World Health Organization

ESSENTIAL HEALTH TECHNOLOGIES

Accreditation Bodies in other WHO Regions

Jeanette Twell

6July2011

Overview

- ILAC
- Accreditation
- International Standards vs Guidance
- Auditing (NATA)
- EQAS/Proficiency Testing
- Take home message

International Laboratory Accreditation Cooperation (ILAC)

- Developing and harmonizing laboratory and inspection accreditation practices
- Promoting laboratory and inspection accreditation to industry, governments, regulators and consumers
- Assisting and supporting developing accreditation systems
- Global recognition of laboratories and inspection facilities via the ILAC Arrangement, thus facilitating acceptance of test, inspection and calibration data accompanying goods across national borders

International Laboratory Accreditation Cooperation (ILAC)

- Established for 30 years
- The ILAC network consists of 135 bodies representing 88 different economies
- Worldwide there are almost 35,000 laboratories accredited by an ILAC signatory
- There are over 6000 accredited inspection bodies
- Accreditation bodies have been evaluated by peers as competent
- Africa, Asia, South America under represented

Accreditation using standards from the International Organization for Standardization (ISO)

ISO 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

Accreditation using standards from the International Organization for Standardization (ISO)

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

Two areas of expertise

1. **QMS (common to many areas)**
2. **Subject matter expert**

Auditor?

- **qualifications/training of auditor**
- **CV/experience**
- **supervision**
- **'registered' 'certified'**
- **personal attributes**

(the NATA model)

Standards

Standards?

- **Biological standards**
- **Standards – documented consensus**

ISO 17025 – General laboratory
ISO 15189 – Medical laboratory
ISO 17043 – Proficiency programme

Guidance Towards Accreditation

'Guidance' towards obtaining internationally recognized accreditation

AFRO/WHO/CDC
GLI
CLSI
etc

Note: Laboratories often perform a variety of tests.

Clinical and Laboratory Standards Institute (CLSI)

'Guidance'

CLSI -

Quality Management System: A Model for Laboratory Services; Approved Guideline – Fourth Edition (June 2011) 160 pages

- **QMS model**
- **Quality System Essentials**
- **Path of Workflow Concept**
- **Phases of Implementation of QMS**
- **Ethics**
- **References**
- **Appendices (forms for auditing, validation of processes, quality manual etc)**

External Quality Assurance Schemes (EQAS)

Participation **is a requirement for accreditation (if EQAS is available).**

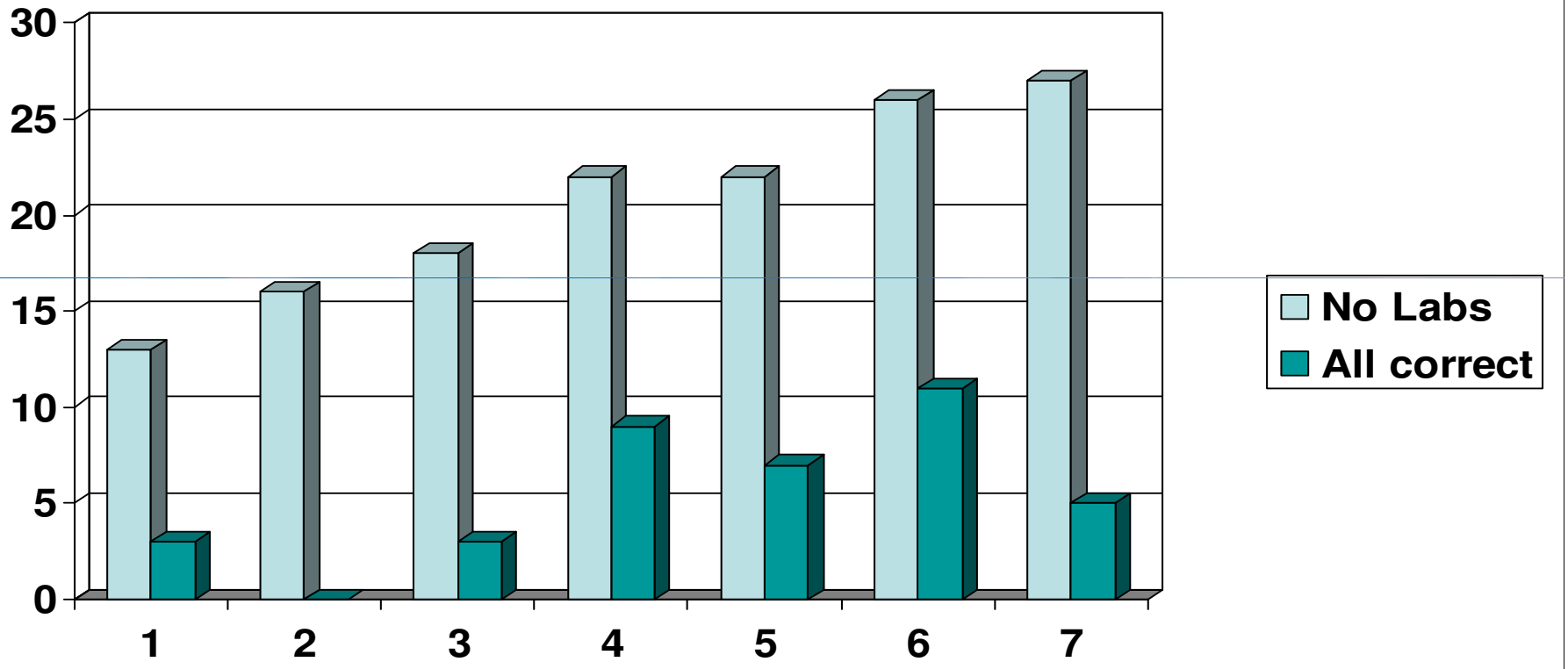
(If EQAS not available, lab is expected to 'improvise')

Why?

- **Check test is OK - secondary gain (cut off values etc) (peer compared – e.g. in 'real time via internet)**
- **Check lab and lab personnel can perform, interpret and report results**

– *primary purpose*.

QAP Molecular Diagnostics



Take Home Messages

- EQAS / Proficiency Testing – essential for accreditation, primarily tests laboratory
- Auditors – skilled at auditing, QMS and technical
- International Standards (used to accredit) vs Guidance towards accreditation

Take Home Messages

- **Accreditation – creates an expectation of a recognized standard of 'best practice'**
- **ILAC – International 'best practice' for accrediting laboratories – expanding influence and membership**

WHO role?

WHO and Accreditation

Questions?