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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 increase 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

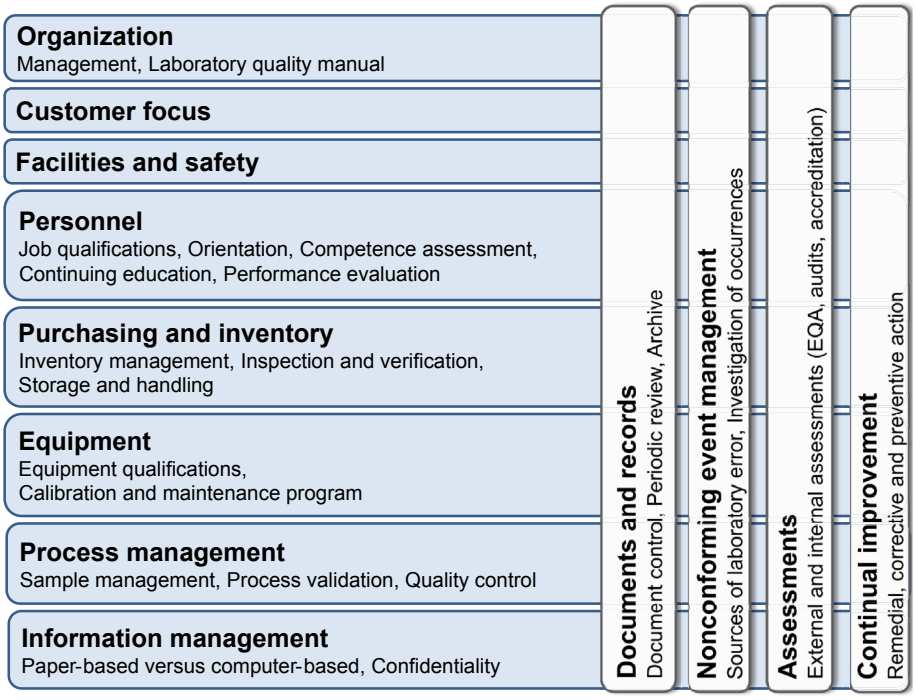

Fig. 1. Twelve quality system essentials of CLSI document QMS01-A4: Quality Management System: A Model for Laboratory Services [7]. General themes displayed horizontally, transversal themes vertically.

Table 1
Landmarks towards accreditation of medical laboratories in sub-Saharan Africa

No.	Landmark	Outcome
1	Maputo declaration on Strengthening of Laboratory Systems, Maputo, January 2008	'Maputo declaration,' issued by 33 countries together with WHO, World Bank and Global Fund for AIDS, TB and Malaria, calls on low-resource countries to develop national laboratory strategic plans and policies to strengthen laboratory services and systems as integral part of overall health system (tiered lab networks for multiple diseases) [12].
2	Joint WHO-CDC Conference on Health Laboratory Quality Systems, Lyon, April 2008	Statement issued calling for countries with limited resources to develop quality laboratory systems using staged approach leading to accreditation. It was suggested that national laboratory standards establish minimum requirements, and national reference laboratories were encouraged to meet international standards (ISO 15189).
3	58th session of WHO Regional Committee for Africa, Yaoundé, September 2008	During the 58th session of the WHO Regional Committee for Africa, member states adopted resolution AFR/RC58/R2 to strengthen public health laboratories in WHO African region at all levels of the healthcare system.
4	5th meeting of Regional HIV/AIDS network for Public Health Laboratories, Dakar, September 2008	It was agreed that the network should broaden its scope beyond HIV/AIDS and associated diseases to become an integrated network encompassing all labs, without limitation of a disease-specific designation.
5	WHO-AFRO Stepwise Laboratory Accreditation preparedness scheme, Kigali, July 2009	WHO-AFRO launched Stepwise Laboratory Quality Improvement Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA), in presence of its partners and government health officials from 13 African countries.
6	59th session of WHO Regional Committee for Africa, Kigali, September 2009	During the 59th session of the WHO Regional Committee for Africa, member states adopted resolutions AFR/RC59/R2 and AFR/RC59/WP/3, calling for strengthening of public health laboratories and other centres of excellence to improve disease prevention and control.
7	African Society of Laboratory Medicine (ASLM), Addis Ababa, March 2011, http://www.aslm.org/	This pan-African professional body aims to set up integrated laboratory services, to develop national laboratory policies and strategic plans for tiered laboratory networks and to improve quality systems and accreditation preparedness.
8	Ministerial Call for Action on Strengthening of Laboratory Services in Africa, Cape Town, December 2012	During the first international ASLM conference in Cape Town, this ministerial call was undersigned by six African countries. By November 2014, this call was signed by 13 African countries.
9	Global Health Security Agenda (GHSA), Washington, DC, February 2014, https://www.ghsagenda.org/	GHSA is collaborative effort from governments, international organizations and civil society to promote global health security as international priority. GHSA currently includes almost 50 countries and is coordinated by a multilateral steering group of 10 countries together with international organizations such as WHO, FAO, OIE, Interpol, ECOWAS, UNISDR and the European Union.
10	Freetown declaration on Developing Resilient Laboratory Networks for GHSA, Freetown, October 2015	Freetown declaration was issued by more than 20 African countries, together with ASLM and WHO AFRO. It calls for a new framework for functional tiered laboratory networks into disease surveillance systems and public health institutes.

Adapted from Alemnji [13] and Andiric and Massambu [14].
ASLM, African Society of Laboratory Medicine; CDC, Centers for Disease Control and Prevention; ECOWAS, Economic Community of West African States; FAO, Food and Agriculture Organization of the United Nations; GHSA, Global Health Security Agenda; HIV, Human Immunodeficiency virus; MOH, Ministry of Health; OIE, World Organization for Animal Health; SLIPTA, Stepwise Laboratory Quality Improvement Towards Accreditation; SLMTA, Strengthening Laboratory Management Toward Accreditation; TB, Tuberculosis; UNISDR, United Nations Office for Disaster Risk Reduction; WHO, World Health Organization; WHO-AFRO, World Health Organization Regional Office for Africa.

limited results. Though there has been some success at integration of HIV with TB services, other examples are few [19]. The encouraging data on the uptake of SLMTA belie the fact that the vast majority of accredited laboratories are HIV and TB reference laboratories [16,20] with few (4/23, 17%) accredited SLMTA laboratories in sub-Saharan Africa performing clinical bacteriology. Moreover, most external quality assurance (EQA) programmes centre on HIV, TB and malaria [23–28].

Antimicrobial resistance enters the scene, but tools are lacking and performance is poor

Although the critical need for diagnosis of bacterial infections is long established [10], clinical bacteriology has only recently achieved prominence with policymakers, prompted by the increasing recognition of the looming crisis of AMR (Table 2). In October 2015, the Freetown declaration launched a framework to establish functional tiered public health laboratory networks to AMR surveillance in Africa [22,58]. In addition, the United Nations General Assembly recently launched several internationally coordinated actions on AMR. Of note, most of these initiatives focus on public health implications—particularly outbreak management (in line with the International Health Regulations [29]) rather than on individual patient care.

The predicted impact of the AMR crisis casts a new urgency on the need to improve performance levels. In 2012 a publication of an EQA session among reference laboratories in sub-Saharan Africa revealed serious shortcomings in bacterial identification and antimicrobial susceptibility [30]. Adding to the difficulty is the lack of appropriate tools for training and implementation of QMS in clinical bacteriology. For instance, the SLMTA toolkit includes only few examples about clinical bacteriology.

Fig. 2. Map of sub-Saharan Africa showing countries with medical laboratories that have been accredited to internationally recognized standards by April 2017. Numbers below countries' names refer to number of accredited laboratories in that country.

Clinical bacteriology and QMS: a difficult fit

Clinical bacteriology deals with multiple specimens, indications and requirements for sampling and transport. Culture-based bacteriology requires skilled operators, is difficult to automate and leaves much to the individual laboratorian's discretion. In the post-examination phase, there are issues of interpretation (contaminating or colonizing flora) and reporting (e.g. preliminary results of Gram stain, cultures in progress) and application of expert rules [31–33]. Clinical bacteriology is therefore less amenable to QMS than other laboratory disciplines, which have single targets and generate automated quantitative results that allow for statistical monitoring.

Particular challenges in sub-Saharan Africa

Adapting QMS to local realities proves difficult in sub-Saharan Africa [34]. Besides the well-known limitations of infrastructure, equipment, consumables and staff, additional issues merit comment. Most laboratories in sub-Saharan African hospitals are small [34] and provide haematology, clinical chemistry, parasitology and sometimes blood transfusion services on a 24/7 basis. Staff not familiar with QMS may associate quality with goodness rather than with conformance to requirement [6]. In view of the small scale and daily burdens, quality essentials such as assessments, customer focus and process management may be perceived as superfluous, and the concept of prospective risk management may be too unfamiliar [34]. Further, the digitalization of laboratory and hospital information, automation and bar code tracking—which have dramatically reduced errors at all examination phases [6,35]—are not yet implemented in sub-Saharan laboratories and the requirement to validate and secure laboratory information software (LIS) tools is difficult to meet [34]. An additional challenge in many low-resource settings is the lack of unique identifiers for patients with naming practices leading to many people with the same name or names that change over time, lack of identity cards and exact birth dates.

Table 2
Overview of main international initiatives dedicated to containment of antimicrobial resistance

No.	Initiative	Scope
1	Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR), 2008 (http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/agisar/en/)	WHO AGISAR consists of a multidisciplinary team of over 30 internationally renowned experts and supports WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals.
2	Global Antibiotic Resistance Partnership (GARP), 2009 (http://www.cddep.org/garp/home)	GARP is a project of CDDEP and is funded by the Bill & Melinda Gates Foundation. GARP has supported the creation of multisectoral national-level working groups in eight selected low- and middle-income countries whose mandate is to understand and document antibiotic use and antibiotic resistance in the human and animal population and to develop evidence-based proposals to encourage introduction of measures to contain antimicrobial resistance.
3	Global Health Security Agenda (GHSA), 2014 (https://www.ghsagenda.org/)[a]	One of the 11 GHSA action packages focuses on AMR, and includes development of a national action plan based on a 'one health' approach; development and implementation of guidelines and standards for infection prevention; development and use of guidelines for antibiotic use; access to at least one reference laboratory for each country capable of identifying at least three of seven WHO priority AMR pathogens.[b]
4	Global Action Plan on Antimicrobial Resistance (GAP-AMR), 2015 (http://www.who.int/antimicrobial-resistance/global-action-plan/en/)	This WHO action plan sets out five strategic objectives: (a) improve awareness and understanding of AMR, (b) strengthen knowledge through surveillance and research, (c) reduce incidence of infection, (d) optimize use of antimicrobial medicines in human and animal health, (e) ensure sustainable investment in countering AMR. The action plan underscores the need for a 'one health' approach, involving human and veterinary medicine, agriculture, finance, environment and well-informed customers.
5	Global Antimicrobial Resistance Surveillance System (GLASS), 2015 (http://www.who.int/drugresistance/surveillance/glass-enrolment/en/)	GLASS, developed by WHO, is a platform for global data sharing on AMR worldwide, initially focusing on eight priority bacterial pathogens in humans.[c] Currently more than 30 countries are participating.
6	United Nations General Assembly, 2016	Global leaders met at the United Nations General Assembly to commit to fighting antimicrobial resistance together. This was only the 4th time in the history of the UN that a health topic was discussed at the General Assembly (HIV, noncommunicable diseases and Ebola were others).

AGISAR, Advisory Group on Integrated Surveillance of Antimicrobial Resistance; AMR, antimicrobial resistance; CDDEP, Center for Disease Dynamics, Economics and Policy; GAP-AMR, Global Action Plan on Antimicrobial Resistance; GARP, Global Antibiotic Resistance Partnership; GHSA, Global Health Security Agenda; GLASS, Global Antimicrobial Resistance Surveillance System; UN, United Nations.

[a] Refer to Table 1 for a general description of GHSA.

[b] WHO list of AMR pathogens of concern includes [3]: *Escherichia coli,* resistance to third-generation cephalosporins (ESBL) and to fluoroquinolones; *Klebsiella pneumoniae,* resistance to third-generation cephalosporins (ESBL) and to carbapenems; *Staphylococcus aureus,* methicillin resistance (MRSA); *Streptococcus pneumoniae,* resistance (nonsusceptibility) to penicillin; nontyphoidal *Salmonella* (NTS), resistance to fluoroquinolones; *Shigella* species, resistance to fluoroquinolones; *Neisseria gonorrhoeae,* decreased susceptibility to third-generation cephalosporins.

[c] GLASS priority pathogens for surveillance are: *Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii, Staphylococcus aureus, Streptococcus pneumoniae, Salmonella* spp., *Shigella* spp., *Neisseria gonorrhoeae*.

Implementing QMS in clinical bacteriology in low-resource settings: best practices

Implementation of a QMS comprises all 12 Quality System Essentials, but approaches and priorities may vary according to the local situation [6]. Below, we present some best practices about how to implement QMS in clinical bacteriology on site. They are compiled from existing literature (though mainly conducted in high-resource settings) complemented with our own experience.

Connect to national regulations and public health laboratories

Alignment with national regulations is imperative and will guide towards legal requirements such as participation in EQA programmes [36]. Much can be adopted from the expertise of the disease-specific control programmes of malaria, HIV/AIDS and TB and their respective reference laboratories: they provide logistic support (equipment and quality-assured consumables and stains) and dedicated procedures, job descriptions, forms and logbooks in local languages [37]. In addition, they organize trainings, external quality controls, on-site supervision visits and meetings with the laboratory heads. They further offer advanced techniques, coordinate surveillance activities and create national laboratory networks for diffusing of knowledge and competencies [22,38].

Participate in EQA programmes

EQA programmes improve laboratory performance (provided implementation of corrective actions in case of failures) and are cost-effective [30,39]. They allow the participants to benchmark and monitor their competence and to verify their methods; in addition, they provide didactic and educational stimulus [6,40]. Beyond that, EQA programmes provide health authorities with information about overall competence of laboratories, *in vitro* diagnostics' performance and training needs [6,28,39,41]. EQA programmes further generate excellent opportunities to integrate vertical disease control programmes, for instance by sharing distribution canals and increasing nationwide coverage [28,39]. Short turnaround times, swift communication (e.g. sending correct answers directly after closure), well-structured didactic reports and—in our experience—personalized feedback and EQA-oriented trainings are instrumental to a productive EQA session [39].

Observe and understand the local scene, find support and allies

Support from the healthcare facility management at all levels is essential to success, as is a well-functioning relationship between clinicians and laboratory staff. A strategy that has proved powerful in antibiotic stewardship activities is the 'engagement of peer

champion advocates' [42], which means engaging individual laboratorians, clinicians and administrators to promote a culture of quality. Clinicians can play a role at the pre- and postanalytical processes, for example, by promoting de-escalation of antibiotics based on culture results. Insights in the perceptions, attitudes and interactions of the clinical, nursing and laboratory staff are therefore helpful to guide and prepare interventions [43,44]. In line with what has proved to be successful in malaria treatment, joint training for clinicians and laboratory staff are recommended [45]. Further, the overarching QMS of the hospital can be used to connect for support in logistics (transport, procurement, maintenance, biosafety and waste management) and staff management (training, orientation and evaluation).

Start softly—choose for feasibility and impact

Before formally starting-up a QMS, time to observe and analyse the laboratory activities must be taken, to get acquainted with the workflow, terminology and vocabulary, product names and abbreviations used as well as with laboratory and hospital staff and the healthcare's context. As noted elsewhere, personal interactions provides a solid basis for collaboration [46].

Starting with a project that can be easily accomplished and has a high impact is recommended [6]. Topics can be found close to the work space and include for instance biosafety (rational use of gloves and masks), labelling of shelves and storage space and standardization of labelling of consumables. In addition, 'fewer are better,' which means that no more than one topic every six months should be addressed [6].

Keep documents and communication simple and straightforward

Communication must be efficient and adapted to the size and complexity of the laboratory [6]. Standard operating procedures (SOPs) will be among the first documents to be written or updated. A good SOP is presented in an appropriate font type and lay-out (legible), easy to understand (readable) and conveys clear and unequivocal information (comprehensible); it presents sufficient procedural details [47] is pretested and verified [6,48]. Given the extended templates of QMS-recommended SOPs (CLSI QMS02-A6 template lists 17 sections [49]), so-called bench aids or job aids are welcome as a quick reference at the work place—provided document control [6,47,48]. The urge for legibility, readability and comprehensibility also applies to other documents particularly if used at the workplace: stock cards, check lists, flow diagrams and graphs. In the African context, the importance and impact of respectful verbal communication cannot be overemphasized and occasions for face-to-face interactions with clinicians and other stakeholders should be fully exploited [47,48].

Learn from your mistakes

Reducing medical errors ranks first among the benefits of a successful QMS implementation and error review has been the oldest approach of the 'Nonconforming Event Management' [7]. Error review consists of tracking errors up to the identification of root cause(s) and subsequent design and implementation of corrective and preventive actions [50]. Most errors occur in the pre- and postexamination processes (about 60% and 25% respectively) [6,51], but given its manual and subjective workup, clinical bacteriology is also vulnerable to errors in the examination phase [52]. Apart from 'expected' and easily detectable errors (e.g. failing to comply with SOP, not acting on out-of-range quality controls), there are hidden errors such as failures of Gram stain reading, species identification and antimicrobial susceptibility testing [32,53].

In our experience, error review is an excellent portal of entry to activate QMS and it can be applied from the early phase of implementation of the QMS, whereas alternative approaches such as monitoring of quality indicators and internal audits require a more advanced implementation. Of note, most analytical errors in clinical bacteriology proved to be related to knowledge and skills and therefore can be efficiently addressed by teaching, training and learning [52]. Educational programmes should be straightforward, explain the science behind the error and stress the 'do's and don'ts'; moreover, overlap and redundancy are appropriate [47].

Be present at the bench and organize daily supervisory review

Supervision of culture workup is another traditional approach towards laboratory quality and is particularly relevant for clinical bacteriology [54]. Supervision at the workplace—in preference at a daily basis and at a fixed time—is a valuable tool for bench-side teaching, tuning of operator-subjective examinations (such as Gram stain) and boosting compliance with SOPs. Daily supervision also allows for timely detection of procedural deviations such as unapproved modifications, ill-advised shortcuts and use of outdated products inserts [47].

Look for locally adapted solutions

A creative mind helps to design local solutions on the road to ISO 15189. Low-cost low-tech, feasibility and acceptability are key. As an example, printed request forms may guide the prescriber towards harmonized indications and relevant requests. Standardized abbreviations may be agreed upon and recorded. Risks to sample mismatch and mislabelling of subcultures can be mitigated by arranging the physical space and workflow at the bench and sticking to the one-by-one rule used at specimen transfer and distribution [55]. A particular risk is inoculating multiple isolates on a single petri agar, which should be limited and well controlled. Electronic sign-off of documents may be replaced by hand-signing before or after laboratory meetings. Other tools of traceability include writing in different colours according to the day of incubation, use of standardized laboratory forms and implementing a journal passing along information between staff covering night shifts [6].

Stimulate ownership and create a positive climate

A QMS must be visible in the laboratory and must express progress and achievements. A clear workplace such as described in the SLMTA toolkit (Module 1—Productivity management) with well-designed bench aids displayed is conducive to QMS but also attractive for staff, trainees and visitors. Staff should be invited to SOP and document writing and verification, but should not be overloaded. A constructive and critical attitude including reporting and reviewing errors should be encouraged. As stated above, laboratory management must assure clear commitment and involvement in the implementation of the QMS, amongst others by visible presence at meetings and trainings, respecting short feedback loops and keeping good and timely records [6,50].

Needs and opportunities to extend QMS and training tools to clinical bacteriology

Existing tools to facilitate QMS (Table 3), such as the WHO AFRO's SLMTA toolkit and the WHO, Centers for Disease Control and Prevention and CLSI Laboratory QMS Training Handbook and Toolkit can be easily extended with real-life cases of clinical

Table 3
Examples of open-access tools for the implementation of laboratory quality management systems

No.	Tool	Scope
1	WHO/NCID External Quality Assessment Programme (EQAP) in Africa, 2002 (http://www.who.int/ihr/publications/policy_procedures_eqa/en/)	WHO/NCID EQAP tests the proficiency of microbiologic testing for epidemic-prone diseases by laboratories in the African region.
2	WHO-CDC-CLSI Laboratory Quality Management System Training Toolkit, 2009 (http://www.who.int/ihr/training/laboratory_quality/doc/en/)	Training toolkit intended to provide comprehensive materials that will allow for designing and organizing training workshops for all stakeholders in health laboratory processes.
3	Quality Manual Template, 2013 (http://www.who.int/ihr/training/laboratory_quality/quality_manual/en/)	Quality manual template supplement to the laboratory quality management system training toolkit, Module 16—Documents and records.
4	WHO-CDC-CLSI Laboratory Quality Management System Training Handbook, 2011 (http://www.who.int/ihr/publications/lqms/en/)	Handbook that covers topics essential for quality management of public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents. The handbook is linked to the training toolkit on laboratory quality management system.
5	WHO Laboratory Assessment Tool (LAT), 2012 (http://www.who.int/ihr/publications/laboratory_tool/en/)	Document that describes the general process for assessing laboratories and provides two questionnaires to help assess national laboratory systems (Annex 1) and individual laboratories (Annex 2).
6	WHO-AFRO Guide for Establishing Laboratory Based Surveillance for Antimicrobial Resistance, 2013 (http://apps.who.int/medicinedocs/documents/s20135en/s20135en.pdf)	Guide that provides background information and defines key steps for countries to conduct AMR surveillance for meningitis, bacteraemia and common enteric epidemic-prone diseases in national bacteriology reference laboratory.
7	Laboratory Quality Stepwise Implementation (LQSI) Tool, 2015 (https://extranet.who.int/lqsi/)	Web-based tool that provides a stepwise plan to guide medical laboratories towards implementation of quality management system in accordance with requirements of ISO 15189. Developed by Royal Tropical Institute Netherlands for World Health Organization [56].
8	Basic Laboratory Information System (BLIS) (http://blis.cc.gatech.edu/index.php)	Open-source system to track patient specimens and laboratory results, developed by C4G (Computing for Good) and implemented through AFENET [57].
9	WHONET (http://www.whonet.org/)	Free software developed by WHO Collaborating Centre for Surveillance of AMR for management and analysis of microbiology laboratory data with special focus on analysis of antimicrobial susceptibility test results. WHONET 5.6 with 2016 breakpoints is the most commonly used around the world and offers support for 27 languages. WHONET 2017 with GLASS support is currently only available in English.

AFENET, African Field Epidemiology Network; BLIS, Basic Laboratory Information System; AMR, antimicrobial resistance; CDC, Centers for Disease Control and Prevention; CLSI, Clinical and Laboratory Standards Institute; EQAP, External Quality Assessment Programme; GLASS, Global Antimicrobial Resistance Surveillance System; LAT, Laboratory Assessment Tool; LQSI, Laboratory Quality Stepwise Implementation Tool; NCID, National Institute for Communicable Diseases—South Africa; WHO, World Health Organization.

bacteriology—for instance in the SLMTA's 'Meet the Clinician' activities and the 'Clinicians Handbook,' or its modules of specimen collection, work area management and test result reporting.

Although hardware and network costs remain barriers, implementation of a LIS has benefits at all three examination processes; LIS further provides opportunities to educate prescribers, guide therapeutic decisions and detect hospital infection outbreaks in real-time. LIS supports other Quality System Essentials such as purchasing, inventory and assessments (e.g. analysis of corrected reports as a proxy for near errors) [6,52]. Currently, free-of-charge LIS are made available (Table 3).

Conclusion

Across sub-Saharan Africa and over the last decade amazing strides have been made to implement QMS in the laboratory diagnosis of HIV, malaria and TB. It is now time to extend this success to clinical bacteriology, given the momentum generated by the declining burden of malaria and the need to contain the emergent AMR. Taking into account the particularities of both clinical bacteriology and the context of low-resource settings, existing national networks can be strengthened towards competences in clinical bacteriology and training tools can be adapted to integrate clinical bacteriology. Best practices can facilitate the implementation of QMS in clinical bacteriology in hospital settings. Given the extensions of clinical bacteriology to antibiotic stewardship and infection prevention, this step will ultimately boost a culture of quality to all sectors of healthcare in low-resource settings.

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Transparency Declaration

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