

KEY CONSIDERATIONS FOR INTRODUCING POINT OF CARE DIAGNOSTIC TECHNOLOGIES IN NATIONAL LABORATORY PROGRAMMES: A FORTHCOMING RESOURCE

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Reaching the UNAIDS 90-90-90 treatment targets will require a massive expansion of HIV diagnostic services to ascertain HIV status and monitor the viral load of those initiated on and continuing ART.

The current scenario for HIV diagnostics does not meet the immense needs of the world's 36.7 million people living with HIV (PLHIV).¹ Exclusive reliance on conventional diagnostic technologies means that many clients do not have access to same-day test results, and instead wait days, weeks or sometimes months while their specimens and results are transported to and from centralized laboratories. These long turn-around times often result in high rates of client loss to follow up and delayed care and treatment decisions for both children and adults.

A key strategy to meet the testing and diagnostic needs of PLHIV is the scale up of innovative testing, while strengthening existing laboratory systems. One such approach is strategic deployment of Point of Care (POC) testing, which will expand access to diagnostics and enable clients to receive test results during the same visit. A combined approach, maximizing the potential impact of all available tools, is key to enable meeting targets of treatment for all.

WHAT IS POINT OF CARE TESTING?

POC testing refers to testing that takes place during a client visit, with results provided during the same visit. 'Near Point of Care' also refers to testing on-site and rapid results, higher level facility. POC and near POC devices are easy-to-use products that do not require complex specimen preparation, constant electricity, refrigeration, sophisticated laboratory infrastructure, or highly skilled human resources (see Table below for additional benefits and challenges).

Although conventional, laboratory-based technologies have formed the backbone of national testing programs for many years, their ability to expand access has been hampered by systems challenges, which include unreliable sample transportation networks, sample integrity issues, instrument failures, and laboratory network workflows. **Optimizing the balance between conventional laboratory network and POC testing in a country can strategically increase access to testing and diagnostics, and ultimately improve health outcomes.**

- **POC early infant diagnosis (EID):** Offering infant virologic testing at the point of care will help ensure that HIV-exposed infants are tested, diagnosed and quickly linked to life-saving care and treatment.
- **POC viral load (VL):** Same-day VL results may enable better monitoring of treatment, adherence counseling interventions, and faster enrollment on second- or third-line treatment regimens when needed.
- **POC CD4:** In settings where CD4 is indicated, offering POC CD4 staging and monitoring at testing and treatment sites may help improve linkage to care, address the need for prophylaxis for opportunistic infections, and make timely clinical decisions.

As of July 2016, there are two WHO Prequalified devices² on the market for Infant Virologic Testing and EID (Alere™ q and Cepheid GeneXpert®) and two devices for CD4 (Alere™ Pima and BD FACSPresto™). The [UNITAID HIV/AIDS Diagnostics Technology Landscape³](#) provides a comprehensive biannual update on the status of new diagnostic technologies.

SUMMARY OF BENEFITS AND CHALLENGES RELATED TO POC AND NEAR POC TECHNOLOGIES

	BENEFITS		CHALLENGES / LIMITATIONS	
Access to results	<ul style="list-style-type: none"> • Results are produced at the site where the test is performed • Same-day test results allow for immediate clinical decisions 	<ul style="list-style-type: none"> • Shorter turnaround time for test results reduces the likelihood of loss to follow up 	<ul style="list-style-type: none"> • May not necessarily result in improved health outcome if a client is not linked to care and treatment • Patient wait time in the clinic while the result is being generated may be long 	<ul style="list-style-type: none"> • Clinic or patient flow may not be configured to provide same-day results
Efficiency	<ul style="list-style-type: none"> • Most EID and VL POC devices can run approximately 8-20 tests per day, per instrument 		<ul style="list-style-type: none"> • The throughput of POC and near POC devices is lower than throughput at the central level (at the central level one person can run 100 or more specimens per day) • Determining where to place POC devices can be challenging in low volume areas 	<ul style="list-style-type: none"> • If volume is high, multiple POC devices may be needed to process the test volume, increasing the cost per test; if volume is low, cost per test may be higher due to lower utilization
Cost	<ul style="list-style-type: none"> • The cost per result received could become comparable to conventional testing, depending on the type of device used, the type of test run, and where the device is 	<ul style="list-style-type: none"> placed. In addition, prices of devices and test cartridges are expected to decrease over time 	<ul style="list-style-type: none"> • Cost per test run is still higher than conventional 	
Operability	<ul style="list-style-type: none"> • POC devices can be operated by non-laboratory personnel • Requires fewer procedural steps and commodities • Reagents and controls do not require refrigeration have a shelf life of approximately 9 months • Probability of specimen degradation will likely be less of an issue due to immediate testing 	<ul style="list-style-type: none"> • Some devices use low specimen volume, which is better for the client • POC devices have built-in quality controls • Many devices use capillary whole blood applied directly into the cartridge, rather than spotted on DBS, requiring less specimen preparation (with the current exception of VL) 	<ul style="list-style-type: none"> • POC devices will require reagent storage and inventory management 	<ul style="list-style-type: none"> • The potential for unintended use is greater (e.g. inappropriate specimen type)
Infrastructure	<ul style="list-style-type: none"> • Tests can be performed in wider range and number of sites with fewer infrastructure requirements • Most POC devices are portable, light-weight and operable without constant electricity or air conditioning 	<ul style="list-style-type: none"> • In remote and hard to reach sites, avoids reliance on weak specimen referral systems and/or centralized testing facilities 	<ul style="list-style-type: none"> • Additional field-based human resources and/or training may be required • Supervision and quality assurance may be more difficult due to a greater number of and more dispersed sites 	<ul style="list-style-type: none"> • Near POC devices require constant electricity, computer interface and some degree of temperature control for storage (cartridges)

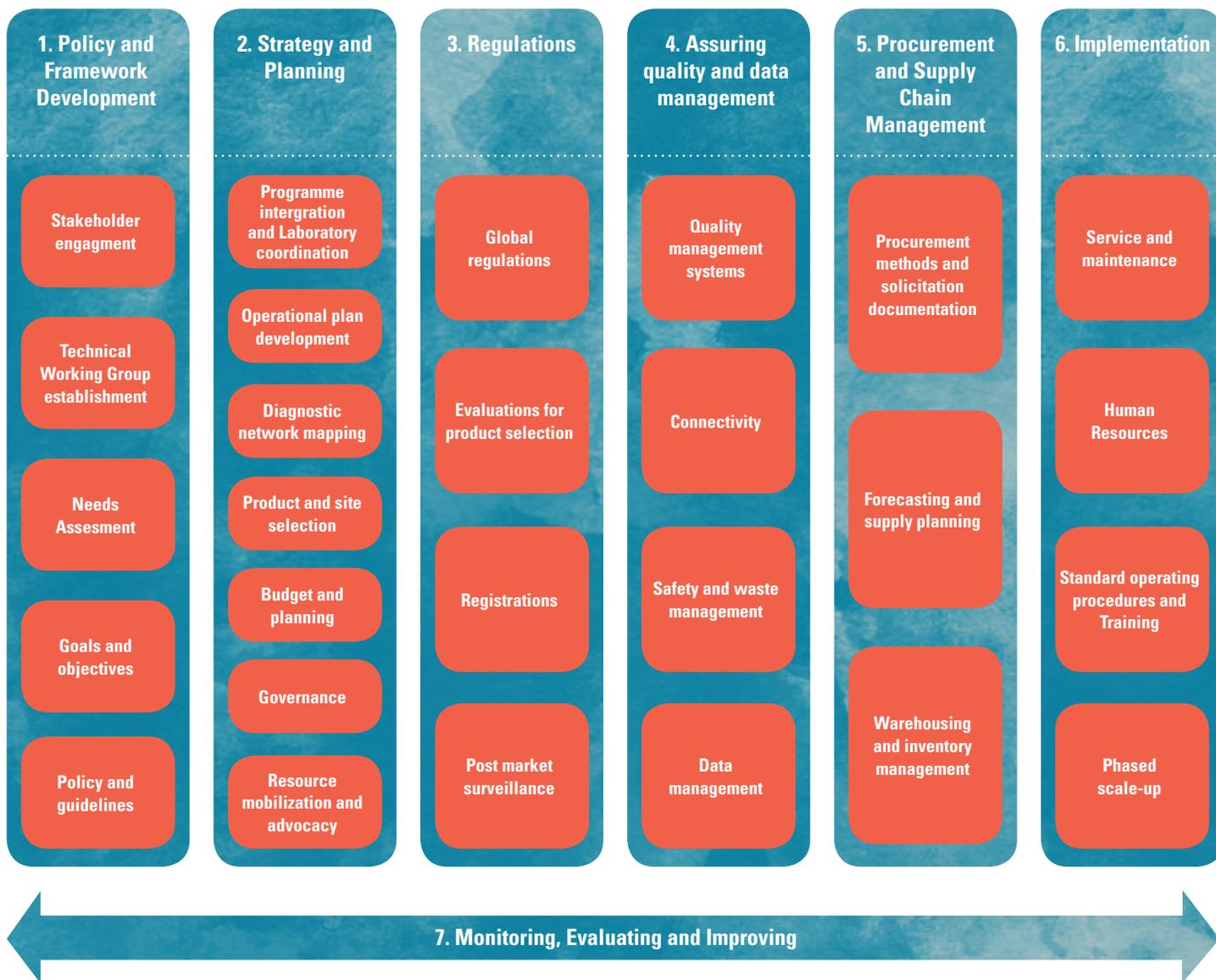
SCOPE OF THE KEY CONSIDERATIONS DOCUMENT

The forthcoming *Key Considerations for Introducing Point of Care Diagnostic Technologies in National Laboratory Programmes* provides necessary information to guide discussions at national and subnational levels. It will introduce topics to consider during national policy and strategy planning, regulation, procurement and supply chain management, quality assurance and data management, and program

implementation. The document focuses on POC HIV diagnostics and monitoring for: virologic testing for EID, CD4 staging and monitoring, and (VL) testing for treatment monitoring.

The *Key Considerations* document provides background on HIV POC testing and its potential contribution to meeting the 90-90-90 treatment targets, outlines the steps for introducing HIV POC technologies (see Figure below), and includes links to tools and resources.

FIGURE. COMPONENTS OF THE KEY CONSIDERATIONS DOCUMENT



¹ UNAIDS, 2016

² http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

³ <http://www.unitaid.eu/en/resources/publications/technical-reports#hiv>

For additional information, visit: <http://www.childrenandaids.org/partnership/point-of-care>
Join the POC community of practice: https://knowledge-gateway.org/hiv_poc

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