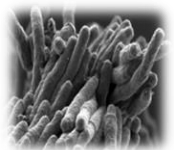# Evaluation and piloting of TB-LAMP assay for the diagnosis of PTB in Lusaka

Eddie Samuneti Solo
(BSC, MPH)
12.12.2019
LTWG meeting

Outline
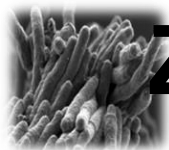
➢Introduction

➢Part 1. Evaluation study of TB-LAMP

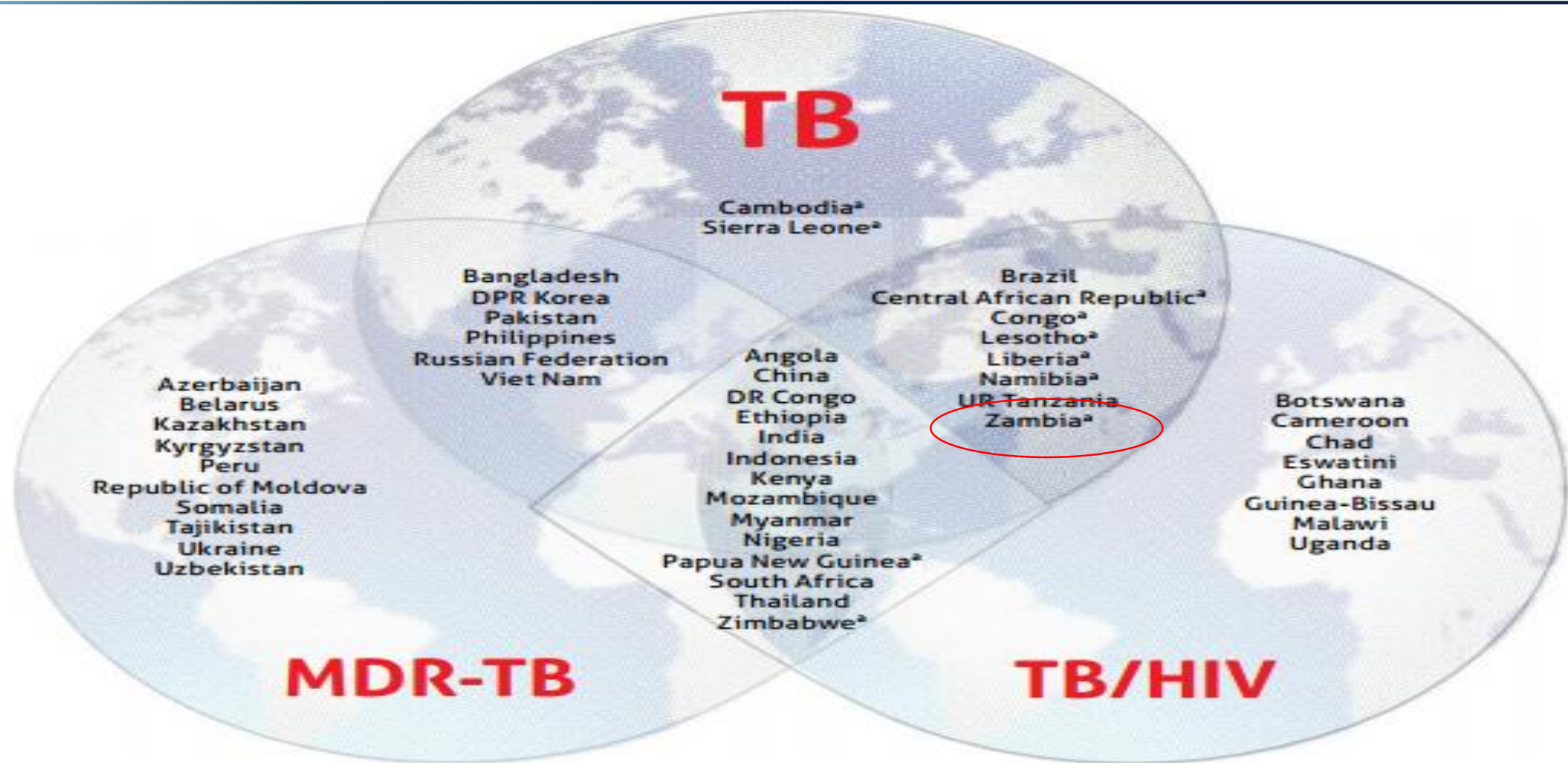➢Part 2. Pilot study of TB-LAMP

➢Conclusions

➢Recommendations

Introduction

diagnostic tools in use

Incidence: 346/100 000

ZAMBIA

POPULATION: 17 MILLION

2017

62 000 FELL ILL WITH TB

38 000 males
24 000 females
7 500 children

36 010 TB cases notified

25 990 people not notified or not diagnosed

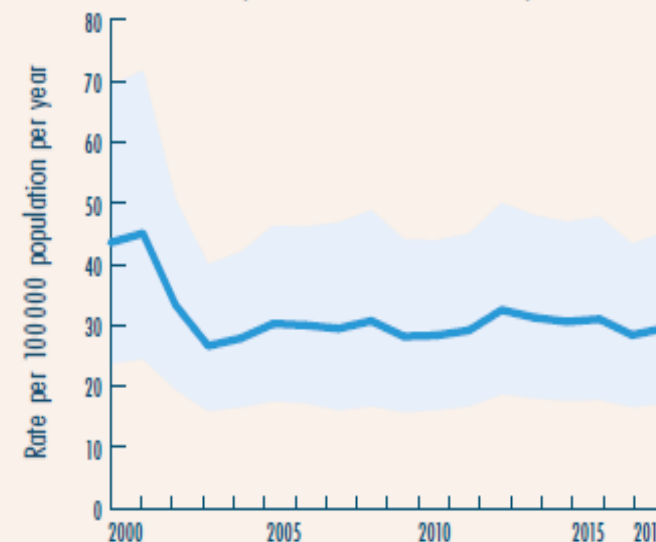## 18 000 TB DEATHS

including **13 000 deaths** among **people with HIV**

TB MORTALITY 2000-2017
(Excludes people with HIV)

Rate per 100 000 population per year

80
70
60
50
40
30
20
10
0

2000 2005 2010 2015 2017

Diagnostic tools (Microscopy)

- Inexpensive

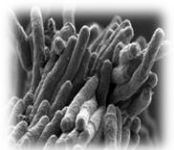- Poor sensitivity
  (20 – 60%)

- False negatives and missed TB cases

Diagnostic tools (Xpert MTB/RIF)

Molecular tool

High sensitivity
(> 80%)

High equipment maintenance cost
(air conditioned and dust free rooms,
replacement of modules)

TB-LAMP assay (WHO endorsed 2016)

- Molecular tool

- High Sensitivity
  (>80%)

- Low equipment maintenance cost
  (robust equipment)

- WHO policy guidance
  -labs with inadequate infrastructure
  -replacement for smear microscopy

Part 1. Evaluation study of TB-LAMP in Hospitals laboratories

January – July 2018

Clinical Sciences Research and Reports

Evaluation of TB-LAMP assay for the diagnosis of pulmonary tuberculosis in Lusaka, Zambia

Solo ES[1]*, Mbulo G[1], Shibemba AL[1,2], Lungu PS[2], Nsama D[2], Zulu FM[2], Muzyamba J[3], Mwanza C[1] and Muyembe M[4]

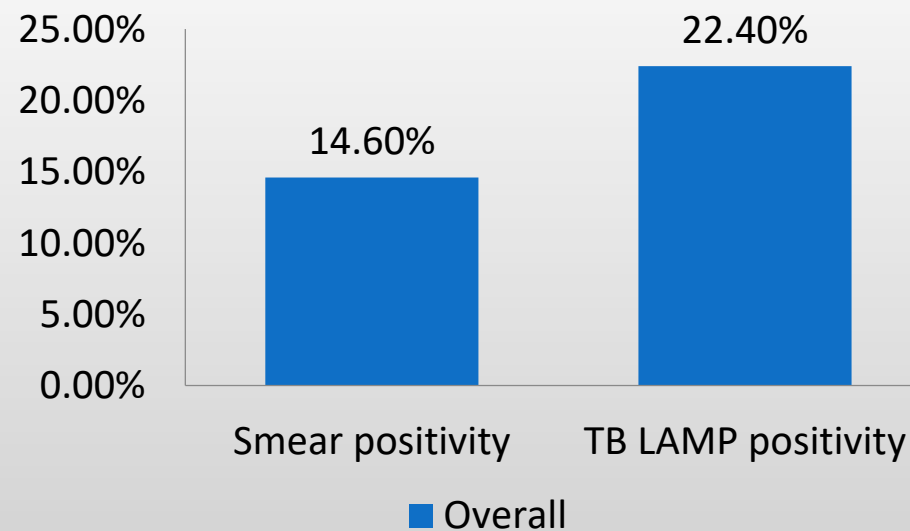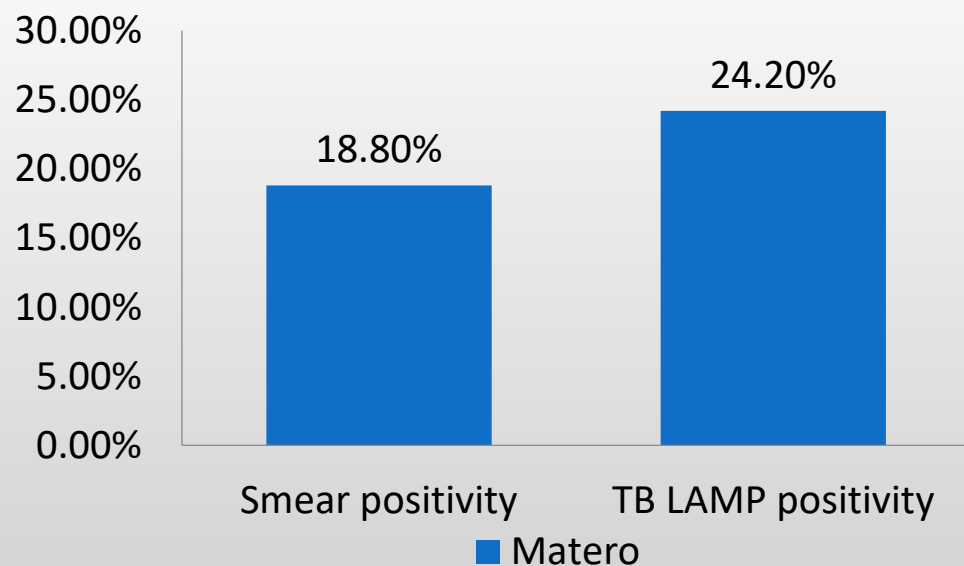[1]Department of Pathology and Microbiology, University Teaching Hospital, Lusaka, Zambia
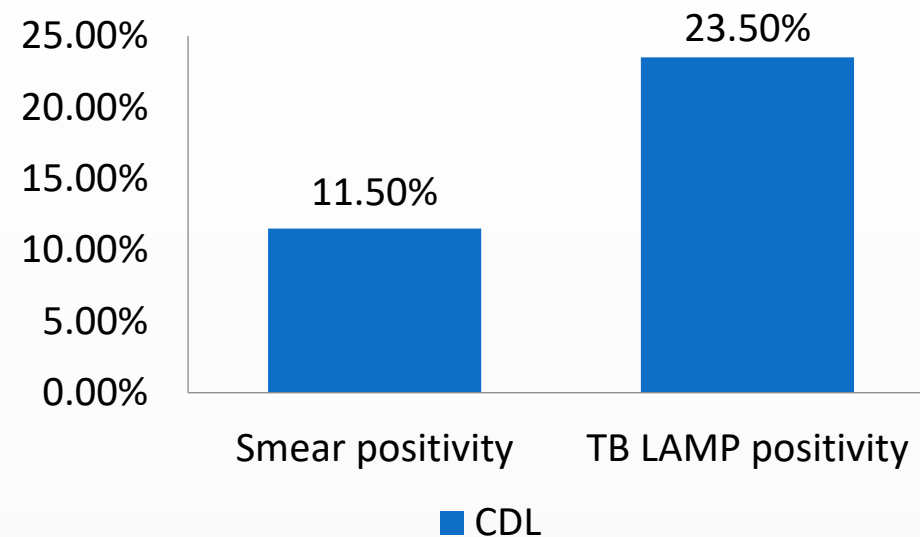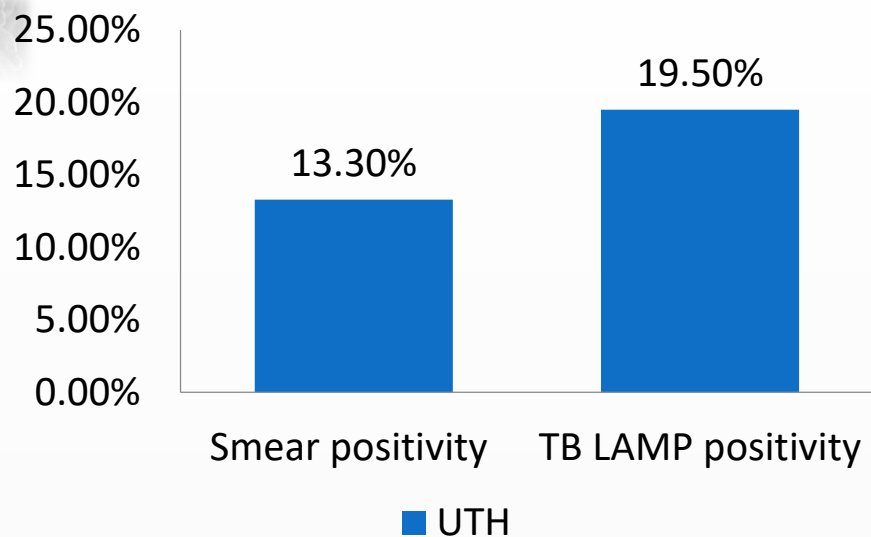
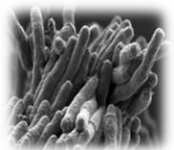[2]Ministry of Health, Ndeke House, P.O. Box 30205, Lusaka, Zambia

[3]Chest Diseases Laboratory, P.O. Box 30205, Lusaka, Zambia

[4]Matero Hospital, P.O. Box 50827, Lusaka, Zambia

Evaluation study results for TB-LAMP in Lusaka (2018)

Conclusions of the evaluation study

❑ TB-LAMP had demonstrated superior performance compared to microscopy in high level labs

❑ There was need to understand operational feasibility of TB-LAMP in settings of intended use (health center labs).
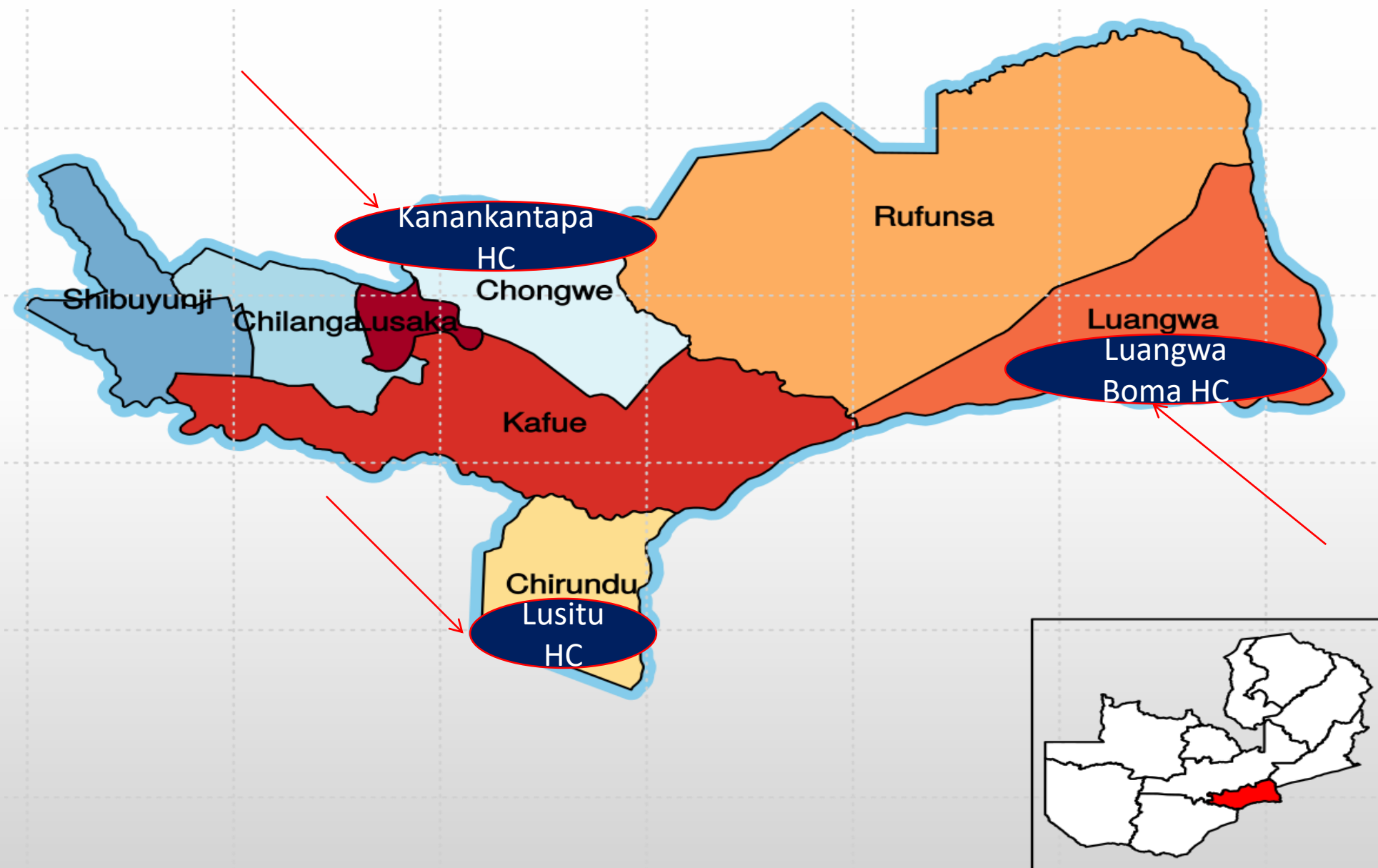
❑ MoH recommended pilot study in RHCs

Part 2. Piloting of TB-LAMP in RHCs laboratories

August - September 2019
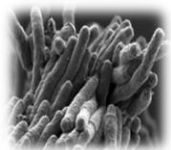
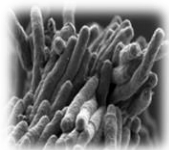# 3 RHCs selected as pilot sites

3 Staff trained (one per pilot site)

Pilot outputs/ measurables

1. Clinical performance of TB-Lamp (detection rates)

2. Usability/acceptability by staff

3. Notification rates

Clinical performance (detection rates)

○luangwa

		Smear		
		+	-	total
LAMP	+	0	2	2
	-	0	165	165
	total	0	167	167

sensitivity —
specificity 99%
total 99%

○kanakantapa

		Smear		
		+	-	total
LAMP	+	1	3	4
	-	0	168	168
	total	1	171	172

sensitivity 100%
specificity 98%
total 98%

○lusitu

		Smear		
		+	-	total
LAMP	+	3	0	3
	-	0	164	164
	total	3	164	167

sensitivity 100%
specificity 100%
total 100%

Overall detection

○total

		Smear		
		+	–	total
LAMP	+	4	5	9
	–	0	497	497
	total	4	502	506

sensitivity 100%
specificity 99%
total 99%

Usability/acceptability by staff

➢ **Technical usability of TB-LAMP assay:**

Basing on required expertise, TAT and efficiency, all the 3 staff declared that TB-LAMP was technically usable.
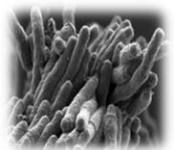
➢ **Opinion on comparing TB-LAMP and microscopy:**

When asked for a judgement between the two methods, all the 3 staff preferred to use TB-LAMP method against microscopy

➢ **Foreseen challenges:**

 2 staff highlighted safety concerns

 1 staff indicated challenges with power interruption

➢ **Repeat rate:** no cross contamination and no indeterminate results were reported.

Conclusions

- TB-LAMP assay increased TB detection rate twice compared to microscopy (from 4 to 9 cases) during the two months of pilot

- Staff that performed TB-LAMP testing expressed satisfaction with this method and recommended for its adoption and roll out to other HCs.

Recommendations

- We recommend that NTP replaces smear microscopy with TB-LAMP method for screening presumptive TB patients in HCs without GeneXpert machines.

- Safety fears and power interruption challenges highlighted by staff need to be addressed during roll out.

Acknowledgments

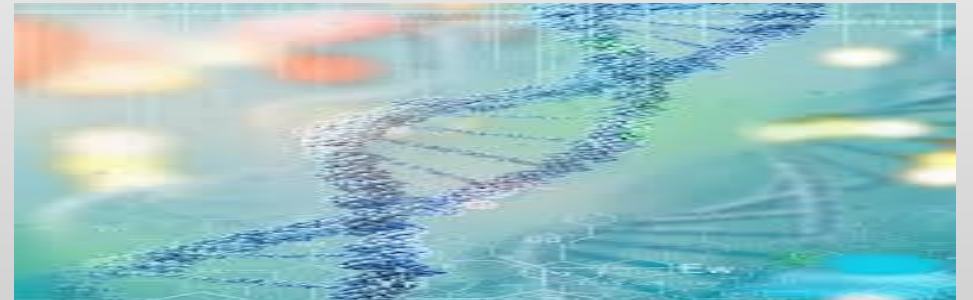Staff at:
- Kanakantapa RHC,
- Lusitu RHC
- Lwangwa Boma RHCs

Japanese Ministry of Health, Labour and Welfare.

Republic of Zambia
MINISTRY OF HEALTH

Human
Diagnostics Worldwide

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Biogroup

Thank you/discussions