

#### FROM RESEARCH TO POLICY TO IMPLEMENTATION:

# THE TB-LAMP EXPERIENCE IN THE PHILIPPINES

Rosarie Villabito Gabuya, MHSS, RN

DEPARTMENT OF HEALTH RESEARCH INSTITUTE FOR TROPICAL MEDICINE NATIONAL TUBERCULOSIS REFERENCE LABORATORY



| Estimates of TR burden®  | 2018                                    | Number (thousands            | Rat  | é<br>nonvdation) |
|--|---|------------------------------|--|------------------|
| Mortality (excludes HIV+TR)  |   | 26 (22-20)                   | (per 100 000 population)<br>24 (20-28)     |                  |
| Mortality (HIV+TR only)  |   | 20 (22-30)                   | 0.57 (0-3.8)                               |                  |
| Incidence (includes HIV+TB)<br>Incidence (HIV+TB only)<br>Incidence (MDR/RR-TB) <sup>∞</sup> |   | 591 (332–924)<br>96 (3.9–18) | 554 (311–866)<br>9 (3.7–17)<br>17 (7.3–30) |                  |
|  |   |                              |  |                  |
|  |   | Estimated TB incidence t     |  |                  |
|  | 0-14 years                              | > 14 years                   | Tota                                       | al               |
| Females  | 36 (9.5-63)                             | 146 (38-254)                 | 182 (62-30                                 | 03)              |
| Males  | 39 (10-68)                              | 370 (97-643)                 | 409 (138-6                                 | 379)             |
| Total  | 75 (33–118)                             | 516 (223-809)                | 591 (332-9                                 | 924)             |
| TB case notifications, 20  | 18                                      |                              |  |                  |
| Total cases notified   |   |                              |  | 382 543          |
| Total new and relapse  |   |                              | 371 668                                    |                  |
| <ul> <li>% tested with rap</li> </ul>  | id diagnostics at time                  | of diagnosis                 |  | 36%              |
| - % with known HI  | / status                                |                              | 27%  |                  |
| - % pulmonary  |   |                              | 98%  |                  |
| - % bacteriological  | ly confirmed <sup>∞∞</sup>              |                              |  | 36%              |
| Universal health coverag   | e and social protection                 | n                            |  |                  |
| TB treatment coverage (r   | dence), 2018                            | 63% (40–110)                 |  |                  |
| TB patients facing catast  | ophic total costs, 201                  | 7                            | 35% (33–37)                                |                  |
| TB case fatality ratio (est  | imated mortality/estin                  | nated incidence), 2018       | 0.05                                       | (0.03-0.07       |
| Drug-resistant TB care, 2  | 2018                                    | Pr<br>New cases              | eviously treated cases                     | Total<br>number* |
| % of bacteriologically con<br>tested for rifampicin resist                                   | nfirmed TB cases<br>stance <sup>3</sup> | <1%                          | 24%  |                  |
| Estimated % of TB case   | s with MDR/RR-TB                        | 1.7% (1.1-2.5)               | 16% (13-20)                                |                  |
| Estimated MOR/DR TR  | asee among notified                     |                              |  | 5 300            |

bacteriologically confirmed cases000

Laboratory-confirmed cases

Patients started on treatment\*\*





(4 200-6 400)

MDR/RR-TB: 7 276, XDR-TB: 52

MDR/RR-TB: 6 125, XDR-TB: 52

### **TB Burden in the Philippines**





SOURCE: National TB Prevalence Survey 2016, Philippines

### TB Burder ( in the relieve of the TB Laboratory Network)

日日



- 2,872 TB Microscopy Laboratories (TMLs)
- 12 Regions with TML using LED-FM
- 403 Rapid TB Diagnostic Laboratories (RTDLs)
- 107 sites to be added this year

#### **29 TB Culture Laboratories**

- 6 labs with Non functional MGIT (liquid culture)
- 9 Drug Susceptibility Testing Laboratories
- 2 Line Probe Assay Sites



### **Xpert coverage and usage statistics, 2018**

| Indicator  | Data          |
|--|---------------|
| Total no. of Xpert machines in the country                 | 323           |
| Xpert machines linked with diagnostic connectivity network | 41            |
| Total no. of Xpert tests done in 2018                      | 480,666       |
| Proportion of Xpert tests with Invalid/ Error/ No results  | 3.5% (17,094) |
| Use ULTRA cartridges (Yes/No, %)                           | No, 0%        |
| No. Xpert machines linked                                  | N/A           |



### abc )tory Network

### EVALUATION PROCESS AS DONE FOR TB LAMP



#### TIMELINE OF ACTIVITIES INVOLVING THE TB-LAMP EVALUATION



RESEARCH INSTITUTE FOR TROPICAL MEDICINE

3]

### Local Evaluation for TB LAMP

### PHASE 1

- TB-LAMP performed at <u>central level</u>
   <u>laboratory</u>
- Diagnostic performance evaluation and end-user appraisal
- Total participants = 279



## PHASE 2

 TB-LAMP performed at <u>peripheral</u> <u>level laboratories (n=5)</u>

3

- Diagnostic performance evaluation
   and end-user appraisal
- Total participants = 507



### Local Evaluation for TB LAMP

### PHASE 1

- TB-LAMP performed at <u>central level</u> <u>laboratory</u>
- Diagnostic performance evaluation
   and end-user appraisal
- Total participants = 279



### **FINDINGS**

3



- More sensitive than smear microscopy (66.3, *p*=0.001)
- <u>Similar sensitivity</u> to Xpert (93.0, *p*=0.109)
- <u>Similar specificity</u> to both smear microscopy and Xpert (97.9 and 95.8)
- Received <u>positive feedback</u> from endusers (n=2), citing ease of use and shorter time to obtain results

### Local Evaluation for TB LAMP



- <u>More sensitive</u> than smear microscopy (66.1, *p*=0.0013)
- <u>Similar sensitivity</u> to Xpert (68.9, *p*=0.4545)
- <u>Similar specificity</u> to both smear microscopy and Xpert (97.47 and 94.8)
- Received <u>positive feedback</u> from endusers (*n*=10), citing ease of use and shorter time to obtain results

### PHASE 2

 TB-LAMP performed at <u>peripheral</u> <u>level laboratories (n=5)</u>

3

- Diagnostic performance evaluation
   and end-user appraisal
- Total participants = 507





## **CONCLUSIONS AND RECOMMENDATIONS**

- TB-LAMP has good diagnostic performance both in a central laboratory setting and local field conditions
- Intended users gave <u>positive feedback</u> on the test and found it easy to use
- The technology could be integrated into the country diagnostic algorithm following <u>further assessment</u> covering cost effectiveness and <u>once logistics are in place</u>



### Local Evalue Integration into the TB Control Program

Philippines TB LABORATORY NETWORK STRATEGIC PLAN 2018-2022 A Sub-Plan of PhilSTEP-1

Strategy 1.1: Increase availability and accessibility of WRD, LPA, and culture/DST services

Performance targets and outputs:

- 1.1.1 100% of presumptive TB cases are tested using WRD
- 1.1.2 100% of RR-TB cases are tested using second line LPA and phenotypic DST









TB-LAMP proposed to be included in the revised TB diagnostic algorithm as an <u>alternative primary diagnostic</u> <u>test in settings where access</u> to Xpert is limited\*

\*Subject to change depending on the policies to be adopted by the Philippine NTP

SOURCE: National Tuberculosis Control Program – Manual of Procedures 6<sup>th</sup> Edition, Pre-Final Text (September 27, 2019)



# SYSTEMATIC SCREENING FOR PTB IN ADULTS $\geq$ 15 YEARS OLD WITH UNKNOWN HIV INFECTION STATUS



### SYSTEMATIC SCREENING FOR ACTIVE PULMONARY TB FOR PLHIV



## 4 Integration into the TB Control Program



#### SUBJECT: Interim Guidelines on the Use of the Loop-Mediated Amplification Test for Tuberculosis (TB LAMP) as Rapid Diagnostic Tool in Selected Sites Under the National TB Control Program

specificity comparable to those of the Xpert MTB/RIF in the detection of bacteriologically confirmed TB. Other observations included increased number of specimens processed per run.

The National TB Control Program, seeing the technology as a means to increase case detection while complementing its current tools, opted to implement TB LAMP in selected sites to assess for its possible scale-up and inclusion in the country's diagnostic algorithm. A total of six machines will be made available in selected sites under the Centers for Health Development of Metro Manila, CALABARZON, and MIMAROPA (see Annex A) through a research collaboration program with the Japan International Cooperation Agency.

In view thereof, all facilities that are to be installed with TB LAMP are directed to adhere to the guidelines for its use, as detailed below. Refer to Annex B for the algorithm.

- TB LAMP shall be used as initial diagnostic test for bacteriological confirmation of presumptive TB in adults with no known risk factors for drug resistance; Xpert MTB/RIF shall be used for those with known risk factors for drug resistance.
- TB LAMP shall be used for sputum specimens only; one sample shall be collected per patient.
- 3. TB LAMP-indeterminate samples shall be re-tested using an aliquot of the same sample.
- TB LAMP-positive patients shall be screened for rifampicin resistance by Xpert MTB/RIF using an aliquot of the same sample.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1113, 1108, 1135 Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: fiduque@doh.gov.ph



### 4 Integration into the TB Control Program

#### USE OF TB LAMP AS INITIAL DIAGNOSTIC TOOL FOR TB



\* At least one of the following, with or without additional signs and symptoms for TB: 1) with chest X-ray findings suggestive of TB; 2) cough of  $\geq$ 2 weeks, or; 3) cough of any duration with additional signs and symptoms in risk groups

\*\*Includes: 1) anyone ever treated for TB, 2) close contacts of MDR-RR TB, 3) nonconverter of patients on TB treatment with category I, II and isoniazid resistant TB (if known), and; 4) people living with HIV (PLHIV)



### **ABOUT THE PILOT IMPLEMENTATION**



- TB-LAMP deployed as <u>primary diagnostic</u> <u>tool</u> in selected health facilities for <u>presumptive TB patients with low risk for</u> <u>drug resistant TB</u>
- TB-LAMP positives tested with <u>Xpert</u> to screen for RIF resistance

#### Sites:

- 1. San Lazaro Hospital
- 2. Commonwealth Health Center
- 3. Las Piñas City Health Office
- 4. Santa Rosa City Health Office I
- 5. Antipolo City Health Office
- 6. San Jose Rural Health Unit, Romblon
- Conducted from April to September 2019

### Pilot Implementation Assessment

### **FINDINGS**



RESEARCH INSTITUTE FOR TROPICAL MEDICINE

5



### **EXPERIENCES OF PILOT SITES**

- Smearing, staining, and microscopy entail a lot of time and effort. While, in using TB LAMP, the procedure is simple and user-friendly.
- TB LAMP alleviates heavy workload from Xpert MTB/Rif assay.
- The number of tests done using TB LAMP is greater than Xpert in the same span of time.
- Specimen collection for TB LAMP eliminates the burden for collecting 2 specimens.
- Turnaround time and releasing of result can be released on the same day the specimen is processed.



### **CHALLENGES ENCOUNTERED**

- Unable to maximize the use of detection reagents when few specimens are processed.
- Challenging to perform in the beginning due to the number of steps



# Pilot Imp 6 Usage Beyond the Program Evaluation

### **IMPROVING CASEFINDING IN URBAN HOSPITALS**





- Part of the TB Innovations and Health Systems Strengthening Project of the FHI360
- Selected large private and public hospitals (n=3) in urban areas were installed with equipment and their staff capacitated for conduct of TB-LAMP in settings where workload for Xpert is high
- Started last August 2019 up to June 2020



### **6** Usage Beyond the Program Evaluation

### **MASS SCREENING IN PRISONS**



PHOTO COURTESY OF ICRC

- Part of the ACCESS TB (Advancing Client-centered Care and Expanding Sustainable Services for TB) Project under the Global Fund grant in the Philippines
- TB-LAMP to be deployed in selected prisons for use in mass screening among detainees
- To be conducted in 2020



## **Cost Effe (6)** Usage Beyond the Program Evaluation







- Philippines is a high TB burden country and based on estimates, we are <u>not finding enough bacteriologically</u> <u>confirmed cases</u> to curb the TB epidemic
- We need more testing and <u>TB-LAMP is a viable option</u> to the country based from evidence gathered through our research and pilot implementation
- TB-LAMP has been proposed in national policies to be used by the program but is <u>currently being further</u> <u>evaluated</u> by the Department of Health – Health Technology Assessment Unit prior to adoption for routine use





- Eiken Chemical Co., Ltd.,
- Japan International Cooperating Agency
- Department of Health, Philippines
- Research Institute for Tropical Medicine-National Tuberculosis Reference Laboratory













#### FROM RESEARCH TO POLICY TO IMPLEMENTATION:

# THE TB-LAMP EXPERIENCE IN THE PHILIPPINES

Rosarie Villabito Gabuya, MHSS, RN

DEPARTMENT OF HEALTH RESEARCH INSTITUTE FOR TROPICAL MEDICINE NATIONAL TUBERCULOSIS REFERENCE LABORATORY



