Part 3: Evaluation

This section details the evaluation methods used to assess NE outcomes and provides considerations for adapting an evaluation for a similar intervention and other public health programs.

Evaluation Methods

The NE intervention was developed, implemented, and evaluated using qualitative and quantitative methods as well as Indigenous Research Methodologies (IRM).

The evaluation of the NE intervention followed three research aims for the evaluation approach:

Aim 1: Refine, tailor, and finalize the components of the intervention

Aim 2: Test the efficacy of NE for 14- to 18-year-old youth

Aim 3: Evaluate the fidelity and acceptability of NE

This was done through an exploratory study, evaluation of a pilot intervention, and evaluation of the NE intervention. All evaluations were designed with the tribal-university research team and community advisory board to include quantitative, qualitative methods, and Indigenous methods.

The first phase of the study focused on better understanding the sexual and reproductive health behaviors among Fort Peck AI adolescents through an exploratory study. For the formative phase, tribal-university research team developed mixed methods study that included in-depth interviews, focus groups, and surveys. The team interviewed 112 AI men between the ages of 18 and 24 years old. Based on the results of the study, and feedback from the Fort Peck Tribal Council, the research team developed a pilot intervention for male and female AI youth designed to promote healthy sexual and reproductive health behaviors.[21,22]

The next phase was to evaluate the pilot intervention, a school-based curriculum for youth and parents and a cultural mentoring program that included 17 youth and 12 parents. The purpose of the pilot was to improve SRH outcomes among AI youth through a focus on individual, family, and community level factors. Mixed methods were used to evaluate the pilot intervention, including pre/posttest design and focus groups. The results of the exploratory study and pilot intervention were used to develop and implement a holistic SRH intervention for youth on the reservation, resulting in the NE multi-level intervention.[21]

The next phase, the efficacy phase, evaluated the effectiveness of the NE intervention on condom use and other birth control use and sexual risk behaviors in AI youth. To assess the effectiveness of the NE SWD intervention on AI youth, data from the five schools was collected at four time points through student and parent surveys and a reflexive inquiry.

Level 1 - Student participation was assessed using a student survey administered in the five participating schools at baseline, 3-month mid-intervention, post-intervention, and 3-month post intervention.

Level 2 - Parent participation was assessed with a parent/legal guardian survey administered in the home or at school at baseline, post-intervention, and 3-month post-intervention.

Level 3 - The cultural component was assessed with measures in both the student and parent surveys.

Level 4 - Barriers, facilitators, and solutions of Fort Peck organizations' ability to coordinate SRH services for AI youth at Fort Peck were assessed through reflexive inquiry, a process of self-reflection for researchers. This process helped assess, process, and explain how SRH services for AI youth were coordinated and accessed within a tribal context.

The evaluation also explored the fidelity and acceptability of the NE intervention using focus groups and tracking logs. The tracking logs collected intervention dose, adherence

to intervention protocols, use of intervention skills by research participants, and intervention acceptability within each school. The 6 focus groups with 6 to 8 individuals were completed at each school at the end of the intervention.

Iya Waste ("to speak good words") was the final phase of evaluating the NE intervention's efficacy, fidelity, and acceptability. The CAB and tribal-university research team reviewed the data through an iterative participatory reflective process to discuss the meaning of the quantitative and qualitative data within the social, cultural, and political context of the Fort Peck reservation to tell the story of NE. This process was important to integrating IRM into clinical trials by using narration to tell the story of what took place and understand the process and outcomes of the NE intervention.[22]

We did a lot of listening with this information.

People requested things we could improve on in our program. Again, depending on the community, things happening in a community might not have been happening in another.

This helped us get to know what was happening in individual communities.

- Olivia Johnson

The only thing to consider is really talking about the evaluation. It was a combo of traditional and Indigenous evaluation methods. It's a mixed method of looking at quant outcomes and storytelling as an evaluation method.

Trying to understand from a more traditionally Native perspective, what are the outcomes and stories you would tell that demonstrates this is successful. These are not always the same outcomes.

– Molly Secor

Evaluation Findings

Overall, Overall, NE documented the facilitators and barriers to implementing a SRH multilevel intervention with Fort Peck..[23,24,25]

Our evaluation results showed that facilitators to our first trial's acceptability include:

- Integration of local cultural knowledge
- Youth engagement with multiple teaching modalities
- Leveraging community relationships to support delivery
- Supporting caregivers
- Fostering of school administrative support

Participants perceived our positive outcomes as restoring cultural knowledge, learning about healthy relationships, encouraging sexual behavior change, and promoting healthy communication with sex partners and among family members.

Considerations for Program Evaluation

The following section outlines some important considerations when designing and evaluating public health programs and/or interventions like NE.

Sample Size

It is important to consider sample size when testing the efficacy of an intervention. Calculating a target sample size helps you to know how many people you need to ensure study insights are accurate.

Randomization

Within a stepped wedge design, the intervention will be provided to every participant, but at varying stages within the timeline of the project. Randomization occurs before any data collection happens, and will involve randomizing the schools into an order of intervention sequence. Baseline data was collected from all participants at all five schools on May 30, 2019. We then randomized the schools to an order that would receive NE intervention- either 1st, 2nd, 3rd, 4th, or 5th; this randomization happened on May 31, 2019. The five schools were randomly assigned to their place in the order by the data analyst, using single sequence random assignment. Once the intervention began at a given school, the students completed additional assessments at mid-intervention, immediate post-intervention, and 3-month follow-up time periods.

Below are some resources available to calculate sample size:

GPower

https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower

RiskCalc.org

https://riskcalc.org/samplesize/

Clinicalc.com

https://clincalc.com/stats/samplesize.aspx

Figure 5 outlines how NE's stepped wedge design was originally planned for implementation prior to the COVID-19 pandemic and how NE's implementation as augmented to meet due to the COVID-19 pandemic

Figure 5. NE SWD Sequence Augmentation Due To The Covid-19 Pandemic

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

*Change in original sequence due to the COVID-19 pandemic

Blinding

Blinding ensures that participants are unaware of the group they have been randomized into to receive the intervention. Blinding prevents bias in a study. It was important to the Fort Peck Tribal Executive Board and the CAB that all youth and families be able to participate in NE if they wanted to. With our stepped wedge design, youth and families for each of the schools participating in NE were eventually randomized into the intervention and able to participate.

Data Collection and Analysis

Organizing the data

The organization of data and the data collection process are critical components in supporting a successful research project and data analysis plan. You will want to keep a detailed filing system for every step of data collection. If used, physical surveys should be kept in a lockable filing system. Data from digital data collection sources should be kept in a secure, online server (e.g. Dropbox, Google Drive, Microsoft OneDrive) to maintain the safety and confidentiality of the data. This will also help maintain backups in the event any problems arise. Files will need to be organized by type of data (youth versus parent survey), as well as timing of survey (pre-intervention, mid-intervention, post-intervention, 3-month post-intervention, or any additional intervals). Having an organized filing system will ensure that the data cleaning and analysis tasks run as smoothly as possible.

Working with REDCap

Data should only be exported once all participants have completed their intervention and all surveys have been completed. When assessing the data from REDCap, you will want to ensure that all data has been collected from all participants, and that there are no repeated student/parent surveys. Once all student/parent ID's have been accounted for within REDCap, the data should be transferred into the REDCap online server system. There will then be a baseline, mid-NE, post-NE, or 3-month post-NE survey event name denoting the multiple surveys. After uploading all of the data from REDCap, you will want to download the entire dataset as a .csv file and save it within your secure server (Dropbox, Google Drive, Microsoft OneDrive).

Data Cleaning

It is especially important to make sure that there is adequate information on what data is kept where, the differences in multiple versions of the data, as well as a codebook regarding all variables collected in each survey. A codebook should reflect all of the items asked of participants and show how they were numerically coded. This is most important for data analysis- if variables are inconsistently coded, or if there is any confusion within the variables, this will have a direct impact on the results of the entire study. During the data cleaning process, you will want to make sure that all versions are kept and archived in the event of a problem in coding later. If you do not know how, or are not comfortable with cleaning your own data, you will want to schedule and budget enough time and money to make appropriate accommodations.

Working with Statisticians

Understanding your research project, the aims of your research, and your data will provide you with a great foundation when meeting with your statistician. The more you understand your research goals, the better you will be able to communicate with your statistician what you would like to specifically examine. In order for your statistician to do their best job, you will need to provide them with a cleaned dataset, the codebook with corresponding values, and you will want to meet regularly to ensure any problems are promptly clarified.

Quantitative Analyses

Quantitative analyses focus entirely on the numeric data within your research project. This is why your dataset will need to be as numerically accurate as possible; when there are problems within quantitative data, the statistician will run into numeric and conceptual problems that will further delay their ability to conduct analyses. This specific project can include the following quantitative analyses: linear, logistic, and negative binomial regressions; multilevel modeling; cluster analyses; factor analyses (exploratory and confirmatory); and structural equation modeling.

You will want to make sure that you discuss your goals with your statistician, so that you are on the same page when it comes to analyses and the possible interpretations of resulting analyses. The more you and your statistician can collaborate on your main objectives, the better they will be able to ensure your research question is assessed in the most appropriate way. Once analyses are completed and reviewed with the immediate research team, you will want to return this information to key, community stakeholders to discuss the findings. This will likely provide you with real-world insight into your initial findings. It can also provide the statistician with feedback and suggest follow-up analyses. Analyses often take an iterative approach. This means that you will likely conduct initial analyses a few times to gain insight into the data, and run follow-up analyses to provide clarification where necessary.

Evaluation			
	Description	**Method of Community Engagement**	**Impact on Multilevel Intervention**
NenÜnkUmbi/ Edahiyedo (We Are Here Now)	This project aims to reduce sexual and reproductive health disparities among 14-18-year-old AI youth. There are four levels of intervention (individual, family, community, systems). We use a Stepped Wedge Design within a CBPR framework and qualitative and quantitative methods as well as Indigenous Research Methods.	The evaluation was designed with the tribal-university research team and community advisory board to include quantitative and qualitative methods. Iya Waste ("to speak good words") was also used for evaluation. The community advisory board and tribal-university research team engage in iterative participatory reflective to discuss the meaning of the quantitative and qualitative data within the social, cultural, and political context of the Fort Peck reservation in order to tell the story of NE.	• Integration of quantitative, qualitative, and Indigenous Research Methods • Co-learning and co-sharing between community advisory board and tribal-university research team in determining how contextual factors influence NE's implementation and outcomes Tells the story of how NE was implemented and identifies events and situations relevant to trial implementation in addition to analysis of outcome variables

Qualitative Analyses

Qualitative data will include information from the (semi-structured) interviews, focus groups, and Feasibility, Acceptability, and Sustainability (FAS) forms that were collected during the study. In contrast to the numeric data, this data is exclusively in narrative form and will analyze the quotes from the participants for common themes. Using an inductive analytic approach, the research team will examine qualitative data using codes and then generate themes from these codes. Coding qualitative data can be done by hand, or using software programs like NVivo or Atlas.ti.

For more information on software programs, see the following resources:

Atlas.ti

https://atlasti.com/

NVivo

https://lumivero.com/shop/

Focus groups and individual interviews. We set up focus groups with parents, kids, and educators so we got a well-rounded collection of information. It was just dependent on the community.

In Wolf Point, we had big groups of people, but this was difficult to replicate in other communities. In Poplar, Brockton, and Frazer, we did small groups or individual interviews with parents and educators.

We found that if we put them in their comfort zone we got a lot more information. I can talk to a group about whatever, but some people feel like this material is embarrassing and private.

Having one-on-one conversations in their home or office made them more willing to ask questions and talk about things. We recorded these. Had them transcribed so that they could be part of our research

— Olivia Johnson

Interview transcripts concerning romantic and sexual relationships were subject to an inductive analytic strategy. First, line-by-line coding was conducted to generate a set of "open codes," followed by a second round of "axial" coding to reduce the set of open codes to a manageable set of categories.

Table 2 shows axial codes for the impact of the COVID-19 pandemic on our research participants.[15]

Axial Code	Description of Axial Code
CARING	Describing acts of self-care/caring for others (or not) during the pandemic across different areas of life, discussing how individual behaviors (e.g., sheltering in place, keeping social distance, buying groceries online) and personal choices affected others during the pandemic (contributing or not to the spread of COVID-19)
COUPLEXP	Being in a relationship during the pandemic. Challenges and experiences (personal or friends) of relationships during the COVID-19 pandemic. Participants discussing experiences related to infidelity, communication, or wondering how people managed their relationships.
FEAROTHERHEALTH	Participant describing feeling anxious worried, or fearful about a family member, friend's health, or general concern during the COVID-19 pandemic.
FEARPERHEALTH	Feeling anxious, worried, or fearful about personal health during the COVID-19 pandemic.
LACKSOCRESP	Describing a lack of social responsibility/ concern for others regarding the risk of coronavirus transmission/infecting others. Describing people not caring or considering others' health during the COVID-19 pandemic.
NOCHANGE	People not making any changes in their lifestyles due to the COVID-19 pandemic.
NOFEAROTHERHEALTH	Participant sharing ***not*** feeling anxious, worried, or fearful about personal health during the COVID-19 pandemic.
NOROMANTICREL	Describing ***not*** being involved (participant or friend) in a romantic or sexual relationship during the COVID-19 pandemic.
RISKYBEHAV	Describing engagement in risk taking behaviors during the pandemic. Risk taking behaviors included going to parties, drinking alcohol, and "hooking up" Perceiving an increase in youth partying and opportunities to engage in risk taking behaviors. Describing reasons to engage in risk behaviors.
ROMANTICREL	Involved (participant or friend) in a romantic or sexual relationship during the pandemic, describing COVID-19 effects on romantic relationships.
SOCIALMEDIA	Role of social media on people's lives during the pandemic. Use of social media for romantic or sexual relationships during the pandemic.

Adaptation tips: Give the data a context; validity data with what team is seeing; clarifying what the interpretation really means; clarify with the research team; narration of the context – third observation of participant observation; understanding relationship dynamics between people; situational environments; in school communities are central to the cohesiveness and culture of the community.

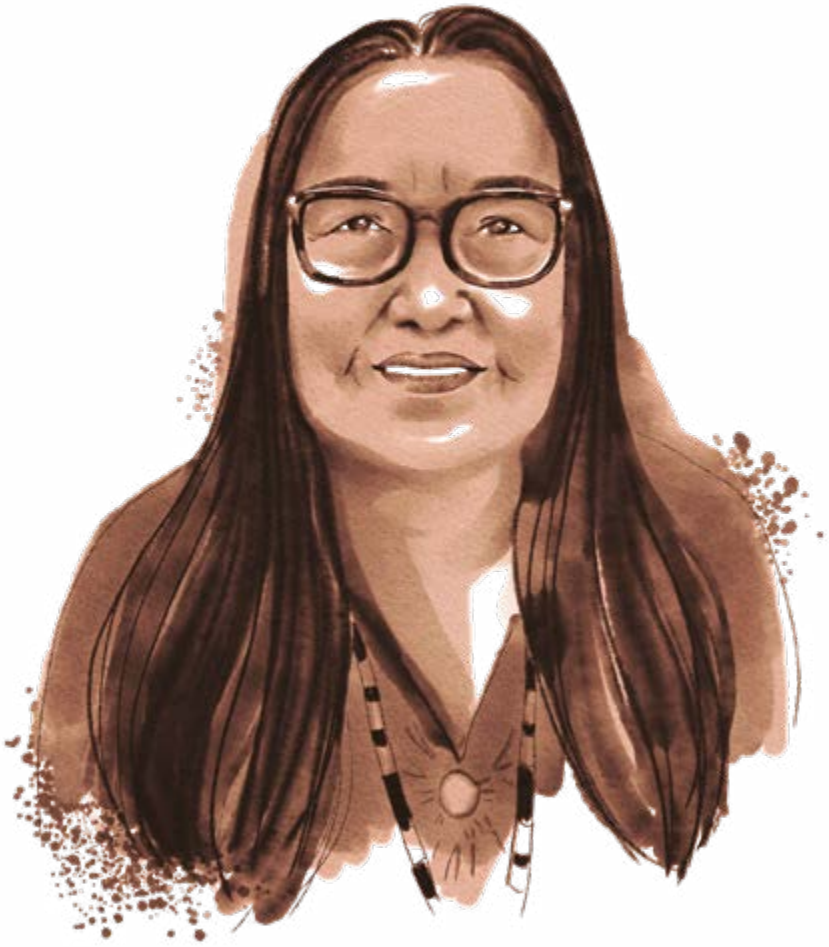
– Jeffrey Thiele

Fidelity, Acceptability, Sustainability

The importance of evaluation of NE cannot be understated. Forms can be used by student teams to ensure fidelity of implementation; this means that you are implementing the intervention as it is designed and intended. When things happen, and they will, you can use the fidelity tracking form to document what happened that was different or not according to the intended intervention plan. When collecting qualitative data (seeing, hearing, feeling, noticing, observing, creating) you can narrate the information or even take a photograph of what is happening. NE utilized participatory data collection methods and narrative discussions to include parent perspectives on their children's participation in NE, including Native STAND and cultural mentoring.

It's not just tracking fidelity, if you did it or not. But include the fidelity monitoring in the evaluation. It helps in an iterative way because it helps with sustainability and assuring the impact of the program. These extra things happened... this informs how you can implement it next time. Fidelity and acceptability monitoring in iterative.

– Molly Secor



"Evaluation is an important aspect of the learning process, its' critical for any intervention focused on a sexual and reproductive education to be acceptable to the cultural standards of a Tribe. As researchers and teachers, we need to be aware of the sensitivity of providing this type of intervention. The sensitivity of a sexual health intervention needs to have an approach that requires "buy-in" from the student, parent, and teacher of the curriculum. The best way to measure the effectiveness of the intervention is to engage students, parents, and educators through a discussion forum. Although the data is collected and gives us an individual perspective of the intervention, it is critical to have a verbal discussion with groups of people to complete assessment through verbal expression of their concerns."

- Paula Firemoon

The importance of fidelity, acceptability, and sustainability is a critical aspect of conducting evaluating the outcomes of an invention amongst Native American youth. Understanding the importance of evaluation is an inherent characteristic of Native Americans. Young children from an early age are encouraged to learn from their mistakes. Since most Native Americans respect grandparents/elders as the teachers of young children, we realize how significant they are in childhood development.