

# Global Program for Onchocerciasis Elimination

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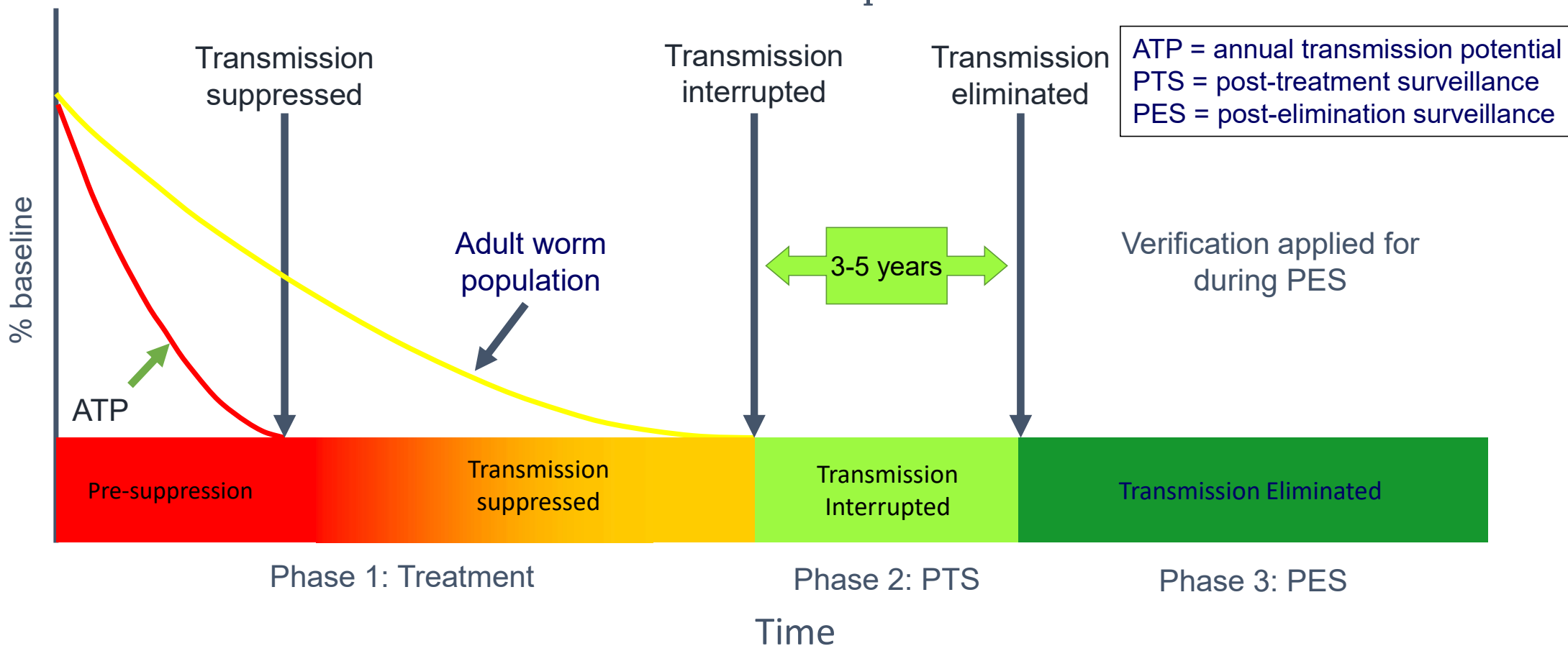
# Diagnostics: current gaps and research priorities

Second OAE meeting  
Universiteit Antwerpen  
Campus drie Eiken



# 1. Introduction-Onchocerciasis elimination phases

## Onchocerciasis Elimination phases



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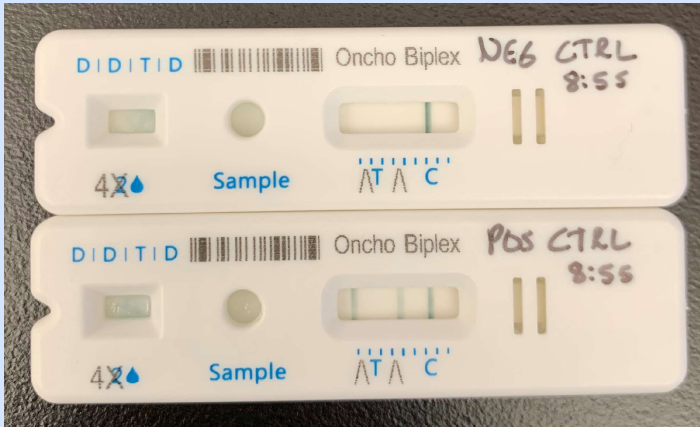
# Diagnostics

- Key point: relatively small investments have led to rapid progress on several new diagnostics
  - RDTs
  - qPCR for blackflies
  - New ELISA



RDTs

# Onchocerciasis Lateral Flow Assays



**Overarching goal:** to standardize process for how new diagnostics are evaluated and compared

## Tests

- DDTD – biplex
- GADx – monoplex



## Lab evaluation

- CDC
- 4 versions of DDTD test evaluated
- 2 versions of GADx test evaluated

## RDT Comparisons - Field



Joint effort by CDC and NTD-SC



Overarching goal: to standardize process for how new diagnostics are evaluated and compared in the field



Specific aim: to assess feasibility, ease of use, and performance at point-of-use in the field



Data collection by NTD program teams and local research/implementing partners

## Oncho RDT evaluation status as of 9/18/2023

| Site        | Evaluation type                         | Start           | End*     | Sample size | Partners                                   |
|-------------|---|-----------------|----------|-------------|--|
| South Sudan | Feasibility + performance (field only)  | Ongoing (June)  | December | 700         | Univ. of Antwerp, Amref Health Africa, MoH |
| Benin       | Feasibility (field only)                | Ongoing (July)  | October  | 1,000       | CDC, Sightsavers, MoH, AFENET              |
| Tanzania    | Performance on DBS (lab only)           | September*      | October  | 900         | NIMR Tanga lab (MoH)                       |
| Mozambique  | Feasibility + performance (field only)  | Mid-November*   | March    | 400         | Sightsavers, MoH                           |
| Ghana       | Feasibility + performance (field & lab) | Late September* | February | 1,700       | NMIMR                                      |

\*Tentative



# Ov16 ELISA

## Development of a new **ELISA** based on protein (Ov16) expressed in **mammalian** expression system

### Changes to new assay:

- Pre-coat plates
- Include HumAb IgG4 standard curve
- Use TMB as substrate, which allows removing avidin-enzyme step
- ~ 2 hour run time, defined cutoff and development time



# Ov16 Assay Comparison

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|                       | Samples per plate | Plates per day* | Total samples per day | Total per week | Limitations  |
|-----------------------|-------------------|-----------------|-----------------------|----------------|--|
| CDC AP/OEPA ELISA     | 40**              | 2-3             | 80-120                | 320-480        | <ul style="list-style-type: none"> <li>• High variability</li> <li>• Lack of publicly available validation data</li> </ul>   |
| SD ELISA              | 40**              | 4               | 160                   | 640            | <ul style="list-style-type: none"> <li>• Low specificity</li> <li>• High cost</li> </ul>   |
| Ov16m ELISA (new CDC) | 40**              | 4               | 160                   | 640            | <ul style="list-style-type: none"> <li>• SOP requires internal approval at CDC</li> <li>• Will require DTAG review before full introduction to programs</li> </ul> |
| DBS on RDT            | 96                | 3               | 288                   | 1152           | <ul style="list-style-type: none"> <li>• Need confirmation from WHO that data are acceptable for stopping surveys</li> </ul>                                       |

Slide 11

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This actually should be 1 or 2 for the DBS on RDT

Elder, Eric (Scott) (CDC/DDPHSI, 2023-09-19T00:01:01.842

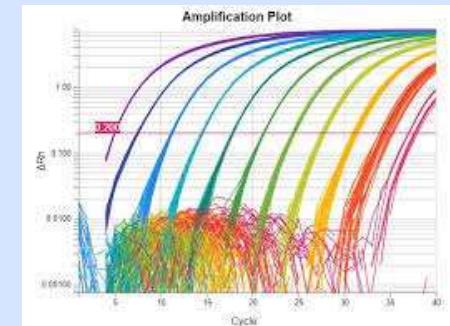
# Detection of *O. volvulus* by qPCR in blackflies



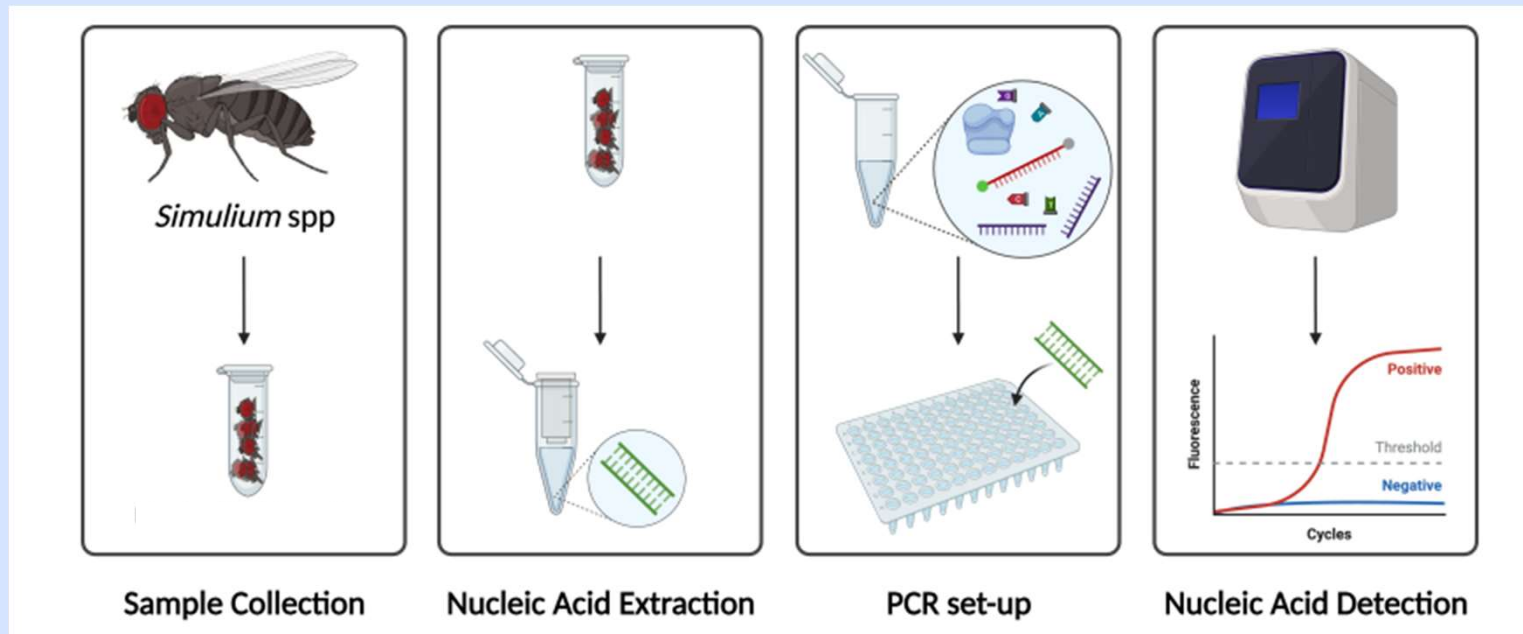
World Health  
Organization

# Oncho qPCR in blackflies

- ND5 qPCR assay has several other advantages over currently used O150 PCR-ELISA protocol
  - Improved sensitivity and specificity
  - Shorter time to results and fewer reagents
  - Easier to standardize QA/QC
  - Less prone to cross-contamination issues
  - Reagents can be shipped at ambient temperature
  - Commercially available positive control plasmids and internal extraction control



# Overview of new qPCR method for oncho detection in blackflies



**1. Blackfly Head separation.**

100 flies/pool

**2. DNA extraction**

**3. qPCR**

# Oncho qPCR in blackflies - current activities

- CDC conducted internal validation of new procedures
- Additional QA/QC measures are being added
  - Proficiency and training sample panels
  - Standardized SOPs and training plans
  - Cross-validation across different qPCR instruments/reagents
- Field evaluations/validations in endemic country labs





# Smith College Oncho qPCR Training – June 18<sup>th</sup> to 24<sup>th</sup>

- 16 representatives from the following countries:
  - Tanzania, Ghana, Benin, Malawi, Cameroon, WHO ESPEN, Mali
- Survey to assess training and participant experiences/perspectives of training and new assay compared to O150 PCR ELISA







# Oncho qPCR in blackflies – next steps, gaps/challenges

- Field evaluations in endemic country labs
  - Procurement of equipment and supplies
  - In-country trainings with partners
  - Tanzania and Ghana trainings ongoing
- Laboratory network and expansion of testing
  - qPCR kits and shipping distribution hub
  - Standardized QA/QC procedures and guidance
  - What is the best model for an Oncho qPCR lab network?
  - Map expected need for testing vs. laboratory capacity for testing and formulate model for network to address gaps

## qPCR implementation by country checklist

| Country      | Institution   | Funding/project           | Tissuelyser II  | In country Training Visit      |
|--------------|---|---------------------------|---|--------------------------------|
| Tanzania     | NIMR Tanga  | CDC-USAID stop MDA OR     | Will ship shortly   | August 7-11th                  |
| Ghana        | NPHRL   | CDC-USAID stop MDA OR     | Arrived in lab  | September                      |
| Ghana        | CSIR  | COR-NTD USAID stop MDA OR | Share with NPHRL  | September                      |
| Cameroon     | CRFiMT  | COR-NTD USAID OEM OR      | Arrived in lab  | TBD – running samples at Smith |
| Benin        | CREC  | CDC-USAID stop MDA OR     | Not USAID approved yet                                      | TBD                            |
| Benin        | IRCB  | CDC-USAID stop MDA OR     | n/a   | TBD                            |
| Malawi       | Malawi Univ. of Science & Technology / Vector Disease Control Lab | COR-NTD USAID stop MDA OR | Not USAID approved yet                                      | TBD                            |
| Burkina Faso | ESPEN lab   | End Fund                  | Funds available, ESPEN lab in process of arranging purchase | TBD                            |
| Mali         | Faculty of Medicine and Odontostomatology of Bamako               | End Fund                  | Not sure?   | virtual by Smith               |

# Oncho qPCR in Blackflies Timeline

Q2 2023

**CDC:** Conduct internal validation and submit to CDC review board

**CDC and Smith:**  
Create standardized SOPs and training materials

Q3 2023

**Smith College Training:**  
June/August

Q4 2023

**WHO:**  
OTS/DTAG meetings

Q1 2024

**OR partners:** Include onsite training and qPCR testing of collected samples from stop MDA OR (Ghana, Benin, Tanzania, Malawi); Further comparison to O150 PCR ELISA if OTS/DTAG recommends

Q2 2024

Identification of partner/s that could facilitate procurement and distribution of "qPCR kits". Plans for next steps for implementation