Forecasting and Supply Planning for the Scale-up of New Point-of-Care EID/VL Technologies[1]

Purpose

Developing a laboratory forecast is critical for ensuring the continuity of supplies and minimizing stock-outs as a new technology is deployed. While it is ***not*** recommended to develop parallel forecasting processes or supply chains, during the scale-up of new devices, it may initially be necessary, to utilize a mix of forecasting approaches that are responsive to program scale-up and rapidly changing deployment plans. Once a new diagnostic has been brought online and scaled up, service level data, consumption data (logistics), along with morbidity data, should be used to complete the national quantification process in an integrated way.

Quarterly supply plan monitoring is essential for tracking consumption and adjusting forecasts if needed. In addition, if demand for Point-of-Care (POC) diagnostics increases significantly, it may lead to a balancing decrease in demand for conventional laboratory-based testing, such that forecasts for both POC and conventional platforms will require adjustment. It is, therefore, critical that forecasting for POC during the scale-up phase, and forecasting for conventional laboratory-based diagnostics, be undertaken at the same time in a systematic and integrated way.

The ForLab tool is designed to generate forecasts across an entire laboratory program. When sufficient data is available to populate ForLab, or other national quantification tools, the use of separate POC forecasting methods should be discouraged, and POC forecasting efforts should be fully integrated into the general laboratory quantification process.

The following forecast approach is intended to accommodate the rapidly changing circumstances encountered when implementing a new technology.

Methodology

The ***initial forecasting approach***[2] should use site-level early infant diagnosis (EID) and viral load (VL) historical testing volumes (where available), active patient volumes, and the anticipated implementation

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[2] Note this forecasting approach is only recommended during the initial scale-up phase. Once forecasting for POC diagnostic commodities are integrated into national laboratory quantification, it is assumed that forecasts will follow standard practice (2-5 year forecasts) to ensure continuity of health products.

dates at each site to develop a 12-month forecast by quarter. All facilities identified as current or potential POC testing sites should be included in the forecast, and designated as "current", "approved" or "potential" in order to indicate likelihood of implementation. If planned dates of introduction are known, these should be incorporated in the forecast.

Expected POC EID Volumes

Expected POC EID testing volumes should be calculated taking into account (1) current national HIV infant testing algorithm, (2) the expected 4-6 week testing volume from historical volumes and the annual growth rate of HIV-exposed infants, (3) anticipated birth testing volume, and (4) the anticipated referral testing volume. These four figures should be combined to generate an annual POC EID testing volume per site.

Expected POC VL Volumes

Expected POC VL testing volumes should be calculated taking into account (1) national guidelines on the use of VL, (2) the expected 1st and 2nd VL test volumes based on historical testing volumes and annual ART cohort growth, (3) expected VL testing volumes for target populations (B+ women and HIV+ children), and (4) the anticipated referral testing volume. Based on the chosen testing strategy for POC VL – all ART patients, 2nd line VL only, target populations – the total expected POC VL volume is calculated.

Device Capacity

The daily testing volume per site should be determined based on the expected test types (including EID, VL, HCV and TB where appropriate) and number of testing days per year. This will be compared to the maximum device daily throughput to identify sites that are at risk of exceeding available capacity.

Forecasting Approaches and Assumptions

Ideally, a combination of methods should be used to improve overall forecasting efforts, with adjustments made to account for missing data, or quality related issues that could impact confidence in forecasting outputs.

- Consumption and service data: These forecasts rely on historical AMC (average monthly consumption) and testing data to assist in predicting future testing demand and/or product usage. This forecasting approach relies on historical data, which may not be available for new programs. In this case, similar tests or product introductions could be used as a proxy to estimate demand.
- Demographic and target-based forecasting methods are used in conjunction with service and consumption base forecasts when possible. When sites do not have historical consumption or testing volumes, forecasts can apply the national EID/VL coverage rate to the PMTCT population or ART cohort registered at the facility, and apply a scale-up or implementation rate to estimate product needs. However, this must be carefully managed to avoid excess quantification.

- Consideration should be made for initially increasing EID and VL testing volumes at new POC sites, on the assumption that, as availability of a POC device becomes known in the community, demand might increase. However, this must be carefully managed to avoid excess quantification.
- The forecast should take into account rolling implementation by adding the quarterly volumes per site. Once a site is implemented, it should be assumed that it will continue to test in all the subsequent quarters over the forecast period.

For a list of key data points needed for a robust scale-up forecast for POC EID and VL, see Annex A.

Connectivity

Programs should consider the implementation of connectivity to assist with collecting the necessary data for forecasting and supply planning. Such data has the advantage to account not only for the number of samples tested, but also for losses due to internal quality control (IQC) failures, which ultimately provide a more accurate view on commodity consumption. Successfully implemented connectivity can allow for real-time management of information in a powerful way; however, programs should make contingency plans to collect the necessary information should disruptions to the connectivity system prevent access to relevant information, such as through manual data extraction.

POC connectivity solutions can also be used to transmit test results and associated data via the wireless network, or an internet connection. When consistently transmitted or collected this data can be displayed on dashboards and integration with national laboratory information management systems to provide insights on POC testing, which can be used to assist with stock management, quality assurance, and program management.

For additional information about the benefits of diagnostics connectivity see the *Global Laboratory Initiative's Quick Guide to TB Diagnostics Connectivity Solutions*.

Supply Planning

- The supply plan must account for the procurement and supplier lead times for each product as well as realistic time required for country-specific importation processes (See the *Procurement and Implementation Timelines* section).
- The supply plan should include a running buffer the equivalent of 2-3 months of stock (MOS), while keeping in mind that consumption will grow as more instruments are placed. (Each added site should have 2-3 MOS when added, based on projected AMC).
- It is important to consider the shelf life of the reagents in the set-up of inventory control parameters for commodities to be held at every given time. For example, if a product has a shelf life of 12 months from date of manufacture, and the procurement and custom clearance lead times are estimated at 3 months, hence a residual shelf life of no more than 9 months can be expected at delivery. Consequently, the supply plan should be designed for the program not to hold quantities higher than 9 MOS (including the buffer) per time. This would be lower for

products with a shorter shelf life from date of manufacture such as currently observed for POC EID commodities (subject to improve over time).

- It is recommended that purchasers consider the use of staggered deliveries, thus allow various product lots (with different expiry dates) to be delivered at different times, even if part of the same procurement order. However, special attention must be given during the introduction and rapid scale-up phases, where unpredictable consumption trends may occur.
- Lead times are often sensitive to total demand on the supplier; hence, any unexpected contingencies should be monitored closely to ensure continuity of supply.
- Volumes must take into account stock keeping units and/or packaging units for ordering and in-country supply chain distribution.
- Volumes for time periods further out are assumed to be tentative and should be re-forecast during subsequent quarterly revisions.

Procurement and Implementation Timelines

Each site should be designated as using/planning to use an existing POC device or needing a new device procured to begin implementation.[3] For sites needing a new device, the model should indicate the first quarter in which POC testing will be implemented at the site. For example, if POC EID will begin on a new GeneXpert in May 2017 and POC VL will begin in October 2017, the forecast should identify that device for initial implementation in Q2 2017.

In order to allow for order placement and delivery, the implementation timeline should be offset by the expected lead times to determine when orders need to be placed. For most HIV POC commodities, it is recommended to set the order date at least 3 months prior to the expected implementation date. For example, tests to be utilized in Q1 2018 may require about 3 months for the product to be ordered, produced, shipped, custom cleared and registered in warehouses; thus, the supply plan should account for the order to be placed early Q4 2017.

[3] Note that various assays have different waste disposal requirements, even if used on the same instruments. It is essential to check the manufacturer's waste disposal guidance for reagent waste. Therefore, before considering the use of existing platforms for a specific assay, ensure that when a new assay is considered for use on existing instrument that access to the necessary waste disposal infrastructure is readily available for or within that health facility or can be set up.

Annex A: Key Data Points for Developing a POC EID and VL Scale-up Forecast

A robust scale-up forecast for POC EID and VL will require the following national-level data points:

- EID coverage (% of HIV exposed infants receiving an EID test) at baseline
- National HIV infant testing algorithm
- Number of births from HIV-exposed mothers in each health facilities
- PMTCT coverage at 6 weeks of age
- Historical EID testing positivity rates per health facility
- At birth EID coverage – *as applicable*
- HEI Annual Growth Rate
- Annual VL tests per year per patient
- Elevated VL rate
- National VL testing coverage
- Annual ART cohort growth rate
- Strategy for POC VL use – All ART patients, 2nd-VL following elevated first, B+ women and children or a combination of strategies
- Number of testing days per year, if it is not to be constantly available

In addition, the following data points will be required for each potential POC EID and/or VL site:

- Facility name
- Type of facility – *hospital, clinic, health center, etc.*
- POC device to be implemented – *Alere Q, GeneXpert 4m, GeneXpert 16m, Omni, SAMBA II*
- Anticipated test types to be run at the site – *EID, VL and/or TB*
- Anticipated instrument downtime
- Presence of existing POC device or need for a new device
- POC EID Site Selection Status – *current site, MOH approved site, potential site, not considered*
- POC EID Implementation Year
- POC EID Implementation Month (if known) or half of the year (e.g. 1H 2017)
- Total Population of PMTCT/HEI registered at the facility
- HEI Positivity Rate
- Actual EID Volume (most recent year available)
- Implementation month or quarter for start of at-birth testing
- EID referral rate, for POC testing sites are planned to be used as testing hubs
- POC VL Site Selection Status – *current site, MOH approved site, potential site, not considered*
- POC VL Implementation Year
- POC VL Implementation Month (if known) or half of the year (e.g. 1H 2017)
- Size of ART cohort registered at the facility
- Number of B+ women registered at the facility
- Actual VL Testing Volume (most recent year available)
- VL referral rate (as available)
- POC TB implementation year and month (as available)
- POC TB anticipated volumes for subsequent 2 years (as available)