Overview of Multi-disease Integrated Testing

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Across sub-Saharan Africa, infant case finding lags behind testing rates in adults

Progress in the 1st 90 for infants is not being realized at a similar rate as for adults

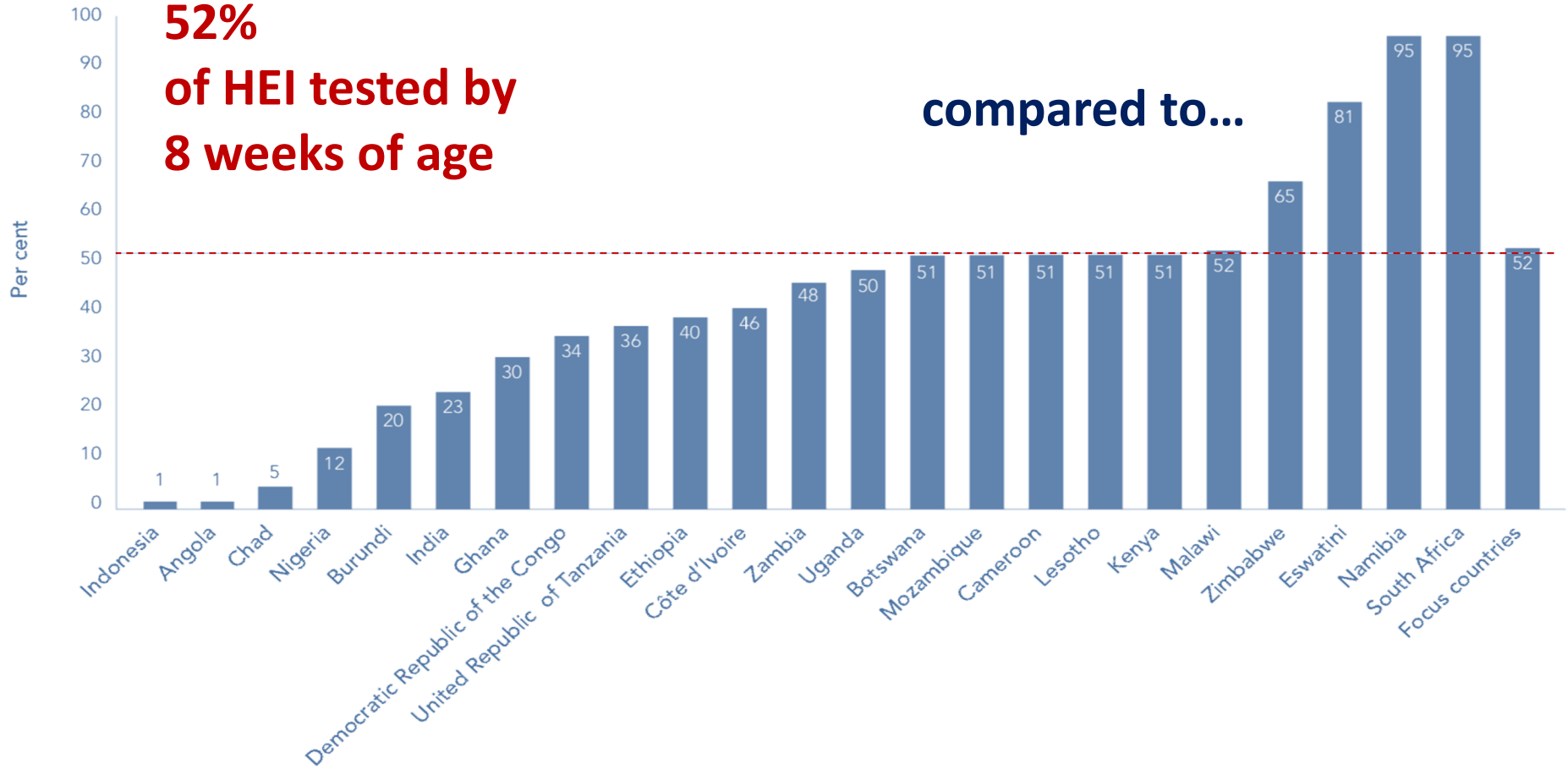
Figure 11. Nearly half of HIV-exposed infants are not tested

Percentage of children born to women living with HIV who were tested for HIV within eight weeks of birth, 23 focus countries, 2017

52%
of HEI tested by
8 weeks of age

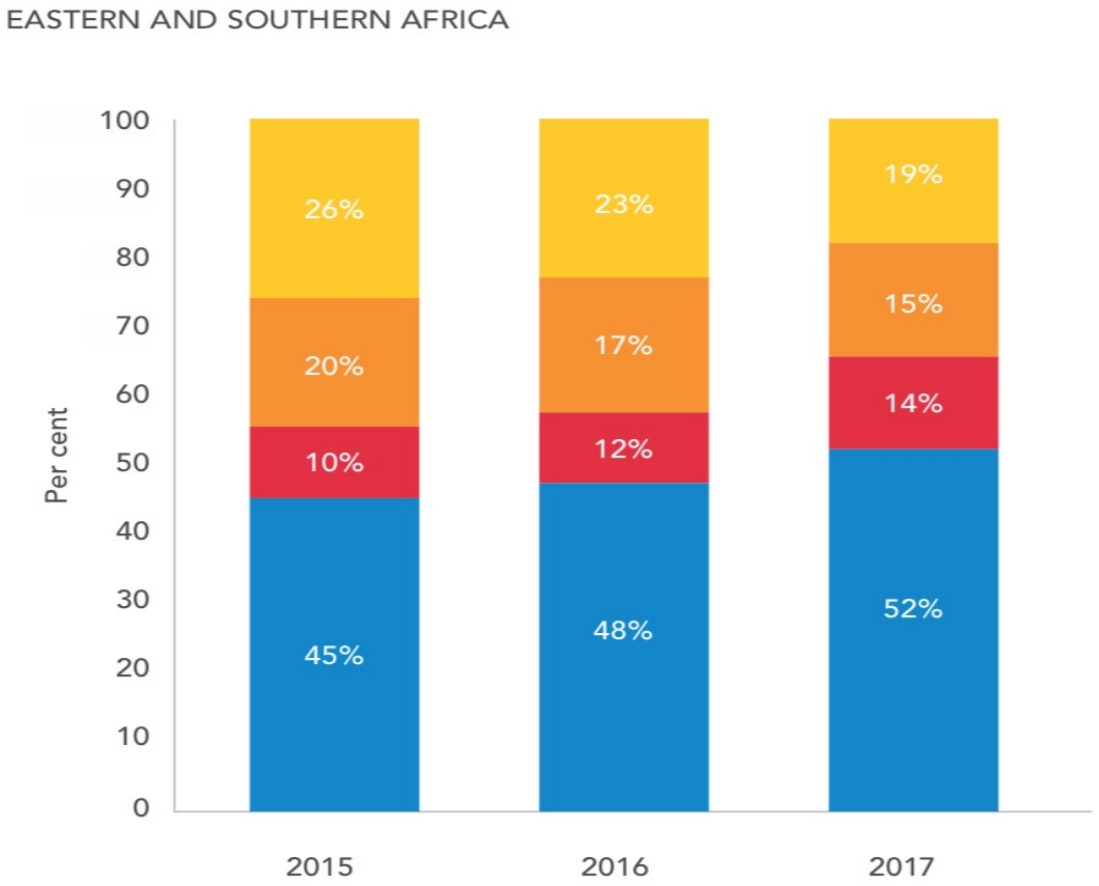
compared to…

75% [55-92%]
of PLHIV know
their HIV status



Monitoring PLHIV on ART is critical to achieving viral suppression targets

Though more people are being diagnosed and placed on treatment, the gap in the 3rd 90 is growing



Testing gap: Percentage of people with HIV who do not know their status and are not on treatment

Treatment gap: Percentage of people living with HIV who know their status but are not on treatment

Viral suppression gap: Percentage of people living with HIV who are on treatment but not virally suppressed

Virally suppressed: Percentage of people living with HIV who are on treatment and virally suppressed

Source: UNAIDS special analysis, 2018.

"The 'viral suppression gap' is growing more prominent." - UNAIDS 2018

Point-of-care (POC) testing offers an opportunity to address coverage and quality gaps in molecular testing

Services to manage PLHIV ***have been tremendously decentralized***

Centralized laboratory systems maximize throughput *but often do so at the expense of rapid result availability*

- May lead to missed opportunities for more critical clinical decisions, such as HIV diagnosis for infants or management of clients with unsuppressed VL

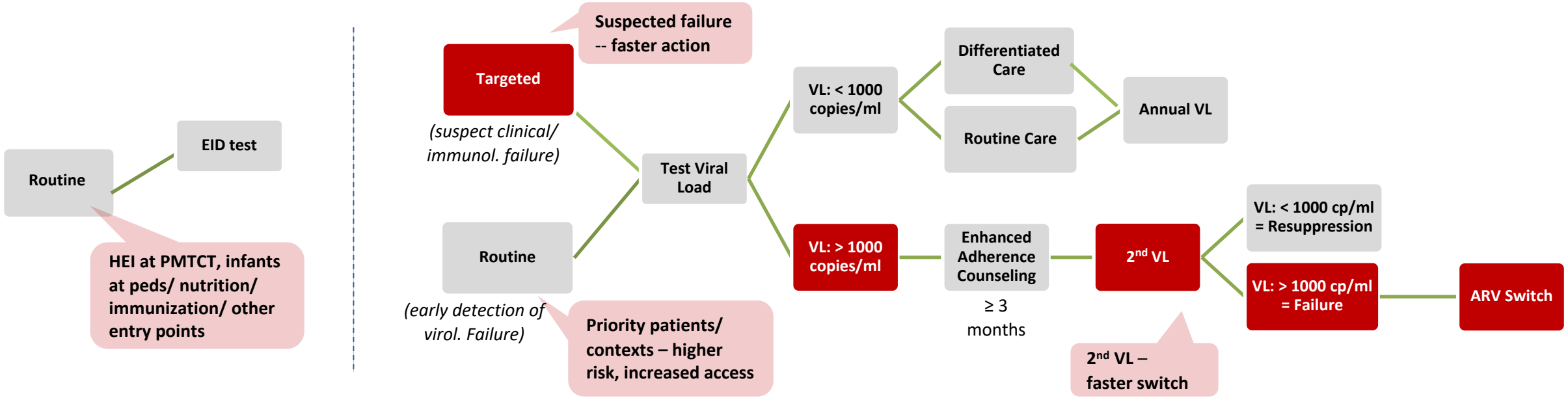
POC testing for EID and CD4 has been shown to increase rates and timeliness of clinical action[1] *(linkage to care, ART initiation)*

- **But management of decentralized testing fleets** can be capital, resource intensive and complex without accompanying supportive systems

Initial implementation strategy to offer POC testing is **Multi-disease integrated testing** on existing GeneXpert devices. Integration represents an opportunity to increase access and minimize costs for POC testing

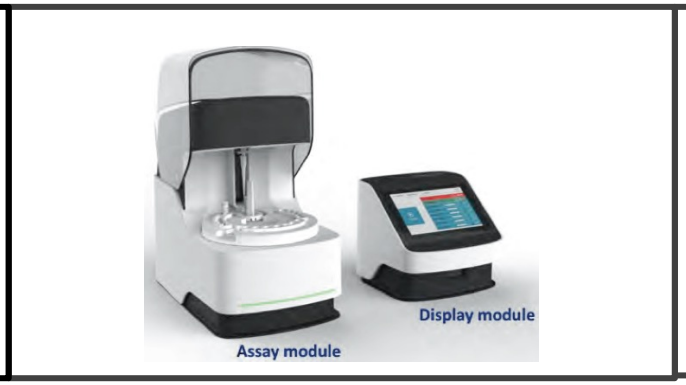
[1] *Vojnov L et al 2016, Mwenda R et al 2018, Jani IV et al 2018*

POC testing is currently being considered for certain priority populations who could most benefit from rapid DNA-PCR test results



HIV exposed infants (HEI)	• to ensure timely diagnosis and improve rates of early treatment initiation
Pregnant and breast feeding HIV+ women	• to promote re-suppression and avert vertical transmission (20-25% risk of MTCT from women with unsuppressed VL)
Children/adolescents	• to ensure early detection of virological failure , can have higher rates of unsuppressed VL
AHD Persons with advanced HIV disease	• ensure more rapid viral suppression and lower the risk of disease progression
Patients on ART failing 1st VL	• to ensure early ARV switch, can have increased morbidity & mortality with prolonged elevated VL

There are currently 3 POC products approved by regulatory authorities to offer EID and/or HIV VL



	Cepheid GeneXpert		DRW Samba II		Abbott m-PIMA (formerly AlereQ)	
Assay	HIV-1 Qual (EID)	HIV-1 VL	Qual Test for EID	HIV-1 Semi-Q test (VL)	HIV-1/2 Detect (EID)	HIV1/2 VL
Regulatory	WHO PQ, CE-IVD	WHO PQ, CE-IVD	CE-IVD	CE-IVD	WHO PQ, CE-IVD	PQ under review CE-IVD
Sample	1 DBS, 100ul WB	1ml plasma	125ul WB	200ul plasma	25ul WB	50ul plasma
Time to result	1h55m (DBS) 95 mins (WB)	95 mins	95 mins	90 mins	52 mins	70 mins

A large existing fleet of GeneXpert devices established through National TB Programs has multiplexing capability to run different disease assays

	Cepheid GeneXpert			
Assay	HIV-1 Qual (EID)	HIV-1 VL	HCV VL	HPV VL
Regulatory	WHO PQ, CE-IVD	WHO PQ, CE-IVD	WHO PQ, CE-IVD	WHO PQ, CE-IVD
Sample	1 DBS, 100ul WB	1ml plasma	1ml plasma	Cervical swab
Time to result	1h55m (DBS) 90 min (WB)	90 mins	90 mins	60 mins

HBV VL released in Dec 2018

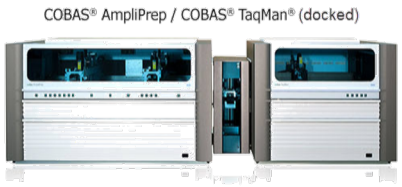
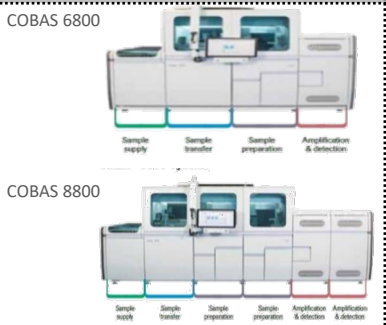
Over 2,800 GeneXpert systems have already been procured for TB testing in PEPFAR-focus countries.

Current utilization of existing devices is generally **less than 50%.**

Source: Cepheid 2017

A range of centralized platforms can also offer integrated testing

National programs have invested heavily in nucleic acid amplification testing (NAT) platforms (which detect DNA and RNA) that are capable of testing a range of diseases and may have spare capacity

		Roche CAP/CTM 96	Roche 4800/ 6800/8800	Abbott m2000sp	Hologic Panther
					
Max daily throughput (incl. controls)		168 (8hrs); 312 (24hrs)	384/960 (8hrs); 1,344/3,072 (24hrs)	96 (8hrs); 288 (24hrs)	320 (8hrs); 1,220 (24hrs)
Test Menu	**HCV VL**	✓	✓	✓	✓
	HBV VL	✓	✓	✓	✓
	HIV EID	✓	×[2]	✓	×[3]
	HIV VL	✓	✓	✓	✓
	MTB	×	✓	✓	×
	HPV	×	✓	✓	✓

[2]Cobas 4800 offers regulatory-approved EID; [3]Currently under validation in the US

Multi-disease integrated testing can leverage existing instrument fleet

Reduces

- Infrastructure costs
- Annual service contracts
- Training and mentorship costs
- Laboratory space
- Monitoring activities

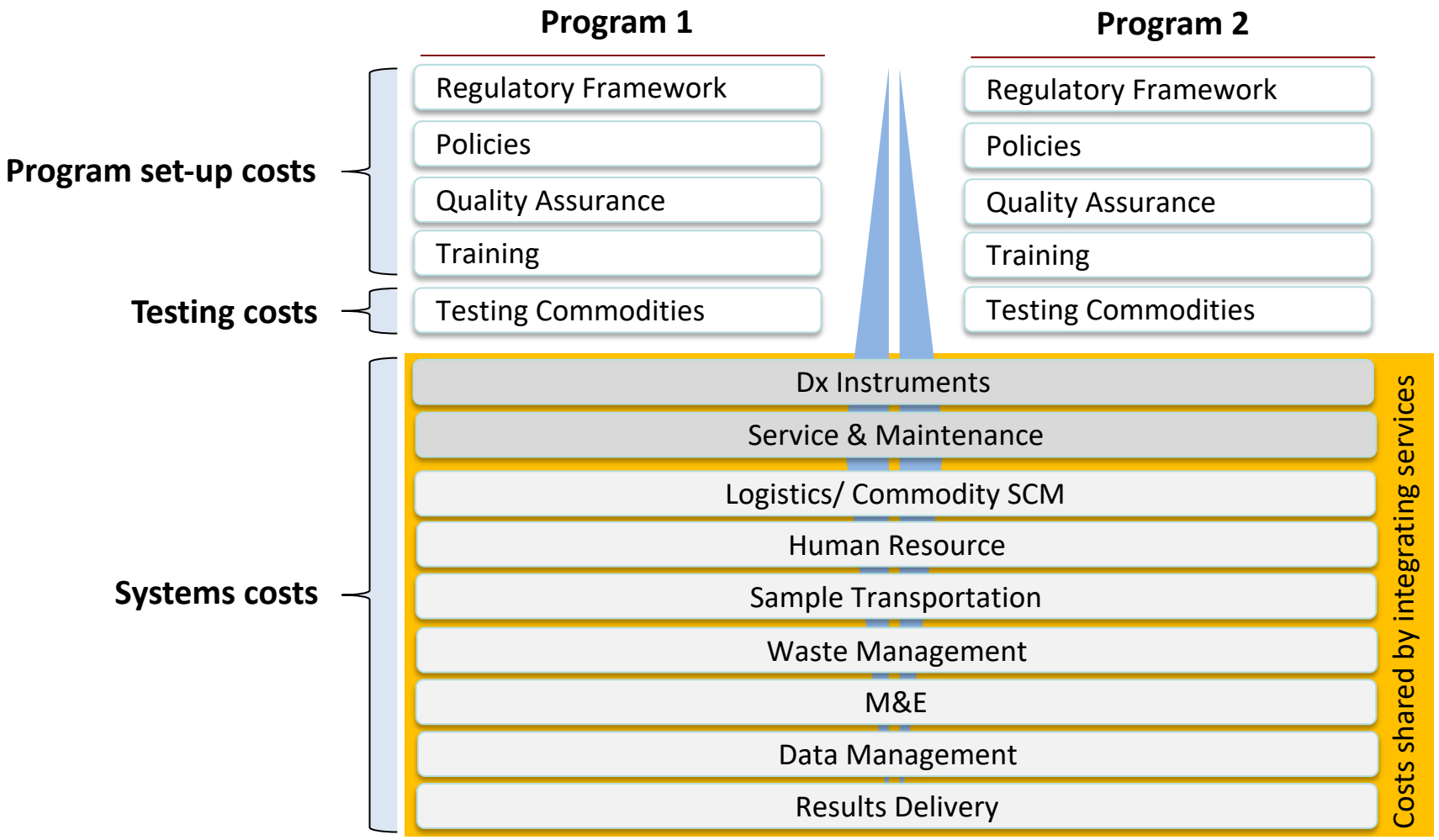
Increases

- Access to testing
- Program coordination
- Testing quality
- Cost-efficiency

Multi-disease integrated testing brings benefits to all programs sharing infrastructure:

- Cost-sharing for fixed costs to maximize utilization and reduce all-in cost per test
- Increasing access to devices and sites that would be otherwise unaffordable
- Improved quality by increasing and coordinating monitoring and training
- Increased negotiating power for test prices and S&M
- Leverage on data management, sample transport and supply chain systems

Integration of care services can be realized in most of the system areas and is expected to generate efficiencies and better services provided to the patients

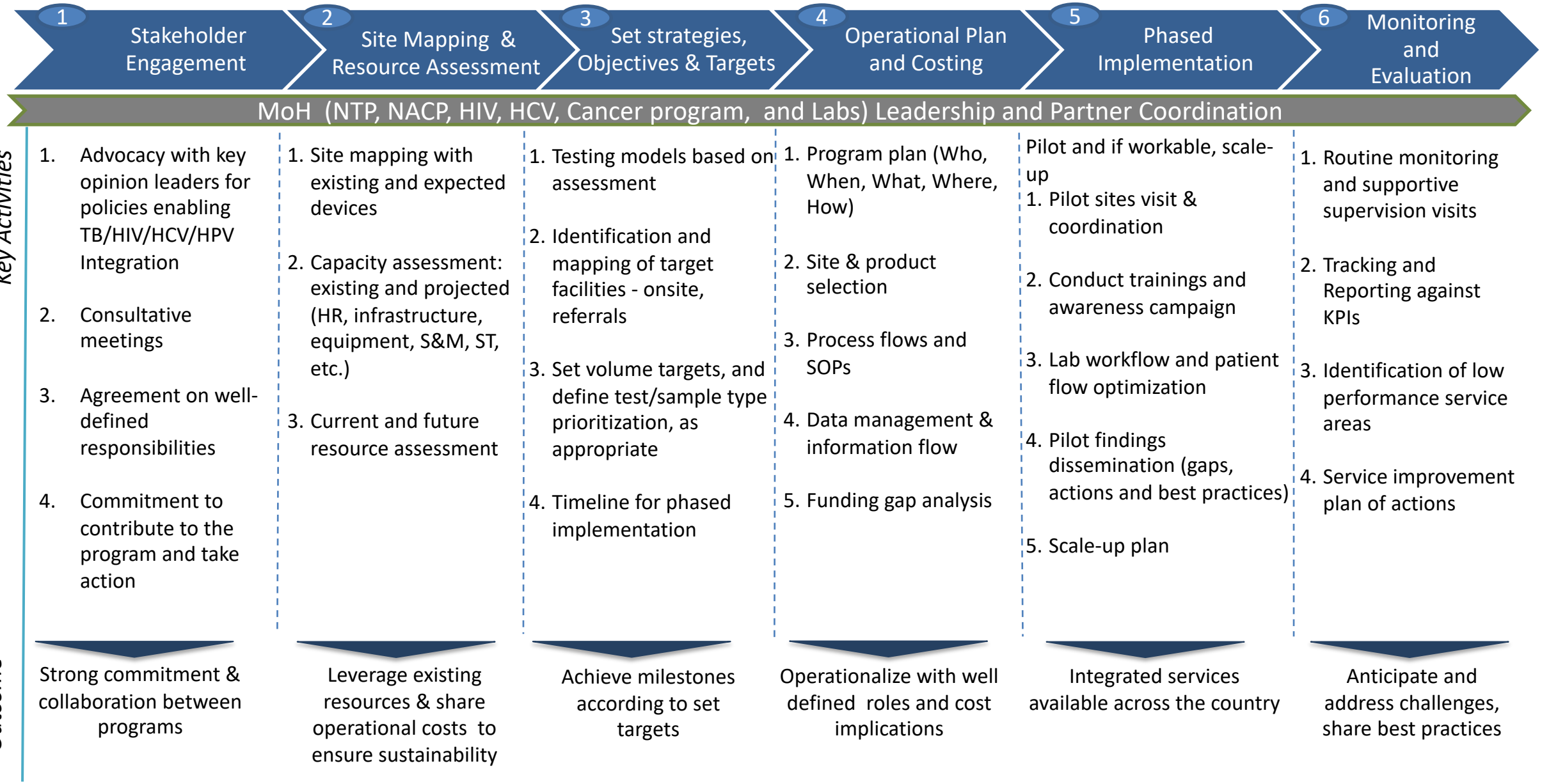


WHO: Considerations for Adoption and Use of Multi-disease Testing Devices

There many areas where multiplexing can yield improved efficiency, not only though **higher utilization** of the device, but also through leveraging and **combining laboratory support systems**, such as training, mentorship, and connectivity

WHO, 2017: Considerations for adoption and use of multidisease testing devices in integrated laboratory networks

Integration Implementation Framework



Thank you!