

Case definitions core group

DOTS expansion working group meeting, Lille, October 2011

Revised definitions of TB case and treatment outcomes

Why?

- **New Molecular Tests (WRD*)** now recommended for rapid diagnosis of TB in high HIV and high MDR settings
- WRD will be used *for diagnosis* in place of conventional bacteriology in high HIV and high MDR-TB settings
- Danger of increased complexity in R&R → opportunity to improve systems

*WHO-endorsed Rapid Diagnostics

STAG recommendations (June 2011) and next steps

- Acknowledged need to update and simplify definitions
- Changes should not compromise trends monitoring
- Allow mechanism for reporting the diagnosis method after registration for culture confirmed cases
- Simplify definitions for MDR-TB (failure/success)
- Pursue consultative process with countries
- Update R&R system in settings rolling out Xpert (start in 2011)

Current case categories

Definite

- Culture-pos
- Smear-pos

Case

- Definite
OR
- Other cases
put on tx

Retreatment

- After
default
- After failure
- Relapse

Proposed case categories

First and recurrent episodes

Microbiologically diagnosed

- Culture-pos
- WRD*-pos
- Smear-pos

Clinically diagnosed

- Histology-pos (EPTB)
- Others put on tx (incl. CXR, TST)

Treatment change

- After interruption
- After failure

* WHO-endorsed Rapid Diagnostics

Main case disaggregations

Microbiologically
diagnosed
new + recurrent

+

Clinically
diagnosed
new + recurrent

- Microbio / clinical dx
- HIV status
(tested, HIV-, HIV+,
ART)
- 4 age groups
(0-4, 5-14, 15-49,
50+)
- Sex
- **Smear status?**

Treatment changed disaggregations

Treatment change
after
interruption

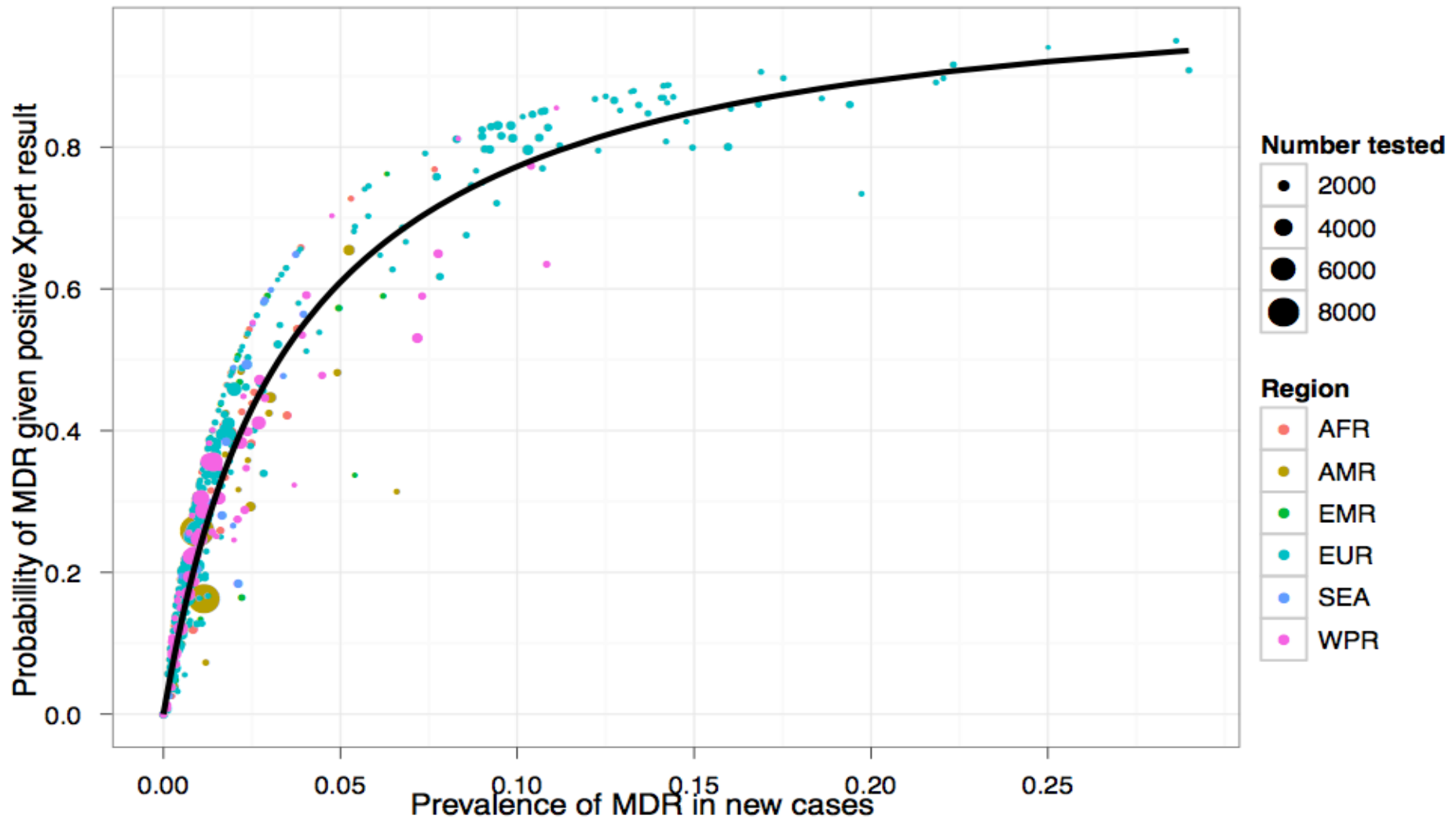
+

Treatment change
after
failure

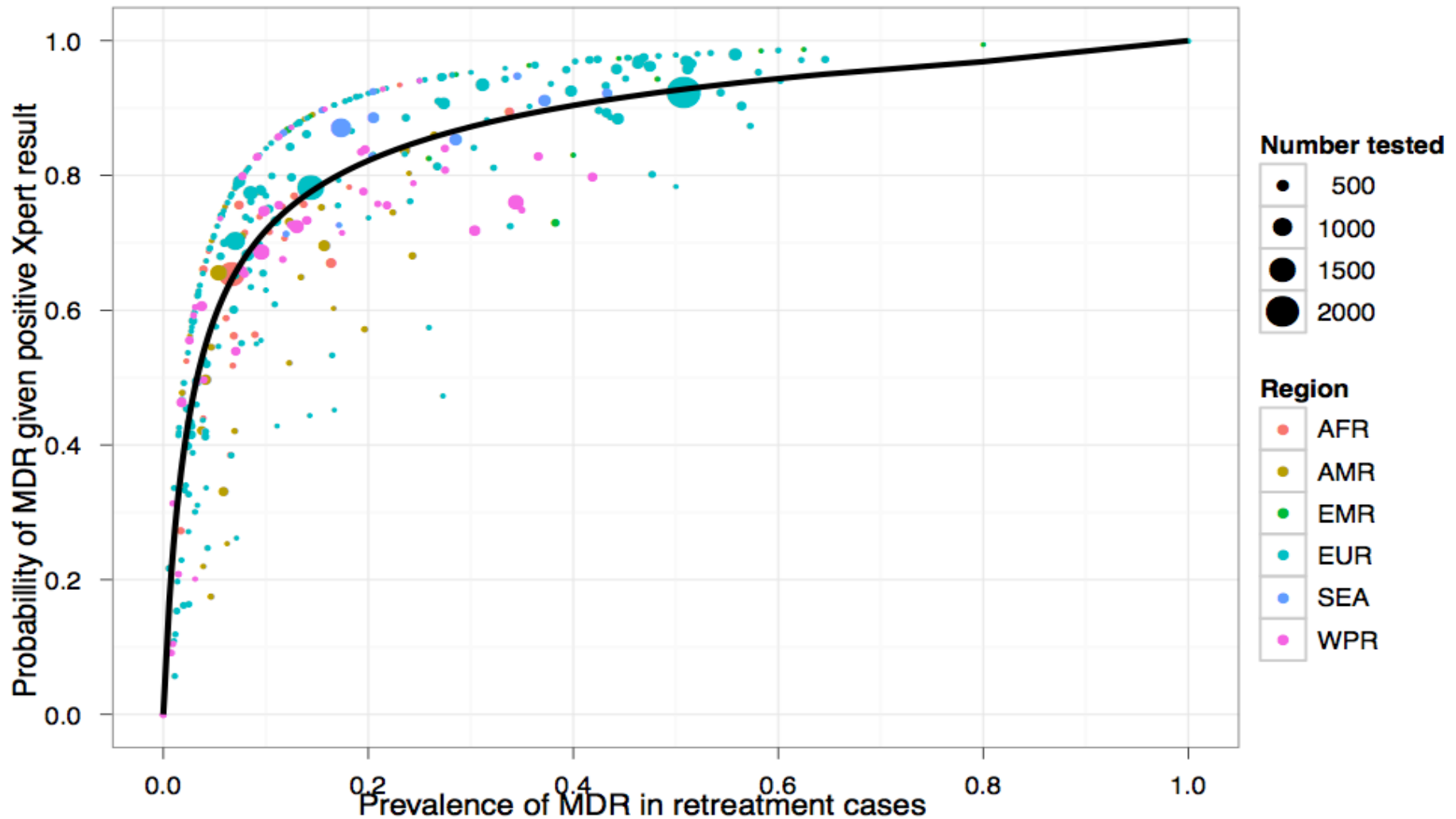
DR status

- tested
- MDR
- RR confirmed

Predictive values of Xpert MTB/RIF as proxy for MDR in new cases



Predictive values of Xpert MTB/RIF as proxy for MDR in retx cases



MDR case definition

MDR-TB Confirmed

- DST: resistant to R and H

RR-TB Confirmed

- DST or LPA: R⁺ H⁻
- WRD: R⁺ and RR \geq 15% in same patient group (DRS)

Updated treatment outcomes

NON MDR

Cured

Completed

Failed

Died

Interrupted

Not evaluated

Success

MDR

Success

Failed

Died

Interrupted

Not evaluated

Non MDR outcome definitions

- Cure (3 criteria):
 - no signs of continued active disease
 - tx completed
 - bacteriological success documented
- Failed
 - clinical or bact deterioration
 - signs of continued active disease
 - deterioration requiring tx change
- Completed
 - tx completed, no evidence of failure or cure

Current definition for an MDR cure

MDR patient completed tx according to protocol, > 5 consecutive negative cultures from samples at least 30 days apart in final 12 months of tx OR only one culture positive AND no clinical deterioration AND followed with > 3 negative cultures > 30 days apart

Proposed MDR tx outcome definitions

- **Success** treatment completed as intended without evidence of failure
- **Failure** termination of tx or need for tx change (≥ 2 classes)
 - Lack of smear/cult conversion by 2 months after end of intensive phase AND/OR
 - Bacteriological reversion (≥ 2 pos specimen ≥ 30 days apart) after conversion to negative AND/OR
 - Adverse drug reactions

Treatment outcome disaggregations

- Option 1
 - New and recurrent
 - Treatment change
 - HIV+ (all together)
- Option 2
 - New and recurrent bacteriologically diagnosed
 - New and recurrent clinically diagnosed
 - Treatment change
 - HIV+ (all together)

Treatment outcomes by sex only in case based eRR systems

Reducing complexity

	Current categories	Proposed categories
Cases	38	29
Outcomes non MDR	40	23
Outcomes MDR	18	15

Next steps

- Discuss and achieve consensus
- Pilot in Xpert settings
- Revise paper-based forms
- Roll-out through 2012-13