

A black and white photograph of a microfluidic pipette array. The pipettes are arranged in a grid and are positioned over a tray of small, clear plastic wells. The image is slightly blurred, focusing on the tips of the pipettes.

# A Novel Incentive Model for Uptake of Diagnostics to Combat Antimicrobial Resistance

CONTRACT RESEARCH REPORT  
MAY 2023

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**Please cite this report as:**

Firth, I., Pan, J., Towse, A., Steuten, L., 2023. A Novel Incentive Model for Uptake of Diagnostics to Combat Antimicrobial Resistance. OHE Contract Research Report, London: Office of Health Economics. Available at: <https://www.ohe.org/publications/novel-incentive-model-uptake-diagnostics-combat-AMR>

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### Funding and Acknowledgements

This contract research report was commissioned and funded by Roche Diagnostics. We would like to thank the experts who were interviewed or attended the roundtable for their valuable input which has informed the novel payment model presented in this report. The final text is the sole responsibility of the authors.

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# Executive Summary

## ANTIBIOTIC STEWARDSHIP IS KEY TO COUNTERING RISING RATES OF AMR

Antimicrobial resistance (AMR) is a pressing global issue. Resistance, particularly to antibiotics, threatens our ability to treat common infections in the future. This threat is compounded by the weak antibiotic pipeline and a lack of new antibiotics reaching the market. The rising level of AMR has large economic implications too, with prolonged hospital stays and a need for more costly novel treatments for pathogens/diseases that would otherwise be treatable with cheaper existing antibiotics, putting extra strain on already stretched healthcare systems.

In the face of this 'perfect storm', there is a clear need to prioritise stewardship activities to preserve antibiotics and reduce the rate of resistance. NICE defines antimicrobial stewardship as 'an organisational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness' (NICE, 2022a). Stewardship activities therefore encompass all activities related to ensuring the right medicine is prescribed to the right patient at the right dosage for a suitable duration (Shrestha, Zahra and Cannady, 2022).

## ROLE OF DIAGNOSTICS IN AMR STEWARDSHIP

Diagnostics can support antibiotic stewardship by informing clinical decisions and reducing inappropriate antibiotic prescribing. Diagnostics that are used to support antibiotic stewardship include a range of technologies, from PCR-based, genomic, and microbiological tests that can be administered either at the point of care (PoC) by non-clinical staff or processed at a laboratory. Despite their potential to support antibiotic stewardships, diagnostics are underutilised in the context of AMR. Low adoption in clinical practice also means there is a lack of research and development into innovative, high-value diagnostics creating a vicious cycle of low adoption and weak innovation.

Where high-value diagnostics that address an unmet need do exist, there is a range of challenges which limit their adoption at levels needed to support antibiotic stewardship:

### Challenge 1: Poor incentives for high-value diagnostic innovation

Payers often exhibit a low willingness to pay for high-value, innovative diagnostics stemming from their value to AMR, often going unrecognised. This leads to low incentives for manufacturers to invest in R&D for high-value innovative diagnostics. We define 'high-value innovative diagnostics' as diagnostics that address an unmet need, are highly accurate, actionable and easy to implement.

### Challenge 2: Low willingness to invest in diagnostics for AMR from local budget holders

The cost associated with diagnostics, particularly in comparison to the relatively low cost of antibiotics, and a lack of awareness of the value of diagnostics for supporting antibiotic stewardship limits the willingness of local budget holders to purchase diagnostics for AMR and the willingness of clinicians to adopt them into clinical practice (Huddy et al., 2021).

### Challenge 3: Low evidence of value at the point of adoption

What often compounds the prior two challenges presented above is the lack of compelling evidence showcasing the clinical value of the innovative diagnostic. This is in part due to regulatory evidence requirements being different for diagnostics than for medicines. Evidence of the value of diagnostics is not routinely collected, and value assessment is often not done at all or not conducted in a systematic way, partly because it is more complex for diagnostics (Oosterhoff et al., 2016) than for therapeutics. Poor evidence of value means payers are not willing to pay for diagnostics above

covering costs, and clinicians are unwilling to adopt diagnostics because they cannot judge the value they bring.

### A NOVEL INCENTIVE MODEL COULD REDUCE THE BARRIERS TO ADOPTION OF DIAGNOSTICS

We propose a novel payment model to overcome these barriers to adoption of diagnostics to support antibiotic stewardship. The proposed payment model is a value-based, aggregated procurement mechanism. The specific mechanism of implementation of the payment model will vary across countries depending on the structure of the health system and processes for adoption of health technologies. However, the payment model should have the following general design criteria:

1. Procurement must be **aggregated** at a level above the individual provider such that providers are cost-neutral to the use of a diagnostic (i.e., using the diagnostic will not increase the cost of delivering care).
2. The procurement level must be **value-based**, informed by a value assessment based on evidence of efficacy and value.
3. The payment contract must be negotiated over **multiple budget cycles** to generate a form of exclusivity and revenue certainty for developers.
4. Eligibility for the novel payment model is **limited**, therefore, not all diagnostics that could support antibiotic stewardship would automatically gain reimbursement through this mechanism.
5. Eligibility criteria for the mechanism should be based on **health system priorities** set by payers and informed by international unmet need.
6. The payment model must be accompanied by specific **education and behaviour change** initiatives to support the uptake of diagnostics reimbursed within the scheme.

The incentive model process would have three steps:

#### 1. Value demonstration:

The value of the diagnostic should be assessed and used to determine whether the diagnostic is eligible for the payment mechanism and how much the diagnostic should be reimbursed within the mechanism. Value demonstration will incorporate an eligibility screen and a broad value assessment.

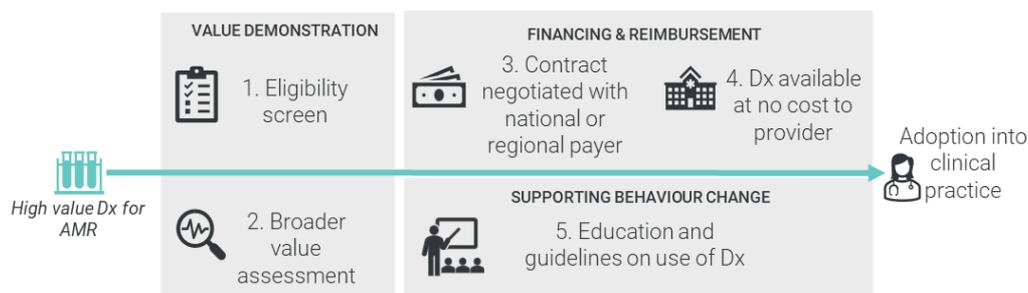
#### 2. Financing and reimbursement

Manufacturers will be paid directly by national payers or regional payers, and the contract amount would be informed by the broader value assessment and set over a minimum of three years. The diagnostic will then be available nationally or regionally, and providers will be able to use diagnostic tests and equipment directly from manufacturers of diagnostics under the payment model at no cost.

#### 3. Supporting behaviour change

The incentive model needs to be supported by education and behaviour change initiatives to encourage the uptake of the diagnostic. Education and behaviour change should be funded through national AMR action plans and fit into existing national clinical education processes and incentive structures.

### SCHEMATIC OF NOVEL INCENTIVE MODEL FOR DIAGNOSTICS (DX) THAT HELP TO COMBAT AMR





The vital attention that the economics of antibiotics is receiving, including initiatives such as the NICE-NHS England pilot in the UK and the PASTEUR Act in the US, is a moment of opportunity to redefine how health technologies with a large impact on global public health should be procured. While these initiatives for antibiotic development are promising, addressing the antibiotic resistance crisis requires both development of new antibiotics and more appropriate use of existing ones. Appropriate use of antibiotics relies on diagnostics, so the efforts taken to incentivise antibiotic innovation will be wasted if incentives for diagnostics are overlooked. Much has been said about the importance of diagnostics to the AMR crisis, but now is the time for policymakers to act.

# 1 Introduction

## 1.1 The ‘silent pandemic’ of AMR

Healthcare systems depend heavily on the availability of effective antibiotics to treat bacterial infections. However, rising antimicrobial resistance (AMR), and a lack of novel antibiotics both in the market and in the pipeline in particular, have led to the ‘silent pandemic’ of AMR with few solutions (Dodson, 2021; Murray et al., 2022).

NICE defines antimicrobial stewardship as ‘an organisational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness’ (NICE, 2022a). To combat antibiotic resistance, health systems must improve stewardship of existing antibiotics as well as incentivise the development of new antibiotics to replace those with high resistance rates.

Recent policy developments, like the UK AMR Pilot and the US PASTEUR Act which aim to incentivise the development of new antibiotics, will take a long time to have an impact on antibiotics launched (NICE, 2022a). For stewardship of existing antibiotics, there is growing consensus that diagnostics are vital to delay the accumulation of resistance (Fischer et al., 2021; Vogler et al., 2021; CDC and AdvaMedDx, 2016; FIND, 2018).

## 1.2 Background of diagnostics for AMR

Antibiotic resistance develops through any exposure of bacteria to antibiotics, whether they are needed or not. Diagnostics can reduce antibiotic resistance by reducing inappropriate antibiotic prescribing and, therefore, unnecessary exposure of bacteria to antibiotics. Clinicians are under increasing pressure to reduce antibiotic prescribing to reduce resistance but lack the means to identify which of their patients can be safely monitored without an antibiotic prescription. Accurate diagnostics can therefore enable the reduction in antibiotic use by targeting ‘low-value’ inappropriate prescriptions and avoiding the health cost of withholding antibiotics from patients who need them (Pew, 2020).

Diagnostics can also increase the therapeutic benefit of an antibiotic for those patients who do need them by better tailoring their treatment. Tailoring treatment can include prescribing a targeted antibiotic based on the causative pathogen or monitoring infection to set the optimal length of a course of treatment (Turner et al., 2017; Boyer et al., 2019; Dryden et al., 2011; Llewelyn et al., 2017). Beyond better prescribing, an important but often neglected role of diagnostics is to support the clinical development of antibiotics by supporting recruitment of participants in clinical trials with specific drug-resistant infections. Diagnostics can help to build the evidence base for new antibiotics by giving a clearer picture of the effectiveness of an antibiotic against specific bacteria and resistance profiles.

Despite their associated benefits, diagnostics which support AMR stewardship face a range of challenges to being adopted into clinical practice. Diagnostics are generally not a part of many countries’ AMR Action Plans and therefore do not have high political recognition over other interventions to curb antibiotic usage. Furthermore, the cost of diagnostics to the healthcare provider is higher than the cost of the antibiotic, and often the cost of the diagnostic is incurred in one area of the health system (e.g., primary care), but the benefits are realised in another (e.g., hospitals).



Furthermore, reimbursement processes for diagnostics vary substantially between countries and are often cost-based, reducing the incentives for developers of innovative diagnostics where the clinical value may be high but may not generate a sufficient return on investment. Where value assessment is used, diagnostics are complex to evaluate because it is hard to isolate the impact of a diagnostic in a care pathway. They also have special economic characteristics as they have a higher value at a population level than their therapeutic benefit to the individual patient. While these diagnostics do have value to the individual patient, as outlined above, they importantly generate additional value by providing information which then reduces inappropriate prescribing, thereby reducing the build-up of resistance.

Diagnostics, therefore, face suboptimal uptake in clinical practice because, typically, there is no immediate financial consequence for inappropriate prescribing while, at the same time, the cost of using a diagnostic before a prescription is relatively high. Furthermore, the pipeline for new diagnostics, which would allow point-of-care (POC) testing and quick turnaround needed to inform a prescribing decision, is considered insufficient to meet unmet need (Anderson, Cecchini and Mossialos, 2019). Together these challenges pose large barriers to the adoption of diagnostics to support AMR stewardship and prevent the benefits of reducing AMR from being realised.

### 1.3 Project Overview

In this project, we have aimed to identify a novel incentive model for diagnostics which supports AMR stewardship to address the challenges to their adoption and barriers to their innovation. The insights presented in this report were informed by a pragmatic literature review, semi-structured interviews and a roundtable with international diagnostics and AMR experts from both academia and industry from the US, China, England, Japan, and Germany.

## 2 The Current Landscape of Diagnostics for AMR

### 2.1 The role of diagnostics in combatting AMR

Antibiotics are most frequently prescribed empirically based on a patient's symptoms. Because symptoms of infections are often non-specific, empirical prescribing is frequently inappropriate: i.e. use of antibiotics when they are not needed, use of broad-spectrum antibiotics while awaiting diagnostic results or use of an antibiotic when a different antibiotic would be more effective (Dryden et al., 2011). Globally, most antibiotics are prescribed in the community setting (81%<sup>1</sup> in England in 2020 (UK Health Security Agency, 2020)) and are often given for viral or self-limiting respiratory tract infections. It is a problem throughout the world. One study estimated levels of inappropriate prescription in the US at 43%, and it is also an important issue in low- and middle-income countries (LMICs) (Ray et al., 2019; Anderson, Cecchini and Mossialos, 2019).

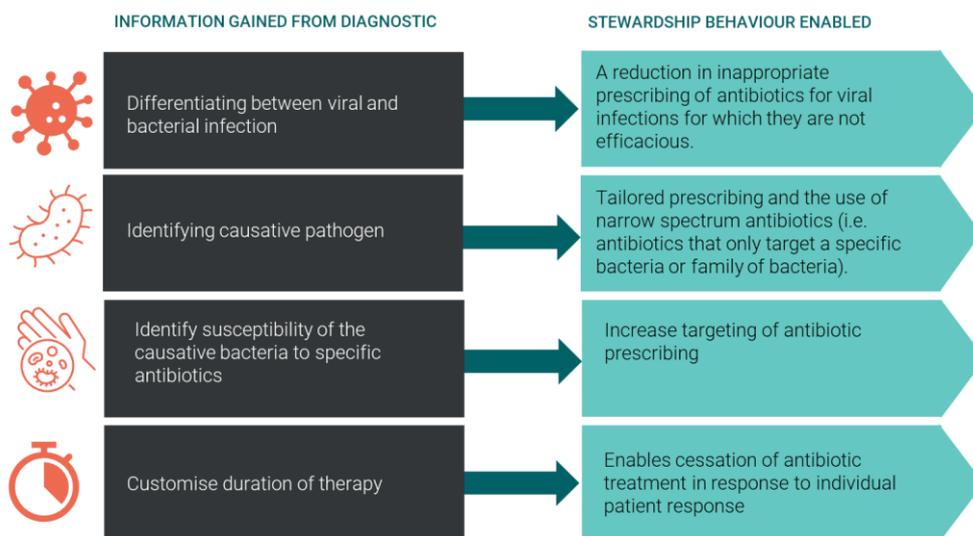
Diagnostics can reduce inappropriate prescribing in the following ways (Wellcome Trust, 2016; Antoñanzas, Juárez-Castelló and Rodríguez-Ibeas, 2021; Barbut et al., 2014):

1. Identifying the causative bacterial pathogen of an infection allows for more tailored prescribing. For example, differentiating between viral and bacterial infection and reducing prescribing of antibiotics for viral infections for which they are not efficacious. It also enables the use of narrow-spectrum antibiotics (i.e., antibiotics that only target a specific bacteria or family of bacteria).
2. Identifying the susceptibility of the causative bacteria to specific antibiotics or families of antibiotics to increase targeting of antibiotic prescribing.
3. Customising the duration of therapy by allowing de-escalation or cessation of antibiotics based on the individual patient's response to treatment (Spellberg, 2016; Heilmann et al., 2021)

Figure 1 below provides a summary of the benefits of diagnostics in supporting better antibiotic stewardship.

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<sup>1</sup> This includes prescribing across GP practices, dental surgeries and other community settings combined.



**FIGURE 1: OVERVIEW OF DIAGNOSTIC BENEFITS AND STEWARDSHIP BEHAVIOUR ENABLED**

## 2.2 Types of diagnostics for AMR

There is a range of diagnostic technologies that reduce inappropriate antibiotic prescribing in different ways. They broadly fall into technologies to detect the causative pathogen and technologies to identify antibiotic susceptibility/resistance (van Belkum et al., 2019; Plüddemann et al., 2014). Technologies can either be designed to be delivered at the point of care (PoC) or to be processed away from the point of care (e.g., in a laboratory). PoC tests provide rapid results, often in less than 30 minutes, and are conducted outside of a laboratory, generally near the patient being tested (Lisby and Schneider, 2021). Lab-based tests may require the sample to be sent to a laboratory, where trained technicians process the sample, requiring a longer time to obtain results than with PoC (Trenti, 2021). The lag time to result depends on the infrastructure available within the care facility, for example, whether the hospital has in-house equipment for complex testing capability. Although laboratory-based testing requires a longer time to a result, a high volume of samples can be tested while maintaining high-quality results generating greater efficiency due to economies of scale.

Diagnostic technologies are generally in-vitro diagnostics (IVDs), whereby testing is conducted on samples taken from the human body, such as blood or tissue (FDA, 2022). These include antimicrobial susceptibility tests (AST), blood cultures, polymerase chain reaction (PCR)- based tests and microbial genome sequencing (Vasala, Hytönen and Laitinen, 2020).

## 2.3 The current landscape for adoption of diagnostics

Diagnostics are financed, appraised, and reimbursed in very different ways across countries but also across different care settings within the same health system. We summarised a generalised pathway for diagnostic adoption in England, Japan, Germany, and the US in Appendix 1.

As different diagnostics have different attributes, for example, in terms of time to results, accuracy of test results, and convenience to take the test, it is important to note that patients in different countries do not have the same preferences for the attributes of diagnostic tests to manage AMR in



primary care. Failure to account for such differences during test development could reduce test uptake, result in continued overuse of antibiotics, and hamper marketisation (Mott et al., 2020).

Because of the high level of variability in the processes of adopting diagnostic technology into health systems, the rest of this paper discusses barriers and solutions in general terms to commonly seen processes across different countries. The barriers may be more or less relevant in different contexts and countries. In addition, the novel incentive model proposed in Section 4 focussed on general criteria rather than presenting a ready to implement process because the processes will have to be tailored for the range of current approaches seen across different countries. Its aim, however, resonates strongly with recent research showing that incentivising the use of AMR diagnostics as a policy option is favoured by a wide range of stakeholders in six European countries but (to date) has been lacking in prominence in the policy literature (Coburn, et al., 2021)

## 3 The Barriers to Development and Adoption of Diagnostics to Combat AMR

In this section, we will deep dive into the barrier to the uptake of diagnostics to combat AMR.

### 3.1 Barriers at each stage of the development to adoption process

#### Innovation: Barriers related to the commercial incentives for companies to invest in R&D for diagnostics for AMR

The cost to manufacturers of running clinical trials to collect high-quality data of efficacy and value is high. Coupled with the perception that payers have a low willingness to pay for diagnostics, there are limited returns to the manufacturer for investing in evidence development beyond technical efficacy. In some cases, continual validation of the diagnostic is needed to ensure they remain effective against emerging strains of pathogens, driving costs associated with evidence generation even higher.

There is also difficulty associated with the identification of areas of unmet need and demand so that specific use cases for diagnostics can be developed, for example, for high-performance diagnostics (Morel et al., 2016; Van den Bruel and Hayward, 2018). For many diagnostic technologies, it is difficult to protect innovation as laboratory developed tests have different regulatory requirements compared to commercial diagnostics (Spitzenberger et al., 2022).

#### Value Assessment: Barriers related to how the value of diagnostics is assessed by payers.

Value assessment for diagnostics is challenging because, as explained above, evidence on the full value of a diagnostic to society is rarely collected in diagnostic development (Lingervelder et al., 2021; van der Pol et al., 2021). When manufacturers are able to collect evidence on efficacy and cost-effectiveness, it may take up to nine years on average to accumulate the necessary evidence required by health technology assessment (HTA) agencies (Van den Bruel and Hayward, 2018). Current regulatory approval is often based on technical success (i.e., sensitivity and specificity), so there are limited incentives for companies to develop evidence showing the broader value of diagnostics in many markets (van der Pol et al., 2021). Recent EU legislation aims to increase the evidence requirement on in vitro diagnostics entering the EU market, so these barriers may change in the coming years (European Parliament, 2017).

HTA/value assessment for diagnostics is conducted at a very decentralised level and can therefore focus on cost savings rather than supporting innovation or value (Callea et al., 2017). Decentralisation means HTA frameworks for diagnostics are not as mature or sophisticated as they are for therapeutics (Garfield et al., 2016). HTA is also technically harder for diagnostics than for therapeutics because there is more uncertainty about the impact of a diagnostic on clinical outcomes because clinical pathways vary substantially across care settings, and it is hard to isolate the impact of one diagnostic within the pathway. Finally, the broader value of increasing stewardship and reducing resistance are not typically accounted for in HTA processes.

### Financing and Reimbursement: Barriers related to how resources for AMR are allocated within the health system budget.

In many countries, only specialised or high-cost diagnostics are eligible to be reimbursed at a national level, a category which does not generally include diagnostics for AMR. In many countries, diagnostics are paid for through Diagnostic Related Groups (DRGs) for inpatient care (Fischer et al., 2021). DRGs do not incentivise the use of a diagnostic over empirical prescribing because they add extra costs. There are also large upfront costs associated with implementing many innovative tests, such as equipment and training, which may not be sufficiently covered by the diagnostics budget, making the diagnostic unaffordable (Morel et al., 2016).

Budget silos may also exist within provider organisations, meaning that the total diagnostics budget is disaggregated across multiple budget holders, leading to conflicts of interest (John et al., 2022). While there are some mechanisms for pooling procurement for lab tests, this is often not the case, such as PoC tests. Furthermore, diagnostics may not be cost-saving within the budget cycle in which they are procured, even though they may generate savings in the longer term or generate clinical improvements without cost savings. Cost-plus reimbursement is often used for diagnostics as value-based approaches (e.g. HTA) are not routinely applied in the context of diagnostics. For health systems utilising tariffed pricing, like DRGs, the price is linked to the price of existing diagnostics which disincentivises the innovation of high-value diagnostics (Morel et al., 2016).

### Adoption: Barriers related to how diagnostics are introduced and used within clinical practice.

Different healthcare departments or services across healthcare systems are assessed on meeting a range of clinical and operational targets. Decision makers do not prioritise diagnostics over other budget categories that are perceived to offer quicker wins in terms of either cost savings or care improvement. There is also a lack of guidelines from professional societies and governments on best practices on the use of diagnostics (CDC and AdvaMedDx, 2016) and a lack of strategy for diagnostics within national AMR action plans. Budget holders, therefore, do not invest time and resources into the procurement and training required to incorporate diagnostics into clinical use.

Budgets for diagnostics may be allocated across care settings meaning the clinician using the diagnostic often does not experience the cost savings of using it (e.g., primary care and hospital care) and, therefore, lacks the incentive or business case to implement the diagnostic (Morel et al., 2016; Huddy et al., 2021). The cost of diagnostics relative to the treatments they 'ration' is high, and it is often less costly for clinicians to see if an antibiotic works than to check with a diagnostic test.

As evidence of clinical impact and value is rarely collected in diagnostic development, clinicians do not have good evidence to support the adoption of a diagnostic into their decision-making (van der Pol et al., 2021). In addition, physicians can be concerned about the imperfect accuracy of tests for making high-stakes decisions and whether relying on diagnostics undermines clinical judgement (Huddy et al., 2021). There is also concern that using diagnostics can cause delays in workflows which is a significant disincentive to use diagnostics for capacity constrained health systems (Eley et al., 2018).

## 3.2 The problem facing adoption of diagnostics

The barriers at each stage of the procurement process presented can be summarised into three challenges which limit the adoption of diagnostics that could help to combat AMR.



### Challenge 1: The poor incentives for high-value diagnostic innovation due to low willingness to pay for innovation.

The low willingness to pay for diagnostics means that there are low incentives for high-value innovation (i.e., diagnostics that are highly accurate, actionable and easy to implement).

### Challenge 2: Low willingness to invest in diagnostics for AMR from local budget holders

The cost associated with diagnostics, particularly in comparison to the relatively low cost of antibiotics, reduces the willingness of decision-makers, including clinicians, to purchase diagnostics for AMR (Huddy et al., 2021).

### Challenge 3: Low evidence of value at point of adoption

There is poor evidence of the clinical value of a diagnostic at market launch, which compounds both of the previous barriers: payers are often not willing to pay more for diagnostics than covering costs, and decision-makers and clinicians are unwilling to adopt diagnostics.

# 4 Novel Incentive Model to Encourage Innovation and Adoption of Diagnostics That Support AMR Stewardship

## 4.1 Why a novel incentive model is needed

Many public health problems suffer from both a market failure on the supply-side and suboptimal behaviour on the demand side. Examples include antibiotic resistance, the shortage of treatments for diseases prevalent in low- and middle-income countries and poor equity in global access to Covid-19 vaccines. In the previous section, we summarised the three barriers which limit the innovation and adoption of diagnostics which combat AMR:

1. The poor incentives for high-value diagnostic innovation due to the low willingness to pay for innovation.
2. Low willingness to invest in diagnostics for AMR from local budget holders
3. Low evidence of value at the point of adoption.

Therefore, diagnostics which help to combat AMR require a solution that:

- Incentivises innovation that addresses unmet need and
- Changes in adoption behaviour for diagnostics within the health system.

Novel payment models, which differ from the traditional volume-based model of paying for health technologies, can be designed to change both demand-side and supply-side behaviour. Different pull incentive models have been used in healthcare. Often these are implemented principally to shape incentives for innovation, but they can also be designed to shape demand-side behaviour. Existing (non-price) incentive models for medical innovation (Mestre-Ferrandiz et al., 2022) can be drawn from to design a solution for AMR diagnostics (Coburn et al., 2021).

### Volume-delinked subscription or 'Netflix' models to incentivise innovation

Subscription, or 'Netflix'-style, models allow payers to pay a pre-agreed fee for a medical technology in regular intervals over multiple budget cycles. Subscription models ensure budget and revenue certainty for payers and developers, respectively. Developers are incentivised to invest, and payers are encouraged to adopt high-value technologies (Boluarte and Schulze, 2022). Subscription payments can be delinked from volumes used and are applied in situations where a volume-linked model leads to either over- or under-consumption of the product.

#### **Volume delinked subscription model to appropriately limit usage**

The UK AMR pilot is using a subscription model with an annual value-based payment up to a cap of £10 million a year for ten years. By paying for the antibiotics delinked from volumes, the health system sets stewardship policies without an impact on revenues and therefore incentivises future

investment in antibiotic R&D. In the AMR pilot, hospitals will continue to pay for antibiotics by volume in their budgets to avoid overconsumption.

### Volume delinked subscription to increase usage

A subscription model has also been used to increase the usage of hepatitis C treatments where concerns about the budget impact of direct-acting antivirals were preventing the adoption of eradication programmes. In Louisiana, USA and in Australia, subscription models were negotiated between the manufacturer and payers with the aim of eradicating hepatitis C from the population (Moon and Erickson, 2019; Sood et al., 2018; Trusheim, Cassidy and Bach, 2018). The model allowed payers to recognise the broader value to the health system of an eradication policy while limiting the uncertainty of budget impact (Moon and Erickson, 2019).

### Advanced Market Commitments to incentivise innovation

Advanced Market Commitments (AMCs) have been proposed for products for low- and middle-income countries where aggregated willingness to pay is high but upfront commitment to pay for innovation is low. An AMC has been used to reward pneumococcal vaccine development and, more recently, was adapted into an aggregated procurement model under COVAX to pay for Covid-19 vaccines (Kremer, Levin and Snyder, 2020; WHO, 2022). The model has also been adapted by making the reward value-based to incentivise high-value innovation. The value-based adjustments have been proposed in the context of tuberculosis therapies and Covid-19 vaccines (Chalkidou et al., 2020; Towse et al., 2021). A similar aggregated procurement model has recently been suggested for diagnostics to combat AMR for low-and middle-income countries (Berman et al., 2022).

### Market Entry Prizes to incentivise innovation

Prizes can be used as rewards for innovation in a system with weak commercial incentives. Prizes are a form of pull incentive used where commercial incentives are weak. Patent buy-outs are a form of prize fund where a fund buys the patent rights to a product. The product is then made available at lower cost-linked prices (Banerjee, Hollis and Pogge, 2010). Prizes are already widely used in the diagnostics space, including the NIH Antibiotic Resistance Diagnostics Challenge and the Longitude Prize (NIH, 2020; Longitude Prize, 2022).

## 4.2 Requirements for a novel incentive model for diagnostics

A novel incentive model for diagnostics could help to reduce the supply-side and demand-side barriers to the adoption of high-value diagnostics and harness their potential to reduce the burden of AMR. In this section, we present design criteria that are needed for a novel incentive model to increase the adoption of diagnostics for AMR drawn from the barriers presented in the previous sections.

An incentive model for diagnostics should have the following criteria:

1. Procurement must be **aggregated** at a level above the individual provider such that providers are cost-neutral to the use of a diagnostic (i.e. using the diagnostic will not increase the cost of delivering care).
2. The procurement level must be **value-based**, informed by a value assessment based on evidence of efficacy and value.
3. The payment contract must be negotiated over **multiple budget cycles** to generate a form of exclusivity and revenue certainty for developers.

4. Eligibility for the novel incentive model is **limited**, therefore, not all diagnostics that could support AMR would automatically gain reimbursement through this mechanism.
5. Eligibility criteria for the mechanism should be based on **health system priorities** set by payers informed by international priorities.
6. The incentive model must be accompanied by specific **education and behaviour change** initiatives to support the uptake of diagnostics reimbursed within the scheme.

Table 1 shows how the criteria for the novel incentive model would address specific barriers to adoption of diagnostics that support AMR stewardship.

**TABLE 1: OVERVIEW OF HOW INCENTIVE MODEL CRITERIA ADDRESS BARRIERS TO ADOPTION**

Barrier	How criteria match to barriers to adoption
The poor incentives for high-value diagnostic innovation due to the low willingness to pay for innovation	<ol style="list-style-type: none"> <li>1. The procurement level must be value-based, informed by a value assessment based on evidence of efficacy and value.</li> <li>3. The payment contract must be negotiated over a number of budget cycles to generate a form of exclusivity and revenue certainty for developers.</li> <li>4. Eligibility for the novel incentive model is limited, therefore, not all diagnostics that could support AMR would automatically gain reimbursement through this mechanism.</li> <li>5. Eligibility criteria for the mechanism should be based on <b>health system priorities</b> set by payers informed by international priorities.</li> </ol>
Low willingness to invest in diagnostics for AMR from local budget holders	<ol style="list-style-type: none"> <li>1. Procurement must be aggregated at a level above the individual provider such that providers are cost-neutral to the use of a diagnostic (i.e., using the diagnostic will not increase the cost of delivering care).</li> <li>5. Eligibility criteria for the mechanism should be based on <b>health system priorities</b> set by payers informed by international priorities.</li> <li>6. The incentive model must be accompanied by specific education and behaviour change initiatives to support uptake of diagnostics reimbursed within the scheme.</li> </ol>
Low evidence of value at the point of adoption	<ol style="list-style-type: none"> <li>2. The procurement level must be value-based, informed by a value assessment based on evidence of efficacy and value.</li> <li>4. Eligibility for the novel incentive model is limited, therefore, not all diagnostics that could support AMR would automatically gain reimbursement through this mechanism.</li> </ol>

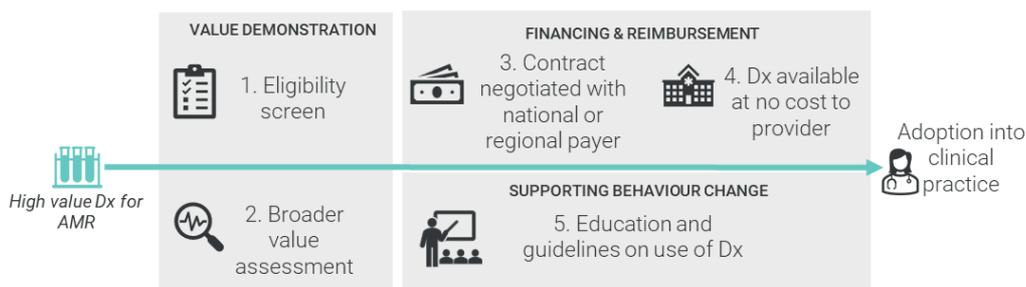
### 4.3 The proposed incentive mechanism: how an aggregated, value-based payment model would work

The aggregated, value-based model has three stages that are outlined below and in Figure 2:

1. Value demonstration

2. Financing and reimbursement
3. Supporting behaviour change

**FIGURE 2: SCHEMATIC OF NOVEL INCENTIVE MODEL FOR DIAGNOSTICS THAT HELP TO COMBAT AMR**



### Value demonstration step 1: eligibility screening

The decision whether a diagnostic is eligible for the incentive model should be underpinned by this assessment, with the expectation that some minimal threshold of sensitivity, specificity and usability be reached to qualify. The eligibility screen could score diagnostics criteria similar to ones proposed for the valuation of antibiotics where additional points are available for WHO priority pathogens, intensive care setting indications, the populations that they target, level of novelty and cross-resistance to existing therapies (Rex and Outterson, 2016). A checklist covering specific considerations for the value assessment of diagnostics has also been proposed by Kip et al. (2018) to cater for the unique constraints of diagnostics from a societal perspective.

There is the expectation that not all diagnostics relevant to AMR that enter the market would be reimbursed via this incentive mechanism. The mechanism would be available only to products that meet the pre-defined eligibility criteria, otherwise, the traditional payment mechanism would be used. In this way, payers are able to tailor the pull incentive to reward only innovation that addresses urgent unmet need.

### Value demonstration: step 2: broader value assessment

Following a positive eligibility screen, an economic evaluation of the diagnostic would be conducted. As explained in previous sections, diagnostics suffer from undervaluation by health systems because they have additional value beyond the therapeutic value to the patient being diagnosed which are not captured. Value assessment frameworks could be used to identify and quantify the population-level value. Recent recommendations highlight the need for health technology assessment (HTA) to be adapted for technologies targeting antibiotic resistance, including diagnostics, as current approaches are not appropriate (Colson et al., 2021).

Costs and benefits will be modelled along the entire clinical treatment pathway and will also include the broader value elements of diagnostics relating to their role in averting the rise in AMR and other broader value elements such as health system capacity value (i.e., the value of a technology in 'freeing up' capacity within the health system) recently considered in the context of vaccines (Brassel et al., 2021; Karlsberg Schaffer et al., 2017). Time horizons for economic evaluation should be long enough to accurately reflect the benefits of diagnostics and is likely to require modelling over multiple years rather than the days or weeks usually modelled for diagnostics.

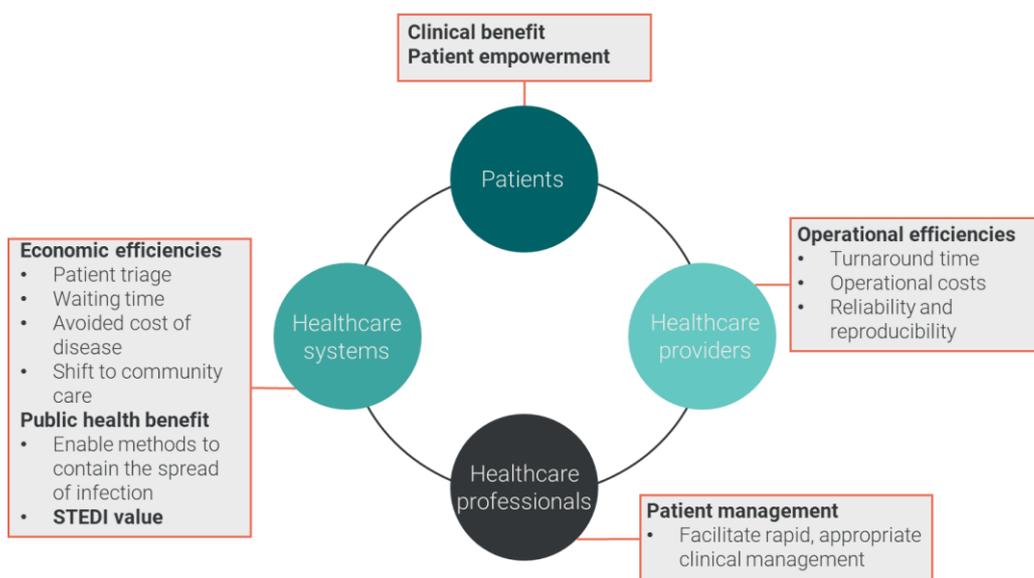
The so-called "STEDI"-framework, referring to Spectrum, Transmission, Enablement, Diversity, and Insurance value, conceptualises the broader value of antimicrobials and could inform the value

framework for a diagnostics assessment (Rothery et al., 2018). STEDI has recently been implemented within the value assessments carried out as part of the UK AMR Pilot for antimicrobial treatments (NICE, 2022b; c). Previously, the Value of Diagnostic Information (VODI) framework also suggests that value relating to patients (clinical benefit), health systems (economic efficiencies), healthcare professionals (patient management) and healthcare providers (operational efficiencies) should be considered to capture the full value of a diagnostic (Wurcel et al., 2019). As these frameworks partially overlap (see Figure 3), the VODI and STEDI conceptual frameworks should be used to design a value assessment methodology for the incentive scheme. Crucially both frameworks recognise that there is a public health benefit to technologies to counter AMR and that the value of diagnostics is felt by health systems and society more broadly rather than just the patient.

The broader value assessment should be carried out by national HTA agencies or regional agencies in countries where there are no relevant national bodies. Decision-making (for inclusion in the scheme or the value assessment itself) should not be done at the provider level (i.e., a single hospital).

The value assessment recommended relies on additional data collection by the manufacturers to what is currently collected for regulatory approval. Methods and requirements for the evaluation of diagnostics should be published by HTA agencies to support manufacturers who will have to invest in additional data collection to demonstrate that their diagnostics meet the requirements of the scheme. The relevant health outcome measure currently used in value assessment (e.g., Quality Adjusted Life Year [QALY] or clinical benefit) for each country should be incorporated into the evaluation to support the case to decision-makers that the diagnostic generates health gains to the patient and the population.

**FIGURE 3: VALUE OF DIAGNOSTIC INFORMATION SCHEMATIC INCLUDING STEDI POSITIONING. ADAPTED FROM WURCEL ET AL. 2019**



## Financing and reimbursement

Following a positive assessment, the contract would be negotiated between the payer and the manufacturer for multiple budget cycles, ideally covering a minimum of three years. The contract period is important for manufacturers as it generates some exclusivity and revenue certainty needed

for the incentive to be robust. In a context where laboratory developed tests (LDTs) often bypass patent-based exclusivity, the exclusivity generated by the aggregated incentive model is an important feature of the incentive for diagnostics to support AMR.

Manufacturers should be contracted directly by national payers reflecting the broader value that diagnostics bring to society, informed by the value assessment outlined above. The total value should be sufficiently large to incentivise research and innovation for future diagnostics. Determining an affordable level of incentive for diagnostics will require an analysis of the diagnostics market globally to determine an appropriate level of investment to stimulate innovation. A similar approach was conducted for antibiotics and has become the basis of pull incentives for antibiotics like the UK AMR pilot (Outterson, 2021).

The contract will specify an upper limit of volumes provided in the system based on a forecast of best-case uptake. If adoption is lower than anticipated, manufacturers would still receive the full contract amount. In this way, payers are incentivised to support uptake within the system to avoid a scenario of overpayment relative to the value generated by the diagnostic within the system. If the contract amount is allowed to vary, there is no certainty for manufacturers, and there is no incentive for the health system to develop systems to improve adoption such that the aims of the incentive model will not be met.

The national payer will have a contract directly with manufacturers at a set volume-price level for a set time frame with a specified minimum value (i.e. volume) threshold. At the end of the time frame, the contract will be renegotiated between the payer and the manufacturer. There will be no option for the payer to cease payment during the fixed term to ensure that the incentive for innovation is robust and generates a period of exclusivity.

The diagnostic should then be available nationally or regionally, depending on the structure of the health system. Providers procure diagnostic tests and equipment directly from manufacturers of diagnostics under the scheme at no cost for the duration of the contract. The scheme should be funded through an ear-marked budget specifically for diagnostics to help combat AMR, which covers both inpatient and outpatient care and hospital and non-hospital care settings.

#### Potential models for financing

The potential options for financing a novel incentive mechanism that relies on aggregation depend on the structure of the health system and the way that decision-making for the health system is spread across the system. Below we will present options for how the mechanism could be financed that are suited to different levels of decision-making aggregation.

##### ***Linked to pull incentives for antibiotics***

In countries where there are national pull incentives in place for antibiotics, the contracting mechanism for diagnostics could be managed as part of that process. In the model of companion diagnostics, diagnostics for antibiotics can support the adoption of high-value antibiotics through pull incentive mechanisms in all the ways outlined in section 2.1 above.

##### ***Nationally aggregated contracting***

In centralised health systems, like the UK and Japan, contracts for diagnostics to help combat AMR that are eligible for the novel incentive mechanism would be funded through a national level budget that would make products available at a national level. The contract would be estimated using national estimates of volumes used.

Similar to some pull incentives for antibiotics, the contract for diagnostics eligible for the incentive mechanism could be a subscription-based payment. Under the subscription model, the developer and the national payer would agree upon an annual fee which would not vary depending on the volumes of diagnostics used within the system. The subscription model could be managed either nationally or regionally.

### ***Sub-nationally aggregated***

The contract would be negotiated at a sub-national level either with a regional payer (e.g., China) or an insurance company (e.g., US).

The greater the level of aggregation, the more benefit of the model will be to both developers and the health system, given the burden of value-assessment required. However, if the assessment takes place multiple times within the system, it will lead to inefficient and excessive additional resource use.

### Supporting behaviour change

Once the diagnostic has been approved within the scheme, to increase adoption, it should be added to clinical guidelines, and specific education and training to increase adoption should be supported. These initiatives should be funded through national AMR action plans and fit into existing national clinical education processes and incentive structures where possible. Specific targets and incentives for the uptake of diagnostics across both community and hospital-based care may also be appropriate to drive uptake but will have to be managed at a national level. Health systems can also monitor stewardship through diagnostics; for example, through the share of antibiotic prescriptions supported by a diagnostic test to encourage a culture shift within clinical practice in both primary care and hospital care settings.

### Incentives for change

It is possible that, even if diagnostics are cost-free at the point of use by the health care provider, they will still be underutilised for practical or cultural reasons. Pay for performance incentives could be used to overcome these barriers as they have been shown to have an impact on provider behaviour (Yuan et al., 2017; Ellegård, Dietrichson and Anell, 2018). Pay for performance systems could be applied strategically to areas where diagnostics are underutilised, and the impact of poor stewardship is likely to be significant. Examples include empirical prescribing of antibiotics for respiratory infections without prior C-reactive protein (CRP) testing to support the case that the infection is bacterial rather than viral.

Pay for performance metrics for underutilised diagnostics under the model could be added to existing systems to incentivise clinical practice targets. For example, the Quality Outcomes Framework (QOF) for general practice in England and the Cancer Clinical Care Pathway model in the US give a financial reward to providers who follow evidence-based care pathways (Feinberg et al., 2012).

In hospital settings, adaptations to the HRG/DRG reimbursement system can be used (Aragón, Chalkley and Kreif, 2022; Scheller-Kreinsen, Quentin and Busse, 2011). For example, diagnostics within the mechanism could generate an add-on for the DRG/HRG or fee-for-service models (Scheller-Kreinsen, Quentin and Busse, 2011). Given these pay-for-performance models are an additional expense over and above the contract with the developer, they would only be beneficial in instances where there is significant underutilisation of the test. The requirement for a value assessment within the mechanism based on both clinical and population-level data is also designed to support behaviour change, and therefore, the pay-for-performance mechanisms are not likely to be extensively used.

## 4.4 Limitations of the novel incentive model

While an aggregated, value-based incentive model for diagnostics, as described above, can incentivise innovation of diagnostics for AMR and increase adoption, there are some limitations to this model that need to be mitigated.

Firstly, the key assumption of this proposed financing system is that the payer is willing to fund a bespoke incentive model. Currently, AMR action plans tend not to strongly feature diagnostics, and therefore diagnostics are likely to be undervalued and underfunded within the AMR space. It is imperative that key decision-makers recognise the role diagnostics can play in AMR prevention and stewardship. Only after the value perception towards diagnostics changes from being a 'nice to have' to a 'must have' will such an incentive model be successful. The aim of this model is not to become a tendering cycle based on cost, whereby prices are driven down. The model is designed to be value-driven with a rate of return that is adequate to support innovation within the industry. In addition, the long-term nature of the proposed contracting arrangement is designed to provide some revenue certainty for developers.

Secondly, the evidence generated would need to meet certain quality standards for the value assessment, which will require a significant amount of investment from manufacturers to run the necessary clinical trials. Manufacturers would need to conduct post-marketing studies if certain required evidence is not available at the point of evaluation. However, the investment from industry is in the context of a greater return due to 1) higher contract value, 2) added exclusivity generated by contracting with national bodies, and 3) increased adoption because of a better value proposition to clinicians. Publication of assessment guidelines for diagnostics for AMR by assessment bodies is, therefore, a key enabler to ensure companies are willing to engage in such a mechanism. This will enable manufacturers to focus their evidence generation efforts on the evidence that is most useful for assessment.

Finally, our research suggests that there is a risk that clinicians will still not use diagnostics even if they are free due to the time and resources required to train staff and administer the test and the perception that they do not generate significant value. Even if they are used, they may not be sufficient to change physicians' prescription behaviour regarding antibiotics (van der Velden et al., 2022). The utilisation of clinical guidelines and increased emphasis on diagnostics within clinical education may overcome this challenge. In countries such as the Netherlands, additional stewardship initiatives like education and pay for performance on the use of diagnostics have increased their use (Van Buul et al., 2020). Therefore, additional support will be needed on top of an incentive model to encourage the adoption of high-value diagnostics and embed them in antibiotic stewardship practice, particularly in countries where uptake is low (Hocking et al., 2021).

## 5 Conclusion

Diagnostics have a vital role in the fight against AMR. They have the potential to reduce low-value usage of antibiotics and increase the efficacy of antibiotics where they are needed. However, the context for the development, procurement and adoption of diagnostics is complex and presents multiple barriers to the realisation of the full value of diagnostics by the health system.

Currently, there are a host of challenges that prevent further research and development as well as the uptake of diagnostics within clinical practice. The fundamental barrier is a lack of information on the value of diagnostics available to those deciding to implement (i.e., purchase) and adopt (i.e., use) them. For payers in charge of implementation, the evidence available at the time of launch to assess whether a diagnostic offers value for money is usually poor. For clinicians in charge of adoption, it is often not possible to observe the value of using a diagnostic in a particular clinical scenario. The lack of willingness to implement and adopt diagnostics is compounded in the case of AMR, where the true value is only realised at a system or population level and through reduced resistance over time.

The low willingness to pay for diagnostics, in part due to lack of value recognition, reduces incentives for companies to invest in their development and clinical evaluation. Systems of value assessment and procurement of diagnostics are not designed to evaluate their broader value, and developers are not always rewarded for developing high-value diagnostics. And even high-quality evidence that could be used to demonstrate the value to decision-makers does not guarantee higher reimbursement levels, as systems are dominated by cost-based and reference-based reimbursement. These factors generate a vicious cycle of low investment and low uptake in diagnostics in general and particularly in diagnostics for AMR. Poor uptake of diagnostics limits antibiotic stewardship.

Recent innovative value assessment, reimbursement, and financing models developed for antibiotics can be a source of inspiration in the context of diagnostics. We argue that a novel incentive model for diagnostics could be an appropriate solution for two reasons. Firstly, it would increase the uptake of diagnostics because it reduces the price sensitivity of local decision-makers by centralizing the investment decision at a national level. Secondly, it would also incentivise high-value innovation by providing a value-based return on investment for successful innovators. A novel incentive model, beyond the financial incentives, generated would also be a mechanism by which to improve standards of processes to procure diagnostics. Having a contract value significantly higher than current cost-based revenues, tied to a rigorous value assessment, will incentivise companies to invest in R&D and evidence development which will also support uptake by clinicians.

The incentive model will have to be implemented differently according to the structure of the health system, procurement processes and responsibilities of key stakeholders. However, the key features should remain the same. The key features of the incentive model are:

1. Procurement must be aggregated at a level above the individual provider such that providers are cost-neutral to the use of a diagnostic (i.e., using the diagnostic will not increase the cost of delivering care);
2. The procurement level must be value-based, informed by a value assessment based on evidence of efficacy and value;
3. The payment contract must be negotiated over multiple budget cycles to generate a form of exclusivity and revenue certainty for developers;



4. Eligibility for the novel incentive model is limited, therefore, not all diagnostics that could support AMR would automatically gain reimbursement through this mechanism;
5. Eligibility criteria for the mechanism should be based on health system priorities set by payers informed by international priorities; and
6. The incentive model must be accompanied by specific education and behaviour change initiatives to support the uptake of diagnostics reimbursed within the scheme.

The vital attention that the economics of antibiotics is receiving at the moment, with the NICE-NHS England pilot in the UK and the PASTEUR Act in the US as examples, should be seen as a moment of opportunity to redefine how health technologies with a large impact on global public health should be evaluated and purchased. In addition, addressing the antibiotic resistance crisis is reliant on both development of new antibiotics and the preservation of existing ones through more appropriate use. Appropriate use of antibiotics, in turn, relies on diagnostics. Therefore, the effort to incentivise antibiotic innovation will be wasted if incentives for diagnostics are overlooked. While a lot has been said about the importance of diagnostics in addressing the AMR crisis, policymakers and payers must go beyond strategy and act.

## References

- Anderson, M., Cecchini, M. and Mossialos, E., 2019. *Challenges to Tackling Antimicrobial Resistance*. [online] World Health Organisation, p.274. Available at: [https://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/432790/Challenges-to-tackling-antimicrobial-resistance.pdf](https://www.euro.who.int/__data/assets/pdf_file/0007/432790/Challenges-to-tackling-antimicrobial-resistance.pdf) .
- Antoñanzas, F., Juárez-Castelló, C.A. and Rodríguez-Ibeas, R., 2021. Using point-of-care diagnostic testing for improved antibiotic prescription: an economic model. *Health Economics Review*, 11, p.29. 10.1186/s13561-021-00326-y.
- Banerjee, A., Hollis, A. and Pogge, T., 2010. The Health Impact Fund: incentives for improving access to medicines. *Lancet (London, England)*, 375(9709), pp.166–169. 10.1016/S0140-6736(09)61296-4.
- Barbut, F., Surgers, L., Eckert, C., Visseaux, B., Cuingnet, M., Mesquita, C., Pradier, N., Thiriez, A., Ait-Ammar, N., Aifaoui, A., Grandsire, E. and Lalande, V., 2014. Does a rapid diagnosis of Clostridium difficile infection impact on quality of patient management? *Clinical Microbiology and Infection*, 20(2), pp.136–144. 10.1111/1469-0691.12221.
- BARDA, 2022. *BARDA Detection, Diagnostics, And Devices Infrastructure (DDDI) Medical Countermeasures Program*. [online] Available at: <https://www.medicalcountermeasures.gov/barda/dddi/> [Accessed 18 May 2022].
- van Belkum, A., Bachmann, T.T., Lüdke, G., Lisby, J.G., Kahlmeter, G., Mohess, A., Becker, K., Hays, J.P., Woodford, N., Mitsakakis, K., Moran-Gilad, J., Vila, J., Peter, H., Rex, J.H. and Dunne, W.M., 2019. Developmental roadmap for antimicrobial susceptibility testing systems. *Nature Reviews Microbiology*, 17(1), pp.51–62. 10.1038/s41579-018-0098-9.
- Boluarte, T. and Schulze, U., 2022. *The Case for a Subscription Model to Tackle Antimicrobial Resistance*. BCG, p.41.
- Brassel, S., Neri, M., Schirmacher, H. and Steuten, L., 2021. *The Value of Vaccines in Maintaining Health System Capacity in England*. [online] Office of Health Economics. Available at: <https://www.ohe.org/publications/value-vaccines-maintaining-health-system-capacity-england> .
- Callea, G., Armeni, P., Marsilio, M., Jommi, C. and Tarricone, R., 2017. The impact of HTA and procurement practices on the selection and prices of medical devices. *Social Science & Medicine (1982)*, 174, pp.89–95. 10.1016/j.socscimed.2016.11.038.
- CARB-X, 2021. CARB-X 2020-21 Annual Report: CARB-X surpasses all goals in first five years in combatting antibiotic resistant-bacteria. *CARB-X 2020-21 Annual Report: CARB-X surpasses all goals in first five years in combatting antibiotic resistant-bacteria*. Available at: <https://carb-x.org/carb-x-news/carb-x-2020-21-annual-report-carb-x-surpasses-all-goals-in-first-five-years-in-combatting-antibiotic-resistant-bacteria/> [Accessed 18 May 2022].
- CDC and AdvaMedDx, 2016. *A Public Health Perspective on Antimicrobial Resistance Diagnostics*. Centers for Disease Control and Prevention, p.17.
- Chalkidou, K., Garau, M., Silverman, R. and Towse, A., 2020. *Blueprint for a Market-Driven Value-Based Advance Commitment For Tuberculosis*. [online] Centre for Global Development. Available at: [https://www.cgdev.org/sites/default/files/MVAC-Blueprint-Final\\_2.pdf](https://www.cgdev.org/sites/default/files/MVAC-Blueprint-Final_2.pdf) [Accessed 25 Apr. 2022].
- Coburn, J., Bone, F., Hopkins, M. M., Stirling, A., Mestre-Ferrandiz, J., Arapostathis, S., & Llewelyn, M. J. 2021. *Appraising research policy instrument mixes: a multicriteria mapping study in six European countries of diagnostic innovation to manage antimicrobial resistance*. *Research policy*, 50(4), pp.104-140.
- Colson, A.R., Morton, A., Årdal, C., Chalkidou, K., Davies, S.C., Garrison, L.P., Jit, M., Laxminarayan, R., Megiddo, I., Morel, C., Nonvignon, J., Outterson, K., Rex, J.H., Sarker, A.R., Sculpher, M., Woods, B. and Xiao, Y., 2021. Antimicrobial Resistance: Is Health Technology Assessment Part of the Solution or Part of the Problem? *Value in Health*, 24(12), pp.1828–1834. 10.1016/j.jval.2021.06.002.
- Dodson, K., 2021. *Antimicrobial Resistance is the silent pandemic we can no longer neglect*. [online] unfoundation.org. Available at: <https://unfoundation.org/blog/post/antimicrobial-resistance-is-the-silent-pandemic-we-can-no-longer-neglect/> [Accessed 26 Apr. 2022].
- Dryden, M., Johnson, A.P., Ashiru-Oredope, D. and Sharland, M., 2011. Using antibiotics responsibly: right drug, right time, right dose, right duration. *The Journal of antimicrobial chemotherapy*, 66(11), pp.2441–2443. 10.1093/jac/dkr370.

- Eley, C.V., Sharma, A., Lecky, D.M., Lee, H. and McNulty, C.A.M., 2018. Qualitative study to explore the views of general practice staff on the use of point-of-care C reactive protein testing for the management of lower respiratory tract infections in routine general practice in England. *BMJ Open*, 8(10), p.e023925. 10.1136/bmjopen-2018-023925.
- European Parliament, 2017. *European Parliament and Council. Regulation on in vitro diagnostic medical devices. 2017/746*. [online] Available at: <https://eur-lex.europa.eu/eli/reg/2017/746/2017-05-05> [Accessed 22 Jul. 2022].
- Feinberg, B.A., Lang, J., Grzegorzczak, J., Stark, D., Rybarczyk, T., Leyden, T., Cooper, J., Ruane, T., Milligan, S., Stella, P. and Scott, J.A., 2012. Implementation of cancer clinical care pathways: a successful model of collaboration between payers and providers. *Journal of Oncology Practice*, 8(3 Suppl), pp.e38s-43s. 10.1200/JOP.2012.000564.
- FIND, 2018. *Accelerating Diagnostics Use to Prevent Antimicrobial Resistance- AMR Strategy 2018*. [online] FIND. Available at: <https://www.finddx.org/wp-content/uploads/2018/04/FIND-AMR-Strategy-WEB.pdf> [Accessed 26 Apr. 2022].
- Fischer, S., Vogler, S., Windisch, F. and Zimmermann, N., 2021. *HTA, Reimbursement and Pricing of Diagnostic Tests for CA-ARTI: An international overview of policies (Task 5.5)*. [online] VALUE-DX. Available at: [https://www.value-dx.eu/wp-content/uploads/2021/04/VALUE-DX\\_Report\\_Task5.5\\_Deliverable5.2\\_Final.pdf](https://www.value-dx.eu/wp-content/uploads/2021/04/VALUE-DX_Report_Task5.5_Deliverable5.2_Final.pdf) [Accessed 9 Feb. 2022].
- Garfield, S., Polisen, J., S Spinner, D., Postulka, A., Y Lu, C., Tiwana, S.K., Faulkner, E., Poullos, N., Zah, V. and Longacre, M., 2016. Health Technology Assessment for Molecular Diagnostics: Practices, Challenges, and Recommendations from the Medical Devices and Diagnostics Special Interest Group. *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, 19(5), pp.577–587. 10.1016/j.jval.2016.02.012.
- Gotham, D., Moja, L., van der Heijden, M., Paulin, S., Smith, I. and Beyer, P., 2021. Reimbursement models to tackle market failures for antimicrobials: Approaches taken in France, Germany, Sweden, the United Kingdom, and the United States. *Health Policy*, 125(3), pp.296–306. 10.1016/j.healthpol.2020.11.015.
- Heilman, R.L., Mathur, A., Smith, M.L., Kaplan, B. and Reddy, K.S., 2016. Increasing the Use of Kidneys From Unconventional and High-Risk Deceased Donors. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 16(11), pp.3086–3092. 10.1111/ajt.13867.
- Hocking, L., George, J., Broberg, E.K., Struelens, M.J., Leitmeyer, K.C., Deshpande, A., Parkinson, S., Francombe, J., Morley, K.I. and de Carvalho Gomes, H., 2021. Point of Care Testing for Infectious Disease in Europe: A Scoping Review and Survey Study. *Frontiers in Public Health*, 9, p.722943. 10.3389/fpubh.2021.722943.
- Huddy, J.R., Ni, M.Z., Barlow, J. and Hanna, G.B., 2021. Qualitative analysis of stakeholder interviews to identify the barriers and facilitators to the adoption of point-of-care diagnostic tests in the UK. *BMJ Open*, 11(4), p.e042944. 10.1136/bmjopen-2020-042944.
- Karlsberg Schaffer, S., West, P., Towse, A., Henshall, C., Mestre-Ferrandiz, J., Masterson, R. and Fischer, A., 2017. *Additional Elements of Value for Health Technology Assessment Decisions*. [online] Office of Health Economics. Available at: <https://www.ohe.org/publications/additional-elements-value-health-technology-assessment-decisions> .
- Kip, M.M.A., IJzerman, M.J., Henriksson, M., Merlin, T., Weinstein, M.C., Phelps, C.E., Kusters, R. and Koffijberg, H., 2018. Toward Alignment in the Reporting of Economic Evaluations of Diagnostic Tests and Biomarkers: The AGREEDT Checklist. *Medical Decision Making: An International Journal of the Society for Medical Decision Making*, 38(7), pp.778–788. 10.1177/0272989X18797590.
- Kremer, M., Levin, J. and Snyder, C.M., 2020. Advance Market Commitments: Insights from Theory and Experience. *AEA Papers and Proceedings*, 110, pp.269–73. 10.1257/pandp.20201017.
- Lingervelder, D., Koffijberg, H., Kusters, R. and IJzerman, M.J., 2021. Health Economic Evidence of Point-of-Care Testing: A Systematic Review. *Pharmacoeconomics - Open*, 5(2), pp.157–173. 10.1007/s41669-020-00248-1.
- Lisby, J.G. and Schneider, U.V., 2021. Point of care testing for infectious disease: ownership and quality. *Journal of Antimicrobial Chemotherapy*, 76(Suppl 3), pp.iii28–iii32. 10.1093/jac/dkab247.
- Longitude Prize, 2022. 60-minute diagnostic tests tackling antibiotic resistance to be eligible for £8m Longitude Prize. *Longitude Prize*. Available at: <https://longitudeprize.org/press-release/60-minute-diagnostic-tests-tackling-antibiotic-resistance-to-be-eligible-for-8m-longitude-prize/> [Accessed 22 Jul. 2022].
- Mestre-Ferrandiz, J., Shaw, B., Chatterjee, C., Ding, J., Singh, P., Hopkins, M.M. 2022 *Policy instruments (nonprice) for medical innovation. Oslo Medicines Initiative technical report*. Copenhagen: WHO Regional Office for Europe.

Moon, S. and Erickson, E., 2019. Universal Medicine Access through Lump-Sum Remuneration - Australia's Approach to Hepatitis C. *The New England Journal of Medicine*, 380(7), pp.607–610. 10.1056/NEJMp1813728.

Morel, C., McClure, L., Edwards, S., Goodfellow, V., Sandberg, D., Thomas, J. and Mossialos, E. eds., 2016. *Ensuring innovation in diagnostics for bacterial infection: Implications for policy*. Copenhagen (Denmark): European Observatory on Health Systems and Policies.

Mott, D.J., Hampson, G., Llewelyn, M.J., Mestre-Ferrandiz, J., Hopkins, M.M. 2020. *A Multinational European Study of Patient Preferences for Novel Diagnostics to Manage Antimicrobial Resistance*. *Appl Health Econ Health Policy*, 18(1), pp.69-79.

Murray, C.J., Ikuta, K.S., Sharara, F., et al., 2022. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *The Lancet*, 399(10325), pp.629–655. 10.1016/S0140-6736(21)02724-0.

NICE, 2022. *NICE reaches important milestone in the UK's efforts to tackle antimicrobial resistance. | News and features | News | NICE*. [online] Available at: <https://www.nice.org.uk/news/article/nice-reaches-important-milestone-in-the-uk-s-efforts-to-tackle-antimicrobial-resistance> [Accessed 30 Jun. 2022].

NIH, 2020. *Antimicrobial Resistance Diagnostic Challenge*. [online] National Institutes of Health. Available at: <https://dpcpsi.nih.gov/AMRChallenge#:~:text=The%20Antimicrobial%20Resistance%20Diagnostic%20Challenge,spread%20of%20drug%20resistant%20bacteria.>

Oosterhoff, M., van der Maas, M. E., & Steuten, L. M. (2016). A Systematic Review of Health Economic Evaluations of Diagnostic Biomarkers. *Applied health economics and health policy*, 14(1), 51–65. 10.1007/s40258-015-0198-x

Outterson, K., 2021. Estimating The Appropriate Size Of Global Pull Incentives For Antibacterial Medicines. *Health Affairs (Project Hope)*, 40(11), pp.1758–1765. 10.1377/hlthaff.2021.00688.

Pew, 2020. *National Survey Reveals Barriers to Outpatient Antibiotic Stewardship Efforts*. [online] The Pew Charitable Trusts. Available at: <https://www.pewtrusts.org/-/media/assets/2020/09/nationalsurveyrevealsbarriersoutpatientantibioticstewardshipefforts.pdf> [Accessed 26 Apr. 2022].

Plüddemann, A., Onakpoya, I., Harrison, S., Shinkins, B., Thompson, A., Davis, R., Price, C.P. and Heneghan, C., 2014. *Position Paper on Anti-Microbial Resistance Diagnostics*. [online] Centre for Evidence-Based Medicine, Nuffield Department of Primary Care Health Sciences. Available at: [https://www.cebm.net/wp-content/uploads/2015/07/AMR-Diagnostic-technologies\\_10-June-2015.pdf](https://www.cebm.net/wp-content/uploads/2015/07/AMR-Diagnostic-technologies_10-June-2015.pdf).

Van der Pol, S., Rojas Garcia, P., Antoñanzas Villar, F., Postma, M.J. and van Asselt, A.D.I., 2021. Health-Economic Analyses of Diagnostics: Guidance on Design and Reporting. *PharmacoEconomics*, 39(12), pp.1355–1363. 10.1007/s40273-021-01104-8.

Ray, M.J., Tallman, G.B., Bearden, D.T., Elman, M.R. and McGregor, J.C., 2019. Antibiotic prescribing without documented indication in ambulatory care clinics: national cross sectional study. *BMJ*, 367, p.l6461. 10.1136/bmj.l6461.

Rex, J.H. and Outterson, K., 2016. Antibiotic reimbursement in a model delinked from sales: a benchmark-based worldwide approach. *The Lancet Infectious Diseases*, 16(4), pp.500–505. 10.1016/S1473-3099(15)00500-9.

Sood, N., Ung, D., Shankar, A. and Strom, B.L., 2018. A Novel Strategy for Increasing Access to Treatment for Hepatitis C Virus Infection for Medicaid Beneficiaries. *Annals of Internal Medicine*, 169(2), pp.118–119. 10.7326/M18-0186.

Spellberg, B., 2016. The New Antibiotic Mantra—"Shorter Is Better". *JAMA internal medicine*, 176(9), pp.1254–1255. 10.1001/jamainternmed.2016.3646.

St John, A., Hopstaken, R., Tirimacco, R., Audehm, R. and Price, C.P., 2022. Implementing point-of-care CRP testing for better diagnosis of acute respiratory infections. *The British Journal of General Practice: The Journal of the Royal College of General Practitioners*, 72(715), pp.87–88. 10.3399/bjgp22X718517.

Towse, A., Chalkidou, K., Firth, I., Kettler, H. and Silverman, R., 2021. How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, 24(5), pp.625–631. 10.1016/j.jval.2020.12.008.

Trenti, T., 2021. Synergy Between Point-of-Care Testing and Laboratory Consolidations. *EJIFCC*, 32(3), pp.328–336.

Trusheim, M., Cassidy, W. and Bach, P., 2018. Alternative State-Level Financing for Hepatitis C Treatment-The 'Netflix Model' - PubMed. *JAMA*, 320(19), pp.1977–1978. 10.1001/jama.2018.15782.

UK Health Security Agency, 2020. *English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) report 2020 to 2021*. p.209.

Van Buul, L.W., Monnier, A.A., Sundvall, P.-D., Ulleryd, P., Godycki-Cwirko, M., Kowalczyk, A., Lindbaek, M. and Hertogh, C.M.P.M., 2020. Antibiotic Stewardship in European Nursing Homes: Experiences From the Netherlands, Norway, Poland, and Sweden. *Journal of the American Medical Directors Association*, 21(1), pp.34-40.e1. 10.1016/j.jamda.2019.10.005.

Van den Bruel, A. and Hayward, G., 2018. Diagnostic evidence cooperatives: bridging the valley of death in diagnostics development. *Diagnostic and Prognostic Research*, 2(1), p.9. 10.1186/s41512-018-0030-9.

Vasala, A., Hytönen, V.P. and Laitinen, O.H., 2020. Modern Tools for Rapid Diagnostics of Antimicrobial Resistance. *Frontiers in Cellular and Infection Microbiology*, 10, p.308. 10.3389/fcimb.2020.00308.

Vogler, S., Habimana, K., Fischer, S. and Haasis, M.A., 2021. *Novel policy options for reimbursement, pricing and procurement of AMR health technologies*. [online] Global AMR Hub. Available at: [https://globalamrhub.org/wp-content/uploads/2021/03/GOe\\_FP\\_AMR\\_Report\\_final.pdf](https://globalamrhub.org/wp-content/uploads/2021/03/GOe_FP_AMR_Report_final.pdf) [Accessed 25 Apr. 2022].

Wellcome Trust, 2016. *Four diagnostic strategies for better-targeted antibiotic use*. [Workshop report] Wellcome Trust. Available at: <https://wellcome.org/sites/default/files/diagnostic-strategies-for-better-targeted-antibiotic-use-wellcome-jul15.pdf> [Accessed 9 Feb. 2022].

WHO, 2022. *COVAX- working for global equitable access to COVID-19 vaccines*. [online] Available at: <https://www.who.int/initiatives/act-accelerator/covax> [Accessed 18 May 2022].

# Appendix

## Landscape Analysis of current processes for adoption of diagnostics

Health systems vary in the processes they use to appraise and reimburse novel diagnostics (Fischer et al., 2021). Differences arise due to variation in health system structure, clinical guidelines and value assessment processes, as well as differences in procurement processes and payment models. In addition, the uptake of diagnostics varies across care settings (e.g. hospital-based care and community-based care) and across different kinds of diagnostics (e.g. PoC tests, laboratory tests and technologies not relevant for AMR, such as devices like ultrasound scanning).

Below we present four case studies to illustrate the variation in value assessment, financing, and reimbursement of diagnostics.

### England

#### **VALUE ASSESSMENT, FINANCING, AND REIMBURSEMENT FOR DIAGNOSTICS**

Value assessment is conducted on a national level by National Institute for Health and Care Excellence (NICE) and on a localised/regional level by local commissioners (i.e. Care Commissioning Groups (CCGs)). The assessment is based on diagnostic test accuracy, clinical outcomes and cost-effectiveness modelling along the care pathway for which the diagnostics are used. A positive NICE evaluation does not trigger mandatory reimbursement by regional payers, but it will inform their own value assessment or reimbursement decision-making.

Procurement of diagnostics is done at a geographically disaggregated level: either by CCGs or individual hospitals/GP practices. Considerations are generally driven by budget constraints, with diagnostics usually allocated a small percentage of the overall hospital/practice budget. Prices are often negotiated through block tendering processes by individual hospitals and by CCG for primary care practices.

Reimbursement for the use of the diagnostic is included within the tariff for diagnostic-related group (DRG) basis for hospitals which classifies patients with similar clinical diagnoses. GP practices are reimbursed through a risk-adjusted capitation fee for patients at the practice. For some diagnostics in some disease areas, the Quality Outcomes Framework pays GPs for doing diagnostic tests, although these are rarely in-vitro diagnostics (e.g., COPD or asthma).

**IMPLICATIONS FOR DIAGNOSTICS IN ENGLAND**

England has a much more variable process for the adoption of diagnostics than for therapeutics, with NICE decisions not triggering mandatory funding from NHS England. This causes adoption of diagnostics to be taken at a local level leading to heterogeneity in coverage across England which is often driven by budget concerns.

**DIAGNOSTICS AS PART OF THE UK AMR ACTION PLAN**

The UK's 2019-2024 Action Plan underpins its 20-year vision to effectively contain and control AMR. The action plan contains 15 actions, one of which is the development and access to diagnostics. The success of this action will be measured by the percentage of prescriptions supported by use of a diagnostic test or decision supported tool by 2024.

The UK is committing to incentivise R&D for new diagnostics and supporting the rapid uptake of diagnostics as well as supporting the rapid uptake of diagnostics. They aim to do this through a range of activities, such as addressing R&D gaps, working with the NHS and industry to tackle the barriers to adoption of new innovative diagnostics, as well as making antimicrobials and diagnostics a priority area for the Accelerated Access Pathway (UK Government, 2019).

Japan

**VALUE ASSESSMENT, FINANCING, AND REIMBURSEMENT FOR DIAGNOSTICS**

Value assessment is carried out at the national level by the Central Social Medical Council/Central Committee. The assessment is based on 'clinical benefit assessment' with economic evaluation only an option after two or three years and used for the purposes of establishing price discounts on selected technologies. Approval by the Central Committee triggers a nationally recognised approval and price and puts the diagnostic onto the national formulary list for both public and private insurers. Prices are set by the Central Committee based on a mixture of international and internal reference pricing and cost-based pricing.

Adoption of diagnostics is determined solely by the provider. All providers are reimbursed for using the diagnostic based on a finite points system distributed across medical products across the country. For hospitals, diagnostics are paid by diagnostic procedure combination (DPC), which is a similar concept to DRGs. Primary care providers are paid on a fee-for-service basis, where there is a 30% co-payment from the patient, and the remaining 70% is reimbursed by the government.

**IMPLICATIONS FOR DIAGNOSTICS IN JAPAN**

Japan has a very closely controlled points-based remuneration system and a reliance on reference pricing that limits the application of value-based pricing. Decisions to implement diagnostics are taken at a provider level, meaning adoption into clinical practice is highly variable.

**DIAGNOSTICS AS PART OF THE JAPAN AMR ACTION PLAN**

The most recent AMR Action Plan in Japan was the 2016-2020 National Action Plan on AMR. The action plan consisted of five key goals including to promote research and development to secure the means to prevent, diagnose and treat the antimicrobial resistant infections. To this goal, Japan has implemented five key strategies, two of which have associated policies which relate to the optimisation of existing methods of diagnosis and the promotion of R&D in the development of novel diagnostics. There were no policies focussed on greater usage of diagnostics in clinical practice (The Government of Japan, 2016).

## Germany

### VALUE ASSESSMENT, FINANCING, AND REIMBURSEMENT FOR DIAGNOSTICS

Value assessment is done by the Evaluation Committee within the Gemeinsamer Bundesausschuss (G-BA) using a 'light' clinical effectiveness analysis of the diagnostic (sensitivity and specificity) and the reimbursement price. The upper price limit for a new diagnostic ranges between EUR 100 – 400. Clinical efficacy drives the assessment, but economic elements are discussed. Private insurers also operate in the German market and set their own price for medical technologies, and they are not bound by the G-BA decision.

Positive assessment from G-BA translates into mandatory reimbursement for statutory health insurance providers, but private insurers can make their own reimbursement decisions. The decision to use a diagnostic is at the discretion of the provider but is generally informed by treatment guidelines developed by professional societies. For the outpatient setting, providers are remunerated for delivering the diagnostic by a specific outpatient code. The G-BA can either adjust an existing outpatient code or generate a new code when a new diagnostic is approved. Manufacturers can provide rebates to providers for delivering a certain diagnostic.

#### IMPLICATIONS FOR DIAGNOSTICS IN GERMANY

Germany has a long approval process and an explicit price cap for diagnostics that limit the ability to implement value-based pricing.

#### DIAGNOSTICS AS PART OF THE GERMAN AMR ACTION PLAN

The DART 2020 is the most recent German AMR national action plan aimed at fighting antibiotic resistance, covering the period of 2015-2020. The plan features six primary goals, one of which focusses on 'breaking chains of infection early and avoiding infections'. This goal has an associated action to determine the problems and obstacles used in diagnostics, such as blood culture diagnosis and the detection of *Clostridium difficile* and determining the possible solutions to these challenges (The Federal Government, 2020).

## USA

### VALUE ASSESSMENT, FINANCING, AND REIMBURSEMENT FOR DIAGNOSTICS

Value assessment is done at the discretion of private insurance companies. The process is neither defined nor nationally standardised, although individual value assessment approaches can be used to inform other providers, such as the Molecular Diagnostic Services (MoDX) Program and Medicare. Care guidelines are developed by professional associations. Medicare has a role in shaping the market in the US as prices set by the Centers for Medicare and Medicaid Services (CMS) are used as reference prices by private insurers. Medicare bases its coverage decisions on whether a product or service is reasonable and necessary. For diagnostics, that is defined as: reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member<sup>1</sup>. The assessment dictates whether the people under that insurance provider will have a certain diagnostic covered by their insurer or whether they would have to pay out of pocket for its use. Medicare decisions can happen at a local level by carrier advisory committees which decide on local coverage determinations, or at a national level by the CMS secretary. Screening decisions are only taken at the national level.

An insurer decides whether to cover the cost of a diagnostic in their coverage plans. If they decide not to cover it, clinicians can still use the diagnostic, but the patient would have to pay out of pocket for it. Reimbursement is traditionally based on internal reference pricing (also called cross-walking).



Cost-based pricing is used when there are no similar technologies to reference by so-called gap filling. There are a few recent examples of genetic tests (e.g., for cancer risk factors) that have received much higher reimbursement rates than for in-vitro diagnostics through negotiations with insurers. Hospitals are reimbursed by insurers through a DRG system. If a new diagnostic is particularly expensive, there can be add-ons to the DRG.

**IMPLICATIONS FOR DIAGNOSTICS IN THE US**

The US uses a cost-based system for price-setting of diagnostics, but cases of predictive genetic tests demonstrate that insurers may be willing to pay much higher prices for selected cost-saving products where the downstream economic value had been well-established and in response to relatively strong patient, clinical and societal pull.

**DIAGNOSTICS AS PART OF THE USA AMR ACTION PLAN**

The US 2020-2025 National Action Plan hinges upon five key goals, one of which is to advance the development and use of rapid and innovative diagnostic tests for identification and characterisation of resistant bacteria. They present a three-pronged approach to this goal. Firstly, to develop and validate new diagnostics by supporting 10 new AMR related diagnostics projects across the US. Secondly, to support research to determine the appropriate use of diagnostics by inviting research applications and supporting research on the appropriate use of CARB-related diagnostics. Thirdly, to stimulate the appropriate adoption and use of diagnostics by supporting development of guidelines for use of new and existing diagnostics (U.S Government, 2020).



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Founded in 1962 by the Association of the British Pharmaceutical Society, the Office of Health Economics (OHE) is not only the world's oldest health economics research group, but also one of the most prestigious and influential.

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- The costs of treating, or failing to treat, specific diseases and conditions
- Drivers of, and incentives for, the uptake of pharmaceuticals and prescription medicines
- Competition and incentives for improving the quality and efficiency of health care
- Incentives, disincentives, regulation and the costs of R&D for pharmaceuticals and innovation in medicine
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- Health and health care statistics