Use of point-of-care viral load among critical populations

IDC
September 2019
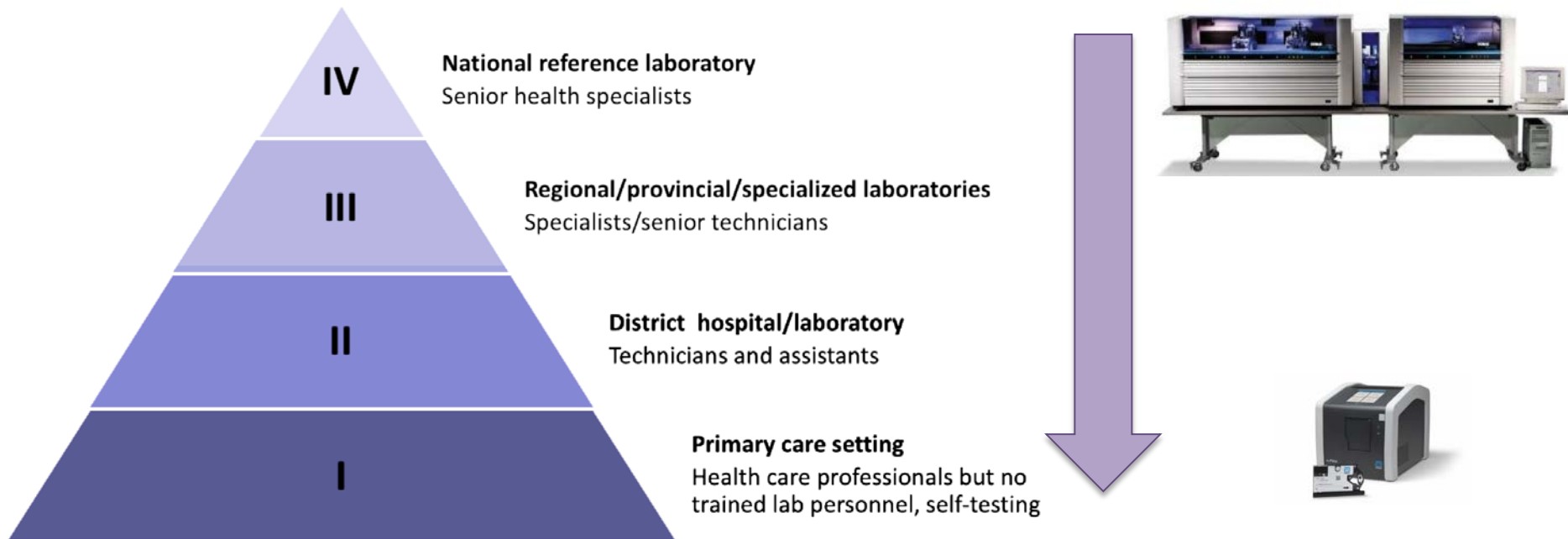
World Health Organization

Diagnostics structure

HIV TREATMENT

HIV and hepatitis laboratory structures have typically been very centralized: molecular and immunological assays requiring significant infrastructure.
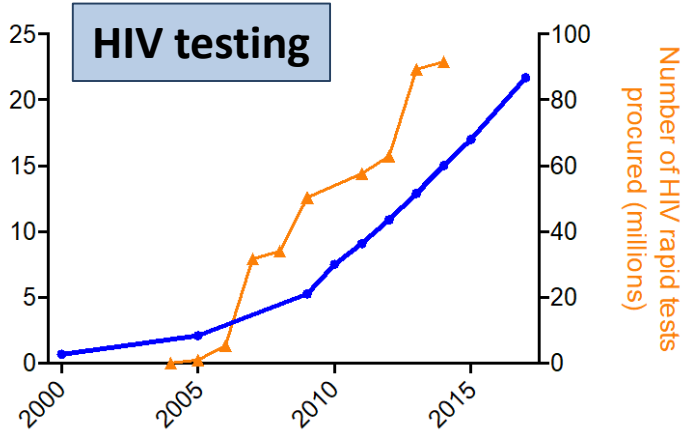

IV National reference laboratory
Senior health specialists

III Regional/provincial/specialized laboratories
Specialists/senior technicians

II District hospital/laboratory
Technicians and assistants

I Primary care setting
Health care professionals but no trained lab personnel, self-testing

High quality, robust new technologies are allowing for greater decentralization and testing closer to the patient.

World Health Organization
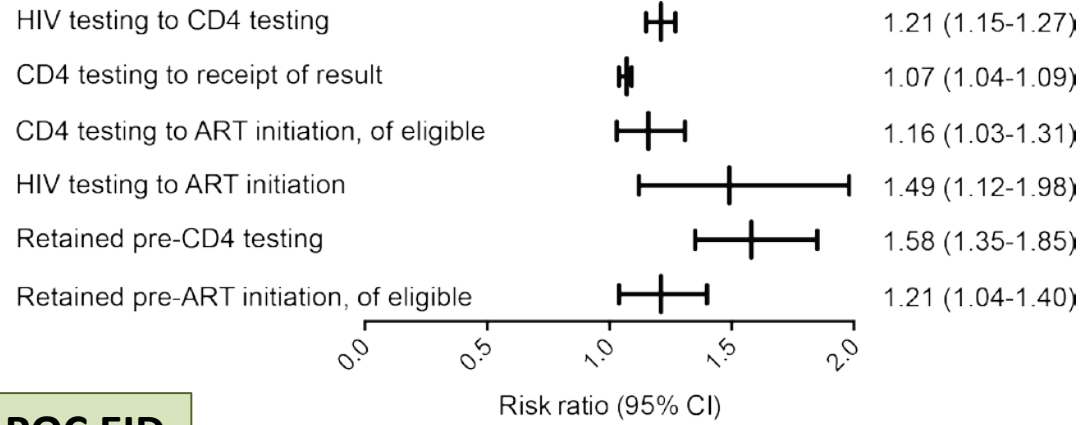
Impact of POC testing – on identification and treatment initiation

HIV TREATMENT

HIV testing

POC CD4 for treatment initiation

	Risk ratio (95% CI)
HIV testing to CD4 testing	1.21 (1.15-1.27)
CD4 testing to receipt of result	1.07 (1.04-1.09)
CD4 testing to ART initiation, of eligible	1.16 (1.03-1.31)
HIV testing to ART initiation	1.49 (1.12-1.98)
Retained pre-CD4 testing	1.58 (1.35-1.85)
Retained pre-ART initiation, of eligible	1.21 (1.04-1.40)

POC EID

Country	Setting	Device/ Sample	# of sites	n	% result return to caregiver		TAT result return	% ART initiation		TAT ART Initiation
					≤ 30# days	Same day		≤ 60 days	Same day	
Mozambique (Maputo, Sofala)	cRCT	AlereQ, WB	SOC - 8	1876	0.32%	0%	125	12.8%	NA	127
			POC - 8	2034	98.7%	98.2%	0	89.7%		0
Malawi	Observa-tional pre/post	AlereQ, WB	7 pre	963	18.1%	0%	56	41.9%	43.8%	38
			7 post	789	100%	99.5%	0	91.1%	70.7%	0

Near point-of-care viral load technologies

Assay	Evaluator	Sample type	Sample size	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]
Abbott™ m-PIMA HIV-1/2 VL[b]	WHO prequalification/ United States Centers for Disease Control and Prevention	Plasma	421	95.1% (91.7–97.5%) *(23)*	99.4% (96.8–99.9%) *(23)*
Cepheid Xpert® HIV-1 Viral Load	WHO prequalification/ United States Centers for Disease Control and Prevention	Plasma	439	94.14% (90.37–96.76%) *(29)*	98.50% (95.68–99.69%) *(29)*
	Meta-analysis	Plasma	3790	96.47% (95.10–97.47%) *(72)*	96.59% (92.90–98.39%) *(72)*

[a] Sensitivity and specificity using a treatment failure threshold of 1000 copies/mL.
[b] No meta-analysis has yet been prepared because of a lack of published independent technical evaluations.

**For consideration in 2020 Consolidated Guidelines revision**

World Health Organization

POC VL in general population

Results – Primary Study Outcomes

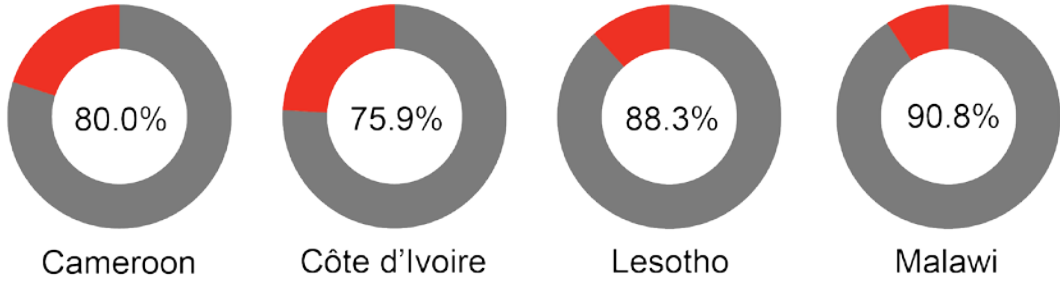|	Intervention Arm	Standard-of-care Arm	Absolute Risk Difference	Non-inferiority (1-side 95% CI) P value
Viral suppression (<200 copies/mL) **and Retention in care at study clinic**	89.7% (175/195)	75.9% (148/195)	**13.9%**	(≥7.6) <0.001

After 12 months of clinical follow-up, the intervention increased viral suppression and retention in care at the study clinic by 13.9% (95% CI 6.4 - 21.2)
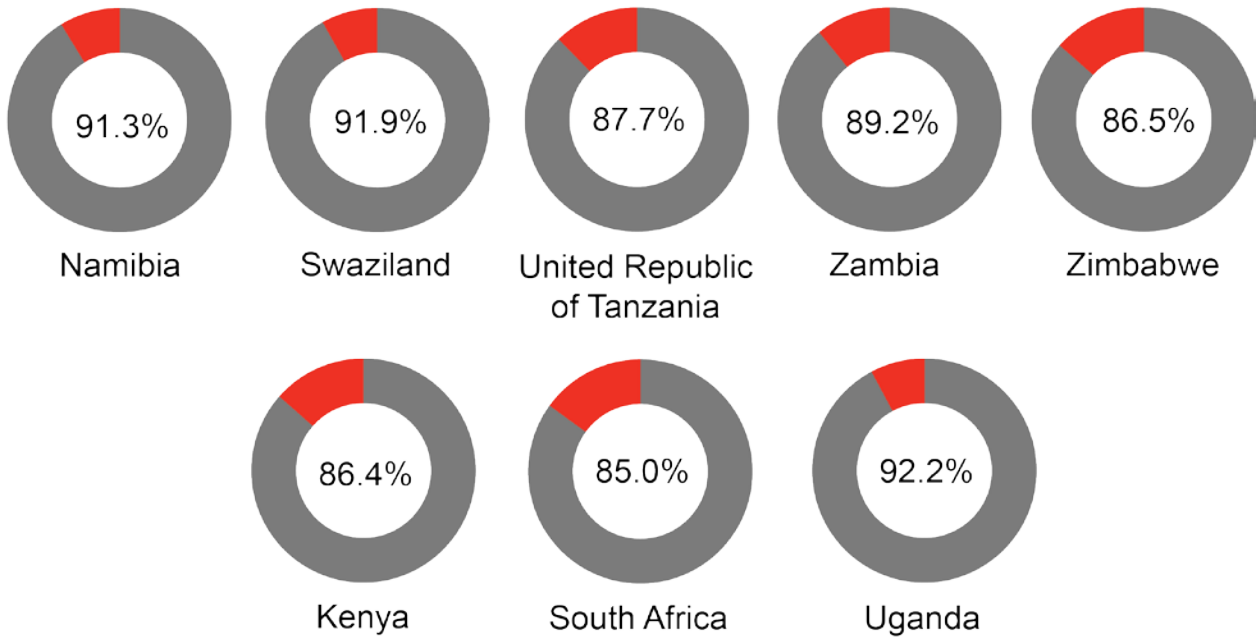
Results – Follow-up HIV Care & Treatment

Drain P *et al*. CROI 2019
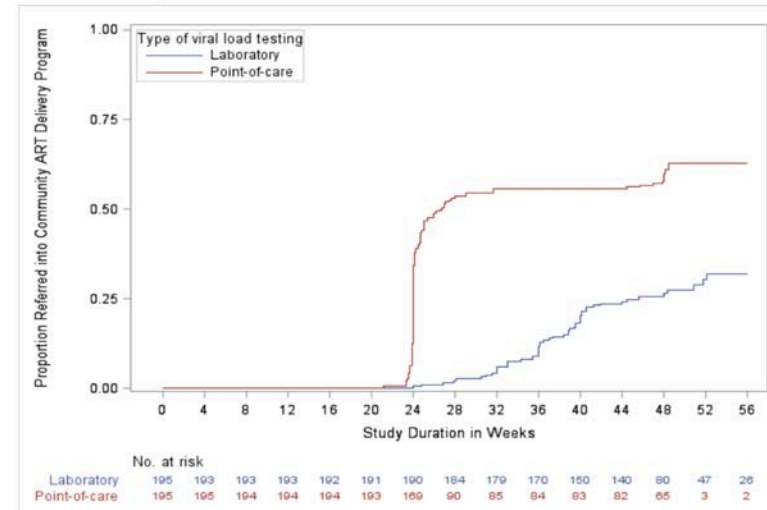
High viral suppression rates across countries

HIV TREATMENT

Suppressed
Non-suppressed

80.0% Cameroon
75.9% Côte d'Ivoire
88.3% Lesotho
90.8% Malawi

Population based HIV impact assessments, 2015-2017

91.3% Namibia
91.9% Swaziland
87.7% United Republic of Tanzania
89.2% Zambia
86.5% Zimbabwe

86.4% Kenya
85.0% South Africa
92.2% Uganda

National viral load dashboards: 2017

Key questions:

1) How might this change with DTG?

2) How do we best manage those unsuppressed to reduce transmission and improve patient health?
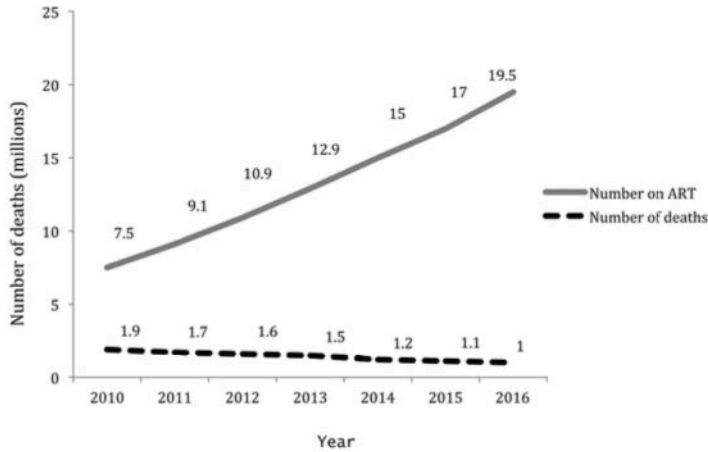
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What is the impact of POC VL?

There is currently no WHO recommendation to use point-of-care or near point-of-care technologies for treatment monitoring; however, impact studies and implementation considerations are ongoing.
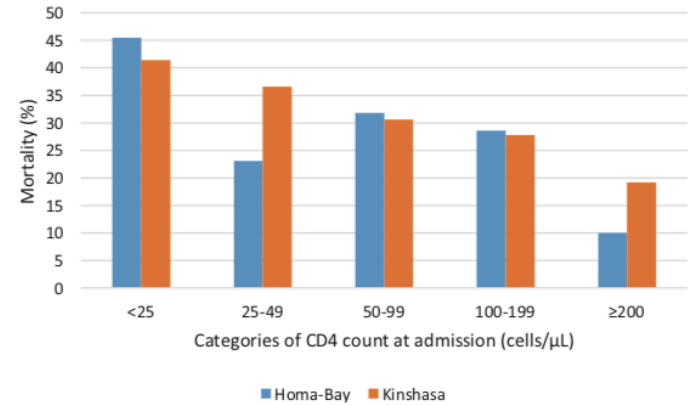

Pregnant women

Infants and children

POC VL

Advanced disease

Re-entering care

Suspected failing

World Health Organization
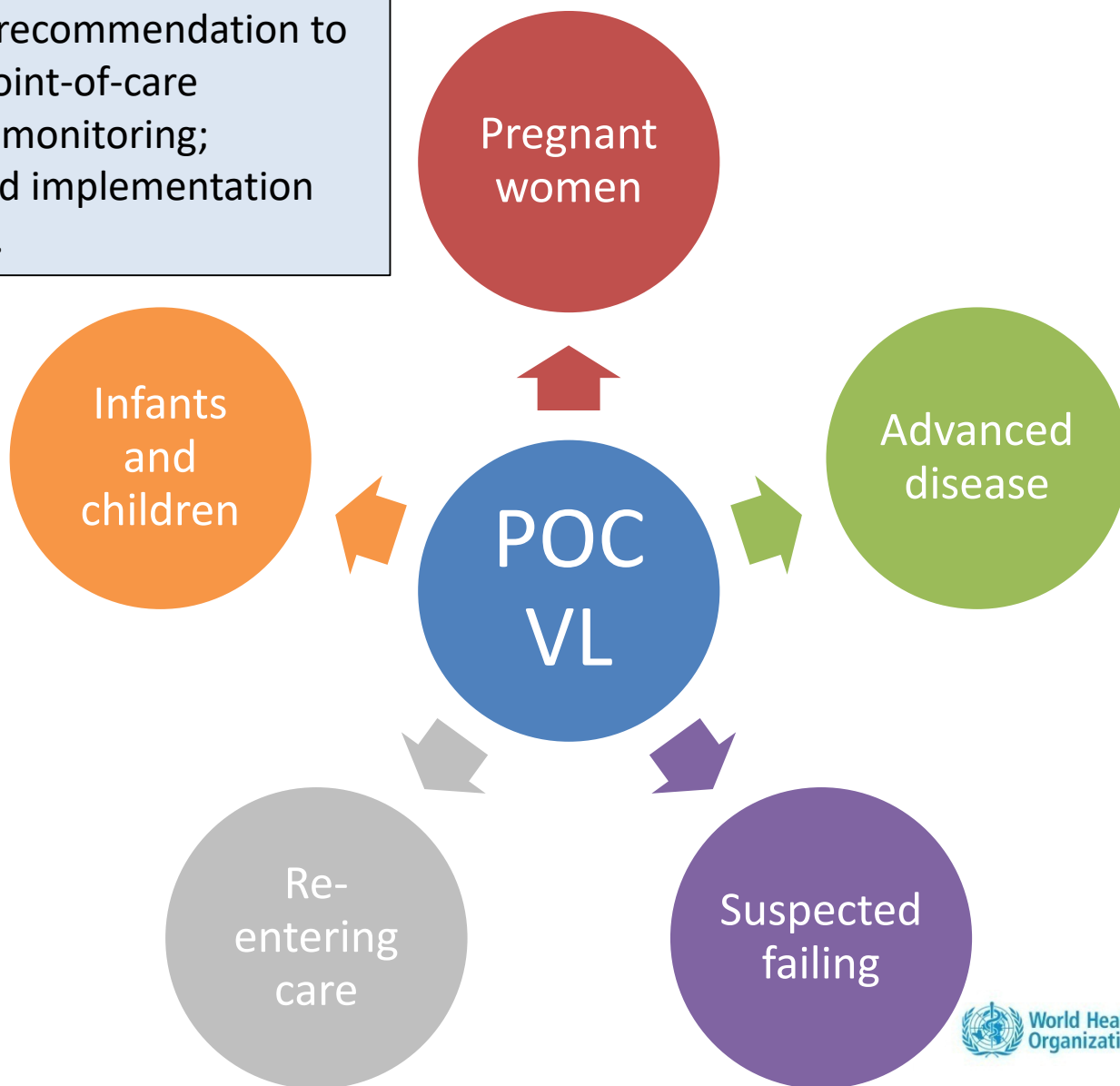
Advanced disease:
a persistent problem

Figure 1. Number of patients receiving ART and number of deaths. Abbreviation: ART, antiretroviral therapy.

Calmy CID 2018

Figure 1. Mortality among patients diagnosed with tuberculosis, stratified by CD4 cell count at admission, Homa-Bay, Kenya (n = 80) and Kinshasa, Democratic Republic of Congo (n = 248).

Ousley CID 2018

Clinical Infectious Diseases

Advanced HIV Disease
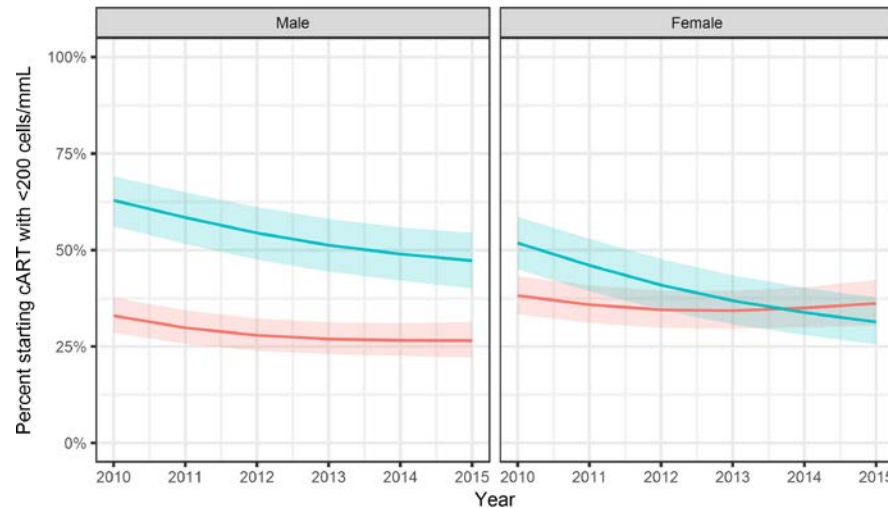
Volume 66, Issue suppl_2
1 April 2018

IeDEA cohort 2018

Questions?