Access to NTD diagnostics and WHO response

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Challenges with NTD diagnostics

Diagnostics will play a critical role in achieving NTD road map targets

Access challenges:

- Market for NTD diagnostics unattractive to manufacturers
- Limited availability of high sensitivity and specificity tests
- Quality of many NTD diagnostics uncertain
- Some NTD diagnostics have been discontinued
- Scarce public investments in NTD diagnostics
- Absence of coordinated global need estimates and procurement mechanisms





[1] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. 2017. Available at: https://eur-lex.europa.eu/eli/reg/2017/746

Landscape analysis of NTD diagnostics



Number and type of diagnostics available for NTDs.





- Of 125 diagnostics tools commercially available for NTDs included in the analysis, RDT accounts for 33%, EIA accounts for 34%, and PCR accounts for 10%.
- Demand less than 1 million units per year for each disease (except lymphatic filariasis and dengue)



WHO Diagnostics Procurement Management Process



WHO procures diagnostics for-

- Lymphatic filariasis
- Visceral leishmaniasis (for high-burden countries in Eastern Africa only)
- Human African trypanosomiasis (HAT, sleeping sickness)
- Yaws
- Chagas disease



Update on Lymphatic filariasis (LF) diagnostics (1)

Progress

- Since 2016, >5 million Filariasis Test Strips procured by WHO alone for 48 countries
- Global demand has been met through consortium (MSD-Eisai-GSK-BMGF) funds, USAID and countries
- Coordination of efforts: monthly calls with manufacturer and procuring partners to generate and update forecasts, prioritize allocation of orders

Challenges - Risks

- Potential supply gap of FTS
- lot-to-lot variability in Brugia RDT

Opportunities

- Validation in lab and field of new RDTs (LF Ag; Brugia Ab)
- WHO ERPD completed



Filariasis Test Strip Procurement (2)





Global procurement of Filariasis Diagnostic Tests (3)





Update on Visceral Leishmaniasis (VL) diagnostics (1)

Global forecast

- Leishmaniasis procurement steering committee meets quarterly
- Global annual forecast compiled and shared with manufacturers

Process

- WHO negotiates price and signs a longterm agreement (LTA) to include in WHO catalogue.
- All orders processed through WHO procurement unit in Kuala Lumpur

Health Products	Manufacturer	Method of Procurement
Rk39	Mologics, UK & Inbios, USA	LTA – Negotiated Price
DAT	AMC Medical Research, Netherlands Institute of Tropical Medicines, Antwerp, Belgium	RPE

ERPD

• ERPD concluded

Lab evaluations in process coordinated by WHO TDR in Kenya and Ethiopia



VL diagnostics procurement forecast (2)





Note: Procurement data from 2022 reflects the forecast for Q3 and Q4 only.





Way forward..

- Collaborative efforts towards advocacy and resource mobilization to secure access to NTD diagnostics?
- Forecasting of NTD diagnostics to be coordinated by WHO?



