Ethical Considerations in Oncology and Palliative Care Research During COVID-19

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Abstract
Background: Researchers and clinicians must collaborate to consider alternative approaches to conduct standard protocol activities and deliver interventions during the pandemic. The COVID-19 pandemic has required researchers at many institutions to modify traditional in-person research to virtually delivered activities and still adhere to healthcare ethical principles of beneficence, justice, and respect for persons. Our objective is to describe ethical considerations faced by nurse investigators who modified research conducted in pediatric oncology during the COVID-19 pandemic. Methods Review of research case examples. Results Two research study case examples are presented, including remote-participant recruitment via Facebook advertising and a virtually delivered web-based legacy intervention in a pediatric oncology randomized clinical trial. Challenges to modifying in-person approaches to remote strategies are also discussed, with examples of advantages and disadvantages presented from a study testing a human–animal interaction intervention for children with cancer. Discussion Our case information may assist other investigators in planning virtually delivered behavioral strategies for populations that may prefer the convenience of remote participation in research studies because of multiple family responsibilities in the care of a family member, during the pandemic and after. As researchers understand more about subjects’ preferences to receive protocol activities (i.e., virtual vs. in-person delivery), they may be able to reduce risks of being unable to collect data because eligible subjects declined or withdrew from a study due to multiple-home responsibilities during the care of a family member with a serious or life-limiting condition.

Keywords
coronavirus, virtual research, research ethics, research design

Background
Coronavirus disease 2019 (COVID-19) is an acute respiratory illness caused by the novel coronavirus severe acute respiratory syndrome coronavirus (Centers for Disease Control and Prevention [CDC], 2020). The COVID-19 global pandemic led to an unprecedented impact upon all individuals across the United States and worldwide, including healthcare providers and scientists (CDC, 2020). The impact of the COVID-19 pandemic is also affecting almost every aspect of individuals’ access to community resources, individual and family-life decisions, and requirements for individuals to adapt to new workplace locations in their homes. Responses to COVID-19 included rapidly implemented Congress and CDC recommended public safety policies on March 27, 2020, in the United States, such as (1) community social-distancing guidelines (e.g., mask mandates; stay-at-home mandates; suspension of in-person educational activities for students in grade schools and colleges/universities; closure of early childcare programs; closure of community gyms and public sports events; immediate implementation of new remote work and educational programs; closure of national and public parks; limited public access to resources at grocery stores and pharmacies; closure of dine-in restaurants); (2) hospital patient protection guidelines (e.g., screening protocols for visitors seeking healthcare assessment at emergency department

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entrances; limited or no visitation access to admitted patients by friends or family members; suspension of elective surgeries; and (3) related healthcare patient protection guidelines (e.g., providing only emergency dental care; limited therapy services, such as physical, occupational, and speech therapy) (Coronavirus Aid, Relief, and Economic Security [CARES] Act, 2020). Safety policies have evolved over time with the changing nature of the virus and subsequent variants. For example, some of the March safety policies were removed when infection rates decreased but later reemerged with the rising spread of the Delta variant.

The COVID-19 pandemic has also resulted in changes to traditional provider–patient appointments (adults and children) and pediatric oncology consultations. For example, some appointments are being conducted virtually rather than in-person to minimize the risk of exposure for healthcare providers and patients (Bettini, 2020; Centers for Medicare and Medicaid Services [CMS], 2020; Humphreys et al., 2020). Additionally, the effect of the COVID-19 pandemic on the continuation of investigators’ currently approved research protocols (i.e., testing of essential vs. nonessential [behavioral] interventions) has become uncertain and the impact of modifying specific research protocol activities (e.g., virtual vs. face-to-face recruitment efforts and consenting procedures; delivery of behavioral interventions) has yet to be reported in the literature.

The National Institute of Health (NIH) research funding has acknowledged the potential difficulties that the pandemic has on research planning and protocols by extending designated deadlines for investigators, who (1) were planning to prepare and submit new grant applications; (2) were needing to prepare required NIH reports; and (3) are recipients of NIH funding and currently starting or implementing a research protocol (NIH, 2019). In response to COVID-19, the NIH (2019) also released supplementary grant opportunities for investigators to apply for in their necessary work to modify active research protocol activities to be delivered virtually (e.g., subjects’ direct entry of survey responses into an online HIPPA compliant database).

Because of COVID-19 social-distancing restrictions in healthcare settings in the United States, many currently approved face-to-face research protocols categorized as behavioral studies (e.g., qualitative interviews; nonpharmaceutical intervention testing) have been suspended temporarily. Some investigators have been directed to provide modified protocols to their local Internal Review Boards to abide by new recommended virtual-delivered protocol activity guidelines for research categorized as nonessential research protocols (e.g., communication, behavioral, and education-focused interventions). During the pandemic, an example of Institutional Review Board (IRB) guidelines to initiate or continue research involving human subjects at one Midwest university included the following criteria: (1) research that can be conducted without in-person intervention or interaction with research subjects; (2) research that explicitly improves or protects the lives of its participants by providing treatment or other medical care; (3) research that is directly connected to addressing the COVID-19 crisis; and (4) research that is limited to procedures which are performed in conjunction with a regularly scheduled visit. This Midwest University’s IRB guidelines were issued based on the guidelines released by the Office of Human Research Protections (OHRP, 2020).

Additionally, other unexpected research protocol delivery implications for investigators with active studies have occurred during the COVID-19 pandemic. One necessary implication for investigators included the need to make immediate modifications to their approved research grant budgets, such as (1) temporarily suspending research staff team members’ salaries and travel activities related to planned start-up training activities of team members in other states and future data-collection site visits and (2) seeking permission from funding agencies to extend projected timelines to recruit eligible participants and delivery of approved interventions. Another immediate implication for investigators has included developing new protocols to adhere to COVID-19 restrictions. Examples of modifying standard in-person research strategies by principle investigators to remote technology-supported approaches include implementing (1) remote training of research team members via a web-based teleconferencing tool (e.g., Zoom; Microsoft Teams); (2) electronic consenting procedures for eligible human subjects via web-based technology, such as the Research Electronic Data Capture (REDCap) platform; and (3) online entry of responses on study surveys by participants via a secure electronic data-collection platform, such as REDCap.

The use of social media sites (e.g., Facebook, Instagram, LinkedIn) to identify and recruit eligible human subjects to participate in research studies has been increasingly used by investigators (Gearhart, 2015). To date, there are no universal regulatory and ethical guidelines to help investigators avoid any ethical issues when using social media sites for recruitment efforts (Gelinas et al., 2017). One tenet is that investigators should evaluate planned recruitment efforts via social media according to three approaches; first, to identify an equivalent traditional (off-line) variant or equivalent to the social media technique (online) to be used; second, to consider appropriate ethical considerations (i.e., beneficence, respect for person, justice); and third, to strive to normalize social media recruitment techniques (e.g., to resemble traditional recruitment strategies) and evaluate potential differences in terms of ethical norms and considerations (Gelinas et al., 2017).

Hence, when researchers choose to modify traditional recruitment efforts (off-line) to a social media (online)
format during the pandemic or in future studies, they need to carefully consider factors that may predispose human subjects to any insufficient ethical safeguards. According to Gelinas et al. (2017), the use of social media as a recruitment strategy requires investigators to consider two ethical principles. One, the ethical principle of respect is focused on the individual’s sense of privacy (i.e., respect for persons and/or others; ability to effectively control one’s sense of privacy). The second ethical principle to consider is any risk of not adhering to beneficence (i.e., first do no harm; minimize possible harm). Investigator transparency is crucial and involves conveying accurate information to eligible subjects about study aims and protocol activities and providing honest responses to subjects’ questions.

Methods

This paper will present two cases and related ethical principles faced by nurse research investigators when needing to modify planned interventions and protocol activities for children with cancer during the COVID-19 pandemic. The cases will focus on virtual technology approaches and ethical considerations in pediatric oncology care. Specifically, Case 1 will describe remote participant recruitment via Facebook and consenting procedures. Case 2 will describe remotely delivered behavioral interventions. Each case and related ethical principles will be presented below.

Results

Case Presentations

Case 1: Remote Participant Recruitment via Facebook and Consenting Procedures. Some research studies requiring in-person patient approaches to enroll participants were paused during COVID-19. Suspending or closing approved studies can create an ethically tense environment where researchers cannot continue their obligations to offer individuals the choice of participating in research and contribute to the well-being of current and potential study participants. Some researchers pivoted to use remote participant recruitment strategies, rather than suspending or stopping research. The use of remote (or virtual) recruitment and consenting procedures can strengthen the Belmont framework for evaluating research using the following: ethical principles of beneficence, respect for others (or autonomy), and justice in several ways (HHS, 2020). First, the ethical principle of beneficence can be strengthened by allowing researchers to continue their work remotely to advance scientific discoveries that ultimately may contribute to the health and healthcare of all individuals. Second, the ethical principle of autonomy (respect for others) can be strengthened by not only allowing patients to choose whether or not to participate in a research study but also to consider participating remotely in a study in the convenience of their home or another preferred location. Also, the ethical principle of justice can be strengthened by remotely recruiting a larger pool of eligible subjects and that may represent a more diverse range of demographic and ethnicity characteristics of targeted participants.

Innovative research advertising procedures have been successfully used to remotely recruit pediatric palliative care populations (Akard et al., 2015a; Akard et al., 2016; Cho et al., 2021). Remote recruitment strategies can include advertisements through listservs, social media, or paid online services (e.g., Cloud Research). Facebook advertising may be particularly useful to recruit patients and family members as many individuals may be staying at home and spending increased hours on social media while practicing social distancing. Supplementary funding mechanisms specific to COVID-19 may be opportunities to fund such strategies.

Our recently completed R01 (Grant number R01NR015353, PI: Akard) is an example of a palliative care study that successfully used remote recruitment strategies prior to the pandemic (Akard et al., 2020; Cho et al., 2021). In this study, the research team conducted a remote randomized clinical trial to test the effects of a web-based legacy intervention for children with advanced cancer and their parents. The entire study was conducted with no in-person contact between research staff and study participants. Researchers used Facebook advertising to access parents of children aged 7–17 years with advanced cancer (e.g., relapsed or refractory).

Study advertisements were delivered over three years, targeting parents who (1) were aged 18 years or older; (2) were living in the United States; (3) were any sex (male or female); and (4) had interests related to pediatric oncology (e.g., expressed interest in or liked other Facebook pages related to childhood cancer). The Facebook advertisement contained an electronic REDCap link that included a brief study description and initial screening questions. Potentially eligible parents were then asked to complete basic demographic questions and provide their name and contact information. The study coordinator contacted interested individuals via phone or email within one week to describe the study and confirm eligibility.

The principle investigator developed and managed the advertisements with input from the study team throughout the first 2.5 years of enrollment. Due to slow recruitment toward the end of the study, a digital advertising agency managed the advertising campaign during the last six months of recruitment to achieve the target sample size. Additionally, the agency (1) developed and launched a recruitment video for Facebook; (2) developed/evaluated various Facebook advertising campaigns (e.g., likes, video views, link clicks); and (3) evaluated target
audiences (e.g., mothers/grandmothers over 30, journalists, faith groups, cancer groups, friends of page). We added 10 monthly postings to our study Facebook page to increase credibility and presence. Advertisements included a link to an electronic REDCap survey that included screening and demographic questions, followed by questions asking for parent contact information so the study coordinator could follow-up via phone to discuss the study further and facilitate the additional study activities.

The entire Facebook campaign generated 41,974,103 total impressions (number of advertisements shown), reached 8,292,290 people (maximum number of people in audience), and resulted in 363,407 unique clicks to our screening survey. The study successfully enrolled 300 total participants (150 children and 150 primary parent caregivers), reaching our target analysis sample of 100 child–parent dyads with less attrition than planned. Women (72%–81% of unique clicks) responded to advertisements more often than males (19%–27% of unique clicks). Additional analyses conducted by the professional advertising agency for ads delivered during the last six months of recruitment suggested that mother, grandmother, and cancer group audiences responded best, while journalist and faith group audiences responded worst (target audiences selected based on groups including, or with access to, potentially eligible participants). Link click campaigns yielded the majority ($n = 24,269$ unique clicks; 84%) of clicks to the screening survey, while driving potential participants to a website did not work well ($n = 4,098$ unique clicks; 14%). Lead campaigns ($n = 83$ unique clicks; <1%) guiding users to a website to enter contact information were costly and produced no enrollments. Full details about the Facebook advertising campaign and results are published elsewhere (Cho et al., 2021).

**Case 1 Ethical Considerations.** Investigators conducting research with human subjects are required to honor ethical principles described in the Belmont Report which serves as an ethical framework for research in the United States (U.S. Department of Health and Human Services [HHS], 2020; Sims, 2010). Adherence to three major ethical principles (beneficence, justice, and respect for persons) ensures the protection of the rights of research participants. Investigators that choose to use remote consenting procedures should include strategies to honor ethical principles for in-person informed consent procedures and avoid unintended harm to participants (i.e., personal embarrassment, loss of dignity, disclosure of information without permission) when using social media apps for remote informed consent procedures (Gelinas et al., 2017). In the context of remote social media recruitment and consenting procedures, three essential strategies include (1) using HIPPA compliant technology to ensure the protection of individuals’ personal information and related ethical principles (i.e., respect for person and beneficence); (2) providing information to participants on how to manage the privacy setting option on the selected social media (e.g., Facebook) to be used for research activities; and (3) being mindful to avoid sharing remotely collected information from participations with nonmembers of the study team (e.g., email communication). Additionally, while nurses at the bedside are obligated to enact these ethical principles when caring for all patients, researchers are obligated to do the same for study participants (Beauchamp & Childress, 2013; The Ethics Thinkers, 2017).

**Case 2: Remotely Delivered Behavioral Interventions.** Remotely delivered interventions can also serve as alternative strategies to continue palliative care research and practice, thus also promoting beneficence, autonomy, and justice during COVID-19 restrictions. Remote intervention delivery may be accomplished by the use of phone services, videoconferencing (e.g., Zoom, Skype, FaceTime), mobile app approaches, or web-based technologies. Such remote interventions have been used successfully in palliative care populations. For example, our legacy intervention for children with cancer was first developed as an in-person digital storytelling activity (Akard et al., 2015). The intervention was next expanded to a web-based technology format (Akard et al., 2020), requiring no in-person contact and increasing participant access. We have other ongoing research that has included in-person interventions (e.g., music therapy intervention, yoga) successfully delivered via videoconferencing platforms, despite initial thinking this was not possible. Our music therapy intervention study (Akard et al., 2021), in particular, has resulted in unanticipated gains, including decreased participant burden by not being required to come to the hospital/clinic for services and greater patient access. Researchers should be open-minded to consider remote intervention delivery methods if such approaches might allow for their research to continue during COVID-19.

**Case 2 Ethical Considerations.** Some study designs (e.g., descriptive, qualitative, nonrandomization) may lend themselves to more efficient virtual (remote) protocol activities (e.g., e-consenting, interviews, data collection). In comparison, although virtual recruitment methods and delivery of interventions may also be more efficient in meeting study goals, such methods also require investigators to assess potential ethical risks and plan strategies to reduce identified ethical concerns that may be in jeopardy of not being honored. The same three principles of beneficence, justice, and respect for others pertain to protocol adherence. Delivering interventions remotely is not
always appropriate, and even in the current environment, may not be feasible to accomplish research aims or fairly distribute resources in such challenging times. For example, investigators should implement strategies to uphold the ethical principles of beneficence and respect for others, such as ensuring only IRB-approved team members have access (e.g., password-protected) to web-based interventions to review recordings of the delivered intervention.

Recruiting participants via social media advertisements create questions for investigators about potential inequities related to the ethical principle of “justice” not being honored (e.g., recruitment should be fair and equitable in terms of subject selection) (Gyure et al., 2014). For example, some of the eligible pool of participants may not be informed about a study related to their lower socioeconomic hardships (e.g., not having a home computer or internet access or a cell phone) or their health literacy status in the use of social media apps. Hence, investigators should plan to include diverse community recruitment efforts to distribute study information to strengthen fairness in recruitment efforts.

In a second study involving human–animal interactions prior to COVID-19, children newly diagnosed with cancer and their parents were randomly assigned to a group that interacted with a registered therapy dog for 15 min prior to visits in the pediatric hematology clinic and a group receiving usual care (McCullough et al., 2018). We learned that children spent the majority of their time holding, petting, and brushing the dog, and those human–animal interactions were helpful in reducing parental anxiety. The tactile experience was an essential aspect of that study and is difficult, if not impossible to replicate remotely. In an extension of that study, we are now examining the impact of human–animal interactions on children with advanced cancer and their families (Grant number R21HD097757, PI: Gilmer). Unfortunately, the study was suspended temporarily when nonessential hospital personnel were restricted to the hospital in response to COVID-19, particularly with immunocompromised vulnerable children. In deciding not to transition to remote delivery of the human–animal interactions intervention in this study, which could have been accomplished to some extent via a medium such as Zoom or Skype, our team considered several advantages and disadvantages (Table 1). We determined that we could not successfully complete the projected specific aims which required biomarkers of vital signs, salivary cortisol, and serum epinephrine/nor-epinephrine to explore the impact of human–animal interactions on children with advanced cancer and their families. However, we have now planned a protocol that will be conducted remotely in the future to advance the science.

| Table 1. Advantages and Disadvantages of Transitioning Human–Animal Interactions to Remote Delivery |
|---------------------------------------------------------------|---------------------------------------------------------------|
| **Advantages**                                               | **Disadvantages**                                             |
| Research could continue without a sustained interruption     | Unplanned time-consuming tasks to transition to remote interventions (e.g., regulatory approvals, training of new staff) |
| Local and distance students not allowed in the hospital could be involved in remote study aspects | Disruptions to already stressed hospital staff with added use of technology for remote interventions |
| Continuation of discovery through research                    | Specific aims of previously designed and funded study could not be addressed* |
| Potential benefits to families (e.g., convenience of their own home and personal schedule) | Evidence of the benefits of remote HAI interventions are unknown |
| Opportunities to explore new and different study aims         | Unable to compare impact on children newly diagnosed with cancer to children with advanced cancer |

Note: *Unequivocal rationale to pause study.
in response to COVID-19. Principle investigators and their research teams should pause to consider research protocol modifications for remote research recruitment, consenting, and delivery strategies as potential alternative options versus being quick to assume it is not possible. However, patient and researcher safety and well-being must remain the top priority. Our ultimate goal remains to enhance life and decrease suffering for individuals with serious illnesses and their families, and that goal currently includes individuals across the globe impacted by the COVID-19 pandemic.

Now more than ever, nurses and clinicians are in ideal positions to collaborate with researchers in a combined effort to maintain healthcare ethical principles outlined in the Belmont Report (beneficence, justice, and respect for others) during the COVID-19 landscape and beyond. Scientists should be keenly aware of national and institutional policies (Yip et al., 2016) surrounding safe research practices, but they often are not at the bedside or in the clinical environment to understand the stress level of our patients and families. Especially for vulnerable children with cancer and their family members dealing with additional stress related to the pandemic, the expertise of pediatric oncology nurses and clinicians is critical to help inform how researchers can best maintain patient well-being, do no harm, respect patient and family choices, and use resources fairly. Scientists and clinicians should collaborate to determine whether it is ethically appropriate to conduct research in regard to clinician, staff, and patient stress and burden. For example, one of our studies in the neonatal intensive care unit could have continued in-person per policies, but remained 100% remote based on provider recommendations due to parent stress related to COVID-19.

**Future Research**

Conducting all research activities to honor recognized ethical principles related to science is a crucial part of human subjects’ research. Due to the need for many investigators to modify standard in-person research activities to remote (or virtual) delivery, we recommend investigators evaluate and report the potential impact on all aspects of future remote delivered protocol activities, such as (1) time to recruit subjects, (2) retention of subjects, satisfaction with virtual interactions with the research team, and (3) potential impact on the outcomes of randomized clinical trial outcomes. We also recommend investigators consider recruitment strategies and involvement in intervention activities for subjects without internet access, with literacy limitations, and/or other physical limitations that may make remote study participation either impossible or more challenging. We encourage investigators to focus special attention on practical considerations of research recruitment and participation etiquette because it can impact potential demographics of recruited participants, research results, subjects’ satisfaction with study participation, and relationships with research teams.

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