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Azithromycin, RECOVERY, and the power of large, simple trials

One of the many challenges for clinical trials during a pandemic such as COVID-19 is the need to provide reliable and clear answers rapidly. High-quality, adequately powered, simple randomised clinical trials have been crucial in advancing knowledge of potential treatments for COVID-19.[1] Principles underpinning such trials include the use of the uncertainty principle to determine eligibility, which allows for rapid enrolment of participants and streamlined data collection, making these studies easy to implement in routine practice.[2] Platform and adaptive trial designs further improve the large, simple trial concept, allowing investigation of multiple experimental therapies throughout the trial with sufficient statistical power for clinically relevant outcomes.[3]

RECOVERY represents a large, simple, randomised platform trial. Results for other potential treatments for COVID-19—ie, dexamethasone, hydroxychloroquine, and lopinavir–ritonavir—have been published previously.[4–6] In *The Lancet*,[7] the RECOVERY Collaborative Group report the results of a trial of azithromycin in patients admitted to hospital with COVID-19. Azithromycin is a widely available, inexpensive drug, and has an excellent safety profile for other conditions; thus, if shown to be effective and safe, it could represent a treatment option for patients with COVID-19. The trial enrolled 7763 participants, of whom 2582 patients were randomly allocated to receive azithromycin (500 mg once per day by mouth or intravenously for 10 days or until discharge) and 5181 patients were randomly allocated to receive usual care alone. The trial took place at 176 hospitals in the UK. Outcomes were ascertained through a 1-page electronic case report form and linkage to national health data systems. The mean age of study participants was 65·3 years (SD 15·7), approximately a third (2944 [38%] of 7763) were women, and the median time since symptom onset was 8 days (IQR 5–11). The investigators found no benefit of azithromycin for the primary outcome of 28-day mortality when added to the standard care regimen (rate ratio 0·97, 95% CI 0·87–1·07; p=0·50). There was also no difference between groups in duration of hospital stay. In addition, among those not on invasive mechanical ventilation at baseline (94% of the included participants), no difference was seen in the proportion meeting the endpoint of invasive mechanical ventilation or death. Results were similar across all prespecified subgroups.

The strengths of the RECOVERY trial were the use of concealed randomisation, the intention-to-treat analysis, and the large sample size. Limitations that merit consideration are the open-label design and the fact that 17% of patients in the usual care group were given azithromycin or another macrolide antibiotic.

The results of this investigation into azithromycin as part of the RECOVERY trial confirm and extend those of the COALITION II trial,[8] which showed that the addition of azithromycin to standard of care treatment did not improve the clinical outcomes of patients admitted to hospital with severe COVID-19. Given that the addition of azithromycin to existing standard of care regimens

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did not improve outcomes in the RECOVERY and COALITION II trials, routine use of azithromycin in patients admitted to hospital with COVID-19 should be avoided, to allow better allocation of health-care resources.

Collaborative research efforts such as RECOVERY, COALITION COVID-19 Brazil,[8-10] and SOLIDARITY[11] are evidence that pragmatic, randomised clinical trials can be promptly initiated in different countries and settings during a pandemic, as we have seen with COVID-19. Ongoing randomised clinical trials from these collaborative research efforts and from other groups are testing other potential therapies for COVID-19 such as anticoagulants, newer antivirals, anti-inflammatories, and immunomodulatory agents. Results from these studies will help to inform treatment decisions in clinical practice. The experience and the knowledge gained from successfully launching these studies in a matter of weeks has important implications for research not only in COVID-19 but also for future pandemics and for common diseases.[12] Finally, innovations such as big data technologies and linkage with electronic health records, mobile applications, and wearable devices can further transform pragmatic randomised clinical trials, making them larger, more efficient, and easier to implement.

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Research in forced displacement: guidance for a feminist and decolonial approach

The COVID-19 pandemic has deepened inequities and undermined health, human rights, and gender equality for forcibly displaced populations.[1,2] The United Nations Refugee Agency estimates that, at the end of 2019, there were 79·5 million people forcibly displaced as a result of persecution, conflict, violence, human rights violations, or events seriously disturbing public order.[3] Evidence about the needs of these populations is crucial to tailor effective and equitable responses, but data collection efforts are faced with considerable new challenges during the COVID-19 pandemic. Many researchers are attempting to overcome such challenges by collecting data remotely, but doing so creates ethical and practical concerns that risk perpetuating gender, racial, and other inequities. For example, the gender divide in mobile phone ownership,[4] internet access, and digital literacy creates barriers to data collection from women, further silencing their voices and that of other groups without access to these technologies. Overcrowded living spaces, mobility restrictions, and lack of autonomy over technology use (due to COVID-19, gender norms, or both) exacerbate ethical concerns regarding confidentiality, privacy, and safety during remote data collection.

The ongoing pandemic has also exposed persisting power hierarchies between researchers and forcibly displaced populations. These populations experience power asymmetries in their position as the so-called beneficiaries of humanitarian research and action,