Diagnostic Advisory Group - Point of Care testing for patients with acute respiratory symptoms – ARI Hubs

The Diagnostic Advisory Group is made up of stakeholders and industry and is intended to be a forum for NHS and industry to work together to deliver solutions to real challenges and aim for tangible benefits across the system. The aim is to improve performance and develop new technology.

At the meeting, David Wathey, Deputy Director of the Department of Health's Medtech Directorate reminded the attendees of the content of the Strategy.

- Performance
- Equipment
- Workforce
- Data
- Network Maturity

The Medtech team can be contacted via dxteam@dhsc.gov.uk

DHSC are hoping to take time in the autumn to give voice to their views in more detail and thinking about what lies ahead.

BIVDA members are invited to provide feedback on their thoughts of what should be contained in a future strategy to Helen. BIVDA is also developing our next strategic plan and over the coming months, members and stakeholders will be invited to input into this.

The DIAG meeting is chaired by Rhydian Phillips, who provided an overview of the achievements to date with current approval of over 170 Community Diagnostics Hubs with a further announcement due in the next few weeks.

The meeting scope focuses very much on the future of diagnostics and looking ahead at what are the next priorities to address, and to continually review what aspects of the current strategy need to be retained and what the future trends and opportunities are.

Rhydian discussed the challenges across the system, particularly in relation to imaging, improving delivery performance in histopathology and expanding the use of POCT especially around Emergency Departments and management of chronic diseases.

The meeting then split into breakout sessions which addressed a set of problem statements for each challenge.

POCT for ARI: Problem Statement.

To promote the widespread use of POCT devices, NHS England needs device agnostic evidence demonstrating:

- *Clinical cost-effectiveness*
- *Where on the pathway POCT devices can deliver most benefit*
- *Details of any practice changes that may be needed.*

- *Can we work together to build this evidence base, focusing initially on POCT for respiratory conditions?*

- *Is there an opportunity to make existing evidence device agnostic?*

- *Considering alternative sources of research support and designed to be delivered in a time/resource challenged environment.*

In advance of the DIAG meeting on 27th July, BIVDA held an internal meeting on 26th July 2023 to which members of the Infectious Diseases WP and Near Patient Testing WP were invited to attend.

A summary of the meeting and responses for follow up were provided to NHSE which incorporated the views of members on this topic and existing evidence available. BIVDA passed all members details to NHSE who provided a response or statement at the pre-meet.

In essence, the discussion and feedback stated that an ARI Pathway definition is required that includes all the RTIs being assessed, and this should be provided to all ARI hubs with dedicated staff. The triage model in the pre-read was not an ARI Pathway and allowed too much variation. A single study protocol should be specified and an emphasis on the funding and resource for POCT training required. Members agreed that a responsible person within the Trust/ hospital for the POCT (lab champion) to ensure devices all running correctly would be effective. The discussion at the pre-meet included the view that cost effectiveness must include an AMR value adjustment e.g. each patient did not prescribe an Abx that might have been, so preventing risk of downstream AMR issues.

Unfortunately, NHSE attempted to set up pilots which were funded during the winter of 22/23 which were not taken up and therefore the opportunity to gather specific evidence in this manner has passed. They are now looking at ways to collaborate with industry to gather the necessary evidence from existing data to answer their questions. This will then be put together into NHS guidance for ICBs and community settings. The intention for this evidence to formulate the centralised guidance is the reason behind the agnostic requirements. NHS England are clear that market access for suppliers, localised procurement and innovative and suitable solutions are not affected by bias resulting from technology specific evidence being promoted. The evidence needs to demonstrate the procedural and system benefits and not the technology performance data.

This is something that BIVDA strongly advocates and has argued against single source roll outs overall. However, if the guidance can use evidence that may not be agnostic to demonstrate the effectiveness of this POCT intervention, and the risk of giving undue advantage to any one supplier is mitigated by the type and quality of evidence being used, it is not necessary to generalise or be too strict on whether the technology is identifiable from the data.

The context in which this group and subsequent workstream is form the basis that Acute Respiratory Infections are one of the largest causes of emergency department (ED) attendances and general practice consultations. In 21/22, approx. 74% of 1.14million ARI attendances to ED were not admitted, indicating a large proportion could have been managed in the community.

A surge in acute respiratory infection (ARI) activity across all healthcare settings for winter 22/23 was predicted, challenging the delivery of primary, emergency and elective care. To use ED and ambulance capacity effectively, increased capacity for face-to-face assessment of ARI patients in the community was needed.

In Autumn 2022, NHS England provided ARI hub guidance, support and funding, to integrated care systems (ICSs) to roll-out dedicated ARI hubs nationally to manage and respond to these pressures more effectively. ARI hubs were established by primary care teams to support patients with urgent clinical needs by providing same day, face-to-face access to appointments for adults and children.

363 ARI Hubs provided 729,808 appointments between Dec 22 –March 23, supporting local systems to manage ARI demand over winter and help prevent hospital attendance.

In the context of Point of Care Testing, clinical assessment can confirm the most likely reason for the presentation is infection, without diagnostic services, ARI Hubs are limited in their ability to offer further management. By combining a clinical assessment with identification of the potential infecting agent and CRP testing, patients could be triaged to the correct service and managed more efficiently.

POCT could facilitate appropriate antibiotic prescription practices, initiation of treatment for influenza and COVID for high-risk groups and advice on self-management.

Integration can also be developed with services such as COVID oximetry@home and Virtual Wards allowing more patients to be cared for at home.

The problem is that whilst there has been a significant increase in POCT options with good performance data that can match lab-based tests, the uptake of these tests in community settings is low and clinical utilisation has not improved across the system. NHS England believe that this is due to there being gaps in the evidence. This includes input from frontline clinicians on how these work in a community setting, how these tests integrate into the patient pathway, how this maximises clinical impact for patients and what the tangible cost/benefits are.

Research and evaluation in ARI Hubs is challenged by intermittent and short term funding, services set up with short notice at times of crisis and the workforce often made up of locums. The services are stretched and the time to do research and evaluation is not allowed for in clinic timings. The opportunities for research and evaluation in ARI Hubs are great, with high patient volumes for a single disease area, a broad geographical spread, with patients with co-morbidities, and a generally well population, therefore there is a potential for high impact across the system in terms of pathways, patient experiences and relieving pressure on acute services.

The purpose of the breakout session on this topic was to develop a different approach to establish research or evaluations which can be aligned to the needs of clinicians and patients.

The questions that NHSE want to answer are:

- Which patient groups to target.
- Does testing change diagnostic or management outcomes.
- Antibiotic prescription patterns with POCT.
- Populations where POCT provides greatest impact.
- How a combined respiratory viral and CRP testing model would impact outcomes.
- Including additional healthcare appointments, ED attendance, mortality.
- Qualitative data to understand clinicians' and patients' views on POCT.
- Patient acceptability and onward health seeking behaviours.
- Qualitative data understand enablers and obstacles for broader uptake of POCT.
- Health economic evaluation.

These gaps leave a lack of information on the most appropriate way to improve patient outcomes using POCT outside the acute setting. Until this is resolved, there will be poor uptake of POCT and patients will not have access to new and improved technology in this area. The ARI hubs' problems have wider relevance to POCT in other community settings, where similar poor uptake has also had limited progress.

During the breakout session, NIHR said that the data they already have from hubs doesn't identify whether they alter the down-stream treatment pathway or whether these are the same, but they just identify the severity of infections. It isn't really known how POCT impacts the ongoing patient pathway.

What the ideal diagnostic would look like was discussed, and it is recognised that not one size fits all, and what is the biggest burdened patient group, as this already affects the cost effectiveness assessment.

It is not clear how the work already undertaken by ARI hubs can be reviewed to provide evidence.

BIVDA focused the conversation onto establishing what the evidence is to be used for, in terms of addressing resistance or to demonstrate that investment will be beneficial which would be presented differently. Some evidence from BIVDA members has been provided already and should be placed into a framework which matches the list of evidence that was identified during the pilot in winter 2022/2023 which didn't materialise. Then the gaps can be seen, and further evidence generated by industry or partners when the extent of the gaps is known.

NHSE stated that it is less about push back and more about take up. They want to be able to say to service providers like virtual wards that certain tests should be taken up, and what the benefit would be for flow and workforce and patient benefits.

The problem could be looked at in two parts. The first, with data that isn't recognised and assembled in the format that can be used for the guidance that NHSE wants to issue. The second includes questions like what good looks like and the requirement for more forward planning of future data generation to show a successful intervention in this area. This is generally a systemic challenge and needs to increase the appetite to address this specific challenge. It is always unpopular to defund an acute trust. NHSE is keen to see ICBs evolve to take in strategic thinking and to understand where they can invest in community care to take the pressure off other settings. There is a clear difference between clinical evidence and financial evidence, and this is what is needed to be determined.

The evidence that is needed must reflect the clinical area which the POCT is to be used and needs to follow existing processes. If a process needs to be changed, NHSE and the service provider in any community setting needs to understand the motivations and model behind it.

This means that the evidence now also needs to answer whether POCT changes clinical management, if it does, what are the patient groups that it will affect the most and what are the onward clinical pathways of these patients expected to be. The effects on morbidity and mortality also need to be identified.

In conclusion, there was agreement that the group needed to focus on how to build evidence to scale POCT in a way to deliver NHS benefits for patients and reduce pressures across the system.

A key challenge for the evidence is to ensure moving away from being product specific and test level towards showing patient benefit and to convince the clinical community of the quality of testing and to adapt to the setting that it would be used. This needs to show how POCT can be used and how it demonstrates that its use is beneficial and a cost benefit and whether it affects the management of patients and the resulting pathway.

NHS England wants to provide guidance to the NHS in a similar manner to that for virtual wards in combination to improve access to rapid results and allow antibiotic stewardship and reduce the pressure on acute care.

NHS England will further review the demand signalling work through the AAC and with Robert Annan and his team in collaboration with the NIHR Innovation Observatory and NICE, who have carried out a comprehensive horizon scan to examine potential infection diagnostic innovations. Alongside this work, his team has also mapped the clinical pathway for urinary tract infections, sepsis and lower respiratory tract infections to determine the challenging points where innovations were most required in the NHS. Some BIVDA members were involved with these mapping exercises through the Infectious Disease Working Party over the past months. Together, these two pieces of work demonstrate a need to clearly define clinical need to inform diagnostic development and for strengthening the dialogue between the NHS and industry partners.

NHS England will review and distribute the questions that the evidence needs to answer, and BIVDA will work with NHSE and members to go through the known available evidence to look at how to re-shape it to make the case for POCT without giving undue advantage to any product. The procurement and funding of this will be at ICB level.

The next steps are to assemble the information into a coherent record of common themes and specifics and to send materials from the groups. It is anticipated that task and finish groups will be created and bring other stakeholders such as commercial and procurement.