



STRENGTHENING  
INFORMATION  
SYSTEMS AND  
LINKAGES TO CARE

9

# STOP TB FIELD GUIDE

Stop  Partnership



# 9

## **STOP TB FIELD GUIDE**

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INFORMATION  
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LINKAGES TO CARE**



## StopTB Field guide 9: Strengthening Information Systems and Linkages to Care

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**FIELD  
GUIDE**

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## **PURPOSE OF THIS DOCUMENT**

This document is one in a series of 11 field guides produced by Stop TB Partnership in collaboration with the Global Fund to Fight AIDS, Tuberculosis and Malaria, KIT Royal Tropical Institute, Interactive Research and Development Global (IRD), and multiple global experts and implementation partners. These field guides rely on the practical experience and expertise of implementers and are meant to help national TB programmes and other TB programme managers to identify the best strategies for finding people with TB who are missed by routine health services.

This document is not to be treated as guidance, but rather as a collection of considerations when seeking to implement better informational systems for improved TB programme monitoring. It attempts to simplify the complex topic of information system design and presents examples from implementation practice.

This field guide has gone through extensive peer review by the agencies and individuals acknowledged below. It presents a range of examples from peer-reviewed literature and implementation practice. Where not cited, examples are provided by TB REACH.

## Acknowledgements

The production of these field guides represents a significant effort, bringing together more than 60 experts from over 30 different institutions globally in the spirit of partnership to help address a major barrier in the TB response: the fact that millions of people with TB are still missed by the current routine health systems.

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# Abbreviations

<b>DHIS2</b>	District Health Information System 2
<b>DOTS</b>	Directly observed treatment, short-course
<b>DR-TB</b>	Drug-resistant tuberculosis
<b>DS-TB</b>	Drug-susceptible tuberculosis
<b>FHIR</b>	Fast Healthcare Interoperability Resources
<b>GIS</b>	Geographic information system
<b>GLI</b>	Global Laboratory Initiative
<b>HIV</b>	Human immunodeficiency virus
<b>HL7</b>	Health Level Seven
<b>LIMS</b>	Laboratory information management system
<b>M&amp;E</b>	Monitoring and evaluation
<b>MDR-TB</b>	Multidrug-resistant tuberculosis
<b>MoH</b>	Ministry of Health
<b>NTP</b>	National tuberculosis programme
<b>PTLFU</b>	Pre-treatment loss to follow-up
<b>SLA</b>	Service Level Agreement
<b>SOP</b>	Standard operating procedure
<b>TB</b>	Tuberculosis
<b>UPI</b>	Unique patient identifier
<b>WHO</b>	World Health Organization



# 1. INTRODUCTION: WHY INVEST IN INFORMATION SYSTEMS FOR TB?



# 1. INTRODUCTION: WHY INVEST IN INFORMATION SYSTEMS FOR TB?

Finding and treating people with tuberculosis (TB) is a multi-step process involving awareness generation, prevention, screening, testing, diagnosis, treatment initiation, multiple follow-ups and finally a successful treatment outcome. This, by necessity, involves recording data at each step of the process, not only to track patients' progress through the TB care cascade, but also to understand key indicators of programme performance that can inform the decisions of programme managers and policy makers.

Various types of data systems can be used at different points in the TB diagnosis, treatment and care cascade, for example:

- Laboratory information management systems (LIMS)
- Patient surveillance systems
- Pharmacy management systems
- Adherence tracking systems
- Notification systems

All of the above have the potential to be relevant for the management of TB patients. Throughout this document, the term "information system" refers to any system that is used to transfer data relevant for TB programme management.

There is an acute need for adequate data management in TB programming. In the mid-1990s, the World Health Organization (WHO) rolled out a standardized system for paper-based recording and reporting of TB patient data, from diagnosis to treatment outcome. This system, which includes geographical, administrative and quality control information, is a key element of the WHO DOTS (directly observed treatment, short-course) strategy, as well as its successor, the Stop TB Strategy (1). By the mid-2000s, more than 99% of the world's reported TB cases were being recorded and reported in countries that had adopted the WHO-recommended system. Largely due to the implementation of this system, TB data are comparable across many thousands of treatment facilities worldwide. The standard datasets that countries use to provide data to WHO allow for reporting on the global TB epidemic and progress in TB care and prevention (2).

Information systems supported by mobile technologies have the potential to enable programme implementers to collect patient data from different sources and locations. Data can be made easily accessible in a case record format, and used for faster, easier reporting and analytics.

Information systems can benefit programmes that are focused on finding the missing people with TB by improving treatment linkages for those diagnosed and by improving reporting of those who may have been diagnosed and treated but not notified. Bringing these individuals under notification generally has the benefit of ensuring access to national minimum standards of diagnosis, treatment and investigation, and improving the completeness of data for epidemic response planning. Below are some examples of data systems currently being used in TB control programmes:



- **eTB manager:** a desktop-based tool for managing multiple layers of TB programme data on TB patients, medicines, laboratory testing, diagnosis, treatment, and outcomes.<sup>1</sup>
- **NIKSHAY:** India's web-based solution built to record notifications for the country's TB and multidrug-resistant (MDR-) TB patients, and to use these data for patient monitoring and research.<sup>2</sup>
- **QuantTB:** a quantification and early warning system for TB medicines, aimed at improving procurement processes, ordering and supply planning.<sup>3</sup>
- **DHIS2** (District Health Information System 2): used as an aggregate data system at the national level in more than 40 countries in Africa, Asia and Latin America.

<sup>1</sup> <http://siapsprogram.org/tools-and-guidance/e-tb-manager/>

<sup>2</sup> <http://ehealth.eletsonline.com/2013/01/nikshay-online-tool-for-monitoring-tb-control-programme/>

<sup>3</sup> <http://siapsprogram.org/tools-and-guidance/quanttb/>

Compared to the paper-based systems currently still in use in many settings, well-designed digital information systems, including the ones cited above, are

faster, more efficient and more secure. Box 1 summarizes the potential benefits of moving from a paper-based to an electronic system (3).

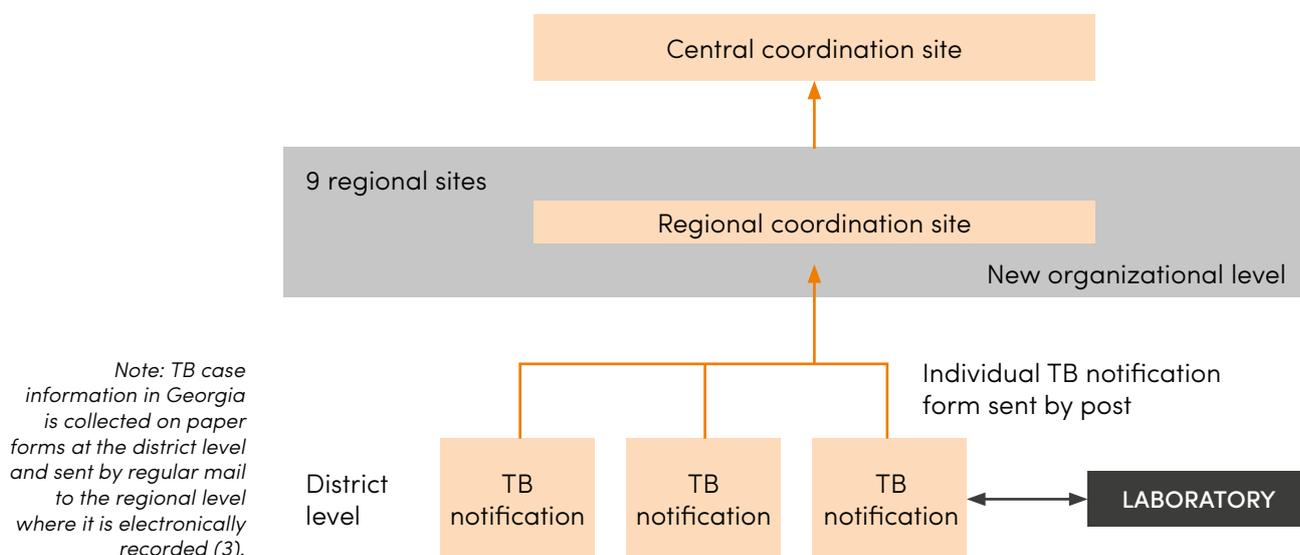


Large amounts of information notwithstanding, data are frequently underutilized for programmatic course correction for a variety of reasons, such as the following:

- Paper-based systems continue to be a key method of information sharing (sometimes in a hybrid setting, with data being shared via both paper-based and electronic routes); this type of system may not lend itself to quick aggregation, analysis and data-driven decision-making in the short term (see Figure 1 for an example).
- Sometimes, even when electronic systems have been set up, workflow changes at implementation level do not change to incorporate the usage of electronic systems.
- Project protocols often require data to be aggregated at the end of a quarter (or even a year), which does not lend itself to agile decision-making.
- Programme designs often do not include protocols for data utilization.

Figure 1.

Example of paper-based reporting system in Georgia



**Potential benefits to be realized when TB data are captured through an electronic information system rather than a paper-based one**

- **Data quality.** Validation checks and feedback can be an integral part of recording and reporting in electronic systems; e.g. 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.** Paper-based systems make data aggregation, analysis and reporting to higher administrative levels tedious and labour-intensive tasks, whereas electronic systems automate some of the tasks, thereby reducing the workload involved; e.g. electronic systems may preclude the need to capture information multiple times because of possible linkages to other source data.
- **Data access.** Electronic records can be transferred to and shared at different administrative levels, which enables a rich quantity of data to be available for analysis, interpretation and use.
- **Timeliness of information.** Electronic systems can automate the aggregation process, thereby saving time and effort and reducing 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. By contrast, well-designed electronic systems can be modified relatively quickly.
- **Data analysis and reporting.** When data are available in a 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, spatial analysis and research. It becomes easier to produce and disseminate annual reports at the national level.
- **Managing complex data.** The complexity of data has increased in recent years, especially with greater attention to the diagnosis and treatment of DR-TB. Data complexity is easier to manage in an electronic system, provided adequate data management procedures and staff are available; electronic systems also allow for richer data to be collected and analysed.

## 1.1 Why focus on data and information systems now?

Among the 4.1 million people missed each year by state notification systems, many are likely tested for TB, but not placed on treatment or recorded in national registers due to failures in communication between the entities responsible for implementing the various steps in the TB screening, testing and treatment cascade. WHO guidance states that people with TB should be notified at the point of diagnosis in order to track those who are diagnosed but not registered for treatment. However, the current practice of many national systems, particularly the manual ones, is to focus on notification at the point of treatment registration. (Even though facilities have “laboratory registers” as well as “treatment registers”, these are not routinely compared for consistency or for follow-up.) While it is worthwhile to monitor impact on notified diagnosis, it is fundamental to TB control that people confirmed with TB diagnosis but not initiated on approved treatment receive follow-up. Lack of communication and data management leads to a large portion of TB patients being missed.

A systematic literature review performed in 2018 looked at 48 studies to understand notification timeliness (4). The review found that only a minority of existing notification systems meet predefined, standardized or disease-specific timeframes. The review also found that while electronic systems reduce delays in reporting, the implementation of such systems requires considerable effort. Information and data management is of crucial importance in TB prevention and care in order to ensure that 4.1 million people are linked to services. However, even in settings where national TB programmes (NTPs) have introduced electronic systems, challenges persist. This field guide approaches TB data management from an implementation perspective, looking at how to build systems, roll them out, and utilize the data collected, and examining potential challenges at each step. This field guide also attempts to unpack the complex topic of data management in TB, describing some systems that have already been designed and implemented and making further suggestions as to how technology can be harnessed to serve the mission of finding the people with TB who are currently being missed.

## 1.2 Complexities in information systems and current landscapes

Technology advances in software development, design and performance have led to the creation of multiple systems for the collection and analysis of TB data. However, several gaps exist in terms of designing effective information systems for TB interventions (and effectively utilizing them). The information systems problem is not purely a matter of building good software. Therefore, it is important to understand the challenges involved in building, managing and using TB-related information systems:

- **Heterogeneity of screening data:** Screening and diagnostic algorithms vary across countries and even across projects in the same country, owing to the variation in symptoms, risk factors, and availability and use of different diagnostic tests. This makes it difficult to develop a single digital tool for TB screening and to compare and analyse screening data from different countries and projects. This limitation represents a disadvantage for creating unified reporting systems at the global level and for sharing learning experiences between settings.

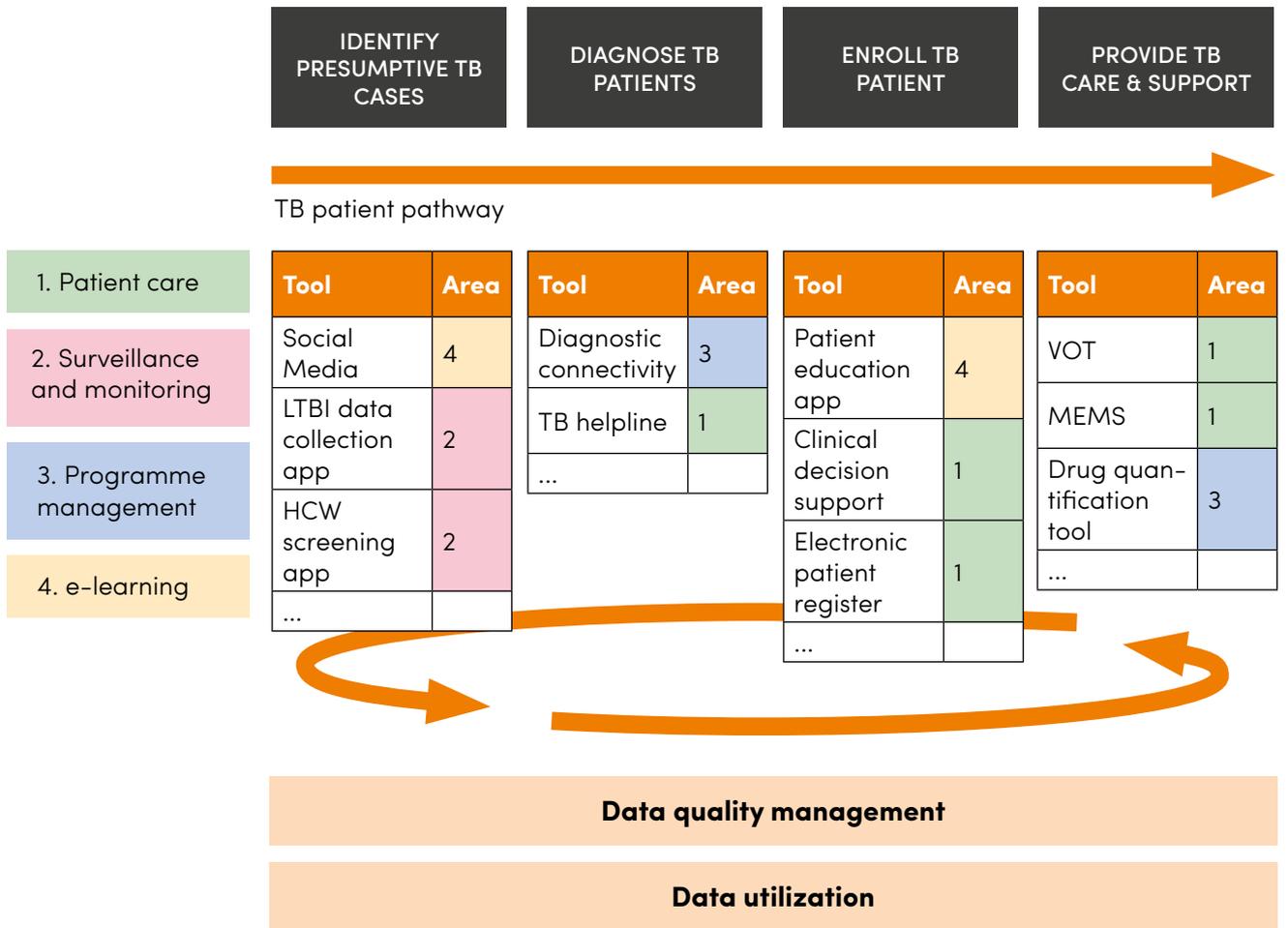
- **Missing data:** TB indicators and required data fields are quite well-defined, but operational reasons may prevent programme staff, especially data collectors, from finding necessary data, which may not even be available (e.g. patient addresses).
- **Limited analytical capacity of the end-user:** Many TB programmes do not have the technical capacity to make use of the vast amounts of new (and existing) data that information systems can make available. This limited capacity represents a massive lost opportunity to apply the evidence being generated in order to make decisions on course correction around programmatic improvements.
- **Multiple parallel systems:** TB programmes considering electronic systems for TB recording and reporting have three options: 1) choose from pre-designed options; 2) work with an existing and often confusing array of systems that may or may not link with the existing health information infrastructure in the country, or 3) have something custom-built. Given these choices, multiple recording and reporting systems exist globally, each tailored to specific types of TB recording and reporting; each with its own strengths and limitations; and each functioning in isolation. At the global level, this leads to the issue of data heterogeneity described earlier, while at the national level, this may lead to fragmentation in data and duplication in reporting. For example, there have been cases where multiple donors have funded different systems in the same country – one for DS-TB, another for DR-TB, and to further complicate the issue, a third system for HIV – without linking the systems together. This means that the data for one HIV patient who is first notified as a DS-TB patient but is later found to have DR-TB will be split across three different systems. Many countries are using aggregate data systems like DHIS2 at the Ministry of Health (MoH) level. In such cases, any additional systems should be configured to report into the DHIS2.
- **Limited ownership and accountability:** The ultimate ownership of a national TB information system rests (or should ideally rest) with the NTP or with even higher agencies such as the MoH. However, there are several reasons as to why this does not happen. NTPs often do not have the capacity to determine what would work best for their context from an information systems standpoint. Technical IT capacity within NTPs is often limited, leaving them at the mercy of private providers for even simple modifications and maintenance tasks. KNCV's Digital Health Assessment approach<sup>4</sup> (see Figure 2 and Section 7) addresses this issue by working closely with governments to assess existing information systems and to identify any opportunities and gaps along the patient care pathway that can be addressed by digital solutions (5).
- **Resource issues:** Donors, programme managers and implementing groups often fail to realize that an information system for a large intensive case-finding programme requires a significant investment in time, human resources, and capital – an investment that goes beyond simply developing and deploying a system and buying phones or computers for data entry and reporting. Information systems are long-term investments and will usually undergo multiple iterations and enhancements before they can pay back dividends in the form of efficiencies from digital data collection and analysis and improved treatment outcomes. Success requires programme staff to be actively involved in the design and implementation of information systems. If programmes do not budget and plan adequately for these systems, this shortsightedness can have negative impacts ranging from simple under-utilization of the system to complete failure of the information system initiative.

Overcoming these challenges requires thoughtful approaches, some of which are discussed in this document.

<sup>4</sup> <https://www.kncvtbc.org/en/what-we-do/digital-health/>

Figure 2.

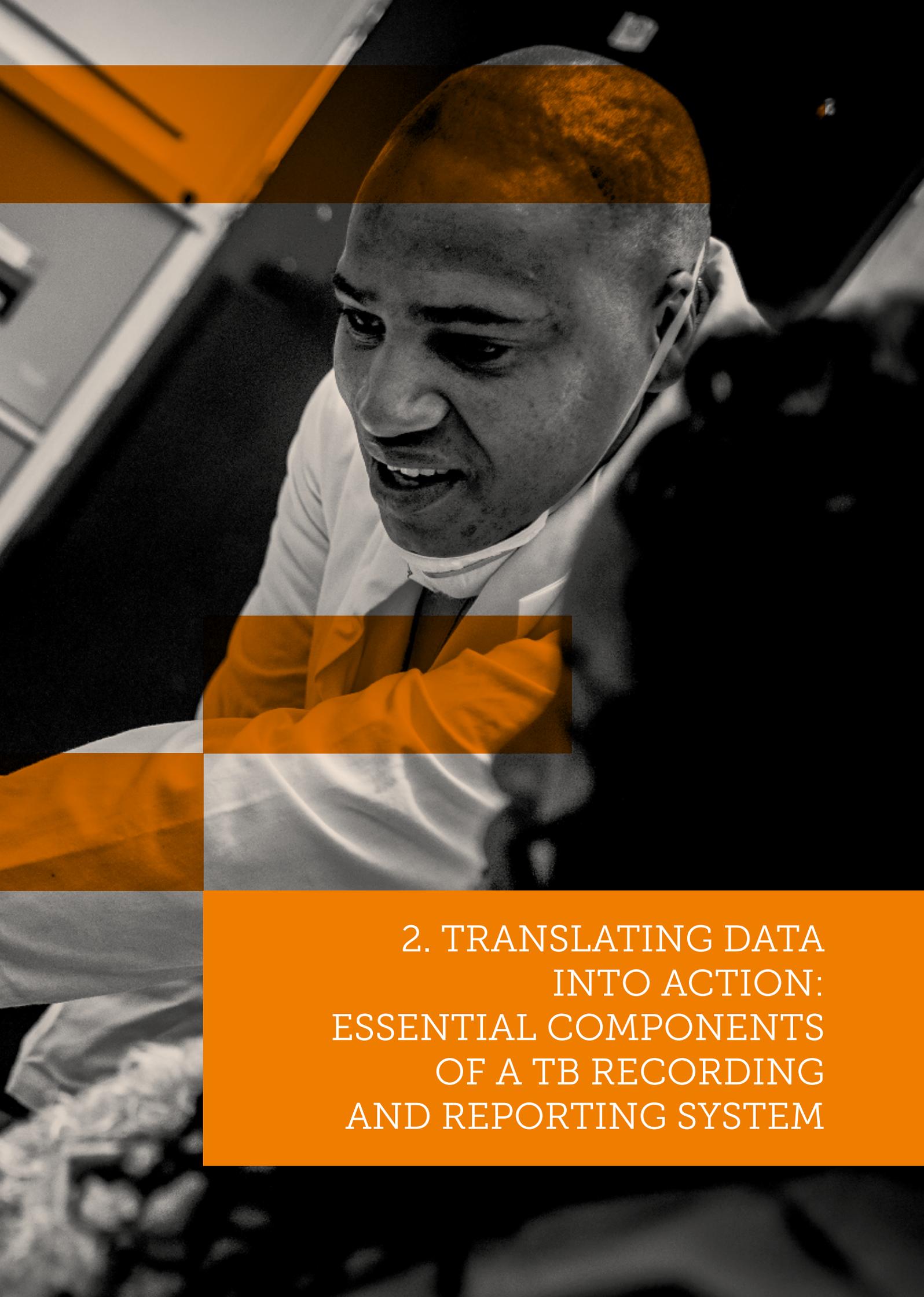
Example of a completed digital health activities framework



**HCW:** health-care worker; **LIMS:** laboratory information management systems; **LTBI:** latent tuberculosis infection; **MEMS:** medication event monitoring system; **VOT:** video-supported treatment for TB

Source: WHO's Handbook for the use of digital technologies to support tuberculosis medication adherence (6)





2. TRANSLATING DATA  
INTO ACTION:  
ESSENTIAL COMPONENTS  
OF A TB RECORDING  
AND REPORTING SYSTEM

## 2. TRANSLATING DATA INTO ACTION: ESSENTIAL COMPONENTS OF A TB RECORDING AND REPORTING SYSTEM

TB control efforts need to be tailored to local conditions, as the disease's epidemiology depends on geography, age, gender and presence of coinfections or comorbidities, among other factors. To effectively control TB epidemics, it is desirable to shift from a centralized approach in which local data are deposited into national databases for aggregated analyses, to a bidirectional one in which local partners have the capacity to collect and analyse data and then use those data to design locally responsive interventions. (The bidirectionality may need to include some restrictions; e.g. all partners can view the information but not necessarily edit it). This shift requires lo-

cal TB programmes to make better use of existing data, expand routine data collection, and make informed use of targeted surveys (7). At the most basic level, effective bidirectional use of data not only entails active engagement with programme staff on a more frequent basis than quarterly reporting meetings, but also requires capacity-building so that staff can identify local gaps in the patient care cascade. It also requires a higher degree of autonomy (as local capacities increase) and even additional resources to permit staff to respond to gaps that are detected.

### 2.1 Notification systems

Notification is a key requirement for understanding the size of the TB epidemic in a country or region. Notification to the NTP means that every time an individual is confirmed as having TB, the government is informed. In countries where the private sector occupies a large portion of the health care space, it is important that private providers also notify cases to the NTP. In many countries (e.g. India, Indonesia, Myanmar), TB is legally notifiable, which means that providers are mandated by law to report counts of confirmed TB cases to the NTP. However, in practice, many private providers may not report TB because it is cumbersome and there is no incentive for them to take on the task. Engaging with the private sector to drive notification of TB cases is a complex issue described in detail in the field guide in this series dedicated to the topic.

One of the key challenges with notification for both private and public providers is determining what information needs to be communicated to the NTP. Given that notification is an added task for care providers, it is important to resist the temptation to ask for too much data. The dataset requested from providers should contain the bare minimum number of variables needed to generate meaningful reports.

Unique patient identifiers (UPI; please see Box 2 for definition), addressed in more detail in later sections, are of crucial importance for notification because a patient may visit more than one private provider and end up being reported in the system twice. The use of UPIs allows users to identify data duplication, correct patient counts, and connect lab data to treatment and notification. Enabling private providers to use UPIs expands the NTP's insight into where patients are being diagnosed and treated.

Use of UPI's has been implemented by India's NIKSHAY system and also in the online TB notification system developed in Indonesia by the USAID-funded Challenge TB initiative. Aside from providing insight into the size of local TB epidemics, notification systems also ensure tracking of diagnosed patients and their enrolment into treatment and care. For this reason, it is important that notification systems collect contact information such as phone numbers and home addresses (with appropriate security mechanisms built in to protect patients' privacy) in order to facilitate patient follow-up.

## Box 2.

### Definition of unique patient identifier (UPI)



Any alphanumeric code used to uniquely identify a patient within a health register or a health records system.

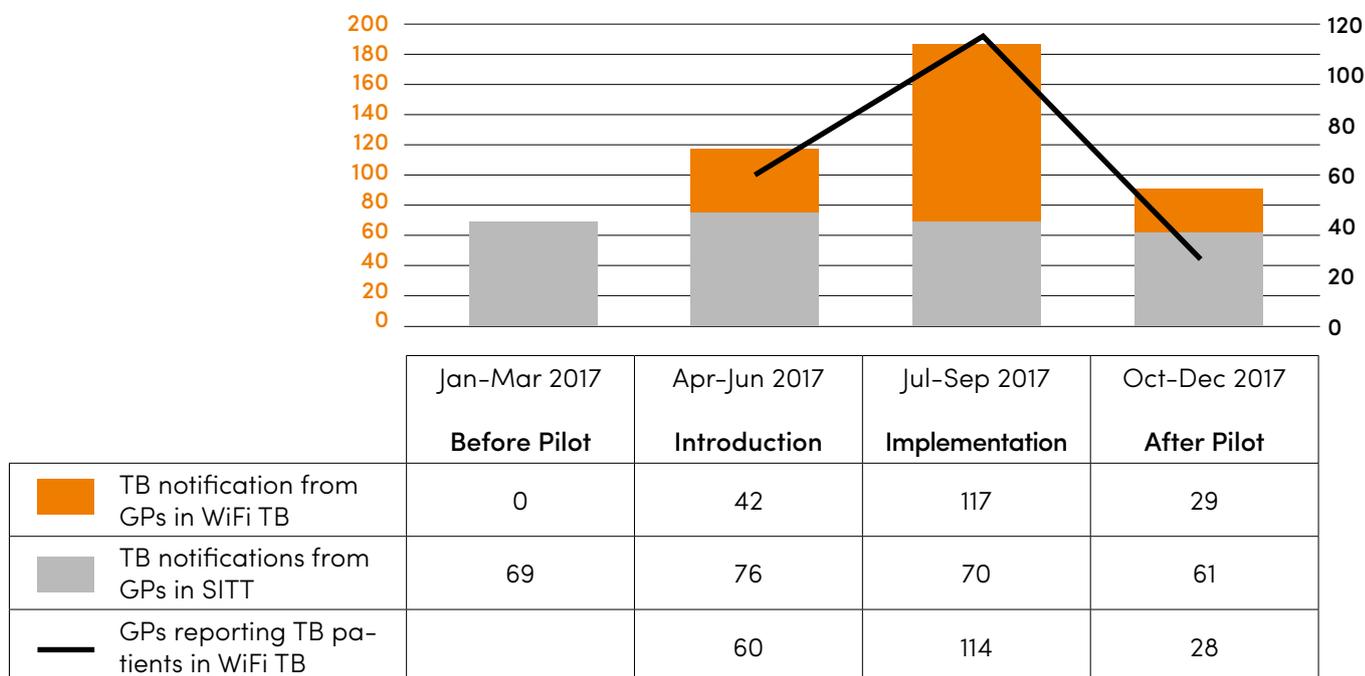
*Source: Segen's Medical Dictionary 2012*

An electronic notification system can be conceptualized as a simple mobile app like WiFi TB (8) (please see Figure 3). General practitioners (GPs) can register in the system and then report cases on a regular basis. Some constraints related to mobile apps are that they require smartphones and data connectivity, which may not be available to all private providers. Notification can also be done from mobile

phones using a structured SMS message that is sent to a phone number linked to an NTP-operated server that can understand the message and translate it into a case report. As with general information systems for TB, notifications should also ideally be linked to a reporting system or dashboard so that incoming data can be effectively monitored.

Figure 3.

TB patient notifications from GPs in SITT (the national surveillance system) and through WiFi TB (80 sites) in Indonesia, Jan–Dec 2017 (left-hand scale), and number of GPs reporting TB patients through WiFi TB application (right-hand scale) (8)



## 2.2 Tracking pre-treatment loss to follow-up

Pre-treatment loss to follow-up (PTLFU) refers to the situation in which bacteriologically-confirmed TB patients are not reported to the NTP as having initiated treatment. (This may include patients who have died.) The causes of PTLFU are often systemic and may include the following scenarios:

- Patients start “shopping” around for care at private clinics after a diagnosis is provided to them in the public sector;
- Patients are diagnosed at an NTP clinic but referred to another clinic because of geography-based treatment eligibility protocols; patients are then lost between the two institutions;
- Patients provide specimens for laboratory examination, but do not return to the health facility for confirmation of diagnosis.

PTLFU is a key failure in the TB patient care pathway. Moreover, because it signifies delays in care, PTLFU is associated with significant mortality (9). The rates of PTLFU can range from 4% to 38% in different settings (10). NTPs’ monitoring and evaluation (M&E) systems often do not cover the entire patient care process from screening to treatment outcome. An effective information system can potentially address this challenge. PTLFU can be systematically captured in national reporting systems by using UPIs from the point of initial screening (or point of diagnosis) so that laboratory and treatment records can be linked for every patient. This direct linkage will permit active tracking of patients lost to follow-up.



Programmes and projects have utilized a wide range of interventions to minimize PTLFU, some of which can be enabled and informed by the use of electronic systems. Such interventions have included SMS reminders to patients to present at treatment initiation sites, counselling, referrals, “case management support” or “patient escort support” (e.g. programme staff walk or drive a confirmed patient to a treatment site), enablers (e.g. transport money), improved turnaround times for lab reporting, on-site GeneXpert testing, simplified testing algorithms and improved access to diagnostic facilities.

In Pakistan, the Zero TB Initiative in Karachi and Peshawar used a dedicated call centre as a patient registration and follow-up system from the time of initial sputum specimen submission or chest X-ray. An online electronic medical record system helped the call centre to capture data on individuals who submitted sputum, those who tested positive for TB, and those who initiated treatment. Those individuals who had not started on treatment were traced by phone calls; if there was no response, a programme staff member attempted a home visit. In India, World Health Partners served as a private provider interface agency in Patna by engaging with private rural health care practitioners and offering them mobile phone adherence tracking, alerts and reminders. This was coupled with incentives and a web-based electronic recording system that facilitated various case-management tasks for the providers (11).

It is important to assign accountability for PTLFU not just to programme field staff, but also to a dedicated M&E team led by a senior team leader who can keep close tabs on weekly (or even monthly) loss to follow-up rates. By the time quarterly reporting cycles are completed, it may be too late to bring patients onto treatment. However, it is important to use incentives and administrative pressures with care when attempting to resolve PTLFU, as this can result in falsification of data in extreme circumstances.

## 2.3 Reporting systems

Reports help users at different levels of TB programmes understand how the programme is progressing based on key indicators or metrics. Reports designed for different users will vary in the level of granularity needed. For example, reports designed for an NTP manager would ideally be high-level reports on key indicators for the country and perhaps for individual provinces. Reports for lower level managers in the health system generally require more detail. For example, district TB officers may want to see performance metrics for all of the towns in their district and may be interested in operational details that would be too much information for the NTP manager.

### Quarterly reports

It may be most efficient to automate reports that are needed at a set frequency (e.g. quarterly) such that, for example, the Q1 report is auto-generated and available to view on April 1. (It is worth noting that treatment outcomes for the same quarter may only be available in the next one.) For systems in which data are entered offline or retrospectively, however, it is advisable to allow time for users to upload any data not yet entered into the system.

Table 1.

## Report needs by user type

User Type*	User's Typical Role	General Reporting Need
Field Personnel**	Community or facility-based TB screeners, lab technicians, GPs	See own performance, perhaps on a mobile device or website
Field Supervisors	Managing a group of field personnel or lab staff	See performance of field personnel under their supervision. Programmes may choose for supervisors to have limited visibility on data from other teams.
District Health Officers	Managing the programme within the district; responsible for meeting screening and/or treatment targets and timelines; reporting to provincial level	See programme performance/indicators for district at a granular level of detail. May need to see high-level data from other districts. Would benefit from the use of charts and graphs
Provincial Health Department	Managing the programme within the province; responsible for meeting screening and/or treatment targets and timelines; reporting to national level	See performance/indicators for province at high level by default, with the ability to drill down to district level as needed. May need the ability to see high-level data from other provinces. Would benefit from the use of charts and graphs
NTP Manager	Managing country programme; reporting to health ministry	See performance/indicators for the country at a high level by default, with the ability to drill down to province or district level as needed. Would benefit from the use of charts and graphs
M&E Team	Responsible for tracking project performance and indicators, quality checks, etc.	See detailed reports on performance and indicators for all geographical levels

\* Note that all types of users may not be present for all types of systems. This table is meant to be illustrative as opposed to prescriptive

\*\* This could be an individual GP in a case notification context

### Day-to-day management

Reports for day-to-day management should be available on-demand, with users provided with a visual interface that they can use to generate reports, filter reports based on criteria such as date and location, and sort data as needed. As with other aspects of system development and design, report development is also an iterative process. More or different reports may be needed as programme staff learn more about their own programmes and identify new variables that could be important for assessing programme performance. Similarly, changes to protocol or new developments in TB control can necessitate modifications in the way data are presented. In time, the system can even provide recommendations automatically based on certain thresholds.

### Privacy constraints

Regardless of whether a report is automated or generated on-demand, it is important that reports show data in an easily consumable way, but also with appropriate “privacy filters” and patient identifiers so that individual patients cannot be identified when moving to the consolidation and analysis of data. (Issues related to UPIs are explored in more detail in Section 3.2. of this field guide.) This is best done using dashboards with charts and graphs, as well as giving the option to download data in Excel, CSV or other formats for deeper analysis. Business intelligence tools, such as Pentaho, Microsoft BI and Tableau, among others, are often used to create powerful reporting and analytics dashboards. Dashboards can also be used to display geographical data, as described later in Section 3.

## 2.4 Optimizing use of laboratory data

Modern TB programmes rely on tests (GeneXpert, culture, smear, etc.) to diagnose TB. Tests are also used to track the progress of treatment, as both DS- and DR-TB treatments involve scheduled follow-up tests. Conversion is an important milestone in a patient's treatment programme. Given that diagnostics are such a key part of the TB care cascade, there is much to be gained by using digital systems for lab data.

### Preventing loss to follow-up

A positive diagnosis is a sign that the patient in question needs to be started on treatment as soon as possible. However, given that laboratories do not start people on treatment, a care provider needs to be informed. Systems like GxAlert and DataToCare allow for Xpert test results to be sent directly from GeneXpert machines to central servers, from which care providers can receive the information via email, SMS, or other medium. Similarly, an LIMS could be set up for any diagnostic device that allows data to be sent to an external system. This is usually done using health information exchange standards such as Health Level Seven (HL7), as described in Section 3. The same can also be done by equipping clinics with an SMS printer that receives results directly from the laboratory via SMS and prints them out.

### Tracking lab performance

Having GeneXpert data (or other test data) consolidated in a single place can provide important insights into how laboratories are performing. Error rates can be remotely monitored, enabling quick remedial action if necessary; non-performing laboratories can be identified, prompting the move of diagnostic devices to locations where they may be better utilized; inventory of consumables (e.g. GeneXpert cartridges) can be monitored; and device warranties can be tracked so that scheduled service and maintenance are carried out in a timely manner, increasing uptime e.g. user errors can be differentiated from machine errors allowing programmes to rectify the problem through training or repair/replacement.

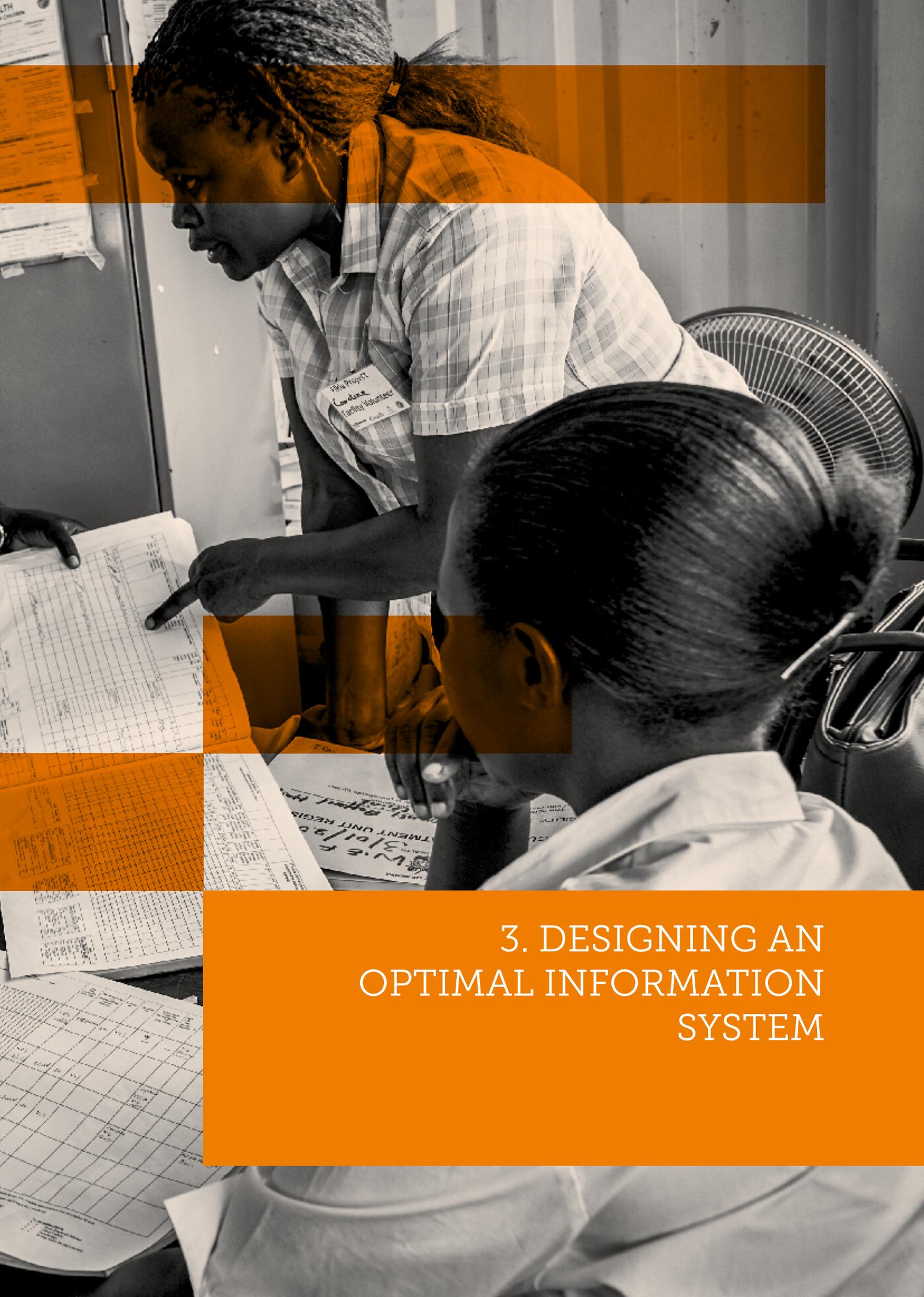
Digital information systems can also be used to ensure that samples are correctly labelled and recorded (spot vs. morning, diagnostic vs. follow-up, type of specimen), and that the information is automatically available to lab technicians who then test the sample. Alternatively, if sputum was not collected, it may be important to record (and then report on) the reason why. In sputum transport networks, a digital system could be used to track the sample as it moves between locations in the same way that courier systems enable the tracking of deliveries. Lost, contaminated or low-quality samples can also be recorded in these systems, providing an important indicator for evaluating sputum collection and transport methods. (The Global Laboratory Initiative's guide on diagnostics connectivity provides very valuable insights into sputum collection and transport (12).) In addition to making labs more efficient, aggregated diagnostics data can also give early insights into how disease indicators are changing in the communities.



THE REFERRAL PROCESS

MINISTRY OF HEALTH

Referral No.	Referral Date	Referral Type	Referral Status	Referral Source	Referral Destination	Referral Reason	Referral Outcome	Referral Date	Referral Status	Referral Source	Referral Destination	Referral Reason	Referral Outcome
1	2023-01-01	Emergency	Completed	General Practitioner	Emergency Department	Acute abdominal pain	Admitted to hospital	2023-01-02	Completed	General Practitioner	Emergency Department	Acute abdominal pain	Admitted to hospital
2	2023-01-03	Specialist	Pending	General Practitioner	Specialist Clinic	Chronic hypertension	Referral pending	2023-01-05	Pending	General Practitioner	Specialist Clinic	Chronic hypertension	Referral pending
3	2023-01-06	Emergency	Completed	General Practitioner	Emergency Department	Acute chest pain	Admitted to hospital	2023-01-07	Completed	General Practitioner	Emergency Department	Acute chest pain	Admitted to hospital
4	2023-01-08	Specialist	Completed	General Practitioner	Specialist Clinic	Chronic kidney disease	Referral completed	2023-01-10	Completed	General Practitioner	Specialist Clinic	Chronic kidney disease	Referral completed
5	2023-01-11	Emergency	Completed	General Practitioner	Emergency Department	Acute respiratory distress	Admitted to hospital	2023-01-12	Completed	General Practitioner	Emergency Department	Acute respiratory distress	Admitted to hospital



### 3. DESIGNING AN OPTIMAL INFORMATION SYSTEM

# 3. DESIGNING AN OPTIMAL INFORMATION SYSTEM

The previous section outlined the need for TB information management systems that can effectively utilize data, while this section describes the optimal features of such an information system. The features described in this section are based on project experiences specific to TB management settings. They are aligned with the nine “Principles of Digital Development”<sup>5</sup>, a set of nine principles developed by a global working group in 2014–2016. These principles represent a valuable resource with actionable insights for implementers interested in applying digital technologies to development programmes.

Figure 4. The principles of digital development



## 3.1 Key system considerations

### Emphasis on the end-user

It is most important that the information system meet the needs of the people who use it. While this may sound obvious, many systems end up being designed and deployed without ever asking end-users about their specific needs. This can also happen when an existing solution is deployed in a different setting without adequate assessment and needs analysis. Furthermore, systems deployed with no end-user in mind are ineffective. If end-users find the system difficult and cumbersome to use, they will naturally either not use it at all or use it only because they are mandated – not because the system improves their day-to-day work.

Different end-users have different needs. For example, for a mobile app, the kind of visual interface needed by TB screeners working in the community will be very different from that needed by data entry operators retrospectively entering data into a screening form using a web-browser. Even though the data these individuals are entering are the same, a different type of interface is needed because they are working in different contexts. Consideration should also be given to the fact that TB screeners’ roles may vary across different countries.

<sup>5</sup> <https://digitalprinciples.org/principles/>

While NTP managers need to have data presented to them in an easily consumable way via a dashboard, those working at lower levels of the health system need to see reports in much more detail. An optimal system is one that has been designed after thorough analysis of the needs of different types of end-users (5). The system should also have a feedback loop for end-users to report back about problems in the system. Users should be consulted regularly (particularly after changes are made to the system) to ensure that the system is continuing to meet their needs.

### Reports and dashboards

A key use of information systems is to make data readily available for decision-making. This means that data need to be available in an easily consumable form, usually in a dashboard where key indicators are easily accessible. Data in the form of charts, graphs and tables can be used by programme managers and policy makers to assess programme performance, identify gaps that need intervention, and make decisions about protocols and standard operating procedures (SOPs).

India's NIKSHAY system (see Box 3) allows for different dashboards for different levels of providers, and the viewing of real-time notification data down to the health facility level.

### Box 3.

#### India's NIKSHAY system

In June 2012, India launched an electronic system called NIKSHAY – a combination of two Hindi words NI and KSHAY meaning eradication of tuberculosis – for tracking the nation's TB notifications. The system had the following objectives:

- Establish real-time TB surveillance through case-based-web-based electronic recording and reporting;
- Monitor treatment;
- Develop and make available a TB notification and registration system for both public and private sector use;
- Improve the quality of care by health service providers;
- Support the treatment of patients and reporting of cases;
- Increase transparency and accountability;
- Provide follow-up alerts for adherence;
- Provide the data required for planning at national and state levels;
- Provide TB-related information on epidemiological / social impacts.

While still a work in progress, the system has helped to bridge the public and private sector, allows for real-time notification tracking, aids in the procurement of medicines for each district, and is adding flexibilities and enhancing data management possibilities.

Figure 5. NIKSHAY system screenshot

	National	Public	Private	Total
	National	79525	15786	95311
State Name				
	State Name	Public	Private	Total
+	Andhra Pradesh	4452	1854	6306
+	Arunachal Pradesh	141	0	141
+	Assam	1489	50	1539
-	Bihar	2065	147	2212
District Name				
	District Name	Public	Private	Total
-	Aurangabad-BI	46	0	46
TBU Name				
	BARUN	3	0	3
	DAUDNAGAR	6	0	6
	DEO	4	0	4
	DTC AURANGABAD	17	0	17
	GOH	0	0	0
	HASPURA	0	0	0
	KUTUMBA	1	0	1
	MADANPUR	6	0	6
	NABINAGAR	5	0	5
	OBRA	3	0	3
	RAFIGANJ	1	0	1

### **Role-based access and restrictions**

Optimal systems provide different levels of access to different types of users. For example, the ability to edit a patient's treatment regimen in the system may be restricted to clinicians only. Similarly, many systems may limit users' access to data that are not relevant to their geographical region (e.g. provinces and districts). Such restrictions are important not only from the perspective of data integrity, but also in terms of patient privacy.

### **Designed in accordance with available infrastructure and context**

Context is an important consideration when designing systems. For example, a system that requires constant connectivity to the Internet will not work in areas where such connectivity is not available. Similarly, a system that is designed to operate on a massive cloud-based server infrastructure will not run off a laptop server, nor will an app designed for Apple devices work on more commonly used Android devices. An optimal system, therefore, is designed keeping in mind the context and available infrastructure in the setting where it will be used.

### **Health information exchange standards and data dictionary**

Standards already exist for the exchange of clinical and administrative data between software applications used by various health care providers, such as HL7 and the up and coming FHIR (Fast Healthcare Interoperability Resources) standard. FHIR was created by the same consortium that created HL7; however, it is considered easier to implement because it utilizes very commonly used web-based application programming interface (API) technologies, including REST with XML or JSON, and Atom feeds. Data can be exchanged seamlessly among systems that are built to conform to these standards, allowing for improved interoperability (not only from a systems perspective but also from a user perspective). In situations where the same data need to be entered into multiple systems, the interoperability brought about by standards compliance can reduce the data entry burden on staff and result in reporting efficiencies.

To ensure interoperability when systems are designed, implementers may request that developers provide a data dictionary or devise one on their own. A data dictionary defines each term in the system and can be used to ensure consistency across the system (e.g. "sample type" means the same thing throughout the system and all "sample type" drop-down menus contain the same options). This consistency is also important for enabling correct and accurate reporting and facilitating linkages to external systems, including the national system. Software systems like OpenMRS have data dictionaries that can be mapped to recognized medical terminologies such as SNOMED, ICD9, ICD10 and LOINC.

### **Linkages with diagnosis and treatment**

Diagnostic and follow-up tests are a critical point in the patient care cascade. In an optimal system, diagnostic devices are linked into the information system (where the device supports this) so that test results are automatically input into the system without the need for manual entry. This automatic entry can be combined with an active alert system to inform caregivers and programme coordinators of test results. This step is particularly important to prevent PTL-FU and decrease the time to treatment initiation. In cases where devices do not permit direct integration, the information system should either include a data entry and reporting interface for lab staff or be linked to the laboratory's information system, depending on the context. These linkages prevent test data from being entered into two different systems or being reported on paper (which requires data entry staff to come to collect results or have the results sent to them).

## Scalability and adaptability

### Scalability

Given that TB programmes operate at varying levels of scale and that protocols and processes can change based on new information, it is important for information systems to be scalable and adaptable. Scale can mean both geographical scale (e.g. a system must have room to add new basic management units (BMUs) and address hierarchies) and scale in terms of the amount of data and number of users the system can support. This means that both the software and the hardware should be built to support scalability and to not slow down noticeably when dealing with large amounts of data.

### Adaptability

Adaptability can take different forms. Some adaptability can involve end-users configuring the system for themselves, e.g. setting simple preferences and user roles, updating facility directories, etc. However, some changes to the system require a programmer to actually change the way the system works. The more adaptable a system is, the more easily and quickly such changes can be made.

### Public–private mix

Besides notification, an optimal system will not only support public-sector data entry and analytics, but also data and interactions in the private sector as well. (Notification systems are discussed in more detail in a later section.) Private sector TB care can vary in scale and scope across countries, and it is much more effective for an information system to allow inclusion of both sectors. The degree to which private sector providers can use a national TB information system will vary, because many private providers, particularly those in large private sector hospitals or upscale clinics, have their own electronic systems. The national system can facilitate private providers reporting into the system by providing a data standard to make all systems compatible.

## 3.2 Key system components

### Patient identifiers

UPIs are a cornerstone of a good information system. A UPI is used to link patients to their test results, follow-up visits, and outcomes and to ensure that reporting is done correctly. If implemented broadly, UPIs may also be used to link patient data across systems, for example between the LIMS and the treatment initiation tracking system. Unfortunately, UPIs are not always straightforward to implement. The decentralized nature of TB programmes coupled with the fact that many systems are used offline makes it difficult to generate UPIs in real-time at the point of care in most settings. While national ID numbers, where available, can be used as UPIs, it must be kept in mind that vulnerable and marginalized populations in many settings do not have national IDs (and are often those most in need of care). Therefore, provisions must be made for these situations.

Other options for UPIs include biometrics (most commonly fingerprints), but these require specialized equipment and infrastructure for registering and searching. In addition, fingerprints are often difficult to accurately match for young children and those involved in manual labour (e.g. miners). Another possibility is pre-printed, centrally generated UPIs in the form of barcodes or text on sticker paper distributed to health facilities. These can then be pasted onto a physical ID given to the patient (please see Figure 6). Given that physical IDs can be lost, however, an optimal system would make it possible to search for patients to a reasonable degree of accuracy using other criteria such as date of birth, name, phone number, etc. It is important to note that the link between the UPI and the individual patient information should only be accessible at the level of care.

Figure 6.

Using a UPI to track a sample to the lab and to send out an alert with the result



ID assignment at enrolment



ID affixed to sample cup



ID scanned to retrieve and update patient record at lab



ID used to find enrolment site, contact information and send SMS alert to caregiver

Source: Indus Health Solutions (IHS)

### Case-based data for the entire care continuum, including “active alerting”

Ideally, an information system for TB patient management should enable the recording and reporting of individual patient data at every step in the care cascade from screening to diagnosis, notification, treatment initiation, follow-up tests and visits and through to outcome, including referral. Patients

re-enrolled in treatment (e.g. due to relapse or determination that the patient has DR-TB) should appear in the system with a link to their prior treatment record, thus presenting an integrated view of a single individual’s history and facilitating more effective management of patient data.

### Active alerts

Active alerts are an important way to keep programme staff informed of important intervention points in the case cascade for a patient or key programmatic event. For example, active alerts regarding missed follow-ups, positive diagnoses, drug supply below minimum thresholds and other similar events enable programme staff to adopt a more active intervention approach, unlike a passive approach whereby staff need to open a report or patient record to view this information. Alerts can be implemented in different ways, depending on the context in which the system is operating. Examples include pop-ups when logging in to a web-based system, SMS alerts sent to a phone, visual alerts on a mobile app, or even email alerts. It is useful for the system to have a mechanism for users to indicate that they have responded to an alert.

### Linkages with national health information and inventory infrastructure

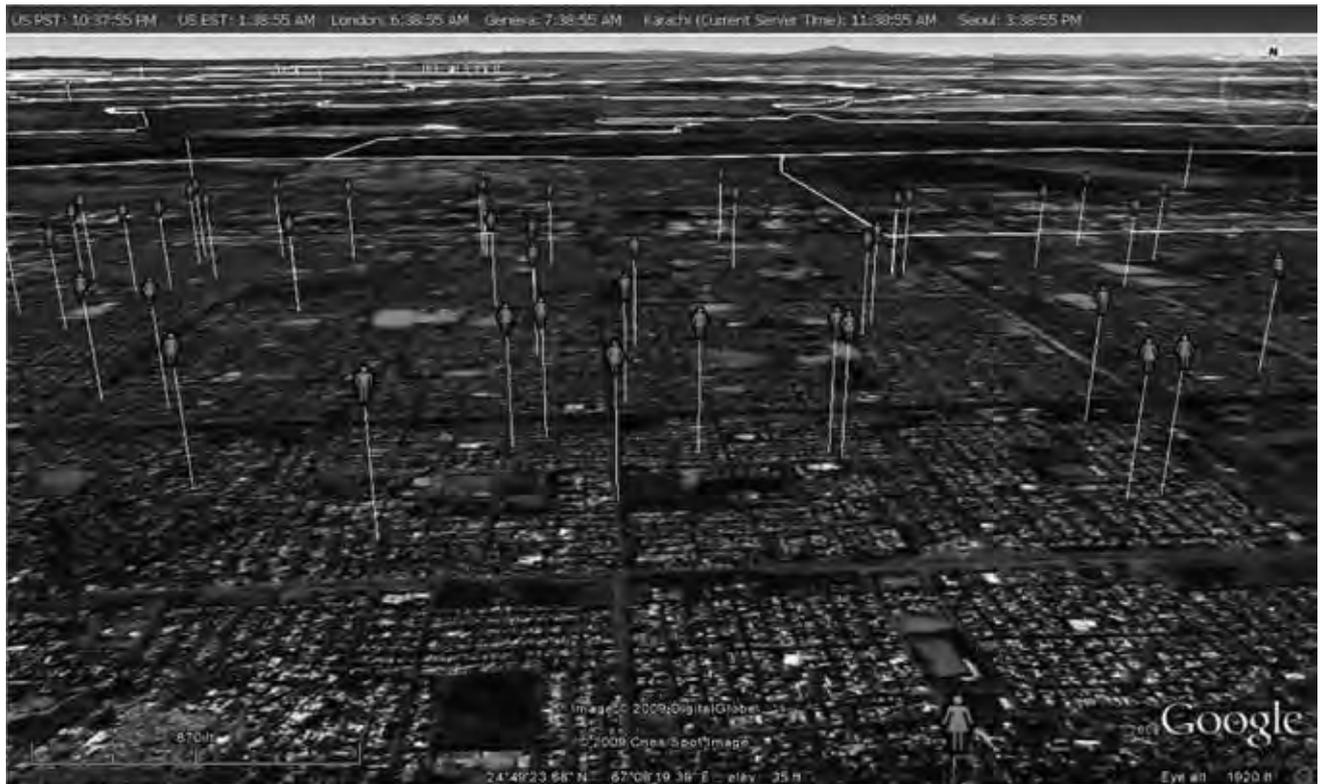
The TB information system should link with the country's central health information system (if there is one) and/or to other appropriate health systems, e.g. HIV, inoculation tracking systems. This means that the variables being collected by the TB information system should align with the country's national indicators and variables. While national case-based systems are not common, many countries do have national aggregate data systems like DHIS2; it is important for the TB information system to link with the national system so that the government has access to correct and complete data for national reporting and decision-making. It is important for TB programmes to keep track of inventories, particularly drug inventories. Understanding where medicines are located, when they need to be replenished, and how to transfer them between locations when needed can be part of the functionality of the information system. For example, India's NIKSHAY system allows district TB offices to plan procurement of medicines. Information systems that are linked to laboratories can also be used, for example, to update lab inventory such as GeneXpert cartridges, smear slides, etc. Similarly, information systems that track drug disbursement can be used to track drug inventory.

### Geographical Information

A key part of an optimal information system is the ability to view data geographically on a map. Being able to see facilities on a map and understand where patients are seeking care can help programmes to identify gaps in the health system as well as disease clusters. The Indus Hospital MDR-TB system stores GPS-encoded locations of patients in its database, which can then be displayed on a map (see Figure 7). For community-based programmes, recording the location of each data entry event (e.g. a screening event) and then viewing these locations in a geographical information system can offer an important window into understanding how community health workers operate. For example, it may be possible to track the route taken by community health workers in order to shed light on their day-to-day work. The ability to display notification trends graphically using charts or maps is especially useful in identifying unusual changes or spikes over time or in particular areas. Some concerns over privacy and the use of GPS and GIS mapping have recently emerged. Consequently, implementers need to be aware of these concerns in order to protect patient privacy and prevent stigma against particular communities.

Figure 7.

MDR-TB hotspots in Karachi



Source: *Electronic recording and reporting for tuberculosis care and control (3)* and IRD



6

KEMENTERIAN KESEHATAN RI  
KEMENTERIAN KEMASYARAKATAN DAN TRANSFORMASI DIGITAL

KEMENTERIAN KESEHATAN RI  
KEMENTERIAN KEMASYARAKATAN DAN TRANSFORMASI DIGITAL



## 4. RECOMMENDED PROCESS OF DEVELOPMENT

# 4. RECOMMENDED PROCESS OF DEVELOPMENT

The process for developing a robust information system should consist of five steps: planning, piloting, monitoring, iterating and maintaining. These five steps are described in detail below.

## 4.1 Plan

The first step to building (or buying) an optimal information system for TB management is to plan. Section 5 of this field guide outlines the resources needed to create and run these systems; it is important to ensure that those resources are in place or can be made available when needed as the system is developed and deployed, and enters maintenance phase. While Section 2 outlines the various features and characteristics of an optimal system, it must be understood that context and available resources will often determine what can and cannot be built (or bought). Some components may already be in place, while others

will need to be built from scratch. Those components that are in place may not be functioning well and may require changes and enhancements. Multiple stakeholders should be consulted in the planning phase (see Table 2 below). Careful planning will enable systems to mature over time when resources are available and ensure that the minimum set of features needed for a TB programme to use the system effectively are available from the outset. Since this minimum will vary by country and context, programmes will need to decide on their priorities and plan accordingly.

Table 2.

## Inputs from different stakeholders when designing an information system

Stakeholder	Type of Input
NTP management	Buy-in for the system, TB programme priorities, funding and timelines, ownership of data. If the system is being funded by private or donor sources, NTP agreement to take ownership of the system in some agreed timeframe
TB Technical Experts and M&E staff	Data dictionary, content and content validation, programme workflows, indicators, reporting requirements
Lab Management (e.g. from NRL and other labs)	Sample collection and test recording workflows, lab indicators and reporting, diagnostic device connectivity
Implementation teams	Field constraints, e.g. terrain, network connectivity, power constraints, field team workflows and management structures
Software Developers	Building or configuring the system. Must be aware of the system scope and requirements
NTP IT Staff	Planning server hosting and (where needed) system handover processes
Field Staff, GPs, Lab Technicians	Identifying pain points with current system, as the ones who use it every day. User interfaces and data workflows must make things easier for these users for the system to succeed.

## 4.2 Pilot

Before going live, each feature should be piloted in the field to ensure that it is working as expected.

There are many reasons as to why a system may not function as intended, for example:

- The software development team did not understand exactly what was needed.
- The programme team did not understand field realities.

While there is no guarantee that the pilot will bring all gaps in an information system to light, the process usually serves to

highlight any major issues. It is important to remember that exposing a large number of users to a problematic system on day one may lead to a loss of trust that is very hard to rebuild, even once the problems are fixed. By piloting the system with a small number of users in a specific area, this risk is minimized. Programmes must plan for pilots, building them into budgets and project timelines. Not planning for pilots and rushing to roll systems out quickly to meet unrealistic timelines can result in the complete failure of an information system.

**Phases 1, 2, 3, 4:** Basic Information about facilities and officials in the RNTCP, information on TB cases initiated on DOTS, notification of TB and registration system: This will involve registration of health establishments and data entry of notified TB cases at TU and district level.

**Phase 5:** Programmatic Management of DR-TB: Details of MDR-TB requests and results will be uploaded by DST labs, and treatment details will be uploaded by the treatment centres.

**Phase 6:** SMS-based treatment monitoring and follow-up: Push query and pull information on treatment adherence from DOT provider on a weekly basis with periodic SMS alerts to patients.

**Phase 7, 8:** Linkages between facilities for transfer and referral: Linkage of various public health establishments and track the transfer of patients from one centre to another. The data entry for referral will be done at the TU level and the receiving TU will be alerted through various channels.

**Phase 9:** Handheld device use: NIKSHAY application will be made available on Android handheld devices.

**Phase 10:** Multiple entry mode: This will include mapping and defining the output of automatic machines for rapid diagnostics for TB.

**Phase 11, 12:** Web-based TB notification and mobile, IVRS-based notification for private health facilities

**Phase 13:** Automated output with inbuilt statistical software 4

**Phase 14:** Programme management: This phase will enable electronic transfer of incentives to relevant stakeholders, including medicine and logistics management.

**Phase 15:** Proposal tracking system

**Phase 16:** GIS mapping of DR-TB cases & TB cases notified

*\*From 'NIKSHAY' – harnessing Information technology for delivery of enhanced TB care by R. Jitendra.  
<http://medind.nic.in/nac/t12/i1/nact12i1p4.pdf>*

## 4.3 Monitor

Once a system has been piloted and rolled out in the field, it is important to carefully monitor its use. For a system to be effective, data collection must be done accurately and in a timely manner, collected data must be validated and (if needed) cleaned, and reports must be viewed regularly. It is important to understand whether the system is i) being used and ii) being used effectively.

Monitoring can be carried out remotely by looking at reports; however, it is also important for system developers to visit the field, speak with the end-users and observe them using the system. This will give end-users the opportunity to identify pain points in the system and suggest useful system features that would make their work more efficient.

## 4.4 Iterate carefully

In a system working at scale where many users may be working offline, repeated changes can result in disruption in the field, different users working with different versions of the system, and inconsistent data being collected. While critical bugs may need to be fixed urgently using hotfixes, it is generally advisable to have a regular release cycle in which new versions of the system are released at a set frequency (e.g. one a week or one a month). This frequency may be high during the initial stages of system deployment, but should become lower over time. With a set schedule, the programme and field teams will know when to expect a new release and what changes to expect in the release. In many systems, releases may require data col-

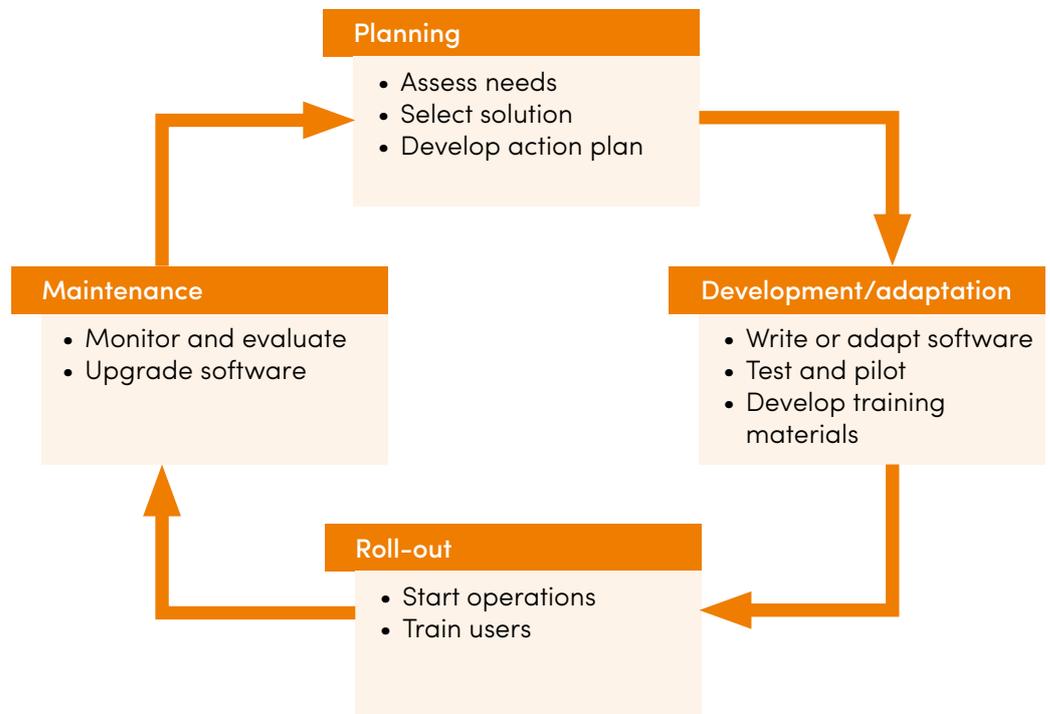
lected offline using older versions of a system to be uploaded before upgrading to the new version. These dependencies and prerequisites should be clear to all users of the system so that new versions can be released and used without causing disruption.

## 4.5 Maintain

Once a system has been rolled out and any major initial changes have been made, IT support and software development support are still required. Continuous engagement between the programme and the IT and development teams is important to ensure that things continue to run correctly and problems are dealt with quickly and efficiently. This is similar to having a support contract for a diagnostic device.

Figure 8.

The four-step cyclical implementation process used by Management Sciences for Health.



Source: WHO's *Electronic recording and reporting for tuberculosis care and control* (3)

# 5. RESOURCE REQUIREMENTS

The screenshot displays the GeneXpert Data Systems software interface. The main window is titled "GeneXpert Data Systems" and includes a menu bar with "User", "Data Management", "Reports", "Setup", "View Results", and "About". Below the menu bar is a toolbar with icons for "Create Test", "Check Status", "Setup Test", "View Results", "Define Assays", "Define Graphs", and "Maintenance".

The interface is divided into several panels:

- Left Panel:** Contains fields for "Sample ID" (7659-659799), "Assay" (KpertMTB Rif-Ke day 64), "Version" (5), "Reagent Lot ID" (15804), "Test Type" (Standard), "Sample Type" (Other), "Other Sample Type", "Notes" (F.18, V81 NJ, HRO), "Start Time" (11/02/15 08:33:20), "End Time" (11/02/15 09:20:54), "Status" (Aborted), "Upload Status" (Unloaded), and "User" (None).
- Top Panel:** A table with columns "Description", "Notes", and "Time". It lists four test runs with their respective descriptions and times.
- Bottom Panel:** A graph titled "Fluorescence" showing a signal over time. The y-axis ranges from 0 to 200. The x-axis is labeled "Time (min)". The graph shows a baseline signal that remains low throughout the run.

At the bottom of the window, there are buttons for "View Chart", "Export", "Report", "Upload Test", "Select Assays", and "View Test". The system tray at the bottom right shows the time "12:28 PM" and the date "11/02/15".

## 5.1 Software requirements

It is important to be very clear about what exactly a TB programme requires the information system to do. To this end, the programme must be very specific about the patient journey, variables to be collected at each step of the journey, who collects the data, what the reports should look like, and who will be using the system for collection, validation and analysis. Often, the software developers formalize these aspects in a requirements document following extensive consultation with the programme. This document provides the blueprint for the software development team to create the system. The more clarity there is around the needs of the TB programme, the greater the chances that the early versions of the developed system will meet those needs. It is critical to remember that software developers may not understand TB control and so the information passed to them needs to be as detailed as possible.

It is also important to understand and document who has access to what data. In general, a good guiding principle is that a user should have access to the data they need to do their job and not more. For programmes using mobile tools for data collection, offline connectivity is usually an important requirement so that work can continue unimpeded for the most part in situations where connectivity is not available.

## 5.2 Implementation plan

After determining requirements, it is essential to create an implementation plan in consultation with the software development team. This plan should detail when specific components of the system will be made available to test and use, ideally synchronized with when the programme will actually start implementing those processes in the field. As a basic example, for a programme just starting out, it is more important to have a screening tool in place up-front than a follow-up tool, since the first follow-up will likely not happen until a month or two after the first patient is diagnosed. The implementation plan should also detail timelines for end-user feedback, the timelines by which a delivered component should be tested in the field, and the timelines by which any changes and bug-fixes must be incorporated before the component goes live. It is usually not a good idea to build the whole system first and then test it in its entirety. A better and more efficient approach is usually an iterative one, whereby implementers get to try out different components at different stages of development and provide feedback. Of course, this means that implementers need to be involved throughout the whole process. Having a detailed implementation plan agreed to by all stakeholders will ensure that all groups are aware of how the system will be introduced and improved over time, thus helping to manage expectations over timelines, scale, the features that will be made available over time, and the effectiveness of the system.

## 5.3 Infrastructure and equipment

Good software will fail in the absence of adequate hardware infrastructure. This means that programmes must plan to purchase appropriate servers and data entry devices (e.g. phones, tablets, laptops, desktops, barcode readers, fingerprint readers, printers) as per the needs of the information system. The placement of these systems, where the various parts should be installed and in what format are important considerations. For example, it may be easier for a care provider or data entry operator sitting at a desk in a facility with a good Internet connection to enter data on a laptop or desktop as opposed to a mobile device. Meanwhile, for a frontline health worker in the field, using a tablet may be easier than a phone owing to the larger screen size. In some environments, however, a phone may be the better option, as the visibility of the tablet may present a greater security risk. These decisions should be made in consultation with the software development team.

Servers must have adequate specifications, database backups should be automated, and physical and remote access controls should be in place to prevent data loss and/or data theft. It is also important to factor in Internet connectivity for mobile devices, computers and servers.

## 5.4 Ownership and hosting

Data ownership and hosting are critical components of information systems that are often overlooked until very late in the process of building and deploying these systems. Generally, the data collected using information systems is owned by the NTP. If private providers are involved, however, they must be consulted about ownership and protocols for data sharing need to be developed. If data need to be shared with a donor or other external party, patient privacy must be a key consideration when deciding what

can be shared. Confidentiality agreements should ideally be signed with third parties or individuals who are managing the software and/or hosting for the programme in order to provide recourse if patient privacy is breached. Another important question is where servers and data are hosted. Many NTPs are averse to the idea of their data being physically housed in other countries. For many countries, this means either opting for locally based hosting service providers (who are often more expensive than large foreign cloud providers) or hosting servers themselves at the NTP or other government infrastructure.

Regardless of the choice of hosting location, key things to keep in mind are the following:

- Servers must be equipped with backup power and ideally also backup Internet connectivity so that data entry is not impacted by outages.
- Servers usually require 24/7 air-conditioning and other environmental protections from dust and humidity, as well as protection from power surges and voltage fluctuations.
- Technical support should be available so that problems with server infrastructure can be quickly identified and resolved. A comprehensive Service Level Agreement (SLA) should be developed (an SLA can serve as a commitment between the service provider and the users or NTP. Specific aspects of the service – quality, availability, responsibilities – can be agreed between the service provider and the service user).

Another important ownership consideration is ownership of the software. This is less of a concern when using an open-source tool, but programmes should ensure that they have access to the latest version of the software source code. When dealing with custom-built proprietary systems, it is important to ensure that developers make the code available to the programme. For proprietary systems that are purchased “off-the shelf” (rare in the TB world), programmes should be aware that they will not usually have access to the code (barring a special agreement to the contrary); consequently, they will be locked in with that vendor for as long as they continue to use the software.

## 5.5 Human resources

Aside from commissioning individuals or firms for software development and hosting, implementers must plan for human resource capacity to carry out field implementation, training, and ongoing maintenance and technical support. Additionally, it is critical to be prepared to recruit staff for data management, data cleaning and data validation, and at least one individual to liaise with the software development team and represent the programme in discussions on requirements, roll-out plans, and support.

## 5.6 Funding and other programmatic support

Funding is obviously critical for the purchase or development of software systems and required hardware and equipment. However, there must be funding available for ongoing maintenance and changes to the system. While everyone strives towards developing an optimal system, no system deployed in the field will be perfect on day one. Field experience can instigate changes. Changes might also be needed after additional programmes or sub-programmes/studies have been initiated, there is a desire to integrate with other systems in use or there are advances in TB control (e.g. existing information systems had to be updated to incorporate GeneXpert when it began to be deployed; now systems need to be updated to use the Ultra cartridge). Consequently, it is critical for programmes to understand that funding for information systems is not a one-time need. A significant amount of funding is needed up-front for active development and then roll-out. However, it is equally critical for some level of funding to be available long-term for maintenance and enhancement of the system, to repair/replace/upgrade hardware, and to provide connectivity for data entry devices and servers. Whether NTPs use this funding to build internal capacity for these tasks or commission a software vendor or IT firm to do them is implementation-specific and will vary from country to country, depending on national strategy and priorities.

Donors have increasingly encouraged the use of information systems, and system development is often seen as a milestone for TB programmes. However, it is important that NTPs truly buy in to these systems, meaning that governments need to find ways to fund these systems beyond grant timelines and make data use and analysis a major part of their TB control efforts.

LESOTHO NATIONAL TB CONTROL PROGRAMME  
REQUEST FOR SPUTUM EXAMINATION

6. MEASURING THE IMPACT OF THE INFORMATION SYSTEM

SPE  
PURPOSE

SI  
DIAGNOSIS  
OR  
FOLLOW UP

(TB treatment)

RESULTS-LABORATORY

SPECIMEN	APPEARANCE			AFB RESULTS*	REMARKS
	MUCOPURULENT	BLOOD STAINED	SALIVA		

AUG 16 9:00

Grading of specimens should be noted (2+2+1+1) is

LESOTHO NATIONAL TB CONTROL PROGRAMME  
REQUEST FOR SPUTUM EXAMINATION

Suspect No: 686/11 Lab No: \_\_\_\_\_  
Patient's District No: \_\_\_\_\_

Up to 3 Separate Specimens from the same patient may be sent with one form

NAME	SURNAME	AGE	SEX	DOCTOR	DATE

ADDRESS FOR RESULTS (Specify ward, clinic, hospital etc.) OPD

SPECIMEN TYPE: SPUTUM:  OTHER:  (Specify)

PURPOSE OF REQUEST:  DIAGNOSTIC (Investigation of possible case, NOT currently on TB treatment)  
OR  
 FOLLOW UP (Patient currently on, or completing treatment)

APPEARANCE ONLY

SPECIMEN	MUCOPURULENT	BLOOD STAINED	SALIVA	AFB RESULTS*	REMARKS

\*Grading of specimens should be noted (2+2+1+1) is

EXAMINED BY: \_\_\_\_\_

This section addresses a set of questions relating to impact evaluation of new or existing information systems that have been modified, and especially purpose-specific electronic databases. The general principles of evaluating TB programs apply, i.e. district, province and national official notifications and prevalence surveys should be the principal impact measures, and the care cascade should be enumerated at every feasible step in the process of TB care. Some questions to consider when designing M&E tools and measuring the impact of the information system include the following:

- **Can repeat measures be triangulated for consistency?** It is common to find that large increases in diagnosis or treatment shown in project databases have little effect on existing (usually manual) notifications from a specific geographic area. Common causes include (earlier) testing of people with TB symptoms who would have presented for TB care in any case; and people with TB symptoms travelling within the encompassing area to seek care from the project. Differing inclusion criteria based on head count or cohort membership may affect the comparison of corresponding monthly, quarterly and annual data between systems.
- **Are additional notifications seen at district/provincial/national level?** Against a completely stable baseline, even a tiny number of additional notifications would be detectable; but in practice, time-series fluctuate so that small increases are not visible against background noise. Fluctuations follow the granularity of programmatic activities, and simple confidence intervals are not generally helpful at district level. Nevertheless, quantifying and understanding time-axis variation may be important, for example, when the 'signal' observed at the centre of an intervention attenuates at progressively larger encompassing areas. Observing such a dose-response effect adds credibility to surveillance efforts as a whole.
- **Can prevalence be estimated directly?** Successive, adequately powered and well-conducted prevalence surveys are the gold standard of TB impact assessment. In the case of IT interventions, such surveys may result in the identification of local factors that will enable notifications to correlate better and therefore act as a more reliable guide to direct control efforts. National surveys are geographically stratified and weighted to be representative of the whole country, but re-analysis of nearby clusters may be a good starting point.
- **Can stable baselines and comparison populations be established?** Whether the unit considered is a hospital, a district, a province or even perhaps a country, the first question is 'Impact compared to what?' Judgment is almost always required, together with time taken to explore how existing systems actually work; and to explain trends, gaps and errors. Programme credibility will depend on how well the surveillance picture can be characterized. Separate aspects of impact will need separate baselines and controls, e.g. DR-TB, children and the elderly; and it may require ingenuity to design a method to disentangle improved reporting from the effect of co-existing TB care interventions.
- **Has there been overall increase in laboratory testing?** A point that is often overlooked is that without a population-level increase in testing, it is unlikely that missing people with TB will be found. This means that laboratory linkage generally needs to be a parameter of IT system evaluation. Existing systems that notify at the point of treatment initiation may have poor ascertainment of diagnostic testing (especially in private laboratories), and the linking of records to ongoing individual patient care may not be present at all.



- WHO's m-Health tool published in 2011: [New horizons for health through mobile technologies](#)
- WHO's 2012 guide on ERR: [Electronic recording and reporting for tuberculosis care and control](#)
- PATH and WHO developed a toolkit in 2013 to help public health managers plan the implementation of information and communications technology (ICT) in health information systems; it draws on lessons learned during project Optimize, a 5-year partnership between WHO and PATH to help optimize the vaccine supply chain: [Planning an information systems project: a toolkit for public health managers](#)
- A 2015 article in the Lancet that describes how locally tailored responses that are informed by appropriate data can be crafted and used: [Data for action: collection and use of local data to end tuberculosis](#)
- UN report on m-Health: mHealth for development
- WHO's 2016 summary of plans to profile and support the development of priority digital health products to support the scale-up of WHO's End TB Strategy: [Digital health for the End TB Strategy: developing priority products and making them work](#), and [Target Product Profiles for digital health products for the End TB Strategy](#)
- A 2017 paper from India that looks at the feasibility and yield of presumptive TB case referrals with rural health care providers using mHealth technology: [Using mHealth to enhance TB referrals in a tribal district of India](#)
- Information on India's mHealth tool for TB: <https://nikshay.gov.in/AboutNikshay.htm>
- A 2016 article that describes ongoing mHealth approaches to monitor and enhance TB treatment adherence: [mHealth for tuberculosis treatment adherence: a framework to guide ethical planning, implementation, and evaluation](#)
- Project description of PATH's digital system supports adherence to TB treatment in Viet Nam: [Using mHealth to combat multidrug-resistant tuberculosis across Vietnam](#)
- A 2015 report from WHO: [Digital health for the End TB Strategy](#)
- GLI's 2016 guide that provides valuable information on logistics, results reporting, data management, monitoring and evaluation, and standard operating procedures around specimen referrals: [Quick guide to TB diagnostics connectivity solutions](#)
- WHO's 2018 publication on adherence-related technologies: [Handbook for the use of digital technologies to support tuberculosis medication adherence](#)

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This document is one in a series of 11 field guides produced by Stop TB Partnership in collaboration with the Global Fund to Fight AIDS, Tuberculosis and Malaria, Interactive Research and Development Global (IRD), KIT Royal Tropical Institute, and multiple global experts and implementation partners. The field guides rely on practical experiences and expertise of implementers and are meant to help national TB programmes and other TB programme managers to identify the best strategies for finding people with TB who are missed by routine health services.



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