

Experience with service and maintenance of TB molecular diagnostics

Wayne van Gemert

Diagnostics Technical Officer, Stop TB Partnership

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GeneXpert service and maintenance via warranty

- Countries procuring GeneXperts receive an initial 24-month warranty with the option to purchase extended annual warranties
- Cepheid's GeneXpert warranties only cover:
 - Sending refurbished modules and other parts
 - Sending XpertCheck calibration kits
 - They do NOT cover in-country on-site visits of the authorized service provider: countries must make separate contracts with their service providers or try to build internal capacity to do some functions (e.g., swapping failed modules, running calibration kits)
 - As a result: many countries face challenges in keeping instrument fleets optimally functioning



GeneXpert service and maintenance via warranty (2)

- Extended annual warranty price is \$2,898 (4-module instrument):
2017 CHAI bottom-up costing analysis = \$1,690
 - Many countries forgo warranties and pay Cepheid ad hoc to send refurbished modules and other parts; ad hoc payments are challenging to manage
- Not many countries have been able to execute contracts with authorized service providers for comprehensive service at optimal pricing or have managed to build internal capacity

AccessCare for comprehensive GeneXpert service and maintenance

- In 2017, a small group of countries started to be offered comprehensive service and maintenance contracted directly with Cepheid under a cartridge surcharge model: AccessCare
- AccessCare covers warranty plus in-country on-site visits including for swapping of failed modules and any other repairs, and annual preventative maintenance visits
- A surcharge price on each cartridge procured (TB, HIV VL/EID, SARS-CoV-2, etc), enables all instruments to be covered anytime tests are purchased
- Early draft contracts contained vague terms and conditions with minimal accountability and lack of cost justification, so Stop TB GDF led the development of a model Service Level Agreement (SLA), including monthly KPI reporting
- **Example results:** country had backlog of > 150 non-functioning modules replaced; 6 months later, >90% of non-functioning modules replaced in ≤ 5 days

Model Service Level Agreement: KPIs

- Percentage of modules that were functioning at the end of the month (**module uptime; target > 95%**)
- Percentage of module swaps that were timely (**within 10 days; target: 90%**)
- Percentage of other repairs and replacements that were timely (**within 20 days; target: 90%**)
- Percentage of XpertCheck preventative maintenance activities that were timely (**≤ 30 days past annual scheduled date; target: 95%**)
- Percentage of requests that received a timely response (**≤ 2 working days; target 95%**)
- Percentage of instruments installed in the past month that were installed within 10 days of site readiness (target 90%)
- Description of any trainings provided by the Service Provider in the month, including location(s) and numbers of participants:
- Total number of individuals currently employed by the Service Provider who have completed a certification or recertification training programme with Cepheid within the past 90 days

AccessCare: Challenges

- Very few countries are being offered AccessCare; roll-out is slow
- AccessCare is not feasible in countries where service providers currently have limited capacity or offer pricing that is not agreeable to the country
- Country-specific costs are opaque: Cepheid has a confidential costing calculator
 - Costing is heavily based on the number of cartridges projected to be procured across the fleet; Cepheid's projections may differ from country's projections
 - In countries that are prioritizing patient access and have low average instrument utilization, the resulting high AccessCare price may be unattractive
- Country negotiations can be protracted and risk delay of orders of cartridges
- Contracts do not have teeth: poor service provider performance against KPIs may not have consequences

Comparison of Service and Maintenance

	GeneXpert warranty (any HBDC country)	GeneXpert AccessCare	Truenat warranty (through Stop TB GDF)
Replacement/repair of instruments and parts	Yes	Yes	Yes
On-site visits for replacement/repair of instruments and parts	No	Yes	Yes, and if an instrument is not repairable at site, a stand-by machine is provided
Annual preventative maintenance visits	No	Yes	No
Monthly KPIs reported	No	Yes	Yes (pilot)
Duration	2-year initial; 1-3 year extensions available	Annual with extensions, moving to 3 years	1-year initial; 1-5 year extensions available
Cost	\$2,898 per year for 4-module instrument	Cost per test procured; variable by country	\$1,120 per year, regardless of instrument model
Connectivity	Most countries rely on third-party software; Cepheid does not have visibility on functioning of instruments		In-built connectivity functionalities provide opportunity for Molbio to have visibility on functioning of instruments

Lessons learned

- Service and maintenance packages function most effectively when they:
 - Are offered directly from the manufacturer, without need for price negotiations with local agents
 - Include on-site visits and anything else required for comprehensive servicing and preventative maintenance
 - Entail monthly KPI reporting against targets, to provide accountability of the performance of the manufacturer and their local agent
- Having access to real-time data on instrument performance through connectivity would be valuable:
 - For manufacturers and countries to have the data needed to quickly identify specific instrument problems and to be able to proactively address identified problems
 - For countries and partners to be able to systematically monitor quality of service and maintenance provision and hold manufacturers accountable



Wayne van Gemert
waynev@stoptb.org

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