TB laboratory services in the Western Pacific Region

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World Health Organization

Role of laboratory services in TB control

- **Diagnosis of all TB cases**
- **Monitoring response to treatment**
- **TB surveillance**
  - **notifications**
  - **drug resistance**
- **Selecting effective treatment regimens: MDR-TB**
- **Training sites**
- **Operational research**

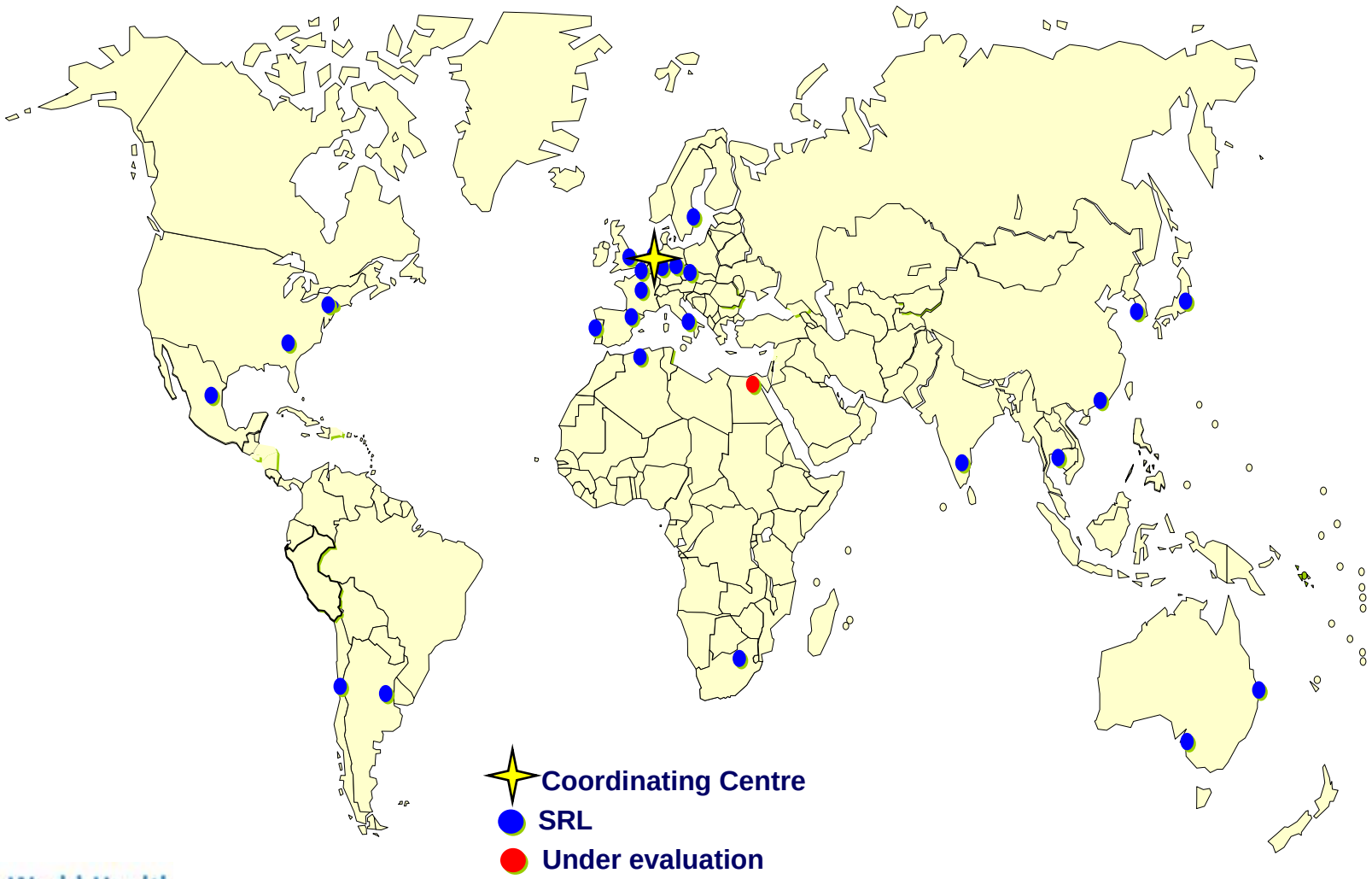
Poor lab performance translates into:

- Unreliable diagnosis results (smear, culture, DST)
- Diagnosis delays (pulmonary disabilities)
- Mismanagement of cases (e.g. MDR)
- Inappropriate therapy
- High case fatality (e.g. HIV-TB)
- Missed opportunities to stop TB transmission, low case detection

Poor lab biosafety translates into:

- Laboratory technicians exposed to TB, including MDR-TB / XDR-TB
- Contamination across samples
- Unreliable results

Supranational reference laboratory network



World Health Organization

Five International TB Laboratories in WPR

RIT, Tokyo Japan	**KIT, Seoul, Korea**	**Hong Kong, China**	**QMRL, Brisbane, Australia**	**IMVS, Adelaide, Australia**
Cambodia	Viet Nam	China	PIC*	PIC*
Mongolia		Lao PDR		
Philippines				

* Pacific Island Countries

Patlab network in the Pacific

- Objectives:
  - to improve the quality of sputum microscopy through external quality assessment
  - To expand surveillance for drug resistance
- A network of 4 Pacific TB Reference Labs:
  - QMRL (Brisbane, Australia)
  - IMVS (Adelaide, Australia)
  - MDL (DLS, USA)
  - PPTC (Wellington, New Zealand)

Regional network activities

- Technical assistance to countries: visits, national meetings, training, external lab services (EQA, DRS)
- NTP-Lab meetings: Cebu 2002, Hangzhou 2004, Siem Reap 2005, Kuching 2007
- Lab consultation workshop: Manila 2006, Ha Noi 2007
- Technical Publications for the WPR:
  - Regional guidelines for QA
  - Guidelines for QA in the Pacific Island Countries

National lab networks

- Level 1: peripheral
- Level 2: intermediate
- Level 3: National TB Reference Laboratory

Internal and external quality assurance at all levels

Peripheral level (level 1)

- **Located at primary health centers or district hospitals**
- **Activities**
  - Sputum collection
  - Smear microscopy
  - Recording and reporting
  - Slide collection for EQA
- **Manpower: ≤ 1(2) worker(s); > 2-3 < 20 smears per day**
- **Population coverage: 100-200K**

Intermediate level (level-2)

- **Located at regional health institutions including hospitals**
- **Activities**
  - Services to clinics: FM/ZN smear microscopy
  - Culture / ID of MTB; referral services
  - Support activities: (supply of reagents/materials, training; EQA for smear microscopy including supervision)
- **Manpower:** 2-3 workers (only for TB work)
- **Population Coverage:** 500 - 1,500K

Central level (level 3)

- **Part of the central public health laboratory, research laboratory, or upgraded laboratory in the country's principal tuberculosis institution**
- **Activities**
  - National reference laboratory for the TB program
  - Policy development and planning
  - Development of standardized manuals and guidelines
  - Training
  - Quality Assurance
  - Routine activities: smear microscopy, culture and DST

Current TB lab network capacity

	microscopy	**culture**	**DST**
Cambodia	186	3	1
China	3,227	327	187
Lao PDR	154	0	0
Mongolia	36	1	1
Philippines	1,946	9	9
PNG	79	1	1
Viet Nam	874	30	2

Mean population coverage of services

	1,000 pop. per mic. unit	**million pop. per culture**	**million pop. per DST**
Cambodia	75	4.7	14
China	408	4	7
Lao PDR	38	-	-
Mongolia	72	2.6	2.6
Philippines	43	9.2	9.2
PNG	75	5.9	5.9
Viet Nam	96	2.8	42

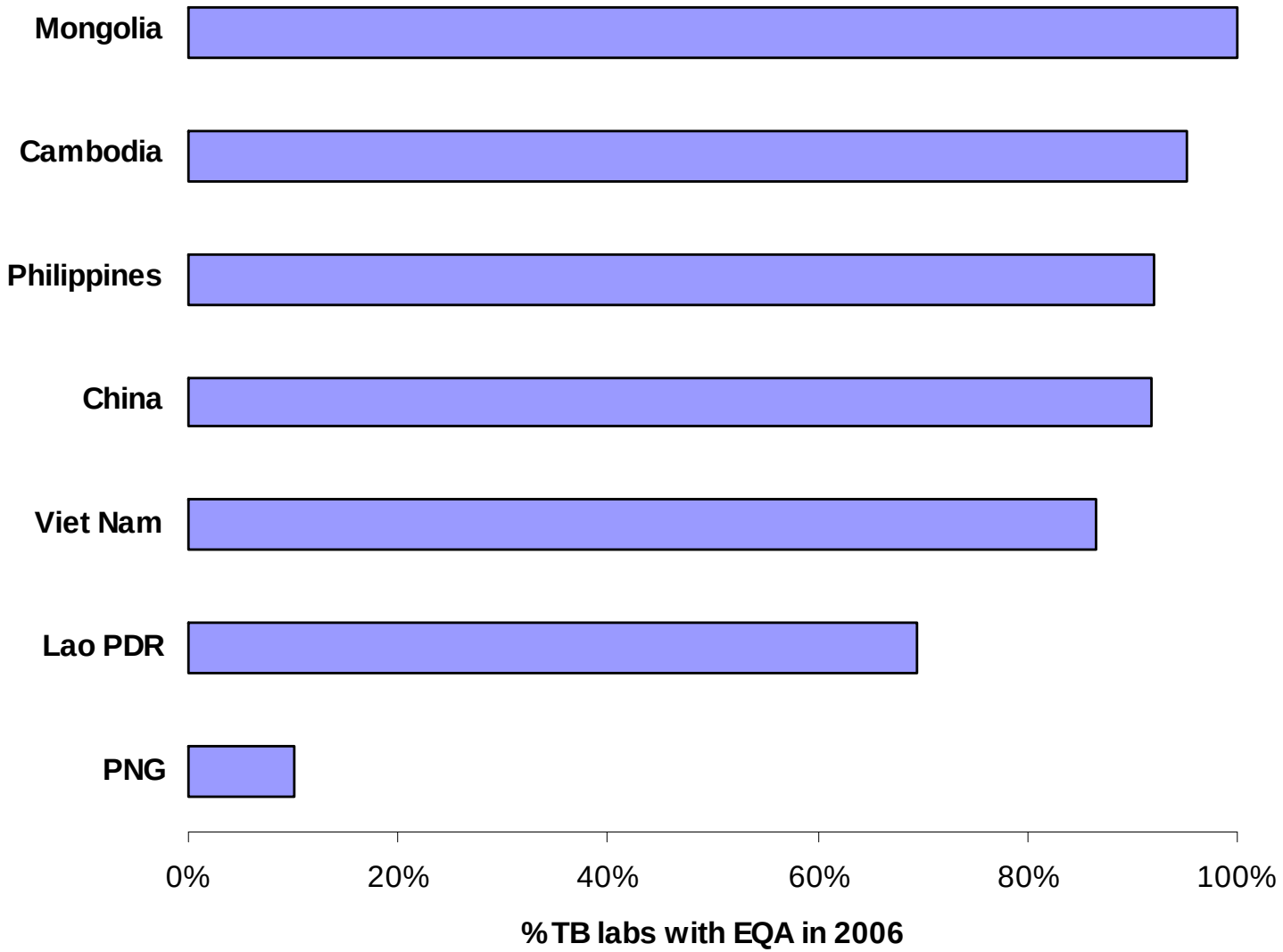
Quality assurance

- External quality assessment (EQA) and panel testing
- Internal quality control (QC)
- Quality improvement with supervision and site visits

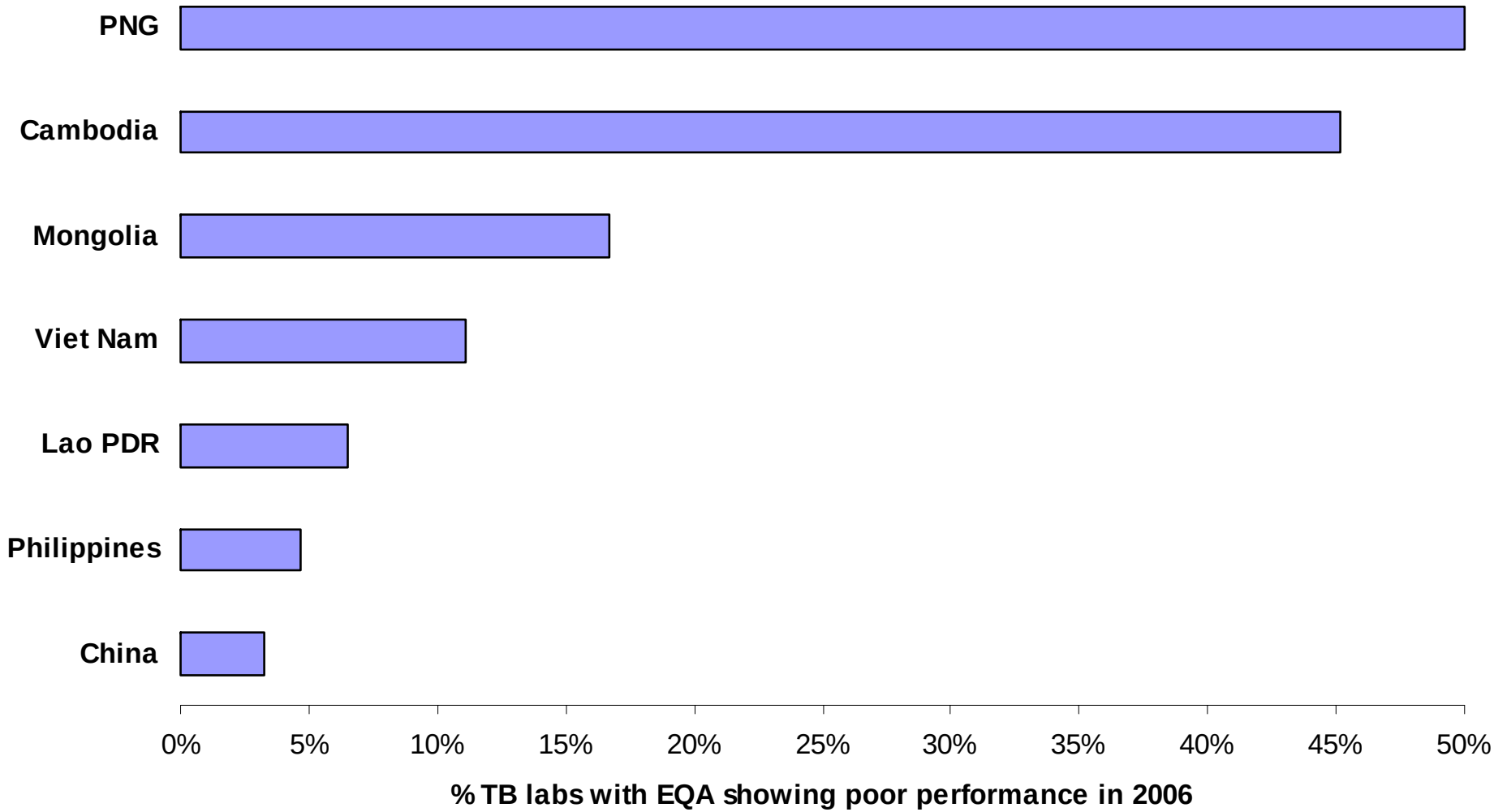
External Quality Assessment

- Early warning-system for problems
- Measure of laboratory quality
- Valuable benchmarking tool
- Indicator of where to direct improvement efforts

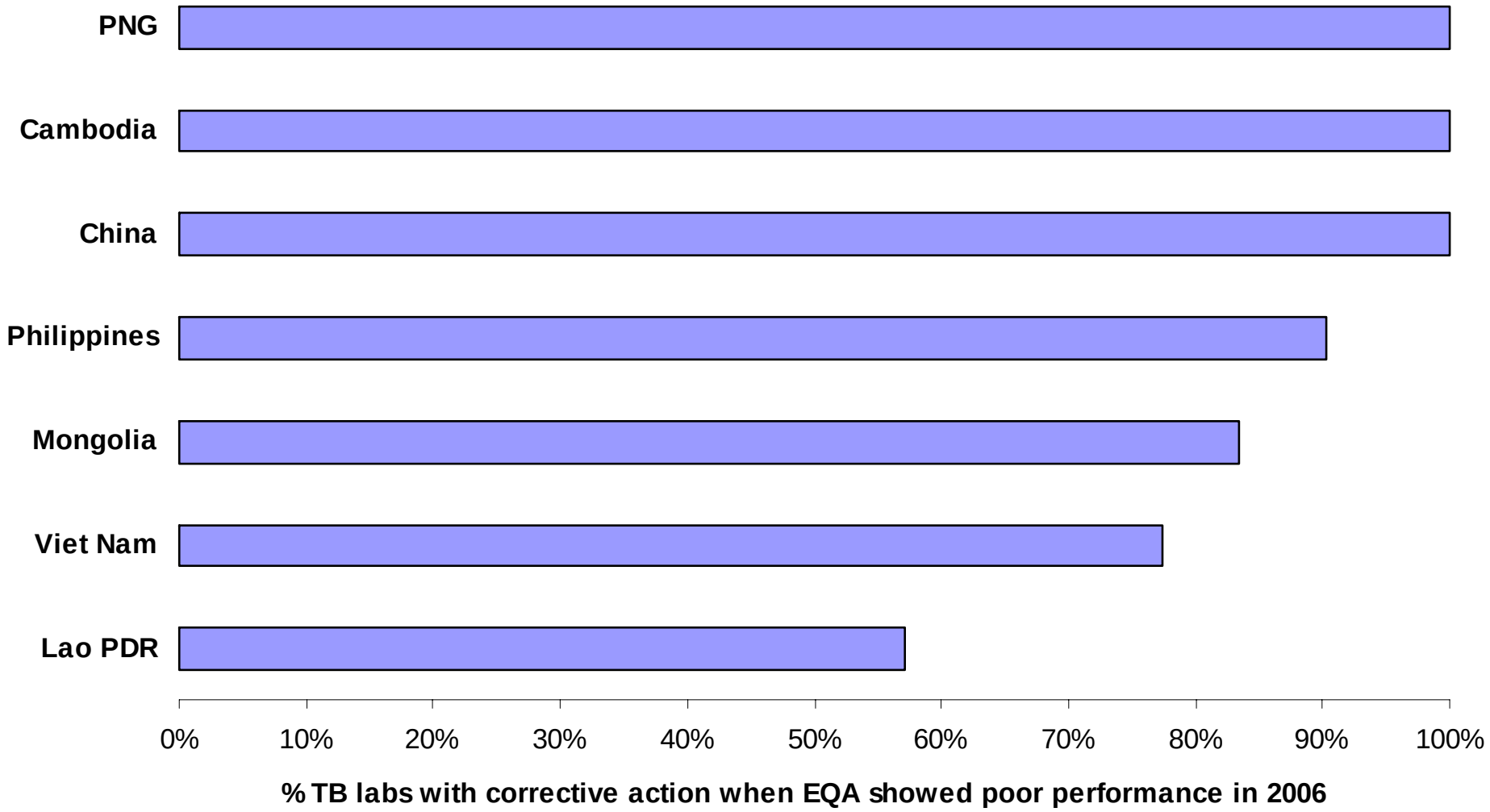
Coverage of EQA for microscopy (%)



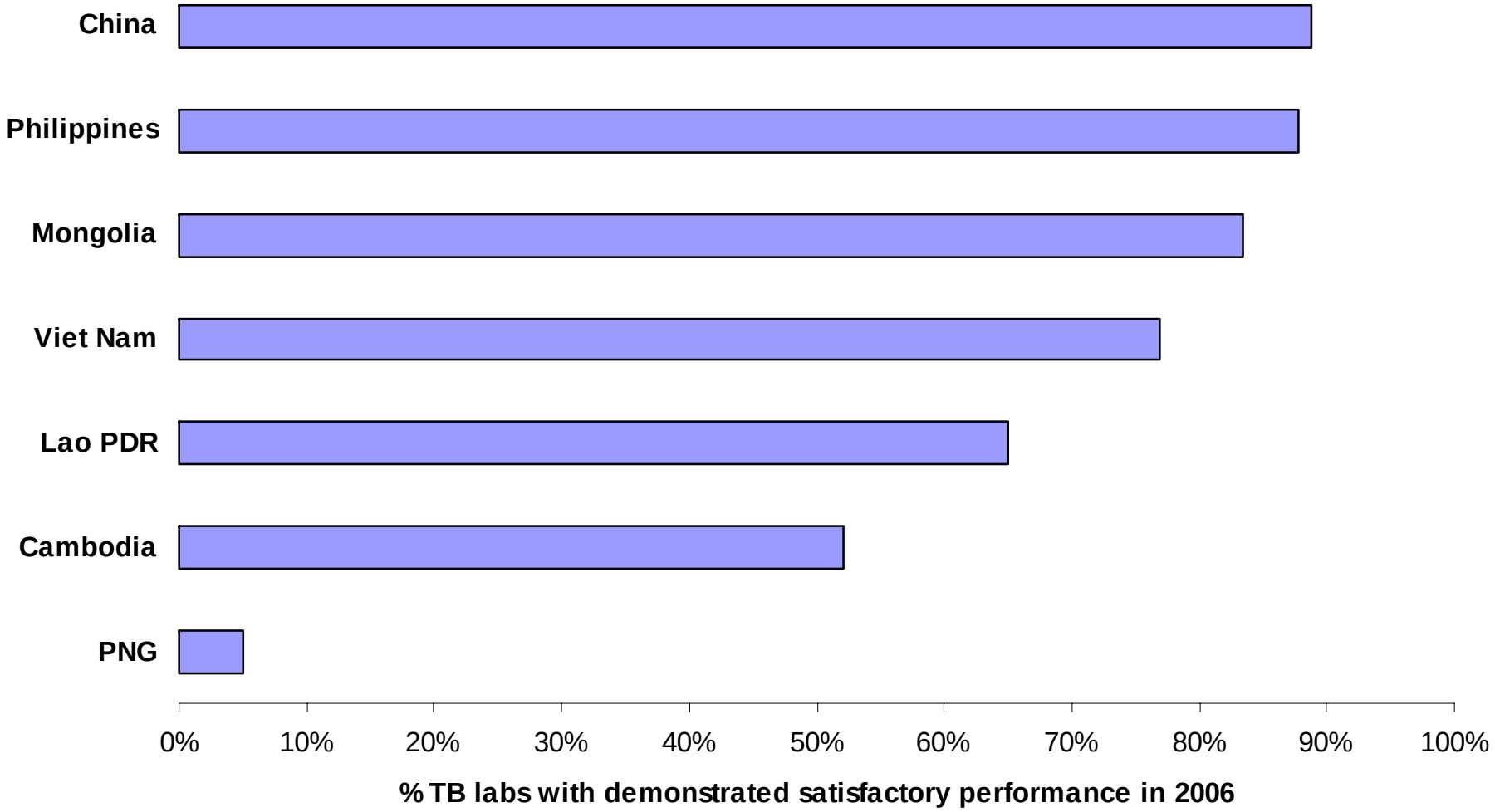
High % of unsatisfactory EQA results in several countries



Units with corrective action when poor performance (%)



Insufficient % of units with documented satisfactory lab performance



Measuring performance

- Turnaround times
- Timeliness of AFB-smear, culture and DST
- Availability of SOP
- Timeliness of information flow
- Reliability of tests (e.g. % satisfactory EQA results)

Culture and DST

Epidemiological and programmatic conditions are changing

- The number of repeatedly sputum negative TB cases is higher in HIV settings
- Many countries are implementing DRS and some are monitoring MDR-TB trends
- Second line drugs are widely available
- A growing number of countries implement programmatic management of MDR-TB
- Culture and DST are increasingly used in resource limited countries, in particular in general hospitals

Current issues with culture and DST

- No quality assured culture and DST beyond drug resistance surveys and GLC-approved programs
- No national policy on the use of culture for diagnosis
- No policy in most HBCs on the use of DST beyond GLC-approved programs and DRS
- **BIOSAFETY** level of DST labs

Conclusions

- Increasing coverage of QA programs for microscopy
- Insufficient overall performance of microscopy units
- Increased use of non-quality assured culture and DST, but incomplete mapping of facilities
- Inadequate biosafety monitoring of lab facilities
- Lack of policy for the use of culture for diagnosis
- Insufficient involvement of lab managers in NTP budgeting and applications for external funding