

TB laboratory services in the Western Pacific Region

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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**

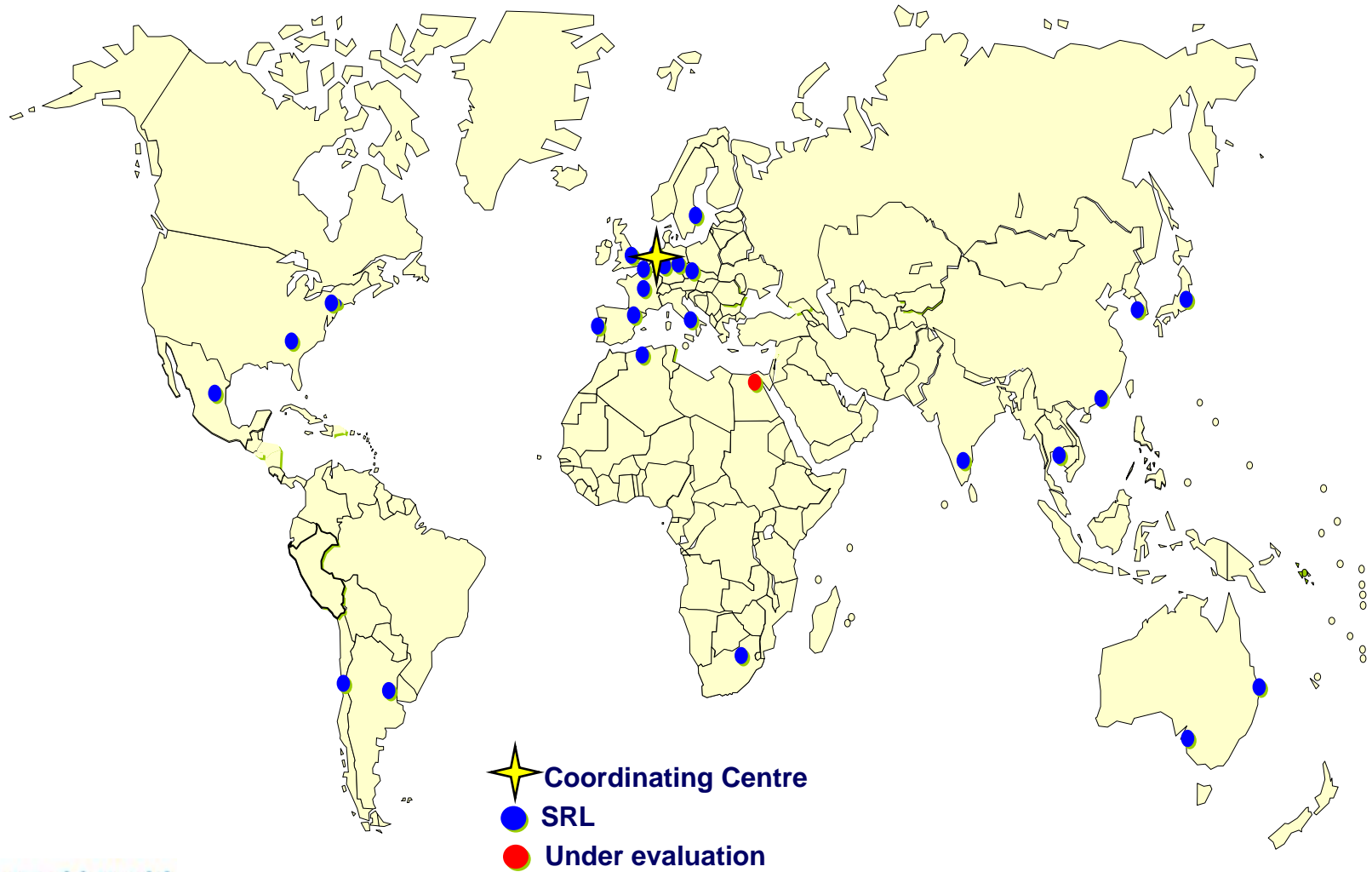
Poor lab performance translates into:

- 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



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: $\leq 1(2)$ 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

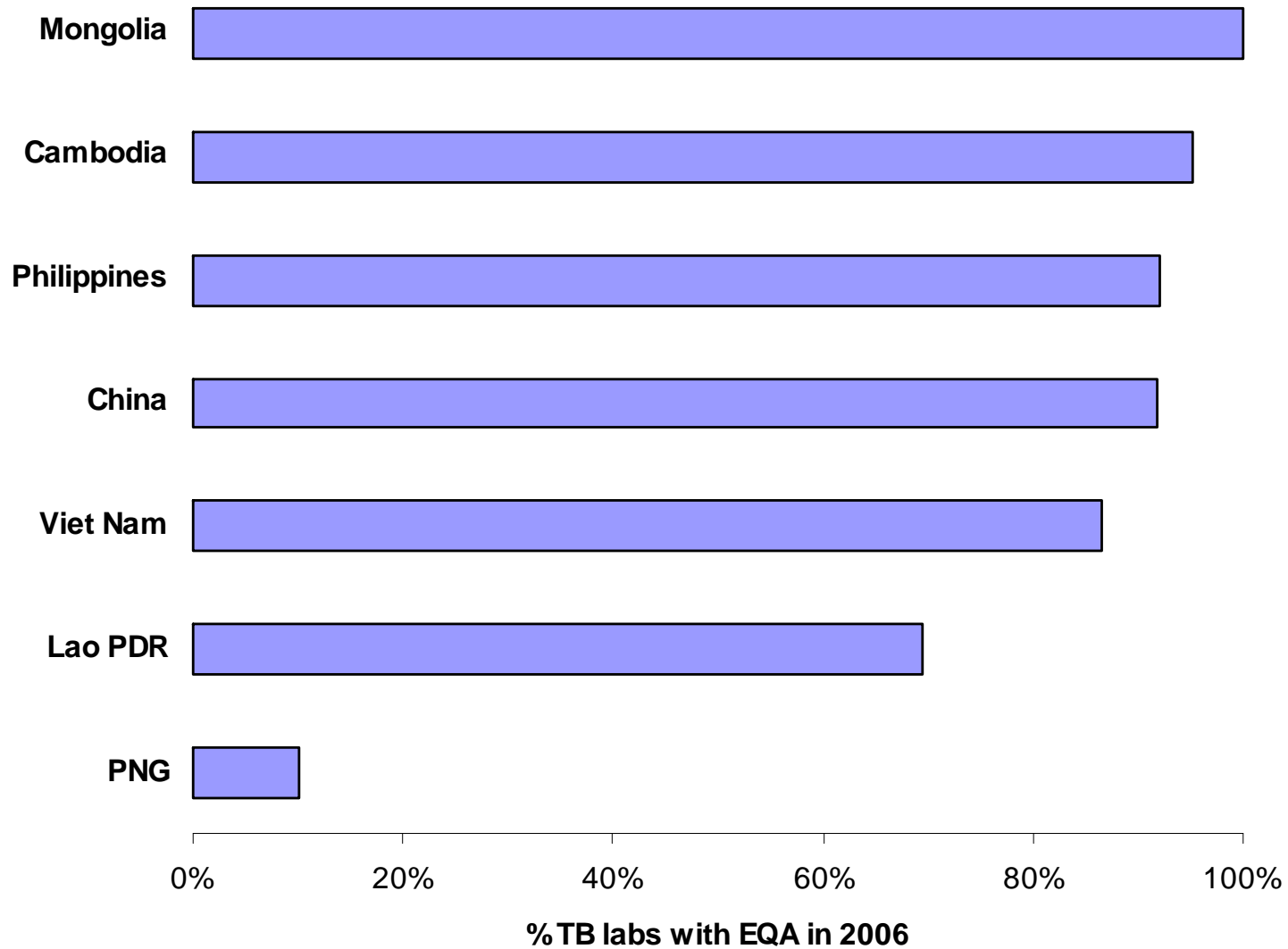
Quality assurance

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

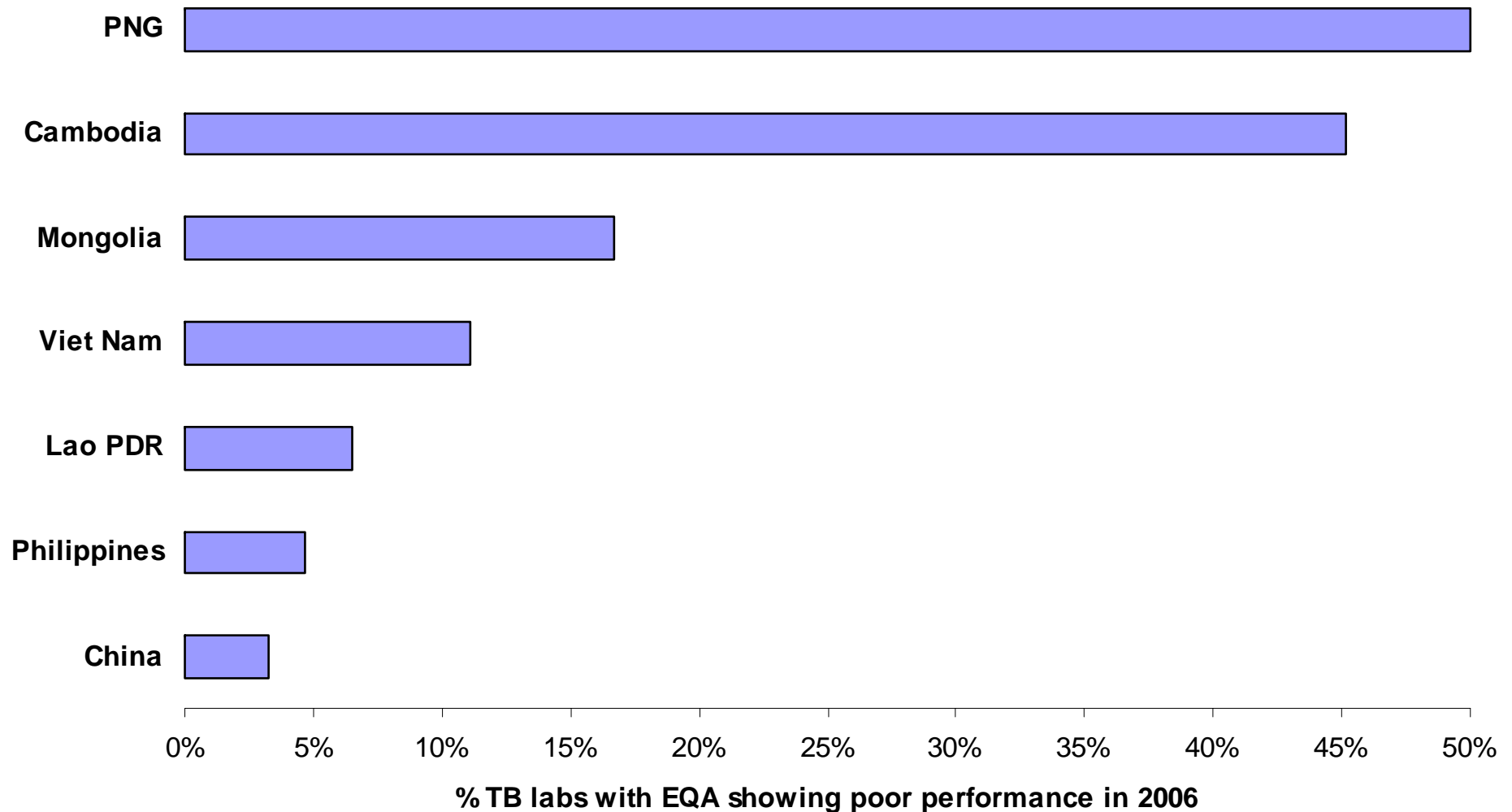
External Quality Assessment

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

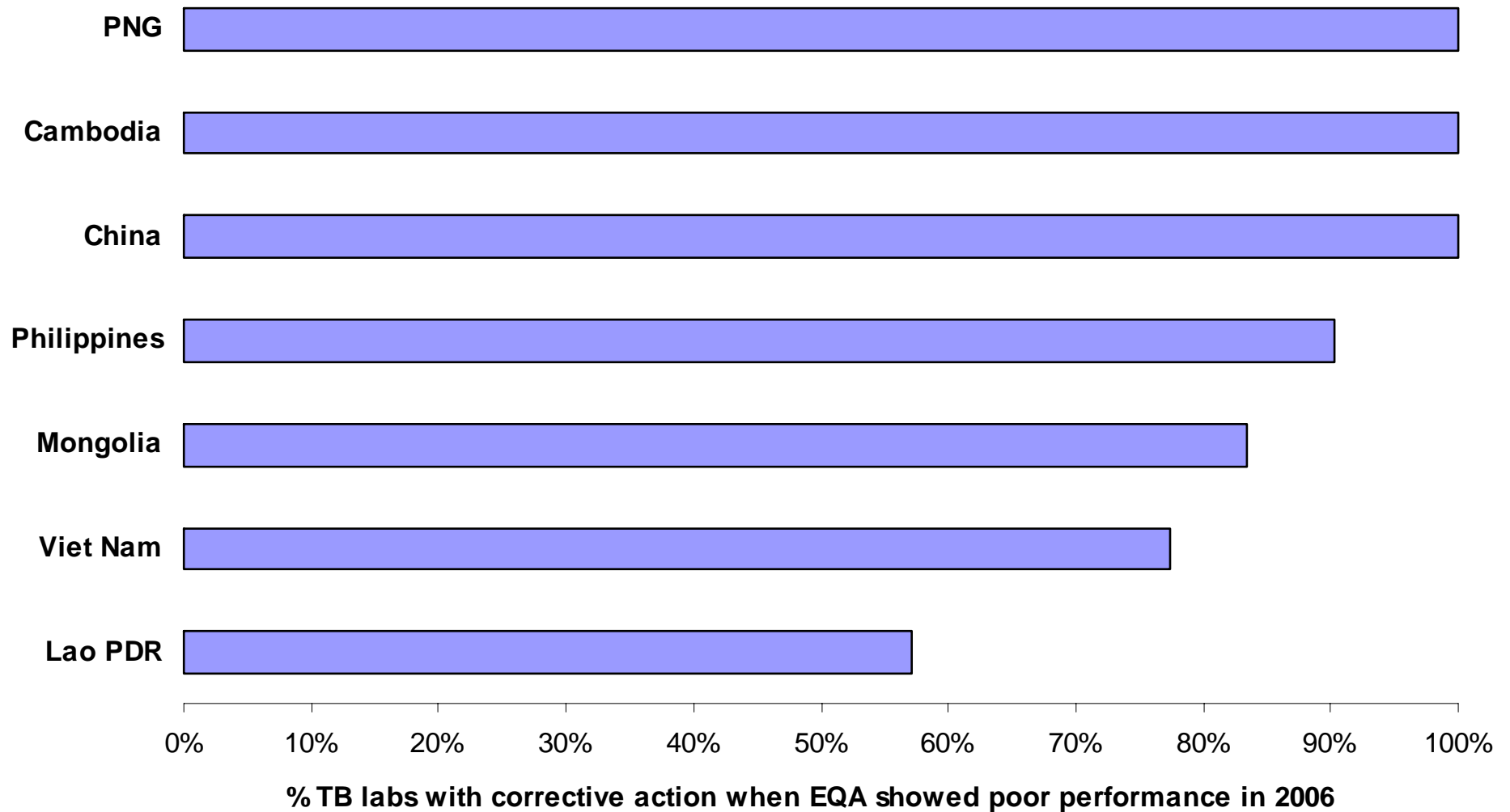
Coverage of EQA for microscopy (%)



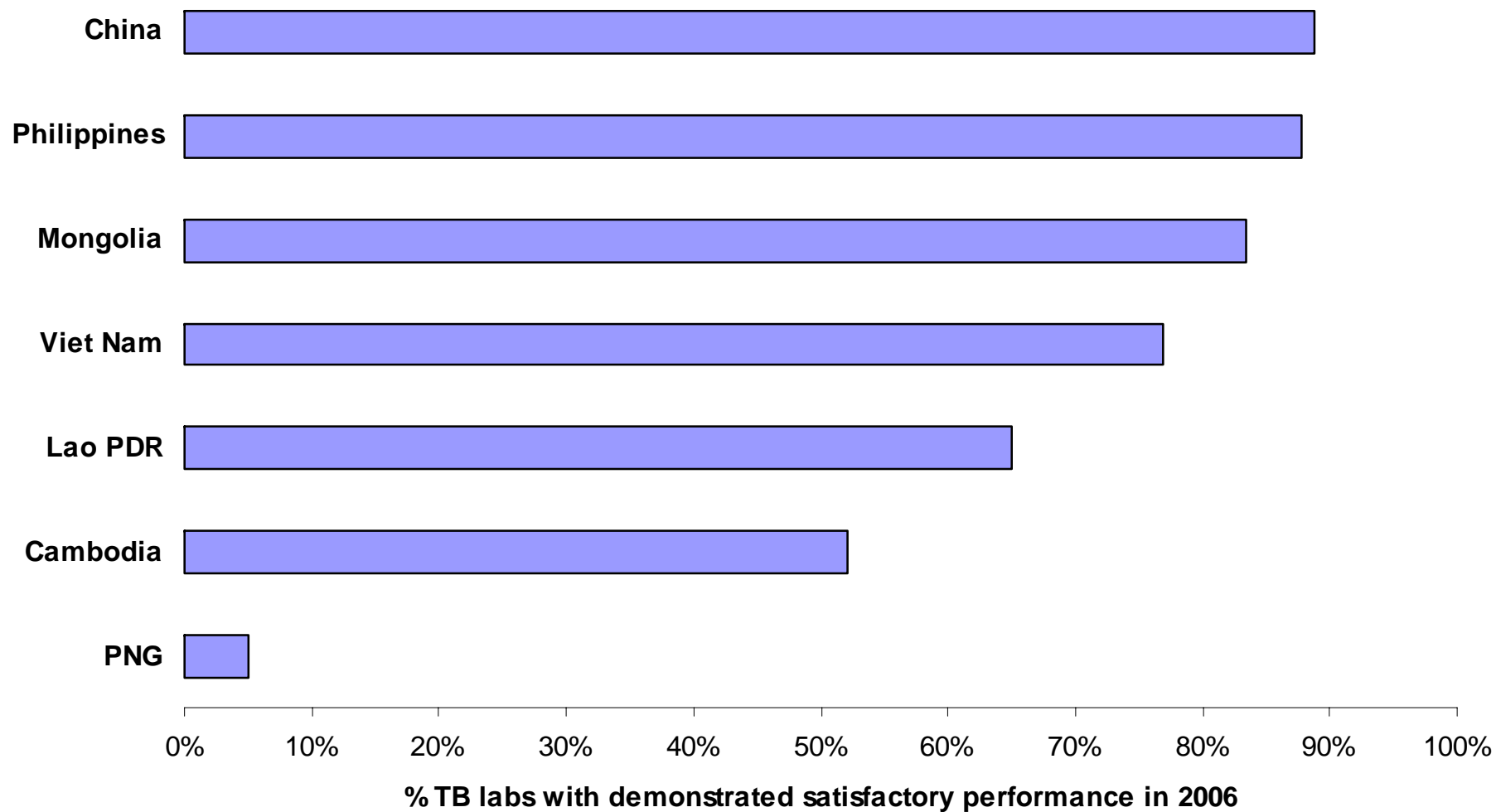
High % of unsatisfactory EQA results in several countries



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