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SARS-CoV-2 serosurveys in low-income and middle-income countries

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) serosurveys provide crucial information on previous SARS-CoV-2 infections in communities.[1] These surveys are particularly useful in low-income and middle-income countries (LMICs), where limited testing capacity inhibits the ability to monitor COVID-19 burden through routine care and contact tracing.[2]

We represent a global group of clinical, programmatic, and research leaders that, through long-term collaborations between Partners In Health and national ministries of health, are supporting COVID-19 response data collection and analysis needs in eight countries. SARS-CoV-2 serosurveys are included in the broad set of activities that we are supporting; however, as our teams began developing core technical documents on the design and analysis of serosurveys, we realised that there were divergent opinions on individual protocols within these serosurveillance activities, specifically as to whether or not to return SARS-CoV-2 antibody test results to the individual participating in the serosurvey activity. There are many reasons why this topic is debatable, and we highlight some of our key considerations to help other teams designing SARS-CoV-2 serosurveys in LMICs to think through these issues, and to generate a broader discussion as to the pertinence of returning SARS-CoV-2 antibody test results when done as part of serosurveys in different countries.

As a starting point, we compiled experiences from others implementing SARS-CoV-2 serosurveys within Latin America, the Caribbean, and Africa—the regions where our programmes operate. In the most recent search (completed on Dec 10, 2020), we identified a limited number of serosurveys that were either published works or preprints, and a handful more through combing news and social media or through our personal networks.[3–11] Of the 16 serosurveys we identified, only two had documentation of individual protocols and so we contacted the study leads for more details. We received replies from eight study leads, of which six reported that all sampled individuals received the results of their antibody tests. These individuals noted the right of participants to know, individual study institutional review boards protocols, as well as the importance of being open and transparent with participants as the central reasons for providing these results to the survey participants, informing our discussion regarding the return of results. For two studies, results were not automatically returned, although in the case of the study from Malawi, results were available to individuals upon request. The two studies that had documentation on individual protocols followed up positive individuals with either immediate quarantine in a hotel or a COVID-19 treatment centre, in the case of Togo, or testing of all adult household contacts immediately or the next day, in the case of southern Brazil.

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Even when considering the experiences from the projects mentioned here, our group continued to discuss the pros and cons of returning test results to individual participants without reaching consensus. Noting that countries might have different recommendations, and that even within countries, recommendations might vary based on the target population. Those in favour of returning results focused largely on the rights of individuals to know the outcomes of their tests and the need to respect individuals' autonomy. Some country sites are considering result-specific interventions, such as follow-up testing or extending testing to household contacts, in which case results must be returned to individuals to proceed.

Those against returning results focused on the poor test properties, particularly the risk of false positives early in the epidemic, and the lack of a full understanding of SARS-CoV-2 infection dynamics. Knowledge is still unfolding in relation to how previous infection confers immunity and how long immune protection might last. Further, some individuals expressed fear about the implication of results being misinterpreted—eg, requiring quarantine for seropositive individuals, or positive results leading to potential stigma and discrimination.

As we discussed returning results to individuals, we identified other key factors that should be considered and discussed in tandem for SARS-CoV-2 serosurveys. National institutional review boards should be consulted early as these institutions might have clear guidance on if and how such results should be communicated to participants. Regardless of the return of results, community sensitisation will be key for gaining trust and buy-in for participants, and if results are returned, this sensitisation can prevent issues surrounding unnecessary stigma. Staff must be trained, not only on safe and high-quality testing procedures, but also on ensuring confidentiality of test results. Pretest counselling accompanied by context-specific support materials will be important for individuals participating so that they better understand COVID-19 risks, the antibody testing process, and COVID-19 risk factors. If returning results, post-test counselling will be equally important to ensure patients correctly interpret the results and complete the appropriate follow-up activities. Finally, country sites should continue toward validating the antibody tests for their specific setting to ensure that the test properties are known, which is important for both interpreting individual test results and for adjusting overall prevalence estimates.[1,2]

Our discussions around returning test results to individuals participating in SARS-CoV-2 serosurveys evoked differing opinions based on a range of ways of approaching the issue, and have as of yet not led to a resolution. We hope this Comment will bring this conversation to a broader community, encouraging global health regulating bodies to develop related guidance. Notably, there was no discussion or explicit recommendations on individual reporting of serosurvey results in the latest WHO COVID-19 surveillance protocols for health-care workers. As stakeholders in LMICs implement serosurveys, we advise these teams to make full protocols, including the details of individual testing and public support of decisions. We believe that it is important to capture the participants' experiences with SARS-CoV-2 serosurveys, and their desire to know the antibody test results, as their views should be central to the discussion moving forward.

We declare no competing interests.

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The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines

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Few medicines are awaited as eagerly as COVID-19 vaccines. Extraordinary efforts by scientists, regulators, and developers enabled the European Medicines Agency (EMA) to recommend the first EU conditional marketing authorisation (CMA) for the BioNTech COVID-19 mRNA vaccine (nucleoside-modified) BNT162b2 (Comirnaty)[1] some 9 months after the COVID-19 pandemic was declared. On Dec 21, 2020, the European Commission granted CMA, following the EMA's positive opinion, to BNT162b2 for active immunisation of individuals aged 16 years and older to prevent COVID-19, which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2]

CMA is used in EU legislation for emergency situations in response to public health threats. This authorisation requires demonstration of a positive benefit–risk balance, allowing for additional post-marketing data to be provided on the condition that the company supplies these data as specific obligations within defined timelines. Specific obligations generally include clinical studies and exceptionally, in the context of emergencies, studies to provide further assurance on the pharmaceutical quality of the vaccines. The EMA's evaluation was expedited by making use of rolling reviews, specifically designed by the EMA, that allowed assessment of discrete datasets as soon as they became available. The EMA collaborated with several non-EU regulators and WHO throughout the assessment, under existing confidentiality arrangements, and has engaged with the International Coalition of Medicines Regulatory Authorities to ensure global alignment.[3]

Vaccine efficacy of BNT162b2 in the pivotal trial, which is still ongoing (NCT04368728), was high at 95% (95% CI 90·3–97·6) and the safety profile was adequate.[4] The most commonly reported adverse reactions include injection site pain, fatigue, headache, myalgia, chills, arthralgia, and pyrexia, and safety aspects are included in the EU's risk management plan.[5] Currently, the only important identified risk is anaphylaxis. Vaccine-associated enhanced disease will be monitored as a potential risk, although it is at present a theoretical concern not observed with COVID-19 vaccines. Although there might be challenges in keeping participants in placebo groups in ongoing phase 3 clinical trials, long-term safety and efficacy follow-up of trial participants, possibly for up to 24 months, is planned.[5]

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