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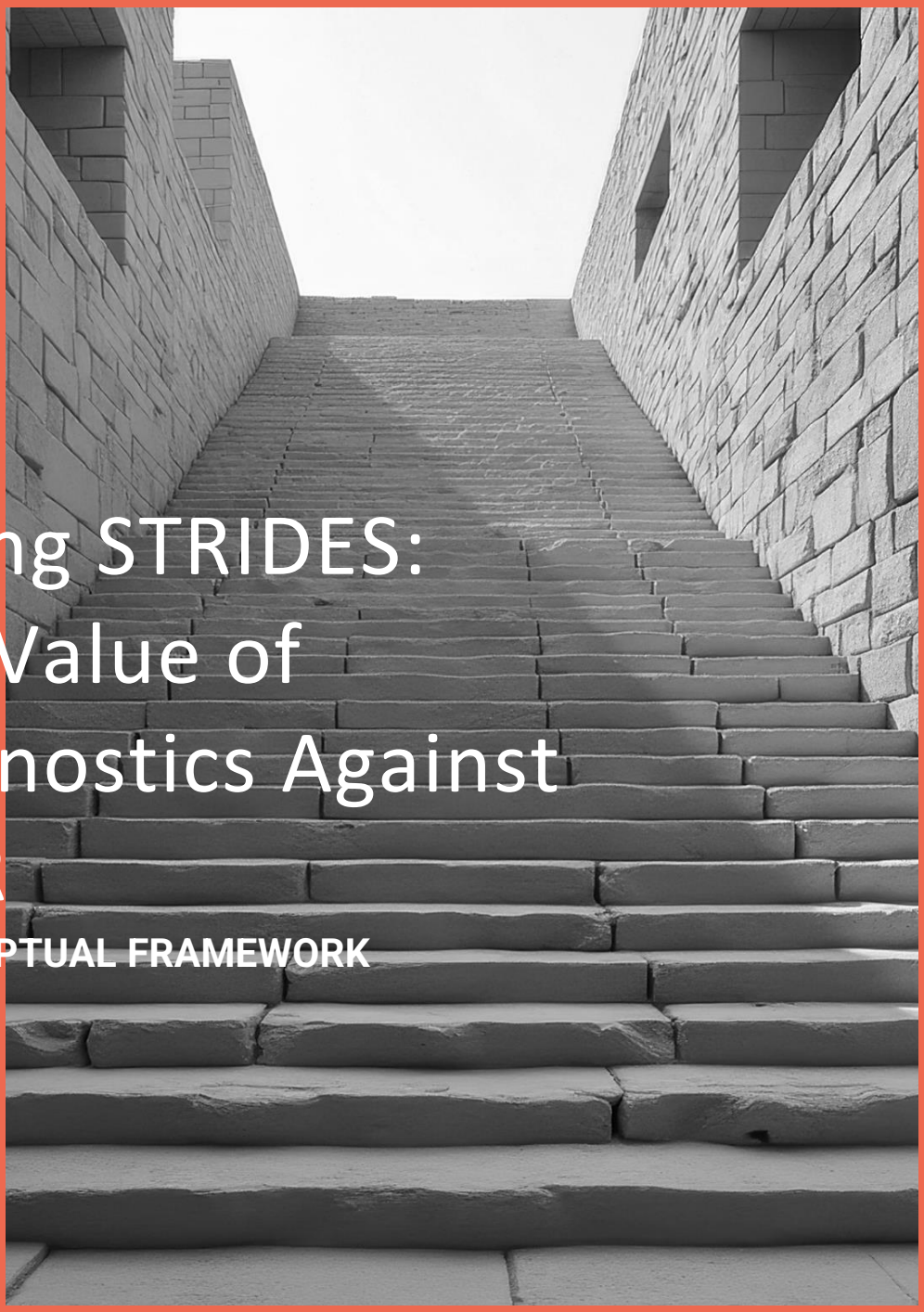

Taking STRIDES: The Value of Diagnostics Against AMR

A CONCEPTUAL FRAMEWORK

CONTRACT RESEARCH REPORT
JUNE 2025

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Henry Fong
Office of Health Economics, London

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Corresponding Author:
Grace Hampson
ghampson@ohe.org

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Executive Summary

Addressing a critical gap in AMR policy and evaluation

Antimicrobial resistance (AMR) is a global health crisis, projected to cause up to 10 million deaths annually and impose economic costs exceeding $150 billion by 2050. Diagnostics are essential in curbing AMR—by guiding the appropriate use of antimicrobials, informing infection control, and enabling better surveillance and treatment outcomes. Yet, despite this, diagnostics remain underutilised in both policy and practice.

One major barrier to the uptake and effective use of AMR diagnostics is the systematic undervaluation of their contributions across health systems. AMR diagnostics are not consistently or comprehensively assessed through value assessment or reimbursement frameworks, meaning their broader societal and population-level benefits are often overlooked. This under-recognition limits policy prioritisation, discourages innovation, and perpetuates structural and financial disincentives.

This report introduces STRIDES, a new conceptual value framework for AMR diagnostics that evolves and extends the established STEDI framework originally developed for antimicrobials. Importantly, STRIDES is not a replacement for existing value frameworks for healthcare interventions and diagnostics but a complementary addition—designed to capture the unique and synergistic value of diagnostics in the fight against AMR. The aim is to support a more comprehensive and systematic valuation of AMR diagnostics by decision-makers and payers across settings, ensuring that their broader benefits are recognised in decision-making and reimbursement processes. Such recognition of the potential breadth of value of AMR diagnostics is key to incentivising innovation, aiding adoption, and curbing AMR.

What STRIDES adds: a diagnostic-specific value framework

The STRIDES framework was developed to address limitations in the scope of existing health technology assessment (HTA) and reimbursement frameworks, which fail to capture the full value of diagnostics in the context of AMR. It complements the general and diagnostic-specific value elements already considered in many HTAs, such as clinical outcomes, cost offsets, and the "value of knowing". The framework introduces seven AMR-specific value elements that are tailored to the unique role diagnostics play in preserving antibiotic effectiveness and projecting public health:

- **Spectrum value**: Enables use of narrow-spectrum antibiotics by identifying specific pathogens and resistance patterns.
- **Transmission value**: Reduces the spread of infectious and resistant pathogens through earlier detection and control.
- **Research value**: Supports the development of new antimicrobials by improving trial recruitment and design.
- **Insurance value**: Helps preserve last-line antimicrobials and mitigate catastrophic AMR outbreaks.

- **Diversity value**: Facilitates more varied and targeted antimicrobial use, reducing resistance selection pressure.
- **Enablement value**: Allows safe continuation of high-risk medical procedures by ruling in/out infections.
- **Surveillance value**: Enables real-time, accurate monitoring of resistance trends.

Each element is grounded in literature, validated by international expert consultation, and illustrated in this report through real-world examples. Together, these value elements provide a comprehensive add-on to typical approaches to HTA, to fill a critical gap in current evaluation frameworks and support a more comprehensive understanding of the value that AMR diagnostics bring to health systems and society.

Key findings and implications

1. **Diagnostics are foundational to antimicrobial stewardship and the fight against AMR**, yet their indirect and system-level impacts are not adequately captured in current reimbursement models or policy frameworks.
2. **The STRIDES framework demonstrates that AMR diagnostics offer value beyond individual patient outcomes**, including population and long-term health system benefits.
3. **Applying STRIDES may help unlock investment and innovation in AMR diagnostics, as well as access to and utilisation of these critical technologies**. By aligning economic evaluations with the true value of diagnostics, we can further strengthen the potential of AMR diagnostics in the fight against AMR.
4. **STRIDES elements are synergistic**, emphasising that maximum value from existing antimicrobials can only be unlocked when diagnostics and antimicrobials are used together.
5. **Expert stakeholders recognise STRIDES as a necessary evolution of STEDI for use with AMR diagnostics**, reflecting the need for AMR diagnostic-specific guidance to inform policy, HTA, and procurement.

Conclusions

STRIDES offers a robust, conceptual framework to capture the full value of AMR diagnostics. It provides a critical step towards appropriate value assessment of AMR diagnostics, raising awareness of the multifaceted benefits of AMR diagnostics, and how they generate value for patients, health systems, and society.

Future research should explore how STRIDES can best be operationalised, to test feasibility of implementation, and to examine how the remaining barriers to adoption of AMR diagnostics can be overcome. Continued 'strides' towards the adoption of AMR diagnostics are critical if we are to realise the potential of these valuable tools in the fight against AMR.

1. Introduction

1.1 Diagnostics are critical in fighting AMR

Antimicrobial resistance (AMR) is a growing global health crisis. AMR contributed to an estimated 4.7 million deaths worldwide in 2021, a number expected to nearly double by 2050 (Naghavi et al., 2024). AMR is estimated to cost $66 billion a year globally in direct health care costs, with potential for this to increase to $159 billion by 2050 (McDonnell et al., 2024). Public Health England (PHE) found at least 20% of antibiotic prescriptions were inappropriate, exacerbating the problem of AMR (Public Health England, 2018). The situation is compounded by stagnation in the development of new antimicrobials, leaving healthcare systems ill-equipped to address the rise of resistant infections.

Antimicrobial stewardship is a critical strategy for slowing the spread of resistance by promoting the judicious use of antimicrobials. It offers a sustainable solution to preserve the efficacy of existing antimicrobials (Nathwani et al., 2019; NICE, 2025) and supports strategic plans for curbing AMR (NICE, 2025). Diagnostics are a critical pilar of antimicrobial stewardship serving as gatekeepers to antibiotic prescribing by curbing overuse and enabling the prudent deployment of narrow-spectrum alternatives. They also serve to generate crucial data on AMR emergence and trends. Diagnostics therefore contribute to improved population health as well as patient outcomes, and allow for a more efficient use of scare resources within the healthcare system (Peri et al., 2024; Clark et al., 2023; Pavia et al., 2024).

1.2 Challenges in adoption of diagnostics against AMR

Despite their importance, the adoption of diagnostics against AMR, otherwise termed AMR diagnostics, faces significant behavioural, economic, and structural barriers.

Clinician / health care professional behaviour: In primary care settings, where most antimicrobials are prescribed, clinicians and other health care professionals, often constrained by time, may perceive antimicrobial prescribing as quicker and more cost-effective than ordering a diagnostic test. Limited training and education on the utility of diagnostics exacerbates this issue, with healthcare professionals frequently citing concerns about the accuracy, cost-effectiveness, and clinical impact of testing on antimicrobial prescribing decisions (Hoste et al., 2025; O'Neil, 2015). Jinks et al. (2024) conducted a survey of health care professionals which found antimicrobial stewardship efforts such as improvements to guidelines around diagnostic use and greater educational campaigns for clinicians would aid the implementation of AMR diagnostics.

Misaligned incentives and limited reimbursement mechanisms: The adoption of novel diagnostic tests is further constrained by incentives created by financial silos (Woelderink et al., 2006), whereby the cost of diagnostics is placed onto one provider sector (e.g., primary care) while the benefits (e.g., reduced hospitalisations) accrue elsewhere. The same applies to financial silos within hospitals, where diagnostic costs are incurred by laboratory departments, while the benefits are realised on the wards and at the overall hospital level.

Moreover, existing reimbursement models for diagnostics fail to reflect their broader societal benefits, as they are often assessed based on immediate analytical performance rather than their impact on clinical decision-making and as such their long-term impact on patient outcomes, health systems and AMR.

Reimbursement processes for diagnostics vary by country but often rely on cost-based models or inclusion in bundled care payments (Wellcome Trust, 2016). For example, in many countries (such as UK, Japan, US) diagnostics are paid for through Diagnosis Related Groups (DRGs) (or similar) for inpatient care (Firth et al., 2023). DRGs do not incentivise the use of a diagnostic over empirical prescribing because they add extra costs. This creates a disconnect between the level of reimbursement and the value diagnostics provide in terms of health benefits and cost savings.

These means of reimbursement do not account for the value that diagnostics offer at the population and societal level.

Lack of policy prioritisation: Unlike antimicrobials, diagnostics are frequently omitted from AMR action plans, receiving less recognition from policymakers, compared to other interventions aimed at reducing antimicrobial use (AMR Industry Alliance, 2024). Solving this is critical as it will allow patients to get the right antibiotic more quickly, which would help the larger market issues with antibiotics too.

Together, these barriers significantly hinder the uptake of diagnostics in practice, limiting their potential to support antimicrobial stewardship and reduce AMR. Addressing them requires a better understanding of how to explicitly value AMR diagnostics. Doing so will highlight the value of diagnostics to clinicians, support value-based reimbursement processes and shift policy prioritisation towards AMR diagnostics.

1.3 Assessing the full value of diagnostics against AMR: transforming STEDI into STRIDES

Challenges in assessing the full value of products and interventions against AMR are not unique to diagnostics. Coined by Outterson and Rex (2020) and building on work by Karlsberg-Schaeffer et al. (2017), the STEDI-framework was developed to enable a more complete value assessment and incentivise the development of new antimicrobials. In this context, STEDI refers to elements of value potentially generated by antimicrobials including Spectrum, Transmission, Enablement, Diversity, and Insurance value. The STEDI-framework was a critical component of the NICE-NHS England subscription model for evaluating and purchasing antimicrobials in the UK (NHS England, 2023).

STEDI-elements are also relevant for AMR diagnostics because diagnostics drive how antimicrobials are used. However, the STEDI framework cannot be directly applied to AMR diagnostics because of four reasons mentioned below. So, just as STEDI extends traditional value frameworks, we propose that a framework tailored to AMR diagnostics—one that builds upon and enhances, rather than replaces, existing frameworks for healthcare interventions and diagnostics - is essential because:

Diagnostics have distinct value pathways from antimicrobials
Traditional value assessment frameworks may overlook the patient-level value generated by AMR diagnostics, as their contribution is indirect, shaping clinical decisions rather than exerting a direct therapeutic effect like antimicrobials:

- Diagnostics are not interventions in isolation, but rather influence decision pathways, which requires a different approach to valuation.
- Diagnostics indirectly help to treat infections by guiding appropriate antimicrobial treatment and preventing misuse of antimicrobials. This synergistic impact between diagnostic and antimicrobial is difficult to quantify using existing frameworks.

A dedicated framework ensures that both direct and indirect benefits of AMR diagnostics are systematically captured.

1. **Diagnostics unlock the maximum potential value of antibiotics**

AMR diagnostics serve as complementary technologies to antibiotics, identifying cases in which they will be most effective (i.e. the presence of a specific pathogen and/or the absence of resistance), and when they are not needed. The highest value is therefore only achieved when AMR diagnostics and antibiotics are used together. For example, the use of PCR tests for *Enterobacterales* was associated with a decrease in time until appropriate therapy and subsequently 14-day and 30-day mortality (Satlin et al., 2022). This complementarity in the context of AMR has not been considered in any value framework to date.

2. **Traditional cost-effectiveness analysis (CEA) does not typically consider the population-level benefits of interventions against AMR, such as elements included in the STEDI framework**

Traditional CEA frameworks risk undervaluing AMR diagnostics because they focus on individual patient outcomes and (often siloed) healthcare costs. AMR diagnostics however, generate both patient and population-level benefits (e.g., reduced transmission) both of which have a downstream impact on health system resource use.

The STEDI framework was crafted to better capture the broader benefits of interventions against AMR, spanning both individual patients and populations. Though applicable to diagnostics, its use has largely been confined to antimicrobials. A framework tailored to diagnostics would allow these STEDI values to be systematically incorporated into the evaluation of tools designed to detect AMR.

3. **A comprehensive framework should also allow for recognition of additional health system value**

While STEDI was originally developed to capture the value of antimicrobials, STRIDES modifies and expands these definitions to reflect the specific contributions of diagnostics. In addition to offering value in line with the STEDI-derived elements as adapted in STRIDES (spectrum, transmission, enablement, diversity, and insurance), diagnostics also provide other types of value including:

- **Research value:** The benefit associated with facilitating the quality and efficiency of clinical trials and other studies for new antimicrobials. Research value acknowledges the indispensable contribution of diagnostics in enabling the development of new antimicrobials. Accurate identification of pathogens and resistance mechanisms is foundational to trial design, patient stratification, and the measurement of treatment efficacy. In this way, diagnostics not only support antimicrobial stewardship today but also catalyse the innovation needed for tomorrow's AMR landscape.

- **Surveillance value**: The benefit associated with monitoring AMR emergence and trends using information generated by diagnostics. Surveillance value recognises the central role that diagnostics play in monitoring AMR trends, informing therapeutic guidelines, infection control strategies, and guiding public health responses. Without reliable, real-time diagnostic data, efforts to track resistance patterns and implement targeted interventions remain limited and reactive.

These additional value elements represent critical mechanisms through which diagnostics deliver value, reflecting the evolving role of diagnostics in both clinical and public health settings which has, until now, remained largely unaccounted for in existing frameworks.

Incorporating these additional value elements transforms STEDI into **STRIDES: a diagnostic-specific framework that reflects the full spectrum of value generated by AMR diagnostics.** STRIDES (Spectrum, Transmission, Research, Insurance, Diversity, Enablement, Surveillance) enables a more comprehensive and fit-for-purpose approach to assessing, funding, and incentivising diagnostics—aligning economic evaluation with the true impact these technologies have on patients, providers, health systems, and global public health.

1.4 This report

Diagnostics play a vital role in optimising antimicrobial use and supporting appropriate infection treatment and, in turn, in preventing the emergence and spread of AMR. This research seeks to establish a diagnostic-specific value framework for AMR, building on the existing STEDI framework and evolving it into a framework called "STRIDES".

STRIDES highlights the unique benefits of diagnostics in promoting antimicrobial stewardship and mitigating AMR. Just as STEDI extends traditional value assessments for health technologies, STRIDES is intended to serve as a complementary extension tailored to the value of AMR diagnostics.

Methods for the development of the framework are presented in Chapter 2, with the framework set out in Chapter 3. We provide a definition, explanation and examples for each of the elements included in the framework. Chapter 4 provides a discussion around the progress this framework represents and the next steps that will be necessary to turn this into an operational value assessment tool and thus realise the full potential of AMR diagnostics.

2. Methods

2.1 Literature review

To inform the development of a comprehensive value framework that extends traditional assessment approaches by incorporating elements specific to antimicrobial diagnostics, we conducted a targeted literature review to identify relevant value components and assess their applicability to AMR diagnostics. The four key sources listed below were used as a starting point for the targeted literature review, and snowballing methodology used to find further literature:

- The value assessment framework for diagnostic tests (Ferrante Di Ruffano et al., 2012);
- The STEDI framework (spectrum, transmission, enablement, diversity, and insurance) for assessing the broader value of novel antibiotics (Karlsberg Schaffer et al., 2017; Rothery et al., 2024);
- The companion diagnostics value framework (Garrison, Mestre-Ferrandiz and Zamora, 2016);
- The NICE Diagnostic Assessment Programme guidance for HTA of diagnostics (NICE, 2011).

Ten broader value elements relevant to antimicrobial diagnostics were identified, which together formed a preliminary **AMR diagnostic framework**. This framework was split into three broad categories: 1) General value elements; 2) Diagnostic-specific value elements; and 3) STRIDES elements (related to the original STEDI elements, defined further in Chapter 3).

Definitions for elements within the first two categories were derived from the literature. For the STRIDES category, there were only a few clearly-defined definitions for each of the elements in the literature. As such, definitions for the original STEDI elements within STRIDES were adapted to a diagnostic context where appropriate from Brassel et al., (2023). Definitions for the additional elements within STRIDES, as well as all explanations and examples, were based on OHE analysis of the literature regarding potential elements of value for AMR diagnostics.

2.2 Roundtable

A virtual roundtable of 10 international experts was convened on 31st March 2025 to validate and refine the preliminary AMR diagnostic value framework. The group reflected multiple stakeholders, including clinical experts, HTA representatives, policymakers, and academic health economists from countries including Canada, USA, Belgium, England, Italy, and Switzerland.

The roundtable specifically focused on validating the STRIDES category of the framework. Whilst the first two categories acknowledge AMR diagnostics can have broader societal impacts, such as on productivity, or benefits specific to diagnostics in general, e.g. the value of knowing, these elements have been defined and discussed elsewhere and were therefore not the focus of the roundtable. In contrast, the STRIDES value elements are the least well-defined and required most validation in the context of AMR diagnostics. Moreover, STRIDES elements distinguish AMR diagnostics from other interventions by recognising the population-level benefits they generate via their impact on antimicrobial stewardship. It is therefore especially crucial to discuss and define these elements to prevent systematic undervaluation.

A pre-read for the roundtable was developed based on the literature review explaining the need for a value framework specific to AMR diagnostics, the elements within the proposed framework, and definitions, explanations, and examples for each of the STRIDES elements.

During the roundtable, each element was presented alongside the following questions to stimulate discussion among participants:

1. Are the definitions, explanations, and examples provided for each value element complete and accurate?
2. Are there other ways in which diagnostics create and/or support this type of value?
3. In what context(s) would this element generate the most value?
4. Are the examples accurate and appropriate?
5. Are you aware of (additional) evidence to support the examples given?
6. How can the explanations and supporting evidence be improved?

The roundtable discussions were recorded and summarised to analyse where changes to the framework should be made.

2.3 The framework

The preliminary framework based on the literature search was refined and updated using insights from the roundtable. Additional examples for some elements of the STRIDES category suggested at the roundtable were researched and added into the framework. The framework is set out in detail in Chapter 3.

3. The value framework: taking STRIDES

The value framework for AMR diagnostics is shown in Figure 1. It extends from the general value elements and the diagnostic-specific value elements, which apply without restriction to a comprehensive value assessment of AMR diagnostics, into STRIDES as the additional components of value generated by AMR diagnostics.

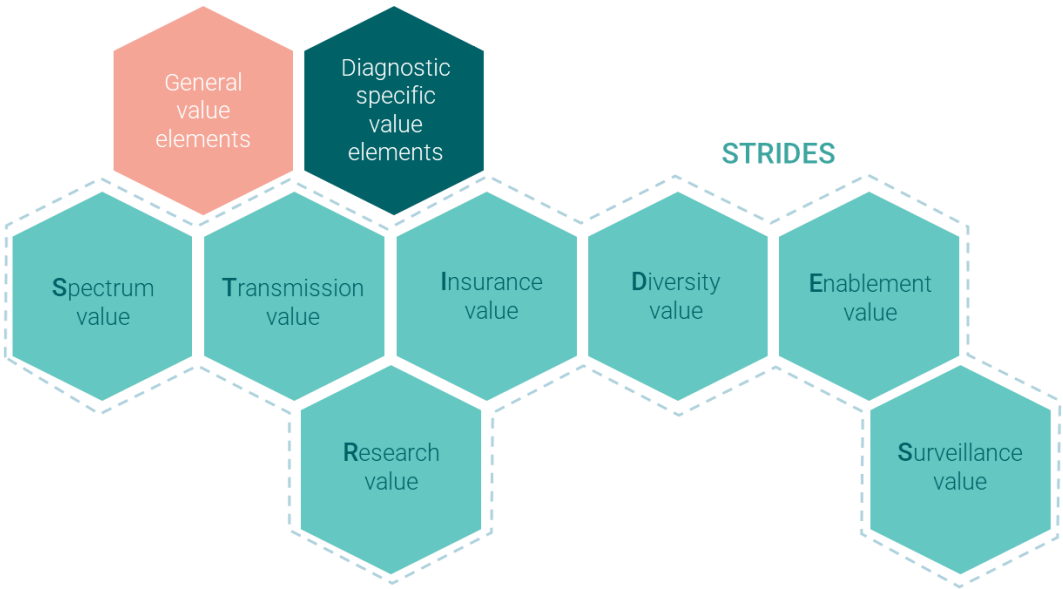

FIGURE 1: VALUE FRAMEWORK FOR AMR DIAGNOSTICS

1. **General value elements** capture elements that are not specific to diagnostics or antimicrobial interventions, but (potentially) apply to all healthcare interventions. This ranges from value elements included in current value assessment processes, such as clinical benefits (including clinical outcomes, mortality, quality adjusted life years [QALYs]) and cost-offsets, to broader components of value such as productivity impacts and equity. The majority of these elements have previously been discussed in the literature in value frameworks such as the ISPOR value flower (Lakdawalla et al., 2018).

2. **Diagnostic-specific value elements** capture elements that are specific to diagnostics as an overall group of interventions, but not specific to AMR diagnostics, and are thus not the primary focus of this report.

3. **AMR-specific value elements for diagnostics (STRIDES)** includes elements that capture the value of a diagnostic in facilitating antimicrobial stewardship and reducing AMR. In addition to the five STEDI elements it includes surveillance and research value.

The inclusion of the 'general value elements' and 'diagnostic-specific value elements' categories serve to underline that value elements deemed relevant for the routine evaluation of health care

technologies and diagnostics are also relevant for AMR diagnostics, and that the STRIDES elements that form the core focus of this report are **in addition to** these more generalised value elements.

The value elements detailed in the framework do not cover specific *attributes* of the test itself, instead the elements focus on ways in which those attributes create value. Different combinations of diagnostic attributes are likely to lead to different levels of value across different value elements. Example diagnostic attributes are set out in Box 1.

There are four types of diagnostic information for an AMR diagnostic, which dictate the type(s)of value the diagnostic can generate:

1. **Nature of infection**: Differentiating between viral and bacterial infections facilitates prevention of unnecessary antibiotic prescriptions for viral infections.
2. **Type of bacteria**: Identifying the causative pathogen enables tailored antibiotic prescribing and the use of narrow-spectrum antibiotics, which target specific bacteria or bacterial families.
3. **Susceptibility**: Confirming that the causative bacteria are susceptible to specific antibiotics or antibiotic families ensures effectiveness of treatment.
4. **Resistance**: Identifying resistant strains avoids unnecessary antibiotic exposure and guides de-prescribing efforts when resistance has been identified.

A further three characteristics also influence the magnitude of value that can be generated by an AMR diagnostic:

1. **Time-to-result:** The speed at which results are delivered affects how quickly appropriate treatment decisions can be made. Faster results enable earlier intervention and the potential impact of the diagnostic.
2. **Accuracy of test:** High accuracy minimizes false positives and false negatives, ensuring that treatment decisions are based on reliable data. This ensures subsequent prescribing decisions are correct and generate value.
3. **Multiplexing capacity:** The ability to test for multiple pathogens or resistance markers increases efficiency of diagnosis and provides clinicians with a more comprehensive picture with which to make prescribing decisions.

BOX 1: DESCRIPTION OF DIAGNOSTIC ATTRIBUTES

3.1 General value elements

For this report, we focus on clinical benefits and net costs only. However, in contexts where existing value frameworks or HTAs include broader considerations—such as productivity, equity, severity of illness, or other wider value elements—these should also be considered when evaluating AMR diagnostics. These broader elements are reflected in the ISPOR value flower, which offers a more comprehensive lens for assessing value beyond traditional cost-effectiveness (Lakdawalla et al., 2018).

Clinical benefits

Diagnostics deliver clinical benefits by ensuring that the right antibiotic reaches the right patient at the right time. They do this by providing the types of information outlined in Box 1. By addressing critical questions around the nature of infection (viral vs bacteria), the type of bacteria, and confirming susceptibility or resistance, diagnostics support clinical decision making through initiation, optimisation, de-escalation, and discontinuation of antibiotics. Diagnostics can thereby aid in maximising treatment outcomes while minimising treatment duration and infection-related complications (Wellcome Trust, 2016).

Within value assessments these benefits can be captured in various ways, including analysis of specific clinical outcomes, hospital (re-)admissions, mortality, and/or quality-adjusted life years (QALYs). The challenges of doing this, e.g. combining diagnostic accuracy data with results from antibiotic non-inferiority trials, are outside the scope of this report and have been documented elsewhere (Gupta, 2011).

Net costs

AMR diagnostics have an upfront cost and may require resources such as health care professional time for administration. Due to siloed budgeting in health care, they are sometimes mistakenly considered to increase the cost of care (Price, McGinley and John, 2020) .

In reality, they have significant potential to *reduce* costs through shorter hospital stays, reduced complications, and reducing (unnecessary) antibiotic use (Timbrook et al., 2017; Walker et al., 2016; Brigadoi et al., 2022; Nault et al., 2016). An evaluation of net costs is therefore critical in demonstrating the true cost (or savings) associated with AMR diagnostics, including savings realised throughout the full cycle of care.

3.2 Diagnostic-specific value elements

Value of knowing

The value of knowing refers to the benefit derived from knowing the outcome of a test, even if there is no (immediate) action taken as a result of this information (Neuman et al., 2012; Garrison, Mestre-Ferrandiz and Zamora, 2016). In the context of AMR, the value of knowing can establish itself in different ways. For patients and caregivers, receiving a clear diagnosis even in the absence of a treatment, can reduce uncertainty, inform personal decisions, and improve mental well-being (Clark et al., 2013). This is exemplified in infections in children, e.g. meningococcal disease, where parents found it difficult to cope with uncertain prognoses and expressed that enhanced support can be provided through improved access to information (Sweeney et al., 2013). For clinicians, knowing whether an infection is bacterial or viral can guide appropriate use of antibiotics. Even if there is no targeted therapy for a viral infection, a diagnostic that reveals this helps avoid unnecessary antibiotic prescription and contributes to public health by reducing AMR. For multidrug-resistant organisms (MDROs) or other contagious pathogens, diagnostic results guide infection control interventions (e.g., patient isolation, contact precautions), which are valuable regardless of treatment availability. The "knowing" facilitates containment and protects both patients and healthcare professionals.

3.3 STRIDES

Spectrum value

Definition: The benefit associated with using narrow-spectrum antibiotics (NSA) instead of broad-spectrum antibiotics (BSA). This minimises collateral damage to the treated individuals' microbiome and reduces selection pressure on non-targeted pathogens, thereby slowing the emergence of AMR.

Diagnostics generate spectrum value via two avenues:

- Facilitate targeted NSA prescription as opposed to BSA (e.g. empirical prescribing)
- Preventing the use of BSAs as diagnostic tools (i.e. 'trial of antibiotics')

Facilitating NSA prescription

In acute, severe infection, time-to-treatment initiation is a strong predictor of mortality (University of Chicago, 2024). In the absence of early pathogen confirmation, clinicians often rely on BSAs due to their efficacy against a wide range of microorganisms (Idelevich and Becker, 2019). However, BSA use can disrupt the gut microbiome, weaken the immune system, and increase susceptibility to opportunistic infections, thereby promoting resistance development (Modi, Collins and Relman, 2014). NSAs exert less ecological pressure, limiting gene transfer between bacterial species, and reducing the likelihood of AMR emergence (Modi, Collins and Relman, 2014; O'Neil, 2015).

Accurate, rapid diagnostics support early pathogen identification and resistance profiling, enabling clinicians to prescribe appropriate NSAs. This facilitates timely de-escalation from BSAs, helping preserve their effectiveness and maintain microbiome integrity (MacVane and Nolte, 2016). By preventing unnecessary exposure to both broad- and narrow-spectrum antibiotics, diagnostics deliver value at both patient and health system levels (O'Neil, 2015; Wellcome Trust, 2016).

An example of diagnostic spectrum value can be seen in the context of bloodstream infections and urinary tract infections (UTIs) caused by *Escherichia coli* (E. coli) (Mueller and Tainter, 2023). *E. coli* is a gram-negative commensal gut bacterium that is typically harmless, although pathogenic variants can cause serious infections (Mueller and Tainter, 2023). The current "gold standard" for UTI diagnosis is urine culture, which, combined with clinical symptoms, can take up to 48 hours to yield results (Palmqvist et al., 2008). In the interim, clinicians often resort to empirically prescribed BSAs, which may disrupt the gut microbiome and promote AMR (Kostakioti, Hultgren and Hadjifrangiskou, 2012; O'Neil, 2015).

Rapid diagnostics help bridge this gap by significantly reducing the time from sample collection to actionable results. Multiplex polymerase chain reaction (PCR)-based assays can identify a wide range of *E. coli* strains with greater speed and accuracy (Brons et al., 2020; Lehmann et al., 2011; Zimoń et al., 2024). For instance, a novel ultrafast PCR thermal cycler has demonstrated pathogen detection from urine samples in as little as 52 minutes (Brons et al., 2020). Such technologies facilitate earlier and more targeted treatment with NSAs, reducing unnecessary BSA use, preserving microbiome integrity, and delivering tangible spectrum value.

Preventing the use of BSAs as diagnostic tools

Another important mechanism by which diagnostics deliver spectrum value is by preventing the use of BSAs as diagnostic tools—commonly referred to as the 'trial-of-antibiotics' (Divala et al., 2023). In settings where diagnostics are unavailable, clinicians may empirically prescribe BSAs and interpret treatment response to confirm or rule out the presence of infection.

A notable example is in the diagnosis of *Mycobacterium tuberculosis (MTB)*. Patients with suspected *MTB* are often given BSAs such as amoxicillin or azithromycin, which have negligible activity against *MTB* (Divala et al., 2023). Those who respond are deemed MTB-negative, while non-responders are presumed MTB-positive and subsequently treated with anti-MTB agents (Divala et al., 2020, 2023). However, evidence shows that this approach provides limited diagnostic utility and minimal benefit in reducing hospital admissions or mortality (Divala et al., 2023).

This empirical strategy results in substantial overuse of BSAs. Divala et al. (2020) estimate that 26.5 million antibiotic courses are used to assess 5.3 million smear-negative MTB suspects worldwide every year. This highlights a significant opportunity for spectrum value through the implementation of effective, rapid point-of-care diagnostics. Such tools would eliminate the need for diagnostic BSA trials and enable appropriate use of NSAs for confirmed infections (WHO, 2020).

Transmission value

Definition: The benefit associated with preventing the spread or outbreak of infections and antimicrobial-resistant pathogens.

Diagnostics generate transmission value via two avenues:

- Enabling earlier detection of causative pathogens, which facilitates effective antimicrobial prescribing and infection control measures, thereby reducing opportunities for onward transmission.
- Reducing inappropriate and unnecessary antimicrobial prescribing, which curtails the development and spread of resistance that could otherwise lead to outbreaks (indirect).

Faster treatment and infection control measures

Diagnostics reduce transmission by enabling timely identification of pathogens and resistance mechanisms, supporting rapid initiation of effective antimicrobial therapy and infection control actions (Kaprou et al., 2021; Wellcome Trust, 2016). Quicker treatment limits the duration during which a patient is infectious and reduces bacterial load, thereby decreasing transmission risk (Sen et al., 2000). The benefits of preventing immediate outbreaks provide transmission value which extends from patients to healthcare settings and the broader community (CDC, 2025).

For example, Manore et al. (2019) modelled the impact of point of care testing (POCT) on non-typhoidal *Salmonella* outbreaks. They found that diagnostic use led to smaller, shorter outbreaks compared to scenarios without diagnostics, due to a reduction in patients receiving improper treatment. Among different diagnostic modalities, antibody-based tests showed the lowest rates of inappropriate prescribing—largely driven by faster turnaround times. Full deployment of diagnostics resulted in a 50-90% reduction in total costs and achieved the lowest cost per life saved, demonstrating measurable transmission value in both health and economic terms.

Rapid detection of resistant pathogens also supports the implementation of infection prevention strategies such as patient isolation and outbreak containment, helping to limit the spread of resistance genes in healthcare settings (Yamin et al., 2023). The real-world recognition of this value is seen in policy measures such as the Centres for Medicare & Medicaid Services (CMS) Hospital-Acquired Condition Reduction Programme, which penalises hospitals in the worst-performing quartile of hospital-acquired infection (HAI) metrics through reduced Medicare payments (CMS, 2024). Timely diagnostic testing is essential for identifying and reporting HAIs where pre-admission or bedside testing that identifies infections early can support hospitals in upholding HAI performance by informing timely infection control measures and reducing avoidable transmission.

Curtail resistance to slow (ongoing) transmission and potential outbreaks

Diagnostics also help curb transmission indirectly by reducing unnecessary antibiotic use which fosters resistance and makes infections more difficult to treat. By accurately distinguishing between viral and bacterial infections, identifying causative pathogens, and determining resistance profiles, diagnostics guide appropriate prescribing—avoiding needless antimicrobial exposure (Kaprou et al., 2021; Tacconelli, 2009; Wellcome Trust, 2016).

A modelling study estimated that POCT for community-acquired acute respiratory tract infections could reduce BSA use by over 7,500 defined daily doses per 100,000 people annually, and lower *Streptococcus pneumoniae* resistance by 0.3% across ten years (Van Der Pol et al., 2022). With *S. pneumoniae* being the leading cause of various common bacterial infections such as pneumonia, otitis media, and meningitis (Weiser, Ferreira and Paton, 2018), and 40% of the strain being resistant (CDC, 2024), this modest shift can have a meaningful impact when it comes to reducing clinical and

economic burden. Reducing resistance decreases the likelihood of prolonged or untreated infections that contribute to transmission (Cillóniz et al., 2018).

Furthermore, limiting the circulation of resistant pathogens reduces the risk of resistance gene dissemination via horizontal gene transfer (HGT)—a key mechanism by which bacteria pass resistance to one another, compounding the AMR problem (von Wintersdorff et al., 2016). Reducing the spread of resistant pathogens is particularly important in the context of HGT.

Beyond individual patient management, diagnostics enable pathogen surveillance, which is essential for early outbreak detection and informing infection prevention strategies (Jauneikaite et al., 2023). This broader role of diagnostics in AMR surveillance is further explored under the **surveillance value** section.

Research value

Definition: The benefit associated with facilitating more efficient, targeted, and informative antimicrobial research and development activities which is critical to curb AMR.

Diagnostics generate research value via the following avenue:

- Enabling pathogen-specific antimicrobial clinical trials and real-world studies through real-time identification of pathogens and resistance mechanisms.

Facilitating pathogen-specific antimicrobial research

AMR diagnostics are essential for advancing antimicrobial research by enabling accurate, rapid identification of pathogens and resistance mechanisms—capabilities that are increasingly necessary for the development and evaluation of novel antibiotics (O'Neil, 2015; Paul et al., 2022; Wellcome Trust, 2016). Without diagnostics, research on AMR cannot be optimally conducted, as pathogen specificity is fundamental to both understanding resistance mechanisms and testing the efficacy of targeted treatments.

The discovery of antibiotics is difficult, especially for agents targeting gram-negative bacteria, which are responsible for a significant proportion of severe infections (O'Neil, 2015; Theuretzbacher et al., 2023). A major challenge in antibiotic development, particularly for NSAs, is recruiting eligible patients with confirmed infections caused by specific pathogens (Paul et al., 2022; Wellcome Trust, 2016). Traditional culture-based methods are too slow to meet the time constraints of clinical trial recruitment, leading to inefficiencies and higher costs due to unnecessary screening of ineligible participants (O'Neil, 2015; Paul et al., 2022). For example, a study on *Pseudomonas aeruginosa* infections in cystic fibrosis patients demonstrated the resource intensity required to screen large populations for relatively rare infections (Hickey et al., 2010).

Rapid diagnostics solve this by enabling real-time patient identification based on confirmed pathogen presence. This allows for smaller, more targeted enrolment cohorts, improving trial efficiency and cost-effectiveness. Rapid POCTs are particularly valuable for studying serious hospital-acquired infections (HAI)—such as hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP)—which are often caused by multidrug-resistant (MDR) gram-negative organisms (Enne et al., 2014; Jones, 2010). These infections are challenging to treat and study. Diagnostics that allow for timely accurate recruitment can reduce the time-to-trial and improve the likelihood of meaningful outcomes (Enne et al., 2014).

The CREDIBLE-CR trial (a phase 3 study evaluating cefiderocol for carbapenem-resistant infections) exemplifies this approach. As a pathogen-focused trial, patients were only eligible for enrolment if

diagnostics confirmed infection with a carbapenem-resistant gram-negative pathogen, verified through either culture or rapid molecular testing (Bassetti et al., 2021). This diagnostic-led inclusion ensured the recruited population matched the trial's objective, provided clinically relevant results, and reduced the trial cost (Paul et al., 2022; Jorgensen and Rybak, 2018).

Turning to recent technological advances, machine learning and novel diagnostic technologies are increasingly supporting antimicrobial research (Kim et al., 2022). For instance, whole-genome sequencing (WGS) combined with machine learning can enable earlier detection of resistance mechanisms and offering deeper insights into pathogen evolution, virulence, and treatment response—beyond what conventional culture-based methods can provide (Wang et al., 2022a). As the quality and breadth of diagnostic data improve, these technologies will increasingly play a role in the discovery and development of future pipelines (Yang et al., 2019).

Insurance value

Definition: The benefit associated with AMR diagnostics enabling the preservation of last-line antimicrobials for future use when other treatments fail, and reducing the risk of catastrophic AMR outbreaks through earlier detection and containment of resistant infections.

Diagnostics generate insurance value via two key avenues:

- Reducing inappropriate or unnecessary use of last-line antibiotics, thereby slowing resistance development and preserving their long-term effectiveness.
- Enabling early identification and control of resistant infections, thereby preventing large-scale AMR outbreaks that could otherwise overwhelm healthcare systems.

Preserving last-line antibiotics

Diagnostics contribute to antimicrobial stewardship by supporting the appropriate use of antibiotics and avoiding premature reliance on "last resort" antibiotic options. Reserve antibiotics, or "last resort" medicines, are vital for treating multidrug-resistant infections and must be safeguarded to retain their future utility (WHO, 2023).

In the absence of rapid, accurate diagnostics, clinicians may resort to empiric use of last-line antibiotics to ensure immediate coverage—particularly when the causative pathogen or resistance profile is unclear. This practice risks accelerating resistance to critical antimicrobials and undermines their role as a safety net in AMR emergencies.

A clear example of the erosion of insurance value can be seen in the treatment of gonorrhoea. While older antibiotics such as penicillin and ciprofloxacin remain effective in many cases, they are no longer routinely used in the UK due to historical resistance concerns (O'Neil, 2015). Instead, last-line agents such as cephalosporins and azithromycin were widely adopted as precautionary measures (Merrick et al., 2022). This led to increasing resistance, particularly to azithromycin, prompting a change in UK treatment guidelines from dual therapy to ceftriaxone monotherapy in 2019 (Merrick et al., 2022). Had diagnostics been available to identify cases still susceptible to older antibiotics, the cephalosporins and azithromycin could have been reserved, maintaining their last-line status and insurance value.

Preventing large-scale outbreaks

In addition to preserving last-line antimicrobials, AMR diagnostics generate insurance value by helping to prevent large-scale outbreaks of resistant infections (Chan et al., 2023). Through early and accurate identification of resistant pathogens, diagnostics enable more timely infection control measures, targeted treatments, and containment strategies that reduce the likelihood of resistant strains spreading unchecked. This preventive function goes beyond immediate clinical benefits to address broader systemic risks, particularly the potential for widespread AMR outbreaks that could overwhelm healthcare infrastructure and compromise the effectiveness of routine medical procedures reliant on effective antibiotics.

The prevention avenue of insurance value is particularly important given the unpredictable but potentially catastrophic nature of AMR crises. Much like an insurance policy protects against rare but devastating financial losses, diagnostics provide a form of "health system insurance" by lowering the probability and potential severity of future AMR-driven health emergencies. The value created is not only in the avoided cases of infection today but in reducing the systemic risk that a resistant pathogen could trigger widespread morbidity, mortality, and economic disruption. This long-term protection is distinct from the transmission value typically captured in assessments focused on immediate infection control benefits.

For example, molecular diagnostics such as matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF-MS) are capable of detecting novel carbapenem-resistant *Klebsiella pneumoniae* strains in hospitalised patients (Wang et al., 2022b). Early detection enables swift isolation of cases and targeted antimicrobial therapy, which not only curbs the immediate spread within the hospital (which is a form of transmission value) but also prevents the establishment of a new, highly resistant lineage in the community. Without such diagnostic intervention, the strain could spread silently, becoming endemic and significantly increasing the future burden of hard-to-treat infections (Wang et al., 2023). The insurance value here lies in averting a scenario where healthcare systems face widespread failures of last-line treatments, leading to higher mortality rates and curtailed access to life-saving procedures such as surgeries, chemotherapy, or organ transplantation.

The role of diagnostics in preventing short-term transmission is further discussed under the **transmission value** section.

Diversity value

Definition: The benefit associated with evidence-based variation in prescribing and enabling the use of a wider range of effective antimicrobials across the health system, thereby reducing reliance on commonly used agents and lowering the likelihood of resistance developing against any single class.

Diagnostics generate diversity value via two avenues:

- Facilitating more targeted prescriptions and use of a wider range of narrow-spectrum and novel antimicrobials, reducing reliance on a limited set of agents.
- Providing clinically relevant information to support personalised, diversified prescribing strategies.

Allowing a wider range of antimicrobial prescriptions

The utility of a new antimicrobial depends not only on its availability but also on its integration into diversified treatment strategies. In the absence of pathogen-specific information, clinicians often rely on empirical prescribing, particularly in acute settings where treatment must be initiated quickly. This often leads to clinicians defaulting to BSAs, which are perceived as broadly effective and clinically "safer" when the causative agent is unknown (Tarrant et al., 2021; Wellcome Trust, 2016). Their broad action is perceived to increase initial treatment success, and can minimise legal and professional risks (Tarrant et al., 2021). However, this entrenched prescribing pattern discourages the use of narrower-spectrum or less familiar antimicrobials, limiting diversity in prescribing (Pandolfo et al., 2022).

Diagnostics can help shift this pattern. By providing timely, pathogen-specific data including resistance profiles, they increase clinician confidence to select narrow-spectrum or less commonly used agents, even in urgent care settings. This promotes a more even distribution of antimicrobial use, reducing the ecological pressure on any single drug class and slowing resistance development (Spaulding et al., 2018).

In a US modelling study, Gordon et al., (2024) demonstrated that introducing an additional antimicrobial into the standard of care pathway—creating a three-line rather than a two-line treatment strategy—can reduce AMR by 9.03% over ten years, avoiding $64.3 million in hospitalisation costs, and yielding 153,000 additional quality-adjusted life years (QALYs). Diagnostics can facilitate this diversification of prescribing strategies, delivering both health and economic value through increased diversity.

Additionally, advanced diagnostic platforms with multiplexing capabilities can identify a wide array of pathogens and resistance markers, facilitating tailored treatment while preserving the effectiveness of a wide range of antimicrobials. This expands the potential for diagnostics to maintain the utility of not just a single agent, but an entire class of critical antibiotics.

Enabling personalised and diversified prescribing strategies

Diagnostics also support diversity value by enabling antimicrobial selection tailored to individual patient characteristics and clinical presentation—expanding the use of (various) agents safely and effectively across the population. For example, (Goebel, Trautner and Grigoryan, 2021) proposed a urinary tract infection (UTI) stewardship model that integrates patient-specific factors (such as age, symptoms, comorbidities, and pathogen type) with diagnostic information. Their model differentiates UTI from asymptomatic bacteriuria, sexually transmitted infections, and other non-bacterial causes (Goebel, Trautner and Grigoryan, 2021). By differentiating between bacterial colonisation as well as different types of infections, diagnostics can help clinicians distinguish among causes and guide evidence-based prescribing variations across the set of applicable agents.

Furthermore, in UTI cases, patient-specific factors like allergies, kidney function, and co-morbidities significantly influence antibiotic choice. Diagnostics—particularly when integrated with clinical decision support systems (CDSS)—can guide this process. For instance, individuals with penicillin allergies must avoid beta-lactams; those with impaired renal function should not receive nitrofurantoin; and patients with hyperkalaemia should avoid trimethoprim (NICE, 2024). By integrating diagnostic and patient data, AI-driven CDSS have been shown to reduce inappropriate prescribing and lower broad-spectrum antibiotic use in UTIs (Shapiro Ben David et al., 2025). This approach not only improves individual care but also helps shift prescribing away from overused agents, supporting greater antimicrobial diversity.

Enablement value

Definition: The benefit associated with enabling modern medical treatments or procedures to proceed by reducing infection-related risks and constraints.

Diagnostics generate enablement value via three avenues:

- Facilitating timely and effective antimicrobial prescriptions, enabling treatments and procedures that require infection control or absence of infection to proceed.
- Preventing inappropriate antimicrobial use which protect the microbiome immunomodulatory functions, impacting both short- and long-term outcomes.
- Preventing AMR development to improve treatment effectiveness and medical procedure outcomes, divert healthcare resources from infection management, and improve healthcare capacity (indirect).

Facilitating timely and effective antimicrobial prescriptions

Diagnostics support the safe and timely delivery of medical procedures by identifying infections and resistance profiles, or confirming the absence of infection (Kaprou et al., 2021). This is particularly important for high-risk interventions such as surgery, chemotherapy, and immunosuppressive therapies, which require sterile conditions or low infection risk.

For example, immunocompromised patients—such as those undergoing chemotherapy or immune checkpoint inhibitor therapy—are highly susceptible to infections. Delays in diagnosing and treating infections in these individuals can lead to treatment interruption, disease progression, and reduced survival (Burns et al., 2022). A systematic review highlights the unmet need in diagnosing acute infections in these patients, where conventional methods may be slow and inconclusive (Hill et al., 2024). Molecular diagnostics such as PCR and metagenomic sequencing provide rapid, non-invasive broad-spectrum pathogen detection, and are especially useful for immunocompromised patients with atypical or polymicrobial infections (Hill et al., 2024). In these cases, diagnostics enable timely antimicrobial therapy, reducing treatment delays and supporting continuity of care.

Protecting microbiome immune response

Antibiotics—especially broad-spectrum agents—can disrupt the gut microbiota, impairing its immunomodulatory function (Martins Lopes et al., 2020), and influencing treatment efficacy and toxicity, particularly in oncology settings (Huang et al., 2019; Francino, 2015). For instance, studies have shown adverse effects of BSA use on cancer treatment efficacy and survival (Ahmed et al., 2018). By identifying scenarios where antibiotics are unnecessary, diagnostics can prevent disruption of gut microbiota, thereby supporting immune responses and improving outcomes in cancer therapies.

In neonatology, protecting the developing microbiome is particularly important. Neonates, particularly in the early postnatal period, are highly vulnerable to severe bacterial infections due to immature immune systems (Cohen et al., 2023). Early bacterial neonatal infections (EBNIs), dominated by maternal *Group B Streptococcus (GBS)* colonisation and *E. coli* associated UTI, are typically managed with intrapartum antibiotic prophylaxis (Miselli et al., 2022). However, the rise of resistant *E. coli* producing extended-spectrum β-lactamases (ESBLs) complicates prophylactic strategies, necessitating careful antimicrobial stewardship where clinicians need to account for factors such as resistance emergence, as well as antimicrobial exposure, which causes microbiome disruption (Miselli et al., 2022). Diagnostics can support early and accurate identification of infections, reduce diagnostic uncertainty, and enable more judicious antibiotic use (Doenhardt et al., 2020).

Beyond infection prevention, diagnostics can minimise unnecessary exposure to antibiotics in neonates. Although antenatal antibiotic use can reduce maternal morbidity, they are associated with impaired neonatal feeding, altered gut microbiome development, and increased risks of infant morbidities both immediately after birth and later in life (Brockway, 2024; Luo et al., 2021). Minimising unnecessary neonatal antibiotic exposure is linked to earlier progression to autonomous feeding (Jefferies, 2014), with benefits for growth, neurocognitive development, and long-term health outcomes (Duong et al., 2022). In this context, diagnostics deliver enablement value not just in the short term, but across the life course.

Preventing AMR development to improve treatment effectiveness

Despite the high burden of Surgical Site Infections (SSIs), many cases go undiagnosed due to the absence of routine microbiological confirmation. Aboderin et al. (2024) found that most SSIs are not microbiologically confirmed, with 80% of patients not receiving wound swab, leading to empiric, non-targeted antibiotic use and high resistance rates. Among those tested, 69% of cases involved multidrug-resistant organisms (Aboderin et al., 2024). This gap has serious implications. Teillant et al. (2015) estimated that up to half of the pathogens responsible for SSIs and a quarter of those causing infections after chemotherapy in the US are resistant to standard prophylactic antibiotics. As resistance to standard prophylactic antibiotics increases, patients are put at risk during surgery, chemotherapy, and immunosuppressive therapies. A projected 30% reduction in antibiotic efficacy could result in 120,000 additional infections and 6,300 infection-related deaths annually (Teillant et al., 2015).

SSIs caused by resistant pathogens are associated with longer hospital stays and increased costs, placing strain on healthcare systems and diverting resources from elective or non-infectious procedures (Weigelt et al., 2010). By uncovering under-diagnosed infections and enabling targeted treatment, diagnostics deliver enablement value by preventing the development AMR at the population level, leading to more effective antibiotic treatment, improved medical procedure outcomes, shortening hospitalisations, and freeing up of healthcare capacity. This value differs from traditionally captured cost-offsets as it is an indirect release of resources through reduction in population-level AMR, rather than a direct release through more effective treatment at the level of the treated individual.

Surveillance value

Definition: The benefit associated with providing accurate, comprehensive, real-time surveillance data for monitoring the emergence and spread of AMR. This enables optimised antimicrobial use and strengthens surveillance strategies.

Diagnostics generate surveillance value via two avenues:

- Enable real-time and longitudinal monitoring of AMR patterns.
- Informing burden and distribution of resistant pathogens at regional, national, and global levels to guide clinical practices and antimicrobial stewardship.

Enabling real-time and longitudinal monitoring of AMR patterns

Diagnostics provide timely, actionable resistance data that strengthen surveillance at both the local and system level. For instance, institutional antibiograms—typically updated annually—can be enhanced with rapid diagnostics to reflect real-time resistance trends (Jauneikaite et al., 2023; Klinker et al., 2021; Truong et al., 2021). This enables more responsive updates to empiric antibiotic therapy and infection control protocols. Advanced diagnostics such as nucleic acid amplification technology (NAAT) and matrix-assisted laser desorption ionization-time of flight mass spectrometry

(MALDI-TOF-MS) support antimicrobial stewardship teams by delivering near real-time data on resistance patterns (Vasala, Hytönen and Laitinen, 2020).

Real-world evidence supports the impact of real-time surveillance. Sherry et al. (2022) found that real-time genomics data on the transmission of MRDOs influenced infection control behaviour among healthcare providers. Similarly, Jauneikaite et al. (2023) demonstrated how sequencing technologies helped reclassify neonatal infections originally thought to be maternally transmitted as healthcare-acquired, prompting changes to practice.

Whole-genome sequencing (WGS) further strengthens longitudinal surveillance by detecting resistance mutations and tracking transmission dynamics at a granular level (Fasciana et al., 2019; Zhao et al., 2016). This improves long-term understanding of evolving resistance profiles and informs future treatment and prevention strategies (Franklin et al., 2021).

Guiding clinical practices and antimicrobial stewardship

Beyond monitoring, diagnostic-generated epidemiological data play a role in informing broader clinical and public health decision-making. By identifying geographic hotspots for resistant pathogens, diagnostics support the early recognition of localised outbreaks. When resistance patterns indicate that a pathogen is no longer susceptible to commonly used treatments, treatment protocols can be updated to avoid ineffective antibiotics and prioritise those with proven efficacy (O'Neil, 2015). This allows healthcare systems to adapt rapidly, reducing treatment failures and slowing resistance spread. In turn, these insights can guide the strategic deployment of diagnostic tools and prioritise areas for new test development (Okeke et al., 2011).

Diagnostics also allow resistance data to be disaggregated by region and setting. Local resistance patterns such as those tracked in hospital or regional surveillance systems, are often more actionable for clinicians than national averages and can inform hospital-specific empiric prescribing practices (Gajic et al., 2022). These data can support the design of tailored antimicrobial stewardship interventions that are better aligned with local resistance pressures.

In regions where real-time diagnostic capacity is limited and that rely heavily on empirical prescribing, diagnostics still offer value through the aggregation of historical resistance data. These data help inform treatment guidelines that increase the likelihood that first-line empirical therapies will be effective (Santu, 2024). Over time, this can help shift practice patterns toward more evidence-based prescribing, even in resource-constrained environments.

A summary of the ways in which the STRIDES elements generate value, at which level(s) (patient or population) and over which time horizon(s) is given in FIGURE 2.

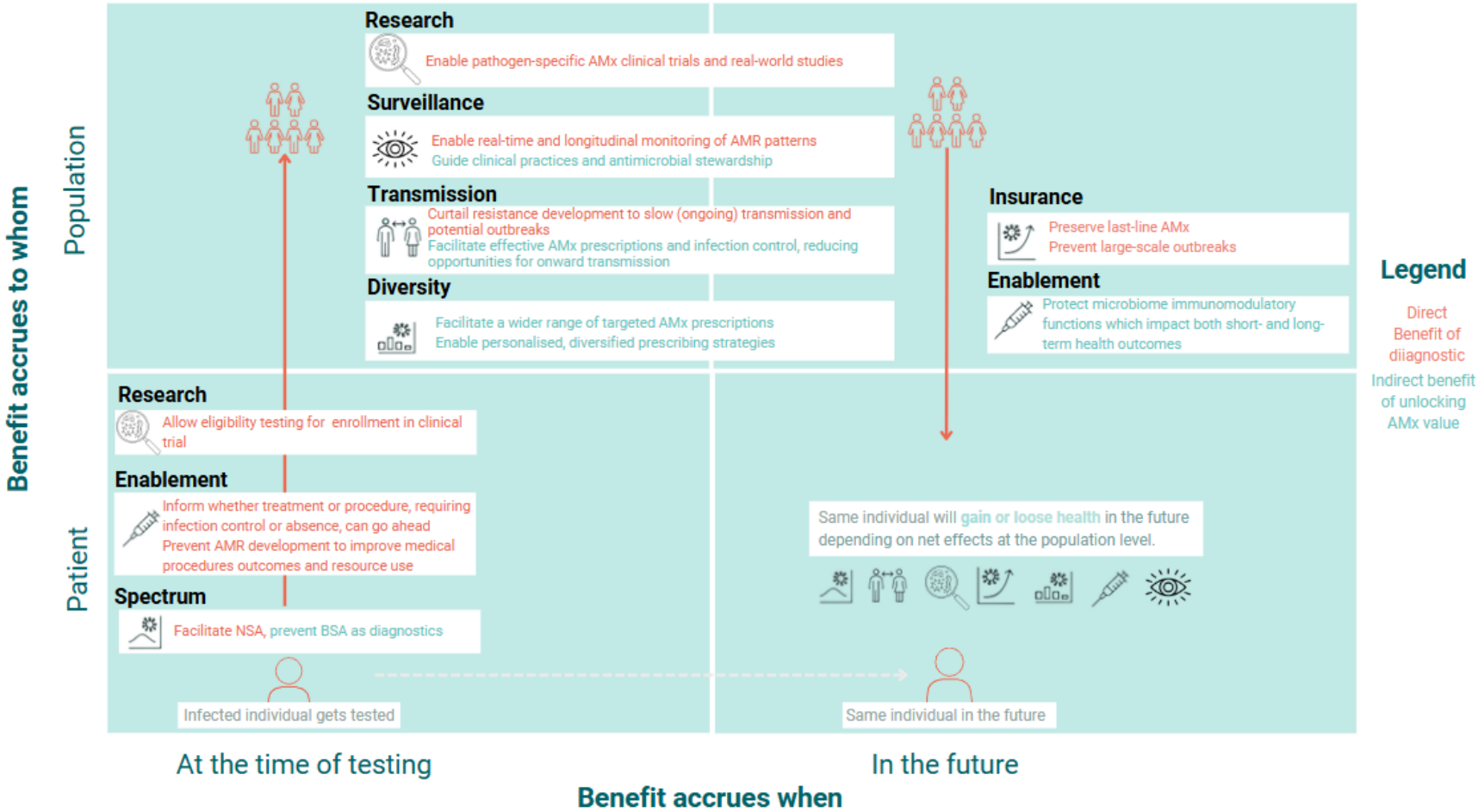

FIGURE 2: CHARACTERISING THE STRIDES FRAMEWORK (Brassel et al., 2023)

Abbreviations: AMx: antimicrobials; BSA: Broad spectrum antibiotics; NSA: Narrow Spectrum antibiotics.

4. Where next?

4.1 Progress and next steps

The framework provided here is a country-agnostic conceptual framework setting out the various potential sources of value of AMR diagnostics. Rooted in published evidence and validated by an expert panel, it provides a critical step towards appropriate value assessment of AMR diagnostics, raising awareness of the multifaceted benefits of AMR diagnostics, and how they generate value for patients, health systems, and society in the fight against AMR.

The framework is not, however, in its current form, an operational value framework or blueprint for HTA.

Operationalising the framework

Should decision makers wish to include the value elements set out here in a decision-making framework, this could be done either quantitatively or qualitatively.

To include them **quantitatively** there would need to be feasible means of measuring or modelling each element and a means of combining them (e.g. via multicriteria decision analysis). Indeed, measurement and weighting of the value elements proved challenging in previous attempts to operationalise the STEDI framework for antibiotics (NICE and NHS England, 2022). Still, the original STEDI report explicitly warns against limiting attention to only those elements that are easy to measure as over-deterministic (Karlsberg Schaffer et al., 2017). They state that HTA and decision-making are pragmatic in many settings, and decisions often factor in unquantified value elements. Whilst it is tempting to focus on the 'low hanging fruit' to make quick progress, this should not be to the exclusion of the other elements, particularly when there is little agreement about which elements are easy to implement, or which are most important to decision makers (Karlsberg Schaffer et al., 2017).

With this in mind, and off the back of the challenges raised by these initial attempts to operationalise the STEDI framework, OHE developed a roadmap for further development and quantification of STEDI (Brassel et al., 2023). A similar exercise could be undertaken here, to explore how the elements of value set out in STRIDES could be measured, weighted and aggregated.

Many countries use deliberative committee processes to make reimbursement decisions, and therefore **qualitative** inclusion may be a more natural fit. However, this gives rise to its own challenges, as the value elements may still need some form of weighting (e.g. via a more discursive form of multi-criteria decision analysis), and it can be difficult to translate qualitative impacts into decisions.

Whichever approach is taken forward (qualitative or quantitative), case studies, in which specific AMR diagnostics are selected and their value explored against the value elements set out here, would be of high value.

Remaining barriers

In Chapter 1 we highlighted three key categories of barrier to the adoption of diagnostics: i) clinician behaviour, ii) misaligned incentives and limited reimbursement mechanisms, and iii) lack of policy prioritisation. Setting out the full potential value of AMR diagnostics, as done in this report, goes some way to overcoming parts of these challenges. By paving the way for more comprehensive value assessment we are closer to achieving appropriate reimbursement (and therefore incentivisation for the development) of diagnostics, and by setting out the full range of benefits, we hope to see AMR diagnostics move up the policy agenda. However, further research into how incentives can be realigned (including consideration of bundled payments and siloed budgets) is warranted, and should build on our existing work in this area (Firth et al., 2023). Research should include exploring different funding models and sources (e.g. whether the wider public health benefits could/should be funded by a different pot than those benefits which occur to the patient and the health system).

Exploration of the remaining barriers and potential solutions to these barriers with key stakeholders will be critical to further progress. There is also a clear need for further education to increase awareness among HTA bodies and health care payers of the threat of AMR, and the benefits of AMR diagnostics in particular.

4.2 Concluding remarks

AMR is a global health crisis, compounded by the overuse and inappropriate prescribing of antimicrobials. Diagnostics are critical in the fight against AMR, ensuring patients who need antimicrobials receive them and unnecessary antimicrobial use is minimised. However, adoption of diagnostics in this space is low due to under recognition of the value they offer, amongst other factors.

A conceptual framework that sets out the full range of benefits offered by AMR diagnostics is critical in demonstrating the distinct value pathways offered by AMR diagnostics, the complementarity between AMR diagnostics and antimicrobials, the population-level benefits of interventions against AMR, and the additional value elements specific to diagnostics in this context. The framework presented here lays the foundation for this value framework specific to AMR diagnostics that is based on, but not limited to, the STEDI-framework.

Further research is needed to develop and refine the ideas presented here, to explore how they can be operationalised, to test feasibility of implementation, and examine how the remaining barriers to adoption of AMR diagnostics can be overcome. Continued 'strides' towards the adoption of AMR diagnostics is critical if we are to realise the potential of these valuable tools in the fight against AMR.

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