



## Effects of the COVID-19 Pandemic on Emergency Care Research Activity Within the United States

Since the first confirmed case of COVID-19 disease was reported by the US Centers for Disease Control and Prevention (CDC) in January 2020, more than 38.6 million cases of infection with the SARS-CoV-2 virus have been reported within the United States, including more than 623,000 deaths. The effects of the global COVID-19 pandemic within the United States have been both profound and enduring over the intervening two years since the first case of COVID-19 disease was reported.

In addition to the tremendous morbidity and mortality burden inflicted by COVID-19 upon the American populace, this pandemic has had a devastating effect upon the American healthcare system. Healthcare institutions in this country continue to reel from the effects of the pandemic, including unprecedented shortages of medical supplies, inpatient beds, and trained personnel to meet the growing demands of the pandemic. As the "front door" to the healthcare system, emergency departments are specially challenged to accommodate the barrage of both COVID and non-COVID patients seeking care in an already taxed system.

Acute care research has always presented a unique challenge to investigators, due to the increased difficulty of securing informed consent from critically-ill patients and the stresses associated with performing research interventions in a chaotic environ such as that commonly encountered in the emergency department (ED). The COVID-19 pandemic has greatly accentuated these challenges, as researchers continue to experience restrictions to their access to eligible patients, including also shortages of trained research personnel, and other limitations to pre-COVID activities imposed upon them by well-meaning hospitals and academic institutions. Because of these restrictions, emergency medicine (EM) investigators have experienced significant and unexpected difficulties in completing scientific inquiries that were predicated upon access to ED patients who are now less approachable or less available for enrollment than they were before the onset of the COVID pandemic.

Many patients who would have previously sought care in the ED prior to the pandemic are avoiding ED visits due to fear of COVID exposure, and many others are unwilling to engage in clinical research due to the risk of COVID-19 transmission due to research activities that may seem to them to be non-essential to their medical care. This has led to a perceptible decline in clinical research enrollments in many EM studies that might have otherwise been successful prior to the COVID-19 pandemic. Institutional restrictions on the accessibility of patients to research personnel also serve to reduce the ability of clinical research personnel to enroll patients in previously approved protocols.

Institutional measures to reduce potential COVID-19 exposure, the unprecedented attrition of research technicians, and diminished access to eligible subjects continue to plague EM

researchers. Consequently, EM investigators may have continued difficulty meeting enrollment figures in the COVID era, due to a variety of factors, including moratoria on non-COVID research, social distancing or remote learning that may have impacted educational research, research resources diverted to COVID projects, and other policies that make enrollment of subjects more challenging in the COVID era.

Recognizing the importance of acute care research, and the potential for institutional COVID restrictions and other challenges that may adversely impact enrollment in clinical research studies during the COVID era, the American College of Emergency Physicians (ACEP) and Society for Academic Emergency Medicine (SAEM) jointly suggest that both federal and private sponsors of acute care research consider the special challenges inherent to conducting research during the current pandemic. Accommodations should be made to ensure that successful completion of the research aims are possible despite current restrictions. We suggest that investigators and sponsors who have shown an abiding interest and commitment to furthering research advancing the health and well-being of American citizens remain cognizant of the special challenges facing EM researchers during this global pandemic.

Medical research is an important endeavor that must not be adversely affected by the current pandemic. Indeed, methodologically sound and important clinical research must be encouraged and supported, especially considering current challenges to subject enrollment. In the case of federally funded projects, we suggest that Principal Investigators reach out directly to their federal Program Officers to seek extensions on ongoing research projects and other accommodations to enable successful completion of their research mission despite current roadblocks.

We feel that emergency care research is more important now than ever before. Although national attention has been focused upon the COVID-19 pandemic over the last two years, many other medical conditions warrant our continued attention. It is especially important now, as our country rebounds from the worst pandemic that we have seen in over a century, that we join as a country in seeking novel and effective advancements to medical care for other conditions. We must prevent important advances to medical care from becoming yet another casualty of the COVID-19 pandemic.

## **References**

 Centers for Disease Control and Prevention (CDC). COVID-19 Mortality Overview [Internet]. 2021 August 25 [cited 2021 August 27]. Available from: <a href="https://www.cdc.gov/nchs/covid19/mortality-overview.htm">https://www.cdc.gov/nchs/covid19/mortality-overview.htm</a>.