The Fleming Fund

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Promoting sustainability of the supply of reagents and consumables for AMR surveillance

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Acronyms

ABC	Automated blood culture system
AMR	Antimicrobial Resistance
AST	Automated susceptibility testing
DALY's	Disability Adjusted Life Years
DFAT	Department of Foreign Affairs and Trade
DHSC	Department of Health and Social Care
GPA	Global Procurement Agent
HH	Human Health
LMICs	Low- and middle-income countries
LMIS	Logistics Management Information System
MoH	Ministry of Health
NRLs	National Reference Laboratories
OOP	Out of Pocket
PEA	Political Economy Analysis
QPPU	Quantification and Procurement Planning Unit
ToC	Theory of Change
UK	United Kingdom
UNICEF	United Nations Children's Fund
USA	United States of America

Introduction

The Fleming Fund is a UK Department of Health and Social Care (DHSC) initiative that supports up to 25 low- and middle-income countries (LMICs) to strengthen national surveillance systems for antimicrobial resistance (AMR). Since 2017, the Fleming Fund has addressed the lack of quality-assured data for use in policy and clinical practice, taking a systems approach to invest in laboratory upgrades, human resource capacity strengthening, data production and data use, policy and governance. This provides not only surveillance data, but also important diagnostic services in both human and animal health.

A key issue is how these surveillance and diagnostic systems can be sustained after the Fleming Fund ends. One critical component of sustainability for both the human and animal health sectors is the supply of laboratory consumables and reagents. These items represent a significant recurrent cost and are at risk of stock out, meaning the surveillance systems and diagnostic services are easily disrupted.

The purpose of this paper is to:

- Examine the specific challenges to the sustainability of reagents and consumables within the human health sector.
- Describe ways to promote the sustained supply of these items.
- Reflect on the implications of the situation for health systems and suggest avenues for further exploration.

The challenges

A positive result of Fleming Fund investment is a large increase in testing of biological samples, with a cumulative 2.6 million human health (HH) tests undertaken from mid-2020 to the end of 2023. This results from an increase in the number of supported sites (clinical and veterinary laboratories), and improvements in laboratory infrastructure at these sites (e.g. installation of blood culture instruments), plus an increase in demand for bacteriology services. The proportion of human health (HH) laboratories across all regions equipped with a working automated blood culture system (ABC) has risen from 39% to 84% in this period (excluding Myanmar and Sri Lanka).

Testing all eligible samples for bacterial diagnosis as part of routine HH clinical care (passive surveillance) provides benefits – both direct and indirect – compared with widespread reliance on presumptive treatment (based on suspected diagnosis) with antibiotics for suspected bacterial infections. Patient benefits include improved prescription of effective antibiotics, leading to better clinical outcomes and DALYs[1] averted (better guided treatment, decrease in AMR infections); less time in hospital, less time out of work for patients and their careers, and less money wasted on ineffective treatments. Analysis of samples taken from patients is used both for the immediate clinical care of that patient and to feed into datasets which inform policy on antimicrobial use and local prescribing guide-lines. A passive surveillance system, in other words, can be regarded as a byproduct of good clinical care.

To work effectively and safely, a passive surveillance system requires a sufficient supply of a broad range of items, from latex gloves, petri dishes and other glassware, and standard laboratory items such as transfer pipettes. Blood culture bottles, at around £2.90 – £4.00 per bottle, are a considerable cost, especially in relation to limited hospital budgets for laboratory services, and relative to health spend per capita in many LMICs. Globally, there are issues with blood culture bottle shortages, and it can be problematic to ensure a regular supply.

A recent Editorial by *The Lancet Microbe*, Rethinking blood culture, highlights the blood culture bottle shortage in the USA and the overreliance on a small pool of manufacturers.[2] The absence of a competitive market contributes to higher costs for patients and healthcare facilities. Another piece argued that the cost of blood cultures was a barrier to diagnosis in low-income and middle-income countries (LMICs); in more than half of LMICs surveyed, the median price paid by patients for a blood culture exceeded $5.[3] The current situation also results in frequent stock-outs with blood culture bottles described by some observers as the 'weakest link in the chain'.

The Fleming Fund currently covers a large proportion of costs for HH surveillance systems, including equipment (alongside service and maintenance) and consumable needs, staff training, protocol development and implementation of data systems. Governments cover a lower proportion of system costs, typically contributing to staff salaries, utility bills at sites and other routine recurrent expenditures.

The issue of how consumables are funded beyond the Fleming Fund is critical. If there is insufficient funding by the government for the ongoing purchase of consumables, laboratory tests may stop or only be performed if funded by patients' out-of-pocket (OOP) costs. Where supplies of

Blood culture bottle(neck)s for Automated Blood Culture (ABC) equipment

Suppliers of Automated Blood Culture (ABC) equipment usually rely on proprietary blood culture bottles preloaded with reagent which must be bought from the same manufacturer to work in their machines. While a non-branded, non-automated (manual) option was available when selecting equipment for Fleming Fund supported laboratories, this had its own disadvantages including higher training needs and lower quality and consistency.

The ABC option was therefore selected to reduce the need for a highly trained workforce (and partially address the problem of high staff turnover), reduce reliance on complex reagent and media preparation and supply chains, improve the quality of results and reduce biohazardous waste.

However, the cost of the branded consumables is regarded as comparatively high by the receiving countries. A further supply chain challenge is that the items are 'made to order' so manufacturers do not sit on stock and only produce the items after receiving orders. When demand is high, this can lead to long lead times. An additional challenge is a global shortage (and consequent price increase) of raw materials required to manufacture bottles. Cheaper generic blood culture bottles are available in theory, but do not come with the same level of assurance for manufacturing quality and shelf life.

1. DALY means Disability Adjusted Life Years – it is a standardised measure of effectiveness of health treatments across different conditions considering quality of life as well as extension of life

2. The Lancet Microbe. Rethinking blood culture. Lancet Microbe 2025; 6: 101060.
3. The cost of blood cultures: a barrier to diagnosis in low-income and middle-income countries Hyland, Peter et al. The Lancet Microbe, Volume 6, Issue 8, 101125

consumables are erratic, the evidence suggests that clinicians will use what is available until supplies run out, rather than rationing these based on prioritisation, which affects the quality of AMR surveillance and clinical care. Sustainability can only be achieved if the current 'funding gap' is reduced through a combination of increased government contributions and reduced costs through improved economy, efficiency and effectiveness of diagnostic services and AMR surveillance.

Action to promote sustainability of consumables

As the Management Agent for the Fleming Fund, Mott MacDonald has spearheaded programme-wide initiatives to address sustainability. This includes Political Economy Analysis (PEA) to help understand factors related to sustainability; developing a better understanding of the costs and benefits of surveillance to support domestic (and development partner) resource mobilisation; and strengthening capacity to forecast requirements and costs of consumables to support budgeting decisions and efficient procurement. These initiatives are described in more detail below.

Political Economy Analysis – PEAs have been conducted for all partner countries to understand and inform better responses to country-specific factors related to sustainability. Aside from rich descriptions of the implementation context, the PEA reports include a specific section on future funding for laboratory tests.

Analysis of the PEAs reveals that in some settings, government budget allocations extend to free laboratory and diagnostic tests, although this can depend on type of test and patient income. Alternatively, payments for laboratory tests may fall under national or private health insurance schemes, and/or be subject to direct charges to patients themselves. These can form part of cost recovery efforts at the hospital level. For example:

- In Vietnam social health insurance includes laboratory tests, including clinical anti-microbial susceptibility testing (AST). While the extent of cover depends on patient type, most have access to laboratory services with some co-payment OOP.
- In Khyber Pakhtunkhwa province in Pakistan, testing for inpatients is mostly reimbursed through the government's Sehat Sahulat (social health insurance) card. Some facilities with autonomy and revenue can independently decide to sustain testing. The Hayatabad Medical Complex in Peshawar, for example, earns revenue through a portion of the fees earned from staff using the premises after hours for private practice.

The PEAs also unpack some of the specific challenges around budgeting and procurement that affect the sustainability of testing services. For example:

- In Timor Leste, although laboratory tests are provided free at public hospitals, the costs for microbiology testing are borne mostly by the Fleming Fund, with little contribution from the Ministry of Health. Starting in 2025, MoH has begun to allocate budget for laboratory equipment maintenance; however, the commitment has not yet materialised. Some long-standing issues with the MoH's pooled procurement mechanism include delayed and wasteful purchasing resulting from erroneous product specifications. There is also an issue with over-reliance on short-term contracts with suppliers because of anti-corruption safeguards.
- In Nepal, financing of diagnostic tests in the health sector involves a mix of public funding, OOP expenditures and support from international donors. Although the state provides free basic health services, patients often seek services from the private sector due to perceptions about quality. Nepal's evolving National Health Insurance Programme suffers from low enrolment rates and high dropouts. Many diagnostic tests, including blood cultures, are not classified as 'basic health services' so must be self-funded by patients. The allocation of budget by government is generally insufficient and income generated from charges goes into pooled hospital funds that are allocated by hospital administrations with little transparency.

The PEA process requires country grantees to analyse these findings and consider where they may be able to exert influence. Findings feed into country level sustainability plans and revisions to country investment strategies.

Sustainability plans – To ensure that sustainability is systematically and proactively addressed, Mott MacDonald requires all grantees to develop country level Sustainability Plans. Recognising that capacity, motivation and resources are all required, these plans classify sustainability goals and actions and provide a reporting framework for tracking progress.

Country grantees' sustainability-related activities include, for example, advocacy for funding for surveillance costs using

Policy engagement for sustainability of consumables in Uganda

In Uganda, the costing study has been disseminated to the Government. The Fleming Fund is working with the Quantification and Procurement Planning Unit (QPPU) within the Ministry of Health to improve resource mobilisation and data utilisation. The Fleming Fund grant has helped establish a Parliamentary Forum on AMR launched last year. This forum is advocating for budget allocation for AMR containment through the Health Committee of Parliament. Data on the potential impact of AMR on reducing milk production, as well as human health impacts of multidrug resistant infections, have proved effective advocacy strategies.

Important in the path to sustainability is first to get items onto national drug procurement lists; discussions on allocations and quantities can then follow. Staff from the NRL and QPPU have met with the Fleming Fund's global procurement agent (GPA) to agree on prioritisation of essential supplies, with some consumables added to government procurement lists and being made available at the Country's Medical Stores. Some items, e.g. blood culture bottles – at around £4 per bottle – are regarded as too expensive to be purchased by the government at this time. Mott MacDonald has started discussions with The Global Fund Country Coordinating Mechanism to explore including this item in their procurement.

dissemination of results through media coverage and opinion pieces; sessions with Parliamentarians to raise awareness of AMR and the benefits of surveillance; provision of technical support on amending essential drugs lists; and supporting ministries of health to negotiate with suppliers. Our forthcoming sustainability learning brief analyses enabling factors in the countries most advanced in the journey to sustainability.

Costs and benefits study – Information on costs and benefits is important for securing domestic resources as well as further development partner investment. In 2022, Mott MacDonald published a study, 'Foundations for Costing and Benefit Identification of National AMR Surveillance', analysing data from Uganda. This work built on previous studies, adding important dimensions. It included the costs of other elements of a system, besides data generation, needed for AMR surveillance to be effective – such as national reference laboratories (NRLs), central policymaking and implementation, and monitoring and evaluation. It also incorporated animal health.

The study estimated the total costs of an AMR surveillance system, including early investment costs, for the initial three years and the subsequent ten years. The average annual cost of operating an AMR surveillance system for human and animal health was found, in Uganda, to be £2.5M over the initial three years, reducing to £1.7M annually for the next ten years (reflecting initial high costs of renovation and investment in capital equipment). The study estimated laboratory sample throughput based on the assumption of the equipment running at half of its capacity, although more accurate figures will soon be available based on actual throughput data. In this study, the average cost per human health sample comes down from £14.77 in the first three years (which includes the initial investment) to £9.87 per sample for the subsequent ten years. Notably, unit costs remain high.

Although it was not possible to calculate fixed and variable costs precisely, there is a high ratio of fixed costs to variable ones, which means that scale is important if looking at the metric of cost per sample. While cost per sample reduces as volume increases, the total cost of testing does still increase – driven especially by the high costs of consumables and reagents. In some settings the current volume of testing may be unaffordable at current pricing levels. Follow up work to this study currently ongoing in Nepal and elsewhere will yield further information on fixed versus variable costs. The variable cost element will be especially useful to domestic governments in decision-making on sustaining systems, and at what level, after the costly initial investment has been covered.

Forecasting and central procurement – Cost-effective prices of consumables and reagents clearly have a major influence on AMR surveillance sustainability over the longer term, while in-country procurement capacity (including accurate forecasting and budgeting) is also important. The Fleming Fund decided to use a hybrid approach for procurement, in which a professional global procurement agent (GPA) purchases high-value equipment items, for example, mass spectrometers and automated susceptibility testing instruments, to obtain preferential pricing, while country grantees are the main purchasers of supplies and reagents, to help build local procurement capacity and systems. For all countries, a common Programme Procurement Catalogue was developed by Mott MacDonald with around 200 items, from petri dishes to biosafety cabinets. The catalogue was populated using equipment/reagent needs identified during site assessments as well as contextual information to create country-specific catalogues.

Three major consumables, however – blood culture bottles, automated susceptibility testing (AST) kits and MALDI-TOF reagents – have moved from country grantee to central procurement. This was to mitigate the high risk of stock out and to ensure equipment is used with the correct reagents.

At the suggestion of the GPA, a logistics management information system, *mSupply*[4], was successfully introduced for these items to grantees across the programme. *mSupply* is an integrated system which can be used offline. It is open source and used in national programmes elsewhere – for example by UNICEF in South Sudan, by Timor Leste under a DFAT programme, and by the Government of Laos.

4. *mSupply* is a leading Logistics Management Information System (LMIS) for health supply chains in low-resource settings. Used in over 30 countries around the world, it is an end-to-end solution, incorporating procurement, forecasting, warehousing, distribution and last-mile mobile solutions.

As the Management Agent, Mott MacDonald supported the complex forecasting for the three items. We conducted a survey to assess quantities needed based on previous use. The data was seen as incomplete for this purpose, so this was combined with other methods using disease prevalence, bed and laboratory capacity, and ratios of adult/children patients, to finetune the forecasts, and factor in the different types of blood culture bottles – paediatric, aerobic and anaerobic – required. AST kits are even more difficult to estimate as only positively identified bacterial samples require AST, and the ratio of positive to negative tests may change over time as clinicians receive data from test results, which helps improve targeting of testing. All forecasts were sense-checked with regional teams and orders were placed with the GPA.

The *mSupply* system is highly regarded by country grantees, programme staff and government officials, as reported in the recent pilot study in Uganda and Tanzania. Laboratory end users described it as a 'game-changer' because of its pivotal role in facilitating the forecasting process. Users have praised the system for its ability to enable precise data collection on inventory levels, usage rates, and demand patterns, crucial for accurate forecasts.

The automated calculations feature reduces the risk of human error and improves the reliability of forecasts by calculating future needs based on historical data. Additionally, *mSupply* supports scenario planning, allowing users to model and prepare for different demand scenarios, such as surges in demand for laboratory supplies during outbreaks. Users have highlighted the system's real-time visibility and inventory tracking capabilities, which enable them to see exactly what is available at any given moment. The system also tracks shipments and deliveries, providing updates on what country grantees have received and what is still in transit.

This real-time visibility ensures transparency and accountability, as all stakeholders can access up-to-date information on stock levels and movements enhancing decision-making, resource allocation and timely interventions to address potential shortages or surpluses. Although currently limited to three items, during the rollout of *mSupply*, many countries expressed an interest in including some of the more difficult to procure items (such as control organisms and antibiotic disks) and other products that might benefit from a pooling mechanism (such as growth agar).

The system is currently a *push* system, to country grantee level only. Ultimately, the rollout of the system to the site level, with a 'pull' system whereby government staff at sites order what they need, and actual consumption data can be viewed, would bring even greater benefits. Technically, moving to a pull system at the site level would provide the 'missing link' in the entire supply chain, providing real-time visibility on usage rate (accurate quantification), costs analysis based on accurate numbers for a given period, and quality monitoring, all hallmarks for a sustainable model. Extending *mSupply* to a pull system at the site level is being trialled in Uganda, and results are awaited. Depending on the resolution of technical issues and hardware requirements at the site level, an expansion of the pilot to five-six countries is proposed during phase 2.

mSupply is suitable to be taken over by governments at programme end. Logins to the system could be transferred as an asset and ministries of health could obtain their own licences to continue without great expense.

Conclusions and way forward

The Fleming Fund's Theory of Change (ToC) is centred on the pathways to achieve improved AMR surveillance, ultimately to reduce morbidity and mortality from AMR. Each element of the ToC is critical – a surveillance system cannot happen without the data generated through quality-assured bacteriology testing, nor without the use of this data to make changes to lists of essential medicines, and prescribing guidelines and behaviours.

In an ideal scenario, a passive human health surveillance system is sustainably maintained. This is the most cost-effective scenario because even if we cannot yet quantify them, we know that multiple benefits result, such as information for improved clinical care, early detection of outbreaks, and evidence-based guidance for antimicrobial use.[5] Improved clinical care for patients has immediate resonance with constituent audiences and expectations for testing and correct prescribing drive demand (and resources) for laboratory testing. The maintenance of the system should, in many cases, eventually be funded by domestic sources as part of the wider health system investments in laboratory services, yielding ongoing benefits after the initial investments have been covered by external support such as the Fleming Fund. In many countries, however, a further interim external funding source will be needed before domestic resources take over.

The reality of domestic resource constraints and changes to the external funding landscape, however, means that risk and contingency planning are needed. Risks of stockouts

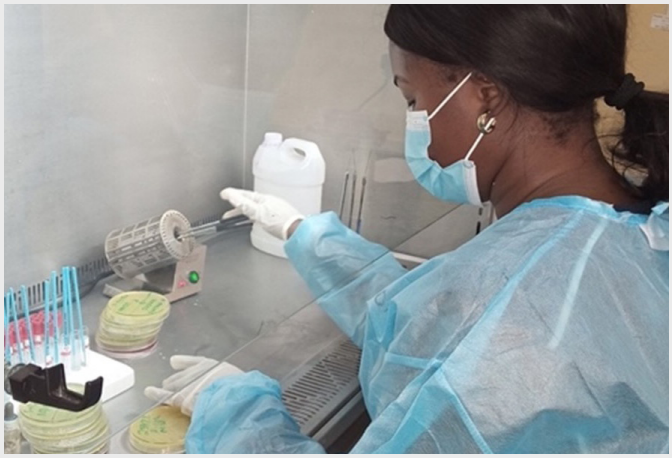
5. Foundations for Costing and Benefit Identification of National AMR Surveillance. 2022 Fleming Fund. Dan Whittaker

of consumables are real, resulting in ruptures to laboratory testing and loss of data for surveillance or clinical care. In this scenario, it is better to have a plan of what the health system can afford, rather than risk ad hoc stockouts, which undermine the functioning of the clinical diagnostic services and the surveillance system.

Key issues include the quality of data, not just quantity, as good quality representative data from one site (e.g. the national referral hospital) might be better than worse quality, intermittent data from more sites (which would be a reversion to the status pre-Fleming Fund). At the same time, it is important to note that data from in-patients in hospital with severe infections will not be representative of the whole population and of resistance profiles in many common non-severe bacterial infections. The reliance on data from seriously ill patients in in-patient settings for decision-making on first-line treatment could potentially lead to premature changes to drug treatment guidelines because the problem is overestimated. A well-thought-out strategy is needed, informed by local epidemiology, a prioritised list of the country's main concerns and rooted in an understanding of costs and available resources.

To generate useable and sufficient data will require sustained levels of testing. Even though the basic recommendations for antibiogram preparation, as set out in the Clinical and Laboratory Standards Institute document M39, suggest as little as 30 annual samples per pathogen may be enough for acceptable analysis[6] it requires a large volume of testing to achieve even 30 viable isolates. This is because in most settings, blood cultures yield an organism only in about 10-15% of samples taken, so for every 1000 tests, we can expect to recover around 100-150 blood culture positive samples. However, these must then be identified to species level (with 10 or so possible organisms), and once these are broken down into species (and subspecies), there will be a requirement for several thousand tests to be done to collect 30 samples of a 'rarer' pathogen. It is also necessary to have at least this minimum number at each level of analysis (e.g. ward, hospital, district, etc). Every country will have contextual differences in relation to AMR surveillance needs, but government needs to consider what it can afford to collect, ensuring that it funds the entire system that is required, including maintenance of equipment, quality assurance of data, data analysis and use, and system governance.

This could have implications for further cost/benefit analysis; rather than only costing laboratory throughput and variable



costs based on assumptions around a country's testing capacity, a good starting point might be to consider first the minimum volume of testing that is acceptable to allow effective surveillance to continue. Though not optimal, this is preferable to allowing surveillance efforts to fall away entirely. Ultimately, ensuring an effective surveillance system survives will have the greatest impact on long-term quality of clinical care.

Another lever of sustainability is to influence the pricing of consumables, especially those which are restricted to specific manufacturers. Arguably, there is a need for international pressure of improved pricing for LMICs, and non-restrictive technologies. *The Lancet* has suggested a need for standardised blood culture bottles or systems that allow interchangeability during shortages.[7]

Central procurement has already translated to negotiated price reductions based on greater volumes, but further efforts may be required. In the way that Gavi has secured tiered pricing for LMICs to buy vaccines at cheaper prices, advocacy could be used to seek further price reductions or allow new market entrants as global goods. Certainly, there is scope for external funders – such as the Pandemic Fund and others – to continue pooled procurement arrangements started under the Fleming Fund to help with market shaping.

As the Fleming Fund nears its end date, Mott MacDonald and country grantees are supporting governments to reflect on their achievements, identify critical sustainability gaps and embark on the necessary prioritisation using evidence generated from the Fleming Fund's almost decade-long investment.

6. CLSI. Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data. 5th ed. CLSI guideline M39. Clinical and Laboratory Standards Institute; 2022

7. *The Lancet Microbe*. The cost of blood cultures: a barrier to diagnosis in low-income and middle-income countries. 2025:101125