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COMMENTARY

Research ethics during a pandemic (COVID-19)

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The current pandemic with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in a major global health crisis.[1] This has put tremendous strain on healthcare systems around the world and naturally raises issues concerning the allocation of scarce resources. It presents a clear and urgent need for research into management of the disease in individuals and of the epidemic in populations. Addressing this need around the world raises practical and ethical issues for the scientific research community internationally.

There have been several recommendations addressing ethical issues which arise during global health emergencies, including the current COVID-19 pandemic.[2-4] These partly serve to set guidance based on distributive justice to allocate limited healthcare resources appropriately, and have been based on the relevant ethical principles of justice, beneficence, utility, respect for persons, liberty, reciprocity and solidarity. With regards to fair allocation of scarce resources during the COVID-19 outbreak, recommendations have been made in line with the utilitarian approach of maximising benefits and are based on four guiding principles: (1) maximising total benefits produced by scarce resources, (2) treating equivalent cases equally, (3) promoting and rewarding instrumental value (benefit to others) and (4) giving priority to the worst off.[5]

More practical guidelines relating to critical care access have been set based on urgency of medical need, the likelihood and duration of clinical benefit and the change in quality of life.[6] Algorithms have been adopted to maximise patient safety and to direct the appropriate use of resources in the event that they become scarce.[7]

Recommendations have also been set to prioritise research in COVID-19-related work with immediate and mid- to long-term priorities.[3,4] The immediate aims focus on accelerating research that can contribute to containing the spread of this epidemic and helping those affected to receive optimal care. The mid- to long-term priorities stemming from experience of this pandemic are to develop global research platforms aiding preparedness for the next unforeseen epidemic and to encourage research, development and equitable access, based on public health needs, to diagnostics, therapeutics and vaccines.[4] The process of prioritisation to meet the above needs will result in reallocating staff and resources towards COVID-19-related activities, which will naturally have its pros and cons. The imperative for research must therefore be balanced by the need to avoid unduly diverting resources, including personnel, equipment and healthcare facilities, from other critical clinical and public health efforts.[2] Emphasis must also be put on the need to coordinate research within and between research institutions as well as with government bodies to avoid overlapping protocols amidst changing standards of care, which is particularly pertinent in settings where resources are limited.

Despite the pressures that typically surround pandemics to implement treatments with a promising rationale directly including research invitations, the research community should assert the benefits of testing treatment hypotheses with methodological rigour.[8] This approach has arguably led to reliable improvements in treatment, for example, demonstrating the ineffectiveness of hydroxychloroquine and benefits of dexamethasone for patients with COVID-19.[9,10] While the investigators have used established methods such as randomised controlled trials, they have chosen to expedite publication of the results before traditional peer review, using press releases and preprint archives such as bioRxiv and medRxiv.

Many of the issues mentioned above will affect institutional review and medical ethics boards (IRBs) and research ethics committees (RECs) around the world as they continue to administer research governance during the health emergency. The majority of guidance for IRBs during the COVID-19 pandemic have focused on the logistics of clinical trials, with less focus on new study submissions during this outbreak.[11,12] IRBs and RECs are tasked with prioritising new study submissions and modifying ongoing research activity while staying true to the ethical principles and international guidance discussed above.

We therefore propose recommendations to guide research governance during the COVID-19 pandemic:

(1) Review of new research study submissions may be expedited, but not compromised in quality, particularly in relation to fair consent, the safety of study participants and ensuring methodological validity to answer the scientific question asked. Scrutiny should be applied to the publication strategy emphasising good publishing practice, with the need for data transparency and peer review balanced against the benefit of expediting knowledge of study results in a rapidly developing pandemic.
(2) Research methodology should be assessed in the context of potentially stretched clinical resources. The best designs will be conducive to the delivery of direct clinical care and good designs will be complementary. Research that competes for resources such as staff, protective equipment and hospital capacity should be carefully assessed as described above, but may be justified in the immediate term to help contain the pandemic and to help those affected to receive optimal care, for example, in the testing of novel treatment and vaccines.
(3) As the coronavirus pandemic develops, COVID-19 will come to sit among other medical conditions in the clinical landscape. COVID-19-related research should be considered alongside research into other conditions and evaluated on the same terms. In the short term, research into COVID-19 is likely to be prioritised due to its clinical urgency and the imperative to study the ongoing pandemic as it develops.
(4) Research that was planned or ongoing before the pandemic may need to be reassessed and formally reviewed, for example, in relation to risks to study participants, particularly the impact on patients who are already suffering from life-threatening and, in some settings, highly stigmatised disease, or to comply with public health control measures such as social distancing requirements.

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