

***HOW TO PLAN AND IMPLEMENT CONNECTIVITY SOLUTIONS***

Facilitator Guide (FG5)

SUMMARYOF MODULE AT A GLANCE

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| **Purpose of module:** | To provide participants with an overview of diagnostics connectivity solutions, familiarize participants with their functionalities and requirements, and introduce participants to the resources available to learn more about diagnostics connectivity solutions and the current products’ functionalities. | |
| **Total time of module** | 1 hour 15 minutes | |
| **CONTENT OUTLINE** | | |
| **Power point: How to plan and implement connectivity solutions** | Aim: To familiarize participants with diagnostics connectivity solutions, including their uses, and what is needed to establish and implement one, in terms of software, hardware, internet connectivity, personnel and costs. | 20 minutes |
| **Discussion questions** | 1. What are the three components of a diagnostic connectivity solution? 2. What are advantages of electronic data over paper-based data? 3. How can diagnostic connectivity solutions can benefit TB programmes? 4. What should be included in a Data Use agreement with a software provider? 5. What are budgeting requirements during the preparation, set-up/installation and operational phases of a connectivity system? | 15 minutes |
| **Exercise: Functionality of a data connectivity solution** | Aim: Functionality of a data connectivity solution | 40 minutes |
| **Handout and exercise/prac­ticals in module:** | 1. Worksheet 1: Functionality of a data connectivity solution (W1:PM5) |  |
| **Additional resources or references:** | 1. GLI Quick Guide to Diagnostics Connectivity Solutions:<http://stoptb.org/wg/gli/assets/documents/gli_connectivity_guide.pdf> 2. A comparison of available data connectivity solutions for TB diagnostics: <www.tinyurl.com/gliconnectivity> |  |

Module notes

Slide 4 This module is based on the *GLI Quick guide to TB diagnostics connectivity solutions.*

Slides 7-11 (How can connectivity solutions be of use to your TB programme?):

* Remote monitoring and quality assurance: The head of a national reference laboratory or other authority can easily see how many tests are being performed and where, what are the results, and which sites are underperforming or experiencing abnormal results or errors, which may highlight a need for troubleshooting, device repairs, targeted on-site supervision, or retraining of technicians. Automated messages and warnings may be set and triggered when established thresholds are reached that require further investigation and follow-up.
* Sending results automatically to clinicians: Test results (or a subset of them; for example, rifampicin-resistant test results) can automatically and instantly upon result availability be sent to a clinician’s phone or email, SMS printer or other clinical results reporting mechanism, allowing for faster patient follow-up.
* Sending results automatically to laboratory information management systems or electronic registers: Some software can also be configured to allow for additional patient information to be entered; for example, a patient’s HIV status or prior TB treatment history could be captured, aiding a programme to measure testing coverage and implementation of diagnostic algorithms. In the absence of an existing laboratory information management system or electronic register, some software may also be used to create the foundation for electronic patient medical records.
* Inventory management: Replenishment of inventory can be managed before stock out, or potential expiring cartridges can be prioritised or moved to other sites. In addition, the tracking of lot numbers can identify poor performance and abnormal error rates for quality assurance purposes. Likewise; certain software can track the status of warranties and when they approaching the time for renewal, as well as the need for upcoming calibration checks.
* Surveillance: Software can avoid repeat enumeration of samples from the same patient and programme performance can be shared with appropriate agencies and disease prevalence can help understand future care needs. Connected diagnostics are expected to enhance the capacity of national TB programmes to generate performance indicators and provide data for the top 10 indicators of the End TB Strategy.
* Data Access: Software can usually be configured so that subsets of data are made available to those that need it for maximum utilisation whilst easing the burden of information overload for those who don’t. Information can also be shared securely with partner organisations and manufacturers for support and product improvement purposes. Secure systems also protect the privacy of the patient.

Slide 12 (What connectivity software is needed)? Connectivity software platforms have been developed by diagnostics manufacturers (for example, C360 by Cepheid, USA, for GeneXpert®) as well as by third-party companies and organisations, including GxAlert™/Aspect™ by SystemOne, DataToCare™ by Savics, and Connected Diagnostics Platform by FIND.

The MOH may also want to select a software that can collect and use data from different diagnostic devices, e.g. GeneXperts® and Alere PimaTM analysers. Connectivity software platforms may have complementary functionalities, justifying implementation and use of more than one software platform in the same country. For example, a country might use a manufacturer’s software so that the data can be sent directly for troubleshooting and maintenance purposes, while also using another software platform for supply management or remote monitoring.

Slide 14 (What hardware is needed?) Data from connected diagnostics must be stored on a server. These servers can be either hosted directly by a MOH or by a third party.

In order to send data from the diagnostic device to the server, the device will need access to the internet. This capability is typically provided by a modem, which can be in various locations:

* Some diagnostic devices have in-built modems, but this is an exception.
* Modems may be present in the companion computer if the diagnostic device has one, such as in the desktop or laptop computer accompanying a GeneXpert. These computers often have Ethernet or Wi-Fi connection capabilities; however, most laboratories lack an existing broadband internet connection that is needed in order to make use of the computer’s Ethernet or Wi-Fi connection capabilities.
* A 3G/2G modem in a USB internet dongle may be an option. These dongles contain SIM cards and access to the internet is provided by a cellular provider. Although they are relatively inexpensive, dongles carry a risk of being removed, misplaced and misused. Many countries that have relied on USB dongles have struggled to keep them present and functioning at the computer for extended periods of time.
* Standalone desktop modems (also known as smart routers) are generally the more reliable option but are more expensive. Desktop modems are separate from the diagnostic device and companion computer. The diagnostic device or computer will need to connect using Wi-Fi, Ethernet cable, RS-232 serial cable, or another connection to the modem, which then connects to the internet using cellular networks by way of SIM cards inserted into the modem. If the computer doesn’t have Wi-Fi capability to connect to the modem, an Ethernet cable or Wi-Fi dongle will be required to connect the computer to the desktop modem. It may be required to setup a firewall and limit internet sites for certain applications to limit misuse of device computer and the data package.
* Some desktop modems provide the ability for dual- or quad-SIM deployments to leverage multiple mobile networks in a country, capacity for improved remote support, and internal security software to encrypt data and prevent unauthorised use of the data. However, desktop modems are not without their shortcomings. Many do not initiate retransmissions after network or power failures. Based on their experience in the field, CHAI has conceptualised the ‘Node’, a mini-server modem/router combination in a box which is described as a more robust and secure solution for automatic transmission in fragile connectivity environments, and is less vulnerable to unintended use compared to a PC with comparable software controlling the router.

Where cellular networks are used to connect devices, it is advisable also to make use of private Access Point Names (APN) and Virtual Private Networks (VPN). In conjunction with desktop modems, these allow additional security and usage protection by limiting the use of data to the intended purpose, i.e. the SIM card cannot be used for general internet browsing as well as reducing the risk of acquiring a computer virus. Private APNs are generally not available when using prepaid SIM cards.

Additional hardware that is recommended for use with desktop modems are external antennas. These allow stronger and more stable connections if the modem is accessing the internet using cellular networks.

Slide 15 (Internet connectivity: SIM cards and data plans): In resource-limited settings, the modem as described above will usually need to access the internet via cellular networks such as 2G, 3G and 4G. For the modem to access the cellular network it will need a SIM card with an active data plan.

The data plan (measured in Megabytes-MB or Gigabytes-GB) should be sufficient to allow the transmission of data from all connected devices to the server. The data plan should also be sufficient to allow updates of anti-virus software and remote troubleshooting capabilities from the solution providers.

Data plans come in two variants:

* Prepaid – Data are purchased in advance and once depleted will need to be topped up again. Generally, these plans are not advisable: countries using them frequently struggle to keep SIM cards activated and topped up. The top-up process often requires the SIM to be removed from the modem, there is often a lack of visibility of the remaining credit available on the SIM cards, and the process requires human intervention.
* Postpaid – Data are paid monthly after use. This requires a contract to be in place with the network provider, and credit terms to be established in advance of launching the network.

SIM cards and data plans are often provided by the solution vendors but should be verified in the assessment, planning and budgeting stage of the connectivity project.

Slide 16 (Hosting options): Hosting of the data collected generally has two options.

* Direct hosting using an in-country server: When the server is in-country, the MOH may have complete control over the data. This option requires adequate infrastructure, financial resources, and IT personnel to configure and maintain the server, including renewing software licenses and hardware upgrades. In-country servers will also need to budget for periodic offsite backups, a failover system, and feature upgrades. When hosting a connected diagnostic application within a MOH, a quarterly upgrade plan should be established to ensure the MOH can leverage all new features and security measures in place by the selected provider.
* Third party hosting: Modern third party hosting platforms are highly secure, provide redundancy against data loss, are quickly scalable and are a good option when a country does not have the IT capacity to properly configure and maintain an in-country server. Third party hosting is available for a monthly or annual hosting fee and is almost always cheaper than a dedicated in-country self-hosted server simply due to economies of scale of the business models of hosting companies. Some manufacturers offering a proprietary connectivity solution may require the testing and device data to be stored on a designated third party hosting platform.

Slide 17 (Data ownership and security): If the chosen connectivity solution is being hosted by the connectivity software provider or on a third party hosting platform, a Data Use Agreement signed by the MOH and the connectivity software provider is recommended. Such an agreement should assign ownership of all data to the MOH, grant the MOH the decision to share access with selected parties, describe in detail the planned storage and security of the data, and any planned use of the data by the software provider, ensuring that patient data remains confidential and not disclosed to unauthorised users or used by the software provider outside of the terms of the agreement.

If the hosting and management of the servers is in-country, then no Data Use Agreement would be needed with the software provider unless the provider has some form of remote connectivity to the servers for maintenance and troubleshooting purposes where access to data would be possible. A Data Use Agreement may nevertheless be beneficial to have with any in-country service providers or other selected parties to whom access to data would be granted.

Slide 18 & 19 (Personnel needs during the operational phase): Allocation of in-country staff with designated mandates and responsibilities is required for the operational phase, i.e. post set-up of the connectivity solution. This team will be responsible for the continued operation, utilisation and maintenance of connectivity solutions:

* National, regional and local level data monitoring: Persons should be assigned to systematically monitor data on a weekly or biweekly basis. Thresholds should be established related to error levels, underutilisation of tests, under/oversupply of stock, or other metrics, and identified sites should be followed up per a standard operating procedure (SOP). Quarterly review of data by an M&E team should review trends in device utilisation and test results, and data related to patient access/coverage.
* IT/network support: Server maintenance will be required if data are hosted in-country. IT support is also required to troubleshoot connectivity issues that may arise at the site level.
* Data connectivity administration: Administrative support will be needed to ensure data invoices are paid or sim cards are topped up if applicable.
* Training: Continued training of existing users and training of new users will be required to ensure maximum benefit and minimum issues.

Slides 20-23 (Budgeting):

The costs required to set-up and operate a connectivity solution are highly country dependent, yet there are a number of common budget items. The following items should be budgeted to ensure a comprehensive solution:

Preparation phase:

* Landscape assessment: In-country assessment of existing systems and infrastructure (both laboratory and connectivity) by a diagnostics connectivity solutions provider, and sensitisation of stakeholders. This assessment leads to recommendations on the utility applications of the planned diagnostic connectivity solution, data needs and a costed roadmap.

Set-up/installation phase:

* Hardware and equipment: Smart routers/modems, server, Wi-Fi dongles, antennas, SIM cards. All hardware should be suited for harsher environments.
* Configuration of server and customisation of connectivity solution to collect country specific-indicators, create reports, web dashboards and/or notifications. Optional: development of API connections, for example with Laboratory Information Management Systems (LIMS), Electronic Medical Records (EMRs) or patient management tools
* Implementation workshops/trainings: Workshops on data collection, data use and management, day-to-day operations of connectivity solution and installation/roll-out training
* Installation and roll-out of connectivity solution: On-site installation of modems/routers and set-up of connectivity solution in laboratories, including in-country travel costs
* Diagnostics connectivity solutions provider: Project management and consultancy to ensure proper roll-out

Operational phase:

* Running costs for connectivity: Monthly mobile data costs, server hosting, license costs for connectivity software (if any), and ancillary services including messaging, antivirus or updates
* Remote or in-country technical support: Technical support from the implementing software service provider to users during daily use, user- and permission administration, platform development, IT-support and updates
* In-country human resources: Data monitoring and supervision, IT/network support, administrative support, and programmatic support for follow-up trainings and capacity building to ensure programmatic impact

Depending on needs for software customisation and variability in travel, training, personnel, consultancy, project management, hardware and data costs, the first-year preparation and set-up costs for a connectivity diagnostic solution for a network of approximately 10 GeneXperts may vary between 40,000 and 80,000 US dollars, and ongoing expenses in the operational phase may vary between 5,000 and 10,000 US dollars annually. For a network of approximately 100 GeneXperts, the first-year preparation and set-up costs may vary between 100,000 and 200,000 US dollars, and ongoing expenses may cost between 10,000 and 30,000 US dollars annually. Additionally, budget for in-country human resources should be included for data monitoring and supervision, IT/network support, data connectivity administration, refresher trainings and training of new users.

EXERCISE: FUNCTIONALITY OF A DATA CONNECTIVITY SOLUTION

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| **Purpose of exercise:** | To make participants consider their own country situation and which functionalities of data connectivity solutions would be most useful; familiarize participants with the online data connectivity solution comparison |
| **Preparation:** | * Break into 2 or more groups * Each group ranks from 1 to 4 the top functionalities they would want from a diagnostics connectivity solution in their country * Using the online comparison of functionalities of currently available connectivity software, each group selects the software(s) that would be the best fit for their needs * Access to the online comparison of available data connectivity solutions (www.tinyurl.com/gliconnectivity) * Reconvene in the larger group for a facilitated discussion on each group’s ranked functionalities and selected software(s) |
| **Materials required:** | Full list of materials participant’s need   * Pens * Flipcharts * Computer with internet |
| **Total time of exercise:** | 40 minutes |
| **Feedback expected:** | Share your findings with the group |

CONDUCTING THE EXERCISE

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| Read out instructions (shown above in “preparation”) | 2 minutes |
| Break into groups, give paper/marker to each group, and then groups should allot roles of note taker and presenter for end of exercise. Individuals in groups read and understand the functionalities in the online comparison of data connectivity solutions | 15 minutes |
| Discussion in groups about rankings of functionalities, using the flip charts | 15 minutes |
| Report back to full group using flip charts | 10 minutes |

Debriefing exercise/practical

Each of the groups should read aloud their ranked functionalities, providing brief justification of each. Any differences between groups should be highlighted and discussed.

Key messages from exercise/practical

There may be different opinions on what functionalities are most useful (remote monitoring may be perceived as being more important than sending results to clinicians, French language may be perceived as being very important, etc.), so there is not a single right answer.

Integration of a system(s) is a topic that comes up in many modules. Integration should be examined and viewed holistically for all health programmes.

MODULE ANSWERS

1. What are the three components of a diagnostic connectivity solution?

1. A connectable diagnostic device that produces electronic data
2. A software platform that receives and interprets data
3. A means to transmit data from the device to the software platform and to a server

2. What are advantages of electronic data over paper-based data?

1. Electronic data is less time consuming and less prone to transcription errors
2. Newer diagnostics produce results data in digital format (also known as electronic data)
3. Electronic data can be rapidly and accurately sent simultaneously to different recipients according to their needs, and can be easily analyzed

3. How can diagnostic connectivity solutions benefit TB programmes?

1. Remote monitoring and quality assurance
2. Sending results automatically to clinicians
3. Sending results automatically to laboratory information management systems or electronic registers
4. Inventory management
5. Surveillance
6. Data Access

4. What should be included in a Data Use agreement with a software provider?

1. Ownership of all data by the MOH
2. MOH power to share access with selected parties
3. Planned storage and security of data, and any planned use of the data by the software provider
4. Assurance that patient data remains confidential and not disclosed to unauthorized users or used by the software provider outside of the terms of the agreement
5. Other requirements that are specified in national policies

5. What are budgeting requirements during the preparation, set-up/installation and operational phases of a connectivity system?

1. Preparation phase: Landscape assessment
2. Set-up/installation phase: Hardware and equipment; configuration and customization of connectivity solution; implementation workshops/trainings; installation and roll-out of connectivity solution; diagnostics connectivity solutions provider
3. Operational phase: running costs for connectivity; remote of in-country technical support; in-country human resources