Advancing Efficient and Timely Community Access to SARS-CoV-2 Serology Testing in Europe: a Multi-stakeholder Consensus

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Abstract

Background: Currently there is no clear consensus on the use, value, benefits, and impact of serology testing as part of a comprehensive SARS-CoV-2 testing strategy. The lack of clarity on the use of this strategy in policies and guidelines may have serious implications on the efforts to curb the pandemic. The aim of this paper is to elaborate an experts and community consensus on the use of serology testing as an effective method to respond to and mitigate the impact of the pandemic. The recommendations herein can help build community awareness and guide advocacy strategies.

Methods: A desk review was conducted to inform a working document that was subject to a multistage process of validation and feedback by a group of renowned experts. The multi-stakeholder group of experts, representing the European and international levels, convened to inform and validate the recommendations.

Results: The consensus offered eight policy recommendations organized in two main themes. The first group of recommendations provides guidance on the role and value of serology testing to contain and understand the COVID-19 pandemic. The second group targets health system strengthening aspects necessary to support the appropriate delivery of serology testing.

Conclusions: Recommendations seek to indicate how SARS-CoV-2 serology testing may positively impact national health systems, country economies and local communities. The pertinence of the recommendations is to communities in Europe, and beyond, and relevant to multiple stakeholders. Given the rapidly changing scenario, this set of recommendations should be considered a live document.

Key words: COVID-19, SARS-CoV-2, severe acute respiratory syndrome coronavirus 2, COVID-19 diagnostic testing, serologic tests, consensus, pandemics, health emergency, global health emergency, Europe

Introduction

On December 31, 2019, news released from the city of Wuhan in China, alerted of an outbreak of cases of an unknown type of viral pneumonia, later identified as a novel coronavirus and given the name of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The World Health Organization (WHO) declared SARS-CoV-2 a public health emergency of international concern on January 30, 2020 and a global pandemic on March 11. Shortly thereafter, the European region was officially pronounced one of the epicentres of the pandemic, amounting a death toll of 701,991 by January 28, 2021 [1].

The burden imposed by the SARS-CoV-2 pandemic has directly and indirectly permeated all sectors of society, with diverse types or degrees of impact experienced among countries of varying income levels [2,3]. Morbidity and mortality rates have been especially elevated among the high-risk and vulnerable populations [4-6], with Europe being the world region at highest risk due the elevated percentage of people living with underlying health conditions [7]. Furthermore, socio-economic disparities may put segments of the population at higher risk [8-11].

In the absence of effective treatments or universal access to vaccines, alternatives used to suppress the virus transmission included public health measures such as nationwide lockdowns. Although strict non-pharmaceutical measures have been effective in controlling the spread of the virus [12], they are not viable long-term solutions given their negative socio-economic consequences, such as the loss on Gross Domestic Product (GDP) and development of human capital due to the disruption of economic and educational activities, respectively [13-15]. In this context, a key prevention and containment strategy is the detection of SARS-CoV-2 infection through various types of tests that can support important aspects like diagnosis, case management, and tracking the spread of the virus.

Among the proposed tests for SARS-CoV-2, there are two main types of approaches. The first is based on a reverse transcriptase-polymerase chain reaction (RT-PCR), a molecular-based test method usually employed to detect an active pathogen in the body. The second is a serology test, based on an antibody/antigen reaction, which detects a body's humoral immune responses to a current and/or prior infection. This type of test shows that the body has produced antibodies following the exposure to the virus and can help to confirm prior infections even after the immune system has eliminated the virus.

Currently, there is no clear guidance supporting the use, value, benefits, and impact of serology testing as part of a comprehensive SARS-CoV-2 detecting strategy. The lack of clarity on policies and guidelines regarding the role of serology testing on decisions related to restriction measures may have serious implications on the efforts to curb the pandemic. Departing from a sound bibliographic review, this paper aims to provide an expert and community consensus on the effective use of serology testing as a method to respond to and mitigate the impact of the pandemic. Ultimately, the recommendations herein intend to enable the implementation of SARS-CoV-2 serology testing to support mitigation strategies at the regional, national, and local levels to build community awareness, and to guide advocacy strategies.

Methodology

Five renowned European and international experts on testing policies and strategies joined an online panel facilitated by Policy Wisdom, LLC. Their academic backgrounds included microbiology, infectious diseases, virology, epidemiology, and health policy. Throughout the three months from August to October 2020, a multistage validation and feedback process was carried out.

As the first step, we created a working document from a desk review of literature, policies, and epidemiological data. The search was guided by five pre-established topics:

- Medical and scientific perspectives on SARS-CoV-2 serology testing,
- The impact of the SARS-CoV-2 outbreak on recipients of care within society, health systems, and vulnerable communities,
- The implications of serology testing in Europe, including resource-limited settings,
- The economic and labour force impact of the pandemic on various sectors such as tourism, trade industries, and education, and how serology testing might support decision-making to mitigate the adverse effects of resuming activities,
- Existing limitations of SARS-CoV-2 serology tests and barriers to their widespread application, and
- Opportunities and advantages of an effective serology testing strategy.

Experts convened in a two-session meeting to inform and validate the contents of the working document and to discuss and propose a set of recommendations. The paper was then updated using this and subsequent written feedback. After reaching a consensus, the final document was approved by all panellists.

Results

Impact on population health

Morbidity and mortality rates have been especially elevated among the high-risk and vulnerable populations, while the pandemic has also worsened conditions for those who regularly need to access health facilities. Among the highest risk populations for the disease are (1) the elderly, particularly in long term care facilities (LTCF), (2) those with comorbidities, including communicable and non-communicable diseases, (3) vulnerable communities, which include those in outbreak-prone settings, and (4) healthcare workers. Europe has documented higher rates of infections among individuals over 70 years old and higher mortality rates in those above 65 [4,5]. Regional reports show figures of up to 88% mortality among those 65 years of age and above [16]. Furthermore, several countries including Italy, France, Germany, Sweden, Belgium, and the U.K., reported outbreaks in nursing homes, which accounted for a considerable fraction of their recorded fatalities [6].

Patients with comorbidities or underlying health-compromising conditions, such as diabetes, cancer, HIV, cardiovascular, chronic kidney, and chronic respiratory disease as well as other risk factors, such as obesity or smoking have also been shown to be disproportionately affected. Europe is the world region with the highest percentage of population that could be at risk due to underlying health conditions [7]. Additionally, those with chronic illnesses and other health-compromising conditions have had reduced access to healthcare services and medicines due to the burden on the health system imposed by the pandemic. Simultaneously, many patients may hesitate to visit health centres either for fear of infection, unclear communication on whether they can, and lack of understanding about which type of facility is safest to visit.

Moreover, socio-economic disparities may carry additional risks to certain sections of the population, particularly those of lower-income and/or marginalized communities [8]. Many low-income individuals live on daily wages and simply cannot forego employment and/or their economic livelihood depends on what are deemed as essential jobs. This situation exposes them to potential infection leading to an increased risk of outbreaks. Likewise, vulnerable or marginalized communities face extreme disparities that lead to increased difficulties in accessing healthcare (including laboratory testing) whether it be for economic reasons, literacy, transportation, language, cultural, or other barriers [9]. Among the most vulnerable populations are migrants (including seasonal workers that migrate between east and west Europe, and North Africa), correctional institution inmates, and the homeless [10,11].

Secondary effects of the pandemic may exacerbate the clinical situation of those who are already suffering mental health conditions, such as depression, anxiety, and other similar disorders, as well as a surge in new mental health cases [17,18]. Stay-at-home measures, loss of employment as well as the stress associated

with a pandemic situation and risk of infection have contributed to this effect [16]. Multiple sources identify healthcare workers among the most affected, including risk for suicide [11,17,19]. Lastly, preliminary reports have also suggested an increase in intimate partner violence in Europe during the outbreak. [20].

Broader Socio-Economic Impact

Although essential, imposing stringent non-pharmaceutical interventions has severe negative effects on country economies. According to the OECD, it is estimated that for every month that a country is in total lockdown, it loses up to approximately 2% of its GDP [13]. With most of the workforce under lockdown, unemployment rates have soared causing a domino effect in which almost all sectors of the economy have suffered [21,22]. International trade has slowed significantly and areas such as travel and tourism, as well as sports, food and entertainment have been especially affected. According to the World Travel & Tourism Council (WTTC), tourism generates 10,3% of global GDP, making it an important driver of the global economy. For countries such as Spain and Italy the contribution of tourism to their GDP is even higher than the global average, 14,3% and 13,0% of their GDP in 2019, respectively. It is predicted that 13 million jobs in the travel and tourism sector will be lost in Europe due to the SARS-CoV-2 pandemic, resulting in a tourism GDP loss of 633 billion [23].

The closure of schools and universities has also had great impact, limiting access to quality education, and sometimes resulting in students being unable to continue their studies. The disruption of classes at schools and universities has also placed an extra burden on society, causing concern for the short and long-term impact on the development of human capital and workforce [14,15]. Women and girls have been particularly affected by physical distancing measures, with a heavy loss in employment and lack of access to education. As the UN reported, decades of progress in women's rights have been scaled back in a matter of months [24,25].

SARS-CoV-2 Serology Testing

Several types of serology tests exist and each one has a different use depending on the setting and application. Currently available serology tests, or immunoassays, to detect SARS-CoV-2 antibody responses are designed for the detection of antigens or antibodies. Tests to detect the two main isotypes of antibodies, immunoglobulin M (IgM) and immunoglobulin G (IgG), are those most used to determine subject immunity. IgM represents an early antibody response during the acute phase of infection and may indicate current or recent infection. On the other hand, IgG, which are usually produced at a later stage, may indicate that a patient has been exposed, but was/may also still be infected, with or without symptoms. Immunoglobulin A (IgA) antibodies can also be detected in mucosal secretions or in serum samples but are often associated with earlier production of antibodies, shortly before IgM, and not associated with longer term immunity. SARS-CoV-2 antibody production, however, seems to differ from the typical scenario in that IgM and IgG tend to appear at the same time, while other models depict IgA and IgM developing simultaneously, with IgA even outlasting IgM antibodies in some instances [26].

Testing methods and setting needed to take and process samples, may also influence access and turnaround time of results. Antibody tests can be carried out either by laboratory-based assays or with rapid diagnostic tests (RDT). While the processing of samples for laboratory-based assays are more centralized, laboratories can analyse a higher number of samples. RDTs usually take 15-30 minutes to complete and are easily conducted and processed in decentralized settings. In general, laboratory-based assays generate more accurate results as they can provide qualitative (whether antibodies are present) and quantitative (amount of antibodies present) data as opposed to RDTs that only provide qualitative results [9]. The choice will depend on the application setting and on the scope of testing. Convenience and easier access to patients at point-of-care (POC) could be a preferable option of RDTs, yet it may require additional confirmation from more reliable laboratory-based assays.

Certain limitations of antibody tests have raised concerns, including their reliability or accuracy for detecting

SARS-CoV-2 infection due to possible cross-reactivity [27]. Antibody test accuracy is evaluated by its specificity and sensitivity. While specificity measures a test's ability to correctly generate a negative result (true negative rate), sensitivity measures how often a test correctly generates a positive result (true positive rate). In clinical settings no assays reach 100% accuracy in both specificity and sensitivity. Based on the prevalence of infection in a determined population, the specificity and sensitivity of tests are used to determine the positive predictive value (PPV) and negative predictive value (NPV). Predictive values permit assessment of the effectiveness of a specific testing strategy to determine the accuracy and reliability of serology tests at the individual and at population levels [9]. Choosing a test with higher specificity may be preferable in populations with low prevalence of the disease. Nevertheless, if not possible, the use of tests with lower specificity could be accompanied by orthogonal testing algorithms [28].

Additional concerns arise from the fact that some individuals may produce very low levels of antibodies, which may be missed by serological tests [29]. Furthermore, there is some indication that a classic long-term immunity may not exist for SARS-CoV-2 infection. In fact, some studies have documented reinfections [9,30], and others suggest neutralizing antibodies may wane after two to three months, especially for those who experience mild or asymptomatic cases [29,31]. These ambiguities have implications for determining herd immunity and understanding the proportion of the population that must be immune at the community level to cease high rates of transmission.

Benefits of SARS-CoV-2 Serology Testing

Serology testing can help enrich epidemiological data through sero-surveillance to inform policymaking at different levels, especially when asymptomatic cases seem to be high. While some preliminary studies estimated the proportion of asymptomatic cases at 17.9%, others go as high as 40% [32,33]. Although serology tests cannot replace RNA tests in hospital settings, they may provide additional information to support decision making on patient clinical diagnosis [34]. Hence, conducting serology tests in the clinical setting, when the index of suspicion is high, but SARS-CoV-2 cannot be detected, represents an opportunity to determine if a patient had been infected, providing relevant data that can help complete datasets and enhance preparedness. Finally, implementation of systematic serology testing and sero-surveillance could also provide an alternative method to less accessible and affordable lab RNA testing [35]. To summarize, evidence suggests that serology testing can be used as one of the tools to control virus transmission, prevent community spread, and meet public health and community needs and demands.

Serology testing might also be beneficial for research purposes, especially under scenarios where the virus is still new and less prone to mutations and genetic diversification. The use of serological tests to assist the development of effective treatments and/or vaccines is prescribed in this context [36], as so is research to identify the role of neutralizing antibodies [37,38].

Challenges of SARS-CoV-2 Serology Testing

Although WHO has acknowledged the importance of serology testing for epidemiological surveillance and research purposes, it provides limited guidance and support on implementation, and lacks emphasis on the value of other possible benefits. The existing WHO interim guidelines on the use of POC immunodiagnostic tests recommends molecular testing as a gold standard [37], and in the latest interim guideline indicates serology testing as complementary in specific cases [39].

At the regional level, the European Commission has acknowledged the overall utility of serology testing [40], releasing its guidelines on SARS-CoV-2 testing in April 2020 [41]. That same month, the ECDC published its Strategies for the Surveillance of COVID-19 [42]. However, neither of these documents set a clear plan for rolling out serology testing across the region. Meanwhile, some European countries have independently implemented serology testing strategies, while others are still lagging [9,43] (see Supplementary Material 1). A list of sero-epidemiological studies conducted in the region can also be found on the ECDC's website [44]. The fragmented initiatives across the region might result in the loss of opportunities to gather critical

information in an organized manner at a crucial time. Furthermore, in absence of comprehensive guidance, access to quality testing might be hindered due to insufficient supply and availability, and, in some cases, limited health systems capacity (effective infrastructure and a trained health workforce) [45].

Policy Recommendations

The eight policy recommendations offered in this paper focus on two main themes: the first four recommendation address the role and value of serology testing to contain and understand the SARS-CoV-2 pandemic, and the last four address issues around health system strengthening. As shown in Fig. 1, serology testing might be a valuable resource and should be considered as part of a larger comprehensive pandemic preparedness and mitigation strategy. Currently serology testing is primarily recommended for sero-surveillance and research purposes; however, this study found the need to define targeted pathways and a framework for ultimate introduction of serology testing to complement the existing strategies along with new scientific and clinical data as it becomes available. Active promotion of well-designed projects should facilitate this goal. Moreover, evidence suggests - and this paper recommends - to prioritize by geographic hotspots and to consider serology testing as part of national containment strategies to jumpstart the economy for full control of epidemics.

1. Serology testing should be considered as part of a larger comprehensive pandemic preparedness and mitigation plan for SARS-CoV-2 pandemic

- In the absence of specific pharmaceutical interventions and considering the high number of mild/asymptomatic cases, national plans should rely on different types of strategies and diagnostic tests available with serology testing recognized as a key component of the plan and take into consideration human rights and individual freedom.
- Immediate and rapid action is necessary to scale up the coordinated use of antibody tests to add knowledge to better understand the SARS-CoV-2 pandemic and the body's immune response. This can be established through the development and implementation of clear and thorough guidelines at the regional, national, and local levels.
- A robust testing policy, with capacity building and institutional strengthening as well as sufficient budget allocated to support it, will contribute to improve preparedness for upcoming waves of SARS-CoV-2 infection. It will also help countries plan for any future epidemics, ensuring greater national security.

2. There is a need to define targeted pathways and a framework for ultimate introduction of serology testing to complement the existing strategies along with new scientific and clinical data as they become available. Active promotion of well-designed projects should facilitate this goal

- European and national plans to obtain sero-surveillance data should be reinforced and promoted. Sero-surveillance data can be used to help strengthen the health system and understand where resources need to be allocated.
- Data gathered from serology testing should be collected at all levels, from the broader national level to the community level, to conduct sero-surveillance and identify sectors of the population that are especially at risk, in efforts to provide tailored interventions.
- Random samples gathered should be used to assess antibody prevalence and to conduct research on SARS-CoV-2 antibodies that will help inform the future development of vaccines and treatments. This includes the future use to distinguish between vaccine versus natural immunities and see if, in these conditions, measurable levels of antibodies can be detected.
- Epidemiological information collected from serology testing should continue to be systematically added to national surveillance systems as these data are vital to monitor trends and inform public health measures and control strategies. Countries can join global efforts [46] to improve further guidance and contribute to the global information pool on SARS-CoV-2.
- A matrix should be defined to help monitor and evaluate implementation of serology testing strategies, ensuring that information is properly collected and that the system is consistently improved; in addition to quantitative data, qualitative data should also be gathered in the community environment.
- Currently RT-PCR testing is the primary recommended tool for diagnosis of SARS-CoV-2; however, in the rare case of the lack of availability and affordability of such tests, or suspicion of infection with negative RT-PCR tests, serology tests can be used within the proper timeframe to support clinical decision-making and patient management.

3. More active serology testing at the community level should be prioritized for geographic hotspots

- As countries begin to lift physical distancing measures, testing in communities most at risk is essential to better understand how the virus acts as well as to possibly prevent and control community transmission.
- There should be a careful selection and prioritization of groups for sero-surveys based on risk-levels. Health disparities should be assessed and based on available data, while prioritization should consider including the following populations: healthcare workers, the elderly (especially in LTCFs, as well as personal support workers in these facilities), those with co-morbidities and people living in geographic hotspots.
- Tests should be free of charge and/or affordable in the context of public testing. Test results and what they mean in terms of protection and its durability should also be accessible to individuals.
- Community preparedness, through increased knowledge, awareness and understanding of serology testing and how it can benefit the community, should be considered to reduce stigma and facilitate access to diagnosis and treatment.
- Data privacy should be guaranteed, and testing conditions and confidentiality standards should be communicated to individuals prior to testing.

4. National containment strategies to jumpstart the economy for full control of epidemics should also rely on serology testing

- Serology tests should not be used to determine when employees can go back to work safely, or people can/cannot travel. Issuing of so-called immunity "passports" or "certificates" would have many associated risks, including creation of a false sense of security and perceptions of reduced risk leading to less use of personal protective measures. This may lead to further spread of the virus, possible stigmatization, limitations for employment and freedom of movement, and potentially a black market for immunity passes.
- Serology testing is essential to better understand antibody prevalence, which would allow for an increased level of safely returning to a pre-pandemic level of activity, even if we are still far from such a scenario. Consequently, there is a need to continue implementing all safety measures for infection prevention and control across different sectors of society, while ensuring protection in accordance with human rights and ethical standards.

Figure 1: **Recommendations on the role and value of serology testing to contain and understand SARS-CoV-2 pandemic**

The introduction of serology testing would also require the reinforcement of the national health system infrastructure and capacity for optimal test performance and guarantee supply. Attention needs to be paid to ensure the use of high-quality serology assays considering both the analytical (i.e., high-level specificity and sensitivity) and clinical characteristics of patients. Finally, governments should clearly communicate

and engage with different stakeholders to raise awareness and ensure access to testing opportunities (see Fig. 2).

Figure 2: **Recommendations for health system strengthening to support appropriate serology testing within the SARS-CoV-2 pandemic**

Discussion

Non-pharmaceutical measures taken by countries have varied depending on specific situation and socio-cultural context. As countries begin to lift some of these restrictions, different strategies have been considered. While some European countries are currently only contemplating occupational health and safety measures in the workplace and/or learning environments as part their exit strategy, other countries have recognized the positive role that serological testing might play. Given the inconsistencies in how serology testing strategies are being carried out, aligned guidance and a more coherent approach are necessary to support policy-level decision-making.

Whether a country is experiencing no burden of cases, sporadic cases, a cluster of cases/outbreaks, or community transmission, it should be continuously vigilant. Different testing strategies will yield different outcomes in understanding the true spread and severity of the virus sub-epidemics between countries and different populations at risk. Since mild/moderate or asymptomatic cases may go untested, the complete picture of the epidemiological situation cannot be fully understood in the absence of tests that can capture these cases. It is important to generate reliable and comprehensive information by conducting well-designed, scientifically, and ethically sound studies.

Sero-epidemiological population-based studies on antibody prevalence in defined communities would be essential for generating supportive data (such as prevalence, incidence, and fatality rates), and improve

surveillance, monitoring, and forecasting of SARS-CoV-2 infection in populations, which could support the development of effective public health intervention strategies. At the community level, sero-epidemiological information could provide a basis for better understanding of viral spread in terms of the geographic mechanisms behind the emergence of local and regional outbreaks. Additionally, it can provide data on selective distribution among diverse populations, such as those most vulnerable and sub-populations with higher risk due to comorbidities. Factors such as race, ethnicity, socio-economic status, and other aspects that can lead to marginalization or vulnerabilities, should be considered when performing sero-epidemiological studies and developing health policies. Conducting serology testing on vulnerable subsets of the population should be approached in a carefully planned manner so as not to place such populations at greater risk.

Serological testing can also post additional benefits to control the pandemic. Detection of mild or asymptomatic cases can provide better clarity to authorities, identifying true attack and mortality rates, as well as the potential role of immunity (including herd immunity), which can help better define and adapt policies to respond to viral patterns and develop effective prevention and control strategies. Furthermore, it could help assess the effectiveness of using non-pharmaceutical interventions in suppressing and containing the virus transmission.

Challenges may also arise from the inclusion of serological testing among testing strategies. Europe is a heterogeneous region with different social, economic, political, and cultural ethos and perspectives that can influence the use and uptake of serology testing. Further constrains may arise from insufficient supply and availability of quality tests and health workforce. An increase in demand could also outweigh the test production capacity, having further cost implications. A guidance on the role of serological testing must include actions directed at bringing awareness among policymakers and regulatory authorities. Dialogue is an essential factor that can enhance community engagement and coordinated policy action.

Conclusions

Due to this lack of comprehensive guidance at the global and European levels, there has been a diverse approach to SARS-CoV-2 testing policies, weakening the potential benefits that serology testing can bring to addressing the challenges posed by the pandemic. Europe is a heterogeneous region that can influence the use and uptake of serology testing. The global challenge demands the generation of reliable and accurate epidemiological information that can timely inform policy making, whether for diagnostic, treatment, and prevention strategies. Serological testing is critical to respond to this demand.

The policy recommendations offered in this paper intend to enable the implementation of SARS-CoV-2 serology testing to support mitigation strategies at the regional, national, and local levels, to build community awareness and guide advocacy strategies. With the situation evolving rapidly, it is important to notice that this paper should be considered a “live” document that must be updated as new evidence emerges.

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Conflict of Interest Statement

While Abbott Laboratories has sponsored the production of this manuscript, it is fully independent of any influence from the company on the contributing authors. The included recommendations are based on a review of literature and publicly available evidence, as well as the subsequent expert deliberations to reach consensus on the subject matter.

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Author Contributions

All author contributed equally to this work.

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