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Review

Setting up laboratory-based antimicrobial resistance surveillance in low- and middle-income countries: lessons learned from Georgia

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ABSTRACT

Background: Antimicrobial resistance (AMR) is a growing problem worldwide, with an estimated high burden in low- and middle-income countries (LMICs). In these settings, tackling the problem of AMR is often constrained by a lack of reliable surveillance data due to limited use of microbiological diagnostics in clinical practice.
Objectives: The aim of this article is to present an overview of essential elements for setting up an AMR surveillance system in LMICs, to summarize the steps taken to develop such a system in the country of Georgia, and to describe its impact on microbiology laboratories.
Sources: A literature review of published papers using PubMed and experiences of experts involved in setting up AMR surveillance in Georgia.
Content: Basic requirements for implementing a laboratory-based surveillance system in LMICs can be captured under four pillars: (a) governmental support, (b) laboratory capacity and quality management, (c) materials and supplies, and (d) sample collection, data management, analysis and reporting. In Georgia, the World Health Organization Proof-of-Principle project helped to start the collection of AMR surveillance data on a small scale by promoting the use of microbiological diagnostics in clinics, and by providing training and materials for laboratories. Thanks to governmental support and a strong lead by the national reference laboratory, the AMR surveillance network was sustained and expanded after the project ended.
Implications: This review describes the Georgian approach in building and expanding a functional AMR surveillance system, considering the elements identified from the literature. The introduction of quality management systems, standardization of guidelines and training paired with targeted capacity building led to improved laboratory standards and management of patients with bloodstream infections. Reliable AMR surveillance data may inform and facilitate policy-making on AMR control. The Georgian experience can guide other countries in the process of building up their national AMR surveillance system.
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Introduction

Antimicrobial resistance (AMR) is a threat to adequate treatment and prevention of infectious diseases and disproportionately affects low- and middle-income countries (LMICs) [1,2]. Infections with resistant bacteria have been associated with increased

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morbidity, mortality and healthcare costs [3], and have a distorting effect on society as a whole.

Valid AMR surveillance data are needed to estimate the extent of the spread of AMR, to identify its drivers, and to develop targeted AMR control strategies and measure their impact. However, many LMICs face problems in obtaining high-quality, representative surveillance data [4,5]. Challenges faced include under-utilization of microbiology diagnostics, as well as technical, infrastructural and behavioural challenges in the implementation of clinical microbiology [6].

Clinical microbiology laboratories play an essential role in the fight against AMR [7]. Their activities include, but are not restricted to, identification and antimicrobial susceptibility testing (AST) of bacteria found in clinical samples. The routine use of microbiological diagnostics in patient care directly contributes to the containment of AMR by guiding the targeted and appropriate use of antibiotics (antibiotic stewardship), infection prevention and control in healthcare facilities, and it forms the basis for laboratory-based AMR surveillance.

Following the adoption of the WHO European AMR action plan in 2011, in 2012 the Central Asian and European Surveillance of Antimicrobial Resistance (CAESAR) network was created as a collaborative effort of the WHO Regional Office for Europe (WHO/Europe), the Netherlands Institute for Public Health and the Environment (RIVM), and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID). CAESAR complements the surveillance data generated by the European Surveillance of Antimicrobial Resistance Network (EARS-Net) for countries of the European Union and European Economic Area [8]. CAESAR's aim is to improve AMR surveillance in non-EU countries in the WHO European region by providing support in all steps needed to create a functional AMR surveillance system [9]. One of CAESAR's activities in particular, the Proof-of-Principle (PoP) project, has been developed for countries with limited routine collection of clinical samples, to improve clinical care for patients admitted with suspected bloodstream infections (BSIs): for example by demonstrating to clinicians the value of microbiological diagnostics, improving active case finding and communication between microbiologists and clinicians, strengthening laboratory capacity, and improving data management and analysis [10]. Georgia, an upper-middle-income country [11], joined the CAESAR network in 2015 and was the first country to participate in the PoP project. To set an illustrative example for other LMICs, we explore here what constitutes successful implementation of AMR surveillance in LMICs and describe the benefits and impact of joining a regional surveillance system (i.e. CAESAR) in Georgia [12].

Methods

The focus of this paper is on AMR surveillance based on routine clinical microbiology laboratory results from patients with suspected bacteriological BSIs visiting healthcare facilities. The literature was searched for articles describing requirements and experiences of setting up human AMR surveillance systems in LMICs (Box 1). Papers published before 2000 or not written in English were excluded. In addition, reference lists of the retrieved papers were scanned for suitable literature. This paper first explores prerequisites for building an AMR surveillance system in LMICs based on the literature found, followed by a discussion of the impact and experiences from building such a system in Georgia.

What is needed to set up an AMR surveillance system?

In general, AMR surveillance requires an enabling environment and a commitment to quality of care, which would allow professionals from different areas of the healthcare system to adhere to good clinical practice, to communicate well, to harmonize practices, and to carry out tasks in a timely and high-quality fashion. This multifaceted or multidisciplinary approach relies on a functional infectious disease diagnostic cycle: clinicians taking and submitting clinical samples to the microbiology laboratory, a bacteriology laboratory able to perform species identification and AST, as well as a system to report, collate, analyse and interpret data to inform those who need to take action [13,14]. With the successful implementation of an AMR surveillance system, the collected standardized and validated data can guide countries in developing empirical treatment guidelines, evidence-based public health policies and interventions. Fig. 1 shows a set of essential elements for developing AMR surveillance. When these building blocks are in place, the system can expand in a stepwise manner.

Governmental support

Experiences with implementing AMR surveillance in eight South Asian and Southeast Asian countries have shown that the sustainability of a surveillance system and continued training depends on internal government funding and sustained support from policy-makers [5]. This includes the development of a national action plan (NAP) for AMR as well as funding sources for its implementation [13,15,16], the establishment of a national reference laboratory (NRL) and the forming of a coordination committee with Ministry of Health (MoH) engagement [13,15,16].

Laboratory capacity and quality management

Laboratory capacity is too often the bottleneck for AMR surveillance. Establishing internal quality assurance and participation in external quality assessment (EQA) programmes for laboratories, development and updating of national standard operating procedures (SOPs) to ensure standardization and harmonization of laboratory procedures, as well as continuous training and motivation of staff are all important tools to build this capacity and ensure quality [5,13,15,17,18]. Seale *et al.* recommend that countries appoint a central coordinating laboratory which could fulfil and/or coordinate the above functions [15]. In addition, using guidelines for surveillance ensures standardization of the selection of specimens, organisms and antibiotics for testing [5,16].

Materials and supplies

To meet international standards for AST, bacteriology laboratories require an adequate infrastructure, including reliable equipment, a sustainable supply of quality consumables and

Box 1
Search strategy. PubMed was searched for articles using the following combination of search terms

(surveillance [tiab] OR ("Public Health Surveillance"[Mesh])) AND (antimicrobial resistance [tiab] OR AMR [tw] OR antibiotic resistance [tiab] OR ABR [tw] OR drug resistant infections [tiab] OR ("Drug Resistance, Bacterial"[Mesh])) AND (patient [tw] OR human* [tw]) AND (implement* [tw] OR "set up" [tw] OR "setting up" [tw] OR facilitat* [tw] OR barrier* [tw] OR success* [tw] OR challeng* [tiab] OR obstacle* [tiab] OR opportunit* [tiab]) AND ("Developing Countries"[Mesh] OR "developing countries" OR "developing country" OR low income countr* [tiab] OR middle income countr* [tiab] OR low resource setting* [tiab] OR third-world countr* [tiab])

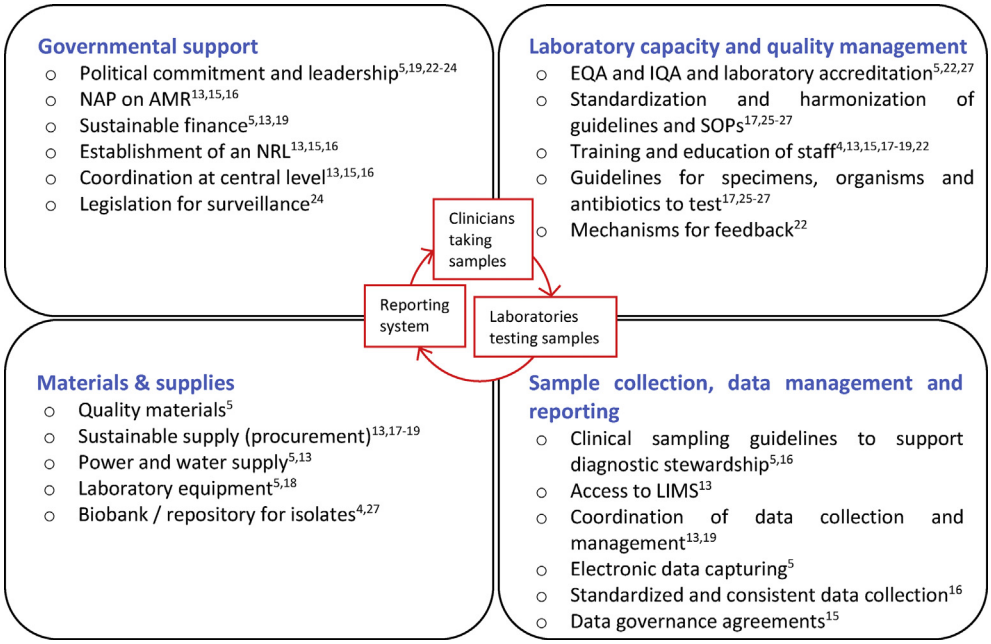

Fig. 1. Essential elements for developing AMR surveillance, supporting the infectious diseases diagnostic cycle [4,5,13,15–19,22–27], NAP, national action plan; NRL, national reference laboratory; EQA, external quality assessment; IQA, internal quality assurance; SOP, standard operating procedure; LIMS, laboratory information management system.

appropriate staffing [13,17–19]. LMICs in particular struggle to address specific shortages in supplies of water, electricity and infrastructure to allow laboratories to function properly [5,13]. The successful implementation of a sustainable AMR surveillance programme in Nepal—a country with poor access to good-quality reagents, inadequate storage facilities of reagents and frequent power failure—has shown that encouraging laboratory management in incorporating supplies in their laboratory procurement plan is effective and sustainable [17].

Sample collection, data management and reporting

An effective AMR surveillance programme requires a high level of diagnostic stewardship, including all stages of diagnostic practice, from procedures that guide specimen selection and collection, through processing of the clinical samples in the laboratory, to the reporting and interpretation of results [5,20]. Clinical guidelines should be in place to ensure that the right patients are properly sampled. Implementing laboratory information management systems (LIMS) in LMICs, instead of paper-based data recording, improves AMR surveillance by reducing workload and errors, and enables standardized data reporting to a national collection point [13,19]. The WHONET data management software provides these features and is freely available [21]. However, for the many laboratories without such systems or sufficient IT support, appropriate human resource allocation is required for manual data entry.

Experiences from piloting the PoP project in Georgia

Before Georgia joined CAESAR in 2015, clinical microbiology laboratories in hospitals were heavily underutilized (1.8 blood cultures/1000 patient-days), most laboratories were working with low-quality materials for AST, using outdated guidelines, without quality control or confirmatory testing. In the last decade, however, Georgia has made significant progress in reforming the healthcare system. Universal Health Care was introduced in 2013, allowing citizens access to medical services, and the healthcare budget was doubled [11]. Efforts to address AMR were increased, as demonstrated by the development of a National Strategy for Combating AMR according to the WHO's Global Action Plan on AMR [28], and by joining the CAESAR network. In addition, Georgia participated as the first country in the PoP project, which was carried out from July 2015 to December 2016 in four hospitals and led by a team of trained national project coordinators.

Governmental support

The rising threat of AMR and the WHO resolution (WHA68.7) calling for member states to develop a national AMR strategy urged the Georgian government to the following actions.

National action plan on AMR. The Georgian NAP for AMR was approved in 2017. The primary goals are to promote the rational use of antibiotics, introduce and maintain surveillance of AMR and improve infection prevention and control practices in healthcare facilities.

Sustainable finance. As microbiological diagnostics consumables were funded through the CAESAR project for the duration of the PoP project, sustainable funding was needed in order to keep up activities after the project ended. Management of participating hospitals was willing to increase the budget for microbiological diagnostics because the PoP project showed that better targeted treatment, resulting from using microbiological diagnostics, led to cost savings. In addition, new regulations required hospitals to monitor the occurrence of specific infections and laboratories to establish a quality management system (QMS). Also, the government decided to subsidize the NRL for AMR surveillance activities, covering expenses for confirmatory testing.

Establishment of an NRL. The R. Lugar Centre for Public Health Research at the National Centre for Disease Control and Public Health was appointed as NRL, as a prerequisite for the PoP project implementation. During the project, laboratories sent bacteria isolated from blood cultures to the NRL for confirmation of identification and AST results, which strengthened the role of the Lugar

Centre as reference laboratory, and created ample opportunity to engage and communicate with clinical laboratories participating in the project. As a result, the Lugar Centre has maintained its status as NRL, and has been providing technical and human resource support across the country. In addition, the NRL processes blood cultures for clinics in the state programme that do not have the in-house laboratory capacity to perform such tests.

Coordination at central level. A national AMR expert committee was established after the PoP project ended, which provides coordination and oversight at the central level, and evaluates the implementation of the NAP.

Legislation for surveillance. Several orders and decrees have been adopted since 2015 to promote AMR surveillance through accountability, and to regulate, among other things, QMS in laboratories and monitoring of infections in hospitals.

Laboratory capacity and quality management

External and internal quality assurance, and accreditation. The NRL and the network laboratories have been enrolled in the CAESAR EQA programme since 2015. Furthermore, the NRL provides a quarterly national EQA programme for the country's laboratories, starting with 11 laboratories in 2016 and expanding to 25 laboratories in 2020. Results of this programme are used for feedback and education of the laboratories. In addition, the NRL currently mentors 17 laboratories to establish internal quality assurance programmes. Further quality control is ensured by confirmatory testing of exceptional phenotypes and unexpected results performed at the NRL, using phenotypic and genotypic methods. Since 2016 it is mandatory for laboratories to send to the NRL 'alert' organisms and organisms with unlikely AST results requiring confirmation. After the Lugar Centre initiated its function as NRL, it received ISO 15189 accreditation in 2017. In 2021–2022 the NRL will work to acquire accreditation as EQA provider (ISO17043).

Standardization and harmonization of guidelines and standard operating procedures (SOPs). The NAP requires all laboratories to use the European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidelines for AST. At the moment, approximately 60% of laboratories participating in the national network have adopted EUCAST guidelines, and the other 40% will switch in the near future. The PoP project's SOPs for blood sampling, sample processing and AST were shared within the national network and are now used by most of the hospitals and laboratories.

Training and knowledge. Training of clinicians and laboratory staff was an important aspect of the PoP project. Initially, training was given by WHO experts and consultants, but during the project training and support was taken over by the NLR. After the project, the NRL continued to train new members of the network and organizes annual microbiology network meetings, data collection workshops, symposia and lectures. As a member of the CAESAR network, Georgia has access to annual training and support from WHO/Europe and ESCMID.

Materials & supplies

Sustainable supply of good-quality materials. To ensure timely receipt of supplies, the NRL aids laboratories with tender procedures. The NRL performs quality verification testing and provides laboratories with a list of reliable manufacturers. This way, the quality of consumables procured by laboratories is ensured. In addition, the national laboratory network frequently communicates with manufacturers and providers within Georgia, to prevent and address supply-chain issues. In case of severe disruption of the supply chain, hospitals have emergency funds to procure materials following other procedures.

Sample collection, data management and reporting

Access to laboratory information management systems. Enabling electronic data collection for laboratories using paper-based forms is one of the priorities for the national AMR committee. In 2019, a WHONET training was organized by the WHO for the national team and the network laboratories, but follow-up training is needed.

Coordination of data collection and management. The AMR surveillance data obtained during the PoP project was the first data from Georgia submitted to the CAESAR network, as part of the 2016 report. Since then, the NRL submits AMR surveillance data to CAESAR with the support of the WHO and the Netherlands Public Health Institute (RIVM).

Electronic data capturing and standardized and consistent data collection. As a result of the PoP project, the same isolate record forms are used by all laboratories, or alternatively, AST results are entered in WHONET. The NRL developed a routine for standardized data collection from the network laboratories and enters the data into an electronic database to be exported to CAESAR. Post-analytical steps (e.g., data entry, feedback report) were standardized by the national AMR committee.

Clinical sampling guidelines to support diagnostic stewardship. Significant progress was made in promoting diagnostic stewardship among clinicians, as this was one of the main goals of the PoP project. Training and guidelines on which patients to sample, and improved timeliness and reliability of the AST results led to increasing appreciation of microbiological diagnostics by clinicians, as it allowed them to use the results in their treatment decisions. This was demonstrated by the increasing number of blood culture samples taken: 5.9/1000 patient-days during PoP, a result that was sustained in 2019 with 6/1000 patient-days (median; range 2–13) [29]. Clinicians as well as hospital administrations indicated that the project helped to decrease the usage of antibiotics by allowing de-escalation of antibiotic therapy.

Expansion of the surveillance network

After the PoP project ended, the main challenge was how these encouraging improvements could be sustained and potentially expanded beyond the initial group of hospitals, which could then constitute a growing AMR surveillance network. The national AMR surveillance committee played an important role in leading the transition from PoP project to routine AMR surveillance. A strong collaboration was established, and between 2017 and the present the AMR surveillance network expanded from four to 25 laboratories, providing services to approximately 200 hospitals (mostly multidisciplinary general hospitals), covering about 70% of the population in Georgia.

Conclusion

Surveillance of AMR in LMICs is most likely to be successfully implemented when tailored to a country's level of capacity. This paper presents essential elements that were implemented in Georgia and other LMICs, which have helped to establish AMR surveillance systems in these settings. These findings can provide guidance to other LMICs aiming to establish AMR surveillance systems. The PoP project managed to promote diagnostic stewardship and blood sampling by clinicians, and increased their trust

in microbiology results, which in turn promoted antimicrobial stewardship, one of the aims of AMR surveillance. Once these building blocks of an AMR surveillance system come into play, the challenge is to maintain this activity and continuously improve the quality of each step involved. Georgia managed to transition from a project-type set-up to a sustained system, thanks to high-level commitment and leadership, which led to the availability of government funding and sustained support from policymakers and a strong functioning NRL.

Transparency declaration

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