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FOREWORD

February 2020 our lives changed dramatically. The COVID-19 pandemic wreaked havoc with our personal worlds. Over the ensuing years, false starts and stops, occasioned by newly emerging variants of the SARS virus, tempered our hopes for its abatement and led to lingering uncertainties. The same proved to be true of our professional work, here research on the health of American Indian and Alaska Native peoples. Ongoing studies initially ground to a halt. Partner communities struggled to ensure their survival; research became seen as less significant except as it shed light on COVID-19 risk, exposure, mitigation, testing, and eventually vaccine effectiveness. Prospective study participants declined recruitment for fear of exposure to the virus; programs and communities closed their doors to protect members. Universities suspended research for similar reasons, to protect participants and staff. We agonized how to retain critical staff and remain ready to restart this work. Sponsors debated approaches to ameliorating the consequences for the studies they supported; budgetary concerns threatened entire programs of research. The science and its implementation were thrown into turmoil as investigators wrestled with if they could continue their studies, what compromises would be required, and how to proceed, if possible.

But, just as the general response to the pandemic reminded us of the strengths in our communities, the resilience of our traditions, and the innovativeness of humankind, so too the creativity of investigators in collaboration with Native communities shone through in answering the challenges to their research. Deeply embedded in these circumstances, I came to appreciate how thoughtfully and nimbly colleagues and their partners pivoted to address the often daunting problems posed by the pandemic. Thus, when Drs. Elliot and Around Him approached us to assemble a special issue of the Journal that speaks to this task, I could not have been more pleased. The authors and they offer timely insights into the problems faced, the solutions that surfaced, and the strategies developed and carried out to advance their work. The lessons learned are instructive and testify to the possibilities when scientists and community join in common cause. Thank you!

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INTRODUCTION TO THE SPECIAL ISSUE

IMPACT OF THE COVID-19 PANDEMIC ON RESEARCH WITH AMERICAN INDIAN AND ALASKA NATIVE POPULATIONS

Deana Around Him, DrPH, and Amy J. Elliott, PhD

Abstract: The COVID-19 pandemic forced health research programs across the world to close or pause, threatening the progress of basic science, clinical and social science research, and research careers. Impacts of the pandemic on research occurring with American Indian and Alaska Native (AI/AN) peoples, which is often conducted using community-based and -engaged approaches, offer an opportunity to understand how community-research partnerships shaped decision-making and facilitated adaptations to study design, recruitment, data collection, program implementation, and analyses. The COVID-19 pandemic disproportionately impacted AI/AN peoples, exacerbating many of the health and social inequities already being examined in community-based and -engaged research projects. The nine articles in this special issue share insights from research focused on a variety of topics from food security to diabetes prevention and parenting skills training. In the face of the pandemic, the research teams drew on experience and skills garnered by engaging the perspectives and wisdom of community partners and rooted in the principles of community-based participatory research to respond to shifting research priorities, new processes for remote consent and data collection, and increased needs for clear communication, connection, and support. Lessons from these research teams challenge us to think about how we can carry forward beneficial adaptations to best serve community needs, especially as the pandemic continues and the potential for similar global crises increases.

Health research faced an unprecedented challenge during the COVID-19 pandemic, with travel restrictions and strict lockdown measures forcing academic institutions to close or pause research programs around the world. All types of ongoing research were interrupted during this

time and onset of new studies delayed. Numerous articles have been published on the effects of the pandemic on basic science, clinical research, and the impact on researchers (e.g., constraints on publication opportunities, funding, networking, hiring) (Sohrabi et al., 2021; Boughey et al., 2021; Fleming et al., 2020; Weiner et al., 2020), but far less attention has been paid to the effects on community-based research. This special issue of *American Indian and Alaska Native Mental Health Research* focuses on the impact of the COVID-19 pandemic on American Indian and Alaska Native (AI/AN) health research, which oftentimes draws on community-based and community-engaged research approaches. Research teams were encouraged to reflect on changes to study design, data collection, participant engagement, and analytic strategies prompted by the pandemic to share how adaptations were made and explain lessons learned.

The COVID-19 pandemic served to highlight and exacerbate health disparities, with AI/AN populations suffering a disproportionate burden of COVID-19 illness, death, and economic ramifications (Arrazola et al., 2020). The Centers for Disease Control and Prevention (CDC) reported an overall COVID-19 incidence that was 3.5 times higher for AI/AN persons (Hatcher et al., 2020). The pandemic layered upon existing economic struggles, health care access challenges, and health inequities, challenging even the most resilient.

It is now common practice that community-based approaches, including community-based participatory research (CBPR), within AI/AN health research is most successful when driven by the community and true collaborations are apparent at all stages (Holkup et al., 2004). This shift in thinking has been driven by Tribal Nations insisting on changes to how research was historically conducted to help prevent misuse and misrepresentation, and to ensure the research is relevant to the needs of AI/AN peoples. The National Institutes of Health (NIH) and other federal entities have involved Tribes to a greater degree in recent years through various initiatives (e.g., Environmental influences on Child Health Outcomes [ECHO] Program), and there are now specific funding mechanisms to support AI/AN health research (e.g., Native American Research Centers for Health [NARCH]).

Researchers that use a CBPR, or related, framework often find these studies have extended timelines to adequately engage key partners and ensure community participation at all stages of the research process (Holkup et al., 2004; Christopher et al., 2011). Typically, multiple regulatory bodies are involved, and may even require individual review of study protocols (Around Him et al., 2019). It also takes time to establish trust and common understandings. It can take a research team years to develop the necessary relationships and earn trust and collaboration from Tribal

Nations and community members prior to the initiation of a project. The infrastructure to support this work is often complex, with multiple sites involved in studies and sometimes great distances separating data collection sites, study personnel, and researchers.

This special issue was conceived by looking at the ramification of COVID-19 on our own AI/AN research programs and speculating how others approached and dealt with this challenging time. Oftentimes journals are limited in space, and publications of study results may not allow adequate room to describe the changes to research design and data collection that occurred in response to the pandemic. Questions like, "Did the pandemic serve to weaken study designs? Were there cases where study designs were, in fact, strengthened as a result? What was the impact and role of the community partnerships?" came to mind. We wanted to give researchers an opportunity to tell their stories of this unique time in history and share lessons that can be carried forward to continue shaping a research environment that benefits AI/AN peoples.

The articles selected for inclusion in this special issue reflect a wide range of study designs, populations involved, and topics of interest. The research teams come from vastly different geographical regions and have varying compositions of institutions involved, including Tribal entities, academic centers, health systems, and community agencies. Despite this diversity and the unique circumstances in each project, clear themes emerged. These overarching themes included shifting of research priorities, pivoting to remote consenting and data collection, and improved communication, connection, and support.

The spring of 2020 required all of us to dramatically shift our day-to-day activities as major areas of society were shut down and travel became severely restricted. Many studies that were in the early stages of their work pivoted their research priorities to better serve their partners during this extremely trying and stressful time. This shifting of research priorities was particularly apparent in the Maudrie et al. (2022) project on food security with the Baltimore Native community. The investigators kept with the original topic of study, as food security issues have been exacerbated with the pandemic, but they shifted their research design and purpose to understand how the pandemic impacted food security to help inform community efforts. Rink et al. (2022) were also able to expand the purpose of their study to inform how public health disasters impact sexual and reproductive health among AI/AN youth. These are just a couple of the examples of how the research teams were able to meet current needs and provide timely information during this unprecedented time.

Others also adapted their research programs but focused on resiliency and the role of culture in responding to the pandemic. Kelley et al. (2022) were in the process of implementing a program with the goal of increasing cultural resilience and sustaining cultural participation over time with four Tribes in the Northern Plains. The pandemic required a shift to remote modalities for mentoring sessions and trainings, but the researchers did find the program could be successfully delivered in a virtual format, although not as optimal as in-person sessions. Patel et al. (2022) also shifted rapidly to a virtual format in their project on sexual reproductive health for Native youth. They found benefits of the virtual format in flexibility for scheduling and coordination and even cited the virtual format was preferred by some participants. However, concerns with the virtual format included struggles with engaging some youth.

Other projects were well into study implementation when the pandemic hit, requiring shifting of research protocols and data collections methods mid-stream. Sinclair et al. (2022) were in their third year of a study on diabetes prevention for AI/AN men when they were forced to pivot to remote enrollment and implementation processes. While they found many advantages to the remote data collection strategies, challenges were found for participants juggling multiple personal and work demands on their time, particularly for those considered essential employees. The editorial written by Hunter et al. (2022) summarizes many of these themes in their descriptions of the challenges in adapting study protocols to remote implementation and the challenges of maintaining CBPR best practices.

Sahota et al. (2022) also shifted delivery of their Positive Indian Parenting curriculum to a virtual format but delivered boxes of supplies for each family so they could retain the hands-on and kinesthetic activities of the program. They used more videos and provided tablets to families to ensure access to the online environment. This pilot study demonstrated the importance of the foundational relationships established with both the collaborating entities, as well as the funders, in being able to make the necessary adaptations to the program during an evaluation study. Bec et al. (2022) also reported on the importance of these community relationships in their adaptation of an educational curriculum on suicide prevention and how shifting to a remote environment impacted the delivery and types of individuals able to participate. Similar themes of the importance of strong community connections are emphasized in Steinberg et al.'s (2022) manuscript on Tribal Turning Point, a lifestyle intervention to reduce risk of type 2 diabetes in AI/AN youth.

As you read through these diverse studies and experiences, we hope they will challenge you to think about lessons learned from conducting research with AI/AN populations during the COVID-

19 pandemic and how we can carry forward beneficial adaptations to best serve community needs. Each research team represented in this issue faced significant challenges to established programs, while balancing the unprecedented personal and community demands of the pandemic. While it is unknown how prominent remote enrollment and data collection will be in the future, it is clear the pandemic will have lasting effects on how community-based research is conducted. Which study aspects are better suited for in-person delivery? Which are better suited for remote delivery? Do certain populations respond better to one format over another? How can we ensure adequate access to online environments for all? These questions, amongst many others, are likely to become topics of future conversations that should serve to enhance AI/AN health research going forward. Community-based and -engaged research is in the unique position to rapidly respond to needs and increase, even more, the relevance of this important work to the health research enterprise.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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IMPACTS OF COVID-19 ON A FOOD SECURITY STUDY WITH THE BALTIMORE NATIVE COMMUNITY

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Abstract: Urban American Indian/Alaska Native peoples experience disproportionate levels of food insecurity when compared to the general US population. Through a collaborative research partnership between Native American Lifelines of Baltimore, an Urban Indian Health Program, and a Johns Hopkins Bloomberg School of Public Health student-led research team, food security was identified as a priority issue. A sequential explanatory mixed methods study was planned to explore food security and food sovereignty in the Baltimore Native community prior to the COVID-19 pandemic. Due to the local impact of COVID-19, a community-based participatory research approach guided the community-academic team to revise the original study and increase understanding of how the pandemic impacted food security in the community. This article highlights the lessons learned and strengths of using a community-based participatory approach to guide adaptations made due to COVID-19 to this research study. By utilizing a co-learning approach and emphasizing flexibility, we were able to collaboratively collect meaningful data to drive future community solutions to food insecurity while building an evidence base for policy changes to better support urban Native food security.

INTRODUCTION

Since the arrival of settlers in North America, American Indian and Alaska Native (AI/AN) peoples have experienced disproportionate health and social inequities due to colonialism and a legacy of oppression (Brave Heart & DeBruyn, 1998). These trends continue today with AI/ANs facing high rates of non-communicable diseases, including type 2 diabetes, cardiovascular disease, and mental health disorders, as well as infectious diseases such as HIV, tuberculous, and influenza (Indian Health Service, 2021; Gounder et al., 2014; Schmit et al., 2017). Infectious diseases have

historically and more recently impacted AI/AN communities at higher rates compared to the general population. For example, the AI/AN mortality rate due to H1N1 flu was four times higher than that of the general population (Centers for Disease Control and Prevention [CDC], 2009). Unfortunately, this trend continued with the onset of the COVID-19 pandemic, as AI/ANs were 3.5 times more likely to be diagnosed with COVID-19 and nearly twice as likely to die from COVID-19 than non-Hispanic Whites (Arrazola et al., 2020). COVID-19 has exacerbated ongoing social and health inequities (e.g., food insecurity, lack of electricity and running water) stemming from colonization and structural racism among AI/ANs (Burki, 2021). However, tribal and urban AI/AN communities have demonstrated immense strength and fellowship while following community values to take care of one another (Arrazola et al., 2020; Howard-Bobiwash et al., 2021; Aulandez et al., 2021; Manson & Buchwald, 2021).

The COVID-19 pandemic brought a new set of health and economic challenges for all people in the United States but especially to the most vulnerable members of communities. As society worked together to control the spread of COVID-19, millions of people lost their jobs or significant portions of their incomes, resulting in economic instability (Bennen, 2020). Increased economic concerns combined with sudden food shortages in the United States resulted in unpredictable food access and unprecedented food insecurity prevalence (Schanzenbach & Pitts, 2020). Food security is defined as a "household economic and social condition of limited or uncertain access to adequate foods" (Coleman-Jensen et al., 2014, pg. 2). Food security is an important determinant of physical health as well as mental health. Prior research shows that food insecurity is associated with increased risk of depression (Leung et al., 2015) and for those living with diabetes increased diabetes distress and decreased medication adherence (Silverman et al., 2015).

For many communities where food security was an existing concern, access to food became an imminent threat and priority during the pandemic. People of color are more likely to experience food insecurity and to live with obesity in part due to high rates of poverty, unemployment, and other conditions resulting from systemic racism (Bell et al., 2019; Holt-Giménez, 2018). Pre-pandemic estimates of food insecurity in AI/AN communities ranged from 25% to 61% (Coleman-Jensen et al, 2019; Bauer et al., 2012; Tomayko et al., 2017; Jernigan et al., 2017). In the five years prior to the onset of COVID-19, national food insecurity prevalence was consistent at around 11-12% (Bauer, 2020). By March and April 2020, the national prevalence jumped to 38%, more than tripling food insecurity prevalence (Fitzpatrick et al., 2020; Bauer, 2020). While estimates of food

security for AI/AN peoples vary greatly by region, several studies have found that urban AI/AN peoples are more likely to be food insecure than their rural AI/AN counterparts (Jernigan et al., 2017; Tomayko et al., 2017). Several explanations have been offered for this phenomenon including that urban AI/ANs are excluded from participation in AI/AN-specific food support programs like the Food Distribution Program on Indian Reservations (FDPIR; Jernigan et al., 2017). In some cases, COVID-19-specific funding restrictions prevented Urban Indian Health Programs (UIHPs) from purchasing and distributing foods to their community members (Maudrie et al., 2021). To date, there are no publicly available data for urban AI/AN food security rates during the COVID-19 pandemic. Further, to our knowledge, this is the first mixed methods study regarding food security during the COVID-19 pandemic in an urban Native community.

Food and food security are vital to AI/ANs' physical, mental, emotional, and spiritual health and well-being. For example, certain local foods are vital for tribal gatherings and ceremonies that promote community health, connectedness, and cultural traditions (Vernon, 2015; Loring & Gerlach, 2009; Cidro et al, 2015). Many AI/AN communities are working to reclaim food sovereignty – often defined as the "rights of peoples to healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and the right to define their own food and agriculture systems" (Forum for Food Sovereignty, 2007, p. 9). Through food sovereignty movements, communities produce traditional foods and locally based solutions while working to mitigate the effects of health inequities. The food sovereignty movement gained momentum during the COVID-19 pandemic as communities worked to support food security of their most vulnerable members through community feeding initiatives and "resilience gardens" (Hoover, 2020). However, there is still a developing understanding of how food sovereignty can be practiced by AI/AN peoples living in urban settings, who may have limited access to growing space and even more limited resources than their rural relatives (Ciro et al., 2015). Further, the COVID-19 pandemic presents new challenges to food security and food sovereignty for urban Native communities, and these challenges have caused ripple effects on the holistic health and well-being of these communities.

In 2019, the Baltimore AI/AN community expressed that food security was a priority to address in collaborative research. The Johns Hopkins Bloomberg School of Public Health research team, led by a student researcher (author TM), began to work on this priority. However, the COVID-19 pandemic illuminated the imminent needs of the community. While the pandemic created barriers to planned research methods, there were opportunities to adjust methods in

innovative ways. Furthermore, in line with Indigenous values and community-based participatory research (CBPR), the community-academic partnership was strengthened to provide resources during this public health crisis and care for the community. The purpose of this paper is to: 1) Describe the current community-academic partnership; 2) Describe the original planned research study and revised methods due to the COVID-19 pandemic; and 3) Provide lessons learned for current and future research.

METHODS

Community-Academic Research Partnership

Baltimore Native Community and Community Research Partner

Baltimore City is located on the ancestral and contemporary homelands of the Piscataway and Susquehannock peoples (Maryland State Archives, n.d.). Today the Baltimore Native community is composed of over 25,000 Native peoples representing many tribes from across the United States and with many individual community members belonging to more than one tribe (Urban Indian Health Institute, 2018). Native American Lifelines (NAL) is a Title V Urban Indian Health Program (UIHP) that serves AI/AN tribal members living in Baltimore City and the surrounding area. NAL consists of eight core staff members who represent six tribes and several non-Native allies. NAL is designated as an outreach and referral program by the Indian Health Service, which means they provide behavioral health services, health promotion and disease prevention activities, dental care, case management services, purchase of care, and cultural programming (NAL, n.d.).

The NAL Executive Director (KHL) and Clinical Director/Counselor (DR) were closely involved with all aspects of the research process and co-authored this paper. KHL is a lifelong resident of Baltimore and descendent of Shawnee and Assiniboine peoples. She is an applied medical anthropologist with 15 years of experience working in urban Indian health. DR is a Blackfeet descendent and was born and raised in Baltimore. DR has a Master of Science in Clinical Psychology and is a Licensed Clinical Professional Counselor.

Academic Research Team

The lead author TM is a citizen of the Sault Ste Marie Tribe of Chippewa Indians and a PhD student at the Johns Hopkins Bloomberg School of Public Health (JHBSPH). TM has been an urban Native person her whole life and spent much of her professional career working with

UIHPs before starting graduate school. Shortly after moving to Baltimore in fall 2019, TM became involved with the Baltimore Native community through NAL. Author CJN is an early career researcher with professional and lived experience with food insecurity. CJN provided consultation and feedback on the interpretation and implications of this project within the larger literature. VBJ is a Choctaw citizen and public health researcher and interventionist specializing in food systems and health promotion in Indigenous communities. Author JG was TM's advisor in the Master of Science in Public Health program at JHBSPH and is a non-Native researcher who has over 20 years of experience partnering with Native communities. Author VMO is a citizen of the Cherokee Nation and a Seminole Nation descendant and lived most of her life as an urban Native community member. She has ten years of community-engaged research experience with tribal and urban Native communities focused on mental health promotion and suicide prevention. She also serves as TM's PhD advisor.

Community-Identified Research Priority

Through formal and informal conversations between NAL staff, community members, and the student researcher, food security was quickly identified as an area of concern. Following these discussions, TM identified a small student specific funding source through the JHBSPH Urban Health Institute to fund Baltimore health research. In October 2019, the student researcher worked with NAL to develop a research plan to better understand how food insecurity impacts the Baltimore Native community to generate community-based solutions. Through this collaboration, NAL shared that they were interested in using grant funding they had recently received (outside of this project) to support community food sovereignty but were unsure of what food sovereignty would mean or look like for their community. In partnership with NAL, a rapid community needs assessment identified food security as a top concern for community members during the early stages of COVID-19 (Maudrie et al., 2021).

The original proposed project aims (prior to COVID-19 pandemic) were to: 1) Build a collaborative research partnership between NAL and JHBSPH; 2) Conduct a sequential explanatory mixed methods study to understand food security in the Baltimore Native community; and 3) Identify acceptable and feasible community-generated strategies to improve nutrition and food security for the Baltimore Native community. The research was designed as an explanatory mixed method study (Ivankova et al., 2006) to be conducted in two phases – an initial quantitative data collection and analysis phase, assessing food security and basic demographics, followed by a second phase consisting of qualitative data collection and analyses informed by the quantitative

findings to explore the varying experiences of individuals with food security challenges and elicit community-driven solutions to nutrition and food security.

Phase 1: Original Plan (quantitative)

Participants

We aimed to include 100 participants who a) self-identify as AI or AN, b) are 18 years or older, and c) live or work in the Baltimore metropolitan area.

Measures

Food security would be measured using the USDA 10-item Adult Food Security Survey Module (USDA & Economic Research Service, 2012), which categorizes respondents into four ranges of food security: high, marginal, low, and very low. A demographics survey would include age, gender, income, tribal affiliation, race and ethnicity, household size, and other basic health indicators related to nutrition and food security (e.g., type 2 diabetes).

Procedure

Phase 1 recruitment was expected to be a hybrid of in person and online (see Table 1 for Phase 1 procedure). Measures would be completed online via REDcap, a secure online survey tool (Harris et al., 2009). Participant compensation would include a $10 gift card. Phase 1 data was intended to be analyzed to explore associations between demographics and food security to inform Phase 2 qualitative research, following explanatory mixed methods research (Ivankova et al., 2006).

Phase 2: Original Research Plan (qualitative)

Participants

The second qualitative phase intended to conduct in-depth interviews (IDIs) with a subset of participants ($n = 4$) from each of the four categories of food security identified in Phase 1.

Qualitative Data Collection Instrument

IDIs planned to ask about experiences with food insecurity, perceptions of food sovereignty, and perceived local food access solutions.

Procedure

Recruitment would occur via telephone or email to schedule in-person interviews (see Table 1). Compensation would include a $20 gift card and small gift of traditional foods.

Dissemination Plans

Following CBPR principles, the student researcher carefully planned dissemination to occur during all phases of the original study. Study findings were to be disseminated through a variety of methods to ensure access to information for all interested community members, including informational flyers and handouts, social media postings, and in-person community debriefing sessions following both phases of data collection and analyses, concluding with a community feast. Additionally, we intended to create community reports that would be accessible (i.e., free of academic and technical jargon) to community members and for NAL staff to use in future grant applications and to inform food security and nutrition programming. To respect the intellectual and cultural rights of the Baltimore Native community, we made plans to consult with and co-write with our NAL community partners and other interested community stakeholders prior to publishing or presenting research findings. We planned on publishing several papers including interested community stakeholders and NAL staff as co-authors.

Approvals

The student researcher and NAL co-created a Memorandum of Agreement to describe the responsibilities of each party during this study. We intended to submit the Johns Hopkins University Institutional Review Board (IRB) application after thorough collaboration with NAL in early spring of 2020; however, this was interrupted due to COVID-19.

RESULTS
Resulting Study Adjusting for COVID-19 Challenges

Due to COVID-19, JHBSPH students and faculty were abruptly transitioned to working remotely, and nearly all in-person research was halted at the university level. Further, NAL was unable to hold community gatherings or meetings and shifted to contactless methods of community outreach whenever possible. NAL had an established telehealth program prior to the pandemic and were able to expand this program rapidly to meet community needs. Further, NAL shifted to a hybrid model of onsite and remote work for employees and a near complete pivot to telehealth and virtual gatherings and activities for community members.

The IRB application process was planned to begin in March 2020, but due to the abrupt halt on in-person research and rapidly shifting community needs, the project was paused for several months. During this time, NAL conducted rapid community needs assessments via phone interviews and quickly adjusted their efforts to attempt to meet community needs (Maudrie et al.,

2021). During the COVID-19 pandemic, it was urgent that our academic research team exhibit flexibility, a key component of CBPR (Israel et al., 1998). To assist the community with time sensitive priorities, we temporarily paused our research plans and shifted efforts to supporting NAL's COVID-19 initiatives. These types of shifts are common in CBPR and in line with CBPR principles of flexibility, building upon strengths and resources of the community, and fostering a collaborative partnership at all research phases (Israel et al., 1998). The student researcher shifted priorities to assist NAL in addressing urgent community needs by advising on the food-related portions of COVID-19 relief efforts, as well as by providing nutrition education through several community webinars and virtual events. Additionally, TM and VMO were able to serve the community by volunteering at NAL run COVID-19 vaccination clinics. VMO and TM also worked on several other COVID-19 resources that included NAL staff in development or were provided to NAL to distribute. For example, NAL staff helped with the cultural adaptation and implementation of a Psychological First Aid online training and resource guide for COVID-19 frontline workers in AI/AN communities (Johns Hopkins Center for American Indian Health, n.d.-a); this online training is currently being evaluated. Further, VMO and TM were part of a team at Johns Hopkins Center for American Indian Health (housed in JHBSPH) to culturally adapt and disseminate Indigenous children's storybooks to help families cope with the pandemic (Johns Hopkins Center for American Indian Health, n.d.-b; Johns Hopkins Center for American Indian Health-c; O'Keefe et al., 2021). NAL staff were provided with copies of these storybooks to distribute to Native families in Baltimore with children under 10 years of age. Further, our team promoted a collaborative partnership at all phases of the research through regular meetings with NAL and incorporating feedback and guidance from NAL in a timely manner. As described, this community-academic partnership demonstrated use of CBPR principles during the COVID-19 pandemic. These CBPR principles included building upon strengths and resources of the community, exhibiting flexibility in partnerships, and fostering a collaborative partnership at all phases of research. The types of research plan adaptations and community service described in this paper are not unusual within CBPR; however, the COVID-19 pandemic presented unique challenges that were overcome using a CBPR approach.

In August through October 2020, the student researcher met virtually with NAL staff to discuss how to adapt the original research plan for the Baltimore Native Food Security Study to fit COVID-19 precautions. Several changes were made to the original research plan to support equitable participation from vulnerable groups within the Baltimore AI/AN community and to

ensure participant safety considering COVID-19. These changes are in line with CBPR principles of collaborative partnership at all phases of research, as well as using an iterative and cyclical approach to research (Israel et al., 1998). Overall, these changes included adjustments to study design, data collection, and study timeline. After collaborative meetings between TM and NAL, the IRB application was submitted in September 2020. After several rounds of revisions and amendments, IRB approval was received in January 2021 (JHBSPH IRB #: 13176). The differences between the planned research study prior to COVID-19 and the final research study with amended methods/procedure due to COVID-19 are described in Table 1. Below we describe the revised research study and actual recruitment numbers for each phase of the study.

Table 1
Comparison of planned study and the study resulting from COVID-19 changes

	Planned Study	Revised Study
Phase 1		
Participants	100 AI/AN adults living in the Baltimore metro area	250 AI/AN adults living in the Baltimore metro area
Measures	• USDA Food Security Module • Demographics	• USDA Food Security Module • Demographics • Food Stress questions • COVID-19 Challenges questions
Recruitment	• In person: community events (e.g., powwows and community programming) • Telephone • Online: Social media postings	• Telephone • Online: Social media postings
Data collection	• In person: Participants could opt to complete the survey in person on a REDcap application on a study laptop • Online: Participants could complete the survey via a link to the REDcap application	• Online: Participants could complete the survey via a link to the REDcap application • Telephone: If recruited by phone call they could complete the survey verbally or had the option of having the survey emailed to them
Phase 2		
Participants	Four participants from each of the four categories of food security (e.g., high, marginal, low, very low) from Phase 1 study sample (total=16 interviews)	Recruited participants from each of the four categories of food security (e.g., high, marginal, low, very low) from Phase 1 study sample, total actual sample was 11 participants
Measures	IDI guide topics: • Food security	IDI guide topics: • Food security • Food sovereignty • Solutions to food insecurity
Recruitment	Phase 1 participants recruited via telephone	Phase 1 participants recruited via telephone and email
Data collection	Planned to be in person at NAL office	All interviews were conducted via Zoom (audio or audio + video format)

Phase 1: Revised Plan (quantitative)

Participants

We had 250 AI/AN adults living in the Baltimore metro area participate Phase 1 of the research. We were able to increase our planned sample to improve statistical power.

Measures

We included the USDA Food Security Survey Module (USDA Economic Research Service, 2012) and demographics surveys as originally planned. Based upon our collaborative meetings with NAL, we added four food stress questions. These food stress questions are an expansion of the concept of food security and explore other food-related stresses, including having time to purchase and prepare foods, the availability of kinds of wanted foods, being on a special diet, transportation to food sources, and not having enough money for food. These questions originate from the Gathering for Health study (Elm & Handeland, 2020). We also added two questions related to COVID-19 challenges based on recommendations from several virtual meetings with the NAL staff. COVID-19 challenges questions included: 1) During the early stages of the pandemic there was a general recommendation to purchase two weeks' worth of food at a time. Were you able to comply with recommendations to purchase two weeks' worth of food throughout the pandemic? (*Yes* or *No*); and 2) Did you encounter any of the following changes due to the COVID-19 pandemic? Check all that apply (*Inability to feed yourself or your family*; *Limited availability of household items*; *Reduced access to healthcare*; *Reduced access to medications*; *Inability to pay bills; Inability to pay rent or mortgages; Difficulties working due to lack of childcare; Inability to work due to illness other than COVID-19; Inability to work due to yourself or a family member contracting COVID-19; None of the above*).

Procedure

Due to COVID-19 prevention strategies (e.g., physical distancing), our recruitment strategy was altered to be entirely virtual. Recruitment strategies were revised to include only virtual options (e.g., social media postings on the NAL Facebook and Instagram) and via telephone. NAL reviewed and approved all social media postings and created and shared a list of eligible individuals meeting inclusion criteria from their community contact list. The student researcher called eligible individuals and invited them to take the survey verbally via phone or to complete the survey via a link emailed to them. This strategy was designed to be more inclusive of those who may not have internet access by providing an option to complete the survey by phone.

We completed the Phase 1 quantitative survey within 6 weeks. All participants were provided with a $10 gift card.

Phase 2: Revised Plan (qualitative)

Participants

A total of 11 participants were recruited from Phase 1 to participate in Phase 2 in-depth interviews (IDIs), a qualitative research method used to gather comprehensive information from participants.

Measures

In line with the explanatory mixed methods research design, our original research plan stated that after Phase 1 data collection was completed that all data would be analyzed to inform the content and sampling frame for Phase 2. Unfortunately, only the questions related to food security were able to be fully analyzed before beginning recruitment for Phase 2 due to time constraints related to the academic school year and grant requirements. While this did not necessarily change the proposed sampling frame for Phase 2, it is possible that if all data had been fully analyzed, IDI guides would have been revised to include new questions or to probe deeper on COVID-19-related struggles. Throughout Phase 1 data collection, IDI guides were developed in close partnership with NAL, and several questions were added and modified. Of particular interest to NAL were food issues beyond food security, including disordered eating and nutrition knowledge. These interests emerged as our community partners noticed several examples of disordered eating behaviors (both restrictive and binge eating) and several instances where community members demonstrated a lack of understanding of basic nutrition. NAL was particularly interested in learning about what forms of nutrition education are desirable to community members, as well as what community members envision as steps towards food sovereignty for the Baltimore community. The input and edits to IDI guides from NAL were key to ensuring that interviews were productive and provided concrete suggestions for improving existing and future programming and partnerships. This IDI guide is available in Appendix A.

Procedure

Recruitment for Phase 2 interviews mirrored our pre-COVID-19 research plan. We recruited participants from the Phase 1 sample with the intention of recruiting four individuals from each of the four levels of food security. We faced some difficulties reaching participants as

many phone numbers provided by Phase 1 participants were invalid or disconnected. When we were able to reach eligible participants and they agreed to participate in an interview, they were offered the option of completing the interview over the phone or Zoom at that time or to schedule the interview for a future time. The majority of participants preferred to complete the interview at the time of their recruitment call and several preferred to use the phone in option rather than the video call function of Zoom. TM conducted all IDIs and wrote analytic memos throughout the data collection process to interpret preliminary findings, to document the research process (Tobin & Begley, 2004), and to practice reflexivity (Saldaña, 2016). TM discussed initial findings with senior members of the research team. After 11 interviews, the team agreed that data saturation was reached, and interviewing was ceased at this point to conserve resources. Participants were provided with a $20 gift card for their time. However, the original plan of providing a small gift of traditional foods was not able to be fulfilled due to complications of ordering and distribution of these gifts in a safe and cost-effective manner.

Dissemination Plans

We shifted our dissemination plan to be entirely virtual due to COVID-19 restrictions. The student researcher regularly attended NAL virtual events to build and maintain relationships with community members. Preliminary findings relating to the prevalence of food insecurity and demographics in the study sample were presented by TM to NAL during a staff meeting. In collaboration with NAL staff, our new dissemination plan is to host a webinar presenting study results for Phase 1 and 2 to the community via Facebook Live. We will also produce infographics with key findings to be shared on NAL social media platforms. In addition, we will generate reports for community members and NAL staff to be shared via the NAL website, Facebook page, and community emails. As COVID-19 restrictions continuously change, we are cautiously planning to host an in-person feast to share study results with participants and interested community members in Spring 2022.

DISCUSSION

While food security was an existing problem for urban Native peoples nationally (Jernigan et al., 2017; Tomayko et al., 2017), it is likely that COVID-19 worsened food security among these communities. Our collaborative study represents one of the first steps to understanding food security, food stress, and food sovereignty among community members to drive local solutions for

the Baltimore Native community. To our knowledge, this study is the first to holistically examine food security prevalence, food stress, and food sovereignty during the COVID-19 pandemic in an urban Native community. While COVID-19 changed our community-based mixed methods research plan, we adapted to the new context with community guidance that ultimately strengthened our community-academic partnership and informed our revised research to understand and respond to the imminent food-related needs of the Baltimore AI/AN community. Our community-academic team learned several lessons and gained new insights on strengths that guided our research study during the COVID-19 pandemic.

Lessons Learned

Our study was significantly affected by COVID-19 and changes to the study included revisions to the measures, recruitment procedure, evaluation, and dissemination plans. During the pandemic, the use of an online survey platform provided several strengths. First, it was relatively easy and effective for NAL to share the survey link via social media. Additionally, participants were able to take the survey at their convenience. We quickly recruited participants for the online survey, demonstrating that recruiting via social media may be a fruitful avenue for future research.

While our original qualitative protocol included in-person and virtual options, the fully virtual environment may have made it more convenient and accessible for some community members to participate. We found that most participants we enrolled chose to be interviewed using the call-in function on Zoom rather than using video, which may have allowed for participation for those without a smartphone or video enabled device. It is possible that participants who were engaged in remote work/school may have been experiencing "Zoom fatigue." Due to the shift from work to home and virtual work environments for many and the added potential stress and mental health impacts related to the COVID-19 pandemic, participants may have decreased willingness to participate in more virtual activities, like Zoom or phone calls, in addition to their existing work and social responsibilities.

Limitations

There are also potential limitations of this study that the community-academic research team learned during this process. One limitation is that it is possible that Elders or others without access or knowledge of technology usage (e.g., Zoom) may have felt uncomfortable participating if they would have typically chosen in-person research participation. Additionally, in many tribal

cultures sharing information or stories may only occur in person or during certain times of the year. Throughout interviews, many participants expressed that they wished to be able to meet in person and share food together, suggesting that in-person interviews may be more desirable or more culturally acceptable within this community. Further, there may be participants who did not have access to internet or phone due to socioeconomic factors who would have been interested in participating. This potential subset of participants experiencing socioeconomic challenges, before or during the pandemic, may have experiences and perspectives regarding food security, food stress, and food sovereignty that would be important to capture to understand community-driven solutions. These described limitations outline multiple ways in which selection bias may have occurred in our sample.

Strengths of a Community-Based Participatory Research Approach

Despite the various challenges that COVID-19 presented to our study, using a CBPR approach was a major strength and an appropriate approach for adapting research plans. Through ongoing meetings with our community partner, we were able to iteratively revise questions in the survey to better understand COVID-19 challenges that participants faced, as well as to add questions to interview guides to better understand and serve the local community's imminent needs. Adding questions that served our community partner's needs was important for promoting a co-learning approach and ensuring that our research had real world implications for addressing social inequities, an important tenant of CBPR (Israel et al., 1998). Though there were delays to the study, the amended timeline provided the student researcher time to ensure that the research truly reflected community priorities especially during a time of immense change. Other Native researchers have emphasized the importance of planning for flexibility in timelines when conducting research in partnership with Native communities (LaVeaux & Christopher, 2009). Our ability to be flexible with our research timeline led to other opportunities to provide direct service and support community initiatives and health needs (e.g., hosting a webinar, helping with community food relief boxes, distributing storybooks to families and children) during COVID-19.

To build upon the community-academic partnership, the research team co-wrote a paper describing the strengths and needs of Urban Indian Health Programs (UIHPs) during COVID-19 (Maudrie et al., 2021). This collaborative manuscript promoted co-learning and aimed to advocate for changes to data collection and policy changes that could impact the Baltimore Native community and other UIHPs nationally. Collectively, these activities demonstrate the deep

commitment and respectful partnership between NAL and the JHBSPH research team beyond this specific research study.

Future Directions

The results of the quantitative survey and qualitative interviews are forthcoming and will be available in the forms of community reports, flyers, as well as peer reviewed manuscripts. As analyses for these data progress, the community will be involved in interpretations of data through the form of community research advisory meetings. Food security, nutrition knowledge, and disordered eating continue to be concerns for the Baltimore Native community and other urban AI/AN communities. Further research is needed to explore the complicated relationships between mental health and food security, including the long-term mental health effects of food insecurity. Future community research partnerships should continue to explore and implement community-driven and sustainable solutions to food system issues, including food sovereignty, among urban AI/AN communities and especially during times of local and national crisis. The importance of CBPR principles was emphasized, especially using an iterative approach to research design, facilitating collaborative partnership in all research phases, and addressing health from a strengths and ecological perspective. Future partnerships with this community-academic research team will include collaborative data analyses and interpretation, co-writing results, and moving through the dissemination phase. Future collaborative work includes creating a formal community research council to guide additional research and community-driven solutions to food security and nutrition topics.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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APPENDIX A
In-depth Interview (IDI) Guide

Individual Experiences with Food Security:

1. Several weeks ago, you took a survey which is how we got in contact with you for this interview. This survey was attempting to measure food security. Have you heard of this concept? Can you tell me what food security means to you?

    Potential probes:

    a. Have you ever heard this term before? How was it used?

    b. What do you think it means to be food secure?

    c. Are there certain types of foods you think are necessary for food security?

2. For the rest of our conversation today we are going to use this definition just to make sure we're speaking about the same thing. I'm now going to read you a brief definition of food security.

    a. Food security is access by all people at all times to enough food for an active, healthy life. Food security includes:

        i. The availability of nutritionally adequate and safe foods.

        ii. The ability to acquire acceptable foods in socially acceptable ways.

    b. Food insecurity is limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways.

    Do you have any questions about this definition? Or anything that you think should be added to this definition? (Probes: Is there anything about this definition that does not fit your idea of food security? Is there anything that you think should be removed?)

3. Have you experienced times where you, or your family, have not met these requirements and therefore would be considered food insecure?

    Probes:

    If yes:

    a. Can you tell me about what that was like? And when this occurred (i.e., childhood, etc.)

    b. How did you (or your family) respond to that situation?

    c. Do you believe that experiencing food insecurity changed your relationship with food in the short or long term? Can you tell me about that?

If no:

    d. How do you think you would respond to that situation?

    e. Where would you seek support?

    f. Why do you think you've never experienced food insecurity? (e.g., probe on protective factors)

Community Food Security:

For the rest of this conversation, we are considering community to mean American Indian/Alaska Native people living in the Baltimore metro area or in Baltimore city.

4. Can you tell me what you know about food insecurity in the Baltimore Native community? Probe on:

    a. Perceived prevalence

    b. If they have seen or heard of different nutrition supports people access (food banks, SNAP, WIC, etc.)

    c. Barriers and supports to food security

    d. How the community supports food access

    e. How does the problem manifest itself (i.e., do you see people taking home leftovers from community events or overeating, etc.?)

5. Can you tell me about food security within the Baltimore Native community? Are there any problems? Why do you think these exist?

Potential probes:

    a. Individual factors (socioeconomic status, priorities)

    b. Family factors (family size, household size, who in the household is last to eat, preferential food allocation within house)

    c. Community factors (geographic location, transportation access, grocery stores)

    d. Can you tell me about food access? Availability? Affordability?

    e. Are there differences in accessibility, affordability, and availability of food in different parts of the community? (probe on geography, gender, age)

6. What are the strengths related to food security at the community level?

    a. How does the community address food insecurity?

    b. What resources are in place to avoid the problem if it does not exist?

7. What else could be done to improve this community's food security? (probe to explain what they think possible solutions could be).

8. Do you think the Baltimore Native community experiences other food related issues?
    Probe on:

    a. Eating disorders (over or under eating, restrictive vs indulgent behaviors around food)

    b. Obesity causing food behaviors.

    c. Nutrition knowledge

    d. (SKIP if already covered earlier) Stress because of food (including money, lack of time, availability, access)

        i. What this stress might manifest itself as?

        ii. What are coping strategies for food related stress?

9. Can you tell me about important cultural foods to the Baltimore Native community and you as a Native person?
    Probe on:

    a. What are some cultural foods that are important to you? What about the community in general?

    b. How do you think people get these foods? Are they easily accessible? Affordable? Available?

    c. What are ways you think access to cultural foods could be increased?

Food Sovereignty:

10. Finally, I would like to ask you a few questions about a concept called food sovereignty. Have you ever heard of food sovereignty? Can you tell me what it means to you or your understanding of the concept?

a. If they need help read definition: Food sovereignty is the right of people to healthy culturally appropriate foods that are produced sustainably. It also includes the right of communities to define their own food and agriculture systems. Indigenous food sovereignty often expands on these ideas by incorporating spiritual and emotional relationships to foods and the land. Do you have any questions about this concept before we move on?

11. Can you tell me what you think food sovereignty would look like for the Baltimore Native community? Does it look different for rural vs urban native peoples?

12. How do you think food sovereignty relates or doesn't relate to food insecurity in your community? (probe on relations)

13. What do you think a food sovereignty movement could look like in your community? Probe – who needs to be involved? What are the steps needed for a movement?

Thank you very much for your time and insight in this important topic. Before we end our meeting, I would like to ask if there is anything else about food access, food stress or food sovereignty in your community that you think we should discuss.

If not: Thank you so very much for your time and insight, I am so grateful for your help and support in this important project.

ADAPTATIONS DUE TO THE COVID-19 PANDEMIC IN A COMMUNITY-BASED PARTICIPATORY RESEARCH RANDOMIZED CONTROL TRIAL EXAMINING SEXUAL AND REPRODUCTIVE HEALTH OUTCOMES AMONG AMERICAN INDIAN YOUTH

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Abstract: In this manuscript, we present changes in study design and analytical strategy due to the COVID-19 pandemic for Nen ŨnkUmbi/EdaHiYedo ("We Are Here Now," or NE). NE is a community-based participatory research multi-level randomized control trial using a stepped wedge design to address sexual and reproductive health disparities among American Indian youth. Adaptations in NE's research design, data collection, and analysis due to the COVID-19 pandemic were made based on meetings with tribally based research team members and outside non-Indigenous researchers involved in NE, as well as the study's Community Advisory Board and the Data Safety Monitoring Board. Based on these iterative discussions, decisions were made to: 1) reorganize the sequence of NE's stepped wedge design clusters, and 2) include additional quantitative and qualitative data collection and analysis in the research design that specifically addressed the impact of COVID-19 on the research participants. These adaptations have the potential to foster greater scientific knowledge in understanding how to address unanticipated 3-way interaction effects in randomized control trials with tribal communities. Findings can also contribute to understanding how public health disasters impact sexual and reproductive health among American Indian youth.

INTRODUCTION

In response to the COVID-19 crisis, the National Institute of Minority Health and Health Disparities (NIMHD) framed the COVID-19 pandemic as an unfortunate opportunity to improve community-based interventions by rigorously exploring the etiology of health disparities and their intersections in vulnerable populations (Webb Hooper et al., 2020). The National Institutes of Health's Coronavirus Strategic Plan emphasizes the need to examine the psycho-social,

behavioral, and age-specific consequences of COVID-19 related to vulnerable populations (National Institutes Health, 2020). Furthermore, leading global health institutes have encouraged researchers to document deviations from study protocols as well as conduct risk assessments of the impact of COVID-19 on randomized control trials (RCTs) (European Medecines Agency, 2020). Thus, the unprecedented circumstances of the COVID-19 crisis carry direct implications for both the implementation of RCTs and the analysis of data derived from RCTs with Indigenous communities in the United States.

In this manuscript, we present the changes in study design and analytical strategy due to the COVID-19 pandemic for *NenŨnkUmbi/EdaHiYedo* ("We Are Here Now," or *NE). NE* is a community-based participatory research (CBPR) multi-level, multi-component RCT using a stepped wedge design (SWD) to address sexual and reproductive health (SRH) disparities among American Indian youth. In the proposal for *NE,* we considered a limitation of the RCT's SWD was the possibility that an unobserved 3-way interaction will exist for time by cluster by intervention. The COVID-19 pandemic is a befitting example of a 3-way interaction effect. The COVID-19 pandemic is producing this interaction in real time as COVID-19 continues to pose problems in American Indian communities (Hatcher et al., 2020; Stone et al., 2021; Strassle et al., 2022). Given this, we have the unique opportunity to observe the impact of a 3-way interaction on an RCT design and sexual risk behaviors among American Indian youth. In this paper, we discuss a mixed quantitative and qualitative methods approach that will delineate and elucidate two concerns: 1) the potential effects of the COVID-19 pandemic on *NE*'s primary outcome variable, and 2) direct effects of the COVID-19 pandemic on *NE*'s study design.

Background

The overall goal of *NE* is to reduce SRH disparities among American Indian youth aged 14 to 18 years living on the Fort Peck Reservation in northeastern Montana. *NE* uses a community-based participatory framework and includes a five-member Community Advisory Board that collaborates with the Fort Peck-based research team and researchers from outside the community to make implementation, analysis, and dissemination decisions about the study. In brief, *NE* includes four intervention levels: 1) an adaptation of school-based SRH curriculum called *Native Stand,* designed to address individual-level factors that lead to sexual risk behaviors; 2) a family-level, home-based curriculum tailored to increase communication between adult family members and youth about SRH topics; 3) a cultural mentoring component at the community level that pairs

American Indian youth with adults and elders to discuss traditional American Indian beliefs and practices about SRH; and 4) a mobilizing strategy to activate a multi-sectoral network of youth-servicing organizations at the systems level in the reservation community to coordinate SRH services for American Indian youth. For the purposes of this manuscript, we focus solely on the individual-level youth data collection and primary outcome variable.

Primary Outcome Measure

NE's primary outcome measure is the number of times a condom was used during sexual intercourse (anal or vaginal) in the month preceding the administration of a survey. The survey is implemented at baseline and at 3, 9, and 12 months.

Potential Effects of the COVID-19 Pandemic on NE's Primary Outcome

There are numerous reasons to suspect that the COVID-19 pandemic is affecting *NE*'s primary outcome. First, American Indian people in the United States have historically experienced increased risks for infectious diseases, and American Indian communities may be particularly susceptible to COVID-19 (Riley, 2010). Effective COVID-19 mitigation strategies that have been implemented nationally include the prioritization of life-saving resources, using personal protective equipment, allocating health care workers to hardest-hit areas, employing mobile health clinics in underserved communities, and improving health care systems for universal protection (Attipoe-Dorcoo et al., 2020; Koonin et al., 2020). It is unknown whether American Indian youth have received access to such mitigation strategies and preventive measures and how behavioral mitigation strategies such as social distancing and home quarantine (if practiced) have affected American Indian youths' sexual activity. Emergent research suggests that increased barriers to contraceptive access and use, the desire to be pregnant and have a child, sexually transmitted infection (STI) testing and treatment, and intimate relationship violence and abortion care are heightened among American Indian youth due to the COVID-19 pandemic (Ahmed, 2020). Lindberg et al. (2020) suggest that the pathways to these negative SRH outcomes are associated with pandemic-related social and economic changes (social distancing, sheltering in place, school shutdowns, economic insecurity) and proximal influences (nearness to sexual partners, privacy, affordability and access to SRH care). Also, there is acknowledgment that the pandemic has had mental health effects on the general population, exacerbated by self-isolation, fear, and social distancing (Biel & Hamrah, 2021; D'Amico et al., 2020; Davalos, 2020; Urbatsch & Robledo, 2020). Previously documented research demonstrates that poor mental health is a major contributing factor to SRH in American Indian youth (Anastario et al., 2020; Anastario et al.,

2013). It is probable that mental health effects associated with the pandemic may alter behaviors associated with American Indian youths' sexual behavior. Taken together, the potential impacts of mitigation strategies and mental health factors on *NE*'s primary outcome measures carry direct implications for understanding secular trends associated with the COVID-19 crisis in the context of *NE*'s SWD trial.

Site

NE takes place on the Fort Peck Reservation, located in northeastern Montana. Approximately 8,000 enrolled tribal members live on the reservation, which spans 2.1 million acres. *NE* is currently being implemented in five communities, four of the communities are on the reservation and one community is on the border of the reservation.

ADAPTATIONS TO RESEARCH DESIGN, DATA COLLECTION, AND ANALYSIS DUE TO COVID-19

To address COVID-19-related adaptations in research design, data collection, and analysis, meetings were held with research team members from the reservation and the university, the Community Advisory Board, and the Data Safety Monitoring Board (DSMB). Based on these discussions, decisions were made to: 1) reorganize the sequence of *NE*'s SWD clusters, and 2) include additional quantitative and qualitative data collection and analysis in the research design that specifically addressed the impact of COVID-19 on the research participants and primary outcome variable.

Approval for Adaptations

Changes made to the study design were discussed and agreed upon with the study's Community Advisory Board, research team, and DSMB members. Subsequent ethical approval for the changes were received from the Fort Peck Tribes Institutional Review Board and the Montana State University Institutional Review Board.

Adaptations to the Stepped Wedge Design

The COVID-19 crisis also has presented unique methodological concerns for *NE*. To comply with National Institutes of Health guidance on COVID-19 and to ensure minimal risk to and increase safety of our research team and research participants at Fort Peck Reservation, the

original randomization of the clusters in *NE's* SWD had to be reorganized. The original randomization of *NE*'s clusters was: High School 1 (cluster 1); High School 2 and High School 3 (cluster 2); and High School 4 and High School 5 (cluster 3). The reorganization of the clusters included moving High School 2 to the end of the cluster sequence to create a fourth cluster with High School 3 remaining in cluster 2 (Table 1 & Table 2).

Table 1
NE original stepped wedge design

Original Step	Cluster	Baseline	
		N	%
1	High School 1	212	46.39
2	High School 2	151	33.04
2	High School 3	41	8.97
3	High School 4	25	5.47
3	High School 5	28	6.13

Table 2
NE adapted stepped wedge design

Adapted Step	Cluster	Baseline	
		N	%
1	High School 1	212	46.39
4	High School 2	151	33.04
2	High School 3	41	8.97
3	High School 4	25	5.47
3	High School 5	28	6.13

The foundational premise for moving High School 2 to the end of the cluster sequence and keeping High School 3 in cluster 2 was ensuring minimal risk of COVID-19 transmission on the reservation through considerations of each school's class size and the distance from the Fort Peck Community College where the research team was located. High School 3 is a smaller school with 41 students and required minimal travel by the Fort Peck Community College-based research team across the reservation, whereas High School 2 is one of the larger schools on the reservation with 151 students and is geographically distant from the Fort Peck research team. The combination of a large student body and the requirement of travel across the reservation by tribal research personnel increased risk of COVID-19 transmission during the COVID-19 pandemic at the

reservation from September 2020 to June 2021. High School 3 required minimal travel by tribal research personnel as the town is close to the Fort Peck Community College and High School 3 is much smaller with a high school class size of 41 students, thereby reducing possible risk of COVID-19 transmission. This adaptation resulted in 33% of the closed cohort sample changing the order in which they were randomized to receive the intervention and an augmentation of steps to the SWD trial from three steps to four.

While the SWD trial provides unique flexibility in allowing us to retain this relatively large cluster, the alteration in the randomization sequence does raise questions regarding the estimation of an unbiased intervention effect even when there are secular trends. In a SWD trial, clusters (as opposed to individuals) are the unit of randomization (Barker et al., 2016). In cluster randomized trials, the randomization process increases internal study validity and increases the perceived fairness and transparency of allocation. In the context of a SWD trial with a closed cohort design (such as *NE*), the randomization sequence alteration affects a large number of individuals associated with the cluster (33% of the closed cohort). The vulnerability of SWD trials to confounding time effects has resulted in suggestions that it is important to avoid changes in intervention delivery to cohorts receiving the intervention and that this particular aspect of the study design needs careful planning (Hargreaves et al., 2015). In one SWD trial where non-random sequential assignment of clusters to the intervention occurred for what the authors described as logistical and ethical reasons, the study subsequently received criticism for its inability to control for secular trends in the outcome and for undermining the estimation of an unbiased intervention effect (Didiodato & McArthur, 2016; Dreischulte et al., 2013). In terms of *NE,* changes in our SWD design were necessary because of the unanticipated interaction effect of the COVID-19 pandemic with our study. For this research, we plan to conduct enriched sensitivity analyses regarding secular trends in *NE*'s primary outcome variable and site-specific aberrations in the randomization sequence associated with *NE*'s SWD trial with additional quantitative and qualitative data collected in our study.

Adaptations to Data Collected

Additional Quantitative Data

To better understand how COVID-19 was affecting *NE*'s primary outcome variable as well as sexual risk behaviors additional data was needed. Thus, in Spring 2020, at the onset of the COVID-19 pandemic, we added specific questions to the existing youth survey asking about the

impact of COVID-19 on SRH. These questions focused on topics related to the barriers and facilitators associated with sexual risk behaviors during the pandemic. Examples include questions about frequency of sexual activity, depression, substance use, access to SRH services at the reservation, communication with parents about the pandemic, and adherence to tribal public health mandates about the pandemic. These questions were adapted from newly developed measures for COVID-19 (Table A1) (PhenX, 2020; National Institute of Environmental Health Sciences, 2020).

Sample Size, Power, and Quantitative Analytical Strategy

NE's original power analysis determined that a sample size of 456 would allow the detection of a 0.14 increase in the proportion of condom use relative to the frequency of sexual intercourse from baseline to the 12-month observation period. To test for effectiveness of the *NE* intervention, generalized linear mixed-effects models will be used to model the primary and secondary outcomes, which are the most frequently employed analytic method to adjust for the longitudinal nature of SWDs (Barker et al., 2016; Hussey & Hughes, 2007). After implementing baseline data collection, conditions presented by the COVID-19 pandemic necessitated altering the sequence of intervention receipt for one of the sites that was already randomized to receive the intervention. Furthermore, the COVID-19 pandemic is likely to alter truancy, which affects attrition and bias in the closed cohort design. To address these issues, the study team determined we would: 1) loosen the restriction of the closed cohort design; 2) examine the impact of the COVID-19 pandemic on the primary outcome variable; 3) conduct sensitivity analyses at trial-end to examine whether the alteration to the randomization sequence carries implications for estimates of *NE*'s effectiveness; and 4) consider new power calculations.

Our inclusion of the COVID-19 section in our quantitative survey will assist us in evaluating *NE*'s primary outcome variable and cluster-centered aberration in the randomization sequence. We plan to explore COVID-19-related correlates in relation to the primary outcome variable, which is the number of protected anal or vaginal sexual intercourse acts reported during the month preceding the survey. General linear models will be used to separately test for associations of *NE*'s primary outcome variable with COVID-19-related factors, with particular attention paid to the potential effects between study sites. To control for Type I errors due to multiple tests, we will use a Bonferroni-Holm correction procedure to determine statistical significance (Holm et al., 2011; Rubin, 2016). Second, we will incorporate findings from these analyses into our considerations of

the generalized linear mixed-effects models that are proposed to test for effectiveness of the *NE* intervention at trial end. At trial end, our new analytic strategy will include sensitivity analyses to determine appreciable differences in the primary outcome associated between the sites. Appreciable deviations associated with the aberration in the randomization sequence may require statistical adjustment in the longitudinal models. Adding the COVID-19 quantitative and qualitative data will help us to better understand overall alterations to the secular trend as well as unique site-specific factors.

Finally, the unique conditions presented by the COVID-19 pandemic and alterations to the study design have required a re-assessment of the study's power calculations. Given that baseline data and cluster-sizes are more readily available, the research team is currently developing simulation-based power calculations informed by the new conditions.

Additional Qualitative Data

In addition to collecting COVID-19-specific quantitative data, collection of qualitative data was planned to provide deeper insights into the experiences, perspectives, and behaviors of *NE*'s youth participants as they relate to the pandemic (Tenny et al., 2021). Thirty-one in-depth interviews with American Indian youth from *NE*'s 5 school sites were conducted. The in-depth interviews included 5 sections related to the following: 1) social impact of COVID-19 on family and school life; 2) tribal governance, economics, and environment; 3) relationships with friends and family; 4) access to medical services as well as SRH services; and 5) sexual behavior and other types of behaviors (Table A2). We purposively sampled youth from the 5 high schools participating in *NE* from May 2021 to August 2021 and included 6 youth per study site.

Qualitative Data Analysis

The in-depth interview data is currently under analysis using an inductive analytic approach. We will examine interview data to allow for the emergence of themes by the sequential development of open, axial, and theoretical codes (Charmaz, 2006; Strauss & Corbin, 2008). Atlas.ti software will be used to develop open codes. Subsequently, axial and theoretical codes will be developed, presented, and discussed with *NE*'s Community Advisory Board for a final analysis. At trial end, we will triangulate the qualitative data from our in-depth interviews with the results from the quantitative analyses of the primary outcomes to understand appreciable effects of the COVID-19 pandemic on secular trends in the primary outcome variable, as well as methodological alterations to SWD trial. Results will inform our ability to develop an adjustment strategy for future analyses emerging from *NE.*

DISCUSSION AND CONCLUSION

The COVID-19 pandemic presents unprecedented methodological challenges for communities and researchers currently implementing SWD trials during the pandemic. These methodological challenges require the documentation of deviations that are in line with best practices and following the recommendations of leading research agencies worldwide (Hargreaves et al., 2015). However, there remains a need to collect critical data regarding such deviations that can inform sensitivity analyses and analytic adjustments implemented at the end of RCTs.

The adaptations made to our study design and analytical strategy were made in partnership with the tribal partners and outside researchers involved in *NE*. Our adaptions were agreed upon as a group to, first and foremost, mitigate risk and ensure the safety of the Fort Peck-based research team, the tribal members participating in our study, and the overall health and safety of people living at the Fort Peck Reservation. Second, our adaptations were based on an analytical need to observe the impact of COVID-19 on sexual risk behaviors and our RCT SWD design. Our COVID-19-related quantitative and qualitative data collection provides a mixed-methods strategy that has the potential to sequentially address whether COVID-19-related factors were associated with *NE*'s primary outcome variable. It is an example of how tribal-academic research partnerships can collaborate to address challenging public health crises taking place in Indigenous communities that are outside the scope of work of funded research projects. Finally, our reassessment of the study's power mid-intervention is not traditional but is nonetheless important so that a broader understanding of the new conditions presented by the COVID-19 pandemic on the study can be understood. The results of this study will foster greater scientific knowledge in understanding how to address unanticipated 3-way interaction effects in RCTs with tribal communities. Further, it will help us understand potential deviations associated between sites that are now the aberrations in the randomization sequence. Finally, our findings can contribute to understanding how public health disasters impact SRH among American Indian youth.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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APPENDIX

Table A1
COVID-19 and behavior survey questions

Topic Area	Quantitative Questions	Response Options
Communication with Parents or Guardian	• Were you quarantined at home with your parent or guardian or another relative or friend during the State stay-at-home order during spring 2020?	• Yes, I was quarantined with another relative or friend. • No, I did not adhere to stay-at-home guidelines during the Montana stay-at-home order in spring 2020. • Yes, I was quarantined with my parent or guardian.
	• If you quarantined and adhered to State's stay-at-home order, did you speak with your parent/guardian/relative/friend about the topics listed below.	Check all that apply. • Any topic about sex • Going to IHS or another health care provider about birth control or condoms • Going to IHS or another health provider about getting an STI or pregnancy test • Your feelings and emotions during the pandemic
Access to Sexual and Reproductive Health	• Did you access services from Indian Health Service or Reservation Name (RN) Tribal Health for things like condoms, birth control, a pregnancy test or a sexually transmitted disease test during the State and RN stay-at-home order in spring 2020? • If you did not access services during the State stay-at-home and RN order, did you want or need to access services for things like condoms, birth control, a pregnancy test or a sexually transmitted disease, but could not? • Has concern about contracting COVID-19 prevented you from accessing services from Indian Health Service or RN Tribal Health for things like condoms, birth control, a pregnancy test or a sexually transmitted disease test?	All question responses. • Yes • No

continued on next page

Table A1 continued
COVID-19 and behavior survey questions

Topic Area	Quantitative Questions	Response Options
Worries About COVID	• Were you worried about contracting COVID-19?	• Yes • No
	• Did you stay at home more, the same amount of time, or less, due to concern about contracting COVID-19?	• I stayed home more due to COVID-19. • I stayed home the same amount as before COVID-19. • I stayed home less due to COVID-19.
Sexual Behavior	• Did you have sex with MORE PEOPLE OR LESS PEOPLE because of COVID-19? • Did you have sex MORE or LESS TIMES because of COVID-19? • Did you use a condom MORE or LESS TIMES because of COVID-19?	All question responses. • I have not had sex. • I had sex more times. • I had sex less times. • I had sex the same amount of times.
Substance Use	• During the Sheltering in Place orders in the State and RN, I drank alcohol (such as beer, wine, hard liquor, or malt liquor) more or less. • During the Sheltering in Place orders in the State and RN, I used marijuana more or less. • During the Sheltering in Place orders in the State and RN, I used drugs (such as meth, cocaine, ecstasy, heroin, or inhalants) more or less.	All question responses. • I did not drink alcohol/use marijuana/use drugs at all. • I drank less alcohol/use less marijuana/use drugs. • I drank more alcohol/use less marijuana/use drugs. • COVID-19 did not impact my drinking/marijuana use/drug use.
Emotions	• During the Sheltering in Place Orders in the State and RN, I felt hopeless. • During the Sheltering in Place Orders in the State and RN, I felt sad. • During the Sheltering in Place Orders in the State and RN, I felt fearful. • During the Sheltering in Place Orders in the State and RN, I felt lonely.	All question responses. • None of the time (0 days) • Rarely or a little of the time (1-2 days) • Some of the time (3-4 days) • Most or all of the time (5-7 days)

Table A2
COVID-19 qualitative interview guide questions

Topic Area	Questions
Social Impact of COVID-19	• How has the Covid-19 pandemic impacted your friends and family? Tell us what it has been like. • What was it like for you to not go to school during the height of the pandemic? • Tell me about the ways in which COVID-19 has affected attendance at your school. • What else has changed at your school because of COVID-19? • How has school generally been for you since COVID-19 started? • What differences have you seen in your friends and family because of COVID?
Tribal Governance, Economics, Environment	• Did you pay attention to tribal politics and the decisions the Tribes were making about COVID-19? Why/Why Not? • What have you heard your friends and family talk about related to how the Tribes have handled COVID-19? • What did you think of the curfews the Tribes put in place? Did your friends and family pay attention to the curfews? Why/why not? • Tell me about the instances of people NOT social distancing that you experienced. • What kind of money issues did you see come up with your friends and your family last Spring because of COVID-19?
Relationships	• Now I want you to think about social media and apps like Instagram, SnapChat, Twitter, Kik Messenger, and Tik Tok, or any others that might be widely used around here. How has your use of those apps changed because of the COVID-19 pandemic? • How did the sheltering in place last Spring impact the relationships of people around you? What types of things did you see happen in your friends' relationships and in your family because of COVID-19? What is different now? • Even though there were a lot of laws and regulations following COVID-19, there were still a lot of people who continued to socialize and visit with their friends and family. Tell me about what that was like for you.
Access to Services	• Tell us what it has been like trying to get medical health. What was it like to go to IHS or Tribal Health or the hospital? • Were you able to get any kind of birth control, STI test, the morning after pill, or pregnancy test during the pandemic? • Where have you received most of your information about COVID-19? • Have you ever been tested for COVID-19? Would you know where to get tested if you wanted a test?

continued on next page

Table A2 continued
COVID-19 qualitative interview guide questions

Topic Area	Questions
Sexual Behavior and Other Types of Behaviors	• Are you in a romantic and/or sexual relationship? If so, how did the COVID-19 pandemic affect your relationship? • What did you see your friends doing in terms of partying and hooking up with other people over the past year? • How did people in romantic relationships maintain their romantic relationships after the start of the pandemic? • How did what you see your friends doing in terms of partying and hooking up make you feel? • Have you felt worried or anxious about your health during the COVID-19 pandemic? • Have you felt worried for the health of your family or friends during the COVID-19 pandemic? • Have you known anyone who has died during the COVID-19 pandemic? Tell me more about that.
Protection from COVID-19	• What measures have you and your family been taking to protect yourselves from becoming infected with COVID-19? • Have you relied on prayers, sweats, the use of plants like sage, cedar, bear root, echinacea or sweetgrass, or other traditional ceremonies to protect yourself during COVID-19? • How did what you see your friends and family do to protect themselves from COVID-19 influence your behavior to protect yourself? • When did you start seeing people wearing masks? When do you wear a mask? Where do you get your masks from? • Tell me about your use of alcohol, if any, during the COVID-19 pandemic. • Tell me about how the local stores and other local businesses may have put up signs or stickers to tell you to do things in order to protect yourself from COVID-19.

RISING ABOVE: COVID-19 IMPACTS TO CULTURE-BASED PROGRAMMING IN FOUR AMERICAN INDIAN COMMUNITIES

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Abstract: The COVID-19 pandemic has disproportionately impacted American Indian and Alaska Native (AI/AN) communities. Tribes, tribal organizations, AI/AN youth and community-serving programs, and tribal health organizations have responded and adapted programs and services in response to the COVID-19 pandemic. This paper explores how COVID-19 impacted Native PRIDE, an American Indian non-profit organization, and the tribal communities involved in the Intergenerational Connections Project (ICP). Native PRIDE utilized a mixed-method Indigenous Evaluation Framework (IEF) to reflect on COVID-19 impacts. Qualitative data collected during the COVID-19 pandemic and quantitative data from an online survey helped Native PRIDE explore impacts and recommendations for future programming. With a focus on context and relationship, this paper explores what was felt, observed, and known by program participants and Native PRIDE staff in the delivery of ICP during the COVID-19 pandemic. Results from this evaluation are a reminder of the importance of strengthening cultural resilience by providing access and opportunities for AI/AN youth, elders, and adults.

INTRODUCTION

American Indians and Alaska Natives (AI/ANs) experienced greater impacts from COVID-19 than the general population (Tai et al., 2021). In the United States, the overall incidence of COVID-19 among AI/AN persons was 3.5 times higher than non-Hispanic White persons (Hatcher, 2020), and the mortality ratio was 1.8 times higher than non-Hispanic White persons (McLernon, 2021). A recent study called attention to the impacts of COVID-19 on AI/AN youth, with one of every 168 AI/AN children experiencing orphanhood or death of caregivers due to

COVID-19 (Hillis et al., 2021). Disproportionate mortality and incidence are not the only negative outcomes associated with the pandemic that is observed in AI/AN communities. AI/AN communities experienced social, cultural, and economic shifts that impacted their physical and mental well-being. Shelter-in-place policies prohibited gathering and participation in cultural and traditional activities, long associated with individual and collective well-being in AI/AN communities (Owen et al., 2021). Studies published early in the pandemic reported higher rates of depression, suicidality, and COVID-19-related stressors among AI/AN adults (Burton et al., 2020; Fitzpatrick, 2020). Economic shifts also occurred as AI/AN communities experienced decreases in revenue due to the closure of tribal businesses and tribal lands. Some tribes reported losing at least 40 percent of their revenue since the beginning of the pandemic (Gregg & Lozarr, 2021). Other tribes reported increases in operating costs and reductions in cultural programming and health care services (Gregg & Lozarr, 2021).

Tribes, communities, and organizations throughout Indian Country demonstrated a rapid response to the COVID-19 pandemic. They prioritized the needs of the elderly and populations at higher risk for COVID-19-related complications. Stories of hope, resilience, and kinship systems inspired many. Tribes were among some of the only groups in the United States that focused on collective well-being. Communities across Indian Country established policies, adapted services, and developed resources to keep individuals and families safe. Tribes partnered with federal agencies during the pandemic, including the US Centers for Disease Control (CDC), Federal Emergency Management Agency (FEMA), and Indian Health Service (IHS). Tribes also established routine COVID-19 surveillance, implemented rapid coordination and response, applied innovative communication strategies, and led inventive education and service delivery strategies (Humeyestewa et al., 2021; Oleribe et al., 2021; Pratt et al., 2021). Public health communications and safety messaging throughout Indian Country were adapted to reflect the culture, traditions, language, and experiences of AI/AN people (O'Keefe et al., 2021). Many tribal health programs transitioned to virtual service delivery and outreach such as telehealth services, online classes for K-12 students, and the use of social media for connection, risk communication, and resource sharing (Stevens et al., 2020; Kuhn et al., 2020). While there is a broad understanding of COVID-19 impacts on Indian Country as presented here, there is a lack of information about how culturally based programs in AI/AN communities adapted during the COVID-19 pandemic.

Research has well documented that cultural and spiritual practices in health interventions can improve health outcomes for AI/AN communities (Owen et al., 2021; Pomerville & Gone,

2019). AI/AN cultural and spiritual practices also promote community and cultural connection, both protective factors in the experience of trauma (Schultz et al., 2016). During the COVID-19 pandemic, tribes across the country quickly responded to the emerging threat by adopting safety measures, closing or adapting tribal in-person services, and canceling tribal gatherings. Cultural celebrations including pow wows and tribal Feast days were canceled, and spiritual practices including sweats and ceremonies were not offered. Communities saw a decline in the spiritual and cultural interventions offered as a result of shelter-in-place policies. This decline occurred during a time of intense uncertainty when AI/AN communities were faced with disproportionate adverse outcomes from COVID-19. This was a time when culturally centered programming that promotes healing and well-being was needed, but limited. However, many culturally based programs across AI/AN communities adapted services to continue healing interventions. It is essential to document how organizations adapted programming during the COVID-19 pandemic to further strengthen the capacity of tribal programs to respond to future emergencies in AI/AN communities to continue cultural and spiritual-based programming. This paper highlights the work of how one culturally based program, Native PRIDE's Intergenerational Connections Project (ICP), adapted healing interventions during the COVID-19 pandemic.

Native PRIDE and the Intergenerational Connections Project

Native PRIDE[1] is an American Indian-owned non-profit organization that works with Native people to develop and implement cultural- and spiritual-based programs that inspire wellness and healing. Native PRIDE's programs address at-risk behaviors such as substance abuse, bullying, negative peer pressure, unhealthy relationships, suicidal ideation, and fatalities among AI youth. In October 2016, Native PRIDE received funding from the Administration for Native Americans (ANA) to implement the ICP with four tribes in Montana and South Dakota. Tribal locations included two schools, one recovery center, and one youth-serving organization. ICP's goal was to increase cultural resilience and sustain cultural participation over time with youth and elders. ICP activities focused on the use of cultural resilience, culture-based programs that incorporate spirituality (healing), youth-adult mentorships, peer-counseling strategies (youth helping youth), creating safe and sacred opportunities that allow Native youth to break the unhealthy cycles of historical trauma (colonization), and strengthening Native youth's facilitation

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[1] www.nativeprideus.org

skills among their peers and community. The COVID-19 pandemic greatly impacted the delivery of this project during a time when many Native communities were unable to engage in cultural and traditional practices.

During the first year of ICP, sites identified a list of cultural activities they wanted to complete. Elders were matched with youth and completed activities such as beading, fasting, culture camps, visits to sacred sites, regalia making, gourd dancing, language classes, plant identification classes, and storytelling. The Good Road of Life (GRL) training was a primary component of the ICP. Elders and youth from each of the sites completed at least one GRL training during the five-year project. During the last 18 months of ICP, only two in-person GRL trainings were offered due to COVID-19 meeting restrictions. Goals of the GRL training were to strengthen cultural resilience, increase social support, develop leadership skills, and promote healthy relationships. Previous publications by Native PRIDE demonstrate the positive impacts of GRL on building resilience and sources of strength in communities and individuals (Kelley et al., 2018; Kelley & Small, 2020; Kelley et al., 2020).

Figure 1. Timeline of COVID-19 impacts on Native PRIDE ICP

December 2020	Last Good Road of Life (GRL) in-person training in one tribal community before pandemic
January 2020	Term "COVID-19" emerges, team discussions begin about potential impacts to culture-based programming
February 2020	Native PRIDE recognizes that most in-person events will be canceled due to the COVID-19 pandemic
March 2020	Meetings with four tribal communities to discuss alternative elder-youth mentoring activities and culture-based programs
June 2020	First Zoom-modified GRL training occurs, technology is an issue
December 2020	Zoom-modified GRL trainings continue, individualized support provided for tribal communities, refocused on workplace wellness, grief, loss, managing stress, anxiety, and isolation
March 2021	Native PRIDE online survey sent to all sites and previous GRL attendees to document impacts of ICP and COVID-19
July 2021	First in-person culture camp offered at Bear Butte, South Dakota, ICP GRL training and victory celebration with sites in South Dakota, student evaluation intern travels to tribal communities and creates a video of ICP accomplishments
August 2021	Second ICP GRL in-person training and victory celebration with sites in Montana, student evaluation intern travels to victory celebration and tribal communities to support data collection for final evaluation
September 2021	Virtual ICP/ANA grantee closeout celebration, video shared with all grantees, ICP student guest speaker shares how he received a college scholarship during COVID-19 and is rising above the challenges he experienced

The primary goal of this paper is to explore how COVID-19 impacted Native PRIDE, a culturally based program in Indian country, and tribal communities involved in the ICP, and how the project staff and tribal communities adapted services to meet program goals. A secondary goal is to reflect on what was felt, observed, and known during the COVID-19 pandemic and adaptations that were made.

METHODS

Native PRIDE hired an external evaluator at the beginning of the 5-year ICP. This evaluator worked closely with Native PRIDE and sites throughout the project. A hallmark of the Native PRIDE ICP external evaluation model is building community capacity for evaluation with student evaluation interns. Over the five-year project, the evaluator trained 10 AI students and community members in research methods, survey development, data collection, data analysis, and dissemination. The evaluator and AI student interns worked closely with Native PRIDE's CEO, Dr. Clayton Small, to develop alternative strategies for data collection, outreach, and the continuation of elder-youth mentoring and cultural activities during the COVID-19 pandemic.

Native PRIDE utilized an Indigenous Evaluation Framework (IEF; LaFrance & Nichols, 2010). The IEF synthesizes Indigenous ways of knowing and western evaluation practice. Importantly, the IEF situates the evaluation in context and relationship to the place, setting, and community with which the evaluation is carried out (LaFrance & Nichols, 2010). Within this context, Native PRIDE reflected on program impacts, value, connection, and meaning. The Native PRIDE evaluation on *rising above* COVID-19 draws on community values and aspirations using five guiding questions informed by the IEF: 1) What did you see? 2) What did you feel? 3) What did you hear? 4) What do you know now? and 5) How did you rise above?

The evaluation explored the impacts of the COVID-19 pandemic on ICP efforts using a mixed-methods, culturally centered approach. The mixed-methods evaluation included both quantitative and qualitative methods. Qualitative measures included informal interviews conducted during site meetings with Native PRIDE staff, tribal site coordinators, and the evaluation team. In these interviews, staff reflected on the COVID-19 pandemic, lessons learned, and recommendations for future work. The staff provided insight into how the COVID-19 pandemic impacted Native PRIDE. Quantitative measures included an online survey, sent to GRL program participants, that explored the impact of COVID-19 on tribal communities. The online survey link was disseminated by email to site coordinators who then forwarded it to youth and

elders involved in ICP and GRL trainings. Only participants that attended the GRL training (the individuals served with this funding) were included in the analysis. Upon completing the survey, respondents were entered into a raffle and had the chance to win a $50 gift card.

The online survey included 15-questions to document the overall impact of ICP and the impacts of COVID-19. Information about program impacts (12 survey questions) will be reported in a separate publication and submitted to the funding agency. This paper reports on three of the survey questions that directly examined the impacts of the COVID-19 pandemic and GRL trainings. One question examined the overall impact of GRL trainings on participant well-being. Participants were asked, "Think about how you feel today compared to before you attended the GRL ICP training. For each statement, rate any changes that came from your participation in the training(s)." Response options were based on a 5-point Likert-type scale where 1 = Much Better, 2 = Somewhat Better, 3 = About the Same, 4 = Somewhat Worse, 5 = Much Worse. This question is directly tied to participant involvement in the GRL ICP training during the COVID-19 pandemic and demonstrates the potential benefits of participation in culture-based programming during the pandemic. The other two questions related to COVID-19 mental and physical health impacts. Participants were asked, "How has COVID-19 impacted your education or career plans?" with an open text response option. Lastly, participants were asked "How has COVID-19 impacted you?" with fixed response options. Participants were asked to select all response options that apply, see Table 1. Response options were created based on the team's knowledge of COVID-19 impacts and previous work completed by Native PRIDE.

Analysis

Quantitative data from the online survey were analyzed using basic frequency counts and descriptive statistics in Microsoft Excel (Version 2110). We reviewed mean scores for each statement and percent agreement, where applicable. The evaluation team utilized a modified content analysis approach (Hsieh & Shannon, 2005; Schreier, 2012) to analyze qualitative data collected during virtual meetings, trainings, phone calls, and emails during the COVID-19 pandemic. Using a modified content analysis approach, qualitative data responses were coded by emerging themes and categorized under the IEF questions. After the initial content analysis, the evaluation team sent themes and responses to IEF questions to the Native PRIDE team. Five local staff reviewed the themes and IEF responses to situate the evaluation in context and relationship to the place, setting, and community with which the evaluation was carried out (LaFrance &

Nichols, 2010). The Native PRIDE team agreed on the coding and responses to IEF prompts from the content analysis. These are presented in the findings section of this publication.

FINDINGS

Impacts from COVID-19

In total, 141 people completed the survey. It was not possible to calculate the actual survey response rate as emails were forwarded from the evaluation team to project staff at the four sites to disseminate. The analysis presented here includes only those individuals that attended a GRL training in the past five years during the ICP ($n = 76$). Of the 76 participants that attended a GRL training in the past five years, 54% were female ($n = 41$), 43% male ($n = 33$), and 3% were non-binary/third gender ($n = 2$). The average age of respondents was 25.69 ($SD = 16.73$, range 13-73 years). Tribal affiliation varied. Most were affiliated with the Ogalala Sioux Tribe (45%) or the Fort Peck Tribes (26%). The number of GRL ICP trainings attended in the past five-years varied. All respondents completed at least one GRL ICP training, with a mean of 2.65 trainings ($SD = 1.57$, Range 1 to 5 trainings). Respondent roles varied; 47% were attendees ($n = 35$), 33% youth role models/mentors ($n = 25$), 13% clan leaders ($n = 10$), 3.5% mental health professionals ($n = 3$), and 3.5% unknown ($n = 3$).

When asked about their participation in the GRL trainings that took place during the COVID-19 pandemic, results show that respondents ($n = 72$) feel that they are much better with regard to healthy choices, participation in cultural activities, and the ability to seek help when needed. Briefly, 51% feel much better about healthy choices ($n = 35$), 45% feel much better about their ability to seek help when they need it ($n = 32$), and 45% also feel much better about participation in cultural activities ($n = 32$).

We asked, "How has COVID-19 impacted your education or career plans?" Responses ($n = 66$) were open text and varied. The most frequent open text responses were related to difficulties with online learning. One respondent wrote, "I don't have Wi-Fi so I could not do the work." Another wrote, "School is different, and it is a lot harder to learn." Respondents expressed challenges related to limits to social activities, not being able to see friends, feeling depressed, family impacts, and feeling lonely. One respondent wrote, "I lost all motivation to do anything, even to get up." Another respondent wrote, "I am an in-person learner so it's a struggle sometimes

just something I have to get used to." Several responses related to missed opportunities to attend trainings, changes to college plans, and loss of friends and family members.

We asked respondents how the COVID-19 pandemic has impacted them using fixed responses and instructed them to select all responses that apply. These are the top COVID-19 impacts reported by survey respondents in order of impact in Table 1.

Table 1
COVID-19 impacts as reported by survey respondents (n = 130)

COVID-19 Impacts	n	% of Responses
Are not as active	25	19%
Other*	23	17%
Have not been able to participate in cultural activities and ceremonies	20	15%
Are more anxious	16	12%
Are not able to access resources they need to stay healthy	12	9%
Don't have anyone they can talk to about how they feel	9	7%
Feel more depressed	9	7%
Don't feel positive about the future	6	5%
Don't have access to reliable technology and therefore are getting behind in school	6	5%
Engaging in unhealthy behaviors	3	2%

*Other responses (*n* = 23) were sports, everything is virtual, no impacts, being a teen mom, nervous about the army, closer to a higher power, and feeling shy.

Rising Above

With the COVID-19 impacts in mind, the team reflected on what they saw, felt, heard, and know using IEF prompts as a guide (LaFrance & Nichols, 2010).

What did you see?

Our four partnerships in Montana and South Dakota had to be creative to deliver the cultural activities to their youth, elders, and community by Zoom webinars, digital stories, and other videos of sacred sites. The gatherings had to be smaller in size due to COVID-19 protocols. During a normal year, the youth and elders would have journeyed to the sacred sites to camp, make offerings, and prayers. This was not possible due to COVID-19. Sites adapted to COVID-19

meeting restrictions. One site created a 45-minute video of their sacred sites located on the Northern Plains. The students viewed this video, and their homework assignment was to prepare a short presentation to be delivered at their annual pow wow. They also completed a written report on their thoughts and feelings after viewing the sacred site videos. Documenting the reach of activities and the impact transitioned from paper to online methods. This impacted our ability to evaluate the full reach of activities and youth perspectives. We observed fewer social interactions and dialogue between participants during in-person gatherings and virtual meetings. Before COVID-19 our evaluation team would attend events in person, take photos and use photos as a data source, conduct interviews on-site, and collect paper surveys. The transition to online methods made it difficult to fully evaluate the value and impact of activities.

What did you feel?

The pandemic highlighted the ongoing health disparities among AI/ANs in the United States. There were many losses to families, friends, and coworkers. The traditional funeral services and hospital visits were not allowed due to COVID-19, and this made the grief work and healing more difficult. The youth were impacted as a result of their social isolation from their peers and school activities. Youth reported being depressed, anxious, and frustrated. Rural isolation and lack of internet services and laptops made virtual education and training difficult. Despite the negative impacts, youth, adults, elders, and tribal leaders demonstrated resilience amidst the challenges. For example, one survey respondent wrote, "Native PRIDE taught me to depend on my strengths when I am down." Another responded, "I continue to use my cultural ceremonies Inipi and Sundance for strength." The communities quickly adopted life-saving measures and supported one another, getting to the vaccination thresholds that would allow in-person activities. Through the strength of our Native culture and spirituality, the tribal communities continue to rise above the negative impacts of the COVID-19 pandemic.

What did you hear?

We heard from our youth, adults, and elders the sorrow they felt for the loss of their friends and family members. We also heard stories of post-traumatic stress disorder (PTSD) and severe side effects of those recovering from COVID-19. The pandemic put our Native communities in survival mode where the schools and community centers were transformed into sites to deliver food, clothing, medical equipment, and housing for community members. We also heard stories of children who lost both parents to COVID-19 and were seeking shelter from relatives and social

services. Many adults lost their jobs and were unable to pay their mortgage and car payments. This financial burden created much anxiety for both youth and adults.

What do you know now?

We know now that culture- and resilience-based mentoring, activities, and training can be successfully delivered in a virtual format, although it is not as impactful as in-person sessions. We also know the power of Native spirituality and ceremonies that continue to give hope and faith to the people during the pandemic and during the losses that continue to occur to community members. The pandemic reminded us that our Native spirituality is our greatest source of strength. The ongoing trauma, tragedies, threats, and other stresses, for example, the murdered and missing AI/AN men and women, continue to occur in our communities. Therefore, we are reminded of the importance of strengthening cultural resilience by providing access and opportunities for our youth, elders, and adults.

How did you rise above?

Our communities coped with the ongoing trauma using cultural resilience that we have acquired over many generations who have witnessed and experienced the impact of colonization upon our Native people. It is not new to us, and we have the valuable cultural teachings that guide us in our pursuit to be a good relative to those that are suffering losses and other stresses in their lives. It is important to be mindful that we need to focus on each day and not to be overwhelmed and anxious about what might happen in the future and to keep hope and faith alive through cultural teachings. Cultural teachings can be shared in small virtual activities with youth, elders, and adults and we can inspire hope and purpose by encouraging people to be peer mentors, to be flexible, compassionate towards each other, and have faith in the creators. Our ICP victory celebrations in July and August 2021 with our four ICP communities in Montana and South Dakota were successful in honoring the accomplishments of the youth and elders during the past five years in the ICP.

Limitations

Results presented here outline how Native PRIDE and four ICP communities continued to implement a culture-based mentoring program during COVID-19. The IEF and guiding questions are not meant to be generalizable or comprehensive. Rather, responses to the IEF questions are intended to provide insight about rising above during the COVID-19 pandemic. These responses

reflect the perspectives of Native PRIDE staff and site coordinators. Additional responses and lessons on rising above may have emerged if more individuals were involved in the qualitative data collection.

COVID-19 impacts documented in the online survey represent only those individuals that completed the survey; they do not represent all AI/AN youth, elders, or communities. Since the time the data were collected (March 2021), impacts may have changed or become more pronounced. Even with these limitations, the Native PRIDE story of rising above must be known and shared. Findings presented here contribute to a larger body of Indigenous literature that underscores the importance of culture, spirituality, and being a good relative (Fleming & Ledogar, 2008).

Final Thoughts

Native PRIDE recognizes that the lessons learned during COVID-19 are gifts of knowledge, grace, perseverance, and patience. These lessons may be useful to other AI/AN community-based projects as they navigate the uncertainty of COVID-19. Communities rise above. Skills, relationships, and knowledge gained during the ICP will sustain elders, youth, and communities as they begin the next journey of their lives, beyond COVID-19, rising above.

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FEASIBILITY AND ACCEPTABILITY OF VIRTUAL IMPLEMENTATION OF A SEXUAL REPRODUCTIVE HEALTH TEEN PREGNANCY PREVENTION PROGRAM FOR NATIVE YOUTH

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Abstract: American Indian/Alaska Native (Native) youth face high rates of substance use, teen pregnancy and sexually transmitted infections. In response to the COVID-19 pandemic, Respecting the Circle of Life (RCL), a sexual reproductive health and teen pregnancy prevention program for Native youth and their trusted adult, was adapted and delivered in a virtual format with Native youth in a rural, reservation-based Native community. This manuscript describes the adaptation process, feasibility, and acceptability of virtual program implementation. The manuscript describes the process of rapidly shifting the RCL program into a virtual format. In addition, a mixed-methods process evaluation of implementation forms, program feedback forms, in-depth interviews with participants, and staff debriefing sessions was completed. Results show virtual implementation of RCL is both feasible and acceptable for Native youth and their trusted adults. A key benefit of virtual implementation is the flexibility in scheduling and ability to have smaller groups of youth, which offers greater privacy for youth participants compared to in-person implementation with larger groups. However, internet connectivity did present a challenge for virtual implementation. Ultimately, sexual and reproductive health programs seeking to reach Native youth and families should consider virtual implementation methods, both during and outside of pandemic situations.

INTRODUCTION

American Indian and Alaska Native (Native) youth endure inter-related health disparities related to poor substance use and sexual health. Recent research shows Native youth are the second most likely to initiate sex before age 13 compared to all other racial groups, increasing the potential

frequency and duration of exposure to unprotected sex (Centers for Disease Control and Prevention [CDC], 2019). Though teen pregnancy rates in general are declining, Native females have the highest teen birth rate (29.7 vs. 17.4/1,000 nationally) and the highest repeat teen pregnancy rate in the United States (Martin et al., 2018). In 2018, Native teens had the second highest rates of chlamydia, gonorrhea, and syphilis in the nation—2.8 times higher for chlamydia (2445.1 vs 890.7/100,000), 4.2 times higher for gonorrhea (554.9 vs. 132.9/100,000), and 4.6 times higher for syphilis (14.4 vs. 3.1/100,000) than their White peers (CDC, 2019). Early substance use initiation and progression to use and abuse increases risk for sexually transmitted infections (STIs) and unintended pregnancy. Native youth more often report first alcohol use before age 13 than other youth (18.7% vs. 15.0% for all races) and greater frequency of current drinking (32.6% vs. 29.2% for all races). These trends of early initiation and current use are similar for marijuana, prescription drugs, cocaine, heroin, and other illicit drugs (CDC, 2019).

These health disparities may be further exacerbated by the COVID-19 pandemic which is disproportionately impacting Native communities. Even though adolescents and young adults are at lower risk of hospitalization and severe illness due to COVID-19 for now, the pandemic has and will continue to affect other aspects of young adult health, including their physical, mental, and social health (Lindberg et al., 2020). Key focal points of socialization and community resources, such as schools and community centers have closed, adding further stress to already overburdened health systems in tribal nations. The global focus has necessarily shifted to saving lives, with restrictions and lockdowns limiting individuals' access to vital reproductive and substance prevention health services, commodities (like condoms and contraceptives), and education (Lindberg et al., 2020; Sharma et al., 2020). In many Native communities, including those where this project takes place, most schools did not have sexual health education classes prior to the pandemic, and those that did have since removed it from the curriculum in favor of prioritizing core subject matter amidst the transition to virtual and hybrid learning.

The pandemic also creates logistical and economic barriers to obtaining sexual and reproductive health commodities (like contraceptives) and access to health services due to lockdowns, prioritization of COVID-19-related medical services, and loss of earnings (Lindberg et al., 2020). Young adults living with relatives or guardians may lack access to confidential and private sexual and reproductive health care. This lack of privacy in other settings has shown reduced use of sexual reproductive health services and lower contraceptive use among adolescents and young adults (Copen et al., 2016; Fuentes et al., 2018; Lindberg et al., 2020).

Lindberg et al. (2020) recommend developing and disseminating online sex education curricula to address these emerging gaps for adolescents and young adults, which are further aggravated by COVID-19. Though the body of evidence for Native-specific online and internet-based sexual health programs is small, some have found success using this method of implementation. Some have raised concerns that virtual programs for youth may be impersonal and have little success in engaging youth or improving sexual/reproductive health outcomes, especially in Native contexts (Black et al., 2018). Others have found that this impersonality may actually be an advantage among youth (including non-Native youth), as an online platform affords youth a veil of anonymity for talking about sensitive topics, especially for sexual-minority youth who may not want to disclose their sexual orientation (Schwinn et al., 2015).

Those who have developed online and internet-based sexual health programs with Native and other minority youth have found that it can increase accessibility and enhance reach of culturally grounded programs for at-risk minority youth and their parents (Black et al., 2018; Guilamo-Ramos et al., 2015; Kalichman et al., 2006; Markham et al., 2016). Involving parents in these internet-based approaches has also proven to be successful in improving parental communication and sexual health knowledge (Guilamo-Ramos et al., 2015; Shegog et al., 2021). Promisingly, Native adults have had high engagement in online evidence-based interventions (Hiratsuka et al., 2019; Sacca et al., 2021; Stotz et al., 2021). There is also existing evidence that online sexual health programming can effectively engage both Native parents and teens, such as the "Talking is Power" text messaging service (Sacca et al., 2021). Other sexual reproductive health programs for Native youth have also been successfully adapted from in-person implementation (Black et al., 2018).

The Respecting the Circle of Life (RCL) program is a proven evidence-based teen pregnancy prevention and sexual health promotion program that was originally developed to be delivered in-person (Tingey et al., 2017, 2021; Patel et al., 2021). The Johns Hopkins Center for American Indian Health received a grant, as well as institutional and tribal IRB approval, to implement the RCL program with Native youth ages 11-19 and their trusted adults, slated to begin in Summer 2020. In late Spring 2020, the program team made the decision to convert RCL from an in-person to virtual program, to ensure the safety of our staff and community. The pandemic has forced many programs to make this pivot from in-person to virtual implementation, and the authors hope that this publication will add to the growing body of literature on converting and implementing programs for Native youth in a virtual and online format. This publication will outline our team's pivot to virtual

programming, as well as the acceptability and feasibility of virtual sexual health programming among youth and trusted adult participants in the community we implemented this program in.

METHODS

Converting RCL Curriculum from In-Person to Virtual

In-Person Program

The RCL program was originally designed to be implemented with youth ages 11-19 and their trusted adult (TA; a parent or caregiver selected by the youth), through eight youth peer-group lessons and a ninth, home-based youth-TA lesson. All lessons were to be delivered in-person. The eight peer-group lessons would be taught during a 10-day basketball camp (the first two days would not include any lessons but would be a time for registration), where enrolled youth ages 11-19 would spend two hours each day learning basketball skills and then receive one RCL lesson (~2 hours per lesson). RCL lessons would be delivered to self-selected peer-groups of 8 to 12 youth, comprised of the same gender and age-ranges. Youth would then complete a ninth lesson which would be delivered in the home of the participant together with their enrolled TA. All classroom lessons would be taught by two Native paraprofessional facilitators, then one of these same facilitators would teach the ninth lesson to the youth and their TA at home.

Pivot to Virtual Implementation

As COVID-19 cases were rising in the participating community and stay-at-home orders were put in place, the program team made the decision to switch to a virtual-only approach for implementation. To shift from an in-person to virtual curriculum, key changes were made to the duration of the program, activity implementation style, and program structure. These changes were determined in tandem by the program team, curriculum team, key tribal stakeholders, and the target population as necessary for optimal implementation in a virtual format. The key changes are as follows: 1) platform choice, 2) lesson length, 3) facilitation structure, 4) pacing, 5) lesson materials, 6) lesson privacy, and 7) curriculum adaptation.

Platform Choice

The target population and key tribal stakeholders were surveyed over the phone to ascertain internet availability and platform preference to ensure that the platform chosen would be accessible and accepted by the community. Zoom was chosen as the platform of choice.

Lesson Length

It was determined that the lessons would be shortened. The nine (eight lessons for youth only, one lesson for youth and their TA) 2-hour lessons would be cut to 45 minutes to 1-hour lessons in the virtual format, as attention spans were known to be shorter during a virtual, screen-based intervention (Wiederhold, 2020). This led to ten, 45–60-minute lessons for youth, and two, 45–60-minute lessons for youth and their TA for the virtual format. The program team determined it was important to keep the youth-TA lesson as results from past RCL evaluations have shown the youth-TA lesson enhances and extends RCL program impacts (Patel et al., 2021; Tingey et al., 2015, 2017, 2019).

Facilitation Structure

It was determined that the original facilitation structure would be maintained. Each youth lesson would be taught by two Native paraprofessional facilitators, and each youth-TA lesson would be taught by one Native paraprofessional facilitator over Zoom. Lessons would still be taught to youth in self-selected peer groups of up to 10 youth. Youth were informed of the peer group structure and asked to select and enroll with their own peer groups, with the knowledge that the groups could be comprised of any gender and age mix that the youth felt comfortable in and could be as small as one youth or as large as ten youth.

Pacing

Lessons would be self-paced for groups, as opposed to being taught over the course of eight consecutive days. Self-selected peer groups worked with their assigned facilitators to determine a pace for completing the program as a group. This was done with great flexibility, as some groups could readily determine their availability ahead of time and other groups needed a week-by-week scheduling approach due to the many disruptions to daily life brought on by the pandemic.

Lesson Materials

Workbooks and lesson materials (e.g., condoms) would be necessary for effective implementation and, thus, would be safely delivered by mail or home drop-off to youth and TA participants prior to their first lesson, based on participant preference.

Lesson Privacy

TAs and youth were asked to take part in the lessons in a private, secluded location to ensure confidentiality and encourage participation. If a private, secluded location could not be

readily found, facilitators worked with participants to identify such a location, like unoccupied rooms at project offices or school classrooms.

Curriculum Adaptation

Converting the in-person curriculum to a virtual format constituted the brunt of the adaptation process and contributed to the above aspects of adaptation. A deep dive of the curriculum was conducted by the curriculum team, in tandem with experienced Native facilitators and community stakeholders, to better understand what aspects of the program could remain the same in a virtual context, as well as activities that would need to be significantly altered to ensure key messages were retained. The entirety of the RCL curriculum was outlined, lesson by lesson, activity by activity, with key messages and facts laid out. Then, each activity was analyzed and reviewed for virtual implementation by the curriculum team. This analysis included looking at the activity with an eye for: 1) What could remain as is; 2) What needed slight modifications (for example, instead of writing something on the board, it would be shared via a PowerPoint slide or written on a document shared on the screen); and 3) What could be altered in style, but not in content (for example, instead of a live demonstration showing the effects of oil-based and water-based lubricants on condoms, a short video could be used).

Careful consideration was taken to better understand how lessons could be adapted for virtual implementation by the curriculum team. Activities that were tactile and required large group participation would be difficult, if not impossible, to conduct in a virtual format. A few of these instances resulted in activities being dropped from the virtual implementation, but for most activities, the key messages were reinforced in a manner conducive to a virtual format. For example, many RCL activities required that the facilitators write on poster papers, but the virtual format allowed youth to add their own thoughts by typing or drawing on the Zoom whiteboard.

Some concepts normally taught in a lecture style format during in-person programming needed to be altered to be more appealing and engaging virtually. The team found animated, engaging, age-appropriate videos by reputable sexual health education content creators, like Advocates for Youth's AMAZE.org, that very closely matched the RCL curriculum, which were used in the virtual RCL program in place of a lecture-style format (Advocates for Youth, n.d.). The content of the videos was matched with curriculum content to ensure that no messaging or concepts would be lost when altering activity formats. Lesson activities were also adapted to better use features of Zoom, including the whiteboard, polling, and share screen. In addition, alternate, visual

methods were selected to convey key messages, including using PowerPoints with images as well as medically and factually accurate videos to better engage youth compared to a lecture-style format.

RCL was originally intended to be iterative, with large key concepts reinforced and taught in increments over the course of eight consecutive days. As the virtual format would be self-paced, ideally implemented over the course of six weeks, the iterative nature of the original RCL format would not be as effective as more time could pass between lessons and retention of minute details may be lost by youth. Thus, the structure of RCL was reorganized to accommodate these changes in the delivery timeline. Instead of being broken up over several lessons, facilitators taught key concepts together and more holistically during each lesson to prevent loss of nuance needed to learn larger concepts.

Finally, most of the activities were adjusted for time, shortening examples or time spent in discussion, allowing the main points to be highlighted while maintaining interest in the virtual format. The adapted lessons were shared with expert Native facilitators for final comment before piloting, with the intention that ongoing facilitator feedback would be incorporated as the curriculum was implemented to strengthen the program.

Final Curriculum and Training

This careful adaptation of the RCL curriculum resulted in twelve, 45–60-minute lessons (10 for youth only and 2 for youth and their TA). It is important to note that much of the content of RCL remained the same, with all key content kept intact. See Table 1 for a detailed comparison of lessons and activities of in-person and virtual formats of RCL. Once the RCL curriculum was adapted to a virtual format, all facilitators were thoroughly trained in the virtual curriculum, as well as in using Zoom and related technical skills. The trainings for facilitators were conducted virtually and required that facilitators conduct virtual mock implementation, or teach backs, to practice teaching the virtual RCL program to the larger group of facilitators and the curriculum team, to mimic the virtual implementation they would do with participants. These trainings took place over the course of two weeks and were recorded so that facilitators could always have the trainings on hand for reference.

Virtual Implementation Participants

Participants were youth and their TA who participated in RCL. Youth were ages 11-19, had primary residence on or near the participating tribal reservation community, self-identified as

Native American ethnicity, and had a TA willing to participate in the program. TAs could be parents, guardians, grandparents, aunts, uncles, or any adult 18 years of age or over in the community with whom the youth felt comfortable. Participants were recruited using safe, socially distanced measures, including word of mouth, social media, partnerships with local schools, and flyers posted in community gathering spots, such as grocery stores. Facilitators explained the program and assessment structure over the phone or on a video call prior to enrolling youth, TAs, and parents and legal guardians (if youth were under the age of 18).

Table 1
Comparison of RCL curriculum before and after adaptation

RCL In-Person Curriculum	RCL Virtual Curriculum
Lesson 1: Building Respect: We're in this Together - Overview - Group Cohesion - Group Agreements - Family Tree - Decision Making Steps 1-2	Lesson 1: Overview and Family Tree - Overview - Group Agreements - Family Tree
Lesson 2: Honoring Ourselves and Our Values - Identifying Risks - Values	Lesson 2: What are the Risks? Identifying Risks
Lesson 3: Puberty: Understanding What's Happening to You - Decision Making Step 3 - Resources - Identity - Puberty and Anatomy	Lesson 3: Making Decisions: Resources, Values, and SPIRIT Problem Solving Tool - Resources - Values - Decision Making Steps 1-6
Lesson 4: The Best Decision for Me! - Communication with TA - Peer Behaviors - Condom Demonstration and Experiments - Decision Making Step 4	Lesson 4: The Human Body and Puberty - Identity - Puberty and Anatomy
Lesson 5: Communicating for a Healthier You - Decision Making Steps 5-6 - Communication Games - Communication Styles - Consent and Sexual Assault	Lesson 5: Protection - Peer Behaviors - Condom Demonstration and Experiments
Lesson 6: Reducing My Risk for STDs & Pregnancy - Showing You Care - STD and Unplanned Pregnancy Game - Contraceptive Methods	Lesson 6: Communication - Communication with TA - Communication Styles

continued on next page

Table 1 continued
Comparison of RCL Curriculum before and after adaptation

RCL In-Person Curriculum	RCL Virtual Curriculum
Lesson 7: The Skills and Wills to Make My Own Choice - Teen Parent Speaker - Sticking with Values and Decisions - Safer Sex Guidelines	Lesson 7: Sex: A Decision for Two Consent and Sexual Assault
Lesson 8: Looking Towards my Future - Goal Setting - Identifying Concerns - Being a Leader - Review - Building Self-Esteem	Lesson 8: Showing You Care - Showing You Care - Contraceptive Methods
Parent/TA Lesson - Sexual Health 101 - RCL Youth and Parent/TA Video - Effective Communication - Condom Demonstration - Talking with Your Youth Roleplays - Goal Setting	Lesson 9: Respecting Values - Teen Parent Video - Safer Sex Guidelines - Sticking with Values and Decisions
	Lesson 10: Goals - Goal Setting - Identifying Concerns - Being a Leader
	Parent/TA Lesson Part 1 - Sexual Health 101 - RCL Youth and Parent/TA Video - Condom Demonstration
	Parent/TA Lesson Part 2 - Effective Communication - Talking with Your Youth Roleplays - Goal Setting

Measures

Our goal was to understand the feasibility and acceptability of delivering RCL in a virtual format. Demographic data, including age and gender, was collected for all participants. Implementation Forms (IFs), Program Feedback Forms (PFFs), and In-Depth Interviews (IDIs) were specifically designed for this program and conducted with youth and TA participants. IFs were specific to each lesson, with 12 youth IFs and 2 TA IFs, with each IF taking ~5-10 minutes to complete. Youth and TA participants were asked to complete IFs immediately after receiving each lesson. The IFs included questions with response options on a five-point Likert scale

(Strongly Agree to Strongly Disagree) asking about particular activities and the lesson overall (e.g., "I liked this activity," "I like that this lesson was taught virtually [over the phone, computer, or tablet]"). The IFs also included multiple choice knowledge questions to check for understanding. PFFs asked about the program as a whole and were completed once by youth and TAs within two weeks of program completion.

IFs and PFFs were delivered via emailed survey, where participants could complete them on their own phones, computers, or other devices. All emailed surveys were sent from and stored on REDCap, a secure data management and capture program with a HIPPA compliant server. If participants preferred hard copies of IFs or PFFs, they were safely delivered to and collected from participants following standardized safety protocols, and then manually entered into REDCap by program staff. All data were collected using a unique participant identification number. Youth received a $30 gift card and TAs received a $20 gift card for completing all IFs and PFFs. Youth also received one weekly raffle prize entry per completed IF, which included prizes with a monetary value of <$50 such as blue tooth headphones, bikes, and tents. Facilitators reminded participants to fill out the IFs and PFFs at the end of the lesson and gave verbal, email, and/or text reminders to all participants to complete the forms, with further reminders if forms were not filled out within 2 weeks of the expected return date.

After program completion, youth and TAs were asked if they wanted to participate in an optional IDI to speak about their experience participating in the virtual RCL program. IDIs were conducted to deepen understanding of virtual implementation acceptability and feasibility among participants. IDIs followed a written qualitative guide, took place over the phone or Zoom, and took approximately 1 hour to complete. To reduce response bias, the IDIs were conducted by program staff that participants had not interacted with before (e.g., not their lesson facilitators). Youth and TAs received a $20 gift card for participating in the IDIs.

Continuous Quality Improvement

As this was a new format for RCL, continuous quality improvement was used to further adapt the program during virtual implementation. IFs and PFFs were analyzed in real time, with data summarized weekly. In addition, weekly debriefing lessons with facilitators and program staff were conducted to review the information from the IFs and PFFs and discuss feedback from facilitators, to better understand virtual program implementation, as well as assist in resolving any issues that arose. Debriefs took place over Zoom and were facilitated by the Program Coordinator.

It should be noted that immediate steps were taken to alter activities that facilitators found to be culturally incompatible, and those same activities were then found to be culturally competent after alteration. Through the weekly debriefs, language in the RCL virtual curriculum was refined and technical glitches were addressed. In addition, the debriefs provided a space for facilitators to discuss tips and strategies for virtual implementation, such as engaging youth over a screen and how to navigate between documents and platforms.

Analysis

Responses on IFs and PFFs were grouped. "Strongly agree" and "agree" were combined, "neither" was left as its own group, and "strongly disagree" and "disagree" were combined, resulting in 3 groups. Data was assessed across lessons. The total count of the responses and the percentage of responses for each group were calculated for questions that were the same across all implementation forms. For PFF data, the total count of the responses and the percentage of responses were calculated for each question by group.

IDIs were conducted with youth and TAs after completion of the program. Twelve youth and 12 TAs participated in an interview and were asked about their experience with the RCL program using an interview guide developed by the team. Additionally, 11 debrief meetings with program staff over the course of the implementation process were recorded and transcribed. In total, 35 transcripts (youth, TA, and debriefs) were coded and analyzed. Computer-assisted qualitative data analysis software NVivo was used for data management. The qualitative analysis process followed an inductive thematic approach using four distinct phases: familiarization of data, codebook development, code assignment, and theme identification. The codebook was developed collaboratively with the analysis team and two coders were used to ensure reliability. The themes drawn from the transcripts were discussed by the analysis team and synthesized for the purpose of this publication. Counts for debriefs and IDIs for TAs and youth were tallied by theme, as explored in the results below.

RESULTS

Implementation Forms (IFs) and Program Feedback Forms (PFFs)

In total, 550 IFs were collected from 60 youth participants across twelve lessons and 79 IFs were collected from 41 TA participants across two lessons, and 37 youth PFFs and 37 TA PFFs

were collected. At time of analysis, 37 youth and TAs had completed the program. Overall, youth and TAs were in accordance with each other in their views across IFs and PFFs. Youth and TAs enjoyed participating in the RCL program virtually, with 87.73% of youth and 92.65% of TAs indicating that they liked doing RCL virtually in results from the IFs (Table 2). Similarly, 81.25% of youth and 100.00% of TAs indicated that they liked doing RCL virtually in results from the PFFs (Table 3). RCL was well liked—94.59% of youth and 100.00% of the TAs liked the RCL program overall (Table 3). When asked in the PFFs, 43.24% of youth and 62.16% of TAs wished that there were more youth lessons (Table 3). Overall, 92.57% of youth and 100.0% of TAs indicated that they understood the way things were explained (Table 2). Ease of joining lessons was also assessed—72.72% of youth felt that it was easy to get online and join lessons, and 91.18% of TAs felt that their child was able to get a computer and internet to join the lessons (Table 3).

Only 11.15% of youth and 13.16% of TAs in the IFs indicated that the lessons were too long, while only 10.99% of youth and 6.58% of TAs indicated that the lessons were too short (Table 2). The majority of youth and TAs felt comfortable asking questions according to the IFs, with 83.90% of youth and 100.00% of TAs agreeing or strongly agreeing with the statement, "I feel comfortable asking questions" (Table 2). Likewise, in the PFFs, 89.19% of youth and 97.29% of TAs felt like they could ask their facilitator questions (Table 3). In regards to whether facilitators were acceptable to participants, 94.59% of youth and 100.00% of TAs felt that the facilitators knew what they were talking about and were knowledgeable (Table 3).

In-depth Interviews (IDIs) and Debriefs

Overall, many participants felt that virtual implementation provided an effective alternative to in-person implementation during the COVID-19 pandemic. Nine TAs specifically cited COVID-19 safety as a reason that virtual implementation was preferred, stating that safety was taken into consideration, as well as ensuring that youth would still receive RCL. The virtual format allowed youth to be comfortable and engaged in RCL ($n = 1$ debrief, $n = 5$ TAs, and $n = 2$ youth). Another explicit benefit of virtual implementation was the flexibility for scheduling and coordination, often due to the facilitators' willingness to schedule (and re-schedule) around TA and youth availability ($n = 4$ TAs). TAs and youth cited that the virtual format was preferred, both given the pandemic and as a personal preference over in-person ($n = 3$ TAs and $n = 4$ youth). The videos, which otherwise would not have been included, were seen as advantages of the virtual format by both facilitators during debriefs and TAs ($n = 1$ debrief and $n = 2$ TAs).

Table 2
Implementation Form (IF) results

	Strongly Agree or Agree %(n)	Neither %(n)	Strongly Disagree or Disagree %(n)
Youth			
I liked doing this activity virtually	87.73% (415)	9.31% (44)	2.96% (14)
I felt comfortable asking questions	83.90% (448)	12.36% (66)	3.75% (20)
The lesson was too long	11.15% (60)	33.64% (181)	55.20% (297)
The lesson was too short	10.99% (59)	31.28% (168)	57.73% (310)
I understood the way things were explained to me during this lesson	92.57% (498)	6.32% (34)	1.12% (6)
Trusted Adult			
I liked doing this activity virtually	92.65% (63)	7.35% (5)	0.00% (0)
I felt comfortable asking questions	100.00% (7)	0.00% (0)	0.00% (0)
The lesson was too long	13.16% (10)	35.53% (27)	51.32% (39)
The lesson was too short	6.58% (5)	43.42% (33)	50.00% (38)
I understood the way things were explained to me during this lesson	100.00% (76)	0.00% (0)	0.00% (0)

Table 3
Program Feedback Form (PFF) results

	Strongly Agree or Agree %(n)	Neither %(n)	Strongly Disagree or Disagree %(n)
Youth			
Overall, I liked the RCL Program	94.59% (35)	5.41% (2)	0.00% (0)
I liked that the program was taught online/virtually	81.25% (26)	15.63% (5)	3.13% (1)
I wish there were more lessons	43.24% (16)	32.43% (12)	21.62% (8)
It was easy to get online and join lessons	72.72% (24)	12.12% (4)	15.15% (5)
My facilitators knew what they were talking about	94.59% (35)	2.70% (1)	2.70% (1)
I felt like I could ask my facilitators questions	89.19% (33)	10.81% (4)	0.00% (0)
I enjoyed learning the things I did during the program	91.89% (34)	8.11% (3)	0.00% (0)
The skills I learned during the program are useful	89.19% (33)	0.00% (0)	10.81% (4)
Trusted Adult			
Overall, I liked the 2 RCL TA-youth lessons	100.00% (36)	0.00% (0)	0.00% (0)
I liked how the lessons were taught virtually	100.00% (34)	0.00% (0)	0.00% (0)
I wish there were more lessons for myself and my child	62.16% (23)	37.84% (14)	0.00% (0)
My child was able to get a computer and Wi-Fi/ internet to join the lessons	91.18% (31)	8.82% (3)	0.00% (0)
The person who taught my lessons was knowledgeable	100.00% (36)	0.00% (0)	0.00% (0)
I felt like I could ask questions during the lessons	97.29% (36)	2.70% (1)	0.00% (0)

Virtual implementation was not without its concerns. Facilitators struggled with engaging some youth, including some who would not turn on their cameras, making it difficult to ascertain engagement ($n = 5$ debriefs). "Zoom fatigue" was also mentioned (n = 1 debrief and n = 2 TAs) as youth were tired of being online all day due to a combination of virtual schooling and virtual RCL. Six TAs felt that RCL would have benefited from in-person interaction and rapport building, which felt missing in a virtual format. Some youth and TAs noted that there were external conflicts that prevented smooth RCL implementation, including scheduling conflicts, as well as competing commitments, like work, family, and pandemic-related disruptions, that prevented the youth and TAs from having a dedicated focus on RCL ($n = 2$ debriefs, $n = 4$ TAs, and $n = 2$ youth).

A small number of youth, TAs, and facilitators felt that in-person implementation would be preferable to virtual implementation of RCL for a variety of reasons. Some felt that in-person implementation would improve comfortability and openness of the youth ($n = 1$ debrief and $n = 3$ TAs), increase youth engagement with facilitators ($n = 3$ TAs and $n = 1$ youth), and increase youth engagement in the material by virtue of more hands-on and in-person experiences ($n = 1$ debrief, $n = 1$ TA, and $n = 1$ youth). Peer support was also cited as an advantage of in-person implementation, including the potential to increase youth engagement with their peers ($n = 3$ TAs and $n = 1$ youth). Others felt that in-person implementation would be a hinderance, especially for more shy youth who may be hesitant to openly participating and asking questions in a group setting ($n = 3$ TAs and $n = 4$ youth).

Content appropriateness varied, but was generally found to be acceptable across age, topic area, and culture. Age and gender were often cited as reasons that the content did not feel appropriate. Three debriefs and 2 TAs cited that their youth, who in all instances were 11 years of age, were too young for the RCL content. However, 7 TAs and 1 youth cited that the content was age appropriate across the 11 to 19 age range. Two TAs and 1 youth stated that male youth were not mature enough for the content, compared to female youth. Overwhelmingly, however, the content was found to be appropriate, relevant, and covered topics that may be uncomfortable but were deemed necessary and useful to learn ($n = 2$ debriefs, $n = 12$ TAs, and $n = 6$ youth).

Culturally, many mentioned that sexual and reproductive health is not spoken about openly in their community, especially between certain relatives, and could be a cause for discomfort, though these same people expressed that the content itself was valuable and should be spoken about and taught ($n = 1$ debrief and $n = 7$ TAs). Seven TAs mentioned that the content was

culturally appropriate, and some also flagged that including Elders in the content emphasized the cultural appropriateness of the material by virtue of their buy-in (n = 7 TAs).

Specific curriculum content was also highlighted during the debriefs and IDIs. Two activities were flagged by facilitators to be changed for clarity and cultural context during four debriefs, including an activity on the family tree that required a refresher training for facilitators and an activity on contraceptive methods that was augmented with visuals for clarity. The curriculum specificity was praised, including the value of workbooks filled with statistics and facts that TAs and youth could reference long after program implementation ended (n = 3 debriefs and n = 7 TAs). TAs and youth praised the overall RCL curriculum flow and comprehensive nature of the content (n = 9 TAs and n = 3 youth). Some activities were highly praised or disliked. TAs and youth thoroughly enjoyed roleplaying (n = 4 TAs and n = 1 youth) and the goal setting activities (n = 3 TAs and n = 4 youth). The condom demonstration was viewed by some as an uncomfortable activity, though it was acknowledged as teaching a valuable skill (n = 2 debrief, n = 3 TA, and n = 3 youth). Two TAs and 2 youth specifically mentioned enjoying the condom demonstration as it taught valuable, concrete skills that TAs felt they would not have known how to teach to their youth themselves. The youth/TA lessons were also well received by the majority of TAs and youth interviewed, and most often seen as a source of increased communication and relationship building between the youth and TA (n = 11 TAs and n = 9 youth).

RCL program delivery, including facilitator personalities, group implementation, timing, and scheduling were discussed during the interviews. Thirteen TAs found that the facilitators themselves were pleasant, knowledgeable, and warm, which encouraged participation in RCL. In terms of group size, there were mixed thoughts. Some youth seemed to desire one-on-one lessons, especially if they were shy (n = 3 debriefs, n = 1 TA, and n = 6 youth), while some youth wanted to participate in RCL with their peers or siblings in a group setting (n = 1 debrief, n = 3 TAs, and n = 4 youth). Facilitators mentioned that some lessons went over time, and that pacing was difficult (n = 6 debriefs), but both TAs and youth felt that the lessons were the appropriate length of time and had nice pacing (n = 5 TAs and n = 2 youth). Scheduling was also frequently mentioned by facilitators, TAs, and youth as a difficulty. Facilitators often struggled with back-to-back lessons leading to longer working days and having to re-schedule often with participants (n = 3 debriefs). However, TAs and youth found the flexibility in scheduling as helpful and allowed for better engagement in RCL, especially when lack of internet connectivity required rescheduling (n = 5 TAs and n = 4 youth).

Specific questions targeted technology accessibility and use. A common issue flagged by facilitators, TAs, and youth alike was internet connectivity (internet cutting in and out or not connecting at all) as a barrier to easy implementation, requiring quick thinking on the part of facilitators or even rescheduling of lessons ($n = 3$ debriefs, $n = 7$ TAs, and $n = 6$ youth). Some of these participants cited intentionally seeking Wi-Fi-accessible areas to ensure that they could join RCL lessons, including sitting in their vehicles at restaurant parking lots to use their Wi-Fi. However, there were some participants who did not find internet connectivity to be an issue ($n = 4$ TAs and $n = 2$ youth). Overall, phones, tablets, and computers were used by participants to join RCL lessons. Facilitators found that when participants joined by phone, participants could not clearly see lesson material on the smaller screen, hindering thorough engagement ($n = 3$ debriefs). TAs and youth did find it easy to join and engage in the virtual programs using their phones, tablets, and computers ($n = 2$ TAs and $n = 4$ youth). Zoom was preferred and found to be an easy and functional option for virtual implementation by all 12 TAs interviewed and 11 youth interviewed.

DISCUSSION

It seems both feasible and acceptable for Native youth and their TAs to participate in a virtual sexual reproductive health teen pregnancy prevention program, as evidenced by the generally positive results outlined in detail above. Overall, both youth and TAs enjoyed their time in the program and seemed to understand the content and material taught in a virtual format.

Youth and TAs reported similar experiences with the virtual implementation of RCL. Both groups overwhelmingly enjoyed completing RCL virtually, felt comfortable asking questions, understood the material being presented, and felt that the lessons were of appropriate length. It should be noted that speaking about sexual and reproductive health may be uncomfortable, as highlighted by the IDIs, and may have factored into overall participant comfortability in asking questions, as mentioned by several TAs during their IDIs. The condom demonstration activity was mentioned as an uncomfortable activity for some, but it is integral and valuable in sexual and reproductive health programs, including RCL (Tingey et al., 2015, 2017). Many youth and TAs also acknowledged its utility, despite feeling uncomfortable.

A key benefit of virtual implementation is the flexibility afforded to participants in finding times that work best for them. Times are fixed in an in-person format, which may pose a barrier to

enrollment for some participants. In addition, the ability to have smaller or one-on-one groups afforded privacy and appealed to youth who were shyer and more reticent to participation and engagement in sexual reproductive health content in larger group or in-person settings. This emphasizes the important need to continue offering virtual or hybrid modes of implementation to reach participants who may not otherwise join in-person programs, even if and when pandemic-related safety requirements are no longer a concern.

Technological barriers, specifically internet connectivity, presented a challenge for implementation, and in many cases led to rescheduling of lessons, adding a burden to facilitators and participants alike. In the participating community, efforts had been made to increase internet access at a large-scale level during the pandemic, especially as many youth were participating in remote learning for school, though internet connectivity gaps remained. It should also be noted that many youth who participated in the virtual RCL program received laptops from school for remote learning, which were used by some youth to participate in RCL virtually. Internet and computer access must be a key consideration for virtual implementation of programs, especially in similar rural settings.

Adapting an in-person program to a virtual format required tremendous effort on the part of curriculum, program, and implementation staff to thoughtfully adapt the curriculum and implement it. In addition to this publication, there are also other helpful resources that exist to aid in adapting an in-person program to a virtual format, such as the Healthy Native Youth: Virtual Adaptation Guidebook (Trevino & Gaston, 2020).

Our virtual program presented additional challenges for recruitment, as participants needed to be able to reliably access online platforms and previous programs did not necessarily rely as heavily on online-based recruitment strategies. Our team persisted by adapting word of mouth as a recruitment strategy by contacting local schools for partnerships and using catchy social media posts to recruit. However, high quality training of staff to use new technology is needed to ensure smooth virtual implementation, which can be time intensive. Also, the added costs of upgraded licenses of virtual platforms like Zoom must be taken into consideration, as certain features can only be used in upgraded platforms.

Further research may be warranted to compare in-person RCL and virtual RCL outcomes. In addition, further research would be needed to better understand the specific gender and relationship dynamics of the self-selected groups formed for RCL virtual implementation. In addition, further research on the adaptation and implementation of sexual health programs into

virtual or hybrid contexts for Native youth would be valuable to better understand how programs like RCL can continue during the pandemic and beyond.

Limitations

There are many limitations to consider. First, this project was conducted to better understand how virtual implementation of RCL is received by participants and not to draw any conclusions about its utility or impact. Data for IFs and PFFs was collected via self-report from youth and TA participants, which could have resulted in biased reporting. PFF data was collected at the end of the program, which may have impacted recall. Though all participants who completed the program were asked if they would like to participate in an IDI, only those who agreed participated in the IDI portion, and this may have led to response bias. This process evaluation was conducted mid-program to better understand feasibility and acceptability for continued implementation, and results may change when RCL virtual implementation is complete. In addition, the findings are from a specific tribal community, and may not be applicable to other Native and non-Native communities.

CONCLUSION

Virtual implementation of RCL, an evidence-based sexual and reproductive health teen pregnancy prevention program for Native youth is feasible and acceptable, although not without important considerations. Programs seeking to reach Native youth, both during and outside of a pandemic, should consider virtual implementation to confer necessary education and skill building during an important period of adolescent development.

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STRONG MEN, STRONG COMMUNITIES: REVISION OF A DIABETES PREVENTION INTERVENTION FOR AMERICAN INDIAN AND ALASKA NATIVE MEN DURING THE COVID-19 PANDEMIC

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Abstract: This paper describes the revision of the in-person Strong Men, Strong Communities (SMSC) study to a remote protocol and highlights key successes, challenges, and critical lessons learned applicable to remote trial implementation. The SMSC study is the first randomized controlled trial to exclusively recruit American Indian and Alaska Native men into a diabetes prevention intervention. The five-year randomized controlled trial was in its 42nd month with 99 subjects enrolled when the COVID-19 pandemic ceased all in-person research. The study protocol was revised to accommodate remote implementation which required multiple protocol and procedural changes, including the use of Facebook for national recruitment of participants; alteration of the informed consent process; use of REDCap for independent participant completion of informed consent; revised eligibility criteria; and use of Zoom to deliver intervention classes. The remote study protocol proved superior to the in-person protocol in terms of recruitment, retention, engagement in intervention classes, and efficiency of data collection. Challenges to participation and retention included competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) to COVID-19. Future studies are needed to evaluate the effectiveness of a remote protocol in the absence of a pandemic.

INTRODUCTION

American Indian and Alaska Native (AI/AN) men have striking health disparities compared to both men of other races/ethnicities and AI/AN women (Centers for Disease Control and Prevention [CDC], 2021). For example, life expectancy for AI/AN men is 5 years less than for AI/AN women (75.8 vs. 81.1 years) and nearly three years shorter compared to non-Hispanic White (NHW) men (U.S. Department of Health and Human Services, 2022). Diabetes and obesity

are major public health issues for AI/AN men and increases in diabetes are largely attributed to an increase in obesity (CDC, 2020). The prevalence of obesity is 48% in AI/AN men versus 31% in NHW men CDC, 2018; Zhao et al., 2022), and diabetes prevalence and diabetes-related mortality is twice that of NHW men (CDC, 2019, 2021).

Outcomes from Diabetes Prevention Program (DPP) randomized controlled trial (RCT) and the Special Diabetes Program for Indians Diabetes Prevention demonstration project (SDPI-DP) indicate that type 2 diabetes can be prevented or delayed with lifestyle interventions that improve modifiable risk factors such as diet, increased physical activity, and weight loss (Eriksson & Lindgarde, 1991; Jiang et al., 2013; Knowler et al., 2002; Lindstrom et al., 2003), yet few studies have included large numbers of minority male participants or AI/AN men in particular (Jiang et al., 2018; Jiang et al., 2013; The Diabetes Prevention Program Research Group, 1999). For example, among 3,234 DPP participants, only 171 were AI/AN, of which 32% were men (Knowler et al., 2002). Similarly, only 25% of 2,553 AI/AN SDPI-DP participants were men (Jiang et al., 2013).

On average, men account for only 27% of participants across 244 studies (Pagoto et al., 2012). Extant literature offers little guidance on effective strategies to increase recruitment or retention of men in lifestyle interventions, although many explanations have been posited for the low participation rates among men of all races in lifestyle interventions and diabetes risk reduction programs (Pagoto et al., 2012; Taylor et al., 2013). In particular, recruitment of men in clinic-based programs is difficult because they tend to seek clinical care less often than women (Galdas et al., 2004) and generally present with more advanced disease (Beckford-Ball, 2006; Holley-Mallo & Golden, 2021). AI/AN men's perceptions of normative health behaviors and gender roles may also discourage participation (Marak & Tuennerman, 2013; Sinclair, Gonzales, et al., 2020). These results suggest that existing efforts to recruit men, especially men of color, into lifestyle interventions are insufficient and that tailored recruitment efforts are necessary. Moreover, there is an urgent need for diabetes risk reduction programs tailored to the unique values and habits of AI/AN men. Therefore, the Strong Men, Strong Communities (SMSC) in-person RCT was developed to evaluate the effect of a community-based, culturally informed lifestyle intervention on modifiable diabetes-related risk factors among AI/AN men.

During the pandemic, clinical trials have faced unprecedented logistical barriers including social distancing protocols, study staff and participant's fears of potential exposure during study visits, reduction of in-person research staff, and policies deeming study visits non-essential, necessitating adoption of remote methods to sustain research (Loucks et al., 2021; Marra et al.,

2021; Omary et al., 2021; Valmorri et al., 2021). However, researchers have capitalized on the need to transform the landscape toward a more equitable and efficient future through implementation of remote study models (Izmailova et al., 2020; Loucks et al., 2021; Randell et al., 2021; Vogl et al., 2021). To date, there is minimal experience in defining best practices in this domain. Here, we present the methods used in launching and implementing a fully remote, longitudinal diabetes prevention study with AI/AN men. We describe the revision of the in-person SMSC study to a remote protocol and highlight key successes, challenges, and critical lessons learned applicable to remote trial implementation.

METHODS

In-Person Study Protocol

The SMSC study protocol (Table 1) has been described in detail elsewhere (Sinclair, Carty, et al., 2020) and was approved by the Washington State University Institutional Review Board (IRB). Briefly, the specific aims of the SMSC study are to (1) refine the SMSC intervention in response to feedback from focus groups in three recruitment sites, (2) compare change in diabetes risk scores (primary outcome) and modifiable diabetes risk factors (secondary outcomes) between the intervention and wait list control groups, and (3) evaluate the ability of SMSC to retain 80% of 240 AI/AN male participants aged 18–75 years with no previous diagnosis of type 1 or type 2 diabetes.

The SMSC study is a blocked partially clustered RCT to compare the effects of the SMSC between two groups: intervention and waiting list control group. SMSC is a manualized intervention and group facilitation is guided by a peer educator manual. Peer educators, and other site staff who performed recruitment and data collection, attended a series of standardized in-person and virtual trainings led by the Principal Investigator and university data management team.

Recruitment

Men, ages 18-75 years, who self-identified as AI/AN race, were overweight or obese (BMI ≥ 25 kg/m^2), and who did not have a physician-diagnosis of type 1 or type 2 diabetes were recruited in Minneapolis, Minnesota; Portland, Oregon; and Phoenix, Arizona using the following strategies: local health fairs and powwows, Native-serving organizations and clinics, sporting events, local media releases (print, radio), and social media (i.e., Facebook). Men were screened at the events or scheduled an in-person screening appointment. Eligible and interested men

completed an in-person informed consent process and a 1.5-hour baseline data collection visit, after which time they were randomized using REDCap to either the intervention or wait list control group. After cohorts of 10 men completed their baseline assessment, they were block randomized into the two conditions using the cohort as a block.

Data Collection and Measures

Data collection for participants in both allocation groups occurred at baseline, 3 months (post lifestyle classes), and 6 months (post maintenance phase). Men randomly assigned to the immediate intervention group also completed a 12-month data collection visit to assess maintenance of weight loss during the 6-month no-contact period. Waitlist control group participants were offered the same classes after the 6-month data collection.

A survey and clinical measures were collected at each data collection visit. Survey data were collected in REDCap (REDCap, 2022). Sociodemographic data collected included age, educational attainment, marital status, health conditions, prescription medications, family history of chronic disease, annual household income, employment status, and alcohol and tobacco use. The survey also included questions about dietary and physical activity habits, healthy lifestyle support from family and friends, stress, discrimination, and resilience. The primary outcomes were weight and a Diabetes Risk Score (Strong Heart Study, 2011) which is a prediction equation for incident diabetes; specifically, it predicts the risk of type 2 diabetes in the next 4 years for someone who does not currently have diabetes. It was designed for AI/ANs aged ≥ 35 years and is based on the following variables: sex, age, waist circumference, hypertension medication (yes/no), systolic and diastolic blood pressure, sisters or brothers with diabetes (yes/no), fasting glucose, A1C, triglycerides, and ratio of urinary albumin and creatinine. A fingerstick sample of blood was collected to assess A1C, glucose, and lipids. A urine sample was collected from each participant for the microalbumin/creatinine test. Systolic and diastolic blood pressure, height, weight, and waist circumference were also measured.

Previous research that engaged AI/ANs in an intervention with similar design and aims (Jiang et al., 2013) suggested that a sample size of 240 men would provide ~80% power to detect a difference of 0.40 in the primary outcome of change in Diabetes Risk Score. Loss to follow-up of approximately 20% increases the minimum detectable difference to 0.44. Power for secondary outcomes varies, but, as an example, the study would have excellent power (~94%) to detect a 0.5 *SD* difference in fasting glucose between the intervention and control groups.

Strong Men, Strong Communities Intervention

The SMSC intervention is a modified version of the Group Lifestyle Balance (GLB) curriculum (Kramer et al., 2009; Seidel et al., 2008) that was adapted from the original DPP (Diabetes Prevention Program Research Group, 2002). Social cognitive theory (Bandura, 1986) informed the DPP and GLB interventions and both programs include behavioral strategies, such as dietary and physical activity self-monitoring, participant self-weighing, goal-setting, and behavioral modification for weight loss and physical activity (Diabetes Prevention Program Research Group, 2002). The SMSC intervention retained the curriculum topics, content, goals for physical activity and weight loss, social cognitive theory as the behavior change theory, and behavioral strategies from the GLB program.

Adaptations for the SMSC intervention were informed by focus groups conducted with 151 AI/AN men in the three recruitment sites (Sinclair, Gonzales, et al., 2020). The impact of settler colonialism and resulting historical trauma (Brave Heart et al., 2011) in AI/AN males includes the challenge of defining their roles and position in contemporary society. An important goal of the pre-intervention focus groups was to understand how the collective traumatic history of AI/AN communities has contributed to the erosion of traditional roles and male identity development. In the focus groups, men described health-related values and norms and their roles as men in the context of hegemonic masculinity juxtaposed with traditional roles as AI/AN men (Sinclair, Gonzales, et al., 2020). Men recognized that individualism, economic success, material wealth and social class status are hegemonic masculine aspirations, but these were not mentioned as goals by most focus group participants. Instead, men discussed the importance of providing for family and community and the desire to perform acts that would first benefit the community rather than themselves. Men who put family and community first were considered warriors and physically, mentally, and spiritually healthy. For many participants, AI/AN culture, values, and expectations shaped their definitions of manhood, health, and the behaviors and goals they aspire to. Therefore, social cognitive theory constructs and GLB content were combined with selected cultural symbols and themes, cultural patterns and concepts, values, norms, and relationships identified in the focus groups to promote healthy eating, physical activity, and weight loss. For example, being healthy was linked to being a warrior throughout the SMSC intervention. Intervention activities were hypothesized to improve psychosocial variables of problem solving, behavioral capability, self-control procedures, emotional coping response, and self-efficacy for healthy lifestyle behaviors.

Intervention participants attended 12 weekly one hour in-person lifestyle classes with a male AI facilitator to learn strategies for healthy eating, physical activity, and stress reduction, and engaged in facilitator-led physical activity. Following the 6-month data collection, six maintenance phase classes were delivered every other week over 3 months. Maintenance phase classes were delivered by the same peer educator and focused on providing 1) continued support for lifestyle changes and 2) opportunities for peer-led physical activity in a small group setting. Brief text messages of one to two sentences were also sent to intervention participants twice each week (n=24) during the 3-month maintenance phase to reinforce and encourage healthy eating and physical activity. Waitlist participants were offered the same intervention after completion of the 6-month data collection.

Retention

A store gift card was offered to participants for each data collection visit: $25 for baseline, $50 for 3-month follow-up; $75 for 6-month follow-up, and $100 for 12-month follow-up. A light meal was served at each intervention session, and when available, wild game, salmon, trout, wild rice, or other traditional AI/AN foods were offered. Public transportation vouchers for travel to and from the study sites were offered to participants who requested them. Incentives related to the topic of each session (i.e., water bottles and logbooks with the study logo, digital weigh scales, measuring cups, stretch bands, etc.) were offered at intervention sessions.

Multiple methods were used to maintain contact with participants including documentation of work, home, and cell phone numbers, home and email addresses, confirming whether text messages would be accepted, and obtaining contact information of friends, relatives, or coworkers who would know how to contact them if their phone service was terminated, or mailing address changed. Participants received reminder telephone calls, text messages, and/or emails 2 days prior to and the day of each intervention session and data collection appointment. Participants who missed a session received a phone call from the peer educator; the peer educator let them know they were missed, asked why the session was missed for tracking purposes and provided a reminder for the next session.

Retention was measured as total number of SMSC sessions and data collection visits attended in Months 1–3 (range = 0–12) and Months 4–6 (range = 0–6). Because SDPI-DP found that full participation in all sessions strongly predicted reduced diabetes incidence compared to anything less than full participation (Jiang et al., 2013), binary indicators of full participation in the intervention

and maintenance phases would also be calculated. Study retention was to be measured as the total number of follow up data collection visits completed (range = 0–4 for intervention; 0–3 for control) and as binary indicators of completing each individual follow-up visit.

Table 1
Strong Men, Strong Communities revised protocol

Study Activity	Pre-COVID-19 Protocol	Revised Protocol
Recruitment	Local face-to-face recruitment in each site	National recruitment through geographically targeted Facebook posts, study website, listservs, virtual Native events, snowball sampling methods, local and regional newspapers, existing networks throughout the U.S.
Eligibility Criteria	• Self-reported American Indian or Alaska Native men • 18-75 years of age • Reside in or near the identified recruitment sites • BMI ≥25 kg/m^2 • No prior diabetes diagnosis	• Self-reported American Indian or Alaska Native men • 18-75 years of age • Reliable residential internet access • Computer or smartphone • Active email account • BMI ≥25 kg/m^2 • No prior diabetes diagnosis
Enrollment with Informed Consent	In-person	REDCap with participant electronic signature
Study Intervention	• In-person small cohorts of men • Lifestyle classes - 12 weekly classes • Maintenance phase - 3 months in duration, every other week • 2 motivational text messages each week	• On Zoom small cohorts of men • Lifestyle classes - 12 weekly classes • Maintenance phase - 2 months in duration, every other week • 3 motivational text messages each week
Data Collection	In-person	REDCap and Zoom
Primary Outcome	Diabetes risk score calculated with: • Gender • Age • Taking hypertension medications for high blood pressure? • Do you have any brothers or sisters who have diabetes? • Hemoglobin A1c (A1C) • Fasting blood glucose • Triglycerides • Urinary albumin and creatinine ratio • Systolic and diastolic blood pressure • Waist circumference	• Weight – goal of 7.5% weight loss from baseline weight • Dietary habits and consumption • Physical activity habits and frequency

Study Pause Period Due to COVID-19

On March 16, 2020, all in-person recruitment and enrollment activities were suspended. The five-year RCT was in its 42nd month with 99 subjects enrolled. Following discussion with the Washington State IRB, follow-up visits with previously enrolled subjects were conducted by phone. As the pandemic's severity became clearer and the timeline to return to in-person contact was unknown, the study protocol modification from in-person to fully remote recruitment, data collection, and implementation was developed. The revised protocol was approved by the Washington State IRB in June 2020 and the National Institutes of Health in July 2020. However, the Minneapolis and Portland sites decided not to continue with the study because of demands of the pandemic, leaving the Phoenix site as the sole partner in the remote study protocol.

Pandemic Study Protocol

The specific aims of the study remained relatively intact. Aim 1 had been completed prior to the COVID-19 pandemic. For Aim 2, the primary outcome was revised to weight loss with secondary outcomes of dietary habits and consumption and physical activity habits. It was no longer feasible or affordable to collect the data needed to calculate the Diabetes Risk Score. Aim 3 was revised to evaluate the ability of SMSC to retain 80% of 150 participants rather than 240 participants as originally planned. The SMSC study design remained a blocked partially clustered RCT to compare the effects of the SMSC between two groups: intervention and waiting list control group.

In transitioning to an all-remote data collection process, several changes were made to both protocol and standard operating procedures. Phoenix and Washington State University staff developed the revised study protocol and coordinated and conducted all study procedures. The peer educator and other staff who performed recruitment and data collection attended standardized remote trainings via Zoom which were led by the Principal Investigator and university data management team.

Recruitment

To ensure completion of data collection and access to the intervention classes, three additional eligibility criteria were added to the original criteria: ownership or access to a computer, tablet, or smartphone; reliable internet access; and an active email account. Laptops, tablets, and smart phones were not provided to participants. Due to social distancing restrictions, a study website and Facebook page were created for national recruitment of AI/AN men. Other

recruitment strategies included posting the recruitment flyer to listservs, joining virtual Native events to advertise the study, snowball sampling methods, and advertisements in local and regional newspapers and with existing AI/AN networks throughout the United States. Facebook advertisements were focused on geographic regions where large populations of AI/AN people reside such as Washington, Oklahoma, New York, North and South Dakota, Oregon, Montana, Alaska, California, New Mexico, Nevada, Colorado, and Arizona. Men who were interested in the study could either contact study staff directly through the phone number or email listed on the recruitment flyer or enter their contact information on a secure study website. SMSC staff would call the person to describe the study and complete the eligibility screening over the telephone or via Zoom.

Data Collection and Measures

Eligible and interested men were emailed a REDCap (REDCap, 2022) link to independently read and electronically sign the study consent form but were encouraged to contact study staff if they had any questions about the study before signing. After REDCap notified staff that a consent form was signed, another REDCap link was sent to the participant to independently complete the study survey which remained the same as the pre-pandemic survey. Staff also contacted the participant to schedule a HIPAA-compliant Zoom data collection meeting and let him know that a data collection kit would arrive in the mail within a few days of their call. Participants were instructed to open the kit but not to collect any of the data until instructed to do so during the Zoom data collection meeting with study staff. The data collection kit included a body weight scale; a tape measure to collect height, waist, and hip measurements; and a blood glucose monitoring system that included an instruction booklet, glucose meter, lancing pen and lancets, 10 testing strips, several band aids, sterile alcohol prep pads, gauze, chux (i.e., disposable absorbent pads), and a pen. Also included in the data collection kit was a folder with detailed instructions to prepare for the Zoom data collection meeting, a page to record the date and time of each scheduled Zoom data collection meeting, instructions for collection of a fasting blood glucose, and detailed and illustrated instructions for the collection of fasting blood glucose, height, weight, and waist and hip circumference. There was also a section in the folder where participants could record their individual values for each measurement.

The single data collection kit had all the supplies each participant needed for three data collection meetings, and they were instructed to keep everything in the kit for the 3- and 6-month data collection meetings. The 12-month data collection with participants randomized to the

immediate intervention group was discontinued due to the short remaining funding period. Incentives included a store gift card for each data collection visit: $25 for baseline, $50 for 3-month follow-up, and $100 for the final follow-up.

During the Zoom data collection meeting, study staff asked if the participant had any questions regarding the informed consent and reviewed any unanswered REDCap survey questions with participants to obtain responses and reduce missing data. Study staff then guided the participant through the contents of the kit, instructions provided in the kit, and how to use the glucose meter and accurately measure height and waist and hip circumference. Participants completed all measures with their Zoom camera turned on so study staff could ensure accurate measurements and verify measurements. After 10 men completed their baseline assessment, typically after 2 weeks, they were randomized into the two conditions using the cohort as a block as in the in-person protocol and provided group-specific instructions.

Sample Size

Assuming a within subject correlation of 0.7, a within group correlation of 0.1, and an intraclass correlation of 0.3, a sample size of 150 men (75 wait list control and 75 among 15 intervention groups) will provide at least 80% power to detect a standardized difference of 0.39 in weight. With potential 20% attrition, this effect size increases to 0.43.

Strong Men, Strong Communities Intervention

The SMSC curriculum was mailed to each intervention participant prior to the first Zoom delivered class. The content, duration, and frequency of intervention classes (i.e., 12 weekly, 1-hour classes) remained the same but were delivered using Zoom. The AI male peer educator continued to lead the lifestyle classes using the same SMSC curriculum and facilitated physical activities that could be performed in a home setting with no equipment including push-ups, sit ups, squat jumps, lunges, and yoga. A PowerPoint presentation was developed that mirrored the curriculum content and was presented in each class. Incentives such as stretch bands, yoga mats, and pedometers were mailed to participants to support their physical activity.

The maintenance phase was reduced to twice monthly meetings over 2 months rather than 3 months to accommodate the remaining funding period. The peer educator facilitated physical activity during four Zoom classes delivered every other week. The frequency of text messages to reinforce curriculum content was increased to three per week (n=36) rather than two per week (n=24) in the in-person study protocol. The final data collection occurred at the end of the maintenance phase, and waitlist control group participants were offered the same Zoom-delivered

classes and curriculum. Strategies used for the in-person protocol were retained to maintain contact with participants for the COVID-19-adapted protocol.

RESULTS

During the 6-month recruitment period, 285 men completed the eligibility screening. A total of 180 men were eligible and 172 completed the informed consent process. Reasons for ineligibility included BMI < 25 kg/m^2, existing physician-diagnosis of type 2 diabetes, lack of internet access, and unavailable for, or no interest in attending, intervention classes. Only 158 of 172 (92%) individuals completed all data collection activities and were randomized. The mean age among participants was 39 years ($SD = 10$) and ranged from 18 – 70 years; mean BMI was 36 kg/m^2 ($SD = 8$) and ranged from 25.1 to 63 kg/m^2; mean fasting blood glucose was 103.5 mg/dL ($SD = 15$) and ranged from 60 to 174 mg/dL. The final data collection for the remaining cohorts and analyses are underway.

DISCUSSION

The COVID-19 pandemic has caused unprecedented disruptions affecting nearly every aspect of research. This paper provides the description of an in-person diabetes prevention intervention for AI/AN men and the study protocol revisions during the COVID-19 pandemic. As devastating as the pandemic has been, it has also provided an opportunity to identify effective strategies to recruit a historically excluded population and test differing implementation modalities.

The SMSC remote protocol revealed that recruitment through Facebook and the internet could reach AI/AN men of all ages across the United States and proved more effective than in-person recruitment. For example, during the three and a half year in-person study across three sites, we were only able to recruit and randomize 99 AI/AN men compared to the remote recruitment in which 158 AI/AN men were recruited and randomized in 6 months with only one partner site. However, engagement in new social media platforms took time and daily posts and audience relevant content were required to keep viewers engaged. It took nearly 4 months before the SMSC Facebook page produced a significant increase in recruitment. The SMSC AI social media staff person created multiple posts each day that were intended to emphasize the strength, roles, and importance of men in AI/AN communities and to motivate men to be healthy for their family and community. Participants who gave permission were frequently featured on the SMSC Facebook

page wearing their SMSC t-shirt and being physically active. Some participants provided testimonials on Facebook by describing the impact of the SMSC study on their health and well-being and encouraged other AI/AN men to join the study. The AI male facilitator also posted content on the SMSC Facebook page to recruit AI/AN men and to offer exercises men could perform in their homes or yards that did not require exercise equipment.

Retention was higher using the remote protocol. For example, retention in the pre-pandemic study was 62% compared to 87% in the current remote study. Reasons for loss to follow-up in the in-person study included movement of participants from the city to their reservation making them unable to attend in-person classes, disconnected phones, limited hours of operation by the site partners, and lack of interest in attending in-person classes.

In the remote study, the convenience of joining classes from one's home and the AI male peer educator were instrumental in retention and engagement during classes. The process during classes was similar for the in-person and remote protocols. However, the level of personal information that participants shared differed between the in-person and remote classes. For both protocols, the peer educators began the first class with each cohort by sharing the story of his own journey to wellness and personal challenges he had faced in his life, and he assured participants that he was there to support them in their wellness journey. This level of relationship building and accountability to one another is critical in AI/AN communities (Wilson, 2008). Subsequently, men felt comfortable sharing personal stories; life challenges with stress, anxiety, and depression; and how being overweight or obese affected their personal relationships and physical abilities. Sharing stories is an integral part of AI/AN culture. Stories allow listeners to draw their own conclusions and to gain life lessons from a more personal perspective (Wilson, 2008). Stories allow us to see others' life experience through our own eyes. This information may then be internalized in a way that is difficult for abstract discussion to achieve (Wilson, 2008). Weekly debriefing sessions were conducted with peer educators from both protocols to monitor implementation and make corrections and revisions as needed. Discussions with peer educators indicated that men seemed much more comfortable sharing intimate details of their health journey during remote classes compared to the in-person classes. For example, a participant in the remote protocol described his difficulty with personal hygiene due to his weight and the negative impact his weight had on intimacy with his partner. This level of sharing did not occur in the in-person classes. This could, in part, be attributed to the remote nature of Zoom meetings where individuals may feel less

inhibited because they are not sharing a physical space with others and can easily choose to never see other individuals on the Zoom call again.

There was higher retention of participants in the remote protocol (70%) compared to the in-person study (40%). Reasons for attrition during the in-person protocol included the transient nature of many urban AI/AN men's lives where frequent movement between their reservations and the city is common; competing daily demands that made in-person class attendance difficult; and the limited operating hours of one of the recruitment sites. The remote protocol also experienced challenges to participation and retention, including competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) and community members to COVID-19. However, despite the impact of COVID-19, participants said they appreciated the remote delivery of the SMSC study because they could join from the safety of their homes; the small group meetings provided a space for men to discuss the impact of the pandemic on their lives and talk and learn together; and for some, it allowed their children to participate in the peer-led physical activities, which was only possible with the virtual adaptation. Men expressed a desire to keep the SMSC Facebook page active and to continue offering online workouts for AI/AN men to join after their participation in the study ended. Several AI/AN male guest speakers have performed Facebook Live events for participants and shared their challenges, successes, strength, and words of encouragement. Overall, remote processes proved to be more efficient and effective for AI/AN men because they could participate in the study from their homes and felt less inhibited in a remote environment.

The participant support team was equally critical to the success of the remote intervention. First, they reduced barriers to enrollment by guiding participants in the use of Zoom and through the enrollment process via Zoom and made certain that participants received their data collection kit and SMSC class materials. Second, the team promoted retention by sending multiple reminders to participants about scheduled classes and data collection meetings, made sure participants received their incentives and study t-shirt, and were always available to talk with participants. Finally, they ensured scientific rigor and data quality by following the revised study protocol and meeting face-to-face on Zoom for all data collection visits.

Limitations

Despite the many strengths of the remote study protocol, there were limitations and challenges. For example, eligibility criteria required participants to have internet access, a computer or smart phone, and an email address. The technology related criteria limited the study

to individuals who had income to support these requirements and the knowledge to use email and Zoom. The remote protocol also experienced challenges to participation and retention, including competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) and community members to COVID-19.

CONCLUSION

Disparities in clinical trial enrollment, particularly among AI/AN communities, are well-documented (Hodge et al., 2000; Vigil et al., 2021). Barriers to participation range from structural factors including required time commitments, distance and transportation to research sites, hidden costs, and a legacy of fear and mistrust stemming from historical atrocities in biomedical research (Carpio, 2004; Hodge, 2012; Pacheco et al., 2013). Remote models may provide greater efficiency, increased scale, wider geographic catchment areas, and the ability to reach a more representative population, including those unable or unwilling to travel for in-person study visits (Cheema et al., 2021; Greenberg et al., 2021; Loucks et al., 2021; Randell et al., 2021).

The pandemic has provided the opportunity to test a remote study protocol and identify best practices to recruit AI/AN men into a RCT. Remote clinical trials may reduce barriers to research engagement resulting in more representative samples. A critical evaluation of this approach is imperative to optimize a paradigm shift in research (Naz-McLean et al., 2021). SMSC fills a striking gap in approaches to increase AI/AN male recruitment and participation in lifestyle programs that reduce diabetes risk. Now that multiple vaccines are available and people are returning to work and in-person interaction, it will be important to continue research with AI/AN men to evaluate the effectiveness of a remote study protocol after the pandemic.

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POSITIVE INDIAN PARENTING: A UNIQUE COLLABORATIVE STUDY IN THE AGE OF COVID-19

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Abstract: Positive Indian Parenting (PIP) is a culturally based training developed by the National Indian Child Welfare Association in the mid-1980s that has been widely used across Indian Country. However, quantitative studies on its efficacy have not been conducted. This manuscript reports on the study design and development of an ongoing pilot study evaluating PIP and related adaptations that occurred within the context of the COVID-19 pandemic. Adaptations to the study were required to accommodate social distancing requirements, including changing to virtual platforms for curriculum delivery, fidelity monitoring, and data collection. Lessons learned include the importance of flexibility and supportive collaborations among study partners, including unique relationships with funders, that have enabled the ongoing study adaptations during the pandemic.

INTRODUCTION

The COVID-19 pandemic has impacted every part of life in American Indian and Alaska Native (AI/AN) communities, and research is no exception. In fact, social and health disparities mean that AI/AN communities have greater vulnerability to the virus (Hatcher et al., 2020) and have had to be especially cautious about containing its spread and mitigating its damage (Hills et al., 2021). In particular, tribal child welfare and related family support and training programs are by necessity adapting services and supports to engage families that need help. Direct in-person contact with parents has been drastically limited. However, the need for parent support and training has, if anything, increased as families have quarantined in their homes, supported children in virtual schooling, and often experienced increased financial pressure, even as services to meet

basic needs were less available (Brown et al., 2020; Chen et al., 2021; Indigenous Futures Project, 2021).

Virtual innovations in response to social distancing requirements (CHOP Policy Lab, 2021; Ramos et al., 2021) have accompanied unprecedented challenges to conducting research with AI/AN communities. As a result, the future of research in Indian Country is likely to be forever changed even after the pandemic has ended. This paper reports on the transformations that occurred (and are ongoing) within a pilot evaluation study of Positive Indian Parenting (PIP) in response to the COVID-19 context.

Background: Positive Indian Parenting (PIP) Pilot Study

PIP is a culturally based parenting training developed by the National Indian Child Welfare Association (NICWA) for AI/AN families in 1985-1986 (NICWA, 2021). The curriculum developers reviewed literature on traditional AI/AN parenting practices, consulted with key cultural informants, and systematically collected AI/AN community oral traditions about child-rearing and child development. PIP draws on cultural strengths within Indian child-rearing practices using storytelling, cradleboards, harmony, lessons of nature, traditional behavior management, and praise. It also addresses the historic impact of boarding schools, intergenerational trauma and grief, and forced assimilation on parenting. PIP allows for cultural adaptations as well; trainers can tailor it to their own communities by adding stories and teachings from the local culture. The curriculum has been in use in tribal communities for over 30 years and has been cited as an important training by various AI/AN organizations and agencies (Tribal Access to Justice Innovation, 2021; Healthy Native Youth, 2021; Rocky Mountain Tribal Leaders Council, 2021). It is also recognized by the Oregon Department of Human Services for foster parent certification training requirements (Center for Native Child and Family Resilience, 2021) and in the First Nations Behavioral Health Association Catalog as an effective behavioral health practice for AI/AN communities (Substance Abuse and Mental Health Services Administration, 2018).

Since PIP's inception, it has been used by tribes, urban Indian communities, Canadian First Nations, and states as a practice that strengthens parenting skills by drawing from and reclaiming Indigenous parenting values. In the last 30 years, NICWA has trained over 10,000 PIP trainers, who in turn train dozens, and sometimes hundreds, of AI/AN parents and caregivers (the term "parent" is used throughout this paper to refer to anyone who serves in a parenting role).

Communities have anecdotally reported to NICWA that families to whom they have delivered PIP have had improved parenting skills and family well-being as a result. However, there has been no comprehensive, robust evaluation of PIP that provides quantitative evidence of efficacy.

With the passage of the Family First Prevention Services Act (FFPSA) (P.L. 115-123) in 2018, there is an opportunity for states and some tribal governments to access federal funding for certain prevention services, including in-home parent skill-based services and programs. In order to qualify for this funding, programs must be approved by the federal Prevention Services Clearinghouse.[1] To be admitted into the clearinghouse, programs are required to have an evidence base that shows significant differences in outcomes. In addition, the FFPSA requires that in-home parent training programs be directly provided to a parent or caregiver to be eligible for inclusion in the clearinghouse. Thus, the present moment is a critical time to begin testing whether PIP can be established as an evidence-based program to ensure this valued culturally based curriculum is eligible for possible addition to the clearinghouse for tribes and tribal organizations.

A pilot evaluation study of PIP (approved by the Biomedical Research Alliance of New York (BRANY) Institutional Review Board (IRB)) is currently being conducted as an efficacy trial and first step towards conducting future studies of PIP's effects on target outcomes in parent and child well-being. Although PIP was designed to be used in both group settings and one-on-one, there has not yet been extensive data collection on either modality, nor any data comparing the two in efficacy. For multiple reasons, including the value of peer learning and sharing, peer support, ability to reach more parents, and the importance of shared parenting by extended family members, PIP has been used in group settings more often than one-on-one according to anecdotal reports NICWA has received. Throughout the years, however, some communities have also reported anecdotally to NICWA that they have presented PIP in a one-on-one setting. Given that neither group or one-on-one delivery have yet been systematically examined, the research project team chose to first conduct an efficacy study of the one-on-one modality due to the requirements of the Prevention Services Clearinghouse, which stipulates parent skills training programs should occur "in-home" or directly to individual families. A longer-term goal for the research team is to evaluate the efficacy of PIP in both the one-on-one and group modalities in future studies.

The goal of the pilot study is to prepare for a larger national study through refining strategies for partnerships with tribal sites, recruitment of families, implementation of the in-home PIP delivery model and randomized waitlist-controlled study design, and collection of data on

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[1] https://www.acf.hhs.gov/opre/research/project/title-iv-e-prevention-services-clearinghouse

fidelity of PIP delivery and family outcomes. Lessons learned from the pilot study will build a foundation for the future national study, and evidence generated from both studies will be submitted for a review of PIP by the federal Prevention Services Clearinghouse under the FFPSA.

The pilot study will lay the groundwork for evaluating target outcomes related to children's and adult caregivers' well-being. The pilot study seeks to include 60 self-identified AI/AN parents or caregivers with at least one child under the age of 12 living in the Cowlitz Indian Tribe's service area. The study uses a randomized, waitlist-controlled study design. This study design was chosen by the partners because it offers both scientific and cultural rigor. From a scientific perspective, the waitlist design allows a comparison between a group that has received PIP and one that has not at the same time points. This modified randomized control trial design has the strength of being able to evaluate causal relationships between PIP as an intervention and the outcomes of interest. The cultural values of equity and collectivism are also honored in this study design. All families participating in the study will ultimately receive PIP so that no participants are in a "placebo" group without any intervention provided. In the cumulative decades of experience of this study team, AI/AN communities, especially those with limited resources, tribal leaders, and community members have historically perceived randomized controlled trials with placebo arms as problematic because of their desire for all study participants to receive potentially beneficial interventions (Rink et al., 2020). In addition to ensuring that the control group is offered PIP, this waitlist design benefits scientifically from a likely common circumstance in which there is a natural delay in PIP delivery to families due to interest in receiving the eight-to-ten-week curriculum exceeding a given agency's caseload capacity. This pilot evaluation study is a critical precursor for examining the feasibility of this approach for a future multi-site, full-scale randomized, waitlist-controlled evaluation study of one-on-one delivery of PIP.

Eligible caregivers who consent to participate in the pilot study provide baseline data via a survey that includes measures of outcome and moderator domains of interest. Once baseline data have been collected, participants are randomized to either an intervention or waitlist-control group. If a caregiver is assigned to the intervention group, they are scheduled to begin receiving one-on-one delivery of PIP. Then, they complete a second survey approximately 10–12 weeks after beginning PIP and the third survey approximately six months after the second survey. This data collection schedule is in line with the Prevention Services Clearinghouse's supported practice requirement of sustained effect for at least six months beyond the end of the intervention. The waitlist-control group also receives two more surveys, the second approximately 10–12 weeks

after baseline, and the third approximately six months later. Outcome measures administered at baseline and tracked over time assess cultural connectedness, parent-child bonding, parental self-efficacy, parent stress, and child neglect. Parental depression, which will be examined as a potential moderator, is assessed at baseline only.

In this article, we describe the unique aspects of partnership development and funder relationships that set a strong foundation for this pilot study. Next, we present data on virtual delivery of PIP and reflect on adaptations made in our study, which were necessitated by the pandemic's requirements for social distancing and other public health precautions. Finally, we discuss lessons learned about research in AI/AN communities from this rich experience.

PARTNERSHIPS AND RELATIONSHIP DEVELOPMENT

The ability of the PIP pilot study to adapt to the quickly changing context of the pandemic was largely possible because of strong development of partnerships and funder relationships before COVID-19. Partnerships include those among the study organizations, as well as with the study's Advisory Council. Funder relationship characteristics that have been notable in this study include involvement in troubleshooting unexpected challenges in the study, a multi-year commitment to the project, and flexibility in how funding is used as the study context has changed in the age of COVID-19.

The study partners include NICWA (PIP developer), the Cowlitz Indian Child Welfare program (tribal partner), and Child Trends (evaluation partner), with critical technical assistance and early formative support for this project provided by Casey Family Programs (CFP). CFP was the initial funder in 2018 and provided a small award of flexible funding in succeeding years. The Doris Duke Charitable Foundation became the primary funder in 2021, and the William T. Grant Foundation funded supplemental research activities, including an exploration of the feasibility of accessing tribal child welfare administrative data for use in a future full-scale evaluation of PIP. A project Advisory Council was established in 2020 and includes an elder from the Cowlitz Indian Tribe, an original author and trainer of the curriculum, a longstanding trainer of PIP, an expert in the use of culturally based teachings in the treatment of child maltreatment, and a legal and policy expert in tribal child welfare. The guidance offered by the Advisory Council has been an invaluable resource for the project team as the study encountered delays and required shifts in project design to respond to changing circumstances with our tribal study site during the pandemic.

Within the dynamic context of the pandemic, all partners have engaged in continuous dialogue about adaptations that may be necessary to accommodate changing needs and potential implications for evaluation and evidence building efforts going forward. Three specific challenges addressed collaboratively by the partners were the shift in delivery mode, recruitment, and changing partner roles. First, the initial study design involved in-person delivery of PIP by Cowlitz Indian child welfare program staff to families randomized to the treatment group. However, as the pandemic unfolded, partners worked together to collectively plan and transition to virtual delivery; a process that included the purchase of iPads, provision of internet hotspots in some cases, delivery of materials and boxes of supplies to families in ways that best met their needs, and adaptation of curriculum delivery (via PowerPoint slides and videos of culturally specific content). Secondly, broad recruitment of families initially commenced through community flyers, booths/outreach at community events, and notice about the availability of PIP training in tribal newsletters and communications. Tribal child welfare staff, who were already working with and trusted by many families, proved to be particularly effective recruiters, and as the pandemic emerged and evolved, more targeted recruitment of families through specific services the tribe provides beyond child welfare, like childcare, was adopted. Finally, some partner roles changed as a result of the pandemic. Cowlitz Indian child welfare program staff capacity shifted as the pandemic continued and the demand for responding to specific, immediate child welfare needs grew, resulting in a decline in delivery of the PIP training. In turn, NICWA staff began to provide PIP training to families in the study. The shift to virtual delivery also meant that data collection could be fully done online, and Child Trends was able to meet that need with existing staff in lieu of embarking on the process of recruiting and hiring of in-person data collectors based in the tribal community during a pandemic.

VIRTUAL DELIVERY AND COVID-19 IMPACTS

To adapt to the COVID-19 pandemic, delivery of the PIP curriculum within the pilot study quickly shifted to a virtual environment when the need for social distancing became clear. The Cowlitz Indian child welfare program team used many creative methods to adapt, including making boxes of supplies for each family for the hands-on and kinesthetic activities used in the curriculum; preparing to securely and efficiently share videos of an elder telling traditional stories created for use in the pilot study; and providing tablets to each family to ensure they could access virtual PIP sessions in a secure online environment. At NICWA, fidelity monitoring of PIP sessions was shifted to virtual as well, as is described in greater detail below. Data collection with families was also

moved to an online platform by the Child Trends team. PIP delivery in a virtual platform has occurred throughout Indian Country during the pandemic as NICWA found in a recent survey conducted to examine the landscape of virtual PIP delivery (results to be published separately).

Virtual Delivery Adaptations in the PIP Pilot Study

In the PIP pilot study, the Cowlitz Indian child welfare program team took the lead in deciding how to manage COVID-19 precautions in providing PIP to families. By the end of March 2020, Cowlitz Indian child welfare program staff were no longer able to conduct home visits. Entering a home was on a case-by-case basis and only permitted if a case rose to a certain level of urgency. The Cowlitz Indian child welfare program decided to continue to provide PIP to families but move to virtual delivery. NICWA was able to offer consultation and technical assistance around virtual delivery, as they also had to move several other national trainings to a virtual platform. Table 1 summarizes adaptations made during the transition to virtual delivery, their positive and negative impacts, and lessons learned through the process of adapting to virtual delivery.

Recruitment and Staffing

The Cowlitz Indian child welfare program relied heavily on social media and email to recruit participants for the study. The study flyer was posted to the Cowlitz Indian Tribe's social media accounts as well as sent to all staff emails. The Indian child welfare team would typically attend all Cowlitz community events where they are able to interact with community members and engage them with the program. Due to the pandemic, most in-person events were canceled leading to a loss of community engagement. Without the face-to-face interactions, an opportunity was missed in getting families excited about joining the study. In person, potential participants would be able to hear directly from staff what to expect and ask any questions that they may have. Losing out on that opportunity to have those conversations proved to be a barrier to recruitment of families.

The study's recruitment flyer contained contact information for a designated Cowlitz Indian child welfare staff person as point of contact and information about PIP and the study. When that designated staff person left their position, edits to the flyer needed to be made and submitted to the IRB for review. The project team discussed establishing a static contact number (i.e., Google Voice number) that could be easily redirected to another trainer in the event of further staffing transitions to avoid the need for repeated recruitment flyer updates. It was decided by Cowlitz Indian child welfare staff that one point of contact with a locally recognizable number was more

manageable, and the number was replaced with that of a new staff member. The project team respected the tribal partner's preference for maintaining a locally identifiable phone number and process that met their team's needs in a time of constant change.

Staff turnover was a challenge that the Cowlitz Indian child welfare program team faced while providing PIP training to parents. The Cowlitz Indian child welfare program typically has three staff workers and a program director. In general, staff turnover tends to be frequent in child welfare, and this was no exception for the Cowlitz Indian Tribe during the onset and continued experience of the COVID-19 pandemic. Cowlitz Indian child welfare staff were carrying full caseloads as well as providing PIP to two to three families each week. When one staff member relocated and ended their position with Cowlitz Indian Tribe, remaining staff had to pick up their caseloads, which also included PIP training. While trainers enjoyed engaging in PIP sessions with families, they simply did not have the capacity to absorb the caseloads of a missing team member and keep up with their own clients. One trainer explained that they worried about building rapport with a client who had an existing relationship with the staff member who left; it turned out that they were able to pick up where the other trainer had left off and build rapport with the client despite not having a prior relationship with them.

Fidelity Monitoring Adaptation

Like PIP curriculum delivery, fidelity monitoring needed to be adapted for virtual delivery as well. Originally, fidelity monitoring was to be in-person with the families. It was designed in this way to be culturally sensitive, as Cowlitz Indian Tribe partners gave feedback that it would be less invasive to have the fidelity monitor in-person rather than have a video camera recording the session with parents. As trainers moved to virtual delivery of PIP to study participants, it made sense that the fidelity monitor would also join virtually in real time observing the PIP session. This option worked well for the parents, and for the trainer and fidelity monitor, but required revisiting fidelity monitoring data collection procedures, as is discussed below. Fidelity monitoring results are not yet available as the pilot study remains in early stages of participant recruitment at the time of publication.

The original fidelity monitoring protocols and rating guides were developed prior to COVID-19. With key guidance and support from Child Trends and CFP, the NICWA team developed a fidelity monitoring tool that could be used to ensure scientific rigor and consistency in how the curriculum was delivered during the study. To develop the fidelity monitoring tool,

NICWA's research director, Puneet Sahota, interviewed NICWA PIP trainers and the author of the PIP curriculum, all of whom identify as AI/AN. Interviews were conducted with open-ended questions and used an ethnography orientation. In response to the pandemic-related shift to virtual monitoring, NICWA staff also developed a fidelity observation rubric to retain the rigor of the original fidelity measure, as is discussed in more detail below.

PIP can be adapted to local sites through the inclusion of culturally specific stories and parenting traditions, but there are core components needed for fidelity across all sites. These core components were elucidated through interviews that NICWA's research director conducted with the PIP author and NICWA PIP training staff. The PIP manual was reviewed page by page by the NICWA research director and PIP author and trainers, who pointed out on each page which aspects were critical for fidelity. NICWA's research director then recorded those comments in detailed ethnographic fieldnotes. This process revealed that both content and format aspects of the curriculum's delivery were important for fidelity (please see Appendix A for themes that were incorporated into the fidelity checklist). In other words, it was not only about covering specific content in the curriculum, but also how the training is delivered that is critical for fidelity. For example, asking parents/caregivers what parenting techniques they tried to apply from the last session of the training and how that went, as well as the time spent building a relationship between the PIP trainer and parent, especially early in the course of the curriculum delivery, were important fidelity components. The PIP trainer's interaction with the parent models interpersonal skills that parents can use in positive parenting, which is why these style/format items are important along with content delivered. In sum, the oral delivery of this knowledge through ethnographic interviews with NICWA's experts in PIP allowed the NICWA team to develop consensus on core components for fidelity.

Interview notes were then transcribed into a fidelity memo, which was a detailed narrative document describing both content and format aspects of the PIP curriculum necessary for fidelity by session. This memo was then reviewed by the NICWA staff experts in PIP who were interviewed; they provided oral and written feedback to NICWA's research director. NICWA PIP experts' edits were incorporated into the draft and sent back again to them for feedback in an iterative process over several drafts. Essentially, NICWA's research director served as ethnographic interviewer and scribe, collecting and translating qualitative data through collaborative interviews into a research document, the fidelity memo, that could be used to ensure scientific rigor in the PIP pilot study. The same iterative process of interviews, scribing,

translating, and multiple rounds of editing by the NICWA AI/AN PIP trainers and PIP author was then used to develop a fidelity checklist to serve as a quantitative rating scale in the pilot study. To support efficient entry and analysis of the fidelity monitoring data, the Child Trends team programmed the tool into REDCap, a secure online project management and data collection platform also used to administer participant surveys in the pilot study, and provided critical scientific consultation about creating the quantitative rating scale for the fidelity checklist.

When the COVID-19 pandemic began, the NICWA team revisited the fidelity memo and checklist to discuss what each component might look like virtually, especially those that were about format (e.g., social or relationship building time in each session). The PIP curriculum author, Terry Cross (Seneca Nation), then developed a qualitative rubric on which ethnographic participant-observer notes could be recorded by the fidelity monitor for each critical fidelity memo item. NICWA's research director, Puneet Sahota, reviewed the rubric for consistency with the fidelity checklist scoring and to provide feedback on scientific rigor. The NICWA fidelity monitor, Alexis Contreras (Grand Ronde), then received training in how to use this rubric. She practiced using fidelity monitoring tools during simulated PIP sessions, while NICWA's research director checked the rubric notes and fidelity checklist for consistency.

The NICWA team was initially concerned that virtual fidelity monitoring on Zoom might be perceived by parents/caregivers as intrusive, but this did not turn out to be the case. The fidelity monitor introduced herself and described her role at the beginning of each session she monitored and conveyed to participants that she was not evaluating them, but rather was observing the PIP trainer. She then turned her camera off. One parent commented at the end of a session that they had "forgotten" the fidelity monitor was there. She was able to unobtrusively conduct fidelity monitoring, perhaps even more so than it would have been in-person. It was easier for parents/caregivers to "forget" she was present when her camera was off and audio was on mute than it would have been if she had been physically in the room with them at their home while they were receiving the training. The experience of fidelity monitoring itself has been very positive especially with the creation of the qualitative rubric, which has helped the NICWA fidelity monitor adopt the perspective of a parent receiving PIP. She was able to be fully present as a fidelity monitor through using the qualitative rubric to take field notes, more so than if she had been doing quantitative scoring only on the fidelity checklist during the session. Instead, she used her field notes on the rubric to score for fidelity on the checklist immediately after a session had ended.

Table 1
Study adaptations made in transition to virtual delivery

Specific Adaptations and Justification	Potential Positive Impacts of Adaptation	Potential Negative Impacts of Adaptation	Lessons Learned
The Cowlitz Indian Tribe transitioned to providing PIP virtually via Zoom to individual parents/caregivers rather than via in-home, in-person trainings, in response to new agency policy triggered by the pandemic that limited in-home visits to a case-by-case basis and only if a case reached a certain level of urgency.	• Tribal child welfare workers able to reach more families across the Cowlitz Indian Tribe's geographically large service area. • Reduced potential barriers to families' participation (e.g., transportation, childcare). • Reduced PIP trainers' time required for travel, increasing time available for the work itself.	• Scheduling parents/caregivers for virtual trainings was more difficult than scheduling in-person trainings. • Parents/caregivers were more likely to cancel trainings at the last minute. • Parents/caregivers were more likely to not attend training sessions without advance notice. • Many parents/caregivers seemed to be experiencing "Zoom fatigue" as school and other meetings were also occurring virtually. • Some parents/caregivers struggled with the technology platform for virtual trainings (Zoom) that hindered their participation. • Some parents/caregivers experienced poor internet connections that disrupted trainings and inhibited their engagement.	• Pre-meetings between parents/caregivers and trainers to review technology allowed trainers to assess parents'/caregivers' comfort with necessary technology and helped trainings run more smoothly. • True parent/caregiver engagement in the virtual training was possible to achieve, but took more effort by the trainer; using video (rather than audio-only) in trainings increased engagement and supported trainers connecting with parents/caregivers.
Fidelity monitoring was performed virtually as a component of virtual trainings.	• Reduced fidelity monitor's time required for travel, conserving related funding resources for the study.		• Turning their camera off after introducing themselves allowed fidelity monitors to observe virtual trainings with minimal interruptions.

Table 1 continued
Study adaptations made in transition to virtual delivery

Specific Adaptations and Justification	Potential Positive Impacts of Adaptation	Potential Negative Impacts of Adaptation	Lessons Learned
Training content was adapted and prepared for virtual delivery. Trainers created PowerPoint decks and handouts to share written content with parents/caregivers and adapt planned lessons. Other media were incorporated into virtual trainings. For example, a video created by Cowlitz tribal elder and PIP trainer Patty Kinswa-Gaiser was shared virtually via Zoom rather than during an in-person training as originally intended.	• It was easier for trainers to ensure fidelity to the curriculum by laying out the main themes and exercises of the training in PowerPoint. • Trainers easily were able to appropriately customize the curriculum by adding personal pictures and anecdotes and local, culturally specific content to support rapport building with parents/caregivers.	• Some of the hands-on activities were more difficult for families to complete during virtual training delivery. • Some of the lessons that directly relied on trainers and parents/caregivers being in-person were adapted for virtual delivery in ways that may have lessened their impact (e.g., instead of trainers gathering traditional plant medicines with parents/caregivers while teaching about their uses, trainers gathered medicines in advance and sent them to parents/ caregivers with other supplies (see below).	• PowerPoint can be a helpful tool for keeping material organized in virtual delivery.
The Cowlitz Indian child welfare program team created boxes with loaner iPads, handouts, materials for projects, and supplies needed to complete PIP hands-on activities and delivered them to parents/ caregivers as they were scheduled to begin PIP trainings.	• Parents/caregivers had the tools and materials they needed to support successful participation in advance of PIP trainings.	• It was more difficult for parents/caregivers to follow virtual instructions for some hands-on activities (e.g., making a cradle-board), and many parents/ caregivers preferred to continue without completing the activities. • Unsuccessful attempts to complete activities during virtual training sessions may have hindered relationship building between trainers and parents/ caregivers.	• Careful attention to creating clear and easy-to-follow instructions for hands-on activities and creative re-thinking of activity formats is necessary for successful incorporation of hands-on elements in virtual trainings.

CONCLUSIONS AND LESSONS LEARNED

The project team identified five significant lessons learned from our experience implementing the PIP pilot evaluation to date within the context of the COVID-19 pandemic.

First, the primacy of relationships is central to our work together. Our respectful relationships began with seeking formal tribal council approval to participate in the project, followed by a (pre-COVID-19) in-person meeting of the initial project partners that was hosted by the Cowlitz Indian Tribe. This meeting included NICWA, Child Trends, and CFP. Throughout the project, we emphasized communication in planned and structured ways as well as in unplanned and immediate ways to respond as issues came up. Within the research team, staff drew on their collegial relationships with each other and marshalled complementary skill sets. For example, at NICWA the staff with expertise in PIP brought critical knowledge to the fidelity tool development process. NICWA's research director, in turn, facilitated the translation of this knowledge into the fidelity memo and scoring instrument.

As a team, NICWA used ethnographic research methods (qualitative interviews, field notes) and community-based participatory research processes to develop fidelity monitoring procedures for the pilot study and adapt them to the pandemic context. As noted above, NICWA's research director transcribed the knowledge communicated to her by cultural experts on staff at NICWA. Then, there was an iterative process with NICWA's cultural experts on staff providing feedback and edits on multiple drafts. Community-based participatory research principles have also been engaged throughout the development and implementation of the pilot project overall. We found this collaboration within our team to be powerful, and it strengthened our working relationships with each other.

Second, the Cowlitz Indian child welfare program benefited from the flexibility to innovate with PIP training delivery supported by technical assistance from NICWA. Although the initial study design involved in-person, one-on-one delivery of PIP, tribal service delivery protocols did not allow for that in the pandemic environment. NICWA had been converting some of its own in-person trainings (for tribal child welfare workers) to virtual delivery, including NICWA's PIP train-the-trainer institute. When Cowlitz Indian child welfare program staff decided they wanted to deliver PIP to parents virtually, NICWA was well-positioned to support them in thinking through content adaptation, training skills, and logistics. Funders unequivocally supported the transition to virtual delivery.

Third, the community liaison position, a tribal elder, on the Advisory Council has been invaluable. The input and feedback from a seasoned community member intimately familiar with the community, the tribal government, and the child welfare program served our project well at every major decision point.

Fourth, we learned early on about the benefit and challenge of tribal child welfare workers providing PIP training to parents on top of their service delivery responsibilities. One benefit was that the tribe had secured independent funding on their own outside of the PIP study to support the delivery of the curriculum and hired related staff. Therefore, there was already infrastructure in place to provide PIP to study participants. In addition, tribal child welfare workers are experienced in working with families, and in most cases, already had existing relationships with the families. That trust and comfort led to higher levels of engagement from parents. The challenge was that we had to be sensitive to the workers' caseload, which shifted over the course of the pandemic, and balance the pace of recruiting families into the project with service delivery and PIP training capacity.

Finally, the team learned about specific strategies and tools that support virtual delivery and related fidelity monitoring. Having boxes of materials available to families ahead of time and technology tools such as tablets and PowerPoint made for a smooth transition to virtual delivery in some respect. The advantages of virtual delivery include accessibility to families and facilitated transmission of local cultural knowledge through sharing videos on Zoom. For fidelity monitoring, one challenge with virtual sessions was for the fidelity monitor to stay fully present, but the qualitative rubric developed for taking field notes proved useful, as did waiting until the end of the session to fill out the quantitative fidelity scoring checklist.

The future of research in Indian Country is likely to be significantly impacted by the COVID-19 pandemic, with virtual tools taking on a new role. Tribes and other research organizations involved in similarly partnered studies may benefit from some of the relationship nurturing and communication strategies as well as the approach to developing a fidelity monitoring rubric described in this paper. Likely, all research partners and funders will be challenged to be more flexible and accommodating of ongoing adaptation over the course of future research studies; careful documentation and ongoing sharing of lessons learned—both effective and ineffective strategies attempted—will aid the field broadly. The PIP study team will continue to constantly reassess the landscape for this project and adapt within the continued dynamic context of the pandemic.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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APPENDIX A
Fidelity Monitoring Checklist

Positive Indian Parenting Program Fidelity Checklist

Purpose:

This checklist is a tool for Positive Indian Parent (PIP) trainers and program evaluators to ensure that PIP is being delivered as the curriculum developers intended. PIP is unique in that it was designed with standard content to be covered in all communities but allows for parts of the curriculum to be tailored to each local community's culture and context. This fidelity checklist helps trainers and evaluators to ensure that PIP training delivered in an in-home/one-on-one format as well as in group settings includes all of the elements it is designed to include.

This checklist could be used by a trainer to prepare for training and as a self-monitoring tool immediately after each session. It could also be used by an observer/rater, as part of an evaluation effort, who would watch the training being delivered and note whether or not the key elements were included.

Before sessions:

1) Complete an introductory home visit.
2) Find out what ages the child(ren) are in the home.
3) Find out what specific parenting issues the caregivers in the home are facing.
4) Make clear your role in the community and that you are serving as a parenting trainer for the PIP sessions.
5) State that you are a mandatory reporter and explain what that means.

Format items to check for all sessions, should occur in this order:

1) Start by preparing the learning space in a culturally appropriate way for that tribe or region. For in-home instruction, this means entering the home respectfully following local protocols for greeting, entering, seating, etc. and asking the family how they would like to begin "in a good way."
2) Print and give participants the suggested agenda for each session.

3) Include warm-up when noted below under specific sessions when that is critical for fidelity.

4) Ask parents what parenting techniques they tried from the last lesson and how that went.

5) Give brief lecture/talk (or for in-home, read aloud).

6) Discussion and/or exercise.

7) Give brief lecture/talk (or for in-home, read aloud).

8) Discussion and/or exercise.

9) Social time/relationship building.

10) Remind parents to practice what they are learning before the next session.

Style items to check for in all sessions:

1) Informal, friendly tone

2) Provide frequent positive feedback

3) Activities should be experiential in nature

4) Incorporate movement and kinesthetic activities

Content items to check by session:

Session 1:

1) Indian children were traditionally highly valued and respected.

2) Emphasize that where we learn to parent is important, and we might have to unlearn harsh boarding school parenting.

3) Emphasize that parents should focus on their strengths in parenting.

4) Complete the exercise "Suppose You are an Elder."

5) Complete the exercise "The Old Ways."

6) Social time/relationship building.

Session 2:

1) Storytelling was traditionally a large part of parenting.

2) Storytelling is an effective way to teach children values and to think for themselves.

3)   Make a logical transition from the content on storytelling to the content on listening. The important message is that all communication is about relating a story. Communication/storytelling requires both a teller and a listener. Children have a story to tell us if we listen.

4)   Complete the warm-up exercise: "Tell or Read a Story"

5)   Complete the exercise "Walking in the Child's Moccasins."

6)   Complete the exercise "What Would You Say."

7)   Social time/relationship building.

Session 3:

1)   Complete one of five options given for warm-up exercises.

2)   Traditional ways of nurturing helped children to form attachments and develop.

3)   Traditional nurturing ways included wrapping practices, such as cradleboards, swaddling, and other similar techniques.

4)   Children can only be expected to have understanding and behavior that is appropriate to their age and developmental stage.

5)   Age-appropriate developmental expectations specific for children in the home are covered.

6)   Complete the discussion questions following Lecture 1.

7)   Complete the discussion questions following Lecture 2.

8)   Complete exercises on nurturing and readiness.

9)   Social time/relationship building.

Session 4:

1)   Planning for harmony means preventing problems before they start.

2)   Discuss at least four examples of how to do this from those discussed in the manual. Some examples include place things out of reach of children, don't schedule appointments for when kids need a nap, and bring things like snacks and toys with you when leaving the house.

3)   Emphasize that children need to know what is expected of them beforehand to help foster harmony.

4) As long as they are safe, learning from the natural environment is a good thing and traditional in Indian communities. It is not the job of a parent to interfere with every lesson that a child can learn, and they are not the only teacher of those lessons.

5) Complete the discussion questions following Lecture 1.

6) Complete the discussion questions following Lecture 2.

7) Complete exercise on planning for harmony.

8) Social time/relationship building.

Session 5:

1) Discipline and teaching go hand-in-hand. Self-control is the goal.

2) Discipline doesn't have to be negative. It can be positive, like helping a child learn how to do something right that was not correct the first time.

3) Expectations of children should be made clear to them ahead of time. Guidelines for how to do this were discussed (p. 174).

4) Consequences should be age-appropriate.

5) Rules, expectations, and consequences should be consistent for all caregivers of a child.

6) Complete the discussion questions following Lecture 1.

7) Complete the discussion questions following Lecture 2.

8) Complete exercise on logical outcomes.

9) Social time/relationship building.

Session 6:

1) Complete warm-up exercise "Mother Nature is Our Teacher."

2) Our job as parents is to prepare children for the world, including social norms and what is acceptable and not.

3) Remind parents to honor themselves and to understand how their own traumas and historical trauma may be affecting them recently and today.

4) Encourage children to observe the world around them and ask them "What did you learn?"

5) Cover all principles on p. 199-200: responsibility, faith in self, self-awareness, interpersonal skills, situational skills, good judgment, and spiritual strength.

6) Remind parents it is their choice what kind of person they want to raise.

7)   Complete the discussion questions following Lecture 1.

8)   Complete the discussion questions following Lecture 2.

9)   Social time/relationship building.

Session 7:

1)   Complete warm-up exercise, "Something You Like About Your Child."

2)   Praise was an important part of traditional parenting—both verbal and non-verbal.

3)   Recognizing children's talents and spending time with them are ways of giving praise.

4)   Catching children being good is an important strategy for giving praise.

5)   Complete the discussion questions following Lecture 1.

6)   Complete the discussion questions following Lecture 2.

7)   Complete the exercise on giving and receiving praise.

8)   Social time/relationship building.

Session 8:

1)   Complete warm up exercise, "Children Learn What They Live," including handing out the related sheet from manual and reviewing it.

2)   Indian parents and children face a number of challenges in today's context.

3)   Discuss all challenges under "What Our Children Face Today" (p. 233-234).

4)   Parents don't have to be perfect. They may have to practice many times before a parenting strategy becomes a habit.

5)   Complete the discussion questions following Lecture 1.

6)   Complete the discussion questions following Lecture 2.

7)   Complete the exercise "Growing up Indian" (American Indian/Alaska Native). Make sure to focus on what people did and didn't like about growing up Native, not just growing up in general.

8)   Complete the exercise on goal setting.

9)   Social time/relationship building.

For more information about PIP fidelity and fidelity monitoring, please contact NICWA at training@nicwa.org.

ADAPTING PC CARES TO CONTINUE SUICIDE PREVENTION IN RURAL ALASKA DURING THE COVID-19 PANDEMIC: NARRATIVE OVERVIEW OF AN IN-PERSON COMMUNITY-BASED SUICIDE PREVENTION PROGRAM MOVING ONLINE

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Abstract: This paper presents how a community mobilization program to prevent suicide was adapted to an online format to accommodate the impossibility of in-person delivery in Alaska Native communities during the COVID-19 pandemic. The intervention, Promoting Community Conversations About Research to End Suicide (PC CARES), was created collaboratively by researchers and Alaska Native communities with the goal of bringing community members together to create research-informed and community-led suicide prevention activities in their communities. To continue our work during the COVID-19 pandemic and restrictions, we adapted the PC CARES model to a synchronous remote delivery format. This shift included moving from predominantly Alaska Native participants to one of a mainly non-Native school staff audience. This required a pivot from Alaska Native self-determination toward cultural humility and community collaboration for school-based staff, with multilevel youth suicide prevention remaining the primary aim. This reorientation can offer important insight into how to build more responsive programs for those who are not from the communities they serve. Here, we provide a narrative overview of our collaborative adaptation process, illustrated by data collected during synchronous remote facilitation of the program, and reflect on how the shift in format and audience impacted program delivery and content. The adaptation process strove to maintain the core animating features of self-determination for Alaska Native communities and people as well as the translation of scientific knowledge to practice for greater impact.

INTRODUCTION

Youth suicide disproportionately affects remote and rural Indigenous communities. Colonization, historical trauma, and culturally misaligned, underfunded, underutilized health infrastructure and other compounding factors result in youth suicide being a significant health inequity (Wexler et al., 2008; Wexler et al., 2012, Allen et al., 2021). There is a clear need for culturally relevant, early suicide prevention that mobilizes multiple sectors of the community to reduce risk and to take action to recognize, respond, and lower suicide risk before a crisis.

Promoting Community Conversations About Research to End Suicide (PC CARES) was designed to be an in-person suicide prevention program for communities in Alaska. PC CARES has been developed since 2014 by and for Alaska Native people in rural Alaska. The program thrived on leadership from trained local facilitators and in-person, regular gatherings of a variety of community members, including parents, tribal leaders, teachers, and community health workers. PC CARES engages adults who interact with young people across multiple community sectors such as education, health and human services, and even families. It is built on the notion that community members are cultural and community experts who are in the best position to create working solutions to locally prioritized health problems. Building on community infrastructure and expertise, our intervention provides a model for participants to develop evidence-informed, coordinated, and self-determined early responses to prevent suicide. The theoretical underpinnings and previous studies of the model are reported on elsewhere (Wexler et al., 2016; Wexler et al., 2017; Lee et al., 2018; Trout et al., 2018; Wexler et al., 2019).

The COVID-19 pandemic presented unprecedented challenges for community-based program delivery which were further exacerbated by the remote and rural context of Alaska. Local, state, and federal public health guidelines addressing the COVID-19 pandemic have included limitations on group gatherings, stay-at-home orders, and other physical distancing recommendations which curtail in-person programs. Social (limited indoor gathering options and crowded housing) and material (limited hospital capacity) conditions in Alaska, as well as the ongoing legacy of colonization, have impacted the COVID-19 response to the pandemic, making in-person delivery of programs particularly challenging.

This paper presents the process of adaptation to respond to the restrictions of the COVID-19 pandemic by making PC CARES a synchronous remote program beginning in fall 2020 during the worldwide lockdown policies. Our community advisors shared that health service providers were overburdened with evolving caretaking needs as the pandemic unfolded. So, project

leadership determined that school-based participants had the ability and were a fitting audience for our adapted online suicide prevention intervention. Moving online was challenging due to the extremely limited internet connectivity of some rural areas (Sevelius et al., 2020; Rahman et al., 2021; Stone et al., 2021). School staff (teachers, school administrators, and principals) have regular access, influence, and interaction with students—a high risk age group for suicide. They also benefit from the use of school internet connectivity to attend programs, while most households did not have the ability to attend events or even school online. However, in Alaska, many non-Native people work for local school districts. The adaptation literature often focuses on adapting therapies and prevention programs from Western-centered to Indigenous/other marginalized perspectives (Bernal & Rodriguez, 2012; Barrera et al., 2017). In contrast, here we describe adaptation of an Alaska Native-centered model to a majority White, school staff audience. We present the epistemological shift from Alaska Native self-determination toward cultural humility and respectful collaboration with community members for school-based staff, with multilevel youth suicide prevention remaining the primary aim. This reorientation can offer important insight into how to build more responsive programs for those who are not from the communities they serve.

PC CARES Model

Originally a locally facilitated, in-person program, PC CARES was designed and actively managed in partnership with Alaska Native communities to shift suicide prevention efforts from top-down, clinically managed crisis interventions to community-based primary and secondary prevention efforts, carried out by those who regularly interact with young people (Wexler et al., 2016). The model contains three core elements: (a) translating research into useable formats so that participants can develop self-determined, community-driven solutions through each session (called "learning circles"); (b) introducing prevention information which spans the prevention spectrum (universal, selective, and indicated prevention; postvention) to highlight tools and ideas at multiple "points of entry" for suicide prevention; and (c) engaging with stakeholders in both formal and informal support systems to spark participant-led prevention actions at multiple levels of the social ecology: individual, interpersonal, family, school, and community (Wexler et al., 2016). In its pre-COVID iteration, the PC CARES facilitators were mostly Alaska Natives recruited from each village where the program was being delivered. Participants to the program would come from a variety of community sectors, including parents, tribal leaders, teachers, and community health workers.

Figure 1. PC CARES Learning Circle structural design
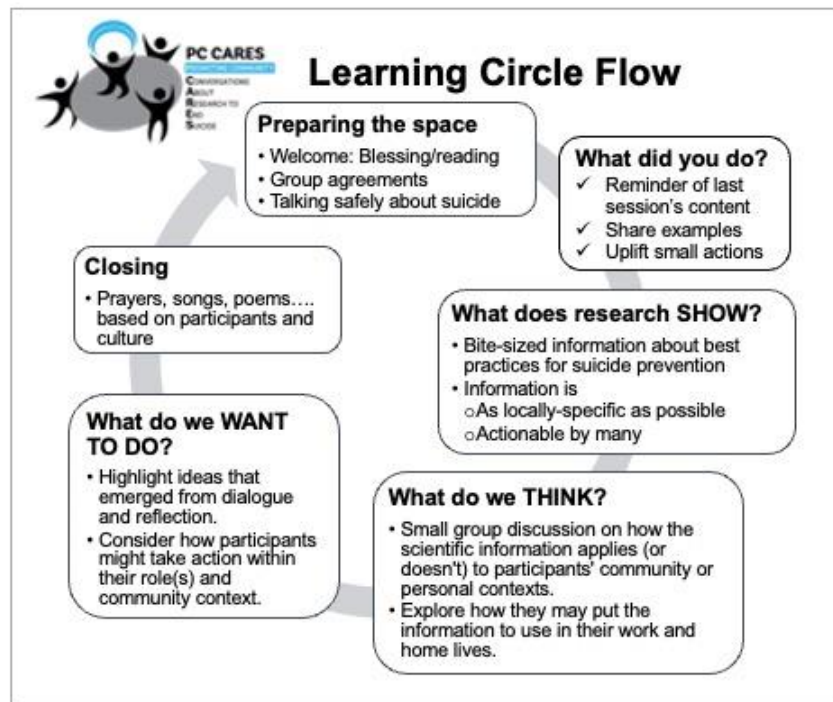
While each PC CARES learning circle covers a different topic, all follow the same structural design (see Figure 1). For more information about theories, approaches, and outcomes of the PC CARES program, please see Wexler et al., 2017; Trout et al., 2018; Wexler et al., 2019.

Embedded structures of local collaboration and accountability are an important feature of the PC CARES approach which allows community members to guide the design and implementation of research evidence from their knowledge of local needs and priorities (Wexler et al., 2016). Four key structural features of collaboration and accountability are: (a) a research and implementation team comprised of both researchers and local Alaska Native wellness advocates who bring together expert knowledges of both the research literature and the local needs, priorities, and practices; (b) meeting monthly with the PC CARES Local Steering Committee comprised of Alaska Native community experts providing feedback and guidance to the PC CARES research and implementation team; (c) feedback and conversation with Alaska Tribal Institutional Review Boards for approval of protocol; and (d) bidirectional knowledge sharing facilitated by the learning circle structure itself, where participants are encouraged to critically examine research information and devise plans for evidence-informed action in their own lives. In addition, PC CARES researchers seek regular support and advice from a Research Advisory

Board, composed of mental health research experts, many with extensive experience of community-based research in rural Alaska communities.

COVID-19 Pandemic Context in Alaska Communities

COVID-19 disproportionately impacts American Indians and Alaska Natives (AI/AN) in the United States. AI/AN communities have experienced forced social changes and colonization leading to intergenerational trauma, as well as social, economic, and political inequalities that increase health inequities and reduce access to shared protective factors (Kirmayer et al., 2014; Wexler et al., 2016, 2017; Pollock et al., 2018; Gone & Kirmayer, 2020). Consequently, AI/AN communities have some of the highest rates of COVID-19 infection and morbidity among all ethnic groups in the United States, despite limited and inadequate representation of AI/ANs in data (Centers for Disease Control and Prevention (CDC) 2021; Hill et al., 2021; Hicks et al., 2022). In addition to the health impact of COVID-19, AI/AN communities are also severely impacted by the social, cultural, and economic consequences of sheltering in place to prevent transmission of COVID-19 (Owen et al., 2021). For Indigenous communities, healing and resilience are intrinsically related to culture and traditional practices including community gatherings and shared activities (Walters & Simoni, 2002; Kirmayer et al., 2016; Walters et al, 2020; Kuhn et al., 2020).

The COVID-19 pandemic is associated with distress, anxiety, and depression, with stronger impacts on vulnerable people (Fleischman et al., 2021; Yunitri et al., 2022). If compared with previous epidemic crises, mental health consequences of the pandemic, including suicidal behavior, are likely to be present for a long time and peak later than the actual pandemic (Sher, 2020; Farooq et al., 2021). In the context of the COVID-19 pandemic, culturally responsive, cross-sector suicide prevention programs like PC CARES are critical braces to the support system for Alaska Native young people (Brenna et al., 2021). In accordance with federal, state, and tribal mandates, and in keeping with cues about social, cultural, and mental health needs from Indigenous communities and mental health organizations across the United States, our team pursued the option of online delivery.

Adapting Programs

To improve the reach, engagement, effectiveness, and sustainability of prevention interventions, research has highlighted the need to address specific priorities and understandings of diverse groups (Bernal & Rodriguez, 2012; Cabassa & Baumann, 2013; Barrera et al., 2017;

Baumann et al., 2017). To prevent suicide, building contextually and culturally specific interventions that can be flexibly applied is especially critical for Indigenous Peoples impacted by social, structural, and political arrangements stemming from lasting legacies of colonization (Kirmayer, 2012; Wexler et al., 2015). By relying on local culture and knowledge, suicide prevention programs can have a stronger impact (Kral, 2016; Allen et al., 2021). Some rely on adaptation: modifications to existing programs to better fit a specific community context, including language, content, and mode of delivery. Adaptation improves implementation and outcomes in Indigenous and other contexts because this process acknowledges and addresses the needs of diverse cultural groups and encourages and integrates community voices and perspectives into the endeavor (Fisher, 2005). To ensure community buy-in and sustainability, adaptation processes must be centered around community partnerships and assess needs and priorities of a specific context (Rapkin, 2019).

Changing modes of delivery is an important adaptation. Here, the PC CARES program moved from a community setting with a pair of local facilitators to a synchronous remote setting with a diverse team of facilitators. During the COVID-19 pandemic and subsequent restrictions, there has been a widespread shift to online delivery for prevention programs. This change led to many challenges for programs to think through, such as technological access (e.g., access to hardware, practice using software) and training of facilitators for online delivery (Barden et al., 2021; Li et al., 2021). In addition, challenges to adaptation are exacerbated in Alaska by the remoteness of communities and underdeveloped technological infrastructures. Online program literature for Indigenous communities highlights the need for local capacity building, community ownership, and empowerment in online tool design and implementation (Peiris et al., 2019; Povey et al., 2020; Stephens et al., 2020). As such, partnership with community members is paramount to ensure that tool design, information, and implementation are culturally responsive and contextually appropriate.

Fitting a program to a particular community context—including mode of delivery—occurs through navigation among and between epistemologies and practical concerns, while maintaining some of the research basis on which the program was developed. This process has been characterized as a balancing act (Ivanich et al., 2020). We describe a unique incarnation of this balancing act as we explain how a collaborative team of Alaska Native and outsider researchers and facilitators adapted an in-person Alaska Native-centered community-based model for use with a mostly non-Native school staff audience using synchronous remote delivery. We present the shift from an empowering stance aimed at supporting Alaska Native self-determination, toward a more reflexive and culturally humble yet animating stance for non-Native school professionals.

METHODS

Narrative Overview of Collaborative Reflection

This study uses a reflexive approach to describe the processes by which the PC CARES team utilized community-based action research strategies to rapidly adapt the PC CARES intervention. The PC CARES team worked consistently over the period of May 2020-May 2021 to adapt and deliver PC CARES curriculum in synchronous remote facilitation to ~90 school-based participants across two Alaska school districts. Our adaptation goal was to meet emergent needs for continuing community suicide prevention activities in rural Alaska communities throughout the socially disruptive pandemic, while accommodating necessary physical distancing practices and policies.

Throughout and following the adaptation of the online iterations of the PC CARES intervention, our team engaged in collaborative reflections in weekly team meetings, monthly meetings with the Local Steering Committee, and with facilitator feedback immediately after the delivery of each learning circle. Our team reflections included the regular use of reflective prompts such as:

"What worked really well in the learning circle?"

"What do you think would make the next session even better?"

"Is there something else that may be important for us to learn or think about from this class session overall?"

Data used in this paper stems from these collaborative reflection exercises. Key themes were drawn from team meeting notes, narratives from our adaptation experience, and observations conducted by the first author whose reflections will be embedded in an ongoing ethnography of the PC CARES program. In this way, the PC CARES team participated in collaborative reflection: a process by which members of a community reflect together through social interactions and the outcomes of this process.

Our Adaptation Process

To make PC CARES a synchronous remote program because of the pandemic restrictions, we had to adapt the program from in-person to online delivery. Moving our program online constrained the pool of participants from Alaska communities that could join our delivery due to the unstable access to internet in rural remote villages. We focused our participant recruitment to

school-based professionals such as teachers, administrators, and principals who have opportunities and resources for suicide prevention as key youth-serving institutions, and importantly, a reliable internet connection at the school. School professionals were already part of our in-person deliveries with other professionals such as health care providers, community workers, community leaders, and parents recruited through affiliation with tribal councils or health care centers. By recruiting primarily school-based participants for the online delivery, we effectively reduced the range of sectors involved in PC CARES. Additionally, a consequence of targeting our recruitment to schools is that most school district employees are non-Native and often came from the lower 48 states to teach. Therefore, we had to adapt PC CARES from an in-person mainly Alaska Native audience to an online non-Native group.

We distinguish two main adaptations of the program: (a) adapting the implementation process and (b) adapting the curriculum. Adapting the implementation process meant delivering the program online instead of in-person, in a different setting (schools only) with a new population (schoolteachers, administrators, and principals). Adapting the curriculum meant shifting the PC CARES epistemological framework (from self-determination of Alaska Native communities to culturally humble actions of non-Native school staff) and processes to fit a different target group. The adaptation of the curriculum resulted in the following changes in the program (Table 1).

Table 1
PC CARES Curriculum adaptation from in-person to online

Curriculum Before	Curriculum After	Explanation
Learning Circle 1: Cultural Wellness	**Learning Circle 1: Context and Youth Development**	• We kept this learning circle largely the same in flow and content. • For our pivot from self-determination for Alaska Natives to cultural humility (See section called Curriculum Adaptation), we highlighted colonization, forced assimilation, and ongoing intergenerational trauma as context for recent data on Alaska Native youth suicide. This context is provided by a video from local facilitators. • Rather than a large group discussion of the video, we asked two Indigenous wellness advocates on the facilitation team to respond to the prompts written in the community-based curriculum. This underlined Alaska Native experiences with colonization.

continued on next page

Table 1 continued
PC CARES Curriculum adaptation from in-person to online

Curriculum Before	Curriculum After	Explanation
Learning Circle 2: Support for Youth	**Learning Circle 2: Prevention**	• Restructuring the curriculum with our school participants in mind, we put forward topics around means restriction at home, central to suicide prevention but complicated for school actors to implement; however, we also included content about non-demanding acts of kindness, which we knew teachers would feel comfortable trying out with their students right away. • We added pivots away from white-dominant culture to the introduction section of the learning circle.
Learning Circle 3: Prevention	**Learning Circle 3: Grief and Healing**	• This session lays the groundwork for the new learning circle to follow. • In our delivery schedule, it is facilitated around the winter holidays. Because community facilitators and Local Steering Committee shared how their communities were grieving during this time, we added information about children's grief to the content.
Learning Circle 4: Grief and Healing	**Learning Circle 4: Postvention in Schools**	• This entirely new learning circle features content developed from a scoping literature review (Williams, in press) done to understand the research basis of recommendations made to schools for postvention. It was designed to be delivered in February/March, with enough time left in the school year to allow participants to begin the cross-sector collaboration necessary for designing sustainable postvention plans with community input.
Learning Circle 5: Review and Next Steps	**Learning Circle 5: Support for Youth**	• Near the conclusion of the learning circle series, we knew this session would be squarely in school staff's skillset. We retained all the elements of content including grouping pairs in triads to practice reflective listening skills.
	Learning Circle 6: Review	• This session keeps much of the content of the original Learning Circle 5, without planning/decision-making at the end. Participants revisit each learning circle and reflect on the community-level and individual-level changes they enacted over the course of the school year.
	Learning Circle 7: Moving on with Vision	• "What does the research show" in this learning circle stems from research on sustainment in community interventions—a new addition to the curriculum. • We also added a community showcase where 2 participants from a community who had implemented several successful prevention and wellness initiatives over the course of the year shared what they did and how they were able to work together. Their stories served as illustrative examples of how to support community-level change.

Adapting Our Implementation Process

From Trained Alaska Native Facilitators to Collaboration between Academics and Indigenous Wellness Advocates

Instead of a train-the-trainer approach, with local people trained as PC CARES facilitators, our adaptation required that learning circles be facilitated by the PC CARES research and implementation team, comprised of academics (Dr. Lisa Wexler, Dr. Diane McEachern, Tara Schmidt, Suzanne Rataj, and Lauren White), Indigenous wellness advocates who co-created the program (including Roberta Moto, Wellness Director, and Tanya Kirk, Native Connection Coordinator, Maniilaq Association), and experienced facilitator and team leader Josie Garnie (a village-based counselor supervisor, Norton Sound Health Corporation). The team was intimately familiar with the curriculum, had experience working with one another and facilitating PC CARES in communities in rural Alaska, and offered community and cultural perspectives important for learning. This change in facilitation roles was important because learning circles foster communities of practice primarily through dialogue. Changing the facilitators of the dialogue from local village facilitators to the academic-community team was likely to impact how the message is conveyed, interpreted, and applied. Considering that participants of PC CARES also changed, the switch to a facilitation team composed mainly of researchers may have been beneficial to the conventional understandings of credibility and likely bolstered program fidelity. In this decision, we considered the costs of sacrificing "community ownership," important for the decolonial framework of PC CARES (Trout et al., 2018), against the high demands and challenges caused by the pandemic in the remote north. The adaptations required modifications involving changed facilitation roles, reflexive processes, changes in content, and a shift to digital and online interactive tools. Through reflexive processes with the community-academic team, activities were refined, roles clarified, and digital tools were learned and eventually mastered.

The PC CARES program was presented and approved by two Alaska Tribal Institutional Review Boards (IRB) prior to delivery in the community in Spring 2019. Considering the important change of program implementation and process caused by turning the program into a synchronous remote facilitation, we submitted an amendment to our protocol to both tribal IRBs and were approved in September 2020. Presenting research and getting it approved by the Tribal IRBs is an important milestone in collaboration with communities and ensuring that local voices are part of, listened to, integrated, understood, and heeded during the adaptation process.

From Local Community Knowledge to School Insider Knowledge

In-person PC CARES was facilitated by trained community members and delivered in villages to participants coming from multiple sectors of the community (i.e., parents, teachers, counselors, community health professionals). Thus, there were pre-existing relationships between local facilitators and most of the participants. Additionally, facilitators would have been embedded in local ways of knowing, history, and social life of the community, which enabled them to aptly lead discussion about outcomes of the program. While some PC CARES researchers and team members have training in education research and are teaching university-level courses, none of us are teaching in the K-12 school setting. With the help of our school-based partners, we adapted session activities to suit the new participant group, and we maintained our core group of researchers and Alaska Native community members as PC CARES facilitators each month. This way, the program still included community voices while being delivered by the academic-community team.

From In-person to Online Delivery: Creating a Responsive and Respectful Space on Zoom

Creating a respectful space online was important for the team. We made sure to include some ground rules to talk safely about suicide, to establish clear guidance for Zoom communication that made space for everyone, and to remind participants collectively to listen to one another. Moving the delivery online also meant rethinking facilitation space. Participants were not gathered in-person where there is often room for informal conversation. Synchronous remote facilitation on the Zoom software used Google documents, chats, and small break-out groups to encourage interactions. The facilitation team kept their cameras on throughout class and were active on the Zoom chat to answer queries, provide links to documents, and respond to participants. To respect the privacy of what is being discussed during the learning circle, we decided not to record the break-out group sessions. Instead, we asked for participants to consent on whether we could use their comments written on the Google documents for research while providing confidentiality. Comments written in the chat would not be used for research. Throughout the session, participants were invited to respond to information or ask questions in chat, verbally, or by writing anonymously on a Google document. These comments provided a basis for the next session to revisit ideas and plans for putting the suicide prevention and wellness information into action.

Curriculum Adaptation

The shift in participants from mostly local Alaska Native community members to mainly White teachers from the lower 48 states was catalyzed by our online delivery adaptation. This shift—from prompting local action in one's *own* community to cross-cultural collaborative action—introduced new challenges and demanded some important curriculum changes to PC CARES learning circles. In prevention programs, there is a tendency towards cookbook approaches to conceptualizing culture that ultimately reify stereotyping processes and replicate Western notions of moral and scientific authority, flattening complex experiences and sociocultural phenomena to individual pathologies (Johnston & Herzig, 2006; Wexler & Gone, 2012; Smith, 2021). Our team surmised, through collaborative reflection, that modeling and teaching prompts for cultivating a reflexive and culturally humble stance before presenting the scientific research was an important way to maintain PC CARES's decolonial commitment.

Shifting Away from White Dominant Culture

The in-person curriculum introduced Alaska Native suicide disparities as deeply linked to colonization and the importance of self-determination for prevention. For the online school delivery curriculum, our team explicitly invited critical self-reflection and cultivated a posture of cultural humility for outsider participants (Chang et al., 2012; Rosen et al. 2017). To do this, we incorporated small shifts away from white dominant culture to "something else" into learning circles 2-6 as seen in Jones and Okun (2001; see Table 2). These shifts, titled 'Our intention in this course', were inserted and explained at the beginning of each learning circle. Academic-based facilitators discussed the concepts outlined in Table 2 and elaborated using their own experiences from working in rural Alaska Native villages as non-Indigenous service providers. The inclusion of these examples provided a critical perspective on dominating paradigms which have shown to help cultivate critical self-reflection and cultural humility (Rosen et al. 2017). We also wished to encourage participants to foster stronger relationships, centering local priorities, practices, and knowledge, as well as supporting self-determined actions by Indigenous Peoples within and across their cross-cultural efforts for change. Reflecting on this effort, one participant shared, "I appreciated PC CARES facilitator saying: 'that more (important) is seeing what the communities need instead of bringing our ideas of what should be happening in the community.'" The small shifts and related stories are adaptable and can change depending on the context of the program delivery.

Table 2
Summary of the 2020-2021 PC CARES prompts to shift away from white dominant culture (adapted from Jones & Okun, 2001)

	Our intention in this course: To shift...	
Learning Circle	**From This**	**To That**
Learning Circle 2: Effective Prevention	**Perfectionism** Mistakes are seen as personal, reflect badly on the person - the person is seen as a mistake. Little time for learning.	**Appreciation** Mistakes are valued as opportunities for learning. People verbally show their appreciation for each other.
	Paternalism No consultation or transparency in decision-making. Taking over projects, mediating, and facilitating others.	**Partnership** Decision-making is clear, affected parties are consulted. Evaluations include staff/students at all levels. Leadership of frontline communities is respected and nurtured.
	Competition Taking unearned credit for wins or co-opting local organizing efforts or the work of other staff. Treating core campaign issues as more important than issues that other people are working on.	**Collaboration** Taking time to build relationships based on trust. Focus is on "building a bigger pie" instead of fighting over a slice. Mutual support and promotion of each other's' projects and issues.
Learning Circle 3: Grief and Healing	**Transactional Relationships** Detached "professional" communication, for the purpose of completing a transaction and efficiency. Reaching out or acknowledging people only when you need something from them.	**Transformational Relationships** Building trusting relationships internally and externally that are based on trust, understanding, and shared commitments. Even in the simplest ways, taking time to see, greet, and acknowledge each other to sustain caring connections, especially when there's "no time" to do so. Space to appropriately be in one's majesty and to share in each other's cultural bounty.
	Overworking as an Unstated Norm Encouraging people to work through weekends and into the night (directly or passively by setting up work plans that are unachievable in a 40-hour week) - ignoring how Black, Indigenous, and People of Color (BIPOC) have been historically and systemically requested to take on physically taxing work by white bosses.	**Self-Care/Community Care as a Norm** Actively encouraging a culture of self-care and community care in which people care about each other's physical and emotional well-being, support time boundaries, and are considerate of time zone difficulties, parental needs, personal health issues, etc. Work plans include unscheduled time to enable space for inevitable unpredictable tasks that emerge.
Learning Circle 4: Postvention	**Transactional Goals** Transactional deliverables/quantifiable are ranked above meaningful engagement or qualitative goals. Rushing to achieve numbers.	**Transformational Goals** Working towards meaningful engagement with depth, quality; using qualitative goals in addition to whatever deliverables a foundation is asking for. The timeline for the deliverables includes enough time for quality.

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Table 2 continued
Summary of the 2020-2021 PC CARES prompts to shift away from white dominant culture (adapted from Jones & Okun, 2001)

Learning Circle	Our intention in this course: To shift…	
	From This	**To That**
Learning Circle 5: Support for Youth and Everyday Caring	**Perfectionism** Mistakes are seen as personal, reflect badly on the person – the person is seen as the mistake. Little time for learning.	**Appreciation** Mistakes are valued as opportunities for learning. People verbally show their appreciation for one another.
Learning Circle 6: Review and Next Steps	**Individualism and Separateness** Focus is on single charismatic leaders, working in isolation, from each other and from other organizations.	**Community and Collectivism** Working together from a "movement" lens. Understanding that to change everything, it takes everyone. Understanding interdependence of social struggles. Working for healthy communities for all members, supporting those impacted by suicide, and working collaboratively on community/organizational changes.

Because of the shift in audience, we added emphasis on centering local Alaska Native knowledge, culture, and history, and building strong community relationships *before* taking action for suicide prevention. This difference subtly shifted team positionalities for "insider" (local Indigenous wellness advocate) and "outsider" (researcher and social worker) facilitation team members. For example, the in-person iteration of PC CARES included mostly Alaska Native community members, including the facilitator. This meant the facilitator had local insights on community practices and often spoke local languages (Yup'ik, St. Lawrence Island Yup'ik, and Iñupiaq). In contrast, during the breakout groups of the online delivery, sometimes Alaska Native facilitators were the only Indigenous people present, with the majority being White teachers. Teachers from outside communities brought more classroom-centered perspectives to discussions and sometimes asked basic questions about local culture, processes, and protocols, which the Alaska Native facilitators had expertise and were provided space to answer. If questions on Alaska Native perspectives arise during the plenary sessions of the learning circle, Alaska Native facilitators and participants were invited to speak.

Legitimizing Both Indigenous Pedagogical Practices and Scientific Knowledge

PC CARES also had to adapt to the expectations of the new participant group. PC CARES utilizes Indigenous pedagogical practice relying on lived experiences and storytelling (Wexler et al., 2016). During facilitation, most time is usually allocated to the "what do we think" and "what

do we want to do" discussions among community members. However, with the online school-based group, the process of legitimization of scientific knowledge increased expectations about the time spent sharing best practices based on research. In contrast to the in-person iteration of PC CARES where community members eagerly talked about their lived experiences and how they related to information presented, the online school staff asked for the original papers, additional readings, and more data. Many had questions during the "what do we know" sections of the learning circle, which made the section longer than the usual 10 minutes or less. To accommodate the needs of participants, we included additional readings and the academic-facilitators held office hours. Even with the increased time spent sharing evidence-based strategies for prevention, some school-based participants observed PC CARES' unique emphasis on situating suicide within the specific historical and cultural contexts of the villages. They appreciated repeated prompts and strategies to ground their suicide prevention actions in collaborative cross-cultural and cross-sector relationships.

A school-based participant describes their expectation of decontextualized information sharing and acknowledges the benefits of emphasizing the importance of incorporating village culture, priorities, and protocols while respectfully collaborating with local community members:

> *I was expecting a lot more lecturing and more of statistics and I was really surprised how in depth they went into the village. I wasn't expecting it to be so village related... I was expecting for someone to be doing this that didn't understand the village life and was throwing this stuff at us, like a lot of classes. Truthfully, I was very impressed […]. So, I was really grateful to see that it was more directed to that subject and helped us teachers really be able to find a plan and focus on a plan for not only the school but the community as well.*

In sum, the PC CARES adaptation to synchronous remote facilitation and subsequent change in participant demographics led to an important epistemological switch in the PC CARES curriculum content. The program went from emphasizing action for Alaska Native self-determination to highlighting the importance of cultural humility and local collaboration as plans are created to take action for suicide prevention in predominantly Alaska Native communities.

Matching the Content to Participants: Surface Adaptations
In addition to the epistemological switch, several surface adaptations were needed to match content to the school-based participants. Partnering with school districts presented a unique

opportunity to help participants planning for postvention in schools. Postvention planning aims to help students, faculty, and staff cope with the traumatic experience of a student suicide, increase safety and support to reduce suicide risk, and establish protocols that guide a coordinated institutional or community response. At the request of school district partners, we compiled resources and evidence on best practices for postvention (Williams et al., in press) and coupled this with the importance of partnering with the community to respond respectfully when suicide occurs. Also, many of the participants worked with elementary school children, so new content about addressing grief in children was added to the grief and healing learning circle to help tailor the intervention to the needs of its participants. The sequencing of the learning circles was reordered to create space for the postvention session earlier in the year, allowing time to develop a school postvention plan and to accommodate holiday breaks in December and March.

The in-person model culminated with a review of the learning circle content and a discussion among community members about how to move forward as individuals (parents, teachers, community health workers) and as a community. Since some of participants in the online PC CARES course were participating from disparate communities within the same region, there was not a deliberate process within the sessions to plan collectively for next steps. However, we invited participants to examine their current strengths, ideas, and assets to plan for community change initiation or sustainment. As part of the curriculum adaptation, we added another new learning circle on key factors supporting sustainable community change for the last session. This final learning circle grouped discussions based on villages and schools and gave groups a chance to share their successes, ideas, and develop strategies for prevention going forward.

Challenges We Faced

The rapid adaptation and successful delivery of PC CARES online was facilitated by many vectors. However, in moving a community-based suicide prevention program online we also faced challenges. Issues included technological and internet bandwidth discrepancies between participants and incorporating community voices in the delivery.

Navigating Online Space and Participants

Online facilitation and online teaching are often student-centered, meaning that participants are expected to actively participate in co-constructing teaching content and knowledge (Fraoua, 2021). This principle is inherently important for the learning circle organization of PC CARES,

which relies on participation and discussion. However, it was difficult to ensure all participants could engage in the session fully due to several technological and even meteorological phenomena (e.g., blizzards) impacting internet accessibility.

First, during remote facilitation of PC CARES, participants had their cameras on and off. Excluding PC CARES team members and facilitators who kept their camera on the entire time, about 10% of participants had their camera on during the facilitation in plenary session and 50% when in smaller discussion groups. Internet bandwidth capacity was usually stated as the reason why participants did not put their camera on. At some sites, several participants shared one computer, limiting their engagement in conversations. During our surveys after each learning circle, we found that 20% of the respondents reported at least some issues with internet connectivity. Others decided to have their camera off for reasons unknown to us. Considering that the program happened in school settings, lack of privacy, no webcam available, or even gaps in technological knowledge between participants are potential explanations. Not being able to see participants made it difficult to assess their engagement and, more importantly, created a barrier to assess participants' feelings. Thus, we checked in often with participants to invite them to comment or ask questions verbally in the chat.

Second, we noticed that some participants did not have the necessary material to participate orally in the program. In some cases, there were groups of participants sharing the same computer without a working microphone. Delivery in an online setting meant working within constraints of available materials. We made sure to engage with these participants in the Google document notes and in written conversations in the chat.

Third, the COVID-19 pandemic changed the landscape of synchronous remote facilitation and learning. The concept of Zoom fatigue is increasingly present in the literature and refers to the fragilized emotional state of participants after spending days in meetings and online deliveries (Peper et al., 2021). Furthermore, using online platforms creates risks of multitasking behaviors. Multitasking behaviors have been shown to increase in online learning settings relative to in-person course (Lepp et al., 2019). Using the PC CARES learning circle structure, facilitators opened with mindfulness activities and recitations of texts or a prayer. We hoped the opening would help participants' focus and attention with reduced multitasking behaviors by increasing engagement in the program.

Fourth, weather caused internet issues. The first online cycle of PC CARES was delivered from Fall 2020 to Spring 2021. During Alaskan winter, we noticed that wind and snowstorms

impacted attendance to learning circles, such that schools closing, and leaving some participants—and even facilitators—with unstable internet connections. Most commonly, participants' audio, video, or ability to remain in the session cut in and out. Although most participants didn't experience problems, issues with connectivity can have a big impact on participants' ability to take in the information and to engage with the course activities, thus affecting the depth of their learning.

Lastly, it was difficult to coordinate and monitor participants according to their registered email addresses and Zoom accounts. We found that participants often signed up for registration with their formal name, but sometimes used usernames or nicknames on Zoom. Some school computers had classroom or facility-related usernames already programmed into their Zoom settings. We had to privately message participants during each session to identify who was attending the session. In addition, facilitators struggled to identify and address participants in small groups designed for facilitated dialogue when names were not displayed. These small complications compile to create challenges to developing a comfortable and trustworthy space for dialogue compared to in-person facilitations where facilitators get to know participants and create interpersonal relationships from the start of the learning circle and throughout, including during breaks.

For a program that is based on connecting to one another and coming together as a learning community, these technical issues made it difficult to foster similar bonds compared to the in-person learning circles. We had to adjust expectations and adapt to create some other options for connectivity such as offering office hours, sending emails, utilizing Zoom's private chat function, communicating via an online platform designed for uploading resources, sharing participant responses to small group discussions, and offering additional materials to help participants utilize what they had learned.

Sharing Community's Voices in the Learning Circles

Another challenge we encountered relates to positionality. Throughout the delivery, we reflected on the positionality of the academic-based team and our role in delivering a program co-created with Alaska Native partners. While we changed epistemology, which meant guiding mostly non-Indigenous participants to grasp concepts of self-determination for Alaska Natives, fewer than half of the facilitators of the online delivery were Alaska Native, although most facilitators have spent extensive time in Alaska. Throughout the delivery, we added storytelling from research team members with experience working in the region, who shared their personal experience as "outsider" practitioners working in Alaska Native communities to address

challenges and systemic issues while leaving much space for Alaska Native facilitators and participants to share about their communities and culture. We continuously reflected on power discrepancies and how to best include Alaska Native knowledges and perspectives.

DISCUSSION

Confronted with challenges posed by the COVID-19 pandemic, PC CARES adapted its implementation process (switching to synchronous remote facilitation) and curriculum (with epistemological switch and subsequent curriculum changes). Instead of designing an original online program or pausing the intervention altogether, the PC CARES research team and Local Steering Committee members decided to adapt the existing PC CARES model to the new context of COVID-19. The existing curriculum, based on core values of PC CARES, provided a solid foundation on which to tailor this online adaptation. We highlight in Table 3 some drivers to the adaptation process and delivery of the PC CARES adaptation which we will develop in the section below.

Table 3
Vectors of adaptation of the PC CARES program

Categories of Adaptation	Vectors of Adaptation
Long-term continuous partnership with community members	• Ongoing partnership with community partner built over 10+ years of collaboration • Pre-existing trust between research and implementation team and community partners • Regular meetings with community partners and direct line of contact • Reflexive space to talk about white supremacy, colonization, racism, and power imbalances
Budget and team capacity	• Funding support for the implementation team and for tribal health corporation where community partners work • Full-time staff in the program • Moving online meant more budget for participant outreach
Flexibility of the curriculum	• Adaptable learning circle structure (see Table 1) • Program focused on participant-generated solutions, meaning that the program can be tailored to new audiences
Institutional support	• Longstanding relationship with school districts facilitated access to school-based delivery • School allocated training time for staff, which significantly increased participation • Tribal health partnerships that included collaboration with and implementation of PC CARES as a central part of the suicide prevention initiative • Alaska Tribal Institutional Review Board reviewed, provided feedback, and supported the new program • Research Advisory Board composed of mental health research experts, many with extensive experience of community-based research in rural Alaska communities

Long-term Continuous Partnership with Community Members

A strong partnership with community members that pre-exists the adaptation process is a cornerstone of the adaptation literature (Barrera et al., 2017; Ivanich et al., 2020). In Wexler and colleagues (in press), we emphasized that the ongoing partnerships between the PC CARES research and implementation team and community members in various regions of Alaska was a strong driver of adaptation. Many of these relationships have been built over decades of working together prior to the existence of the PC CARES program and are embedded in key structural features of collaboration and accountability of the program (see PC CARES model section). The experience of working together on adaptations while maintaining continuity across time is important. Many of the Local Steering Committee members were involved in the previous adaptation of PC CARES from one Northwestern region in Alaska to use in Western Alaska and provided invaluable comments and guidance of the program (Wexler et al., in press). This mobilization in such a short amount of time was only possible because of the pre-existing trust between the team and Local Steering Committee members. We also harnessed pre-existing relationships with school district administrators which enabled us to adapt some aspects of the curriculum and activities to school with the guidance of people with experience of the Alaska school system. Throughout the adaptation of the curriculum and implementation process, as well as for evaluation of results and planning for next iterations, we met regularly with community partners who guided the adaptation of the curriculum. Additionally, throughout our ongoing and collaborative partnership established between team members and Local Steering Committee members, we have established together a space fostering honest and reflexive conversation around white supremacy, colonization, racism, and power imbalance. This has led to critical discussions during our adaptation and has continued to help us as we reflect weekly about how to carry out the program in ways that align with values of collaboration and cultural humility.

Budget and Team Capacity

Long-term viability of a project is often determined in terms of funding capacity, which enables programs to continuously respond to community needs. PC CARES is supported by an R01 grant from the National Institutes of Mental Health and is supported by complementary grants awarded to tribal health corporations. When COVID-19 formed a barrier to the in-person model of PC CARES, the research team submitted a revision of the project, which allowed the team to

devote time and resources to adapt PC CARES to fit synchronous remote facilitating. Local Steering Committee members were also remunerated for their time. Team capacity is a strong vector to adaptation, as several of the staff working for PC CARES are working full time on the project.

Flexibility of the Curriculum

Adapting PC CARES to online delivery was also made possible thanks to the flexibility of the curriculum. The core of the program relies less on specific recommendations and more on the ways in which we ask people to engage with research information to build a community of practice grounded in Indigenous self-determination and multilevel action (Wexler et al., 2016). A deep epistemological adaptation like the one we presented here was only possible because of the adaptable nature of the learning circle format and the community supports which were already in place as part of the PC CARES approach. While we kept similar elements of research evidence and still emphasized self-determination, it was presented to a non-Indigenous audience as cultural humility. Thus, we kept the core of the program, its learning circle structure, and the central role of fostering community engagement intact.

Institutional Support

Adapting PC CARES to be delivered to school staff was made possible thanks to partnerships with school districts in Alaska. We leveraged longstanding relationships with colleagues working in local school districts, contacted school district administrators, and engaged them in planning for online delivery. School districts allocated time for staff to participate in the PC CARES training and provided stable internet connectivity needed to participate. In turn, we provided continuing education credits to PC CARES participants as further incentive to their participation. The PC CARES online iteration was also made possible through the guidance, review, and approval from two of the Alaska Tribal IRBs. The support of the two IRBs is important to protect community members and to ensure an institutional collaboration between the researchers and the local partners. We benefited from expert guidance from mental health researchers, many of whom have been working on community-based research in rural Alaska for many years, in the form of Research Advisory Board, who we met regularly with. Also, three key Local Steering Committee members and facilitators of the PC CARES program are employed by a tribal health and social service organizations whose grant on suicide prevention includes PC CARES activities. As such, the PC CARES team leveraged local

institutional (tribal IRBs, tribal health and social service organization, school districts) and university institutions to pivot to online program delivery.

CONCLUSION

In adapting a co-created, community-based suicide prevention program working across sectors to move from in-person to synchronous remote delivery, we learned that no matter the space, PC CARES can continue to transform suicide prevention in Alaska. Focusing on school districts was important to engage and work with an institution that serves (and can reach) most of the youth and children in our partnering regions; school districts are key to youth suicide prevention and provided the infrastructure for their staff to participate virtually in a region with low bandwidth. Working with school districts meant adapting our curriculum and implementation processes to match our new participant demographic. Therefore, using our reflexive space, we adapted the program to move from Alaska Native self-determination to reflexive and culturally humble action for people not from the region. This switch is not common in the adaptation literature which often focuses on Western-to-Indigenous instead of Indigenous-to-Western direction of adaptation. Overall, vectors of adaptation for the online iteration of PC CARES (such as long-term ongoing partnership with community partners) match important concepts of the adaptation literature (Barrera et al., 2017; Ivanich et al., 2020). We also found that moving the program online meant rapidly leveraging time, relationships, and networks with the support and direction of community partners and institutional support. The PC CARES model was built around flexible methodology, which enabled us to adapt the curriculum and the implementation process of the program while keeping core elements of PC CARES. Adapting PC CARES, which relies on interpersonal relationships and community momentum to online delivery was not without challenges, including technological and internet issues and navigating power and narrative in the delivery of the program. Collaborative team reflections throughout the delivery enabled us to find solutions to these challenges.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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LESSONS ON RESILIENT RESEARCH: ADAPTING THE TRIBAL TURNING POINT STUDY TO COVID-19

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Abstract: Tribal Turning Point (TTP) is a community-based randomized controlled trial of a lifestyle intervention to reduce risk factors for type 2 diabetes in Native youth. TTP began in 2018 and was interrupted by the COVID-19 pandemic in 2020. In this paper we aimed to understand 1) how the pandemic impacted TTP's operations, and how the TTP team successfully adapted to these impacts; 2) how the effects of COVID-19 and our adaptations to them were similar or different across TTP's research sites; and 3) lessons learned from this experience that may help other Native health research teams be resilient in this and future crises. Using a collaborative mixed methods approach, this report explored five a priori domains of adaptation: intervention delivery, participant engagement, data collection, analytic strategies, and team operations. We derived three lessons learned: 1) ensure that support offered is flexible to differing needs and responsive to changes over time; 2) adapt collaboratively and iteratively while remaining rooted in community; and 3) recognize that relationships are the foundation of successful research.

INTRODUCTION

Tribal Turning Point (TTP) is a randomized controlled trial that aims to reduce risk factors for type 2 diabetes in American Indian (Native) youth. Participants were recruited from three community-based research sites in Arizona and New Mexico: two rural communities within the Navajo Nation and one urban site in the Phoenix metropolitan area. The TTP program is a culturally adapted, group-based lifestyle intervention administered by trained community members employed by the University of Colorado as Professional Research Assistants (PRAs).

This study builds on the success of an earlier pilot study (Sauder et al., 2018) and will rigorously evaluate the effect of TTP on diabetes risk factors in a larger sample of Native youth, with the long-term goal of disseminating this evidence-based program to other Native communities.

Like nearly all research studies, TTP was abruptly impacted in early March 2020 when the spread of SARS-CoV-2 led the World Health Organization to declare COVID-19 a pandemic. Since that time, the TTP team (PRAs, managers, and investigators) has collaborated to adhere to study protocols in the face of ongoing challenges. This report explores the characteristics and strategies that have allowed the TTP clinical trial to progress during the first 18 months of the global pandemic. Specifically, it addresses: (1) how the COVID-19 pandemic impacted TTP's operations, and how the TTP team successfully adapted; (2) how the effects of COVID-19 and our adaptations to them were similar or different across TTP's reservation and urban research sites; and (3) what lessons the TTP team learned from this experience that may help other Native health research teams be resilient in this and future crises.

METHODS

TTP Protocol

TTP is a youth-focused adaptation of the Diabetes Prevention Program (DPP), which has demonstrated efficacy in adults and has been disseminated nationally (Diabetes Prevention Program Research Group, 2009; Albright & Gregg, 2013). The TTP clinical trial enrolled Native youth aged 7-10 years with overweight or obesity (age and sex-specific BMI $>=85^{th}$ percentile) and who had at least one caregiver willing to participate in the program with them. This age range was targeted because of the greater potential for changing health behaviors before they are well-established and before the metabolic transitions of puberty begin.

The original study design included plans to collect data on anthropometric, metabolic, and behavioral risk factors for type 2 diabetes at the baseline visit, at 6 months (midway through the TTP program), at 12 months (immediately after completing the program), and at 24 months (1 year after completing the program). After the baseline visit, child-caregiver dyads were randomized to either the intervention group or a control group. Participants were recruited in "waves," with new intervention and control group classes starting every six months.
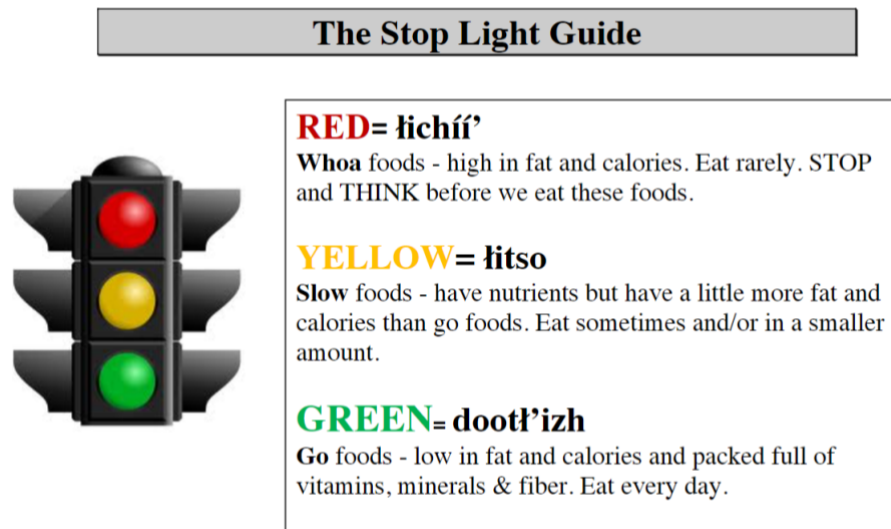
Figure 1 illustrates the 24-month timeline of study activities for the intervention (top) and control (bottom) group participants. The TTP intervention includes 12 in-person group classes and

Figure 1. Tribal Turning Point study timeline by randomization group
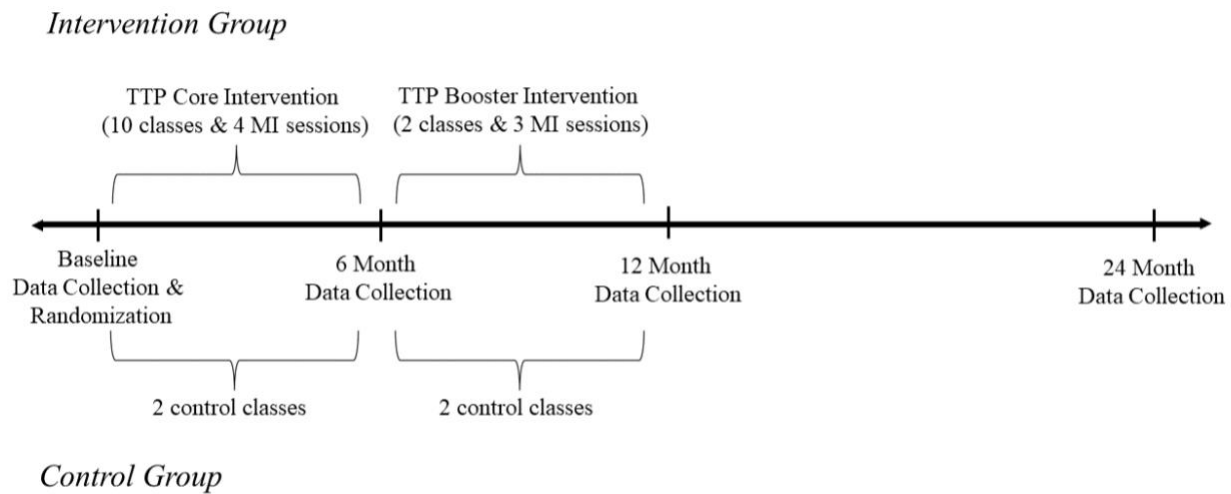
7 in-person individual family support sessions that utilize motivational interviewing (MI) strategies to assist participants in meeting TTP goals. These classes and sessions were held on weekday evenings over the course of one year. Intervention classes included a guided group workout, a healthy meal, and interactive lessons about nutrition, physical activity, setting goals, and maintaining healthy habits that integrate culture and language. PRAs used detailed manuals developed during the pilot study to guide program delivery, which included concrete and easy-to-understand learning tools (e.g., the Stop Light Guide, adapted for TTP from Epstein et al., 2008; see Figure 2). Classes and individual sessions occurred every week during the first six months of TTP (the "core" portion) and every month in the latter half of the program (the "booster" portion). Participants could earn "Wellness Bucks" for attending the program and completing goal tracker worksheets, which they redeemed for prizes like bikes, MP3 players, and weaving kits at the end of the program.

Families randomized to the control group received four in-person group classes held on weekday evenings over the course of one year. Topics for these interactive classes included bike safety, sun safety, CPR and first aid, substance abuse, bullying, art as medicine, and recycling. Whenever possible, classes were led by local Native experts to help expose families to additional programs and opportunities in their community.

Two PRAs were hired at each research site in spring 2018. PRAs are community members with varying amounts of public health education and experience, who receive ongoing training in data collection and health promotion. Participant recruitment began in summer 2018. At the

Figure 2. The Stop Light Guide

The Stop Light Guide

RED= łichíí'
Whoa foods - high in fat and calories. Eat rarely. STOP and THINK before we eat these foods.

YELLOW= łitso
Slow foods - have nutrients but have a little more fat and calories than go foods. Eat sometimes and/or in a smaller amount.

GREEN= dootł'izh
Go foods - low in fat and calories and packed full of vitamins, minerals & fiber. Eat every day.

Navajo Nation sites, recruitment occurred primarily through connections with local schools and Indian Health Service facilities. In Phoenix, partners at the Phoenix Epidemiology and Clinical Research Branch (PECRB) of the National Institute of Diabetes and Digestive Kidney Disease (NIDDK) helped recruit family members of those enrolled in other research studies, and PRAs built connections with urban Native community organizations and school-based Native American education programs.

Mixed Methods Exploration of COVID-19 Adaptations

We used a collaborative and strength-based approach to explore the TTP team's experiences during the COVID-19 pandemic. Our process was intentionally iterative, with time and space set aside for both personal reflection and team dialogue. To ground our exploration, we began by creating a timeline (Figure 3) of TTP activities during the pandemic based on a review of study documents including protocols, data collection procedures and forms, e-mail communications, photographs, tracking spreadsheets, and Institutional Review Board (IRB) submissions. The timeline informed both the qualitative and quantitative data analyses and was in turn revised based on the results gleaned from these analyses. While it began as a visualization of TTP's activities alone, through team dialogue the timeline expanded to include many tribal, state, institutional, and national events and milestones that influenced TTP's adaptations. The final version illustrates the complexities of adapting a multi-component, multi-site intervention study to the dynamic, and sometimes conflicting, contexts of different communities.
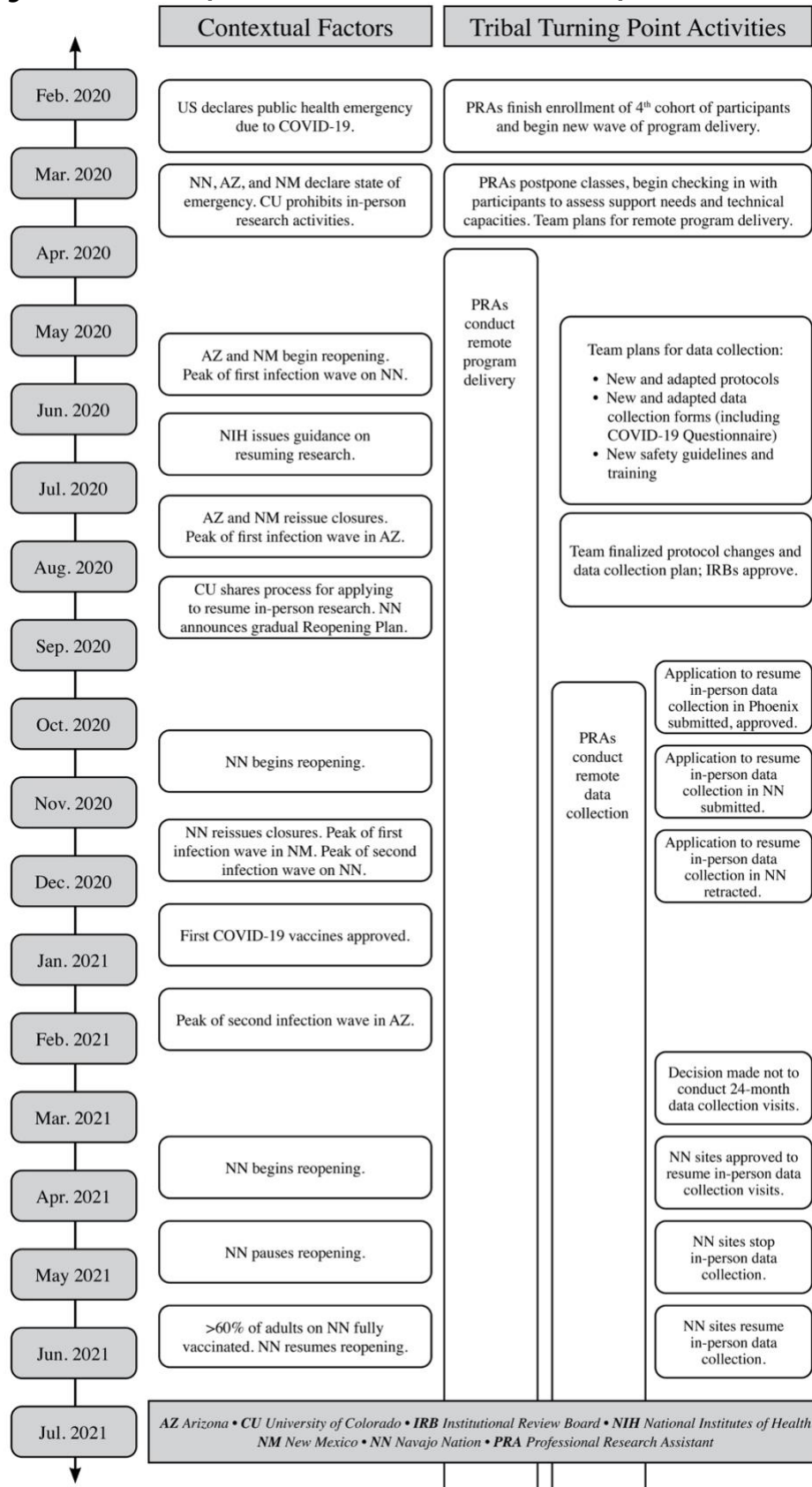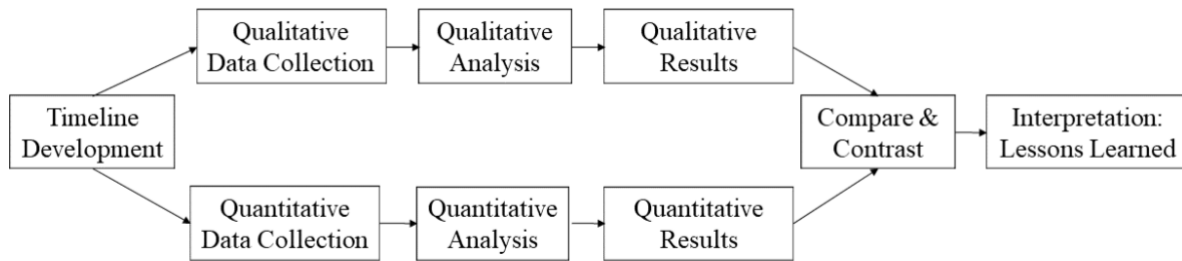
Figure 3. Timeline of COVID-19 activities and contextual factors

Figure 4. Mixed methods triangulation design convergence model used to explore TTP experiences during COVID-19

We used a mixed methods triangulation design called the convergence model to guide our exploration (Figure 4) (Creswell & Plano Clark, 2017). The purpose of the convergence model is to combine differing and complementary data by analyzing qualitative and quantitative data concurrently and separately. The convergence model enables researchers "to end up with valid and well-substantiated conclusions about a single phenomenon" (Creswell & Plano Clark, 2017, p. 65), in this case, TTP's experiences during COVID-19. Data were gathered and analyzed for each of five domains of interest (intervention delivery, participant engagement, data collection, analytic strategies, and team operations) that were determined a priori through discussions among managers and investigators.

Analysis

Qualitative Analysis

The TTP managers (one project manager [R.S.] and one data manager [J.B.]) conducted a rapid qualitative analysis to identify similarities and differences in team members' experiences of COVID-19 adaptations across the research sites. Rapid qualitative analysis is an efficient, accurate, action-oriented approach that is ideal for answering clearly defined research questions (Hamilton, 2013, 2020). Rapid qualitative analysis has been found to produce valid, reliable findings in a shorter timeframe than traditional qualitative analysis, minimizes the burden on the research team, and is well-suited to projects that aim to yield practical guidance (Gale et al., 2019; Vindrola-Padros et al., 2020). As a quality assurance and performance evaluation project, this work was exempt from Institutional Review Board oversight.

The managers developed a 10-question semi-structured guide based on the draft timeline and the five domains of interest (Table 1). The project manager invited the staff at all three sites to participate in the analysis by sharing their experiences of TTP's COVID-19 adaptations; four of

the five agreed. The project manager met with those four PRAs (P.B., D.G., S.N., and D.Y.) via Zoom to discuss the questions; these site-specific conversations were then transcribed. Transcriptions were sent to each PRA so that they could ensure their perspectives were accurately portrayed, and the managers then summarized each one using a standard template. After ensuring the consistency and completeness of the summaries, the managers consolidated the key points into a matrix with rows for each domain and columns for each site. The managers reviewed the matrix independently to identify emergent patterns of similarity and difference, then met to discuss the predominant themes.

Table 1
Questions asked by the project manager of the PRAs during site-specific conversations, by domain

Domains	Questions
Timeline	• What jumps out to you on this timeline? Why is it important? • Is anything missing from this timeline? If so, what?
Program Delivery	• Tell me about making the shift from doing TTP classes and individual sessions in person to doing it remotely.
Participant Engagement	• Tell me about how COVID-19 affected TTP participants in your community. • Tell me about your experiences communicating with participants during the pandemic.
Data Collection	• Tell me about what your experience was like when we were developing the new data collection visit protocols, the Safety Plan, and all the new forms that went along with them. • Tell me about when you first started doing fully remote data collection visits. What was that like? • Tell me about what it was like doing in-person visits in new ways.
Team Operations	• How did you stay connected with the rest of the TTP team during the pandemic?
Other	• Are there any stories you can share that show TTP's success or resilience during COVID?

Quantitative Data

Quantitative data include the self-reported effects of COVID-19 on TTP participants, which address the participant engagement domain, and data comparing pre-COVID-19 and during-COVID-19 program attendance and 12-month retention, which address the program delivery and data collection domains, respectively. All quantitative data were gathered by PRAs and collaborating partners at ACKCO (an American Indian professional services firm) and at the NIDDK PECRB. Quantitative data used in this report were extracted from the secure TTP

Research Electronic Data Capture (REDCap) database. The data manager cleaned and descriptively analyzed all quantitative data in SAS version 9.4.

Triangulation and Integration

After separately analyzing the qualitative and quantitative data, key findings from each analysis were integrated by domain to address the first two research areas: COVID-19's impacts on TTP and its adaptations, and how these experiences differed across sites. These data were then integrated across domains to address the third research area: lessons learned from TTP's experiences that may help other research teams. These interpretations were discussed and refined by PRAs, managers, and investigators.

RESULTS

Figure 3 presents a timeline of major events and changes to TTP, as well as key contextual events that shaped these adaptations. While initial reports of COVID-19 began to circulate in early 2020, the TTP team was recruiting and enrolling a new cohort of participants at all three sites. As the PRAs transitioned from data collection to program delivery, the University of Colorado, the Navajo Nation, and state governments issued emergency orders and imposed new safety measures. Throughout the pandemic, the team adapted study operations to the dynamic local influences and corresponding guidance from these multiple institutions and communities, which sometimes varied across research sites. The results of our exploration of adaptations and their effects (aim 1) are summarized in Table 2; results illustrating similarities and differences across sites (aim 2) are summarized in Table 3.

Table 2
Summary of aim 1 results: Effects of and adaptations to COVID-19 by domain

Domain	Qualitative Results	Quantitative Results
Intervention Delivery	• The team transitioned from in-person to remote delivery in response to COVID-19 shutdowns. • Remote delivery protocol development was collaborative and iterative.	• Mean program attendance during the pandemic was 9 classes/sessions, similar to the pre-pandemic mean of 10 classes/sessions.
Participant Engagement	• Some participants struggled to remain engaged in TTP during the pandemic due to stress, communication barriers, and competing priorities. • The team's flexibility, creativity, and empathy were key to sustaining engagement.	• 7% of children and 18% of adults had or likely had COVID-19. • 25% of families lost a loved one to COVID-19. • 54% of families experienced moderately or extremely negative impacts from COVID-19.

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Table 2
Summary of aim 1 results: Effects of and adaptations to COVID-19 by domain

Domain	Qualitative Results	Quantitative Results
Data Collection	• The study team collaborated to create safety plans, visit protocols (including for adapted in-person visits and new remote and hybrid visits), and data collection forms. • Coordinating and implementing changes was sometimes stressful and required compromise, but was ultimately worthwhile because it ensured participant safety.	• 71% of participants completed 12-month BMI measures before COVID-19, as compared to 53% during COVID-19. • 62% of participants completed 12-month insulin measures before COVID-19, as compared to 36% during COVID-19.
Data Analysis	• TTP's existing quantitative and qualitative analysis strategies and guiding frameworks will address the potential effects of COVID-19 on study outcomes. • Analyses will control for timing of data collection in reference to baseline, as collection of some measures were delayed due to COVID-19 restrictions. • COVID-19 will likely influence the way study results are interpreted.	• N/A
Team Operations	• Communication across TTP sites was already primarily virtual before COVID-19, but the shift to remote work required creative and flexible solutions, especially for intra-site collaboration. • During the pandemic, new types of support were provided by managers to PRAs and PRAs to one another.	• N/A

Table 3
Summary of aim 2 results: Similarities and differences of COVID-19 across sites by domain

Domain	Qualitative Results	Quantitative Results
Intervention Delivery	• PRAs at the Navajo Nation sites used mainly phone calls and mail to deliver the intervention remotely. • PRAs in Phoenix used mainly a mix of phone calls and video-based platforms to deliver the intervention remotely. • All PRAs were highly flexible to meet participant needs.	• Mean program attendance during the pandemic was 14 classes/sessions in Phoenix and 10 classes/sessions at the Navajo Nation sites.
Participant Engagement	• PRAs at all sites responded to participant experiences and needs with empathy and patience.	• 19% of child participants in Phoenix and 4% in Navajo Nation had or likely had COVID-19. • 38% of adult participants in Phoenix and 14% in Navajo Nation had or likely had COVID-19. • 38% of families in Phoenix and 22% in Navajo Nation lost loved ones to COVID-19. • 31% of families at the Phoenix site and 59% at the Navajo Nation sites reported experiencing negative impacts from COVID-19.

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Table 3 continued
Summary of aim 2 results: Similarities and differences of COVID-19 across sites by domain

Domain	Qualitative Results	Quantitative Results
Participant Engagement	• PRAs at all sites responded to participant experiences and needs with empathy and patience.	• 19% of child participants in Phoenix and 4% in Navajo Nation had or likely had COVID-19. • 38% of adult participants in Phoenix and 14% in Navajo Nation had or likely had COVID-19. • 38% of families in Phoenix and 22% in Navajo Nation lost loved ones to COVID-19. • 31% of families at the Phoenix site and 59% at the Navajo Nation sites reported experiencing negative impacts from COVID-19.
Data Collection	• In-person data collection resumed earlier at the Phoenix site than at the Navajo Nation sites in response to local conditions. • Each site had its own specific visit protocols to address unique geographical and institutional requirements.	• Completion rates for 12-month BMI measures during COVID-19 were 48% in Phoenix and 54% at the Navajo Nation sites. • Completion rates for 12-month insulin measures during COVID-19 were 48% in Phoenix and 33% at the Navajo Nation sites.
Data Analysis	• N/A	• N/A
Team Operations	• Team communication was often more challenging at the Navajo Nation sites than the Phoenix site due to more limited phone and internet connectivity.	• N/A

Intervention Delivery

In the first weeks of the shutdown the TTP team collaborated to determine how best to deliver the program remotely. The PRAs first drew on methods used before the pandemic to make up sessions with families who had missed a TTP session, which consisted of mailing class handouts to the participants and speaking with them by phone to review the main points and answer questions, as well as conducting individual sessions by phone. Based on this existing make-up delivery system and on discussions with the PRAs, the project manager created a brief set of guidelines for remote program delivery during COVID-19 that included information about additional remote delivery modes (e.g., e-mail and videoconferencing), instructions to help participants prepare for remote sessions, and changes to the Wellness Bucks reward system. The PRAs, as experts in delivering the TTP curriculum, used the existing coach's notes, individual session scripts, and participant handouts to determine the key points of each class and how best to cover them remotely. While the written content and session objectives remained unchanged, some program activities designed for in-person classes, such as group reflections and active multi-player games, had to be adapted, condensed, or removed for virtual individual delivery.

Remote program delivery was challenged by varying technological capacities across and within sites. Some participants on the Navajo Nation lacked internet access, and others had poor cell phone service. Only a few were able to receive e-mailed materials or conduct remote classes using videoconferencing; most communicated with the PRAs primarily by text messages and phone calls and received materials by mail or remote drop-offs. Ultimately, the PRAs on the Navajo Nation continued to use a remote delivery method similar to the original protocol for make-up classes. In contrast, at the Phoenix site the PRAs were able to record videos of the content for each class, e-mail or text the video links and handouts to participants, and then review key points with most of the participants via HIPAA-compliant videoconferencing platforms, such as Zoom. Later in the pandemic, the Phoenix PRAs were also able to conduct live classes via Zoom. Individual session delivery methods followed similar patterns across the sites. PRAs at all sites worked closely with individual families to assess and meet their needs.

The transition to remote program delivery began in March 2020 and was implemented at all sites by June. The PRAs attribute the success of remote delivery to reducing class content to just the essential points, which meant skipping some details but made the material more accessible and comprehensible to participants. PRAs also highlighted the importance of their share-then-review method, which included extra communication with participants prior to each remote class to ensure they were prepared to discuss the material. The principal investigators also allowed the PRAs to continue to deliver "core" program content after the 6-month midpoint, recognizing that many participants had not been able to engage with the program in the early stages of the pandemic (the same allowance had been made pre-pandemic when families missed sessions). Such flexibility allowed the PRAs and participants time to catch up on classes and individual sessions that had not been completed. This combination of strategies led to attendance rates that closely matched pre-pandemic levels: on average, participants in the intervention group completed 10.16 classes and individual sessions during the pandemic, as compared to 9.71 pre-pandemic (see Table 4), out of a possible total of 19 (12 classes and 7 individual sessions). The mean number of classes/sessions was similar across sites during the pandemic (10.22 at the Navajo Nation sites and 13.86 in Phoenix). Pre-pandemic attendance differences across sites (9.12 classes/sessions at the Navajo Nation sites vs. 17.50 in Phoenix) are attributable to the greater number of pre-COVID-19 intervention participants at the Navajo Nation sites ($n = 26$) as compared to Phoenix ($n = 2$).

Table 4
Intervention program attendance pre-pandemic vs. during pandemic, by location and overall
(n=85)

	Navajo Nation Sites		Phoenix Site		Overall	
	Pre-Pandemic (*n*=26)	During Pandemic (*n*=46)	Pre-Pandemic (*n*=2)	During Pandemic (*n*=11)	Pre-Pandemic (*n*=28)	During Pandemic (*n*=57)
Mean Number (SD) of Intervention Classes/ Sessions Completed	9.12 (6.89)	10.22 (6.73)	17.50 (0.50)	13.86 (6.34)	9.71 (6.98)	10.16 (6.66)
Mean Percent of Intervention Classes/ Sessions Completed	47.98%	53.78%	92.11%	72.93%	51.13%	53.46%

Table 5
Participant-reported physical and mental health impacts of COVID-19, by location and overall
(n=89)

	Navajo Nation Sites (*n*=73)	Phoenix Site (*n*=16)	Overall (*n*=89)
Enrolled children who had or likely had COVID-19	3 (4.11%)	3 (18.75%)	6 (6.74%)
Enrolled adults who had or likely had COVID-19	10 (13.70%)	6 (37.50%)	16 (17.98%)
Families who lost a loved one to COVID-19	16 (21.92%)	6 (37.50%)	22 (24.72%)
Families who experienced moderately or extremely negative impacts from COVID-19	43 (58.90%)	5 (31.25%)	48 (53.93%)

Participant Engagement

COVID-19 imposed a drastic change in lifestyle, priorities, and stress levels for TTP participants. Table 5 summarizes data from a COVID-19 questionnaire administered to TTP families at all visits during the pandemic, from August 2020 through August 2021 (the most recent data from each participant is used, as some provided this data at multiple visits), which illustrates some of the self-reported physical and mental effects of the pandemic. While relatively few child participants likely had COVID-19, nearly 1 in 5 adult participants reported that they were likely infected, and 1 in 4 families lost a loved one to the pandemic. A higher percentage of families at the Navajo Nation sites reported that they had experienced moderately or extremely negative impacts as a result of the pandemic compared to the Phoenix site.

When the pandemic first began, the PRAs contacted participants to see how they were doing. In the ensuing months, the PRAs continued to check in and continuously provided participants with important COVID-19 safety information via culturally appropriate infographics, flyers, and electronic resource lists shared via mail, e-mail, text messages, and social media. The same array of communication methods was used to offer updates on study changes and to send reminders about classes and individual sessions. At one of the Navajo Nation sites, a PRA volunteered with community organizations to help provide food, water, and hygiene products to families in quarantine, including some TTP participants. At all sites the PRAs also continued traditional retention strategies, such as sending birthday cards to child participants.

Since families had not planned to engage in TTP via virtual methods when they enrolled, the team had to adapt to the specific technological capacities of each household. The PRAs had to creatively find ways to adhere to the spirit and intent of TTP while allowing participants to engage more effectively from home. PRAs demonstrated flexibility in finding a consistent day and time each week to meet with each family, but also recognized the need for patience as families made the difficult shift to working and learning from home and dealt with the physical and mental strains of pandemic life.

At the Navajo Nation sites, where many families traveled to their PO boxes at infrequent intervals, PRAs sometimes dropped off class materials at participants' doorsteps or sent materials by e-mail if families had access to home internet. Even in our urban site, where most participants could receive class materials via e-mail, many families lacked home printers and struggled to complete class worksheets. When families told the PRAs they were having trouble accessing enough copies of the TTP goal trackers, the PRAs encouraged them to make their own and text photos to the PRAs when the trackers were complete (see Figure 5).

The PRAs emphasized the importance of relying on their existing interpersonal connections with participants to sustain engagement. Responses were often slow to come; the PRAs reacted with patience and empathy. During some individual sessions the PRAs simply listened, allowing participants to unburden themselves of their worries and providing validation of their emotional experiences. During some class review calls, PRAs asked a question only to learn from a child participant that their parent had left mid-class to run an errand. One PRA said participant engagement during COVID-19 sometimes felt like digging a ditch with a spoon. Yet, the PRAs were able to sustain their relationships with the majority of the participants, as illustrated in the attendance data described in the previous section.

Figure 5. A typical TTP goal tracker (top) and two participant-made goal trackers (bottom)
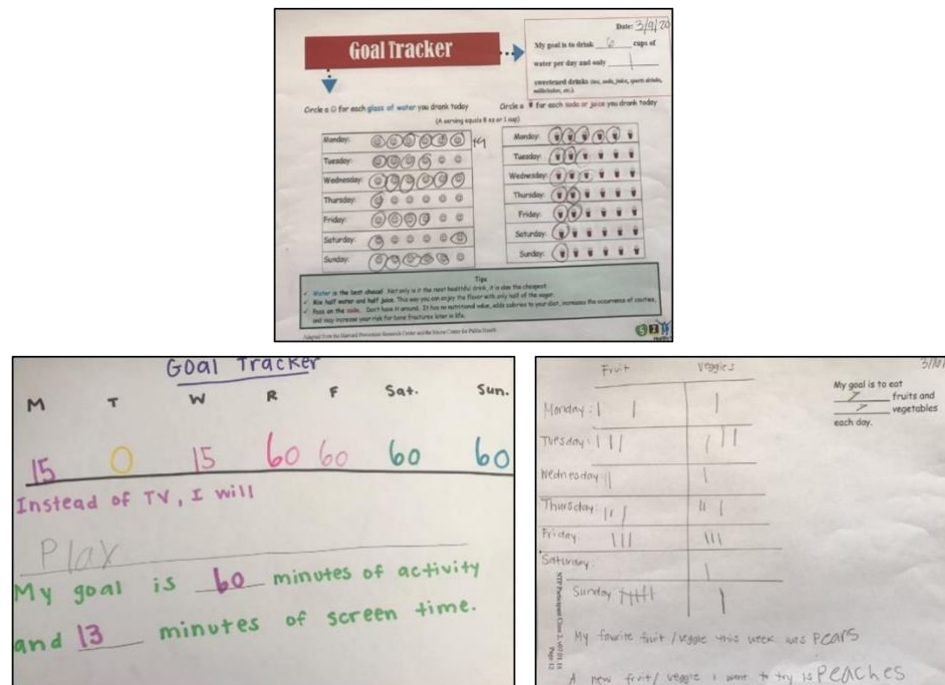
Data Collection

Data collection was not conducted during the first several months of the pandemic, as TTP's wave-based recruitment structure results in six-month gaps between collection phases that aligned with the start of the pandemic. This allowed the TTP team to spend time discussing, developing, and editing thorough visit procedures that incorporated new safety measures and data collection strategies. Most of the discussion centered on how to minimize participant and staff contact during data collection visits. The result was a series of protocols offering a range of visit options, as well as a scheduling script to help the PRAs determine the most appropriate visit type for each family.

The fully remote visit protocol included instructions for PRAs to drop off visit materials (including paperwork, an accelerometer, a scale, a stadiometer, and gift cards) on the doorstep of a participant's home at an agreed-upon day and time, walk the family through the visit by phone or video, and then retrieve the completed paperwork and other materials from the doorstep. This visit type allowed for the collection of data to assess one of TTP's primary outcomes (i.e., height and weight, which participants could measure themselves with staff guidance), but not the other (i.e., a fasting venipuncture to measure insulin, which required in-person interaction between

PRAs and participants). The adapted in-person clinic protocol prioritized the data that could not be gathered remotely and detailed enhanced safety precautions. It also demarcated which data collection measures participants could be encouraged to complete remotely to reduce in-person exposure. In the "hybrid" visit option, only priority measurements took place in person and nearly all other data collection took place remotely. Additional adapted versions of these visit protocols (e.g., an in-person outdoor home visit protocol) were developed later as seasonal and institutional changes created new opportunities for innovative data collection methods.

The project manager drafted a COVID-19 Research Safety Plan containing basic information about COVID-19 and expectations for PRAs and participants around personal protective equipment, disinfecting, screening, and reporting. Many other supplemental documents were also created, such as a COVID-19 screening form that PRAs administered to participants before visits and a follow-up fact sheet provided to participants after visits with basic information about COVID-19 symptoms and what to do if exposed. In addition, various updates were made to existing data collection forms and the REDCap database.

After these initial documents were drafted by the project manager with input from the PRAs, each site team met repeatedly for several months to identify issues and suggest edits. For the Navajo Nation sites, this included adding questions to the scheduling script to find out more about where families lived before a drop-off (e.g., whether their road was likely to become muddy when it rained, precluding a remote drop-off). For the Phoenix team, this meant incorporating safety measures and screening questions required by TTP's partners at the NIDDK PECRB, who provide essential support for data collection at that site.

All PRAs received training on the final plans from the project manager via Zoom and were then asked to sign a code of conduct acknowledging they agreed to follow the safety requirements. The project manager followed up about safety questions and concerns on weekly Zoom meetings with each site, made documents available in a shared online drive, and provided periodic updates and reminders via e-mail. The visit protocols and safety plan were viewed as living documents and were continuously updated to address changing circumstances. As these new visit protocols, safety plans, and associated materials were developed and updated, changes were also made to the TTP Study Protocol. These documents were submitted to TTP's IRBs at the University of Colorado, the National Institutes of Health, and the Navajo Nation Human Research Review Board.

For the PRAs, the development of new documents was often stressful. Safety was everyone's priority, but varying institutional rules and differing interpretations of the emerging

scientific evidence led to some challenging conversations and necessitated compromises. In addition, these new multi-part visit protocols and additional safety precautions required a great deal more time and effort from the PRAs than traditional visits. Ultimately, however, the lengthy visit adaptation and reimplementation processes were perceived as worthwhile because they resulted in clear roles and responsibilities and protocols that flowed well. Although learning the new protocols was difficult for the PRAs, they witnessed the value of the changes when participants expressed their willingness to attend visits and their appreciation for the new safety requirements and options. The PRAs stated that the participants' cooperation and enthusiasm were the key to the success of data collection during the pandemic.

While remote data collection was implemented by all sites in September 2020, in-person data collection resumed at different times for each of the sites—in October 2020 at the Phoenix site and in May 2021 at the Navajo Nation sites—in response to varying local safety conditions. Approval processes were lengthy, as they involved submissions to multiple institutions. For the Phoenix site, approvals were granted by both the University of Colorado and the National Institutes of Health in late September 2020. However, when applications for the Navajo Nation sites were submitted to the University just weeks later, COVID-19 infections had begun to increase, and the applications were retracted. In-person research activities were not approved for the Navajo Nation sites until March 2021, were paused when the Navajo Nation reissued shelter-in-place orders in April 2021, and resumed in May 2021 when reopening recommenced. The team then continued to monitor local case rates and other metrics in each community to ensure that visits remained safe.

In early 2021, after reviewing data collection and retention data from the past year, TTP investigators made the difficult decision to forego the 24-month data collection visit at all sites in order to reallocate resources to 12-month data collection efforts. The changes in BMI and fasting insulin from baseline to 12 months are the primary outcomes of TTP; focusing the PRAs' time and energy on collecting this data was deemed essential to the evaluation of the TTP intervention. Amendments to the study protocols were submitted to and approved by all necessary IRBs, the Data Safety and Monitoring Board, and the NIH study sponsor in spring and summer 2021, and PRAs began informing participants of the change by letter and at visits.

Due to the collaborative efforts of the participants, PRAs, managers, investigators, and partners to adapt TTP's data collection activities, the number of participants completing 12-month visits increased steadily throughout spring and summer 2021. However, it was exceedingly difficult to schedule visits with some participants; even when scheduled, the increased complexity

of multi-part visits led in some cases to incomplete data (e.g., completed questionnaires but no specimens collected, or vice versa). As of August 2021, the 12-month retention rate among participants impacted by the pandemic remained lower than for that of participants who completed TTP prior to the pandemic for both primary outcomes (see Table 6). Completion rates for height and weight measures during the pandemic, which could be collected remotely, were similar across sites (54.44% at the Navajo Nation sites and 47.83% in Phoenix). Insulin completion was lower at the Navajo Nation sites (33.33%) than at the Phoenix site (47.83%), likely because the Phoenix team was able to conduct more in-person 12-month visits earlier in the pandemic, whereas the Navajo Nation teams had to gather remote data first, then re-engage participants to conduct partial in-person visits months later.

Table 6
12-month data on primary outcomes collected pre-pandemic vs. during pandemic (n=178)

Measurement (**Outcome**)	**Navajo Nation Sites**		**Phoenix Site**		**Total**	
	Pre-Pandemic (*n*=**61**)	**During Pandemic** (*n*=**90**)	**Pre-Pandemic** (*n*=**4**)	**During Pandemic** (*n*=**23**)	**Pre-Pandemic** (*n*=**65**)	**During Pandemic** (*n*=**113**)
Participants with complete height and weight (BMI) measures at 12 months	70.49%	54.44%	75.00%	47.83%	70.77%	53.10%
Participants with complete venipuncture (insulin) measures at 12 months	62.30%	33.33%	50.00%	47.83%	61.54%	36.28%

Analysis Strategies

Because TTP continues to recruit participants and deliver the program, data analysis has not yet begun. However, we suspect that the COVID-19 pandemic has impacted TTP participants in ways that will affect their anthropometric, metabolic, and behavioral outcomes. We do not anticipate difficulty in accounting for the effects of COVID-19, as longitudinal studies in which participants are enrolled over time must plan for time-based adjustments. Our existing analysis plan is therefore well suited to account for the potential "history effect" introduced by the pandemic (for an in-depth discussion of this effect and related implications of COVID-19 on study validity see Mara and Peugh, 2020). In short, the imposition of COVID-19 does not in itself change the analytical strategy to be employed, although it will likely change the way the findings are

interpreted. Moreover, power to detect significant program effects will be impacted if attrition is higher than was anticipated during the planning of the trial.

TTP also aims to explore multi-level factors related to participant engagement, program implementation, and potential for sustained delivery. COVID-19 presents an unexpected but measurable factor in TTP's implementation and will be addressed through data gathered in alignment with our guiding frameworks: the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model and the Practical, Robust Implementation and Sustainability Model (PRISM) (Glasgow et al., 1999; Feldstein et al., 2008; Glasgow et al., 2019). The Model for Implementation Design and Impact (MADI) is one tool with which we may elucidate the specific impacts of study adaptations on outcomes (Kirk et al., 2020).

Team Operations

Due to its community-based, multi-site structure TTP always utilized remote communication methods (e.g., phone calls, texts, e-mail, Zoom meetings) and shared documents via secure online servers (e.g., REDCap, cloud-based drives) to stay connected across hundreds of miles of distance. The project manager visited each site every few months and study-wide in-person meetings occurred annually. The pandemic halted in-person interactions, forcing the team to use only remote communication and to find new ways to support one another. This transition was especially challenging for the site-based PRA teams, which had previously worked together in shared offices. PRAs on Navajo Nation had more limited access to reliable internet connectivity at home than the PRAs in Phoenix, which impacted communications with both participants and the study team and required creative solutions, flexibility, and empathy from managers and fellow PRAs. However, all PRAs had to find new ways to do intra-site team activities that they had previously accomplished in person, including increased use of Zoom, phone calls, and text messages. PRAs were encouraged to bring home materials from the offices, and some additional equipment was purchased to support their remote work. The managers also sent the PRAs two "self-care" packages containing items such as cloth face masks, thermometers, scented candles, tea, seeds, and handwritten cards.

Managers strove to offer team-based support via weekly site-team Zoom meetings and monthly full-team Zoom meetings. Managers also provided interpersonal support through regular one-on-one calls, which gave PRAs a private space to share ideas, discuss their work, and ask for help. Some PRAs wanted more structure, and requested additional reminders and check-in calls;

others asked for more independence, such as working in evenings and on weekends to accommodate family care during the weekdays. TTP had always allowed for flexible schedules, including evening and weekend work, so that PRAs could adjust to participants' schedules; however, finding a balance between participant, PRA, and study needs during the pandemic required ongoing conversation. Sometimes Zoom meetings became phone calls if internet connections did not cooperate, and e-mailed notes were always sent after meetings to ensure key messages were not lost in broken audio. The PRAs acknowledged that the respect, clear communication, and genuine care demonstrated by the managers and investigators during the pandemic was crucial to the continuation of the study and added that these same characteristics were critical in their own relationships with the participants.

The PRAs also drew strength from their site teams. Several PRAs emphasized the importance of finding new ways to communicate with and support one another and how vital it was to have others to reach out to for encouragement in difficult times. Teamwork across sites was limited due to their physical separation and the vastly different circumstances in which they were operating. However, all of the PRAs expressed their appreciation for the opportunities to connect as a team that did take place, including trainings, debriefs, and staff meetings.

DISCUSSION

The qualitative and quantitative results of our exploration illustrate the deep impacts COVID-19 has had on TTP, the myriad ways in which the team has adapted to these difficult circumstances, and the primarily positive outcomes of these efforts. Intervention delivery and data collection transitioned to primarily remote methods, and sustaining engagement—with participants as well as within the study team—was challenged by technological limitations and the strains of adjusting to pandemic life. Creativity, flexibility, and clear communication across all levels of the study team emerged as essential features of TTP's resilient response. The fruits of these efforts are evident in the program attendance data, which are comparable to pre-pandemic levels and are similar across sites; however, the 12-month retention data illustrates that even the best adaptations cannot overcome all obstacles.

The results also illustrate the complexity of multi-site research adaptation. The Navajo Nation PRAs relied on phone calls and mail to deliver the program remotely, while the Phoenix PRAs were able to incorporate more videoconferencing and e-mails. Some participants at each site

experienced COVID-19 infections or lost loved ones, although participants at the Navajo Nation sites reported more negative impacts from the pandemic than Phoenix site participants. Due to differences in local contexts, the Navajo Nation sites were approved to resume in-person data collection more than five months later than Phoenix; this forced the Navajo Nation PRAs to rely longer on fully remote data collection visits, which likely contributed to the lower rate of completed 12-month insulin measures.

Many aspects of the TTP team's experience during the COVID-19 pandemic mirror those of other clinical research studies. Eighty percent of clinical trials were either interrupted or postponed by COVID-19 (van Dorn, 2020), and there is a growing literature exploring the effects of the pandemic on research. However, while the existing literature on adapting clinical trials to COVID-19 offers a wealth of advice about what research study leadership should or should not to do (e.g., McDermott & Newman, 2020; Mitchell et al., 2020; Perez et al., 2020; Shiely et al., 2021), it provides little information about the processes by which study teams arrive at effective decisions or how they work through the challenges of implementing them. Several articles have focused on only one domain of adaptation, such as in-person data collection visits (Padala et al., 2020; Kreuger et al., 2021) or data analysis strategies (Mara & Peugh, 2020). The few articles that summarize how studies adapted across domains and lessons learned from this experience are either about hospital-based interventions, such as cancer trials (e.g., Marcum et al., 2020), or about behavioral interventions for adults (e.g., Röhr et al., 2020). We were not able to find any articles exploring COVID-19 adaptations to behavioral interventions for children or for Native populations.

This paper fills this gap in the literature. Rather than dictating what study teams ought to do in times of crisis, we have chosen to highlight the TTP team's underlying values, which guided the strategies we employed—in other words, not just *what* we did to adapt effectively, but *how and why* we did it. The lessons we present arose out of iterative discussions of key qualitative and quantitative findings and cut across the domains of interest. They represent the core principles the TTP team believes allowed us to meet the challenges of the COVID-19 pandemic.

(1) Ensure the support offered is flexible to differing needs and responsive to changes over time

Everyone involved in a research study, including participants and staff, needs clear, consistent, and trust-based communication in times of crisis and uncertainty. There is no one-size-fits-all approach; effective support will look different for different people and must be able to adapt to changing circumstances.

We found that participants needed flexibility in their modes of communication, their schedules, and their opportunities to engage with program content. Keeping participants up to date on how the study was adapting and how those changes would impact them was particularly important. This lesson aligns with results from two recent systematic reviews that showed building participant-researcher trust, improving participant understanding of the study's purpose and components, and employing personalized, continuous contact are all effective retention strategies (Wong et al., 2021; Nicholson et al., 2015). In addition, in their recommendations for clinical trial adaptation during COVID-19, McDermott and Newman (2020) argue that "Participants should be informed of necessary changes in protocol and how this may affect the risk associated with study participation. For many randomized trials, communication from research staff is likely to help protect against dropout or nonadherence by reassuring participants that their trial involvement remains important, even during the pandemic" (p. 2135). The TTP team found that the most essential factor in all communications was providing a clear set of options and allowing participants to choose for themselves if and how to engage.

We also learned that managers must support PRAs across their spectrum of need by offering what material, technological, structural, and interpersonal help they can within the professional and financial limits of the study. This includes managers asking PRAs what they need, repeatedly and without judgment. In any crisis, we encourage PRAs to communicate with participants, and managers to communicate with PRAs, from a place of curiosity and empathy. Providing such support is key to enabling the study team in delivering the program and collecting data with fidelity and to enabling participants to fully engage in these study activities.

(2) Adapt collaboratively and iteratively while remaining rooted in community

Implementation of a research study always involves some form of adaptation; crises simply place a spotlight on this process. Carefully planning and documenting adaptations helps ensure they are effective, allows for analyses that assess how the adaptations impacted study outcomes, and supports planning for re-implementation of successful interventions in new settings (Bauer & Kirchner, 2020). When adapting study materials or processes, we recommend that research teams slow down and think creatively and collaboratively about each decision point. In the midst of a crisis it can feel like action is needed right away, but the TTP team found that workable adaptations developed only after several group planning sessions, pilot testing, and readjustment. We also found that sometimes the best adaptations were those that already existed within the study (e.g.,

TTP's make-up session method, which became the basis of remote program delivery), while others required new ideas. Studies at the same site or center may also learn from one another: for example, at the Phoenix site TTP was approved to begin in-person data collection visits before many other studies in their shared clinic space, which made the TTP PRAs role models and sources of key knowledge for staff on other studies.

Above all, adaptation should be guided by community. The centrality of community in Native health research is well established. As Whitesell at al. (2018) explain, interventions must be tailored to cultural and community context to ensure the study's rigor and outcomes. While many have written about the importance of community and culturally based intervention development at the start of a study (e.g., see Dickerson et al., 2020; Walters et al., 2020), community-based adaptation mid-study is less discussed. Jernigan et al. (2020) recently argued that we need more dissemination of study implementation strategies, including adaptation, in Native communities to ensure the scaling up and sustainment of successful interventions.

Making community-centered decisions requires incorporating information from outside the research team by seeking guidance from tribal and state authorities, community organizations, and other local sources. Managers and investigators, especially those who are not on site, may need to rely on PRAs to help identify and share pertinent safety updates, as well as to "read" the status of their community. What this process looks like in one tribal nation will differ from another, which will differ in turn from urban Native communities. Once information is gathered, additional time and effort are needed to apply it to study decisions and to resolve conflicts among different communities and institutions. TTP's COVID-19 timeline (Figure 3) illustrates our experience of this interplay between community context and study adaptation. Despite the pandemic-era popularity of the phrase "we are all in the same boat," in a multi-site team, different team members will likely be in different boats, even as they face the same storm. Some communities will be more impacted than others at various times and will have different resources to respond with. Equality of response is typically not the answer; instead, we recommend using an equity lens to adapt to each community's circumstances.

(3) Recognize that relationships are the foundation of research

The essential role of relationship in research has been explored at length by numerous Native researchers. For example, Wilson (2008) explains the concept of relational accountability by observing that researchers "are accountable to ourselves, the community, our environment or

cosmos as a whole, and also to the idea or topics that we are researching. We have all of these relationships that we need to uphold" (p. 106). To this list we would add the relationships that researchers, both Native and non-Native, have with one another as they work toward shared aims. These relationships are essential for making sound decisions and implementing those decisions effectively under challenging circumstances.

We recommend that research teams think critically and speak openly about who is giving input into which decisions across all levels of the study. High-level changes to study design always require investigator leadership. However, detail-oriented adaptations must be developed with PRA input or they are unlikely to be implemented with fidelity. In all cases, when collaboration takes place around a proposed change everyone should be clear on who is empowered to make the final decision; otherwise, team members whose input is not integrated may refuse to implement the decision or may disengage from future decision-making efforts.

When conflicts around decisions arise, teams should weigh the risks and benefits from multiple perspectives. Hsu et al. (2021) stress the ethical dimensions of the research decision-making process during the COVID-19 pandemic. However, not all members of the study team may have the same perspective on what is ethical. In a participatory analysis with diverse Native stakeholders, Parker et al. (2019) found that Native health research ethics differ from the Western research ethics outlined in the Belmont Report. Yuan et al. (2014) also found that Native research ethics in urban settings may differ from those on reservations. These complexities require us to be gentle with ourselves and our teams, especially during periods of disagreement. Decisions made under uncertain circumstances are incredibly challenging and will not always bring the results we intend. We attribute much of TTP's resilience during the pandemic to our ability to prioritize listening to and learning from one another's perspectives and to remaining united in improving the health of Native communities.

CONCLUSION

In this paper we have summarized the effects of COVID-19 on the TTP study, how our team has adapted to these challenges, the outcomes of these adaptations, and how these effects, adaptations, and outcomes have compared across research sites. We considered five domains—intervention delivery, participant engagement, data collection, data analysis, and team operations—and used the results of our mixed methods triangulation analysis to derive three cross-

cutting lessons learned. Some of these lessons, such as the importance of community-based adaptations and of making space for diverse ethical viewpoints in decision-making, are perhaps most relevant to research teams working with Native populations. Other lessons, such as the need to plan for adaptations in advance and to be flexible and supportive in times of crisis, will likely resonate with public health research teams more generally. The TTP team offers these lessons not as novel ideas, recognizing that many have been written about by others before us. Rather, they represent a consolidation of resilience strategies that we hope will support the successful adaption of Native research studies both during the ongoing COVID-19 pandemic and in future crises.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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AUTHOR CONTRIBUTIONS

The project manager and data manager proposed the design of this manuscript, gathered qualitative data, conducted quantitative and qualitative analyses, wrote and edited the paper, and coordinated collaborations across the study team. The PRAs collected quantitative data, provided qualitative data, and contributed to multiple rounds of editing to ensure their perspectives were being accurately portrayed and that the lessons learned resonated with their experiences. The investigators approved the approach to the manuscript and contributed to the writing and editing process.

COMMENTARY

BETWEEN TWO WORLDS: IMPACTS OF COVID-19 ON THE AI/AN HEALTH RESEARCH WORKFORCE

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Abstract: The COVID-19 pandemic has had devastating global and national impacts including major loss of life, economic downturns, and ongoing impairments to mental and physical health. Conducting health research has remained a priority and has helped mitigate some of the COVID-19 devastation; however, challenges to research have arisen due to COVID-19 prevention strategies and changing community priorities for research. The purpose of this article is to focus on a critical piece of the health research process with American Indian and Alaska Native (AI/AN) communities and the AI/AN health research workforce. Throughout this editorial, we provide challenges faced while conducting research with AI/AN communities during the COVID-19 pandemic including changes to research processes and ongoing research studies, taking on multiple roles in academic spaces, and mourning for continuous community loss while continuing to conduct research that may benefit AI/AN communities. Using a strengths-based lens, we also provide examples of flexibility, adaptation, and resilience in the face of the ongoing COVID-19 pandemic.

INTRODUCTION

Impact of COVID-19

The COVID-19 pandemic has had a profound global impact with over 6 million confirmed deaths and 960,703 confirmed deaths in the United States alone (World Health Organization, 2022). COVID-19 mitigation protocols, including social isolation and distancing, have protected some community members from the virus; however, over a year of social isolation has also caused psychological harm (Da et al., 2020; McPhee et al., 2020). Additionally, individuals working in

essential positions (e.g., grocery stores, hospitals) are not able to isolate and are at increased risk of viral infection (Goldman et al., 2021). COVID-19 in the United States has contributed to increases in mental health conditions including depression and anxiety and increases in alcohol consumption (Calina et al., 2021; Saltzman et al., 2021). All communities have felt the impacts of COVID-19; however, some communities have experienced disparities in morbidity and mortality due to socioeconomic factors like working in essential positions and an inability to isolate after COVID-19 exposure due to overcrowded housing (Goldman et al., 2021; Kakol et al., 2021; Saltzman et al., 2021).

Impact of COVID-19 on AI/AN Communities

COVID-19 has had a disproportionate impact on the health and economy of AI/AN communities (Weiner et al., 2020). Throughout the pandemic, AI/AN individuals and communities in the United States have experienced severe inequities in structural and social determinants of health, including lack of basic resources such as running water and electricity (Brosemer et al., 2020; Silva et al., 2021). Tribal Nations also have some of the highest levels of household overcrowding in the United States (Singleton et al., 2009). These disparities made COVID mitigation strategies, such as frequent handwashing and quarantine, a challenge for many AI/AN communities (Kakol et al., 2021). In addition, due to rurality and other issues, health care is often either impossible or near impossible to access (Kakol et al., 2021). COVID-19 has also had a profound impact on Indigenous determinants of health, which acknowledge that AI/AN health is influenced by sociopolitical, historical, and cultural factors, such as sovereignty, connection to land, language, cultural teachings, experiences with racism, and access to health care (Greenwood et al., 2018). Tribal sovereignty, which is the right of AI/AN Nations to govern themselves, empowered tribes to enforce their own mask mandates, secure their borders, and identify their own vaccine priority groups, such as traditional language speakers and elders (Brown, 2021; Hiraldo et al., 2021).

The purpose of this article is to describe the challenges experienced by AI researchers and scholars who are engaged in research with AI/AN communities during the COVID-19 pandemic. We (the authors of this article) identify as parents, siblings, daughters, family members, and as members of AI communities. We also identify as AI women who engage in research with AI/AN communities as a doctoral candidate (CC), a postdoctoral scholar (AMH), an Assistant Scientist (JR), and an Assistant Professor (AAJ). Throughout the article we describe challenges we have

faced while conducting research with AI/AN communities during the COVID-19 pandemic including changes to research processes and ongoing research studies, taking on multiple roles in academic spaces, and mourning for continuous community loss while continuing to conduct research that may benefit AI/AN communities. We intentionally provide strengths-based examples of flexibility and adaptation, beginning with a spotlight on the protective factors, to highlight the ongoing resilience exemplified by AI/AN communities during the COVID-19 pandemic. It is this resilience that has ensured AI/AN collective survival since time immemorial.

PROTECTIVE FACTORS

For centuries, AI/AN communities have had to negotiate and fight for political, spiritual, and humanistic rights, all of which are at the heart of AI/AN sovereignty. Along with this fight, AI/AN scholars and practitioners have struggled with the lack of representation of AI/AN peoples within academia, where AI/AN peoples are often excluded from data and reporting and omitted from decision making practices within curriculum and research (Shotton et al., 2013). This lack of representation has unfortunately translated to all facets of AI/AN life, including health equity, access to essential services, and data representation. These inequities have contributed to the disproportionate impact of COVID-19 on AI/AN peoples. This editorial aims to highlight the impact of COVID-19 within AI/AN communities through our experience as AI/AN scholars from a strengths-based lens. Indigenous health is often discussed from a deficit-based perspective but, as Indigenous scholars, we have a collective responsibility to highlight and learn from the positive aspects and experiences within AI/AN communities that have reinforced health, culture, family, and community during these trying times.

Based on the practices of "exercising" sovereignty (i.e., physical activity in performance of cultural, political, and spiritual citizenship), Leonard and colleagues (2021) identified protective factors that protect AI/AN communities from stressors like a pandemic (Ali-Joseph, 2018). Community, relationality, abundance, strength, and resilience were all identified as protective factors for AI/AN communities throughout the pandemic. In spite of the disruption that COVID-19 had on the lives of AI/AN peoples, including cancelation of indoor events and preventing community cultural activities, AI/AN communities employed unique strategies to mitigate the spread of COVID-19. For example, many AI/AN Nations closed their borders, where no one was allowed on tribal land without Tribal identification or proof of residence. From the Navajo Nation and Hopi Tribe in Arizona to the Qualla (Eastern Band of Cherokee) Boundary in North Carolina

and Georgia, AI/AN Nations implemented boundary restrictions to keep their community members safe (Humeyestewa et al., 2021; Leonard et al., 2021). Border closures minimized traffic, and many families capitalized on recommendations to physically distance by spending more time outside and enjoying nature. Communities also shifted from in-person to virtual programs that incorporated physical activity and collective support. For example, the 2020 Virtual "Just Move It" run/walk series in the western Navajo Nation had record breaking participation and incentivized participants to track and share their movement on virtual platforms.

We have seen AI/AN people utilize social media to reimagine community in digital spaces such as the "Social Distance Powwow" on Facebook and the #ExercisingSafeSweats social media campaign launched by the Northwest Native American Center of Excellence on Instagram. This campaign encouraged community members to "protect the ones you love by practicing your ways at home" (Leonard et al., 2021). These examples of leveraging protective factors through physical activity promotes an abundance-based approach to AI/AN community experiences in response to COVID-19, rather than focusing on deficit language and responses. As AI/AN people, we have to remember, encourage, and honor these experiences as we continue to navigate through the pandemic. As sovereign Nations, the political, cultural, and spiritual citizenship of AI/AN people is strong and abundant. While AI/AN communities worked creatively to protect themselves from COVID-19, the health research community was working to sustain important studies and to start new COVID-19 studies that might benefit AI/AN communities.

COVID-19 AND RESEARCH

COVID-19 has had a major impact on research in general. The influence was "rapid, dramatic, and no doubt will be long term" (Weiner et al., 2020). The COVID-19 pandemic has forced AI/AN researchers, and those conducting research with AI/AN communities, to adapt to shifting research priorities while using their areas of expertise to address pandemic challenges.

Inequities in Research Funding

Researchers have experienced challenges through all phases of the research process beginning with meeting funder expectations and quick proposal deadlines to shifting research focus and publishing studies that are generalizable to the larger population (Radecki & Schonfeld, 2020). These challenges often conflict with best practices for conducting research with AI/AN

communities that include allotting time and space for partnership building, listening to AI/AN community research priorities, and recognizing the diversity that exists between each AI/AN community (Wallerstein et al., 2019). Although national funders recognize the importance of best practices for conducting research with AI/AN communities, COVID-19 has exacerbated research funding inequities due to the aforementioned challenges. For example, the National Institutes of Health (NIH) awarded $308 Million for research on AI/AN health in 2020, just 0.01% of the total amount awarded for that same time period (National Institutes of Health [NIH], 2021). During the same year, AI/AN communities experienced tremendous disparities in COVID-related morbidity and mortality (Khatana & Groeneveld, 2020; Rodriguez-Lonebear et al., 2020). Research funding was, and continues to be, direly needed to explore underlying factors and impacts of the COVID-19 pandemic on AI/AN communities. Such findings will help AI/AN communities with future emergency and pandemic preparedness. This specific challenge, structural health inequity, has yet to be addressed.

Outreach and Engagement

Another challenge in the process of conducting research with AI/AN communities during the COVID-19 pandemic is the process of outreach and engagement with research participants and partnering organizations. Before COVID-19 spread throughout the United States, face-to-face community outreach was imperative to establishing research and programmatic relationships between academic institutions and AI/AN communities (Wallerstein et al., 2019; Whitesell et al., 2020). AI/AN communities have experienced unethical practices in research throughout history that have, justifiably, caused distrust and disinterest in the research process (Beans et al., 2019; James et al., 2018). Researchers need to continuously work to establish trust by building equitable relationships, conducting outreach activities, and providing positive research engagement experiences. Due to social distancing mandates and stay-at-home orders, community outreach, stakeholder engagement, participant recruitment, and implementation were adapted to focus on virtual connection including through telephone, social media, and live video chat services. For example, one author's study converted recruitment materials to image files and shared them on Facebook and Instagram. This study also inserted QR codes on recruitment materials to easily redirect participants to a website that provided study and contact information. In another example, the Navajo Nation frequently used Facebook Live to disseminate COVID-19 messaging. The challenge to outreach and engagement was met by relying on academic-community relationships

that existed before COVID-19 and by leveraging the social capital of AI/AN scholars and allies who conduct community based participatory research (CBPR).

The shift from face-to-face engagement to virtual recruitment and relationship building hit roadblocks in many AI/AN communities. The lack of technological infrastructure imposes a digital divide among AI/AN communities that most of the United States does not face (Smith, 2021). These communities are often in rural or isolated areas with 50-88% of homes on tribal lands lacking internet/broadband access (Wang, 2018; Graves, 2020). In some communities, up to 50% of homes do not have phone service (National Congress of American Indians, 2021). AI/AN communities and the authors have addressed this issue by applying for and using federal COVID-19 funds to improve community infrastructure by increasing broadband capabilities, improving telemedicine services, and even developing computer labs for the community (Stephens et al., 2020).

Changes to Research Approval Process

Research review is a critical step to maintaining tribal sovereignty. Respectful research review includes following tribally defined procedures and maintaining open lines of communication throughout the life of the research project. Tribal research review serves as one extra layer of protection against harmful or poorly designed research, and it also allows AI/AN Nations to determine their own research priorities. Obtaining approval for research with AI/AN communities can be challenging, often adding extra steps for approval and extra time allotted before research can officially begin (Research Data Alliance International Indigenous Data Sovereignty Interest Group, 2019; Wallerstein et al., 2019). The process of obtaining research approval in multiple AI/AN communities is often complex with each individual community having its own process (Research Data Alliance International Indigenous Data Sovereignty Interest Group, 2019). Some AI/AN communities have established research review boards while others may require a presentation before different levels of community leadership (Tribal Council, partnering Tribal departments, etc.). In some cases, Indian Health Services (IHS), the Bureau of Indian Affairs (BIA), and other government entities add additional steps to the approval process. COVID-19 has led to changes in the research approval process for those attempting to conduct research with AI/AN communities. Based on authors' experiences, there was a time period early in the pandemic where review boards and Tribal leadership either canceled or postponed reviews.

Review boards did not meet for a multitude of reasons including the urgent need to redirect tribal resources towards COVID-19 response efforts and a lack of broadband and phone access to host virtual meetings.

At the logistical level, Tribal departments had to adjust to altered work schedules and a shift to virtual review processes. In response to the shift to virtual processes, authors observed research review boards modify their procedures to include teleconference and/or virtual Zoom platforms. These logistical changes, coupled with an increase in pandemic-related research proposals, led to extended research review timelines. Authors experienced and observed other researchers working with AI/AN communities quickly adapt to these changes by prioritizing early and consistent communication with AI/AN research review boards and committees.

Modified Study Designs, Methods, and Analyses

Finally, COVID-19 has had an impact on the study design, methods, and analyses involving research with AI/AN communities. In one instance, a randomized controlled trial (RCT) intended for implementation in July 2020 was adapted into a virtual service delivery program available to the same population over Zoom video conference (Patel et al., 2022). In altering the study design, the intervention shifted from a group-based model to individual lessons. While this adaptation was both feasible and acceptable, internet connectivity presented a challenge for virtual implementation (Patel et al., 2022). In another author example, a community-based study had to be paused until the partnering tribal communities allowed for in-person research due to the lack of infrastructure, lack of funds to improve connectivity, and near impossibility to move the intervention to a virtual platform.

In-person research in progress at the beginning of the COVID-19 pandemic faced participant dropout and increased safety concerns for continuing participants. In general, researchers had to adjust their analyses to account for participants who did not finish the study due pandemic-related (e.g., participant infection) or other reason (Cro et al., 2020). Studies that were not able to modify their study design quickly due to budgetary or personnel concerns faced extended timelines. New research that has been proposed and/or started since the start of the COVID-19 pandemic has had to include study designs and methods that allow for flexibility in participant engagement and data collection that might not be the most desirable form of data collection. For example, in-person interviews and focus groups have switched to virtual platforms, running the risk of losing valuable contextual information that occurs in-person (Pocock et al.,

2021). Additionally, working with AI/AN rural communities presents challenges including issues with internet connectivity, further limiting the forms of data collection and quality of data for analysis. Authors have observed AI/AN research participants demonstrate incredible flexibility and patience with researchers during the pandemic, often taking the time to learn new forms of technology and even traveling to locations with reliable internet. Researchers working with AI/AN communities have also adapted to these changes by becoming more familiar with new forms of data collection and analysis (Cro, 2020; Gray, 2020). Although COVID-19 challenges have strained research with AI/AN communities, adaptations have been made in order to continue conducting valuable research that may ultimately benefit Tribal Nations. Collectively, the pandemic-induced increase in broadband access and technological literacy among AI/AN people has narrowed the digital divide. Resulting long-term benefits may include increased telehealth visits, increased virtual schooling options, and more remote work opportunities for AI/AN community members.

AI/AN SCHOLARS ENGAGED IN RESEARCH

The lack of AI/AN representation in research has been cause for alarm, so much so that the largest research body in the United States (NIH) has prioritized the recruitment of "underrepresented populations" including AI/AN peoples into the research workforce and as participants in studies (NIH, 2019). Community participation in research has allowed AI/AN communities to define their own strategies for prevention of disease and promotion of health and has led to the development of therapies and interventions that are culturally appropriate for AI/AN peoples (Stanley et al., 2020). Although research with AI/AN communities has been successful, there have been dire consequences when research is conducted without community input and when AI/AN researchers are not involved. Exploitative research practices have ranged from misuse of biospecimens to continued perpetuation of harmful stereotypes by non-AI/AN researchers who do not understand the historical factors that cause the disparities we see today (Hoss, 2019; James et al., 2018; Stanley et al., 2020).

Research practices guided by AI/AN communities, particularly by applying CBPR approaches, have been shown to successfully address concerns about research ethics (Wallerstein & Duran, 2006). CBPR engages the community throughout the research process from identifying its own research priorities to increasing community capacity to conduct research (Brayboy & Deyhle, 2000; O'Toole et al., 2003; Viswanathan et al., 2004). AI/AN researchers are integral to

the research process and workforce because they often have lived experiences that connect them with AI/AN research participants. Further, AI/AN researchers serve as advocates for ethical treatment of their communities and are also continuously advocating for the use of AI/AN methodologies and theoretical frameworks. AI/AN researchers often bear the responsibility of connecting academic and research institutions with AI/AN communities. Challenges to conducting research with AI/AN communities have been met with flexibility, creativity, and by leveraging the cultural capital of AI/AN scholars and allies.

AI/AN scholars have experienced a unique struggle during the COVID-19 pandemic that has made engaging in research even more challenging. Academic professionals experience stress and burnout due to overloaded schedules packed with research, service, and teaching duties (Minter, 2009). AI/AN women, in particular, face challenges including feelings of isolation as the only AI/AN person in their department, feeling their research is undervalued, struggling to find AI/AN mentors, trying to balance academic and family demands, having to go outside their departments for intellectual support, and experiencing racial/ethnic and gender bias (Tippeconnic-Fox, 2008). Given that COVID-19 influenced 55% of university and college faculty to seriously consider a career change or early retirement, we expect this estimate is higher among AI/AN faculty (Tugend, 2020).

Cultural Capital

As AI/AN people, it is not just about individual success and well-being, it is about our responsibility to our people in our communities and our homelands. This collective thought is at the core of our identity as AI/AN peoples. This collective worldview, unfortunately, does not often translate into academia. As scholars, we have academic standards, deadlines, and reviews every semester in order to advance successfully within our respective careers. During COVID-19, these expectations and standards seemed obsolete and secondary to the impact of COVID-19 within AI/AN communities. AAJ often found herself wondering why writing a "self-evaluation" within her faculty tenure review was necessary when families were struggling to survive. With two young children at home who deserved attention, with students who were struggling to log into class, and with AI/AN communities losing elders, it was an internal struggle to care about publishing work and meeting deadlines. AAJ reconciled that academic excellence would be impacted because family, communities, and children came first and deserved more attention.

Grief and Helplessness

As AI/AN scholars, we grieved with our communities over the loss of relatives, friends, teachers, and elders. Grief was compounded by the inability to grieve through ceremony and without social connectedness, and by the social structures that restrict bereavement leave to losses in the immediate family. Perhaps the most devastating impact on AI/AN communities was the loss of elders, traditional knowledge keepers, and language speakers. AI/AN elders are pillars of the community and are revered for their cultural knowledge and resilience through decades of assimilation efforts. The magnitude of their passing was immeasurable. In many cases, their passing meant the loss of language, stories, songs, plant medicine teachings, and ceremony. As members of AI/AN communities, AI/AN scholars have had to manage feelings of helplessness along with personal and collective grief. Like many AI/AN relatives, AI/AN scholars took on a caregiver role for family members who contracted COVID-19. We take on many roles as AI/AN scholars on top of conducting research including academic teaching, mentoring younger AI/AN scholars, providing resources to our tribal communities, disseminating accurate and trustworthy COVID-19 information, caring for family, and caring for community.

Teaching and Mentoring

As AI/AN faculty and scholars, we have a responsibility not only to meet teaching and research standards, but also to take care of our students and the communities they come from. By nurturing our AI/AN students, AI/AN faculty and scholars often take on an "Auntie role," where we become the support system students need while away from home. To some of us, this is the most important role as an AI/AN scholar, and one that takes precedence over all other responsibilities. We recognize the hardships AI/AN scholars endure and acknowledge the support systems that carried us through those challenging times. As AI/AN women scholars, we feel a cultural and matrilineal responsibility to help younger AI/AN students succeed in academia. COVID-19 placed a tremendous strain on AI/AN students' ability to "log in" and participate in class due to connectivity issues, caretaking responsibilities, and the loss of several family members. Unfortunately for many AI/AN students, they faced difficult decisions about whether to continue with school or move back home and help with family. While this certainly should never have to be a choice for any student, many of AAJ's AI/AN students felt they did not have support from non-AI/AN faculty and, therefore, had to leave their studies behind. With so few AI/AN

faculty within academia, it is our responsibility to advocate for our students. Rather than teaching the core principles of her discipline, much of the last year and a half was spent on the phone with AI/AN students helping them through personal hardships and with drafting emails to their other professors, explaining the need for extensions and additional resources (AAJ). The clash between AI/AN relationality and Western constructs of academia came to a head during COVID-19, as education inequities for AI/AN students, staff, and faculty became more apparent within our daily lives. We take solace in the fact that we are supportive "Aunties" to AI/AN students and can provide a safe space for them to learn, mourn, and find their own balance within community and academia.

CONCLUSION

As Native women, we are deeply invested in the health and advancement of AI/AN peoples, and we cannot separate our identity as Native women from our work. For this reason, all of our research, service, work experience, and teaching center around health promotion and disease prevention for AI/AN communities. These truths did not change during the COVID-19 pandemic. In fact, COVID-19 may have served as a reminder to AI/AN scholars that protecting our communities and families is the most important responsibility we have. As a critical piece of the health research workforce, AI/AN scholars have struggled to push through with research while dealing with constant worry and collective grief caused by COVID-19. However, with support and understanding from funders, academic institutions, allies, and our own communities, we have made changes and adaptations. Additionally, we have gained strength after learning the creative ways our communities have strategized to protect their citizens and lifeways. Through the COVID-19 pandemic and future public health emergencies, we aim to continue "being good relatives" by centering our research, teaching, and service on promoting health among AI/AN students, colleagues, and communities.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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