September 16, 2024

Pioneering Pathways: Implementing shorter TB Preventive Treatment, Populations at risk and more.

Moderated by:
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Exploring country experiences from **Indonesia**, **Ethiopia** and **Tanzania**; and expertise from the IMPAACT4TB research and aspects to consider for Private Sector involvement in TPT care provision.

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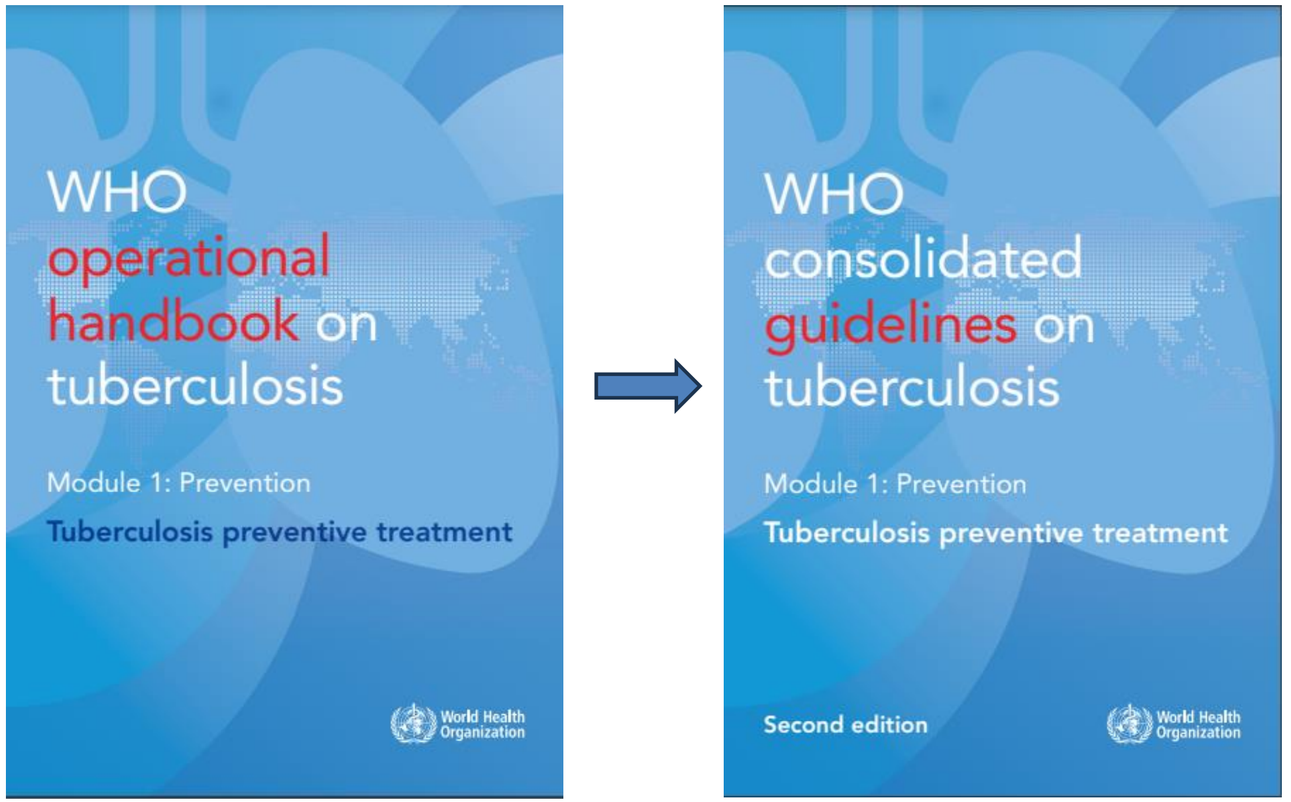
IMPAACT4TB update

Makaita Gombe

Market Access Director - The Aurum Institute

Context

49% TPT uptake in 2019 (GTB)



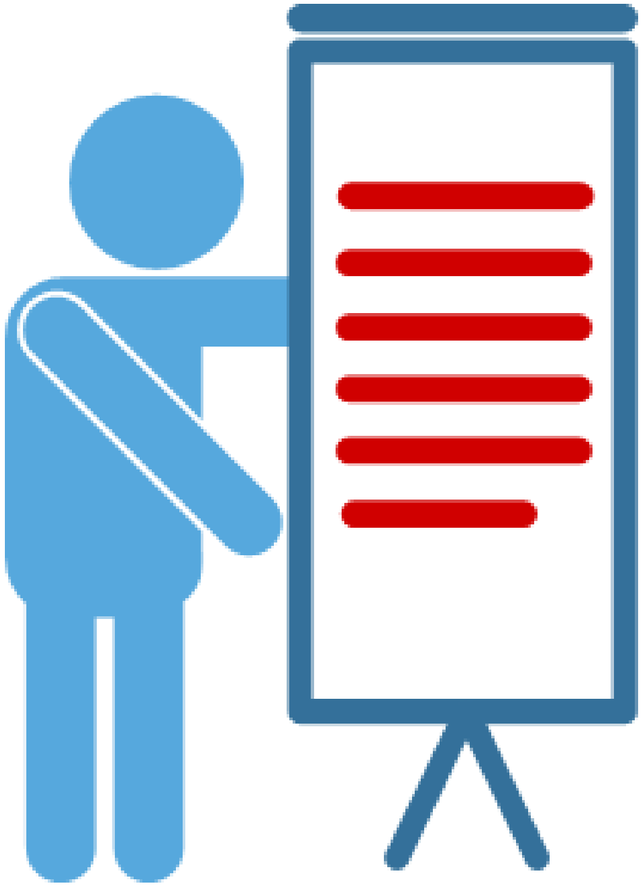
2018 2024

What has been done?

Project Overview:

- **Evidence generation** on 3HP across different populations and service delivery methods to ensure scale up is ongoing.
  - DOLPHIN study generated evidence for the safety of the co-administration of 3HP and DTG without adjusting the dose of DTG
  - DOLPHIN TOO investigating 3HP initiation in ART naïve PLHIV
  - TBTC Study 35 to inform dosing of 3HP in children under 2 years old
  - CHIP-TB investigating 3HP for child contacts
  - Choice Architecture Study investigating an opt-out strategy to increase TPT uptake within ART clinics
- **Supply side interventions**
  - Reduce the price of a patient course
  - Incentivize development of optimal formulations and increase in global capacity of rifapentine-based formulations

Way Forward?



Further evidence generation to expand to all populations in need:

- Dolphin Kids (evaluating 3HP with DTG based ART) results expected in June 2025
- Dolphin Moms (evaluating 3HP & 1HP in pregnant women with HIV) results expected in June 2025
- One to Three comparing 1HP to 3HP among PLHIV and HHCs results expected in June 2025
- Crush Study evaluating use of crushed adult rifapentine in children, enrolment complete results expected in July 2024
- Paediatric formulation feasibility study – Zimbabwe, Cambodia, Ethiopia starting in July

What was achieved in the end?

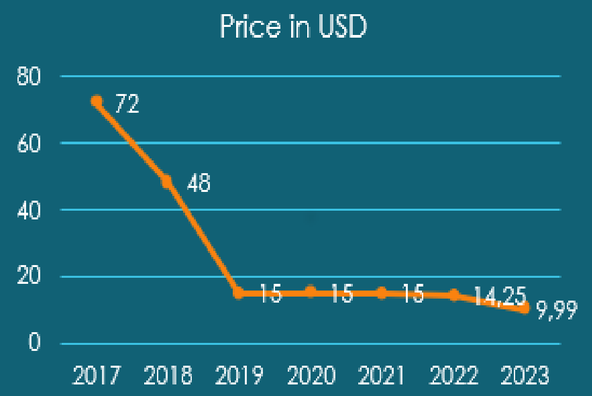
Unitaid WHO

Governments; Global Fund; USG/GDF

Price of 3HP

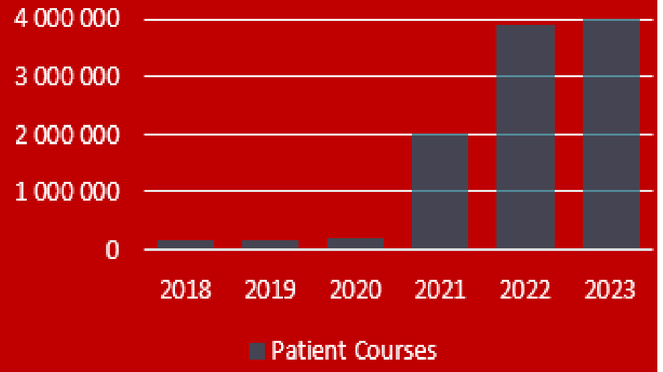
The price dropped from $72 in 2017 to $14,25 in 2022 and $9,99 in 2023 for the FDC. 1HP is available at $17- $18.

Peadiatric - $6.53-$15,20



Rifapentine Manufacturing Capacity

Increased from 180k patient courses in 2018 to over 4,5 million in 2023.



Global 3HP procurement

Over 10 million patient courses of rifapentine-based TPT have been purchased across 99 countries.

Community advocacy fostered guideline update, demand generation & scale-up

Rifapentine manufacturers

sanofi

150MG RPT (FDA)

NEW

PEADIATRIC: 150MG RPT DT FS TASTE-MASKED (WHO PQ)

MACLEODS

300 RPT/300 INH FDC (WHO PQ)

300MG RPT (WHO PQ)

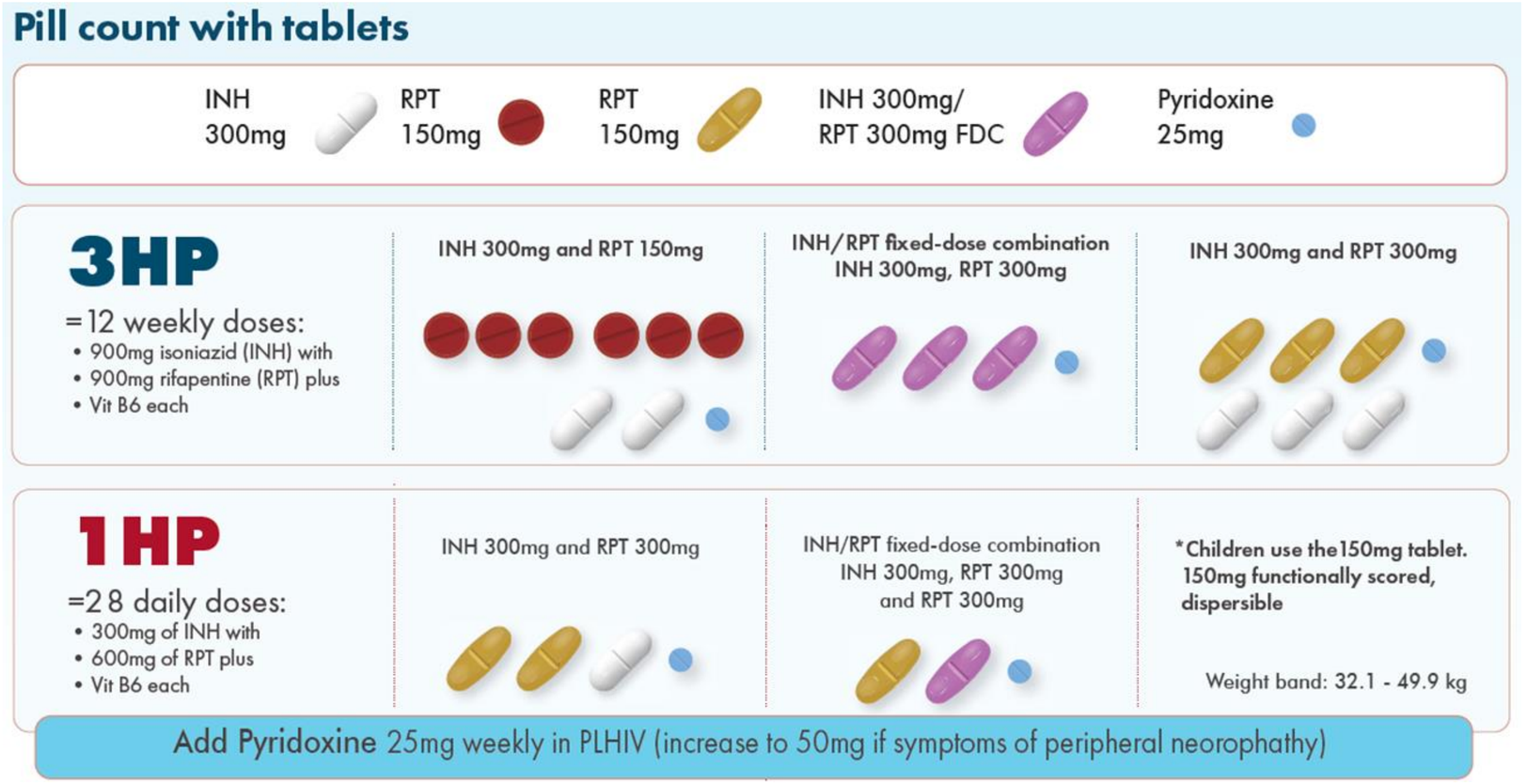
LUPIN

300 RPT/300 INH FDC (N/A)

300MG RPT (ERP)

High treatment completion 92% among PLHIV (96% stable on ART, 80% ART naïve) and 90% among Household contacts

What are my shorter TPT regimen options?



- Mixed feedback from clinicians on preference between 1HP and 3HP – urban 1HP, rural 3HP. **3 pill burden daily high for HHCs and PLHIV**
- **1HP FDC** and 3HP FDC pack?
- 300mg singles; 3HP FDC and **bulk pack with FDC blisters and 300mg singles**? – can give 36 FDC for 3HP or 28 FDC + 28 300mg singles for 1HP

Early Market Access Vehicle (EMAV)

Eligibility

- Eligibility for accessing the ceiling price extends to public sector buyers and funders:
  - Governments of Eligible Countries
  - United Nations-related organizations, non-governmental organizations and not-for-profit organizations.
  - Development and/or public health financing mechanisms, or a procurement agent appointed by any of the entities above.

Available resources

- Maximum available - 1,000,000 tablets (~27,000 patient courses)

Procurement and Supply chain

- EMAV procurement to go through the Global Drug Facility (GDF) purchasing mechanism through the Aurum Institute supply chain person.
- EMAV will fund the ex-works costs of the product and shipping to the warehouse.
- EMAV will not fund in-country distribution - Unitaid requires the eligible buyer/implementing partner to be responsible for in-country distribution, healthcare worker capacitation and implementation.
- Aurum will provide technical support, training materials and tools to support country scale-up

Acknowledgements

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TAG
Treatment Action Group

World Health Organization

Stop TB Partnership
GLOBAL DRUG FACILITY

i+ solutions
universal access to essential medicines

Practical experiences of early implementers rolling out shorter TB preventive treatment: Indonesia

Yeremia Runtu

Yayasan KNCV Indonesia

Country context

Country population size

277 million[1]

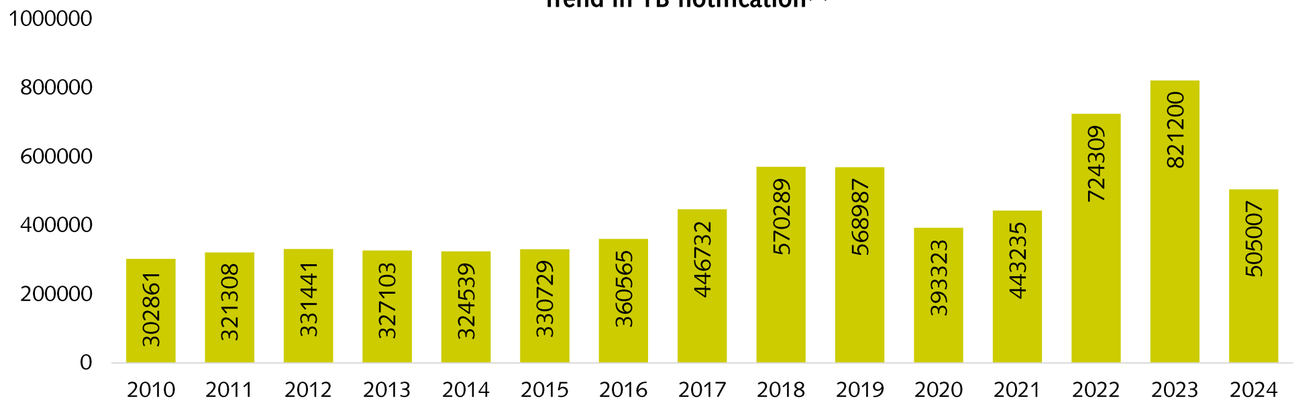
Upper-middle income country[1]

2nd

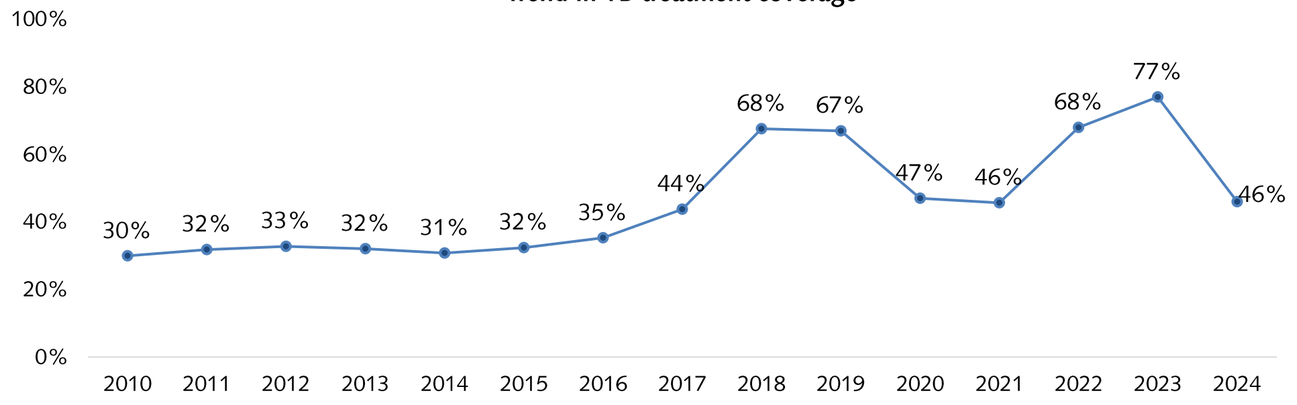
Indonesia is the second highest in TB burden

Indonesia is included in the three global lists of high-burden countries for TB, HIV-associated TB and MDR/RRTB[2]

Trend in TB notification[3]



Trend in TB treatment coverage[3]



Coverage of TPT for household contacts[4]

2021		2022		2023		2024	
Achievement	Target	Achievement	Target	Achievement	Target	Achievement	Target
0.3%	29%	1.3%	48%	2.6%	58%	8.9%	68%

Coverage of TPT for PLHIV[5]

2021		2022		2023		2024	
Achievement	Target	Achievement	Target	Achievement	Target	Achievement	Target
4.2%	40%	9.5%	45%	7%	50%	9%	55%

Source:

(1) World Bank, 2024
(2) Global TB Report, 2023
(3) Data for 2010-2020 from The 2022 TB Control Program Report; 2021-2022 from Final Data for Global TB Report, MoH; data 2023 from MoH as of March 2024; data 2024 from MoH as of August 2024
(4) Data for 2021-2022 from The 2022 TB Control Program Report; data 2023 from MoH as of March 2024; data 2024 from MoH as of August 2024
(5) Data for 2021-2022 from The 2022 TB Control Program Report; data 2023 from MoH as of July 2023; data 2024 from MoH (achievement of January-July) as of August 2024

Policy context

2012

Indonesia provided the standard INH 6-month regimen for PLHIV

2016

The same regimen is offered for HHC under 5 years old

2019

The IMPAACT4TB project introduces a shorter 3-month INH and RPT regimen (3HP)

2020

- Guidelines for LTBI and TPT administration for PLHIV are established.
- Target groups are expanding to include household contacts of any age, as well as other HIV-negative risk groups such as immunocompromised patients, prisoners, health care workers, and individuals living in community settings.

What were the problems to address for roll-out of shorter course regimens?

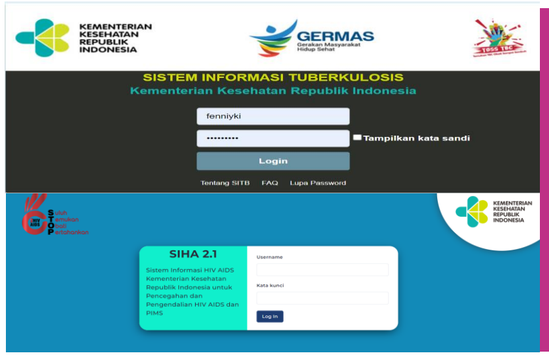
- **Policy**: unavailability of PMTPT guideline
- **Human Resources**: limited understanding of the TPT advantages from HCWs
- **Resources**: unavailability of TPT IEC materials
- **Logistics**: unavailability of rifapentine
- **Surveillance Systems**: not all TPT related variables are already available in the national TB and HIV surveillance systems
- **Public Awareness**: Lack of awareness of the TPT advantages

How did we approach the problems?

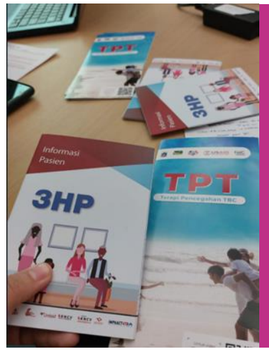
Developing PMTPT national guideline

3HP procurement for 25.000 doses and in-country distribution

Health care worker capacity building and community engagement



Strengthening the national TB and HIV surveillance systems



Developing IEC materials

IMPAACT4TB
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- Starting the use of 3HP in 6 piloting provinces on the island of Java
- Dec 2020 – Jun 2021, 53 PLHIV and 503 HHCs enrolled on 3HP

Challenges along the way?

Limited understanding & engagement

- Misperception about TPT in community

Logistical barriers

- Shortages of TST in health facility, subdistrict, and district level

Access to required testing for HHCs

- Chest X-Ray is not covered by National Health Insurance

Service delivery

- No SOP available for TPT implementation

Surveillance systems

- Lack of treatment monitoring (aDSM) module

What was achieved in the end of the project?

Improved 3HP TPT uptake

- HHCs with enrollment number of 503 patients, the completion rate reached 94%
- PLHIV with enrollment number 53 the completion rate for PLHIV reached 98%

Strengthened the Information, Education, and Communication by providing

- Pocketbook for HCWs and patients
- Flip chart

Health workers capacity building

- Trained around 4,500 health workers over 3 years period.

Community involvement

- Trained 153 participants for TB-HIV community

What remains as existing challenges at this point of time?

Contact Investigation for HHCs remains suboptimal

(26% out of estimated contact investigations)

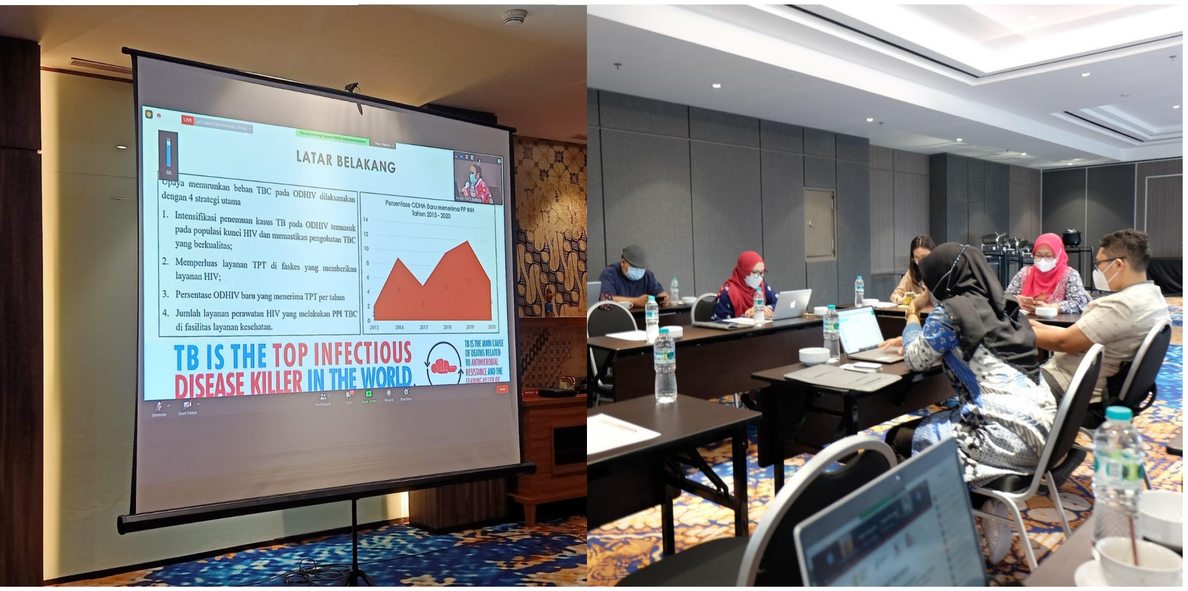
Stock shortages of 3HP

Low perceived risk of becoming infected by TB

CXR and TB infection testing have not been financed by National Health Insurance

TPT in private sector remains untouched

Way forward



- Integration of TPT and active case finding/wide mass screening
- Strengthening contact investigation mechanism
- Expanding TPT in private providers
- Advocacy for CXR and TBI testing for “healthy people” to NHI
- TBI and TPT communication strategy especially for HHCs

What are lessons learned?

Health Office

- Self-funded TPT capacity building for HCWs
- Cadres training funded by domestic budget

Community engagement

- Collaboration with community to raise awareness for acceptance in nation wide implementation

Health Services

- Involving psychologist to improve TPT acceptance among PLHIV
- One-stop service for PLHIV including TPT

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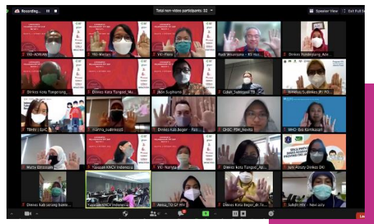


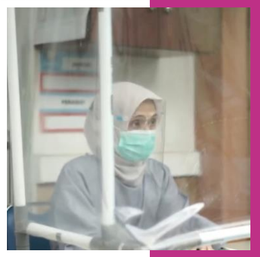

- Ministry of Health of Indonesia
- Health Offices
- Healthcare workers
- Civil society organizations and community cadres
- Donors and partner organizations
- People affected by TB and their family

Pioneering Pathways: Implementing shorter TB Preventive Treatment, Populations at risk and more

Learn more at:
kncvtbc.org
auruminstitute.org
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yki4tbc.org

Thank you

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YAYASAN KNCV INDONESIA

Practical experiences of implementers rolling out shorter TB preventive treatment: Ethiopia

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MINISTRY OF HEALTH - ETHIOPIA

Outline

- Country context
- Policy context
- What were the problems to address for roll-out of shorter course regimens?
- How did we approach the problems?
- What was achieved in the end?
- Challenges along the way?
- Lesson learned
- Way forward

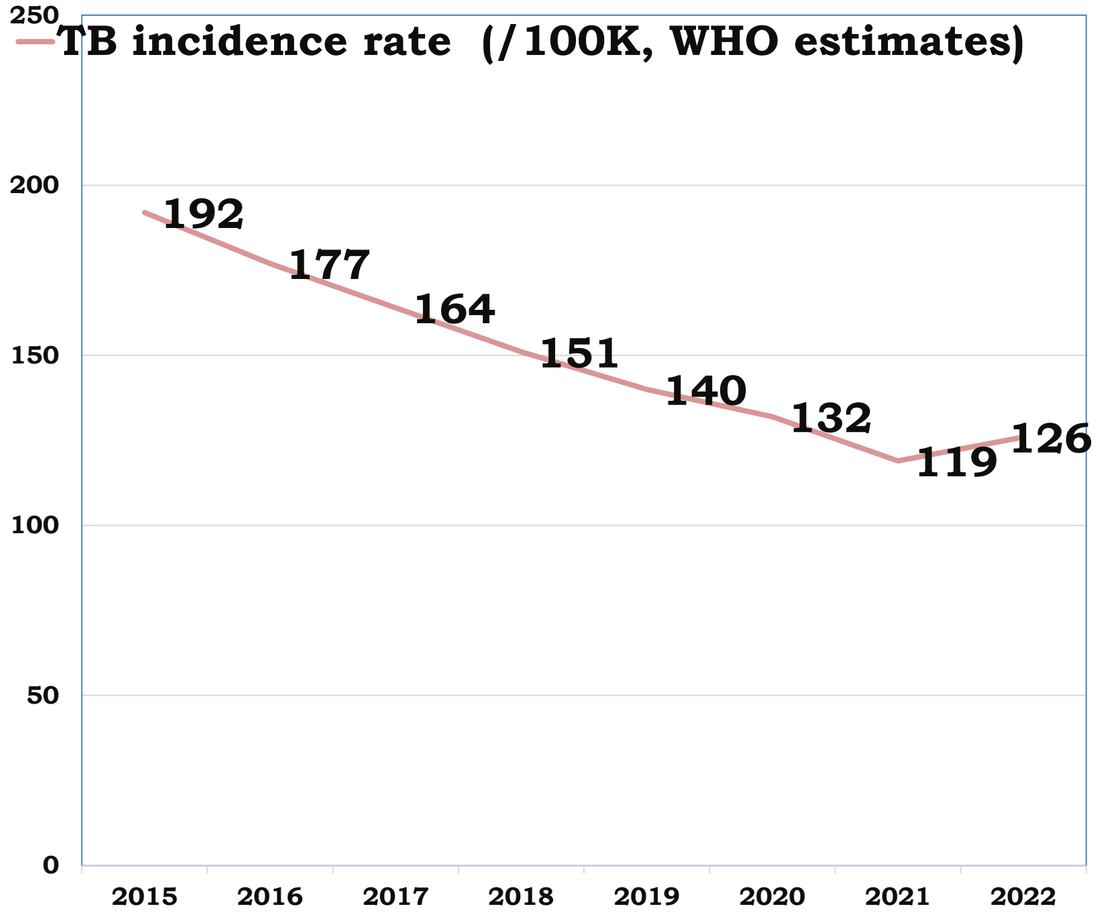
Total population

129 million

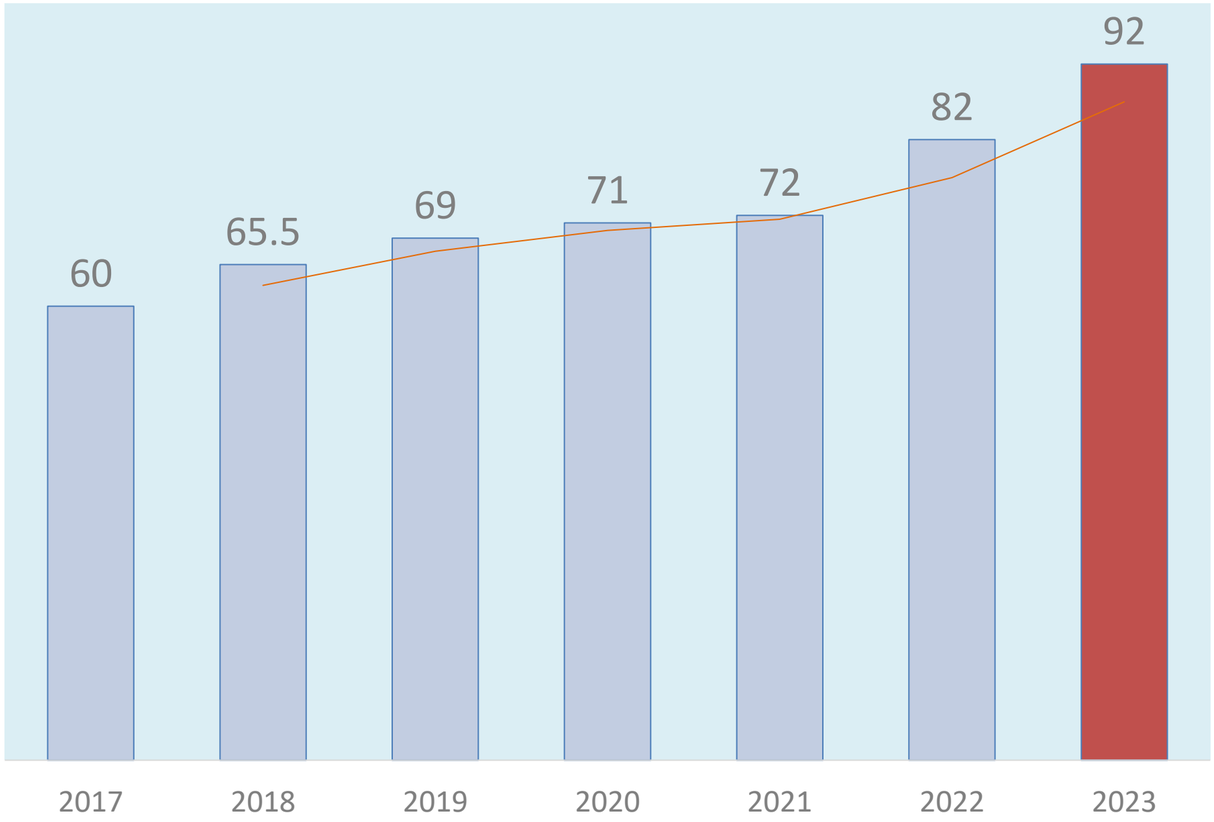
Country context

- Ethiopia is among the 30 high TB and TB/HIV burden countries globally.
- TB Incidence rate stands at 126/100,000 pop. with an estimated156,000 (105 000-217 000) incident TB cases in 2022
- TB Mortality rate stands at 17/100,000 populations with an estimated 21,000 (13 000-31 000) TB deaths in 2021.
- Estimated RR/MDR 2000
- Health Services
  - 17,550 HPs,
  - 3,735 health centers and
  - 353 hospitals are available
  - 2000 PPM

TB Incidence reduction from 2015-2022



Trends of TB treatment coverage %



Policy context

- **TPT policy before the IMPAACT4TB project: IPT for 6 month for PLHIV and children under 5 years contact of pulmonary TB cases**
- **National Tuberculosis and HIV Programmatic management of LTBI, Addendum developed in March 2020**
  - Key updates
- **New alternatives for TPT regimens have been included**
  - 3HP for those aged 2 and over
  - 3HR for those aged under 2
- **Target/eligible groups expanded**
  - People aged between 5 and 15 who are HIV negative and who have been exposed to an index case with pulmonary TB
- **Updates to recording and reporting tools to reflect these updated alternative regimens and eligible groups**
- **The addendum**
  - Provided guidance that is consistent with global WHO recommendations of 2018
  - Considered feasibility of options for the management of LTBI in the context of Ethiopia.

What were the problems to address for roll-out of shorter course regimens?

- In Ethiopia, only 49% of the PLHIV newly enrolled in care and 22 % of under 5 children who are contacts of bacteriologically confirmed PTB cases were started on IPT in 2018.
- The country has continued its commitment to ending TB by enhancing the concerted efforts to achieve the minimum target set at UNHLM to provide TB preventive therapy to a total of 490,000 high risk individuals between 2018-2022.

- Unavailability of WHO recommendation for 3HP at early phase of project start up
- High cost of 3HP
- Government not ready, need for donor support for implementation
- Limited amount of Rifapentine support through I4TB : Pilot implementation
- Need for waiver for importation of Rifapentine and the need to include in the Essential Medicine list(EML)
- The need to include into Integrated pharmaceutical and logistic system(IPLS)
- Need for the integration of 3HP into the eDHIS2 system

How did we approach the problems?

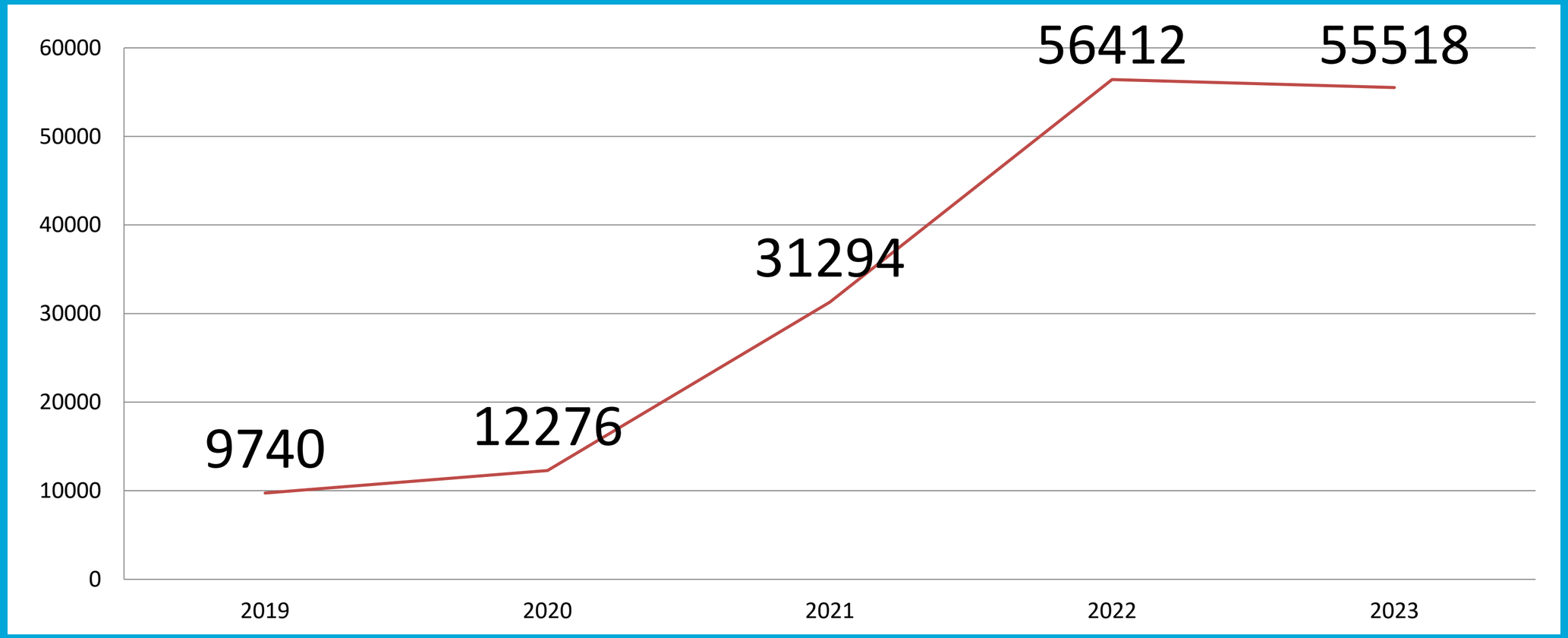
- 3HP is incorporated into national guidelines of HIV and TB (addendum).
- Establishment of task force on TPT/ 3HP, joint implementation plan
- Importation and distribution of Rifapentine.
- Rifapentine listed in EML, EFDA supported with pre-import permit (waiver to import)
- Training of trainers and cascade trainings.
- Revising the recording and reporting tool
- Pilot implementation - I4TB: 150 target sites in Oromia, SNNP, Sidama, and Addis Ababa.
- PEPFAR/ CDC support and expansion to additional high HIV load facilities in AA, Oromia, SNNP, Sidama, South-West Ethiopia, Amhara and Gambella regions.

What was achieved in the end?

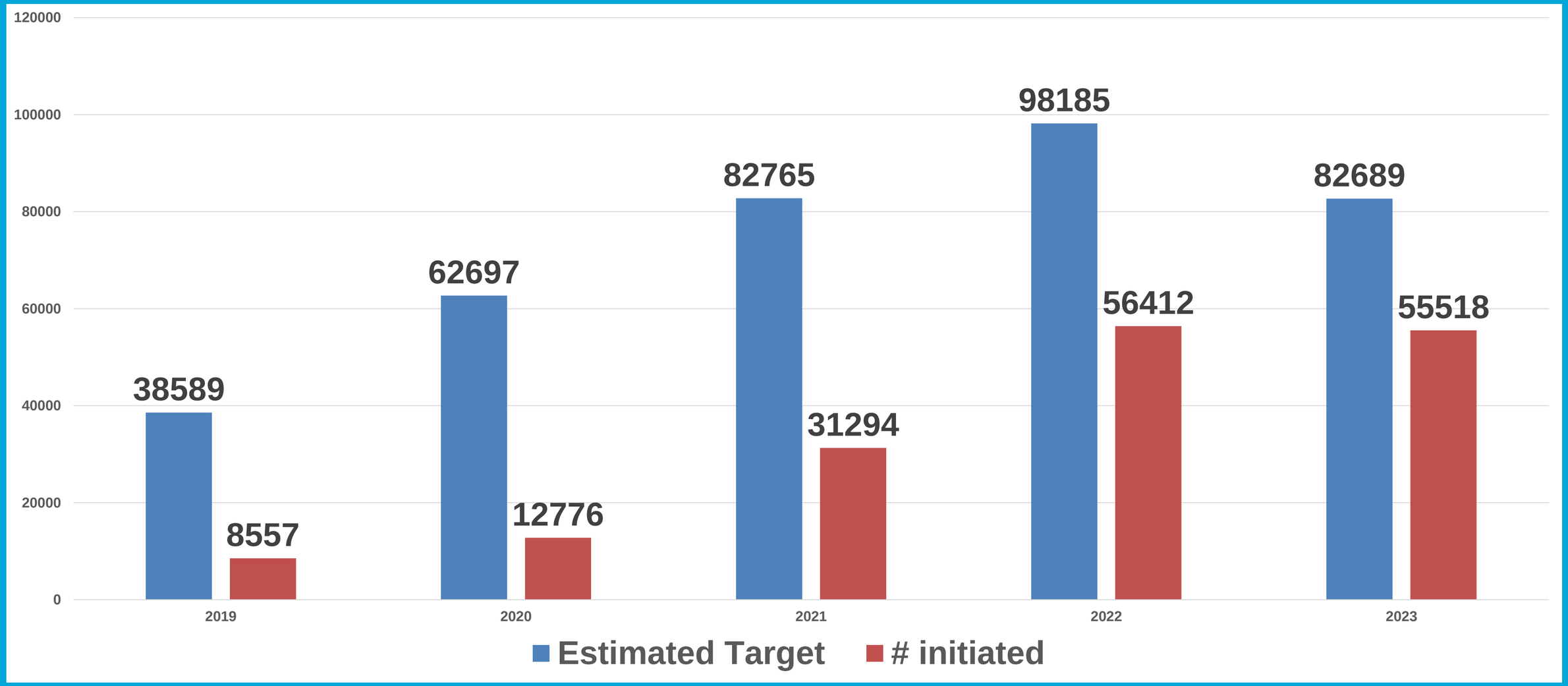
- Ethiopia adopted the global TB prevention recommendations with the aim to address the end TB strategy and guide the implementation of TPT in eligible population.
- So far, Ethiopia has been implementing TPT for PLHIV and <15 years age contacts of BCPTB.
- For shorter regimen 3HP scale up was nationally launched in May 2022 in Ethiopia .
- MOH put procurement order for loose Rifapentine in GF for the year 2023 and beyond
- All TPT regimen integrated into the national HMIS and disaggregated by TPT regimen both for HIV and TB.
- Integration into the existing IPLS: Quantification with GF budget, integrated distribution for FDC (PLHIVs) and Rifapentine (for child contacts)

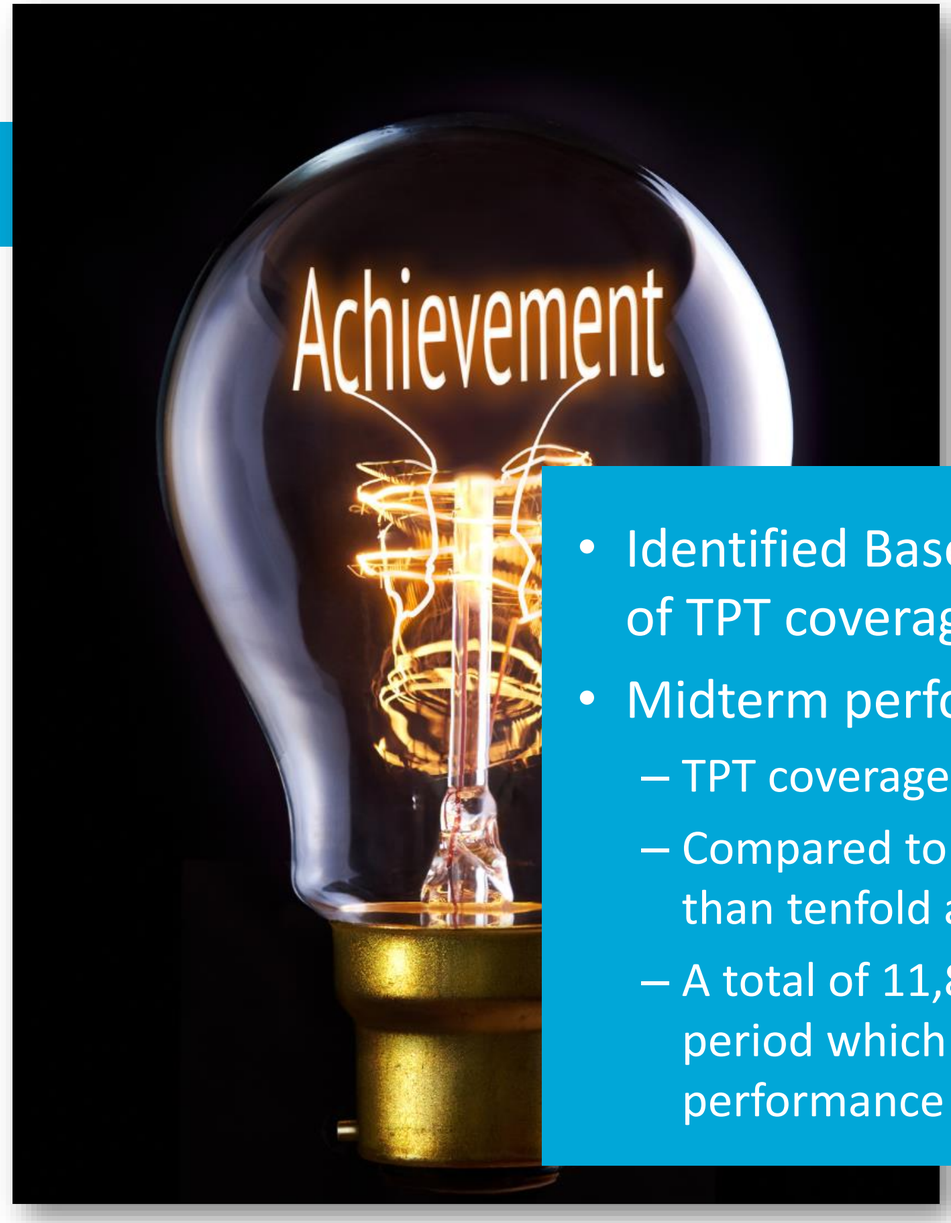
TB Preventive Treatment Progress

The national TB program performance shows that the TPT enrollment among <15years household contacts is improving progressively.



Progress against UNHLM target (under 15 years)

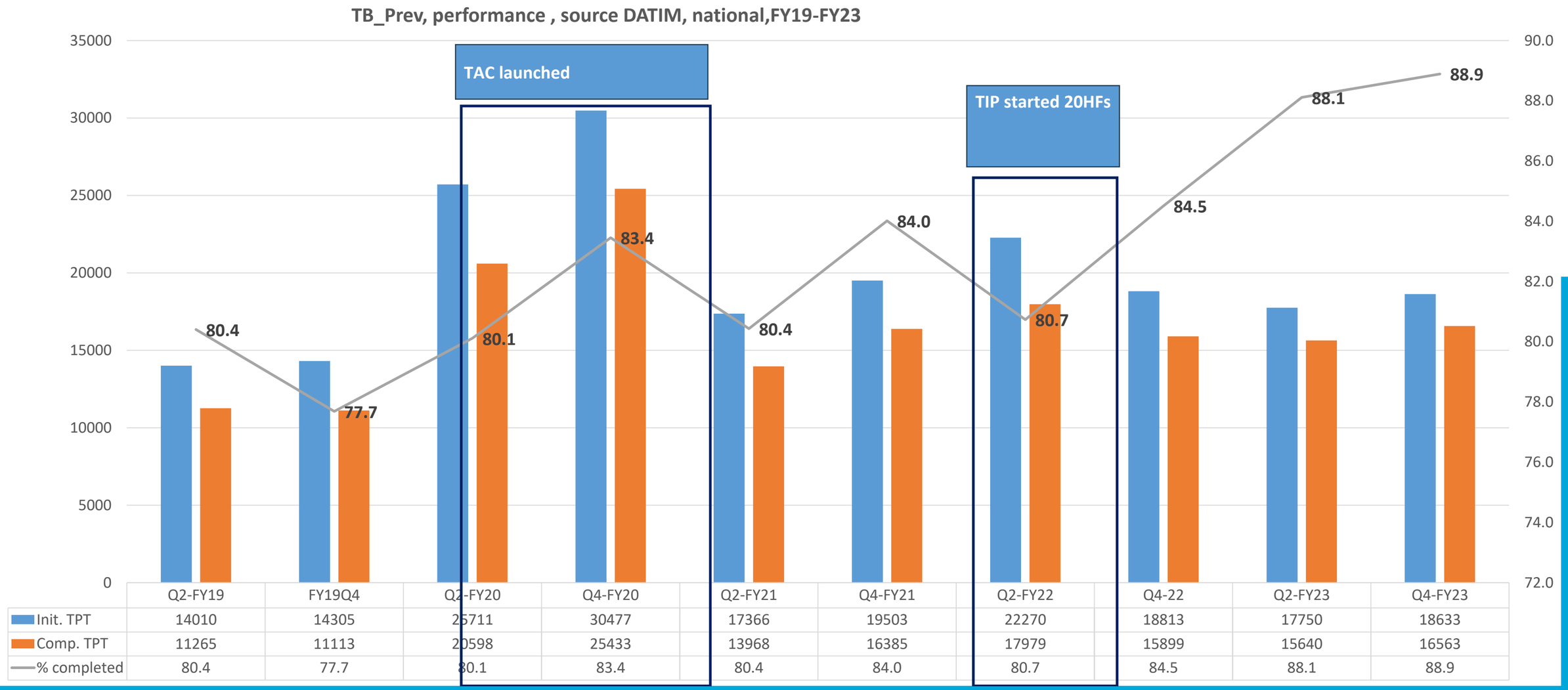




TPT acceleration Campaign (TAC) for PLHIV: Major achievement

- Identified Baseline TPT program status and made realistic estimation of TPT coverage gap.
- Midterm performance of the TAC showed that:
  - TPT coverage gap for the same cohort shrank to 35% at 6th month.
  - Compared to baseline, monthly TPT uptake at the TAC sites increased more than tenfold at month 6 (238 Vs 2768).
  - A total of 11,825 existing and newly enrolled clients received TPT during this period which is five-fold increment compared to the preceding semiannual performance report.

TB Surge Interventions Increased TPT Uptake FY19, Q2-FY23, Q4, PEPFAR supported sites



	Q2-FY19	FY19Q4	Q2-FY20	Q4-FY20	Q2-FY21	Q4-FY21	Q2-FY22	Q4-22	Q2-FY23	Q4-FY23
Init. TPT	14010	14305	25711	30477	17366	19503	22270	18813	17750	18633
Comp. TPT	11265	11113	20598	25433	13968	16385	17979	15899	15640	16563
% completed	80.4	77.7	80.1	83.4	80.4	84.0	80.7	84.5	88.1	88.9

Plans toward meeting the UNHLM targets

- Currently, TBLLD has plan to expanding and implement TPT for eligible target groups (adult household contacts, clinical risk groups and high TB transmission settings) from July, 2024

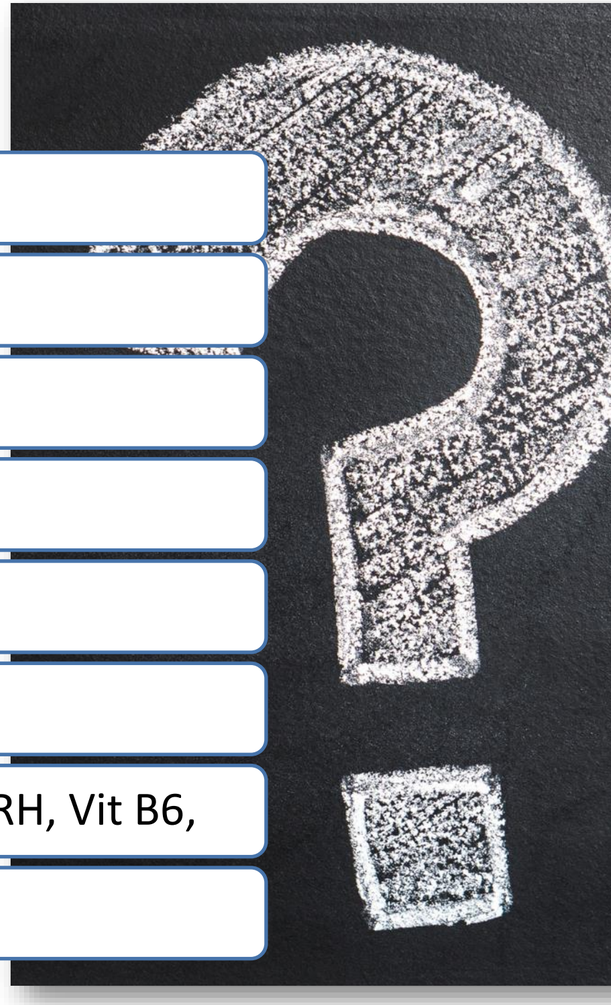
Estimate TPT Targets	2023	2024	2025	2026	2027	2023-2027
TPT Contacts above 5 years	51,439	53,423	67,628	70,690	65,045	**308,225**
TPT, child contacts (under-five)	**31,250**	**33,648**	**39,595**	**40,565**	**36,549**	**181,607**

Plans toward meeting the NSP targets

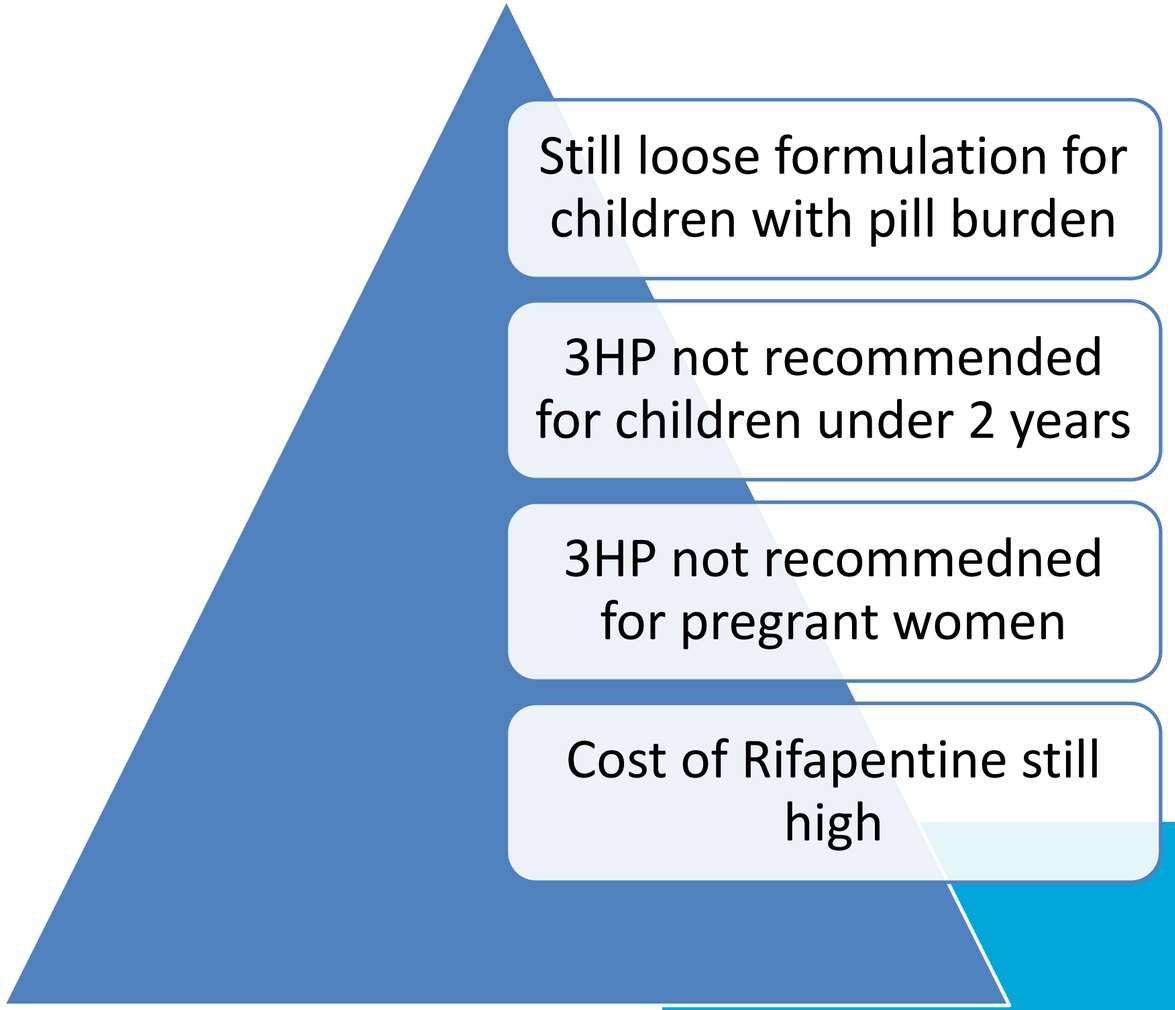
Estimate TPT Targets	2023	2024	2025	2026	2027	2023-2027
TPT Contacts above 15 years	70,927	74,741	77,775	81,936	85,417	**390,796**
TPT, child contacts (under-15 years)	**53,095**	**55,250**	**58,206**	**60,679**	**62,088**	**289,918**

Challenges along the way?

- Delay on project implementation and 3HP delivery
- Global shortage of Rifapentine (3HP drug production and distribution)
- COVID-19 pandemics, low production capacity of pharmaceuticals, logistics
- Report of Nitrosamine impurity, error on package insert information,
- Utilization of loose formulation for children, pill burden to child and care giver,
- Sustainability of supply at HFs, Frequent stock out, expiry of low volume items like INH100,
- Facilities do not report and request 3HP drugs (simple quota system/ push), also true for INH, 3RH, Vit B6,
- Attrition of trained providers, staff rotation



What remains as existing challenges at this point of time?



What are lessons learned?

- Integration into the existing system -guidelines, training materials, forecasting and quantification, DHIS2,
- National scale up along with integration of 3HP commodities into existing IPLS system
- The need for strong follow up during initiation of new implementation

Way forward

- Implementation of TPT for all HH contact and other risk groups
- Implementation of TPT for DR-TB contact(Levofloxacin for 6 months).
- Implementation of 1HP in Prison set up
- Improved the TPT coverage to achieve the UNHLM and NSP target

Acknowledgements

- UNITAID
- IMPAACT4TB
- KNCV Tuberculosis Foundation
- AURUM Institute
- MOH-NTP
- Healthcare Facilities

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MINISTRY OF HEALTH - ETHIOPIA

Practical experiences of implementers rolling out shorter TB preventive treatment: Tanzania

Dr. Peter Neema
Program Coordinator
National TB/HIV Program
Tanzania

Glossary

- 6H: 6-months Isoniazid monotherapy
- CEM; Cohort Event Monitoring
- CSO: Civil Society Organisation
- DP: Development partners
- HCW: Health care worker
- NASHCoP: National AIDS, STI, and Hepatitis Control Program
- MSD: Medical Stores Department
- NIMR: National Institute for Medical Devices
- NTEC: National TPT Expert Committee
- NTLP: National TB and Leprosy Program
- OR: Operational Research
- PORALG: President's Office Regional Administration & Local Government
- TMDA: Tanzania Medicines & Medical Devices
- U5HH: Underfive household contacts

Country context

- Tanzania is among 30 countries with high TB burden (TB & TB/HIV) with the population size of 61,000,000 residents as per 2023 census.
- For 2022 TB notification was 101,000 patients
- Tanzania started the provision of TPT in 2007 (6H) to U5HH and 2011 to PLHIV.
- The 2018 UN High-Level Meeting on ending TB (UNHLM) targets reaching 870,700 people with TPT in Tanzania by the end of 2022
  - 119,990 under-five household contacts of bacteriologically confirmed TB patients,
  - 176,769 other household contacts of bacteriologically confirmed TB patients and
  - 573,941 PLHIV

National TPT Experts Committee (NTEC)

- Following implementation challenges like adherence, uptake, fluctuating commodity supply, the PS MoH formulated the NTEC to provide technical advice on the scale-up of TPT services in Tanzania (Nov 2021).
- The committee comprises national experts from MoH (NTLP, NASHCoP, CP), PORALG, NIMR, MSD, TMDA, DPs (WHO, USAID, CDC), IPs, and CSOs.
- The committee has conducted various consultative meetings with the following deliverables:
  - Review of the literature and other existing evidence
  - Developed National TPT Scale-up Plan 2021-2025 (with a costed roadmap and transition plan of TPT from INH to new shorter regimens)
  - Forecasting/Quantification of the commodities
  - Formulation of the key recommendations for implementation

National TPT Scale-Up Plan

The National TPT Scale-up Plan (phasing in of new TPT medicines) has 4 phases:

- Planning Phase (Q4 2021 – Q2 2022)
- Pre- Implementation (Q3 2022 – Q4 2023)
- Routine Implementation and scale-up (Jan 2024-onwards)
- Program Evaluation (Q3-Q4 2025)

- NTEC had liaised with NIMR (Mbeya and Muhimbili Centers) to conduct the OR/implementation research on TPT implementation feasibility.
- The OR has been conducted and helped to inform the rollout of shorter TPT regimens and programmatic implementation of TPT in the country.

Global Fund TPT Strategic Initiatives - KNCV contracted to provide TA with WHO.

- **TPT M & E plan:** developed
- **TPT M & E tools:** r & r tools developed and distributed
- **Updating of databases for TB & HIV programs to accommodate new TPT regimens (Electronic TB and Leprosy Register – ETL and Care & Treatment Clinics (CTC) for PLHIV:** completed
- **TPT Training packages:** developed and ToT training done.
- **IEC materials for demand creation: finalized and distributed:** key TPT msg & safety monitoring: print, audio & video format done
- **Printing and distribution of IEC:** done

ETL and CTC integration: **Final Stage**

WHO Prevent TB APP adoption to ETL + a digital adherence package: **Ongoing**

Protocol for Cohort Event Monitoring (CEM); developed and training will follow: **Fund Needed**

Challenges along the way?

- **Lack of access to pediatric-friendly formulations for 3HP** (in 2021 when recommendations were made).
- **Limited adoption of diagnostic tools for TBI** (Operational research – OR on prevalence of TBI in grps needed).
- **Capacity building to DOT providers at TB clinics.**
- **Follow-up and Adherence:** Challenges in monitoring and adverse event reporting.
- **Stock out INH:** for continuing patients, pregnant women, contraindication to rifamycins due to transition progress – training, distribution, legacy stock management.
- **Inadequate recording and reporting:** due to CTC update, insufficient tools & knowledge.

What was achieved in the end?

- Roll out of shorter TPT regimens in the country through shorter regimens Jan 2024.
- Most of NTEC & TPT SI deliverables were met

Guidelines, SOPs,IEC materials and M & E Tools

Medicines:

3HP/3HR

Community and stakeholder engagement

Pharmacovigilance:

ADSM/CEM

Capacity Building:

5,069 HCW

1,516 Coordinators

Research:

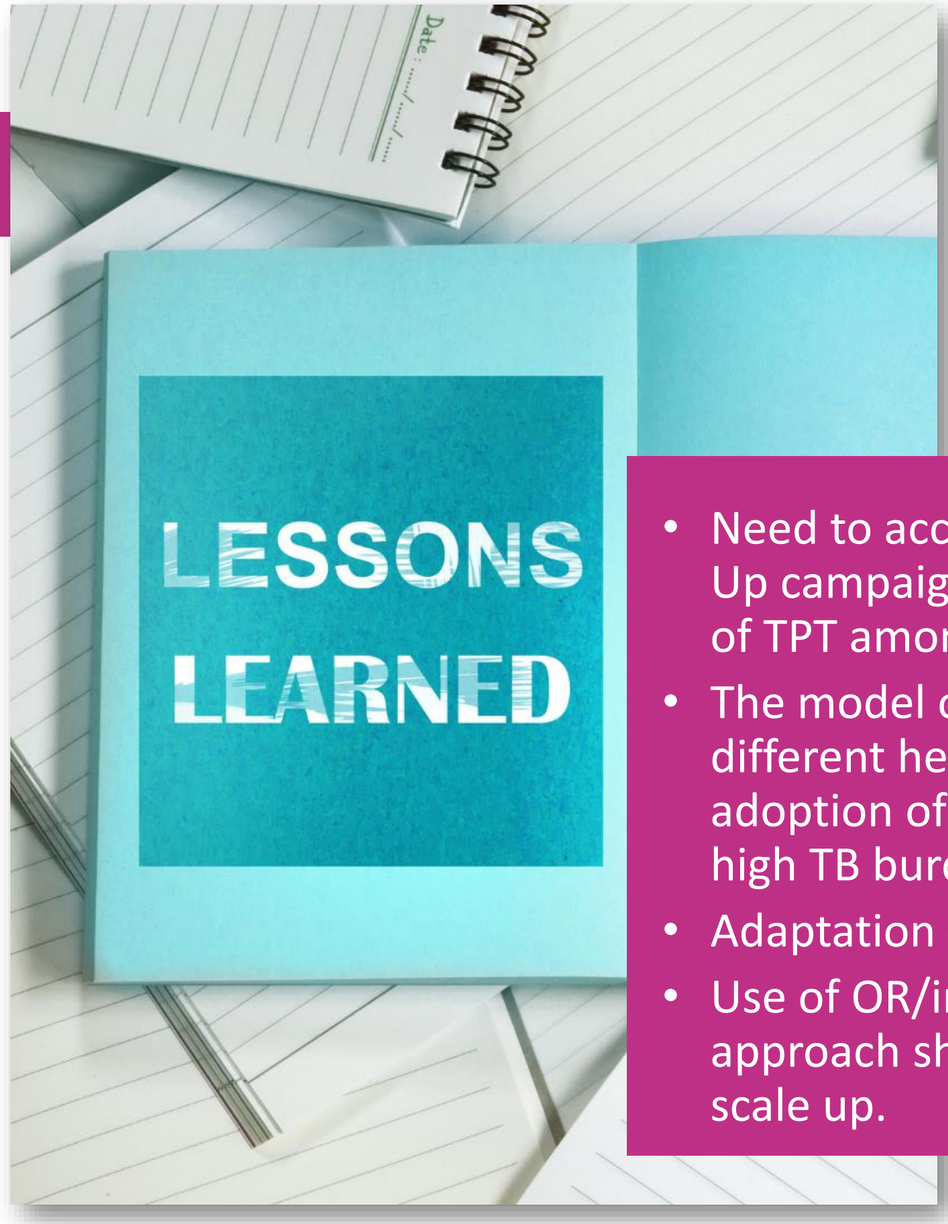
feasibility family approach to TPT

Supply Chain Management:

forecasting, ordering, and distribution of 3HR/3HP

Resource mobilization:

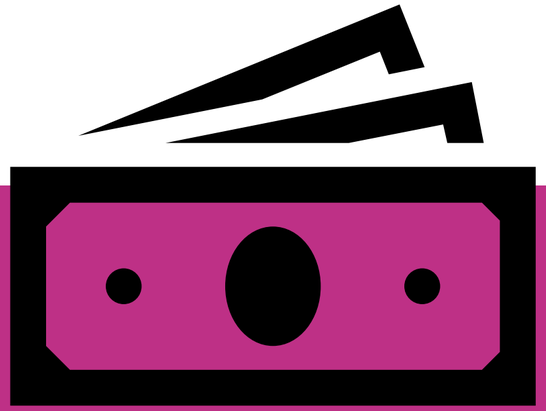
GFATM, USG (CDC, USAID, DOD), WHO, KNCV



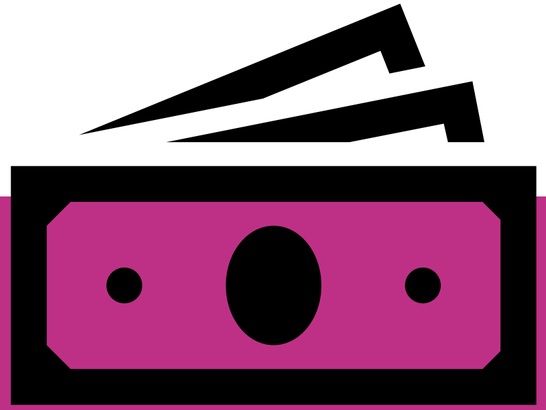
What are lessons learned?

- Need to accelerate TPT uptake and catch up with a mop up campaign. TPT Mop Up campaign in TZ for 14 days across 26 regions that translated into high uptake of TPT among PLHIV who were not covered.
- The model of using expert committees with a mix of multi stakeholders and different health professionals in programmatic scaling up of any intervention and adoption of new technologies should be employed by all countries especially high TB burdened countries in TPT scaling up.
- Adaptation of prevent TB APP to DHIS2 and modified community TB APP
- Use of OR/implementation research to inform implementation – facility centred approach showed high uptake/high demand and adherence to inform national scale up.

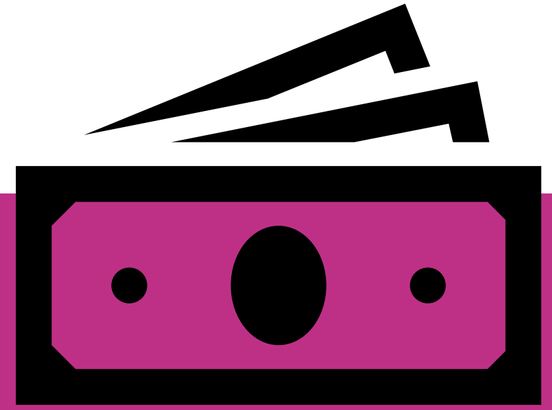
What remains as existing challenges at this point of time?



Inadequate funds for the CEM



INH stock out & Inadequate funds for the management of legacy stock



Insufficient funds for capacity building for CHWs

Way forward

- Vertical TPT Legacy stock management to be integrated with the MOH general legacy management.
- E-learning platform development (has been finalized awaiting launching).
- Development and dissemination of the TPT community package.
- Continuous mentorship to HFs & CHWs.
- Scale up TPT to the other at-risk groups: prisoners, miners, PWUD & >5HH (planned to start with a pilot Oct-D).
- Integration of TB/HIV data to be reflected in ETL.
- Timely TPT supply chain: forecasting, procurement, distribution and monitoring.

Acknowledgements

Unitaid SAVE LIVES FASTER
IMPAACT4TB PREVENTING TB TO END TB
KNCV TB PLUS
THE AURUM INSTITUTE
THE GLOBAL FUND
USAID FROM THE AMERICAN PEOPLE
World Health Organization
NTLP NATIONAL TUBERCULOSIS & LEPROSY PROGRAMME
END TB TANZANIA
NASHCoP
amref health africa
MDH MANAGEMENT AND DEVELOPMENT FOR HEALTH
NATIONAL INSTITUTE FOR MEDICAL RESEARCH
PEPFAR U.S. President's Emergency Plan for AIDS Relief
MKUTA
PEPFAR USAID Afya Yangu Southern
Elizabeth Glaser Pediatric AIDS Foundation
thps Tanzania Health Promotion Support

Research findings to accelerate scale-up of TPT

Christiaan Mulder, PhD
Senior epidemiologist
KNCV Tuberculosis Foundation

IMPAACT4TB Pioneering Pathways
16 September 2024

What did we study to improve TPT service delivery?

1) CAT study in PLHIV

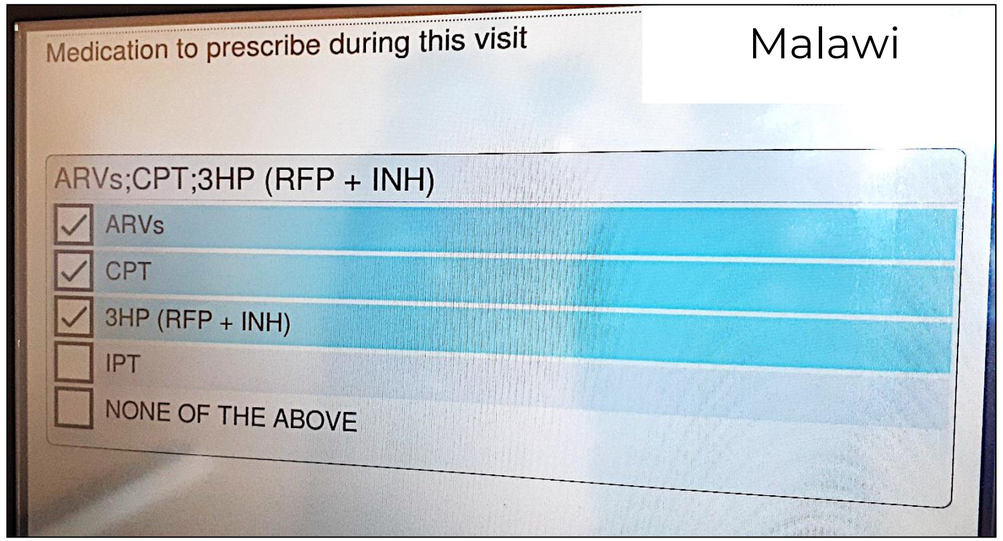
We tested the effectiveness and acceptability of making TPT the default choice for clinicians in **Malawi**, Mozambique, and Zimbabwe

2) CHIP-TB in household child contacts

We tested whether home-based TPT services can improve TPT uptake among household child contacts aged < 15 years compared to the facility-based standard of care in **Ethiopia** and South-Africa

CAT - Intervention design

- A **default prescribing tool** linking TPT to ART prescription
- The tool was developed in collaboration with key stakeholders in each country:
  - **Mozambique & Zimbabwe** – **TPT-specific prescribing sticker** placed on clients' personal docs
  - **Malawi** – **default prescribing module** built into the national HIV point-of-care **Electronic Medical Record (EMR)**



CAT - Results

	Mozambique			Malawi			Zimbabwe		
	Standard implementation	**Choice architecture**	**Rate difference (CI) p-value**	**Standard implementation**	**Choice architecture**	**Rate difference (CI) p-value**	**Standard implementation**	**Choice architecture**	**Rate difference (CI) p-value**
Number of clinics	10	10		10	9		9	9	
Indicators									
Monthly number of new ART clients Mean (sd)	20.0 (27.0)	19.0 (28.0)		21.5 (17.3)	18.0 (8.7)		14.9 (8.3)	13.6 (6.6)	
Monthly number of new ART clients prescribed TPT; Mean (sd)	17.9 (27.0)	18.0 (27.0)		12.4 (11.0)	9.2 (5.7)		8.4 (7.3)	8.5 (6.2)	
Primary outcomes									
Mean of cluster-level proportions of new ART clients prescribed TPT (95% CI)	70.9% (48.3%, 93.6%)	86.9% (78.9%, 94.9%)	-16.0 (-38.3, 6.3) p-value=0.15	56.5% (44.7%, 68.4%)	55.5% (43.0%, 68.0%)	1.0 (-14.9, 16.9) p-value=0.89	56.2% (37.2%, 75.1%)	55.9% (35.8%, 76.1)	0.2 (-25.2, 25.8) p-value=0.98

- During the period of study implementation, we observed **no difference** in **TPT prescribing** to **new ART clients** in Malawi or Zimbabwe (approximately 56% across countries and arms)
- We did observe **an increase in TPT prescribing** to **new ART clients** in **Mozambique (87% vs 71%)** but this difference was **not statistically significant**

Shearer K, et al. (Submitted)

CAT – Qualitative findings Malawi

HCWs perceived advantages of CAT	HCWs perceived disadvantages of CAT
Lessens the work - HCWs spend less time prescribing TPT since the steps were automated and all medications were pre-ticked	**Reduces critical thinking, autonomy**, and potentially is **overly directive**
Acts as a reminder - more than half of the HCWs from intervention clinics perceive CAT as a reminder to prescribe TPT	**Fear for over-prescribing** (mis-trust of the system) – might resulted in under-prescribing

CHIP-TB - Intervention design

Home-based

Health extension workers (HEWs) conducted contact management in the HOME

- Intervention designed with input from
  - TB and HEWs programs
  - Implementing partners
  - Health facility managers
  - TB providers
  - HEWs
- TPT initiation and follow up task-shared between HEW and TB focal person
- Symptomatic children were referred to the facility for medical evaluation
- Integrated with other HEW services of care

CHIP-TB – Trial results

Primary Outcome	Home-based (95% CI)	Facility-based (95% CI)	Difference (95% CI) p-value	IRR (95% CI) p-value
Mean Number of Child Contacts aged < 15 years INITIATED on TPT per TB patient	1.70 (1.21, 2.18)	1.34 (0.81, 1.87)	0.36 (-0.30, 1.02) 0.27	1.24 (0.81, 1.89) 0.32

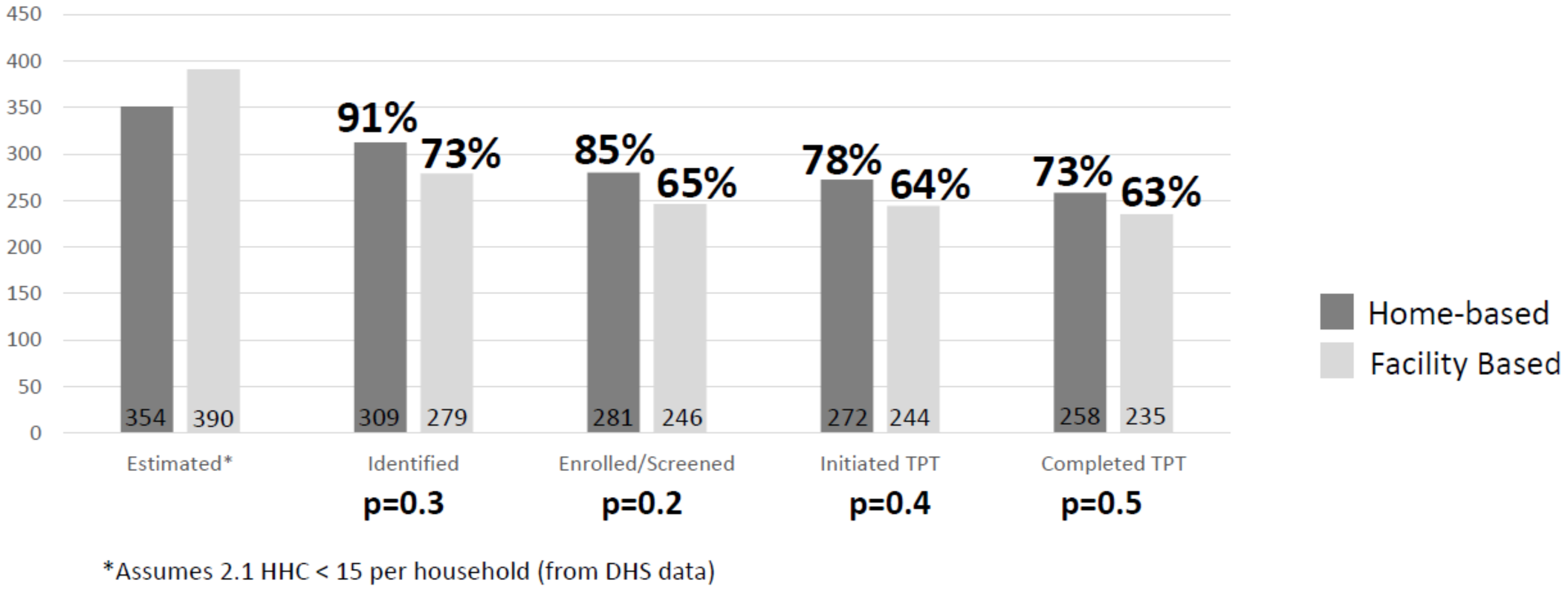
More child contacts < 15 years were initiated on TPT per TB patient in home-based vs facility-based arm, though this difference was not statistically significant

Secondary Outcome	Home-based (95% CI)	Facility-based (95% CI)	Difference (95% CI) p-value	IRR (95% CI) p-value
Mean Number of Child Contacts aged < 15 years IDENTIFIED per TB patient	2.03 (1.36, 2.70)	1.52 (0.96, 2.08)	0.51 (-0.29, 1.31) 0.20	1.24 (0.83, 1.87) 0.30

More child contacts < 15 years were identified with home-based vs facility-based arm, though this difference was not statistically significant

Salazar-Austin N, et al. (Submitted)

CHIP-TB – TPT continuum of care

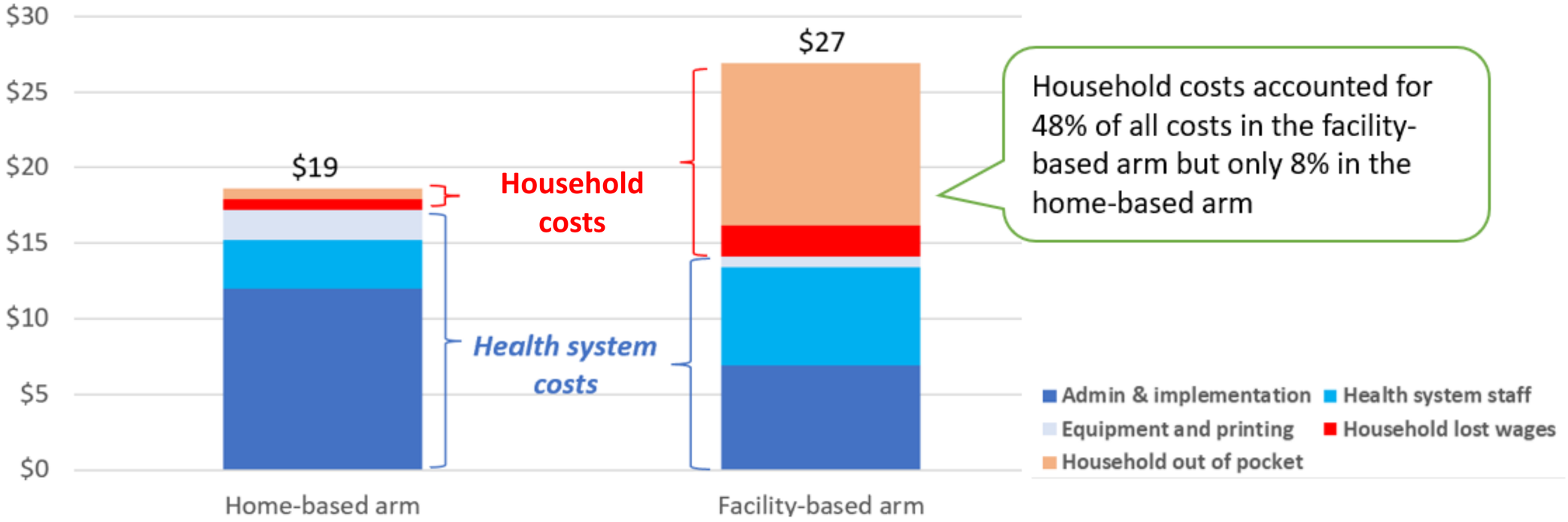


*Assumes 2.1 HHC < 15 per household (from DHS data)

There is no difference in the proportion of children who progressed through the care cascade in the home-based vs facility-based arm

Salazar-Austin N, et al. (Submitted)

CHIP-TB – Cost of TPT provision per household



Malhotra A, et al. (in preparation)

CHIP-TB – Implementation strategies of home-based TPT services

Barriers and Facilitators	Implementation Strategies	Needed to support implementation
Facilitators • Reduces caregiver burden (time, cost, etc.) • Home-based contact investigation will increase identification of household contacts • Home-based programming elevates importance of TPT in individual households and in the community • Reduced transmission of communicable illness in the health center (TB, COVID-19 etc.)	1. Task-sharing contact investigation and TPT management among HEW and TB focal person 2. Service integration to offset increased HEW workload 3. Community awareness campaigns to improve family-level acceptability of intervention and TPT	• Education on TB infection & TPT for HCWs, caregivers and community • Training on intervention protocols and implementation to HEWs, TB focal persons, pharmacists, etc. • Supportive supervision of HEWs to ensure fidelity to intervention and maintenance of clinical sills • HEW medical record for family folder • Clinical support tools to assist with decision making • Registration book • Referral papers • Portable scale • Personal protective equipment • Transport for HCWs • Drug forecasting and ordering
Barriers • Concern that necessary equipment for adequate contact investigation will not be available in the household • HEWs lack transportation or adequate reimbursement to make home visits in rural areas • Overworked, understaffed health extension program • Home-visits are potentially stigmatizing • Increased access to TPT may result in drug stock outs		

Salazar-Austin N, BMC Health Services Research 2024

Conclusions

- From CAT we have learned that other barriers for TPT uptake among PLHIV seems more important than making TPT prescribing more routine. However, those HCWs who used the CAT intervention were generally satisfied with the new approach and felt the added value -> TPT prescribing default option in EMR in Malawi

- From CHIP-TB we have learned that it´s feasible, acceptable, and effective to decentralize contact investigation and TPT management to the household level, using a task-shared approach between community health workers and facility-based TB focal persons. This family-centered approach could help expand access and increase affordability to TPT for millions of children exposed to TB in their homes.

Acknowledgements

- Unitaid
- National, regional, and district program staff
- Study staff
- HEWs Ethiopia
- JHU, Aurum, WHO, TAG, CHAI

Engaging Private Health Sector in Delivering Short Term TB Preventive Treatment (TPT)

Dr. Vijayashree Yellappa

Division of TB Elimination and Health Systems Innovations

KNCV Tuberculosis Foundation

Challenges

COMMUNITY RELATED

- Limited engagement of communities
- Reluctance

PROGRAM RELATED

- Low number of contacts reported
- Limited availability of diagnostic tool for TBI
- INH stock out

PROVIDER RELATED

- Limited adaption of diagnostic tool for TBI
- Delayed initiation
- Missed opportunities

What is Unknown

1. Private providers' participation is sub – optimal in short term TPT delivery

2. What are the enablers and challenges of engaging the private sector in TPT implementation ?

What is Private Health Sector

"Comprising all providers who exist outside the public health sector, whether they are philanthropic or commercial, and whose aim is to treat illness or prevent disease"

	Formal providers	Informal providers
For - profit	• Qualified providers having clinics/polyclinics, nursing homes, and super speciality hospitals • Private Laboratories and Radio Imaging	• Providers formally trained in traditional medicine, but practising modern medicine • Informal providers, practising with no training whatsoever (including retail pharmacists)
Not for- Profit	• Faith based hospitals • Charitable hospitals	• Voluntary health Workers

Private healthcare dominates in most of the countries with the highest TB burden

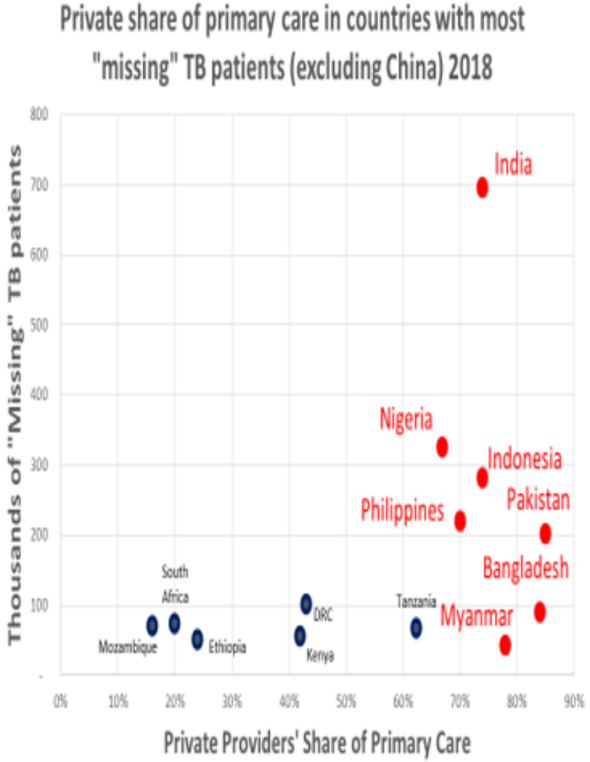
In **7** countries

with **62%** of the total missing cases in 2018,

private providers account for **65%-85%** of initial care-seeking,

yet they contributed just **23%** of TB notifications,

equivalent to just **16%** of estimated incidence.



Patient Preferences-Public vs Private

'Missing People' - Out of 10 million people who fell ill with TB in 2017, only 6.4 m were notified (3.6 m cases were not notified)

Two third of people preferred private care providers for initial consultation.

Only 19% of total TB cases were notified from private providers (equivalent to just 12% of estimated incidence)

Source: *Engaging private health care providers in TB care and prevention: a landscape analysis. WHO; 2018*

Findings from Patient Pathway Analysis

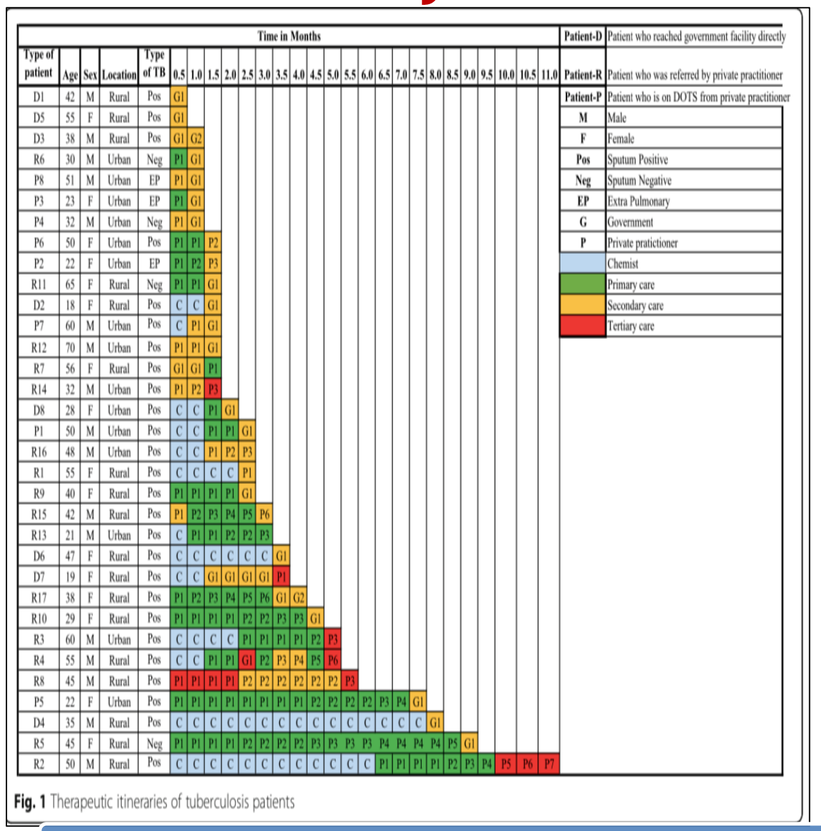
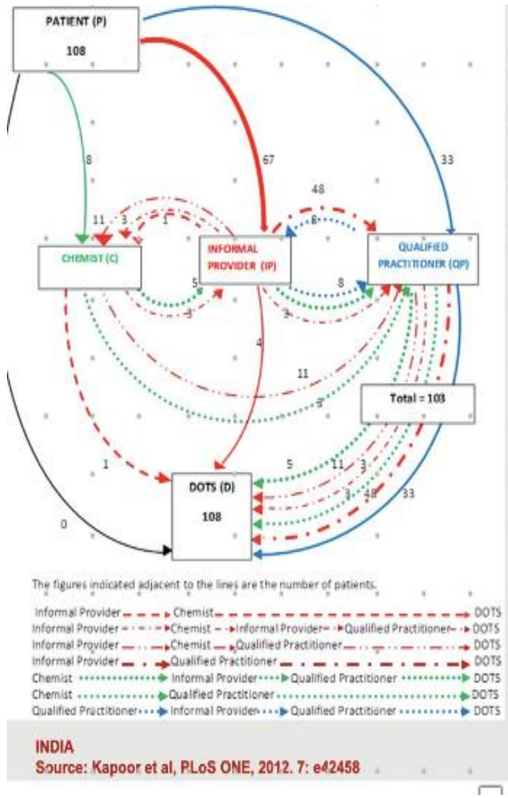
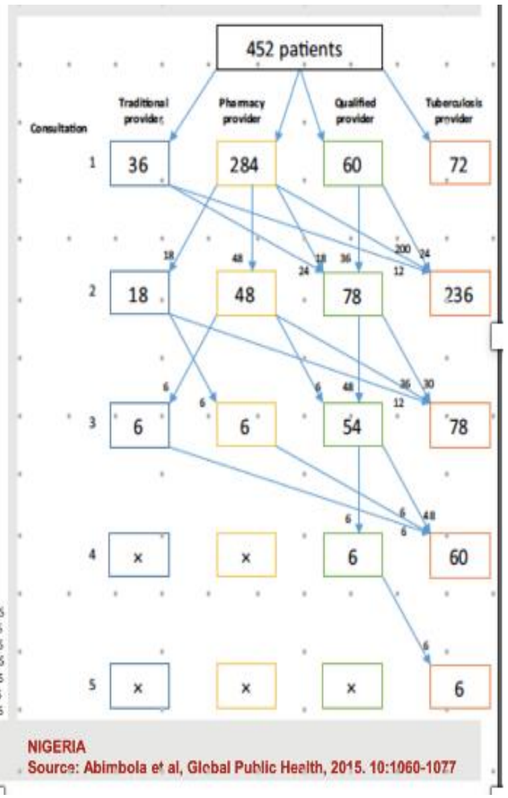


Fig. 1 Therapeutic itineraries of tuberculosis patients



INDIA
Source: Kapoor et al, PLoS ONE, 2012. 7: e42458



NIGERIA
Source: Abimbola et al, Global Public Health, 2015. 10:1060-1077

- Long cascade of care
- Nature of care not standardised
- Lack of notifications
- High out of pocket expenditure
- Lack of adherence support

Partnering with private providers is a key strategy in many NSP for TB

WHO Guidelines for TB PPM (Public Private Mix)

10 August 2023

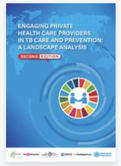
Developing enhanced TB public-private mix (PPM) data dashboards in high PPM priority countries to ensure...

Download Read More

24 August 2022

Guide to develop a national action plan on public-private mix for tuberculosis prevention and care

Download Read More



21 May 2021

Engaging private health care providers in TB care and prevention: a landscape analysis, second edition

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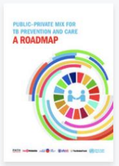


18 August 2020

Public–private mix for TB prevention and care: a roadmap

Download Read More

11 December 2015

Framework for the engagement of all health care providers in the management of drug resistant tuberculosis

Download Read More

1 December 2015

A situation assessment tool to engage all relevant care providers in drug-resistant tuberculosis (DR-TB)...

Download Read More

24 September 2015

Best practices in engagement of all health care providers in the management of drug resistant tuberculosis

Download Read More

15 February 2010

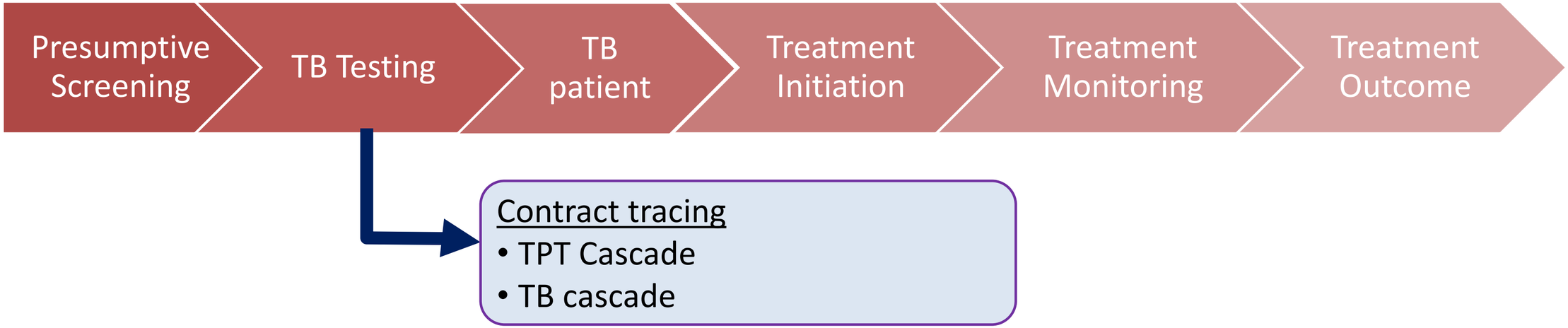
Public-private mix for TB care and control : a toolkit

Download Read More

PPM refers to engagement by the National TB Programme with private sector providers who provide TB care and services

Source: https://www.who.int/news-room/questions-and-answers/item/public-private-mix-ppm-for-tb-care-and-control

Private Sector Contribution in TB Care Cascade - Evidence



- Enhances quality of diagnosis, treatment, decentralise and make treatment conveniently accessible for patients
- Increases case detection and reduce diagnostic delays
- Offers improved and equitable access to TB care for all patients
- Reduces out-of-pocket expenditure
- Ensure gathering of essential epidemiological data

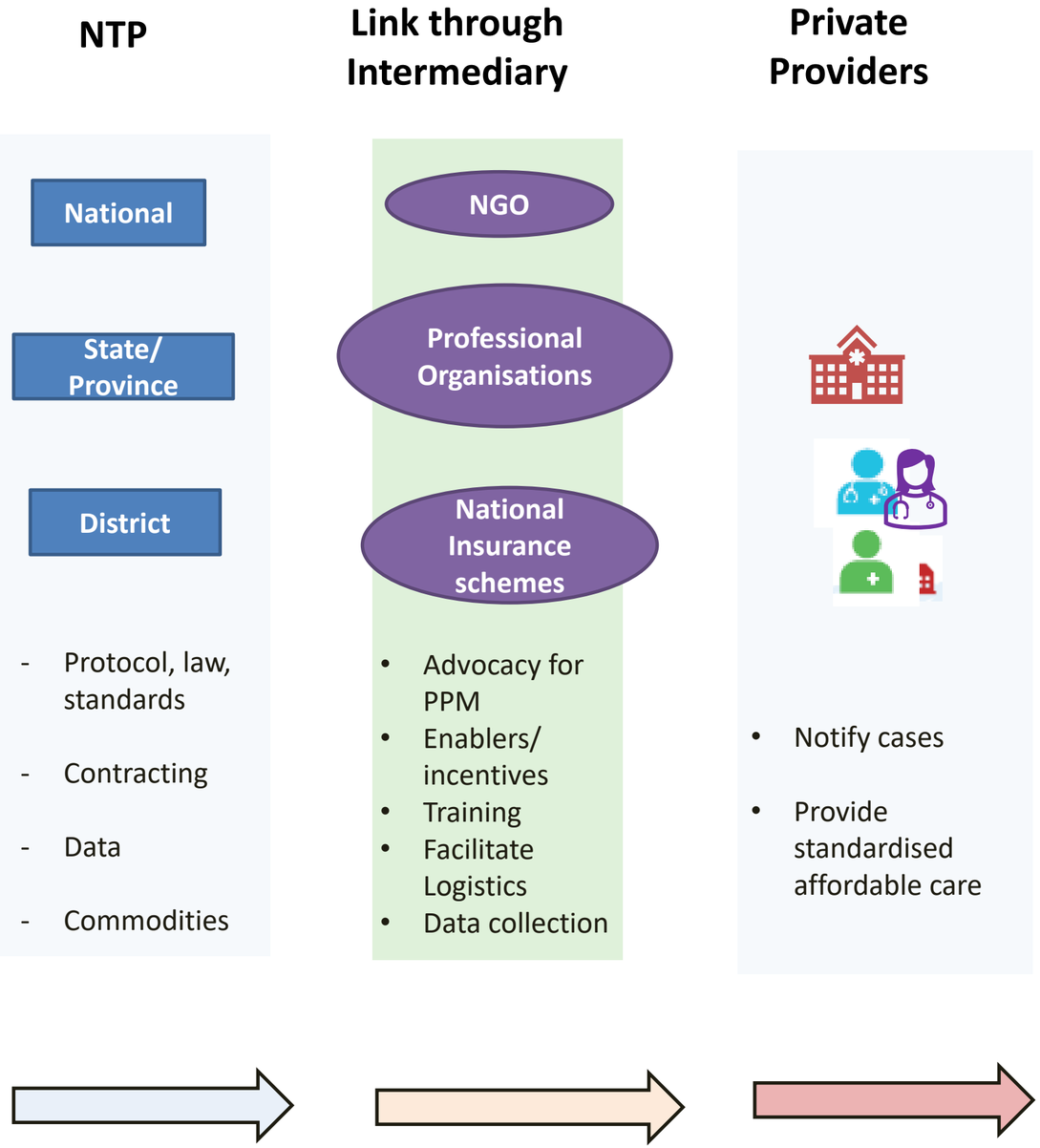
Patient should be at the centre of every partnership option

PPM TB Service Delivery Models: Linking Providers

- Intermediary Linkage role
- TB awareness, engagement, training, data, quality, enablers/ incentives
- Logistics/ facilitate access to commodities (TB diagnostic tests, medicines, supplies)
- Intermediary organizations (e.g. India, Bangladesh, Pakistan, Myanmar, Nigeria)

- Professional Association
  - Pulmonology, chest physicians (e.g. Indonesia)
  - Pharmacy associations (e.g. Nepal)

- Health insurance schemes (Philippines and Indonesia)



Market-based approaches

Strategies	Definitions	Objectives
Contracting	Purchasing services from private providers, and applying benchmarks for the types of services provided, quality of care, amount of services and/or health outcomes	Increase range of choice and encourage more efficient and higher quality services
Social marketing	Using commercial channels, techniques and communications approaches to market products with a public health benefit	Increase population coverage and effectiveness of products with a public health benefit
Social franchising	Using commercial channels, techniques and communications approaches to market networks of service providers	Substantially increase reach of goods and services with a public health benefit

Legal/Administrative Approaches

Strategies	Definitions	Objectives
Accreditation/ certification	Setting and enforcing standards- organisations	Raise standards of care/health outcomes/efficiency
Licensing	Setting and enforcing standards- individual providers	Raising standards of individual practitioners by setting and enforcing criteria for practice
Pricing mechanisms	Setting, monitoring and enforcing prices of drugs, devices, medical consultations, etc	State monitors and enforces price of essential drugs and medical technology
Technology regulation	Formal state approval and reimbursement structures, process and enforcement	State controls safety, efficacy and cost of health care by regulating availability/sale of pharmaceuticals and medical technology
Market regulation	Includes anti-monopoly/competition laws, consumer protection mechanisms and enforcement	State protects citizens from (high) monopoly pricing

Global TB PPM Dashboard

PPM Typology
Standardize definitions

- Ownership: public, private for profit and faith-based organizations
- Health facility classification: community, primary, secondary and tertiary

TB PPM Indicators

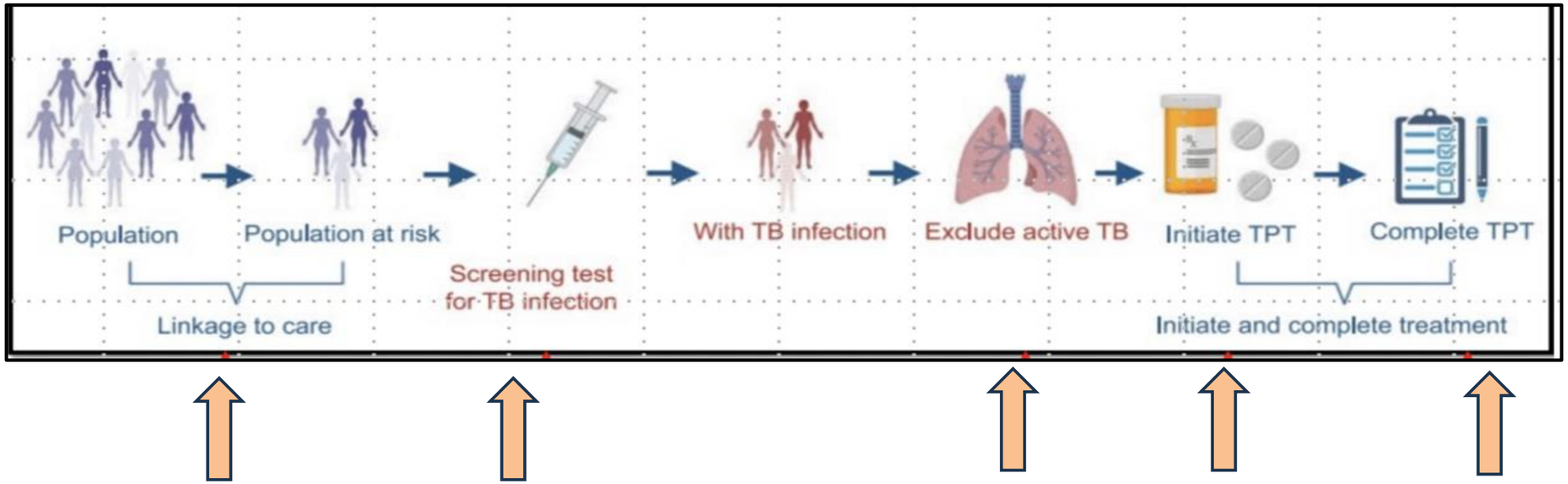
- Increase scope of PPM indicators to be reported globally
- Indicators relevant along the TB care cascade

Category	Indicator
Outcome	Successfully treated
Service Coverage	Initiated on TPT
	Received program drugs
	Bacteriologically confirmed
	Testing bacteriologically confirmed for drug resistance
	Testing for drug resistance (WRD)
	Presumptives tested with WRD
Surveillance	Presumptives TB patients
	Notified TB Patients
Provider coverage	Providers active
Other denominators	Estimated TB Incidence
	Estimated Population

7 PPM Priorities Countries

Bangladesh,
India,
Indonesia,
Kenya,
Nigeria,
Pakistan, and
The Philippines

How to Make TPT Integral to TB PPM Efforts



Aim: Making Short-term TB preventive treatments accessible

Challenges

- PP reluctance and scepticism
- Lack of awareness
- Lack testing facilities for TB infection
- Fragmented healthcare systems
- Lack of policies to engage private sector

The Road Ahead – Call for Action

1. How to improve access and sustainability of short term TPT in private sector ?

2. What are the modalities to foster collaborations between public health programs and private providers?

3. How to strengthen policy frameworks to support Private providers in TPT implementation?

4. What works for whom? And Why ?

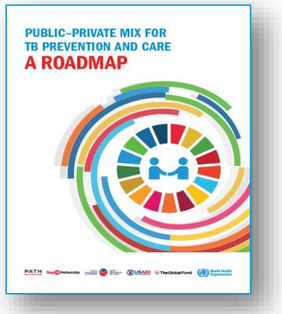
1. Documentation of TPT policies
2. Mechanisms in place to engage private sector (HR, Funding, etc)

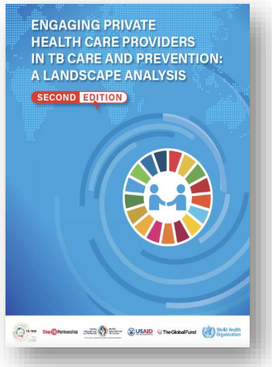
Insights into provider's practices, challenges and enablers for TPT implementation

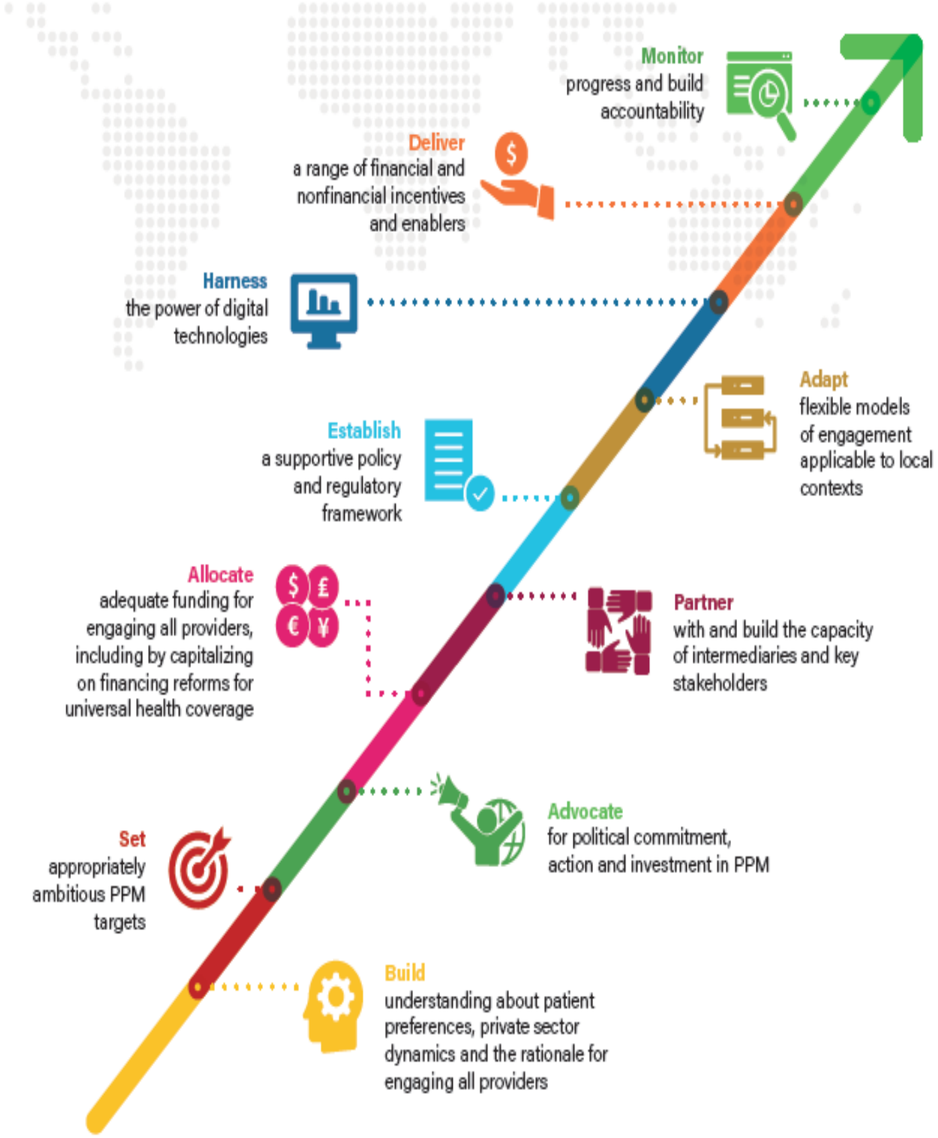
Development of a strategic flexible models to engage private sector in TPT implementation

REACHING THE MISSING MILLIONS THROUGH PPM FOR TB PREVENTION AND CARE

PPM ROADMAP
10 key priorities for action







PPM Data dashboards
for enhanced action and accountability to end TB *(https://www.who.int/teams/global-tuberculosis-programme/public-private-mix-data-dashboards)*

TB PPM Learning Network

TB•PPM Learning Network
Quality TB care for all people by all providers

www.tbppm.org

Pioneering Pathways: Implementing shorter TB Preventive Treatment, Populations at risk and more.

Learn more at:

kncvtbc.org

auruminstitute.org

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Thank you

Unitaid SAVE LIVES FASTER

IMPAACT4TB PREVENTING TB TO END TB

KNCV TB PLUS

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