Journal of Clinical and Translational Science

www.cambridge.org/cts

Developing adaptive capacity and preparedness in clinical and translational science

Boris B. Volkov[1,2], Miriam A. Bredella[3], Jamie Mihoko Doyle[4] and Cecilia Sorensen[5]

[1]University of Minnesota Clinical and Translational Science Institute, Minneapolis, MN, USA; [2]Institute for Health Informatics and Division of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN, USA; [3]Massachusetts General Hospital and Harvard Catalyst, The Harvard Clinical and Translational Science Center, Harvard Medical School, Boston, MA, USA; [4]Division of Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health, Bethesda, MD, USA and [5]Columbia University School of Public Health and Medical Center, New York, NY, USA

Editorial

Cite this article: Volkov BB, Bredella MA, Doyle JM, and Sorensen C. Developing adaptive capacity and preparedness in clinical and translational science. *Journal of Clinical and Translational Science* **7**: e51, 1–2. doi: 10.1017/cts.2023.7

Received: 6 January 2023
Revised: 11 January 2023
Accepted: 12 January 2023

Keywords:
Clinical and translational research; translational science; adaptive capacity; emergency preparedness; environmental change

Address for correspondence:
B. B. Volkov, PhD, Clinical and Translational Science Institute, Institute for Health Informatics, and Division of Epidemiology and Community Health, University of Minnesota, 717 Delaware Street, Minneapolis, MN 55414, USA. Email: volk0057@umn.edu

© The Author(s), 2023. Published by Cambridge University Press on behalf of The Association for Clinical and Translational Science. This is an Open Access article, distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike licence (http://creativecommons.org/licenses/by-nc-sa/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the same Creative Commons licence is used to distribute the re-used or adapted article and the original article is properly cited. The written permission of Cambridge University Press must be obtained prior to any commercial use.

The key purpose of this thematic issue is to improve processes, programs, and services of research organizations focused on clinical and translational science (CTS) research by informing approaches to strengthening their adaptive capacity and preparedness (AC&P). "Adaptive capacity," "preparedness for rapid change/emergency," and "high-quality lessons learned" provide an overarching conceptual background for this edition. In general, "adaptive capacity" can be defined as the capacity of systems, institutions, humans, and other entities to adjust to potential damage, take advantage of opportunities, or respond to consequences [1,2]. A public health emergency caused by the COVID-19 pandemic posed multiple challenges and caused interruptions to CTS research, programs, and services. Disseminating knowledge about emergency adaptation and preparedness challenges, as well as impactful strategies to overcome them, can help address the research and translational barriers that institutions have been tackling all along.

With contributions from a diverse audience of clinical and translational scientists, the manuscripts in this issue share experiences, principles, concepts, data, and lessons learned that may help institutions and networks anticipate, prepare, respond, and adapt to rapidly emerging challenges. The areas of scientific investigation include improving our understanding of and building AC&P in institutions, agencies, research teams, and community partners and sharing promising applications of AC&P theory and practice.

Utilizing the Local Adaptive Capacity (LAC) Framework [1,3], the environmental scan [1] of AC&P of Clinical and Translational Science Award (CTSA) Program hubs illuminates the challenges created by public health emergencies, such as conducting research as universities shut down, sustaining programs, and services that traditionally occurred in person, the need for quick decision-making and governance, support for underserved populations, and addressing the continuously evolving research and data requirements. The scan also describes scientific/research opportunities presented by the emergency, as well as innovativeness, flexibility, bravery, and optimism of the diverse teams of health professionals, clinical and translational science researchers, administration and informatics specialists, and community partners working hard to overcome those challenges and harness opportunities. There is an anticipation of a further increase in prioritizing research studies, engaging communities and stakeholders, boosting technological capabilities, bolstering research infrastructure centers across the nation, and optimizing national and international collaborations to fight pandemics, novel diseases, and any public health disasters.

Our colleagues from the New Jersey Alliance for Clinical and Translational Science (NJ ACTS) [4] contribute to a better understanding of regulatory mechanisms during an emergency by identifying and comparing metrics illustrating the efficiency and efficacy of their research mobilization efforts during COVID-19. Their analysis of data from the Institutional Review Board, the Clinical Research Units, and the Office of Research and Sponsored Programs suggests that by rapidly making process improvements and adaptations, their institution effectively responded to challenges posed by the pandemic, including a significant increase in IRB-approved studies in 2020, the enrollment of adult and pediatric participants for COVID-19-related research, study income, and decrease in turnaround time for approval of COVID-19 studies.

Bittar *et al.* from Indiana University [5] focus on the effect of COVID-19 on stress and anxiety levels in early- to mid-career women researchers. Anxiety and stress as well as personal and family demands were assessed through validated questionnaires. The majority of participants had moderate anxiety and stress levels and about 20% had high levels and worried about their professional goals and reduced research productivity. Major concerns also revolved around finances, childcare, and job security. The authors recommend that institutions and funding

agencies should take these concerns into consideration and provide support enhancing adaptive capacity and resilience of our research workforce.

Roberts *et al*. from the Medical University of South Carolina [6] describe their experience of conducting a pediatric randomized clinical trial during the COVID-19 pandemic and their shift to virtual procedures. The authors developed a process by which clinical sites could transition to a virtual approach to complete all aspects of a trial safely and effectively. The described virtual procedures enhanced the ability of the investigators to establish relationships with participants who were previously beyond their reach but presented several challenges and required additional resources. The methods of recruitment, consent, and implementing the study may be useful in populations facing geographic or institutional challenges to in-person participant contact—during public emergency situations and beyond.

A special communication on digital and virtual strategies to advance community stakeholder engagement in research during the COVID-19 pandemic is shared by colleagues from Johns Hopkins University (JHU) [7]. The Community Research Advisory Council (C-RAC) at JHU which aims to promote community engagement in research needed to transition to virtual meetings. Serving as an example of an unexpected positive side effect of a crisis, the attendance at C-RAC meetings by the community increased after the transition to virtual operations, indicating that when community needs are assessed and addressed, and technical support is provided, digital strategies can lead to greater community collaborations.

Continuous improvement and broader understanding of how to better prepare and adapt require building strong capacity for systematic monitoring and evaluation, with robust mechanisms for dissemination of the essential data, lessons learned, and successful practices across research organizations, disciplines, and communities. Grounded in perceptions of diverse stakeholders, evaluative activities should begin with the ongoing analysis of the existing and anticipated needs, priorities, assets, and opportunities, followed by rigorous assessment of the efficiency, effectiveness, and sustainability of preparedness and adaptation programs, processes, and structures.

Systematic research, careful consideration, and forward-looking decision-making by the clinical and translational science community are needed to develop and apply principles, concepts, policies, and practices that would enable swift and effective response and adaptation to rapidly emerging challenges and needs at multiple levels in diverse circumstances. Vulnerabilities in existing clinical trials infrastructure that were exposed during COVID-19, for instance, have garnered the attention of the White House Office of Science and Technology Policy (OSTP). On 10/26/2022, OSTP published a Request for Information (RFI) in the Federal Register [8] to solicit suggestions on governance models for conducting emergency clinical trials to ensure that these studies can be carried out efficiently across different institutions in the wake of future disease outbreaks and other national emergencies. This RFI is supported by the 2022 National Biodefense Strategy [9] for Countering Biological Threats, Enhancing Pandemic Preparedness, which was developed based on lessons learned from the COVID-19 pandemic.

These lessons are essential as we move into a future which is made more complex and unpredictable by climate change. Multiple public health crises are unfolding together, and the ongoing impacts of climate change have a constant "syndemic" presence, often linked in origin to competing crises. Climate change influences the emergence and reemergence of infectious and noninfectious human diseases as well as compounds chronic health issues with climate-driven disasters and erosion of the tenets of safe and secure livelihoods. Climate change and human health are growing areas of importance for CTS—given the current trends and the need for actions and adaptations [10]. In the future, we hope to see more manuscripts describing innovative approaches, studies, and efforts related to the mitigation of and adaptation to environmental change-related health challenges.

Acknowledgments. This work was supported, in part, through the following National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) grants: UL1TR002494, KL2TR002542, and K24DK109940. The content is solely the responsibility of the authors and does not necessarily represent the official views of the contributors' institutions, NCATS, or NIH.

Disclosures. The authors have no conflicts of interest to declare.

References

1. **Volkov BB, Ragon B, Doyle JM, Bredella MA.** Adaptive capacity and preparedness of Clinical and Translational Science Award Program hubs: Overview of an environmental scan. *Journal of Clinical and Translational Science* 2022; **6**(1): e89. DOI: 10.1017/cts.2022.400.
2. **Core Writing Team RKP and LAM** (eds.). *IPCC, 2014: Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change.* Geneva, Switzerland, 2014. (https://www.ipcc.ch/report/ar5/syr/)
3. **Jones L, Ludi E, Levine S.** *Towards a characterisation of adaptive Capacity: A framework for analysing adaptive capacity at the local level.* Overseas Development Institute, 2010. (https://ssrn.com/abstract=2782323)
4. **Thaman P, Tafuto B, Gélinas C, Gaur S, Neubauer JA.** The NJ Alliance for Clinical and Translational Science (NJ ACTS) experience: Responding at "warp speed" to COVID-19. *Journal of Clinical and Translational Science* 2022; **6**(1): e62. DOI: 10.1017/cts.2022.383.
5. **Bittar N, Cohee A, Bhamidipalli SS, Savoy A, Ismail HM.** Emotional distress, stress, anxiety, and the impact of the COVID-19 pandemic on early- to mid-career women in healthcare sciences research. *Journal of Clinical and Translational Science* 2022; **6**(1): e93. DOI: 10.1017/cts.2022.417.
6. **Roberts JR, Chervinskiy SK, McCulloh R, *et al.*** Conducting a pediatric randomized clinical trial during a pandemic: A shift to virtual procedures. *Journal of Clinical and Translational Science* 2022; **6**(1): e115. DOI: 10.1017/cts.2022.453.
7. **Byiringiro S, Lacanienta C, Clark R, *et al.*** Digital and virtual strategies to advance community stakeholder engagement in research during COVID-19 pandemic. *Journal of Clinical and Translational Science* 2022; **6**(1): e121. DOI: 10.1017/cts.2022.457.
8. **Science and Technology Policy Office**. *Request for information; Clinical research infrastructure and emergency clinical trials*. 87 FR 64821. (https://www.federalregister.gov/documents/2022/10/26/2022-23110/request-for-information-clinical-research-infrastructure-and-emergency-clinical-trials)
9. **White House Office of Science and Technology Policy**. *The 2022 National Biodefense Strategy builds upon administration S&T priorities for pandemic preparedness* 2022. (https://www.whitehouse.gov/ostp/news-updates/2022/10/18/the-2022-national-biodefense-strategy-builds-upon-administration-st-priorities-for-pandemic-preparedness/#:~:text=The%20National%20Biodefense%20Strategy%20and,assess%2C%20prevent%2C%20prepare%20for%2C)
10. **Solway J, Kenyon N, Berglund L.** Clinical and translational science and climate change: Time for action. *Journal of Clinical and Translational Science* 2022; **6**(1): e57. DOI: 10.1017/cts.2022.9.