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**

		Baseline	
Original Step	**Cluster**	**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**

		Baseline	
Adapted Step	**Cluster**	**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.

REFERENCES

Ahmed, Z. (2020). *COVID-19 could have devastating effects on adolescents' sexual and reproductive health and rights*. Guttmacher Institute. https://www.guttmacher.org/article/2020/06/covid-19-could-have-devastating-effects-adolescents-sexual-and-reproductive-health

Anastario, M., FireMoon, P., & Rink, E. (2020). Sexual risk behaviors and the legacy of colonial violence among Northern plains American Indian youth: A mixed methods exploratory study. *Social Science & Medicine*, *258*, 113120. https://doi.org/10.1016/j.socscimed.2020.113120

Anastario, M. P., Fourstar, K., & Rink, E. (2013). Sexual risk behavior and symptoms of historical loss in American Indian men. *Journal of Community Health*, *38*(5), 894-899. https://doi.org/10.1007/s10900-013-9695-8

Attipoe-Dorcoo, S., Delgado, R., Gupta, A., Bennet, J., Oriol, N.E., & Jain, S.H. (2020). Mobile health clinic model in the COVID-19 pandemic: Lessons learned and opportunities for policy changes and innovation. *International Journal for Equity in Health*, *19*, 73. https://doi.org/10.1186/s12939-020-01175-7

Barker, D., McElduff, P., D'Este, C., & Campbell, M. J. (2016). Stepped wedge cluster randomised trials: A review of the statistical methodology used and available. *BMC Medical Research Methodology*, *16*, 69. https://doi.org/10.1186/s12874-016-0176-5

Biel, M. G., & Hamrah, O. (2021). Editorial: Learning from the pandemic: "Building Back Better" through research on risk and resilience with diverse populations. *Journal of the American Academy of Child & Adolescent Psychiatry*, *60*(4), 445–447. https://doi.org/10.1016/j.jaac.2021.02.001

Charmaz, K. (2006). *Constructing grounded theory: A practical guide through qualitative analysis*. Sage.

D'Amico, E. J., Palimaru, A. I., Dickerson, D. L., Lu Dong, Brown, R. A., Johnson, C. L., Klein, D. J., & Troxel, W. M. (2020). Risk and resilience factors in urban American Indian and Alaska Native youth during the coronavirus pandemic. *American Indian Culture & Research Journal*, *44*(2), 21– 48.

Davalos, C. (2020). Working with Native Youth during a Global Pandemic. *News from Native California*, *33*(4), 12–14.

Didiodato, G., & McArthur, L. (2016). Evaluating the effectiveness of an antimicrobial stewardship program on reducing the incidence rate of healthcare-associated clostridium difficile infection: A non-randomized, stepped wedge, single-site, observational study. *PLOS ONE*, *11*(6), e0157671. https://doi.org/10.1371/journal.pone.0157671

Dreischulte, T., Grant, A., Donnan, P., & Guthrie, B. (2013). Pro's and con's of the stepped wedge design in cluster randomised trials of quality improvement interventions: Two current examples. *Trials*, *14*(S1), O87. https://doi.org/10.1186/1745-6215-14-s1-o87

European Medicines Agency. (2020, July 2). *Implications of coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials*. https://www.ema.europa.eu/en/implications-coronavirus-disease-covid-19-methodological-aspects-ongoing-clinical-trials

Hargreaves, J. R., Prost, A., Fielding, K. L., & Copas, A. J. (2015). How important is randomisation in a stepped wedge trial? *Trials*, *16*, 359. https://doi.org/10.1186/s13063-015-0872-1

Hatcher, S.M., Agnew-Brune, C., Anderson, M., Zambrano, L.D., Rose, C.E., Jim, M.A., Baugher, A., Liu, G.S., Patel, S.V., Evans, M.E., Pindyck, T., Dubray, C.L., Rainey, J.J., Chen, J., Sadowski, C., Winglee, K., Penman-Aguilar, A., Dixit, A., Claw, E.,… McCollum, J. (2020). COVID-19 among American Indian and Alaska Native persons — 23 States, January 31–July 3, 2020. *MMWR. Morbidity and Mortality Weekly Report*, *69*(34), 1166-1169. https://doi.org/10.15585/mmwr.mm6934e1

Holm, L., Grenoble, L., & Virginia, R. (2011). A praxis for ethical research and scientific conduct in Greenland. *Études/Inuit/Studies*, *35*, 187. https://doi.org/10.7202/1012841ar

Hussey, M. A., & Hughes, J. P. (2007). Design and analysis of stepped wedge cluster randomized trials. *Contemporary Clinical Trials*, *28*(2), 182-191. https://doi.org/10.1016/j.cct.2006.05.007

Koonin, L. M., Pillai, S., Kahn, E. B., Moulia, D., & Patel, A. (2020). Strategies to inform allocation of stockpiled ventilators to healthcare facilities during a pandemic. *Health Security*, *18*(2), 69-74. https://doi.org/10.1089/hs.2020.0028

Lindberg, L. D., Bell, D. L., & Kantor, L. M. (2020). The sexual and reproductive health of adolescents and young adults during the COVID-19 pandemic. *Perspectives on Sexual and Reproductive Health*, *52*(2), 75-79. https://doi.org/10.1363/psrh.12151

National Institute of Environmental Health Sciences. (2020, June 10). *Disaster Research Response (DR2) resources portal: COVID-19 collection of research tools*. National Institute of Health. https://tools.niehs.nih.gov/dr2/index.cfm/main/search/#/params?selectedFacets=EXP_BIO_VI_COV&searchTerm

National Institute of Health. (2020). *NIH-wide strategic plan for COVID-19 research*. https://www.nih.gov/sites/default/files/research-training/initiatives/covid-19-strategic-plan/coronavirus-strategic-plan-20200713.pdf

PhenX Toolkit. (2020, June 10). *COVID-19 protocol library*. https://www.phenxtoolkit.org/covid19

Riley, J. C. (2010). Smallpox and American Indians revisited. *Journal of the History of Medicine and Allied Sciences*, *65*(4), 445-477. https://doi.org/10.1093/jhmas/jrq005

Rubin, D. B. (2016). Evaluations of the optimal discovery procedure for multiple testing. *The International Journal of Biostatistics*, *12*(1), 21-29. https://doi.org/doi:10.1515/ijb-2015-0027

Stone, M. J., Close, R. M., Jentoft, C. K., Pocock, K., Lee-Gatewood, G., Grow, B. I., Parker, K. H., Twarkins, A., Nashio, J. T., & McAuley, J. B. (2021). High-risk outreach for COVID-19 mortality reduction in an Indigenous community. *American Journal of Public Health*, *111*(11), 1939–1941. https://doi.org/10.2105/ajph.2021.306472

Strassle, P. D., Stewart, A. L., Quintero, S. M., Bonilla, J., Alhomsi, A., Santana-Ufret, V., Maldonado, A. I., Forde, A. T., & Nápoles, A. M. (2022). COVID-19–Related Discrimination Among Racial/Ethnic Minorities and Other Marginalized Communities in the United States. *American Journal of Public Health*, *112*(3), 453–466. https://doi.org/10.2105/ajph.2021.306594

Strauss, J., & Corbin, A. (2008). *Basics of qualitative research: Techniques and procedures for developing grounded theory* (3rd ed). https://doi.org/10.4135/9781452230153

Tenny, S., Brannan, G. D., Brannan, J. M., & Sharts-Hopko, N. C. (2021). Qualitative Study. In *StatPearls*. StatPearls Publishing.

Urbatsch, D., & Robledo, J. (2020). Native American groups address mental and behavioral health as COVID-19 wears on. *Indian Life*, *41*(1), 7.

Webb Hooper, M., Nápoles, A. M., & Pérez-Stable, E. J. (2020). COVID-19 and racial/ethnic disparities. *JAMA*, *323*(24), 2466. https://doi.org/10.1001/jama.2020.8598

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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

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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?

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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.