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Commentary

Challenges of Clinical Research Administration During the COVID-19 Pandemic

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Abstract. In early 2020, clinicians and researchers rushed to understand the SARS-CoV-2 virus and how to go about treating and preventing it. Caring for patients while simultaneously learning about a disease not seen before created challenges on several levels. Much of the spotlight was on the researchers doing this critical work; however, these narratives remind us of the enormous effort and commitment shown by IRB members and research administrators responsible for research infrastructure. Despite the sense of urgency and obligation to plan and conduct clinical research during the pandemic, IRBs guaranteed that researchers still adhered to the core ethical principles that protect the rights and welfare of human subjects so that critical research could continue. Many themes emerge in these stories, including the need for flexibility in processes for both staff and research participants and the perception that IRB members serve as “research gatekeepers.” With approaches to clinical research evolving, the SARS-CoV-2 pandemic may be the catalyst needed to make sustainable improvements to our research processes, roles, and goals.

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The COVID-19 pandemic first reached the United States in Seattle but it was only a short time later that it appeared in New York City to create a crisis, the scale of which had not been seen before. New York was about to become the epicenter of the pandemic but the magnitude of the crisis and the impact that it was about to have on all of our lives was not immediately clear to most people in the United States regardless of whether you were a clinician, researcher, administrator or the average person on the street.

Central to the challenge was the need to understand the virus, the disease, and how to go about treating and preventing it—and we were literally starting from scratch. This meant caring for patients while simultaneously trying to learn about a disease that had not been seen before, creating challenges on several levels. While much of the spotlight remained on researchers doing this critical work, many things happened behind the scenes that were necessary to keep the research machinery working. These stories remind us of the enormous effort and

commitment shown by individuals and teams that are responsible for much of the research infrastructure—without whom the pandemic would look very different today than it does currently. Reading through these stories from IRB administrators, many common threads emerge as we think about the pandemic's impact and what this might mean for those of us engaged in research. As Stefanie Juell pointed out in these narratives—"pandemics don't last forever," which is fortunate. However, the opportunities to learn from the pandemic will fade with time if allowed to do so—if not, the lessons learnt could serve us well moving forward.

Human Challenges

Like many other non-patient-facing parts of academic medical centers, the IRB staff left campus in March 2020, unclear of when they were coming back. More importantly, they continued their important and mission-critical work remotely through the pandemic, despite being as Juell describes, "exhausted, scared, frustrated, overworked and overwhelmed"—similar to what many of us in healthcare have experienced. The challenges of childcare were front and center as several stories alluded to the challenges of work-life balance—a theme that is consistent across the country—and the need for increased empathy and flexibility with team members was widely acknowledged. Empathy and understanding are more meaningful in the smaller actions that demonstrate their presence—i.e., the acceptance of meeting interruptions as nothing more than "cameos" as Edith Paal states. In short, these stories serve well to remind us of the challenges IRB members and research administrators faced in keeping research at the high standards that we have come to expect. We have much to thank them for as they worked through pandemics and earthquakes.

Technology

The invasion of technology into our lives was already occurring at a steady drumbeat prior to the pandemic but who would have thought that

"you are on mute" would become one of the most common phrases that we would hear every day. While conferencing technologies have their own challenges, the pandemic, as we have come to experience it this past year, would have been unrecognizable without them. While these technologies have their downsides and challenges, the associated benefits abound as well. As Joan B. Cobb Pettit put it, many "miss the dynamic of in-person IRB meetings" while others "really like not having to commute and dress for the office." The challenges of the pandemic on women have been described at length elsewhere and this ought to force us to rethink our current work models. The need to re-examine these is particularly urgent in academia. However, technologies that facilitated work from home have also helped create opportunities for positive memories that would not have happened otherwise—a 20-minute tickle session is an example of a memory that Jennifer Randles will keep, I suspect, forever.

The speed of adoption in a crisis of new technologies and overcoming the technology inertia that is often associated with academic medical centers and healthcare, in general, was a silver lining. While the descriptions of rapid technology adoption abounded in these stories along with some teething troubles, the absence of descriptions of resistance, reluctance, and failure was perhaps even more telling. We will eventually debate how much of this we want to keep (and we should). However, this experience will hopefully inform how other future technology opportunities will be viewed and maybe there will be less inertia in their adoption.

While the adoption of technology on the administrative side is seen as a clear win, implementing these very same technologies in the research realm created some wins and needs to be accompanied by critical questions. As said so eloquently by de Vos, "we must weigh the need for temporary accommodations versus long-term sustainable solutions." A rush to improve patient care with tools that require highspeed internet connections and smartphones can leave out the very patients who would benefit from them the most (i.e., our most vulnerable patients) (Badawy & Radovic, 2020; S. Nouri, Khoong, Lyles, & Karliner, 2020). Similarly, the rush

to engage in technology to overcome the challenges of the pandemic risks creating an additional hurdle for impoverished individuals and people of color to participate in research (Amin, Rae, Ramirez, & Cox, 2020). Having mere access to the technology may not be enough to remove barriers (S. S. Nouri et al., 2019; Weiss & Eikemo, 2017). For example, an in-person interview in a private office could result in a very different outcome than the same interview over a technology interface where the participant remains within earshot of their family members.

Flexibility in Processes

When Stefanie Juell states that, “The IRB’s purpose is not to impede research,” there is an implicit recognition that researchers often perceive that the IRB is an impediment to research. We need to think about how we have managed to create this unhelpful characterization of IRBs—an important component of our research infrastructure—as “a dreaded but necessary institutional hoop” or even worse as a “potential obstruction to conducting research” (Jennifer Randles). Many of the stories highlight the need for and subsequent introduction of flexibility that was missing from their processes pre-pandemic.

Recognizing the need for increased flexibility and the need to revisit processes was a common thread among many stories. Shorter amendment forms and other flexibilities that allow for “reduc[ing] the number of individual submissions coming in,” (Stefanie Juell) or for that matter, implementing the “probably overdue” electronic signature (Brian Moore) are all examples of process implementations that were either considered or accelerated because of the pandemic.

The introduction of flexibility and the movement away from paternalism, at least when participants are not part of vulnerable populations, are examples of what a forced re-examination of processes and assumptions can result in. The real question is, how many of these changes are going to be allowed to persist after the pandemic? There are lessons to be learnt from these changes that ought to inform further review and revisions of

processes—such that additional changes are identified that would benefit participants in particular but research teams as well.

Remote Consents

The ability to obtain consent without an in-person conversation was necessitated by the limitations created by the large number of critically ill, sedated, and ventilated patients—coupled with restrictions on visitors. Perhaps, it is often forgotten that consents for procedures and other clinical activity are often obtained remotely in clinical medicine from family and next of kin all the time in an appropriate and robust manner. These consents are obtained for the most complex of procedures and yet IRBs seem reluctant to embrace this approach.

While the intent of restrictions of how and when consent can be obtained is self-evident, the unintended negative consequences are sometimes less obvious and often overlooked. In her narrative, Hallie Kassan writes that there was increased recognition that criteria more stringent than the Common Rule at an organizational level were not helpful or in the participants’ best interest. Similarly, IRBs that “advocated very strongly in the past for in-person informed consent discussions” (Sujatha Sridhar) moved to recognize that remote consents could be complete and thorough. These changes are likely to benefit both study participants and research teams if allowed to remain in place post-pandemic.

There was concern expressed about the adverse impact of information in the media—graphic or otherwise—and its impact on informed consent. Prognostic information, whether it comes in the form of a study that provides 5-year survival estimates or graphic images in the press, will always inform the willingness of patients to participate in studies—and it probably ought to. In order to make informed choices, patients need to have the information that provides them the broader context to be able to do. Just as we try to move away from paternalism in medicine and empower patients to participate in decision making about their health-care choices, we need to recognize that these very same individuals should be considered capable of

understanding the context in which they are being approached to participate in studies.

Gatekeepers

While IRBs are charged with ensuring the safety of the study participants, it was interesting to note that many stories touched on their perceived role as research gatekeepers. The folly of the research effort that went into studying hydroxychloroquine is less a failure on clinical researchers and IRBs than of the peer-review process that provided the initial data suggesting a benefit where there wasn't any. Let's pause to think what those 104 studies in different subsets of individuals in different locations would have meant had hydroxychloroquine *actually* been an effective therapeutic intervention in at least a subset of individuals. Decisions to launch these studies and participate were not an act of desperation. They were based on the evidence at the time that suggested hydroxychloroquine might work and the need to know if it did—especially given that it has been taken safely by millions of patients for both malaria and lupus.

In the early days of the pandemic, when our understanding of the disease was extremely limited, clinicians were faced with the need to reach for anything that might work. This cannot be equated to circumstances where desperate attempts or offers were made for individual patients. With healthcare systems being overwhelmed and a war-like footing needed at the bedside to care for patients, potential discoveries of successfully repurposed drugs held the potential to save thousands of lives—and would have had significant implications for everyone. The idea that IRBs ought to act as gatekeepers that call into question what to study or that observational research should take a back seat is troubling. Much of what we learnt early in the pandemic resulted from astute bedside observations and the identification of key findings in large observational datasets. While the question of which studies should be undertaken is an important one, shouldn't these questions be asked by the expert clinicians and researchers who have a better grasp on the knowledge gaps and how a particular study might

inform next steps—or should it be the IRB? Doesn't this contradict the notion that IRBs have a “duty to approve sound science that is based on an assessment of submitted materials—not based on political pressures or even external circumstances,” as Stefanie Juell states in her narrative? Is there really a difference between the goals of research and the goals of clinical medicine when there is a complete absence of knowledge of what we were faced with? When something as fundamental as the appropriate timing of intubation and mechanical ventilation is unknown, does therapeutic misconception even exist? Shouldn't we study everything—every little intervention or lack thereof—to understand what we are facing? Shouldn't every action or inaction be subject to scrutiny as we expand our understanding of what we should and should not be doing? If that scrutiny is called research, then isn't that divide somewhat arbitrary and potentially misleading?

Should clinicians have done more in the form of randomized controlled trials rather than choosing to make certain therapeutic maneuvers into the standard of care early in the pandemic? Most would probably agree today in hindsight, but we have to ask what systemic issues led us in the opposite direction. Certainly, some of this was caused by the desire to do *something . . . , anything . . .* because that seemed better than doing *nothing . . .* or so it seemed at the time. The extent to which the choices made are a result of the regulatory burdens and process challenges, as well as how physicians are taught to create or even evaluate reliable data, will need to be studied further. The idea, often perpetuated by medical school deans and department chairs, that only those in basic science labs deserve the moniker of “physician-scientist” and the attendant biases associated with this idea have likely contributed to this. How we do clinical research, particularly in difficult circumstances, is an important question that should inform future process development. With large datasets, as well as rapidly changing technology and data science, the role and value of observational data are changing. With the rapid growth of electronic systems that can capture extraordinary amounts of data and metadata along with the expansion of tools available for analysis,

the volume and value of this type of work will only grow—and has the potential to change the paradigm of how we learn in medicine. Clinical research approaches are evolving, and the pandemic may just be the stimulus needed to re-evaluate processes, roles, and goals.

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