Health technology assessment of point-of-care (PoC) diagnostics for AMR; perspectives and recommendations from an expert advisory panel

Salih F[1], Leonard C[2], Tongio I[3], Wonderly Trainor B[4], Dawoud D[1]

[1]National Institute for Health and Care Excellence, UK
[2]Manchester University NHS Foundation Trust, UK
[3]bioMérieux SA, France
[4]Boston University/CARB-X, USA

Background

It has been estimated that bacterial antimicrobial resistance (AMR) was associated with 4.95 million deaths worldwide in 2019 alone (1). VALUE-Dx is an EU Innovative Medicines Initiative (IMI)-funded project aiming to improve the evidence base for, and access to point-of-care (POC) diagnostics for community-acquired acute respiratory tract infections to improve patient outcomes and facilitate the reduction of AMR. VALUE-Dx is a multidisciplinary consortium, with participation of clinicians, microbiologists, health economists, social scientists, and industry (2). If POC diagnostics are found to be effective in improving patient outcomes and reducing AMR, their uptake would rely on demonstrating their value within health technology assessment (HTA) frameworks which are generally less established for diagnostics compared to pharmacological treatments.

We convened the VALUE-Dx EAP

- An expert advisory panel (EAP) was convened with 12 experts recruited to provide input into VALUE-Dx activities and advice on aspects related to health economics and HTA. The National Institute for Health and Care Excellence (NICE) was the lead for the task of setting up the EAP and organising feedback sessions in collaboration with other consortium partners.
- The EAP was composed of experts with different expertise; clinical, HTA, health economics, regulatory and payers.
- There was flexibility in panel membership that allowed additional guest experts to be invited based on the topics to be discussed and for members to withdraw and new members to be recruited. EAP members were recruited from organisations in various geographical settings (see Figure 1).

We collected feedback from the EAP

- The VALUE-Dx team met with the EAP every 6 months to collect feedback on various topics related to the project.
- HTA of diagnostics, particularly for AMR, was discussed in four meetings between September 2019 and March 2022 and therefore the views of the EAP were impacted by what was seen for diagnostic tests for COVID-19.
- Feedback collected from the meetings was recorded and thematically analysed and key considerations and recommendations for HTA of diagnostics both in general and for AMR were identified.

Perspectives and recommendations of the EAP

- It is important to adopt a formal, standardised approach to the assessment and reimbursement of diagnostics, similar to those in place for pharmacological treatments.
- Assessments of diagnostics for AMR should be carried out in a holistic manner, taking on board the benefit to the health system & society overall as well as the individual.
- When developing HTA submissions for diagnostics for AMR, it is important to prioritise consideration of factors or outcomes based on country-specific policies for AMR, clinical practice, and evidence requirements/frameworks within any given jurisdiction.
- From a European perspective, an EU-wide collaboration to co-ordinate the development, evaluation and implementation of AMR diagnostics is the appropriate approach to tackle AMR, in contrast to the isolated efforts that were carried out for COVID-19 diagnostics.
- The EAP cautioned against the use of overly complex economic models to demonstrate the value of diagnostics, given the limited reliance on health economic models to inform their reimbursement in some European jurisdictions.
- Early transparent dialogue is needed between academia, medical technology diagnostic developers, regulators, HTA bodies, health system payers and implementation experts to achieve the aims of reducing AMR through the use of POC diagnostics.

Learnings from the VALUE-Dx EAP

Expert advisory panels ensure that project outputs are scientifically robust and implementable. These are some learnings from our experience of convening and organising feedback sessions with the VALUE-Dx EAP:

- It is important to establish terms of reference when setting up an expert advisory panel with clear objectives, roles and guidelines for recruitment of and engagement with experts.
- Having a geographically diverse panel with a range of relevant expertise is key to elicit a range of views on project activities and how outputs could be received and implemented in countries of interest.
- For projects spanning more than one year, it is important to support and monitor the continued commitment and availability of panel members to attend meetings and contribute to activities to maximise the value of the panel.

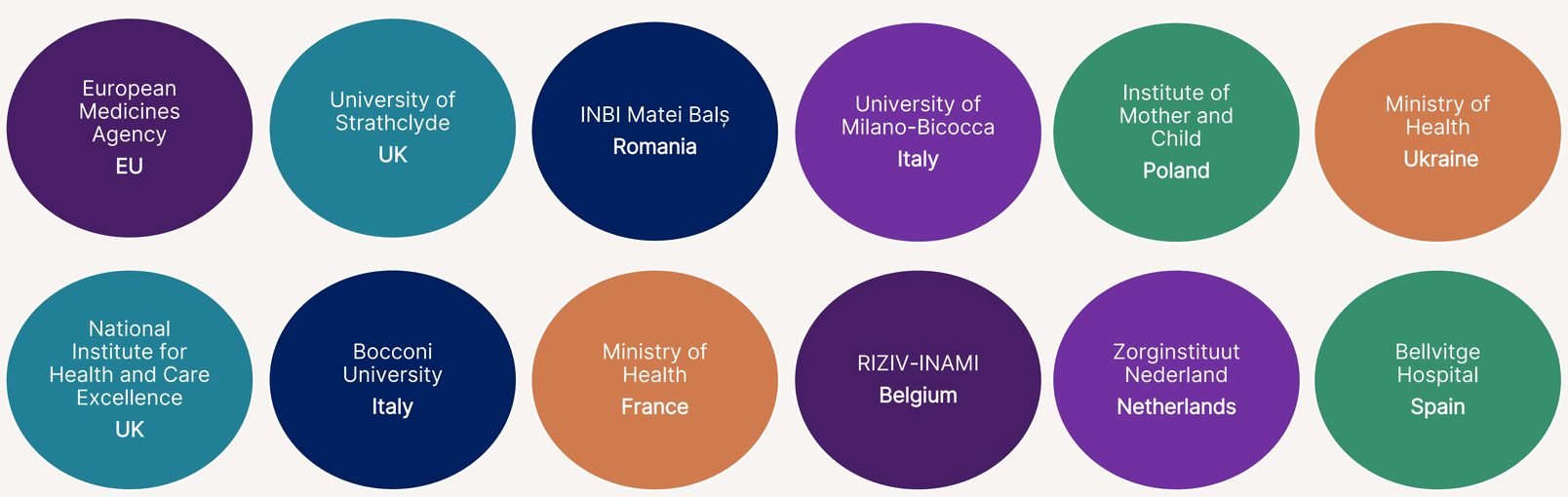


Figure 1. Organisations represented in the VALUE-Dx EAP across the project duration

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References
1. Murray CJL et al. The Lancet.
2. VALUE-Dx https://www.value-dx.eu

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Fatima Salih
Scientific Adviser
National Institute for Health and Care Excellence
Email: Fatima.Salih@nice.org.uk

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