All Inclusive Workstream Update

Integrated Diagnostics Consortium Meeting

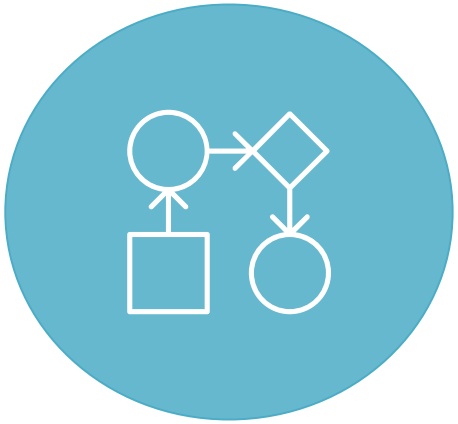
September 2019

Recall: The objectives of the Unitaid all-inclusive pilots were to accelerate the shift toward all-inclusive pricing contracts for diagnostic technologies

1

Establish all-inclusive contract terms

Define and establish widely acceptable all-inclusive procurement supply terms



2

Operationalize all-inclusive procurement in country

Pilot the all-inclusive model to generate evidence for scale up and to identify key implementation steps and lessons learned

UNICEF competitive tender launched in 2018 was used to establish an all-inclusive “price per patient test”

UNICEF tender terms: Bundled price that is inclusive of instrument placement, reagents & consumables, service & maintenance, distribution, controls & calibrators, errors & failures

Countries in scope: Malawi, Tanzania, Uganda, Zimbabwe

Assays: Consistent all-inclusive price across HIV, HCV, HBV, HPV assays

Contract monitoring: A service level agreement (SLA) will be executed and monitored locally between the service provider and government

From six proposals received, two proposals were technically accepted - Hologic ‘s bid was identified as the most competitive and therefore resulted in an LTA award

$12 price includes all supplies & services needed to generate a patient test

$12.00

Global Ceiling Price

$1,128 all-inclusive price per test kit

$11.28 all-inclusive price per test (100 tests per kit)

$12.00 all-inclusive price per patient test (94 patient tests per kit)

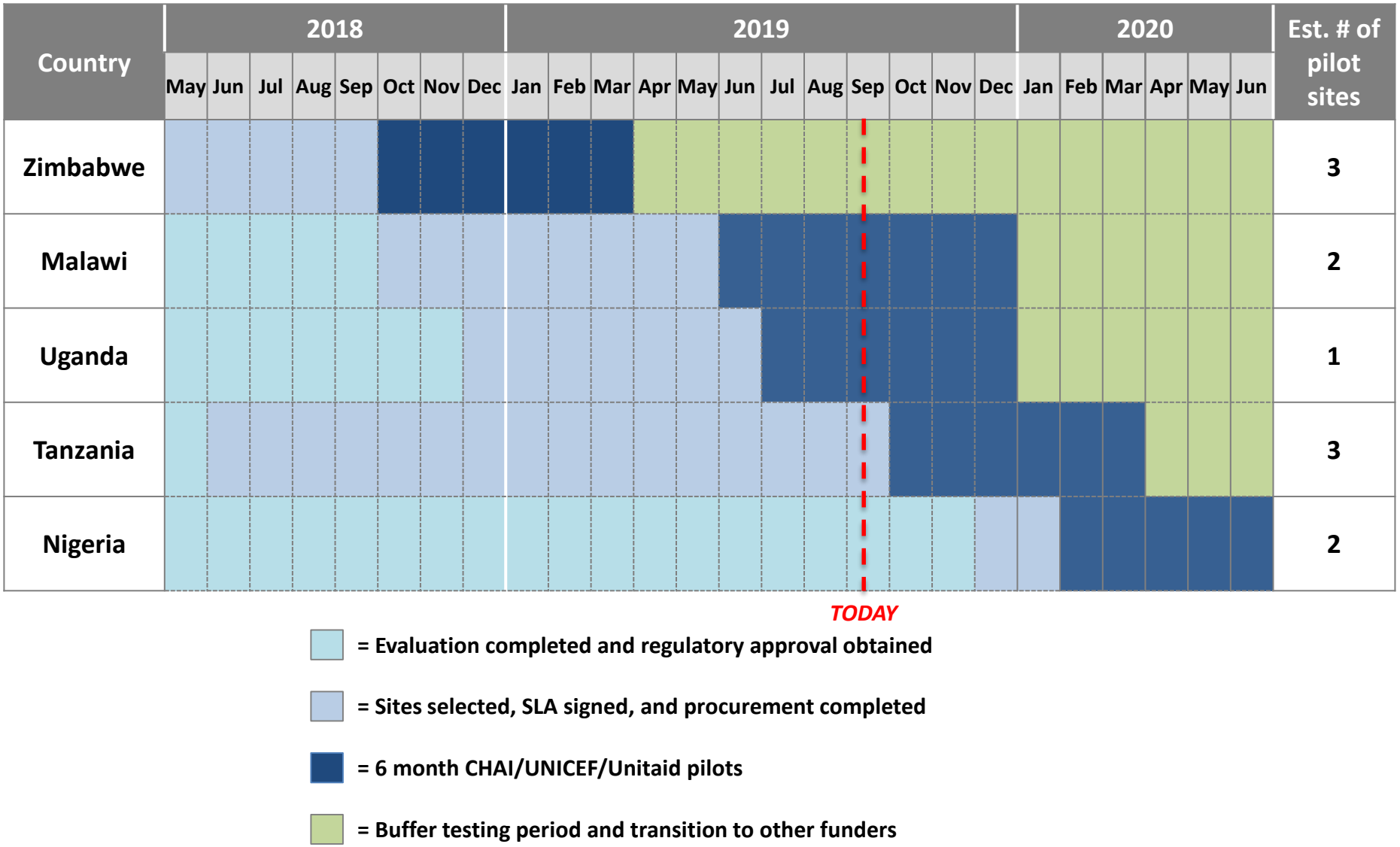
Category		Description
A	**Instrument Placement**	Equipment needed to process samples placed free of charge; includes site inspection, installation, basic connectivity, and ongoing training
B	**Reagents & Consumables**	All reagents and consumables needed to produce a test result in the lab including controls, calibrators, and all supplies needed to process DBS samples
C	**Service & Maintenance**	Cost of servicing and maintaining the Panther system and related equipment, including preventative maintenance, repairs & replacements, and any necessary modifications and updates
D	**Freight & Logistics**	Delivered At Place (DAP) to the testing site or national warehouse. Includes cost of export fees, clearance, carriage, insurance, port charges, and distribution.
E	**Control & Calibration**	The cost of assays used for control and calibration purposes that do not produce a patient result is factored into the all-inclusive price (6 per test kit)
F	**Errors & Failures**	Free-of-charge replacement of tests that fail due to documented instrument errors; corrective action training for labs with high rates of user errors

The all-inclusive price does not include ancillary costs, for example those associated with sample collection, sample transport, laboratory staff time, laboratory infrastructure, generic lab supplies (e.g. primary collection tubes, disposable gloves, etc.), inventory management, or general administration and overhead costs The ceiling price does not include the following additional equipment necessary to run the tests: centrifuge, vortex mixer, and pipettor

All-inclusive contracts shift the burden for optimizing instrument placement to the supplier and address many currently observed barriers to access

Key Features of All-Inclusive Contract	Programmatic Benefits
Instrument placed, not purchased	✓ **Reduces switching costs**; easier to shift to newer, more competitive offerings ✓ **Optimizes the lab network;** reduces instrument under- and over-utilization
Service level agreement with robust KPIs	✓ **Reduces instrument downtime** ✓ **Reduces unexpected servicing costs**
Bundled supplies & direct delivery to the lab	✓ **Reduces supply planning complexity** ✓ **Reduces number of stock-outs** ✓ **No unexpected mark-ups**
Transparent all-inclusive price; no hidden costs	✓ Allows countries to more easily compare bids and undertake **competitive tendering and procurement process**
Single, MoH-owned contract per country	✓ **Reduces procurement fragmentation;** single SLA to cover the entire installed base regardless of funding source

High-level timelines for the all-inclusive pricing pilots



Implementation status in the CHAI/UNICEF/Unitaid pilot countries

		Zimbabwe	Tanzania	Malawi	Uganda	Nigeria
	Overall outlook for Hologic adoption:	Focus on service provider performance	Preparation for the pilot following PS approval	Sites running; focus on boosting volumes	Pilot started – focus on transition planning	Targeting validation start in ~Sept/Oct
Regulatory approvals	**Regulatory approval of Aptima HIV-1 Quant Dx assay (plasma)**					
	Regulatory approval of Aptima HIV-1 Quant Dx assay (DBS)				*Considering validation in Q3/4*	
	Regulatory approval of Aptima HPV assay	*TBC - securing written waiver*		*Waived*	*Waived*	
Pilot prep.	Shortlist of potential pilot sites identified					
	Pilot sites finalized following assessments					
	SLA finalized and signed locally					
	Procurement process initiated					
Pilot implementation	Instruments shipped, installed, and verified					
	Operators trained					
	Routine VL testing underway					
	Quarterly reporting initiated			*Planned in September*		
	Transition plan finalized					
	Transition completed					

= Complete **= In progress** **= Not yet started** **= Not relevant**

Discussion: Lessons learned to date on all-inclusive pricing

Starting list for discussion

Learning	Implication
▪ Countries were often **unaware of the full price** they are currently paying for diagnostic tests	▪ Building awareness amongst key stakeholders about the full price paid for diagnostic tests is vital to empower countries and procurers to negotiate more transparent, all-inclusive pricing deals
▪ **Standard terms in all-inclusive pricing contracts may not always fit with country-specific processes** (e.g. how in-country logistics are handled)	▪ Procurers should be open to adjusting terms in all-inclusive pricing contracts to fit the local country context, e.g. by removing services that suppliers could provide but MoH does not want
▪ Rigorous **monitoring of supplier performance is currently lacking** in many countries	▪ The supplier monitoring systems, tools, and processes set up during the Hologic all-inclusive pricing pilots could be leveraged in the future for other suppliers or countries
▪ Align upfront on **customs clearance** details	▪ Important to have clear agreement on who should be the consignee for the shipment since that can affect the duty free waiver process and clearance timelines.
▪ **Countries can be hesitant to share data with service providers / suppliers**	▪ Will need to clearly demonstrate how sharing monthly instrument data will benefit the MOH and support country goals ▪ Hologic data sharing document was created to address this concern

Annex

Status of Hologic all-inclusive procurement rollout across Sub-Saharan Africa

Unitaid pilot country with routine testing underway

Unitaid pilot country with testing to start this year

Other countries with routine Hologic testing underway

Other countries where Hologic is being discussed or validated

Key Performance Indicators (KPIs)

Integrated Diagnostics Consortium Meeting

September 2019

Unitaid unicef ASLM AFRICAN SOCIETY FOR LABORATORY MEDICINE CLINTON HEALTH ACCESS INITIATIVE

The Hologic SLA also lists Key Performance Indicator (KPI) targets that the service provider is expected to meet

Performance Area			Key Performance Indicator (KPI)	Target
Functional Molecular System	1. Service & Maintenance	1	Percentage of planned maintenance calls performed on schedule	100%
		2	Mean time to response (i.e. avg # of hours lapsed from initial support call to on-site visit)	<24 hours
		3	Mean time to repair (i.e. avg # of hours lapsed from initial support call to job completion)	<48 hours
		4	Number of instrument outages which occur <3 months after any scheduled or unscheduled maintenance or repair work	<2 per instrument per year
		5	Total percentage instrument uptime	>95%
	2. Reporting & Management	6	Percentage of quarterly reports submitted within 30 days of previous quarter-end	100%
		7	Number of customer- or MoH-convened meetings attended by the Service Provider	At least one meeting per calendar quarter (4 per year)
	3. Supply Chain Management	8	Number of stockouts of any reagents or consumables for which the Service Provider is responsible leading to interruptions in testing services	0

KPIs will be reviewed every quarter to identify opportunities for improved performance

KPI will be tracked using a few key tools…

Data sharing instructions for lab staff

REPORTING PROCESS

Activity	Stakeholder Responsible	Timeline
1. Collate & Transmit Data i. PDF export of the Activity Log Report from each instrument ii. PDF export of the Messages Log Report from each instrument iii. PDF export of Maintenance Log Report from each instrument iv. PDF export of Results Report from each instrument for each assay type being run on that instrument	Customer	Monthly, within 15 days of month-end
2. Compile Quarterly Report To be generated based on all instrument performance data that has been shared with the Service Provider	Service Provider	Quarterly, within 30 days of quarter-end
3. Conduct Quarterly Meeting	Customer	Quarterly

SLA tracker (completed by service provider)

KPIs

Tracks progress to date against key performance indicators

Update frequency: **Quarterly**
Date last updated: **2-Apr-18**

No.	Description	Definition	Data Source	Target
1	**Percentage of PM Calls performed on schedule**	Total no. of PM Calls performed on schedule / total no. of PM Calls performed	Date of actual PM Call recorded in *Service Log* tab; date originally scheduled as per *Installed Equipment* tab	**100%**
2	**Mean time to response: average # of hours lapsed from time issue first reported to Service Provider's on-site visit**	Average no. of hours lapsed from 'Issue Reported' to 'FSE On-Site Arrival' for all entries in *Service Log* tab	*Service Log* tab	**<24 hours**
3	**Mean time to repair: average # of hours lapsed from time issue first reported to job completion**	Average no. of hours lapsed from 'Issue Reported' to 'Issue Resolved' for all entries in *Service Log* tab	*Service Log* tab	**<48 hours**

…and will inform decisions made during quarterly review meetings

- ❑ E.g. Corrective actions required to improve service provider performance on KPIs
- ❑ E.g. Corrective actions required by the customer and/or lab staff to improve volumes and performance
- ❑ E.g. # of replacement tests that should be provided for free due to instrument errors or expiries driven by the service provider
- ❑ E.g. Amount of spare part inventory required in country
- ❑ E.g. Adjustments to where Hologic instruments are placed

Discussion: Lessons learned to date on all-inclusive pricing

Starting list for discussion

Learning	Implication
▪ **KPI monitoring has been quite manual** on both the Hologic and customer side, because KPI data is largely around operational performance, hence cannot be pulled out of an instrument	▪ Establishing more automated processes to monitor indicators or a subset of them is possble and can be done by better leveraging LIMS or developing ad-hoc dashboards
▪ **Track consumption closely** during early days	▪ Weekly tracking of consumption rates when routine testing first begins, so supplemental orders can be placed in a timely manner and stock outs can be minimized ▪ Closely monitor demand generation activities
▪ **People can interpret KPIs in different ways** (e.g. should time to repair include issues resolved telephonically?)	▪ Important to clearly define each KPI indicator and how it's measured ▪ Develop a standard dashboard to use across suppliers to ensure consistency in tracking performance
▪ **Local monitoring activities are more likely to succeed if they are built into routine tasks or automated**	▪ Planning to leverage routine tools during the pilots to spot check supplier performance in real time (E.g. Field Service Report)
▪ **Lab staff play a key role in the monitoring process**	▪ Important to invest in training and educating the lab staff and setting clear processes for them to execute the tasks requested

UNICEF has a list of Key performance indictors (KPIs)

Area	Code	Performance Scorecard Indicator	Target	Frequency
Beneficiary & Constituent	3	Percentage of international orders delivered at port of entry at or within agreed upon TAD (all shipments: up to 40 days before TAD AIR shipments: up to 7 days after TAD non-AIR shipments: up to 14 days after TAD)	85%	M
	4	Percentage of complaints with identified correction within 10 workings days from date complaint is validated	85%	Q
Financial performance	7	Percentage of invoices paid within 30 days of receipt (split between supply and freight)	90%	M
	8	Percentage of insurance claims with a value <$25,000 that are closed within 90 days of receipt	90%	Q
	9	Percentage of Statement of Accounts for PS, GAVI and Co-financing transactions issued within 30 days of logistics and financial completion	95%	Q
Internal operations	12	Percentage of all international supplier deliveries for goods are delivered on time	85%	M
	13	Percentage of orders to be shipped by FFs within leadtime	90%	Q
	19	Percentage of Cost Estimates for standard items issued within 10 working days of receipt by center	80%	Q

Annex

Zimbabwe - Key performance indictors (KPIs)

Key Performance Indicators (KPIs)

These are tracked per site and the average KPIs for all sites is shown below:

No.	Description	Data Source	Target	Bindura	Marondera	Kadoma	Average
1	**Percentage of 'PM visits' performed during originally scheduled month**	Month of actual PM visit recorded in *Service Log* tab; month originally scheduled as per *Installed Equipment* tab	**100%**	100%	100%	100%	100%
2	**Mean time to response: average # of hours lapsed from time issue first reported to Service Provider's on-site visit**	*Service Log* tab	**<24 hours**	6:30 hrs	13:09 hrs	18:05 hrs	12:48 hrs
3	**Mean time to repair: average # of hours lapsed from time issue first reported to job completion**	*Service Log* tab	**<48 hours**	11:47 hrs	19:16 hrs	86:35 hrs	39 hrs
4	**Number of anaylzer outages which occur less than 3 months after any scheduled / unscheduled maintenance work**	*Service Log* tab	**<2 per analyzer/ year**	0	0	0	0
5	**Total percentage uptime for all analyzers placed under this agreement**	No. of hours lost due to instrument downtime recorded in *Service Log* tab; no. of hours for which testing services originally scheduled listed in *Testing Sites* tab	**>95%**	99%	94%	83%	92%