

Paediatric treatment trials for COVID-19 are an ethical imperative

Our proposal to perform a randomised trial of antiviral treatments for children with moderate to severe COVID-19 has frequently been met with the view that it is not ethical. Central concerns have been that children frequently have no symptoms (when in fact symptoms occur in 21% of children), that severe presentations are rare (2%)¹ and that treatments should only be evaluated in children once the results of adult trials are available.

Certainly, medical research involving children raises distinctive ethical issues. Children are more vulnerable than most adults, and many lack capacity to provide informed consent to potentially harmful research.² As with all human research, the risks of a trial in children must be carefully weighed against the possible benefits to both research participants and to other children.


Nevertheless, we challenge the notion that therapeutic trials in children with COVID-19 must await completion of adult trials. Of more than 6 million people infected in these last 6 months of the pandemic, up to 10% were children.³ At the time of writing, there were 416 children in the USA with COVID-19 admitted to intensive care.⁴ Furthermore, the spectrum of disease in children is evolving with reports of paediatric inflammatory multisystem syndrome temporally associated with severe acute respiratory syndrome coronavirus 2, a condition for which studies of therapeutic approaches are urgently needed and unlikely to be informed by trials in adults.⁵ Notably, a recent report found that up to 61% of children admitted to intensive care in Canada and the USA are already receiving therapeutic agents.⁶

Risks associated with therapeutic trials in children for COVID-19 can be mitigated by first evaluating medications already licenced in children for other

indications (eg, hydroxychloroquine and ascorbic acid) or medications that have a reassuring safety record when used off-label (eg, anakinra). These agents have established dosing recommendations and safety profiles. While risk cannot be eliminated entirely, the stringent oversight of a clinical trial will mitigate the risk of potential harms posed by these agents—certainly compared with experimental use outside of the context of a trial. If no suitable trial opportunities are available, approval from a hospital drug and therapeutics committee and clinical ethics committee should be obtained prior to use.⁷

A crucial ethical consideration in this evolving pandemic is the urgency of the need for effective paediatric treatments and the number of children who stand to benefit. The potential benefits lie in minimising morbidity and mortality associated with severe disease if treatment is effective and also in preventing unnecessary, costly and potentially harmful treatment if ineffective.

In the race to find treatments for COVID-19, children are being left behind. There is a compelling ethical case to include children in rigorously designed and regulated clinical trials to determine the safety and efficacy of potential treatments for COVID-19 as soon as possible.

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