Journal of Pediatric Psychology, 45(7), 2020, 720–724
doi: 10.1093/jpepsy/jsaa055
Advance Access Publication Date: 17 July 2020
Commentary

Considerations and Future Directions for Conducting Clinical Research With Pediatric Populations During the COVID-19 Pandemic

Colleen Stiles-Shields [1], PhD, Jill M. Plevinsky [2], PhD, Alexandra M. Psihogios,[3,4] PhD, and Grayson N. Holmbeck,[5] PhD

[1]Section of Community Behavioral Health, Department of Psychiatry and Behavioral Sciences, Rush University Medical Center, [2]Division of Behavioral Medicine and Clinical Psychology, Cincinnati Children's Hospital Medical Center, Center for Adherence and Self-Management, [3]The Children's Hospital of Philadelphia, [4]Perelman School of Medicine, University of Pennsylvania, and [5]Psychology Department, Loyola University Chicago

All correspondence concerning this article should be addressed to Colleen Stiles-Shields, PhD, Section of Community Behavioral Health, Department of Psychiatry and Behavioral Sciences, Rush University Medical Center, 1645 W. Jackson Boulevard, Chicago, IL 60612, USA. E-mail: colleen_stiles-shields@rush.edu

Received 21 May 2020; revisions received 22 June 2020; accepted 24 June 2020

The COVID-19 pandemic has impacted nearly every facet of life, including clinical research. Consistent with ethical practice, the first concern of pediatric psychology researchers is the safety of patients, their families, and clinical research staff. Beyond this, many are also wondering how to proceed with upcoming or ongoing research projects. While many of our colleagues are mobilizing to disseminate a large number of resources via listservs, webinars, and publications (Gruber et al., 2020; Padala, Jendro, Gauss, et al., 2020; Padala, Jendro, & Padala, 2020; Weissman et al., 2020), issues pertinent to conducting research with pediatric populations merit their own discussion. Indeed, pediatric patients and their families—particularly those with diminished immune system functioning—face unique uncertainties and distress in response to the COVID-19 pandemic. Pediatric psychologists are particularly equipped to conduct clinical research that will directly translate to interventions that promote mental and behavioral health outcomes for pediatric patients during and beyond the pandemic. Therefore, to serve as a resource for pediatric psychologists and their colleagues, this commentary will provide a brief overview of potential solutions for initiating new projects and continuing ongoing research involving youth with medically complex conditions (Table I summarizes the considerations).

Proposing New Research

While the pandemic has created an unprecedented reality, it is a reality that is likely to be present for some time. Therefore, there are benefits to collecting new data, as insight on how COVID-19 impacts specific pediatric populations and behavioral health will be required to support youth with chronic medical conditions and their families moving forward. Furthermore, incorporating responses to the pandemic within a previously planned protocol may open the door to new funding opportunities (e.g., NIH COVID-19 supplements for funded researchers; *NOT-OD-20-097*, 2020). To demonstrate the feasibility of new research studies to funders, and to support research implementation during shelter-in-place orders and phased reopenings, new research efforts will need to capitalize on digital health technologies for observational studies and interventions (e.g., online, text or app-based, and video visit assessments and interventions; more details on these methods are provided in the *Ongoing Research* section).

Funding Opportunities

Funding agencies have not only mobilized around COVID-19 therapeutics, vaccine development, and

Table I. *Summary of Considerations for Conducting Pediatric Clinical Research During COVID-19*

Recruitment and Consent	• Adapt procedures to allow for remote recruitment, electronic consent/assent, and enrollment • Partner with stakeholders (e.g., interdisciplinary medical clinic staff, schools, advocacy groups) to support recruitment efforts
Data Collection	• Incorporate a variable to distinguish data collected before, during, and after the COVID-19 pandemic • Include a measure, or select items, to assess the impact of COVID-19 on outcomes • Include measures assessing topics relevant to the COVID-19 pandemic (e.g., health-related anxiety) • Adapt existing measures for use on electronic platforms, if possible.
Intervention Delivery	• Adapt existing research protocols to digital platforms for secure videoconferencing • Be agile—the study/intervention may need to shift from remote strategies to in-person approaches, and vice versa, depending on changing COVID-19 guidelines • Plan for sanitation of study devices, remote tutorials on their use via phone/videoconferencing • Pivot participant compensation methods to include digital delivery (e.g., Amazon gift codes) or remote reloading capabilities (e.g., prepaid debit cards) • Assess if additional supports are needed to support intervention engagement (e.g., family lacks broadband internet access)
Reporting Outcomes	• Methods: Include details on any of the above changes made due to COVID-19 • Results: Include information on differences in demographic information, or outcome variables, if collected before, during, and/or after the COVID-19 pandemic • Discussion: Explain limitations to the research due to COVID-19, as well as its unique impact on the findings
Research Training	• Adapt student-led research projects to minimize disruptions to training milestones • Perform research supervision via videoconferencing • Address trainee anxiety about phased re-openings • Provide training in newly relevant topics (e.g., donning and doffing PPE for in-person contact)

Note. All considerations should be made in accordance with your IRB, and other institutional and state guidelines. PPE = personal protective equipment.

screening, but also toward behavioral science. These opportunities offer several relevant funding prospects for pediatric psychologists. For example, the National Institute of Mental Health issued a program announcement for research focused on the mental health response to COVID-19, including how the workforce has adapted to provide mental health care (*NOT-MH-20-047*, 2020). The Patient-Centered Outcomes Research Institute (PCORI) has announced 2.5–5 million dollars in COVID-related research (COVID-19 Targeted PFA, 2020), including adaptations to healthcare delivery, the impact of COVID-19 on vulnerable populations (including individuals with chronic health conditions and/or physical disabilities), and the impact of COVID-19 on the workforce and training. Pediatric psychologists should also explore potential support offered by their institutions (e.g., internal university funds), local and state resources (e.g., state health departments), and private/philanthropic foundations.

Ongoing Research

Remote Recruitment and Consent

With Institutional Review Board (IRB) approval, remote recruitment is possible through multiple channels. First, many IRBs allow for "opt-out" recruitment strategies. This involves sending letters to eligible participants to inform them of the study, allowing study staff to follow-up by phone or email unless they opt out of being contacted about the study. Second, many pediatric patients are already in regular contact with medical providers through virtual visits and school-based health center staff through virtual school contact. Interdisciplinary colleagues who are already in ongoing contact with potential participants may therefore provide helpful means for remote recruitment by referring patients to clinical research staff. It will be important for research teams to carefully track, document, and report how these remote recruitment strategies impact research recruitment and retention rates (e.g., # recruited and # retained from social media vs. mailed recruitment letter).

While IRB approval must be obtained, procedures for remote assenting/consenting are already common practice and may be implemented into existing protocols. Survey platforms such as REDCap have e-Consenting frameworks that are easily and securely deployed (How to use REDCap's e-Consent Framework, 2020). Furthermore, e-Consenting frameworks can be bolstered by teleconsent. While viewing the e-Consent materials in real time, potential participants and their parents/guardians may complete informed assent and consent with research staff over the phone (López et al., 2018; Welch et al., 2016). Once completed, designated research support staff and the participants can be emailed a secure PDF of the signed assent/consent for their records.

Data and Assessment

The COVID-19 pandemic presents several challenges to data collection, including self-report measures, observational data, and biomedical data (e.g., blood draws, saliva collection). Ongoing trials have the opportunity to pivot their focus and adjust research questions, or simply account for the effect of the start of

the COVID-19/shelter-in-place orders in their respective states. At minimum, investigators need to include a variable to distinguish data collected during the pandemic from data collected prior to large-scale changes made in their community due to COVID-19 (e.g., school closures, shelter-in-place orders). This will allow for analyses to examine whether outcomes were affected by the pandemic and whether baseline or longitudinal outcomes data collected before, during, and after the pandemic are significantly different. This will also allow for investigators to account for missing biomedical data unable to be collected during the pandemic. Should restricted sample sizes inhibit the ability to examine statistical differences, effect sizes may be reported instead.

An additional way to assess the impact of COVID-19 on participants is by incorporating newly developed scales into both new and ongoing projects. The National Institutes of Health has compiled a list of COVID-19-relevant data collection instruments for specific populations (Office of Behavioral and Social Sciences Research, 2020). Instruments include the COVID-19 Exposure and Family Impact Survey (CEFIS), which is available in English and Spanish and with separate caregiver and adolescent/young adult versions (Kazak et al., 2020). An additional repository of measures and resources is available through the Center for Open Science (Pfeifer et al., 2020), which has launched an open tracking and facilitation initiative. As there are a growing number of assessment measures relevant to COVID-19, researchers should be selective in the number of items and/or measures they add to their protocols to avoid over-burdening participants. Furthermore, while these instruments may be included in ongoing research studies, an important future direction is to utilize the same COVID-19 impact questionnaire(s) across studies to facilitate comparisons within and between populations over time.

Participant Compensation and Providing Additional Supports

To best support pediatric participants and their families, pivoting their compensation and other methods of research participation support is recommended. Compensation for completing assessments, etc., should be made through methods that allow for digital delivery (e.g., Amazon gift codes) or remote reloading capabilities (e.g., prepaid debit cards). Additionally, funding that was budgeted for in-person activities (e.g., refreshments provided during focus group sessions) may be reallocated to support participants' needs in completing remote research activities. Examples include providing mobile devices, hot spots and/or mobile plans to facilitate study participation for those with access barriers. Of note, researchers should also reconsider making technology ownership an inclusion criterion for research participation, as this will unduly exclude those with limited resources.

Delivery

Adapting existing research protocols for digital platforms may represent one feasible way to continue with studies as planned. While statistical techniques may support gaps in assessments for longitudinal studies, it is likely that delaying time points to "wait out" the disruptions of the pandemic may affect the research more than adapting the protocol. Moreover, changing COVID-19 recommendations over time may require a "hybrid approach" that can quickly adapt from in-person to remote research strategies and vice versa. Protocols can be revised to allow for remote recruitment practices, study monitoring, data collection, study visits, and intervention. Technology offers several opportunities for this, including electronic surveys (e.g., SurveyMonkey, REDCap) and videoconferencing (see Table II for a list of HIPAA-compliant video conferencing services).

However, careful considerations made with consultation with IRBs need to be made with regards to: (a) privacy, (b) confidentiality, (c) overall security, including secure storage of study materials, and (d) reliability and validity of assessment measures. If distributing study devices (e.g., electronic medication tracking caps, study phones, iPads), these devices need to be carefully cleaned prior to mailing and participants will require instructions on how to sanitize them without causing damage upon receipt and return. Additionally, tutorials on their use (e.g., device setup, mobile app tutorials) may be required via telephone, videoconference, and/or visual aids and short videos developed by the research team. Research staff should also provide information to participants about maintaining their safety (e.g., not driving during a telehealth session), confidentiality (e.g., finding a quiet, secure place to talk), minimizing distractions (e.g., turning off the television), and discussing how to integrate and/or ask for breaks (to avoid "Zoom fatigue" or too much continuous screen time) during remote study assessments and sessions. If study protocols require both caregivers and participants to be available, this may require increased flexibility on the part of the research team to best accommodate families and their changing schedules during the pandemic.

Reporting Outcomes

Changes to the typical reporting of Methods, Results, and Discussion are warranted. Specifically, the Methods section should outline any changes to procedures that were made in response to the pandemic, including the aforementioned inclusion of a variable, or additional measure, and to indicate whether recruitment and data collection occurred before, during, or after the pandemic. The Results section should

Table II. *HIPAA-Compliant Videoconferencing Services*

Service	Cost of service	Link
BlueJeans for Healthcare	Starts at $10/month per account	bluejeans.com/use-cases/healthcare
Doxy.me	Free to start	doxy.me
Epic-integrated Vidyo infrastructure (for use via Hyperspace™, Canto™, and Haiku™)	Consult Epic Implementation Executive (EIE), Implementation Director (ID), or Technical Coordinator (TC)	epic.com/software#telehealth
GoTo Meeting	Starts at $12/month	gotomeeting.com/meeting/healthcare
Microsoft Teams	Free to start	microsoft.com/en-us/microsoft-365/microsoft-teams/healthcare-solutions
SimplePractice Telehealth	$10/month per account	simplepractice.com
Vsee	Starts at $49/month	vsee.com/telemedicine
WebEx	Free to start	webex.com
Zoom for Healthcare	$200/month per account	zoom.us/healthcare

Note. These services should be selected in consultation with your IRB and the link should be accessed for the most up-to-date information about these services. Cost of service is presented for general use; pricing may vary based on the desired number of participants for video sessions (e.g., remote focus group sessions). HIPAA = Health Insurance Portability and Accountability Act.

characterize what proportion of the sample was recruited, assessed, and/or intervened with before, during, and after the pandemic and statistical comparisons of these groups should be reported as preliminary analyses. If significant differences emerge, statistical controls should be utilized to account for COVID-19 as a historical confound. Finally, in the Discussion, the authors should list potential limitations to their work as a result of COVID-19, but also potential opportunities for more nuanced understandings of their outcomes based upon this universally experienced external stressor. For example, adherence research might address: difficulties with keeping consistent schedules, obtaining medications from the pharmacy, and loss of insurance and access to healthcare maintenance tasks (e.g., blood draws, routine procedures); whereas, research assessing sleep or eating patterns might address a lack of routine or consider the role of food insecurity due to lost wages during the pandemic.

Future Directions

The COVID-19 pandemic has fostered both unexpected challenges and opportunities for pediatric behavioral scientists. While adapting to the new hurdles of conducting clinical research remotely, pediatric psychologists are tasked with increasing the reach of their research during the pandemic and beyond (e.g., implementing study procedures via digital technologies). These innovations may help to address disparities that existed prior to COVID-19 in our field (e.g., the lack of inclusion of patients who have disengaged from their medical care and/or who face barriers to attending face-to-face visits) and increase the reach of research after the pandemic ends. However, these adaptations may also exacerbate disparities without careful and ongoing attention (e.g., restricting research studies to those with stable internet access or a smartphone). It is also important to consider the impact on pediatric psychology trainees, such as: (a) the need to conduct student-led research projects remotely and minimize disruptions to the timing of thesis/dissertation completion; (b) perform research supervision via videoconferencing platforms; (c) address trainee anxiety about phased re-openings; and (d) provide training in newly relevant topics (e.g., donning and doffing personal protective equipment for any in-person contact, confidentiality and rapport considerations for remote data collection).

Pediatric psychologists are uniquely poised to conduct research during the COVID-19 era. Indeed, we offer a unique skill set for investigating newly relevant research topics, such as how patients and their family members are adhering to COVID-19 mitigation efforts, the downstream impacts of COVID-19 on mental and behavioral health outcomes (e.g., on mood, family functioning, grief/bereavement, and disease self-management), and how COVID-19 may exacerbate health disparities in vulnerable populations. Furthermore, our work with pediatric families and medical teams to promote resilience following medical trauma and/or adjustment to serious illness may inform behavioral interventions for patients with COVID-19 of all ages as they adjust to potentially long-term medical and psychosocial impacts. Taken together, we conclude that pediatric psychologists should: (a) attempt to complete their current research with some pivoting (e.g., inclusion of additional measures, use of digital platforms); (b) contribute to studies on the acute impacts of COVID-19; and (c) anticipate future scientific questions that will address individual and public health outcomes (e.g., factors that impact uptake of COVID-19 screening and vaccinations).

Funding

We are grateful for support from the United States National Institutes of Health, including the National Institute of Nursing Research and the Office of Behavioral and Social

Sciences Research (R01 NR016235), National Institute of Child Health and Human Development (T32 HD068223), and National Cancer Institute (1K08CA241335-01).

Conflicts of interest: None declared.

References

COVID-19 Targeted PFA. (2020, April 21). https://www.pcori.org/funding-opportunities/announcement/covid-19-targeted-pfa. Retrieved 4 July, 2020.

Gruber, J., Prinstein, M., Abramowitz, J. S., Albano, A. M., Aldao, A., Borelli, J., Clark, L. A., Davila, J., Forbes, E. E., Gee, D., Hall, G. N., Hallion, L. S., Hinshaw, S. P., Hofmann, S. G., Hollon, S., Joormann, J., Kazdin, A., Klein, D., Levenson, R., … Weinstock, L. (2020). *Clinical psychological science's call to action in the time of COVID-19*. https://doi.org/10.31234/osf.io/desg9

How to use REDCap's e-Consent Framework. (2020). *University of Illinois, Interdisciplinary Health Sciences Institute*. http://www.healthinstitute.illinois.edu/sites/default/files/How_to_eConsent.pdf. Retrieved 4 July, 2020.

Kazak, A., Canter, K., Phan-Vo, T. L., McDonnell, G., Hildenbrand, A., Alderfer, M., … Deatrick, J. (2020). *COVID-19 Exposure and Family Impact Survey (CEFIS)*. https://www.nlm.nih.gov/dr2/CEFIS_COVID_questionnaire_English_42220_final.pdf. Retrieved 4 July, 2020.

López, C. M., Qanungo, S., Jenkins, C., & Acierno, R. (2018). Technology as a means to address disparities in mental health research: a guide to "tele-tailoring" your research methods. *Professional Psychology, Research and Practice*, *49*, 57–64.

NOT-MH-20-047. (2020). *Notice of Special Interest (NOSI) Regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus*. https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-047.html. Retrieved 4 July, 2020.

NOT-OD-20-097. (2020). *Notice of Special Interest (NOSI) Regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus and the Behavioral and Social Sciences*. https://grants.nih.gov/grants/guide/notice-files/not-od-20-097.html. Retrieved 4 July, 2020.

Office of Behavioral and Social Sciences Research. (2020). *COVID-19 OBSSR Research Tools. National Institutes of Health*. https://www.nlm.nih.gov/dr2/COVID-19_BSSR_Research_Tools.pdf. Retrieved 4 July, 2020.

Padala, P. R., Jendro, A. M., Gauss, C. H., Orr, L. C., Dean, K. T., Wilson, K. B., … Padala, K. P. (2020). Participant and caregiver perspectives on clinical research during Covid-19 pandemic. *Journal of the American Geriatrics Society*, *68*, E14–E18. https://doi.org/10.1111/jgs.16500

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*, e18887.

Pfeifer, J., Ladouceur, C., Byrne, M., Flannery, J., Chavez, S., Cheng, T., Flournoy, J., & Oosterhoff, B. (2020). *Assessment of COVID-19 Experiences (ACE) for Adolescents—Research Tracker and Facilitator*. Open Science Framework. https://doi.org/10.17605/OSF.IO/PY7VG

Weissman, R. S., Bauer, S., & Thomas, J. J. (2020). Access to evidence-based care for eating disorders during the COVID -19 crisis. *The International Journal of Eating Disorders*, *53*, e18961.

Welch, B. M., Marshall, E., Qanungo, S., Aziz, A., Laken, M., Lenert, L., & Obeid, J. (2016). Teleconsent: A novel approach to obtain informed consent for research. *Contemporary Clinical Trials Communications*, *3*, 74–79.