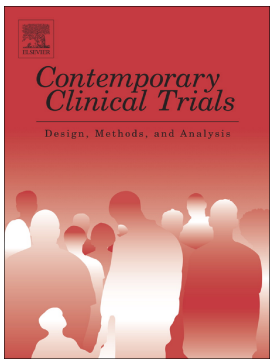

Does the COVID-19 outbreak identify a broader need for an urgent transformation of cancer clinical trials research?

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Does the COVID-19 outbreak identify a broader need for an urgent transformation of cancer clinical trials research?

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The COVID-19 outbreak has disrupted healthcare systems across the United States and the world [1], mandating a self-assessment of workflows in order to reduce exposure risk among patients, staff, and the community at large. Social distancing has become an imperative in order to reduce community transmission of the virus. As a result, organizations are rapidly expanding utilization of video conferencing platforms, telehealth, and other tools to deliver remote care and abide by social distancing measures.

The imperative of reducing community spread and the number of non-urgent visits to healthcare centers, has several implications for research institutions implementing therapeutic cancer clinical trials. For one, patients who can be safely monitored remotely may be given the option for a remote-visit if possible. Secondly, facilities have to redirect resources and staff to attend to a surge of acute cases associated with COVID-19 which may limit the capacity to deliver elective procedures involved in clinical research. Third, non-essential staff, including clinical research staff are increasingly being required to work remotely in order to reduce exposure risk.

These measures, while necessary in the context of the COVID-19 pandemic, also serve as an opportunity to reconsider the utility of frequent in-person visits, rather than remote monitoring, for patients enrolled in therapeutic clinical trials, particularly when the therapeutic is an oral therapy that can be dispensed to the patient by mail or a courier service.

Less than five percent of therapeutic cancer clinical trials adequately accrue a representative sample of racial/ethnic minorities [2]. Travel remains a major burden associated with cancer clinical trials participation [3], and may contribute to disparities in whom they serve [4], and may

be amplified in patients who live in rural areas [5]. Efforts to address this potential barrier to participation have largely focused on addressing indirect costs, such as lodging and gas [6, 7]. However, there is also an urgent need to re-consider the need for high frequency in-person safety monitoring. The level of safety monitoring that is considered "good practice" may be unnecessary for certain investigational therapeutics or a subset of low risk clinical trial participants [8]. Uren and colleagues observed that remote monitoring for complex phase III clinical trials was feasible and led to an overall cost saving for the sponsor and reduced burden on facility resources [9]. Importantly, reducing intensity of in-person visits for cancer clinical trials may help promote equity in recruitment and improved access.

COVID-19 is forcing our hand. It is demanding research institutions to undertake care of patients on clinical trials remotely, when possible. It is pointing out that in some cases, we place undue, and unnecessary burdens on our patients if they wish to avail themselves of clinical trials. And it suggests that in the right circumstances, less may be more. This challenging time in our history may permanently inform the way we think about and design therapeutic cancer clinical trials in order to make them more patient-centered and inclusive.

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