implementing electronic recording and reporting systems for TB care and control.

Developing and implementing an electronic recording and reporting system is an iterative and evolutionary process. Change is a key feature and the technology will keep evolving even during the 1–2 years needed to make the conversion from a paper-based system to an electronic system.

This chapter describes the general implementation phases that are usually followed. The detailed steps within each project can be expanded or adapted according to the complexity of the proposed system and available resources, but the overall process will likely pass through four stages. This chapter will guide you through some key actions that should be taken, practical points for consideration and tips or lessons learnt from real-life examples for each phase of implementation.

The four general phases (**Figure 4.1**) are as follows:

- Planning (including needs assessment and selecting a solution)
- Development/Adaptation (including implementation of plan)
- Roll-out (including pilot phase, training at field and central level and scale-up)
- Maintenance (including monitoring, evaluation and evolution)

The four general phases are best thought of as a continuous cycle, part of a long-term process rather than a one-off event. Many of the key questions discussed in **Chapters 1** and **2** can be revisited with each cycle.

The four general phases can be broken down into more detailed steps that may be adapted to a particular country or situation to form the basis for an implementation action plan.

FIGURE 4.1   **The four-step cyclical implementation process used by Management Sciences for Health** (source: MSH)

Planning
Assess needs
Select solution
Develop action plan

Development/adaptation
Write or adapt software
Test and pilot
Develop training materials

Roll-out
Start operations
Train users

Maintenance
Monitor and evaluate
Upgrade software
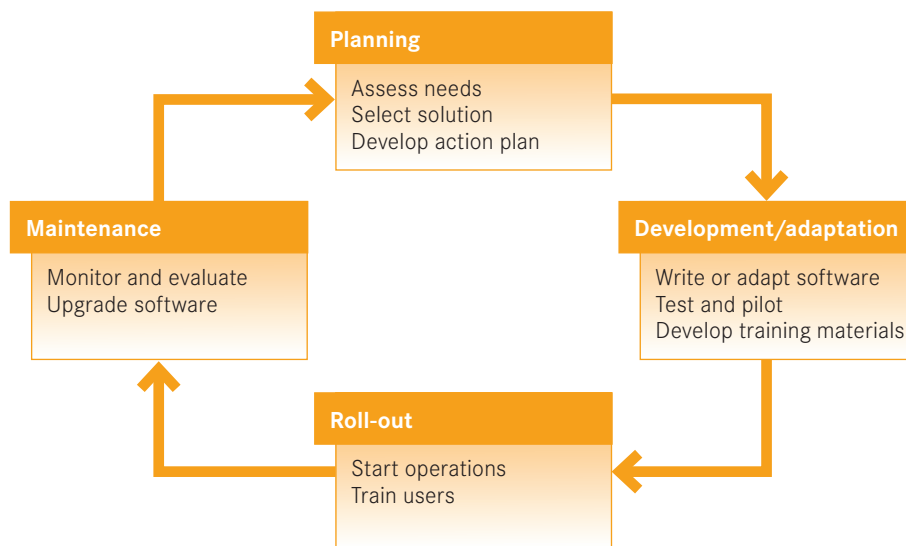
4.2   Planning

Action plan

In addition to an analysis of electronic recording and reporting system requirements (**Chapters 1** and **2**), and deciding who will build and roll out the system and finalize contracts with them (**Chapter 3**), an action plan[1] needs to be developed and agreed by the project's decision-making body (**Section 1.2**) to define and organize the implementation process. The action plan should cover the following points:

a) **System description:** Provide an unambiguous statement of the objectives of the system and detailed descriptions of the system. These will be based on the *functional and non-functional requirements*[2] identified through the analyses discussed in **Chapter 1** and **Chapter 2**, and documentation described in **Chapter 3**. All stakeholders identified in **Sections 1.2** and **1.4** as well as software developers need to reach a common understanding of what is being developed.

b) **Roles and responsibilities:** Identify all parties involved in system start-up, implementation and maintenance, such as the NTP, software developers, project managers, steering committee and end-users (see **Sections 1.2** and **1.4**), and describe their roles during each phase of the implementation. For example, define who has the authority to approve major changes to the project plan, who will be doing system testing, and who will be doing data entry, analysis, data management and system maintenance once the system has been rolled out.

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[1] The PRINCE2 project management approach uses something similar called a *Project Initiation Document.*

[2] Functional requirements describe what a system is to accomplish and how it is supposed to behave, such as data quality processes or production of reports, whereas non-functional requirements describe overall characteristics such as response times or security.

c) **Human resources:** Describe how many new employees or temporary contractors such as software developers or trainers are needed and when they will be engaged.

d) **Funding:** Describe short-term and long-term plans to cover the costs of all phases of implementation as discussed in **Section 2.11**. If funding comes from multiple sources, ensure all costs are covered across the various budgets. Include contingencies, for example to cover potential additional costs if implementation is delayed.

e) **Project plan and timeline:** Provide step-by-step details of all activities that will be carried out, including who will be involved in each activity, start and end dates, milestones and major products to be delivered ("*deliverables*"). Pay particular attention to training activities (IT, non-IT program management, data management, system use at the user level, etc.) and the phases of scale up (for example, going from two pilot sites to 10 sites to district or regional levels to full, nationwide implementation) (**Box 4.1**). Developing a detailed one-year plan with a broader-scale five-year timeline for both implementation and maintenance can be helpful, with the longer-term plan including regular reviews of the system and an adjustment mechanism.

Describe how and when the new electronic recording and reporting system will overlap with and/or replace existing paper-based systems, as discussed in **Section 1.8**. Replacement, if that is the ultimate goal, cannot happen overnight and a transition phase will be needed. Describe how recording and reporting will take place during roll-out, for example whether data will be recorded on paper and electronically at the same time, or whether some data will be transferred to the electronic system from paper.

f) **Expected outcomes:** Provide a clear description of expected outcomes or results. Initial targets or indicators may be process-oriented (for example, completing *deliverables* on time during roll-out; see also **Section 4.5**). Indicators to measure impact on health outcomes and programme performance are needed for longer-term assessments. There is a shortage of high-quality studies evaluating the introduction and use of electronic systems in health care to determine whether and how the advantages claimed for electronic recording and reporting systems are achieved. Indeed, a call to action was issued in September 2011 to "generate the evidence and promote the appropriate integration and use of technologies" for health.[1] Identify impact indicators if possible so that a rigorous impact assessment or cost-benefit analysis could be conducted.

Lessons learnt from recent experience:

- Establish a steering committee and involve all stakeholders identified in **Sections 1.2** and **1.4** in the design and planning process as early as possible. Holding a national workshop is one option to consider if the proposed system is to be implemented nationally (**Figure 4.2**). Engaging stakeholders early and often will maximize their commitment and involvement.

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[1] *Call to action on global eHealth evaluation: consensus statement of the WHO global eHealth evaluation meeting, 9 September 2011*. Bellagio, Bellagio eHealth Evaluation Group, 2011 (available at http://www.ghdonline.org/tech/resource/call-to-action-on-global-ehealth-evaluation/).

Box 4.1

Highlights from Kenya's plan to develop an electronic recording and reporting system for TB care and control[a]

Objectives

To develop, implement (by the end of 2013) and maintain a patient-based and web-based national TB surveillance system that provides high-quality information for evidence-based decision-making at all levels.

Phase 1: Initial steps to start the development of the system (2009)

- Initiate a stakeholder workshop to give input for the renewal of the TB surveillance system;
- Draft a plan and refine through consultation and feedback from field visits at different levels;
- Form a Technical Working Group to guide the development process.

Phase 2: Roll out an interim solution (2009–2010)

- Define data flows from district to province to national levels and associated database management;
- Refine a software tool using personal digital assistants (PDAs)[b] that has already been piloted;
- Roll out an interim PDA data collection platform that uploads data to subnational databases.

Phase 3: Update TB surveillance indicators and definitions (2009–2010)

- Review monitoring and evaluation surveillance tools (including registers).

Phase 4: Upgrade the interim solution to a nationwide web-based system (2011–2013)

- Evaluate phase 2 (note that in 2011 this evaluation resulted in a decision to switch from using PDAs to using tablet computers running the open-source Android operating system[c]);
- Roll out a web-based and case-based national system.

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[a] Source: *Development plan*. Ministry of Public Health and Sanitation, Kenya, 2009.
[b] PDAs are small mobile computing devices that predate "tablet" computers.
[c] http://source.android.com/

- Engage with "owners" or users of other related electronic systems in the country, such as HIV, drug or laboratory systems at the earliest stages of development, as discussed in **Section 1.7**. It may be possible to leverage each other's resources to benefit both or all parties, and there may be lessons learnt from implementing those other systems that could help your process.
- Appoint an experienced project manager[1] and/or a project management team to steer the complex implementation process; to ensure all the necessary stakeholders are consulted regularly; to continually monitor progress and use of resources; to establish and enforce change-management procedures; and to adjust

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[1] Formal project management approaches such as PRINCE2 (see http://www.prince-officialsite.com/ and http://www.best-management-practice.com/gempdf/PRINCE2_2009_Overview_Brochure_June2011.pdf) can be adopted, but a discussion of these approaches is beyond the scope of this document.

FIGURE 4.2   **National workshop on the development of the TB and drug-resistant TB surveillance system in Indonesia, September 2011** (source: KNCV)

plans where necessary to ensure that agreed milestones are achieved with the resources still available to the project.

- Make sure standard operating procedures (SOPs) for current recording and reporting are properly documented and up to date before starting the roll-out of a new system (see also **Section 1.1**). Plan for changes to current processes such as data entry, data quality assurance and reporting before the transition occurs, and develop new SOPs that will be used once the new system has been adopted.

- Plan to develop and disseminate training materials, *training-of-trainers* strategies, user manuals and technical documentation such as data dictionaries, and hardware and software configuration and maintenance manuals. This is vital for long-term sustainability and protects against loss of knowledge and skills caused by staff turnover.

- If external agencies are involved in the first steps of implementation, agree a clear exit strategy and a process to hand over these external agencies' roles permanently to parties within the country after ensuring that these parties have developed the capacity and have the resources to do so.

- Learn from others who have developed and rolled out similar recording and reporting systems. **Section 3.3** mentioned visiting other sites in the context of selecting a solution. These contacts and discussions could be extended for the planning and roll-out phases.

4.3 **System development and roll-out (including pilot phase, training at field and central level, and scale-up)**

There are various approaches to managing software development and testing.[1] Consider how best to establish regular milestones at which users of the system can see and try out what has been developed and to give their feedback. This helps to ensure that the software being developed is what was intended and is fit for the purpose. Regular and open communications between software developers and users are key.

Many factors need to be taken into account during the planning phase, which will affect the piloting and scale up approach chosen, such as size of the country, complexity of the system, the urgency of system implementation and available human and financial resources.

Training of all affected staff is critical for both piloting and scaling up. This covers both technological aspects, such as how to use the software, and procedural and management aspects. Staff need to not only understand how to input data, but also how to manage the data and use the data for decision-making. **Box 4.2** provides a list of data management topics that could be incorporated into training of users of the system such as district health officers, regional officers and NTP staff.

The pilot phase is a good time to test and improve staff training courses. It is much harder to change training approaches and materials once system roll-out has begun. A successful training approach may include a combination of system presentation, on-the-job training and mentoring, supportive supervision and remote support.

It is important to freeze versions of training materials and the system itself during the scale-up phase to maximize consistency in roll-out. As bugs are identified in roll-out, the team can fix them in a systematic way so as to avoid multiple versions of training materials or software in use at the same time.

The data management plan will need to be revised during this transitional phase

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Box 4.2

Sample TB data management activities that could be addressed in data management training

- Procedures to collect and validate TB surveillance data;
- Procedures to transfer TB patient information from subnational levels to national level;
- Reporting on data management activities to monitoring and evaluation and NTP managers;
- Managing and using indicator definitions;
- Ensuring compliance with data file security and integrity procedures;
- Preparing and maintaining data files for monitoring, reporting and research;
- (For staff at the national level, if relevant): Maintaining the database and ensuring backup procedures are implemented;

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[1] In the classic "waterfall" approach, most of the programming is done according to detailed specifications with little interaction with the final users until the software has been delivered. In "agile" approaches, programming is conducted in a series of short iterations lasting maybe one or two weeks, with frequent consultations with system users where each iteration produces a functioning software module. Projects can also use a mixture of these approaches. The merits and pitfalls of these approaches are beyond the scope of this document.

from paper-based to electronic recording and reporting. For example, will existing paper-held data be migrated over to the electronic system? If so, how and by whom? Are there enough trained staff available to carry out these tasks?

It is important to manage the sensitivities of staff during roll-out. Potential problems include:

- a reluctance to switch to a new way of working, especially if it upsets existing staff hierarchies, changes established workflows or conflicts with the culture of doing particular tasks;
- redundancies created by efficiencies generated through electronic recording and reporting may lower morale;
- reconciling the expectations of data management staff at different levels with those of the officers responsible for monitoring and surveillance;
- high staff turnover, making it difficult to ensure all staff are adequately trained;
- workers who are under-qualified or over-qualified for the new work to which they are assigned.

Roll-out may require an adjustment in how staff are managed. Providing a feedback mechanism for staff to voice their opinions, concerns and suggestions engages them in the implementation process and can be an effective way to identify and prioritize improvement to your system.

4.4 Maintenance (including evolution, monitoring and evaluation)
Maintenance

Once roll-out is "complete" and all sites have trained staff and are using the system, it is easy to think that your work is done. However, like a paper-based recording and reporting system, regular training, updating of the system, supervision and monitoring is needed to make sure the system remains fit for purpose.[1]

Plans, budgets and personnel are needed for upgrades, troubleshooting, bug-fixing and improvements, covering both hardware (such as PCs, servers, modems) and software (such as updates to security or anti-virus software on desktop computers, and updates of the electronic recording and reporting platform itself). It is best to have trained staff or contractors available in the long run to oversee or carry out necessary upgrades to both the hardware and software. If an open-source system is not being used it may be necessary to plan and budget for monthly or annual maintenance fees or contract renewal fees that are paid to the owner or developer of the software system (see **Sections 2.7–2.11** and **2.13** for a detailed discussion of these matters).

A long-term maintenance and evolution plan will help to lay down the ground rules for a successful roll-out and ongoing implementation. It is also important to develop change management processes such as a system to record and track all requested and implemented changes to the system (adaptations, fixing bugs, upgrades, etc). Such a tracking mechanism allows for rapid review of the maintenance situation at all levels of the system (reported bugs or requested changes) and allows for transparent

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[1] A set of standards called ITIL for "identifying, planning, delivering and supporting IT services" (http://www.itil-officialsite.com/AboutITIL/WhatisITIL.aspx) is being increasingly used by providers of IT services and may be useful for those responsible for managing the IT component of the TB system.

and organized documentation of these changes, such as actions taken and necessary approvals given (see also **Section 2.9**).

Plan for the worst case scenario and develop a *disaster recovery* or *business continuity* plan. What happens if the server crashes? The NTP building burns down? Funding is cut? Walk through every bad scenario and develop a strategy to address it. Spell out and implement the actions needed to address these contingencies.

Regardless of the initial funders, it is useful to develop and maintain a funding plan which lays out the role of each responsible party in the long-term (see also **Section 2.11**). It may be appropriate to set up a memorandum of understanding or contract to formalize agreements for financial commitments as well as for technical or managerial responsibilities.

Evolution

It is likely that NTPs will want to add new aspects or functions to their electronic recording and reporting system (**Box 4.3**). For example, a country may start with an electronic recording and reporting restricted to MDR-TB patients and then decide to expand the system's scope to include all TB patients. Small changes can likely be folded into regular maintenance plans for the system. However, major upgrades will likely need a new round of the implementation cycle – planning, development, piloting, roll-out, training, and maintenance (**Figure 4.1**) – which takes you back up to the beginning of this document.

Monitoring and evaluation

Like any new approach or intervention, the implementation of an electronic recording and reporting system requires monitoring and evaluation to show progress in roll-out, identify weaknesses in the system that need to be corrected and demonstrate the impact of the overall system.

Indicators can be *process-oriented*, relating to performance of the system during roll-out and maintenance phases or can be *impact-orientated*, relating to the long-term impact on health outcomes and programme performance (see also **Section 4.1f**). **Table 4.1** contains a list of illustrative *process-orientated* indicators which can be used for regular evaluation of a system and can be adapted to match country conditions. For example, if the system is only being implemented for MDR-TB case management, none of the drug-sensitive TB indicators would apply. **Box 4.4** shows how some of these indicators are being monitored in Brazil.

Box 4.3

Evolution of the TB Information Management System in China

The case-based TB Information Management System was launched in 2005 building on the platform of the web-based Infectious Disease Reporting System implemented in 2004 following the SARS (severe acute respiratory syndrome) outbreak of 2003. The third version of the system was launched in 2011 with the addition of a new drug-resistant TB module. This follows an earlier upgrade in 2009 when the system's architecture was changed to reduce the heavy load on its central servers.

The system is made up of modules organized around data collection, quality assessment, output and system management (such as data dictionary management).
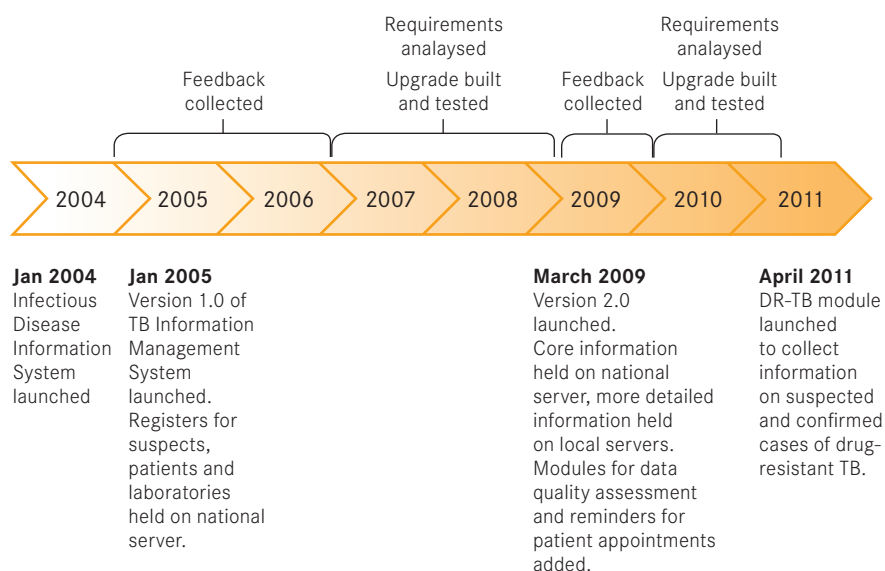
Ongoing challenges
Training: In addition to having to train system administrators in using the upgraded system, frequent staff turnover has meant that there is an ongoing need to train new system administrators.

Data exchange: Establishing standard datasets and mechanisms to exchange data with other public-health systems such as the vital registration system.

FIGURE 4.3 **The evolution of China's TB Information Management System**
(source: Chinese Center for Disease Control and Prevention)

Jan 2004
Infectious Disease Information System launched

Jan 2005
Version 1.0 of TB Information Management System launched. Registers for suspects, patients and laboratories held on national server.

March 2009
Version 2.0 launched. Core information held on national server, more detailed information held on local servers. Modules for data quality assessment and reminders for patient appointments added.

April 2011
DR-TB module launched to collect information on suspected and confirmed cases of drug-resistant TB.

Table 4.1

Possible indicators for monitoring the performance of a TB electronic recording and reporting system.

SYSTEM PERFORMANCE

- % of evaluated functionalities with correct functioning / needing adjustment / with bugs to be fixed
- % of electronic recording and reporting system users trained and active out of target number of users
- Number of months delay in implementing electronic recording and reporting action plan
- User friendliness and operator satisfaction ratings (user survey needed to measure these indicators)
- Quarterly or annual cost of electronic recording and reporting system implementation and maintenance per TB patient entered in the system
- Cumulative annual or monthly downtime of central server (for web-based systems)

SYSTEM COVERAGE

- Number of TB or DR-TB units where the system has been rolled out and is in use (and % out of all units in the country) by the end of a quarter or end of a calendar year.
- Number of TB or DR-TB units trained with at least one person trained and using the system (and % out of all units where the system has been rolled out) by the end of a quarter or end of a calendar year.

DETECTION, REGISTRATION AND TREATMENT

- Number of TB suspects screened for TB and registered in the electronic recording and reporting system during a quarter or during a calendar year.
- % of TB suspects that are screened and registered in the system out of all TB suspects screened and registered during a quarter or during a calendar year.
- Number of TB cases diagnosed and registered in the system during a quarter or during a calendar year.
- Number of TB patients registered in the system during a quarter or during a calendar year with HIV status also recorded.
- % of TB patients registered in the system during a quarter or during a calendar year with HIV status also recorded.
- Number of MDR-TB suspects screened for DR-TB and registered in the system during a quarter or during a calendar year.
- % of MDR-TB suspects screened and registered in the system out of all MDR-TB suspects screened and registered during a quarter or during a calendar year.

TB OR DR-TB PROGRAMME ACTIVITY

- Number of TB or DR-TB patients registered in the system who started treatment during a quarter or during a calendar year.
- Number of TB patients registered in the system during the previous calendar year for whom treatment outcomes have been recorded.
- % of TB or DR-TB patients whose outcomes are being recorded in the system out of all newly registered patients during a quarter or during a calendar year.

DRUG MANAGEMENT (IF APPLICABLE)

- Number of forecast exercises conducted to compare actual second-line drug consumption with projected consumption predicted by the system
- % accuracy between real second-line drug consumption versus projected consumption with electronic recording and reporting system
- Number of stock outs at sites using the drug management component of the system
- Calculated number of months of stock available at a specific time for each drug at each site using the drug management component of the system
- Average time taken during a calendar year to receive a given drug at a given site after an order has been placed

DR-TB, drug-resistant tuberculosis; MDR-TB, multidrug-resistant tuberculosis.

Box 4.4

Examples of how indicators can be used to track implementation progress

Below are two examples of how e-TB manager[a] implementation in Brazil is monitored. **Figure 4.4** shows the number of active system users and the number of health units using the system. Tracking these indicators simultaneously can highlight any lag in training or system use. **Figure 4.5** compares the case notifications with the status of treatment outcomes registered. This shows whether registered cases are being tracked properly in the system.

FIGURE 4.4 **Growth in coverage (number of units) and use (number of users) of e-TB Manager in Brazil, 2005–2010** (source: MSH, Brazil)
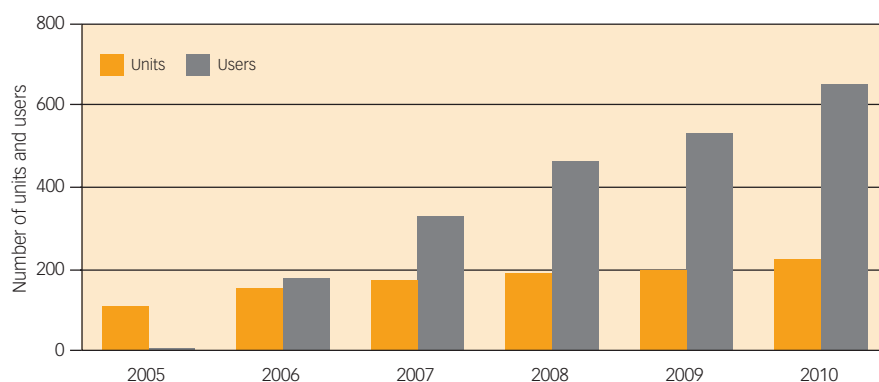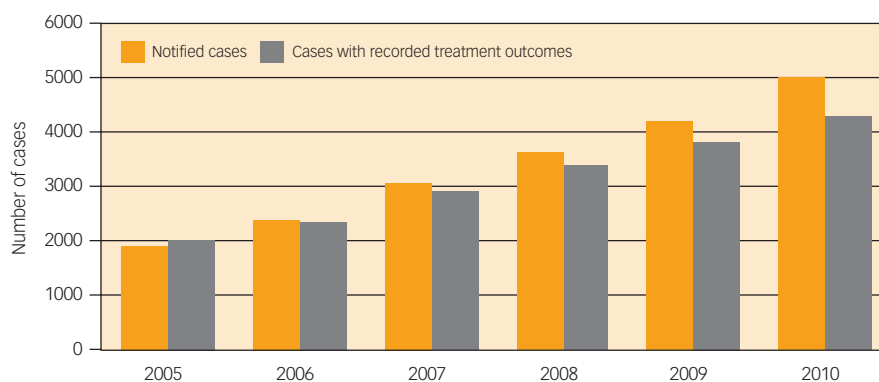

FIGURE 4.5 **Cumulative number of MDR-TB cases notified and number with treatment outcomes recorded in the e-TB manager system in Brazil, 2005–2010** (source: MSH, Brazil)

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a   e-TB manager, developed by MSH with support from USAID, is a web-based tool designed to strengthen TB programmes by integrating case management, medicine control and surveillance information into a single platform. By the end of 2011, it was fully implemented in 5 countries, with another 10 countries that are either planning to, piloting or rolling out the system.

Development of this document

This document is the result of a collaborative project funded by the United States Agency for International Development under the USAID Tuberculosis CARE I, Cooperative Agreement No. AID-OAA-A-10-000020. The project proposal was developed in December 2010 by the World Health Organization (WHO) in close cooperation with the KNCV Tuberculosis Foundation (KNCV) and Management Sciences for Health (MSH).

A document outline and project plan was developed in January 2011 and a core group of authors with experience in designing and implementing electronic recording and reporting systems for TB care and control was identified from KNCV, MSH and WHO. Subsequently, additional contributors with experience in implementing electronic recording and reporting systems for TB care and control and representing all WHO regions were identified and invited to participate in the development of the guide.

A questionnaire about key aspects of electronic recording and reporting was developed in February 2011 and sent to 11 countries with experience in designing and implementing electronic systems for TB care and control. Answers were received from Brazil, China, Georgia, Latvia, Moldova, Pakistan, Romania, South Africa and the WHO Eastern Mediterranean Regional Office.

First drafts of the Introduction, Chapter 1 and Chapter 2 were produced by the core group of authors, building on the answers received in the questionnaires.

A two-day meeting of lead authors and other contributors was held on 27–28 April 2011 at WHO's headquarters in Geneva, Switzerland. Country experiences from Brazil, China, Georgia, Kenya, the Netherlands, Pakistan, Romania, the United Kingdom and of the WHO Eastern Mediterranean Regional Office were presented on the first day. The second day was used to present and discuss the drafts of the Introduction, Chapter 1 and Chapter 2, and to agree on a plan to produce Chapter 3 and Chapter 4.

Following the meeting in April, the core group of authors incorporated examples presented by countries to illustrate the options and recommendations provided in Chapter 1 and Chapter 2 with real practical examples. Chapters 3 and 4 were drafted.

A full draft of the entire guide was sent for review in September 2011 to all authors and participants at the April meeting, and also to 9 reviewers. A final draft was circulated in November 2011 to the same group and also to 22 reviewers. Peer reviewers were selected based on their expertise in TB recording and reporting, HIV recording and reporting and/or their expertise in the development of electronic surveillance systems. Comments were received from 7 of the reviewers contacted.

Finalization of the entire document following internal and external peer-review as well as copy-editing were completed in February 2012.

Adopting electronic recording and reporting is not simply about choosing a piece of software: it is also about changing how people work. This is not a simple undertaking. This document introduces the key questions to be considered and illustrates what the questions, options and recommendations mean in practice by drawing on examples of recent experience from a variety of countries. It is an essential resource for all those planning to introduce electronic recording and reporting systems for TB care and control, or to enhance existing systems.

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