Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

from RNA.[5] The variant detection strategy (ie, rapid variant assay) can be readily combined with a CRISPR diagnostics platform that is already approved as an equivalent diagnostic method to quantitative real-time PCR in India, providing diagnosis and identification of one variant of concern in less than 90 min from sample to result, at a test cost of less than US$15.

The coming months present a challenging scenario: tracking and controlling the spread of such variants and simultaneously understanding their effects on the pandemic. Large-scale sequencing efforts and tailor-made diagnostic solutions, such as CRISPR diagnostics will be crucial.

DC and SM have filed patents relevant to the work and are inventors of a CRISPR diagnostic licensed to Tata Medical and Diagnostics. AA declares no competing interests.

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WHO International Standard for anti-SARS-CoV-2 immunoglobulin

The development timeline of COVID-19 vaccines is unprecedented, with more than 300 vaccine developers active worldwide.[1] Vaccine candidates developed with various technology platforms targeting different epitopes of SARS-CoV-2 are in the pipeline. Vaccine developers are using a range of immunoassays with different readouts to measure immune responses after vaccination, making comparisons of the immunogenicity of different COVID-19 vaccine candidates challenging.

In April, 2020, in a joint effort, the Coalition for Epidemic Preparedness Innovations (CEPI), the National Institute for Biological Standards and Control (NIBSC), and WHO provided vaccine developers and the entire scientific community with a research reagent for an anti-SARS-CoV-2 antibody. The availability of this material was crucial for facilitating the development of diagnostics, vaccines, and therapeutic preparations. This effort was an initial response when NIBSC, in its capacity as a WHO collaborating centre, was working on the preparation of the WHO International Standards. This work included a collaborative study that was launched in July, 2020, to test serum samples and plasma samples sourced from convalescent patients with the aim of selecting the most suitable candidate material for the WHO International Standards for anti-SARS-CoV-2 immunoglobulin. The study involved 44 laboratories from 15 countries and the use of live and pseudotype-based neutralisation assays, ELISA, rapid tests, and other methods. The outcomes of the study were submitted to WHO in November, 2020. The inter-laboratory variation was reduced more than 50 times for neutralisation and 2000 times for ELISA when assay values were reported relative to the International Standard.

The International Standard and International Reference Panel for anti-SARS-CoV-2 immunoglobulins were adopted by the WHO Expert Committee on Biological Standardization on Dec 10, 2020.[2] The International Standard allows the accurate calibration of assays to an arbitrary unit, thereby reducing inter-laboratory variation and creating a common language for reporting data. The International Standard is based on pooled human plasma from convalescent patients, which is lyophilised in ampoules, with an assigned unit of 250 international units (IU) per ampoule for neutralising activity. For binding assays, a unit of 1000 binding antibody units (BAU) per mL can be used to assist the comparison of assays detecting the same class of immunoglobulins with the same specificity (eg, anti-receptor-binding domain IgG, anti-N IgM, etc). The International Standard is available in the NIBSC catalogue.

Initiatives have been launched for the harmonisation of immune response assessment across COVID-19 vaccine candidates, including the CEPI Global Centralised Laboratory Network.[3] CEPI centralised laboratories will achieve harmonisation of the results from different vaccine clinical trials with the use of common standard operating procedures and the same crucial reagents, including a working standard calibrated to the international standard.

The basic tool for any harmonisation is the global use of an International Standard and IU to which assay data need to be calibrated with the use of a reliable method. It is therefore crucial that the International Standard is properly used by all vaccine developers, national reference laboratories, and academic groups worldwide, and that immunogenicity results are reported as an international standard unit (IU/mL for neutralising antibodies and BAU/mL for binding assay formats).

In this manner, the results from clinical trials expressed in IU would allow for the comparison of the immune responses after natural infection and induced by various vaccine candidates. This comparison is particularly important for the identification of correlates of protection against COVID-19; should neutralising antibodies be further supported as a component of the protective response, the expression of antibody responses in IU/mL is essential


Robert Deyrail/Getty Images

For the **WHO International Standard for anti-SARS-CoV-2 immunoglobulin** see https://www.nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=20/136

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to gather a consensus from several clinical trials and other studies on the titre required for protection.

Although the correlate of protection against SARS-2-CoV has not yet been unequivocally defined, antibodies are likely to be at least part of the protective response. The effect of new variants on the evaluation of antibodies is obvious and unequivocal comparisons are required. Reporting the immunological responses from vaccine clinical trials against the International Standard is essential for the evaluation of clinical data submitted to national regulatory authorities as well as to WHO for emergency use listing, especially as placebo-controlled efficacy studies become operationally unfeasible. There will be a substantial effect on the use of the International Standard if regulatory authorities worldwide request data in IU/mL or BAU/mL. We also encourage journal editors and peer reviewers to ensure that the international standard is used as the benchmark in publications and that data from serology assays are reported in International Standard units.

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See Online for appendix

For **WHO data on COVID-19 cases** see https://covid19.who.int/WHO-COVID-19-global-table-data.csv

See Online for appendix

COVID-19 vaccines in high-risk ethnic groups

Black, Asian, and minority ethnic communities worldwide have a disproportionate risk of severe COVID-19. In the UK, as of May 19, 2020, 36% of critically ill patients with COVID-19 requiring intensive care were from Black, Asian, or minority ethnic groups.[1] According to Public Health England, the mortality risk from COVID-19, after accounting for sex, age, deprivation score, and geographical region, is double in Bangladeshi people and up to 50% higher in Black and south Asian people compared with White British people.[1] This finding contrasts with age-adjusted all-cause mortality from previous years, which was lower in Asian and Black people than in White British people.[1] These data imply that COVID-19 has more serious effects in Black and Asian people.

The ethnic groups most affected by COVID-19 are under-represented in the COVID-19 vaccine trial data published so far. Despite efforts to encourage participation from Black, Asian, and minority ethnic groups, of the 552 participants in the phase 2/3 Oxford–AstraZeneca trial (based in Southampton and Oxford, UK), only one participant was Black and 19 were Asian.[2] Large-scale trials also have a smaller proportion of minority groups compared with the populations sampled (appendix).[3-5]

Black, Asian, and minority ethnic individuals are under-represented in research. However, the ongoing pandemic necessitates that access to trials and vaccinations shifts from being equal to being equitable. Study recruitment and participation designs should improve diversity in ethnic groups to maximise the validity of results to the populations concerned. Age and sex are routinely considered in recruitment design—the same should now apply to ethnicity.

In the context of a pandemic that has higher infection and mortality risks in certain ethnic groups, it is important that these specific groups are adequately represented in vaccine trials to evaluate both immunogenicity and efficacy.

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New COVID-19 resurgence in the WHO Eastern Mediterranean region

After 7 weeks of falling numbers of COVID-19 cases, a global upsurge was reported during the week of Feb 22, 2021. This case resurgence was observed earlier in the WHO Eastern Mediterranean region, where, between Jan 30 and Feb 26, 2021, the number of weekly cases increased from 158 004 to 207 424 (31%; appendix).

Multiple factors might have contributed to the increase. These factors include changes in testing capacity or strategy, increased transmission associated with mass gatherings, easing of, or decreased