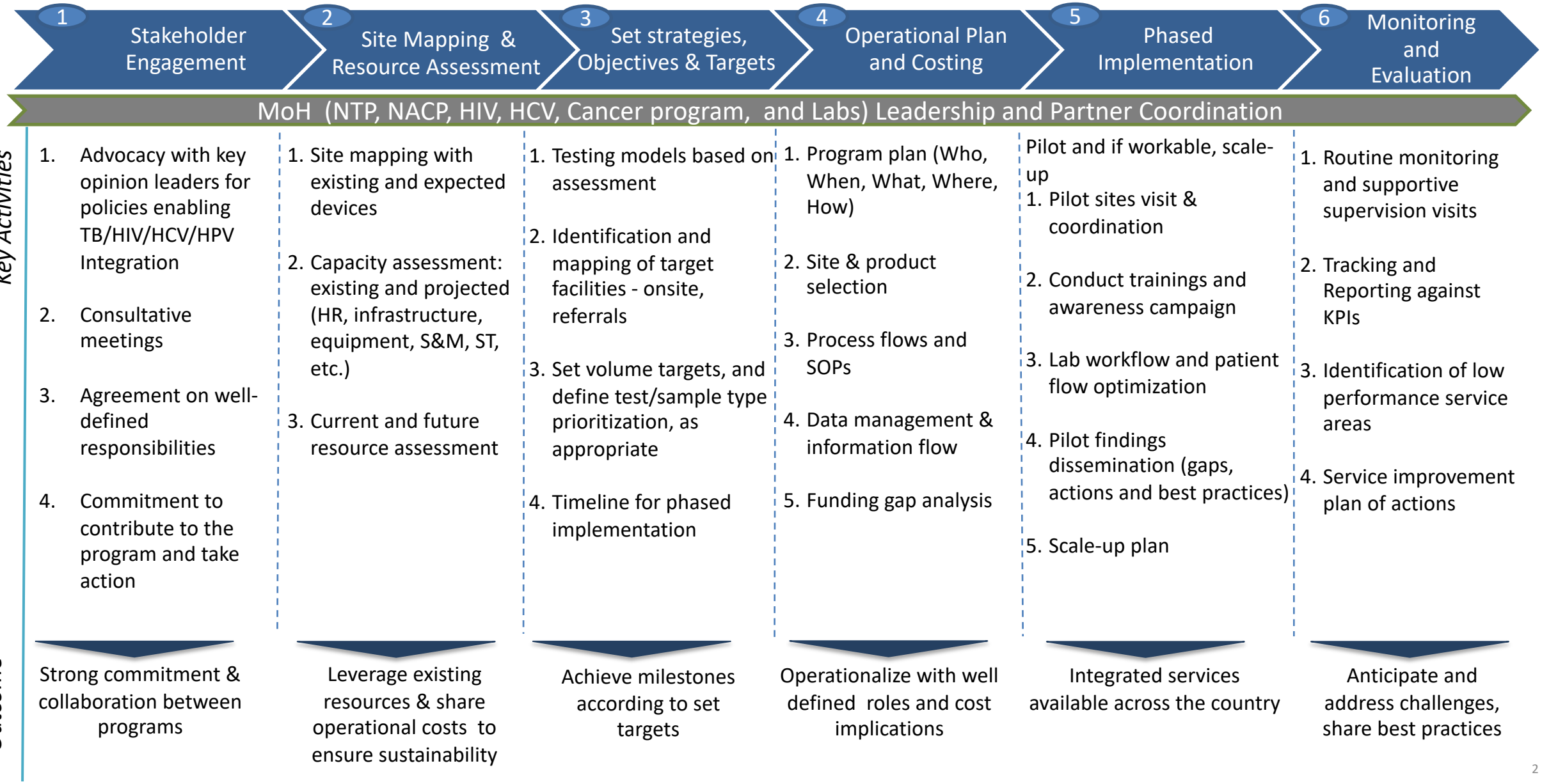
Implementing Integration on GeneXpert devices: Considerations and Lessons Learned

Guidance document, 2019

CLINTON HEALTH ACCESS INITIATIVE

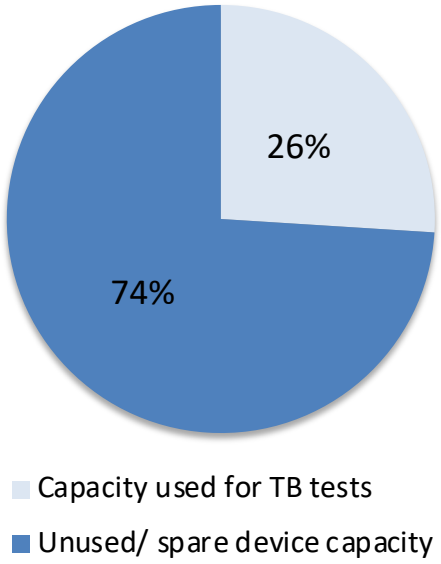
Integration Implementation Framework

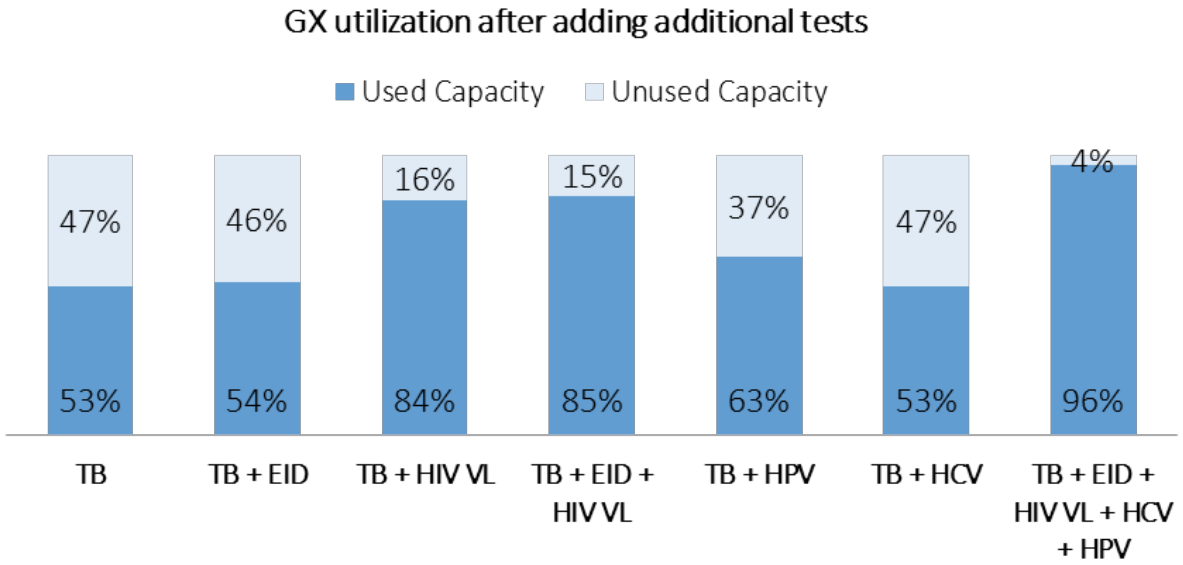


Stakeholder Engagement: Implementation of integrated testing requires working across established vertical program structures

	Barriers	Suggested Approach
Pushback from TB programs	• Concern that additional HIV, Hepatitis, HPV volumes will take up machine capacity limiting the ability to test all TB patients • TB policy changes may lead to increased testing need and the TB program wants to ensure sufficient excess capacity	• Carefully select sites where there is excess capacity • Conduct **site-specific national capacity utilization analysis** to identify potential sites for integration • Physical site readiness assessment • Have a contingency plan for when volumes reach near capacity (extra lab hours, sample transport/referral to other low volume sites, placement of new devices on reaching capacity)
Cost sharing / task sharing	• Large machine downtime/non-functional modules limit available capacity leading to NTP's reluctance to add more tests • Dis-agreement by programs on cost sharing – S&M, upgrades, supply chain management • Devices and HR siloed via funding stream or program	• Coverage of a part of S&M through other programs using GX • Supplier negotiations for device placement at high volume sites • Joint negotiations for S&M • Joint Monitoring & Supervision visits by the MOH staff • Conduct and present **integration cost savings analysis** indicating potential savings to all programs with integration
Political will	• Reluctance of disease specific programs at the MOH to collaborate	• Include all stakeholders in discussion • Sensitize about **improvement of TB patients outcome** with identification of other diseases (treatment, reduced mortality for co-infected) • Use phased implementation to show early impact • Option of key opinion leader visits to other country programs • Routine visits and conversations with users and MOH team

Example of country-specific capacity analysis that can assist to pre-select sites for integration



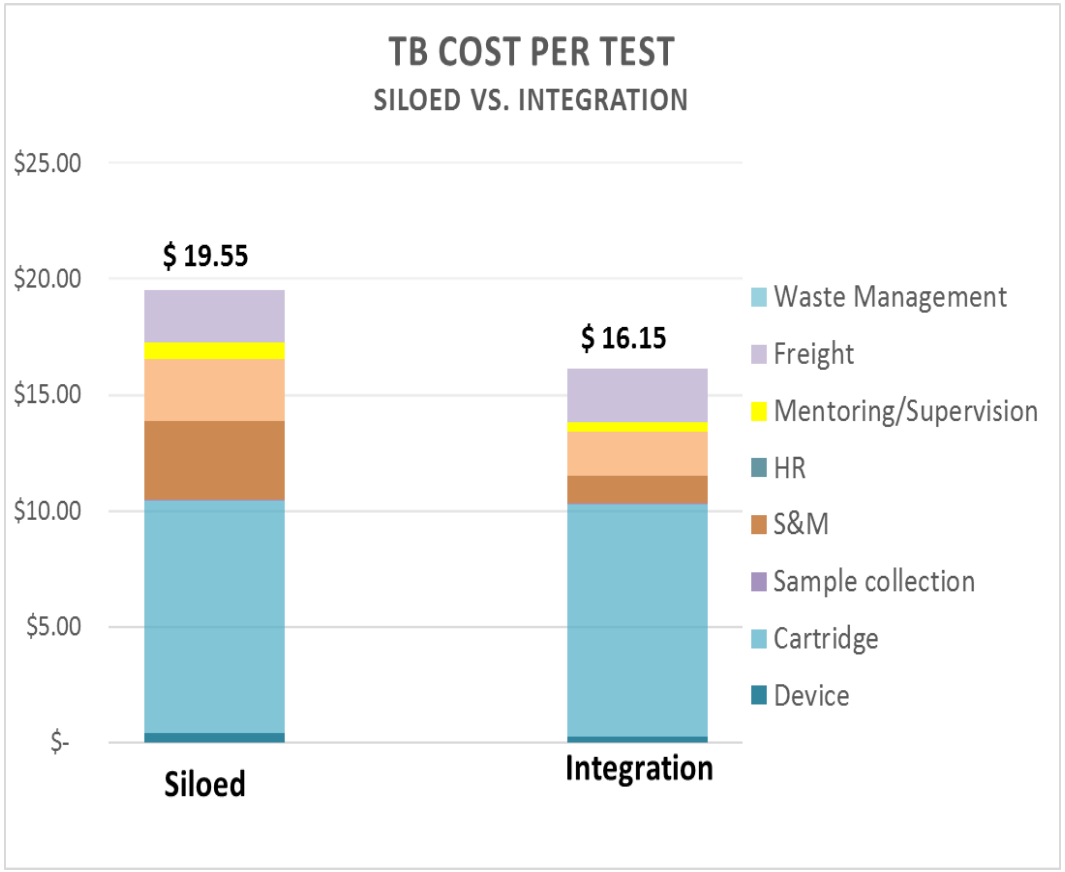


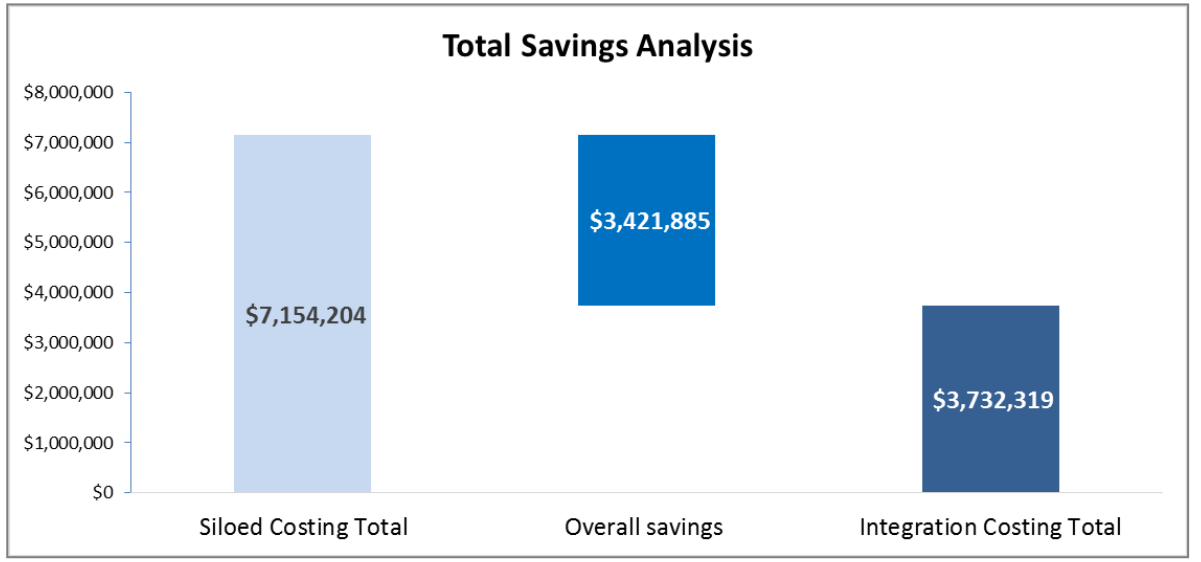
Set thresholds

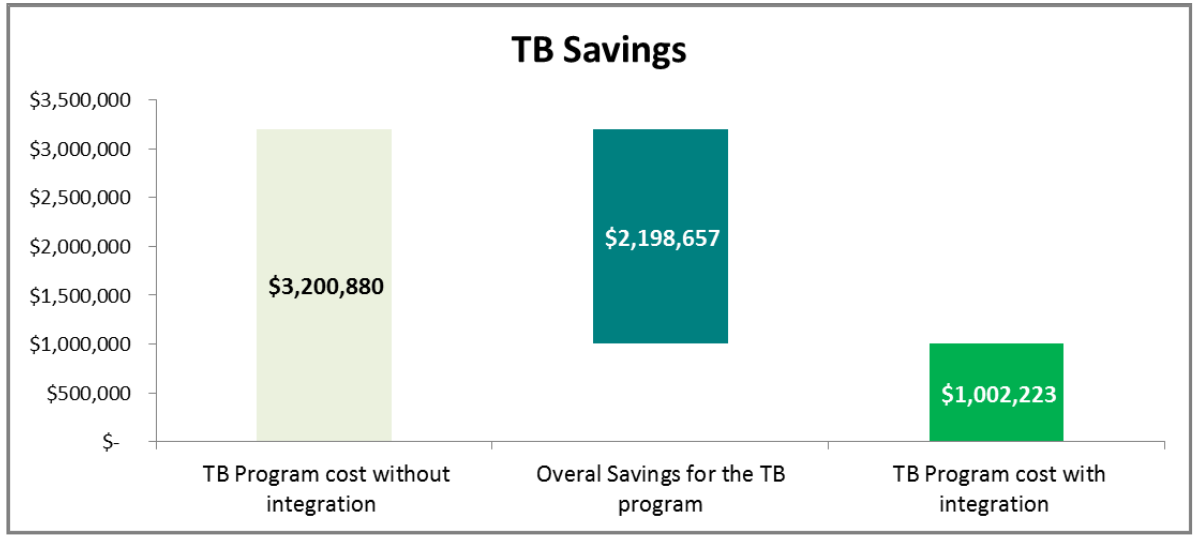
Unused / spare capacity thresholds		Integrate?
Low	10%	No
Medium	25%	Maybe
High	50%	Yes

#	Region	District	Facility Name	Integration scenario					
				TB + EID	TB + HIV VL	TB + EID + HIV VL	TB + HPV	TB + HCV	TB + EID + HIV VL + HCV + HPV
1	Region 1	District 1	Facility 0	Yes	Yes	Yes	Yes	Yes	Yes
2	Region 1	District 1	Facility 1	Maybe	No	No	Maybe	No	No
3	Region 1	District 2	Facility 2	Yes	No	No	Yes	Yes	No
4	Region 2	District 3	Facility 3	Yes	Yes	Yes	Yes	Yes	Yes
5	Region 2	District 4	Facility 4	Yes	Yes	Yes	Yes	Yes	Maybe
6	Region 2	District 5	Facility 5	Yes	Yes	Yes	Yes	Yes	Yes
7	Region 2	District 6	Facility 6	Yes	Yes	Yes	Yes	Yes	Yes

Example of country-specific analysis on estimated cost savings for Integration vs Siloed testing may also be useful with advocacy and stakeholder engagement

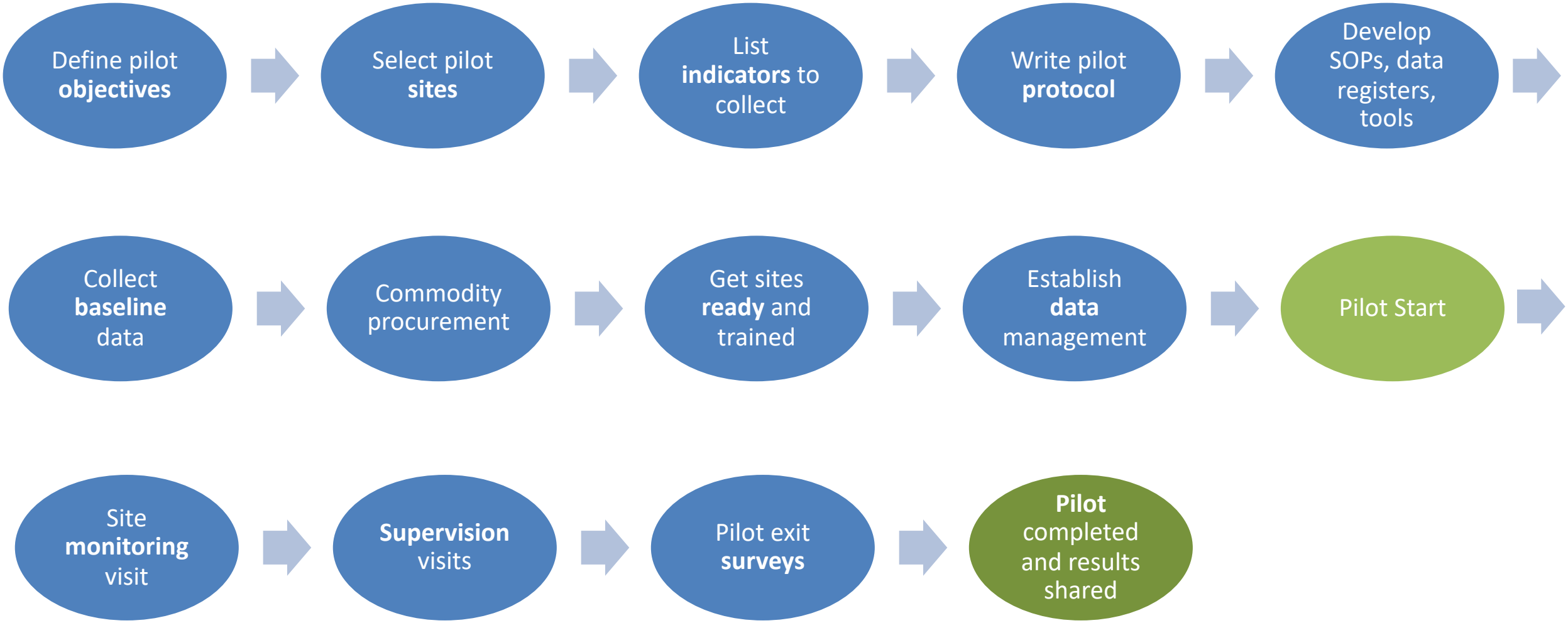






The savings will depend on the cost structure of a particular national program, along with the expected testing volumes

Phased Implementation: Recommended Steps for Integration Pilot and Scale-up



Key lessons learned as integrated testing was rolled out across many CHAI countries

Stakeholder Engagement

- Example decks presenting the rationale for integration on GeneXpert at a country level are helpful to build case
- **Early engagement of facility management** and having regular discussion with them during implementation is crucial
- **Engaging & building capacity** of MOH relevant departments, funding partners from the beginning makes transition seamless
- Presenting analysis of existing and forecasted **GX capacity utilization** is useful to highlight sites suitable for integration
- Presenting **cost savings** from shared costs like setup, S&M, supportive supervision, supply chain management and HR is a good way to advocate for integration
- To ensure proper and timely connectivity implementation, it is important to engage NTP for procurement of GXAlert systems

Resource Assessment

- Availability of **functional power back up** (solar panels/UPS/generators) to ensure consistent supply of electricity would enable maximum utilization of the device and reduce errors
- Investments into **air conditioners** to control temperature, extra **refrigerators** to store samples are needed to avoid downtime
- **Connectivity** solutions can improve monitoring to **clearly track downtime-testing** issues and provide corrective action
- Ensure **Service and maintenance** is clearly outlined which makes it easier to get machines fixed on time
- **Engage with manufacturer** to ensure consistent service and maintenance mechanism in place to prevent service disruption

Quick Tips

Bottlenecks

- Not getting the necessary approvals to assess site level data for analysis
- Low coordination between disease programs

- Limited connectivity, power outages, and poor roads for hub
- Limited number of multi tests devices in focus regions
- No funding to support required infrastructure upgrades

Key lessons learned as integrated testing was rolled out across many CHAI countries

Site selection

- Integrated testing should consider **current and expected capacity utilization** to ensure that all testing demand can be met for testing scale-up due to increased coverage or **changing algorithms** for disease programs
- **Data-driven** transparent site selection and **routine monitoring** of volumes during integration can ensure no-backlog situations
- **Physical** site **assessments** help analyze readiness and gaps before implementation
- **Contingency plans** when devices start to reach near capacity – adding lab work hours to optimize capacity, re-directing volumes to low capacity utilization sites, making case for high throughput devices
- Another success factor: **Willingness** of facility management and staff to support pilot and take ownership beyond pilot

HR Capacity Building

- Ensure that all relevant staff at the facility receive appropriate training to facilitate integration with extra focus on **demand generation, record keeping, sample collection, result interpretation and waste management**
- Providing **joint training** to labs technicians and clinicians from various entry points will help to form a team and create a common understanding before initiation of the implementation and ensure strong linkages
- Include intensive **practical exercises** to make sure everyone is conversant with the device
- Sensitize importance of using various s**ample types (DBS/WB) and specimen collection tubes**
- High turn-over of trained staff can impact workflow and can be mitigated by doing **on-site trainings** during mentorship visits

Quick Tips

- Data in registers varies from actual site data such as for device and module functionality, testing demand
- Dis-agreement on site selection between programs

Bottlenecks

- Staff from pre and post testing not included in trainings
- High staff turn-over and individualization of work

Key lessons learned as integrated testing was rolled out across many CHAI countries

Clinic-lab interface

- **Patient selection and prioritization** should ensure that the highest priority specimens are tested promptly
- **SOPs and guidelines** for clear definition and mapping of sample collection, transport, sample prioritization, testing and result return workflow should be available at clinic and lab
- Need a strong lab-clinic interface to maximize impact of rapid TAT with POC EID by establishing an **open and clear channels of communication** between laboratory & clinics with clearly defined **processes for communication to patients/caregiver**
- Ensure appropriate **referral systems** including sample transport networks are in place to reduce TAT across the cascade
- Define **roles and responsibilities** for staff at each cascade level and hold them accountable for maintaining a strong interface

- Linkage to care systems not defined
- Guidelines and SOPs not readily visible for new staff

Commodities supply

- Assure **accurate and early quantification** of cartridges and consumables for on-site and all spokes
- Account for **procurement disruption** due to time-lag for signing of new prices with the manufacturer, production, shipment and clearance processes
- **Regular consumption monitoring** can ensure timely order placement to avoid stock-outs and corrective action to manage expiries
- **Connectivity solutions** can help monitor site level consumption remotely
- Many decentralized sites may not have incinerators which go up to the **1000°C** required to safely dispose of used cartridges. Establish **waste management scheme** prior to implementation scale up and clear mapping of the incinerators and identify those with the required features and capacity

- National procurement agency's first experience of working for newer type of commodities
- Lack of in-country storage units and supply for commodities

Key lessons learned as integrated testing was rolled out across many CHAI countries

Quality Assurance

- Close follow up and **regular supportive supervision** help identify errors/gaps which can be negated by on-site refresher trainings
- Best practices for M&E, mentorship/supervision that should be put in place to not create duplicative, parallel systems
- Including the GX sites in the **national External Quality Assessment** program to ensure quality adherence
- Real-time device performance data through **connectivity** can filter sites requiring urgent mentorship and supervision support
- **Mentoring through comprehensive teams** (during and post pilot) strengthened patient care and yield more results across the cascade than focusing on "clinical" component alone

Data Management

- Plan to create links or establish data connectivity systems for GX devices to improve TAT across the cascade
- Engaging **local distributor** to conduct software upgrades, new installations leads to quicker response time
- Data systems are helpful to identify **real-time gaps** and take corrective action
- Define **roles and responsibilities** for supplier, implementer, hospital board

- In-country panels not ready
- Delays in conducting supervision visits
- Limited data connectivity

- Data integration of HIV, HPV and TB from GeneXpert
- Only a few GX connected to data systems
- No funding to support data management

Thank You!