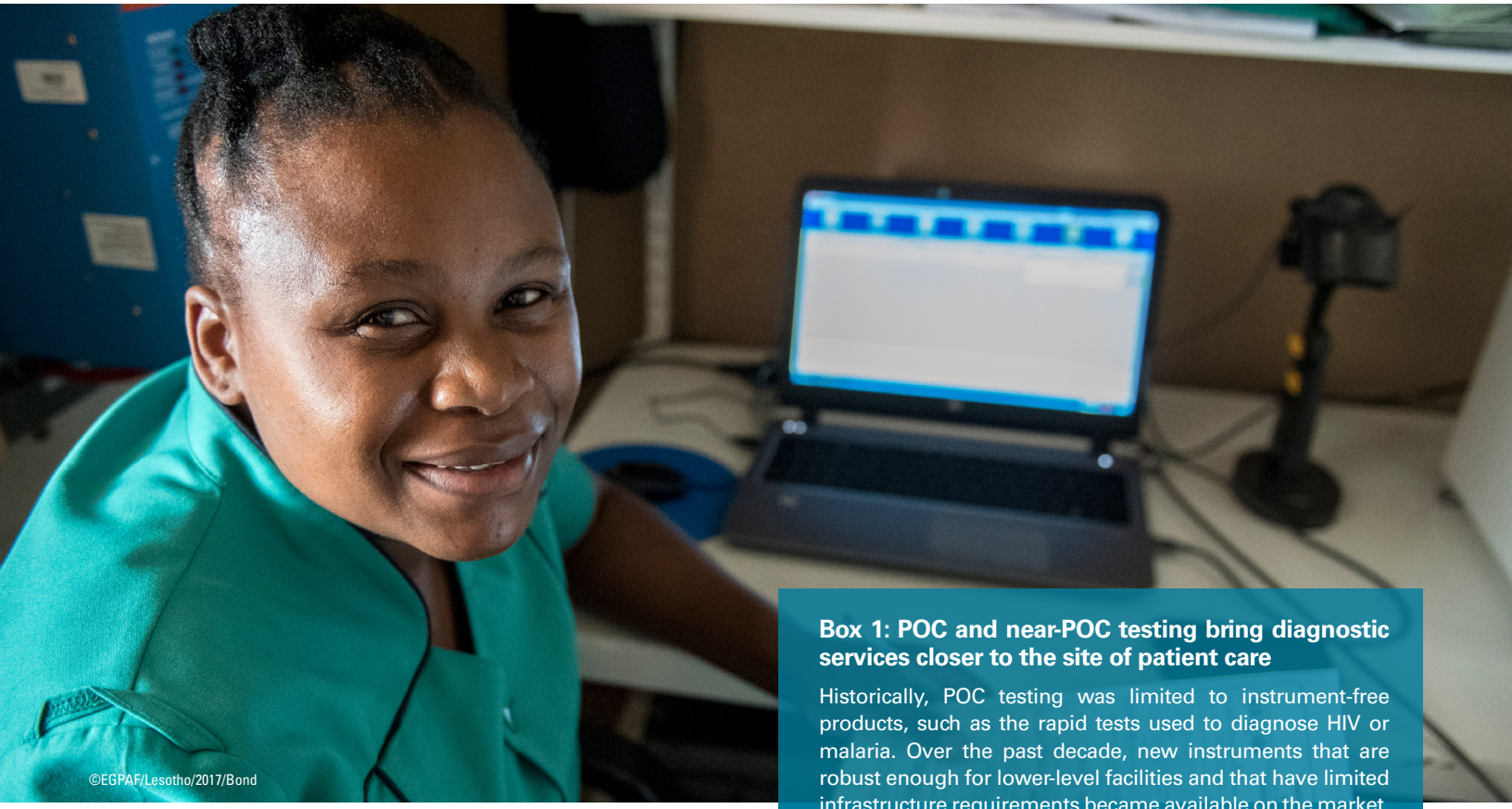

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POINT-OF-CARE CONNECTIVITY ISSUE BRIEF

Introduction to Connectivity

Decentralized diagnostic testing using point-of-care (POC) or near-POC platforms can significantly improve patient care by expanding access to critical diagnostic services, reducing result turnaround time (TAT), and improving linkage to care (see Box 1). Shifting diagnostic services to lower levels of the healthcare system, however, also introduces greater complexity for managing testing programmes and the increased number of testing sites can present challenges to national programmes in monitoring the entire diagnostic network.

Connectivity is the ability of a device to transmit data to another device or system to allow for remote monitoring. Connectivity-enabled POC diagnostic devices can help mitigate challenges associated with decentralized testing by allowing transmission of data from testing sites to a central location where it can be accessed in real-time or at set intervals for regular analysis. Once transmitted, the data can be used to oversee many important aspects of diagnostic testing and ensure that programmes can consistently deliver accurate testing to patients. Connectivity is a key element for providing Ministries of Health (MOH) and key stakeholders the information they need from decentralized testing sites to support timely decision-making and effective management of diagnostic testing programmes. Therefore, investing in connectivity systems should be seen as an essential component for successful decentralization of diagnostic testing.

Box 1: POC and near-POC testing bring diagnostic services closer to the site of patient care

Historically, POC testing was limited to instrument-free products, such as the rapid tests used to diagnose HIV or malaria. Over the past decade, new instruments that are robust enough for lower-level facilities and that have limited infrastructure requirements became available on the market, thus expanding the types of tests that can be conducted outside of centralized laboratories. Today, POC instruments are available for flow cytometry and nucleic acid testing (NAT), allowing CD4 enumeration, early infant diagnosis (EID), viral load monitoring and TB drug resistance testing, among others. These devices can be used at the POC to provide testing to patients, or as near-POC devices testing specimens referred from proximate facilities.

Connectivity Supports POC Implementation

Connectivity directly supports four key aspects of POC testing implementation:

Quality Control (QC) and Quality Assurance (QA). Compared with conventional laboratory-based testing, POC and near-POC testing are often conducted in many more sites, at lower levels of the healthcare system and by non-lab health workers. Connectivity allows programme managers and/or QA officers to use remotely transmitted data to evaluate the overall quality of testing, and identify sites with frequent operator-related errors that would benefit from refresher training. Remote QA monitoring can be used in conjunction with other QA activities, such as proficiency testing, as part of a comprehensive QA system.

Service and Maintenance (S&M). POC and near-POC instruments are typically robust enough for a wide range of environmental conditions, such as heat, humidity and dust. Breakdowns do occur, however, and devices will require occasional servicing. It is critical to be able to detect and prevent forthcoming problems ahead of time and to be able to swiftly reinstate interrupted services following a breakdown. The first step to managing S&M is to know in real-time which devices are operational and which are not. Remotely transmitted data can be used to monitor device use and performance through trends in testing volumes or internal quality control (IQC) failure rates. For example, if sites do not transmit data for a certain number of days, they can be flagged for investigation and repair, if needed. Manufacturers may also be able to assess testing data to identify devices in need of maintenance – for example those experiencing an increase in the frequency of device-related IQC failures – allowing proactive fleet management and reducing the incidence of breakdowns. Finally, sharing utilization data with manufacturers allows them to better understand the performance of their technology in order to conduct fleet-wide improvements.

Forecasting and Supply Chain. Decentralized testing across a large number of sites presents a challenge to forecast testing volumes, track inventory and plan distribution of supplies. Connectivity data can be used by programme managers to remotely track trends in commodity consumption, monitor consumable stock levels at facilities, more accurately forecast commodity needs and refine delivery plans to avoid stock-outs and expiries.

Patient Management and Surveillance. Finally, testing at a large number of sites makes it difficult to collate data for tracking patient-level health indicators and population-level epidemiological trends. MOHs have the option to use connectivity-enabled instruments to track test results using a unique patient identifier and target high risk patients for immediate follow-up, such as infants with a positive EID result. Further, codes can be used within test identifiers to indicate useful information, such as whether a test is conducted on a patient before or after treatment initiation. At the same time, unidentifiable data transmitted via connectivity can streamline and simplify data collection for surveillance of population-level trends, such as changes in viral suppression rates or emerging epidemic hotspots, which would otherwise be challenging to collect in a decentralized testing network.

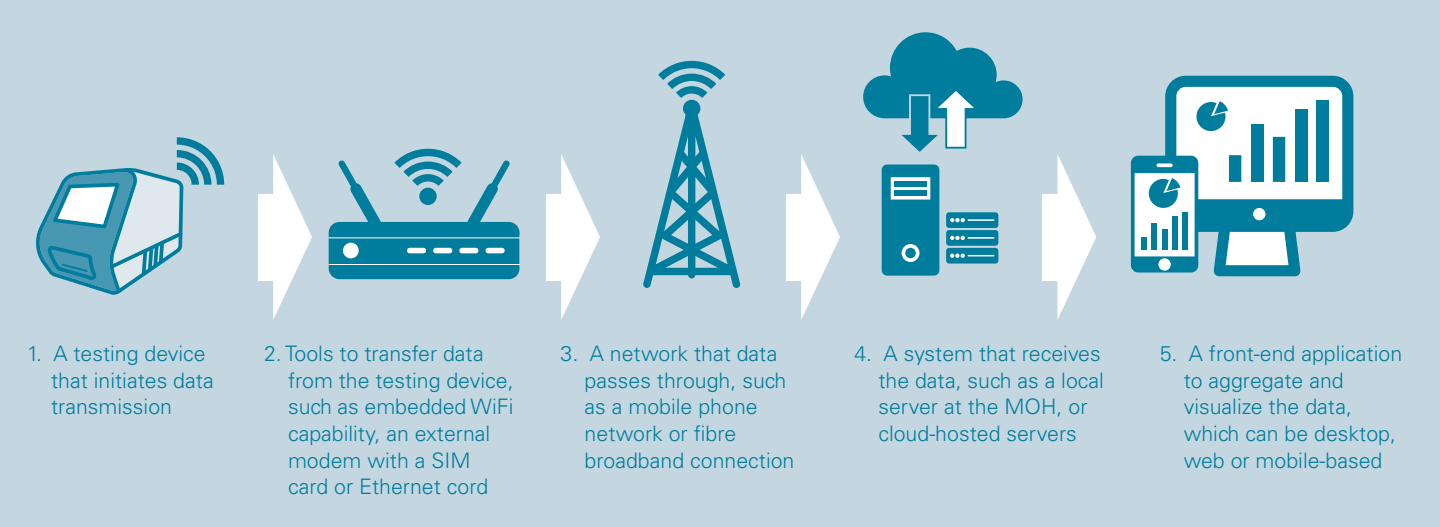
Connectivity options, challenges and considerations

Connectivity solutions, including the tools for data transfer and the applications for data aggregation and visualization, may be provided by the instrument manufacturer, developed independently in-country or purchased through a third party provider (see Figure 1 below). Regardless of who provides the connectivity solution, there are a few key considerations for selecting the appropriate solution:

Functionality

Before selecting a connectivity solution, implementers must ensure the precise technical specifications of all products are understood. This includes which types of data are captured on the device and transmitted, whether data is transmitted automatically by the device (passive transmission) or users must initiate transmission (active transmission), what type of operating environment and infrastructure the system will require (e.g. availability of an Ethernet connection or cellular network) and what services are provided through the connectivity solution supplier. Implementers are encouraged to consider solutions that are compatible with or extendable to data systems for other disease areas, particularly TB, human papilloma virus and Hepatitis and can be integrated across all types of POC and conventional testing to allow comprehensive data visibility.

Figure 1:
Requirements for connectivity



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Hardware

The POC or near-POC device must be connectivity-enabled, either via in-built connectivity – such as Bluetooth or WiFi – or via a port to enable connection to an external modem, which can then transmit via the mobile network. If the latter, the modem selected must be compatible with the POC or near-POC device being used. In both cases an outgoing data connection is required and the solutions chosen must be able to operate at the testing sites, where infrastructure may be constrained. Solutions should take into consideration the strength of the mobile network, the availability of a consistent power source and compatibility with local telecom networks. The network must have sufficient bandwidth to transmit the data file successfully; timely transmission may be impeded by file size, weak coverage, or an intermittent signal. Identifying internet service providers, either for mobile data or a fibre network, is necessary to ensure the connectivity solutions are configured appropriately. Lastly, the choice of which server to use to receive data should be informed by national data security regulations and by the availability of local server infrastructure in the MOH. Server infrastructure must be adequate to provide a reliable connection to remote sites and must have sufficient capacity to handle requests from users without getting overloaded.

Software

Once data has been transmitted from the POC or near-POC device to a server, it must be aggregated and analysed so that programme managers can act on subsequent results. Countries can typically choose a solution from the POC device manufacturer, developed independently in-country, or purchased through a third party provider. See Table 1 for the pros and cons associated with using proprietary systems vs. developing a software solution in-house.

Compatibility

Suppliers – including device manufacturers and third party providers – should provide written confirmation of which connectivity software, modems and other hardware their diagnostic devices are compatible with and conversely which devices are incompatible with connectivity software, modems and other hardware.

Pricing

If the MOH or an implementing partner is procuring connectivity hardware and/or ongoing connectivity services, either in the form of front-end software packages or data transmission, the payment structures for these products and ongoing services should be negotiated upfront and terms should be put in place to

minimize the risk of rising costs and supplier dependency in the future. Connectivity services may be negotiated as a standalone product, or bundled with the reagent, device or service and maintenance costs. Some manufacturers do provide, as part of a comprehensive POC solution, a free-of-charge end-to-end connectivity solution upon purchase of instruments; this includes no initial hardware investment or extra recurrent cost for the buyer. It is therefore important to consider the full cost of ownership when selecting the POC instrument most suited to the country context.

Data security and regulations

Buyers should consider local requirements as to whether data will need to be hosted in-country or remotely. They should also consider data security requirements such as encryption, firewalls and virtual private networks, as well as user authorization, logins and backup data storage. Similarly, buyers should consider the types of data that will be transferred, such as patient or provider identifiers and the country's specific regulations for transferring personally identifiable health data. Understanding data privacy regulations may require consultation with additional ministries within the government (e.g. telecommunications).

Other terms and conditions

If the buyer is procuring ongoing connectivity services, issues such as data confidentiality and ownership, level of technical support, troubleshooting procedures and options for customization should be agreed upon at the time of initial purchase of devices. Detailed Service Level Agreements (SLA) should be established to describe which services the supplier will be responsible for, which services the buyer will be responsible for, and under what circumstances the supplier will no longer be responsible for providing the services required.

Human resources

Once a connectivity solution is selected and installed, dedicated human resource capacity is needed to use and maintain the system. This includes training at multiple levels, including end-users responsible for transmitting data and programme managers responsible for accessing and utilizing aggregated data for decision making. In addition, engineering capacity is required at the central level to maintain the system over time if a country opts for an MOH/partner-developed in-country service model.

Key steps for implementing connectivity

1) **Identify the system users.** Decide who will be responsible for using and maintaining the system on a routine basis, as well as what types and levels of access to data each user should have. It may be helpful to develop clear standard operating procedures outlining who will have access and how data can be utilized.

2) **Verify availability of key resources.** Before establishing connectivity, ensure that reliable internet coverage, server storage, appropriate hardware and software solutions, necessary human resource capacity and sufficient funding for both start up and recurring costs are in place.

3) **Map existing data management systems.** When selecting a connectivity solution, decide how it will link to other information systems already in use, such as the laboratory information management systems

Table 1:

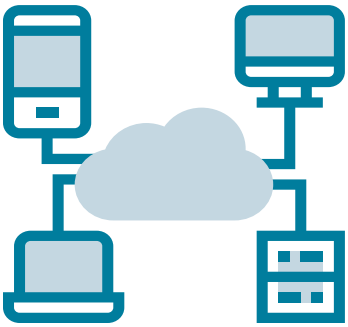
Pros and cons of using systems from device manufacturers or third party providers vs. developing a software solution in-house

	Device Manufacturer or Third Party Provider Systems	MOH/Partner Developed
Pros	Seamless integration with single platform (device manufacturer) or potentially multiple platforms (third party provider). Dedicated technical support. Lower in-country management burden. Device manufacturer can remotely address hardware issue with POC instrument when necessary. System maintenance and oversight provided. Manufacturer/provider can use shared data to improve systems and make upgrades.	Potentially compatible with multiple testing platforms, if designed to be. Increased control over customization of interfaces. Full control and access to proprietary data. Potentially fewer data security concerns. Lower ongoing technical support costs. Minimal risk of price increase.
Cons	Lack of compatibility with other technologies (if platform specific). Potentially limited MOH control of data that travels outside the country. Less customizable interfaces or dashboards. Potential price increases. Dependency on supplier for future upgrades. Limited integration with other MOH data management systems.	Requires significant technical support capacity in-country. Reduced visibility for diagnostic manufacturer to service devices. Greater IT infrastructure requirements for MOH. Increased administrative burden. Requires significant capital investment in hardware.

used in conventional labs, electronic medical records, inventory management systems and national dashboards. In particular, confirm that providers can offer a documented set of application programme interfaces, which allow easy transfer of data between systems to ensure interoperability.

4) **Sign a SLA.** When using a connectivity solution purchased from the device manufacturer or a third party, a formal agreement between the supplier and MOH is necessary to define each party's roles and responsibilities for installing and maintaining the hardware and software. Agreed upon key performance indicators can be included in the SLA to monitor supplier performance and establish minimum acceptable standards.

5) **Establish processes for data analysis.** Once a connectivity system is designed and ready for implementation, stakeholders should determine how and how often the data will be accessed and analysed. For example, online dashboards could be viewed once per week, reports could be automatically sent via email to stakeholders each month, or automatic notifications could be triggered in response to changes in testing volumes, or internal QC failure rates rising above a pre-determined rate. MOHs should be aware that connectivity solutions may not automatically capture the same data points reported through the conventional system or national dashboard. In such cases, M&E processes should be reviewed to assess the compatibility of the connectivity solution with national program priorities. Should additional data be required some programs may choose to continue the use of laboratory requisition forms with manual data entry into the national dashboard to capture information such as patient date of birth, reason for testing, or facility entry point.



Conclusion and recommendations

The increased number of sites offering POC and near-POC testing poses operational challenges to oversee decentralized testing programmes at the district and national levels, therefore visibility into site-level testing data in real-time is a vital component of effective programme management. The emergence of diagnostic technologies that can wirelessly transmit data has enabled countries to monitor testing networks much more proactively and effectively through connectivity-enabled data management. Before implementing POC and near-POC testing, each country should select the appropriate hardware and software for its relevant context. POC and near-POC device manufacturers should be held to high standards for their hardware and software solutions, to ensure that the products and services procured meet each country's required specifications (if applicable) and that the suppliers provide adequate ongoing support. Lastly, when selecting connectivity solutions, sustainability should be addressed from the outset, including consideration of ongoing programme costs, contingency plans to allow for adoption of new technologies and mitigate the risk of future technology switches, integration with existing systems and future expansion to additional technologies and disease areas.

Connectivity offers the opportunity to ensure the delivery of reliable patient care through POC and near-POC testing by ensuring that devices are consistently operational and that operators are trained to provide high quality diagnostic services. Access to real-time testing data enables programme managers to monitor decentralized device fleets more effectively and efficiently, to respond quickly in the event of a breakdown or service interruption, and to centrally monitor inventory across a high number of testing sites. Finally, improved data visibility allows stakeholders at all levels to better understand and react to epidemiologic changes. Connectivity is an integral part of POC testing implementation and is a valuable complement to existing diagnostic and disease surveillance systems.

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