

---

# Revising and developing algorithms for diagnosis of SNPTB and EPTB

New recommendations for HIV prevalent and  
resource constrained settings

Haileyesus Getahun  
Stop TB Department  
WHO, Switzerland  
November 2006



# TB among PLHIV

---

- Annual risk = 5-15%
- Higher chance for smear negative disease
  - SN pulmonary = 24 – 61%
  - Extrapulmonary = 4 – 40%
- Autopsy studies = 14 – 54%
- Scale of problem is underestimated
  - Studies are institution based
  - Most TB services look for smear positives
  - Early death before diagnosis is established



# Policy and practice changes are needed

---

- Expedite diagnosis and reduce mortality
- Special consideration for HIV settings

## The reality is..

- Technology vacuum of TB diagnosis
- Not enough evidence and experience
- Catastrophe posed by the dual epidemic
- Dire need to respond to an emergency



# Process of formulation

---

- WHO convened an Expert Group in Sep 2005
- Draft recommendations developed (Nov 2005)
- Global web-based consultation (Nov 05-Jan 06)
  - 3496 page views and 632 downloads
  - 128 valid feedback ( Spanish, French and English)
  - Individual and collective including official communications
  - Respondents include: NTP, technical agencies, research institutions, TB and HIV specialists etc.
- Expert Group met in Mar 06 and revised
- Endorsed by STAC-HIV and STAG-TB



# Target audience

---

- Definition of HIV prevalent setting
  - Adult HIV prevalence rate among pregnant women is  $\geq 1\%$  or HIV prevalence among TB patients is  $\geq 5\%$ .
  - Setting : country, sub-national administration unit (e.g., district, county), selected facility (e.g., referral hospital, drug rehabilitation centre)
- For countries with national HIV prevalence  $< 1\%$ , national TB and HIV authorities should identify and define HIV prevalent settings



# Case definition

## Smear positive pulmonary TB

---

### Non-HIV settings

- **Two or more** initial sputum smear examinations positive for AFB or;
- **One sputum** smear examination positive for AFB plus radiographic abnormalities consistent with active PTB as determined by a clinician or;
- **One sputum** smear positive for AFB plus sputum culture positive for *M. tuberculosis*.

### HIV prevalent settings-*NEW*

- **One sputum** smear examination positive for AFB and;
- *Laboratory confirmation of HIV infection or;*
- *Strong clinical evidence of HIV infection.*



# Case definition

## Smear negative pulmonary TB

---

### Non-HIV settings

- At least **three** negative sputum specimens for AFB and;
- Radiographic abnormalities consistent with active TB and;
- **No response to a course of broad spectrum antibiotics and;**
- (Decision by a **clinician** to treat with a full course of anti-TB chemotherapy)

### HIV prevalent settings-*NEW*

- At least **two** negative sputum specimens for AFB and;
- Radiographic abnormalities consistent with active TB and;
- **Laboratory confirmation of HIV infection or;**
- **Strong clinical evidence of HIV infection and;**
- Decision by a clinician to treat with a full course of anti-TB chemotherapy;  
OR
- A patient with AFB smear negative sputum which is culture positive for *Mycobacterium tuberculosis*



# Case definition

## Extrapulmonary TB

---

### Non-HIV settings

- One culture positive specimen
- OR
- Histological or strong clinical evidence consistent with active extrapulmonary TB , followed by a decision by a **clinician** to treat with a full course of anti-TB chemotherapy.

### HIV prevalent settings-*NEW*

- *One specimen from an extrapulmonary site culture positive for MTB or smear positive for AFB*
- OR
- *Histological or strong clinical evidence consistent with active extrapulmonary TB and;*
  - *Laboratory confirmation of HIV infection or;*
  - *Strong clinical evidence of HIV infection and;*
  - *A decision by a clinician to treat with a full course of anti-TB chemotherapy.*



# Key recommendations

---

- Algorithms are tailored to clinical condition  
(Ambulatory & seriously ill patients)
- HIV testing to TB suspects along with AFB
- Acceptable number of visits established
- CXR and Culture to be done earlier



# Key recommendations

---

- Vigilance and flexibility to start empiric treatment for suspected extrapulmonary TB in peripheral health facilities
- TB care should include HIV care
  - HIV staging (clinical , immunological)
  - PCP treatment
  - Co-trimoxazole preventive therapy
- Clinical management of extrapulmonary TB be included as TB control programme activity
- Recording and reporting of SN TB improved



FIGURE 1

## Algorithm for the diagnosis of TB in ambulatory HIV positive patient

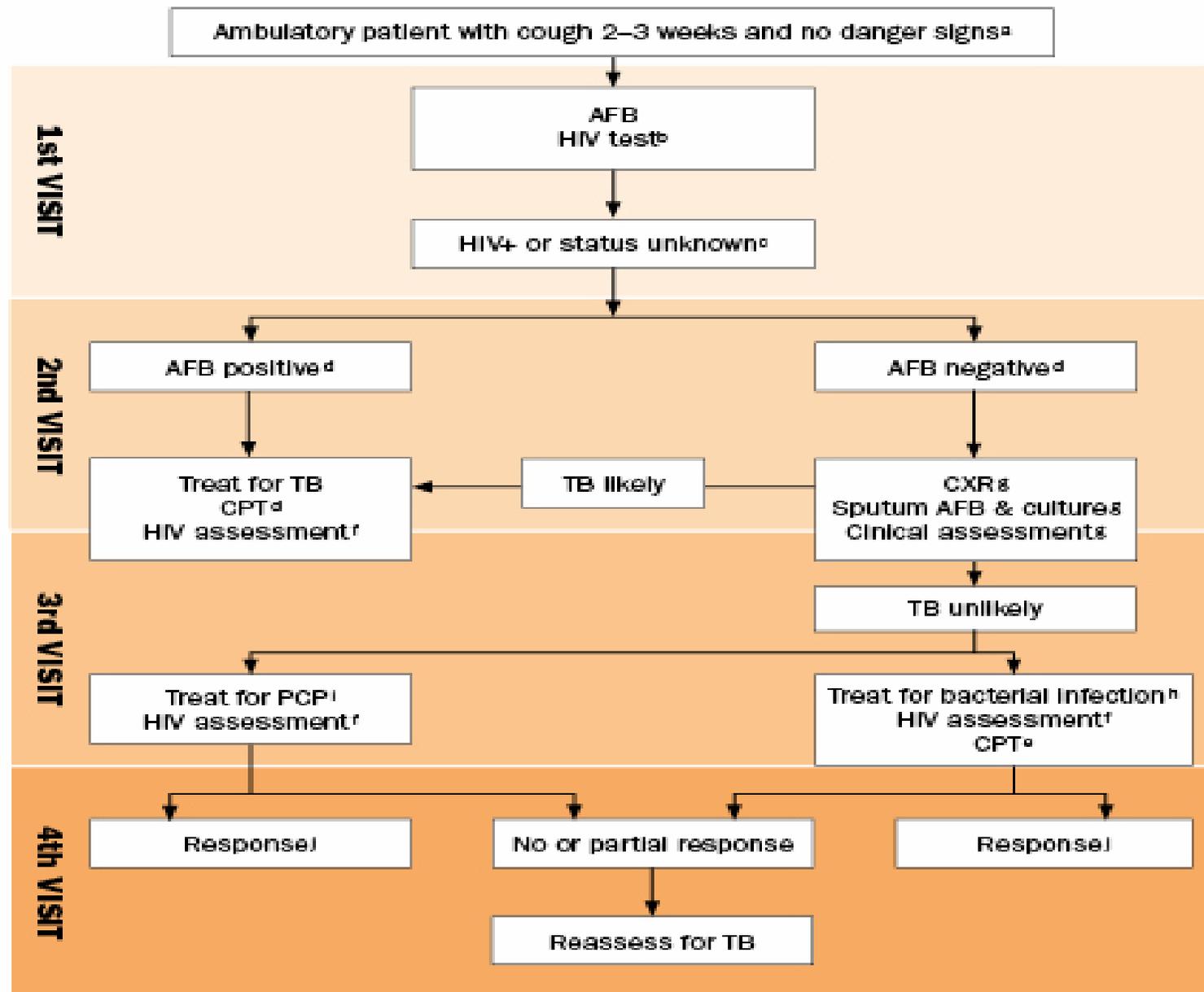
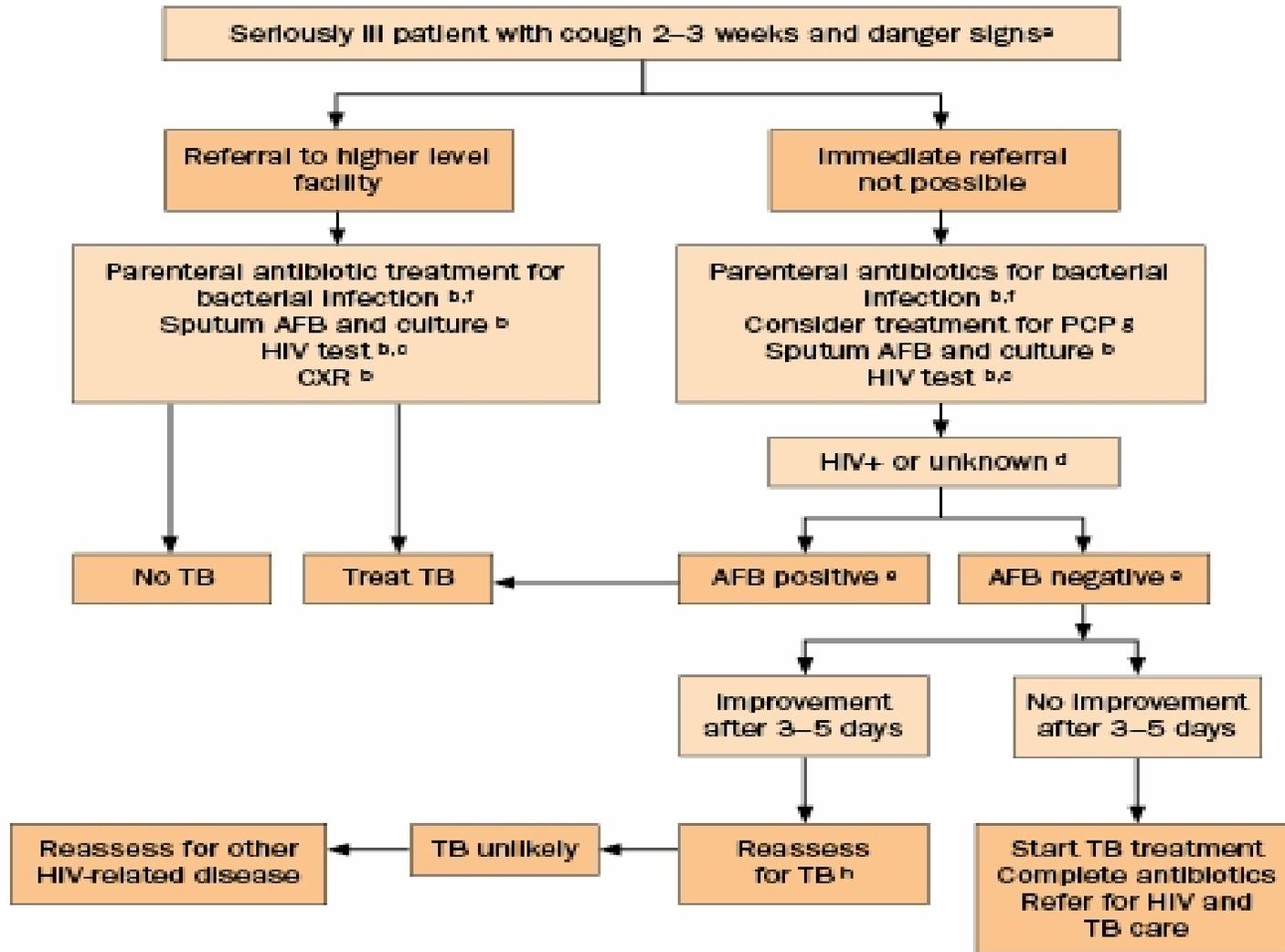


FIGURE 2

## Algorithm for the diagnosis of TB in seriously ill HIV positive patient



# Immediate implementation is crucial

---

- The recommendations are appropriate because
  - Latest available evidence considered
  - Developed through iterative global process
  - Give due emphasis for HIV
  - Maximise the use of existing tools
- Need to be implemented as a response to the emergency of the dual epidemic
- Need to be phased implementation
  - Infrastructure and human resources required



# More evidence through implementation

---

- Along with the implementation harvesting the experiences and building the evidence is crucial
- Evaluation for
  - Effectiveness (speed of diagnosis and mortality)
  - Feasibility (infrastructure and human resources)
  - Cost effectiveness
- Informs rolling policy changes and programme performance
- Generic protocol developed
  - Standardise the minimum information
  - Flexible platform to contribute to policy changes



# Conclusion

---

- Rapid, simple and accurate TB diagnostic tools with point of care and remote location applicability are the answers for TB control in HIV settings.
- The recommendations are interim measures to fill the gap and to respond to the emergency posed by the dual epidemic and the implementation needs to be accelerated.

