RESEARCH ARTICLE

Factors Influencing US Hospital and Medical School Participation in Pediatric COVID-19 Research

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ABSTRACT

BACKGROUND AND OBJECTIVES: Literature suggests that funding for pediatric clinical trials is inequitably awarded. Furthermore, although coronavirus disease 2019 (COVID-19) affected all hospitals, institutions with already limited resources were more severely impacted. We hypothesized that there would be difference in schools and hospitals that were able to participate in the initial round of pediatric COVID-19 clinical research.

METHODS: We searched online databases for preregistered studies using the keywords "COVID-19," "COVID," "SARS-CoV-2," "2019-nCov," "2019 novel coronavirus," and "severe acute respiratory syndrome coronavirus 2." Search results were limited to studies enrolling participants from birth to 17 years, studies started in 2020, and studies originating in the United states. We calculated the proportion of institutions with active COVID-19 pediatric clinical studies in 2020 and compared institutional characteristics between institutions with and without at least one qualifying COVID-19 study, using rank-sum tests, χ^2 tests, or Fisher's exact tests, as appropriate.

RESULTS: We identified 150 allopathic medical schools, 34 osteopathic medical schools, and 178 children's hospitals meeting inclusion criteria. Among included institutions, 25% of medical schools and 20% children's hospitals participated in 1 of the registered pediatric COVID-19 studies the year before the study period. Institutions that participated in pediatric COVID-19 studies had more publications, more National Institutes of Health funding, and more studies registered on Clinicaltrials.gov in 2019.

CONCLUSIONS: Despite the pandemic affecting everyone, participation in early clinical research on the impact of COVID-19 in pediatric populations was concentrated in a few well-resourced institutions that were highly experienced in research.

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Pediatric clinical trials are limited by low enrollment, lack of funding, and inadequate industry support because of many drugs being used "off-label" in pediatric patients.[1,2] Furthermore, many centers lack resources needed to conduct clinical trials, such as centralized research support, dedicated clinical research staff, funding sources to support unfunded or underfunded clinical trials, and experience with the clinical research process.[3–5] Disparities in institutional research capacity may have increased in recent years in the United States, as extramural funding has become increasingly concentrated in a small number of the highly funded institutions.[6] Between 2012 and 2017, only 15 institutions accounted for 63% of pediatric research supported by R01 or equivalent awards from the National Institutes of Health (NIH).[7] In turn, these disparities between institutions may contribute to disparities in representation of patients enrolled in clinical trials. For example, disparities among institutions in clinical research infrastructure have been implicated in the underrepresentation of racial and ethnic minority groups in clinical trials, because patients from these groups are more likely to be served by lower-resourced institutions.[8]

In response to the coronavirus disease 2019 (COVID-19) pandemic, several areas of critical importance have been identified for pediatric clinical research. These include developing testing protocols, exploring the use of available drugs, developing new drugs, evaluating nonpharmacologic interventions, and conducting prospective observational research on the disease course and recovery.[9,10] These research initiatives spanned industry, federal, and institutional funding mechanisms. Because of structural inequality in research capacity across centers, participation in this cutting-edge work is likely to be unequal across medical schools and children's hospitals in the United States. In the short-term, this inequality may lead to disparities in patients' access to novel treatments and interventions. In the long-term, disparate inclusion in pediatric clinical trials can distort the evidence base relating to COVID-19 in pediatric patients, potentially missing important challenges and opportunities for treating this novel disease that are observed outside the few highly funded centers at the forefront of COVID-19 research. To improve COVID-19 trial accrual and representativeness, recent commentary has identified the need to expand research capacity at regional medical centers and community hospitals, which have previously had limited involvement in clinical trials.[11,12]

In this study, we used a US-based registry of clinical trials to characterize the involvement of US medical schools and children's hospitals in registered COVID-19 pediatric clinical research. We hypothesized that schools and hospitals would be more likely to have participated in pediatric COVID-19 clinical research if they had received more funding from the NIH, had greater experience with clinical trials, were considered one of the top schools or hospitals for research in the United States, and had a stronger record of scholarly publication. Our secondary aim was to investigate how these characteristics of each school or hospital were associated with the characteristics of active pediatric COVID-19 research projects, including project funding sources, study designs (interventional versus observational), and planned sample size.

METHODS

This study was conducted by using institutional data from public databases and did not require human subjects research approval. COVID-19 clinical research studies selected for inclusion in our analysis were queried from the ClinicalTrials.gov registry.[13] Following a previous study by Pundi et al, we searched online databases for preregistered studies using the keywords "COVID-19," "COVID," "SARS-CoV-2," "2019-nCov," "2019 novel coronavirus," and "severe acute respiratory syndrome coronavirus 2.[14]" Search results were limited to studies enrolling participants from birth to 17 years,[15] studies started in 2020, and studies originating in the United States. To exclude records for studies that were planned but not started, we limited the search results to studies listed as recruiting, enrolling by invitation, active but not recruiting, suspended, terminated, or completed.

The ClinicalTrials.gov registry was queried on December 31, 2020. For each registered study meeting inclusion criteria, we determined which participating sites were US allopathic or osteopathic medical schools[16,17] and which were US children's hospitals (not including branch campuses, behavioral health treatment centers, or hospitals with a particular specialization such as surgery or oncology).[18] We focused on medical schools and children's hospitals (including freestanding and nonfreestanding hospitals) because these institutions have traditionally led investigator-initiated research in pediatrics. Study participation was credited to each school or hospital on the basis of the ClinicalTrials.gov entry. Because recording of institutional affiliations was not standardized at the time of entry, it is possible that researchers in some studies recorded participation by both the medical school and the affiliated children's hospital (or vice versa). On the basis of the COVID-19 study registration records, we determined the study recruitment stage, design (interventional versus observational), intervention (pharmacologic, nonpharmacologic, or none), external funding (federal, industry, other extramural source, or none), study start date, and target enrollment across all sites.

For each medical school and children's hospital (not limited to the ones with eligible COVID-19 studies), we extracted 2019 data on NIH funding, recent clinical trials activity, and recent scholarly publications using NIH RePORTer, ClinicalTrials.gov, and Scopus databases, respectively (Supplemental Information).[13,19,20] Additionally, we assessed whether each hospital was designated as a teaching hospital, whether each medical school had a pediatrics

residency program, and whether institutions in the study participated in the National COVID Cohort Collaborative (N3C).[21–23] Freestanding hospital status was evaluated on the basis of participation in the Children's Hospitals Graduate Medical Education program[24] and a Web search of hospital descriptions. To measure institutional reputation, we created a dichotomous indicator for whether each institution was listed among the top 10 children's hospitals or the top 10 research-oriented medical schools in the 2019 US News and World Report rankings. Lastly, we coded the geographic region of each institution on the basis of US Census designation (Northeast, Midwest, South, and West).[6]

Summary statistics were presented as counts with percentages or medians with interquartile ranges (IQRs). Analyzing medical schools and children's hospitals separately, we calculated the proportion of institutions with active COVID-19 pediatric clinical studies in 2020 and compared institutional characteristics between institutions with and without at least 1 qualifying COVID-19 study, using rank-sum tests, χ^2 tests, or Fisher's exact tests, as appropriate. In further analysis, we limited the sample to institutions that participated in COVID-19 pediatric clinical research in 2020 and analyzed how institutional characteristics were associated with participation in trials that used an interventional design, received extramural funding support, or aimed to enroll >100 patients. We did not conduct multivariable analyses because of the strong intercorrelation of the independent variables. All analyses were completed in Stata/SE 16.1 (StataCorp, College Station, TX). $P < .05$ was considered statistically significant.

RESULTS

We identified 150 allopathic medical schools, 34 osteopathic medical schools, and 178 children's hospitals meeting inclusion criteria. As of December 31, 2020, 106 study registration records for COVID-19–related pediatric studies were found in the Clinicaltrials.gov registry. After manual screening of study records, a total of 67 unique studies were found in which the study locations included 1 or more of the medical schools or children's hospitals in our analysis. Among included institutions, 37 of 150 (25%) of medical schools and 36 of 178 (20%) children's hospitals participated in 1 of the registered pediatric COVID-19 studies. Because none of the osteopathic medical schools were recorded as participating in these 67 studies, the 34 osteopathic schools were excluded from further analysis (characteristics of osteopathic schools are shown in Supplemental Table 4).

Medical school characteristics are compared by pediatric COVID-19 study participation in Table 1. Schools that participated in pediatric COVID-19 studies had more publications (median 1528 vs 211), more NIH funding (median $114 million vs $6 million), and more studies registered on Clinicaltrials.gov in 2019 (median 2 vs 0; all differences statistically significant at $P < .001$). Additionally, schools participating in pediatric COVID-19 studies were more likely to have a pediatrics residency program (84% vs 64%, $P = .022$) and were more likely to be members of the N3C collaborative (54% vs 28%, $P = .044$), compared with nonparticipating schools. Eight of the 37 schools participating in registered pediatric COVID-19 studies were ranked in the top 11 research schools in 2019 (in that year, the school rankings included a 3-way tie for ninth place).

Results were similar when comparing children's hospital characteristics by pediatric COVID-19 study participation (Table 2). Hospitals participating in this research tended to have more publications (median 59 vs 0) and more clinical trials registered in 2019 (median 2 vs 0). Half of hospitals participating in registered pediatric COVID-19 studies were freestanding hospitals, compared with only 22% of nonparticipating hospitals ($P = .001$). Although median NIH funding was 0 in both groups of hospitals, 31% of children's hospitals with registered COVID-19 studies had received funding from this source in 2019, compared with only 6% of hospitals not represented among registered pediatric COVID-19 studies. Hospital teaching status and participation in N3C were not associated with hospital participation in registered pediatric COVID-19 studies.

The characteristics of the 67 pediatric COVID-19 studies associated with a medical school or children's hospital are summarized in Table 3. The majority of

TABLE 1 Medical School Characteristics According to Participation in Registered Pediatric COVID-19 Studies ($N = 150$ Medical Schools)

Characteristic[a]	Nonparticipating Schools ($n = 113$)	Participating Schools ($n = 37$)	P
Scholarly publications, median (IQR)	211 (60–620)	1528 (546–2699)	<.001[b]
NIH funding, $ millions, median (IQR)	6 (0–47)	114 (0–274)	<.001[b]
Clinical trial registrations, median (IQR)	0 (0–2)	2 (1–3)	<.001[b]
Top 10 designation, *n* (%)	3 (3)	8 (22)	.001[c]
Pediatrics residency, *n* (%)	72 (64)	31 (84)	.022[d]
N3C membership, *n* (%)	32 (28)	20 (54)	.004[d]
Region, *n* (%)			.691[c]
Northeast	24 (21)	11 (30)	
Midwest	28 (25)	7 (19)	
South	42 (37)	13 (35)	
West	15 (13)	6 (16)	
Puerto Rico[e]	4 (4)	0	

[a] All institutional characteristics were assessed in 2019.
[b] *P* value from rank-sum test.
[c] *P* value from Fisher's exact test.
[d] *P* value from χ^2 test.
[e] Puerto Rico is listed separately because it is not included in the 4 US Census regions.

TABLE 2 Children's Hospital Characteristics According to Participation in Registered Pediatric COVID-19 Studies (N = 178 Hospitals)

Characteristic[a]	Nonparticipating Hospitals (n = 142)	Participating Hospitals (n = 36)	P
Scholarly publications, median (IQR])	0 (0–19)	59 (0–345)	<.001[b]
NIH funding, $ millions, median (IQR)	0 (0–0)	0 (0–0.2)	<.001[b]
Clinical trial registrations, median (IQR)	0 (0–1)	2 (0–8)	<.001[b]
Top 10 designation, n (%)	3 (2)	7 (19)	<.001[c]
Teaching hospital, n (%)	131 (92)	36 (100)	.124[d]
Freestanding hospital, n (%)	31 (22)	18 (50)	.001[d]
N3C membership, n (%)	12 (8)	6 (17)	.144[d]
Region, n (%)			.892[c]
Northeast	31 (22)	10 (28)	
Midwest	35 (25)	7 (19)	
South	53 (37)	13 (36)	
West	21 (15)	6 (17)	
Puerto Rico[e]	2 (1)	0	

[a] All institutional characteristics were assessed in 2019.
[b] P value from rank-sum test.
[c] P value from Fisher's exact test.
[d] P value from χ^2 test.
[e] Puerto Rico is listed separately because it is not included in the 4 US Census regions.

registered studies (58%) were observational studies, whereas only 14 (21%) tested pharmacologic interventions. Although 18 studies (27%) received federal funding, the majority (n = 40, 61%) were internally funded. Thirty-four studies (51%) were initiated in the first few months of the pandemic (March–May 2020). Median targeted enrollment across all sites was 430 participants, with 76% of trials (n=51) aiming to enroll >100 participants.

TABLE 3 Registered Pediatric COVID-19 Studies at Included Medical Schools or Children's Hospitals (N = 67 Studies)

Characteristic	n (%)
Study stage	
Active, not recruiting	5 (7)
Enrolling by invitation	8 (12)
Recruiting	49 (73)
Completed	4 (6)
Terminated	1 (1)
Design and intervention	
Pharmacologic intervention	14 (21)
Nonpharmacologic intervention	14 (21)
Observational	39 (58)
Funding source	
Federal	18 (27)
Industry	6 (9)
Other extramural	2 (3)
Unfunded or self-funded	40 (61)
Start date in March to May 2020	34 (51)
Planned enrollment >100 participants	51 (76)

Among 36 children's hospitals with registered pediatric COVID-19 studies, we found that higher scholarly productivity, more NIH funding, and freestanding status were associated with greater likelihood of conducting an interventional trial (P = .022, P = .004, and P = .005, respectively; Supplemental Tables 5–10). Among both medical schools and children's hospitals with registered pediatric COVID-19 studies, institutional characteristics were not associated with the likelihood of conducting a funded study in this area or participating in a study aiming to enroll >100 patients.

DISCUSSION

The COVID-19 pandemic resulted in unprecedented acceleration of basic and clinical science efforts to address pandemic-related health concerns and outcomes while suspending many ongoing efforts in other health areas. Although children were likely to experience mild infection with the novel coronavirus and less likely to be hospitalized because of COVID-19 relative to adults, a wide range of interventional trials and observational studies were launched to identify short- and long-term effects of the novel coronavirus on the pediatric population and to assess the efficacy of various interventions in children affected by COVID-19.[25] Despite the global span of the pandemic, participation in this work was often limited to a few well-resourced institutions. Analyzing industry-funded, federally funded, and institutionally funded studies in the United States, we found that only 25% of medical schools and 20% of children's hospitals were identified as sites for pediatric COVID-19 research in a major clinical trials registry. Higher scholarly activity, higher NIH funding, and greater past experience with clinical trials were associated with increased likelihood of school or hospital participation in any of the COVID-19 research. As the pandemic continues into its second year, and with large-scale pediatric vaccine trials currently underway,[26] new strategies are needed to empower a broader range of institutions to participate in this vital and time-sensitive work.

Medical schools and hospitals face significant obstacles to conducting clinical trials, most notably a lack of resources, regulatory approval barriers, and lack of experience with trial operations.[27] The lack of qualified staff has been noted as a particular barrier, including data managers, statisticians, and pharmacists.[28] Considering investigator-initiated clinical trials, researchers have reported difficulty in finalizing contracts, bottlenecks in ethics committees, and site identification and activation issues that delayed trial start-up.[28] Specific to pediatric clinical trials, the higher safety standards and fear of exploitation from both regulators and the investigators themselves can discourage or delay study initiation.[29] Pediatric studies also may experience greater limitations related to funding and staffing, because funding opportunities specific to pediatric research are limited, and pediatric-trained research staff are in short supply.[29,30] Our

finding that 61% of studies were internally funded indicates that institutions lacking internal funding for research may be limited to participating in projects designed and funded by other entities. Furthermore, the majority of studies identified in our search were started in the first 3 months of the pandemic, underscoring the importance of institutional capacity to quickly design and deploy new clinical research protocols to achieve or maintain leadership in research.

In the second year of the pandemic, the focus of COVID-19–related pediatric clinical trials has expanded to include studying the efficacy of novel vaccines in this population.[31] Ongoing research efforts are also examining the impact of COVID-19 on younger children, infants, and pregnant women (including maternal transmission of virus and antibodies).[32] Several of the COVID-19 clinical trials registered at the outset of the pandemic have focused on testing, and this area of research may be reinvigorated as new testing protocols are developed that take into account availability of vaccines and "reopening" of social spaces. Considering the ongoing and evolving nature of the pandemic, our analysis presents timely data on disparities in COVID-19 research participation among key institutions (medical schools and hospitals) engaged in advancing pediatric clinical science and practice.

On the basis of our analysis, institutions with a history of extramural funding, scholarly productivity, and experience with clinical trial initiation are more likely to take part in pediatric clinical trials related to COVID-19. These institutions typically have strong research reputations and may also have a larger patient population supporting faster enrollment in clinical trials and ability to conduct preliminary single-center research.[33] Institutions serving smaller patient populations, or those without a strong track record in research, may include rural hospitals and medical schools, as well as community hospitals. Ensuring that these institutions can shape and participate in COVID-19 research may help address historical population inequities in access to care.[34] In this study, we found that children's hospitals were less likely than medical schools to be credited with participation in pediatric COVID-19 research in a major clinical trials registry. Among hospitals, we limited our analysis to children's hospitals, which excluded community hospitals that lack a children's hospital designation and may encounter even greater obstacles to conducting research. Further work is needed to better understand how hospitals can leverage research resources at partner institutions or within a larger health system, if applicable, to facilitate their involvement in clinical research.

Collaboration across institutions is a possible means for smaller institutions to build capacity for conducting clinical research by educating staff and sharing best practices. The efficacy of such collaborations has been demonstrated through a significant increase in interinstitutional coauthorship, more thorough training of new research staff, higher grant application and acceptance, and greater research participation among patients from underserved and minority groups.[35,36] Institutions without significant previous experience in clinical research may also benefit from working with clinical trials networks that can connect them into high capacity trials and provide staff training and support.[35] However, these collaborations may not necessarily guarantee a path to research independence for smaller institutions. Larger institutions in these collaborations could receive a higher portion of critical resources from the funding mechanisms such as indirect dollars, lead authorship on the resulting publications, higher salary coverage, and centrally purchased equipment. Limited information exists on starting clinical trials and investigator-initiated research programs at institutions with little or no previous experience in this area. Therefore, further work is needed to identify effective approaches to creating new research programs at both health care facilities and medical schools. By sharing expertise and resources across institutions to facilitate clinical research participation, future initiatives may help empower a more diverse range of institutions and investigators engage in this work. Additionally, the diversity of schools and hospitals must be considered when considering collaborative endeavors, because not all institutions focus on research as part of their mission.

Our conclusions are limited by several aspects of the study design. First, our study was limited to COVID-19 clinical trials that were registered in 2020, whereas COVID-19 vaccines were still in development and while the initial focus of COVID-19 clinical research was in preventing and treating the disease in adults. Second, our assessment of institutional characteristics was limited to publicly available information and did not include additional relevant factors such as the number and roles of research professionals at each site. Among hospitals in particular, the rurality of each institution's location and catchment area may have influenced its capacity to conduct research and recruit study participants, but this factors was not assessed in our study. Our assessment of historical clinical trial participation, in particular, was limited to trials that were newly registered in 2019 and did not account for institutions joining ongoing trials in that year (eg, an institution joining a clinical trial in 2019 that had begun at other sites in 2017).

Because of strong collinearity among independent variables in our study, we did not conduct a multivariable analysis to determine which institutional characteristics may have been associated with pediatric COVID-19 study participation independent of other factors. Furthermore, major vaccine trials, such as Pfizer's COVID-19 mRNA vaccine (NCT0436872), did not meet the qualifications of our study owing to only enrolling patients at hospitals or private clinical trials offices. On the basis of our results, we suspect that some studies conducted at children's hospitals were not credited to the hospital because of the registration record only including investigators' affiliation with a

medical school or university but not with the hospitals where study activities may have been conducted. Finally, our study only captured preregistered studies. Some research related to the pandemic may not have been registered or may not have required registration and was thus excluded from the scope of this study.

CONCLUSIONS

Despite not being as vulnerable as the adult population, the pediatric population has been the focus of a wide range of interventional and observational studies related to COVID-19 over the last year. Despite the pandemic affecting all communities, participation in early clinical research on the impact of COVID-19 in pediatric populations was concentrated in a few well-resourced institutions that were highly experienced in research. New strategies and collaboration are needed to enable more institutions to participate in this vital work.

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