

# Lay testing cadres and point-of-care diagnostic tests: An essential combination in health service delivery

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POLICY FORUM

# Lay testing cadres and point-of-care diagnostic tests for HIV and other diseases: An essential combination in health service delivery

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# Outline

- General availability of POC diagnostics in primary health care facilities (PHC) in LMIC
- General status for task shifting for POC diagnostics
- Scaling up task shifting for POC diagnostics at PHCs to lay health workers (LHW)

# Importance of diagnostics at PHC facilities

- Primary Health Care (PHC) facilities represent a **major entry point into healthcare systems** and close to people's homes.
- POC testing can be the **only viable route when centralized testing is hours away**.
- Lack of access to testing plays a major role in the **under diagnosis** of diseases.

PLOS GLOBAL PUBLIC HEALTH Published: May 2, 2022

## RESEARCH ARTICLE

### Most common reasons for primary care visits in low- and middle-income countries: A systematic review

Jacob Bigio<sup>1,2</sup>, Emily MacLean<sup>2,3</sup>, Nathaly Aguilera Vasquez<sup>1,2</sup>, Lavanya Huria<sup>3</sup>, Mikashmi Kohli<sup>2,3</sup>, Genevieve Gore<sup>4</sup>, Emma Hannay<sup>5</sup>, Madhukar Pai<sup>2,3,6\*</sup>, Pierrick Adam<sup>7</sup>

Table 3. Top nine reasons for encounter and top 10 provider diagnoses in adults coded with ICPC-2, based on four studies.

Reasons for encounter	Rank score	Provider diagnoses*	Rank score
Headache (N01)	29	Hypertension, uncomplicated (K86)	37
Fever (A03)	27	Upper respiratory tract infection (R74)	23
Back symptom/low back symptom (L02, L03)	22	Type 2 diabetes (T90)	18
Cough (R05)	20	Malaria (A73)	10
Pain general/multiple sites (A01)	16	Health maintenance/prevention (A98)	10
Abdominal pain/cramps general (D01)	13	Allergic rhinitis (R97)	9
Vertigo/Dizziness (N17)	11	Pregnancy (W78)	9
Heart burn (D03)	9	HIV/AIDS (B90)	8
Leg/thigh symptom/complaint (L14)	8	Visual disturbance other (F05)	8
		Acute bronchitis/bronchiolitis (R78)	7
		Gastroenteritis/diarrhoea (D73, D11)	7
		Peptic ulcer (D86)	7

# General diagnostic availability in PHC facilities

## Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys

*Lancet Glob Health* 2021;  
9: e1553-60

Harika Yadav, Devanshi Shah, Shahin Sayed, Susan Horton, Lee F Schroeder

- At PHC HIV, malaria, urine glucose & protein, syphilis, urine pregnancy, microscopy, haemoglobin, glucometer, ultrasound.
- Median availability of diagnostics at **PHC** in 10 countries (*Mal, Kenya, Bangladesh, Rwanda, Uganda, Tanz, Senegal, Haiti, Namibia & Nepal*) was **19.1%** [6.4-36.7]
- Availability increased at higher tiers: **advanced PHC 49.2%** and **hospitals 68.4%**.

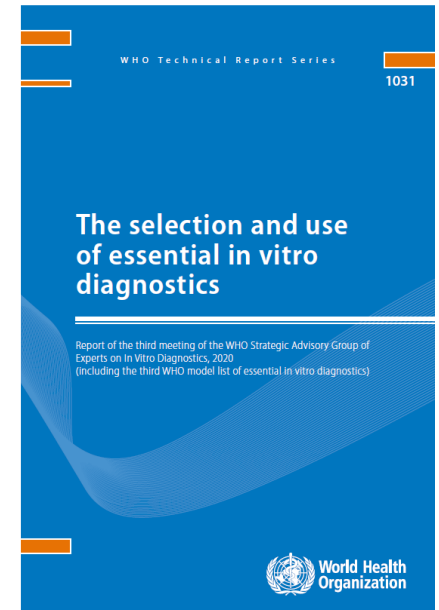
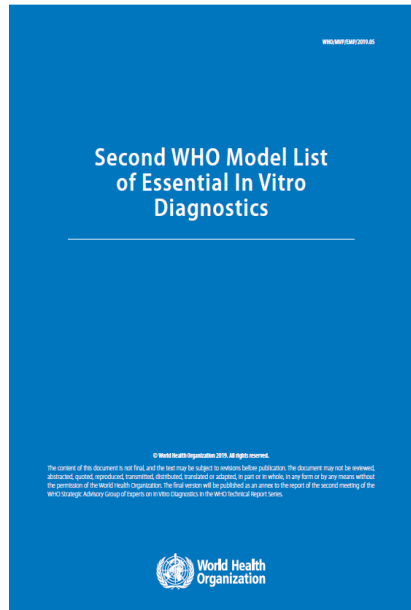
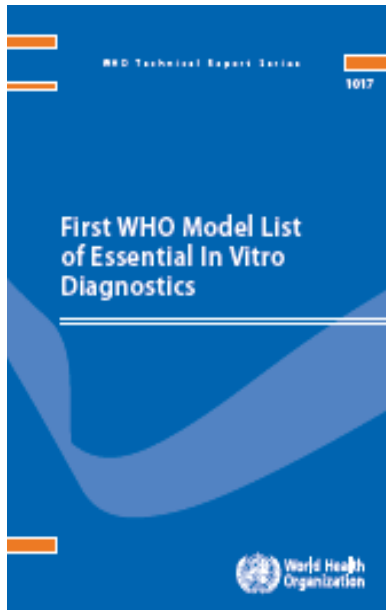
## The Lancet Commission on diagnostics: transforming access to diagnostics

*Lancet* 2021; 398: 1997-2050

Kenneth A Fleming, Susan Horton, Michael L Wilson, Rifat Atun, Kristen DeStigter, John Flanigan, Shahin Sayed, Pierrick Adam, Bertha Aguilar, Savvas Andronikou, Catharina Boehme, William Cherniak, Annie NY Cheung, Bernice Dahn, Lluís Donoso-Bach, Tania Douglas, Patricia Garcia, Sarwat Hussain, Hari S Jyer, Mikashmi Kohli, Alain B Labrique, Lai-Meng Looi, John G Meara, John Nkengasong, Madhukar Pai, Kara-Lee Pool, Kaushik Ramaiya, Lee Schroeder, Devanshi Shah, Richard Sullivan, Bien-Soo Tan, Kamini Walia

- 47% of the global population has little to no access to diagnostics
- Gap is severe at **PHC with about 19%** of LMIC with access to diagnostics (*expect for HIV, malaria*)

# WHO Essential Diagnostic List (EDL)



Nigeria is the first African nation to develop National EDL (NEDL)

# Availability ≠ Accessibility for the population in PHC

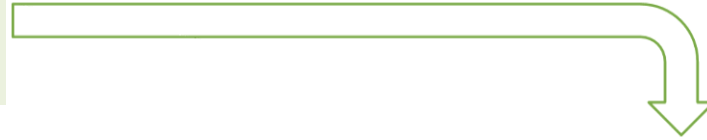
- Mere availability of POC tests in health facilities **does not ensure utilization.**
- Prohibitive **user fees** for basic POC tests
- Conducting POC tests has been shown to be a **burden on highly trained frontline** healthcare workers
- Most PHCs have **no laboratory trained staff**
- The continual emergence of easy-to-use POC tests **has not been accompanied by investment in a cadre of health workers** to support their delivery, especially at decentralized health facilities where patients initially seek healthcare support.

# Task shifting for POC diagnostics

## WHO 2016

### Good practice statement (new)

Trained and supervised non-laboratory staff including lay people, can undertake blood finger-prick for sample collection



## WHO 2019

 PLOS ONE

Published: May 2, 2019

### RESEARCH ARTICLE

Performance of non-laboratory staff for diagnostic testing and specimen collection in HIV programs: A systematic review and meta-analysis

Lara Vojnov<sup>1\*</sup>, Miriam Taegtmeier<sup>2</sup>, Caroline Boeke<sup>1</sup>, Jessica Markby<sup>1</sup>, Lindsay Harris<sup>1</sup>, Meg Doherty<sup>3</sup>, Trevor Peter<sup>1</sup>, Nathan Ford<sup>3</sup>

<sup>1</sup> Clinton Health Access Initiative, Boston, Massachusetts, United States of America, <sup>2</sup> Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, United Kingdom, <sup>3</sup> World Health Organization, Geneva, Switzerland

### WHO recommendation (new)

Lay providers who are trained and supervised to use rapid diagnostic tests can independently conduct safe and effective HIV testing services (*Strong recommendation, moderate quality of evidence*)



## WHO 2021

### WHO recommendation

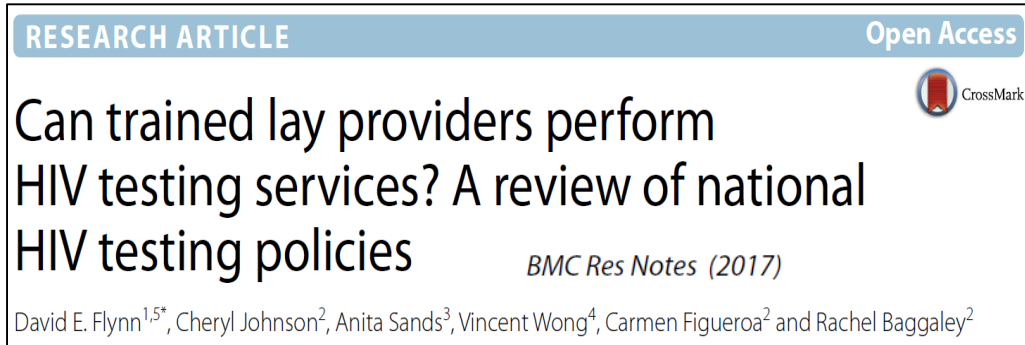
Task sharing of specimen collection and point-of-care testing with non laboratory personnel should be implemented when professional staffing capacity is limited (*Strong recommendation, moderate quality of evidence*)



# Challenges for task shifting for POC diagnostics

➤ Implementation of task shifting has proven difficult in practise:

## 1. Lack of explicit national policy or strategic plans



- *Surveyed National policies for HIV testing services across 50 countries*
- *only 42% allowed LHWs to perform testing using POC tests*
- *64% in African countries*

## 2. Lack of integration of task shifting into national human resource structures and fiscal plans

# Challenges for task shifting for POC diagnostics

3. Support for lay testers and their integration into health systems within countries has been uneven and sometimes driven by NGOs
4. Legal structures, which enforce strict professional boundaries limit extension of the task shifting scope
5. The perceived need for the protection of professional turf by other health cadres, especially laboratory technicians and/or their professional or regulatory bodies not willing to endorse tasked-shifted POC/near POC testing, as seen in some settings

However, there's some progress seen in some countries:  
Malawi (H.D.A), Zim, Kenya, Uganda

# Implementation framework for lay testing for POC diagnostics

National health programs **presently have different lay health worker (LHWs)**

**Review roles & responsibilities** between the various existing LHW

Accredited lay tester **training and supervision**

# List of potential lay testers, the POC tests they could conduct and other activities

Lay testing cadres	POC tests that can be task shifted	Other tasks for lay cadres
Already existing lay cadre or paraprofessional roles in programs	Test/activity	
<ul style="list-style-type: none"> <li>-HTS counselors</li> <li>-Health diagnostic assistants (HDAs)</li> <li>-Lay counselors</li> <li>-Microscopists</li> <li>-Laboratory assistants</li> <li>-Health facility navigators</li> <li>-Phlebotomists</li> <li>-Community health care workers (CHW)</li> <li>-Nurse assistants</li> <li>-All together new cadre</li> </ul>	<p>HIV RDT, CD4 cell enumeration, Visitect CD4 LFA, Cryptococcal antigen (CrAg), lipoarabinomann antigen test (urine TB LAM), Syphilis RDT, pregnancy test, haemoglobin A1c (HBA1c) meters, urinalysis test strips, glucometers, SARS-CoV-2 RDTs, <i>Vibrio Cholerae</i> antigen test, hepatitis B and C RDTs, malaria RDTs, haemoglobinometer, POC nucleic acid tests (NAT) for HIV VL, EID and MTB/Rif.</p> <hr/> <p><u>Sample collections:</u> Dry blood spot (DBS) for HIV viral load (VL) and early infant diagnosis (EID) of HIV, urine, sputum, nasopharyngeal, finger-prick and venous blood.</p>	<p>Navigate priority results, quality control (QC) for all POCT, referrals of samples to higher tier laboratories (hubs) and follow-up on results, stock management of test devices and ancillary reagents</p>

# Key enablers in implementation of lay testing for POC diagnostics

- **Regulatory bodies (*medical and laboratory councils*) hold the crucial position** of potentially guiding:
  - National policy on which POC tests can be task shifted.
  - The development of a framework for user training with certification, and ongoing supervision.
  - Regulatory bodies also have the influence to quell any resistance to task shifting from their members.
- **National program managers and policy makers:**
  - This should be part of broader national health workforce/policy.
- **Others:**
  - Availability of POC tests at PHC as recommended in WHO EDL/NEDL
  - POC test results to be used for patient management

# Maintaining quality POC testing services and sustainability

Indicators of monitoring an acceptable level of quality of testing must be developed,

and these can include daily/weekly internal controls, routine blinded EQC, and ongoing supportive supervision from hub

Long-term sustainability of this framework could be assured

because there are possibly existing LHWs whose scope could be broadened/remodeled

The tasks of lay testers may evolve over time

in parallel with changes in the diagnostic pipeline or disease outbreaks and other health system requirements.

# Conclusion

- **Lay testing cadres** should become a **critical part of a strengthened health system** able to support decentralization of POC testing to the last mile
- **Improved engagements** between key stakeholders is crucial (*Medical laboratory councils or regulatory authorities, policy makers*)
- For real progress for **availability and accessibility of POC tests** in PHCs; we need to attain 'AAA':
  - **Adopt** (*task shifting, WHO EDL*),
  - **Adapt** (*NEDL, task shifting into national policies*),
  - implement and be **Adept**.