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Melanie **Hoste**, Sarah **Tonkin-Crine**, Sibyl **Anthierens**

Description of key facilitators and barriers to adoption of CA-ARTI-Dx and policy and practice recommendations for European community care settings

Deliverable 5.8

VALUE-Dx

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1 Abbreviations

AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
COVID-19	Coronavirus disease 2019
CRP	C-Reactive protein
EAP	Expert Advisory Panel
EMA	European Medicines Agency
ERS	European Respiratory Society
EU	European Union
GP	General practice
HTA	Health technology assessment
IDEA	Implementing new Diagnostics in European community care to Advise management of respiratory infections: a qualitative study
NICE	National Institute of Health and Care Excellence
POC	Point-of-care
POCT	Point-of-care test
RIZIV	Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (National Institute for Health and Disability Insurance)
RTI	Respiratory tract infection
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
VALUE-Dx	Value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
WHO	World Health Organisation
WP	Work Package

2 Executive summary

This report compiles the results and proposes recommendations derived from the **IDEA** *(Implementing new Diagnostics in European community healthcare to Advise on management of respiratory infections: a qualitative study)* study developed as part of Work Package (WP) 5 (Economic Value, Policies and Innovative Funding Models) in VALUE-Dx. VALUE-Dx focusses on generating evidence on the medical, economic, and public health value of diagnostics, specifically point-of-care tests (POCTs) for respiratory tract infections (RTIs), in treating antimicrobial resistance (AMR) in community care settings.

The aim of this study comprised of primary and secondary objectives:

1| **Primary objective:** To explore stakeholders' views and experiences of supporting the adoption of new diagnostic tests in European community care to manage community acquired respiratory tract infections.

2| **Secondary objectives:**

a. To identify the barriers and facilitators to the adoption of new diagnostics in European community care.
b. To understand how leaders from industry, healthcare organisations and other groups work together to support the implementation of new diagnostics.
c. To explore how SARS-CoV-2 diagnostic tests were implemented in European primary care settings during the COVID-19 pandemic to identify lessons which can be learnt for AMS diagnostics.

Stakeholders, such as policy-makers, regulators, the diagnostic industry, and scientific associations, were recruited using purposive sampling and snowballing. Between March 2021 and May 2022, semi-structured interviews were conducted online with stakeholders in Belgium, the UK, and from European Union (EU) -level organisations.

Twenty-six stakeholders participated: 11 from EU organisations, 7 from Belgium, and 8 from the UK. Stakeholders reported that a combination of top-down and bottom-up approaches are optimal for implementation of POCTs. Stakeholders stated that engaging with clinicians to act as champions for POCTs helps raise awareness of tests whilst also generating new evidence on how tests are used. Whilst acknowledging the potential of POCTs for improving patient outcomes and impacting antibiotic prescribing behaviour, some raised concerns on how tests would be used and wanted to see national data on effectiveness and implementation. Coronavirus disease 2019 (COVID-19) catalysed the use of tests in community care, but stakeholders were pessimistic that processes for approving diagnostics during the pandemic would be replicated in the future.

3 Introduction

The public health threat posed by AMR requires communities to use antibiotics more wisely and efficiently to preserve their effectiveness. A more personalised approach to antibiotic prescribing, such as the use of POCTs, better targets antibiotics to those individuals who are likely to benefit, and directs alternative, non-antibiotic treatments to those who are unlikely to benefit, is now a matter of considerable urgency.

Innovative POCTs could transform clinical care, especially in community care settings where the majority of antibiotics are prescribed, by reducing uncertainty about potential benefit antibiotics may offer to individuals. An example is point-of-care (POC) c-reactive protein (CRP) testing which has shown to safely reduce antibiotic prescribing in general practice for acute cough across several European countries (1). However, pre-2020 POCTs have only been used at scale in a few European countries, such as Norway, Sweden, and the Netherlands, to inform antibiotic prescribing decisions in community care settings for common RTIs despite recommendations from the European Respiratory Society (ERS) and the National Institute of Health and Care Excellence (NICE). This is a result of gaps in evidence on their potential medical and health-economic value, the complexity of introducting novel tests into existing care pathways, and healthcare funding models.

As a result of the COVID-19 pandemic, POCTs to identify COVID-19 cases and guide management of patients in the community became commonplace. Europe countries responded to WHO and EU advice on testing and provided community COVID-19 testing for at least those patients with specific COVID-19 symptoms. This revolution in provision of community care services has potential for learning how to utilise and implement POCTs for respiratory tract infections.

Despite the enticing opportunities for health, social, and economic gain, POCTs for use in community care settings, in general, have been inadequately evaluated. Clinical studies have almost exclusively focused only on the analytical performance of tests and have omitted other important value-determinants such as legal-regulatory barriers (e.g. approvals) as well as psychosocial, ethical, and organisational (e.g. uptake) barriers and facilitators all of which require a far deeper understanding to better inform the development of bespoke solutions (2,3). Qualitative research can produce a in-depth understanding of the perceived barriers and facilitators to the adoption of POC diagnostics and their sustained use in European community care settings.

Previous qualitative work exploring the use of diagnostics in primary care has focussed mainly on the views of healthcare professionals, as the key group who use diagnostics, and some studies have also considered patient views (4-7). Research which has explored views on the implementation of diagnostics to change healthcare professional practice has stressed the importance of guidelines which support use of diagnostics, management level encouragement for professionals to adopt change, financial support (reimbursing the new of diagnostics) and diagnostics which fit well with existing workflows (4,6,7). The views of other stakeholders, including those who influence primary care practice through guidelines, regulations and policies, have been explored very little in terms of their influence on antibiotic stewardship (7,8). As such we aim to explore the views of wider

stakeholder groups, beyond healthcare professionals and patients, to identify how the adoption of diagnostics in European community care can be supported at organisation and system levels.

4 Methods

4.1 Study design and participants

Potential participants were identified in a stakeholder mapping exercise, which involved identifying individuals who had expertise relevant to European community care and diagnostics and/or antibiotic stewardship dictated by their role and affiliation. We used information about relevant organisations available in the public domain and identified individuals through the existing network of the VALUE-Dx consortium including WP5 colleagues and the Expert Advisory Panel (EAP) from WP 5.1.

Stakeholders included professionals working in roles related to delivery of care in European community care settings, including guideline developers, policy-makers, the diagnostic industry, reimbursement agencies, regulators, and scientific associations.

4.2 Participant recruitment and interviews

Using purposeful and snowball sampling, we aimed to identify different types of stakeholders, with different roles and from different organisations, in European countries.

Potential participants were invited to participate by e-mail and were provided with a participant information sheet (Appendix 1). We used a snowball technique to identify other eligible individuals through the networks of those participants interviewed.

Interviews were conducted online on Microsoft Teams, following a semi-structured topic guide (Appendix 2) developed by the principal investigators of the IDEA study, with participants giving informed verbal consent at the start of interview. Interviews were conducted in English, audio-recorded, and transcribed verbatim.

4.3 Data analysis

Transcripts were anonymised and uploaded into NVivo 12 for analysis. They were read line-by-line and analysed using thematic analysis (20). Detailed codes were first created inductively for all EU participants and grouped to create sub-categories and categories. These sub-categories and categories were then discussed within the core team and amended accordingly creating an initial data-driven framework. Deductive analysis of the Belgium and the UK transcripts into this framework followed with constant reviews made across the sub-categories and categories to ensure rigor and that they reflected the data in later transcripts. Sub-themes and themes were developed after all transcripts had

been analysed and these were agreed upon between the members of the core team. Findings were discussed during WP5 meetings and with the VALUE-Dx consortium during the annual consortium meeting in September 2022.

5 Results

Initially, stakeholders from EU organisations and from 4 countries (Belgium, the UK, the Netherlands, and Sweden) were to be recruited but we experienced difficulties contacting potential participants in Sweden and the Netherlands as a result of individuals being unavailable due to the COVID-19 pandemic. We instead confined our recruitment to the EU, Belgium, and the UK where the team had stronger existing networks and could approach more potential participants.

A total of 26 participants were recruited between March 2021 and May 2022. Interviews lasted between 24 minutes and 70 minutes (mean 51 minutes). Table 1 displays the stakeholder groups recruited in the EU, Belgium, and the UK.

Table 1. Stakeholder groups of participants

	EU	Belgium	UK
Policy-maker (e.g. Head of directorate for a reimbursement body; Member of a national guideline-development team; Coordinator of an antibiotic policy committee)	2	5	5
Scientific association (e.g. Lead for diagnostics in a government funding body; Member of a pharmacy association; Medical director of a GP association)	5	2	2
Diagnostic industry (e.g. Chief scientific officer; Market access director)	4	0	1

Participants reported on facilitators and barriers that exist on a policy-level, in terms of POCT technology, and in delivery of primary care. They also shared their views on the ways the COVID-19 pandemic might have impacted the future of implementing novel diagnostics. Recommendations for policies and practices tailored for policy-makers and diagnostic developers are summarised in the discussion.

5.1 Policy-level influences

All participants expressed the importance of having sufficient financial resources to successfully implement POCTs in community care settings. Due to limited funding in national health systems, participants reported that diagnostics are in competition with other innovations, in other therapeutic areas for instance, and funding can be disparate

across regions and countries depending on the priorities of governments and their economy.

'I think in certain markets, the funding is not clearly there. And not in many cases, there are some markets that have funding where it's not prioritised so it's for the region or the community or whatever to prioritise the needs of that amount of money that they have to spend. And other markets, there just isn't enough money in the system, I guess, sometimes to fund all the innovations they need. Diagnostics are competing with all kinds of other innovations, of course every spectrum of the health care system. So if it's not clearly outlined that this is an area for focus, then the people deciding how to spend that money often don't prioritise the diagnostics.' P2, Industry, EU

Some EU participants noted that Participants in Belgium and the UK reported that the lack of reimbursement strategies means that POCTs are not adopted by clinicians in community care settings. The ways in which the community care system is currently set up in Belgium and the UK, means that there is no straightforward mechanism where POCTs can easily be embedded into the system. Some UK participants reported that AMR was not seen to impact primary care directly and subsequently felt that clinicians would not want to accept the costs of implementing POCTs for the purpose of tackling AMR. They therefore believed that bulk purchasing of POCTs and procurement on a national level, with delivery to primary care practices could alleviate some of these challenges. In Belgium, primary care is operated mainly as a fee-for-service which participants felt was not ideal for reimbursing clinicians and patients for POCTs. Some suggested that a lump sum fee would be best for practices in Belgium that would include the cost of performing a test. A lump sum fee could include other tests aside from POCTs to help clinicians make a diagnosis.

'General practices (GPs) [in the UK] get a per-capita payment for the patients and their practice, and it's quite a complicated payment system... But they get various bonus payments if they do screening and other things, for diseases and health check-ups, and deliver targets in terms of people being considered for various treatments. But there's no sort of mechanism that says: Aha! Here's the funding route for new point-of-care pathways in primary care.' P19, Policy-maker, UK

'What we are proposing for this kind of testing is that you're paying a lump sum. So maybe it's €26 or €27... So [the patient] pay[s] a certain amount, but everything is included... If you need a fee for every test, in the end, you will have to pay a big amount, but for the same result.' P16, Policy-maker, Belgium

Getting novel technology into the market and approved for use by healthcare systems in Europe is a lengthy and complicated process. Participants pointed out that usually, processes are not straightforward with countries in the EU having different kinds of

criteria that need to be addressed and health technology assessments (HTAs), making it time-consuming and expensive for the industry. Industry participants stated that because healthcare is decentralised in the EU, countries have to be convinced on a national level to adopt diagnostics. Some EU and UK participants reported that current regulations are likely obsolete and need to be changed to reflect the changing diagnostic market. They pointed to Europe's CE-marking for in vitro diagnostics, for instance, as an insufficient standard for assessing diagnostics, compared to the United States which has stricter requirements for clinical performance.

'People also want to talk about where we are with diagnostics and there is nobody from Europe that is able to cover that... Because we don't have a central body. You know it's still a national level and still down with the CE-mark so it's not often an elaborated approach towards testing the performance of the diagnostics.' P7, Policy-maker, EU

'I think the real barrier for us is, as part of the notifiable body – so to get it to CE mark or CA-marking in the future, what needs to happen is that there needs to be a technical evaluation at that stage before. Because they get a CE-mark in this country on self-declaration. That is not good enough.' P26, Policy-maker, UK

EU stakeholders also noted that the inclusion of POCTs in national health guidelines would encourage primary care practices to adopt POCTs and use them before prescribing antibiotics to patients. In addition, stakeholders in Belgium pointed out that if clinicians had a clear framework illustrating the conditions under which POCTs should be used, it would help facilitate their implementation. They suggested that carrying out a HTA may provide recommendations on how POCTs should be used.

'I mean you have this respiratory tract infection testing community by convincing member states to develop regulations that sets the mandatory diagnostic test before prescribing certain antibiotics.' P1, Industry, EU

'The first point would be an analysis. So to have what we call a healthcare assessment study, to give some recommendations on how they [POCTs] should be used, in which conditions, which tests to be used, what are the conditions to be respected to get a reimbursement, for instance.' P13, Policy-maker, Belgium

Stakeholders such as HTA bodies, regulatory and funding bodies, and scientific associations are needed to cooperate in order to implement POCTs in community care. Many participants noted that having these stakeholders engaged and reaching a consensus on how to implement POCTs is crucial to efficiently implement POCTs. However, this is still a challenge primarily for technology developers as it is first, difficult to physically gather stakeholders together and second, to reach an agreement on

implementing POCTs. Some stated that even engaging with key opinion leaders quickly is a barrier. Moreover, there are still disagreements and uncertainty amongst stakeholders on the extent to which POCTs can be beneficial to the management of patients in community care settings because some do not see the value in using them.

'There is one part of the scientific community that is convinced that a new test for instance is really the solution and they see a value in it. And then you have another part of the community that doesn't see that. You're not able to create a consensus there... You even have tests that have been adopted and that have gained guideline endorsement but at the end of the day are not really used.' P3, Industry, EU

Interestingly, participants from Belgium suggested that politics may have an influence over implementation. They illustrated that as Belgium is divided into communities that have authority over healthcare including prevention measures, if POCTs are classified as such, it becomes a political discussion over responsibilities and finances as it falls into the jurisdiction of these communities.

'[In Belgium] You have a federal organisation and federal healthcare, but you also have the communities. So the French-speaking parts, Dutch-speaking parts, and the federated states, that have responsibilities in terms of healthcare. Also, they have the responsibility and the accountability for everything which is prevention... So if you consider diagnostics as a part, rather a part of prevention than a part of therapy, especially if we're talking about screening... It might become political in that, well, this might become a political discussion over who is responsible for it and who should pay for what. Who should decide: 'What types do we choose? Who pays the bill?'' P14, Policy-maker, Belgium

Box 1. Key facilitators and barriers at policy-level

Facilitators

- Robust and cost-neutral reimbursement policies where the burden of cost does not fall on clinicians and patients
- POCTs mentioned in national health guidelines to encourage adoption

Barriers

- POCTs deprioritised as in competition with other innovations in healthcare
- Disparate and limited funding for POCTs across countries and regions in Europe
- POCTs cannot easily be embedded in some existing national reimbursement systems
- Lack of legal frameworks for POCTs in community care that encompasses quality control, reimbursement, and guidance on how POCTs can be used
- Complex regulatory processes and separate HTAs asked for by nations which are time-consuming and expensive for diagnostic developers to navigate
- Current EU regulations on in vitro diagnostics are outdated

- Some EU countries do not mention POCTs in national health guidelines
- Challenging for diagnostic industry to get consensus amongst relevant stakeholders about how POCTs should be implementedwhen seeking consensus
- POCT adoption influenced by politics in some countries adding further complications to implementation

5.2 POCT technology

Stakeholders highlighted aspects of POCT technology such as accuracy, performance, and efficiency as crucial features to ensure they are adopted. However, some EU-level participants, such as regulators, explained that POCT technology may still need further improvements before they can be widely adopted with concerns behind their usability and precision in comparison to diagnostics for COVID-19.

'I do believe that the companies still have a way to go, with the exception of COVID-19 where we're seeing a lot of momentum and supply to actually develop more, so easier to use, faster and more precise diagnostic tools that the community can use.' P6, Industry, EU

There were mixed opinions across stakeholders on the clinical utility of POCTs with some believing that more 'real world' (e.g. non-trial) evidence is needed to demonstrate clinical utility. Belgian and UK participants also stressed the importance of country-specific data which they argued was currently lacking. They pointed to differences between different healthcare systems as existing studies, on cost-effectiveness for example, may not be relevant for their own countries.

'The National Institute for Health and Care Excellence (NICE) committees would often worry if evidence was just from the US, or evidence from China or Russia. There can be major differences in how the health system work... those costs and the way the system operates in the US isn't necessarily reflective of UK practice.' P19, Policy-maker, UK

Moreover, some participants highlighted difficulties in demonstrating cost-effectiveness of POCTs and savings in healthcare costs in relation to AMR compared to treatments where a more direct impact can be seen. They feared that other less costly strategies to reduce antibiotic prescribing have not been extensively adopted in community care and could be focussed on before turning to POC diagnostics.

'But I think my concern mainly has to do with, like, our diagnostic test, the strategy to do that, as there might be other strategies to antibiotic prescription as well, which do not

come with barriers that you do have for testing, like, who is going to pay for the equipment, who is going to pay for the test?' P12, Policy-maker, Belgium

Interestingly, some participants in Belgium and the UK felt uncertain in how POCTs would be used in healthcare settings and were concerned with potential overuse and underuse of POCTs. Some argued that they would not be used in practices if they are too expensive. UK participants believed that if they are incentivised, it may lead to overuse.

'We would want to incentivise GPs to use the test. But then we'd run the risk of over testing... But the question remains open as to what is the right proportion of patients that should have a diagnostic test and there's no clear answer to that question.' P24, Policy-maker, UK

Other stakeholders stated that even if tests are used, test results may be ignored, or patients may still request antibiotics meaning tests have limited impact.

'We have to improve the use of negative results. So if the test is negative, and you trust the test [result], we [have to] interrupt the antibiotic therapy. And this happens very rarely. This is the problem.' P4, Scientific Association, EU

'I have to make a judgment on: 'Do they need antibiotics now?' Currently, if I send a CRP test that has to go off to the laboratory, and then I might not get it back till later that day or the next day, for an outpatient appointment ... But even if I had a point-of-care CRP test in the clinic, it interferes with the way that clinic runs, because I can't ... You know, it's easier for me just to give a patient a prescription...' P19, Policy-maker, UK

'Patients go to the GP expecting something, and this is often why GPs prescribe antibiotics because they're pushed to do something rather than wait.' P2, Industry, EU

Box 2. Key barriers inPOCT technology

- POCTs may need further development on efficiency and performance before they can be implemented
- Lack of national data on cost-effectiveness
- Concerns over the improper use of POCTs (overuse and underuse), raising doubts on the potential impact of POCTs
- POCTs will not reduce diagnostic uncertainty if clinicians don't trust test results. POCTs may need to be implemented as part of a multi-faceted approach to changing prescribing and be insufficient alone.

- Additional contextual and national evidence that establishes how POCTs are used and their impact on prescribing is wanted.

5.3 Delivery of primary care

Stakeholders agreed that, in general, implementing POCTs in primary care involves reorganising the way practices are run. Stakeholders highlighted that even identifying a healthcare professional who would be able to conduct POCTs can be challenging in a context with limited staff and staff time. They highlighted that the introduction of POCTs would likely complicate workflow in practices and therefore, considerations may be needed towards restructuring which can take time.

'...the way somebody runs their primary care practice. If they've got a new patient in the door every ten minutes you know, there are some logistics around POCTs that they need a nurse to deliver the test, and then that nurse then has to feed back the result to the GP to say: 'Oh, it's 150. Do you want to give an antibiotic?' And it interferes potentially with the flow.' P19, Policy-maker, UK

In addition, some stakeholders have stated that POCT equipment may take up space in practices and could potentially complicate consultations if POCTs are located outside of the consultation room.

'...but you have to perform the test yourself, and you're confronted with a machine which you don't know, which may seem, although it is quick, which may seem complicated to perform, and you need to get out of your consultation room, let's say, to go to a room where everyone can have access to the machine, it may complicate your consultation.' P17, Policy-maker, Belgium

Other stakeholders raised the issue of consultation length and whether POCTs fit within this time. As it takes time to perform the test and wait for the results, reorganisation of practices needs to take place to accommodate POCTs within and around consultations.

'Antibiotics are very cheap. I mean you just need to put the name of the drug on the paper, sign, deliver it to the pharmacy or to the hospital and get the drug. It's very easy. The test is different. I mean you need to have a machine. You need to have a test in your office. You need to spend time. You need to register the results in the registry. I mean, or in the clinical profile of the patient. So it's nothing comparable.' P1, Industry, EU

If POCTs are to be implemented in community care at scale, some EU-stakeholders believed that laboratories need to be involved. Stakeholders stated that reference labs

are important to ensure the quality of POCTs and to validate results coming from the community which may create additional barriers in organising workflows.

'So if you perform a test in primary care you want to perform the test outside of the laboratory, then in one way or another the test needs to be validated. So microbiologists will ask for the results, getting some samples to do some frequent review and double check the sensitivity and the specificity of these tests... so this is creating more barriers.... creating more changes in management.' P1, Industry, EU

Belgian stakeholders further felt that laboratories would see a loss of income if POCTs were implemented in community care.

'So in Belgium, you have a lot of labs, medical labs. You have private labs, you have labs that are linked to the hospital, you have the clinical biologist, and the clinical biologists don't want GPs to do this kind of test because for them, it's a loss of income. If they are using it, the GPs are using it, then for them, it's a loss of income. So there will be a lot of struggle, I think, a lot of discussions.' P16, Reimbursement agency, Belgium

Box 3. Key barriers in delivery of primary care

- Logistical and organisational barriers in implementing POCTs, including:
  - lack of staff to perform tests
  - limited space in practices
  - short consultation time
- Laboratories need to validate POCT results which require changes in workflow
- Laboratories may perceive POCT implementation in community care as a threat to their income
- Need for a quality control system for POCTs to ensure performance

5.4 Learning from the COVID-19 pandemic

5.4.1 Extent of regulatory processes impacted by COVID-19

Whilst regulatory processes and wide-scale implementation of diagnostics tend to take time, most stakeholders agreed that acquiring regulatory approvals for COVID-19 tests was unprecedented. They pointed out that POCTs for COVID-19 did not follow the usual pathway for approvals due to the urgency and high demand for diagnostics at the time. Some pointed out that because of the urgency of the situation, processes were accelerated and to some extent, some of the barriers that usually would have existed, were surmounted.

'I think the speed of uptake of the lateral flow test was unprecedented. So instead of any alignment with the payer I guess, which is the arm of the health care system where they evaluate and decide whether to fund something. I think for the later flow tests, so for the antigen tests, this was missing, you know? It was literally a 'demand exceeding supply' situation, where the Ministry of Health of various countries was in contact with [diagnostic company] to purchase tests directly. Without any, of course you know, there was a regulatory evaluation in terms of the product working etc. but usually there's more needed than that. So the uptake was very quick as a result of that...' P2, Industry, EU

However, participants in Belgium and the UK have voiced doubts on the extent of the pandemic's impact on implementing future diagnostics. Their pessimism stemmed from their beliefs that the pandemic was not a reflection of reality as governments were under immense pressure to expand testing capacities and investments were made in that sector.

'COVID-19 is really a specific situation because you know, normally reimbursements in Belgium, it's done via the RIZIV/INAMI (National Institute for Health and Disability Insurance). So the companies submitting a file and the file is examined by the – within the RIZIV/INAMI and advice is given and then the advice is going to the minister and the minister is taking the decision. But in this specific COVID-19 situation it was totally different because there was no time to follow this normal procedure. And a lot of things have been implemented by the government instead of following the procedure that is normally followed. And I think for this testing, it's different than the normal procedure. So you cannot use the COVID-19 example for the implementation of other tests, I think, because it's so specific. We had to be really fast. The situation was really dramatic. So it's a different case, according to me.' P16, Policy-maker, Belgium

'I think in every country, I mean, I can't believe that any country followed standard practice, really... It [COVID-19] was a very different scenario to normal. In ordinary non-COVID situations, there's a very long and arduous path to diagnostic tests being introduced, in the sense that there's no, sort of, – there has not been any functioning sort of rapid pathway to introduce diagnostics' P19, Policy-maker, UK

On the other hand, EU stakeholders pointed out that there were some changes being made regarding regulations for diagnostics. They reported that a new proposal for a legislation is currently being developed in the form of an expert panel that will contribute to evaluating different novel diagnostics at a European level during public health emergencies. In the UK, participants reported that a public consultation was held in the UK on the future regulation of medical devices and UK regulators are currently in the process of reviewing the responses which could help inform future changes for in vitro diagnostics legislations.

'So essentially with the new legislation with the new diagnostic in general, the European Commission is supposed to set up this expert panel that will help evaluating different diagnostics at a European level and now the decision has been to transfer these panels to the EMA (European Medicines Agency), at least to a certain degree. So the EMA will be kind of hosting this expert panel and therefore would have some kind of role in [examining] these different medical devices, in vitro diagnostics and the other point is that in the context of the activity of the EMA task force during emergencies. It was raised as an important factor that this EMA task force should also deal with, not only with medicinal products and vaccines, but also with diagnostics because it is an important component and well, often, these diagnostics are anyway component diagnostics like for therapeutic trials and so on. So having a body that can help European institution and European governments with some advice on the use of some of these diagnostics it was felt important. It's still a work in progress but there is an opportunity here for doing something that could be relevant.' P7, Policy-maker, EU

'There are changes [regulations] that have to be made and we have just concluded our public consultation on the future regulations and I don't know if you've seen that. But if you read that you'll see that there are suggestions around the changes we could make for diagnostics. What we have to do now is review.' P20, Policy-maker, UK

In the UK, some stakeholders were optimistic that COVID-19 has changed the landscape for introducing new diagnostics, with public health agencies and health services will continue to work together to quickly assess new diagnostics entering the market.

'I think the hope would be yes [to a change in landscape for introducing new diagnostics as a result of COVID-19]. And certainly Public Health England [now disbanded] and Medicines and Healthcare Regulatory Agency and the National Health Service, they've had to kind of work closely together and kind of find more rapid ways of kind of working and assessing the evidence and coming to a consensus than they probably ever had to before. So I think, yeah, I mean, I've got some level of optimism.' P19, Policy-maker, UK

On the other hand, there are some stakeholders across the EU, and in Belgium and the UK who are more pessimistic about the long-term impact of COVID-19 on future adoption of diagnostics. They raised concerns over the public resuming to normal activity and barriers related to implementation, would crop up again once the pandemic has eased. They point to other respiratory illnesses such as respiratory syncytial virus and influenza where community testing has existed but never caught on.

'Before COVID-19 there [was] already community testing. I mean for flu, for RSV, and they didn't work. I mean so this is why I'm a little bit pessimistic. I mean covid is going to help but uh you know it's a different animal, when you're in a pandemic, when the pandemic is over. You know what I mean, people come back to reality and normal activity... I

believe what has happened with COVID-19 will not be [translated] to other respiratory tract infections disease in the future. That's my opinion.' P1, Industry, EU

5.4.2 Opportunity for pharmacies to adopt POCTs

Stakeholders reported that the COVID-19 pandemic provided understanding on how to implement diagnostics, including using pharmacies for testing to relieve pressure off primary care. At the time of some of the interviews (2021), pharmacies in some EU countries had not yet offered testing services for COVID-19. On the other hand, Belgian stakeholders posited that when POCTs were introduced in primary care in the past, pharmacies wanted to be involved in testing but clinicians were reluctant. They stated that whilst pharmacist associations were keen to expand their role, primary care organisations and federal health services pushed back as they wanted clarity in defining roles and were concerned over the costs.

'We have experienced some pushback from physicians, both from physician organisations as well as like the federal healthcare service and from the physicians. It seemed to be related to clear role definitions of who is doing what in terms of care, whereas from the federal healthcare service, they seem to be concerned also, like, with the cost of introducing those type of first-line or zero-line settings as an additional channel.' P12, Policy-maker, Belgium

'MSD did a – developed one of those systems, I think a few years ago and then, pharmacists wanted to collaborate, but the physicians were very reluctant. But I think they definitely have a place.' P14, Policy-maker, Belgium

There was, therefore, some hope from participants that pharmacies will continue to be included in prevention through testing beyond COVID-19, paving the way for future diagnostics being adopted in these settings.

'For now, with COVID-19, I think things are really changing because we see pharmacies playing a key role in dispensing testing, either selling tests, giving tests or performing the tests themselves. Before COVID-19 I think that the role of pharmacies was much less obvious in that area. But that is something that may evolve and I think that we're in the middle of a huge potential change for that.' P3, Industry, EU

Some EU and English stakeholders noted that in situations where patients are feeling unwell and primary care services are fully booked, rather than seeking emergency services, patients could visit pharmacies to get tested if they know that these services are available. Stakeholders stressed that clear guidelines and training would be needed to support them.

'The key was to establish very precise criteria to select eligible patients and to determine a clear procedure for community pharmacists to follow. To this end, a decision-making tree was designed by the Steering Committee and made available to all pharmacists. This tree, which takes into account many factors (like the age of the patient, his/her medical history and symptoms), is an insurance that enables pharmacists to avoid mistakes at all stages of the diagnostic process (testing, assessment, referral). Thanks to this method, pharmacists have proved that they could carry out diagnostic tests, including those requiring invasive techniques like nasopharyngeal swabs.' P10, Scientific association, EU

However, some stakeholders believed that spaces in pharmacies may need to be reconsidered if POCTs are to be implemented in order to minimise the risk of transmitting infections.

'But you know COVID-19 has shown as well in retail pharmacists that they need to have special places or special ways to work... to be sure there's no transmission...' P1, Industry, EU

5.4.3 Lessons learnt from the pandemic on adopting novel diagnostics

EU, Belgian and UK stakeholders stated that the pandemic has provided a deeper understanding on how to implement diagnostics, despite the fact it was an unusual scenario. In Belgium, one of the learning points is to observe how other organisations in other counties implement evidence-based practices as they have been quick to translate evidence into practice. For others, the pandemic has shown that GP practices need more resources as they lack staff and equipment.

But if you want to enlarge it to other respiratory tract diagnostics, I think I think we have to go back to the GP practices and also of course invent invest in in GP practices and organisation. What we have learnt the last year and a half is that practices that lack resources in Belgium are not equipped to deal with this [COVID-19]. The staff don't have nurses...' P18, Scientific association, Belgium

In the UK, some of the lessons learnt as explained by stakeholders was the engagement with key opinion leaders in implementing diagnostics and the opening up of new communication channels between stakeholders.

'I think I think everyone who's just been through this pandemic will say that they're a huge, huge lessons to be learnt and huge wins as well through the process. And I think one of the processes shown that sort of system-wide approach to these challenges is the best way. So I think you know placing ourselves as the regulator in that system, very sort

of loud and proud at the forefront and engaging with our stakeholders has been one of the really great lessons learned. Not just for diagnostics, but things like the ventilator challenge as well demonstrated that that cross-system working is the best' P20, Policy-maker, UK

Others have noted that purchasing rapid antigen tests in bulk during the pandemic by the UK's National Health System helped and prevented clinicians from procuring diagnostics themselves.

'So I've learnt from COVID-19 is the power of bulk purchasing and procurement. At the moment, that is the way in which this would work. I think we'd have to procure it if we're going to go into widespread utilisation of devices. I think otherwise there is a difficulty of really, people being left to make their own decisions and their own choices.' P26, Policy-maker, UK

Some stakeholders hoped that there will still be a need for rapid diagnostics following the pandemic, with more emphasis placed on self-testing and that this may be translated to other POCTs. Some felt that the public was more aware of the value of testing and may be motivated to use other POCTs. In particular, UK participants indicated that the public is able to take initiative with using rapid antigen tests, suggesting more confidence in testing and familiarity with certain terminologies related to RTIs. They also expressed that testing may no longer be gate-kept by clinicians.

'I think you know people are more familiar now with using lateral flow tests in the home and they're more familiar with certain terminology as well.' P25, Policy-maker, UK

'But my expectation is that there'll be a lot more self-testing at some point, when we have a self-test that's very reliable. I also think it's very important that there's kind of a better control system in place. So it's great to have self-tests or rapid antigen tests and so on, but I also think there's a place for molecular point of care testing, that enables a very accurate result, but also close to the patient.' P2, Industry, EU

6 Discussion

6.1 Summary of main findings

Stakeholders from all regions reported similar views and experiences. Most participants agreed that top-down influences such as dedicated funding for diagnostics is needed to facilitate the adoption of POCTs in community care. The different regulatory processes in

Europe coupled with the lack of frameworks on how POCTs can be embedded into care pathways suggest that further changes are needed at policy-level. Stakeholders highlighted that the drive for POCT implementation should come from clinicians, who can act as champions of POCTs, engaging with peers and presenting evidence demonstrating organisational and patient benefit.

In contrast, some stakeholders expressed doubts regarding the extent to which POCTs can improve practice in community care. Stakeholders from Belgium and the UK particularly wanted to see national evidence demonstrating the value of POCTs and were concerned over the inappropriate use of POCTs which subsequently, may not have lasting impact on prescribing. Some speculated whether other less costly interventions should be fully explored before adopting POCTs. Participants highlighted that POCTs would be a logistical challenge for implementation. In countries where laboratories are more involved in testing, particular attention may need to be paid on how laboratories can fit in this care pathway.

Finally, participants had mixed opinions on whether the COVID-19 pandemic would have significant impact on the implementation of future diagnostics but agreed that lessons can be learnt. Whilst processes and strategies used to implement POCTs for COVID-19 may not be replicated for future diagnostics due to the differences in contexts, participants posited that COVID-19 has recognised the role of pharmacies in testing in the community. With the European general public more familiar with self-testing, some participants anticipated that this familiarity may be translated to other POCTs.

6.2 Recommendations

We present recommendations for policy-makers, diagnostic developers and researchers based on our results.

Box 4. Recommendations for policy-makers

- Provide dedicated financial resource to support implementation of POCTs.
- Consider cost-neutral funding models such as a lump-sum fees for diagnostics and/or robust reimbursement policies that alleviates financial and logistical burden off end-users.
- Utilise non-financial incentives, as well as financial, such as comparing quality indicators across practices to encourage adoption.
- Consider setting up monitoring systems that can evaluate the impact of POCTs on antibiotic prescription. This would also contribute to collecting real world evidence on use.
- Stronger networks of stakeholders involved in implementation should be formed to encourage further cross-country collaborations for HTAs and facilitation of implementation.
- Define the role of laboratories if POCTs are to be adopted at scale.
- Consider developing a monitoring system to carry out quality assurance on POCTs.

- Explore other community care settings such as out-of-hours services, emergency departments, and pharmacies as areas where patients can access POCTs. Draw on learning from COVID-19 for the implementation and scale-up of rapid antigen tests in community care settings outside general practice.
- Provide clear guidance to healthcare professionals in which patient populations to use POCTs.
- Raise awareness and train clinicians about how POCTs can be used to deliver improved care.

Box 5. Recommendations for diagnostic developers

- Identify and engage with relevant stakeholders as early as possible, even during the product development stage. These may be regulators, reimbursement agencies, and primary care organisations.
- Engage with early adopters, such as clinicians, and support 'champions' who may galvanise adoption amongst other clinicians.
- Provide a convincing narrative with growing evidence on how POCTs improve patient outcomes, optimise antibiotic prescribing, and deliver cost-effectiveness with the support of key stakeholders such as clinicians.
- Provide evidence on how POCTs are used in different contexts and their associated impact on prescribing.
- Consider specific characteristics for POCTs tailored to primary care settings such as:
    - Shorter time-to-result so that tests can fit into a consultation easily
    - Small in size and portable to provide flexibility in where it can be placed in a practice
    - A mechanism for results to be automatically inputted to the electronic medical record

Box 6. Recommendations for future research

- Collect real world evidence on how POCTs are being used to inform specific recommendations on implementation.
- Provide evidence on how implementation of POCTs should be tailored to context e.g. primary care setting, healthcare system, culture.
- Provide further evidence of cost-effectiveness of POCTs, preferably across a range of different healthcare systems.
- Provide evidence of the effectiveness of non-financial incentive schemes to encourage clinician adoption of POCTs.

6.3 Implications of findings

Due to the current set-up of healthcare systems, there are no clear pathways for the implementation of POCTs. National regulatory processes sometimes require national data that demonstrate value of an intervention, and whilst stakeholders echoed this requirement, setting up similar studies to generate evidence is costly, time-consuming, and may not always be feasible. In such a scenario, sharing evidence between stakeholders on how POCTs are used in different healthcare systems and collecting real world evidence may be beneficial in informing implementation strategies.

Stakeholders from the diagnostic industry also wished to see changes made on an EU-level concerning HTAs to avoid different processes and evaluations, and instead move towards a unified approach for diagnostics. In December 2021, a new EU regulation was adopted that will come into effect in January 2025 which focuses on joint clinical assessments and further collaborations between EU countries to reduce the duplication of work for national HTA bodies (9). Indeed, participants in our study noted that strengthening ties between stakeholders to encourage collaboration was one of the main lessons learnt from the COVID-19 pandemic to facilitate implementation of new diagnostics. Although the new EU HTA regulation does address this, MedTech Europe, a European trade association for the diagnostic industry, issued a statement voicing their scepticism over the impact this new regulation will have in reducing barriers for implementing diagnostics (10). This suggests that additional advocacy work will be needed on a policy-level to amend the new HTA regulation to reduce some of these challenges that are specific to diagnostics.

Whilst the diagnostic industry may already be addressing some of the technological characteristics requested by stakeholders, the fact that stakeholders still brought up these characteristics suggest that current POCTs may not be fit for purpose. Additionally, if diagnostic manufacturers have not done so already, speaking with national primary care organisations may be beneficial in provoking interest amongst end-users on POCTs. With some stakeholders still in doubt over the viability of POCTs and whether they will be used, engaging with clinicians through primary care organisations may be instrumental in convincing policy-makers to consider POCTs. This may mean demonstrating that clinicians are interested in using POCT and are able to successfully use POCTs with little disruption to their existing workflows.

6.4 Strengths and limitations

Using qualitative methods helped to explore different stakeholders' views and illustrated the complexity, at multiple levels, of implementing POCTs. Investigating these views at an EU-level provided a macro-level perspective of some of the challenges that technology developers have to face when navigating the European regulatory landscape, whilst national stakeholders provided context. Although the interviews were in-depth, recruiting other stakeholder groups such as patient groups would have added to the scope of the study to understand if patient organisations have an influence over POCT adoption. In addition, recruiting stakeholders from European countries where the use of POCTs in primary care practices is routine could have offered a contrasting example to

further understand how challenges were overcome and what facilitators supported POCTs adoption.

6.5 Conclusion

Our results highlight that successful implementation requires changes on multiple-levels: at a policy-level in terms of funding and efficiently evaluating diagnostics both at EU-level and national; at an organisational-level to embed POCTs in care pathways and practices; and at a clinician-level to get POCTs adopted. Recommendations for both policy-makers and diagnostic manufacturers are provided on how to overcome some of the barriers identified. In addition, some barriers on a policy-level may need to first be tackled before changes can be made on a practice-level. The COVID-19 pandemic has opened up new spaces for testing, such as pharmacies, but stakeholders believed that the accelerated approach to approve COVID-19 diagnostics will not be translated for other diagnostics.

7 Bibliography

1. Little P, Stuart B, Francis N, Douglas E, Tonkin-Crine S, Anthierens S, et al. on behalf of the GRACE consortium. The effect of web-based training in communication skills and an interactive patient booklet and the use of a CRP point of care test in acute respiratory tract infection (RTI): a multi-national cluster randomised factorial controlled trial. The Lancet 2013;382(9899):1175-1182.
2. Horvath AR, Lord SJ, St John A, Sandberg S, Cobbaert CM, Lorenz S, et al. From biomarkers to medical tests: the changing landscape of test evaluation. Clin Chim Acta. 2014;427:49-57.
3. Ferrante di Ruffano L, Hyde CJ, McCaffery KJ, Bossuyt PM, Deeks JJ. Assessing the value of diagnostic tests: a framework for designing and evaluating trials. BMJ. 2012;344:e686.
4. Anthierens S, Tonkin-Crine S, Cals JW, et al. Clinicians' views and experiences of interventions to enhance the quality of antibiotic prescribing for acute respiratory tract infections. Journal of General Internal Medicine 2015;30(4):408-416.
5. Tonkin-Crine S, Anthierens S, et al. Exploring patients' views of primary care consultations with contrasting interventions for acute cough: a six-country European qualitative study. npj Primary Care Respiratory Medicine 2014;24:14026.
6. Cals J, Chappin FHF, Hopstaken RM, van Leeuwen ME, Hood K, Butler CC, Dinant G. C-reactive protein point-of-care testing for lower respiratory tract infections: a qualitative evaluation of experiences by GPs. Family Practice 2010;27(2):212–218.
7. Strandberg EL, Brorsson A, Andre M, Grondal H, Molstad S, Hedin K. Interacting factors associated with low antibiotic prescribing for respiratory tract infections

in primary health care - a mixed methods study in Sweden. BMC Family Practice 2016;17,78.
8. Tonkin-Crine S, Yardley L, Coenen S, et al. Strategies to promote prudent antibiotic use: exploring the views of professionals who develop and implement guidelines and interventions. Family Practice 2013;30(1):88-95.
9. European Commission, 2021. *Regulation on Health Technology Assessment*. Accessed 27 February 2023. Available at https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment_en
10. MedTech Europe, 2021. *EU Regulation on Health Technology Assessment (HTA): MedTech Europe remains highly sceptical about the added value for health systems and citizens.* Accessed 27 February 2023. Available at https://www.medtecheurope.org/news-and-events/press/eu-regulation-on-health-technology-assessment-hta-medtech-europe-remains-highly-sceptical-about-the-added-value-for-health-systems-and-citizens/.

8 Appendix 1

Implementing new Diagnostics in European community care to Advise management of respiratory infections: a qualitative study (IDEA)

PARTICIPANT INFORMATION SHEET

1. ***Background and aims of the study***

The 'IDEA' study is part of the '**Validating diagnostics to combat antimicrobial resistance by optimising antibiotic use'** '**Improving the uptake and Sustainability of Effective interventions to promote Prudent antibiotic Use in Primary care**' (VALUE-Dx) programme (https://value-dx.eu) led by prof Herman Goossens from the University of Antwerp, Belgium.

The main aim of the IDEA study is to explore views and experiences of different stakeholders in introducing new diagnostic tests to community care settings to help manage community acquired respiratory tract infections. We are inviting you to participate in a telephone or face to face interview, which will take approximately 45 minutes, to discuss your views and experiences. We are interested in finding out about existing processes, roles and strategies used within and across different organisations when introducing new diagnostics in community care settings. We would also like to ask you about what barriers and facilitators you foresee to the adoption of new diagnostic tests in community care settings.

2. ***Why have I been invited to take part?***

You have been invited because you are a professional working in a role which is (potentially) connected to the introduction of new diagnostics in community care settings or you are a patient representative. We are interested in talking to guideline developers, policy makers, healthcare managers and managers within diagnostic companies from specific European countries including UK and Belgium. You must be willing to give informed consent to participate. We aim to interview 30-50 stakeholders.

3. ***Do I have to take part?***

No, your participation in the interview is voluntary. You can ask questions about the study before deciding whether or not to participate. You may also **withdraw** at any time without providing a reason and any data collected will be deleted up to the point of publication.

4. ***What will happen in the study?***

If you are happy to take part in the study, you will be asked to take part in a telephone interview (or videocall if you prefer, e.g. Microsoft Teams). The interview will be arranged at a time to suit

you and will take 30-45 minutes. Before starting the interview, you will be asked to give verbal consent, to confirm that you fully understand what taking part in the study will involve and that your questions about the research have been answered. The interview will be audio-recorded with your permission. No video-recording will take place. If you do not consent to being audio-recorded we will not audio-record the interview and instead will make detailed field notes.

5. ***Are there any potential risks in taking part?***

There are no risks in taking part in this study: we will not be discussing sensitive topics, and detail below how your privacy will be maintained.

6. ***Are there any benefits in taking part?***

There will be no direct benefit to you from taking part in this research but taking part may help us understand how we could implement diagnostics in the future and to identify successful and less successful approaches, which may help improve implementation of these strategies.

7. ***Expenses and payments***

The interview is on a voluntary basis and no reimbursement is available. You will not be required to undertake any travel or incur any expenses in order to take part.

8. ***What happens to the data provided?***

The **research data** will be stored confidentially on University of Oxford and University of Antwerp premises and university computer networks. The audio recording of your interview will be stored in password protected computer files. The recording will be sent securely to an independent transcription company who will type up the recording. The company will have been assessed and approved for data security by the University of Oxford or University of Antwerp. Once the recording has been transcribed, the transcript will be checked for accuracy and then the audio-recording will be deleted. **The transcript of the audio recording will be de-identified**. To ensure confidentiality the transcript will not include any names or other defining details that can identify you or your place of work.

Personal data will be stored securely in a locked cabinet at the University of Oxford or University of Antwerp or in password protected files on secure computers and university networks at the University of Oxford and/or University of Antwerp. Personal data will include your name, contact details, age, gender, professional status, organisation, years of experience. This data will include the written record of your oral consent, taken in your interview, which will include your name.

The research team will have access to all research data. The transcription company will only have access to the audio recording of your interview. We will ask all participants for their permission to use direct quotes. All quotes will be de-identified. At the end of the study de-identified transcripts will be stored in an online data repository available for future research where you have given permission for this. We will retain a list of participant names and details against participant numbers. This will be stored on University of Oxford and University of Antwerp computers as password protected files until reports and manuscripts reporting study findings have been published. All de-identified research data and any research documents with personal information, such as records of consent forms will be stored for 10 years after the end of the study. Responsible

members of the University of Oxford or University of Antwerp may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

9. ***Will the research be published?***

The research may be published in peer-reviewed scientific journals and may be presented at scientific conferences but any quotes used will be de-identified.

10. ***Who is organising and funding this work?***

This work is being funded by the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 820755. This JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and Bio-Rad laboratories, BD Switzerland Sàrl, Accelerate Diagnostics S.L. and The Wellcome Trust Limited.

11. ***Who has reviewed this study?***

This study has received ethical approval from the University of Oxford Central University Research Ethics Committee [insert reference number].

12. ***Who do I contact if I have a concern about the study or I wish to complain?***

If you have a concern about any aspect of this study, please contact the research team using the details below and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible: Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD.

13. ***Further information and contact details***

If you are interested in taking part or have any questions, please contact one of the study researchers, Melanie Hoste. We will then contact you to discuss the study and arrange an interview.

Contact details of chief investigators:

Prof Sibyl Anthierens

Address: Department of Primary and Interdisciplinary Care University of Antwerp, Doornstraat 331, 2610 Wilrijk, Belgium. Email: sibyl.anthierens@uantwerpen.be

Dr Sarah Tonkin-Crine

Address: Nuffield Department of Primary Care Health Sciences, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG, UK

Email: sarah.tonkin-crine@phc.ox.ac.uk

Contact details of lead researcher:

Melanie Hoste
Address: Department of Primary and Interdisciplinary Care University of Antwerp, Doornstraat 331, 2610 Wilrijk, Belgium
Email: melanie.hoste@uantwerpen.be

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION

9 Appendix 2

Implementing new Diagnostics in European community care to Advise management of respiratory infections: a qualitative study (IDEA)

TOPIC GUIDE

Briefing

1. Welcome and thanks to participant for agreeing to take part.
2. Introduce self.
3. This interview is for the IDEA study. The aims are described in the participant information sheet. Differences between professionals may arise from different perceptions of settings and organisations, from different priorities, and from different beliefs about healthcare provision. These differences are important to us and we value your unique perspective.
4. If at any time during the interview you do not wish to answer a question, that's okay.
5. I would like to audio record our conversation. The recording will be transcribed, but your data will be pseudonymised. Your name and any names you mention, and any places you mention will be taken out, so that if someone read your interview transcript, they would not know who you are or where you work.
6. Your interview will remain confidential.
7. If, at any stage, you wish to stop the audio recording, please let me know.
8. Do you have any questions?

Topics to be explored

Below is a list of topics to be discussed. The topic guide will remain flexible with respect to what is of importance to participants, however, the key topic of stakeholders' views and experiences of introducing new diagnostic tests to community care settings to help manage community acquired respiratory tract infections will remain the same.

1. Participant views on their organisation and its role in introducing/implementing diagnostics in community care settings.
2. Participant views or experience of supporting the delivery of COVID diagnostic testing through community/primary care services during the COVID pandemic.
3. Participant views or experience of existing processes, roles and strategies used within and across different organisations when introducing new diagnostics in community care settings.
4. Participant views or experience of (potential) barriers and facilitators to the adoption of new diagnostic tests in their community care settings.

Example questions (additional questions may be added during interviews following the topics above):

1. Can you briefly describe your position and role within your organization?
   Prompts: What are your main responsibilities? How does your role link to community care and/or diagnostics?
2. Can you briefly describe the main goals and main activities of your organization?

Prompts: What type of organisation do you work in? How it is funded? Which other organisations do you have links with?

As part of the wider VALUE-Dx programme we are interested in supporting the adoption and sustained use of novel, state of the art, diagnostics in community care settings to help manage respiratory tract infections. Community testing carried out during the COVID pandemic is a specific example of how novel diagnostic tests were rapidly introduced and adopted in community settings to provide additional diagnostic information to clinicians.

3. Can you tell us about any involvement you and your organisation had in providing COVID testing in community settings in your area?
4. What were the processes by which COVID testing was introduced and implemented in your country/area?
   Prompts: What was similar to previous adoptions of new diagnostics? What was different? What went well in terms of implementation? What could be improved?
5. How can the introduction and adoption of COVID diagnostic testing inform the introduction of new diagnostic testing in primary care going forwards?
6. How do you think COVID diagnostics will be used going forwards? How best could they be used alongside other novel diagnostics?

As part of this project we are particularly interested in diagnostics that would include point-of-care tests which can be carried out at the time of patient presentation in community care with results being available to the clinician within minutes, hours or a day or two. They may be tests which use finger prick blood or nose/throat swabs. These tests may help to inform antibiotic prescribing decisions.

7. What are your views on these types of tests being introduced in the community care settings with which you are familiar?
   Prompts: Have you any experience of developing/implementing such tests? How do you think such tests could influence practice?
8. What are the potential benefits to your organisation of implementing novel diagnostics in community settings to aid management of respiratory tract infections?
9. What are the potential disadvantages to your organisation of implementing such diagnostics?
10. How do you think the *introduction and adoption* of such tests in community care could best be supported?
    Prompts: Do you in your role, or your organisation, have a role to support this? What are potential barriers and challenges to this process (political, financial, health care system, local manages/governance, guidelines, available resources, clinicians, patients)?
11. How do you think the *sustained use* of such tests in community care could best be supported?
    Prompts: Do you in your role, or you organisation, have a role to support this? What are potential barriers and challenges to this process (political, financial, health care system, local manages/governance, available resources, clinicians, patients)?
12. How are such tests paid for when used in community care?
    Prompts: Who pays for the test? If patients have to pay how does this work?

13. How do patients typically access such tests?
    Prompts: are they available through general practice? Does the patient have to contact or attend any other healthcare setting (e.g. pharmacy, hospital).
14. What other organizations, departments within an organization, or persons do you think would support the implementation of such diagnostics?
    Prompts: What do you think these supporters would gain from supporting this? Would any organisations oppose this proposal?
15. Who are the key stakeholders to work with on implementing diagnostics in community settings, in your country?
    Prompts: Whose role is central in the achievement of implementing diagnostics? Who should be in charge of which reforms? How can clinical guidelines support implementation of diagnostics?
16. In your experience, what approaches have worked best when trying to implement new technology or practice approach?
    Prompts: Which types of policies or recommendations are most effective? What are the best ways of communicating new changes? Why are these successful? What can we learn from these examples?
17. What approaches have not worked well when implementing new technology or practice approach?
    Prompts: Why have these been unsuccessful? What can we learn from these experiences?
18. What is your vision on a (future) implementation process of diagnostics for community acquired acute infections? How do we move from the current system towards implementation? Which strategies can be used?
19. Lastly, from a scale for 1 (not at all) to 10 (as), how well do you think community care settings in your country are utilising diagnostics for the treatment of respiratory tract infections?
    Why did you pick this score? How would you explain this?

<u>Concluding questions:</u>

- Do you have any additional remarks?
- Is there something that you think we didn't cover that is relevant to this issue / topic?
- Is there someone else you think we should talk to, that you can identify as a key stakeholder in this area?

Thank you for your time.

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