Review

Implementation of quality management for clinical bacteriology in low-resource settings

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ABSTRACT

Background: The declining trend of malaria and the recent prioritization of containment of antimicrobial resistance have created a momentum to implement clinical bacteriology in low-resource settings. Successful implementation relies on guidance by a quality management system (QMS). Over the past decade international initiatives were launched towards implementation of QMS in HIV/AIDS, tuberculosis and malaria.
Aims: To describe the progress towards accreditation of medical laboratories and to identify the challenges and best practices for implementation of QMS in clinical bacteriology in low-resource settings.
Sources: Published literature, online reports and websites related to the implementation of laboratory QMS, accreditation of medical laboratories and initiatives for containment of antimicrobial resistance.
Content: Apart from the limitations of infrastructure, equipment, consumables and staff, QMS are challenged with the complexity of clinical bacteriology and the healthcare context in low-resource settings (small-scale laboratories, attitudes and perception of staff, absence of laboratory information systems). Likewise, most international initiatives addressing laboratory health strengthening have focused on public health and outbreak management rather than on hospital based patient care. Best practices to implement quality-assured clinical bacteriology in low-resource settings include alignment with national regulations and public health reference laboratories, participating in external quality assurance programmes, support from the hospital's management, starting with attainable projects, conducting error review and daily bench-side supervision, looking for locally adapted solutions, stimulating ownership and extending existing training programmes to clinical bacteriology.
Implications: The implementation of QMS in clinical bacteriology in hospital settings will ultimately boost a culture of quality to all sectors of healthcare in low-resource settings. **B. Barbé, Clin Microbiol Infect 2017;23:426**

Introduction

The relevance of clinical bacteriology laboratories in low-resource settings is increasingly recognized in light of the reduction of malaria burden [1,2] and the crisis of antimicrobial resistance (AMR) [3,4]. In contrast to HIV/AIDS, tuberculosis (TB) and malaria, clinical bacteriology does not benefit from disease-specific control programmes and advances towards implementing quality systems are conspicuously few. This review describes the current state of laboratory quality management in clinical bacteriology in sub-Saharan Africa and reflects on the challenges and best practices for moving forward. The target setting is a referral hospital in sub-Saharan Africa with a 'moderate infrastructure' (i.e. including a basically equipped laboratory) [5], where clinical bacteriology (culture-based detection, identification and antibiotic susceptibility testing of bacterial pathogens) is either available or planned. Although this review focuses on sub-Saharan Africa, the recommendations and best practices are applicable to the general context of low-resource settings.

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Quality, Quality Management Systems (QMS) and accreditation

Quality in medical laboratories can be defined as accuracy, reliability and timeliness of reported results [6] and a QMS describes the approach to meet the quality objectives [7]. QMS for medical laboratories are described in international standards [8]. Among them, International Organization for Standardization (ISO) 15189 [9] and Clinical and Laboratory Standards Institute (CLSI) QMS01-A4 [7] are the most widely used and are comparable. They both cover the three laboratory phases: (a) preexamination (indication and test selection, sample collection, transport, reception and accessioning), (b) examination (analysis and quality control) and (c) postexamination (interpretation, reporting, record keeping and notification). In addition CLSI QMS01-A4 introduced 12 Quality System Essentials (Fig. 1). Accreditation is the procedure to formal recognition that a medical laboratory is competent to carry out specific tasks [6]. National regulations either formulate own standards for accreditation or refer to existing QMS standards. For example, ISO 15189 is the standard for accreditation of medical laboratories in Europe.

Progress towards accreditation of medical laboratories in Sub-Saharan Africa

A decade ago an assessment of medical laboratories in sub-Saharan Africa portrayed a failing system with unreliable analyses leading to compromised patient care, unnecessary expenditures and distrust from clinicians and health authorities. The dysfunctional system was declared a 'barrier to healthcare in Africa' [10,11]. There were urgent calls to do better.

Starting with the Maputo declaration in 2008, successive landmark events induced global efforts to strengthen national laboratory health systems in low-resource settings (Table 1). Initiatives from HIV/AIDS and TB control programmes extended to strengthen the general health laboratory system [13,14,15,16]. An unprecedented increas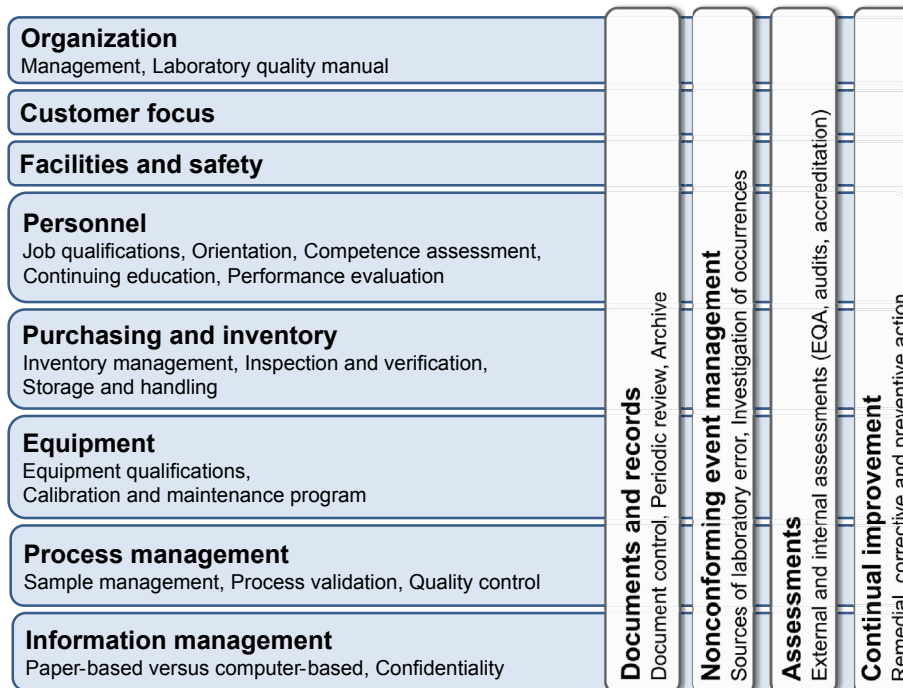e in international funding supported these efforts [12—14,17—19]. Accreditation according to ISO 15189 quality standards was pledged [15]. In 2009 the World Health Organization regional office for Africa (WHO AFRO) launched the Stepwise Laboratory Quality Improvement Towards Accreditation (SLIPTA) programme, which prepares clinical laboratories for ISO 15189 accreditation (Annual ASLM Newsletter 2016) [20]. In addition, WHO-AFRO developed the Strengthening Laboratory Management Toward Accreditation (SLMTA) toolkit to support implementation of SLIPTA [20] (https://www.slmta.org/toolkit/english). In 2011 the African Society of Laboratory Medicine (ASLM) was created to advocate for the critical role and needs of laboratory medicine and networks throughout Africa [13]. By the end of 2016, SLMTA had been implemented by 1103 laboratories in 47 countries worldwide, with Kenya, Ethiopia and Uganda as top three countries (Annual ASLM Newsletter 2016). Of those, 23 African laboratories currently achieved accreditation to international standards (K. Yao, personal communication, February 22, 2017). In addition, the total number of medical laboratories accredited to international standards in sub-Saharan Africa has increased from 380 in 12 countries by May 2013 [21] to 485 in 18 countries by April 2017 (T. Mekonen, personal communication, April 24, 2017) (Fig. 2).

Despite these efforts, the 2014—2015 West African Ebola outbreak highlighted the role of weak diagnostic infrastructure in the affected countries. As a response, the Global Health Security Agenda (GHSA) was launched to promote global health security as an international priority [22].

Challenges to implement QMS in clinical bacteriology in sub-Saharan Africa

The strengthening of the general health laboratory system has fallen short

The intention to leverage HIV-networks and the SLMTA programme to boost general health laboratory systems has yielded

Organization
Management, Laboratory quality manual

Customer focus

Facilities and safety

Personnel
Job qualifications, Orientation, Competence assessment, Continuing education, Performance evaluation

Purchasing and inventory
Inventory management, Inspection and verification, Storage and handling

Equipment
Equipment qualifications, Calibration and maintenance program

Process management
Sample management, Process validation, Quality control

Information management
Paper-based versus computer-based, Confidentiality

Documents and records
Document control, Periodic review, Archive

Nonconforming event management
Sources of laboratory error, Investigation of occurrences

Assessments
External and internal assessments (EQA, audits, accreditation)

Continual improvement
Remedial, corrective and preventive action

Fig. 1. Twelve quality system essentials of CLSI document QMS01-A4: Quality Management System: A Model for Laboratory Services [7]. General themes displayed horizontally, transversal themes vertically.