COMMUNITY-BASED PREVENTION EDUCATION ON ABUSIVE HEAD TRAUMA IN A MONTANA NATIVE AMERICAN COMMUNITY

by

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TABLE OF CONTENTS

TABLE OF CONTENTS-CONTINUED

LIST OF TABLES

Table Page

LIST OF FIGURES

Figure Page

ABSTRACT

This scholarly project cultivated a partnership with a Montana Native American community to develop an implementation method of an evidence-based, abusive-head-trauma-prevention education program. The partnering community felt that more could be done to prevent abusive head trauma. Utilizing the framework of Community-Based Participatory Research and the Rural Nursing Theory, this project identified the best available evidence and then developed multiple methods to implement this prevention material. Multiple lessons were learned and important reflections developed from the project process. These lessons can be utilized to guide future projects. A model for program implementation was developed for future use and implementation of the evidence-based, abusive-head-trauma-prevention program.

INTRODUCTION

Abusive head trauma (AHT), which encompasses shaken baby syndrome (SBS), is a form of physical child abuse involving violent shaking or blunt impact resulting in brain injury (Centers for Disease Control and Prevention (CDC), 2017). The term shaken baby syndrome has largely been replaced by abusive head trauma after medical advances in the understanding of the mechanism of injury. Not only can shaking an infant cause injury, but blunt trauma may also result in severe neurologic sequelae, including cerebral palsy and seizures (Christian & Block, 2009). AHT is preventable and, when it occurs, may result in serious, long-term consequences. These consequences include vision problems, developmental delays, hearing loss, and physical disabilities (CDC, 2017). Spinal cord injury and hypoxic ischemic injuries may also occur and contribute to poor infant outcomes, including death (Christian & Block, 2009). AHT is the most lethal form of physical child abuse and, therefore, an important focus for prevention efforts (Scribano, Makoroff, Feldman, & Berger, 2013).

Background

Abusive head trauma most frequently occurs in children who are less than five years old, with those under one year of age being at the highest risk (CDC, 2017). It is estimated that 40% of deaths resulting from child abuse occur in children who are younger than one year old (Christian, 2017). AHT occurs when a caregiver becomes frustrated or angry because of the infant's crying. This emotion may result in the caregiver shaking the infant, or slamming or hitting the infant's head into an object in an

attempt to make the crying stop (CDC, 2017). Crying and even many of the characteristics of colic are normal in infants and can lead to caregiver anxiety and anger (Barr, 2014).

An infant's anatomy puts them at increased risk of being impacted by acceleration-deceleration injuries, blunt trauma, or secondary brain injuries that result from AHT. The infant has a "proportionately large head, weak neck muscles, soft and developing brain tissue, a thin skull wall, and lack of muscle control" (Stoll & Anderson, 2013, p. 300). Therefore, this developmental period is an extremely vulnerable time in terms of AHT risk.

When studying infant crying behavior, there is a general trend that has been observed throughout the population. Infant crying behavior increases weekly after birth and peaks in the second month of life, then normalizes by four to five months (Barr, 2014). Infants may cry for no apparent reason and be more difficult to console during this time of their lives. Loveland (2015) also discusses the link between the peak incidence of AHT and normal crying behavior at around three months of age. Caregivers may be unaware that this increased infant crying behavior is developmentally normal, placing them at an increased risk of committing AHT (Loveland, 2015).

Determining the prevalence of AHT provides many challenges because of the multiple patient presentations that result from AHT as well as inconsistent medical coding for the diagnosis (Loveland, 2015). Christian (2017) found that infants with AHT may present nonspecifically without a reported history of trauma. Research suggests that this nonspecific set of features results in up to 30% of children being misdiagnosed at the

initial presentation at a healthcare facility. A chart review describing misidentified cases of AHT discovered that four of five of the resulting deaths may have been prevented had the mechanism of injury been recognized earlier. This misdiagnosis proves to be fatal as AHT is the most common cause of death resulting from physical abuse (Christian, 2017).

Narrowing the focus and looking at AHT in the state of Montana, there were 20 inpatient admissions and 21 emergency department encounters for nonfatal AHT between 2010 and 2014. The average number of cases of AHT were four per year when looking at inpatient admission and emergency department encounters. The majority of infants who were admitted for nonfatal AHT in Montana were less than one year of age (Custis, 2015). Discerning the exact number of AHT cases in Montana may be difficult given the role of inpatient admission and emergency department encounter data (C. Custis, personal communication, October 5, 2017). Loveland (2015) adds that "the small number of events makes the calculated rate unstable and difficult to utilize for evaluation purposes tied to AHT prevention efforts" (p. 5).

While the prevalence of AHT is difficult to discern, the devastating consequences of the injuries are apparent. It is estimated that as many as 25% of infants who are victims of AHT will die from their injuries and 80% of infants will experience long-term neurological injury (Loveland, 2015). The significance of AHT not only impacts families and communities, but the healthcare system as a whole.

The healthcare costs associated with AHT are substantial. It was estimated that the average emergency department visit and admission for AHT was between $2,612 and $31,901 in 2012 (Peterson, Xu, Florence, & Parks, 2015). Nationwide, the annual cost of

AHT is approximately $69.6 million U.S. dollars (Peterson, Xu, Florence, & Parks, 2015). This number does not take into account the long-term healthcare costs associated with caring for children who have resultant severe neurological injury.

When evaluating risk factors for individuals most likely to perpetrate AHT, several themes emerge. The perpetrators of AHT are most often male and usually the father of the child, followed by the stepfather, then mother, and female babysitters. Multiple risk factors for AHT exist and include lower levels of education, family stressors, domestic violence, substance abuse, parental depression, financial stressors, and young or single parenthood (Christian, 2017).

In 2009, Montana passed legislation that mandates AHT education. Bill 50-16-103 states that the Montana Department of Health and Human Services shall:

- "develop educational material that present readily comprehensible information on shaken baby syndrome"
- "post the materials on the department's website in an easily accessible format"'
- "the materials required to be produced by this section must be distributed at no cost to the recipients" (Montana Legislative Services, 2009).

Native Americans residing on a reservation in Montana are the target population for this project. While the tribes represented in this area have tribal sovereignty, AHT prevention is a focus of the community. Through the utilization of a community-based participatory approach, specific areas of need were identified by community stakeholders. During a conversation with community members in August of 2017, AHT was identified

as a focus area for prevention. The community experienced at least two cases of AHT in the past year and emphasized the importance of implementing a prevention strategy.

Multiple health disparities exist in the target community putting its members at risk for AHT including poverty, low education rates, adverse childhood experiences, family breakdown, lack of access to care, neglect, and hopelessness (Montana Healthcare Foundation, 2016). In the county in which the reservation resides, the rate of substantiated child abuse was 112 per 10,000 children under 18 years old in 2011. This is compared to the statewide rate in Montana of 29 per 10,000 children less than 18 years old (Maternal, Infant, and Early Childhood Home Visiting, 2013). The child-abuse rate of almost four times the state's average emphasizes the importance of a community-wide prevention effort. In order to address this and the other existing health disparities, a program has been developed that aims to enhance health promotion and disease prevention in the community. An AHT-prevention effort fits into the program's aims by preventing the devastating consequences of the injury.

Statement of the Problem

Abusive head trauma has been identified as a concern after considering community risk factors and through the utilization of community-based participatory approaches. While there are currently methods that exist to provide AHT-prevention education throughout the state, it is unclear if the materials are reaching this geographic location and its residents.

Purpose

The purpose of this scholarly project was to discover evidence-based approaches for the prevention of AHT on one Montana reservation. This project included three main objectives:

1. Evaluate risk factors and current practices in place on one Montana reservation to prevent AHT.
2. Examine the literature to uncover best practice approaches to prevent AHT.
3. Work alongside community members to discover best approaches and first steps for an AHT-education campaign.

Inquiry Question

In residents on a Montana Reservation, does an AHT-prevention education compared to no AHT-prevention education increase level of education immediately following the intervention? Does this impact the number of substantiated cases of child abuse over a two-year time frame?

Conceptual Framework

Because of the nature of the project, two conceptual frameworks were selected to guide this assignment. Both the Rural Nursing Theory (RNT) and Community-Based Participatory Research (CBPR) frameworks have been utilized to direct the project.

Community-Based Participatory Research aims to “create an effective translational process that will improve population health and increase connections with

members of underserved communities" (Hacker, 2013, p. xi). This model was selected because, historically, underserved communities were not included in the research process. This left stakeholders feeling like research was being conducted on them instead of with them. Community-Based Participatory Research is often useful in addressing developing issues in which evidence is lacking—such as with AHT prevention in Native American communities.

The principles of CBPR include acknowledging the community as a unit of identity, building strengths and resources within the community, facilitating a collaborative, equitable partnership in all phases of research (or projects), fostering co-learning and capacity building among all partners, integrating and achieving a balance between knowledge generation and intervention for the mutual benefit of all partners, and focusing on the local relevance of public health problems and on ecological perspectives that attend to the multiple determinants of health (Hacker, 2013). These principles were selected to guide this project in all phases.

The first stage of CBPR is to define the community, engage the community by performing a needs assessment, and identify the project question. The second stage is to design and create a hypothesis and then determine the roles and responsibilities in conducting the project. The third stage is to analyze, interpret, and disseminate the results (Hacker, 2013). The components of CBPR and stages have been used to guide the project.

Because of the rural nature of the focus community, the RNT was additionally used to help guide this project. Several key concepts were considered when thinking

about how this project would unfold and include the self-reliance and independence of rural persons. Additional key concepts that were considered include the lack of anonymity and the outside/insider implications of caring for rural communities. Rural community dwellers often personally know the individuals providing their care (Winters, 2013). This potential impact on the individual's ability and ease of seeking care was considered during the development of this project and performing the community needs assessment.

The RNT states that rural dwellers tend to be skeptical of individuals viewed as "outsiders" (Winters, 2013). While this author is an outsider in the eyes of the community, the tenets of CBPR can be applied in bridging the gap and providing a service to the community. In applying themes from CBPR, while keeping in mind the unique characteristics of a rural community drawn from the RNT, overall community health and disease prevention can be promoted.

Definitions

Abusive Head Trauma: a form of physical child abuse, involving violent shaking or blunt impact resulting in brain injury (CDC, 2017).

Shaken Baby Syndrome: previous name for type of physical abuse now called abusive head trauma (CDC, 2017).

Significance

This project is important to the nursing profession because a distinct role of the profession is to advocate for and protect the health and safety of individuals (American Nurses Association [ANA], 2015). The ANA Code of Ethics additionally states that nurses must "protect human rights, promote health diplomacy, and reduce health disparities" (ANA, 2015, p. v). Part of reducing health disparities is providing education and outreach to at-risk communities. Legislative policy at the state level defines the need for education on AHT. This project represents the intersection of the nursing role in promoting health policy, health education, and prevention.

Organization of the Remainder of the Project

The remainder of this paper will include a discussion on the methods for literature review, methods for the project, results, and the conclusions of the work. The conclusion will include a discussion of the findings and recommendations for future research as well as limitations of this project.

LITERATURE REVIEW

Introduction

A literature review on this topic was conducted to discover interventions that effectively provide education on AHT. The questions that guided the literature review were:

1. What parental/caregiver attributes impact the risk of perpetrating AHT?
2. What AHT-prevention techniques are useful in educating community members and parents?
3. What is the health professional's role in providing AHT education?

Search Methods

Databases

CINAHL, PUBMED, Google Scholar, PsychInfo, and Web of Science were utilized to conduct the literature review.

Search Terms

Search terms utilized for the literature review include: abusive head trauma, prevention, Native American, American Indian, Shaken Baby Syndrome, Period of PURPLE Crying.

Inclusion/Exclusion Criteria

Articles from the last ten years were reviewed. Articles in peer-reviewed journals and dissertations were reviewed. Only articles written in English were reviewed. Exclusion criteria: the article was not written in English or the article did not address prevention or risk assessment of AHT. This left 20 articles for review and included mostly quantitative study designs with some qualitative data being gathered. Several literature reviews were also included.

When searching CINAHL, 13 relevant articles were included out of 55 results. Results were excluded due to irrelevance, duplicates, or low quality evidence. Two separate searches were conducted in PubMed that yielded 100 results. Three were included in the table of evidence (TOE). The rest were excluded due to duplicate results or irrelevance. The searches in PsychInfo yielded 49 results. One was included on the TOE. All others were excluded due to irrelevance or duplicate studies. The Cochrane Library search yielded five search results that were all duplicate studies. The Web of Science search yielded 130 results with two included on the TOE. The rest were excluded because of irrelevance, low quality evidence such as opinion statements or editorials, or duplicate studies.

Results

Parental Attributes Influence Risk of AHT

The first goal of the literature review was to look for and further understand how parental attributes influence the risk of AHT. Berger et al. (2011) discovered that AHT

increased during a time of economic recession as compared to a previous period of growth. However, the authors cite that there was no association between unemployment rate and AHT incidence. This finding may warrant increased prevention strategies during stressful fiscal periods or in economically disadvantaged areas (Berger et al., 2011).

Additional risk factors that have been identified as increasing risk for AHT include being a younger, unmarried, single mother, not taking prenatal vitamins, and short-interval pregnancy (Kelly et al., 2017). Alcohol and drug use, medical history, and socioeconomic status were not found to be significantly correlated to AHT risk (Kelly et al., 2017). High baseline education was significantly associated with increased knowledge of normal infant crying behavior after an AHT-prevention intervention (Reese, Heiden, Kim, & Yang, 2014).

Oral et al. (2011) suggested that there may be a link between infants who have been exposed to recreational drugs and increased incidence of child abuse and neglect. Additional risk factors that were identified as being associated with use of illicit drugs include history of domestic violence, incarceration, and being involved in a drug rehabilitation program (Oral et al., 2011). While being aware of risk factors for AHT and providing prevention to at-risk groups is supported in the literature, Bailhache, Benard, and Salmi (2016) argue that screening programs could falsely identify abusers and alienate particular groups of individuals.

Promising Prevention Strategies

Multiple promising prevention strategies have been discovered through the literature review. Mikton and Butchart (2009) identified home visiting, parent education,

and multi-component programs as being the most successful at increasing AHT knowledge and, therefore, prevention. The Nurse Family Partnership was shown to be correlated with decreased incidence of child abuse; however, no specific articles were identified linking the Nurse Family Partnership or any other home visiting intervention with a reduction in AHT rates (Stout, 2014).

All Babies Cry

All Babies Cry (ABC) is an AHT-prevention program that is based in adult-learning theory and delivers education to families following the birth of their child. One research study was identified that evaluated the program during its delivery in Massachusetts. The study utilized a quasi-experimental design and helped new parents recognize their personal stress and ways to manage it during their child's infancy. The program was well received by parents overall and the majority would recommend it to their friends (Morrill, McElaney, Peixotto, VanVleet, & Sege, 2015). This was the only research identified evaluating ABC. The quality of this research was low, being quasi-experimental without randomization, making it difficult to evaluate the overall effectiveness of ABC.

The Period of PURPLE Crying

Education materials called The Period of PURPLE Crying (PPC) have been developed by the National Center on Shaken Baby Syndrome (NCSBS). The goals of the PPC are to reduce the number of AHT cases, to support caregivers, parents, and family members, and provide education about increased early infant crying. PURPLE is an

acronym to help explain the features of this period of increased crying during infancy and the period is used to reiterate that this time has a beginning and an end. The acronym meaning is:

- P stands for peak of crying and helps parents remember that the behavior peaks in month two and should normalize by month five.
- U stands for unexpected, meaning that the crying may come and go for no apparent reason.
- R stands for resists soothing. The infant may be inconsolable despite caregiver attempts to calm him or her.
- P stands for pain-like face. The infant may appear to be in pain even if they are not experiencing discomfort.
- L stands for long lasting. The crying behavior may occur for up to five hours per day, or even more.
- E stands for evening, meaning that the infant may cry more during the evening and afternoon (NCSBS, n.d.).

Barr et al. (2009) measured how the PURPLE materials impacted parental knowledge and ability to cope with inconsolable crying. The authors found that crying knowledge was higher in the treatment group with mothers being more willing to share information with caregivers after receiving AHT education (Barr et al., 2009). This research was high quality evidence and utilized a randomized controlled trial design. Two groups of mothers were randomized to a control group or the treatment group to receive the PURPLE materials.

The above RCT design was replicated with mothers in Japan to see if the materials were transferrable to another setting. The authors found that the intervention group had a statistically significant increase in crying knowledge and an increased knowledge of methods to cope with inconsolable crying behavior (Fujiwara et al., 2012). The PURPLE materials teach parents and caregivers strategies to cope with inconsolable crying and have been shown to reduce the number of telephone calls to nursing-advice hotlines (Stout, 2014; Zolotor et al., 2015). The theme that AHT prevention is best achieved through education on infant crying and risks of infant shaking was supported throughout the literature (Lopes & Williams, 2016; Ornstein, Fitzpatrick, Hatchette, Woolcott, & Dodds, 2016). Ornstein et al. (2016) also found that the PURPLE materials led to increased knowledge on crying behavior among mothers.

To further augment the effectiveness of a PURPLE AHT-prevention media campaign, Steward, Gilliland, Parry, and Fraser (2015) used Geographic Information Systems maps to understand areas of highest AHT risk. They then targeted a media campaign at the specific high risk areas. The study did not measure the campaign's effectiveness at preventing AHT (Steward, Gilliland, Parry, & Fraser, 2015).

The New York Prevention Program

Keenen and Leventhal (2010) found that SBS video education alone did not reduce AHT or motor vehicle injuries, which was another variable the authors measured. The authors modeled their prevention strategy after the New York Prevention Program. The New York Prevention Program was implemented in multiple hospitals in upstate New York. The intervention educated parents on alternative ways to cope with increased

infant crying through videos and a brochure. Following the education, the parents were asked to sign a commitment statement that they will participate in AHT prevention (Loveland, 2015). The predominant paper on The New York Prevention Program is greater than 10 years old and did not meet inclusion criteria for this literature review. No further studies have been identified to evaluate the effectiveness of The New York Prevention Program.

Other Interventions

Simonnet et al. (2014) found that parents generally had a poor baseline level of education on normal crying behavior and AHT. This idea further supports the notion that education to parents on the normal period of crying is crucial. Additionally, they found that parents obtain knowledge on AHT from television or media. The authors utilized a pamphlet developed by The Francilien Resource Center for Brain Injury (Simonnet et al., 2014).

A literature review by Lopes and Williams (2016) discussed multiple interventions to prevent AHT. Prevention programs with the primary goal of reducing an infant's behavioral stimulation, including REST ROUTINE for Infant Irritability, were evaluated. They found that the implementation of the REST ROUTINE program led to 1.7 hours less of crying per day. However, this study did not measure the incidence of AHT following the program's implementation. None of the similar programs looking at decreased infant stimulation directly measured their impact on AHT (Lopes & Williams, 2016).

Stoll and Anderson (2013) performed a literature review and reported that community involvement, including hands-on education and legislative initiatives, along with parent education is important when creating AHT-prevention campaigns. Education using a multimodal approach, signatures of prevention commitment, and partners with community resources have been shown to be the most effective. The authors developed a visual representation of the findings from the literature review. They do not make recommendations of what particular prevention program to utilize, but state that community involvement, health professional responsibility, and parental education all contribute to the prevention of AHT (Stoll & Anderson, 2013).

Dias et al. (2017) discovered that AHT prevention education was associated with increased self-reported knowledge gains. However, AHT hospitalization rates were not reduced during the studied time frame. The authors in the study utilized an informational DVD and a brochure (Dias et al., 2017).

Healthcare Professional Role

The crucial role of healthcare professionals was a theme that emerged when reviewing the literature on AHT. In an interview with healthcare professionals, the majority thought that PURPLE would be easy AHT prevention to incorporate in his or her practice, appropriate, and applicable to a variety of ethnic groups (Stephens, Kaltner, & Liley, 2014). Stoll and Anderson (2013) identified health professionals as being responsible for educating the public on AHT prevention as well as reporting events. Much of the education on AHT prevention, including the ideal delivery of the PURPLE program, is provided by nurses. Allen (2014) reviewed the literature regarding nurses'

roles in the primary prevention of AHT. Neonatal nurses have an important role in educating parents in AHT prevention prior to their children being discharged from the hospital. The literature review showed that parents have increased ability to cope with inconsolable crying and an understanding of normal infant growth and development following AHT-prevention education (Allen, 2014).

Gaps in the Literature

Following a review of the literature, it was discovered that there is insufficient evidence on how the AHT prevention is carried out in Native American communities. No articles were found addressing AHT material implementation in Native American communities. No articles were identified addressing any prevention interventions of AHT in this population. In addition, many of the interventions focused solely on providing education to the mothers of infants. Targeting interventions at entire communities and caregivers may help further prevent AHT.

There is a lack of high-quality evidence surrounding AHT prevention in Native American communities. Most the of studies have utilized a quasi-experimental design. Many of the AHT-prevention education methods have not been well researched to understand their effectiveness. In addition, many of the studies did not measure actual AHT rates over the studied time period, making it difficult to determine their actual impact.

Two RCTs evaluated the PURPLE materials and showed improved levels of parental knowledge and ability to cope with crying behavior among mothers (Barr et al., 2009; Fujiwara et al., 2012). The literature review also supports educational materials

that raise awareness of AHT, including the PURPLE materials, because of the ease of implementation as compared to other prevention materials (Lopes & Williams, 2016). The PURPLE materials have been the most rigorously and widely studied among the available AHT-prevention materials.

Conceptual Framework

When applying the findings from the literature review back to the CBPR model and RNT, it is clear that more research into the best practices for this community is needed. Utilizing a CBPR methodology and applying concepts from the RNT, more information can be gleaned to help prevent AHT/SBS.

METHODS

Introduction

The purpose of this scholarly project was to:

1. Evaluate risk factors and current practices in place on one Montana reservation to prevent AHT.
2. Examine the literature to uncover best-practice approaches to prevent AHT.
3. Work alongside community members to discover best approaches and first steps for an AHT education campaign.

Initial Approaches

The first action of this project was completed by assessing community risk factors and performing a community needs assessment. Interviews were conducted with the community healthcare providers and stakeholders to understand what was being done in the community to prevent AHT. A healthcare-provider survey was developed to assess current prevention practices and perceptions of AHT education in addition to comfort with providing education on AHT prevention. This survey was distributed to a surrounding health department for voluntary completion (Appendix A).

The second action of the project, searching the literature to uncover the best method of AHT-prevention education was detailed in the previous chapter. As described in the literature review, although promising approaches to AHT prevention were discovered, no evidence specific to approaches to AHT in Native American communities

was found. For this reason, the PURPLE materials were selected as the best evidence available for AHT prevention.

The next action of the project was completed through the development of a best-practice intervention tailored to the community for implementation. The Period of PURPLE Crying education intervention was best supported in the literature, as detailed above. However, evidence of its use among Native American populations and adolescents is lacking.

After collaborating with local community members, it was decided that the education intervention would be initiated with a group of certified-nursing-assistant (CNA) students at the high school level in a single population center. A plan was suggested by community stakeholders to initiate a pilot project to assess how the PURPLE materials could be most effectively implemented. The CNA students were specifically selected because they could take the intervention back to their families and the community to assist with dissemination of the concepts. A group of community college students taking a child-development course was also selected as a potential dissemination group. The idea of further dissemination of the information by community members was an aim of the project and highlighted as a method to improve sustainability.

Setting Sample/Population

The population for this project was a Native American community in Montana that consisted of primarily tribal members, high-school aged, 14 through adult, and all genders. The reservation spans two million acres and approximately 6,000 tribal

members live within its boundaries (State of Montana, n.d.). The reservation has two main population centers and a single population center was selected for the planned intervention. The message was planned for distribution to a select sample of the population with voluntary participation.

Procedures/Measures

Initially, a quasi-experimental design was developed with a pre- and post-test evaluation following the educational intervention. In order to determine the participant's baseline level of knowledge a pre-participation survey was planned to be completed before the education intervention. This survey included several demographic questions and the level of the participants' understanding of the AHT prior to exposure to the education material.

A fidelity agreement was signed with the National Center on Shaken Baby Syndrome stating that the intervention would be carried out as it was initially intended by the organization. This includes an approximately 10-minute video along with educational book for each individual with time for questions at the end. The plan was to show participants the video followed by the post-test survey.

Following the education session, a similar post-participation survey was planned to be given to the students to assess their understanding of the information. The survey contained the same five content questions using a multiple choice style to assess the change in knowledge before and after the intervention. A question assessing how the participant would like to receive the information was also included to explore if a

different mode of delivery, such as social media or email, might be more effective. The initial plan as detailed above was altered to best suit the needs and timelines of the community and will be further discussed in the following chapters.

Data Analysis

The following data analysis section was the proposed method, but was not completed as described. The data collection and analysis processes were altered to meet the necessary timeline for the community. However, the proposed methodology was discussed with the community and approval was received. Data analysis was proposed to be completed using descriptive statistics. A partnership was formed with the Montana State University Statistical Consulting and Research Services (SCRS) for guidance on data collection and analysis recommendations. A two-tailed t-test was proposed to compare the pre- and post-participation scores before and after the education intervention. The SCRS assisted in the development of a data-entry template and assisted with calculating the power required to have a statistically significant outcome. The SCRS found that a sample of three to five students would be required to have a statistically significant or meaningful change after the education intervention (Tran & Flagg, 2018).

The SCRS recommended arranging the data using confidential student identifiers in which the names of the participants were kept separate from the scores and each participant would have a unique identification number (Tran & Flagg, 2018).

Summary

As discussed in this chapter, the methods for this project included the development of a community-based education campaign of SBS/AHT prevention with a pre- and post-test evaluation method developed as well as a community needs assessment and literature review. The approval of the Tribal Institutional Review Board for the protection of human subjects review was sought out prior to proceeding with the project. The project was submitted for an expedited review with extensive care to ensure safety of a potentially vulnerable population. Additional approval by the Montana State University Institutional Review Board to protect human subjects was granted after the approval of the Tribal Institutional Review Board.

RESULTS

Description of the Findings

As discussed in the previous chapters, this project had three primary objectives. The three objectives of the project along with the project results are discussed in the following paragraphs.

Project Aim 1: Evaluate Risk Factors and Current Practices in Place on one Montana Reservation to Prevent AHT

First, shaken baby syndrome/AHT was identified by a community leader as a prevention topic focus that could be improved within the community. This community member is the director of a prevention and health promotion program that focuses on improving health of the tribal members. The program currently does not have an active platform set up to distribute SBS/AHT prevention materials.

Second, at the suggestion of the stakeholders, an additional community member was contacted to assist with gathering supplementary information from the surrounding area regarding prevention practices. A provider survey was distributed to an area health department to determine current practices and perceptions of the staff along with their comfort in AHT discussion points (Appendix A). The surveys were not returned from the providers at the particular clinic. This seemed to be related to few staff at the department and lack of willingness to discuss AHT with a community outsider. The survey was provided as a resource for future use by the healthcare providers.

Third, there is a hospital on the reservation and another just outside the reservation boundary that have signed the Memorandum of Understanding with the National Center on Shaken Baby Syndrome, developers of the PURPLE program (Loveland, 2015). This Memorandum of Understanding states that the hospital has implemented a protocol to deliver the PURPLE materials. In addition, the hospital has distributed the PURPLE materials to women after delivery of their infants and educated the staff on delivery of the program (Loveland, 2015). Women who delivered their babies in the hospital are supposed to receive the first dose of the prevention material.

Finally, there appears to be inconsistent or no implementation of the subsequent doses of the PURPLE intervention in the area. As stated previously, dose two is a reiteration of the initial dose and usually occurs at a well-baby visit or in a home visiting setting. Dose three is a community-wide prevention-education intervention that can occur at any time and does not have to be administered in a sequential timeline in relation to the previous doses (NCSDS, n.d.).

Project Aim 2: Examine the Literature to Uncover Best-practice Approaches to Prevent AHT

The literature was queried to discover best practice with clear gaps apparent related to best practices to prevent abusive head trauma among Native American populations. However, there is evidence to support implementation of The Period of PURPLE Crying as a means to prevent AHT in the general population. There is also support for home-visiting interventions as a method to reduce abusive head trauma and child abuse (Loveland, 2015; Mikton & Burkhart, 2009). The Parents as Teachers (PAT)

program, which is a home-visiting intervention, has already been implemented with this population.

Two randomized controlled trials (RCTs) supported the use of PURPLE among parents as a means to increase AHT knowledge and prevention understanding. The two, high-level studies were utilized to support the use of the PURPLE intervention. While multiple other research articles were identified that recognized the importance of PURPLE in increased prevention knowledge, the two highest quality RCTs were used as best evidence for the use of this intervention. Evidence Table 1 highlights the results of the comprehensive literature review.

Table 1. Randomized Control Trial Evidence Reviewed

Citation: (i.e., author(s), date of publication, & title)	Frame work	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])
Barr, R. et al., (2009). Do educational materials change knowledge and behavior about crying and shaken baby syndrome? A randomized controlled trial.	RCT	Participants were randomly assigned to intervention or control group.	Mothers recruited from hospitals in Vancouver, British Columbia who had a previous delivery. *n=1833.*	Crying knowledge, sharing knowledge, response to crying, responses to inconsolable crying, and self-talk responses to inconsolable crying. Information sharing,	Telephone interview five weeks after birth, diary to facilitate remembering crying behavior, 8-week follow-up.	2-tailed t test. Incidence rate ratios.	Scores measuring crying knowledge were higher in mothers who received the PURPLE materials. No significant difference in shaking knowledge. Response to crying knowledg	Study only included mothers. Outcomes were based on maternal report, not direct observation. Results may not be generalizable to other populations. Study was blinded, randomized. Second

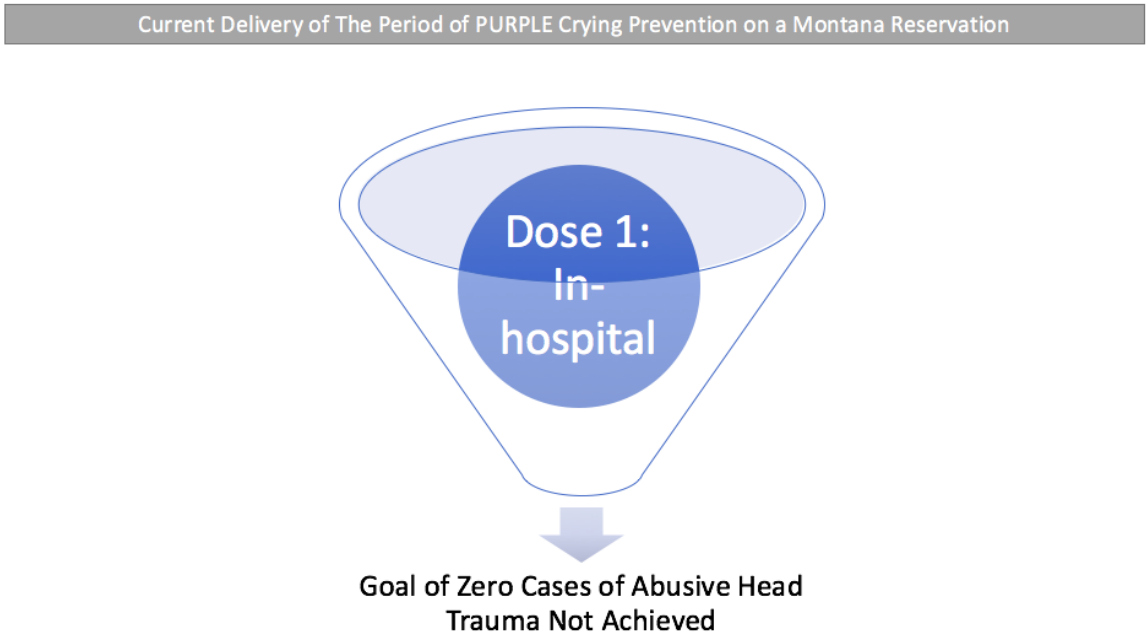
				walking away if frustrated, and the danger of shaking.			e higher among treatment group. More mothers willing to share informati on with caregivers in treatment group.	author is the direction of the National Center on Shaken Baby Syndrome.
Fujiwara et al. (2012). Effectiven ess of educationa l materials designed to change knowledge and behavior about crying and shaken baby syndrome. A replication of a randomize d controlled trial in Japan.	RC T	Participa nts were randomly assigned to interventi on or control group.	Japanese Mothers in Japan. *n*=201.	Mothers received PURPLE materials or control materials sent following birth of child.	Mothers completed diary at 7 weeks and 2 months and had structured telephone interviews.	P values.	Interventi on group scored significan tly higher on crying knowledg e. They also had increased knowledg e of un-soothable crying and walking away.	Convenien ce sampling was utilized. However, high level evidence supporting PURPLE materials.

Project Aim 3: Work Alongside Community Members to Discover Best Approaches and First Steps for an AHT-education Campaign

Multiple lessons were learned through the processes of working alongside community members to discover best approaches and first steps for an AHT-education campaign. Two separate models were developed to illustrate the prevention approach.

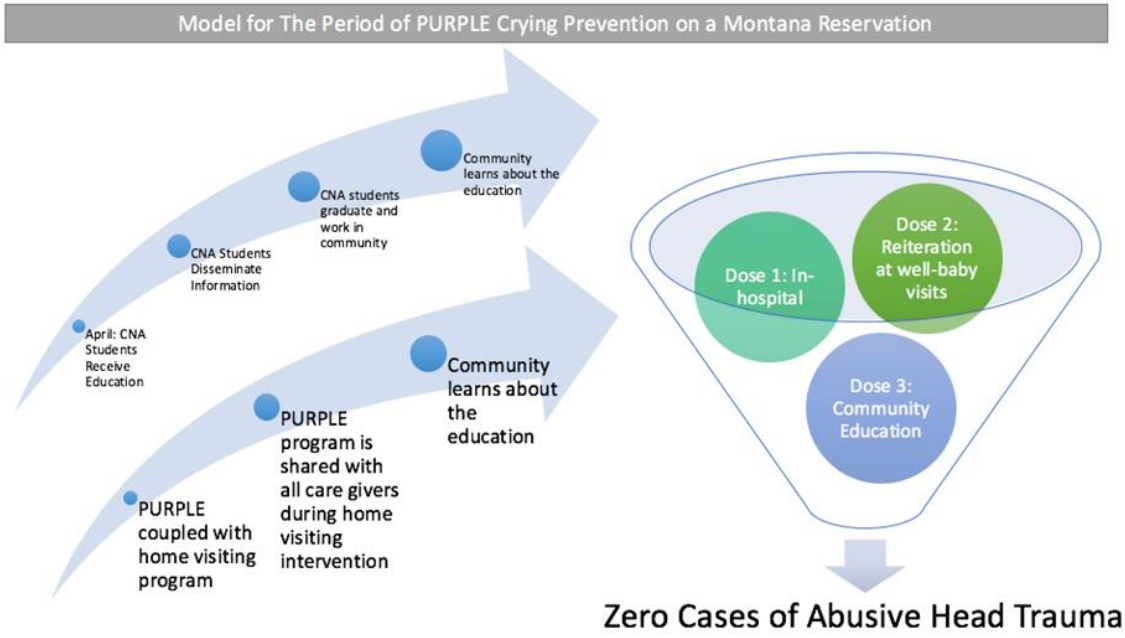
The first illustrated the current PURPLE prevention practices in the community and a second model was developed for an implementation process that could be used in the future.

Figure 1. Current Delivery of the Period of PURPLE Crying Prevention on a Montana Reservation



As you can see the first model illustrated the current, known PURPLE prevention practices that are being implemented in the community. The funnel shape illustrates the community and the circle shows the current prevention practices in place with the end goal of preventing cases of abusive head trauma amongst infants and children. With this current model, more could be done to prevent this type of child abuse.

Figure 2. Model for the Period of PURPLE Crying Prevention on a Montana Reservation



The second model illustrated the proposed plan for the PURPLE implementation process that would augment what is already occurring in the community. The arrows illustrate the sequential prevention steps that would be incorporated to the community's current practices. The growth in the size of the arrows illustrates the amplification of knowledge among the community as the information is disseminated. These arrows enter the funnel and add to doses two and three of the Period of PURPLE Crying to achieve the goal of zero cases of abusive head trauma in the community.

In addition to establishing support for the intervention among the community, multiple lessons were learned through the process of working with the community. Lessons learned, supported in part by two established theoretical approaches (CBPR and RNT), include the following analyses of outcomes. Additional explanation for each lesson is described in chapter five (Conclusion).

1. Partnership development and maintenance is both time consuming and critical.
2. Community-based change can be created through indirect care over time.
3. A statistically significant intervention in one community may be less important than a clinically significant and culturally appropriate intervention in a tribal community.
4. Community-based approaches are rarely neat and may not fit into a preconceived timeline.
5. The timeline of the community must be respected and evolution of the project may take place and should be embraced.
6. A single approach to dissemination of prevention material may not be sufficient.
7. When working with tribal communities, gaining entrée into the community and developing relationships with stakeholders is imperative and may take more time than initially planned.
8. The culture of the community must be understood and respected and should guide decisions. This important detail relies on a community partner, but is often extended further through the use of a community advisory group.
9. Sustainability of the intervention must be considered and planned for prior to implementing a change.
10. The doctor of nursing practice and family/individual nurse practitioner role in prevention implementation is reflected in DNP essentials.

The implications and reflections on each of the lessons learned have been explored in the next chapter.

CONCLUSION

Discussion

This evidence-based prevention project, guided by the Community-Based Participatory Research (CBPR) framework and The Rural Nursing Theory (RNT), focused on developing the framework for an evidence-based AHT-prevention intervention on a Native American Reservation in Montana. Multiple lessons were learned throughout the course of this project that can be used to guide future projects and/or research. Each of the lessons learned mentioned in the results section have been further explored throughout the following paragraphs.

Lessons Learned

1. Partnership development and maintenance is both time consuming and critical.

Partnership development and preservation is a critical facet of creating and sustaining CBPR projects. Holkup et al. (2009) discussed historical trauma experienced by Native American people that must be considered and respected. In the past, Native American communities have experienced negative sequelae from projects or research (Holkup et al., 2009). With this in mind, the utmost respect and gratitude was utilized during the process. This project was approached as a community-led initiative that was meant to improve community health outcomes. The project was to help alter the negative connotation of the word “research” among this community. Tribal IRB support was sought prior to proceeding to ensure community support from leaders. As Christopher et

al. (2011) stated, there are no "protocols to guide research partnership development or maintenance" (p. 250). Because of this, trust building was a crucial component and can only be fostered over time.

2. Community-based change can be created through indirect care over time.

As previously noted in the RNT, outsiders to the community are often viewed with skepticism (Winters, 2013). As an outsider, one way to overcome this barrier was through the specific methods laid out by this project. By providing the resources to community members and then having them own the material and take it into their day-to-day lives, the message extends far beyond what this author alone can deliver. This represented an indirect care delivery of the prevention message that will grow as more individuals are exposed to the content over time.

3. A statistically significant intervention in one community may be less important than a clinically significant and culturally appropriate intervention in a tribal community.

The PURPLE materials represented an evidence-based intervention for AHT prevention from the literature. The program's implementation has suggested that parents have increased knowledge of crying behaviors and methods to cope with this behavior (Barr et al., 2009; Fujiwara et al., 2012). However, it remains unclear how this intervention should be translated to Native American communities. Conversations with leaders and elders in the community reiterated the value of each individual child as a gift and representative of the future. This basic Native American value is embraced by members of the community. Therefore, it was conveyed to me that if a single episode of

AHT was prevented because of this intervention, then the project was a success (K. Smoker, personal communication, April 18, 2017). This represents the meaning of clinical significance over statistical significance in this setting.

4. Community-based approaches are rarely neat and may not fit into a preconceived timeline.

As this project came to a conclusion on the formal timeline developed by the DNP curriculum, additional literature was explored that discussed CBPR principles in working with Native American communities. One of the tenets was to plan for extended timelines (Christopher et al., 2011). This finding aligned closely with what was encountered throughout the process of the PURPLE project. Christopher et al. (2011) stated that it is important to be "sensitive to emerging issues in the community" (p. 253). It became clear in working on this project that the DNP projected timeline for the scholarly assignment would be different from the community-driven timeline.

5. The timeline of the community must be respected and evolution of the project may take place and should be embraced.

Throughout the course of this project, the topic was altered based on community feedback. This action was determined after discussions with the stakeholders to define specific needs and determine what would best meet the current necessities of the program and community. Maintaining an open mind and flexibility allowed for a natural progression of project development based on community input.

6. A single approach for dissemination of prevention material may not be sufficient.

The approach suggested in this project of a pre- and post-intervention survey completed after the PURPLE materials have been disseminated may not be the best approach for the community. In order to show the impact of the intervention, perhaps a qualitative method of data collection would be more feasible or meaningful based on the community's culture and values. As is suggested by the PURPLE program, the material should be delivered in multiple "doses" to the community over time. The developers of the PURPLE program recognized that the delivery of these doses may occur in non-sequential order (NCSBS, n.d.).

While the PURPLE program has made room for nontraditional delivery methods as stated in the program manual (NCSBS, n.d.), no evidence exists to guide this process. Throughout the process of completing this project, it has been reiterated that a one-size-fits-all approach is not appropriate for all settings and may need to evolve over time to meet the community's needs. This project further illustrates the necessity to develop and adapt dissemination strategies over time and through multiple avenues.

7. When working with tribal communities, gaining entrée into the community and developing relationships with stakeholders is imperative and may take more time than initially planned.

Throughout the process of working on the project, additional literature regarding working with Native American communities in carrying out CBPR projects was discovered. This work discussed the importance of first acknowledging the historical experience Native American communities have had with outside projects or research and, second, working to overcome that perception. The only way to complete this task is by

building trust. This was partially completed by using Montana State University (MSU) faculty who had a developed and ongoing relationship with the community members as a guide. Utilizing this already established connection allowed for an extension of the relationship to meet other needs of the community and to continue to foster relationships (Christopher et al., 2011).

8. The culture of the community must be respected and should guide each decision as much as possible. This important detail relies on a community partner, but is often extended further through the use of a community advisory group.

A community partnership was established with a community member and relationships beyond that were formed to learn about the culture and the people. The opportunity to meet with tribal elders on multiple occasions was a way to learn as much as possible about the culture and values throughout the project process. Time was spent in the school-based clinics speaking with and learning from the staff and students. Prior to visiting the reservation this author had the opportunity to meet with MSU faculty to learn about cultural practices prior to travelling to the location.

9. Sustainability of the intervention must be considered and planned for prior to implementing a change.

The plan for this project from the outset was to develop a community-led and community-supported intervention that could be retained by local individuals to improve health outcomes beyond the timeline of this project. Community support was fostered as a means to improve population health and it is the plan that the community will continue to implement this education with the participants.

10. The doctor of nursing practice and family/individual nurse practitioner role in prevention implementation is reflected in DNP essentials.

As stated in the DNP essential educational objectives, the doctoral-prepared nurse practitioner should, "influence health outcomes by providing advanced independent comprehensive health care services including health promotion and counseling, health assessment and diagnosis, disease prevention, and management of health and illness of individuals and families throughout the lifespan" (Montana State University College of Nursing, n.d., para. 9).

This educational goal highlights the important role nurse practitioners have in preventing illness and promoting health among the populations we serve. This project emphasizes the necessity of preventing abusive head trauma before a child is harmed. Abusive head trauma is preventable and, in this project, community relationships have been fostered through CBPR and the RNT to promote health and wellness through prevention.

Limitations

A limitation of this project was the inability to collect data on the DNP curriculum time frame to support the implementation of this intervention. Another barrier to its implementation was my status as an outsider. As defined by the RNT, an outsider is "being exterior to the group, matter, or boundary in question" (Winters, Boland, Raph, & Buehler, 2018, p. 35). Despite attempts to integrate myself into the community as much as possible throughout the course of the project, because I did not live in the community

and am not from the community, I was ultimately viewed as an outsider. As the RNT suggests, rural individuals are often skeptical of outside individuals (Winters, Boland, Raph, & Buehler, 2018). In order to overcome this barrier, the proposed design was to give this intervention back to community insiders to further embrace and disseminate the information.

Another barrier that existed was the distance from the location to where this author is located. The total driving distance that needed to be covered was 447 miles one way. This author was able to travel to the location on three separate occasions to build relationships; however, it is assumed that the project may have moved along more quickly if the distance between the two locations was shorter.

Recommendations

The sustainability of this project was an important factor to consider when implementing any intervention with a population. In order to support the sustainability of the intervention, Montana Bill 50-16-103 can be referenced. As stated in the bill, materials must be easily accessible and free to the public. On the Montana DPHHS website, AHT-prevention information is made readily available and can supplement the PURPLE materials which are available for a fee.

In addition, on the reservation, there is a PURPLE hospital that delivers education to new parents prior to discharge (Loveland, 2015). Part of the PURPLE implementation process includes multiple doses of the intervention to augment the sustainability and exposure to the message. Therefore, it is recommended that the program be implemented

on a community basis after the initial exposure in the hospital setting by parents. This initial in-hospital exposure does not include community members or other individuals who may care for an infant. Therefore, exposing the community to the intervention is imperative for the sustainability of the intervention and potential reduction in the substantiated rate of child abuse.

Implementing the second dose of the intervention in conjunction with the already established home-visiting program being used by the community is another recommendation. This partnership could increase exposure to the message and may catch family members who did not receive the initial education in the hospital setting. Also, if a mother has delivered outside of a hospital setting, this home-visiting encounter would provide another opportunity to deliver educational materials to parents and the infant's caregivers. Figure 2 illustrates a model that was developed to aid in the implementation of this process and was described in chapter four.

Not only should the information be readily available, but additional research should be conducted to understand how this particular intervention translates to Native American communities. Another point of investigation that came up throughout the course of this project was how the material fit into the cultural traditions of the community. Is there a more culturally-sensitive way to deliver this material or a similar message? The PURPLE materials could not be altered to further represent the community's culture and values (K. Copeland, personal communication, October 5, 2017). Therefore, the impact of culturally congruent materials was an additional inquiry question that developed through the process of this project.

To enhance the rapport with the community, several other research articles were reviewed to understand the process of working on CBPR projects with Native American communities. An additional recommendation or area for future inquiry would be to broaden the literature review to include how to best achieve CBPR projects or translational science with Native American communities.

Conclusion

The purpose of this scholarly project was to discover evidence-based approaches for the prevention of AHT on one Montana reservation. This project included three main objectives:

1. Evaluate risk factors and current practices in place on one Montana reservation to prevent AHT.
2. Examine the literature to uncover best-practice approaches to prevent AHT.
3. Work alongside community members to discover best approaches and first steps for an AHT-education campaign.

After examining current prevention practices around the world, The Period of PURPLE Crying was selected as the best evidence-available prevention-education tool. Abusive head trauma is preventable and part of the job of a nurse is to advocate for social justice (ANA, 2015). Our role extends beyond the bedside and can be taken into diverse communities.

This project additionally highlights the importance that health promotion and disease prevention play in the role of a DNP-prepared nurse practitioner. Innovative

strategies must be implemented to stop infants and children from experiencing this type of preventable harm. The project illustrates the DNP's intersection in assessing evidence and then working with diverse communities to implement strategies that can evolve over time. After working alongside community members using CBPR and the RNT, multiple lessons were learned and can be used to work with diverse communities in the future.

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APPENDICES

APPENDIX A

HEALTHCARE PROVIDER SURVEY

(RESOURCE FOR COMMUNITY MEMBERS)

1. Have you heard of the Period of PURPLE Crying education materials for shaken baby/abusive head trauma prevention?
   a. Yes_____
   b. No _____

2. If yes, is this something that you utilize regularly in your current practice?
   a. Yes _____
   b. No _____

3. Under what circumstances do you incorporate educating parents and families about shaken baby syndrome/abusive head trauma?

4. How comfortable are you talking to parents or families regarding the dangers of shaken baby syndrome/abusive head trauma?

5. What local resources are utilized in your community to educate parents and families on shaken baby syndrome/abusive head trauma?

6. Please place an X on your highest level of education.
   - High School
   - Associate's degree
   - Bachelor's degree
   - Master's degree
   - Doctorate degree
   - Other _____

7. How many years have you been practicing? (Please mark with an X the most appropriate)
   - 1-5 years
   - 6-10 years
   - 11-15 years
   - 16-20 years
   - > 20 years

8. What is your health care provider role (RN, CNA, MD, etc.)_____

9. Thank you for your time. Please include any additional comments below:

APPENDIX B

PRE- AND POST-TEST SURVEY

(RESOURCE FOR COMMUNITY MEMBERS)

Please Circle Your Answers:

1. **What is your age**: _____
2. **Gender:**

    a. Female
    b. Male

3. **What do you know about shaken baby syndrome? 0=nothing, 10=everything. Please circle your answer.**
4.

Nothing **Some** **Everything**

0 1 2 3 4 5 6 7 8 9 10

5. **At what age do infants cry the most?**
    a. 2 months-old
    b. 6 months-old
    c. 2 weeks-old
    d. Babies do not cry

6. **What time of day is infant crying behavior the worst?**
    a. In the morning
    b. In the evening
    c. Infants never cry
    d. All of the above

7. **Healthy infants may cry up to 5 hours per day:**
    a. True
    b. False

8. **Sometimes infants cry for no reason:**
    a. True
    b. False

9. **Shaking a baby is dangerous and can lead to:**
    a. Seizures
    b. Physical disabilities
    c. Death
    d. All of the above

Please Circle Your Answers:

1. **At what age do infants cry the most?**
   - **a.** 2 months-old
   - **b.** 6 months-old
   - **c.** 2 weeks-old
   - **d.** Babies do not cry

2. **What time of day is infant crying behavior the worst?**
   - **a.** In the morning
   - **b.** In the evening
   - **c.** Infants never cry
   - **d.** All of the above

3. **Healthy infants may cry up to 5 hours per day:**
   - **a.** True
   - **b.** False

4. **Sometimes infants cry for no reason:**
   - **a.** True
   - **b.** False

5. **Shaking a baby is dangerous and can lead to:**
   - **a.** Seizures
   - **b.** Physical disabilities
   - **c.** Death
   - **d.** All of the above

6. H**ow likely are you to use the PURPLE information in the future?**
   - **a.** Very likely
   - **b.** Somewhat likely
   - **c.** Neutral
   - **d.** Unlikely
   - **e.** Very unlikely

7. **Would you share this information with your family and friends?**
   - **a.** Yes
   - **b.** No

8. **What would be the best way for you to receive this information?**
   - **a. In person**
   - **b. E-mail**
   - **c. Social Media**
   - **d. Other: _____**

APPENDIX C

SUPPORT LETTER FROM PRINCIPAL

IRB Letter of Support for Emily Schmitt

Dear Institutional Review Board Chair and Members:

I am writing to express my support for Emily Schmitt, Doctor of Nursing Practice (DNP) student at MSU-Bozeman to complete a shaken baby syndrome prevention project that is further described below. The educational material from this project will be embedded into the curriculum for the high school students over the next three years to promote the sustainability of the project and provide important education for our students.

Research Overview

1. Project Summary:

The aim of this scholarly project is to provide community prevention education on the Fort Peck Reservation. The prevention topic that has been selected by the community is abusive head trauma. Abusive head trauma is the term that has replaced shaken baby syndrome. Utilizing a best practice education campaign, materials will be disseminated through the community to deliver prevention education. The Period of PURPLE Crying has been identified as the best practice prevention education material available. The prevention education will span the entire reservation, focusing mainly on the two largest population centers. In order to distribute the information, the local community health clinics will be utilized to display the PURPLE materials. Local community health centers will be contacted to further educate the community regarding the PURPLE campaign. An area community college and the high schools are also focus sites to further disseminate the information. The materials will be circulated using social media to advertise the PURPLE campaign message and raise awareness. In order to evaluate the effectiveness of the intervention a pre and post-test survey will be given to individuals exposed to the education information. Data collection will take place in April 2018, in conjunction with Child Abuse Prevention Month.

2. Objectives:

This project has four main objectives:

- Evaluate risk factors and current practices
- Examine literature and uncover best practices
- Implement best practice education intervention
- Evaluate the effectiveness of the education

I believe that this project will be carried out using sound ethical principles and that participant involvement in this research study is strictly voluntary. The DNP student will provide confidentiality of the study results.

Sincerely,

Dwain Haggard

APPENDIX D

FORT PECK IRB APPROVAL

M E M O R A N D U M
……

TO: Emily Schmitt

FROM: Robert McAnally
Chair, Fort Peck Institutional Review Board

DATE: April 27, 2018

RE: Shaken Baby Syndrome/Abusive Head Trauma Community Prevention Education on a Native American Reservation

The above research, described in your submission of April 20, 2018 is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

___ (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

__X__ (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

____ (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

____ (b) (5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

_____ (b) (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be

safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.

APPENDIX E

SUPPORT LETTER FROM KENNY SMOKER

HEALTH PROMOTION
DISEASE PREVENTION
FORT PECK TRIBES

March 7, 2018

IRB Letter of Support for Emily Schmitt

Dear Institutional Review Board Chair and Members:

I am writing to express my support for Emily Schmitt, Doctor of Nursing Practice Student at MSU-Bozeman to complete a shaken baby syndrome prevention project that is further described below.

Research Overview

1. Project Summary:

The aim of this scholarly project is to provide community prevention education on the Fort Peck Reservation. The prevention topic that has been selected by the community is abusive head trauma. Abusive head trauma is the term that has replaced shaken baby syndrome. Utilizing a best practice education campaign, materials will be disseminated through the community to deliver prevention education. The Period of PURPLE Crying has been identified as the best practice prevention education material available. The prevention education will span the entire reservation, focusing mainly on the two largest population centers. In order to distribute the information, the local community health clinics will be utilized to display the PURPLE materials. Local community health centers will be contacted to further educate the community regarding the PURPLE campaign. An area community college and the high schools are also focus sites to further disseminate the information. The materials will be circulated using social media to advertise the PURPLE campaign message and raise awareness. In order to evaluate the effectiveness of the intervention a pre and post-test survey will be given to individuals exposed to the education information. Data collection will take place in April 2018, in conjunction with Child Abuse Prevention Month.

2. Objectives:

This project has four main objectives:

- Evaluate risk factors and current practices
- Examine literature and uncover best practices
- Implement best practice education intervention
- Evaluate the effectiveness of the education

I believe that this research will be carried out using sound ethical principles and that participant involvement in this research study is strictly voluntary, providing confidentiality of research data.

Sincerely,

Kenneth Smoker Jr. MBA
Director Health Promotion Disease Prevention
Fort Peck Tribes

APPENDIX F

CONSENT FORM FOR PROVIDER SURVEY

(FOR COMMUNITY MEMBERS IF NEEDED)

Project Title: Shaken Baby Syndrome/Abusive Head Trauma (SBS/AHT) Community Education on a Native American Reservation

You are being asked to participate in a project to understand your baseline level of knowledge about shaken baby syndrome and comfort discussing shaken baby syndrome/abusive head trauma with your patients. This is in an attempt to gain understanding about what is currently being utilized to discuss SBS/AHT in the community.

Rationale of project: This project may help us to obtain a better understanding of the effectiveness of this particular shaken baby syndrome education program among the community. Your participation may also help us to better understand how to prevent shaken baby syndrome from happening in the future.

Procedures involved: Participation is voluntary. If you agree to participate you will be asked to complete a questionnaire regarding your baseline level of comfort discussing abusive head trauma/shaken baby syndrome with patients. Participation is voluntary and you can choose to not answer any questions you do not want to answer and/or you can stop at any time. The participation or non-participation will not affect the student's grade or class standing. You will be asked to complete an 8 question pre-survey.

Risks and Benefits: There are minimal risks associated with participating in this survey and education. Due to the sensitize nature of the SBS/AHT, it may make participants feel uncomfortable. You are not required to answer all survey questions and may do so as you feel comfortable. The benefits associated with your participation in this project may not directly benefit you, but could help provide education and knowledge to prevent shaken baby syndrome in the future.

Source of funding: The Dr. Helen Jacobsen Lee Endowment has provided funding to support this work.

Confidentiality: Your responses will in no way be tied to your personal demographic information. All possible attempts to maintain your privacy will be completed. Your participation is at no cost to you as the participant.

Please feel free to contact me with any questions you may have:
Emily Schmitt RN, BSN
emily.schmitt1@msu.montana.edu
If you have additional questions about the rights of human subjects you can contact the Chair of the Institutional Review Board, Mark Quinn, (406) 994-4707 [mquinn@montana.edu].

-------- AUTHORIZATION: I have read the above and understand the discomforts, inconvenience and risk of this study. I, _____ *(name of subject),* agree to

participate in this project. I understand that I may later refuse to participate and that I may withdraw from the study at any time. I have received a copy of this consent form for my own records.

APPENDIX G

MONTANA STATE UNIVERSITY IRB APPROVAL

MONTANA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects
FWA 00000165

960 Technology Blvd. Room 127
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-6783
FAX: 406-994-4303
E-mail: cherylj@montana.edu

Chair: Mark Quinn
406-994-4707
mquinn@montana.edu
Administrator:
Cheryl Johnson
406-994-4706
cherylj@montana.edu

MEMORANDUM

TO: Emily Schmitt and Sandra Kuntz

FROM: Mark Quinn Mark Quinn cfj
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: April 30, 2018

RE: *"Abusive Head Trauma Community Prevention Education on a Native American Reservation" [ES043018-EX]*

The above research, described in your submission of April 18, 2018, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

__X__ (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

__X__ (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

____ (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

____ (b) (5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

_____ (b) (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.