

Ensuring AMR Diagnostic Innovation & Uptake

Based on the study

Estimating global patient needs and market potential for priority health technologies addressing antimicrobial resistance

Priority Needs for New AMR Diagnostics

The pivotal role that improved diagnoses can play as part of our global response in tackling the growing burden of antimicrobial resistance (AMR) has been repeatedly emphasised¹, yet progress so far remains limited².

DX ROLES IN THE AMR RESPONSE

- ❖ Improve when & how we use antibiotics
- ❖ Lower antibiotic demand – preserving antibiotic efficacy
- ❖ Reduce the urgency to develop new antibiotics
- ❖ Improve & speed-up development of new antibiotics
- ❖ Improve surveillance & knowledge of AMR

The patent-based system links diagnostic development to its commercialization in one chain. Similar to antibiotics, AMR diagnostics face post-launch challenges in: a) how much successful development will be rewarded and b) securing health system uptake. The priority diagnostic needs that were identified and quantified in this study³ are summarised in ‘EAG’s Prioritised Diagnostics’.

Modelling AMR Markets & Needs

A multidisciplinary, global, Expert Advisory Group (EAG) was formed to identify – initially through a human patient-need led approach – some of the highest AMR patient needs for new health technologies. The four profiles (2 x diagnostics [Dx]; 2 x antibiotics [Tx]) were then quantified in terms of the need (patient numbers) and market potential (peak revenues) to generate global (80% of the world) forecasts to 2040³.

The Dx workstream adopted a bottom-up, static model combining patient estimates with ‘eligibility’ (consideration of the diagnostic context) prior to conversion to revenues. Alternative scenarios were used to explore the high uncertainty of outputs given the weak data availability & hypothetical need profiles.

EAG’S PRIORITISED DIAGNOSTICS



Rapid near-patient globally-applicable culture-independent tests from a single sample to:

- ❖ **Dx1 (Bac. vs other):** Determine if an infection is bacterial or not. To inform whether an antibiotic should be prescribed.
- ❖ **Dx2 (ID/susceptibility):** Rapidly identify the pathogen/s and susceptibility (lack of resistance) for priority MDR Gram negative bacteria. To inform the use of targeted treatment at initiation.

- Recent work by the World Health Organisation (WHO)^{4,5} & other actors was taken into consideration in determining these need profiles
- The profiles here enabled the quantification to be performed & are not full target product profiles (TPPs)⁶ intended for developers

Meeting Priority Dx Needs will be Modestly Rewarded

Global revenue is determined by the total amount all market buyers (healthcare payors) are able, or willing, to pay. Under current market conditions, revenue forecasts for these two aspirational diagnostics are similarly modest at around \$400m by 2040 (i.e., 15 years after launch), with development costs in the range of \$20–150m⁷.

Forecasted global market potentials of ~\$400m, indicate a private value far below their social value

The modest revenues and forecasted uptake of these critical new devices is largely due to a: 1) competitive market landscape and 2) weak rationale (use case) for physicians to use them over empirical antibiotic use. The unfavourable cost/benefit balance grows outside high income countries (HICs).

¹ Ensuring innovation in diagnostics for bacterial infection: Implications for policy. European Observatory on Health Systems and Policies; 2016. <https://www.ncbi.nlm.nih.gov/books/NBK447319/>

² Review of Progress on Antimicrobial Resistance, Chatham House 2019. 2019-10-04-AMR.pdf (chathamhouse.org)

³ Estimating global patient needs and market potential for priority health technologies addressing antimicrobial resistance; 2021: <https://bit.ly/3CUpDKK>

⁴ World Health Organization. (2019). Landscape of diagnostics against antibacterial resistance, gaps and priorities. <https://apps.who.int/iris/handle/10665/326480>.

⁵ World Health Organization. (2020). Target product profiles for antibacterial resistance diagnostics. <https://apps.who.int/iris/handle/10665/331054>.

⁶ Links to WHO TPPs and PPCs [accessed 08082021]

⁷ Mystery Solved! What is the Cost to Develop and Launch a Diagnostic? - Diaceutics [accessed 08082021]

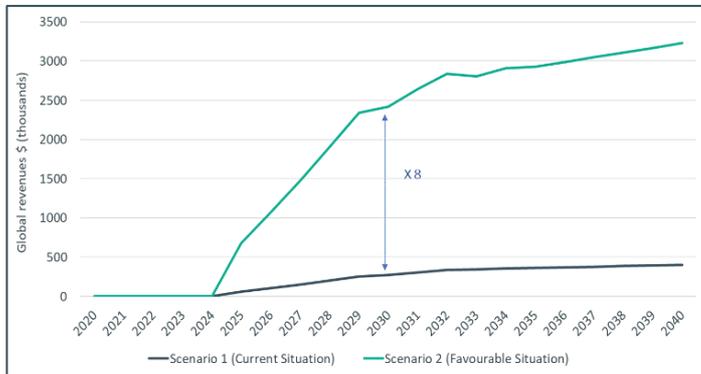
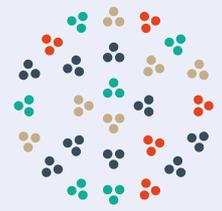


Figure A. Dx1: Global revenue forecasts 2020-2040 (2 x scenarios)

What Difference Could Policy Maker Action Make?

Figure A illustrates the substantially improved market attractiveness that could be achieved through a more favourable market context nurtured by public health actors (see Scenario box below). Dx1 revenues were forecast to increase nearly 8 times over the current situation. This represents **an additional 200 million annual diagnoses globally (i.e., an almost 14-fold increase in global patient reach)** and, by extension, a substantial decrease in unnecessary prescriptions.

❖ **Scenario 1: Base-case (current situation)**

A scenario built on the current situation. Assumes no substantive changes to the Dx context in the next 20 years.

❖ **Scenario 2: Hypothetical (favourable situation)**

Improvements in the policy/AMR context resulting in better uptake, reimbursement, clinician adoption & use (including donor-support for LMIC/LICs).

Dx2 (ID/susceptibility) is substantially less affected by the more favourable scenario, contributing only an additional \$206m in revenues. Yet those increased revenues still translate into **>5 million more targeted prescriptions** – or more narrow-spectrum antibiotics being prescribed – within 20 years, were such actions (assumed by scenario 2) initiated.

The case for policy intervention to support uptake and innovation is compelling

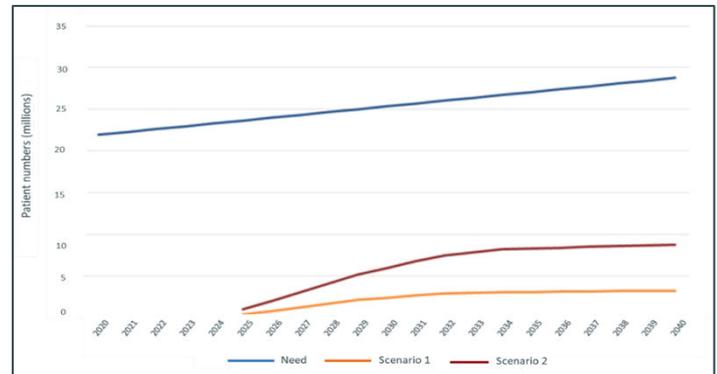


Figure B. Dx2: Projected Need vs. Demand 2020-2040 (2 x scenarios)

Discrepancy in Location of Global Need & Uptake

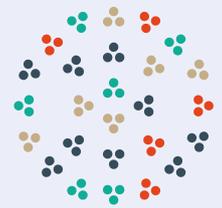
AMR is a truly global challenge yet its impact is higher and growing more rapidly outside HICs (Policy Brief #3). Forecast **global patient needs by 2040 of <800 million Dx1 (Bac. vs other) and <30 million Dx2 (ID/susceptibility)** reflect (but underestimate)⁸ this and highlight that 80% of the forecast need lies outside HICs.

The global need for these diagnostics is highest where uptake will be weakest

As Dx1 (Bac. vs other) is a less sophisticated primary care device, at peak sales in around 15 years, it is forecast to reach only around **2% of its target patients or 17 million patient-diagnoses** in 80% of the world – mostly from lower-middle and low-income countries (LMIC/LICs). In contrast, despite a more favourable ‘use case’ (anticipated to secure up to 10% of eligible patients), Dx2 (ID/susceptibility) – the more sophisticated device for hospital use, with 20 times lower need volume – is forecast to secure **3.2 million patient-diagnoses** at its peak – mostly from upper-middle income (UMIC) countries.

Figure B shows how, under current conditions, expected global uptake and access is forecast to remain a small proportion of the overall need for such a device. With a growing number of narrow-spectrum agents in clinical development, the ‘need’ for a single device such as this (i.e., able to inform prescribing across multiple-agents) is only expected to grow further.

⁸ The authors acknowledge that need & utility are likely both underestimated



Market Intervention Necessary – What Can be Done?

In the current market context, using a diagnostic adds cost and time to both the patient and the health care professional in the short term, while the clinical and cost benefits of their use become evident only in the long term and at a health facility or societal level. Rectifying this disconnect would have substantial public health advantages at the same time as improving the innovation system by ensuring that such urgently needed new diagnostics – to transform the AMR response – are brought to the market and patients globally.

Greater valuation, uptake & use of Dx is possible with existing tools & would help sustain the supply of innovation

The COVID-19 response has shown how transformative change is possible. A previous study⁹ by the Global AMR R&D Hub provided indications of what actions policy makers can take (see Info Boxes below) to achieve a collective progression closer towards a ‘Scenario 2’.

USE OF EXISTING POLICY TOOLS

Many countries already engage in health technology assessment for medical devices, but findings could be better integrated into reimbursement policies.

BROADER DX VALUE-FRAMEWORKS

Broader value-frameworks – such as those being explored within ValueDx¹⁰ – that capture and incorporate longer-term health and economic impacts on the whole health system would improve the flow and rate of innovation.

NOVEL POLICY OPTION

Funding of ‘Dx-Tx pairs’ (complementary or companion diagnostics) – as is common in other therapeutic areas – could begin to reward more targeted and precise use of novel antibiotics.

COVID-19 STEP-CHANGE IN Dx UPTAKE

The unprecedented and very rapid increase in both the availability and uptake of rapid tests – also in LMICs/LICs – for COVID-19 has catalysed important structural shifts both within the private (In vitro diagnostic manufacturers) and public sectors – that could usefully benefit and be seized upon for AMR.

On the basis of the diagnostic workstream of the study, the EAG made the **following recommendations**:

- ❖ Widespread and immediate use of existing policy levers: national-level reform of pricing and reimbursements (ideally backed by broader value-assessment frameworks) must be enhanced.
- ❖ National efforts should be coupled with additional pull support measures in order to reach a scale of return on investment attractive for developers.
- ❖ Substantially progress the dialogue on possible global access, distribution & supply chain mechanisms due to the location of the projected future AMR burden.
- ❖ Further mobilisation of donor-support / coordination options for LMICs/LICs.

“For material progress to happen healthcare systems need to leapfrog to using rapid Dx wherever possible, before using an antibiotic” UK AMR Review 2014¹¹

With many thanks to all those who generously gave their time & insights to this study

The study is available for download from: <https://globalamrhub.org/our-work/studies/market-potential-and-priority-patient-needs/>

For questions or enquiries please contact [Global AMR R&D Hub](#)

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⁹ National Health System Tools to Improve Valuation – Global AMR R&D Hub (globalamrhub.org)

¹⁰ <https://www.value-dx.eu>

¹¹ Review on AMR, Antimicrobial resistance: Tackling a crisis for the health and wealth of nations, 2014