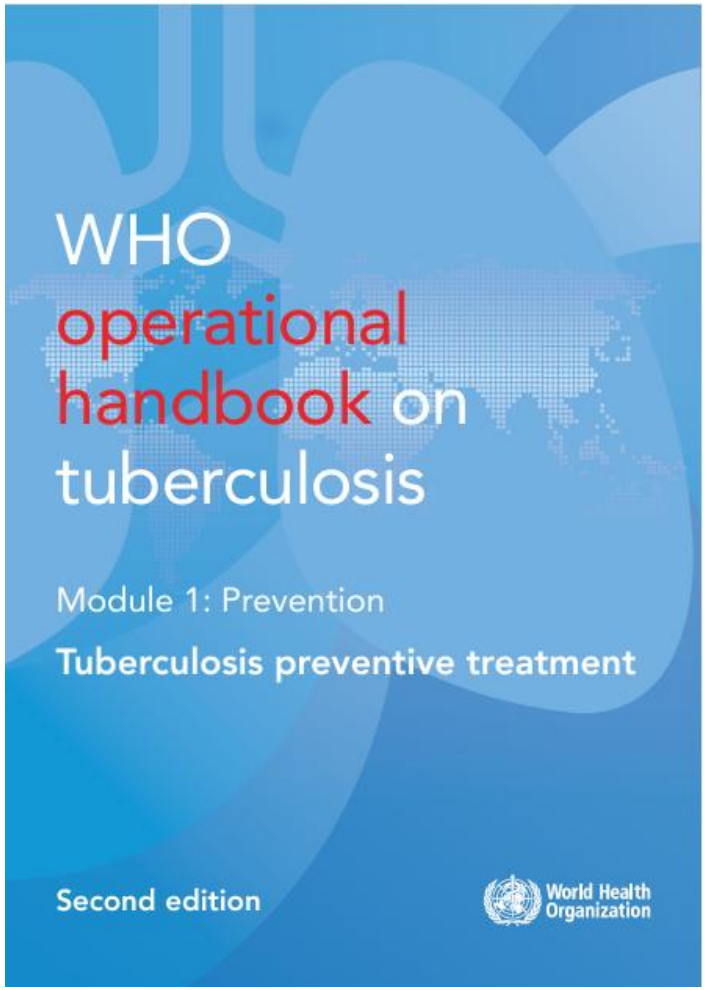
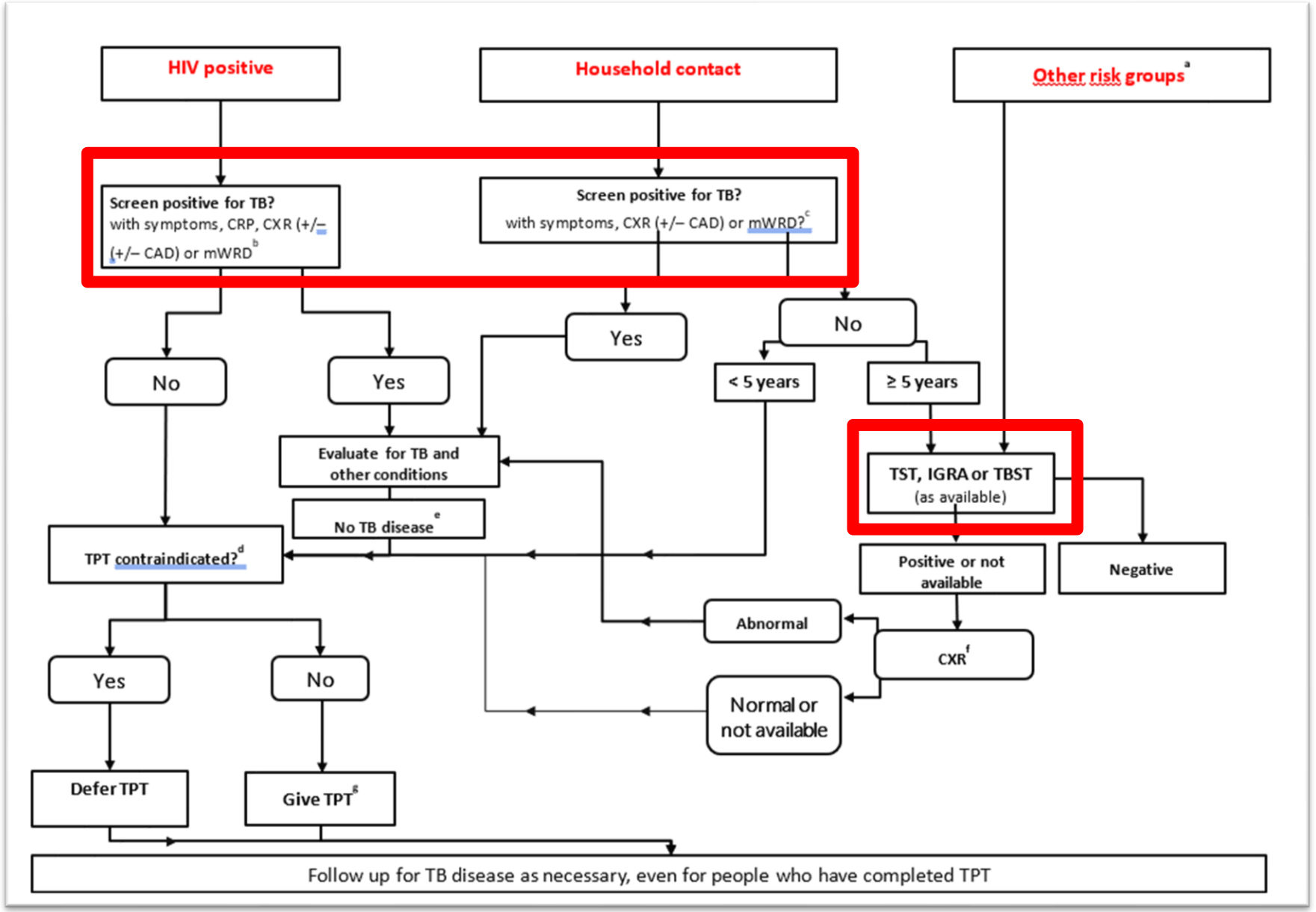
TPT operational handbook

- Evidence to address FAQs
- Provides **complementary details** on TPT critical to the implementation of different elements of PMTPT
  - contact tracing
  - drug dosages
  - drug-drug interactions
  - safety monitoring/ management of adverse events
  - management of TPT interruptions
  - adherance monitoring
  - programme indicators



https://www.who.int/publications/i/item/9789240097773

Combined algorithm for screening and testing before TPT



Drug dosage for TPT according to body weight band

	Amount of tablets or solution by body weight band (in kilograms)												
	3 – 5.9 <3 months	3 – 5.9 ≥3 months	6 – 9.9 <6 months	6 – 9.9 ≥6 months	10 – 14.9	15 – 19.9	20 – 24.9	25 – 29.9	30 – 34.9	35 – 39.9	40 – 44.9	45 – 49.9	≥50
Three month of weekly rifapentine plus isoniazid (3HP)													
Isoniazid 100 mg dt	0.6 (6 ml)	0.7 (7 ml*)	1	1.5	2.5	3	4.5	4.5	6	6	7.5	7.5	9
Isoniazid 300 mg tab	-	-	-	-	-	1	1.5	1.5	2	2	2.5	2.5	3
Rifapentine 150 mg dt	0.5 (5 ml)	0.7 (7 ml)	1.5	1.5	2	3	4	4	5	6	6	6	6
Rifapentine 300 mg tab	-	-	-	-	-	1.5	2	2	2.5	3	3	3	3
Rifapentine 300mg and Isoniazid 300mg FDC tab[c]	-	-	-	-	-	1	1.5	2	2.5	3	3	3	3
One month of daily rifapentine plus isoniazid (1HP)													
Isoniazid 300 mg tab	-	-	-	-	-	-	-	1	1	1	1	1	1
Rifapentine 300 mg tab	-	-	-	-	-	-	-	2	2	2	2	2	2
Six month daily levofloxacin (6Lfx)													
Levofloxacin 100 mg dt	0.5	1	1	1.5	2	2.5	3	3.5	-	-	-	-	-
Levofloxacin 250 mg tab	0.25 (2.5 ml)	0.5 (5 ml)	0.5 (5 ml)	1 (10 ml)	1	1.5	1.5	2	2	2	2	2	3
Levofloxacin 500 mg tab	-	-	-	-	-	-	-	1	1	1	1	1	1.5

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Secondary safety analyses

	LfX (n=1412)	Placebo (n=1431)	Risk ratio (95% CI)	P	P for test of heterogeneity
Grade 3 or above adverse event*					
VQUIN	29 (3.0%)	19 (2.0%)	1.55 (0.87 , 2.76)		
TB-CHAMP	14 (3.1%)	23 (4.9%)	0.67 (0.34 , 1.31)		
Overall	43	42	1.07 (0.70 , 1.65)	0.75	0.06
Grade 3 or above adverse event at least possibly related to study drug					
VQUIN	10 (1.0%)	2 (0.2%)	5.26 (1.16 , 23.95)		
TB-CHAMP	4 (0.9%)	8 (1.7%)	0.53 (0.16 , 1.70)		
Overall	14	10	1.46 (0.65 , 3.26)	0.36	0.02
Grade 3 or above SAEs*					
VQUIN	20 (2.1%)	12 (1.3%)	1.72 (0.85 , 3.49)		
TB-CHAMP	8 (1.8%)	7 (1.5%)	1.23 (0.45 , 3.35)		
Overall	28	19	1.54 (0.87 , 2.74)	0.14	0.59

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Included participants who took at least one study drug dose.

** Up to 21 days after last study drug dose.*

END TB

Secondary safety analyses

	LfX (n=1412)	Placebo (n=1431)	Risk ratio (95% CI)	P	P for test of heterogeneity
Discontinuation of study treatment due to AE(s) of any grade					
VQUIN	71 (7.4%)	11 (1.1%)	6.43 (3.42 , 12.09)		
TB-CHAMP	6 (1.3%)	1 (0.2%)	5.25 (0.64 , 43.13)		
Overall	**77**	**12**	**6.32 (3.43 , 11.63)**	**<0.001**	**0.86**

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END TB

Secondary safety analyses

	LfX (n=1412)	Placebo (n=1431)	Risk ratio (95% CI)	P	P for test of heterogeneity
Musculoskeletal AE of any grade during overall study follow-up (arthritis, arthralgia, or tendinopathy)					
VQUIN	**220 (22.9%)**	32 (3.3%)	7.02 (4.67 , 10.56)		
TB-CHAMP	6 (1.3%)	4 (0.9%)	1.35 (0.36 , 5.06)		
Overall	226 (16%)	36 (2.5%)	6.36 (4.30 , 9.42)	<0.001	0.01

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Levofloxacin adverse events in V-QUIN and TB- CHAMP

- Important difference in risks between children and adults, **good tolerance in children**
- One or more adverse events of **any grade reported in about 32% adolescents and adults** in V-QUIN trial, most grade 1 or 2.
- **Serious adverse events infrequent**, about 1% grade 3 or 4 events not statistically significantly different from placebo arm
- Lfx associated with more **musculoskeletal events** (arthritis, arthralgia or tendonitis) in adolescents and adults, mostly grade 1 or 2.
- **Treatment discontinuation is uncommon**, more frequent among adolescents and adults
- Common adverse events are **dizziness, headache, nausea and abdominal pain**

Cost of DR-TPT

- **Adult**: US$ 9 (Lfx-500 mg)
- **Child**:
  - US$ 5 (Lfx-250 mg non-dispersible)
  - US$ 44 (Lfx-100 mg dispersible)

(*although dispersible is more expensive, TPT is still cost-effective and in long-term net cost savings: TB CHAMP*)

DR-TPT in settings with high-quinolone resistance

- DR-TPT should be considered
- **Drug-susceptibility testing** of presumed source patient encouraged
- **If resistant to quinolones**, alternative TB drugs (e.g., ethionamide, ethambutol) may be considered per DST profile (less effective than 6Lfx).
- Results from the **PHOENIx trial**, in which 26 weeks of **delamanid** compared with isoniazid for household contacts (all ages) of MDR-TB patients expected in mid-2025.

Recording and reporting for the monitoring of PMTPT

1. **How many people are at risk** and could benefit from **TPT/DR-TPT**?
2. How many at-risk people were **evaluated** for TB disease or infection?
3. How many of those eligible **started** TPT/DR-TPT?
4. What were the main reasons for those eligible **who did not initiate** TPT?
5. How many of those initiating TPT/DR-TPT **completed** it?
6. For those who did not complete TPT/DR-TPT what were the main **reasons** (e.g., adverse drug reaction monitoring and management) ?

Prevent TB application

Prevent TB facilitates evaluation of TB contacts at both healthcare settings as well as at the community level. The system supports continuous monitoring of registered individuals across for tuberculosis screening and e treatment, capturing data from the initial rget population, registration, clinical ning, testing for tuberculosis infection, and e treatment. The platform also generates iders when any implementation gap is rehensive performance indicators to

Prevent TB Smart Setup

The national programme/project coordinators can use the smart setup to create a new progra captured at the stage of registration, service delivery and also create context specific alerts, a application in local context. The platform also allows the upload of historic data on index case the management of users and health facilities.

Link to Smart Setup | User manual | Video

Prevent TB Application

The application has two different interfaces which cater to healthcare providers and registere

Healthcare provider module

Healthcare workers can use this module to register new individuals from target populations a screening, test results or referral for tuberculosis preventive treatment. The different sections of the interface enable users to monitor the progress of their clients through the cascade of care for tuberculosis screening and preventive treatment.

Link to web application | Link for Android | Link for iOS |

Client module

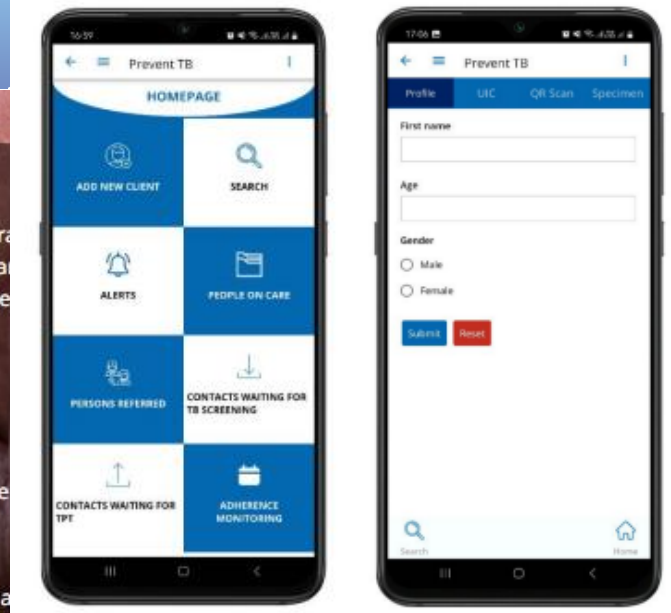
Individuals registered on the platform can use this module to a adherence and drug adverse events. Users can also communica

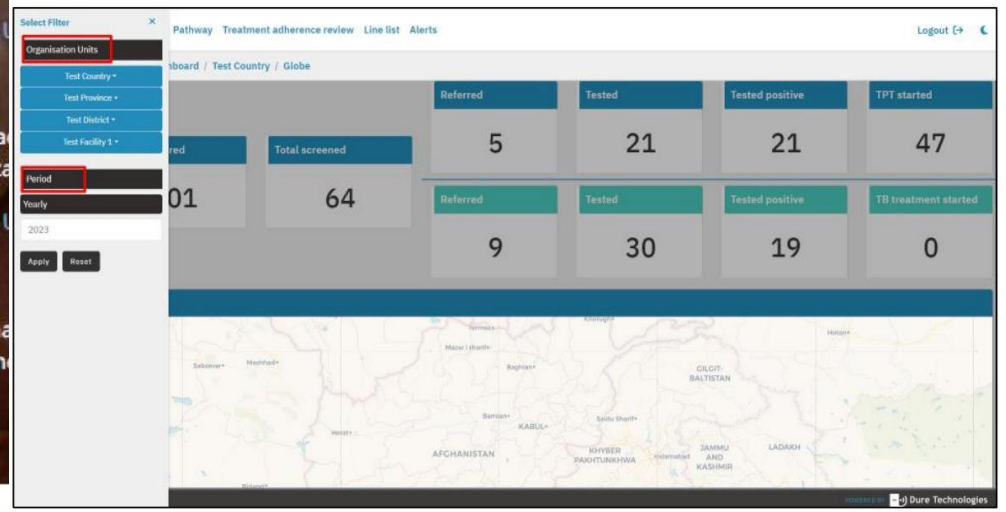
Link to web application | Link for Android | Link for iOS |

Prevent TB Dashboard

The dashboard allows data visualization through interactive cha programme managers in monitoring and evaluation of implem

Link to dashboard | User manual | Video





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https://www.who.int/activities/preventing-tb#app

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Consolidated Guidelines | Operational Handbooks | Training Catalogue | Research and Innovation | English | Log in

WHO TB Knowledge Sharing Platform

Access the modular WHO guidelines on tuberculosis, with corresponding handbooks and training materials.

BETA Version

Ask TB KaSPar, the AI search assistant

Search the WHO TB KSP | AI Search

Drug Dosage Finder

Download WHO TB Knowledge Sharing Platform Application

Desktop Version | Mobile Version

Consolidated Guidelines

WHO guidelines provide the latest evidence-informed recommendations on TB prevention and care to help countries achieve the Sustainable Development Goals (SDGs) and the targets of the End TB Strategy.

Learn more →

Operational Handbooks

The WHO Operational Handbooks on tuberculosis provide users with practical "how to" guidance, with details essential for the proper implementation of the corresponding WHO guidance.

Learn more →

Training Catalogue

The WHO Training Catalogue on tuberculosis consists of online eLearning courses and other training materials to help users implement the corresponding WHO guidance.

Learn more →

Research and Innovation

WHO normative guidance on tuberculosis research and innovation seek to shape the research agenda and innovation landscapes to better detect, prevent and respond to tuberculosis.

Learn more →

Feedback

Photo: David Orr

https://tbksp.who.int/en

Programmatic implementation of DR-TPT- Health system costs

1. Develop/update **national guidelines** to incorporate DR-TPT
2. **Resource allocation** for scaling up DR-TPT
3. **Capacity building**, protocols for screening, baseline assessments, TPT, and management of adverse events
4. **Identification** of all contacts of DR-TB patients and systematic listing
5. **Rule out TB disease-** Symptom screening and clinical evaluation (Chest X-ray, CRP, mWRD)
6. **Testing** for TB Infection
7. **DST of the source case** especially in areas with high fluoroquinolone resistance
8. **Baseline assessment**: contraindications (tendon disorders, CNS conditions, pregnancy, known hypersensitivity)
9. Regular clinical **follow-up** (adverse event reporting)
10. **Adherence support**: counseling and support
11. **Monitoring/evaluation**: track patient outcomes, adherence rates, and adverse events

Acknowledgements

People affected by TB

National TB & HIV programmes

Guideline Development Groups

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Many other experts, donors

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