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Leadership and administration to advance translational science: Environmental scan of adaptive capacity and preparedness of Clinical and Translational Science Award Program hubs

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Abstract

COVID-19 reinforced the need for effective leadership and administration within Clinical and Translational Science Award (CTSA) program hubs in response to a public health crisis. The speed, scale, and persistent evolution of the pandemic forced CTSA hubs to act quickly and remain nimble. The switch to virtual environments paired with supporting program operations, while ensuring the safety and well-being of their team, highlight the critical support role provided by leadership and administration. The pandemic also illustrated the value of emergency planning in supporting organizations' ability to quickly pivot and adapt. Lessons learned from the pandemic and from other cases of adaptive capacity and preparedness can aid program hubs in promoting and sustaining the overall capabilities of their organizations to prepare for future events.

Implementation, Policy and Community Engagement Review Article

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Introduction and Background

Capable leadership, administration, and organization are critical for realizing Clinical and Translational Science Award (CTSA) Program goals. The importance of effective leadership and administration has been reinforced by the COVID-19 pandemic, with the pandemic "present[ing] itself as an exceptional challenge to the national biomedical research enterprise's ability to carry on vital research despite lab closures, respond to the urgent research needs of COVID-19 itself, support the increased clinical needs and enhanced public health response" [1]. The CTSA Program leads NCATS' clinical response at the local, regional, and national level and provides an opportunity to learn how to enhance the translational process. Leaders of the CTSA hubs across the country collaborated in managing critical COVID-19 response efforts at their institutions and quickly shared their experiences, observations, and best practices on medical and operational adaptations to the pandemic, facilitated by network-wide communication workflows established by the CTSA Center for Leading Innovation and Collaboration (CLIC). Leadership and administration play an important role in support of adaptive capacity, defined by Nelson and colleagues as:

> "the decision-making process and the set of actions undertaken to maintain the capacity to deal with future change or perturbations to a social-ecological system without undergoing significant changes in function, structural identity, or feedbacks of that system while maintaining the option to develop. At the collective level, process and action are predicated on effective governance and management structures." [2]

Adaptive capacity intersects with vulnerability and resilience as a positive system attribute, which is affected by management and governance [3]. Considering Defra's guiding principles of good adaptation [4], adaptive actions should be sustainable, proportionate and integrated, collaborative and open, effective, efficient, and equitable, presenting a critical role for organizational leadership and administration. The role of the effective CTSA leadership, management, and administration is paramount in designing, developing, coordinating, and advancing all of these complex areas. This is highlighted in the most recent Funding Opportunity Announcement Element B: Strategic Management Module [5]. Recognizing the importance of preparedness and adaptive capacity, "in the event of a public health or other emergency,

CTSA hubs should be prepared to rapidly realign activities to support research of direct relevance to the emergency or public health need." Specifically, each CTSA hub must have an Emergency Plan and resources allowing a pivot to a virtual leadership structure in the event of an emergency, able to support the response to a public health emergency or other public health need, and to continue ongoing research during the event and redirecting resources for the emerging situation with adaptive capacities and strategies to be implemented to address research needs and continue to impact the CTS enterprise [5].

This paper is part of the Environmental Scan of Adaptive Capacity and Preparedness (AC&P) of CTSA Hubs [6], implemented by a special AC&P Working Group approved by the CTSA Steering Committee in 2021. The overall purpose of the Working Group and this scan was not to evaluate, test, generalize, quantify, or validate any hypotheses, approaches, or interventions, but rather to identify, curate, analyze, and share examples of practices, challenges, and lessons learned related to how CTSA hubs have used their expertise, resources, and collaborations to advance clinical and translational research during emergency. The AC&P Working Group took a pragmatic approach of utilizing the data that had been – or was planned to be – collected through existing mechanisms, aligning with and contributing to the CTSA goals and processes. Data sources included: scientific publications and white papers on CTSAs' (and other) AC&P-related activities; a diverse sample of CTSA hubs' websites: public stories, news, highlights, measures; NCATS and other clinical and translational science organizations' websites; de-identified information from select CTSA hub Research Performance Progress Reports (RPPRs); and expert opinions and experiences of the E-scan implementers, reviewers, and stakeholders [6].

To guide our analysis and understanding of CTSA Leadership and Administration processes and intersection with adaptive capacity and preparedness, we have applied the following key characteristics (or domains) of the Local Adaptive Capacity (LAC) Framework [6,7]: asset base (key assets that allow hubs to respond to evolving circumstances); institutions and entitlements (an appropriate and evolving institutional environment that allows fair access to key assets and capitals); knowledge, information, and learning (the ability to collect, analyze and disseminate knowledge and information to learn in support of adaptation activities); innovation (an enabling environment to foster innovation, experimentation, and the ability to explore pragmatic solutions and opportunities); and flexible forward-looking decision-making and governance (the ability to anticipate and respond to changes with regards to its decision-making, governance, and operational structures). We are looking through the lenses of these domains at what we have learned about how the leadership and administration of CTSA hubs adapt to significant social–ecological disruptions and how translational science organizations may become better prepared for future local and system-wide, scientific and operational challenges.

Asset Base

Through the combination of economic resources and infrastructure, components of an asset base include elements such as financial, physical, natural, social, political, and human capitals that can influence the ability to respond to a crisis [7]. The ability to respond is impacted by the ability to access and control these assets [8]. In many ways, CTSA program hubs themselves became key assets during the pandemic to the organizations and communities they support. One study [9] found that while most hubs felt unprepared for COVID-19, their prompt response in supporting the needs of COVID-19 research had substantial impacts. Jayaweera et al. [9] observed that "institutions with CTSA's involvement in the institutional decision-making were 16.8 times more likely to create a COVID-19 diagnostic laboratory than those without CTSA's involvement in the decision-making process." CTSA program hubs were also instrumental in obtaining funding, facilitating laboratory and clinical spaces, adjusting workflows to support improved timing for IRB review, and developing diagnostic tests for COVID-19.

It would be unfair to claim that CTSA program hubs alone were responsible for key assets; instead, their role as a key asset was maximized by their participation in strategic partnerships. More than a decade of investments from the federal government have established the critical infrastructure and services at CTSA program hubs, particularly in the area of informatics [10]. This infrastructure has been critical to respond to the pandemic, with numerous examples in hubs across the consortium. Many academic medical centers across the country initiated an Economic Recovery Plan which significantly constrained economic resources during the pandemic. Lack of economic resources can limit the overall adaptive capacity of an organization, but partnerships allow organizations to combine resources and respond to public health emergencies in greater scope and more effective, multi-targeted ways. Variables and indicators for organizational adaptive capacity have linkages to the concept of community capacity. According to Robert J. Chaskin:

> "Community capacity is the interaction of human, organizational, and social capital existing within a given community that can be leveraged to solve collective problems and improve or maintain the well-being of a given community. It may operate through informal social processes and/or organized efforts by individuals, organizations, and the networks of association among them and between them and the broader systems of which the community is a part." [11]

Using community capacity as a conceptual lens, the adaptive capacity asset base connects to the idea that access to resources enhances a community's ability to respond to a crisis and increase sustainability in the community [12]. For example, the University of Kentucky Center for Clinical and Translational Science (CCTS) partnered through the CURE Alliance (COVID-19 Unified Research Experts), a multidisciplinary group that was established to support the knowledge and treatment of COVID-19. The CCTS made contributions as a key asset through its Biomarker Analysis Laboratory and by working to produce large quantities of high-quality viral antigens in the fight against COVID-19 [13]. Another example of a CTSA program hub operating as a key asset includes the CTSA-supported Translational Research Institute at the University of Arkansas for Medical Sciences who collaborated with "academic partners across departments and colleges and the state department of health to implement population sampling for COVID-19 seroprevalence testing" [13]. Other notable examples include: University of Minnesota collaborating with local Indigenous community partners in developing evidence-based and culturally appropriate COVID-19 resources; the University of Kansas Medical Center partnering with community health workers to create COVID-19 information in seven languages; the NIH Community Engagement Alliance (CEAL); and the Southern California Clinical and Translational Science Institute creating a workshop series designed to support region's Latinx community information needs [14–17].

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In our analysis of the JCTS COVID-19 Special Edition Survey of CTSA hubs (administered in October 2020), a few pragmatic, asset-related suggestions emerged in responses to the question "What key steps would you advise again if there is another emergency?" Responses included: having robust technology to support remote research activities (e.g., remote consent and conducting study visits); internal resources to track and evaluate the emergency response; the ability to rapidly develop tools to understand local situation; and the availability of the institutional Critical Incident Management Team to bring together key individuals, departments, and field experts to create a unified approach to assessing the emergency and developing a cohesive, comprehensive plan to address it.

The role CTSA program hub leadership and administration can play in ongoing adaptive capacity efforts is a point of attention and ongoing discussion in the program, as highlighted in the most recent UM1 FOA, where NCATS outlines that CTSA program hubs must have a plan for supporting and responding to public emergencies, a plan to pivot to virtual leadership, and a plan to build "adaptive capacities of and strategies" for addressing research needs that impact the clinical translational science enterprise [5]. CTSA program hubs may wish to investigate tools offered by the Federal Emergency Management Agency's, such as "The Pandemic Influenza Continuity of Operations Annex Template" that can serve as a guide for planning the continuity of essential functions [18]. CTSA program hubs may already have continuity plans in place, and this document is intended to enhance or augment those plans. With adaptation, most of the concepts are applicable to COVID-19 and in preparing for future events. Within the guide are several strategies relevant to consider such as mitigation strategies for social distancing, increased hygiene, the vaccination of employees and their families.

Institutions and Entitlements

The adaptive capacity of clinical and health research organizations depends on their equitable access to key assets located in both internal and external environments. Institutions that govern access to these assets can in fact mitigate organizations' ability to adapt to unforeseen environmental variability and change. Institutionalized norms and rules can also promote the emergence of stable and socially integrated organizations with those characteristics that best enable their timely adaptation to the varied demands of their environments [2,7,19].

The CTSA Program coordinates and provides research centers across the country with access to critical assets needed to address the COVID-19 pandemic. The infrastructure and network leveraged by the CTSA hubs to respond to COVID-19 have been enhanced for the pandemic. As scientific and administrative CTSA hub leaders reached out to align their response to the pandemic, their institutions and communities benefited tremendously from existing structures and relationships that had long enabled sharing of research resources, ideas, and best practices, such as those offered by the Trial Innovation Network and the Recruitment Innovation Centers [20,21].

CTSA Program hubs have successfully supported numerous multi-site clinical trials, including randomized, placebo-controlled trials evaluating new and existing treatments for people hospitalized with COVID-19 [22]. However, key challenges were found to have affected CTSA hubs' conduct of these critical clinical trials, including the need for regulatory knowledge to support the institutional response, electronic submission capacity for Food and Drug Administration (FDA) documents, and the timely reallocation of regulatory and legal resources to support patient access to relevant investigational agents and medical devices during the pandemic [23].

A notable example of a CTSA program hub enhancing a university's capacity to respond to the pandemic through the provision of new and existing treatments for people hospitalized with COVID-19 is the University of Michigan's Expanded Access (EA) program. This Expanded Access (EA) program was formally established by an oversight committee of regulatory personnel associated with the CTSA in 2015, with the goal of providing an avenue for U-M patients with no available treatment options to access investigational drugs and devices for clinical therapies [23]. This EA program was designed to position the CTSA to link the separate roles that the FDA, IRBs, and research institutions play in the EA process by providing patients with safe and timely access to investigational agents [24]. Despite enduring barriers and challenges, the experiences of this program suggest that CTSA-based regulatory units have the potential to mitigate the impact of future pandemics and enhance the overall adaptive capacity of research centers across the CTSA Consortium [9].

Local and national CTSA Program leadership have enhanced the adaptive capacity of the clinical and translational research enterprise and worked to enable equitable access to key assets. Relevant best practices that these leaders can promote across the consortia include: (1) the implementation of evidence-based disaster plans that assume the extended disruption of critical infrastructure, (2) the inclusion of partners representing all relevant elements of the institutional response (e.g., senior leadership, security/public safety, physical facilities, environmental health and safety, human resources, finance, communications, etc.), (3) periodic risk assessments to evaluate potential risks and identify any gaps in current preparedness, mitigation, and response capabilities, and (4) the creation of comprehensive all-hazards, incident-specific, detailed plans [25].

Knowledge, Information, and Learning

Parsons et al. [26] have defined adaptive capacity as "the arrangements and processes that enable adjustment through learning, adaptation and transformation." This domain of our report explores CTSAs' ability to collect, analyze, and disseminate knowledge and information in support of adaptation activities – specifically in the area of CTSA hub leadership and administration. The focus is also on a broader notion of learning from our experiences of substantial disruptions and changes. Such gathering and sharing information activities are essential for building adaptive capacity; for example, they include undertaking research, monitoring data, and creating awareness through education programs and events [27].

It is important to be proactive and brainstorm what kinds of crises the organization and individuals may encounter and to define and operationalize which emergencies have the potential to disrupt their work and in which ways [28]. Many crisis types may deeply impact entire organizations and individual researchers, including but not limited to public health emergencies, natural disasters, financial crises, cyberattacks, or research misconduct.

Closely related to adaptive capacity, resilience-building management needs to be flexible and open to learning [29]. We must identify and evaluate essential variables, processes, and drivers that regulate the key dynamic properties of the system and impact the demand and supply of resources and services. Folke et al. [29]

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highlight the utility of a few tools for resilience building in complex, unpredictable systems. For example, 'structured scenarios' and 'active adaptive management' experiments can be designed to help identify alternative futures in ways that reveal critical variables, branch points, and system potential that need to be handled to initiate, control, or avoid change.

Sharing timely knowledge, information, and learning has been demonstrated in the development and implementation of "informatics collaboratives." The University of Alabama at Birmingham CTSA [30] kept knowledge dissemination and stakeholder communication ongoing by holding an online forum on how research operations were modified due to the COVID-19 pandemic. Brief presentations with the key take-home messages highlighted ongoing research processes and projects around campus, featuring medical and research leaders collaborating on addressing pandemic-related issues. Likewise, the Indiana Pandemic Informatics Collaborative [31] convenes a consortium of Indiana's organizations and professionals across government, health systems, university, biosciences industry, and nonprofit sectors that bring their unique perspectives and expertise to bear to overcome barriers, apply state-of-the-art expertise, and ensure that the best data, information and knowledge are put in the hands of decisions makers. They ensure that relevant pandemic data, information, and knowledge-related activities affecting Indiana residents are shared and coordinated across Indiana.

Scholarly publishing also plays a key role in knowledge sharing, with several innovations in this domain occurring in the early days of the pandemic. The emerging dissemination models have been important with the deluge of scholarly works resulting from COVID-19 investigations. Several publishers responded to pressure from the international scientific community to make content openly available through licensing and computationally actionable formats to allow researchers to fully leverage the scholarly literature [32]. Another highly successful effort to meet that call is LitCovid, through the National Library of Medicine [33,34]. LitCovid is a curated and up-to-date scientific hub for information about COVID-19 with access to relevant articles. Likewise, the pressure to rapidly make scientific information available throughout the pandemic has driven an increase in preprint volume as well as greater acceptance of preprints as a component of scholarly workflows. Preprints have offered a critical route to quickly access science in the pandemic, but disruptions to traditional scholarly publishing workflows have been moderate [35]. Hub leadership can support understanding of and innovations in these new modes of dissemination by partnering with their health sciences libraries to offer resources, training, and support for scholarly publishing, preprints, data publishing, and more.

Communications with CTSA stakeholders, including the public at large, reveals that we should continue to share the significance, challenges, and best practices of conducting translational research, especially during extraordinary times. For example, four Massachusetts clinical and translational science centers (at Boston University, University of Massachusetts, Tufts University, and Harvard Catalyst) collaboratively hosted COVID-19 Research Community Forum webinar series focused on COVID-19 research and health equity [36]. These webinars emphasized the dialog and mutual learning that took place between clinical/translational researchers and community members during the pandemic.

According to Karen Emmons, PhD, faculty lead for Harvard Catalyst's Community Engagement program, "with strong community partnerships, we've been able to quickly get a sense of what's happening on the ground during this pandemic" [36]. That knowledge helped researchers and administrators adapt their plans and activities in practical, evidence-based ways. Another organizer of the Community Forum webinar series, Tracy Battaglia, MD, MPH, director of Community Engagement at Boston University CTSI, shared that she did not "think anything other than a pandemic like this can highlight the importance of translating science and research in addressing the health of our public." Coller et al. [21] bring our attention to the opportunity to capitalize on the recently increased public interest in biomedical and translational research (e.g., vaccine development) with broad public education about the value of translational research and the role of the CTSA hubs in response to the pandemic and other public health needs.

Coller and colleagues share: "crisis management is often focused on restoring organizational function to its pre-crisis level, but perhaps a more appropriate goal is to achieve a higher level of function as a result of learning from the traumatic event." Such proactive learning that informs and strengthens our post-traumatic growth should include "reflective assessment, identification of extraordinary role models, identifying opportunities for re-invention of processes, contemplating how the experience connects the institution to the broader community and humanity, and reappraising priorities with regard to what is truly most important" [21].

There is an important role for monitoring and evaluation that should be undertaken in the spirit of continuous organizational learning and improvement and broader understanding of how to better adapt and prepare [27]. Robust, adaptable mechanisms should be considered for sharing such learning across and between research teams, organizations, partners, and disciplines.

Innovation

The clinical and translational science (CTS) community leverages harmonized methods and processes across a national consortium, creating an environment that fosters innovation, experimentation, and the ability to explore niche solutions to leverage new opportunities and advance the discussion on translational innovation [37]. The National Center for Advancing Translational Sciences takes a deliberate approach to ensuring a nurturing environment through their "3Ds Approach": Develop new approaches, technologies, resources, and models; Demonstrate their usefulness; and Disseminate the data, analysis, and methodologies to the community [38]. This approach is especially critical considering the wide range of public and private partners necessary to address today's health challenges, particularly due to COVID-19.

CTS teams pursue local, regional, and national strategies to inspire and sustain innovation. Local strategies include an innovation scorecard [39], based on the Balanced Scorecard approach [40], to support communication and continuous improvement applied to translational science at the University of Texas Medical Branch (UTMB) at Galveston CTSA; and an innovative partnership between a private digital health startup company, a university innovation lab, and an academic health system's cardiology program to advance timeliness and patient-centeredness of cardiovascular care at Washington University in St. Louis [41]. An exemplary regional initiative is the New Normal Match, an online portal that enables potential research participants from across Chicagoland and surrounding states to explore lay-friendly descriptions of publicly recruiting clinical trials and to connect

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with study teams at the three Chicago CTSA hubs: the Northwestern University Clinical and Translational Sciences Institute (NUCATS), the Institute for Translational Medicine (a partnership of the University of Chicago and Rush in collaboration with Advocate Aurora Health, the Illinois Institute of Technology, Loyola University Chicago, and NorthShore University HealthSystem) (ITM), and the Center for Clinical and Translational Science at the University of Illinois at Chicago (CCTS) [42]. A notable national strategy is the Trial Innovation Network (TIN) [43], a collaborative initiative within the CTSA Program and across other NIH units to accelerate the translation of novel interventions to clinical practice by addressing structural and logistical challenges that impede the TIN's mission to execute high-quality trials in an efficient, effective, and economical manner [39,42]. Another excellent example of a national strategy is the I-CORPS@NCATS program based at the University of Alabama at Birmingham to combine business and discovery processes. This 5-week short course is based on successful I-Corps entrepreneurial training programs at the National Science Foundation and at the National Institutes of Health and is designed to support participants at all stages of their innovation journey [44].

Several critical interventions to support and empower innovation have been implemented across the CTSA Program hubs. These interventions support dependable infrastructure and provide dedicated funds to support teams, collaborations, technical requirements, and promising research throughout the pandemic. The University of Minnesota CTSA hub, for example, explored and realized pragmatic solutions to share expertise to many COVID-19 study teams, provide access to COVID-19 data, award funding for COVID-19 studies, make it easier for potential participants to find COVID-19 studies, enable remote consent for COVID-19 studies, and conduct COVID-19-focused research training [45]. Indeed, the CTS system itself has been the target of innovation driving change, as highlighted by the work of CTSA hubs. Considering the Adaptive Capacity Framework adapted from Jones, Ludi, and Levine [6,7], CTSA hubs have developed, demonstrated, and disseminated innovations across model components: asset base; institutions and entitlements; knowledge, information, learning; and flexible forward-looking decision-making and governance (see [6] and other focused articles in this issue).

Bookman and colleagues characterized research informatics in the context of COVID-19 through a survey of CTSA Program hubs [10]. The survey probed challenges, innovations, and recommendations, and highlighted the critical role of informatics in CTS, including "increased reliance by healthcare providers and researchers on access to electronic health record data, both for local needs and for sharing with other institutions and national consortia." Another survey examined the essential importance of biospecimen repositories in the context of COVID-19, identifying challenges and opportunities presented during the pandemic and underscoring the importance of this critical research infrastructure [46].

Innovations in institutions and entitlements have also been examined throughout the CTSA Program, particularly in the context of the impact of COVID-19 and its impact on health equity. Nana-Sinkam and colleagues explored this complex system, considering both a range of roles and impacting factors within the system and the critical role that trust plays in ensuring access of innovations to communities that have been historically marginalized in healthcare and research [47]. Knowledge and information innovations in the CTS system have also been significantly affected, ranging from impacts on communication workflows, technologies, and collaboration to lessons learned about research activities across the consortium that will continue to impact our workforce, research participants, and communities for years to come [48].

Flexible and forward-looking decision-making and governance will be a critical component of the "playbook" to guide this process, as "creative innovations developed in response to the COVID-19 pandemic deserve serious consideration for adoption as new standards, thus converting the painful trauma of the pandemic into 'post-traumatic growth' that makes the clinical research enterprise stronger, more resilient, and more effective" [21].

The University of Minnesota CTSA hub's Dr. Benson notes the value of a learning health system approach to CTS, where healthcare and research are integrated parts of a system. "We are only able to move as nimbly and quickly as we do because we are set up to either succeed or fail rapidly, and then learn from it," he says. "It truly allows us to quickly make decisions, resolve any barriers to research and come together not just for the patient in front of us but also a world that is reeling from COVID-19. We've learned that what moves us, which is making the world a better place, one patient, one learner, one discovery at a time, is best achieved when we do it together" [49].

Flexible Forward-Looking Decision-Making and Governance

The COVID-19 pandemic triggered major challenges and revealed the healthcare and research environment's varying levels of adaptive capacity and preparedness during the crisis. Organizations had an opportunity to reflect on their experiences, learn from their challenges, grow, and generate new approaches within a complex system. Complex systems analysis [50] was designed in response to the global scale, urgency, and complexity of today's challenges. Such analysis can reveal complexities during a pandemic that require clear governance and leadership to "limit the impact of the outcomes on the severity and its importance in planning crisis preparedness" [51]. Strong and clear governance can help an organization's ability to anticipate, incorporate, and respond to changes with regards to its governance structures, operations, and future planning [50]. The CTSAs' reaction to the pandemic was driven by flexible leadership response, along with areas where there were missed opportunities.

Analysis of systems and situations should occur on the national and on the local organizational levels to understand and prepare for a future crisis. Within the CTSA community, the CTSA leadership made swift and difficult decisions that impacted individuals, research programs, and the future of how science is conducted in the research environment. The CTSA community was surveyed to evaluate the impact of the pandemic and the methods used to protect study participants and staff [52]. Some institutions assessed the environment and designed centralized processes and approval mechanisms to provide guidance and decisions concerning the research activities, partners, and even the implementation of safety procedures such as the use of PPE.

Flexible and forward-looking decision-making on the local level within CTSA hubs was demonstrated by the CTSA community playing a critical role alongside university and medical center administration and CTSA leaders. To overcome the pandemic-related challenges and make medical research processes more collaborative, efficient, and impactful, 86% of CTSA hubs were involved to some extent in developing the institutional

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COVID-19-related policies. These bodies along with the university leaders decided to prioritize resources to facilitate research directly relevant to the emergency and pause all clinical trials except for those which are COVID-19 related [52]. One could argue, however, that a downside to the widely adopted "only-COVID-research" policy was that in some cases it could also cause barriers to other kinds of research, inefficient use of research grant funds, and possibly impaired renewals of grants.

Highly important was the goal of keeping clinical workforce and research participants safe by reducing the spread of SARS-CoV-2. There was more collaboration, idea generation, and communication toward common goals than in the past. This included planning and/or implementation of reopening of research activities, primarily for clinical research with lesser involvement for the development and implementation of policies for basic research across all sites. CTSA-supported CRUs played key roles in administering and supporting COVID-19 and vaccine trials [53], including their significant contribution in Phase 3 trials for the Pfizer and Moderna vaccines, the first two vaccines authorized for use in the US.

Shingler-Nance [54] identified five distinct elements of successful leadership during the COVID-19 crisis, which were: staying calm, communication, collaboration, coordinating, and providing support. Across the CTSA environment, leadership had varying degrees of success in each of these elements, but overall, one of the greatest strengths was collaboration on the national level that had not been experienced in the past. The pandemic revealed the gaps in preparedness across the biomedical research community when addressing a crisis. It highlighted challenges with moving to a virtual research environment and the ability to coordinate research efforts nationally. The experience showed that additional planning is needed to help centralize a collaborative response and decision-making effort to align research towards a common goal.

To be better prepared for future crises, the CTSAs should leverage the lessons learned from this pandemic and build on what has been established. They should continue the Community-NCATS governance partnership on network activities around data and research. To prepare for the next pandemic or other public health crisis, they should establish a plan that will prioritize national patient-centered research efforts at a larger scale with effective leadership coordination and unity. The pandemic disaster has also presented an opportunity to engage communities in the work of the CTSAs, including partnership on leadership and decision-making teams. Doing so helps ensure that CTSA activities and clinical trials are equitably representing indigenous groups, refugees, rural populations, children, and underserved communities, in addition to those who do not live near prominent academic medical centers.

The leadership of the CTSA Program and its hubs should consider taking the initiative, well in advance of the next crisis, to evaluate their capacity to rapidly engage across their institutions and collaborate with other entities to address emergency situations. To implement flexible forward-looking decision-making, they should consider nontraditional approaches by engaging those from other disciplines who can offer different perspectives and voices. CTSA leaders should continue their COVID-19 collaboration with other academic partners, medical centers, private partners, community clinics, citizen scientists, and special and underrepresented groups to rapidly generate novel methods and solutions for challenging and complex issues across all populations. It is important to not lose sight of what has been accomplished and use any emergency experience as an opportunity to further optimize for an effective, collaborative research network.

Implications and Conclusion

It is imperative to study, document, learn, and disseminate crisis-related experiences and lessons to build adaptive capacity and preparedness at all levels. Some of the lessons learned and approaches to translational science leadership and administration – grounded in the pandemic experiences and captured by the Environmental Scan – are summarized in Table 1.

Jayaweera et al. [9] note that to improve and refine processes and to make the best use of constrained resources, a consistent, coordinated process of reviewing evolving knowledge must be established. Some general principles can be used to guide the implementation of most interventions designed to enhance the adaptability of clinical and translational research organizations. In general, these interventions should be (1) sustainable, (2) collaborative, (3) equitable, (4) flexible, (5) managed to ensure effective and efficient performance, and (6) proportionate to the most relevant risks involved [4,27]. Each of these broad principles can also be used to identify measures to evaluate the impact of these interventions, even including interventions designed as clinical trials. Quality Assurance guidelines described by Knatterud, et al. [55] can be used to plan and measure the quality of ongoing operations across clinical trial sites to ensure key requirements are met and to assess the degree of adherence to written procedures, policies, and regulations.

Efforts made to enhance the adaptive capacity of clinical and translational research organizations can build on the successful models supported by other federal agencies such as the Disaster Distress Helpline (1-800-985-5990 or text "TalkWithUs" to 66746) set up by the Substance Abuse and Mental Health Service Administration. However, many other efforts aimed at addressing the health, well-being, and day-to-day needs of individuals within research centers are also important to ensure the adaptive capacity of these organizations. Most, if not all of these other efforts, such as the development of guidelines for health researchers about leading virtual meetings [56], are clearly complementary to more rigorous interventions mitigating the impact of the pandemic. These types of efforts to enhance adaptive capacity are also critical to recognize and support since they can run counter to more institutionalized efforts that espouse the same purpose. This dynamic is analogous to the tension that has the potential to arise between efforts made to make novel therapies to COVID-19, such as convalescent plasma, more readily available to patients admitted to academic medical centers through the FDA's Expanded Access programs and the need for health researchers to enroll those patients in the types of rigorous randomized controlled clinical trials needed to determine the therapeutic value of such treatment [21].

Many efforts made to enhance the adaptive capacity of clinical and translational research organizations in the face of the COVID-19 pandemic are informal programs concerning the stress, well-being, and day-to-day needs of individuals within the health research workforce. Efforts made to mitigate the stress of this workforce have included initiating more open discussions about the personal feelings of grief, uncertainty, and confusion that individuals have felt over the course of the pandemic. There are many well-known examples of health researchers who have sought out collaborative ways of promoting their physical, emotional, and social well-being even while adhering to public health safety

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Table 1. *Approaches for translational science leadership and administration in the context of adaptive capacity and preparedness (derived from the AC&P E-Scan)*

Local Adaptive Capacity domains	Approaches for leadership and administration in the context of adaptive capacity and preparedness
Asset base	Developing: robust technology to support remote research and administrative activities; internal resources to track and evaluate the emergency; the ability to rapidly develop tools to understand local situations; and the institutional emergency management team to build a comprehensive approach to assessing and addressing emergencies.
Institutions and entitlements	Advancing collaboration in intra- and inter-organizational leadership networks. Leveraging and expanding existing collaborations, structures, and relationships to share diverse resources, ideas, and strategies.
Knowledge, information, and learning	Keeping ongoing dialog and mutual learning between decision makers, researchers, and community members. Building evaluation and monitoring capacity for continuous organizational learning, improvement, and broader understanding of how to better adapt and prepare. Developing robust mechanisms to share challenges and best practices with diverse stakeholders via multiple channels.
Innovation	Cross-hub collaborations can spark innovations and pragmatic solutions in communication, technologies, and collaboration in response to crises. Adopting local and cross-hub adaptations can lead to an improved "new business as usual" by identifying, acknowledging, and learning from mistakes and failures.
Flexible forward-looking decision making	Collaborating on the national and regional levels to strengthen networks of comprehensive support available to the research community. Building trustful partnership and shared decision making with other academic partners, medical centers, private partners, community clinics, citizen scientists, and special and underrepresented groups.

measures implemented to stop the spread of COVID-19 [57]. Programs were administered to help the health research workforce working within and outside of academic medical centers connect with specialists and support networks to address COVID-related depression, resilience, stress management, and anxiety [58,59].

There are many other ways of promoting the adaptive capacity of leadership and administration of clinical and translational research organizations aside from those described in this manuscript. The profusion of resources that are specific to promoting the adaptive capacity and preparedness of research centers to address disasters speaks to the great diversity and breadth of approaches available to the CTSA stakeholders. These resources include those developed by organizations focusing on disaster preparedness; for example, there are several excellent training and support resources in the inventories of the Network of the National Library of Medicine Emergency and Disaster Resources; TRAIN National Learning Network; Federal Emergency Management Agency National Preparedness Course Catalog; and Preparedness and Emergency Response Learning Centers [60,61].

Further research into collective adaptive capacity is needed to inform leadership and administration in all areas of clinical and translational science. Some of the research and evaluation directions (beyond the scope of this scan) include: adaptive capacity in other national consortia; stakeholders' perceptions of the effectiveness of adaptations; structural and organizational factors that may elucidate differences in institutions' adaptations to emergency; sustainability of non-pandemic research during a pandemic; and the evaluation of collaborative adaptive capacity efforts with community and other program stakeholders.

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