

EAP Working Group

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**Executive summary of Session 1 of the VALUE-Dx Regulatory/HTA/Payer EAP**

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First EAP session

## Meeting overview

The first session of the VALUE-Dx health technology assessment (HTA) and payer Expert Advisory Panel (EAP) was held virtually on 30th September 2020, lasting 3 hours.

There were 11 members of the EAP present in addition to 5 presenters from the VALUE-Dx consortium and 5 session facilitators. A total of 24 observers were present at the meeting.

## Meeting kick-off

Colm Leonard (CL) chaired the session and kicked off the meeting by introducing the EAP session and giving an overview of how the panel would operate using the Zoom Webinar function. He then outlined the agenda and session aims and outline.

## Overview of VALUE-Dx

The VALUE-Dx co-lead, Herman Goossens (HG) gave a presentation to the Panel about VALUE-Dx; vision, objectives, governance, work package (WP) structures and project timelines. HG also gave an update on the progress of the project in terms of the point prevalence audit surveys and their extension due to the COVID-19 pandemic/links to the RECOVER trial, and briefly described the design of the planned clinical trials which will be conducted within VALUE-Dx.

## Questions discussed and feedback received

### Strategic questions and feedback

CL presented an overview of the objectives for Work Package 5 which includes clinical and economic value frameworks and health economics and assessment policy. Jean- Louis Tissier (JLT) then presented a series of questions to the EAP:

1. Do you expect an increased interest in value-based healthcare after the COVID-19 crisis and an acceleration of its implementation by health care systems?
2. What can we learn from successes & failures in implementation of diagnostics in the COVID-19 pandemic to facilitate market entry of in-vitro diagnostics (IVDs) in the non-COVID-19 context (AMR)?
3. What suggestions do you have to accelerate access to cost-effective diagnostics with the potential to reduce AMR (in a safe way while minimising additional burden on industry & healthcare systems)?
4. Do you support a more holistic approach to value assessment of the IVD sector (going beyond the focus of the pharmaceutical sector on “mere patient outcomes” & including additional attributes of value including enablement, transmission, impact on society, system flow etc)?
5. What would be the recommendations for the IVD sector so that a holistic approach would be considered and taken into account?
6. Is an independent HTA process led by an independent authorized body such as NICE in the UK adequate for IVDs?
7. Would a structured, transparent dialogue with manufacturers, academics, regulators, HTA bodies, funders, & the health system from early in product development improve the current situation for IVD assessment?

The EAP discussed the questions posed and provided their opinions. Points of discussion included:

* The COVID pandemic has placed testing and diagnostics in the spotlight with enhanced interest from numerous sectors who previously were not as engaged with this area of healthcare including policy makers, politicians, and the public. It has increased clinical awareness of the need to test and treat to produce optimal patient outcomes. This varies by country/sector due to culture and knowledge and may not fully cover value-based perspectives but more health/medical care aspects. The pandemic has highlighted the importance of looking at how testing can affect population health and individual health. It has also highlighted the threat of infectious diseases and made testing more widely acceptable for the public and clinicians.

There were differing opinions from the EAP on whether this can be leveraged for non-COVID testing or not. For some, there was a feeling that COVID-19 had brought about a clear paradigm shift with testing and treating now being widely accepted. For others, COVID-19 was a national crisis, therefore systems and changes made may only be in place in this extraordinary situation.

* COVID-19 has resulted in clinical practice changes that will become embedded such as the use of telemedicine. When considering non-COVID 19 tests, this should be factored into their implementation with potential different clinical roles and pathways.
* Stakeholders (developers/MedTech/regulators and HTA bodies/payers) need to collaborate early and more widely.
* Learnings from the COVID-19 pandemic include new and exceptional accelerated assessment and reimbursement pathways and highlight the need for the whole cost /benefit of the patient pathway to be taken into account.
* The EAP agreed that a holistic approach was needed for the IVD sector, and it was noted that in general, health economics takes this into account. The impact and value for the population in comparison to the individual was highlighted as well as organisational impact on healthcare. The complexity and differing data sources, and the need to prioritise the selection of factors/outcomes by policy requirements and by jurisdiction were noted to be important to keep assessment realistic in practice.
* There was agreement that dialogues across stakeholder groups would be critical to advance the field, with national HTAs playing an important role; examples of this were provided of networks that have begun to be assembled for innovative technologies.

### Operational questions and feedback

Sarah Tokin Crine (STC) presented the following questions to the EAP relating to interviews with stakeholders (task 5.7) to explore views and experiences of introducing new diagnostic tests in European community care to manage respiratory tract infections, particularly in response to the ongoing COVID pandemic:

1. How can we best recruit these stakeholders across countries?
2. Which organisations should we contact?
3. Which existing networks could we utilise?
4. Which countries should we include?
5. What key questions do you think should we ask about the impact of introducing COVID testing?
6. What is most important to know about implementation of COVID testing?
7. What else do we want to know about how to get novel diagnostics into practice?

The EAP provided suggestions for several agencies, organisations, and groups to consider. These included:

**Organisation types:** Patient organisations, insurance agencies, health care practitioners’ organisations and bodies [i.e. Royal College of GPs (UK)], Manufacturer associations [Confindustria Dispositivi Medici (Italy)], SNITEM (National Union of the Medical Technology Industry) , the association of manufacturers of medical devices that have a IVD section), Global and European networks (WHO, European Centre for Disease Prevention and Control), National clinical guideline developers (Netherlands), Specialist groups that are investigating antimicrobial resistance (AMR) such as the Dutch Working Party on Antibiotic Policy.

**Country specific example for suggested organisations**:

Government departments (Health): Devolved (UK) and regional bodies (Italy, Spain), National MoH across most EU countries, Institute Superior di Sanità (Italy) the leading technical-scientific body of the Italian National Health Service and Department of Devices & Pharma at the MoH.

**Payers:** National departments of health and national HTA bodies and national health insurers: Including HAS (France), Katy Harrison (KH) noted that she can provide full list of national EU HTA bodies, regulatory agencies and payer bodies and work done by the European Network for HTA (EUnetHTA) that lists all the organisations that assess medical technologies, including devices.

They also stated that areas to consider asking about would be whether there has been an increase in the awareness and understanding of key metrics commonly used in diagnostics (e.g., positive predictive value, negative predictive value, sensitivity, and specificity) and if understanding and framing risk was an important factor.

Jorge Villacian (JV) provided an overview of WP1 objectives. This was followed by a series of questions relating to the creation of a technical roadmap to help diagnostic innovators, funders, companies, and research institutions prioritize investment decisions in the field of community-acquired acute respiratory tract infections diagnostics. Panel members were asked to respond to the questions through the online polling application, Slido®.

Three rounds of voting were held on the priority outputs from an earlier Road mapping workshop held by Task 1.3. All EAP attendees were asked to select items that they considered relevant in the medium to long term (5-10 years) for development and implementation of diagnostics for respiratory tract infections in community healthcare. The top 3 priority outputs based on the EAP responses to each voting round were as follows:

* **Future drivers, trends and needs (Round 1):**
1. Individualise healthcare
2. Increasing rate of AMR
3. Antibiotic use
* **Research and development (Round 2):**
1. Innovative pricing and reimbursement policies
2. Rapid diagnostic tests
3. Novel methods, development, broader applications for HTA and regulatory diagnostics in practice:
* **Enablers, capabilities, and resources (Round 3):**
1. Economic modelling for impact assessments
2. Adequate pricing ad reimbursement strategies across countries
3. Partnerships between government, industry, academia, public-private partnerships

There were three further rounds for the EAP to vote on the relative importance of topics and ideas collected during the discussions in the current session, for the next 5-10 years (with each attendee having 3 votes). The top 3 priority topics based on the EAP responses to each voting round were as follows:

* **Future drivers, trends and needs rating based on topics discussed (Round 4):**
1. Infectious diseases seen by society as a real threat due to COVID-19
2. Value of testing is seen in society due to COVID-19
3. a. Desire to have more value-based healthcare

 b. Evolving healthcare systems in response to COVID-19

* **Research and development rating based on topics discussed (Round 5):**
1. Establish broad dialogue between stakeholders along and across the HTA process
2. Establish reimbursement of diagnostics
3. Establish HTA processed to facilitate introduction of diagnostics
* **Enablers, capabilities, and resources based on topics discussed (Round 6):**
1. Well-established resources for value-based healthcare
2. Broader collaboration between EU members (agreement on safety and effectiveness definitions)
3. Education of the public and clinicians

## Closing

CL thanked all Panellists and presenters for their participation in the first Panel session and for NICE staff for organising and facilitating the session.



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