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and unvaccinated controls to ascertain the actual reduction of asymptomatic infection in vaccinated individuals. The early rate reductions seen in HCWs might differ from vaccine efficacy reported in the general population due to their higher exposure risk or due to exposure to more virulent or infectious strains.

Our data show substantial early reductions in SARS-CoV-2 infection and symptomatic COVID-19 rates following first vaccine dose administration. Early reductions of COVID-19 rates provide support of delaying the second dose in countries facing vaccine shortages and scarce resources, so as to allow higher population coverage with a single dose. Longer follow-up to assess long-term effectiveness of a single dose is needed to inform a second dose delay policy.

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Sharon Amit, Gili Regev-Yochay,
Arnon Afek, Yitshak Kreiss,
*Eyal Leshem
eyal.leshem@sheba.health.gov.il

Clinical Microbiology (SA), Infection Control and Prevention Unit (GR-Y), The Gertner Institute for Epidemiology and Health Policy Research (GR-Y), General Management (AA, YK), and Infectious Diseases Unit (EL), The Chaim Sheba Medical Centre, 52621 Ramat-Gan, Israel; Sakler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel (SA, GR-Y, AA, YK, EL)

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MAb for symptomatic COVID-19 in correctional facilities: an important opportunity

Jails and prisons across the USA are at the epicentre of the COVID-19 pandemic. Most of the largest, single-site cluster outbreaks of COVID-19 in the country have occurred in jails and prisons.¹ Much attention has focused on the need for testing, masks, and robust access to vaccination; however, calls to increase access to treatment are largely absent. In November, 2020, the US Food and Drug Administration (FDA) authorised the use of monoclonal antibodies (mAbs) for the treatment of mild to moderate COVID-19 because these treatments prevent progression to severe disease and considerably reduce hospitalisations and emergency room visits.² However, uptake of these treatments has been slow, including in the correctional setting.

In response to the COVID-19 pandemic, as well as implementing widespread surveillance testing of residents and staff, universal mask wearing, small group cohorting, and vaccination of detained individuals at high risk, the Rhode Island Department of Corrections (RI, USA) administered an anti-SARS-CoV-2 mAb approved by the FDA and Emergency Use Authorization to a symptomatic, incarcerated person with COVID-19 on Jan 22, 2021, for the first time. The individual met criteria on the basis of timing of symptoms, age, and presence of comorbidities. There were no complications, and the individual did not require hospitalisation. To our knowledge, mAbs have been sparsely used in correctional settings across the USA. This treatment, and any other approved treatment that has the potential to reduce serious disease and death from COVID-19, should be made widely available to individuals who are incarcerated or detained and meet eligibility criteria.

Incarcerated individuals are at high risk of infection and death from COVID-19³ and are often overlooked in this pandemic. However, they can have a major role in statewide outbreaks.⁴ MAb treatments not only benefit individuals at high risk of disease but can also decrease the burden on over-run community medical centres and hospitals. In the current environment, where implementation of mAbs has proven challenging and many doses of medication go unused nationally,⁵ correctional facilities offer the unique opportunity to efficiently identify and administer this evidence-based intervention.

Health departments, hospital systems, policy makers, and correctional administrations should collaborate to ensure access to evidence-based treatments, such as mAb therapy, as quickly as possible. In this way, society can not only treat a marginalised population at high risk but also efficiently decrease community burden on the local health-care infrastructure.

JB reports being the Medical Director for the Rhode Island Department of Corrections. All other authors declare no competing interests.

*Justin Berk,
Lauren Brinkley-Rubinstein,
Matthew Murphy, Phil Chan,
Josiah Rich
justin_berk@brown.edu

Rhode Island Department of Corrections, Cranston, RI, USA (JB); Warren Alpert School of Medicine, Brown University, RI 02903, USA (JB, MM, PC, JR); Department of Social Medicine and Center for Health Equity Research, University of North Carolina, Chapel Hill, NC, USA (LB-R); Rhode Island Department of Health, Providence, RI, USA (PC); Center for Health and Justice Transformation, The Miriam Hospital, Providence, RI, USA (JR)

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Rationale to continue approving placebo-controlled COVID-19 vaccine trials in LMICs

The COVID-19 pandemic has affected our world like no other virus or disease in the past century. Thus, having a reliable vaccine to prevent its spread is urgent. The scientific community and society received with great hope the issuance of two COVID-19 vaccines by the US Food and Drug Administration for Emergency Use Authorization (EUA). However, this milestone has brought ethical and methodological questions about the continued use of placebo control for new candidate vaccine trials.^{1,2} In January, 2021, our institutional review board approved an application for a phase 3, placebo-controlled COVID-19 trial using a protein-based platform in Ecuador. Here we share our experience and the rationale used to approve this protocol. The following are the justifying elements used in our judgment.

First, we had to consider economic and logistical issues. A proposed strategy to evaluate COVID-19 vaccines after EUA is to run head-to-head randomised trials with non-inferiority designs.¹ Due to an international shortage of approved vaccines, it is not feasible to do this kind of design locally. This constraint is even worse for low-income and middle-income countries (LMICs), which have less capacity to negotiate and purchase vaccines than do high-income countries (appendix). For example, by Feb 12, 2021, Ecuador was able to acquire 8000 doses of the Pfizer–BioNTech vaccine; however,

there is a lot of uncertainty as to when and how many doses we will receive throughout the year to continue our massive vaccination programme.

Second, there is room to claim clinical equipoise in COVID-19 vaccine trials. Although we acknowledge the rigorous development process and comprehensive evaluation that the two vaccines faced to be granted EUA, they are still not completely licensed medical products and are subject to long-term surveillance, especially for safety. The scientific literature shows examples of fully licensed vaccines that have had to be taken off the market due to safety concerns (eg, Rotavirus vaccine).³

Third, some scientists and bioethicists argue that researchers doing clinical trials should treat participants as if they were patients. If that is the case, in the best of their clinical interests, it would be unethical to give the participants a placebo.² We disagree with this argument and recognise that the researcher's obligations differ among participants and patients. After our institutional review board assessed the risk-benefit profile of the new candidate vaccine and concluded that the benefits outweigh the potential risks, we concluded that use of proper informed consent would allow participants to enrol in the trial and accept some risks to collect socially valuable data.² Having multiple vaccine producers to overcome this global shortage scenario is morally and ethically imperative, especially for LMICs.

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**Ivan Sisa, Estefania Noblecilla, Fadya Orozco*
isisa@usfq.edu.ec

College of Health Sciences (IS, FO) and Institutional Review Board (EN), Universidad San Francisco de Quito, Quito 170901, Ecuador

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UK COVID-19 public inquiry and lessons from patient safety

The family accounts of loved ones lost to COVID-19 make for tough reading.¹ The Covid-19 Bereaved Families for Justice group are right to campaign for an immediate public inquiry so that lessons can be learned as quickly as possible to save lives as the pandemic continues. Any suggestions that this would be distracting are against the modern understanding of human factors and the science of crisis management. It is a well established principle of patient safety that, during a crisis, the team should promptly pause to consider a rapid review of whether or not the actions being taken are correct and effective.² It would appear that this is one of the first important lessons that needs to be learned from the patient safety principles of crisis management.

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David K Whitaker
whitaker2000@gmail.com

European Board of Anaesthesiology, European Union of Medical Specialists, Brussels 1040, Belgium; Manchester Royal Infirmary, Manchester, UK

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Learning from crises

In response to the Comment by Jo Goodman and colleagues of the Covid-19 Bereaved Families for Justice,¹ we have every sympathy with the individuals for their loss

For more on the COVID-19 vaccines for EUA by the FDA see <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>



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See Online for appendix