WHO-CDC International Conference on Quality Systems

Workshop on Asia Pacific Strategy for Strengthening Health Laboratory Services,
Bali Indonesia
23-25 June 2009
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International Health Security ...

WHO's milestones

First 21st century's global epidemic. Major economic cost

The International Health Regulations (2005)

Entry into use of IHR(2005)

June 2007

SARS, 2003

Avian Influenza, 2006

Influenza pandemic threat
International Health Security

IHR(2005), a paradigm shift

- From control of borders to containment at source
- From diseases list to all threats
- From preset measures to adapted response

15 June 2007: Entry into force of IHR (2005)
2007 – 2009: Assessment, development of national plan
2009 – 2012: Implementation of national plan

Strengthening the laboratories:
Lyon office strategic areas

- Strong focus on laboratory quality improvement to increase the confidence of clients (physicians, patients, public health authorities)
- Integrated approach (working on systems rather than diseases)
- Activities at global, regional and national level targeting resource-limited countries
WHO-CDC Lyon Conference on Quality Systems

Objectives

- To create awareness for the quality systems approach and calling for the establishment and implementation of national quality standards set for all the health laboratories
  - To review and discuss the quality systems suitable for health laboratories
  - To go over and envisage how to institute integrated quality system fitting well to the national laboratory system
  - To share successful experience and challenges of the countries, which have already made step forward
  - To discuss other important issues relevant to quality systems in detail, including external quality assessment (EQA) and a collective approach for reducing health laboratory relevant errors

- 200 participants from 70 countries
  - proportionately from resource-limited and industrialised countries
  - health policy makers, public health laboratory directors and leading scientists

- No result is better than a poor quality one
  - 60-70% clinical decisions depend on laboratory results
  - pre- and post-analytical phases e.g. quality of sputa samples?
Key agenda of the Lyon QS Conference

- Introduction and sensitization of quality systems approach
- Managerial role of resource limited governments and health care leadership
- Successes and challenges in implementing quality standards
  - Caribbean countries, Tanzania and Thailand
- A reminder and analysis in detail of errors incurred during non-analytic phases
- Breakout discussions
  - EQA
  - Developing national laboratory policies and standards
  - Advocacy for setting and implementing national quality standards
  - Integrated approaches for quality programmes
- Discussions and endorsement of the advocacy paper

WHO-CDC Advocacy Paper on Health Laboratory

- Joint statement of WHO participants
- Accurate, timely and reliable health laboratory testing is essential for the detection, treatment and prevention of diseases
  - Pertinent to all health activities
    - Integrated/cross-sectional approach
    - Laboratory quality system
WHO-CDC Joint Advocacy Paper
Key messages...1

- Organize national structures to support a countrywide laboratory quality system
  - Create laboratory manager post and office in Ministry of Health
  - Allocate adequate financial resources

- Establish national laboratory quality standards
  - Based on internationally agreed standards (e.g. ISO15189:2007)
  - Reflect country specific needs and available resources
  - Consider taking a staged approach: Thai model

WHO-CDC Joint Advocacy Paper
Key messages...2

- Implement major laboratory quality system programmes
  - Establish strategic national plan
  - Ensure sufficient and adequately maintained facilities
  - Ensure safety in all health laboratories
  - Apply appropriate quality systems to all parts of laboratory management and operations
  - Develop a process for monitoring laboratory performance improvement
  - Encourage the development of a structured advisory network for laboratories

- Involve all the stakeholders and interested parties
**Why need to advocate and catalyze quality diagnostic?**

- Critical in almost all aspects of health care
  - Disease prevention and surveillance
  - Diagnosis, therapy and prognosis
    - 60 to 80% of critical clinical decisions based on laboratory data
      - Poor diagnostic service means poor clinical outcomes
- Under-evaluation
  - Health policy makers
    - Diagnostics rarely top the agenda
    - Lack of political commitment = Insufficient funding support
  - Clinicians
- International Health Regulations (2005)

**Equality in quality**

*Issues in resource limited countries*

- Two fronts:
  - under-utilisation of diagnostic testing
    - lack of awareness
      - empiricism is NOT as accurate as physicians believe
e.g. up to 40% of "malaria" cases turned out to be incorrect
    - medical laboratory services not conveniently available/unaffordable
    - insufficient quality management of laboratories
  - a significant level of over-/under- treatment evidenced
    - resulting in unnecessary and untold suffering, wastage of resources...
Medical laboratory quality gaps

- Structural issues
  - weak or little regulatory/quality assurance framework put in place in resource limited settings
    - in contrast to pharmaceutical products
    - putting technologists working in the forefront at unacceptably high risks of occupational infection
      - inappropriately equipped/serviced facilities
      - insufficiently trained/educated personnel, lack of continuing training

- Dilemma
  - International standards exist but not readily feasible/realistic for many with resource constraints, especially for intermediate/district level laboratories
    - leaving them an “all or nothing” situation

  ➔ “staged approach” setting challenging yet achievable milestones to ensure long-term goals are reached

Other major issues in quality

- Low priority at national level with health administrators
  - Lack of awareness
  - Sustainability

- Staff shortage
  - Inadequate expertise and knowledge with technical staff

- Networking of laboratories

- Increasingly difficult logistics for EQAS
Following up the Lyon QS Conference

- Regional/Bi-Regional workshop
  - Bali workshop
  - Other Regions

- Collaboration with external partners
  - Maintenance of laboratory equipment
    - United Nations Industrial Development Organization (UNIDO)

- Publication
  - Detailed Meeting Report

- Country specific support

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April 2009

Staged approach taken
- similar to "Thai model"

National quality standard for medical laboratories set
- based on ISO15189

Vital activities
- capacity building of laboratories and oversight mechanism
- training sessions at various levels
- all the 4,000 laboratories in 41 laboratory regions across the country to be assessed

Well designed strategy with encouraging achievement
- suitable to be disseminated to other countries
Key to success in fulfilling aspired goals

- Highly motivated core staff excelling in understanding of quality and implementation strategy
- Strong leadership shaping orchestral teamwork at all levels across the country
- Formulating quality culture and quality community involving all the stakeholders
  - Training seminars and open dialogue process produce tangible results
  - Sharing the same vision and awareness of the issues
  - Thought-provoking insights and innovative ideas