The CQUIN Learning Network

Partnering to Advance Differentiated Service Delivery

The Laboratory: A Critical Component of Differentiated Service Delivery

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Th evolving role of laboratory in ART delivery

From late 90ies to 2010

One size fits all

Minimal laboratory testing (CD4)

Increase access to ART

From 2010 to date

Customized approach

1 Scale up viral load to triage patients needing intensive versus less intensive care

2 Scale up other laboratory tests to address patients with HIV and non HIV-related needs special needs.

Increase rates of suppression and cost effectiveness of ART

Laboratory to accompany differentiated care delivery

Differentiated groups of patients

Less intensive laboratory monitoring

- PLHIV presenting early
- PLWHIV stable on treatment
- PLWHIV presenting late
- PLWHIV unstable on treatment
- Children and adolescents living with HIV
- Pregnant women
- People with co-morbidities (e.g: TB, CVD)

More intensive, broad and flexible laboratory monitoring

Laboratory in Differentiated Service Delivery Model

What

What clinical, laboratory are needed?

- VL, CD4, OIs, others?

When

How should laboratory testing be provided?

-

Where

Where should testing be delivered?

- Laboratory based? Point of care? At home? At the pharmacy?

Who

Who should execute the tests?

Lab technicians, Other HCWs, VHTs, peers, others?

What: scaling up viral load to triage patients

- Most countries adopted the WHO guideline of 2013 that recommended the use of VL for ART monitoring instead of CD4

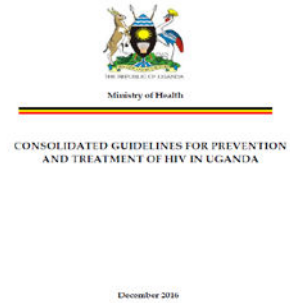
- Almost all countries are implementing this guidelines and most are in the scale up phase, though coverage is still low with most countries having less than 50% coverage.

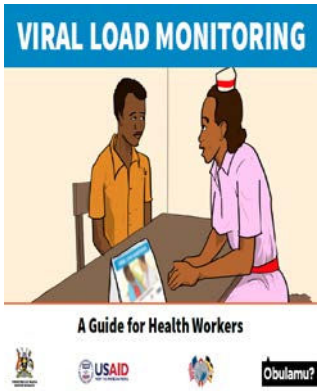
- However some countries have registered tremendous success with coverage close or over 80%. Such countries include S. Africa, Rwanda, Kenya, Uganda etc.

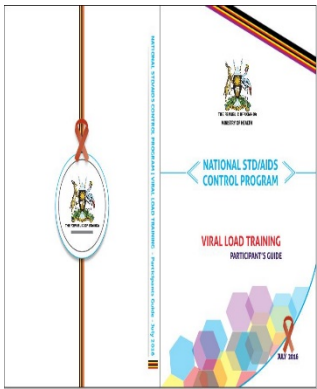
Countries having coverage less than 50% face challenges that include;

- Sample type and transport system,
- Sub optimal laboratory systems and networks,
- Low demand creation efforts
- Poor results utilization
- Logistics and supply chain challenges etc.

- The use of DBS and a functional sample referral system has been a major success factor
- Poor results utilization and demand creation for VL have remained a daunting challenge for most countries





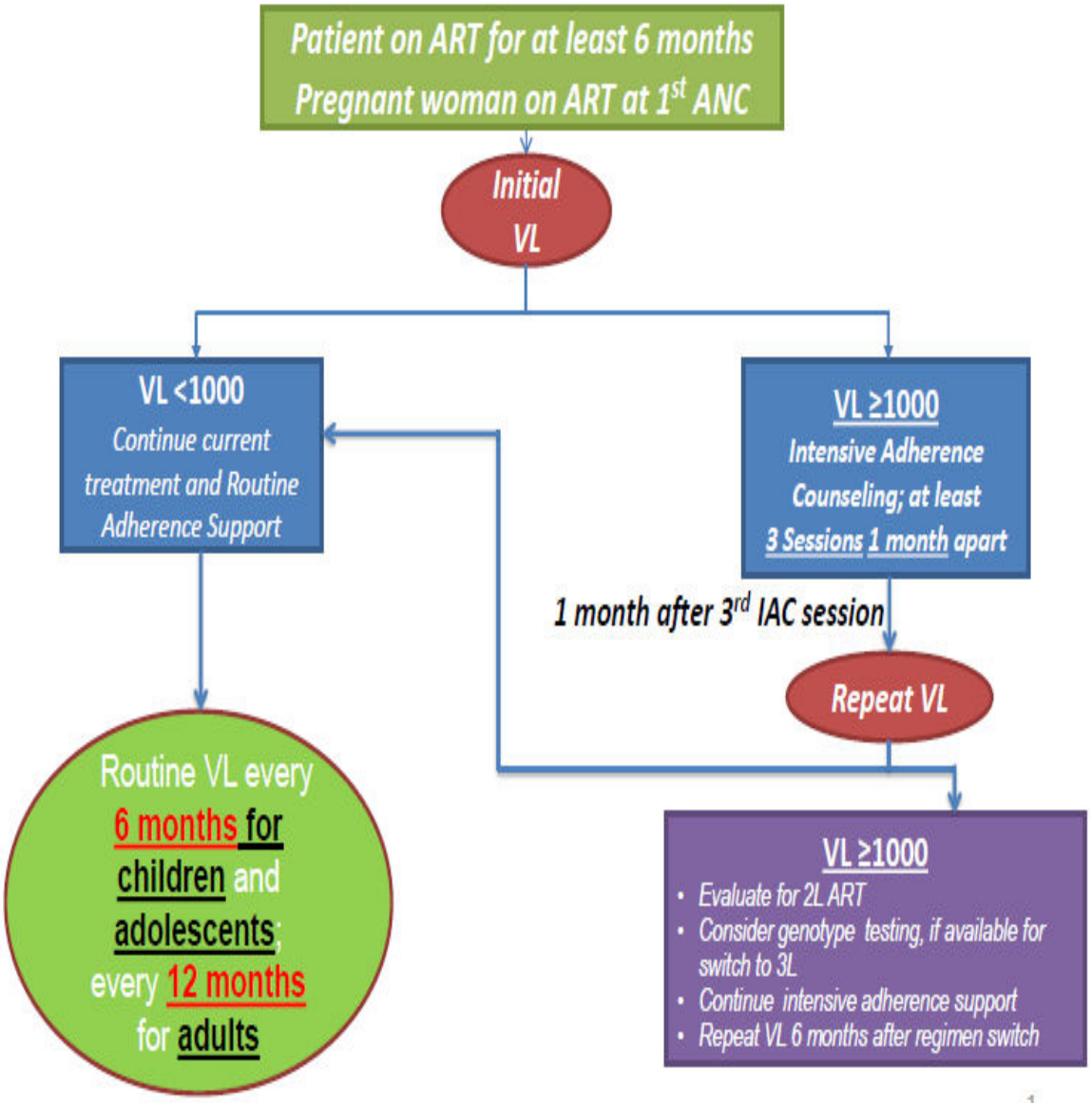


What? Scaling up other tests

VL is not the only test needed by PLHIV on ART, a couple of other tests are need including;

1. Monitoring OIs like; TB, respiratory tract infection in youth, Cryptococcus, CVD, hepatitis B and C, syphilis (pregnant women) etc.
2. Monitoring HIVDR in those failing second line ART
3. Monitoring adherence and the need for a dedicated test for that
4. Continuing CD4 for non suppressed patients, those presenting with OIs or clinical disease despite VL suppression
5. Test for drug toxicity?

When? VL Monitoring Algorithm



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VL RNA/PCR now mainstay of ART monitoring

- All clients on ART≥6/12 get VL test
- VL recommended once a year for supressed adults ≥ 20 years
- Children and adolescents ≤ 19 years get two tests per year
- All HIV+ pregnant women on ART get a VL test at 1st ANC
- Repeat (targeted) test for clients with ≥1000 copies per ml who have undergone IAC
- When should we monitor for co-morbidities (TB, Hep B&C, CVD and OIs?

Where? The Centralized Laboratory option

Centralized laboratory testing especially for high caliber assays like molecular diagnostics and others, will always be needed, since some tests cannot be done at point of care efficiently and cost effectively.

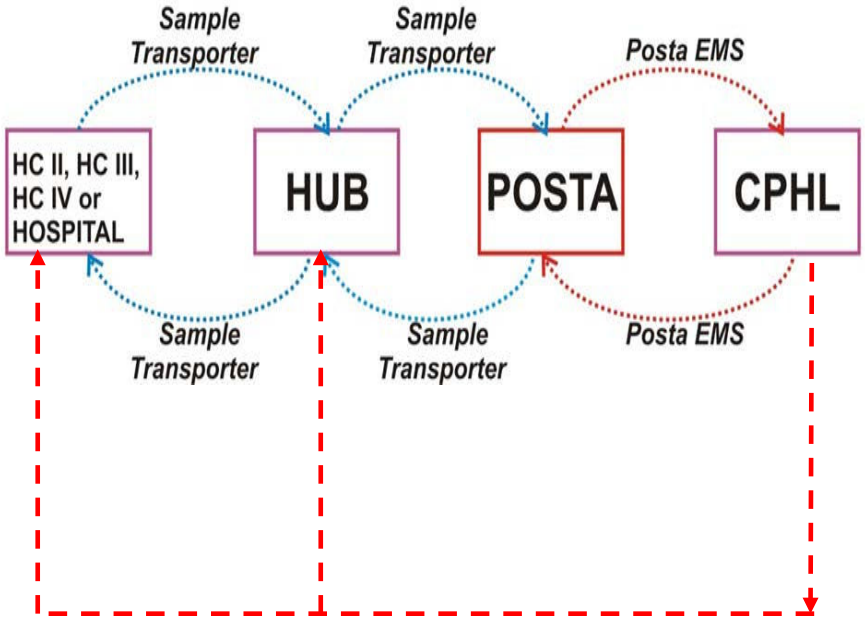
Lots of capacity for VL centralized testing has been built in many countries, but they need to be optimized and complemented with an efficient sample transport network with a wide coverage.

Besides VL centralized testing can support EID, Hepatitis B&C, etc, since the sample equipment would be used.

Other tests like HIVDR may need a super centralized system, while other like TB Gene Expert, CBC, Chemistry etc. may need semi centralized systems through building hubs with a complimentary sample transport system.

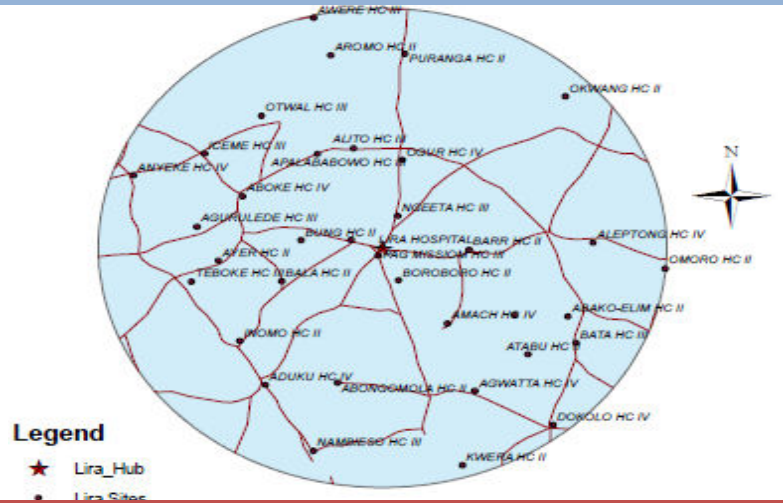
Where ? A Functional Sample Transport System is what can make Centralized Testing Possible.

The Uganda sample transport model, has made their one VL/EID laboratory accessible Countrywide. Could this go up to the community to meet the DSDM?

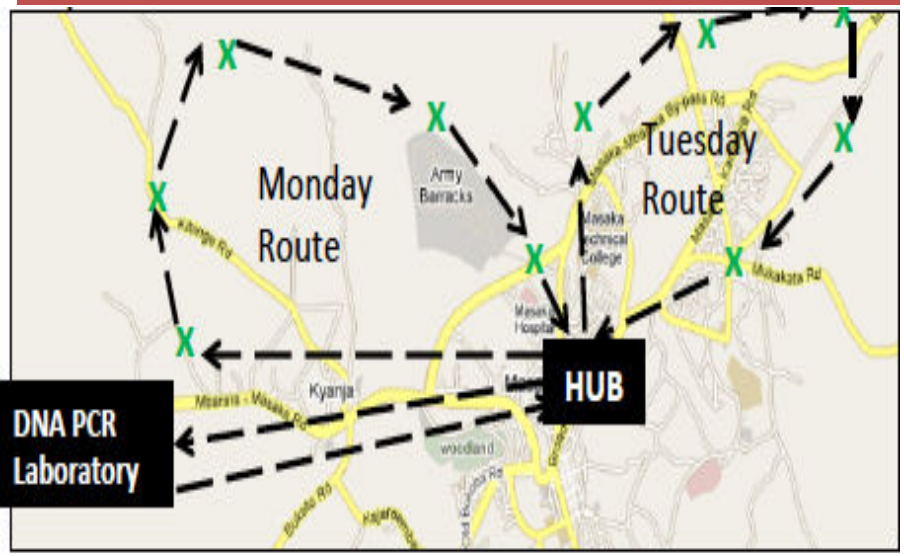


Where? The Hub and Spoke Network has been the backbone of CD4 and OI testing. Community?

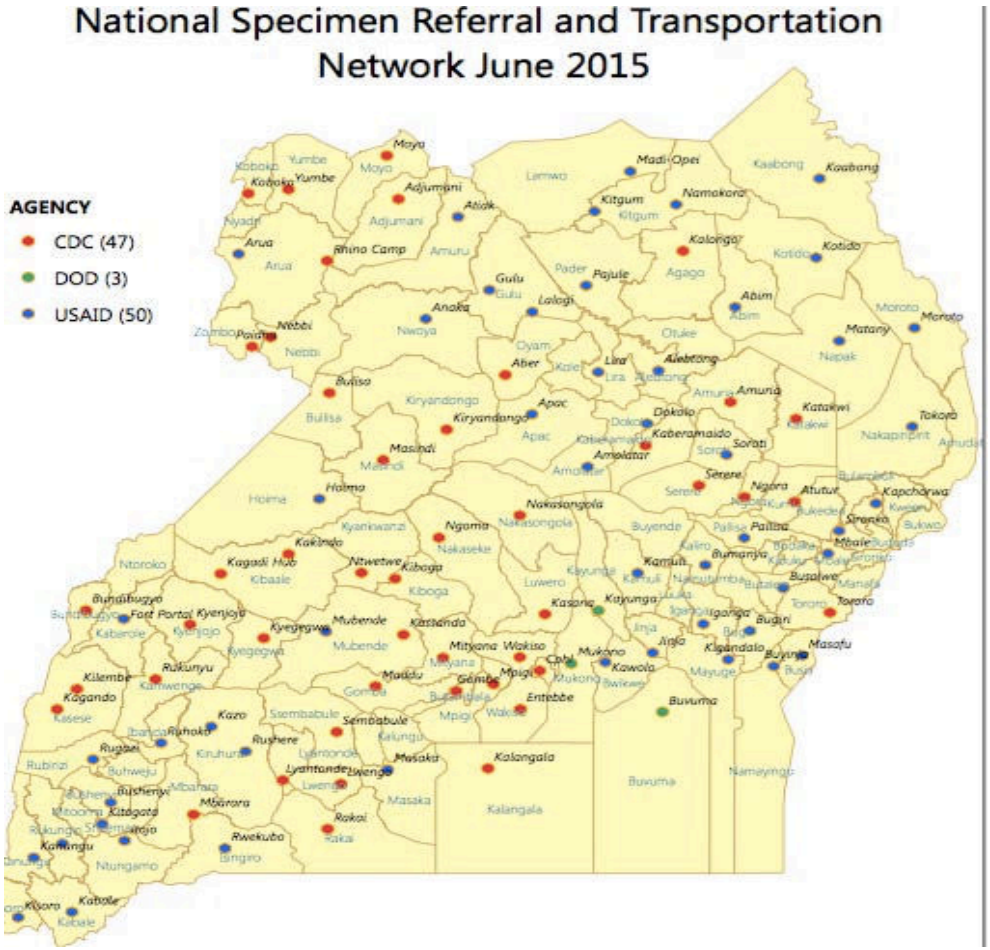
Structure of the hub network



Bike Routing



Map showing current Hub Distribution



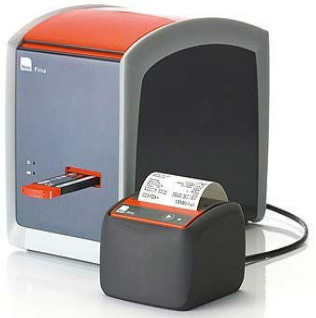
- Total 100 hubs each covering 30 HFs with a national of coverage over 90%

Where? The point of care option

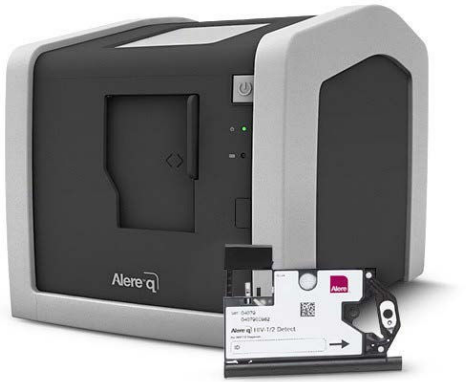
- Point of care option would a game changer only if the POC technology is very simplified and able to give results in a short time.
- However available POCs for VL and EID are relatively robust and will only give you results between 1.5 to 2 hours.
- They are not purely POCs but near POC.
- They can be used in low volume settings in hard to reach areas to complementing centralized testing
- However, before they are scaled out widely, one needs to thing about the following; data mgt, QA, service and maintenance, logistics mgt, waste mgt, HR needs, and cost per test

POCT for VL, EID and CD4 are robust for community use

- These are some of the available POCTs for VL, EID, CD4 and TB?
- Their performance against convectional technologies is good through the evaluations done
- However, non of these is a pure POC, they near PO they need some level o infrastructure
- More POCTs are still needed for other conditions



PIMA for CD4



SAMBA II

Who?

- All conventional technologies will need lab technicians
- POCTs if simplified should be ran by non lab based personnel.
- However, quality issues become more pronounced
- These present POC for VL, EID, TB and CD4 practically need lab based personnel

Considerations for Lab in DCD

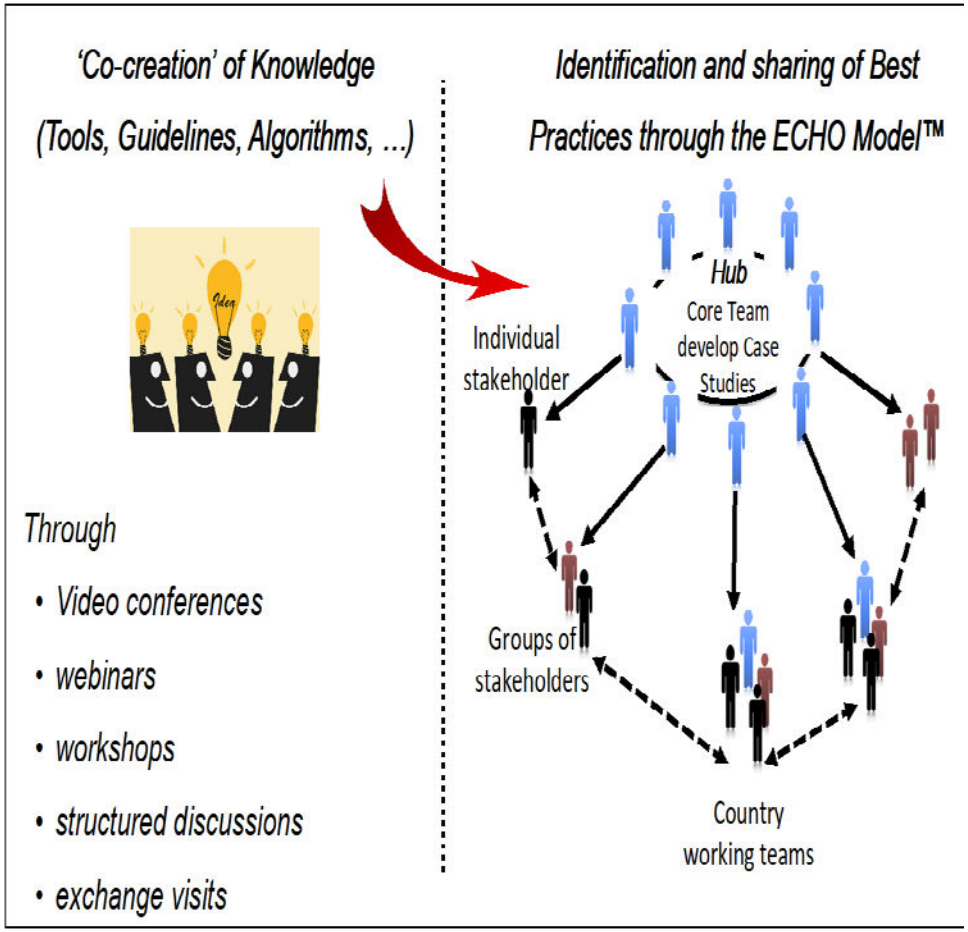
- Training of HR
- increased supervision
- Reagent procurement down to community level
- Ensuring quality of testing at community level
- Ensuring test results are quickly utilized (lab-clinic interface further strengthened
- Implementation research to define where a test can best be delivered

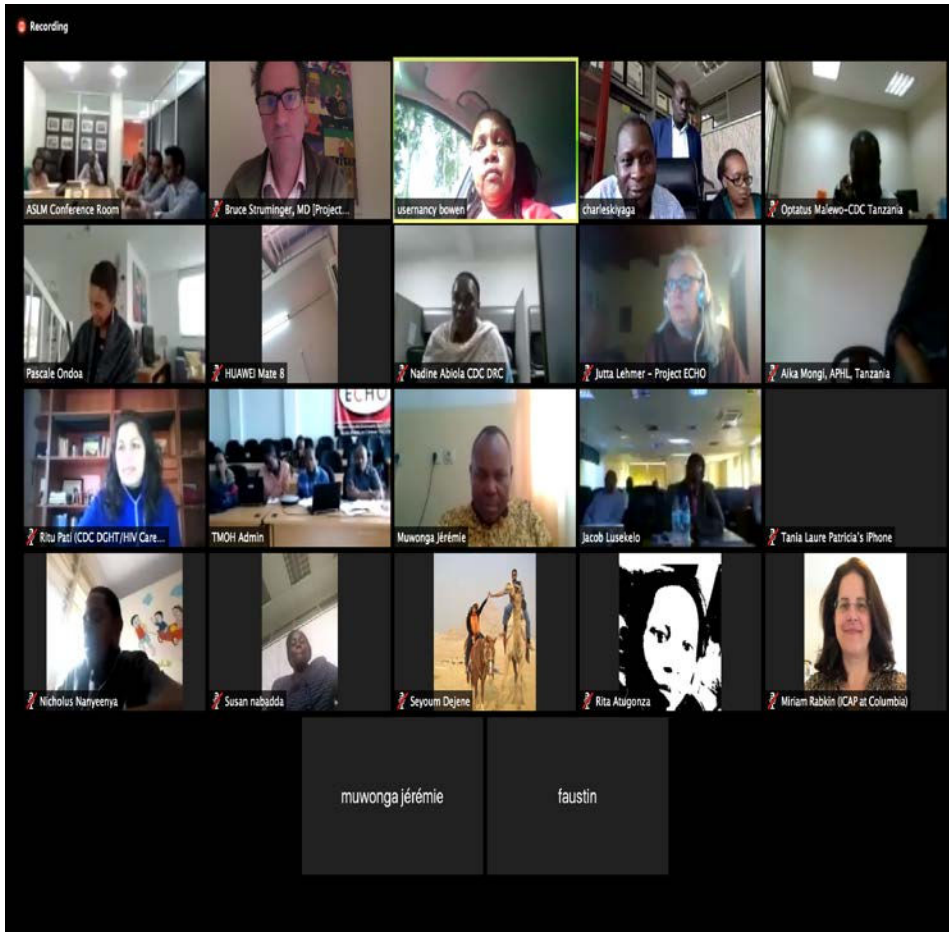
Considerations for Lab in DCD Cont.

- Regulation around new technologies
- What are responsibilities of stakeholders? MoH, WHO, ASLM? Implementing partners?
- Final question: how far can HIV care continue to differentiate and remain cost effective in terms of lab testing?

Laboratory Strengthening Community of Practice (LabCoP) Projectc

The LabCoP project could support the DSDM through identifying and sharing community based laboratory practices, with proven performance that may be employed in the DSDM





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Thank you for listening