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Enhancing clinical microbiology for genomic surveillance of antimicrobial resistance implementation in Africa

Henry M Kajumbula[1], Daniel Gyamfi Amoako[2,3], Sofonias K Tessema[4], Mabel Kamweli Aworh[5], Francis Chikuse[4*], Iruka N Okeke[6], Uduak Okomo[11], Sabelle Jallow[8], Beverly Egyir[12], Aquillah M Kanzi[10], Abdul Karim Sesay[7], Yewande Habibat Alimi[4], Kwabena O Duedu[9] and Olga Perovic[8*]

Abstract

Surveillance is essential in the fight against antimicrobial resistance (AMR), to monitor the extent of resistance, inform prevention, control measures, and evaluate intervention progress. Traditional surveillance methods based on phenotypic antimicrobial susceptibility data offer important but limited insights into resistance mechanisms, transmission networks, and spread patterns of resistant bacterial strains. Fortunately, genomic technologies are increasingly accessible and can overcome these limitations. Genomics has the potential to advance traditional bacteriology in routine diagnosis and surveillance, it often relies on the initial isolation of bacterial strains from clinical specimens using conventional culture methods. Culture-based phenotypic characteristics are essential for making inferences about newly recognized genomic patterns. The Africa CDC Pathogen Genomics Initiative (Africa PGI) aims to enhance disease surveillance and public health partnerships through integrated, cross-continent laboratory networks equipped with the tools, human resource capacity and data infrastructure to fully leverage critical genomic sequencing technologies. For genomic surveillance of AMR, it is essential to optimize routine clinical microbiology laboratory services that are weak in many African countries. In this review, we outline shortcomings in clinical microbiology laboratories across Africa that compromise pathogen genomic epidemiology. We emphasize the necessity of investing in bacteriology and enhancing leadership capacity to fully capitalize on the advantages offered by genomic antimicrobial resistance (AMR) surveillance.

Keywords Microbiology laboratory capacity, AMR surveillance, Whole genome sequencing, Laboratory quality, Workforce

*Correspondence:
Francis Chikuse
ChikuseF@africacdc.org
Olga Perovic
olgap@nicd.ac.za

Full list of author information is available at the end of the article

Introduction

Due to a very high infection burden, poor prevention measures, and limited access to care, including appropriate diagnostics and antimicrobial options, sub-Saharan Africa suffers the highest AMR attributable mortality globally with an estimated case fatality rate of 23.5 per 100,000 people [1–5]. Moreover, surveillance systems for tracking and monitoring the extent and spread of AMR in Africa are inadequate and limited [4]. As such, the Africa CDC launched the Strategic Framework for AMR Control in 2018, highlighting the need to establish laboratory-based AMR surveillance systems as an early priority for AMR containment and management in Africa [5].

Development of advanced sequencing technologies, such as whole-genome sequencing (WGS) or even targeted next generation sequencing technologies has introduced the concept of genomic surveillance, which can provide holistic information on the biology of a bacteria via systematic analysis of its DNA [6]. Genomic surveillance can augment clinical surveillance data by providing additional information such as virulence factors, antimicrobial resistance mechanisms, and transmission dynamics (b). Furthermore, its high resolution and discriminatory power can allow for the differentiation of closely related strains and the identification of transmission pathways with greater precision [7]. Genomic surveillance has proven to be effective at detecting multidrug-resistant strains that were previously undetected through traditional surveillance methods, including the identification of and response to outbreaks of AMR in real-time [8] (c).

Clinical microbiology laboratories play a crucial role in the genomic surveillance of AMR (Fig. 1). They serve as the starting point for receiving, and then processing clinical specimens and they recover pathogens, and determine antimicrobial susceptibility and other clinically-relevant phenotypes [9]. These laboratories also manage significant volumes of metadata (clinical and epidemiological data) relevant to AMR surveillance .Integrating genomic methodologies with robust clinical microbiology practices enhances AMR surveillance and provides essential evidence for interventions and policy development [10]. Magobo et al. [11] applied WGS to uncover the transmission networks of an outbreak of carbapenem-resistant *Klebsiella pneumoniae* (CRKP) in a South African neonatal unit. The two strains of CRKP were linked to poor instrument sterilization and breaches in aseptic technique during the insertion of invasive devices, a finding that guided targeted interventions. In Zambia, where *Salmonella enterica* serovariety Typhi is a major cause of bacteremia, genomics demonstrated that the *S.* Typhi strains in the country generally belonged to the same sequence types as those found elsewhere in Africa and the rest of the world, indicating a possible role of international travel in its spread that was confirmed in multicounty analyses of those and other genomes [12, 13]. Genomics was also able to delineate the key resistance mechanisms to fluoroquinolones [12]. In The Gambia,

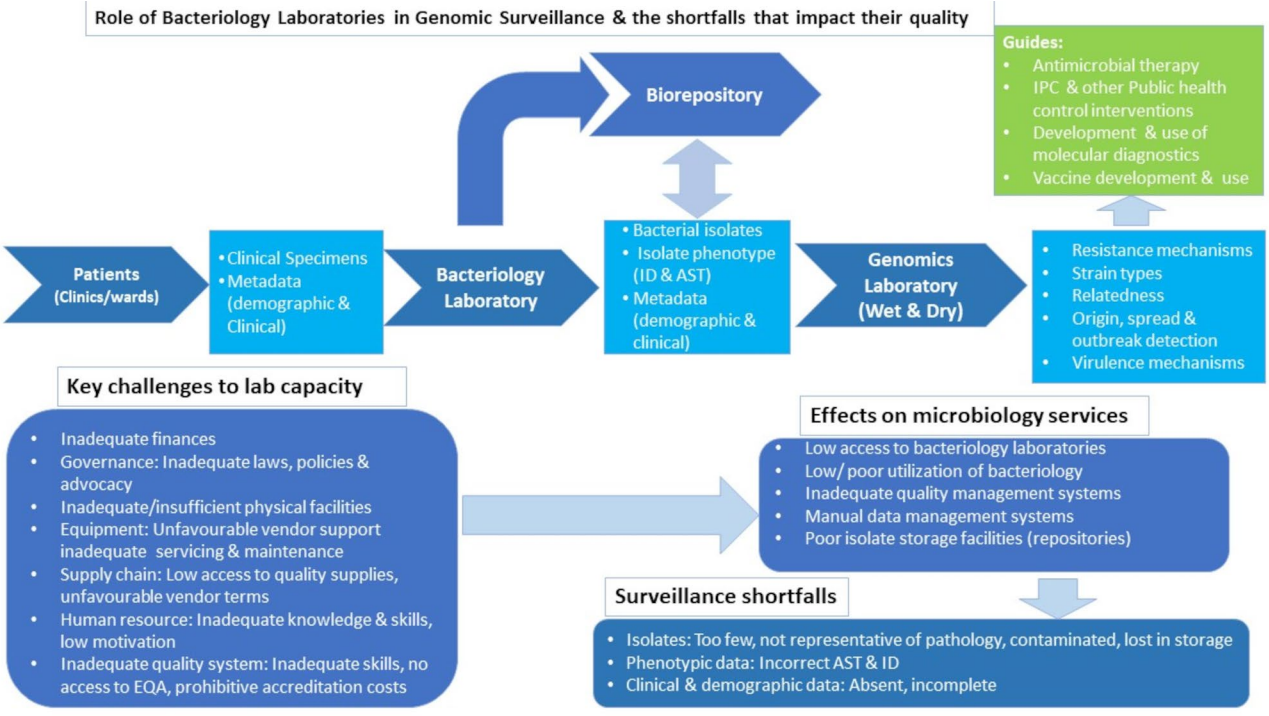

Fig. 1 Microbiology laboratory work flow in preparation for genomic surveillance

genomics complemented bacteriology to demonstrate that mothers, through vertical transmission, were not the major source of infection for neonates with early-onset bacteremia [14].

During the COVID-19 pandemic, several African countries received next generation sequencers and considerable upgrades of their public health laboratories allowing them to sequence and analyse Sars-CoV-2 to monitor the pandemic within their countries. Many countries have since started whole genome sequencing of bacterial pathogens using these platforms. While genomic surveillance will provide a unique opportunity to document and harness the gathered information from the vast bacterial diversity in Africa, enhancing clinical microbiology surveillance to implement genomic surveillance will require a multifaceted approach to address various challenges specific to the continent. Implementation will require investments in laboratory capacity building and infrastructure, including reliable electricity supplies to ensure uninterrupted functioning of sequencers; data management systems to handle and analyse genomic data effectively; and bioinformatics by providing training and resources for laboratory personnel. Collaboration and knowledge sharing among African countries and with global partners will be important in building genomic surveillance capacity. Initiatives such as the Africa CDC's Pathogen Genomic Initiative can facilitate collaboration and information exchange among African countries, enabling them to pool resources to have regional data management systems and to leverage on existing expertise and infrastructure for genomic surveillance efforts.

This review aims to articulate the gaps in clinical microbiology laboratories that should be addressed to maximize the gains from genomic AMR surveillance in Africa.

Availability of clinical microbiology services in Africa

Reliable AMR surveillance programs are built on the analysis of representative numbers of bacterial isolates. In Africa, access to clinical microbiology laboratories is critically low with very few bacterial isolates recovered, usually from patients in well-resourced settings and those with the most severe or persistent infections. Poor access to clinical microbiology services therefore undermines both routine patient management and AMR surveillance programs [15, 16]. Testing practices at the majority of African microbiology laboratories depends on is capacity development. Global surveillance of AMR prevalence should be built on national representative data obtained following standardized statistically meaningful probability sampling methods. Even where functional clinical microbiology laboratories exist, their utilization is often suboptimal. Legba et al. [17] reported that blood cultures were routinely performed in only six of the 27 bacteriology laboratories across Benin and most of these laboratories processed less than 10 specimens monthly. The limited capacity was attributed to inadequate supplies, equipment, and laboratory personnel skills, as well as to the physicians' routine of prescribing antibiotics without laboratory support. Under these circumstances, information on isolates from blood and cerebrospinal fluid, which are among the most reliable anatomical sites for recovering significant isolates, and which inform life-threatening infections, was inadequate. Laboratory improvements must be done in tandem with strengthening diagnostic stewardship so that clinicians order tests when they will support patient care, draw and dispatch appropriate and high-quality specimens and also utilize intermediate and final laboratory results [18].

The Mapping AMR and AMU Partnership (MAAP), a Fleming Fund supported project coordinated by the African Society for Laboratory Medicine (ASLM) conducted an assessment of clinical microbiology capacity in 14 countries on the continent [16]. Remarkably, only 1.3% of the 50,000 laboratories in 14 countries in West, East, Central, and Southern Africa had capacity for routine bacteriology. Moreover, most of the laboratories only routinely performed isolation and susceptibility testing for only five of the 15 WHO GLASS priority pathogens. This limited capacity is reflected in the low AMR surveillance reporting rates on the continent, with only 34% of African countries submitting data to the AMR GLASS by 2021 [4]. In many countries, bacteriological testing is limited to national microbiology laboratories meant to provide reference testing and coordinate quality in lower-level laboratories. An evaluation of the external quality assessment (EQA) performance of 81 public health microbiology laboratories from 45 countries across Africa between 2011 and 2016 revealed numerous issues. Despite being national reference laboratories, only 42% of them produced accurate antimicrobial susceptibility testing (AST) results [19]. Most faced numerous obstacles, including inadequate infrastructure, paper-based reporting, insufficient funding for basic consumables, a lack of power backup solutions, and poor access to the internet. Many lacked automated instruments for bacterial identification and AST, and often misidentified the pathogens due to the limited accessibility of identification tests. Media production was a major challenge, with many laboratories using human blood instead of the recommended horse or sheep blood. Internal quality control procedures were generally weak, and many laboratories didn't use the recommended ATCC control strains.

There is an urgent need to improve laboratory capacity and institute the 'culture of doing culture'. Countries should leverage the lessons, best practices, systems, and infrastructure of relatively well-resourced and

well-established programs, notably HIV, TB and public health emergency response [20, 21]. National and subnational laboratories with microbiology capacity should be developed as hubs to serve health facilities within their catchment areas, and specimen transportation systems need to be established, or where existing, strengthened.

Laboratory quality management system

Quality management systems provide the means of ensuring the accuracy of laboratory results and the reliability, consistency, and customer centeredness of the services. All clinical laboratories must adhere to the quality systems essentials espoused in the ISO 15,189 standards for clinical laboratories. Clinical microbiology laboratories on the continent still face critical quality systems challenges. According to a 2020 survey of 221 laboratories performing bacteriology and antimicrobial susceptibility testing in 14 countries across the continent, only 26 (12%) had quality management systems or were accredited [16, 21]. Their average score based on the Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) tool was 46% for human and 31% for animal health laboratories. Most did not participate in any proficiency testing programs. In addition to the inadequate financing, which impacts all the elements of quality systems, personnel in many African laboratories lack the knowledge, skills, and motivation to implement quality management systems. Additionally, regulatory frameworks, accrediting bodies, and proficiency test providers that are essential for supporting quality systems are not accessible in most countries.

To overcome these bottlenecks, countries, regional organizations, and the African Union and its technical agencies at large, should adopt ongoing initiatives aimed at addressing these critical gaps. The African Society for Laboratory Medicine (ASLM) is working with the National Institute for Communicable Diseases (NICD) in South Africa, Institute Pasteur Dakar in Senegal, and Amref Health Africa serve as regional external quality assurance (EQA) providers on the continent, currently serving 14 African countries that are recipients of Fleming Fund country grants [22].

Remote mentoring and auditing could be a strategy for handling limited laboratory quality management systems (LQMS) expertise, as demonstrated by the John Hopkins University Patient Safety Monitoring in International Laboratories (JHU-SMILE). The SLMTA/SLIPTA approach assesses laboratories, trains and mentors laboratory personnel in quality systems, while supporting them in implementing progressive quality improvement [23–25]. As of 2023, a total of 320 clinical laboratories on the continent had been mentored to obtain international accreditation using the SLMTA/SLIPTA approach [26].

Workforce development and retention

A skilled, motivated, and well-facilitated workforce is indispensable for building access to bacteriological diagnostics. Therefore, the continent needs to address critical gaps in the numbers, competencies, and management of the laboratory workforce. A significant proportion of the estimated global deficit of 840,000 pathology, laboratory medicine and diagnostic imaging professionals is borne by Africa [27]. Some of the fundamental human resource challenges include a low supply of qualified personnel, a lack of robust mechanisms for verifying their credentials, the sluggish uptake of qualified personnel by the public sector, poor remuneration, and poorly defined career paths [28]. The efforts of programs such as Qualifying the Workforce for AMR Surveillance (QWArS) [29], which seeks to train laboratory personnel in microbiology and surveillance skills in 14 countries, ought to be scaled up. To strengthen the quality of pre-service training, the curricula of the various training institutions should be harmonized based on widely recognized normative documents, such as the WHO competency framework for health workers' education and training on antimicrobial resistance [30]. Countries should develop technical expertise through continuous professional development programs and apply ethical approach in promoting institutional values [30]. In addition to standardization, in-service training programs aimed at strengthening bacteriology skills should incorporate mechanisms for recognizing learners' achievements. This is one of the primary objectives of the African Society for Laboratory Medicine (ASLM) Academy, set up in 2020 [31]. To enhance workforce development and retention, it is essential to create progressive career pathways that offer clear, attainable milestones for advancement and continuous professional development opportunities. Examples include transitioning from entry-level technicians, who receive initial training and certification in bacteriological diagnostics, to mid-level specialists, who undergo advanced training and mentor junior staff, and ultimately to senior scientists, who take on leadership roles in management, research, and policy development. Specialization tracks in clinical microbiology, public health microbiology, and research and development further support career growth by focusing on areas such as diagnostic techniques, epidemiological surveillance, and innovative research.

Supportive strategies to facilitate these career pathways include regular training programs to keep personnel updated on advancements, a robust certification system, and mentorship initiatives pairing early-career staff with experienced mentors. Leadership training, achievement recognition, competitive remuneration, and fostering

professional networks and international partnerships are also crucial. By implementing these strategies, we can build a career structure that attracts and retains talent, ultimately strengthening the laboratory workforce and enhancing bacteriological diagnostics across the continent. Investing in human capital is more than just an obligation; it is a transformative opportunity to empower individuals, generate economic growth, and create a healthier future for Africa [32].

Equipment management

Clinical microbiology laboratories depend on a variety of equipment ranging from basic items like refrigerators to more sophisticated systems like the MALDI-TOF. Proper equipment management is a quality system essential and contributes to accurate laboratory results and reliable, uninterrupted services. In Africa, virtually all equipment is imported, often as donations or purchased from grants. As such, many laboratories may not have the equipment most suitable for their functions and may find it difficult to shoulder servicing costs [33]. Equipment vendors often offer less favorable or no service contracts to African laboratories, particularly those in West and Central Africa, and in many countries, biomedical engineers are scarce [32]. The solutions proposed by Fonjungo et al. [34], have proven effective for some countries. These include engaging leadership, formulating policies, training laboratory personnel, and engaging equipment suppliers. In 2023, the Africa CDC published guidance on laboratory equipment management for African Union member states [35]. Countries, and regional organizations could come together to negotiate better terms with equipment suppliers, ranging from pricing to better support services. The myriad of equipment management concerns underscore the need for countries to procure equipment that is suitable for their local conditions, easy to use and service, and for which supplies are accessible. In some instances, optimal equipment options for working in hot and humid African settings are not yet available, emphasizing the need for instrumentation developers to consider our markets when they design and develop equipment with global health applications.

Supply chain, reagents and culture media

Procuring high-quality culture media and reagents in Africa can be a demanding task. As noted by Orekan [36] and Feagins [37], low- and middle-income countries face difficulties and restrictions in procuring these essential supplies. The availability of reputable product suppliers is limited, innovator products may be unavailable and the quality of alternate products from different manufacturers is often inconsistent. According to the WHO classification, media and related reagents are class A (low-risk) in vitro diagnostics and are therefore often not rigorously regulated for quality [38]. Weak or fragmented supply chains can often not assure that reagents are shipped as the manufacturer recommends and cold chains critical for some reagents may therefore be broken, which has considerable impact when shipping to and through geographies with high ambient temperatures, inadequate transportation networks and customs delays. Additionally, the quality of water, quality control measures, and storage of both dehydrated and prepared media also present major challenges to many laboratories in Africa [36].

Collective action at the continental level could be a key solution to some of the supply chain challenges. The Africa CDC and other regional bodies such as the regional economic communities should continue to advocate for negotiated prices, pooled procurement, improved supply chain systems, and the quality assurance of supplies. Local manufacturing of key reagents and supplies on the continent should be enhanced. To assure of quality of culture media and reagents, some of the preparation could be centralized. National reference laboratories or other designated laboratories could be resourced to reconstitute culture media and other reagents under well-controlled and quality assured conditions and distribute them to lower-level facilities.

Laboratory information systems

When analyzing data from clinical surveillance in microbiology, access to clinical and demographic metadata is crucial. However, many laboratories in Africa still rely on manual data management systems, often with incomplete essential metadata. According to the MAAP survey, of the 187,000 tests analyzed, 88% lacked information on patient clinical profiles. This was attributed to the limited availability of electronic laboratory information systems, which were only present in 26% of the laboratories surveyed [16]. These data management obstacles could be overcome by leveraging a number of open-source laboratory information systems. The microbiology component of the ASLM developed African Laboratory Information System (ALIS) could be customized to support AMR data management. Some laboratories could adopt the Wellcome Trust-supported SEDRI-LIMS, which was developed in response to need assessment and therefore has key LIMS and AMR data management functions that low-resource settings require and is currently being implemented in pilot. The Integration of the WHONET system with clinical information systems such as the ACORN platform [39] is an option. By leveraging these systems, data management obstacles can effectively be addressed.

To ensure optimal data management and utilization, microbiology personnel should be trained in the principles of epidemiology and data management and facilities

should have, or have access to, data officers and system administrators that can help tailor data systems and troubleshoot issues on site. Additionally, diagnostic stewardship programs should emphasize data completeness when filling out laboratory request/ order forms.

Bioinformatic computing capacity

Only a few African countries have instituted genomic surveillance, which requires significant computing capacity and storage resources to handle the large volumes of genomic data generated by sequencing bacterial pathogens. This need is essential for both the temporary processing of raw sequencing data and the long-term storage and management of genomic datasets for ongoing analysis and reference purposes. In low-resource settings limited funding may constrain the acquisition of high-performance computing clusters and storage servers required for rapid processing and analysis of genomic data. However, in the short term, a solution can be to use cloud computing services, which allows institutions to access scalable and cost-effective computing resources without the need for significant upfront investments. Also regional collaborations may provide opportunities for shared access to computing infrastructure. Collaboration and knowledge sharing among African countries will be important in building genomic surveillance capacity. Initiatives such as the Africa CDC's Pathogen Genomic Initiative can facilitate collaboration and information exchange among African countries, enabling them to pool resources to have regional data management systems and to leverage on existing expertise and infrastructure to enhance genomic surveillance efforts. For long-term storage of genomic data where maintaining dedicated servers and storage facilities may be impractical, the use of global data repositories such as the National Centre for Biotechnology Information (NCBI), can provide sustainable solutions for archiving and accessing genomic datasets.

Comprehensive policy and regulatory frameworks are needed for African countries to implement effective and sustainable AMR surveillance data mind. These frameworks should address issues of data privacy, data sharing, intellectual property, data storage and ethical considerations. Data privacy is essential to respecting the dignity, autonomy, and confidentiality of people whose samples are sequenced and analysed.

Isolate storage capacity

Properly isolate storage is critical for maintaining viability, purity, and genetic stability. To achieve this, it is essential to follow strict storage protocols and use appropriate storage media at stable, and monitored, temperatures while maintaining accurate archival records. Unfortunately, many African laboratories may lack ultralow temperature (−80ºC) freezers on-site, and are faced with unreliable electricity. More national facilities need to establish biorepositories with appropriate storage capacity where peripheral laboratories can periodically remit isolates for safe long-term storage.

Governance and financing of clinical microbiology laboratories

As articulated by Wertheim [40], governance measures, including accountability, transparency, equity, rigorous government oversight, and international collaborations are pivotal to successful delivery of laboratory services. The Maputo Declaration of 2008 formed a framework that committed political leadership in Africa to addressing laboratory challenges that were limiting the scale-up of services for tuberculosis, malaria, and HIV diagnosis and care [41]. Since then, remarkable improvements have been achieved in HIV laboratory medicine, including the accreditation of 320 laboratories through the SLMTA/ SLIPTA process [26, 41]. This framework and the laboratory policies and strategic plans that accrued from it, as well as the Africa CDC framework on AMR and the African Common Position on AMR [39] should be evoked to galvanize African governments and regional economic communities to support the development of clinical microbiology capacity [42].

Conclusion

We have highlighted incapacitating but fully-addressable shortfalls in clinical microbiology that stand in the way of widespread implementation of genomic surveillance as well as potential solutions to challenges in resourcing, governance, human resources, quality systems, equipment, supply chains and information systems on the continent. Their implementation would ensure that the clinical microbiology network on the continent functions optimally to support genomics, which in turn can extract actionable information from the outputs of clinical bacteriology, including critical information on pathogen mechanisms of resistance, virulence factors and transmission pathways, greatly enhancing the management and control of AMR.

Abbreviations

AMR	antimicrobial resistance
ASLM	the African Society for Laboratory Medicine
AST	antimicrobial susceptibility testing
ATCC	the American Type Culture Collection
CAP	the College of American Pathologists
CRKP	Carbapenem-resistant *Klebsiella pneumoniae*
EQA	external quality assessment
GAP	Global Action Plan
GLASS	the Global Antimicrobial Resistance and Use Surveillance System
GBD	Global Burden of Diseases
HIV	Human Immunodeficiency virus
JHU-SMILE	the John Hopkins University Patient Safety Monitoring in International Laboratories

LIMS	Laboratory Information Management System
LQMS	Laboratory quality management systems
MAAP	the Mapping AMR and AMU Partnership
MALDI-TOF	Matrix assisted laser desorption ionization time of flight mass spectrophotometry
MDR	Multidrug resistant
NICD	the National Institute for Communicable Diseases of South Africa
PGI	the Africa CDC Pathogen Genomics Initiative
PT	Proficiency testing
QWArS	Qualifying the Workforce for AMR Surveillance
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
TB	Tuberculosis
WGS	Whole genome sequencing
WHO	the World Health Organization

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Author contributions
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Data availability
No datasets were generated or analysed during the current study.

Declarations

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Not applicable.

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Competing interests
The authors declare no competing interests.

Author details
[1]Department of Medical Microbiology, Makerere University, Kampala, Uganda
[2]Antimicrobial Research Unit, College of Health Sciences, University of KwaZulu- Natal, Durban 4000, South Africa
[3]Department of Integrative Biology and Bioinformatics, University of Guelph, Guelph, ON N1G 2W1, Canada
[4]Africa Centres for Disease Control and Prevention, African Union, Addis Ababa, Ethiopia
[5]Department of Population Health and Pathobiology, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, USA
[6]Department of Pharmaceutical Microbiology, University of Ibadan, Ibadan, Nigeria
[7]Vaccines and Immunity Theme, MRC Unit the Gambia at London School of Hygiene & Tropical Medicine, Serrekunda, The Gambia
[8]National Institute for Communicable Diseases a division of NHLS and University of Witwatersrand, Johannesburg, South Africa
[9]College of Life Sciences, Faculty of Health, Education and Life Sciences, Birmingham City University, Birmingham, UK
[10]African Society for Laboratory Medicine, Johannesburg, South Africa
[11] Vaccines and Immunity Theme,, MRC Unit the Gambia at London School of Hygiene & Tropical Medicine, Serrekunda, The Gambia, Fajara , Gambia
[12]Bacteriology Department, , Noguchi Memorial Institute for Medical Research, College of Health Sciences, University of Ghana, , Accra, Ghana

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