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Innovations from the Field

Innovations in Prospective Perinatal Research as a Result Of the COVID-19 Pandemic

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In 2020, in-person research activities were stopped because of the spread of the novel coronavirus, severe acute respiratory syndrome coronavirus 2, and the resulting disease, coronavirus disease 2019. Our collaborative team of nurse and midwife scientists at universities across the United States adapted research activities to continue prospective perinatal research during the pandemic. These adaptations included development of new research techniques and the implementation of previously developed, but underused, strategies to conduct research from a distance. These strategies included online recruitment, virtual enrollment and consent, qualitative data collection via video conferencing, new applications of smart phone technology, wearable biological measurement, and participant self-collection of biological samples. In addition to allowing research to continue during the pandemic, these innovative strategies may increase access to research for low-income, rural, and racially diverse pregnant and postpartum populations. Decreased travel requirements, flexible scheduling, wearable devices, and the capacity to self-collect biologic samples may improve recruitment and the experience of research participation. The rapid implementation of these research strategies has advanced innovation toward wider, more inclusive and increasingly diverse perinatal research access, and many of these strategies will continue to be used and refined.
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INTRODUCTION

Researchers and pregnant women face numerous obstacles when conducting and participating in studies focused on the perinatal period. For decades, regulations put in place to prevent fetal injury impeded or prevented individuals from participating in research during pregnancy, making it difficult to use research to assess the risks and benefits of interventions that could be beneficial during pregnancy.[1] The problem of limited research to assist clinical decision-making is compounded for pregnant individuals from minoritized groups, as they are both at increased risk for adverse perinatal outcomes and are underrepresented in existing research.[2] Research specific to pregnancy and research that targets inclusion of minority populations is a national priority as a facet of improving health equity.[3]

There are also multiple, intersectional barriers for pregnant individuals, women, and persons of color for research participation. Specific barriers to research participation include transportation to research sites, a need for childcare, scheduling constraints, language and cultural barriers, and mistrust of the health care and research system.[2] Women may even incur costs to participate in research, including paying for transportation and childcare or missing work to attend research visits. Racism, classism, and rurality are additional areas of intersectionality that contribute to inequality in disparities in research participation and perinatal health outcomes.[2,4]

In 2020, the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) pandemic further impeded research in many health care settings as research and academic centers paused research activities. In response to the shutdown of in-person research enacted to limit the spread of SARS-COV-2, this team implemented research strategies including online recruitment, virtual enrollment and consent, telephone and video data collection, new applications of smart phone technology, wearable devices, and participant self-collection of biological samples (Table 1). Many of these strategies may also mitigate barriers to research participation for individuals who are underrepresented in research.[2] Use of these strategies supported research during the pandemic and also generated or expanded innovations for engaging pregnant individuals in perinatal research more effectively, efficiently, and equitably for the future.

Our collaborative team consists of nurse and nurse-midwife scientists at 5 academic centers across the United States. We each conduct research on issues surrounding labor and birth individually and frequently collaborate across sites.

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Quick Points

- Perinatal researchers adopted or developed new research techniques during the coronavirus disease 2019 pandemic to continue and advance research.
- These new research strategies increase access to research through flexible scheduling, decreased travel, and greater participant engagement.
- Increased access to perinatal research may increase sample sizes, diversify research participation, and improve the quality of data for addressing perinatal health disparities.

We use prospective approaches as well as existing health data to study perinatal physiology and health service use with the goal of improved perinatal outcomes. Our current research includes mixed methods evaluation of intersectionality and implementation of telehealth in nurse-led care settings during the coronavirus disease 2019 (COVID-19) pandemic;[5] changes in physiology (eg, temperature, heart rate variability) and hormone metabolism prior to labor; characterization of latent labor symptoms, biomarkers, and experiences; telehealth options to improve access to maternal mental health care; and team-based perinatal care.

When the COVID-19 pandemic started in March 2020, each of our institutions ceased in-person research activities to prevent spread of the SARS-COV-2 virus. We each adapted research strategies to continue to advance perinatal science despite the pandemic and to reopen our individual studies with social distancing efforts in place. We collaborated through mentorship, partnership, sharing ideas, and developing best practices for distance-based research during the pandemic.

APPROACHES TO IMPROVE ACCESS TO RESEARCH

We met throughout the early months of the pandemic in March through May of 2020, to support each other in pivoting projects, adapting research strategies, and disseminating research findings.[6] Individually, together, and among teams in our institutions, we established strategies. This article describes the research strategies we implemented during the COVID-19 pandemic, including online recruitment, virtual enrollment and consent, qualitative data collection via video conferencing, wearable biological measurement, and participant self-collection of biological samples.

Online Recruitment

Traditional methods used to recruit research participants have included flyers, clinical outreach, and convenience sampling. More recently, advertising online and social media platforms have emerged as ways to reach potential participants especially among diverse populations.[2,4,7] During the COVID-19 pandemic, many studies increased use of electronic recruitment strategies. For example, email addresses can be obtained from companies who market services to target audiences, including companies with apps specific to the perinatal period. Crowdsourced databases of participant self-reported data, such as PregSource, which is sponsored by the National Institutes of Health, are also available for researchers to use. In addition, social media influencers who reach a large, specific audience can also be used to promote study enrollment. This strategy of using influencers to build recruitment may open opportunities to improve sampling diversity and build equity in research as individuals may be more likely to participate if they hear about the study from someone they trust.[8] This is similar to snowball sampling, and influencers have the potential to rapidly accelerate sharing and uptake of a message.

Table 1. Examples of Resources Supporting Described Research Innovations[a]

Research Innovations	Currently Commercially Available Products
Pregnancy apps with availability to purchase ads and directly email users	Ovia, BabyCenter
Social Media platforms with availability to purchase ads and target populations through influencers	Facebook, Instagram, Pinterest, NextDoor, YouTube
Crowdsourced perinatal databases	PregSource
HIPAA-compliant virtual enrollment and consent platform with survey and other data collection capabilities	REDCap, MyCap, ResearchKit
HIPAA compliant with autotranscription capability	Zoom, Cisco Webex, Microsoft Teams
Smartphone survey collection tools	JotForm, Smartsheets, Fulcrum, MyCap
Wearable biologic measurement devices	Bloomlife (contraction monitor), Oura (ring), Garmin (watch), Apple Watch
Microbial collection and stabilization (stool)	DNA Genotek
Microsampling (blood)	Neoteryx

HIPAA, Health Insurance Portability and Accountability Act; REDCap, Research Electronic Data Capture.
[a] These are products that are used or considered by our research team at the time of publication but only represent a small set of the products available commercially.

An example of use of these recruitment modalities is an institutional review board-approved study on decision-making during birth that was conducted by one of the authors in 2020-2021 via a survey of postpartum people (n = 1072). Paper advertisements with a quick response code resulted in a total of 50 responses, less than 5% of the total sample. Online recruitment strategies included paid and snowball personal online sharing about the survey. Paid advertisements on Facebook and Instagram, which cost $0.76 to $0.86 per click and totaled $1000, generated 5 to 10 responses every 24 hours over a one-month period. In addition, approximately 350 participants were reached through emailing users of the Ovia pregnancy app.

Social media sharing of recruitment materials among individuals generated the most participants of any recruitment methods for this study. Specifically, our study team reached out to an influencer who is a young mother who has thousands of social media followers and asked her to encourage participation in the research study via her Instagram postings and YouTube channel. Her viral (unpaid) social media posts yielded 115 completed responses to the survey in just 24 hours. In addition, participants recruited through this influencer had a younger mean age and were more likely to have public insurance when compared with the total sample. All of the participants the influencer recruited were younger than the age of 38 years, with 86% (n = 99) age 29 years or younger, and 37% were recipients of Medicaid insurance.

Virtual Enrollment and Consent

In addition to greater use of online recruitment, many researchers implemented new processes for enrollment and consent during the COVID-19 pandemic.[3] Documentation of consent historically involved the research participant meeting with a member of the study team and signing a paper in ink to affirm their understanding of research risks, benefits, and alternatives as well as their desire to participate. In-person meetings can be particularly difficult to arrange in rural areas and low-volume clinics and for people with rare conditions. Although online methods of consent have been accepted and even preferred by the National Institutes of Health for several years,[9] the COVID-19 pandemic hastened adoption by researchers. Online consent for research has many advantages, such as ready access to the current consent form, creation of accurate time stamps, streamlined auditing, and access to signed forms. The ability to consent to research without having to be in a specific location can reduce barriers to research participation.[10]

Several secure research platforms protect research and health care-related data and have e-consent templates.[11] Some sites include e-consent features such as videos of study procedures, translation, and literacy tools (eg, hovering over words for a definition).[12,13] These embedded features bolster participant understanding beyond what a paper form could offer, include multiple languages, and increase information access for participants with low literacy.[2]

Members of the author team have implemented online consent processes using a federally supported platform, Research Electronic Data Capture (REDCap).[11] Participant access to online documents was paired with telephone or video conferencing to answer participant questions and to interact with potential research participants. These methods have allowed connection and dialogue with interested individuals, even when they are in a different geographic area or have scheduling or language constraints. Preliminary assessment of online consent modalities suggests they are appropriate across different demographic groups of pregnant individuals.[10,14] Online consent, especially when paired with telephone or online access to research staff, has the potential to increase access to research and streamline research efforts while meeting the needs of a diverse research population and may become the most common method for research consent documentation.[2]

Data Collection

Several different methods for collecting data capitalizing on distance research strategies were identified and implemented by members of our team to meet their unique research needs.

Qualitative Data Collection via Video Conferencing

Prior to the COVID-19 pandemic, use of video conferencing for research interviews and focus groups was controversial.[15,16] Some qualitative researchers have observed that data collected virtually may lack some nuance and richness because of missed nonverbal cues and barriers to establishing rapport.[17,18] Additionally, concerns about privacy, confidentiality, data security, access, and comfort with the technology contributed to a preference among many researchers to conduct in-person meetings for qualitative data collection.[16] However, the COVID-19 pandemic spurred rapid expansion of use of video conferencing. In addition, web conference platforms made functional improvements that addressed many previous concerns.

The rapid expansion of telehealth services and research use of video conferencing during the COVID-19 pandemic has encouraged increased availability of video conferencing platforms that are compliant with the Health Insurance Portability and Accountability Act (HIPAA). These platforms include functionality for secure data collection and storage. Video conference platforms also now facilitate audio and video recording and autotranscription services. Generating a video and audio recording along with the autotranscription facilitates analysis.[15,16] When conducting qualitative interviews and focus groups via video conferencing during the pandemic, study authors had similar levels of connection, rapport, and depth of data collection compared with in-person interviews. Participants may also feel more comfortable participating in research from their own homes and appreciate the flexible scheduling and reduced transportation costs and time.

New Applications of Smartphone Technology

Data for intrapartum and immediate postpartum research is typically collected during inpatient care. Many pregnancy, birth, and postpartum events involve emotions (eg, excitement or anxiety) and/or decision-making (eg, deciding when to transition to the hospital during labor) that routinely occur in the community setting. Retrospective self-report of these

events may miss nuances that would be better captured during the experience itself. Increasing interest in smartphone technologies, with nearly ubiquitous use and proliferation of applications targeting pregnancy and labor, has sparked parallel proliferation of smartphone-based research innovations.[19] Smartphone technologies facilitate real-time data collection in all settings. This functionality can help build knowledge about childbearing processes that commonly occur outside of perinatal care facilities, such as the onset of spontaneous labor, postpartum involution, or perinatal sleep patterns.

There are several smartphone apps designed for survey data collection; however, not all of these prioritize study participant security. REDCap now has a HIPPA-compliant application for smartphones, known as MyCap. The app can collect data in a variety of formats relevant to quantitative research (eg, binary, continuous, or categorical variables) and qualitative research (eg, voice to text functionality). Real-time data collection can reduce recall bias, improve data accuracy and detail, and center patient experiences. MyCap is also designed to share content, including text, video links, and study reminders. This opens the exciting opportunity to deliver content to pregnant people while simultaneously capturing data about their frequency and intensity of engagement with this content. For example, the app could share a video with study participants while tracking how much of the video each participant played. Although the application has the same research capacities of REDCap, the patient-facing MyCap interface can be tailored and gamified to enhance interest and engagement.

Our study team is currently using MyCap to collect real-time information about people's experiences during the period between the onset of spontaneous labor through hospital admission for birth. After consenting to participate, the research staff help participants download the study's MyCap app. Subsequently, the participant completes a brief (5 minute) training in the use of the app with the research staff available to answer questions. When the participant begins to have symptoms of spontaneous labor, they use the MyCap app regularly to track contraction frequency and duration and document symptoms and coping methods as the latent phase of labor progresses. Data related to decision points, such as contacting the provider team and presenting to the hospital, are captured via quantitative questions (eg, were you or your partner more motivated to go to the hospital?) and qualitative questions (eg, what is the experience of transitioning to the hospital like for you?). Real-time characterization of people's symptoms of the latent phase of labor, experiences, and decision-making will be used to refine understanding of individual's experience of spontaneous labor.

In addition to this example of MyCap use, many smartphones are routinely designed to capture a variety of data points that might be relevant to perinatal research. There are multiple examples of smartphone data collection using built-in feature of the device.[20,21] Examples include information on activity (eg, acceleration), visual information (eg, light sensors, photo and video information), location (eg, Global Positioning System), sleep patterns (eg, movement), and sound (eg, microphone). Smartphone and digital app technologies are rapidly evolving and will facilitate participant-led perinatal data collection.

Wearable Biological Measurement

Previous monitors for measuring biologic variables tended to be bulky, expensive, and heavily wired, making them cumbersome and difficult to use. Newer wearable devices, such as those embedded in watches or rings, are increasingly comfortable and lightweight, making them easy to use.[22] Some of these devices are Food and Drug Administration (FDA)-approved for temperature monitoring, but many are considered wellness trackers and lack FDA regulation.[23] Wearable devices designed specifically for reproductive health are increasing in number. Examples include uterine contraction monitors and a host of wearable thermometers for tracking body temperature for fertility monitoring.[23,24]

Application of wearable devices to perinatal research may provide highly personalized data in the context of the individual's own environment. Biological tracking with wearable monitors could provide biobehavioral information to research pregnancy, birth, or postpartum experience. Thus, questions such as sleep quality in pregnancy[25] or exercise could be examined in far greater detail and depth than with periodic or self-reported measures.[26] The applications also permit direct data entry, allowing participants to self-report data to augment smartphone-collected measurements. One of our team members is using a wearable ring to measure changes in peripheral physiology (eg, temperature, heart rate variability, movement, and sleep measures) prior to the onset of labor. The ease of use of this device allows continuous data collection throughout pregnancy and the postpartum period with minimal participant burden.

Participant Self-Collection of Biological Samples

Traditional sampling methods require research participants to come to a laboratory or clinic for collection of samples such as blood, serum, urine, stool, hair, or cells via use of check swabs. During the COVID-19 pandemic, many research studies used participant self-collection to avoid in-person contact. For example, one author worked on a multisite study in which all biological samples (blood, stool, saliva) were self-collected by participants, a dramatic departure from prepandemic collection in clinical settings.[27] To make this shift possible, participants received collection materials in the mail and met with research coordinators via the video conferencing software Zoom to make sure they felt comfortable with the self-collection procedures. Self-addressed envelopes were provided for samples to be mailed to the laboratory.

Participant self-collection of biological samples offers several advantages over obtaining specimens at clinical or research sites. Self-collection can simplify biological sampling by reducing the travel time, expenditures, and clinical procedures for collecting samples. Currently, self-collection kits are available for blood, saliva, and feces, and most are stable at room temperature for several days before

processing or freezer storage is necessary. For example, microsampling collection of blood or urine can be used for clinical assays or methods such as metabolomics (the study of small molecule metabolites). Samples are stable for 48 hours at room temperature, negating the need for costly cold-chain shipping.

Self-collection of biological samples can also engage the participant as an active member of the research. Successful self-collection methodologies provide participants with a rationale for sample collection and clear instructions, often using different formats (ie, written, video, conference call with research coordinator).[28] In this way, control of sample collection is moved from the research team to the participant, encouraging research teams to optimize their participant communication to ensure sample quality. When paired with community-based participatory research methods, sample self-collection can foster greater understanding between participants and researchers of each other's needs and priorities.[29] For example, in the multisite study referenced above evaluating metabolites that may underpin symptom burden in Black people with chronic conditions, research coordinators met via video conferencing with participants to answer questions about sample self-collection and, in the process, had more time to hear participant questions about the types of assays that were planned for the samples and suggestions about how to describe the processes of self-collection.[27] Following these conversations, researchers integrated some of these suggestions from participants into updated recruitment and collection script materials.

Technology used in participant self-collection of biological samples can also decrease harm to participants, as smaller amounts of biologic materials can be used compared to traditional sample collection. Participants in the multisite metabolomics study used microsampling devices to self-collect blood samples from a finger stick.[27] This was possible because microsampling only requires a single drop of blood, which is approximately 10 mcL. This is in comparison with the average 10 mL, or 500 to 800 times less blood than is typically collected via normal venipuncture.[30] This reduced amount of biologic material can be especially important when researchers are working with medically fragile or pediatric populations.[29]

Finally, self-collection of specimens allows participants to more easily fit sample collection into their lives. Depending on specimen needs, traditional research studies might ask participants to come to a collection site multiple times per week or day. This requires time off from work or childcare responsibilities and travel to the collection location. Thus, self-collection can increase recruitment and retention of more diverse participants, increasing generalizability to reduce health disparities.

DISCUSSION

Although many of these strategies had been in development, the urgency created by the COVID-19 pandemic along with the sudden volume of individuals requiring clinical and research strategies conducted at a physical distance catalyzed changed in research recruitment, consent, and methods. Use of these strategies has allowed research to continue during the COVID-19 pandemic and also increased access to populations typically underrepresented in research. Implementation of data collection methods such as smartphone apps, wearable devices, and self-collection of samples may have been preferable to in-person data collection methods. Participants reported anecdotally that distant research strategies were convenient, efficient, and empowering and made them more likely to participate, warranting further qualitative and quantitative inquiry.

Given the vulnerabilities faced by many pregnant women who experience disparities related to gender, race, class, and rurality, targeting research toward addressing health inequity is a priority for perinatal research. The research strategies implemented by this team during the COVID-19 pandemic address many of the barriers to research participation for underrepresented populations by encouraging active engagement in sampling, reducing transportation time and costs, increasing flexibility of scheduling, and improving understanding of research purposes and processes.[2] Continued analysis is needed to evaluate these strategies. For example, lack of internet or smartphone access or mistrust of and/or discomfort with technology may offset some of the benefits of efficiency.[4] Although these innovations address some barriers to research participation, sociocultural issues also require further attention, and respectful, equity-focused, patient-centered research requires continuous awareness and research-team education.

CONCLUSION

The COVID-19 pandemic has increased implementation of research innovations. Useful strategies include virtual recruitment and enrollment, e-consent, online qualitative data capture, smart phone data entry, wearable biological measurement, and participant self-collection of biological samples. Further evaluation is needed to thoroughly access if these processes and measures increase access to research participation among all underrepresented populations, including Black, Indigenous, and Hispanic persons, people living in rural areas, and people with low incomes. However, these strategies may have profound positive benefits to perinatal research through increasing participant recruitment and improving engagement and retention.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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All data and material are available upon request to the corresponding author.

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