



# Misdiagnosis of HIV status Malawi Experience

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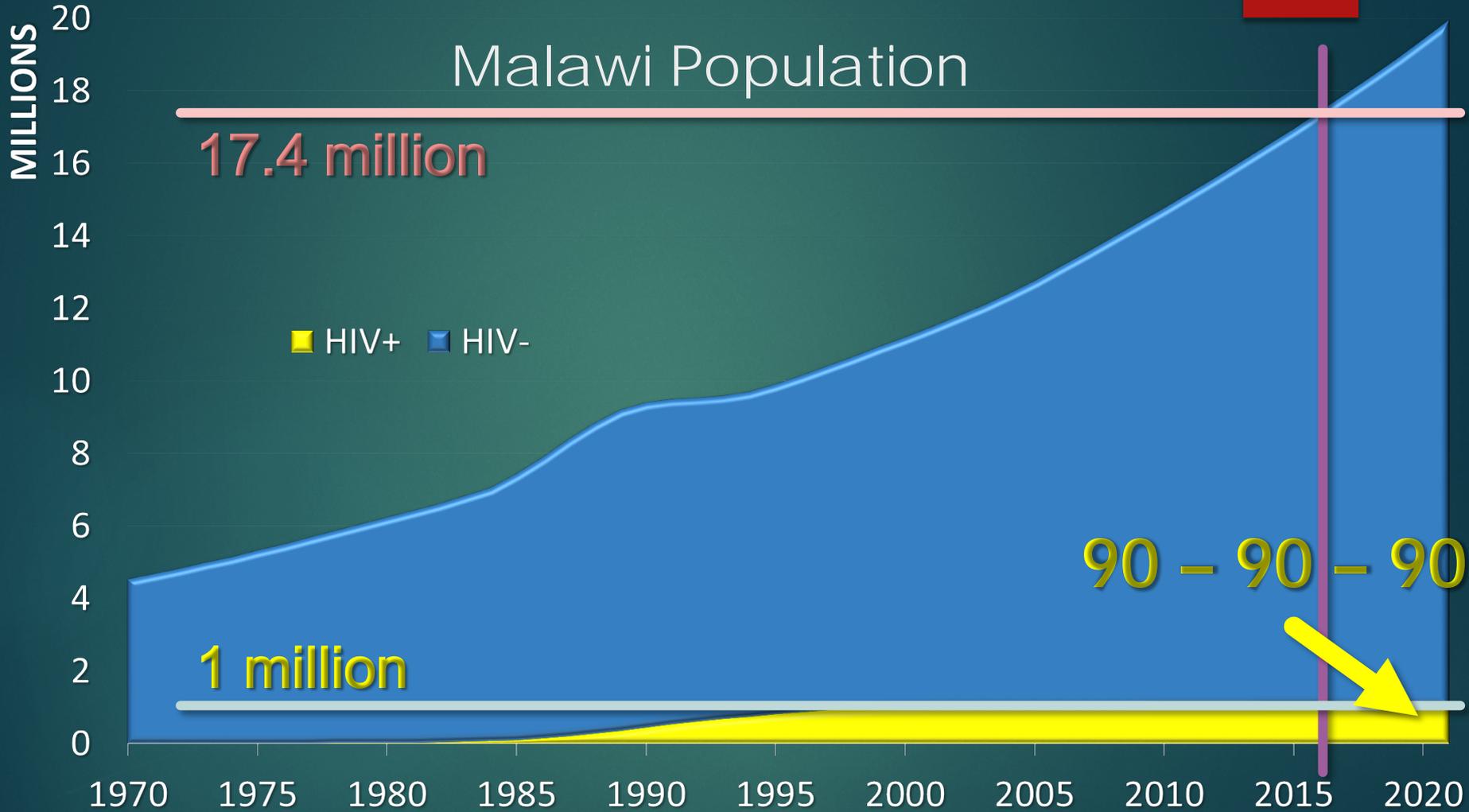
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# Outline



- ▶ Introduction
- ▶ Background
- ▶ Misdiagnosis Reports from the field
- ▶ Factors Contributing to Misdiagnosis
- ▶ Lessons Learnt
- ▶ Way Forward

# Malawi Population



# Background



- ▶ Massive increase in HIV rapid testing since 2004 when Malawi introduced free ART to clients
- ▶ 847 static sites and 188 outreach sites reported (Q4, 2015)
- ▶ To date, over 5,500,000 people tested since introduction of 1<sup>st</sup> time HTC access indicator in July 2007
- ▶ Over 5,000 testers have been trained (health workers, counselors, HSA, HDAs etc...)
- ▶ Task shifting to non health workers and HSAs

# Misdiagnosis Reports from the Field (2012 program evaluation)

Site	# Tested	# Positive Determine	# Positive UniGold (Concordance Test 1 & 2)	# Discordant	Negative Results Given To Discordant Clients	% Determine Positive given Negative Results
A	9,630	685 (7.1%)	680 (99.3%)	5 (0.7%)	3 (60.0%) Bioline	0.4%
B	4,902	857 (17.5%)	856 (99.9%)	1 (0.1%)	1 (100%)	0.1%
C	330	60 (18.2%)	60 (100%)	0	0	0
D	1,320	258 (19.5%)	250 (96.9%)	8 (3.1%)	6 (75.0%)	2.3%
E	430	20 (4.6%)	16 (75.0%)	4 (25.0%)	4 (100%)	20.0%
F	87,855	7,261 (8.3%)	7,000 (96.4%)	261 (3.6%)	225 (80.0%)	3.1%

# Misdiagnosis Reports from the Field cont`



- ▶ HTS Register – not completed or missing (using un-official note books)
- ▶ Clear evidence of non-compliance for PT
  - ▶ All counselors scoring same results at several sites (suggesting copying of PT results)

# Factors Contributing to HIV Misdiagnosis



- ▶ Severe crowding in many facilities leading to conveyor belt testing(batch testing)



# Factors Contributing to HIV Misdiagnosis



- ▶ Poor storage of test kits
- ▶ Test strips not being separated when performing tests (potential for cross contamination)
- ▶ Problematic interpretation of results



# Lessons Learnt



- ▶ Massive expansion in HTS coverage and services is a significant accomplishment, but it should not overlook quality.
- ▶ Alternate approaches needed:
  - One screening test on site
  - Confirmatory testing by different tester
- ▶ Conveyor belt testing (batch testing) leads to compromised testing practices

# Way Forward



- ▶ Re-training testers (skills intensive training) with emphasis on following proper HTS protocols
- ▶ Strengthening compliance to the revised 2016 HTS guidelines
- ▶ Training new counsellors and supervisors with the revised training packages
- ▶ Strengthened supervision and mentorship
- ▶ Continued implementation of PT twice a year
- ▶ Individualized PT panels
- ▶ Change in testing algorithm following test kit evaluation findings and recommendations

# Way Forward cont`

- Group pre-test education for high-volume sites
- Strict monitoring of QC results from all sites
- Review of QC data over-time
- Transition to Dried Tube Specimen (DTS) for both PT and QC
- Strengthen PT Productions:
- Strengthen data analysis of results from the field
- Monitor strict turn-around time for PT scores