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.

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Brazil’s COVID-19 guidelines: political hijack of public health

On Jan 20, 2022, in an unprecedented move, the Brazilian Secretary for Science, Technology, and Innovation overrode the Brazilian guideline for COVID-19 outpatient treatment. The guideline was originally demanded by the Ministry of Health, developed by a team of academics, specialists, and health technology analysts, according to GRADE-ADOLOPMENT methodology.1 The guideline, which recommended against the use of drugs without scientific proof of efficacy, such as hydroxychloroquine and ivermectin,2 was finally approved by the National Committee for Health Technology Incorporation (CONITEC) in December, 2021. In the Brazilian public health system, CONITEC has a central role in evaluating and recommending technology implementation on the basis of the scientific paradigms of efficacy, effectiveness, and cost-effectiveness.

Since the beginning of the COVID-19 pandemic, there has been endless and polarised debate regarding the use of unproven therapies for COVID-19 in Brazil, which, combined, are known as COVID Kit. COVID Kit was popularised by a populist federal government and, unfortunately, was adopted by some members of the medical community who failed to recognise the principles of scientific reasoning in medical decision making.

Paradoxically, the anti-scientific decision against the guideline was taken by a secretary of science. The decision was accompanied by a long note of justification, which made use of epidemiological jargon to define a logic that clearly violated basic scientific principles. First, it suggested that statistical significance should not be a necessary condition for establishing drug efficacy; second, it proposed Bradford Hill criteria as a means to claim drug efficacy in the absence of controlled empirical observations, such as large and low risk of bias clinical trials; and finally, it concluded in favour of the effectiveness of hydroxychloroquine, while claiming that vaccination has no demonstrated effectiveness.3

It is natural for humans to suffer from intrinsic bias in the process of judgement. However, the present situation seems to be the result of a strongly polarised environment that led to this unfortunate conspiracy to replace scientific criteria with political interests.

Brazil has been an example of two opposite phenomena: the tendency of a populist government to undermine science, and the resistance of scientists under a strong democratic regimen that supports freedom of speech. We believe that with the support of the international scientific community, the latter will prevail.

We declare no competing interests.

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1 Schümemann HJ, Wierichow W, Brozek J, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol 2017; 81: 101–10

2 Ministry of Health. Diretrizes Brasileiras para tratamento medicamentoso ambulatorial do paciente com COVID-19. November, 2021. http://conitec.gov.br/images/Consultas/Relatorios/2021/20211112_Diretrizes_Brasileiras_para_Tratamento_Medicamentoso_Ambulatorial_do_Paciente_com_COVID-19.pdf (accessed Jan 22, 2022).

3 Correa LC, Lopes JRP, Garcez FB, Campion EL, Barcelos G, Barreto-Filho JA. Physicians’ preference towards the non-evidence based hydroxychloroquine treatment for COVID-19: the pandemic effect. Evidence 2020; 2: 10–15.

4 National Commission for Health Technology Incorporation. Fundamentação e decisão acerca das diretrizes terapêuticas para o tratamento farmacológico do COVID-19. 2021. http://conitec.gov.br/images/Audencias_Publicas/Nota_Tecnica_n2_2022_SCTIE-MS.pdf (accessed Jan 22, 2022).

Vaccine approval before phase 3 trial results: a consequence of vaccine access inequity

The final phase 3 clinical data for CanSino Biologics’ adenovirus type 5 vector vaccine show that Ad5-nCoV is efficacious.2 However, emergency approval was granted in ten countries before data on its efficacy were available, even though other vaccines were already approved.1 If the results of the trial had been unfavourable, millions of people would have been vaccinated and granted a false sense of protection. If this scenario had happened, the decision to approve the vaccine for emergency use would have been an unforgivable one, given other proven vaccines existed at the time. The authorisation of the unproven vaccine at the time, an already criticisable decision, was the consequence of the COVID-19 pandemic (and governments) aggravating the previously existing health inequities between and within countries.1,2

Apart from Chile and Hungary, the countries that granted emergency use approval were low-income and middle-income countries according to the World Bank.1 With other vaccines, such as those based on mRNA technology, repeatedly out of stock or sold overpriced, the question was not which vaccine to buy, but whether there was any vaccine to buy.3,4 Even towards the end of 2021, a time when many low-income and some middle-income countries had very low vaccine rates, high-income countries were proceeding with the third and fourth doses.3,4 The approval and purchase of vaccines without phase 3 results is a symptom of inequity in vaccine access, which has the unfortunate potential to increase this problem.

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For the World Bank data see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

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No point in travel bans if countries with poor surveillance are ignored

Marc Mendelson and colleagues argue strongly against travel bans to contain newly recognised SAR-CoV-2 variants of concern. We would like to add another aspect: ignoring countries with poor surveillance systems.

South Africa has good epidemiological and genomic surveillance, but many other countries do not. Within 2 days of return to South Africa from Tanzania in January, 2021, a traveller developed clinical symptoms and tested positive for SAR-CoV-2 by PCR. Sequencing using published methods identified the virus as the beta variant of concern, highly likely to have been acquired in Tanzania during its second epidemic wave.

This case highlights the potential for a variant of concern to be introduced from a country that had not reported its presence. Until Dec 23, 2021, Tanzania has not uploaded a single SAR-CoV-2 genetic sequence to GISAID. In fact, Tanzania had not been reporting COVID-19 case numbers at all between May, 2020, and July, 2021, linked to a denialist official stance.

Tanzania’s second wave in early 2021 might have been linked to the beta variant with the traveller acting as a sentinel. Although several countries in southern Africa were listed as so-called areas of variants of concern by Germany in early 2021, Tanzania remained a so-called risk area until being declared a high incidence area from mid-March, 2021.

Perceived as punishment for countries conducting genomic surveillance and reporting openly, the illogical application of travel bans could act as a deterrent to conducting genomic surveillance and, thus, foil their very objective.

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1 Mendelson M, Venter F, Moshabela M, et al. The political theatre of the UK’s travel ban on South Africa. Lancet 2021; 398: 2211–13.

2 Engelbrecht S, Delaney K, Kleinmans B, et al. Multiple early introductions of SARS-CoV-2 to Cape Town, South Africa. Viruses 2021; 13: 526.

3 Tegally H, Wilkinson E, Giovanetti M, et al. Detection of a SARS-CoV-2 variant of concern in South Africa. Nature 2021; 592: 438–43.

4 Buguzi S. Covid-19: counting the cost of denial in Tanzania. BMJ 2021; 373: n1052.

5 Gunther S, Emmerich P, Laue T, et al. Imported lassa fever in Germany: molecular characterization of a new lassa virus strain. Emerg Infect Dis 2000; 6: 466–76.

Booster vaccines for COVID-19 vaccine breakthrough cases?

We read with interest the Viewpoint by Philip Krause and colleagues. Although considerations for boosting COVID-19 vaccine immune responses are surprisingly controversial, several existing non-COVID-19 vaccines have routine three-dose regimens to provide maximum efficacy. A recent study from Israel reinforces the value of a third vaccine dose in individuals aged 60 years or older and the recent decision by the Food and Drug Administration to recommend an additional vaccination in those aged 65 years or older in the USA reflects the need to continue to protect the most vulnerable. Bar-On and colleagues show data supporting an additional dose, but they do not cover efficacy of a third dose for someone who has had a breakthrough infection after full vaccination. These are individuals usually with no underlying known immunogenicity, who, nonetheless, for a variety of reasons (ie, higher exposure to viral inoculum, prolonged exposures to multiple infected people, or a previously undiagnosed mild immunodeficiency) become infected with SARS-CoV-2. Although there are many potential reasons for vaccine breakthroughs, including variants, it might be that a booster dose is most needed in those whose vaccine-induced immunity had already failed. Official data from Israel have shown that in those who receive a third dose, with or without breakthrough infection, there are potential side-effects, although similar to or better than after dose two of the primary series. Careful monitoring is needed for vaccine breakthrough cases since they might be the most susceptible to additional re-infections and might be most in need of another dose of vaccine.

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1 Krause PR, Fleming TR, Peto R, et al. Considerations in boosting COVID-19 vaccine immune responses. Lancet 2021; 398: 1377–80.

2 Bar-On YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 vaccine booster against Covid-19 in Israel. N Engl J Med 2021; 385: 1393–400.

3 Israel Ministry of Health. Link to the lecture: The efficacy of the third dose, recovered individuals’ protection and updates on the monitoring of side effects. Oct 10, 2021. https://www.gov.il/en/departments/news/08102021-01 (accessed Oct 10, 2021).