

Workshop to accelerate the implementation of the Three Is for HIV/TB and earlier initiation of ART in Southern Africa, March 14-18, 2011, Johannesburg, South Africa.

The New WHO guidelines on intensified TB case finding and Isoniazid preventive therapy and operational considerations

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Outline of presentation

- The WHO 12 point policy package and progress
- Progress in implementation in the eight countries
- Key barriers of scaling up of TB screening and IPT
- The 12 recommendations with evidence base
- Key operational issues
- Summary

The WHO 12 points TB/HIV policy package

A . Establish the mechanism for collaboration

1. TB/HIV coordinating bodies
2. HIV surveillance among TB patient
3. TB/HIV planning
4. TB/HIV monitoring and evaluation

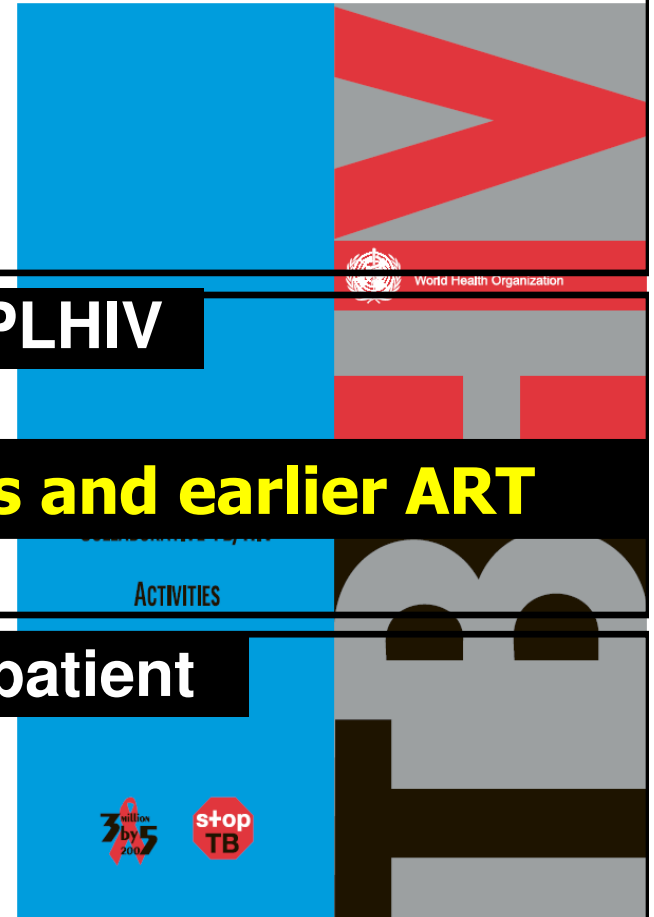
B . Decrease the burden of TB among PLHIV

5. Intensified TB case finding
6. Isoniazid preventive therapy
7. Infection control for TB

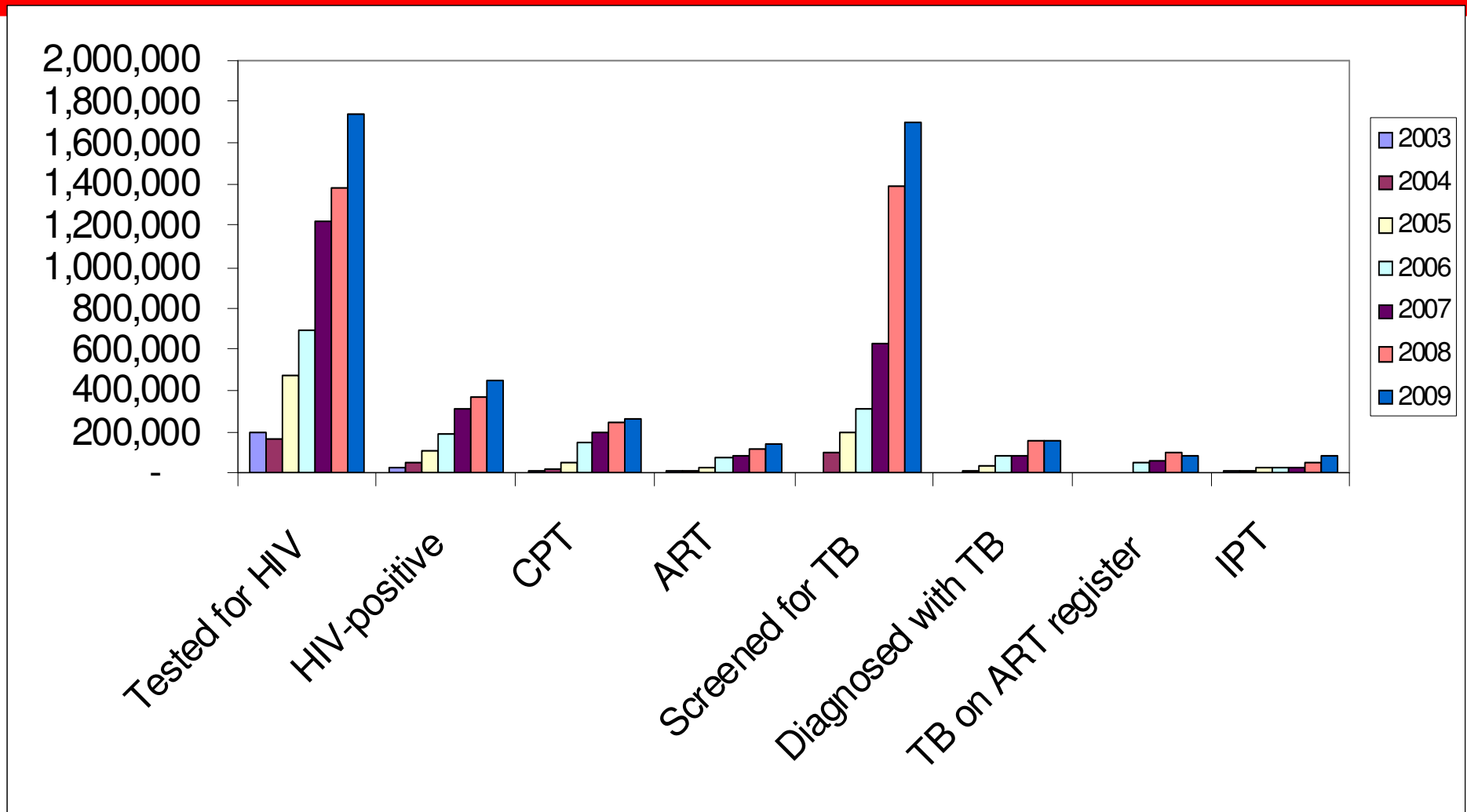
Three Is and earlier ART

C. Decrease burden of HIV among TB patient

8. HIV testing and counselling
9. HIV preventive methods
10. Cotrimoxazole preventive therapy
11. HIV/AIDS care and support
12. Antiretroviral therapy to TB patients.

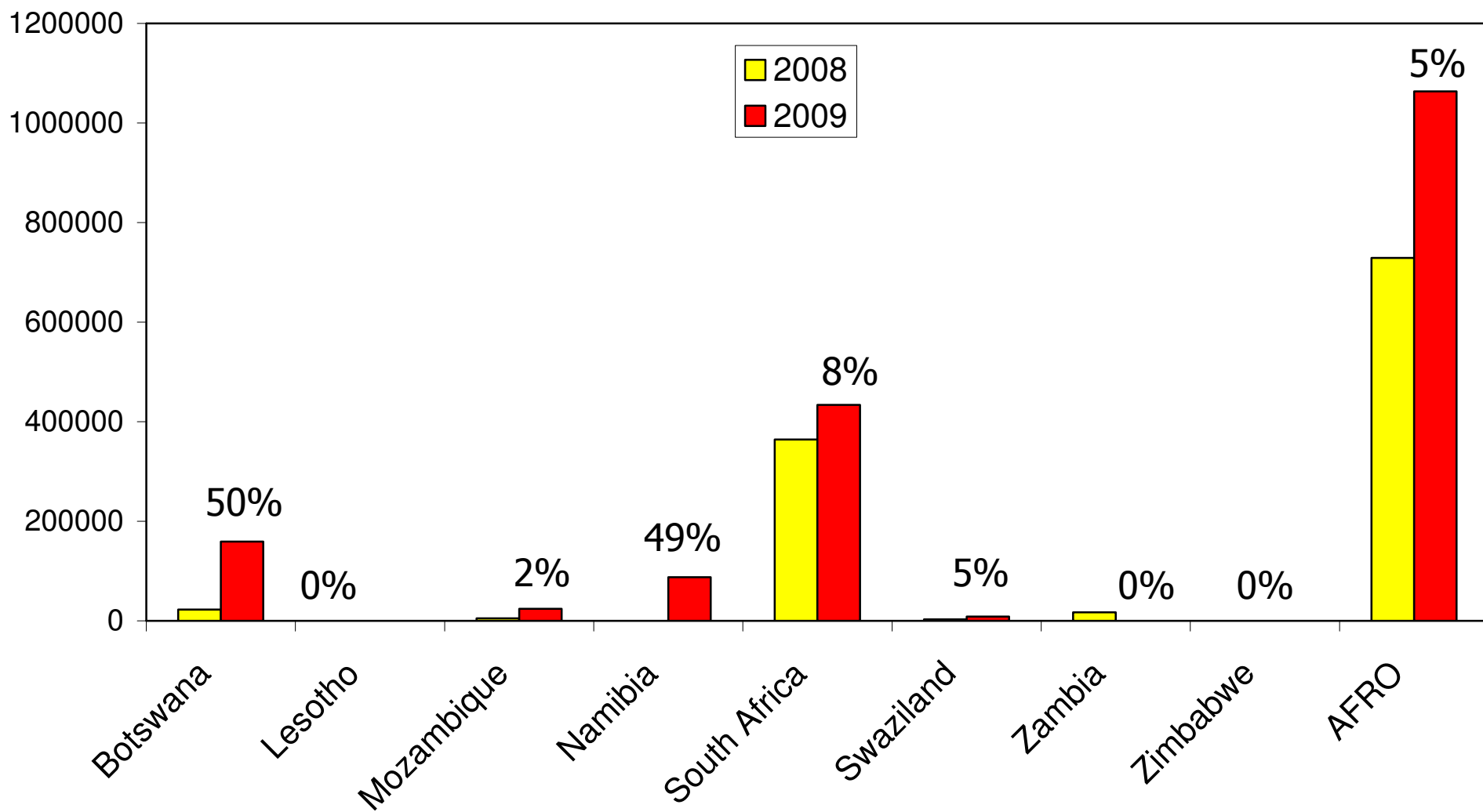


Progress of implementation 2003-2009



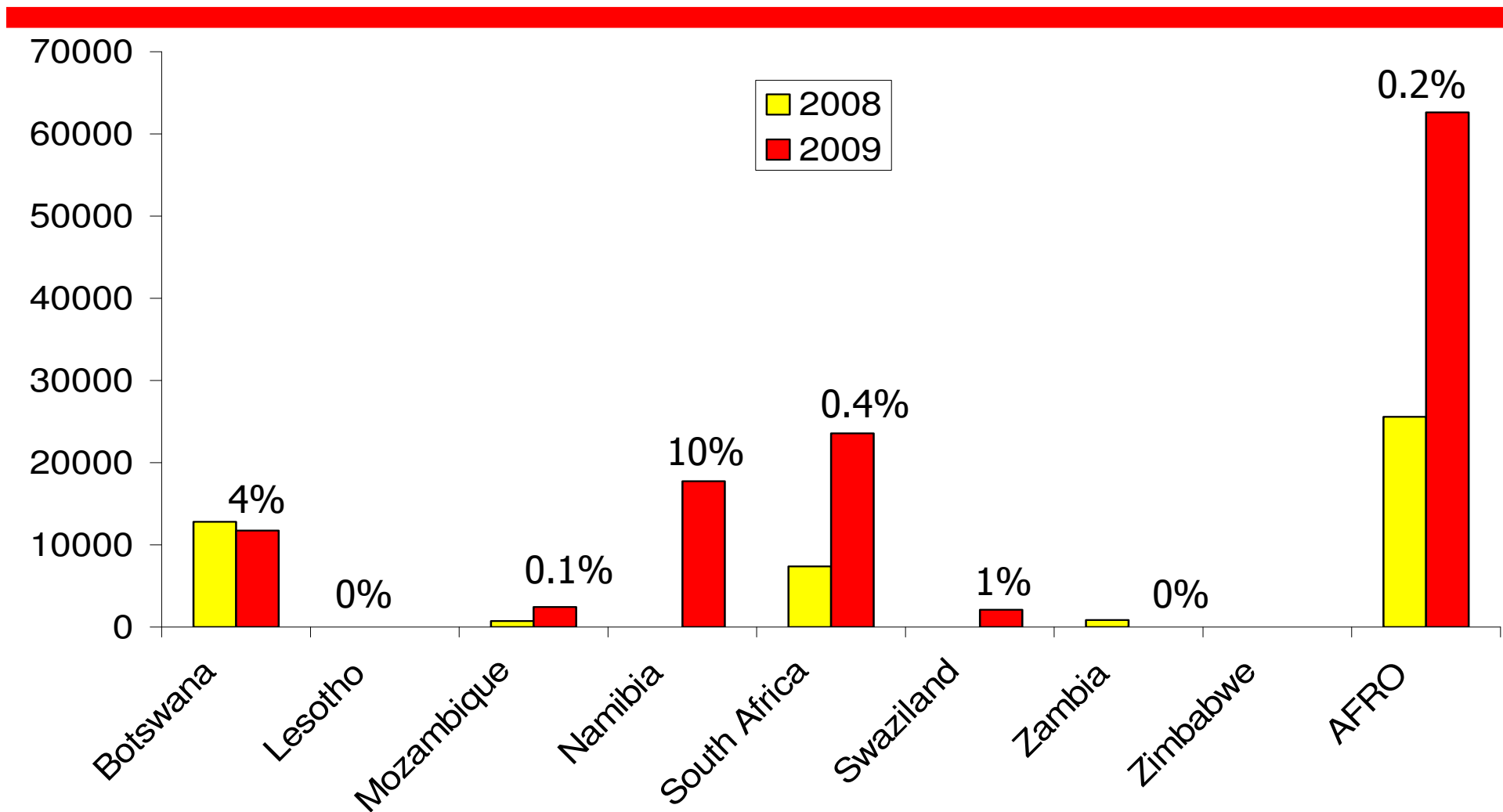
TB screening among PLHIV 2008-2009

(on top of bar: percentage of all PLHIV screened for TB in 2009)

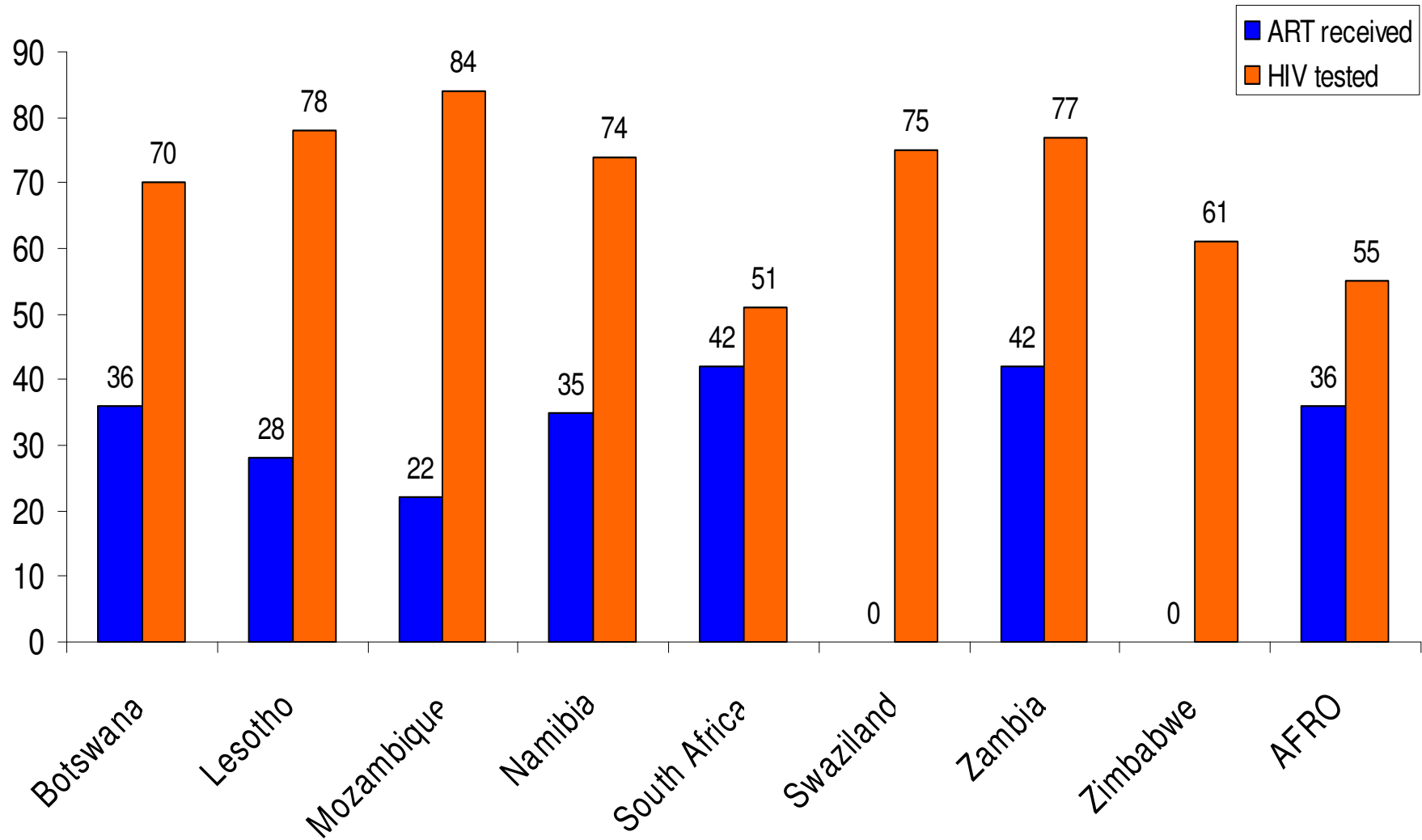


IPT provision among PLHIV 2008-2009

(on top of bar: percentage of all PLHIV provided IPT in 2009)



Percentage of TB patients HIV tested and ART received 2009



Policies in Three Is and earlier initiation of ART

(Courtesy of Soumya Gupta. WHO HIV Department)

	ICF	IPT	TB IC	ART for PLHIV*	ART for TB patients*
Lesotho	✓	✓	✓	≤ 350	All
Botswana	✗	✓	✓	≤ 250	All
Zambia	✓	✓	✓	≤ 350	All
Zimbabwe	✓	✗	✓	≤ 350	All
Mozambique	✓	✓	✓	≤ 250 (update in process)	≤ 350 (update in process)
Namibia	✓	✓	✓	≤ 350	All
Swaziland	✓	✓	✓	≤ 350	All
South Africa	✓	✓	✓	≤ 200	≤ 350

* Current WHO recommendation ≤ 350 for PLHIV and for all TB patients with HIV

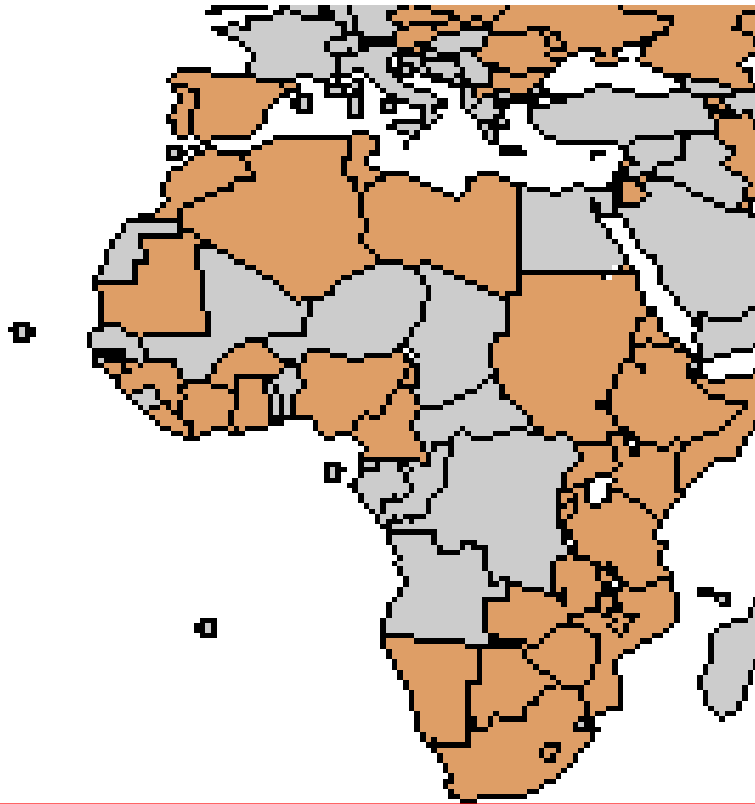
Analysis of current National ART, TB and TB/HIV guidelines (2007-2010)

Vague global policy guidance and perceptions (1993-2009)

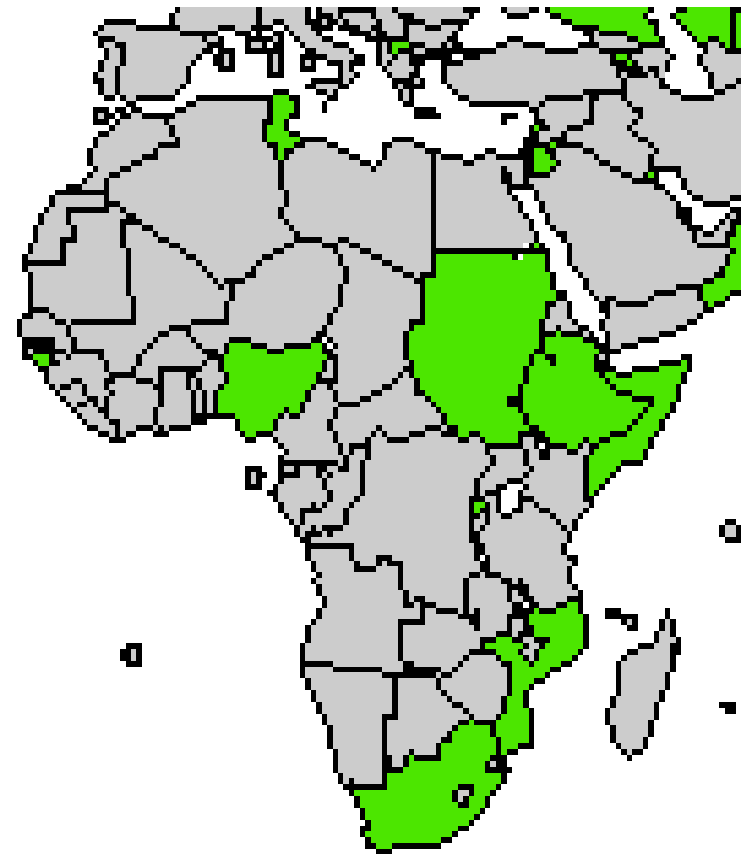
- IPT should be given to TST positives
- Mandatory CXR to "exclude active TB"
- How to exclude active TB before IPT?
- INH exclusive "property" of NTP
- Fear of INH drug resistance
- Weak monitoring and evaluation system
- Weak pre-ART care and neglect to TB

What are the operational barriers?

Mismatch between national policy and implementation



National policy on TB screening in 2006



Reporting on TB screening in 2006

What are the operational barriers?

IPT policy in Uganda, 2006



THE REPUBLIC OF UGANDA

Eligibility criteria for an institution to offer IPT

The following are the minimum requirements for an organization/institution to offer IPT

Human resource:

- Medical Officer
- Laboratory assistant
- Trained counselor
- Pharmacy technician
- Adherence supporters

Infrastructure:

- Functional Laboratory
- X-ray or access to x-ray services
- Counseling room/space
- Consultation room

Equipment and logistics:

- Facilities for TB microscopy
- Facilities for skin testing (mantoux)
- Cold chain system
- Facilities for HIV testing
- Sustainable supply of anti-TB drugs including Isoniazid
- Sustainable supply of HIV test kits

Other key issues:

- If an organization has a TB default rate of greater than 5% it will not be eligible to provide IPT

What are the operational barriers?

Development of a Standardized Screening Rule for Tuberculosis in People Living with HIV in Resource-Constrained Settings: Individual Participant Data Meta-analysis of Observational Studies

Haileyesus Getahun^{1*}, Wanitchaya Kittikraisak², Charles M. Heilig³, Elizabeth L. Corbett⁴, Helen Ayles^{4,5}, Kevin P. Cain³, Alison D. Grant⁴, Gavin J. Churchyard⁶, Michael Kimerling⁷, Sarita Shah⁸, Stephen D. Lawn^{4,9}, Robin Wood⁹, Gary Maartens¹⁰, Reuben Granich¹, Anand A. Date³, Jay K. Varma^{2,3}

Inclusion criteria for studies

- Collected sputum specimens from PLHIV regardless of signs or symptoms;
- Used mycobacterial culture of at least one specimen to diagnose TB and;
- Collected data about signs and symptoms.

All participants in 12 datasets
n=29,523

29,523

Participants with HIV
n=10,057

Participants without HIV or with
unknown status
n=19,466

10,057

Participants not receiving TB
treatment
n=9,870

Participants receiving treatment for
latent or active TB
n=187

Participants with known sputum
smear results
n=9,710

Participants with unknown smear
result, or smear+ and MTB- or NTM+
n=160

Participants with known TB status
n=9,626

Participants in 12 datasets
n=84

9,626

Participants evaluable on 5
symptoms of interest
n=8,148

Participants not evaluable on 5
symptoms of interest
n=1,478

Participants with MTB+ culture
n=495

Participants with MTB- culture
n=7,653

Top five best performing rules (1 of m) in all subjects (n = 8173)

Combination rule	Sen (%)	Spe (%)	LR-	NPV (95% CI) 5% TB prevalence
CC, F, NS, WL	79	49	0.42	97.7 (97.4-98.0)
H, F, NS, WL	76	53	0.46	97.6 (97.2-98.0)
CC, F, WL	74	54	0.48	97.5 (97.1-97.9)
CC, NS, WL	73	59	0.49	97.5 (97.1-97.8)
CC, F, NS	73	61	0.44	97.7 (97.4-98.0)

CC: cough in the last 24 hours; F: Fever; H: Haemoptysis; NS: Night sweats; WL: Weight loss

Top five best performing rules (1 of m) in all subjects with abnormal CXR (n = 2805)

Combination rule	Sen (%)	Spe (%)	LR-	NPV (95% CI) 5% TB prevalence
CC, F, NS, WL, X	91	39	0.24	98.7 (97.1-99.5)
CC, F, NS, X	89	52	0.21	98.9 (97.6-99.5)
CC, F, WL, X	88	42	0.28	98.5 (96.9-99.3)
H, F, NS, WL, X	87	43	0.29	98.1 (97.3-98.6)
CC, NS, W,L X	87	45	0.29	98.6 (97.5-99.3)

CC: cough in the last 24 hours; F: Fever; H: Haemoptysis; NS: Night sweats; WL: Weight loss

Performance of the best rule (one of current cough, fever, night sweats or weight loss)

Setting	Sen (%)	Spe (%)	LR- (%)	NPV (95% CI) 5% TB prevalence
Community	76	61	0.39	97.3 (96.9-97.7)
Clinical	89	30	0.38	98.3 (97.5-98.8)
CD4 < 200	94	22	0.29	98.9 (95.8-99.5)
CD4 ≥ 200	83	34	0.49	96.9 (95.1-98.0)

CC: cough in the last 24 hours; F: Fever; H: Haemoptysis; NS: Night sweats; WL: Weight loss

**Guidelines for intensified
tuberculosis case-finding
and isoniazid preventive
therapy for people
living with HIV
in resource-
constrained
settings**



HIVTB

Recommendation 1 : TB screening

Adults and adolescents living with HIV should be screened with a clinical algorithm and those who do not report any one of;

- current cough,
- fever,
- weight loss or
- night sweats

are **unlikely to have active TB** and should be offered IPT.

(Strong recommendation, moderate quality evidence)

Recommendation 2 : TB screening

Adults and adolescents living with HIV screened with a clinical algorithm and reported one of the following;

- current cough,
- fever,
- weight loss or
- night sweats

may have active TB and should be evaluated to TB and other diseases.

(Strong recommendation, moderate quality evidence)

Recommendation 3

Adults and adolescents who are living with HIV and:

- have unknown or positive TST status and;
- unlikely to have active TB

should receive IPT for **at least 6** months

(Strong recommendation, high quality evidence)

Recommendation 4

Adults and adolescents who are living with HIV in **settings with higher TB transmission** and:

- have unknown or positive TST status and;
- unlikely to have active TB

should receive IPT for **at least 36** months

(Conditional recommendation, moderate quality evidence)

Recommendation 5

- Tuberculin skin test is not a requirement for initiating IPT for people living with HIV
(Strong recommendation)

Recommendation 6

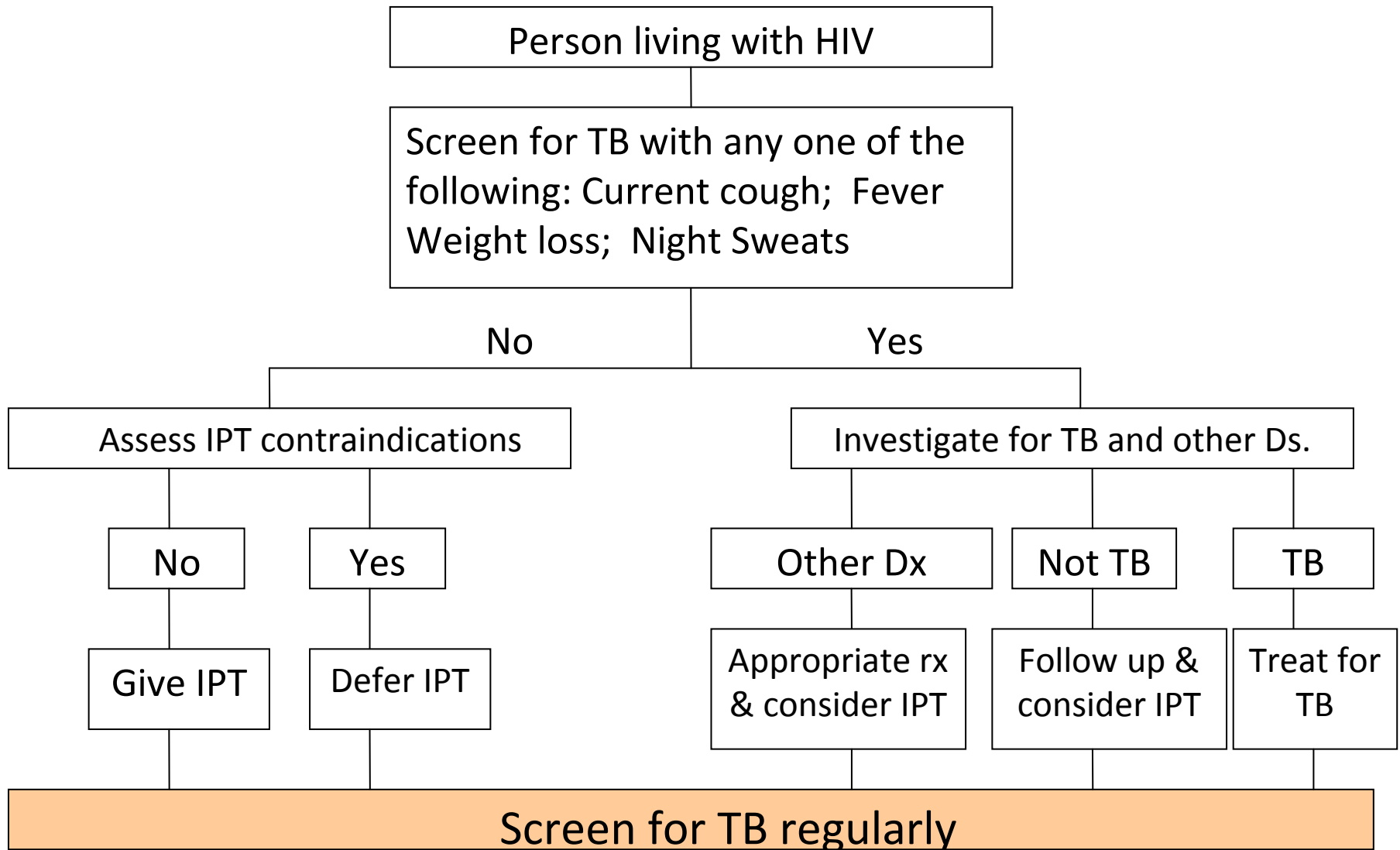
- Where feasible, TST can be used as people with a positive test benefit more from IPT than those with a negative test
(Strong recommendation)

Recommendation 7

Providing IPT to people living with HIV does not increase the risk of developing **INH resistant TB**. Therefore concerns regarding the development of INH resistance should not be a barrier to providing IPT.

(Strong recommendation, moderate quality evidence)

TB screening and IPT algorithm



Recommendation 8: TB screening in children

- Children living with HIV who **do not have poor weight gain***, **fever** or **current cough** are unlikely to have active tuberculosis TB.
(Strong recommendation, low quality evidence)

***Poor weight gain** is defined as reported weight loss, **or** very low weight (weight-for-age less than -3 z-score), **or** underweight (weight-for-age less than -2 z-score), **or** confirmed weight loss (>5%) since the last visit, **or** growth curve flattening

Recommendation 9: IPT in children

- Children living with HIV **who have any one of poor weight gain*, fever, current cough or contact history with a TB case** may have TB and should be evaluated for TB and other conditions. If the evaluation shows no TB, children should be offered IPT regardless of their age.

(Strong recommendation, low quality evidence)

***Poor weight gain** is defined as reported weight loss, **or** very low weight (weight-for-age less than -3 z-score), **or** underweight (weight-for-age less than -2 z-score), **or** confirmed weight loss (>5%) since the last visit, **or** growth curve flattening

Recommendation 10: IPT in children

- Children over 12 months of age who are living with HIV and who are unlikely to have active TB on symptom based screening and have no contact with a TB case should receive 6 months of INH preventive therapy (10mg/kg)

(Strong recommendation, moderate quality evidence)

Recommendation 11: IPT for infants

- Children less than 12 months of age, only those children who have contact with a TB case and who are evaluated for TB (using investigations) should receive 6 months IPT if the evaluation shows no TB disease
(Strong recommendation, low quality evidence)

Recommendation 12: 2° IPT for children

- All children living with HIV who have successfully completed treatment for TB disease should receive INH for additional 6 months

(Conditional recommendation, low quality evidence)

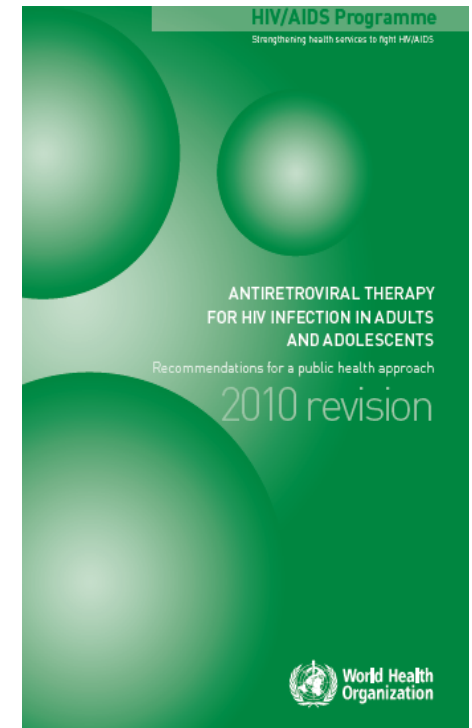
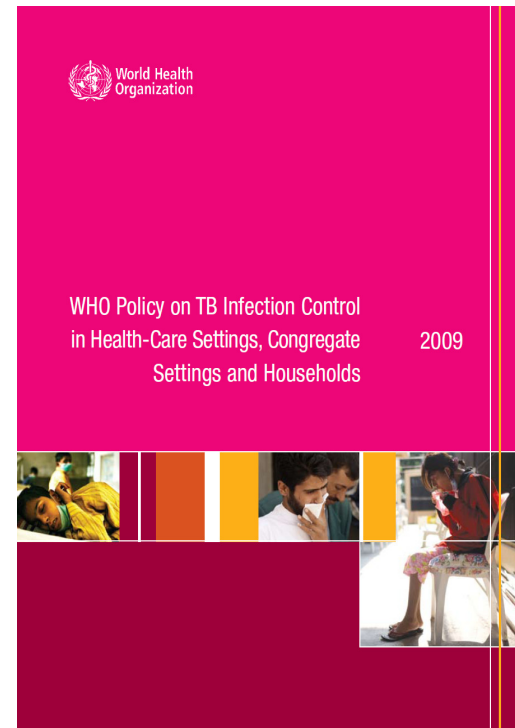
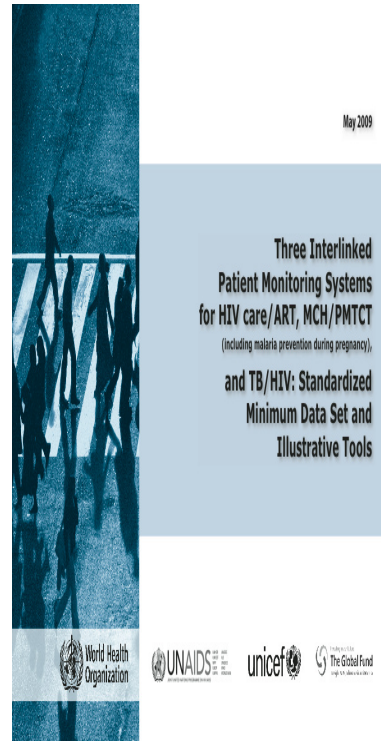
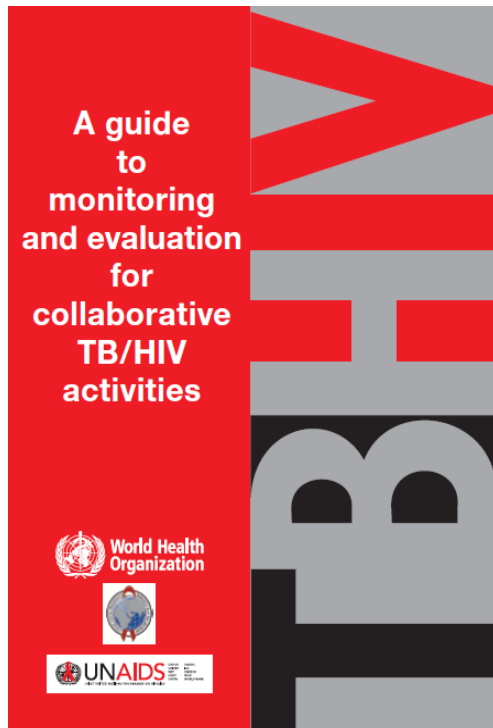
Key operational considerations

- National plan with national targets
- Primary ownership by HIV stakeholders
- Effective INH access and supply system
- Standardised indicators and M and E system
- Adherence and clinical monitoring
- Engagement of affected communities

Summary: what is new?

- Screening for TB only by using symptom based algorithm is sufficient to start IPT for PLHIV
- No mandatory CXR and TST requirement for IPT
- Regular screening of those on IPT at every visit
- Pregnant women, children, those on ART and those who completed TB treatment should receive IPT
- Conditional recommendation of 36 months IPT for settings with high TB transmission among PLHIV

Other important companion documents



Scale up, document and monitor!