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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-ADOLPMENT methodology.<sup>1</sup> The guideline, which recommended against the use of drugs without scientific proof of efficacy, such as hydroxychloroquine and ivermectin,<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup>

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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## 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.<sup>1</sup> However, emergency approval was granted in ten countries before data on its efficacy were available, even though other vaccines were already approved.<sup>1</sup> 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.<sup>1,2</sup>

Apart from Chile and Hungary, the countries that granted emergency use approval were low-income and middle-income countries according to the World Bank.<sup>1</sup> 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.<sup>2,3</sup> 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.<sup>2,4</sup> 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.

I declare no competing interests.

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