EQAsia: National EQA provision pilots (NEQAs)

Module 2: Introduction to NEQA and SOP development

18/04/2024

The Fleming Fund Regional Grants

UKaid from the British people

MOTT MACDONALD

DTU

International Vaccine Institute

Faculty of Veterinary Science • Chulalongkorn University

2024
DTU

Outline

- EQAsia NEQA objectives
- Timeline

- Definitions
- General requirements
- Standard operating procedures (SOPs)
- Process requirements

- EQAsia overview

EQAsia NEQA Objectives

- Build capacities for NEQAs.
- Empower NEQAs to operate independently with confidence.

Timeline

March-July 2024
- Preparation of NEQA documents
- Online consultations and training

Aug 2024
- On-site training in PT panel preparation

Aug-Sept 2024
- 1st NEQA trial

N. of sites: 5 sites
N. of pathogens: TBD

Feb-March 2025
- 2nd NEQA trial

N. of sites: 7 sites
N. of pathogens: TBD

❖ **In between activities:**
Ad hoc QMS support and monitoring
Ad hoc NEQA support and monitoring

Definitions

- **Proficiency Testing (PT):**
  - PT demonstrates laboratory competence and highlights potential issues.
  - Involves interlaboratory comparisons for evaluating performance.
  - Interlaboratory Comparisons (ISO 17043)

- **Purposes:**
  - Evaluation of laboratory performance for specific tests, measurements, calibrations, or inspections.
  - Identification of underlying problems (e.g., methods, training, calibration).
  - Establishing method effectiveness and result comparability.
  - Providing confidence to users of test results.
  - Identifying result discrepancies.
  - Educating labs based on comparison outcomes.

Definitions

- **External Quality Assessment (EQA) programs:**
  - Offer diverse interlaboratory comparisons, extending beyond traditional PT schemes.
  - Focus on complete laboratory workflow insight, not limited to specific measurement or test processes.
  - Typically, continuous programs with long-term monitoring of laboratory performance.
  - Emphasize participant education and quality improvement through advisory and educational feedback.

General Requirements

- **Impartiality and Confidentiality:**

  - The PT provider must ensure the impartiality of its activities, free from commercial or other pressures.
  - Continuous monitoring of activities and relationships to identify threats to impartiality.
  - Confidentiality of participant and customer information is strictly maintained.
  - Information received from external sources (e.g., complaints, regulators) is kept confidential.
  - Identity of the source is protected and not disclosed unless agreed upon by the source.
  - Personnel and external parties involved in PT activities are bound by confidentiality agreements.
  - Participant identities are confidential and disclosed only to authorized personnel unless waived by the participant or customer.

General Requirements

- **Organizational structure:**
  - Define organization and management structure.
  - Clarify place within any parent organization.
  - Outline relationships between management, technical operations, and support services.

- **Personnel responsibilities:**
  - Specify responsibilities, authority, and interrelationships of all personnel involved in PT activities.
  - Include those who manage, perform, or verify work affecting PT results.

- **Documentation procedures:**
  - Document procedures comprehensively to ensure consistent application and validity of PT activities.

General Requirements

- **Key personnel requirements for PT providers:**
  - Authority for management system:
    - Personnel must have authority and resources for implementing, maintaining, and improving the management system.
  - Deviations identification:
    - Ability to identify deviations from the management system or procedures during PT activities.

General Requirements

- **Key personnel requirements for PT providers:**
  - Action initiation:
    - ➢ Authority to initiate actions to prevent or minimize deviations encountered.
  - Reporting responsibilities:
    - ➢ Responsibility to report to management on the performance of the management system and suggest improvements.
  - Ensuring PT effectiveness:
    - ➢ Ensuring the effectiveness of PT activities through authority and resource allocation.

General Requirements

- **Ensuring validity of PT activities:**
  - PT provider must ensure appropriate facilities for PT scheme operations.
  - Document environmental conditions that can impact PT items, measurements, or tests.
  - Control, monitor, and periodically review environmental conditions.
  - Stop activities if environmental conditions compromise validity.

➢ **Examples of environmental conditions:**

- ➢ Biological sterility
- ➢ Dust
- ➢ Electromagnetic disturbances
- ➢ Radiation

- Illumination (light)
- Humidity
- Electrical supply
- Temperature
- Sound and vibration levels

Summary

- **Key points in PT and EQA provider requirements:**
  - General Requirements: Impartiality and Confidentiality
  - Organizational structure and documentation
  - Personnel authority and responsibilities
  - PT vs EQA programs
  - Ensuring validity of PT activities

Standard operating procedures (SOPs)

- **Definition:**
  - SOPs are written documents containing step-by-step instructions for laboratory procedures.
- Purpose:
  - Provide guidance for meticulous execution of procedures by laboratory staff.
- Usage:
  - Each laboratory procedure is associated with its own SOP for standardized execution.

Standard operating procedures (SOPs)

- **Benefits of written SOPs:**
  - Consistency: Ensures uniformity in procedure execution across all laboratory staff, enabling reliable and comparable results over time.
  - Accuracy: Reduces errors and enhances result precision by providing structured guidelines that prevent steps from being overlooked.
  - Quality: Upholds the laboratory's commitment to delivering consistent, accurate, and reliable results, reflecting the essence of quality in laboratory operations.

Standard operating procedures (SOPs)

- **Characteristics of a good SOP:**

  - Detailed, Clear, and Concise: Provides comprehensive step-by-step instructions including critical details such as ambient temperature requirements and precise timing instructions for consistent execution.

  - Accessible to New Personnel: Easily understood by individuals new to the procedure or undergoing training, ensuring consistent performance across staff levels.

  - Review and Approval: Regularly reviewed and approved by laboratory management, demonstrated by signatures and dates, to ensure procedures are current and suitable for use.

  - Regular Updates: Subject to periodic updates to reflect evolving practices and maintain relevance in laboratory operations.

Standard operating procedures (SOPs)

- **Standardized format for SOPs:**

  - Importance of Headers: Headers play a critical role in the standardized format of SOPs, providing essential information to users at a glance.

  - Complete Standardized Header: Typically appears on the first page of each SOP, containing comprehensive details for quick reference by staff.

  - Reduced Standardized Header: Used on subsequent pages, featuring a condensed version of the header to maintain clarity and consistency throughout the document.

TLM/MSH Microbiology Department Policy & Procedure Manual	**Policy # MI/RESP/11/v05**	Page 1 of 5
Section: Respiratory Tract Culture Manual	Subject Title: **SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)**	
Issued by: LABORATORY MANAGER	Original Date: September 25, 2000	
Approved by: Laboratory Director	Revision Date: September 14, 2006	
	Annual Review Date: August 13, 2007	

TLM/MSH Microbiology Department Policy & Procedure Manual	**Policy # MI/RESP/11/v05**	Page 2 of 5
Respiratory Tract Culture Manual		

Standard operating procedures (SOPs)

- **Preparing SOPs:**

  - Scientific Validity Assessment: Prioritize assessing the scientific validity of the procedure before preparing the SOP to ensure accuracy and reliability.

  - Inclusion of Detailed Steps and Instructions: Write comprehensive step-by-step instructions detailing how to perform the procedure accurately and effectively.

  - Reference Relevant Procedures: Incorporate references to any related procedures, such as sample collection instructions or quality control protocols, for comprehensive guidance.

  - Establish Mechanism for SOP Updates: Implement a systematic approach for regularly updating SOPs to reflect changes in practices and maintain relevance.

Standard operating procedures (SOPs)

- **Key components of SOPs:**
  - Title: Clearly states the name of the test or procedure outlined in the SOP.
  - Purpose: Provides information about the test's significance, use case (e.g., screening, diagnosis, treatment follow-up), and relevance to public health surveillance.
  - Instructions: Detailed step-by-step guidance covering the entire testing process, including pre-examination, examination, and post-examination phases.
  - Authorship: Includes the name of the individual who prepared the SOP, ensuring accountability and clarity of responsibility.
  - Approval Signatures and Dates: Indicates the endorsement of responsible officials, along with the dates of approval, aligning with laboratory quality policies and regulatory requirements.

Standard operating procedures (SOPs)

- **Pre-examination instructions:**
  - Sample Collection and Transport: Detailed guidance on proper sample collection, transport to the laboratory, and necessary conditions for sample handling (e.g., use of preservatives, refrigeration, freezing, or room temperature storage).
  - Sample Labelling: Clear instructions reflecting laboratory policies for sample labelling, including requirements for patient identification verification, collection date on sample labels, and completeness of test request forms.
- **Examination instructions:**
  - Laboratory Procedures: Step-by-step instructions for conducting laboratory procedures accurately and efficiently.
  - Quality Control Procedures: Guidance on implementing quality control measures to ensure the accuracy, precision, and reliability of test results.

Standard operating procedures (SOPs)

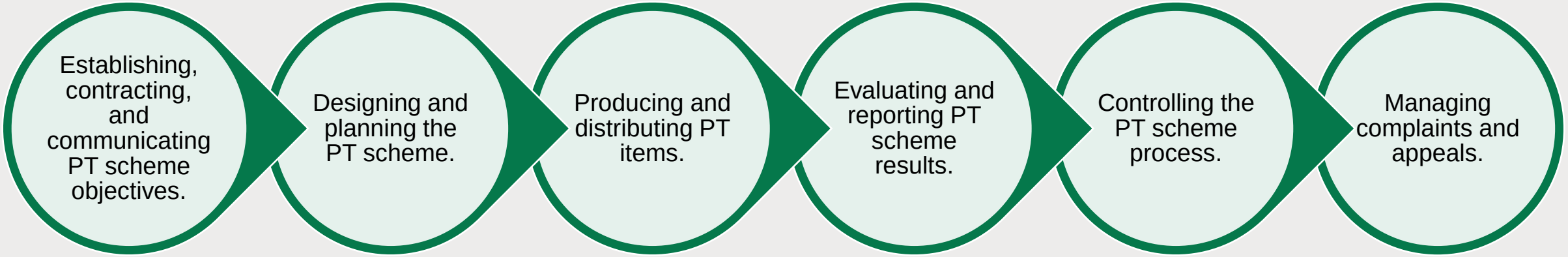
- **Post-examination instructions:**
  - Reporting Results:
    - Detailed guidance on how to report test results, including specifications for units of measurement, normal (reference) ranges, and identification of life-threatening ranges (e.g., "panic values").
  - Dealing with Urgent Reports:
    - Instructions for handling urgent or critical results, outlining procedures for immediate notification and follow-up actions.
  - References to Published Sources:
    - Incorporation of references to published sources of procedures, demonstrating scientific validity and ensuring adherence to established standards.

Standard operating procedures (SOPs)

- **Manufacturer’s instructions:**

  - Test Performance Guidelines: Manufacturers provide test-specific instructions, detailing how to perform the test accurately.
  - Limitations of Manufacturer's Instructions: Manufacturer's instructions may lack laboratory-specific information such as result recording procedures, testing algorithms, and safety practices.
  - Quality Control Recommendations: Manufacturers may suggest quality control procedures, but these recommendations may not align comprehensively with laboratory protocols.
  - Developing Laboratory-Specific SOPs: Emphasize the importance of using manufacturer's instructions as a reference but developing laboratory-specific SOPs to encompass all necessary procedures and policies.

Process Requirements



Process Requirements

- **Detailed information for PT scheme participants:**
  - Objective and Scheme Details: Clear objectives and relevant details of the PT scheme.
  - Participation Criteria: Criteria required for participation in the PT scheme.
  - Performance Evaluation Criteria: Criteria for determining assigned values and evaluating performance.
  - Confidentiality Arrangements: Protocols for ensuring confidentiality of participant information.
  - Timelines: Critical timelines for various phases of the PT scheme.
  - Participation Fees: Any associated fees for participation in the PT scheme.
  - Application Process: Details on how to apply for participation.

Process Requirements

- **Detailed information for PT scheme participants:**
  - Communication and Change Management:
    - Timely communication of PT scheme changes to participants and customers.
    - Maintenance and retention of records for relevant communications by the PT provider.

EQAsia Overview

- **Objective:**
  - Strengthening External Quality Assessment (EQA) services in the One Health sector across South and Southeast Asia.
- **Components of EQAsia:**
  - Rounds of proficiency tests (PT; named EQAs) for antimicrobial susceptibility testing (AST) using WHO and FAO priority pathogens.
    - ➢ Interpretative criteria based on international guidelines such as CLSI and EUCAST.
  - Rounds of training through workshops and webinars covering AST and quality management systems (QMS).
    - ➢ Consultation visits for selected underperforming laboratories post each EQA round.

EQAsia Overview

EQAsia program - Building capacity on AST - NRLs and Regional Laboratories

One Health approach
WHO – GLASS priority pathogens (human health)
FAO – Priority pathogens (animal health and food safety)

EQAs
(2 rounds per year of PT on AST)

1. •Selection of test strains
   •Protocols
   •Internal verification with expert stakeholders
2. •Preparation of webtool for handling expected results
3. •Announcement to participants
4. •Send parcels
5. •Submission of results from participant laboratories
   •Evaluation of AST performance
6. •Individual reporting
   •Summary reporting
7. •Selection of underperforming laboratories for consultation

Training
(site visits, webinars, workshops)

8. •Consultation visits for underperforming laboratories regarding AST methodologies and QMS
9. •CAPA recommendations
10. •2 Webinars per year. Each after every EQA
11. •1 Workshop (3-5 days covering topics of AST and QMS)

Acronyms
AST: Antimicrobial Susceptibility Testing
GLASS: Global Antimicrobial Resistance Surveillance System
PT: Proficiency Test
QMS: Quality Management Systems
CAPA: Corrective and Preventing Actions

EQAsia Overview

- **Fundamental tools for running an EQA:**

1. List of bacterial pathogen strains and antimicrobials for AST:
   - Includes WHO Global Antimicrobial Resistance Surveillance System (GLASS) and FAO priority pathogens.
   - Each EQA provides a suggested list of antimicrobials to test against specific strains.

2. Manuals, Guidelines, Protocols:
   - Essential for handling bacterial strains, including revival, growth, and storage protocols.
   - Documents are stored and downloadable for participants on a dedicated website managed by EQAsia partners from DTU.

EQAsia Overview

- **Fundamental tools for running an EQA:**

3. Webtool for result handling:
   - A dedicated online tool for storing, compiling, and managing EQA participant lab results efficiently.
   - Developed by DTU Corporate IT and hosted on the DTU server.
   - Handles EQA datasets individually, allowing creation of user profiles and reports.
   - Participants access their datasets only; Administrator has access to all datasets.
   - Administrator can create summary reports for all labs or by sector (animal/human health).
   - Customizable for adding expected results before each EQA round.
   - DTU partners are administrators; DTU Corporate IT supports maintenance and improvement.

EQAsia Overview

- **Fundamental tools for running an EQA:**

3. Webtool for result handling:

    - NEQA pilot plan implementation:
        - Individual country units created within the webtool for pilot EQA datasets.
        - Units accessible only to country users and administrators.
        - Users can access their datasets for report creation; Administrators customize and compile datasets for summary reports.
        - EQAsia consortium partner granted access to pilot datasets for guidance and support.

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