Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
The Impact of COVID-19 Pandemic on Conducting Emergency Medicine Clinical Research

Haley Ehrlich¹, Mark McKenney, MD, MBA, FACS¹,², Adel Elkbuli, MD, MPH¹

¹ Department of Surgery, Division of Trauma and Surgical Critical Care, Kendall Regional Medical Center, Miami, FL, USA
² Department of Surgery, University of South Florida, Tampa, FL, USA

Authors disclose no competing interest
Funding: None

Corresponding Author: Adel Elkbuli, MD, MPH
Department of Surgery, Kendall Regional Medical Center
11750 Bird Road, Miami, FL 33175.
Tel: (786) 637-5287
Fax: (305) 480-6625
Adel.Elkbulli@HCAHealthcare.com

The COVID-19 pandemic challenges the status quo of conducting emergency medicine (EM) research.¹ Research generates new knowledge for the advancement of the medical field, abiding by ethical parameters.¹⁻³ As EM is on the frontlines of this global crisis, the aim of this correspondence is to consider the impacts of the COVID-19 pandemic on EM clinical research.

Financial burdens for EM research have been an ongoing concern prior to the COVID-19 pandemic. For example, NIH funding has proved a challenge for EM researchers, garnering only 1.7% of funds.⁴⁻⁶ Additional safety considerations in EM Departments due to COVID-19 drastically increased.⁷ Researchers have the added obstacle of devising pathways to safely continue EM research. There has also been a drop in non-COVID-19 patients. The 31%-45% reduction in ED visits across the US, raises concern for patients not seeking care.⁸ For instance, there had been a decrease in patients presenting with strokes and STEMIs.⁸ This patient
population is a crucial element for research; thus, the potential number of patients that could contribute to EM trials is decreased. On the other hand, COVID-19, though disruptive, has opened up new research opportunities.\(^4,9\) For example, Stanford’s EM Department is funding a study evaluating clinical characteristics of COVID-19 patients.\(^10,11\) Other avenues include exploring topics regarding domestic safety during a pandemic, patient and physician well-being, and alternative communication avenues.\(^3\) Though most institutions around the country have begun to proceed past the COVID-19 crisis, the new pathways devised to maintain research during such unsteady times must be incorporated into future practices, cultivating sustainable research methods that are resilient to crises.

During this crisis, the price of patient-safety must be weighed against the cost of halting clinical trials. However, some clinical trials have adapted to the current circumstances and are carrying out their trials via telemedicine, producing sustainable research methods.\(^12\) Though not all clinical research can be fully conducted via telemedicine, such as interventional research, it can be incorporated through its use in participant virtual consenting and follow-up.\(^13-15\) This spares patients traveling, as well as reduces potential COVID-19 exposure.\(^1\) For non-interventional research, virtual resources offer web-based platforms to execute survey-based studies as well as data processing components of various types of studies. There is a compelling applicability of utilizing telemedicine in a post-COVID-19 era to conduct clinical research. Continued use of telemedicine could allow clinical trials to address patient barriers to care. Addressing financial and geographical barriers, (although technical barriers could be created) could allow for a larger patient population in clinical trials, increasing the statistical power of trials.

Another future application of telehealth is through its ability to continue the exchange of ideas, despite social distancing hindrances.\(^9,13-15\) Virtual technology maintains education; for example, residents can continue their research education and collaborations through online lectures, meetings, and web conferences.\(^9,15\) Previously, virtual resources have been underutilized in research, though in light of the COVID-19 pandemic, its functionality in clinical research is beginning to reveal its efficiency and efficacy. The applicability of telemedicine has to be fully explored.\(^8,13-15\)
In addition to expanding the use of telemedicine into research where applicable, the mental health of EM researchers should be considered moving forward. Throughout this pandemic, researchers should remain cognizant of symptoms of burnout and depression, which include anxiety, fatigue, and an overwhelming sense of sadness, and seek psychosocial support if this occurs.\textsuperscript{16,17} To prevent negative psychological effects, clinical researchers should perform regular self-check-ins, engage in physical activity, and stay connected with family and friends.\textsuperscript{16} Continuing to partake in these discussions is a productive approach to support one’s mental well-being and should be continued even after the end of this global crisis.\textsuperscript{8,16,17}

The future recommendation for EM research productivity should be focused on building and maintaining sustainable practices throughout the rest of the COVID-19 pandemic and into the post-COVID-19 era. We have several recommendations moving forward. For conducting research virtually, non-interventional or observational studies should be adaptable to virtual secure platforms to create alternative efficient, portable methods that can expand participant populations. From this, we can draw on lessons to evaluate how funding may change in the future and implement strategies to maximize EM clinical research. In regard to maintaining good mental health practices, we recommend optimizing proactive measures such as regular physical activity and time with family and friends.

Research, an integral aspect of the EM community, has been affected in many ways by this global pandemic. Safety issues have to be considered to properly decide how best to proceed or temporarily halt research studies. According to the Declaration of Helsinki, “While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.”\textsuperscript{2} Although these are trying times, the creative avenues designed by researchers to continue working ethically fosters inspiration for the future.
References:

1. Padala, P. R., Jendro, A. M., & Padala, K. P. (2020). Conducting Clinical Research During the COVID-19 Pandemic: Investigator and Participant Perspectives. *JMIR Public Health and Surveillance, 6*(2), e18887. https://doi.org/10.2196/18887

2. WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. *The World Medical Association, 9* July 2019, www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. Accessed July 3, 2020

3. Haghani, Milad et al. The scientific literature on Coronaviruses, COVID-19 and its associated safety-related research dimensions: A scientometric analysis and scoping review. *Safety science, 104806*. 7 May. 2020, doi:10.1016/j.ssci.2020.104806

4. Congressional Research Service. (2020). *U.S. Research and Development Funding and Performance: Fact Sheet*. 1953–2018. https://fas.org/sgp/crs/misc/R44307.pdf. Accessed July 3, 2020

5. Narahari, Adishesh K et al. Surgeon Scientists Are Disproportionately Affected by Declining NIH Funding Rates. *Journal of the American College of Surgeons*. vol. 226,4 (2018): 474-481. doi:10.1016/j.jamcollsurg.2017.10.047

6. Chai PR, Carreiro S, Chapman BP, Boyer EW, O’Laughlin KN. Federal Funding in Emergency Medicine: Demographics and Perspectives of Awardees. *West J Emerg Med. 2020;21*(2):304-312. Published 2020 Feb 24. doi:10.5811/westjem.2019.12.45249

7. Emergency Medicine Journal (EMJ). 2020. *Emergency Medicine Journal (EMJ) | An Acute Care Journal By BMJ; COVID-19: A Message From BMJ*. https://emj.bmj.com/. Accessed 15 August 2020.

8. Boserup B, McKenney M, Ellouri A. The impact of the COVID-19 pandemic on emergency department visits and patient safety in the United States [published online ahead of print, 2020 Jun 6]. *Am J Emerg Med. 2020;38*(9):1732-1736. doi:10.1016/j.ajem.2020.06.007

9. Ehrlich H, McKenney M, Elkbuli A. We Asked the Experts: Virtual Learning in Surgical Education During the COVID-19 Pandemic-Shaping the Future of Surgical Education and Training. *World J Surg. 2020;44*(7):2053-2055. doi:10.1007/s00268-020-05574-3

10. University of Miami Funds Fast-Tracked Research Projects to Rapidly Mitigate COVID-19 Impacts. *University of Miami Research Grants*, 14 Apr. 2020, www.trialsitenews.com/university-of-miami-funds-fast-tracked-research-projects-to-rapidly-mitigate-covid-19-impacts/. Accessed July 7, 2020

11. Emergency Medicine. 2020. *COVID-19 Research*. https://emed.stanford.edu/Research/covidresearch.html. Accessed 15 August 2020.NOT-OD-20-087: Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19. National Institutes of Health. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html. Published March 16, 2020. Accessed August 7, 2020.

12. Fogel, David B. Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review. *Contemporary clinical trials communications* vol. 11 156-164. 7 Aug. 2018, doi:10.1016/j.conctc.2018.08.001
13. Elkbuli A, Ehrlich H, McKenney M. The effective use of telemedicine to save lives and maintain structure in a healthcare system: Current response to COVID-19 [published online ahead of print, 2020 Apr 7]. Am J Emerg Med. 2020;S0735-6757(20)30231-X. doi:10.1016/j.ajem.2020.04.003

14. Meneses E, McKenney M, Boneva D, Elkbuli A. Surgical consent during the COVID19 pandemic: Saving lives while in crisis editorial. Ann Med Surg (Lond). 2020;57:163-165. Published 2020 Jul 26. doi:10.1016/j.amsu.2020.07.039

15. Meneses E, McKenney M, Elkbuli A. Reforming our general surgery residency program at an urban level 1 Trauma Center during the COVID-19 pandemic: Towards maintaining resident safety and wellbeing [published online ahead of print, 2020 Jun 9]. Am J Surg. 2020;S0002-9610(20)30353-6. doi:10.1016/j.amjsurg.2020.06.001

16. De Witte, H., Pienaar, J., & de Cuyper, N. (2016). Review of 30 Years of Longitudinal Studies on the Association Between Job Insecurity and Health and Well-Being: Is There Causal Evidence? Australian Psychologist, 51(1), 18–31. https://doi.org/10.1111/ap.12176

17. Xu, Jian et al. Psychological status of surgical staff during the COVID-19 outbreak. Psychiatry research vol. 288 (2020): 112955. doi:10.1016/j.psychres.2020.112955