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Key factors determining the development of SARS-CoV-2 testing strategies in EU countries: a mixed-methods study

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ABSTRACT

Background The WHO and the European Center for Disease Prevention and Control (ECDC) advocated for extensive testing as a crucial pillar in managing the COVID-19 pandemic. Yet, public health emergency responses varied across European countries. In particular, there were differences in the national laboratory capacities and diagnostic testing strategies. This study was conducted during the pandemic to identify the key factors in developing national, SARS-CoV-2 testing strategies across a selection of European countries.

Methods A mixed-methods study, comprising an interview phase and a survey phase, was performed. First, laboratory, policy-making and/or public health experts from different European countries were interviewed between 8 January 2021 and 19 March 2021, to review the development and implementation of national testing strategies.

Second, a cross-sectional survey was conducted among ECDC National Focal Points (NFP) for Preparedness and Response and/or Microbiology between July and October 2022 to validate the interview findings.

Results 12 European experts were interviewed and identified the following key factors determining the development of the national SARS-COV-2 testing strategies in their countries: (1) changing testing goals over time, (2) the prevailing epidemiological situation, (3) testing capacities, (4) availability of reference laboratories, (5) supply and stockpiling of testing material, (6) availability of human resources and (7) quality management standards across laboratories. The experts interviewed stressed the important role of stockpile management, the existence of expert networks, as well as the centralisation of decision-making. Lastly, determining the actors responsible for the testing strategy and putting in place 'coordination, accountability and governance' proved to be pivotal.

The survey outcome with 15 European NFPs demonstrated that the testing strategies generally changed over time to include a broader group of individuals. Furthermore, the actors 'Ministry of Health', 'Public health officials', 'National public health institutes' and 'National Expert and/or advisory groups' were selected as key players by survey respondents.

Conclusions In general, the scope of the testing strategy in European countries included in this study expanded as the pandemic progressed. This study identified key factors discussed by European experts interviewed that contributed to the development of SARS-CoV-2 testing strategies across European countries.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ An effective diagnostic testing strategy is a principal component of a successful pandemic preparedness and response plan. In line with proven deficiencies in diagnostic preparedness during earlier outbreaks, such as the 2014–2015 Ebola virus, many countries' laboratory capacities were strained at the beginning of the COVID-19 pandemic.

WHAT THIS STUDY ADDS

⇒ This study provides information on key factors that play a role in the development of SARS-CoV-2 testing strategies during the first phases of the pandemic.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These findings can be used by researchers and European experts involved in national public health emergency preparedness and response (PHEPR) to develop and/or evaluate their PHEPR plans, with particular attention to how to improve diagnostic preparedness and response.

INTRODUCTION

Following its emergence in China in December 2019, the new SARS-CoV-2 virus rapidly spread globally. This resulted in more than 38 million confirmed cases and 900 000 reported deaths in Europe by March 2021.[1] The COVID-19 pandemic strained national public health emergency preparedness and response (PHEPR) capacities.[2 3] It particularly overwhelmed the testing capacities in most countries.[4 5]

The Director-General of the WHO made it clear early on that extensive testing was a

crucial pillar for the management of the pandemic.[6] The WHO had already recognised the importance of laboratory preparedness in its 2018 Research and Development (R&D) Blueprint.[7] The Blueprint includes a list of priority diseases, as well as a disease X. The addition of a disease X highlights the need to be prepared for a public health emergency (PHE) in the event of the spread of an unknown pathogen.

COVID-19 was a disease X; it was a new and unknown disease. The WHO's January 2020 guidance testing for the virus[8] emphasised the need for extensive testing. Subsequent guidance[9] proposed testing strategy recommendations also focusing on the need for national rapid risk assessments and national implementation of measures for testing and clinical surge. It also encouraged customised country responses. The guidance also acknowledged the need to prioritise specific groups when testing capacities cannot be met.

Similarly, the European Centre for Disease Prevention and Control (ECDC)[10 11] urged national governments to test extensively in high transmission settings, while allowing for flexible and adaptable testing strategies based on their local situation.

There were clear country variations in approaches towards testing within the pandemic preparedness and response.[11 12] Hence, the COVID-19 pandemic provided a unique possibility to explore considerations for developing European national testing strategies during an ongoing pandemic. The pandemic allowed for the assessment of whether the global lesson learnt during past PHEs, such as the 2014–2016 Ebola outbreak, had resulted in improvements in diagnostic preparedness.

Previous literature on past PHEs has documented multiple issues concerning national diagnostic preparedness.[12–14] These include challenges related to the development and manufacturing of diagnostics, sufficient diagnostic capacity, as well as to shortages of necessary products and equipment. They also refer to the lack of a financed global strategy, limited national manufacturing capacities and logistics, the specifics of national healthcare systems, the specifics of national political systems, as well as the effects of societal factors and environmental actors.

Based on the observations made and lessons learnt during the 2014–2016 Ebola epidemic, Perkins *et al*[15] developed a framework for the assessment of diagnostic preparedness. This framework considers a comprehensive number of factors and enablers to speed up the response to the spread of known or unknown pathogens. They name four principal pillars, namely (1) outbreak detection, (2) R&D, (3) manufacturing and distribution and (4) implementation. A total of 17 factors are identified that influence one or two of the above-mentioned pillars.

The pillar 'outbreak detection' is influenced by the factors (1) case definitions and diagnostic algorithms to detect unusual illness, (2) communications and escalation protocols between health workers, the Ministry of Health and WHO, (3) agreements with reference laboratories for pathogen identification and (4) robust global and national surveillance network and strategies.

The pillar 'R&D' is influenced by the factors (1) manufacturer incentives and enabling support for private sector, (2) harmonised and accelerated regulatory processes for emergencies, (3) expert networks to enhance scientific research and best practices, (4) preapproved assays for priority pathogens for known pathogens, (5) accelerated research and design pathway in an outbreak of unknown pathogens, (6) target product profiles for intended use in specific context for known pathogens and (7) predefined strawmen target product profiles for unknown pathogens.

The pillar 'manufacturing and distribution' is influenced by the factors (1) manufacturer incentives and enabling support for private sector, (2) locked manufacturing capacity for rapid scale-up, (3) stockpiling for immediate manufacturing and deployment and (4) distribution, logistics and supply chain partners and capabilities in outbreak region in the alert.

The pillar 'implementation' is influenced by the factors (1) human capacity and training on the ground, (2) mobile laboratories ready for deployment, (3) in-country diagnostics champions and (4) distribution, logistics and supply chain partners and capabilities in outbreak region in the alert.

The framework also identifies five enablers that influence all four pillars. These enablers are (1) sample collection, storage, management, use and sharing, (2) new diagnostic tools, (3) connectivity, data interoperability and information sharing, (4) financing and funding and (5) coordination, accountability and governance.

Although WHO and EU guidelines to PHEPR exist, the availability of international public health guidelines and published literature that adopt systematic approaches to visualise the whole chain of the diagnostic preparedness is limited. Hence, we chose to apply Perkins *et al*'s[15] practical framework as an analytical model to identify the key factors that played important roles in the development of the national SARS-CoV-2 testing strategies in various European countries. We aimed to identify which factors and enablers proposed were salient in European countries in the beginning phases of the COVID-19 pandemic in determining the overall testing strategy in the context of the COVID-19 pandemic preparedness and response. Less attention was paid to the details of the tests chosen, but rather a multisectoral approach was be used to understand how decisions were made within different sectors and at different governance levels.

MATERIALS AND METHODS

This mixed-methods study was conducted within the context of the European Union Joint Action (EU JA) SHARP (Strengthening International Health Regulations & preparedness in the EU). The SHARP JA aimed

to strengthen the implementation of the IHR (2005) and the EU Decision 1802/2013.[16]

This study included semistructured interviews with European public health, laboratory and policy-making experts, followed by a cross-sectional survey with European National Focal Points (NFP) for Preparedness and Response and European NFPs for Microbiology.

Phase 1: the interviews

Interview design

We conducted exploratory semistructured online interviews to examine the development and implementation of the national SARS-CoV-2 testing strategies in the first year (from January 2020 to January 2021) in various European countries. The interview guide was developed by LSKK and reviewed by the coauthors. We asked broad open-ended questions allowing for elaboration on the aspects the experts interviewed felt were pertinent in the development of their national SARS-CoV-2 testing strategies. The questions allowed the participants to answer freely and avoided limiting the extent of the answers due to the interviewer's assumptions. Clarifying or probing questions, as well as deepening questions could be asked when appropriate.

The interview guide was piloted amongst two Dutch professionals working in public health and laboratory departments. Feedback from the pilot was incorporated into the final interview guide (online supplemental annex 1).

Expert recruitment

Country representatives from 26 countries participating in the SHARP JA were invited to suggest 3 experts who were involved in the development and/or implementation of the national SARS-CoV-2 testing strategies in their countries—one expert with public health expertise, one with laboratory expertise and one involved in policy-making. At the end of the interviews, participants were also asked to suggest other experts who may be suitable to be interviewed.

It is unknown how many individuals were approached, and hence which percentage responded positively. The interviewer did not have a relationship with the experts interviewed prior to the study commencement. When invited, the participants were given information about the SHARP JA and its goals.

Data collection

The semistructured interviews took place online between 8 January 2021 and 19 March 2021. Prior to the interview, all participants were informed of the nature and objectives of the study by email. Each participant was asked to sign an informed consent form and send it back. They also received the interview's leading questions, providing the opportunity to prepare.

All interviews were conducted online using the Cisco Webex Meeting platform. They were conducted in English by a female medical doctor and PhD candidate, LSKK, with qualitative research experience. This was done in the presence of CB, who was a female Master student working as an intern and responsible for taking notes. The interviews lasted between 90 and 130 min. The experts interviewed gave oral consent for the interviews to be recorded and transcribed verbatim. The experts received their anonymised transcriptions by email with the opportunity to comment and provide corrections. Their feedback was incorporated in the final transcripts.

All data were collected and stored following the Dutch National Institute for Public Health and the Environment's (Dutch: RIVM) General Data Protection Regulation rules.

Data analysis

LSKK and CB developed a codebook (online supplemental annex 2) based on the framework described by Perkins *et al*.[15] The codebook stated the factors and enablers proposed by Perkins *et al*,[15] with their corresponding definitions. It also allowed for the possibility of identifying potential data-driven inductive codes. The codebook was approved by all coauthors.

We primarily used the codebook to deductively code the interview transcripts. This allowed us to identify the factors and enablers that were described when providing details on the development and implementation of national SARS-CoV-2 testing strategies. The codebook was piloted by LSKK and CB using one transcript and then slightly altered after discussions with the coauthors. The final transcripts were double-coded by LSKK and CB using MAXQDA. They then counted the number of times specific factors and enablers were coded. Three of the authors (LSKK, MCVD and ACGV) performed a further thematic analysis of the coded segments per factor and aggregated them at a pillar level, based on Perkins *et al*'s[15] framework. LSKK thematically analysed all transcripts with ACGV or MCVD. The analysis was discussed by LSKK, MCVD and ACGV.

Phase 2: the survey

Design

To validate the findings of the interviews, we conducted a cross-sectional online survey among another group of European experts between July and October 2022. Here, we invited the designated ECDC NFPs for Preparedness and Response and the NFPs for Microbiology to complete the survey. We used the interview results to guide the development of this survey (online supplemental annex 3). The survey was administered online and consisted of five parts. Some of the questions the respondents saw were dependent on their responses in previous parts of the survey. Part 1 contained demographical questions.

Part 2 contained questions about the respondents' national testing strategy goal(s) and the extent to which these goals(s) had been met across three different time periods. Considering differing epidemiological situations across time in the various European countries, we defined the periods pragmatically as, 1 January 2020–31

May 2020; 1 June 2020–31 December 2020; and from 1 January 2021, until the survey was conducted between July and October 2022. The need for this pragmatic determination of periods was based on the fact that the first 6 months of the pandemic were characterised by a lot of unknowns regarding the SARS-CoV-2 virus as well as relatively limited testing capacities globally.[17] Participants could select at least one of the following testing goal options: (1) to reduce community transmission, (2) to reduce hospitalisation in general, (3) to reduce intensive care admissions and (4) to reduce the need for public health and/or social measures. These options were designed based on the interviews and the research team's personal experience. An 'other' option was also available. A 7-point Likert scale was used to ask if these goals had been met, with answering options of (1) strongly agree, (2) agree, (3) slightly agree, (4) slightly disagree, (5) disagree, (6) strongly disagree and (7) I don't know.

Part 3 focused on the enabler 'coordination, accountability and governance', which was coded most frequently in the interviews. Respondents were asked to select the actors who were involved and those who should have been involved in the development and/or implementation of the national SARS-CoV-2 testing strategy for different target population groups during the three selected periods. The selection of targets and actors that could be chosen was defined by the outcomes of the interviews. The possible targets of the testing strategy were (1) (mildly) symptomatic individuals, (2) asymptomatic individuals testing for work-related reasons, (3) asymptomatic individuals testing for access to (public) facilities, (4) symptomatic individuals in outpatient or clinical departments of (acute) clinical care facilities, (5) (a)symptomatic individuals admitted to, or residing in, long-term care facilities and (6) (a)symptomatic animals. The actors that could be selected were (1) laboratory in clinical institution, (2) private laboratory, (3) commercial manufacturers of testing kids and materials, (4) Ministry of Health, (5) ministry other than the Ministry of Health, (6) national public health institute, (7) regional health governance structure, (8) public health officials, (9) national expert and/or advisory groups, (10) healthcare professionals and/or management in hospitals and (11) healthcare professionals and/or management in long term care. The respondents could also name other relevant actors in an open section.

In part 4, we asked respondents to identify problems they faced during the development of their testing strategy in the laboratory and public health setting, and challenges related to the availability of diagnostic supplies.

In part 5, we asked participants to score how successful they believed their country's national testing strategy was on a scale from 1 to 10, with 10 being very successful.

The survey was piloted amongst three individuals working in public health institutions at the Dutch Centre for Infectious Disease Control within the RIVM. Their feedback was incorporated into the final survey.

Respondent recruitment

We invited 59 ECDC NFPs for preparedness and response from 30 countries as well as 59 NFPs for microbiology from 28 countries to complete the survey.

Data collection

An invitation was sent to the participants by email on 11 July 2022, with a closing date of 23 October 2022. Reminder emails were sent on 30 August 2022, and SHARP JA partners were asked to remind their NFPs during the SHARP JA meetings.

Data analysis

We used the cross-sectional survey data to calculate (1) the frequency with which specific testing goals were selected by the respondents, (2) the frequency with which specific actors were selected as being involved in the development of national testing strategies and (3) the differences between the respondents' responses for the different periods.

RESULTS

Phase 1: the interviews

Response

12 individuals were recommended by SHARP JA experts and contacted for the interviews. 11 interviews were conducted online with 12 people representing 6 different European countries. One of the interviews was held with two experts simultaneously on their request. Of the 12 people interviewed, 5 were public health experts, 6 were laboratory experts and 1 was a policy-maker. Three experts were from Malta, three were from the Netherlands, two were from Croatia, two were from Italy, one was from Latvia and one was from Spain.

The relevant factors and enablers in national SARS-CoV-2 testing strategy development

When focusing on the important factors in the development of the national SARS-CoV-2 testing strategies, one notes that the experts interviewed commented on all pillars proposed in Perkins *et al*'s[15] framework. Some factors (and hence pillars) received more attention than others. The following section elaborates on the factors and enablers that received significant attention in the interviews. Supporting quotations for the pillars elaborated on can be found in quotations in table 1. Supporting quotations for the enabler elaborated on can be found in quotations in table 2.

Pillar 'outbreak detection'

The experts discussed factors relating to the pillar 'outbreak detection' extensively during the interviews. The main themes identified could be categorised as (1) the centralisation of decision-making, (2) the role of reference laboratories, (3) the role of the epidemiological situation and (4) the role of the testing capacity.

Table 1 Supporting quotations for the pillars

Outbreak detection	
Case definition and diagnostic algorithms to detect unusual illness	The centralisation of decision-making *"For instance, Veneto region decided to test more people,…they decided to do a screening of the population and they did it also with serological tests. And so that's why they had a very deep knowledge of the transmission of COVID in the Veneto regions so yeah some regions did [it] differently."* — Italian public health expert
	The role of the epidemiological situation *"That was our main focus during the holidays: how can we detect cases… what is the case definition, and what is the case definition proposed by a national agency, and what is happening in the regions to understand what is happening in the country, and how the case definition has to evolve related to how the communities are dealing with the cases."* — Spanish public health expert
	The role of the testing capacity *"We noticed the shortages and that we needed to restrain, restrict the amount of people that would be tested… I think there was more capacity to also test outside those groups, but that would have meant taking the risk that, let's say within two weeks we had nothing left."* — Dutch laboratory expert
Agreements with reference laboratories for pathogen identification	The role of reference laboratories *"We have a reference laboratory and they make sure that we can, if the diagnostics are not there they will develop it, they will test it, they will validate it."* — Dutch public health expert
Research and development	
Harmonised and accelerated regulatory processes for emergencies	Quality management across laboratories *"But in this sense what was… good that all labs in our network are accredited according to ISO-standard 15189, which also obliges them to perform the testing quality. And then they are also checked by the National Accreditation Bureau. That they perform all the points, let's say according to the standard."* — Latvian laboratory expert
Expert networks to enhance scientific research and best practices	Existing and newly introduced national and international expert networks to enhance research and share experiences *"We are also in the European networks because we coordinated the network for laboratories for several years and we have been involved in projects more directed to laboratories before SHARP…, but it started really before with the network for laboratories. We also participated in the European Mobile Lab laboratory."* — Italian laboratory expert
Manufacturing and distribution	
Stockpiling for immediate manufacturing and deployment	Low supply and stockpile *"Before we didn't anticipate and that is of course a learning moment, but I think nobody anticipated…, were these shortages already at the start of the, of the pandemic… the realization that we cannot buy everything we can think we can buy."* — Dutch laboratory expert

Continued

Table 1 Continued

Distribution, logistics, and supply chain partners and capabilities in outbreak region in alert	The centralisation of stockpile management *"It's centrally managed. The Ministry of Health has a procurement department, and they are responsible for getting all the PPEs, the kit tests, now the vaccine, it has always been their job with anything related to health."* — Maltese public health expert *"There was procurement from the Ministry of Health PCR and serological tests, antigen test, PPE. So, in the beginning, they were working with their own PCRs but when the market was finished all the process was reinstated by the Ministry of Health but all the regions also doing their own work. There was like a parallel system."* — Spanish public health expert
Implementation in country	
Human capacity and training on the ground	Human resources *"So, it's not just that you have the right personnel which are capable to do certain laboratory procedures, especially if they have experience with similar methods, but it is very important to have enough personnel to have back up in this administrative work which follows laboratory testing."* — Croatian laboratory expert
In-country diagnostics champions network	The actor responsible for the testing strategy *"In the beginning already it was not clear whose responsibility it was to realize testing capacity. The Ministry did not have the assumption at the beginning that it would be their responsibility. So they took it, but they took it at the end of March after our new Minister stepped up and said 'I want this to be over. I want to change this'. And so it was, it was of course a new situation. So that is one thing, so who, where did the responsibility lie?"* — Dutch policy maker

The centralisation of decision-making

The experts across all the countries noted that the national centralisation of the different aspects of the testing strategy partly determined the level at which decisions were being made, the degree to which laboratories other than reference laboratories were involved in pathogen identification, and the expected communication between the health professionals working at different institutional levels. For example, Maltese experts described a centralised system, where the decision-making power regarding case definitions lay primarily in the hands of the national government with information provided by the public health department. While over time different hubs were set up to increase the testing capacity, the laboratory analysis continued to take place primarily in the only central hospital on the island. This was in contrast with the situation described by the Italian and Spanish experts. Here, although the national government was responsible for making final national decisions, regions with a high level of autonomy could make and implement their case definitions. In the Netherlands, the experts stated that the national government was also ultimately responsible for the national management of the pandemic. Nonetheless, they also described a high level of autonomy enjoyed by the municipal public health institutions.

The role of reference laboratories

Generally, the experts described reference laboratories as playing an important role in confirmatory testing, as well as developing, testing and validating existing assays. Those laboratories also provided methodological assistance and training to other laboratories when necessary. The decision-making strategies had different effects on the role and position of reference laboratories. For example, Italian, Spanish and Croatian experts described how reference laboratories made ad hoc decisions on which other laboratories to include. This was done by evaluating their techniques and/or validating their laboratory practices. By comparison Dutch experts referred to a pre-existing plan for upscaling the laboratory network.

The role of the epidemiological situation

Different factors influenced in which individuals were eligible for a test in the countries represented by the experts interviewed. These included the evolving knowledge about the virus, its transmissibility, the role of asymptomatic individuals in transmission and the consideration of a country-specific epidemiological and geographical situation. Early in the pandemic, the travel history and symptoms were generally considered important indicators for testing, although the extent of the group tested differed between the countries. Maltese experts described that Malta interpreted this broadly and

Table 2 Supporting quotations for the enabler 'coordination, accountability and governance'

The role of decentralised policy-making	"…*in Italy, we have, in our constitution … regions are allowed to be autonomous. They can almost ignore what the central guidance suggests because they may have a different organization in their territory. So, it's not so clear who finally decides because I must say in the end it's the region who decided because they do what they want.*" — Italian public health expert
	"It's our crisis headquarters, that is established, the government established the crisis headquarters, the members of this are epidemiologists, the director of the Croatian Institute of Public Health, infectious disease specialist professor M., she is director of clinic infectious disease, and the third member is from the government. So, they decide about the criteria, they have of course many specialists which they consult before they give any recommendations or testing for anything regarding corona crisis." — Croatian laboratory expert
The political nature of decisions being made	*"And still we are involved in most of the committees that established the rule, including the national committee that is part of the decision mechanism of the government about the policy of how to fight the outbreak. Even if there is a lot of politics around it so it is difficult to distinguish what is technical and what is politics."* — Italian laboratory expert
	"I would say because interest, economical interest, is an important point yeah it's mainly, I would say the main interest is economic interest and also its, you go to have your, it's like they're politicians, they want to balance between what is needed to control the pandemic but also what is asked by my voters, by the people that vote me, and so this balance sometimes goes in a, I would say, in a wrong way." — Spanish public health expert
	"I think the Outbreak Management Team. Well, they don't decide but they advise and then we decide. But we have so far not overruled their advice. So, I am not sure if that is a unique situation but sometimes you see countries that probably, or maybe where political decision-making would be sometimes ignoring or neglecting the advice of experts. In the Netherlands, we are sometimes accused of doing the opposite." — Dutch policy maker
Familiarity with collaborating actors	*"What went well with them and with everyone else was the fact that my unit has always been working with these people before, so it wasn't something new. They knew me, I knew them and so there was already a relationship set up, so it was easy you know… So that makes it easier to get things done quicker, you know what I mean, you already know how they work, they already know how I work on infectious diseases or notification, so it was easier to pick up."* — Maltese public health expert
	"I think we established very good collaborations, we set up a network of laboratories in our region and there was really new… We started to know the faces of the people who were working, the same worked in other laboratories. It was a very good result." — Italian laboratory expert

aimed to test as many individuals as possible from the beginning. Croatian and Latvian experts stated that their countries stuck closely to defined WHO criteria based on travel history and symptoms. On the other hand, Italian, Spanish and Dutch experts stated that their countries focused primarily on individuals with severe symptoms. Over time, the testing strategies became more inclusive in all the countries. One of the reasons for this provided by some of those interviewed is that the testing strategy was often considered part of a larger set of national non-pharmaceutical measures put in place to curb the spread of the SARS-CoV-2 virus. For example, the Dutch policy-maker stated that increased testing became part of a strategy for opening up society from 1 June 2020. The Croatian public health expert mentioned that economic and touristic incentives may have influenced the decision to not test individuals coming into Croatia in the Summer of 2020.

The role of the testing capacity

The experts interviewed generally felt the national outbreak detection strategy was influenced by the available testing capacity at the beginning of the pandemic. Except for experts from Malta, all experts stated that they

lacked testing materials at one or multiple points in the first year of the pandemic. The development, validation and availability of different test methods restricted the access to SARS-CoV-2 tests in different populations. At the time the interviews were held in early 2021, all countries had expanded their outbreak detection strategy and capacity to include more eligible individuals.

Pillar 'R&D'

Factors related to the pillar 'R&D' received considerably less attention in the interviews. The most frequently commented aspects were (1) the quality management across the laboratories, (2) adherence to quality standards, (3) the role of reference laboratories and of existing and newly introduced national and international expert networks to enhance research and to share experiences. This implied the need to perform quality exercises (as described by Dutch, Latvia and Italian experts) and/or validation by national reference laboratories (as described by Dutch, Croatian and Spanish experts). For further scientific development and exchange of latest information, the experts referred to national and international (eg, WHO) expert meetings, as well as formal and informal national and international collaborations.

Pillar 'manufacturing and distribution'

With regard to the pillar 'manufacturing and distribution', two main themes were identified, namely (1) a low supply and stockpile and (2) the level of centralisation of the management of stockpile and shortages.

Low supply and stockpile

Most respondents reported a shortage of testing material at one or multiple moments in the first year of the pandemic. This was partly attributed to the sudden global increase in demand for specific materials. Besides the global scarcity, there were country-specific reasons, such as the citizens' behaviours. For example, the Latvian expert reported on many citizens getting tested multiple times a day. This resulted in a shortage and the resulting need to implement doctor's prescriptions for testing until the supply was replenished.

The centralisation of stockpile management

The extent of the centralisation of procurement and supply management seemed to play an important role in the perceived national test capacity and distribution. Maltese experts described the advantages of having a centralised management of supplies within a clear predefined procurement system. The advantages include working with actors with experience in this domain. Experts from other countries described (partly) decentralised systems, with regions and/or individual laboratories being responsible for their own procurement and supply management. This had differing reported consequences. For example, the Croatian experts reported on evident regional differences in the availability of the amount of appropriate equipment and space for the equipment. However, laboratories were willing to share capacity across the regions where necessary. Dutch experts stated that the lack of oversight of stockpile and the shortages at the beginning of the crisis were a result of decentralised management. They believed that those responsible got a better oversight of the existing capacity when the procurement became increasingly centralised.

Pillar 'implementation in country'

The experts interviewed regularly referred to the factors related to the pillar 'implementation in country'. Two main themes could be deduced from their responses, namely (1) insufficient human resources and (2) the degree of clarity of who is ultimately responsible for the testing strategy.

Human resources

All experts interviewed described a lack of sufficient human resources. Besides the need for professionals with technical knowledge, there was an increased need for administrative personnel to support the implementation of the testing strategy. Some experts voiced preexisting shortages in public health human resources in their countries. Others highlighted regional disparities in the development of the public health system. Many solved this problem by involving personnel from other laboratories or departments within their institutions, or by involving health professionals or students from other specialties. The rapid growth of the teams involved in COVID-19 diagnostics was challenging, as many newcomers required both theoretical and practical training. The workload increased, with professionals having too many tasks, working overtime or becoming sick themselves. Nonetheless, the inclusion of this workforce was important.

The actor responsible for the testing strategy

In all countries, the final testing strategy decisions were ultimately made by the national governments. However, as mentioned earlier, some experts interviewed suggested the decentralised nature of governance and the healthcare system influenced the determination of who took ownership of the testing strategy. The Maltese experts felt the roles were clear, and the Maltese laboratory experts stated they were able to push for an extensive testing strategy from the beginning of the pandemic. In other countries, the experts described the situation as being complicated by the lack of a clear decision-making process, the failure to put officially documented roles into practice, or the mutual expectation from different institutions that others would take ownership of testing strategy. For example, as the pandemic progressed in the Netherlands, the Dutch Minister of Health ultimately took ownership and made the political decision to make testing available for all.

Enabler 'coordination, accountability and governance'

Of all of Perkins' factors and enablers, the enabler 'coordination, accountability and governance' (from here on referred to as the coordination enabler) was coded

most often (n=501/2249 or 22%). In comparison, the other most coded factors and enablers were 'case definitions and diagnostic algorithms to detect unusual illness' (n=243), 'human capacity and training on the ground' (n=149) and 'agreements with reference laboratories for pathogen identification' (n=128).

Three themes for the 'coordination, accountability and governance' enabler became apparent during interviews. These were (1) the role of decentralised policy-making and the dynamics between centralisation and decentralisation as the pandemic progressed, (2) the political nature of decisions being made, with actors' differing interests and with experts having differing roles in the decision-making, (3) the differences in the extent of how familiar collaborating actors were with each other at the beginning of the crisis across the participating countries.

The role of decentralised policy-making

Experts from the Netherlands, Spain and Italy specifically described the decentralised nature of the health policy-making systems in their countries. They commented on the difficulties this brought in providing a unified national policy. The experts interviewed suggested there were situations in which decentralisation resulted in a lack of clarity on who was to ultimately take responsibility for the national policy.

The political nature of decisions made

Some of the experts interviewed discussed the political nature of decisions subnational and national institutions made. In this context, the role of expert advice in political decision-making was also discussed. Some experts interviewed emphasised the fact that politicians ultimately followed the advice provided by experts. Some also specifically commented on the decisions made based on publicly available WHO guidelines. Yet, some experts also said politicians at times consulted experts and/or accepted their advice as convenient. A Croatian expert specifically mentioned that there were different expert teams on which the national government could rely. However, they felt that the national government sometimes failed to consult all relevant experts.

Familiarity with collaborating actors

The third issue that stood out was the interaction between the experts and other actors involved in the policy-making. In some cases, the experts were already familiar with the actors they collaborated with and had already collaborated with them in the past. In other cases, the collaboration during the pandemic was a new and positive experience that allowed actors to become acquainted with each other. Furthermore, new organisations and networks were created. In some cases, these started informally and were later formalised. The number of actors involved in the decision-making landscape also increased.

Phase 2: the survey

Response

15 NFPs representing at least 7 countries (ie, Czech Republic, Finland, Greece, Hungary, Latvia, Malta and Portugal) (partly) completed the survey. Nine respondents represented SHARP JA partner countries. Six respondents represented countries that were not involved in the SHARP JA and their country of origin was not specified. Eight respondents had predominantly public health expertise, three had laboratory expertise and four had both public health and laboratory expertise.

The national SARS-CoV-2 testing goals

The survey results show that the goals of the testing strategies generally changed over time to include a broader group of individuals. Although the goal to reduce the need for public health and/or social measures was selected least often, it did receive more attention as the pandemic progressed. This was also the case for the goals to reduce hospitalisation in general and to reduce intensive care admissions (figure 1). Interestingly, the attention to the goal to reduce community infection remained constant as the pandemic proceeded. All respondents agreed/or slightly agreed that their national test strategies' goals were met during the different pandemic periods.

The actors involved in the different pandemic periods

To further explore the enabler 'coordination, accountability and governance', a significant part of the survey focused on the actors involved in the development of the SARS-CoV-2 testing strategy. The actors, 'Ministry of Health', 'public health officials', 'national public health institutes' and 'national expert and/or advisory groups' were selected most often by survey respondents, when identifying the actors involved in SARS-CoV-2 testing strategy development in the first 5 months of the pandemic. The actors 'commercial manufacturers of testing kits and materials', 'animal health laboratory' and 'healthcare professionals and/or management in long-term care' were mentioned less often. Zooming into the testing strategies for different focus groups, there seemed to be fewer actors involved in developing the SARS-CoV-2 testing strategy for (a)symptomatic animals (online supplemental annex 4 table 3).

When considering the different time periods, 45% of survey respondents who answered this question reported that more actors were involved in the second 6 months of the pandemic compared with the first 6 months. The actors 'private laboratories', 'regional health governance sectors' and 'laboratory in clinical institutions' received more attention in the second 6 months than they had in the first 6 months. 16% of the survey respondents who answered this question reported that more actors were involved after 1 year than in the second 6 months of the pandemic. Furthermore, all the respondents stated that they felt all actors who should have been involved at the beginning of the crisis were involved as the pandemic

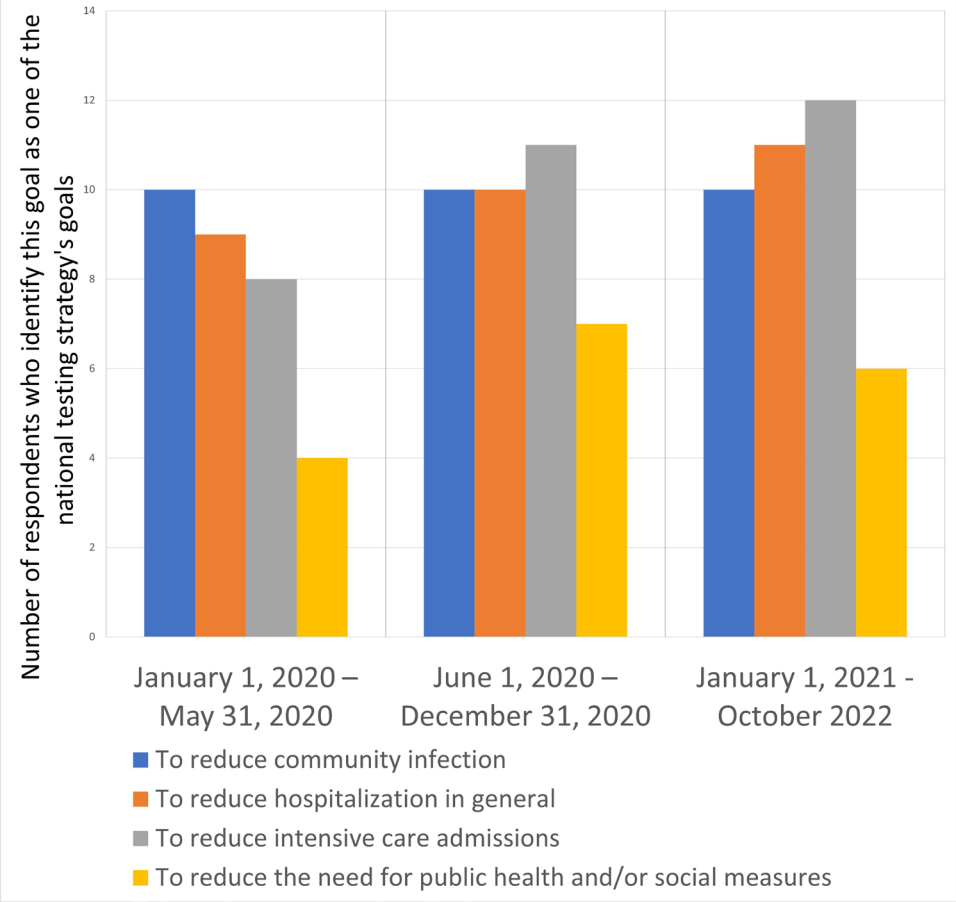

Figure 1 The national testing strategy's goals during the COVID-19 pandemic.

progressed. Two respondents reported they felt that while the pandemic progressed the constitution of actors that were involved was not always adapted to the ones necessary for adequate decision-making.

DISCUSSION

This mixed-methods study showed that aspects of all four of the pillars of Perkins *et al*'s framework[15] were mentioned by European experts interviewed when describing their national SARS-CoV-2 testing. Some factors were mentioned considerably more often than others. The changes in the testing strategies were mentioned frequently, as case definitions changed with evolving knowledge. However, the ability to adapt the testing capacity to suit the increasing demand differed in different countries. The experts interviewed provided the following as reasons for these hurdles: shortages of material, human and logistical resources. The experts also mentioned local differences in the interpretation and implementation of testing goals as another important factor. This was especially relevant as testing strategy development and implementation required coordination at national and subnational levels, as well as between different actors.

Second, the interviews and survey showed that the scope of the goals of the testing strategies generally was extended as the pandemic evolved. There was an increased focus and awareness of the need to reduce infection rates and protect access to possible healthcare. Furthermore, there was attention to the role testing could play in helping countries relax their lockdown measures, as also suggested by Rajan *et al*[2] and Mercer and Salit.[18]

Third, the results have highlighted the importance of considering national and subnational situations when developing testing strategies during a large PHE. This is in line with the WHO's[9] and ECDC's recommendations[10 11] at the beginning of the pandemic, which encouraged country-specific responses. It is also in line with the outcomes of literature on previous PHEs,[12–14] which have documented the role of specific contexts and resources.

Furthermore, the results presented here are generally in line with other studies that have aimed to understand or predict the outcomes of the SARS-CoV-2 testing strategies in different contexts. Those studies have identified (1) a limited availability to produce or procure testing kits and materials,[2 3 18–20] (2) insufficient skilled personnel capable of the different components of testing,[2 3 18 20 21] (3) unprepared laboratory and/or healthcare resources to provide rapid results,[2 3 21 22] (4) the fragmenting role of regionalisation,[21 23 24] (5) the characteristics of the disease,[23 25] (6) the role of individual behaviours/members of the public[22 25] and (7) the need for flexible coordination

between different levels and bodies.[2 3 18 21] Many of the key factors identified in this study were also discussed to some extent during the WHO European Region meeting on lessons learnt from public health laboratory responses to COVID-19, which took place in October 2022.[26]

Strengths and limitations

Undertaking this qualitative mixed-methods study during a PHE is a principal strength, underpinned by access to high-level individuals best equipped to report on the situation in their country. The possibility of recall bias was reduced as information was gathered as the pandemic progressed. Furthermore, the positions of the experts interviewed and NFPs surveyed provided face validity to the results. The themes generated in the study, many of which featured in other literature, were recognised by most, if not all, participants. This increased the credibility of the results.

We do note that only experts from six member states and one policy-maker from one member state were included in the interviews. Also, not all European countries were represented in the survey. A high workload and a high number of mandatory information requests from multiple institutions were identified as important reasons for non-participation during informal discussions with European experts. This reflects the difficulty of including high-level professionals for research during an ongoing large-scale PHE. We acknowledge that this may influence the generalisability of the outcomes of this study. However, we presented these results orally and in written form to European national-level experts and NFPs who are part of the SHARP Joint on multiple formal occasions. During and in between these occasions, there were possibilities for dialogue and feedback. Apart from questions regarding the choice of periods and target populations used in the survey, no objections were made regarding the outcomes of this mixed-methods study.

Pragmatically dividing the first year of the COVID-19 pandemic into three time periods allowed for the detection of possible differences over time and a comparison of individual country situations. However, we recognise the limitation that defining moments and epidemiological situations may differ across European countries. Nonetheless, the triangulated results did seem to show a similar tendency across time in the participating countries.

Future research

The preliminary results provided in this study may be used in the process of improving national diagnostic preparedness and response (DPR). Yet, further research is necessary to have a better understanding of the role DPR should play in overall national PHEPR planning. More research should also be conducted to further explore the relationships between critical actors and stakeholders, as well as the motivations to include or exclude specific actors DPR.

Furthermore, the outcomes of this study can be used as a starting point for future qualitative research aiming to have a more in-depth understanding of certain themes identified within this study, such as centralisation.

Moreover, quantitative research with a larger and more representative sample of European experts in a non-PHE period may allow for the validation of this study's findings. Performing a similar study in a calmer phase of PHEPR, in contrast to during the response to a pandemic, may allow for those who have participated in both the qualitative and quantitative parts of this study to reflect on the COVID-19 pandemic as a whole. It may also facilitate the recruitment of more experts from a wider range of countries to share their experiences and lessons learnt. These additional studies will likely help the future development of concrete national diagnostic preparedness plans.

CONCLUSION

This study identified key factors that contributed to the development of SARS-CoV-2 testing strategies across European countries. It highlighted the changes in the national SARS-CoV-2 testing goals over time, as well as the roles of reference laboratories, the epidemiological situation and the availability of resources necessary for adequate testing capacities. It also emphasised the important role coordination played in different aspects of the testing strategy.

The results may provide researchers and European experts involved in national DPR and/or PHEPR with outcomes to take into consideration systematically when developing their national PHEPR plans. This will help increase the effectiveness of the identification and management of patients in a future PHE.

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research involving humans (WMO). Experts interviewed provided verbal consent for participation in the interviews. The NFPs who completed the survey provided digital consent before completing the online survey. Participants gave informed consent to participate in the study before taking part.

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