

# Terms of Reference for Request for Proposals

## Fleming Fund Country Grant to Malawi

### 1. Overview of this grant

This is a Request for Proposals (RFP) for a Country Grant to support surveillance of antimicrobial-resistant bacteria in Malawi. It has been created in response to a Request for Support from the Government of Malawi (GoM). The grant will be funded by the UK Department of Health and Social Care (DHSC), under its Fleming Fund Grants Programme, which is managed by Mott MacDonald, the Management Agent.

This Fleming Fund Country Grant for Malawi will focus on strengthening One Health governance for Antimicrobial Resistance (AMR) surveillance by capacitating the national AMR coordination committee and technical working groups, supporting ownership and alignment and scaling up a One Health AMR mentoring scheme.

In the human health sector, the grant will support the further implementation of the national AMR surveillance strategy, focusing on capacitating the National Microbiology Reference Laboratory (NMRL) and designated sentinel surveillance sites to improve laboratory performance, data quality, biosafety and biosecurity, and to encourage greater clinical engagement with microbiology services to drive demand for diagnostic bacteriology services. The grant aims to support Malawi in developing a quality assured surveillance system to enable full implementation of the World Health Organization's Global AMR Surveillance System (GLASS).

In the animal health sector, the grant will facilitate the implementation of a national surveillance strategy, again capacitating laboratories to improve quality, biosafety and biosecurity, and data management, and developing surveillance strategies to ensure representative, good quality surveillance sampling in relevant animal populations.

The Grantee will be responsible to Mott MacDonald for all aspects of the grant, including the management of any partners, their performance, technical delivery and financial accountability. The Grantee will be expected to sign the Grant Agreement and will be expected to enter into sub-granting arrangements with partners on the same back-to-back terms.

The Grantee will need to work in close coordination with AMR National Steering Committee, which has been formed to address AMR in Malawi, and other national stakeholders. The Grantee will also be required to harmonise efforts on this Country Grant with other types of grants under the Fleming Fund Grants Programme, namely Regional Grants and the Fleming Fellowship Scheme.

This grant is expected to last 21 months ending no later than September 2021. Grant applications should be in the region of £3 million including all capital and recurrent costs, overheads and management costs.

### 2. Overview of the Fleming Fund

#### 2.1 Introduction

The UK Government has established the Fleming Fund to respond to the global threat of drug-resistant infections due to bacterial Antimicrobial Resistance (AMR). The Fleming Fund will be a critical tool in achieving the resolution of the 68th World Health Assembly, 2015 (WHA A68/20), and in realising the 'Political Declaration of the High-Level Meeting of the United Nations General Assembly (UNGA) on Antimicrobial Resistance, 2016'. These recognise that urgent cross-sectoral rationalisation of antimicrobial use, and prevention and control of infections in humans, animals, food, agriculture, and aquaculture sectors, are key to tackling AMR and call for: innovative research and development; affordable and accessible antimicrobial medicines and vaccines; improved surveillance and monitoring; increased governance on antimicrobial use; and increased international cooperation to control and prevent AMR.

The Fleming Fund aims to address critical gaps in surveillance of antimicrobial-resistant bacteria in low- and middle-income countries (LMICs) in Asia and Sub-Saharan Africa. Countries in these areas are set to bear the highest burden of drug resistant infections. A Global Action Plan on Antimicrobial Resistance (GAP-AMR) has been developed by the World Health Organization (WHO), which acts as the blueprint for a multi-stakeholder global response to averting a global health crisis caused by AMR.<sup>1</sup> The Fleming Fund comprises a number of workstreams (see [www.flemingfund.org](http://www.flemingfund.org) for more information). One workstream provides support to the Tripartite Alliance – the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) – as part of the OH approach. Through funding to the Tripartite Alliance, the Fleming Fund has contributed to the development of National Action Plans (NAPs) in Sub-Saharan Africa, South and South East Asia, and to the building of the evidence base and guidance for AMR surveillance. This work will be critical for the overall success of the Fleming Fund Grant Programme and underpins the delivery of the portfolio of Country and Regional Grants and the Fleming Fellowship Scheme, as these will target capacity gaps identified in NAPs. The Fleming Fund also funds initiatives in academic institutions to develop guidance on the development of AMR surveillance systems.

The Fleming Fund Grants Programme is the largest stream of financial support available through the wider Fleming Fund. The DHSC has appointed Mott MacDonald as the Fleming Fund Management Agent for the Fleming Fund Grants Programme. Mott MacDonald is a global company with expertise in multi-sectoral international development and fund management. On behalf of the UK Government, Mott MacDonald is responsible for funding allocation and oversight of all investments made across the whole portfolio of grants in different activities and in different countries.

The aim of the Fleming Fund Grants Programme is to improve the ability of recipient countries to diagnose drug-resistant infections, with an emphasis on bacterial infections, and to improve data and surveillance to inform policy and practice at national and international levels. The overall goal is to avert the human and economic burden of AMR.

The geographic focus of the Fleming Fund Grants Programme is 20-24 LMICs from Sub-Saharan Africa, and South and South East Asia. It can provide financial support up to 2021 to participating countries via three funding channels:

- Country Grants
- Fleming Fellowship Scheme Grants
- Regional Grants

The Fleming Fund will be independently evaluated by Itad, a specialist evaluation firm appointed by DHSC for this purpose.

## 2.2 Problem statement to be addressed by the Fleming Fund

The main issues to be addressed by Fleming Fund Country Grants are outlined below:

- There are too few trained microbiologists to undertake the volume of testing required for representative surveillance on AMR.
- There are few health facilities that routinely undertake bacterial culture; still fewer facilities that meet the requirements for accreditation, or which do routine antimicrobial susceptibility testing.
- There is no culture of surveillance for AMR in healthcare delivery and there are barriers to developing it.
- There is little perceived use of surveillance data on any level, including low demand for the data from policy makers.

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<sup>1</sup> <http://www.who.int/antimicrobial-resistance/global-action-plan/en/>

- There is a lack of knowledge on the use and consumption of antimicrobial agents across One Health sectors.
- There is a lack of antimicrobial stewardship.
- Logistical challenges are significant: transporting samples in a safe and secure manner under challenging transport conditions; ensuring a quality assured and sustained supply chain for reagents and consumables; and ensuring appropriate servicing of equipment are a few examples.
- Surveillance systems (national, regional and global) that do exist are often vertical in nature, are not linked, and are not integrated.
- There are weak One Health structures and there is poor inter-sectoral collaboration.
- There is a heterogeneous picture across countries and regions in terms of starting points, political will, capability, and donor interest and engagement.
- There are poorly defined and applied quality assurance standards in laboratory testing.
- There is lack of understanding on transmission patterns and drivers such as inappropriate use of antimicrobial drugs across all sectors.

### 2.3 Fleming Fund investment areas and outputs

To address the problems above, the Fleming Fund Grants Programme invests in:

- Laboratory infrastructure enhancement.
- Human resource strengthening and workforce reforms.
- Surveillance systems strengthening.
- Building foundations for AMR surveillance data use.
- Promoting rational use of antimicrobial medicines.

Investment in these areas is expected to achieve the following outputs:

- Improved laboratory skills and conditions for bacterial identification and Antimicrobial Susceptibility Testing (AST); and, therefore, improved data quality.
- A Strengthened One Health workforce with a range of relevant skills for AMR surveillance.
- Stronger AMR surveillance systems and processes at country and regional levels.
- Higher demand for AMR data at regional, country, subnational and facility levels.
- Better knowledge of country level patterns of prescribing practice and use of antimicrobials (particularly for bacterial infection) across sectors.

Fleming Fund outputs are expected to contribute to the following country outputs:

- Increase in quality and quantity of AMR and AMU data collected.
- AMR and AMU data shared in country to support evidence-based policy and practice
- AMR and AMU data shared internationally to improve and inform the global response, in particular via the WHO GLASS programme for human health AMR data.

The RFPs for Country Grants have been designed to ensure that investments and activities contribute directly to outputs. Grantees are expected to adhere to and demonstrate this alignment and contribution to outputs in their applications.

## 2.4 Core principles within the Fleming Fund Grants Programme

The Fleming Fund is built on four core principles. Grantees are expected to demonstrate how they will align with these principles while implementing the grant.

- 1) **Country Ownership:** The Fleming Fund Grants Programme will be implemented in line with national plans and aspirations, as laid out in the National Action Plan. Unless there are good reasons not to do so, Fleming Fund grants will chiefly invest in public sector laboratories and surveillance systems, thereby supporting national public health systems.
- 2) **One Health:** The Fleming Fund recognises that the problem of AMR is a great danger to human health and cannot be controlled without a One Health approach. A specific set of One Health investment parameters has also been developed and is summarised below. This approach is aligned with key documents and guidelines from OIE<sup>2</sup> and FAO<sup>3</sup> as well as the Global Action Plan.
  - a. **Collaborative multi-sectoral governance of AMR:** Leadership and resourcing of AMR surveillance and mitigation measures in all sectors that contribute to the emergence of AMR.
  - b. **Integrated AMR and antimicrobial use and consumption surveillance in all sectors:** Surveillance in humans, livestock, aquaculture, crops, food and the environment to produce information that is interpreted by multi-sectoral teams to help understand factors associated with AMR emergence within and between sectors.
  - c. **AMR mitigation policies and programmes prioritised across multiple sectors:** Evidence-based policies and programmes for AMR mitigation measures that are prioritised across the relevant sectors, based on information generated through AMR and AMU/C surveillance in all sectors.
- 3) **Alignment of Approach:** The Fleming Fund Grants Programme will seek to invest in areas which complement and build on work done to date, rather than create new systems. Grant applicants will need to demonstrate that they understand other actors' work in the field of improved laboratory capacity (both within and outside the sphere of AMR surveillance), improved disease surveillance, and the One Health approach. The Fleming Fund Grants Programme will assess grants for duplication of efforts and/or the development of parallel systems. To the extent possible, prospective Grantees will need to demonstrate how their proposals add value to existing and planned investments and systems.
- 4) **Sustainability:** The Fleming Fund Grants Programme will focus assistance on national systems with a view to long-term sustainability. Investment size and scope should, as far as possible, be aligned with national government spending so that systems created with Fleming Fund grants are sustainable within the public health system. We also recognise that the public good of conducting AMR surveillance means medium- to long-term support, and it is expected that countries that demonstrate good performance will have access to additional funds to provide ongoing support. The lead grantee will be expected to: take a strategic approach to sustainability; identify key challenges and critical factors relating to sustainability; explain concrete strategies specifically designed to address these challenges and factors; and outline an exit strategy.

## 2.5 Fleming Fellowship Scheme

The Fleming Fellowship Scheme is part of the broader Fleming Fund Grants Programme and is managed by Mott MacDonald. Fellowships provide funding to support on-the-job training over an 18- to 24-month programme of structured learning, mentoring and skills development for four to eight Fellows in each investment country. The Fellowships do not duplicate basic training, rather they focus on building advanced

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<sup>2</sup> OIE Standards, Guideline and Resolution on Antimicrobial resistance and the use of antimicrobial agents;

<sup>3</sup> The FAO Action Plan on Antimicrobial Resistance, 2016-2020.

skills and leadership to promote the application of best practice in identified 'Beneficiary Institutions', while promoting the One Health principle. Beneficiary Institutions are organisations such as AMR reference laboratories national epidemiology units in the human and animal health sectors, hospitals and/or national drug administration agencies that add strategic value and complementarity to achieve the Fleming Fund's aims in the country. They are also institutions most likely to derive sustainable benefit from the Fellowship activities.

The initial focus of the Professional Fellowship Scheme is on strengthening the quality of laboratory diagnostic data and the analysis and use of AMR and AMU surveillance data in Beneficiary Institutions. Fellows in each country are supported by mentors who provide the expertise required to support the needs of the Fellows as well as to help them to improve the sustainability of AMR programmes in their institution. The data they generate will be applied to deliver evidence-based approaches to tackling AMR, for example to improve antimicrobial stewardship.

Priority areas to be supported through the Fellowship Scheme are discussed by a Mott MacDonald scoping team together with the national AMR committee in each country and reviewed with the Beneficiary Institutions to which they are assigned. A template is provided for each Fellowship terms of reference which is adapted to the Beneficiary Institutional needs. One, or at most two, expert 'Host Institutions' are matched with all the Fellowships in a specific country. The Host Institution is drawn from a preselected pool, and after attending an initial workshop with the Fellows and Beneficiary Institution, the Host Institution develops a budgeted work plan. Once workplans and budgets have been agreed by Mott MacDonald, Fellows are formally accepted, and their Fellowship activities expensed through the Host Institution.

## 2.6 Fleming Fund activities in Malawi to date

This is the first Fleming Fund Country Grant to be released in Malawi. In preparation for this grant, Mott MacDonald carried out a Scoping Visit in February 2019 which was followed, in March 2019, by Positioning Activities in 7 public health / clinical laboratories and 3 animal health laboratories.

Key stakeholders in the animal and human health sectors have been consulted throughout the process, with strong leadership by the Antimicrobial Resistance National Co-ordination Committee (AMRNCC) and high-level political support for the grant. The Scoping and Positioning visits identified key capacity gaps and challenges, mapped other stakeholders working in laboratory strengthening, and confirmed the need to support development of AMR, AMC and AMU surveillance capability in humans and animals.

## 3. The current AMR situation in Malawi

### 3.1 National Action Plan for AMR

Malawi developed and implemented a Health Sector Strategic Plan I (HSSPI) from 2011 to 2016, which was followed by the Health Sector Strategic Plan II (HSSPII), which runs from 2017 to 2022. The plans are aimed at improving programme continuity within the health sector, and the overall contribution of the health sector to national development. AMR was included in HSSPII as a critical area of intervention: this document therefore provides a framework for the development of the national AMR strategy.

The Malawi AMR National Action Plan (NAP), published as the National AMR Strategy, runs from 2017 to 2022 and provides the operational detail to the HSSPII strategy outline, and is also a response to the global WHO efforts to reduce the impact of AMR.

The NAP was based on both the HSSPII, and a situational analysis undertaken in 2016. The situation analysis highlighted absence of a formally mandated committee for co-ordination of AMR activities, a lack of dedicated budget, poor controls on antimicrobial use, and limited human resources and infrastructure.

The NAP was developed by a multisectoral team comprising representatives from the Ministry of Health; Ministry of Agriculture, Irrigation and Water Development; Ministry of Natural Resources, Energy and Mining;

academia, civil society, and other co-operating partners. The process was coordinated by the Public Health Institute of Malawi (PHIM), which falls under the Ministry of Health. The NAP was launched on the 14<sup>th</sup> November 2018 by the Permanent Secretaries under the Ministry of Health and the Ministry of Agriculture. Development of the NAP was funded by a Global Grant from the Fleming Fund.

The NAP has five thematic areas (Education and Awareness, Research and Surveillance, Infection Prevention and Control, Optimal Use, and Investment and Sustainability) in line with the Global Action Plan on AMR; each will be overseen by a technical working group.

For surveillance, the objectives of the NAP are broad, and aim to: 1) incorporate AMR into the existing surveillance system (with reference to the One Health concept); 2) establish a national coordinating centre for surveillance of AMR; 3) strengthen the national epidemiological surveillance system on AMR in human health, animal health, agriculture and environment; and 4) establish mechanism for regular sharing of AMR data across human, animal health, agriculture and environmental sectors.

Although the NAP includes a budgeted operational plan, it acknowledges that financial resources to support implementation are very limited: there is an expectation that external investment and technical support will be drawn from international partners and global funding mechanisms.

The NAP outlines a costed workplan, which also indicates the roles and responsibilities of each of the key stakeholders, although the aims and objectives are broad – for example, specific surveillance sites are not identified in the document.

### 3.2 AMR Governance Structure

According to the NAP, AMR activities will be managed by the Ministry of Health (MoH) through the AMR National Coordinating Committee (AMRNCC). The MoH, through the AMRNCC, sets the agenda for AMR surveillance in Malawi in collaboration with key stakeholders: these include the Ministry of Agriculture, Ministry of Education and the Environmental Affairs Department who are members of the AMRNCC.

The AMRNCC operates as a subcommittee of the National One Health Committee, which comprises Directors from the Ministry of Health, Ministry of Agriculture, Irrigation and Water Development and the Ministry of Natural Resources, Energy and Mining. There is also representation from cooperating partners, including the World Health Organisation (WHO) and the US Centre for Disease Control (US-CDC). The OH Committee is co-ordinated by the Public Health Institute of Malawi (PHIM) and is chaired by its director.

The technical working group on Research and Surveillance will be responsible for all the activities concerning AMR surveillance and will report to the AMRNCC, which in turn reports to the multisector One Health Committee as above.

The head of the National Microbiology Reference Laboratory is the designated National Antimicrobial Resistance Co-ordinator who acts as the National Focal Point, although they have not been formally identified as such via GLASS. They oversee the co-ordination and function of the AMR core team – this team is not clearly defined in the NAP and at present is essentially the secretariat to the AMRNCC and is responsible for implementation of several components of the NAP, although it does not have formal Terms of Reference.

### 3.3 One Health

The NAP was formulated and structured to be implemented with the responsibility of all health sector stakeholders in Malawi, and, as indicated above, the AMRNCC is a sub-committee of the National One Health Committee, a reflection of the national adoption of a One Health approach. However, at present, the National One Health Committee meets on an ad-hoc basis when there is a public health matter of concern: the focus to date has primarily been with zoonotic disease. The One Health Committee and its subcommittees, including the AMRNCC, have not, to date, been formally constituted by the government and currently operate without designated budgets. Similarly, the key technical working groups for the different thematic areas under the NAP have not been formally constituted.

### 3.4 Other stakeholder activities

Malawi received support from the Norwegian Agency for Development Cooperation (NORAD) to perform a situational analysis (2016) in conjunction with the University of KwaZulu Natal (UKN). NORAD have also funded purchase of equipment and reagents to support AMR surveillance, and, with UKN, have also supported a number of Masters and PhD studentships.

Other external partners include the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW, [www.mlw.mw](http://www.mlw.mw)). Primarily a clinical research programme, the institution also provides a blood culture service to Queen Elizabeth Central Hospital, Blantyre. Similarly, the University of North Carolina Project Malawi (UNC), based at Kamuzu Central Hospital, Lilongwe provides a backup bacteriology services for Kamuzu Central Hospital, and assists the hospital laboratory, and the National Microbiology Reference Laboratory, with reagent supply management and staff training.

### 3.3 AMR Surveillance – human health

Malawi enrolled in the Global AMR Surveillance System (GLASS) in May 2017. By the end of the 2017/2018 data call, the National AMR Reference Laboratory had been identified, and two of the four designated sentinel sites were performing AST. Further development of the surveillance system will be outlined in the National AMR Surveillance Strategy, however, this is still in an early draft form and surveillance activities are therefore still in the pilot stage.

The National Microbiology Reference Laboratory (NMRL), based at the Public Health Institute of Malawi (PHIM) in Lilongwe, has been designated as the AMR reference laboratory. PHIM is currently under the governance of the MoH, however, efforts are being made to establish it as a semi-autonomous statutory body. At present, NMRL has limited capacity due to a lack of budget for reagents, consumables and sample transport, however, the intention as per the NAP is that it will coordinate all AMR surveillance activities, including supervision of sentinel sites, implementation of laboratory quality measures, and co-ordination of procurement for all specialist reagent and consumables required for the surveillance system. NMRL plans to coordinate a national quality assurance program to support the sentinel site laboratories in the surveillance network by providing a proficient testing scheme, confirmatory testing for 5% of organisms isolates, overseeing development of SOPs and protocols, and providing technical training. To date, training has been conducted at sentinel sites but there is little additional progress due to lack of resources. NMRL is also proposed to be the site of the national AMR biorepository.

Government hospitals the C4G BLIS Basic Laboratory Information System (<http://blis.cc.gatech.edu/>), an open source Laboratory Information Management System (LIMS), although the NMRL and Malamolo hospital, one of the proposed surveillance sites, are not currently connected. Technical support for BLIS is provided by Baobab Health Trust ([www.baobabhealth.org](http://www.baobabhealth.org)), a Malawian non-profit organisation. The system allows entry of antimicrobial susceptibility results and has been adapted to include the entry of zone diameters (although it does not interpret them). To access and analyse the data, the National AMR Co-ordinator (or individual sites) have to request the information from Baobab Health Trust: there is no directly accessible dashboard, and only aggregate data can be reported. The capacity to collate, analyse and act on the data will need to be built at NMRL.

### 3.4 AMR Surveillance – animal health

There is no national AMR or AMU surveillance system in animal health sector in Malawi. Antimicrobial Susceptibility Testing (AST) is performed on a small number of samples submitted for diagnostic testing: for example, from mastitis samples in dairy farms. There are no national protocols or SOPs for AMR surveillance, there is no electronic recording of data, and the data is not reported at the national level.

The Central Veterinary Laboratory (CVL), Lilongwe, has been designated as the National AMR Reference Laboratory for animal health. CVL has 2 trained laboratory technicians: neither have been trained specifically in AST and will require support to develop the necessary capacity at the laboratory. CVL does have an epidemiology unit which will be utilised in the surveillance system, however, it does not currently work on

AMR as no data is being generated. The unit is staffed by a single epidemiologist and there is no central database or IT system: information is obtained from paper reports or transfer of spread sheets through emails. Therefore, the epidemiology unit currently has limited capacity to handle the large volumes of data that will be generated from the AMR surveillance system once it is in place.

There are two additional regional laboratories which are intended to be included in the surveillance network. The Southern Regional Laboratory, in Blantyre, and the Northern Regional Laboratory in Mzuzu. Neither are currently doing any bacteriology work, and there is no LIMS or similar IT system.

### 3.5 Laboratory capacity – human health

The Fleming Fund team assessed the NMRL and six proposed human health surveillance sites (see section 4.2, table 1). All laboratories visited are on the WHO-AFRO SLIPTA scheme, the majority of them having 2 stars. However, in general bacteriology diagnostic capacity, quality management systems, and biosafety and biosecurity were poor, and significant investment will be required. Similarly, all sites experience difficulty in obtaining supplies of reagents and consumables due to lack of budget and issues around the current system of centralised procurement via Central Medical Stores.

The National Microbiology Reference Laboratory (NMRL) is housed in the Malawi National Public Health Institute in Lilongwe. NMRL is currently providing services for outbreak investigation (mainly for diarrhoeal disease) and testing of environmental samples, and also provides clinical diagnostic services, including blood culture, for hospitals in the area who do not have functioning microbiology laboratories. In addition, it provides training for the pilot surveillance laboratories, performs confirmatory testing and collates the data. It is enrolled in an international EQA scheme from NICD in South Africa and has a well-developed quality management system. The laboratory uses conventional biochemical methods for bacterial identification, supplemented with manual commercial systems when resources allow.

### 3.6 Laboratory capacity – animal health

The Fleming Fund team visited three animal health laboratories; the Central Veterinary Laboratory, the Southern Regional Laboratory, and the Northern Regional Laboratory. CVL is currently performing some bacteriology testing for diagnosis of common diseases such as mastitis, and this may include AST. However, they are not using protocols that are standardised and agreed nationally. The 2 regional laboratories have no bacteriology capacity.

The Southern Regional Laboratory has no designated bacteriology bench space at present, but with minor renovations an adjacent room could become a bacteriology laboratory. It will also require additional human resources, and support with equipment, consumables and reagents. The Northern Regional Laboratory will also require some renovation, although overall space is sufficient. There are several laboratory staff who have had prior experience in bacteriology, but all will need additional training, especially for AST.

The lack of bacteriology capacity in animal health is due to several factors, including limited operational resources, lack of equipment, lack of skilled personnel, length procurement procedures by the central government and lack of demand for bacteriology from the farming communities. This last is compounded by the small number of trained veterinarians (15 for the entire country), which limits the capacity for diagnostic testing and, importantly, for control of antimicrobial use.

All the laboratories will require support for equipment and reagents, quality management systems, data management systems, biosafety and biosecurity, in addition to human resources strengthening.

CVL should have capacity to coordinate the AH surveillance system and has existing connections to the Southern and Northern regional laboratories. The CVL and the regional laboratories are all supported by the existing structure of veterinary professionals and extension workers within the department of veterinary services, which will be vital for sample collection.

### 3.7 Appropriate use of medicines

Registration of medicines for human and veterinary use is done by the Pharmacy Medicines and Poisons Board under the Ministry of Health. In principle, antimicrobials are prescription only medicines but in practice, drugs are widely available without prescription through official and unofficial vendors, and enforcement of drug regulations are weak and require strengthening. At the hospital level, limited antimicrobial consumption information is available through logbooks for pharmacy requisitions to central medical stores, but dispensed medicines are only recorded in individual patient chart and therefore data on antimicrobial use is extremely limited.

## 4. Scope of this Country Grant

### 4.1 Grant Objectives and Outputs

Objectives and outputs for this Country Grant are summarised below, with more details in Section 7. Applicants should will respond to this RFP by developing and proposing costed activities, and by proposing appropriate indicators (see Section 9). All inputs must be permitted under the list of Eligible Funding Items as outlined in Annex 1. For human health, the Country Grant is intended to support / improve implementation of the WHO GLASS programme and applicants should refer to the roadmap for GLASS participation produced by the London School of Hygiene and Tropical Medicine

(<https://amr.lshtm.ac.uk/wp-content/uploads/sites/12/2016/11/AMR-Surveillance-Protocol.pdf>)

<i>Objective 1: Strengthened One Health governance structure for AMR, AMU and AMC surveillance</i>
Output 1.1: The AMR National Coordinating Centre is supported to effectively organise surveillance in Malawi
Output 1.2: AMRNCC shares AMR knowledge generated through multi-sectoral AMR and AMU surveillance both nationally and internationally
Output 1.3: The multi-sectoral AMR Knowledge, Surveillance and Research Technical Working Group is strengthened to provide technical support to the AMR surveillance system in Human and Animal Health
Output 1.4: A cost evaluation is completed to analyse the cost drivers for establishing AMR surveillance in Malawi and identify lessons for future programmes.
<i>Objective 2: Strengthened AMR surveillance system in the human health sector</i>
Output 2.1: Increased capacity of NMRL to function as a reference laboratory and supporting centre for AMR surveillance
Output 2.2: Sentinel laboratories function well and are included in an AMR laboratory network
Output 2.3: All laboratories have adequate levels of quality assurance and control
Output 2.4: All laboratories have adequate levels of quality assurance and control
Output 2.5: A sustainable specimen transportation system in human and animal health sectors is developed and functional
Output 2.6: A sustainable specimen transportation system for human and animal health sectors is developed and functional
Output 2.7: Increased capacity of the human health AMR surveillance system for data management
Output 2.8: An AMC /AMU surveillance strategy is developed, and implementation started
<i>Objective 3: Strengthened AMR surveillance system in the animal health sector</i>
Output 3.1: Enhanced capacity of CVL to process surveillance samples for bacterial identification and AST, and to function as a supporting centre for AMR surveillance

Output 3.2: Improved capacity of the regional laboratories for basic sample processing to support active surveillance in AH.
Output 3.3: Biosafety and security are enhanced at the reference laboratory and surveillance laboratories
Output 3.4: Good quality passive active, and passive, surveillance samples are regularly sent to CVL
Output 3.5: A national database of verified AMR data is maintained at CVL with regularly sharing of reports with the relevant TWG, AMRCC and other stakeholders
Output 3.6: Data on antimicrobial consumption (AMC) and antimicrobial use (AMU) are shared with the Surveillance and Research TWG, and other stakeholders

#### 4.2 Selected sites

Table 1: list of surveillance sites to be supported by this grant. Degree of support will vary depending on current capacity and expected functions of the laboratory. All sites have had preliminary needs assessments performed by the Management Agent.

Laboratory	Location	Type of site*
National Microbiology Reference Laboratory	Lilongwe	HH
Kamuzu Central Hospital	Lilongwe	HH
Queen Elizabeth Central Hospital	Blantyre	HH
Zomba Central Hospital	Zomba	HH
Mzuzu Central Hospital	Mzuzu	HH
Mzimba District Hospital	Mzimba	HH
Mangochi District Hospital	Mangochi	HH
Malamolo Adventist Hospital	Malamolo	HH
Central Veterinary Laboratory	Lilongwe	AH
Southern Region Veterinary Laboratory	Blantyre	AH
Northern Region Veterinary Laboratory	Mzuzu	AH

\*HH: Human Health; AH: Animal Health.

#### 4.3 Duration and phasing of the grant

This country grant to Malawi is expected to last until September 2021. Any grant activities (costed/no-cost extension) beyond this duration will be based on the successful implementation of this grant.

#### 4.4 Funding envelope

Grant applications should be in the region of **£3 million**, including all capital and recurrent costs, overheads and management costs. This should include a placeholder budget of **£1m** for renovating and equipping the human health laboratories (including reagents relevant for GLASS pathogens), and **£530,000** for the animal health laboratories.

Mott MacDonald is responsible for driving Value for Money (VfM) on behalf of the UK Department of Health and Social Care throughout the Grant programme and will carefully consider how the proposal addresses efficiency, effectiveness, economy and equity in delivering the Request for Proposal (RFP) outputs in relation

to the proposed costs. The Guidance Notes for the Grant Application Form provide more information on different dimensions to be considered as part of a VfM approach.

#### 4.5 Procurement

During the site assessments, the Management Agent compiled an indicative procurement list of laboratory equipment, reagents and consumables. The grantee is expected to confirm the requirements for the laboratories in Table 1 to develop a procurement plan for the laboratories and surveillance sites, utilising the assessment tools provided by the management agent. Additional assessment should be made for infrastructure improvements relevant for bacteriology services. For human health laboratory sites, applicants should include an overall placeholder budget of **£1m**. For the Central Veterinary Laboratory, the applicants should include an overall placeholder budget of **£530,000**.

Highly preferential rates have been secured by the Fleming Fund for the purchase of key laboratory instruments, namely automated blood culture analysers (BACTEC or BacT/Alert), automated antimicrobial susceptibility testing platforms (Vitek II or BD Phoenix), and MALDI TOF mass spectrometers (Bruker or Vitek MS).

To take advantage of these rates, these instruments will be procured centrally by the Management Agent's procurement partner, International Procurement Agency (IPA), who will also co-ordinate delivery.

Blood culture analysers will be supplied to laboratories providing a clinical service, with the final number determined by the laboratory assessments. Two automated AST platforms, bundled together with a mass spectrometry instrument and the necessary databases and linkage software, will be supplied for use in the AMR reference laboratories (animal health and human health). If the reference laboratories do not have sufficient specimen throughput, or do not have the required infrastructure, the instruments may be deployed, with the approval of the Management Agent, to alternative sites.

These items will be paid for directly by the Fleming Fund via a grant to IPA. The costs include the instruments, delivery, import duties (up to 15%), installation, basic training, software and first year service contracts.

Reagent costs and subsequent service contracts will come from the £3m Country Grant budget and should be factored in to this application, as well as all other laboratory equipment and costs.

Suppliers (Biomérieux and Beckton Dickinson) have been preselected by the Management Agent, however, purchase and delivery will be co-ordinated by IPA, and the Grantee will need to work with IPA to confirm readiness for delivery. Purchase of additional instruments, if required, should also be done via IPA, with the approval of the Management Agent, to secure the highly preferential prices offered to the Fleming Fund

The grantee will work in consultation with the Management Agent, the Management Agent's procurement supplier (International Procurement Agency) and the UK Department of Health and Social Care, to determine the most suitable method of procurement for all other laboratory equipment, and to develop reliable stock management and supply systems for consumable and reagents.

The lead grantee will also be expected to:

1. assist with the importation and delivery of equipment and consumables to recipient sites;
2. work closely with the procurement partner (whether IPA or an alternative organisation) to ensure the appropriate delivery sequence of items;
3. maintain an asset register of all items defined as assets by the programme;
4. regularly monitor the items that have been procured by Fleming Fund Grants Programme to ensure:
  - (i) items are being used for intended purpose;
  - (ii) items are being maintained appropriately; and
  - (iii) to report any misuse or misappropriation of assets to the Management Agent.

## 5. Key partnerships, alignment and coordination

The Country Grant must be delivered in alignment with and support delivery of the NAP and the sector specific surveillance strategies.

The grantee will be expected to work with the AMRNCC and secretariat to align with other AMR related initiatives including those undertaken by bilateral and multilateral agencies such as CDC, USAID, FAO, OIE and WHO. The activities to be supported will be for bacterial AMR, AMC and AMU surveillance.

In addition, the Grantee will need to build collaborations and coordination with local academic and research institutions at different levels for technical and other support. Attention will be needed to make the best possible use of the existing initiatives and capacities, and to avoid duplication, particularly with programmes run by the World Bank, CDC and USAID.

## 6. Complementing other grants from the Fleming Fund Grants Programme

The Country Grant for Malawi is expected to work effectively with other grants under the Fleming Fund Grants Programme at the regional level, including the Fleming Fellowship Scheme. For details see [www.flemingfund.org](http://www.flemingfund.org).

The Fleming Fund Regional Grant programme, also managed by Mott MacDonald, will focus on strengthening networking and data sharing on AMR at the regional level. The grantee is expected to liaise, through Mott MacDonald, with this programme where relevant, to maximise the sharing of AMR data and learning at the regional and global levels.

## 7. Detailed Objectives and Outputs

### 7.1 Objective 1: Strengthened One Health governance structure for AMR, AMU and AMC surveillance

#### **Output 1.1: The AMR National Coordinating Committee is supported to effectively organise surveillance in Malawi**

The AMRNCC is a multisector committee comprising AMR focal points from different sectors. It acts as an operational platform for co-ordination of AMR activities among the different sectors. Although mandated by the NAP, the relevant surveillance technical working groups (the TWG for Antimicrobial Use, and the TWG for Knowledge, Surveillance and Research) have not been formally convened, and operations are currently co-ordinated by the AMRNCC itself. The AMRNCC needs support to understand and respond to the outputs from surveillance activities so that it can function effectively as the One Health AMR National Co-ordinating Centre

By the end of the grant we expect that the following will have been achieved:

- AMRNCC has the capacity to fulfil its function as the One Health AMR National Coordinating Centre.
- AMRNCC regularly provides reports to national and subnational levels for use in updating/developing policies and guidelines.
- AMRNCC makes evidence-based decisions on future surveillance priorities and policies to reduce the burden of AMR

#### **Output 1.2 AMRNCC shares knowledge generated through multi-sectoral AMR and AMU surveillance nationally and internationally.**

The secretariat of the AMRNCC is, as per the NAP, responsible for data and information sharing, including nationally and internationally via GLASS. The Grantee should support the AMRNCC to ensure intersectoral sharing of knowledge and results, ensuring alignment with international surveillance systems (e.g. GLASS, OIE).

By the end of the grant we expect that the following outcomes will have been achieved:

- Improved quantity and quality of AMR and AMU information shared nationally and internationally

- An annual national multisectoral AMR conference is held
- Additional sites are reporting AMR data to GLASS.

**Output 1.3: The multi-sectoral AMR Knowledge, Surveillance and Research Technical Working Group is strengthened to provide technical support to the AMR surveillance system in Human and Animal Health**

There is a TWG that consists of experts in Human and Animal Health. To date progress has been achieved in human health while limited activities have been implemented in AH, which undermines the capacity of the ARMCC to take a One Health approach.

The TWG should be supported to strengthen the subcommittee in AH to include relevant stakeholders, for example, the AMR focal point for animal health, veterinary public health specialists, livestock production specialists, fisheries officers, and food safety experts. The TWG ToRs should be developed and ratified, and should include: technical input to the design of AMR and AMU surveillance in animals including the drafting of protocols; contributing to knowledge about AMR and the links between AMU and AMR in animals in Malawi; identifying priorities for further surveillance and/or investigations in animals; working with the department of veterinary services; and identifying opportunities for collaborating with the human health sector in training, equipment procurement and maintenance, purchase of reagents, etc.

If formation of the research and surveillance TWG is not feasible during the life span of the project, the Grantee will have to work with the AMRNCC/AMR core team and ensure that the ToRs for the TWG are embedded, taken care of and done within the function of the AMR core team.

**Expected outcomes**

By the end of the grant we expect that the following outcomes will have been achieved:

- ToRs are developed for multisectoral TWG for AMR surveillance to include the subcommittees in Animal and Human Health
- The TWG is contributing to knowledge on AMR and AMU in human and animals in Malawi
- A National AMR/AMU Surveillance plan is formulated, agreed and implemented among all stakeholders
- Results from the AMR and AMU surveillance in animal and human health and other sources of information on AMR have been shared with the AMRNCC and the multisectoral TWG
- AMR data is analysed in the context of available information on AMU/AMC to improve understanding of the country-relevant drivers.

**Output 1.4: A cost evaluation is completed to analyse the cost drivers for establishing AMR surveillance in Malawi and identify lessons for future programmes.**

The Fleming Fund Country Grant investment is intended to provide the initial stimulus to generate data to support Malawi's response to AMR. Long term sustainability, both for laboratory systems and for the surveillance programme, will depend on the success of the programme, and on demonstration of the value to the country of the investment. The Grantee should therefore undertake a basic cost appraisal to add value to future policy and programming. This should address: actual costs of laboratory improvements (including building human capacity) compared with estimates, identifying examples of good practice, identifying efficiencies and cost savings, and estimating potential impact on other expenditures e.g. hospital drug budgets. Additional factors which could be examined include the cost benefit of preventative maintenance of equipment to preserve long term function. The evaluation should be shared with the relevant TWG and with the AMRNCC to advocate for better use of scarce financial resources, through gains in efficiency that can be invested back into AMR prevention and control.

**Expected outcomes**

By the end of the grant, we expect that the following will have been achieved

- A cost evaluation has been completed and shared with the relevant TWGs and the AMRCC, which includes lessons learned / examples of good practice which can inform further rollout of the surveillance programme.

## 7.2 Objective 2: Strengthened AMR surveillance system in the human health sector

### **Output 2.1: Increased capacity of NMRL to function as a reference laboratory and supporting centre for AMR surveillance**

The National Microbiology Reference Laboratory has been selected as the national reference service for AMR. The NMRL is co-ordinating the pilot surveillance programme but will need support so that it can function fully as a reference laboratory and supporting centre.

The NMRL will need to improve its own capacity in bacterial identification, AST and confirmatory testing for priority pathogens, and will need to develop an inventoried biorepository. Support will be required to develop epidemiology and data management capacity.

The NMRL will also be expected to develop its ability to support sentinel sites in their surveillance activities, for example, developing bench aids and SOPs, and providing a bacteriology / AST EQA service, including supporting sentinel sites to undertake corrective actions if performing poorly.

The NMRL will need to work with the AMRCC and other relevant bodies to develop reliable supply chains for reagents and consumables across the surveillance system to reduce stockouts and wastage. Additionally, the NMRL will need to develop a strategy for dealing with Biosafety Level 3 pathogens in keeping with its position as the national reference laboratory. The Grantee will need to support NMRL to develop these functions, with due consideration to the long-term use of NMRL beyond the life of the grant.

By the end of the grant we expect that the following will have been achieved:

- The bacteriology laboratory has a reliable power supply protected from power fluctuations: this includes a reliable back-up power source and UPS for critical instruments.
- The necessary equipment for bacterial isolation, identification and AST is purchased and installed and staff are trained in its operation.
- A stock management system is in place to ensure reliable supply of reagents and consumables for surveillance activities. This includes a plan for sustainability beyond the end of the Fleming Fund grant
- NMRL has the capacity to do confirmatory testing and quality control of samples.
- NMRL is supporting all operational surveillance sites with training, and mentorship in bacterial identification, AST, and data entry and analysis, and providing an EQA programme
- An inventoried biorepository is established with associated SOPs and policies for use.
- Quality management systems have been strengthened, including for development of the necessary SOPs and policies, and for laboratory staff training and development

### **Output 2.2: Sentinel laboratories function well and are included in an AMR laboratory network**

All the surveillance sites will need support to provide reliable surveillance data, including additional equipment, ongoing maintenance, assistance with procurement and development of stock management systems. Sites will also require IT support to ensure timely reporting while minimising the burden on laboratory staff for data entry.

The Grantee will need to reconfirm the procurement requirements as assessed by the Management Agent. Working with ministries and other donors to avoid duplication, the Grantee should ensure the laboratories have the necessary equipment and service contracts. The Grantee should support the laboratories to ensure consistent supply of quality reagents and consumables, and to develop IT and data management systems.

By the end of the grant we expect that the following will have been achieved:

- All renovations identified by the assessment and as agreed with the Management Agent have been completed.
- All equipment identified by the assessments and agreed with the Management Agent has been purchased and installed, with the necessary maintenance /s service contracts and staff training, and a sustainability plan to ensure ongoing maintenance and training beyond the life of the grant
- Each surveillance laboratory has adequate stocks of reagents and consumables, a stock management system, and a sustainability plan to ensure continuation beyond the life of the grant
- Staff demonstrate competency in specimen processing, bacterial identification, AST, and reporting, with adequate documentation of QC processes
- Each laboratory has a functioning IT platforming allowing efficient entry of surveillance data.
- All surveillance sites are contributing surveillance data suitable for reporting to GLASS
- SOPs and bench aids are in place and being used, with relevant QC processes

### **Output 2.3: All laboratories have adequate levels of quality assurance and control**

All laboratories should be working to acceptable quality standards. Staff should be adequately trained, and appropriate QC organisms need to be available on site and used to monitor the quality of work. All laboratories should be participating in relevant EQA schemes provided by the NMRL and / or other accredited providers.

By the end of the grant we expect that the following will have been achieved:

- Quality management systems are in place in all laboratories.
- Reference strains for IQC are available and being used, and the resulting IQC data is being collected and monitored regularly at a national level.
- All surveillance site laboratories are participating in an EQA scheme: this should include confirmatory testing by NMRL for 5-10% of routine isolates from surveillance sites.
- Surveillance site laboratories are working towards accreditation and are showing progress in the relevant scheme
- Quality and completeness of laboratory and clinical data is monitored and shows improvement over the course of the grant.

### **Output 2.4: Biosafety and security are ensured at the reference laboratory and at surveillance laboratories**

Biosafety and Biosecurity are pillars of a well-functioning laboratory. Biosafety and biosecurity issues were observed in most of the laboratories visited and the Grantee will need to provide the necessary inputs to ensure the safety of laboratory personnel and the wider public.

By the end of the grant we expect that the following will have been achieved:

- The laboratories are equipped with appropriate safety equipment and staff are wearing personal protective equipment while conducting testing
- Biosafety cabinets are operational, maintained and being used by staff appropriately
- A functioning Biosafety and Biosecurity system is in place
- The NMRL has a long-term strategy for dealing with Biosafety Level 3 pathogens

**Output 2.5: A sustainable specimen transportation system in human and animal health sectors is developed and functional**

A transportation system, in which samples can be shipped between the reference laboratories and surveillance sites in a secure and reliable manner without significant delays, is a critical part of a properly functioning AMR surveillance system. In Malawi, laboratory samples are often shipped between sites using public transport networks; however, there is minimal sample tracking and the biosafety aspect of this method has not been assessed. The Grantee should provide support to identify strategies to improve transportation of samples throughout Malawi: this can utilise the current system provided samples can be tracked, and biosafety / biosecurity for both samples and isolates is ensured. Long term funding mechanisms for the transport systems should be considered to allow for sustainability.

By the end of the grant we expect that the following will have been achieved:

- A sustainable, safe transportation system to transport specimens and samples has been developed, including sample tracking
- Staff are trained in sample packing and handling at all sites

**Output 2.6: Clinical staff at the surveillance sites engage with microbiology services to develop**

In many sites, use of existing microbiology services is limited, meaning that data is likely to be unrepresentative. **Ongoing engagement with clinical staff will be necessary across all sites to ensure appropriate sampling of patients, collection of basic patient data, and appropriate response to culture results.** This is critical for establishing a sustainable, passive surveillance programme. Laboratories will need to report results in a timely manner in order to inform patient care, and clinical staff should also be responding to culture results appropriately. Use of the clinical microbiology laboratories should be integrated into standard good clinical care of patients: as guidance, patients being treated for sepsis (i.e. receiving intravenous antimicrobials) should have at least one set of blood cultures taken, plus additional samples as per presenting syndrome, and specimen forms should have basic data regarding clinical presentation and antimicrobial treatment.

By the end of the grant we expect that the following will have been achieved:

- Increased number of good quality blood culture samples sent to the laboratory, with acceptable contamination rates and relevant clinical data recorded on the request form.
- Results are communicated to clinicians in a timely manner
- Clinicians and pharmacists at the surveillance sites demonstrate an improved understanding of how to incorporate bacteriology results into their practice.
- Data generated at the site is analysed locally and being used to inform hospital level decisions on training, stewardship and drug policies. This may be via Medicines and Therapeutic Committees, Antimicrobial Stewardship Committees or similar entities.

**Output 2.7: Increased capacity of the human health AMR surveillance system for data management**

According to the NAP, the central data repository will be housed physically at the NMRL, with human resources based at the Malawi National Public Health Institute. Currently, there is no central national repository although information (including AMR data) recorded in the BLIS systems is stored by Baobab and can be accessed, in a limited form, on request.

The Grantee will need to work with NMRL, the AMRCC and Baobab to ensure that data can be collected, checked and backed up centrally, and that it is available in a format that can be analysed appropriately: for example, by site, by pathogen etc. The Grantee will also need to assist NMRL to develop regular reporting structures for the aggregated data and encourage analysis and action on the critical findings.

By the end of the grant we expect that the following will have been achieved:

- All surveillance sites are recording data electronically and capturing both laboratory and clinical data.

- Appropriate software (WHONET/LIMS) is installed and in use at NMRL and the surveillance sites.
- A national data repository has capacity to handle all data from sites.
- All sites are receiving IT support to maintain LIMS/WHONET as necessary, with a plan for how this is to be continued after the end of the grant.
- Data quality checks are being carried out at site and national level.
- NMRL can monitor and report timeliness and quality of data recording
- NMRL demonstrates the capacity to analyse the data aggregated from the system and generate clinically useful reports and analyse and interpret national AMR surveillance data.
- Clinical and laboratory staff at all sites have been trained in analysis of their own data.
- All surveillance sites show an increase in the quantity and quality of the data reported over the lifetime of the grant.

**Output 2.8: An AMC /AMU surveillance strategy is developed, and implementation started**

There is currently no AMC or AMU surveillance strategy for Malawi and developing this is a priority. Options to be considered include the WHO Point Prevalence Survey methodology, and analysis of consumption data using data from the national regulator and other sources such as wholesalers. The grantee should support the development and implementation of a national strategy and plan for AMC and AMU surveillance.

By the end of the grant we expect that the following will have been achieved:

- A national strategy for AMU and AMC surveillance has been developed.
- AMC surveillance has been conducted at national level
- AMU data has been obtained from agreed sites
- AMR NCC disseminates results to care providers, policy makers and programme managers at county and national level
- A sustainable plan is in place for continuing AMC and AMU surveillance beyond the end of the grant

### 7.3 Objective 3: Strengthened AMR surveillance system in the animal health sector

Malawi has no standardised surveillance system for AMR in the animal health sector. As a starting point, AMR surveillance should be piloted in poultry, as this sector is a potential source of zoonoses and a high user of antimicrobials. The Management Agent, in collaboration with academic partners, has produced a protocol which can be used to develop an active surveillance programme targeting resistance to specified antimicrobials in selected zoonotic enteric bacteria in healthy poultry, as a foundation for developing services which can be expanded subsequently. The protocol will be supplied to the Grantee. However, grantees should take a flexible approach based on country priorities and also may need to adapt the surveillance strategy in the light of any standardised protocols released by FAO / OIE etc.

CVL is the designated national AMR reference laboratory in animal health sector and should be the initial focus of laboratory strengthening. The regional laboratories should be supported to collect, collate and transport samples, and their capacity should also be developed in a stepwise fashion so that ultimately they are able to function as regional bacteriology laboratories when the surveillance system is expanded.

In the initial stages, surveillance in animal health should focus on the following priorities

- Resistant bacteria which frequently cause disease in humans (based on the GLASS priority pathogens for surveillance)

- Resistant bacteria which frequently cause disease in the species under surveillance, which may result in widespread use of antimicrobials or where resistance will have significant economic consequences
- Indicator bacteria: bacterial species where resistance may indicate high levels of antimicrobial use, or where there is a possibility that resistance genes could be passed to more virulent species

**Output 3.1: Enhanced capacity of CVL to process surveillance samples for bacterial identification and AST, and to function as a supporting centre for AMR surveillance.**

The Central Veterinary Laboratory (CVL) is the designated AH AMR reference laboratory, however, at present it is undertaking only a limited number of bacteriology and AST activities due to low demand for bacterial diagnostics from the farming community.

Currently, bacteriology activities at CVL are limited to the culture and identification of common bacteria pathogens including *E. coli* and *Salmonella*.

In the long term, CVL should aim to provide training, leadership and support for the Northern and Southern regional laboratories to allow expansion of the surveillance network.

CVL will require some minor renovations, equipment installation, staff training, and support for supply chain management.

By the end of the grant, we expect the following to have been achieved

- Necessary renovations completed to allow safe, efficient functioning of the laboratory. The Grantee should support such works in consultation with the laboratory management.
- A biorepository for bacterial isolates is established, with relevant training and SOPs for use and access
- Staff are adequately trained for bacterial identification and AST, and for advanced confirmation / characterisation of phenotype (e.g. confirmation of ESBL production, MIC testing)
- Improved supply chain management: the Grantee should support the procurement and provision necessary reagents and materials, including provision and maintenance of ATCC /NCTC strains, and develop stock management systems to prevent stockouts and wastage
- Essential equipment for biosafety / biosecurity and standard bacteriology is procured and installed, with service contracts, training and quality management systems.
- Support the participation of the CVL in international AMR data quality control including proficiency testing (PTs) and accreditation for AMR testing. A quality management system is established, covering equipment, supply chain, training and standard operating procedures.

**Output 3.2: Improved capacity of the regional laboratories for basic sample processing to support active surveillance in AH.**

The 2 regional laboratories are not doing any bacteriology work due to the inadequate capacity and the low demand of the services. Initially, these laboratories should be strengthened to support active surveillance activities in terms of sample reception, packaging, and tracking, and moving to basic processing (e.g. plating screening samples) as the system expands. Biosafety and biosecurity improvements should also be addressed as a priority.

By the end of the grant we expect that the following will have been achieved:

- Good quality samples are collected, processed and /or packaged
- A safe sample transportation system is in place, with associated sample tracking capacity
- Strengthened biosafety and biosecurity at regional laboratories (see below)
- In conjunction with the AMRCC, a veterinary laboratory improvement plan is in place which takes into account the long term needs of the AMR surveillance system and includes stepwise capacity building for the regional laboratories, taking into account expected sample throughput and country priorities.

**Output 3.3: Biosafety and security are enhanced at the reference laboratory and surveillance laboratories**

In consultation with the management agent, the grantee should establish sound Biosafety and Biosecurity measures at CVL and the 2 regional laboratories, to ensure the protection of staff and the public.

By the end of the grant we expect that the following will have been achieved:

- A functioning Biosafety and Biosecurity system is in place
- All waste is properly disposed off
- Samples are collected, processed, packaged and transported in a safe manner
- The laboratories are equipped with appropriate safety equipment and staff are wearing personal protective equipment while conducting testing
- Biosafety cabinets are operational, maintained and being used by staff appropriately
- There is a plan for maintaining the biosafety and biosecurity system beyond the life of the grant.

**Output 3.4: Good quality active, and passive, surveillance samples are regularly sent to CVL**

The initial focus of AMR surveillance in Animal Health will be on poultry as a proxy to study the current antimicrobial use and the emergence / propagation of resistant strains of bacteria in the country. A surveillance protocol should be developed to ensure a representative sampling in different parts of the country – if required the Management Agent will provide a standardised poultry sampling protocol. Field animal health staff will be responsible for the timely collection of samples from healthy poultry in areas that at least include the Southern, Central and Northern regions of the country and delivery to CVL, Mzuzu or Blantyre laboratories for processing or forwarding. Staff will require training in sample collection, transport and processing, and appropriate SOPs will need to be developed, and due consideration should be given to ethical issues such as sampling procedures and data protection. In the initial stages of the grant, the 2 regional laboratories will be responsible for collecting, tracking and forwarding samples to CVL for bacteria culture, identification and AST. As the capacity for AMR testing in the regional laboratories improves, the AMR surveillance activities may be decentralised. Laboratories should also be processing passive surveillance samples if presented by farmers for routine testing from sick animals.

The Grantee will need to support the creation of SOPs, training of field staff to collect and transport samples. Costs of sample collection, transportation and processing will be covered under the Grant. The Grantee will need to support the procurement of sufficient consumables and transport media for samples to be used in the surveillance programme.

***Expected outcomes***

By the end of the grant we expect that the following will have been achieved:

- In collaboration with DVS, an AMR surveillance protocol in poultry (broilers and layers) has been designed and implemented with the aim of estimating prevalence of resistance amongst priority zoonotic bacteria to antibiotics that have been specified by the WHO as critical for use in humans, in broilers and layers sold for meat in high-producing poultry areas of the country
- The required number of samples have been sent to the laboratories for culture, bacteria identification, and AST
- Samples are labelled appropriately, transported in a safe manner, and are accompanied by epidemiological and demographic information

**Output 3.5: A national database of verified AMR data is maintained at CVL with regularly sharing of reports with the relevant TWG, AMRCC and other stakeholders**

At present, the epidemiology unit at CVL does not have a central database, and information is obtained on paper records, and transmitted through emails.

The grantee should support the design and installation of the hardware and software in the epidemiology unit and to be able to collect, collate and or analyse AMR data generated in the surveillance programme. The grantee should support the technical services to support the training of staff in WHONET or any other software that can be used for AMR data management.

The grantee should support the development of an SOP to guide the use of WHONET or any other software that will be used and the arrangements for sharing the data from the network laboratories to the epidemiology unit.

An epidemiologist or Public Health specialist at the epidemiology unit (under the DVS) should be responsible for epidemiological analysis of the data collected through AMR surveillance. The AMR results should be interpreted in the context of data collected on AMU in animals in Malawi.

The Grantee should support quarterly meetings with all contributors of AMR/AMU surveillance data in the animal health sector in Malawi to share and discuss results and issues related to data supply, quality, etc, and should support an epidemiologist to conduct analysis of AMR data produced during passive and active surveillance. The Grantee should also provide support for quarterly meetings with the personnel responsible for the collation and sharing of AMR data at CVL and the regional laboratories to share and discuss results and issues related to data supply and quality.

### ***Expected outcomes***

By the end of the grant we expect that the following will have been achieved:

- The necessary protocols (sampling, data management, data analysis, etc.) to be used in AMR surveillance have been developed in collaboration with the epidemiologist from CVL, and using available guidelines.
- Results for all samples tested under the surveillance programme are entered into WHONET or other fit-for-purpose software, with laboratory results accurately matched to demographic and epidemiological details for each sample
- Data is regularly backed up
- Data is regularly sent from the regional laboratories for collation into a national database at the epidemiology unit through CVL
- Data is analysed, interpreted and shared with the AH TWG and other stakeholders as appropriate
- The epidemiology unit analyses results and shares with the relevant TWGs, CVL, regional laboratories and other stakeholders as necessary

### **Output 3.6: Data on antimicrobial consumption (AMC) and antimicrobial use (AMU) are shared with the Surveillance and Research TWG, and other stakeholders**

In Malawi, the Pharmacy Medicines and Poisons board (PMPB) under the Ministry of Health is responsible for registration of human and animal medicines. Most of the medicines are imported, with records kept by the PMPB, however, PMPB does not have systems to collect or collate other AMU/AMC data. PMPB, in collaboration with the DVS and other stakeholders, should develop capacity to monitor, collect and share reliable AMU/AMC data. AMU data should, where possible, be submitted to the OIE AMU surveillance system.

The grantee should support the development of database for AMU/AMC data. The grantee should support the provision of the technical expertise to train the staff at PMPB and DVS for data collection and analysis, and should promote PMPB and DVS collaboration for surveillance of AMU/AMC in animal health.

### ***Expected outcomes***

By the end of the grant we expect that the following will have been achieved:

- A value chain analysis of the antimicrobial market on consumption and use in order to inform policy on antimicrobial use, regulation and surveillance

- National protocols for AMU and AMC surveillance have been developed.
- AMC surveillance has been conducted at national level
- AMU surveillance has been piloted
- AMC and AMU data is analysed and interpreted by DVS and PMPB and shared with the AH TWG, with input from the CVL epidemiology unit. A common report that interprets results in parallel is presented to stakeholders such as the AMRCC and the multi-sectoral TWG.
- AMU data is reported to OIE.

## 8. Lead Grantee Roles and Responsibilities

The main role of the grantee will be to plan and execute outputs and deliver the objectives listed above. The Grant is designed as an AMR laboratory capacity building and systems strengthening intervention. The grantee is responsible for providing, either through in-house resources alone, or through a partnership or consortium, the expert technical assistance and high-quality support needed to strengthen the selected reference and surveillance sites' capability and capacity to generate and share AMR surveillance data on both a national and international basis.

## 9. Measuring success

Country Grants will eventually be expected to generate results that can be tracked using a standard set of indicators that will monitor progress and achievements within and across Country Grants. A copy of the full list of indicators will be shared in the Application Pack.

However, for the first Country Grant, it is important to note that:

- (i) Applicants are not expected to select from and use these indicators for this first Country Grant. While it is possible that some of the formal indicators may trigger towards later stages of the grant award, the likelihood of this will be reviewed and discussed by Mott MacDonald with the successful applicant.
- (ii) For the purposes of this grant, process level indicators will be used to track progress against the work plan. The grantee is expected to utilise the indicators proposed above or to propose alternative SMART indicators in line with the outputs summarised above. These will then be negotiated and agreed with Mott MacDonald as the Management Agent.
- (iii) No Country Grant will be expected to use all the Fleming Fund indicators. Instead a relevant sub-set of indicators will be proposed by the grantee for joint agreement with Mott MacDonald.
- (iv) The Fleming Fund will be independently evaluated by ITAD, a specialist evaluation firm, who have been appointed by the UK Department of Health and Social Care for this purpose. In addition to measuring grant performance against the objectives and outputs stated above, the grant will also be monitored on the PMPB and DVS collaborate in the surveillance of AMU/AMC data implementation of, and adherence to, the Fleming Fund grant principles described above. All grants are subject to review and evaluation by the evaluators, and full co-operation with the evaluators by all grantees is expected.

## 10. Application requirements

### 10.1 Grant Eligibility Criteria

Potential grant applicants must satisfy the following eligibility criteria before applications will be assessed in detail. Applicants:

- Must demonstrate that they are competent organisations responding to this call for proposals.
- Must have an appropriate track-record in supporting laboratory capacity development, surveillance, capacity building, and One Health.

- Must have experience of programme implementation in Malawi.
- Must demonstrate that they are registered to work within the country, including the provision of essential documents such as articles of incorporation.
- Must demonstrate an understanding of the necessary permissions to operate in Malawi.
- Must be prepared to accept the Grant Agreement terms.
- Must be able to provide the same information and assurances for all sub-grantees, where the application is from a consortium.
- Should be able to provide all information required for due diligence checks, including clear evidence of financial standing and systems of financial management and control.
- Should be able to provide evidence of suitability in the form of references from clients and donors for previous work undertaken within the last three years.
- Can be a single organisation or consortium, though the latter must clearly identify a Lead Grantee with the appropriate governance and coordination mechanisms to manage sub-grantees.
- Can be:
  - International Non-governmental organisations (iNGOs) and other non-profits;
  - UN Agencies;
  - Private companies;
- In line with UK Government financial transparency requirements any for-profit organisations will be asked to declare profit levels.

## 10.2 How to apply

Prospective lead grantees must register their interest to apply by emailing [flemingfundESA@mottmac.com](mailto:flemingfundESA@mottmac.com) to receive an invitation to **the Applicant Information Session**, and an **example of the Application Pack**.

The Applicant Information Session will be organised **in Lilongwe, Malawi, on 28 June 2019**. The details of the venue will be shared with applicants registering their interest.

Ahead of the AIS, an example Application Pack will be shared and will include the application form, budget and milestones template and Guidance Notes. Following the AIS, the **official Application Pack** will be sent out to prospective Grantees who have registered their interest to apply for the grant.

To apply, please complete the application form provided, in line with the Guidance Notes, by the deadline indicated in Section 10.5.

Note the key requirements set out at the beginning of the Country Grant Application Form:

- When submitting the application document, press “Reply All” from the **official Application Pack automated email** that you received with the application documents attached. Do not send it to us from a new email, and do not modify the Subject-line. Only “Reply All” emails will register the documents in our system.
- Keep file sizes as low as possible - there is a 9MB size limit to each individual email that can be received by the grant submission software. You can submit documents by sending multiple emails attaching submission documents to each one. Please follow the instruction (above) using “Reply All” to the original email.
- Applicants should observe the word limit. Additional words outside the limit will be disregarded.
- All documents included as part of the proposal must be submitted by separate e-mail in Word, Excel, and PDF format (body font: Calibri 11pt). Do not send through as zipped files.
- You should include a covering letter, signed by the person authorised to represent your organisation for the submission of this proposal.
- This application is conditional upon your acceptance of the grant agreement (format will be shared in the application pack).

Proposals that do not satisfy these criteria may not be accepted

### 10.3 Evaluation criteria

The Application Pack will include the application form, indicating the scoring and weighting for each section of the application. The Application Pack will also contain Guidance Notes explaining what we are looking for in terms of a good quality response for each question, including approach to Value for Money (VfM).

We would be assessing the application on the following key areas:

Technical capacity to address the different aspects of AMR covered by this Country Grant.

Ability and preparedness to bring stakeholders together in an effective and productive working arrangement, promoting a One Health approach.

### 10.4 Restrictions/limitations

Any conflict of interest, or potential conflict of interest, should be declared to Mott MacDonald when applicants are registering their interest to apply for the grant. If a conflict of interest, or potential conflict of interest, arises after that point the prospective grantee must clearly declare this in their proposal.

### 10.5 Key dates

Publication of RFP: **13 June 2019**

Deadline for registering interest to attend the Applicant Information Session: **21 June 2019**

Applicant Information Session: **28 June 2019**

Deadline for registering interest to apply for the Grant: **01 July 2019**

Application deadline: **17:00 CAT (GMT+2) 31 July 2019**

Anticipated start date of grant: **01 December 2019**

### 10.6 Contact details and support information

Any questions on the Request for Proposals should be sent to [flemingfundESA@mottmac.com](mailto:flemingfundESA@mottmac.com). The Management Agent will endeavour to respond to queries within 72 hours.



## 1. Annex 1: Eligible funding items

### Laboratory Infrastructure Enhancement

- Infrastructure: renovation, redecoration, electricity and water supply, environmental controls, waste and waste disposal.
- Equipment: appropriate equipment for the level of capability; biosafety and biosecurity equipment; automated culture and identification platforms; IT equipment.
- Reagents, durables & consumables: appropriate media, reagents, culture plates, etc; glassware; sample collection consumables.
- Transport and logistics: vehicles or contracted services for transport of goods, and people; safe and secure transport of specimens and samples; logistical support for surveys.

### Human Resource Strengthening and Workforce Reforms

- Training: clinical, veterinary, agricultural and One Health surveillance protocols; biosafety and biosecurity; microbiology, laboratory science and laboratory management; epidemiology and surveillance; genomics; IT training.
- Long-term support: ongoing and refresher training according to the competency and capabilities framework; Fleming Fellowship Scheme.

### Surveillance System Strengthening

- Governance: support for AMR Coordination Committees & working groups; operational planning; cross-sectorial meetings and strategy reviews; evaluation(s).
- Quality assurance and control: site visits and audits, laboratory twinning / mentoring.
- Data: transfer and storage; safety and security; analysis software and training.
- Recurrent costs: utilities, maintenance of equipment, upkeep of laboratory space, small maintenance, personnel costs.

### Building Foundations for Surveillance Data Use

- Support to build demand for AMR data: general awareness among prescribers, dispensers and agricultural consumers (i.e. farm workers, agribusiness); publication charges; workforce training.
- Evidence based strategy, policy and practice change: data / information sharing conferences, meetings and initiatives; conference attendance; IT platforms for data sharing and awareness / transparency.

### Rational use of Antimicrobial Medicines

- AMU/C surveillance: development of strategies for AMU/C surveillance; use of AMU data for appropriate prescribing / informing stewardship programmes.