

A Culturally Tailored Tobacco Cessation Program for American Indians: Program Development

By

Kathryn L. Rollins

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Chairperson Dr. Leon Greene

---

Dr. Christine Daley

---

Dr. David Hansen

---

Dr. Susan Harvey

---

Dr. Bernie Kish

---

Dr. Phillip Gallagher

Date Defended: April 21<sup>st</sup>, 2016

The Dissertation Committee for Kathryn L. Rollins  
certifies that this is the approved version of the following dissertation:

A Culturally Tailored Tobacco Cessation Program for American Indians: Program Development

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Chairperson Dr. Leon Greene

Date approved: April 21<sup>st</sup>, 2016

## **Abstract**

American Indian communities face an ongoing challenge of effectively addressing tobacco related health disparities in an environment that often lacks culturally tailored interventions. This dissertation identified the knowledge, attitudes, and beliefs about SLT and SLT use within the AI community and addressed the program development phases of a culturally tailored SLT cessation program.

A CBPR approach served as the foundational approach to this study. A three phase research plan was created to guide the research team through program development, implementation, and assessment of program materials. The first two phases of the research plan were undertaken as part of this study. Phases 1 and 2 were specifically designed to gather formative data and guide the research team through program development.

Results showed that community members were willing to provide comments and suggestions that influenced the design of an SLT cessation program. Community feedback specifically addressed SLT cessation, which may improve individual and community health and wellbeing within the AI community. The results from this study support a culturally appropriate cessation program for AI that addresses traditional tobacco use. Studies such as this can potentially contribute to a better understanding of strategies to involve community members in all phases of the research process, as well as how to improve the threat of commercial tobacco use in the AI population.

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## **Dedication**

I would like to dedicate this dissertation to my husband Dan, and son Ben. People often asked me why I went back to school to pursue a PhD and the reasons were simple; to make a difference where one is needed, and a career that would allow me to spend more time with you.

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## List of Abbreviations

AI .....	American Indian
AIHREA .....	American Indian Health Research and Education Alliance
AN.....	Alaskan Native
ANBL.....	All Nations Breath of Life
ANSOS .....	All Nations Snuff out Smokeless
CAB .....	Community Advisory Board
CAICH .....	Center for American Indian Community Health
CAIS .....	Center for American Indian Studies
CBPR .....	Community Based Participatory Research
CDC .....	Centers for Disease Control
CMA .....	Critical Medical Anthropology
HSC.....	Human Subjects Committee
IHS .....	Indian Health Services
KS .....	Kansas
KUMC.....	University of Kansas Medical Center
MPH.....	Master of Public Health
NAALS .....	The National Assessment of Adult Literacy
NHIS .....	National Health Interview Survey
NHW .....	non-Hispanic Whites
NIH .....	National Institutes of Health
NE .....	North East
NSDUH.....	National Survey on Drug Use and Health
PI.....	Principle Investigator
PMT .....	Protection Motivation Theory
RGL.....	Reading Grade Level
SLT .....	Smokeless Tobacco
SMOG.....	Simple Measure of Gobbledygook Readability Formula
SKC.....	Salish Kootenai College
TSNA .....	Tobacco-specific nitrosamines

## **Chapter I**

### **Introduction**

American Indians (AI) have the highest rates of smokeless tobacco (SLT) use of any major racial/ethnic group in the US. The rate of SLT use among AI is more than double that of non-Hispanic whites (9% vs. 4%, respectively).<sup>1</sup> Over the last 30 years, rates of SLT use have been rising in some tribal communities with historically low rates.<sup>2-3</sup> As a result of increasing SLT use rates, the number of health disparities in the AI community is growing. Although the negative health consequences of SLT use have been widely acknowledged, the need exists for a culturally tailored SLT program specifically developed for AI.

Tobacco holds cultural significance in many AI tribes, as many individuals see it as a sacred plant that must be respected.<sup>4-6</sup> Because of this, SLT cessation messages and programs portraying tobacco as entirely negative are inappropriate and culturally insensitive. Research has found that AI smokers are more likely to quit if they participate in a culturally tailored cessation program, and the same is thought to be true of SLT users. According to a local survey, 45% of AI SLT users were interested in participating in a culturally tailored SLT cessation program.<sup>7</sup>

Despite the designation as a homogeneous group of people, AI communities are quite diverse, therefore tailoring interventions to the community or culture often is difficult. Research has suggested that a collaborative approach, in which community members and researchers equally contribute expertise, is the recommended method for developing culturally tailored research designs. Community involvement and direction is crucial from concept development to analysis and dissemination, increasing the likelihood of participation and sustainability.<sup>8</sup>

Therefore, this study utilized the recommended principles of Community-Based Participatory

Research (CBPR), designed to involve community member in all stages of research<sup>9</sup>, to develop a culturally tailored SLT cessation program for AI.

### **Project Background**

The American Indian Health Research and Education Alliance (AIHREA) is an alliance of organizations whose mission is to “partner and collaborate with AI peoples, nations, communities, and organizations to improve the physical, mental, emotional, and spiritual well-being of AI throughout the United States through quality participatory research and education programs”.<sup>10</sup> The two primary organizations that compose AIHREA are the Center for American Indian Community Health (CAICH) at the University of Kansas Medical Center and the Center for American Indian Studies (CAIS) at Johnson County Community College. AIHREA partners and collaborates with numerous organization in the Kansas, Missouri, and surrounding states to conduct research and provide services to the AI community.

In 2003, a number of local Indian Health Service (IHS) clients approached IHS because they believed that the available smoking cessation programs did not respect the traditional use of tobacco that many tribes practice. As an outcome, collaborative efforts between the University of Kansas Medical Center, Native people in the Kansas City metropolitan area of Kansas and Missouri, area Kansas tribes, and the Oklahoma Area Office of the IHS developed a culturally tailored smoking cessation program (All Nations Breath of Life, ANBL) to address the needs of the AI community. The goal of the ANBL program was to stop recreational use of commercial tobacco among AI, while allowing those who practice traditional use of tobacco to continue its use through prayer, ceremony, and in other traditional ways. In a natural progression, after the successful launch of ANBL, the research team sought to address SLT cessation as well. Utilizing the successful methods used to address smoking in the AI community and due to the requests by

multiple SLT users in the community, All Nations Snuff out Smokeless (ANSOS) was developed.

In 2014, AIHREA was awarded a National Institutes of Health (NIH) R01 grant (Smokeless Tobacco Cessation among American Indians Using In-person Groups) to develop ANSOS. The goal of the ANSOS program is to stop recreational use of commercial SLT among AI, while allowing those who practice traditional use of tobacco to continue its use through prayer, ceremony, and in other traditional ways. The program was developed with the understanding of the diversity of AI cultures and tribes. Just as an intervention that may be effective for one racial/ethnic group may not be effective for another group, an effective intervention for one tribe may not be effective in another. The creation of ANSOS involved AI from reservations, rural communities, and urban areas to increase generalizability of the program. Community partners include the Kansas City Indian Center, the American Indian Council, Johnson County Community College, the Kickapoo Tribe in Kansas, and The Prairie Band Potawatomi Tribe.

A three phase research plan was created to guide the research team through program development, implementation, and assessment. For the purpose of this dissertation, only a portion of phases 1 and 2 were completed. For the purpose of this study, the focus was on the on the development of a program timeline during Phase 1 and program curriculum during Phase 2. This work was only a small portion of the large amount of work that went into the development of ANSOS. Additional program components (i.e. baseline survey, weekly surveys, phone scripts, facilitator guide, etc.) were completed by other research team members, and therefore were not addressed in detail in this study.

The first two phases of the research plan were specifically designed to gather formative data and guide the research team through program development. Phase 1 addressed program development through formative research gathered from focus groups and interviews. Phase 2 evaluated the appropriateness of program curriculum, also addressing program development. Phase 3 focused on program implementation through a pilot study. Phases 1 and 2 must be completed first, in order to develop the necessary materials that will be used during the pilot program occurring during Phase 3. The information presented in Table 1 describes the aims of each phase of the research plan, the study design for this dissertation, and the additional program components that were created outside of this dissertation.

Table 1

*Phases of the Research Plan*

	<i>Specific Aims</i>	<i>Secondary Aims</i>	<i>Dissertation Study Design</i>	<i>Additional Program Components</i>
<b>Phase 1</b>	To develop a culturally tailored, SLT cessation program for AI using CBPR.	To identify factors which enhance dissemination of a culturally tailored SLT cessation program and contribute to program success or failure.	Focus groups/Interviews (timelines & curriculum)	Surveys, facilitator guide, phone scripts
<b>Phase 2</b>	To develop and assess for scientific accuracy, readability, and cultural appropriateness accompanying educational materials.		Scientific review, Readability assessment and Cultural review (curriculum)	NA
<b>Phase 3</b>	To pilot test, determine the feasibility and acceptability, and estimate the cessation rate of a culturally tailored, group-based SLT cessation program for AI.	To examine nicotine metabolism in AI SLT users.	Pilot program	NA

## **Purpose**

The purpose of this study was to collect information through formative research to be used in the development of a culturally tailored SLT cessation program for AI. A secondary purpose was to assess program curriculum for scientific accuracy, readability and cultural appropriateness.

## **Research Questions**

The following research questions were addressed:

1. What knowledge, attitudes, and beliefs do AI have about SLT and SLT use?
2. What do AI want to experience in a culturally tailored SLT cessation program?
  - a. What factors will enhance dissemination of a culturally tailored SLT cessation program and contribute to program success or failure?
3. What roles do scientific reviews, readability assessments, and community reviews have in the development of a culturally tailored SLT cessation program?

## **Significance**

AI are an ideal audience for tobacco education and cessation due to the number of negative health effects of SLT, in conjunction with the popularity of its use. This study developed a culturally tailored SLT cessation program designed for AI (Phases 1 and 2), in preparation for a pilot of that program (Phase 3). The curriculum developed in this study was the first of its kind in this community. A program of this type broke new ground by conducting research on SLT use in a population in which tobacco use is rarely studied. This study further investigated the extent to which Critical Medical Anthropology (CMA) and Protection

Motivation Theory (PMT) explain variation in the behavioral intentions to participate in a cessation program. The development of this program helped to determine the feasibility and acceptability of a culturally tailored SLT cessation program for AI.

The AIHREA research team leading this study has had success with a culturally tailored smoking cessation program (ANBL) and has significant ties to the AI community. The support from the AIHREA research team, as well as the desire of local AI communities for a culturally tailored SLT cessation program, supports the significance of this study.

### **Scope of the Study**

The scope of this study was to identify factors which enhance the dissemination of a culturally tailored SLT cessation program and create one such program. This study analyzed the knowledge, attitudes, and beliefs of AI, therefore only individuals self-identifying as AI were solicited for participation. To participate in Phase 1 individuals were asked to partake in focus groups and interviews concerning SLT use and cessation program development. Phase 2 consisted of scientific, readability, and cultural assessments on program curriculum.

### **Assumptions**

The following assumptions were made for this study:

1. Participants were a representative sample of AI.
2. Participants responded honestly and accurately to the focus group and interview questions.
3. Scientific review members were a representative sample of experts in their field.
4. Participants were able to comprehend program curriculum set below at or below an 8<sup>th</sup> grade reading level.
5. Community review members were a representative sample of AI.

## **Limitations**

The limiting factors for this study are:

1. A limitation to this study is that it is contextually specific. The generalizability of this study may be limited across contexts and populations.
2. This study selected participants utilizing a convenience sampling <sup>11</sup> technique. Participants chosen for this study were limited to AI attending Native-specific events supported by AIHREA.
3. Information reported was based on individual experience and may have limited the ability for each participant to respond to all questions in the moderator/interview guides.
4. The number of participants in each phase of the research plan may have been limited due the time restraints of this study.

## Definitions

For the purpose of this study, the following definitions were used:

1. **American Indian (AI):** A member of any of the indigenous peoples of the lower 48 contiguous states. Individuals in this study all self-identify as AI.
2. **Cessation:** The process of ending, which for this study refers to the ending of the use of SLT.
3. **Convenience sampling:** A non-random sampling technique that recruits subjects or participants based on their accessibility and proximity to the researcher.<sup>11</sup>
4. **Culturally Tailored:** Adapting curriculum and materials to fit the specific needs of the AI population in this study.
5. **Emic:** Research from the perspective of one who participates in the culture being studied (subjective approach). The emic reviewer in this study is a member of the research team that is also an AI community member.
6. **Etic:** The perspective of someone outside of a community, often the perspective of the researcher. The etic reviewer in this study is a member of the research team who is not an AI community member.
7. **Smokeless Tobacco (SLT):** Tobacco that is chewed or snuffed by an individual, rather than smoked.

## **Chapter II**

### **Review of Literature**

#### **Introduction**

American Indians have the highest prevalence of tobacco use of any major racial/ethnic group in the U.S.<sup>12</sup> Specifically, SLT causes significant health risk to users.<sup>13-15</sup> As a result of high rates of SLT use, the number of health disparities among the AI community is rising. Although the negative health consequences of SLT use have been widely acknowledged, the need exists for a culturally tailored SLT program specifically developed for AI. This research provided an in-depth review of why a need exists to develop a culturally tailored SLT cessation program, as well as how such programs can be developed.

Due to the nature of this subject, this review of literature sought the most current information available. It was important to identify any recent developments related to SLT, cessation program development, and AI health. The literature review presented in this chapter represents studies that were published from the 1969 to 2015. Most of the material after 2000 has not shown significant change, therefore earlier literature was applicable. The inclusion of peer-reviewed studies, articles from scientific journals, textbooks, and electronic resources provided the researcher the necessary documentation to build a strong rationale for the study and methodology components.

The content for this review of literature starts by focusing on the traditional significance of tobacco, followed by a discussion on the impact current tobacco use has on the AI population. Furthermore, the benefits of CBPR and CMA for cessation program development are reflected in a description of the conceptual framework used to guide this study.

## **Tobacco**

Various species of *Nicotiana*, commonly referred to as tobacco plants, are indigenous to North and South America. *Nicotiana rustica*, traditional tobacco, and *Nicotiana tabacum*, commercial tobacco, are two of the most common types. Although both originated in the Americas, commercial tobacco has been modified and is treated with chemicals<sup>4</sup>; it is not the same tobacco that was traditionally used by AI/Alaska Native (AN) tribes. For centuries these plants have been cultivated by diverse populations for different types of tobacco use.

### **Cultural Significance**

The method by which AI initially came into contact with tobacco is difficult to determine. Many tribes have important origin stories about how tobacco came into being, however these stories vary from tribe to tribe. Researchers concluded that tobacco use likely originated in areas of South America and then spread across Central and North America.<sup>5</sup> Some species of tobacco grew wild, while others were cultivated by tribes. According to Pego, et al. (1995), “North American Indians on the West Coast gathered wild tobacco, on the East Coast and the central Plains, they cultivated it for use, and intermediate tribes obtained their tobacco through inter-aboriginal trade.”<sup>5</sup> Although interactions with tobacco varied geographically, it had a cultural and economic impact to most AI tribes.

Tobacco has cultural significance to many AI tribes. Along with plants such as sage, cedar, and sweet grass, tobacco has long been considered a sacred plant.<sup>6</sup> Tobacco has been used traditionally in rituals and prayers for thousands of years and is used for a variety of medicinal and ceremonial purposes. Agriculturally, tobacco was used by medicine men in the reaping of crops to bless the harvest.<sup>5</sup> Spiritually, tobacco smoke carries prayers up to Creator and the Spirit world. Tobacco is used in offerings as a sign of gratitude.<sup>4</sup> In addition to ceremonial use, tobacco

was used medicinally by many tribes. Healers were often given tobacco as a form of payment, and they used dried leaves or smoke to cure physical ailments ranging from toothaches to asthma.<sup>4</sup>

Tobacco use is common for many AI, although conflicting research is found on the impact traditional tobacco use has on commercial tobacco use and its addiction. For example, Pego et al. (1995) suggested that the commercial development and manufacture of tobacco and its reintroduction into the AI culture through acculturation and assimilation may have increased susceptibility for secular use.<sup>5</sup> However, quantitative research on the beliefs, attitudes, and behaviors related to smoking cessation revealed that most participants (current smokers) felt tobacco use for sacred purposes is very different from recreational use.<sup>16</sup> Nevertheless, tobacco use among AI is disproportionately high, creating a significant health concern.

### **Smokeless Tobacco**

Oral tobacco products, otherwise known as SLT, are a diverse collection of products that deliver harmful chemicals and additives to the user.<sup>13</sup> Smoke tobacco is used in various forms, such as cigarettes, pipes, and cigars, whereas SLT is sniffed through the nose (dry snuff) or chewed (moist snuff, snus or pouches, loose-leaf or plug chewing tobacco).<sup>12</sup> The type of tobacco used in a product has influence on the chemical composition and may vary across product categories and brands.<sup>13,17</sup> The information presented in Table 2 provides a summary of the product categories and their identifiers.

Table 2

*Identification of Smokeless Tobacco Types*

Type	Description
Oral (moist) snuff	finely cut, processed tobacco, placed between the cheek and gum
Snus (or pouches)	packet of moist snuff tobacco and flavorings, placed between the upper gum and lip
Loose leaf	shredded cigar leaf tobacco, loosely packed to form small strips, treated with sugar or licorice
Plug	chewing tobacco shaped in blocks or cakes, containing sweeteners and flavoring agents
Nasal (dry) snuff	finely ground tobacco powder sniffed into the nostrils, may contain flavoring or perfumes

*Note.* Adapted from Lawler et al. (2013) and Campaign for Tobacco-Free Kids (2015).

Tobacco plants are naturally rich in a variety of chemical components, such as nitrosamines and alkaloids. Tobacco-specific nitrosamines (TSNA) are compounds exclusively formed from tobacco alkaloids during the growing, curing, and processing of tobacco.<sup>13–14,18</sup> TSNAs are among the major contributors to the carcinogenic activity of tobacco.<sup>13–15</sup> SLT use causes the highest known non-occupational human exposure to carcinogenic nitrosamines, 1,000 times greater than exposure in foods and beverages such as beer and bacon.<sup>15</sup> In addition to the chemical components naturally found in the tobacco leaves themselves, over 500 different additives are added to the tobacco products during fabrication.<sup>19</sup> Carbohydrates and polyphenols are lost during fermentation, leading to the addition of chemicals to improve taste, flavor, and aroma, and to prolong shelf life. Ascorbic acid is added as an antimicrobial agent along with sodium propionate as a fungicide. Ammonia, another additive, is applied to control nicotine delivery.<sup>17</sup> Both naturally occurring and added chemical components contribute to the list of harmful ingredients within tobacco products.

All SLT products also contain nicotine, which is responsible for tobacco dependence, as a major constituent.<sup>13</sup> Addiction is not instantaneous, but rather is a process during which physiologic reactions to nicotine use develop.<sup>20</sup> As nicotine enters the body it acts on receptor sites, triggering the release of brain chemicals called neurotransmitters. One of these neurotransmitters, called dopamine, activates feelings of pleasure and promotes self-administration of nicotine by the user.<sup>18,21</sup> With repeated exposure to nicotine, tolerance to some of the effects of nicotine develops in the form of physical dependence, such as withdrawal symptoms in the absence of nicotine (cravings), in addition to these positive feelings.<sup>21</sup> In an addiction pattern similar to that of recreational drug abuse, the development of tolerance requires users to increase use or dose strength to achieve these same effects.<sup>20</sup> Experiencing these effects from the nicotine can be what makes tobacco so addictive, offering an explanation to why tobacco users may continue to use despite known adverse health effects from additives and TSNA's.<sup>14,20</sup>

### **Health Consequences**

Research documenting the health consequences of SLT use is limited in comparison to cigarette research. SLT is not homogeneous, with significant differences in composition and production present.<sup>22</sup> SLT products differ in the types of tobacco used, physical characteristics, methods of use, duration of use, and moisture content.<sup>23</sup> As a result, monitoring morbidity and mortality have been challenging, therefore limiting the available research.

A review of the literature on SLT studies by Critchley and Unal (2003) concluded that mixed evidence exists linking SLT with health problems.<sup>22</sup> Researchers found some case-control studies finding no increased risk of oral cancer among chewing tobacco users, while another large population-based study found a strong association between SLT use and cancers of the

mouth, salivary glands, and larynx.<sup>22</sup> A study on nasal SLT use in India reported a dose-related response between nasal use and cancer of the oral cavity (controlling for tobacco smoking).<sup>15</sup> Government agencies have concluded that SLT can cause cancer, increase risks for cardiovascular diseases, and compound chronic disease such as diabetes.<sup>24</sup> Because it contains nicotine, SLT is also highly addictive.<sup>24</sup> Addiction offers an explanation as to why tobacco users may continue to use despite known adverse health effects. Although some reports have inconclusive findings related to the connection between SLT and cancer, the literature still provides significant research linking increased SLT use and cancer.

### **Smokeless Tobacco Use & Health**

AI have the highest rates of SLT use of any major racial/ethnic group in the US.<sup>12</sup> In 1991, the Centers for Disease Control (CDC) completed the National Health Interview Survey (NHIS), indicating 5.4 % of AI/AN adults (8.1% of men and 2.5% of women) were current SLT users in comparison to 2.9 % for the overall US population (5.6% of men and 0.6% of women).<sup>25</sup> Data from the National Survey on Drug Use and Health (NSDUH) produced similar results.<sup>26</sup> In 2013, an estimated 66.8 million Americans aged 12 or older were current (use in the past month) users of tobacco products; 8.8 million (3.4%) using SLT specifically. Current rates of SLT use were highest for AI/AN (5.3%), followed by White (4.3%), Native Hawaiians (3.9%), and persons reporting two or more races (3.1%). Rates of past month use of SLT in 2013 were similar to survey rates in 2002 despite a decrease in cigarette use (26.0% to 21.3%).<sup>26</sup> SLT use in the AI population is elevated in comparison to other populations and has not shown improvement despite smoking cessation efforts. A lack of decreased cessation rates yields a greater concern for SLT-related health consequences specific to AI.

SLT-related diseases including cancer, cardiovascular disease, and diabetes are considerably higher in the AI population. In the Northern Plains, AI have a higher incidence of oral cavity and pharynx cancer than non-Hispanic Whites (NHW) (0.8 vs 0.2); a higher incidence of tonsil cancer compared with NHW is found in the Southern Plains (2.0 vs 1.7).<sup>27</sup> Frequency of cardiovascular disease is also disproportionately high among AI people compared with non-Natives.<sup>28</sup> The heart disease death rate is 20% greater, and the stroke death rate 14% greater among AI/AN than all other U.S. races.<sup>29</sup> Furthermore, the prevalence and mortality as a result of diabetes is 1.6 times higher than the general population and increasing regionally.<sup>30</sup> The AI population is a target for intervention and cessation due to the elevated rates of SLT use in conjunction with high cancer, cardiovascular disease, and diabetes rates.

### **Contributing Factors to High Rates of Smokeless Tobacco Use**

As previously discussed, cultural and historical ties may impact current rates of AI SLT use.<sup>5</sup> Although historical ties run deep, modern issues are adding to the tobacco culture in AI communities. Both tobacco sales and marketing, as well as the lack of a successful cessation program contributes to significant SLT use.

One factor contributing to high rates of SLT use is tobacco industry marketing. Though SLT occupies a smaller market compared to cigarettes, it may be experiencing growth in sales and promotion through easily accessible and colorful advertising.<sup>31-32</sup> In 2012, the five major U.S. SLT manufacturers spent more than \$430 million on SLT advertising and promotion alone.<sup>33</sup> To build image and credibility, the industry targets AI by funding cultural events and using cultural designs. Tobacco companies use AI images and cultural symbols in their advertising, such as feathers, warriors, and other cultural images that are eye-catching and appeal to ethnic pride.<sup>31,34</sup> Additionally, tobacco sales are an important economic venture for some

tribes. The sale of online tobacco products generates millions of dollars, a sizeable source of income for some tribes and AI entrepreneurs.<sup>31</sup>

Few programs have been designed to specifically address AI SLT cessation. One program called “Enough Snuff: A guide to quitting SLT for AI” claims to be culturally tailored to AI through appropriate language and artwork. Using a manual, a targeted videotape, and phone support, Enough Snuff has shown positive results in quit rate success among study participants.<sup>35-36</sup> However, neither long-term effectiveness data specifically relating to the AI community nor information regarding the level of cultural appropriateness are available. The lack of an effective culturally tailored cessation program in combination with deep cultural ties, targeted marketing attempts, and financial influence further supports the need to develop one such program.

### **Conceptual Framework**

The theoretical foundation of this research draws from multiple research perspectives and theories. ANSOS was developed using principles of CBPR including: (a) tailoring to meet the needs of individuals and communities; (b) involving participants in program development, implementation, and evaluation; and (c) using ecological frameworks to attend to multiple levels of analysis.

The U.S. government uses the AI designation to describe a heterogeneous group of people. Because of this heterogeneity, tailoring interventions to the community or “culture” often is difficult. Heterogeneity can be addressed by incorporating ideas and practices from many AI cultures. To design the multilevel analysis needed to culturally tailor an intervention to the AI community and to understand the many factors affecting tobacco use among AI, CMA was used as an overarching organizing perspective. CBPR was used to tailor the needs of a cessation

program to community members, while also involving individuals in all phases of the research. The following review of literature will summarize how the theoretical foundations of CMA are appropriate to use with a CBPR approach to study the development of a culturally tailored intervention program.

### **Community-Based Participatory Research (CBPR)**

CBPR is a collaborative approach to research in which all partners equally contribute expertise and share decision making and ownership.<sup>8-9,37-39</sup> Deviating from the predominant research approaches, CBPR involves the affected community in all stages of the research process.<sup>8-9</sup> Community members and researchers collaborate to develop research questions and methods, collect data, analyze data, write publications, and disseminate results.<sup>8</sup> With a CBPR orientation, the creation of evidence can shift from an intervention delivered to a community (best practices) to an intervention developed by the community (best processes), with attention to the ecological environment influencing the outcome.<sup>40</sup>

Although it is referred to as a research method, CBPR is not a strict methodology, but an orientation to research that guides decision making and allows for the use of qualitative and quantitative methods.<sup>8-9</sup> As Cargo and Mercer (2008) suggested, a key strength of participatory research is the integration of researchers' expertise with nonacademic participants' practical knowledge and experiences into a mutually supporting partnership.<sup>41</sup> The CBPR approach pursues a close relationship with participants while incorporating research methodologies as tools and emphasizing the importance of the process in which the research is conducted with the community.<sup>39</sup>

Researchers have been improving the quality and validity of research by embracing the local knowledge and theory of the people involved.<sup>37</sup> Types of research appropriate for CBPR

include descriptive research to understand determinants of health, research to understand disparities, community assessments, and research to design and improve existing community policy.<sup>42</sup> For example, CBPR has been identified as a promising strategy for research aimed at studying and reducing health disparities among marginalized communities.<sup>8,43</sup> Research designs suitable to CBPR are similar to other traditional research designs, except the design must be acceptable to the community partners and the focus of the research must benefit the community.<sup>38</sup> For the purpose of this study design, researchers and community members collaborated to develop a cessation program with the hope of reducing health disparities among the AI community.

**Principles of Community-Based Participatory Research.** CBPR embraces key principles that inform iterative processes, incorporating research, reflection, and action in a cyclical process.<sup>37</sup> The basis of CBPR principles is the focus on relationships between individuals within communities and groups, relations between those groups and communities, and relations between people and their physical environment. No one set of principles is applicable to all partnerships; rather, the members of each partnership need to mutually decide on the values and principles that reflect their collective vision.<sup>8</sup> How well a project successfully implements the key principles is a primary criterion in measuring the effectiveness of the research project.<sup>39</sup>

According to Israel et al. (2013) CBPR has nine guiding principles<sup>9</sup>:

- Recognize the community as a unit of identity;
- Build on the strengths and resources within the community;
- Facilitate collaboration in all phases of the partnership;
- Involve an empowering process to social inequalities;

- Promote colearning among all partners;
- Integrate knowledge and action for the mutual benefit of partners;
- Emphasize an ecological perspective;
- Involve a cyclical and iterative process; and
- Disseminate findings and knowledge gained to all partners.

The concept of community as a part of individual and collective identity is essential to CBPR.<sup>8</sup> The first principle of CBPR *recognizes community as a unit of identity.*<sup>9,39</sup> According to Israel (2013), community as a unit of identity is defined by a sense of identification with and emotional connection to others through common symbol systems, values, and norms; shared interests; and commitments to meeting mutual needs”.<sup>9</sup> A CBPR partnership will attempt to identify and work with existing communities to improve public health.<sup>9,37–38</sup> In this case, the research team recognized and valued the AI community assisting with this study. Both the research team and community members involved in the research process were committed to creating a cessation program that is culturally tailored to the specific needs of the AI community.

CBPR also *builds on strengths and resources within the community.*<sup>9,39</sup> CBPR recognizes and builds on the strengths, resources, and relationships that exist within the communities to address their mutual health concerns.<sup>9,37</sup> These may include individual skills, trust, mutual commitment, and other organizations where community members join together.<sup>37</sup> The commitment, participation, and input from AI community members have and will continue to provide invaluable resources to this study.

The third principle of CBPR *facilitates a collaborative partnership in all phases of research.*<sup>9,39</sup> To the extent possible, all partners are empowered through shared decision making and control over all stages of the research process.<sup>37</sup> Inequalities exist between researchers and

community partners; therefore, an attempt should be made to address these inequalities by developing relationships based on trust and mutual respect.<sup>9,37-38</sup> The research team may also benefit from resources available outside of the immediate community of identity, such as government agencies, academia, and community-based organizations. The CBPR collaborative partnership creates processes that enable all of these parties to equally participate in the research.<sup>37</sup> Community participation and feedback was a vital part of each phase of the research plan for this study.

*CBPR promotes co-learning and capacity building among all partners.*<sup>9,39</sup> CBPR is a co-learning process that facilitates the mutual exchange of knowledge, skills, capacity, and power among all parties involved.<sup>9,37</sup> CBPR recognizes that all partners bring diverse skillsets and expertise and different perspectives to the partnership process.<sup>9,37-38</sup> This process encourages knowledge and information sharing among all members of the research team, including community members, throughout the entire research process.

The fifth principle of CBPR *integrates and achieves a balance between research and action for the mutual benefit of all partners.*<sup>9,39</sup> CBPR seeks to build a body of knowledge about health and well-being while also translating research findings into practice that will benefit the community.<sup>9,37</sup> Not all CBPR partnerships may include an intervention component, but they commit to the translation of research findings into strategies that address community concerns. In the case of ANSOS, research was conducted to further the understanding of the knowledge, attitudes and beliefs of SLT use, while simultaneously addressing the growing health concerns related to tobacco use within the AI community.

*CBPR focuses on the local relevance of public health problems and on ecological perspectives that recognize and attend to the multiple determinants of health.*<sup>9,39</sup> An ecological

approach involves individuals, the immediate context in which they live (e.g., family), and the broader context in which they are embedded (e.g., community, society). Accordingly, this ecological approach considers the multiple determinants of health and disease, for example, biomedical, social, economic, cultural, and physical environmental factors.<sup>9</sup> Development of the ANSOS program sought to understand what contributes to SLT use while considering the social, economic, environmental, and cultural impact on both an individual and community level.

The next principle of CBPR *involves systems development using a cyclical process that includes conducting research and applying its findings to improve community life.*<sup>9,39</sup> The iterative process encompasses all the stages of the research process, including community assessment, problem definition, research design, program implementation, data collection, and analysis, and dissemination.<sup>9</sup> This process generated success, built trust, and developed strategies for sustainability during ANSOS program development.

*CBPR disseminates all findings to partners and involves them in the distribution of results.*<sup>9,39</sup> CBPR emphasizes the dissemination of research findings in language that is understandable, respectful, and useful to all community partners.<sup>9,37-38</sup> The dissemination principle also suggests that researchers consult with participants prior to the publication of materials and acknowledge the contribution of participants.<sup>37</sup> Furthermore, all partners can take part in the broader dissemination of results as coauthors of publications and co-presenters at conferences.<sup>9,37</sup> One of the purposes of the current study was to develop a successful cessation program and appropriately disseminate the study results.

The ninth and final principle of CBPR *involves a long-term process and commitment to sustainability.*<sup>9,39</sup> A long-term commitment often extends beyond a single research project. Even if partners reach a point of discontinuation, they maintain a commitment to the relationships they

have built.<sup>9</sup> Long-term implementation and operation (i.e., project sustainability) is an indicator of how effectively a CBPR approach is applied to a partnership.<sup>39</sup> The AIHREA research team is highly committed to reducing health disparities in the AI community. Prior to the start of this study, team members understood that the research process is a long-term commitment in order to ensure the sustainability of this program.

**Community-Based Participatory Research in the AI Community.** Establishing trust with the AI community is crucial to the success of any intervention program. Too often research has scrutinized, stereotyped, and exploited AI communities, creating uneasy feelings toward researchers and academic institutions.<sup>44</sup> Furthermore, feelings of being exploited for research can exist within a community, further impeding the research process (e.g., recruitment). Poor examples of research in the AI community include the Barrow Alcohol Study<sup>45</sup> and the Havasupai Diabetes Study<sup>44,46</sup>. Both studies failed to follow appropriate research protocols and lacked open communication between researchers and community members. Individuals were labeled with problematic characteristics which resulted in communities feeling stigmatized. The shortcomings of these research studies did not meet appropriate standards envisioned by the study participants. These examples reiterate the importance of the CBPR process in helping communities overcome hesitation to participate in a study, building trust with researchers, and encouraging an appreciation of the research process. CBPR methods have been more effective in AI communities than other intervention methods, in part because developing culturally appropriate programs is nearly impossible without full participation and trust of AI community members.<sup>44</sup> The CBPR approach allows tribal governments, community advisory boards (CABs), and individual's interests to drive the research design. Community involvement and direction is crucial from concept development to analysis and dissemination, increasing the

likelihood of participation and sustainability.<sup>8</sup> Given the existing health disparities within the AI population, the partnership between researchers and community members during the research process is crucial. By using a CBPR approach, community member–researcher partnerships were able to take an approach to the research process that would yield culturally relevant interventions. The research that was conducted for this study aimed to follow each of the nine principles of CBPR. AI were recognized as an existing community that could benefit from a health intervention. Local CABs had previously expressed the want and need for an SLT cessation program. A pre-existing positive relationship was present between the research team and community members. Throughout each stage of the research process, efforts were made to facilitate equal learning among all members of the research team. The research team gained input and feedback from the community to build upon strengths and resources, therefore addressing a mutual health concern.

### **Critical Medical Anthropology (CMA)**

CMA is a theoretical perspective within medical anthropology that blends a critical theoretical framework and ground-level ethnographic approaches to focus on medicine and medical practices. The CMA approach stresses the importance of the philosophical, cultural, and moral systems that are embedded in health practices.<sup>47</sup> Additionally, CMA focuses on the political economy of health. When applied to studying health and health care, the political economy of health can help researchers better understand the political, economic, and socio-historical influences that shape current health problems and the approaches to these problems.<sup>48</sup> Therefore, when undertaking research related to health and illness, a CMA approach is more likely to focus on the social aspects of health (i.e., how wealth, power, and socioeconomic status affect the distribution of disease), rather than quantitative data.<sup>47,49</sup> In order to answer these

questions, anthropologists recognize that exploration utilizing a CMA approach should distinguish four major levels of analysis: (a) the macro-social level, (b) the intermediate social level, (c) the micro-social level, and (d) the individual level.<sup>49</sup>

CMA research in the 1990s brought about new themes related to tobacco research, calling for the cohesive study of the political-economic frameworks and the cultural meaning of tobacco. Anthropologists began considering connections between the tobacco industry, financial and trade institutions, and the spread of commercial cigarettes.<sup>50</sup> Tobacco began to be tied to political and economic globalization and Westernization.

The application of CMA to studies of SLT use and cessation among the AI population is largely appropriate due to the context of social inequality, which includes the history of suppression and attempted assimilation of AI. Furthermore, AI populations are among the most economically disadvantaged in the US and are disproportionately affected by tobacco-related diseases.<sup>7</sup> Utilizing CMA is important in these cases because it explores the nature of how individuals in disadvantaged positions make choices in their lifestyles pertaining to their health. To accomplish this goal, anthropologists often employ a continuum of analysis beginning with the micro-level interactions and extending to the macro-level world-system.

For example, when addressing program development for tobacco cessation, CMA allows one to view nicotine addiction at the micro-social level as a disease with implications specific to AI individuals, at the intermediate level in relation to provider interactions and policies, and at the macro-social level as a disease that affects AI disproportionately due to their disadvantaged political-economic situation.<sup>7</sup> All of which come together to study individual behavior (i.e. SLT cessation) that is influenced by all four levels. The information in Figure 1 illustrates the levels of analysis in program development.

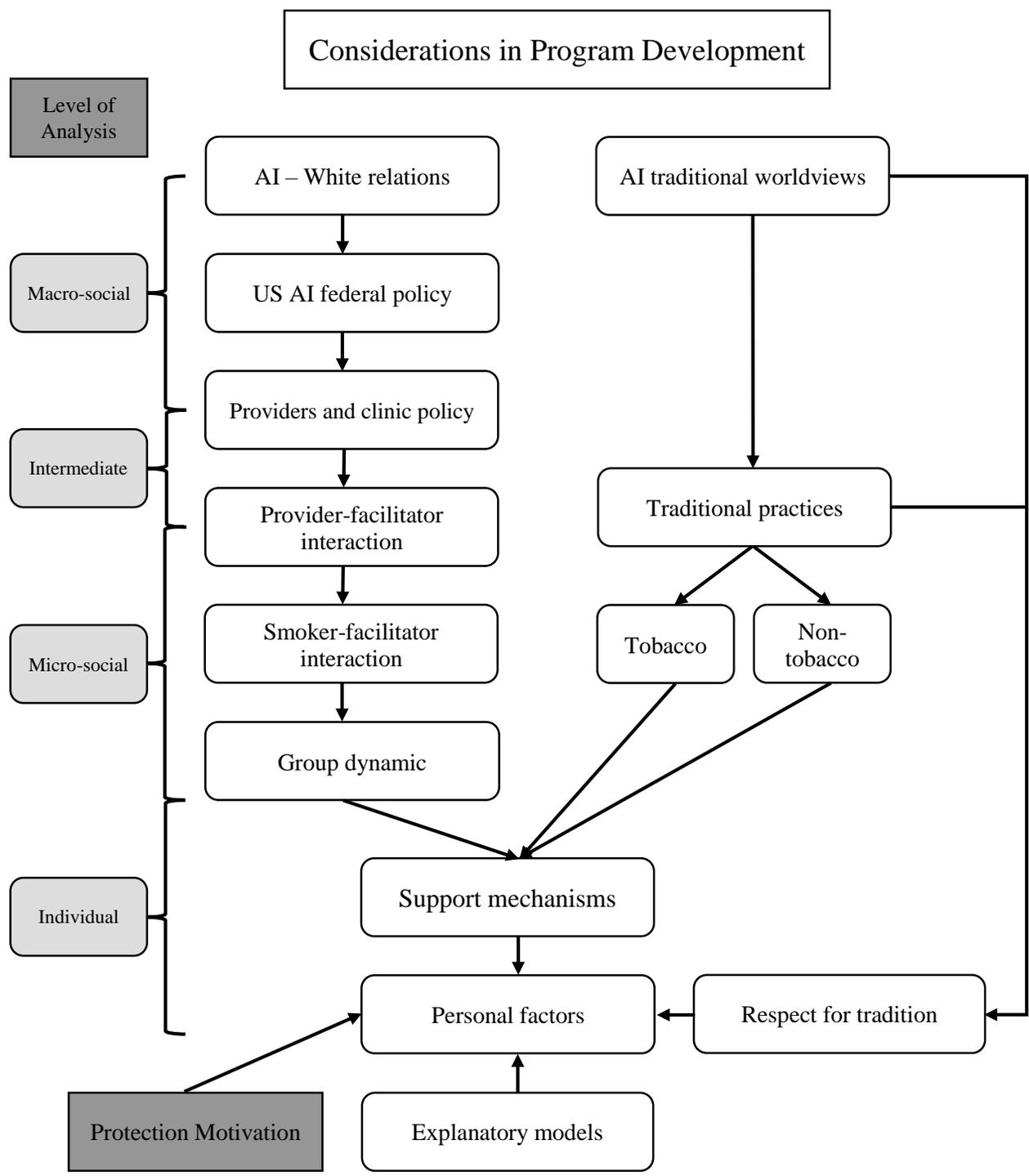


Figure 1: An Application of the Protection Motivation Theory. Note. Adapted from Daley (2014)

## The Protection Motivation Theory

The Protection Motivation Theory (PMT) was originally developed to explain the persuasive impact of fear appeals (strategy for motivating individuals to take action) on attitudes and behavior.<sup>51</sup> A revision to the theory placed an emphasis on the cognitive processes that mediate behavior change.<sup>52</sup> The central question of PMT is whether fear appeals in themselves can influence attitudes and behaviors, or whether their effects are indirect.<sup>51</sup> To ensure that health promotion messages are communicated effectively, many researchers have successfully applied PMT to focus on the prediction of health behavior changes.<sup>48</sup>

Protection motivation refers to the motivation to protect oneself against a perceived health threat and is defined operationally as the intention to adopt the recommended action. The PMT proposes that the intention to protect oneself depends upon four factors<sup>53</sup>: (a) the perceived *severity* of a threatened event (in this example, jaw cancer); (b) the perceived probability of the occurrence, or *vulnerability* (in this example, the perceived vulnerability of the individual to oral cancer); (c) the perceived *response efficacy* or the belief that the recommended action is effective in reducing the threat (in this example, an SLT cessation program to quit SLT and reduce the risk of jaw cancer ); and (d) the perceived *self-efficacy* or the belief in one's ability to successfully perform the recommended action (in this example, the ability to successfully complete an SLT cessation program and quit SLT use). Therefore, a person will have greater motivation to adopt the recommended action if he/she believes that the threat is likely assuming that the current behavior is continued, that the consequences will be serious if the threat occurs, that the recommended behavior is effective in reducing the likelihood or the severity of the threat, and that he/she is able to carry out the recommended behavior.

Similar to CMA, the Protection Motivation Theory (PMT) includes measures to further guide research at the intermediate, micro-social, and individual levels. At the intermediate level, health care providers each have their own policy regarding SLT cessation. The micro-social level includes interactions between SLT users and group facilitators, as well as group dynamics within each cessation group. At the individual level, several factors influence each SLT user, such as support mechanisms, be they the cessation group itself, traditional practices that help or hinder cessation, or respect for tradition, which are all ways an individual understands a health outcome and its treatment, outcomes, and social influences.<sup>7</sup>

### **Summary**

The review of the literature established a greater understanding of the significance of tobacco to AI individuals from different cultures. Traditional uses along with the addictive properties of tobacco have gravely impacted AI health. Existing literature has clearly identified the significant health disparities related to SLT use among the AI population. However, current literature has not identified a scientifically tested culturally tailored SLT cessation program for AI that addresses these health concerns. Following the recommendations of CBPR, the research team worked with community members to gather formative data related to AI and SLT cessation. CMA and PMT guided program development to ensure successful program outcomes. This research aimed to work with the AI community to develop an effective SLT cessation program.

## **Chapter III**

### **Methods**

Chapter III describes the methodology that was used to complete this study. The chapter is arranged in the following manner: An overview of the particular methodology used is presented first. Next, this chapter will discuss Phases 1 of the research plan. Specifically, Phase 1 addressed program development through formative research gathered from focus groups and interviews. Chapter III concludes with a description of the research design that took place during Phase 2 of the research plan. Phase 2 evaluated the appropriateness of program curriculum through a multifaceted design.

### **Purpose**

The purpose of this study was to collect information through formative research to be used in the development of a culturally tailored SLT cessation program for AI. A secondary purpose was to assess program curriculum for scientific accuracy, readability and cultural appropriateness.

### **Human Subjects**

Due to a sensitive history between the AI population and research groups, human subjects' protections were held to the upmost standards. Tribal permission from the Prairie Band Potawatomi Nation and Kickapoo Tribe in Kansas communities was obtained. An application to the University of Kansas' Medical Center Human Subjects Committee (HSC) was submitted for the ANSOS study (Study #00001122) [Appendix A]. All program documents were individually submitted to and approved by the HSC prior to use. Team members (community and academic) completed human subjects training at the University of Kansas Medical Center as well.

## Research Design

This study was mixed methods in nature (e.g. included both qualitative and quantitative aspects) and acted as a formative evaluation. The qualitative design was chosen to explore the knowledge, attitudes, and beliefs about SLT and development of a cessation program from an AI community perspective. Insight from the AI community is crucial during program development, increasing the likelihood of participation, sustainability, and the dissemination of results. Community feedback was gathered using the principles of CBPR and methods developed by the research team, which provided the conceptual framework for this study. CBPR methods have been more effective in AI communities than other intervention methods, in part because developing culturally-appropriate programs is nearly impossible without full participation and trust of AI community members.<sup>44</sup> Both qualitative research methods and the guidelines of CBPR were appropriate tools for this application. Additionally, a quantitative design was selected to ensure an unbiased representation of readability. Readability formulas are objective, quantitative tools for estimating the difficulty of written material without requiring testing to the reader. Texts involving a wide range of content and styles are assessed through readability formulas.

The review of literature for this study offered an understanding of the significance of tobacco within AI cultures<sup>4-6,16</sup>, as well as the substantial health disparities related to SLT use in this population<sup>25-30</sup>, yet revealed a scarcity of information regarding cessation programs to address these concerns<sup>35-36</sup>. Few programs have been designed to specifically address AI SLT cessation. As a result, this study was designed to obtain the information needed to develop a culturally tailored cessation program.

A three phase research plan was created to guide the research team through program development, implementation, and assessment. For the purpose of this study, a portion of Phases 1 and 2 are discussed. Phases 1 and 2 needed to be completed first, in order to develop necessary materials for use during the pilot program occurring during Phase 3. Phase 1 addressed program development through formative research gathered from focus groups and interviews. The research questions addressed during this phase evaluated what knowledge, attitudes, and beliefs AI have about SLT and SLT use, and what AI want to experience in a culturally tailored SLT cessation program. Addressing these questions aided the research team in identifying factors that enhance dissemination and contribute to program success or failure. The research design of Phase 2 focused on the assessment of program curriculum developed for the ANSOS cessation program. More specifically, the research question addressed during this phase evaluated the role of scientific reviews, readability assessments, and community reviews in the development of a culturally tailored SLT cessation program. Addressing this question also assisted in identifying factors that enhance dissemination and contribute to program success or failure.

The work presented in this study addressed only a portion of the ANSOS program components created during program development. Additional program components (i.e. baseline survey, weekly surveys, phone scripts, facilitator guide, etc.) were completed by other research team members, and therefore are not addressed in this study. During Phase 1, the author performed the following duties: acted as a tertiary coder, as well as the etic reviewer during the data analysis of the Montana focus groups/interviews, carried out the role of the etic reviewer during the analysis of the Kansas focus groups/interviews, and facilitated communications between research team members to address final theme development during the comparative study. During Phase 2, the focus was on the readability assessments of the program curriculum,

making corrections to lower the reading grade level (RGL), and reassessing each section after changes were made. Additionally, during Phase 2, contributions to the finalization of themes for the cultural review were made. It was also necessary to keep records of each research process in detail and assist other team members as needed. Table 3 identifies the authors' specific role during each phase of program development.

Table 3

*Specific Roles during Program Development of ANSOS*

Research Study Component	Specific role
Phase 1: Montana Focus Groups/Interviews	Tertiary coder, Etic reviewer
Phase 1: Kansas Focus Groups/Interviews	Etic reviewer
Phase 1: Comparative Study	Theme development
Phase 2: Readability Assessment	Readability assessment & Curriculum improvements
Phase 2: Cultural Review	Theme development
Phases 1 & 2	Recorder, Participated in weekly research team meetings, Assisted team members on other program components (i.e. weekly survey, facilitator guide)

### **Phase 1**

The specific aim of Phase 1 of the research plan was to develop a culturally tailored SLT cessation program for AI using CBPR. This study compared the findings from two independent sets of focus groups. The first set of focus groups were conducted in Montana in 2013 (10 focus groups) and the other in Kansas in 2015 (6 focus groups). Although focus groups were the planned method of data collection, some participants were unable to attend the scheduled focus group meetings, therefore individual interviews were conducted as well (2 interviews in each location). This study is the first to compare and contrast opinions regarding SLT and SLT cessation among AI living in two different regions of the country. The findings from this comparative study illustrated important themes that guided program development during Phase 1

of the research plan. The analysis performed during Phase 1 helped identify factors that may enhance the implementation of a culturally tailored SLT cessation program and contribute to program success or failure. Furthermore, findings were used to finalize the program timeline and curriculum for the pilot study. Table 4 lists the inclusion criteria for the two independent studies.

Table 4

*Inclusion Criteria for the Two Independent SLT Studies*

Montana 2013	Kansas 2015
<ul style="list-style-type: none"> <li>• Self-identify as AI</li> <li>• At least 18 years or older</li> <li>• SKC Student</li> <li>• Current or former users of smokeless tobacco or never used smokeless tobacco</li> <li>• Able to give informed consent</li> <li>• Willing to participate in the study</li> </ul>	<ul style="list-style-type: none"> <li>• Self-identify as AI</li> <li>• At least 18 years or older</li> <li>• Current SLT user or former user who has quit SLT use within the last five years</li> <li>• Able to give informed consent</li> <li>• Willing to participate in the study</li> </ul>

Focus groups and interviews were analyzed during Phase 1 to explore the knowledge, attitudes, and beliefs about SLT and cessation programming from a community perspective. Two sets of focus groups and interviews were used for analysis (labeled as Montana and Kansas). The data collection for the Montana study occurred first, as part of the Tobacco Use among American Indian/Alaska Native Tribal College Students project. The goal of the Tobacco Use among Tribal College Students project was to understand SLT use and beliefs about SLT use on a college campus, leading to the development of policies and cessation programs to address SLT use. Data collection for the Kansas study occurred later, as part of ANSOS program development. ANSOS seeks to stop recreational use of commercial SLT among AI while allowing those who practice traditional use of tobacco to continue its use through prayer, ceremony, and in other traditional ways. This comparative focus group study sought to explore any differences between the knowledge, attitudes, and beliefs of participants.

The purpose behind the use of focus groups and interviews was to gather formative information that would assist in the development of a culturally tailored SLT cessation program. Formative research consists of gathering data needed for the development of intervention programs.<sup>54</sup> It is the process by which researchers identify and evaluate characteristics of the community that are relevant to the health issue of interest.<sup>55</sup> According to Gittelsohn et al. (2006), the formative process is conducted before an intervention to obtain detailed information about the community for whom the intervention will be designed.<sup>54</sup> Formative research allows researchers to better understand the target population and their wants and needs. It allows researchers to make decisions with a community-focused mindset and refines program ideas to ensure success of the intervention.<sup>56</sup>

Formative research methods range from direct observations to in-depth interviews and focus groups. Formative research studies often employ multiple complementary methods, adding to the intervention planning process.<sup>54</sup> The researchers conducting this study set out to gather formative data through the use of focus groups. The purpose of conducting a focus group is to listen and gather information about a particular topic from people who share common interest in that topic, ideally leading to consensus on that topic.<sup>57</sup> Researchers also included in-depth interviews during Phase 1 of the research plan. The purpose of interviewing an individual is to obtain general or detailed information relevant to specific issues.<sup>58</sup> Thus, the interview process was relevant to this research.

As a self-contained method, focus groups explore new research areas. When used in combination with other methods, they provide an opportunity to further preliminary research and clarify findings. The individual interviews provided depth and detail on topics that were only broadly discussed in focus groups. Focus groups and individual interviews are complementary

techniques across a variety of research designs.<sup>59</sup> The combination of research methods may strengthen the overall research project, regardless of which method is the primary means of data collection. For the purpose of this study, the information from the individual interviews and focus groups were analyzed together.

**Focus Groups and Interviews: Montana.** Focus groups and interviews were conducted in 2013 as part of the Tobacco Use among American Indian/Alaska Native Tribal College Students project. Although sessions occurred before the ANSOS project, information gathered was relevant to the development of a culturally tailored SLT cessation program. This data specifically explored the knowledge, attitudes, and beliefs about SLT and the creation of a cessation program.

**Sample & Recruitment.** The participants in the first set of focus groups were individuals living in Montana who self-identified as AI. Participants met all of the inclusion criteria listed in Table 4. Focus group recruitment was led by individuals on the AIHREA research team. Researchers identified potential human subjects protections issues and ensured that all recruitment methods and materials were approved by the appropriate review boards. An on-site staff member conducted pre-recruitment through word-of-mouth across campus. Further recruitment efforts occurred on campus through flyers and word-of-mouth by the research team. In addition, a \$25 gift card to a local store, i.e. Target, was offered as an incentive to participate. A total of 56 participants were recruited and participated in the study. Thirty-one of the participants were male and 25 female. Participants were further stratified based on their SLT use, either Never User or Current/Former User. Demographic information is further explained in Table 5.

Table 5

*Montana Demographics (N=56)*

Characteristics	n	%
<i>Gender</i>		
Male	31	55.4
Female	25	44.6
<i>SLT Use Status</i>		
Never	33	58.9
Current/Former	23	41.1
<i>Age</i>		
18-29	32	57.1
30+	23	41.1
No Answer	1	1.8
<i>Gender/Status/Age</i>		
Never		
Male 18-29	10	17.9
Male 30+	4	7.1
No Answer	1	1.8
Female 18-29	6	10.7
Female 30+	12	21.4
Current/Former		
Male 18-29	11	19.6
Male 30+	5	8.9
Female 18-29	5	8.9
Female 30+	2	3.6
<i>Interview Type</i>		
Focus Groups		
Never		
Male 18-29	10	17.9
Male 30+	4	7.1
No Answer	1	1.8
Female 18-29	6	10.7
Female 30+	11	19.6
Current/Former		
Male 18-29	11	19.6
Male 30+	5	8.9
Female 18-29	5	8.9
Female 30+	1	1.8
Interview		
Never		
Female 30+	1	1.8
Current/Former		
Female 30+	1	1.8

***Moderator's Guide.*** The AIHREA research team has conducted numerous studies related to AI and tobacco utilizing community involvement. Experience with these studies, as well as over ten years of tobacco research with AI provided direction in the development of this study's moderator's guide. The moderator's guide was used during the interviews and focus groups to establish direction and consistency throughout the research process.

The research team, which included trained moderators, collaborated to develop a moderator's guide to ensure that the desired information was collected [Appendix B]. A moderator's guide typically contains general information about the study, instructions for conducting the study, and a list of topics or questions that are used to stimulate discussion. This guide was designed to explicitly assess AI knowledge, attitudes, and beliefs about SLT use and gather information on what type of culturally tailored SLT cessation program would be best for the AI community. The guide was divided into two sections: a) questions for current and former SLT users and b) questions for non-SLT users. Primary questions found in the Moderator's Guide are shown in Table 6.

Table 6

*Moderator's Guide Primary Questions*


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Current or Former SLT Users
<p><i>SLT Use</i></p> <ul style="list-style-type: none"> <li>• How do you define a “smokeless tobacco user”?</li> <li>• Why did you start using SLT?</li> <li>• Do you consider yourself to be addicted to smokeless tobacco?</li> <li>• What are the benefits to using smokeless tobacco?</li> <li>• Do you want to quit using smokeless tobacco? Why or why not?</li> <li>• Do you/did you ever smoke cigarettes?</li> </ul> <p><i>Program Development</i></p> <ul style="list-style-type: none"> <li>• What kind of programs would help people quit using chewing tobacco? Why?</li> <li>• What types of incentives/aids would you want to help you quit using?</li> <li>• What knowledge, attitudes, and beliefs do AIs have about chewing tobacco?</li> <li>• What type of cessation program would help AIs quit using SLT?</li> <li>• What type of motivation would help AIs quit using?</li> </ul>
<p>Non-SLT Users</p> <hr/> <p><i>SLT Use</i></p> <ul style="list-style-type: none"> <li>• What is the first thing you think of when you think about SLT?</li> <li>• How do you define a “smokeless tobacco users”?</li> <li>• How does smokeless tobacco relate to cigarettes?</li> <li>• Why do you think people start using SLT? Why do they continue?</li> <li>• What health problems do you know of that are affected by SLT use?</li> <li>• What do you think are the benefits of using SLT?</li> <li>• Why do you think it's so hard to quit using SLT? Is it harder or easier than quitting cigarettes?</li> <li>• How many of your close friends and family members use SLT?</li> <li>• Is SLT use a problem for tribal college students? Is so, how?</li> </ul> <p><i>Recreational SLT Use</i></p> <ul style="list-style-type: none"> <li>• Do you think a lot of college students use SLT? Why or why not?</li> <li>• Should colleges have a policy about SLT use on campus?</li> </ul>

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**Data Collection.** Two semi-structured in-depth individual interviews and ten focus group were conducted by researchers throughout November 2013. Focus group and interview sessions were held on the SKC campus. Two moderators with previous experience conducting focus groups with AI conducted the interviews and focus groups. The moderators guiding the interviews and focus groups were trained by the PI to establish consistency. Prior to the start of each interview or focus group, participants were given information about the study and provided written and verbal informed consent [Appendix C].

A total of ten focus groups were conducted with a total of 54 participants. Focus groups participants were stratified based on gender and SLT use status (Never User or Current/Former User). Each focus group consisted of 3-5 participants. Participants were individually consented by the moderator prior to the start of the focus group. Focus groups lasted between 60 and 75 minutes and were led by an AI moderator. Focus group sessions were conducted in a welcoming and relaxed setting to encourage participation.<sup>57</sup> Each moderator explained the goals of the focus group and encouraged participants to have positive communication with one another.

The focus groups followed a semi-structured format with open-ended questions. Focus groups were audiotaped using digital audio recorders to keep participants adequately de-identified and transcribed verbatim by a professional transcription service, excluding any identifying information.

Two participants who wished to participate in the focus groups were unable to attend their session at the scheduled time. It was important to gather information from these individuals; therefore two individual interviews were conducted. The interviews consisted of the same open-ended questions used during the focus groups. The same moderators who conducted the focus groups also conducted the interviews. Participants were individually consented by the moderator

prior to the start of the interview. Each interview lasted between 20 and 30 minutes and was led by an AI moderator. Individual interviews were audiotaped using digital audio recorders to keep participants adequately de-identified and transcribed verbatim by a professional transcription service, excluding any identifying information.

The moderator's guide also included moderator prompts to perform member checks at the end of each focus group or interview session (e.g. "Before we finish, I'm going to ask our assistant moderator to give us a brief summary of what was said."). According to Lincoln and Guba (1985), member checks occur when the interpretations and/or conclusions from a study are tested with members of those groups from who the data were originally obtained. Member checks are a crucial technique for establishing credibility in research and validity of an account.<sup>60</sup> In this case, this process occurred informally as an opportunity to review or "play back" the information discussed in each session. Such immediate and informal checking serves as number of purposes: a) it provides the opportunity to assess what it is that the respondents intended by providing certain information, b) it gives the respondents an immediate opportunity to correct or clarify statements, and c) it gives the opportunity for participants to volunteer additional information. Overall, member checks provide an opportunity to summarize data collection, one of the first steps of data analysis.

**Data Analysis.** Data analysis occurred through a combination of methods to analyze the data, including constant comparative method data<sup>61</sup>, triangulation<sup>58</sup>, and a CBPR protocol previously developed by the research team<sup>62-64</sup>. The comparative method was used to develop themes within each major topic area. The constant comparative method requires the researcher to simultaneously code and analyze the data and reinforce theory generation through the process of theoretical sampling.<sup>61</sup> This process required that the data be grouped together on a similar

dimension and assigned a unique descriptor or code.<sup>57</sup> The codes were then placed into broader categories, drawing out themes as they emerged from the data. The research team also used triangulation to enhance the internal validity and trustworthiness of this study. Triangulation refers to the use of more than one method, data source, or investigator to enhance confidence in the research findings.<sup>58</sup> Data triangulation was used to compare data collected through different types of data collection techniques (e.g. interviews and focus groups) and data sources (e.g. transcripts, field notes, and a review of the literature). Additionally, investigator triangulation<sup>58</sup> occurred when multiple members of the research team collected and analyzed the data. Lastly, a CBPR protocol previously developed and frequently implemented by the research team was used for data analysis. The research team's validated approach followed a combination of native and team ethnography, grounded theory, and the principles of CBPR.<sup>62-63</sup> Ethnography, the study of people and culture, results in outcomes that reflect the knowledge of the cultural group studied. More specifically, in native ethnography, individuals from within a culture carry out the ethnographic study of that culture rather than an outsider conducting the research.<sup>63</sup> Team ethnography as described by Erickson & Stull (1998), involves multiple researchers working together in a collaborative and cooperative approach to research.<sup>65</sup> This approach make use of both an insider's (emic) perspective through the community's involvement and an outsider's (etic) perspective through the researchers on the team. The analysis also followed a grounded theory approach in which researchers allowed the themes and theories to grow out of the data rather than analyzing the data with a theory already in place.<sup>63</sup> All of the analysis was done using the same cooperative principles of CBPR that the entire research project followed. Analysis began with the first focus group and continued throughout the study process. The units of analysis were the transcripts and field notes of the focus groups and individual interviews.

Coding followed the combination of methods described in the paragraph above, specifically using the CBPR protocol developed by the research team.<sup>62-63</sup> Before coding began, the PI assigned team members the roles of primary coder, secondary coder, tertiary coder, emic reviewer, or etic reviewer. Each participant was a member of the research team, either a community researcher or academic researcher. The information in Table 7 outlines the qualifications and responsibilities of each role.<sup>63</sup>

To begin the coding process, the coders and PI inductively developed an initial code list from the focus group recordings and transcripts. Once the initial list was developed, the primary coder and the PI worked to create the codebook. After codebook development, the three coders re-read the transcripts to get a general overview of the data. The coders then coded the transcripts by hand, led by the primary coder, and met to ensure that they were coding in a similar manner. Similar topics were identified within the transcripts and observations. These similar units were then condensed into primary, secondary, and tertiary codes. The initial tertiary coder was unable to complete their transcript coding, therefore a new tertiary coder stepped in to complete the coding process. The codes were then organized into categories which led to the development of summary statements.

Table 7

*Roles, Qualifications & Responsibilities*

Role	Qualification	Responsibilities
Primary Coder	Formally trained in qualitative methods Member of the research team who is not a community member	Leads coding meetings Responsible for codebook upkeep Responsible for formal drafting of initial themes and subthemes Participates in all coder activities described
Secondary Coder	Formally trained in qualitative methods Member of the research team who is a community member	Responsible or identification of representative quotes Responsible or review of themes and subthemes prior to sending to reviewers Participates in all coder activities described
Tertiary Coder	Formally trained in qualitative methods Member of the research team (might or might not be a community member)	Participates in all coder activities described
Emic Reviewer	Formally trained in qualitative methods Member of the research team who is a community member	Makes final determination on representative quotes Works with etic reviewer to finalize all themes and subthemes
Etic Reviewer	Formally trained in qualitative methods Member of the research team who is not a community member	Leads overall analysis Works with etic reviewer to finalize all themes and subthemes

*Note.* Adapted from Daley, et al. (2010).

The etic reviewer examined the coded transcripts and summary statement, and compiled the summaries into thematic statements. The etic reviewer returned these thematic statements to the three coders for review. An emic reviewer also assessed the themes for cultural appropriateness, determining if statements accurately and respectfully described things from the perspective of someone within the culture. Themes were initially stratified by gender and SLT use status. After the development of summary statements and a full discussion by the entire research team, there were no significant differences found among strata. The themes were then

finalized through a team meeting consisting of the entire research team to achieve consensus on what the main themes were and how to interpret them. The research team reached consensus on five final themes. Table 8 provides an example of theme development. Consistent communication and feedback among research team members assisted in validating the five major themes that emerged from the interpretation of data and analysis.

Table 8

*Montana Theme Development*

Topic	Theme	Subtheme	Participant Statements
SLT Use	1. Participants described a user of chewing tobacco to be someone who purchases and uses chew on either an occasional or frequent basis.	<ul style="list-style-type: none"> <li>• A smokeless tobacco users was defined as someone who purchases and uses chew, often seen having it in their mouth and with a cup or bottle around.</li> <li>• A smokeless tobacco users was defined as someone who uses chew whether occasional or frequent.</li> </ul>	<ul style="list-style-type: none"> <li>• “Somebody who chews”</li> <li>• “You see them with it more than once”</li> <li>• “It’s in their mouth all the time or an empty bottle with them”</li> <li>• “Anyone who buys and uses it”</li> </ul>
SLT Use	2. Participants began or believe that individuals begin using SLT primarily due to the influence of people around them; they continue to chew due to addiction, habit, or social influence.	<ul style="list-style-type: none"> <li>• Most participations started using as minors. Reasons for starting varied among participants to include: cost, peer-pressure, discrete in comparison to smoking, stress, and to avoid unpleasant side effects of smoking (e.g. smell).</li> <li>• Participants identified peer/family influence, stress, addiction, and the effects of withdraw as barriers to quit.</li> <li>• Participant identified social pressure, stress, trying to be “cool”, and a replacement for smoking as reasons to start using.</li> <li>• Participants felt the largest barrier to quitting SLT use was addiction.</li> <li>• Barriers to quitting included the ability to chew indoors, no second hand smoke, addiction, stress relief, habit and social influence.</li> </ul>	<ul style="list-style-type: none"> <li>• “Peer pressure and curiosity”</li> <li>• “I started in junior high, it was easier to get away with”</li> <li>• “The first time I ever tasted chew I was 4. I saw my cousins taking it and I asked what it was and they put it in my mouth”</li> <li>• “I’m addicted to tobacco period”</li> <li>• “It’s her habit, she need it”</li> <li>• “One the weekends it fun to go out and just kind of goes along with it (speaking of SLT use)”</li> </ul>
SLT Use	3. Participants believe that SLT has negative impacts on physical health.	<ul style="list-style-type: none"> <li>• Participants acknowledged that SLT is harmful to the body and has a negative impact on physical health.</li> <li>• Participants identified oral cancer and disease as health impacts of SLT use.</li> </ul>	<ul style="list-style-type: none"> <li>• “You can lose your teeth or it could give you mouth cancer”</li> <li>• “Mouth sores, lose teeth and wear and tear on the jaw”</li> </ul>

SLT Use	4. Participants who never used SLT saw a complex relationship among smoking, smoke-free policies, and use of chewing tobacco.	<ul style="list-style-type: none"> <li>• Participants believed SLT was more discrete and has less physical side effects than smoking.</li> <li>• Never users thought SLT use is not as common on campus as smoking, although it's harder to identify an SLT user in comparison to a smoker.</li> <li>• Never users thought the disposal of chew in public areas (spit on sidewalks, clogged water fountains) was a problem on campus.</li> <li>• Never users thought tobacco free policies should mirror current smoking rules and encourage responsibility, professionalism and wellness.</li> </ul>	<ul style="list-style-type: none"> <li>• “Lip, mouth, gum cancer”</li> <li>• “If they're around people who don't have cigarettes, they'll go to the next best thing which is chew”</li> <li>• “On basketball trips the coach would get mad if he smelled cigarettes smoke, so I would just chew”</li> <li>• “If you ever ran into a chewer, you wouldn't really see it”</li> <li>• “I really don't know of any rules or see any signs about chew. I've never seen anything like that on this campus”</li> </ul>
Program Development	5. Participants who were current users of SLT had numerous suggestions for creating a culturally tailored program to quit using smokeless tobacco.	<ul style="list-style-type: none"> <li>• Most participants in the current/former groups felt a group-based program would be more successful.</li> <li>• Participants in the current/former groups suggested program content include “scare tactics”, health statistics, and information about SLT.</li> <li>• Having a facilitator that was a past user was more important than having an AI facilitator according to the current/former group participants.</li> <li>• Current/former group participants felt it was most important to have a flexible schedule.</li> <li>• Food related items and things related to physical activity were identified as good incentives by current/former users.</li> <li>• Current/former group participants also emphasized the importance of the inclusion traditional ceremonies and sweets that could help program participants quit.</li> </ul>	<ul style="list-style-type: none"> <li>• “I've tried a six week program and I didn't feel it was long enough”</li> <li>• “ I think peers are one of the best ways to do anything, because you always have somebody helping you out, pushing you forward to be better”</li> <li>• “Pictures of what it looks like before and after”</li> <li>• “Statics/facts, like what percentage of people develop cancer or consequence of chewing”</li> <li>• “Things to settle cravings”</li> </ul>

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**Focus Groups and Interviews: Kansas.** Focus groups and interviews were conducted during Phase 1 of ANSOS program development to gather formative information that assisted in the development of a culturally tailored SLT cessation program. These data describe the knowledge, attitudes, and beliefs about SLT and development of a cessation program from a community perspective.

**Sample & Recruitment.** The participants in this study were individuals living in Kansas who self-identified as AI. Participants met all of the inclusion criteria listed in Table 4. Focus group recruitment was led by individuals on the AIHREA research team. Researchers identified potential human subjects protections issues and ensured that all recruitment methods and materials were approved by the appropriate review boards. Recruitment strategies incorporated flyers and word-of-mouth at Native-specific events, such as pow wows. Additionally, recruitment efforts included word-of-mouth through social media sites, including Facebook and Twitter. Several participants were recruited by word-of-mouth, showing the benefit of respectful interaction within the community. A \$25 gift card to a local store, i.e. Target, was offered as an incentive to participate. A total of 29 participants were recruited and participated in the study. Twenty-six of the participants were male and three female. Participants were divided into two age categories, 18-29 years or 30 years and older. Individuals aged 18-29 years old are less likely to be addicted and less likely to want to quit; therefore, the research team believed it was important to make sure their viewpoints were gathered separately from the 30+ age group. Nineteen participants were in the 18-29 age group, with the remaining ten participants in the 30+ age group. Demographic information is presented in Table 9.

Table 9

*Kansas Demographics (N=29)*

Characteristics	n	%
<i>Gender</i>		
Male	26	89.7
Female	3	10.3
<i>Age</i>		
18-29	19	65.5
30+	10	34.5
<i>Gender &amp; Age</i>		
Male 18-29	16	55.2
Male 30+	10	34.5
Female 18-29	3	10.3
Female 30+	0	0
<i>Interview Type</i>		
Focus Groups		
Male 18-29	16	59.3
Male 30+	9	33.3
Female 18-29	2	7.4
Female 30+	0	0
Interviews		
Male 18-29	0	0
Male 30+	1	50
Female 18-29	1	50
Female 30+	0	0

***Moderator's Guide.*** A moderator's guide was developed by the research team and used during the interviews and focus groups to establish direction and consistency throughout the research process [Appendix D]. This guide was designed to explicitly assess AI knowledge, attitudes, and beliefs about SLT use and gather information on what type of culturally-tailored SLT cessation program would be best for the AI community. The primary questions found in the Moderator's Guide are shown in Table 10.

Table 10

*Moderator's Guide Primary Questions*


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Current or Former SLT Users
<p><i>SLT Use</i></p> <ul style="list-style-type: none"> <li>• How do you define a “chew tobacco user”?</li> <li>• Are you a regular user, if so, why did you start using chewing tobacco?</li> <li>• What are the benefits and drawbacks to using chewing tobacco?</li> <li>• Do you want to quit using chewing tobacco? Why or why not?</li> <li>• Are you familiar with chewing tobacco policies at home, school, work, etc.?</li> <li>• Do you use other tobacco or nicotine products?</li> </ul> <p><i>Program Development</i></p> <ul style="list-style-type: none"> <li>• What kind of programs would help people quit using chewing tobacco? Why?</li> <li>• What types of incentives/aids would you want to help you quit using?</li> <li>• What knowledge, attitudes, and beliefs do AIs have about chewing tobacco?</li> <li>• What type of cessation program would help AIs quit using SLT?</li> <li>• What type of motivation would help AIs quit using?</li> </ul>

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**Data Collection.** Two semi-structured, in-depth individual interviews and six focus groups were conducted by researchers over a 7 month period in 2014-2015. One individual interview took place on a reservation and the other in an urban location. The focus groups were held in two separate locations, one reservation and one urban, both in Kansas. Two moderators with previous experience conducted the interviews and focus groups. The moderators guiding the interviews and focus groups were trained by the PI to establish consistency. Prior to the start of each interview or focus group, participants were given information about the study and provided written and verbal informed consent [Appendix E].

A total of six focus groups were conducted with a total of 27 participants. Focus group participants were separated into groups by age: 18-29 years and 30+ years. Each focus group consisted of 3-5 participants. Participants were individually consented by the moderator prior to the start of the focus group. Focus groups lasted between 60 and 75 minutes and were led by a moderator who self-identifies as AI. Focus group sessions were conducted in a welcoming and

relaxed setting to encourage participation.<sup>57</sup> Moderators explained the goals of the focus group and encouraged participants to have positive communication with one another. Each focus group concluded with a member check to allow for an informal review of the information discussed in each group.

The focus groups followed a semi-structured format with open-ended questions. Focus groups were audiotaped using digital audio recorders to keep participants adequately de-identified and transcribed verbatim by a professional transcription service, excluding any identifying information.

Two participants who wished to participate in the focus groups were unable to attend their session at the scheduled time. It was important to gather information from these individuals; therefore two individual interviews were conducted. The interviews consisted of the same open-ended questions and member check process that occurred during the focus groups. The same moderators who conducted the focus groups also conducted the interviews. Participants were individually consented by the moderator prior to the start of the interview. Each interview lasted between 20 and 30 minutes and was led by an AI moderator. Individual interviews were audiotaped using digital audio recorders to keep participants adequately de-identified and transcribed verbatim by a professional transcription service, excluding any identifying information.

**Data Analysis.** Data analysis for the Kansas focus groups/interviews occurred through the same combination of methods<sup>58,61-64</sup> implemented during Montana focus groups/interviews. Summary statements and themes were initially stratified by age group: 18-29 years and 30+ years. The themes were then finalized through a team meeting consisting of the entire research team to achieve consensus on what the main themes were and how to interpret them. No

significant differences between the age strata were found, therefore final themes were combined. The research team reached consensus on four final themes. The information presented in Table 11 provides an example of theme development.

Table 11

*Kansas Theme Development*

Topic	Theme	Subtheme	Participant Statements
SLT Use	1. Participants described a user of chewing tobacco to be someone who uses it on a regular, chronic, or long-term basis, not someone who uses a particular quantity.		<ul style="list-style-type: none"> <li>• “Someone who chews tobacco on a consistent regular basis”</li> <li>• “Three, maybe four times a week probably”</li> <li>• “Anytime, more than once”</li> </ul>
SLT Use	2. Participants began using smokeless tobacco primarily due to the influence of people around them; they continue to chew due to addiction, habit, or social influence; despite known health effects.	<ul style="list-style-type: none"> <li>• Friends, family members, sports, and work environments were all influences.</li> <li>• Younger participants, ages 18-19 yrs, talked about starting to chew because they believed it either made them look tough or made them cool.</li> <li>• Additional barriers to quitting include the need for stress relief, oral fixation, and triggers to chewing.</li> <li>• Participants over age 30 had a dichotomous view on whether or not chewing is perceived as "cool", some believed it is seen that way, while others believed it has a negative image. Younger participants did not discuss current perceptions of people who chew.</li> <li>• Participants acknowledged that SLT is harmful to the body and have numerous negative physical health effects.</li> </ul>	<ul style="list-style-type: none"> <li>• “I started playing baseball when I was in high school, that’s when I tried it”</li> <li>• “I’d say the influence from elders”</li> <li>• “The addiction, your body needs that nicotine kick”</li> <li>• “If I stop I’ll lose all my friends”</li> <li>• “It can give you mouth cancer or ulcers”</li> </ul>
SLT Use	3. Participants saw a complex relationship among smoking, smoke-free policies, and use of chewing tobacco.	<ul style="list-style-type: none"> <li>• The ability to chew anywhere or be discrete about chewing, unlike smoking, was seen as a barrier to quitting.</li> <li>• Smoke-free or tobacco-free policies were not seen as discouraging chewing tobacco because it can be done discretely without anyone noticing.</li> </ul>	<ul style="list-style-type: none"> <li>• “There are tobacco free zones, but I sat there and chewed, no one ever said anything to me”</li> <li>• “You were allowed to have it, but you can be discreet about it”</li> </ul>

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		<ul style="list-style-type: none"> <li>• Younger participants, ages 18-19 yrs, viewed chewing as safer than smoking because it is less damaging to the lungs; this did not come up in discussions with participants' ages 30+.</li> <li>• Participants believed that, unlike smoking, chewing tobacco does not impact the health of others because there is no secondhand smoke.</li> <li>• Participants in the 18-29 yrs age group did not view smoke-free or tobacco-free policies to be effective.</li> </ul>	<ul style="list-style-type: none"> <li>• "I just try to hide it"</li> </ul>
<p>Program Development</p>	<p>4. Participants had numerous suggestions for creating a culturally tailored program to quit using smokeless tobacco.</p>	<ul style="list-style-type: none"> <li>• Younger participants', ages 18-29 yrs, preferred a group-based program; older participants, ages 30+ yrs, preferred a mix of group and individual sessions with a program.</li> <li>• Food, financial rewards, and positive recognition were seen as good incentives; younger participants also mentioned exercise videos.</li> <li>• Participants' ages 30+ yrs, recommended a program that lasts between 6 and 12 months; younger participants did not come to consensus on program length.</li> <li>• Participants' ages 18-29 yrs suggested the following topics be covered: scare tactics, statistics, healthy alternatives to chewing, and exercise techniques.</li> <li>• Having a previous user of smokeless tobacco who successfully quit was the most important characteristic for a program facilitator, even more important than the person being American Indian.</li> </ul>	<ul style="list-style-type: none"> <li>• "You've got people to support you and to help you and keep you accountable" (referencing group-based programs)</li> <li>• "Being a past user is more important than race" (on group leader)</li> </ul>

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**Comparative Study** Findings from across the 16 focus groups and 4 interviews were compared. The research team met to discuss any similarities and/or differences among the five major themes that emerged from the Montana groups and the four major themes that emerged from Kansas groups.

## **Phase 2**

The specific aim of Phase 2 of ANSOS program development was to develop and assess accompanying educational materials for scientific accuracy, readability, and cultural appropriateness. The educational materials for this portion of the study included Draft 1 of the ANSOS program curriculum. Draft 1 was developed by the research team through adaptations to the ANBL program curriculum. Members of the research team knowledgeable in SLT use modified the ANBL program curriculum to fit the anticipated needs of SLT program participants.

The scientific, readability, and cultural evaluations were a crucial step in program development. The three assessments performed during Phase 2 identified factors that may enhance the dissemination of a culturally tailored SLT cessation program and contribute to program success. Furthermore, they helped finalize the program curriculum for the pilot study.

**Scientific Review.** Evaluation by researchers competent in their field under the peer review process is the leading method used for research evaluations.<sup>66</sup> According to Gibbons & Georghiou (1987), peer review is “premised upon the assumption that a judgment about certain aspects of science, for example quality, is an expert decision capable of being made only by those who are sufficiently knowledgeable about the cognitive development of the field and its research agenda”.<sup>67</sup> Direct peer review is defined as a review by scientific peers that is confined to questions of scientific merit, whereas modified direct peer review is aimed at broadening the

range of criteria to be addressed.<sup>67</sup> Expert evaluations used to assess scientific accuracy of research programs are considered a form of modified peer review. In addition to scientific merit, the review process may concern organizational questions, socio-economic impact of the research, or potential for utilization of the results.<sup>66</sup> Typically, this system of review is expanded to include a variety of areas of expertise, with the goal in mind that the decision-making will lead to programs being evaluated by a broader range of scientific criteria.<sup>67</sup>

Langfeldt (2002) found that in order “to assess the quality of scientific research one has to be a ‘peer’ of the researcher under review (i.e. an expert in the area)”.<sup>66</sup> Expert panels are often gathered to conduct the peer review process, in which they review the current research to make commendations. The primary focus of scientific review in this formative evaluation was to identify the strengths and weaknesses of the ANSOS program curriculum and make recommendations for its improvement, leading to greater dissemination of the results.

***Data Collection.*** For the purpose of this study, program curriculum was reviewed by a panel of four experts in the fields of epidemiology, medicine, and medical anthropology, all of whom have extensive experience and publications in tobacco control. Each expert has worked with AIHREA in the past or is current a member of the AIHREA research team and agreed to assist with the review process. Profile information about the expert group is provided in Table 12.

Table 12

*Professions of Expert Panel*

Profession	Suffix	Number of Participants
Epidemiology	PhD, MPH	1
Medicine	MD, MPH	1
Medical Anthropology	PhD, SM, MA	1
Epidemiology & Medicine	MD, MPH	1
<b>Total</b>		<b>4</b>

Of the three experts, the first is a Professor at the University of Kansas Medical Center (KUMC), Executive Director of the KUMC MPH Program, and Education Core Director at CAICH. He has been working in the field of tobacco control for over 20 years and focuses on reducing health disparities in minority populations. He has been one of the PIs of the All Nations Breath of Life smoking cessation program since its inception. The second expert has widespread experience conducting public health and research activities within multiple minority groups and is a Professor and Director of the Research Division in the Department of Family Medicine at KUMC. He is a practicing family physician and is the Medical Officer for the Kansas City, KS, Wyandotte County Unified Government Health Department. He has been the study physician for all of AIHREA's tobacco focused research. The third expert is the director of CAICH and a Professor of Family Medicine, Preventive Medicine and Public Health, and Indigenous Studies at KUMC. She is a medical anthropologist with further training in public health and community-based interventions. She has been working with AI communities since 1995, focusing on tobacco since 2004. She has been one of the PIs of the All Nations Breath of Life smoking cessation program since its inception and is the PI of the ANSOS program. The fourth and final expert is an Assistant Professor of Preventive Medicine and Public Health at KUMC, as well as a consulting Medical Epidemiologist for the Kansas Department of Health and Environment. He is

a full member of the University of Kansas Cancer Center (KUCC) and CAICH. His primary research area is in cancer prevention and control, with a focus on nicotine dependence and smoking cessation.

**Data Analysis.** Members of the Expert Panel were asked to review an electronic version of Draft 1 [Appendix F] of the ANSOS program curriculum. All four members were sent an electronic copy of Draft 1 to the email address they provided. Experts examined Draft 1 and electronically returned recommendations to the PI to be evaluated by the research team.

The research team corrected any inaccuracies in the program curriculum and sent a second draft to the four experts for a final review. Each of four experts responded with any additional corrections and indicated if they believed the content was acceptable according to their area of expertise. For the purpose of this study, expert opinions are based off of knowledge in their perspective fields and experience in tobacco control. A rubric or specific criteria was not established for the scientific review portion of this formative study.

**Readability Assessment.** Literacy on a foundational level is the ability to read and write. However, the key to understanding the dynamic side of literacy is expanding this basic definition to include the ability to apply what you read and write to effectively meet basic needs.<sup>68</sup> Specifically, if ANSOS program participants are unable to understand and apply the program curriculum, the success of the program will be limited and the health of participants will remain a concern.

In 2006, the U.S. Department of Education published national data on the health literacy of adults living in the United States. The National Assessment of Adult Literacy (NAALS) was used to assess the literacy of more than 19,000 individuals in an effort to better understand how well the population is able to read, understand, and act on the types of materials they encounter

in daily living. Study results revealed that 30 million (14%) adult Americans are functioning at the below basic literacy level, 63 million (29%) at the basic level, 95 million (44%) at the intermediate level, and only 28 million (13%) are functioning at the proficient level.<sup>69</sup> The information in Table 13 provides an overview of the literacy levels as defined by the NAALS. The majority of adult Americans have a below proficient literacy level; therefore, researchers for this study made the assumption that literacy levels should be set at an appropriately low level to increase the likelihood of the average participant's comprehension.

Table 13

*NAALS Overview of Literacy Levels*

Level and definition	Key abilities associated with level	Example
<b>Below Basic</b> indicates no more than the most simple and concrete literacy skills	<ul style="list-style-type: none"> <li>• locating easily identifiable information in short texts</li> <li>• following written instructions in simple documents (e.g., charts or forms)</li> <li>• locating numbers and using them to perform simple quantitative operations (primarily addition)</li> </ul>	Signing a form
<b>Basic</b> indicates skills necessary to perform simple and everyday literacy activities	<ul style="list-style-type: none"> <li>• reading and understanding information in short texts and simple documents</li> <li>• locating easily identifiable quantitative information and using it to solve simple, one-step problems</li> </ul>	Finding a program in a TV Guide
<b>Intermediate</b> indicates skills necessary to perform moderately challenging literacy activities	<ul style="list-style-type: none"> <li>• reading, understanding, and summarizing less commonplace texts</li> <li>• locating information in complex documents and making simple inferences about the information</li> <li>• locating less familiar quantitative information and using it to solve problems</li> </ul>	Identify a specific location on a map  <b>This is the average reading level of American adults</b>
<b>Proficient</b> indicates skills necessary to perform more complex and challenging literacy activities	<ul style="list-style-type: none"> <li>• reading lengthy, complex, abstract texts as well as making complex inferences</li> <li>• integrating, synthesizing, and analyzing multiple pieces of information</li> <li>• locating more abstract quantitative information and using it to solve multi-step problems</li> </ul>	Interpreting a table and comparing two editorial viewpoints

*Note.* Adapted from Kutner & NCES (2006).

It is important to customize educational materials to the audience's level of reading skill. Readability of a given text is the measurement of the reading skills an individual should possess to understand the written text.<sup>70</sup> A readability test is a simple technique used to predict the reading grade level (RGL) of written material. Generally, documents should be written at

approximately the 6<sup>th</sup>-8<sup>th</sup> RGL.<sup>70</sup> Readability tests were performed to ensure documents are at the appropriate reading level for the intended audience. If individuals are able to understand a document they can often apply its meaning, therefore meeting the needs behind the purpose of the content.

**Data Collection.** During Phase 2 of ANSOS program development, a literacy assessment was performed on the ANSOS program curriculum. The instruments discussed in the following section includes the Fry Graph Readability Formula and the Simple Measure of Gobbledygook Readability Formula (SMOG), which evaluated Draft 1 of the ANSOS program curriculum for appropriate RGL, therefore assessing readability. The Fry and the SMOG readability formulas are two well-regarded RGL tools that can be completed by hand. While both give RGL scores, they calculate them in different ways.

The Fry Graph Readability Formula, develop by Edward Fry, is a validated readability test.<sup>71</sup> The graph shown below is the presentation of a readability formula in graphic form. The RGL (or reading difficulty level) is calculated by the average number of sentences (y-axis) and syllables (x-axis) per one hundred words. The averages are plotted into the graph, with the intersecting point determining the reading level of the content assessed. The Fry Readability formula<sup>72</sup> considers a RGL of 5 or less to be superior and between 6 and 9 to be adequate. Directions for using the readability graph are as follows<sup>71</sup>:

1. Select three 100-word passages form near the beginning, middle and end of the text.
2. Count the total number of sentences in each 100-word passage (estimating to the nearest tenth of a sentence). Average these numbers.
3. Count the total number of syllables in all three 100-word passages. Average these numbers. Example calculations are listed below in *Figure 2*.

Example	Sentences per 100 words	Syllables per 100 words
100-word sample	8.0	102
100-word sample	6.5	126
100-word sample	7.2	124
Average	<b>7.2</b>	<b>117</b>

Figure 2: Example calculation using the Fry Method

- Plot on the graph (Figure 3) the Average Sentence Length and Number of Syllables. Plot where the two lines intersect. The area in which the plot falls signifies the approximate RGL of the content.
- Plotting these averages on the graph, they fall in the 4<sup>th</sup> grade area, hence the text is about a 4<sup>th</sup> grade difficulty level.

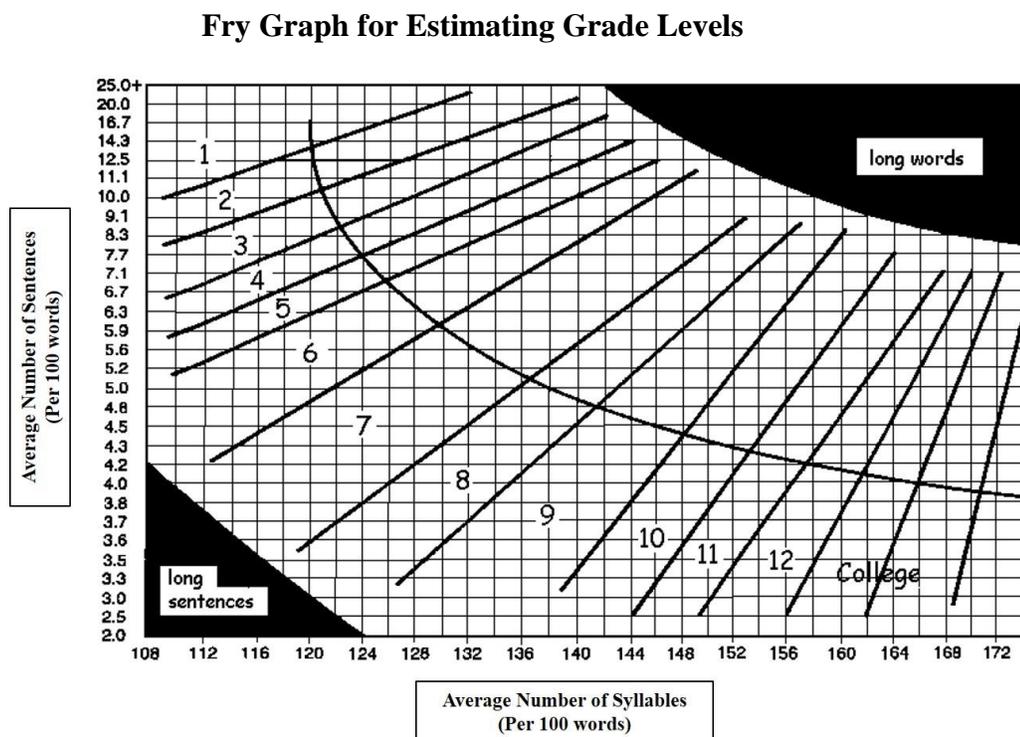


Figure 3: Fry Graph for Estimating Grade Levels. Adapted from Fry (1977).

The Fry Readability Formula is suited for assessing patient education materials and is often used in the healthcare setting. The Fry is favored by health experts, including the CDC<sup>73</sup>, because it requires an assessment of only three 100-word samples instead of the entire document, making it particularly well suited for lengthy patient education materials<sup>70</sup>. Another advantage to this tool is its simplicity in use and the fact that it can be applied manually without the need for a computer or specific software.

Similar to the Fry, the SMOG has a reputation as an accurate and simple tool and is widely used to assess patient education literature.<sup>74</sup> The SMOG formula is an index that correlates highly with other readability formulae, and has been recommended by the American Cancer Society for the evaluation of written materials. Developed by Harry McLaughlin in 1969<sup>73</sup>, the SMOG is a measure of readability that estimates the years of education needed to understand a piece of writing. This tool looks at materials using three samples of 10 sentences and the number of polysyllabic words (three or more syllables) in each.<sup>70,73-74</sup> The greater the number of polysyllabic words, the greater the RGL. In comparison to other readability formulas, the SMOG uses a strict criterion (i.e. it aims for 100% comprehension), thus the grade level scored will often be 1-2 grades higher than other assessments.<sup>70</sup> The SMOG recommends aiming for a RGL of 6 or less.<sup>75</sup> Directions for using the SMOG readability graph are as follows<sup>73,75</sup>:

1. Count 10 consecutive sentences near the beginning, middle, and end of the text to be assessed.
2. In the 30 selected sentences count every word of three or more syllables.
3. Estimate the square root of the number of polysyllabic words counted.

4. Add 3 to the approximate square root. This gives the SMOG Grade, which is the reading grade that a person must have reached if they are to understand fully the text assessed. (*or*)
  1. Count the number of polysyllabic words in three chains of 10 sentences in different parts of the text.
  2. Then look up the approximate grade level in Table 14.

Table 14

*SMOG Grade Level Chart*

Total Polysyllabic Word Counts	Approximate Grade Level
0-2	4
3-6	5
7-12	6
13-20	7
21-30	8
31-42	9
43-56	10
57-72	11
73-90	12
91-110	college-level

*Note.* Adapted from NIH (1994).

Although strengths and weaknesses exist with each readability instrument, there is no consensus as to which readability formula is best suited for assessing patient education materials. As a general rule, it is preferable to use more than one readability method to improve the validity of the results.<sup>70</sup> Using both the Fry and SMOG results in a clear picture of the text assessed because multiple factors contributing to the readability of a document are assessed: the Fry accounts for the number of sentences, their length, and the total number of syllables, and the SMOG considers the number of sentences and the number of polysyllabic words in its evaluation.

**Data Analysis.** For the purpose of this study, the Fry and SMOG readability formulas were used to assess the RGL of Draft 1 of the ANSOS program curriculum. The program curriculum consisted of nine sections. A member of the research team (primary reviewer) assessed the readability of each of the nine sections individually, using both the Fry and SMOG. A second member of the research team assessed the readability of three of the sections individually, using both the Fry and SMOG to establish investigator reliability. The program curriculum should be at an 8<sup>th</sup> RGL or below, to ensure that it is at the appropriate reading level for a participant with average reading ability. Any section with a RGL above 8<sup>th</sup> grade was modified and reassessed to see if readability had improved.

**Cultural Review.** Assessing the readability of a document alone does not guarantee its effectiveness. While readability assessments can measure the structural difficulty of the text, they do not determine if the text is culturally appropriate or relevant. If written documents are not catered to the intended audience, the material fails to engage that particular population, even if the materials are at their reading level. Individual interviews can help provide depth and detail on community-specific topics. Interviews are discussions meant to gather information on a specific set of topics. Piercy (2015) found that “respondents’ answers provide rich, in-depth information that helps us to understand the unique as well as shared circumstances in which they live, and meanings attributed to their experiences”.<sup>77</sup> For the purpose of this study, individual interviews were conducted to obtain feedback from the AI community regarding Draft 1 of the ANSOS program curriculum. Community views and ideas on the cultural appropriateness of the program

curriculum provided depth and detail to the cessation materials, leading to a more reliable program.

***Sample & Recruitment.*** The participants in this study were individuals living in Kansas who self-identified as AI. Participants met all of the following inclusion criteria: a) self-identify as AI, b) 18 years or older, c) able to give informed consent and willing to participate in the study.

Recruitment was led by individuals on the AIHREA research team. Researchers identified potential human subjects protections issues and ensured that all recruitment methods and materials were approved by the appropriate review boards. Each participant was consented before the start of the study [Appendix G]. Additionally, a short demographic survey was given to each participant [Appendix H]. Participants were recruited by word-of-mouth and flyers at a large Native-specific event. A \$10 gift card to a local store, i.e. Subway, was offered as an incentive to participate. A total of 22 participants were recruited and participated in the study.

***Interview Guide.*** The AIHREA research team has conducted numerous studies related to AIs and tobacco utilizing community involvement. Experience with these studies, as well as over ten years of tobacco research with AI provided direction in the development of this study's interview guide [Appendix I]. The interview guide established direction and consistency throughout the research process. This guide was designed to gain a better understanding of how the ANSOS program curriculum should be culturally tailored. The primary questions found in the Interview Guide are shown in

Table 15.

Table 15

*Moderator's Guide Primary Questions*


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Cultural Appropriateness
<ul style="list-style-type: none"> <li>• Do you use or have you ever used chewing tobacco?</li> <li>• What is your gut reaction when looking at this material? What comes to mind when you see this?</li> <li>• What images would you want to see in these materials?</li> <li>• What kinds of activities would you want to see in these materials?</li> <li>• Should we include graphic images, like pictures of mouth cancer? Do you like shock value? Would the community?</li> <li>• What colors do you prefer?</li> <li>• Are there any other facts regarding American Indians and chewing tobacco you would like to see?</li> <li>• Are there any other facts regarding American Indians and tobacco use, including both traditional and recreational use, you would like to see?</li> <li>• Are we missing any topics?</li> <li>• What don't you like?</li> <li>• What is offensive?</li> </ul>

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**Data Collection.** Twenty-two individual interviews were conducted at a large Native-specific event in Kansas. Prior to the start of each interview, participants were given information about the study and provided written and verbal informed consent [Appendix G]. They were provided with answers to any questions they had and all aspects of participation and informed consent were explained.

Interviews were conducted by a two trained AI members of the research team. The moderators guiding the interviews were trained by the PI to establish consistency. All participants were asked the same questions within a flexible framework. Participants were asked questions from the same loose set, with no defined ordering of the questions. Participants were encouraged to talk about their opinions and views through open-ended questions. All interviews were audiotaped using digital audio recorders to keep participants adequately de-identified and transcribed verbatim by a professional transcription service, excluding any identifying

information. Participants' opinions of the cultural appropriateness of the program curriculum were the primary source of data.

**Data Analysis.** A combination of triangulation<sup>58</sup> and CBPR<sup>62-64</sup> techniques used by the research team were used to analyze the data. The two researchers, one etic and one emic, used the transcripts and any field notes to identify summary statements. The summary statements were then presented to the research team to identify thematic statements.

### Summary

The methods for each research question are:

*Research Question One.* A comparative study of two independent focus groups/interview studies (N=85) was conducted to determine what knowledge, attitudes, and beliefs AI have about SLT and SLT use.

*Research Question Two.* A comparative study of two independent focus groups/interview studies (N=85) was conducted to determine what AI want to experience in a culturally tailored SLT cessation program.

*Sub-question a).* Feedback from individual interviews and focus groups on what type of cessation program AI want identified factors that enhance the dissemination of the developed program.

*Research Question Three.* To determine what roles a scientific review, readability assessment and a community review have in the development of a culturally tailored SLT cessation program, a scientific review from four experts, a readability assessment utilizing two readability tools (Fry and SMOG), and community interviews (N=22) were used.

## **Chapter IV**

### **Results**

#### **Purpose**

The purpose of this study was to collect information through formative research to be used in the development of a culturally tailored SLT cessation program for AI. A secondary purpose was to assess program curriculum for scientific accuracy, readability and cultural appropriateness.

#### **Phase 1**

The specific aim of Phase 1 of the research plan was to develop a culturally tailored SLT cessation program for AI using CBPR. Focus groups and interviews were used to gather formative data related to SLT and SLT use. This study compared the findings from two independent studies. One study was conducted in Montana in 2013 and the other in Kansas in 2015. Four themes, highlighting what was important to the participants, emerged from the analysis during Phase 1.

#### **Sample**

Of the two sessions of focus groups and interviews a total of eighty-five participants, a majority of whom were male, participated in focus groups and interviews. Of the 85 adults who participated, 57 were male (67%) and 28 were female (33%). Over half of the participants were in the age range of 18-29 (60%), with the remainder in the 30+ age range (39%). One participant did not list an age. Most participants had some experience with SLT use. Of the adults who participated, 52 were current or former SLT users (61%) and 33 had never used SLT (39%). Breakdown of interview type according to gender and age range was reported as the following:

44% focus group male 18-29 (n=37), 21% focus group male 30+ (n=18), 1% focus group male no age (n=1), 15% focus group female 18-29 (n=13), 14% focus group female 30+ (n=12), 1% interview male 30+ (n=1), 1% interview female 18-29 (n=1), and 2% interview female 30+ (n=2). A summary of results for the demographic data obtained during the Phase 1 comparative study is depicted in Table 16.

Table 16

*Comparative Demographics (N=85)*

Characteristics	Montana n	Montana %	Kansas n	Kansas %
<i>Gender</i>				
Male	31	55.4	26	89.7
Female	25	44.6	3	10.3
<i>Age</i>				
18-29	32	57.1	19	65.5
30+	23	41.1	10	34.5
No Answer	1	1.8		
<i>Gender &amp; Age</i>				
Male 18-29	10	17.9	16	55.2
Male 30+	4	7.1	10	34.5
No Answer	1	1.8	0	0
Female 18-29	6	10.7	3	10.3
Female 30+	12	21.4	0	0
<i>SLT Use Status</i>				
Never	33	58.9	0	0
Current/Former	23	41.1	29	100
<i>Interview Type</i>				
Focus Groups				
Male 18-29	21	37.5	16	59.3
Male 30+	9	16.1	9	33.3
No Answer	1	1.8	0	0
Female 18-29	11	19.6	2	7.4
Female 30+	12	21.4	0	0
Interview				
Male 18-29	0	0	0	0
Male 30+	0	0	1	50
Female 18-29	0	0	1	50
Female 30+	2	3.6	0	0

## Research Question One

This study was designed to develop a culturally tailored SLT cessation program for AI. Individual interviews and focus groups were used to determine what knowledge, attitudes, and beliefs AI have about SLT and SLT use. The findings from this comparative study illustrated that regardless of time or location, community members were willing to provide valuable insight to SLT and SLT use. The first, second, and third themes identified in the Phase 1 comparison, illustrated that participants had definable knowledge, attitudes, and beliefs about SLT and SLT use. The first three themes identified during the comparative study are highlighted in Table 17.

Table 17

### *Comparative Themes from Phase 1: 1-3*

Themes
1. Participants described a user of chewing tobacco to be someone who purchases and uses it on an occasional or regular basis, in no particular quantity.
2. Participants believe individuals start using SLT primarily due to the influence of people around them and continue to chew due to addiction, habit, or social influence; despite known health effects.
3. Participants saw a complex relationship among smoking, smoke-free policies, and use of chewing tobacco.
4. Participants had numerous suggestions for creating a culturally tailored program to quit using smokeless tobacco.

Participants across the groups, despite never, current, or former tobacco use, easily defined SLT and SLT use. Participants reached consensus on the fact that SLT users should include individuals who purchase and chew on any basis, whether occasional or frequent. However, the opinion of how often varied among participants. For example, one participant stated a user should be defined as “someone who uses anytime, more than once”, while another felt “a tobacco users is someone who chews tobacco on a consistent regular basis”. Additionally,

the quantity of use was not comparable among the groups, responses clearly diverted from one another and was often not numerically defined by participants.

Participants in both sessions started using or believed that individuals start using SLT primarily due to the influence of people around them and continue to chew due to addiction, habit, or social influence despite known health effects. Participants often discussed examples of outside influences impacting tobacco use. A prominent sub-theme was that many respondents reported friends, family members, sports, and work environment as influences to chewing. One participant explained that his or her use was influenced from friends on a sports team, “I started playing baseball when I was in high school, that’s when I first tried it”, while another started using due to the “influence from elders” in the community.

Several barriers to quit were also discussed among the groups, although addiction, habit, and social influence were the most common. Participants in both sessions were aware of the impact that addiction and habit have on SLT use and the ability to quit. One participant stated that SLT is “an addiction, and your body needs the nicotine kick”. Another participant, referencing an experience with a family member, believed “it just becomes habit, especially if you’ve done it most of your life”. The role that social influence has on the ability to quit was widely discussed among the groups. Participants reached consensus that individuals continue to use SLT due to social influence. An individual who has never used tobacco believed that social influence may cause current users to keep using SLT, “They’re around it with family and friends. It’s something that they might get used to doing. Part of their everyday life”. Another participant, who is a current user, stated “if I stop, I’ll lose all my friends”.

Participants were aware of the negative health effects of SLT. In both the Montana and Kansas focus group, individuals identified “varying types of cancer, oral disease, and ulcers” as

health problems associated with SLT use. However, many current users indicated that they continue to use SLT instead of cigarettes because they believe SLT has less harmful side effects. One participant stated, “you see a lot of baseball players chewing, some people see it as a safer alternative to smoking, they’d much rather have their jaw taken out than their lungs”. This showed varying knowledge of the health effects of SLT use among the study participants.

Discussions related to smoking, smoke-free policies, and the use of chewing tobacco came up in several focus group and interview discussions in both regions. To begin with, participants identified both similarities and differences between smoking and SLT use. Overall, participants in both groups noted that both forms of tobacco contain nicotine and can lead to addiction. Participants also agreed that individuals might use SLT over cigarettes due to less harmful side effects related to secondhand smoke, as well as the ability to be discrete about chewing. In reference to tobacco substitutions, one participant stated, “That’s what I do, because I’m both a smoker and a chewer. I have two crutches. When I can’t have one crutch, I’ll throw in a pinch of the other.” However, participants had varying opinions regarding the physical health effects of cigarettes vs. chew. For example, one participant in a Kansas focus group felt that “chewing is safer than smoking because it is less damaging to the lungs”, while other participants stated, “it still has the same chemicals” and “chew is just another source of nicotine”.

Participants also felt that using one form of tobacco can be a gateway to another form, or act as a replacement if the preferred form is unavailable. Several participant statements reiterated this belief. “I don’t like to smoke when I’m working cause it makes me tired, so I throw in a dip”, “I can chew instead of standing out in the cold with a cigarette”, “instead of having a cigarette hanging out of my mouth or having to hold it and try to work, I can just throw in the chew and

get to work”, “the coach would get mad if he smelled cigarette smoke on us, so I would just chew”.

Participants who were college students, particularly in the Montana focus groups and interviews, had specific knowledge of tobacco-free policies on their campus. Participants, specifically in the Kansas focus groups and interviews, had specific knowledge of the tobacco-free policies at their places of employment. Participants reached consensus that the majority of schools and business have smoke-free or tobacco-free policies, although they did not discuss the differences between the policy types. They felt that policies should include all types of tobacco use. “I think anywhere they’re going to have policies for smokers, they should include smokeless too”. Participants in both groups felt the frequency of SLT use is not a problem in most locations; they also admit they might not be able to identify users. “If you ran into a chewer, you wouldn’t really see it”. Additionally, current smoke-free or tobacco-free policies were not seen as discouraging to SLT users because it can be done discretely without anyone noticing. “When you’re in class, they don’t notice you’re chewing”. Participants who are current users stated, “there are tobacco free zones, but I sat there and chewed, no one ever said anything to me”, “you weren’t allowed to have it, but you can be discreet about it”, and “I just try to hide it”.

### **Research Question Two**

The findings from this comparative study illustrated that regardless of time or location, community members are willing to provide valuable comments and suggestions regarding development of tobacco cessation programs. Individual interviews and focus groups were used to determine what AI want to experience in a culturally tailored SLT cessation program. The fourth theme identified in the Phase 1 focus group and interview comparison, illustrated that participants had numerous suggestions for creating a culturally tailored program to quit using

SLT. The fourth and final theme identified during the comparative study is emphasized in Table 18.

Table 18

*Comparative Themes from Phase 1: 4*

Themes
1. Participants described a user of chewing tobacco to be someone who purchases and uses it on an occasional or regular basis, in no particular quantity.
2. Participants believe individuals start using SLT primarily due to the influence of people around them and continue to chew due to addiction, habit, or social influence; despite known health effects.
3. Participants saw a complex relationship among smoking, smoke-free policies, and use of chewing tobacco.
4. Participants had numerous suggestions for creating a culturally tailored program to quit using smokeless tobacco.

Program suggestions were discussed in most focus groups and interviews conducted in both regions. Participants in the Montana focus groups who had never used SLT did not provide feedback regarding a cessation program experience. Without any personal knowledge of SLT use, it would be difficult for the participants to make recommendations on what type of cessation program would be best for AI. Participants who were able to address what they wanted in a cessation program from a first-hand perspective discussed a variety of recommendations for program type, length, topics, and incentives.

Although some participants preferred a group-based program, while other preferred an individual program, most participants felt a group-based program would be more successful for the majority of individuals. “One big reason that we all started in the first place was because of group influence, it would be easier to quit as a group as well.” In addition to a group-based program, participants wanted to see additional online and phone-based resources available to

program participants. “Time might be a problem with some people. Offer a service hotline, email, or phone system”. Participants also felt that having a previous user of SLT who successfully quit was the most important characteristic for a program facilitator, even more important than the person self-identifying as AI. One participant stated, “I think it’s important that they used to smoke or chew, more than anything else. You don’t want to hear from somebody who doesn’t know the struggle”. Another thought “Someone who used to chew, because they know what you’re going through and actually have been through it, personal experience”.

When addressing program length, the research team wanted to gather feedback regarding the overall length of the program, as well as the number of meetings each week.

Recommendations for the specific length of the program and the number of meetings each week varied across participants. Participant suggestions for program length spanned from a short program occurring for 1 to 2 weeks to a program meeting every other day over a long period of time. For example, one participant said, “I’ve tried a six week program and I didn’t feel it was long enough”, while another stated, “once a week would be all that I could handle”. However, the groups recognized scheduling inflexibility as a barrier to program success. No matter the program length, the schedule should be flexible to meet each participants’ needs.

Participants offered numerous suggestions regarding program topics and incentives. The most common program topics included statistics on tobacco and health, as well as healthy alternatives to chewing. “Positive topics. Healthy things to do instead of quitting or going straight to all candy. A healthy way to deal with quitting” Participants also frequently mentioned using scare-tactic photos in the program curriculum. One participant suggested, “Topics showing facts. Pictures of cancer or sports figures with no jaw”, while others agreed that scare tactics are

important because “they are reality”. Food, financial rewards, and positive recognition for meeting milestones were seen as good incentives; participants, in the younger age groups also mentioned exercise videos. Participants offered specific suggestions such as, “if you haven’t chewed in six months, then you get something”, “gift cards to get groceries, just simple stuff you earned”, and “something to do with exercise”.

**Sub-question a).** Results from the individual interviews and focus groups on what type of cessation program AI want identified factors to enhance implementation of the developed program. Participants gave feedback on what type of cessation program should be developed. Individuals discussed recommendations for cessation program type, length, topics and incentives. This feedback was used to design the cessation program timeline and guide the development of the program curriculum.

## **Phase 2**

The specific aim of Phase 2 of the research plan was to develop and assess accompanying educational materials for scientific accuracy, readability, and cultural appropriateness. The educational materials for this portion of the study included Draft 1 of the ANSOS program curriculum. Draft 1 was first reviewed by three experts for scientific accuracy. Next, readability of the program curriculum was assessed using the Fry and SMOG readability assessments. To conclude the three part review, community members were interviewed to assess the cultural appropriateness of the curriculum.

### **Sample**

A scientific review conducted by four experts was completed on each of the nine curriculum sections. Additionally, readability assessment using two different readability

formulas was performed on all nine sections of the curriculum. Phase 2 concluded with 22 cultural review interviews. Of the 22 adults who participated in the cultural review, 11 were male (50%) and 11 were female (50%). Over half of the participants were in the age range of 30+ years (68%, n=15), with the remainder in the 18-29 years age range (32%, n=7).

### **Research Question Three**

This study was designed to develop a culturally tailored SLT cessation program for AI. A three part assessment on the program curriculum was conducted to determine what roles a scientific review, readability assessment, and cultural review have in the development of a culturally tailored SLT cessation program.

To determine if a scientific review was necessary to develop a culturally tailored SLT cessation program for AI, a scientific review from four tobacco experts was utilized to evaluate program curriculum for scientific accuracy. Each reviewer offered suggestions for improvement. The results of the scientific review are summarized in Table 19. The research team made corrections to the initial draft of the program curriculum based on the feedback from the experts. The scientific review process concluded with each of the four experts then indicating that they believed the content was acceptable according to their area of expertise.

Table 19

*Scientific Review Data*

Profession	Comments
Epidemiology	<ul style="list-style-type: none"> <li>• Corrected facts about tobacco epidemiology among AI</li> <li>• Corrected information about cessation pharmacotherapy and how it is used with SLT versus cigarette smoking</li> </ul>
Medicine	<ul style="list-style-type: none"> <li>• Corrected information about cessation pharmacotherapy and how it is used with SLT versus cigarette smoking</li> <li>• Updated black box warnings for varenicline</li> <li>• Made modifications to wording for ease of reading</li> </ul>
Medical Anthropology	<ul style="list-style-type: none"> <li>• Made suggestions for more appropriate representation of cultural facts</li> <li>• Corrected facts about tobacco use among AI</li> </ul>
Epidemiology & Medicine	<ul style="list-style-type: none"> <li>• Made modifications to wording for ease of reading</li> <li>• Updated black box warnings for varenicline</li> </ul>

The Fry and SMOG readability assessments were used to evaluate the program curriculum, to determine if a readability assessment was necessary to develop a culturally tailored SLT cessation program for AI. After the initial readability assessments were completed, the research team identified the curriculum sections that required modifications to lower the RGL. A total of four sections required modifications. The section *Chew & Native People* scored at an 11<sup>th</sup> grade RGL and had the highest score of any section. Other sections including *Stress Reduction*, *Traditional Tobacco*, and *Weight Management* scored in the appropriate RGL according to the Fry assessment, but were above the ideal range (6<sup>th</sup>-8<sup>th</sup>) using the SMOG, therefore these sections were simplified as well. No differences in RGL calculations were identified between reviewers. The results from the initial readability assessments are presented in Table 20.

Table 20

*Initial Readability Assessment Results: ANSOS Program Curriculum*

Curriculum Section	Fry Primary Reviewer	Fry Second Reviewer	SMOG Primary Reviewer	SMOG Second Reviewer
Chew & Native people	11 <sup>th</sup> grade	11 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Congratulations you have quit	4 <sup>th</sup> grade		8 <sup>th</sup> grade	
Coping with withdrawal	7 <sup>th</sup> grade		7 <sup>th</sup> grade	
Friends/family & quitting	6 <sup>th</sup> grade		8 <sup>th</sup> grade	
Preparing to quit	3 <sup>rd</sup> grade		6 <sup>th</sup> grade	
Stress reduction	7 <sup>th</sup> grade	7 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Traditional tobacco	8 <sup>th</sup> grade		9 <sup>th</sup> grade	
Weight management	7 <sup>th</sup> grade	7 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Why do people chew	8 <sup>th</sup> grade		8 <sup>th</sup> grade	

The process of reducing the RGL ensures the target reader can process and comprehend the material. According to M. Boyd (1987), suggested guidelines for lowering the reading level of patient education materials and increase the ease of reading include: a) keeping sentences short and to the point, b) avoiding complex grammatical structures, c) writing in an active (versus passive) voice, d) using the second person (you), instead of the third person (the patient or individuals), e) avoiding polysyllabic words, and f) utilizing appropriate visual characters (i.e. adequate spacing, avoid using all caps).<sup>76</sup> For example, in the case of *Chew & Native People*, polysyllabic words such as smokeless tobacco were changed to chew and long sentences were changed to short bulleted lists. A reduction in the number of polysyllabic words and an improved sentence structured lowered the RGL.

Using the above recommendations as a guide and keeping the target audience in mind, each of the four sections of the program curriculum were simplified with the goal of lowering the

RGL. The primary reviewer reassessed the readability of each of the four sections individually, using both the Fry and SMOG to see if readability had been improved. The results from the second readability assessments are summarized in Table 21.

Table 21

*Readability Assessment Results: Modified ANSOS Program Curriculum*

Curriculum Section	Fry	Fry Corrected	SMOG	SMOG Corrected
Chew & Native people	11 <sup>th</sup> grade	8 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Stress reduction	7 <sup>th</sup> grade	6 <sup>th</sup> grade	9 <sup>th</sup> grade	7 <sup>th</sup> grade
Traditional tobacco	8 <sup>th</sup> grade	8 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Weight management	7 <sup>th</sup> grade	7 <sup>th</sup> grade	9 <sup>th</sup> grade	7 <sup>th</sup> grade

The section *Chew & Native People* had the highest RGL after the initial assessment (11<sup>th</sup> grade). After modifications were made, the RGL was lowered to an 8<sup>th</sup> RGL as assessed by the Fry and a 9<sup>th</sup> RGL as assessed by the SMOG. The section on *Stress Reduction* began with a Fry score of 7<sup>th</sup> grade and a SMOG score of 9<sup>th</sup> grade. The RGL was lowered to a Fry of 6<sup>th</sup> grade and a SMOG of 7<sup>th</sup> grade. The section on *Traditional Tobacco* was modified and reassessed. No changes to the RGL were found after modifications. The *Weight Management* section had no change on the Fry assessment after modifications were made (7<sup>th</sup> grade and 7<sup>th</sup> grade, respectively). However, the SMOG score improved from an 9<sup>th</sup> RGL to a 7<sup>th</sup> RGL.

A total of four sections were modified due to a RGL above the 8<sup>th</sup> grade. Figure 4 illustrates the number of original curriculum sections at or below an 8<sup>th</sup> RGL in comparison to the number of sections at or below an 8<sup>th</sup> RGL after corrections were made. According to SMOG results, of the four sections evaluated, none was originally at the appropriate RGL. After modifications were made, 50% of the curriculum sections showed significant RGL improvements. Of the four sections that were reviewed using the Fry readability formula, three

were originally at the appropriate RGL. After improvements were made, 100% of the curriculum sections were at or below an 8<sup>th</sup> grade reading level.

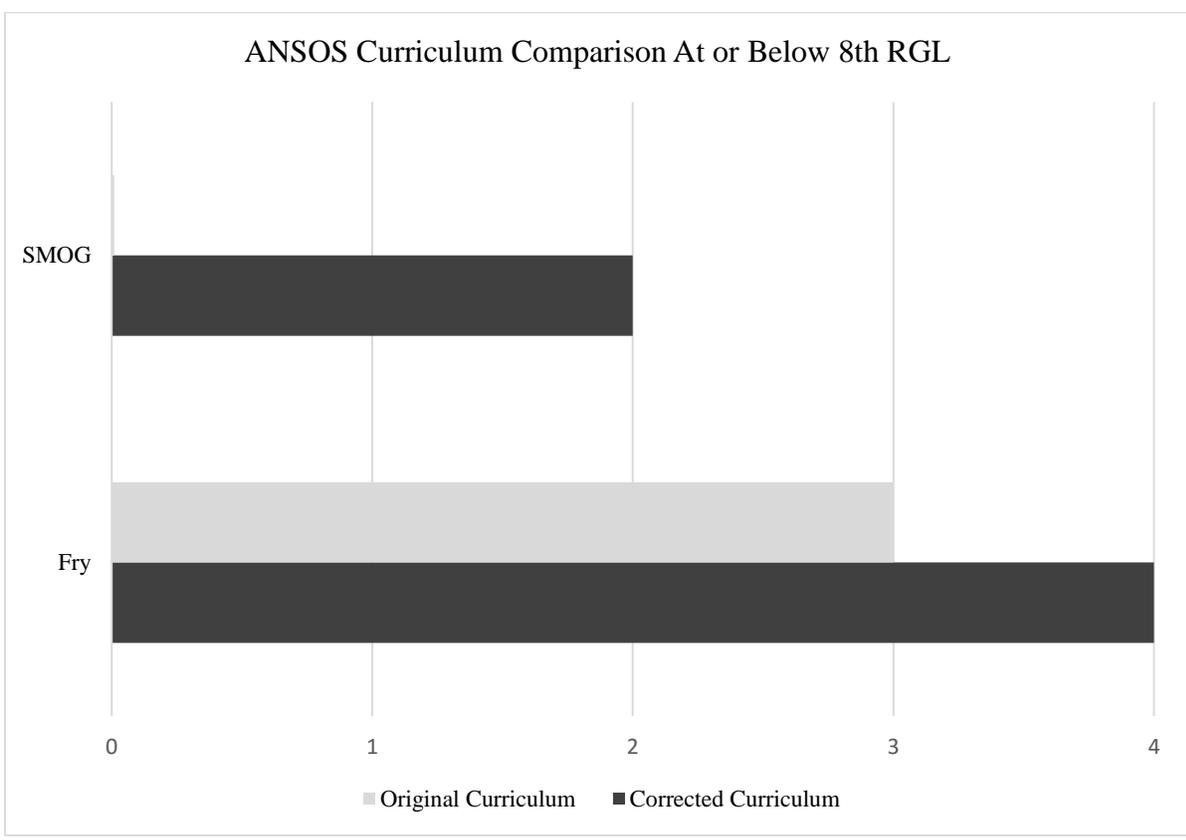


Figure 4: ANSOS Curriculum Comparison At or Below 8<sup>th</sup> RGL

An additional member of the research team assessed the readability of two of the corrected sections individually, using both the Fry and SMOG to establish investigator reliability. No differences in RGL calculations were identified between reviewers. The information in Table 22 illustrates the readability assessment results from each reviewer.

Table 22

*Readability Assessment Results: Modified ANSOS Program Curriculum Reviewer Reliability*

Curriculum Section	Fry Primary Reviewer	Fry Second Reviewer	SMOG Primary Reviewer	SMOG Second Reviewer
Chew & Native people	8 <sup>th</sup> grade	7 <sup>th</sup> /8 <sup>th</sup> grade	9 <sup>th</sup> grade	9 <sup>th</sup> grade
Stress reduction	6 <sup>th</sup> grade	6 <sup>th</sup> grade	7 <sup>th</sup> grade	7 <sup>th</sup> grade
Traditional tobacco	8 <sup>th</sup> grade		9 <sup>th</sup> grade	
Weight management	7 <sup>th</sup> grade		7 <sup>th</sup> grade	

To determine if a cultural review was necessary to develop a culturally tailored SLT cessation program for AI, community members were interviewed to evaluate the program curriculum for cultural accuracy. A total of 22 adults were interviewed. Prior to the start of the interviews, participants were asked to fill out a short demographic survey, asking them questions about themselves including gender, age, area where they grew up, relationship status, if they have children, education level, and profession. Participants were also asked if they currently or have ever used chewing tobacco.

Of the 22 adults who participated in the cultural review, 11 were male (50%) and 11 were female (50%). Over half of the participants were in the age range of 30+ years (68%, n=15), with the remainder in the 18-29 years age range (32%, n=7). Relevant to this research study, the majority of participants interviewed had never used SLT (73%, n=16), nor were current SLT users (95%, n=21). Demographic results from the cultural review interviews are listed in Table 23 below.

Table 23

*Baseline Demographics for the Cultural Interviews (N=22)*

Demographic Variable	n	%
<i>Gender</i>		
Male	11	50
Female	11	50
<i>Age</i>		
18-29	7	31.8
30-39	3	13.6
40-39	3	13.6
50-59	4	18.2
60+	5	22.7
<i>Where did you grow up?</i>		
Reservation	4	18.2
Urban	9	40.9
Rural	8	36.4
Other	1	4.5
<i>Relationship Status</i>		
Married/Living with a partner	9	40.9
Never married	5	22.7
Divorced/Separated	6	27.2
Widowed	1	4.6
Other	1	4.6
<i>Do you have children?</i>		
No	6	27.3
Yes	16	72.7
<i>Education Level</i>		
Some high school or less	0	0
High school graduate/GED	3	13.6
Some college	10	45.5
College graduate	5	22.7
Graduate degree	4	18.2
<i>Profession</i>		
Admin Assistant	1	4.5
College Student	1	4.5
Disabled	1	4.5
Doctoral Student	1	4.5
Eligibility Worker for State of Kansas	1	4.5
Mail Carrier	1	4.5
Ministry	1	4.5
Native American Flautist	1	4.5
Not employed	1	4.5
Office Manager	1	4.5
Parts Clerk	1	4.5
Retired	4	18.2
Self Employed	1	4.5
Commercial	1	4.5

Valet	1	4.5
WTI	1	4.5
Wildland Firefighter	1	4.5
Working for non-profit	1	4.5
No answer	1	4.5
<i>Have you ever used chewing tobacco?</i>		
No	16	72.7
Yes	6	27.3
<i>Do you currently use chewing tobacco?</i>		
No	21	95.4
Yes	1	4.6

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Analysis of the cultural review interviews revealed two major themes: 1) participants felt that program curriculum was culturally appropriate and 2) participants had numerous suggestions to make the program curriculum visually appealing and contextually appropriate for an AI audience. These themes are interrelated, but are discussed separately for clarity.

Overall, participants believed that the program curriculum was culturally appropriate. The majority of participants did not see anything offensive or culturally inappropriate in the program material. Participants' statements regarding the overall program content included, "I think they did a really good job in covering it. Some of the strong points were the family and trying to quit as a family", "I thought it was very concise, I thought it was very on target" and "I'm glad someone is taking the time and interest to address this issue in Indian Country". One participant believed the program material was published by a pharmaceutical company due to the mention of Chantix therapy. The participant had a negative personal experience with that particular drug, therefore it was concerning to the individual. The chapter on pharmacology was removed from the curriculum for other reasons and was not included in the final cessation program.

Participants had numerous suggestions to make the program curriculum visually appealing and contextually appropriate for an AI audience. Participants suggested printing the

program in bright colors (e.g. red, yellow, and orange) and using images of Native individuals to grab the attention of program participants. For example, one participant recommended “use images with the culture that Native people can relate to”, while another suggested “use pictures of what it can do, as well as testimonies of people who quit because of what chewing has done to them”. Participants thought program curriculum should include facts, statistics, and explanations of traditional use specific to the AI community. According to one participant, “the program should talk about the ceremonial use of tobacco and the non-traditional use of tobacco, because there is a difference”. Another participant stated, “I would like to see more statistics about how many Natives actually died from chew each year”.

## **Chapter V**

### **Discussion**

American Indian communities face an ongoing challenge of effectively addressing tobacco related health disparities. Effective approaches to the prevention of tobacco related disease in this community requires a specific and tailored cessation program. It is critical to identify and describe the influence of cultural perspectives within the community. Cultural knowledge and beliefs have a direct influence on the ways communities choose to access health education and treatment services.

ANSOS, a culturally-tailored SLT cessation program, was created to provide the AI community with a cessation program to stop the recreational use of commercial SLT, while allowing individuals who practice traditional use of tobacco to continue its use through prayer, ceremony, and in other traditional ways. This research highlights the importance of community feedback in the development of a culturally-based program.

The primary purpose of this investigation was to gather formative data needed to develop a culturally tailored SLT cessation program for AI. The information gathered was applied to current program materials and used to develop an effective program timeline. A secondary purpose for this study was to assess the program curriculum for scientific accuracy, readability, and cultural appropriateness, to determine if these assessments play a significant role in curriculum development. Research obtained during these reviews was applied to the draft program curriculum that serves as a guide for the ongoing pilot study.

This study followed a qualitative research design and acted as a formative evaluation. During Phase 1, a total of 85 AI participated in interviews and focus groups. Methods developed by the research team were used to determine significant themes that arose from the data. Phase 2

consisted of a three-part assessment of the program curriculum. A scientific review from four experts, a readability assessment using two readability formulas, and 22 individual interviews assisted in the development of program curriculum that will be used during the pilot study.

### **Challenges and Successes**

The challenges of conducting research with AI communities are a direct result of a long-standing distrust of research that has poorly represented this community. Even the best intentions of researchers may go awry in the boundary between the scientific and AI communities. Using a CBPR approach to form academic-community partnerships with AI people may provide a means to rebuild trust in the research process. It was evident in the experience of this research study that CBPR is the most appropriate approach in taking steps to change the negative history of research encounters in AI communities into more productive and beneficial partnerships that effectively addresses health disparities.

Conducting research in a community with cultural differences from the researcher, can pose challenges that may not always be considered. These could include establishing trust and open communication channels among all members of the research team. This is especially true when collecting information about unhealthy behaviors that, based on cultural beliefs, may be considered appropriate by participants. However, by successfully implementing CBPR and engaging the community throughout the research process, challenges can be addressed because of knowledge and understanding of the community's culture(s). Additionally, the community's trust in other community members engaged in the research process, as well as trust in the researcher, is invaluable to the successful implementation of the research project.

Prior to the start of this study, the author established a relationship with the research team and community members. It might be assumed that this would have contributed to an immediate

entry in the development of this research study. However, even with a previous relationship that had developed over time, it was important to build trust with each member of the research team. As an outside community member, the author worked to conduct open and fully transparent research. It was also important to follow-through on commitments, and carry an understanding of the community expectations about the research team's involvement in community activities. While many researchers might not be able to support commitments at this level, these examples provided the author with a greater understanding of the importance of community input and cultural values in CBPR research.

## **Key Findings**

### **Research Question One**

The utilization of interviews and focus groups in this study provided several findings that should help with the development of similar programs. Although the sample of participants was small, there was strong convergence among the groups regarding their knowledge, attitudes, and beliefs about SLT and SLT use in the AI community. Phase 1 participants accurately described and defined SLT and SLT use, and therefore could make an informed decision about participating in a cessation program. Furthermore, participants had specific beliefs about the primary influences that cause AI to start using SLT, as well as the barriers to quit. Results support that social influence has a significant impact on the initiation of SLT use. In an earlier study, Hall and Dexter (1998) studied SLT use in a sample of 1,180 adolescents that included 257 AI. Multiple regression analyses revealed that among adolescent males and females, SLT use was significantly associated with having friends, sibling, parents, and other relatives who used SLT.<sup>78</sup> Social influence, addiction, and habit were identified by participants as prominent barriers to quit. Cessation programs should address factors that facilitate use among AI including community influences

associated with SLT use<sup>5,31,34</sup> and the addictive properties of SLT<sup>13</sup>. ANSOS will specifically address the social influence on initiation and barriers to quit in two cessation program sessions titled *Why do People Chew* and *Friends, Family, and Quitting Chewing Tobacco*.

Attitudes towards smoke-free/tobacco-free policies and the dual use of cigarettes and SLT (i.e. using SLT when smoking is not allowed) were expressed by participants. Campus and work smoke-free or tobacco-free policies seemed to have little impact on SLT use. Participants who were current users often reported continued use of SLT despite current policies. According to non-users, policies seemed to have minimal influence on the continued use of SLT. Results coincide with participant statements regarding the discrete and somewhat secretive nature of SLT use.

Literature has shown that the prevalence of smokeless tobacco use among working adults (3.0%) exceeded the *Healthy People 2020* target of  $\leq 0.3\%$  in the U.S. Although current cigarette smoking prevalence among adults was significantly lower in 2010 (19.1%) than in 2005 (22.2%), the prevalence of SLT use did not significantly differ (2.7% and 3.0%, respectively).<sup>79</sup> The tobacco industry recognizes the increase in smoke-free laws and is rapidly developing new products. Marketing efforts are also counteractive to smoke-free laws. Smokeless products are being marketed to promote dual use, so users can “smoke when you can, dip when you can’t”.<sup>80</sup>

The lack of reduction in SLT use might be attributable to the introduction of new tobacco products into the marketplace (e.g., dissolvable tobacco and e-cigarettes), the increased expenditures on SLT marketing in recent years<sup>81</sup>, or the ineffectiveness of institutional policies. Furthermore, this might suggest that policies do not address dual use of cigarettes and SLT, reducing the impact of policy on promoting tobacco cessation. As a result, the ANSOS program will specifically address poly tobacco use and smoke-free/tobacco-free policy in the cessation

program sessions discussing facts about chewing tobacco, as well as individual telephone sessions.

### **Research Question Two**

Following the guidelines of CBPR<sup>9</sup>, collaborative efforts by community and research team members resulted in the development of an intervention by the community for the community. Comments and suggestions from community members especially built upon the strengths and resources within the community. The commitment, participation, and input from AI community members have and will continue to provide invaluable resources to this study, with the hope of reducing health disparities among AI communities.

With data collected from this study, researchers were able to identify what AI want to experience in a culturally tailored SLT cessation program. Key findings may help in development of future similar programs. It was clear from focus group and interview responses that potential program participants were interested in a culturally-based program and have strong ideas of what methods would work within their communities. Literature supports the use of CBPR techniques for research aimed at studying and reducing health disparities among marginalize communities<sup>8,43</sup> and embraces community feedback offered throughout the research process. The CBPR approach increased community investment in this research and research results dramatically. Participants provided valuable information about potential program type, length, topics, and incentives. The ANSOS program should be primarily group-based and flexible in length. Ideally, program content should address the impact of tobacco on AI health and provide participants with a range of incentives to keep them motivated throughout the quit process.

The findings of this study provided valuable feedback that was used to develop the ANSOS program timeline. During the Phase 1 focus groups and interviews participants expressed the preference for a group-based session that offered flexible scheduling. The program timeline was created to fulfill the needs voiced by the potential program participants. Therefore, ANSOS was developed as a group-based program occurring over a six month time period. It is recommended that groups meet weekly for the first 12 weeks and then monthly over the last 3 months. However, participants have the option to only participate in the first group session and the 6 month session if they wish, with no penalty other than loss of potential incentives. Program meetings will either be in-person or telephone sessions. The availability of in-person and telephone sessions allows individuals to participate each week, despite potential scheduling conflicts. The ability to select the number of participation weeks also contributes to the flexibility of the program timelines. The ANSOS program timeline is presented in Table 24.

Table 24

*ANSOS Program Timeline*

<b>Session</b>	<b>Type of Session</b>	<b>Topics Covered</b>	<b>Brochures/Other Handouts</b>	<b>Incentives</b>
Screening	In-person or via Telephone	Eligibility criteria	Basic Program Information	N/A
Week 0: Intake	Individual In-person	Program information, quit date information, personal history, pharmacotherapy	Pharmacotherapy/NRT Preparing to quit	\$20 gift card \$10 gift card (cotinine) Educational Materials
Week 1: Group	Group In-Person and Telephone (During Week)	Facts about chewing tobacco, personal stories, more questions about the program	Why Do People Chew, Quit Contract, Reasons to Quit Card, Native People & Chewing Tobacco	\$20 gift card T-shirt, quit kit
Week 2: Group 2 (QUIT DATE)	Group In-Person and Telephone	Team Building, Coping with Withdrawal	Coping with Withdrawal, Things Instead Card	USB Car Adapter, quit kit refills
Week 3: Group 3	Group In-Person and Telephone	Stress Management I	Stress Reduction and Relaxation Techniques	stress ball, quit kit refills
Week 4: Group 4	Group In-Person and Telephone	Social Support I	Friends and Family and Quitting Chewing Tobacco	cooler, quit kit refills
Week 5: Individual Session 1	Telephone	Personal Issues	N/A	N/A
Week 6: Group 5	Group In-Person and Telephone	Weight Management, Healthy Eating and Exercise	Weight Management	water bottle, quit kit refills
Week 7: Individual Session 2	Telephone	Personal Issues	N/A	N/A
Week 8: Group 6	Group In-Person and Telephone	Stress Management II	N/A	gym bag, quit kit refills
Week 9: Individual Session 3	Telephone	Personal Issues	N/A	N/A

Week 10: Group 7	Group In-Person and Telephone	Traditional Tobacco	Traditional Tobacco	chair, quit kit refills
Week 11: Individual Session 4	Telephone	Personal Issues	N/A	N/A
Week 12: Group 8	Group In-Person and Telephone	Social Support II; Staying Quit, Program Feedback	Congratulations You Have Quit	multi-tool, quit kit refills
Month 4: Individual Session 5	Telephone	Personal Issues	N/A	N/A
Month 5: Individual Session 6	Telephone	Personal Issues	N/A	N/A
1 week prior to 6-month follow up	Telephone	Reminder and personal issues	N/A	N/A
Month 6: Group 9	Group In-Person	Evaluation of program, spit from quitters (6-month date is from baseline)	N/A	\$40 gift card if >60% in-person sessions \$10 gift card (cotinine) \$20 gift card for program evaluation

Program topics and handouts were evaluated to ensure that the ideas from the research team aligned with the topics suggested during Phase 1. Focus group and interview participants offered numerous suggestions regarding program topics, including healthy alternatives to chewing, current statistics on AI health, and exercise. Each topic suggested by Phase 1 participants was included in either a weekly program topic or brochure/other handout (Table 24).

The majority of Phase 1 participants were male (n=57, 67%). Additionally, literature from the USDHHS found SLT use among females has remained low, although use among males has been increasing steadily.<sup>81</sup> In 2012, percentages of adult current SLT users was 7.1% for males versus 0.4% for females.<sup>81</sup> For those reasons, weekly incentives were selected based on their potential appeal to male participants. Incentives were printed in black, grey, and white. Incentives were also selected to encourage physical activity (e.g. water bottle and gym bag) which was suggested by program participants as a healthy alternative to chewing. In addition, ANSOS participants have the ability to earn financial incentives (e.g. gift cards) for attendance in particular sessions or after completing large milestones.

**Sub-question a).** Interview and focus group results identified factors that should augment the dissemination of this program. Participants gave comments and suggestions on what type of cessation program should be developed. Individuals discussed recommendations for cessation program type, length, topics and incentives. This feedback will be used to design the cessation program timeline and guide development of the program curriculum. Community involvement and direction is crucial from concept development to analysis and dissemination, increasing the likelihood of participation and sustainability.<sup>8</sup> The chances of program

dissemination are enhanced due to the fact that community input led the development of the program.

### **Research Question Three**

The results from the curriculum evaluations revealed that scientific reviews, readability assessments, and community reviews play a significant role in the process of program development. Each review process improved the accuracy and quality of the curriculum, resulting in a final draft that will be utilized during the pilot study. Researchers are confident that the material that will be presented to program participants is both scientifically and culturally accurate, as well as an appropriate reading level.

A review of the curriculum revealed that the process is both necessary and unique. According to Gibbons & Georghiou (1987), it is important to expand the review to include a variety of expertise, leading to an evaluation by a broad range of scientific criteria.<sup>67</sup> Therefore, recommendations in three distinct areas were used. Experts in the field of epidemiology placed an emphasis on potential causes behind SLT use, the relationship between SLT and disease, and methods to quit. Medical facts and statistics were reviewed by physicians with extensive knowledge in tobacco cessation. Feedback from the anthropologist ensured that the curriculum included cultural and moral considerations embedded in health practices. Comments from members of the scientific community identified both strengths and weaknesses of the program curriculum. The research team worked to improve any inaccuracies in the curriculum, and built upon any strengths. As a result, program curriculum that will be used during the pilot study has improved scientific accuracy.

With data collected from this study, it was concluded that readability assessments assisted in the development of program curriculum. Readability tests are performed to ensure

documents are at the appropriate reading level for the intended audience. Individuals who are able to understand a document can often apply or carry out the meaning of the content. More specifically, if ANSOS participants are unable to understand and apply the program curriculum, the success of the program will be limited and the health of participants will remain a concern.

Readability assessments were found to be an asset during program development. The first readability assessments revealed several curriculum sections with high RGLs, above acceptable criteria set by the research team. After improvements to the curriculum were made, a second readability assessments showed appropriate RGL for the majority of program curriculum sections. The sections *Chew & Native People* and *Traditional Tobacco* had final SMOG scores of 9<sup>th</sup> grade, which is outside of the ideal range, large in part to culturally appropriate terminology. Several Native names, terms, and historical stories contributed to the cultural relevance of these sections. The information in Table 25 contains examples of the terminology that contributes to the cultural significance of the program curriculum, yet increased the RGL. Although the RGL is above the research teams' goals, we are confident that individuals will be able to read and understand these two sections because they are familiar with native terminology.

Table 25

*Different Names by which the Tobacco Plant is known in Native languages of North America*

Language/ Tribe	Name for Tobacco
Tsa-tsa-la-gi (Cherokee)	Tso-la or tsa-lu (fire in the mouth)
Tsitsistaestse (Cheyenne)	Tse'nemoo'o
Passamaquoddy	Dumawai
Narragansett	Ottomaok
Mshkodenyek (Prairie Band Potawatomi)	Asema (tobacco) or Nensema (Indian Tobacco)
Kickapoo	Nessamon
Ottawa	Sema
Lakota	Canli
Cree-Montagnais	Tcistema
Navajo-Apache	Nat'o

The need to provide adequate, readable, and understandable materials is evident, according to the results of this study. A negative consequence of providing cessation program curriculum of a high readability level is that only people with a least high school education can read and understand the material. According to the 2003 NAAL, approximately 14% (30 million) of American adults read at a below basic literacy level (5<sup>th</sup> grade).<sup>69</sup> If this deficit applies to the pilot study populations, then a large number of participants would be unable to or have difficulty reading the initial curriculum, deeming the readability assessments necessary. The ANSOS program serves as a role model to other health organization offering cessation education, by providing their participants with adequate written materials.

There is a distinct difference between the culturally tailored program developed for this study and other AI SLT cessation programs. Severson et al. (2007), produced a cessation guide for AI that has shown positive results in quit rate success.<sup>40</sup> However, data specifically relating to the AI community or information regarding the extent of cultural review was not available, questioning the true cultural appropriateness of the material. Following the guidelines of CBPR<sup>9</sup>, community members and researchers were able to take an approach to the research process that would yield culturally relevant intervention. A cultural review provided significant feedback regarding the cultural accuracy and appropriateness of the curriculum. Community views and ideas provided depth and detail to the cessation materials that will engage the AI population. The suggestion offered during the cultural review led to written documents being catered to the intended audience, increasing the accuracy of the program curriculum.

## Chapter VI

### Summary, Conclusions, and Recommendations

#### Summary

Smokeless tobacco use in the AI population is leading to significant health concerns among individuals. Although the negative health consequences of SLT use have been widely acknowledged, a lack of culturally appropriate programs inhibits successful quit attempts within the community. Establishing culturally tailored SLT cessation programs may be particularly important to overcome the health disparities experienced by this community and fight back against tobacco manufacturers.

AI have a unique history and cultural ties with tobacco. The most difficult aspect of designing a cessation program for participants is often catering the program to the represented group. The methodology used in this study resulted in a successful method for gathering preliminary data using a CBPR approach. The strategies for involving community members in all phases of the research process can be used by other CBPR teams, particularly those teams working with marginalized communities. Although this is a rigorous process, this approach might prove valuable to the development of sustainable and effective approaches to the embedded health disparities facing AI and other underrepresented groups across the U.S.

The shared voices and lived experiences of study participants provided the content and structure to the developing ANSOS program. The significance of utilizing a CBPR approach cannot be overemphasize in developing meaningful partnerships in AI communities that address current health disparities that are important to the health of their members. The resulting outcomes provided the means for the community to take the next steps is reducing the rates of SLT use through a culturally tailored SLT cessation program.

This study was designed to gather the initial data needed in the early stages of program development. Specifically, it addressed the knowledge, attitudes, and beliefs of AI individuals. Additionally, what AI want to experience in a culturally tailored SLT cessation program was determined. The significance of scientific reviews, readability assessments, and community reviews during program development phases were also evaluated and further assessed by examining the ANSOS program curriculum.

This study was carried out utilizing both qualitative and quantitative research methods. The qualitative process included a number of focus groups and interviews to gather community feedback, while also examining the scientific and cultural accuracy of program materials. Quantitative methods were used as readability assessments evaluated the RGLs of the program curriculum. Study results were specifically used to develop a SLT cessation program timeline and curriculum. Although the number of participants was small, given the lack of research on smoking cessation among AI, the results from this study add to the knowledge in this area, as an initial step toward developing targeted interventions. The results obtained from this study led to the following conclusions and recommendations.

### **Conclusions**

Based on the results obtained in this study, the following conclusions were made:

1. It is possible to obtain community comments and suggestions regarding SLT cessation program development for AIs.
2. AI community members play an important role in the CBPR process and have an interest SLT cessation program development.

3. The comments and suggestions provided by participants and tobacco experts influenced the delivery of SLT cessation, which can improve individual and community health and wellbeing.
4. Improving the scientific accuracy, reading grade level, and cultural accuracy of program curriculum strengthens the overall quality of program materials.
5. In order to facilitate a future pilot study, a detailed program timeline was developed to include:
  - a. the length of the program,
  - b. the type of session (group or telephone),
  - c. the topics and program curriculum sections that will be covered, and
  - d. participation incentives.
6. The program curriculum that will be used during the pilot study is scientifically accurate, the correct reading level for an individual with average reading ability, and culturally appropriate for the intended audience.

### **Recommendations**

The following recommendation are derived from the findings of this formative study:

1. Formative research has a significant impact on program development, as it helps to identify factors that enhance dissemination and contribute to program success.
2. The results of this study should be used to guide the continuing development of the ANSOS cessation program.
3. The program outcomes (timeline and curriculum) developed during this study should be implemented during the ANSOS pilot study.

4. Studies such as this can contribute to a better understanding of how to improve the threat of commercial tobacco use in the AI population.
5. The results of this study were specifically tailored to the local community's wants and needs, therefore future research may follow similar procedures, but must be designed to meet the needs of the population of interest.
6. Future research should address the relationship between smoke-free/tobacco-free policies and the dual use of tobacco products.

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**Appendix A**

HSC Documentation

# The University of Kansas Medical Center

Human Research Protection Program

## APPROVAL OF PROTOCOL

July 14, 2014

Christine Daley  
cdaley@kumc.edu

Dear Christine Daley:

On 7/14/2014, the IRB reviewed the following submission:

Type of Review:	Initial Study
IRB#:	STUDY00001122
Title:	Smokeless Tobacco Cessation among American Indians Using In-Person Groups
Investigator:	Christine Daley
IRB ID:	STUDY00001122
Funding:	NIH, Funding Source ID: 1 R01 MD007800-01A1
Documents submitted for the above review:	<ul style="list-style-type: none"> <li>• Full Committee Project Description Updated July 2014</li> <li>• Administrative Certification SLT Cessation Among American Indians</li> <li>• SmokelessTobacco PRMC Full Approval Letter</li> <li>• Cover Letter</li> <li>• SLT Response to Provisos July 2014</li> <li>• SLT Response to Provisos</li> <li>• Grant Application</li> <li>• SLT Protocol TRACK CHANGED 2</li> <li>• SLT Protocol CLEAN 2</li> <li>• Study 1122 consent TRACK CHANGED 2</li> <li>• Study 1122 consent CLEAN 2</li> </ul>

The IRB approved the study from 7/14/2014 to 7/13/2015 inclusive. Before 7/13/2015 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 7/13/2015, approval of this study expires on that date.

Mail-Stop 1032, 3901 Rainbow Blvd., Kansas City, KS 66160  
Phone: (913) 588-1240 Fax: (913) 588-5771 humansubjects@kumc.edu

Your approved, stamped consent documents are found under the Document tab in your protocol. The consent forms posted in our electronic system are the only valid versions for documenting informed consent.

In conducting this protocol, you are required to follow the requirements and Standard Operating Procedures posted on our website at:

<http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board.html>

Sincerely,

Karen Blackwell

**Appendix B**

Moderator's Guide Montana Focus Groups

**Tobacco Use Among American Indian/Alaska Native  
Tribal College Students  
Smokeless Tobacco Use Moderator Guide**

Prior to the start of the focus group, all participants will be given information about the study and will be asked to sign informed consent forms. They will be provided with answers to any questions they may have and all aspects of participation and informed consent will be explained. Anyone who does not wish to participate or will not sign a consent form will not be permitted to participate. All focus groups will be led by a moderator, assisted by an assistant moderator. The assistant moderator will take notes while the moderator leads the group.

This is intended as a guide for the focus group moderator. As each focus group progresses, follow-up questions may be asked on any of the topics discussed. Questions will flow from one to the next guided by the group. Participants will be informed that they may choose not to answer any questions that they are uncomfortable answering prior to the start of the focus group. Topics not included in this guide will not be brought up by the focus group moderator. This guide is intended for use by community members and will focus on smokeless tobacco, with an emphasis on what current users would like to see in a quit smokeless program. Focus groups will be stratified as follows, and questions about smokeless tobacco will be modified as appropriate for each stratum.

Smokeless Tobacco Focus Group			
Current and Former SLT User		Never Used	
Men	Women	Men	Women
3	3	3	3
N=30	N=30	N=30	N=30
Total: 12 groups (120 participants)			

Focus group participants will each receive a \$25 gift card to a local store, i.e. Amazon.

*Thanks again for agreeing to participate in this study. As we talked about before, we're audio-taping this focus group and we will be transcribing it. We won't put your name on the transcript and we won't use your name in conjunction with any quotes we may use. We are very interested in finding out about tobacco use among American Indian/Alaska Native tribal college students. Our ultimate goal is to figure out what current and former SLT users would like in a quit using program and to learn about tribal college students' knowledge, attitudes and beliefs about SLT.*

*Before we start the focus group, we would like each of you to fill out our demographic questionnaire. It asks you questions about basic demographic information, like your age, tribal affiliation, and history of smokeless tobacco use if you have any. I will go through the questionnaire and as I go along, please ask me any questions that you may have.*

***PARTICIPANTS WILL BE GIVEN DEMOGRAPHIC QUESTIONNAIRE***

.....

**QUESTIONS FOR CURRENT AND FORMER SLT USERS**

*Now I'd like all of you to come together so we can talk as a group. The group discussion should last approximately one hour. First we'll talk about smokeless tobacco use among college students. Then we'll break for a few minutes and when we come back together, we will talk about what students want in a quit using smokeless tobacco program. Does anyone have any questions before we get started?*

**1. Smokeless Tobacco Use:**

- **How do you define a “smokeless tobacco user”?**
- **Why did you start using smokeless tobacco?**
  - Why do other people start using smokeless tobacco?
- **Do you consider yourself to be addicted to smokeless tobacco?**
  - If so, when did you first consider yourself to be addicted?
  - Why do you consider yourself to be addicted?
- **What are the benefits to using smokeless tobacco?**
- **Do you want to quit using smokeless tobacco? Why or why not?**
  - Do you think you could quit smoking if you wanted to? Why or why not?
- **Do you/ did you ever smoke cigarettes?**
  - What is the difference between cigarettes and smokeless tobacco?
  - Did you use cigarettes and smokeless tobacco at the same time as or one after the other?

*Now we'll take our quick break. When we come back in about 10 minutes, we'll talk about what students want in a quit using smokeless tobacco program. Are there any questions before we break?*

***BREAK FOR ABOUT 10 MINUTES***

*Welcome back. Did anyone think of anything during the break that they want to bring up? Now we will talk about quit using smokeless tobacco program.*

## **2. Quit Smokeless Tobacco Program:**

- **What kind of program would help students quit using smokeless tobacco (*Phone based, in-person individual, in-person group based, via website*)? Why?**
  - How often should students make contact with the program? Why?
  - How important is it that the facilitator is American Indian?
  - How long would you like the program to be?
  - Would you prefer a group based program or individual program?
  - What information would you specifically want included in the program?
- **What types of incentives/aids would you want to help you quit using?**
  - Some examples of what we provide for our quit smoking program are: stress balls, relaxation CDs to help with stress, workout videos to counter potential weight gain, etc.
  - Should the program provide similar medications used to help people quit smoking?

### **QUESTIONS FOR NON-SMOKELESS TOBACCO USERS**

*Now I'd like all of you to come together so we can talk as a group. The group discussion should last for approximately one hour. First we'll talk about smokeless tobacco use among college students. Then, we'll break for a few minutes and when we come back together, we'll talk about campus policies related to smokeless tobacco use. Does anyone have any questions before we get started?*

#### **1. Recreational Tobacco Use – Smokeless Tobacco:**

- **What is the first thing you think of when you think about smokeless tobacco?**
- **How do you define a “smokeless tobacco user”?**
- **How does smokeless tobacco relate to cigarettes?**
- **Why do you think people start using smokeless tobacco? Why do they continue?**
- **What health problems do you know of that are affected by smokeless tobacco use?**
- **What do you think are the benefits of using smokeless tobacco?**
- **Why do you think it's so hard to quit using smokeless tobacco? Is it harder or easier than quitting cigarettes?**
- **How many of your close friends and family members use smokeless tobacco?**
- **Is smokeless tobacco use a problem for tribal college students? If so, how?**

*Now we'll take our quick break. When we come back in about 10 minutes, we'll talk more specifically about the site we plan to design. Are there any questions before we break?*

### ***BREAK FOR ABOUT 10 MINUTES***

*Welcome back. Did anyone think of anything during the break that they want to bring up? Now we will talk about traditional tobacco use.*

## **2. Smokeless Tobacco Use on College Campuses:**

- **Do you think a lot of college students use smokeless tobacco? Why or why not?**
- **Should colleges have a policy about smokeless tobacco use on campus?**
  - If so, what should it be?
  - Should campus policies about smokeless tobacco be similar to campus policies about cigarettes? Why or why not?
  - What is SKC's policy about smokeless tobacco use on campus? Do you agree or disagree with it?

*Before we finish, I'm going to ask our assistant moderator to give us a brief summary of what was said. If we got anything wrong or you want to clarify, please tell us.*

*(Note: Assistant moderator will give a brief summary and participants will modify as needed.)*

*Once again, thanks so much for your time today. Through these focus groups, we hope to learn more about smokeless tobacco among tribal college students. We have some information about the health effects of smokeless tobacco and about our quit smoking program, All Nations Breath of Life, if you would like. Does anyone have anything they want to ask us? Thanks again!*

**Appendix C**

Consent Form Montana Focus Groups

**Summary of Consent Form for Tobacco Use Among American Indian/Alaska Native  
Tribal College Students Project  
Smokeless Tobacco Focus Group Participation**

As an eligible person (age 18 or older and a current college student attending a tribal college), you are invited by Principal Investigator Won Choi, PhD, from the University of Kansas Medical Center, to take part in the Tobacco Use Among American Indian/Alaska Native Tribal College Students project. The purpose of this project is to study tobacco use among American Indian/Alaska Native tribal college students to determine what influences students to start smoking and keep smoking. Focus groups and surveys will gather information that will be used to design future programs to help students stop smoking. This project will run for five (5) consecutive years. Your participation is voluntary. You can choose to quit at any time or refuse to answer certain questions. If you have questions, you will get them answered prior to your participation in this project.

If you decide to participate in this portion of the project, you will be asked to take part in a focus group to be held on the Salish Kootenai College campus during the school year. The focus group questions will address student's knowledge, attitudes and beliefs about smokeless tobacco and the creation of a quit smokeless tobacco program. The focus group will last 60-90 minutes and will be digitally-recorded. The recordings will be transcribed. We will not use your name on the transcript and we will not use your name in conjunction with any quotes we may use. Focus groups will be grouped by gender (male/female) and by smokeless tobacco use (current/former and never used). You will be asked to provide basic demographic information (gender, age, tribal affiliation, smokeless tobacco status, etc.).

You will be given information about smokeless tobacco use. You may or may not benefit from the information provided. Care will be taken to safeguard the information you provide but under rare circumstances confidentiality breaches may occur.

There are no costs associated with taking part in this project. You will receive a \$25 gift card for participating in the focus group.

If you think that you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director of Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

If you decide to participate in this project, the information collected about you will be kept confidential. Your health information is protected by government laws on privacy and KUMC is required to get your permission to use information about you for this project. Basic demographics, contact information, and your responses are the only personal information collected about you.

This information is kept at KUMC until the project is finished and a report is written. Digital recordings are retained for six (6) years in accordance with KUMC's Research Records Retention

Policy. Once the recordings have met the retention requirements, they will be destroyed per KUMC's policies. Only the people who oversee research will be able to look at your information. Nothing that can identify who you are will be published with the results of this project. If you change your mind, you can cancel the permission to use your health information by writing to Dr. Won Choi, Preventive Medicine and Public Health, Mail Stop 1030, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. If you do not want your information used in this project, you should not participate in the focus group.

*I have read the information about the Tobacco Use Among American Indian/Alaska Native College Students project and I agree to participate. If I have any questions, I can contact the Principal Investigator, Dr. Choi at 913-588-4742 or the Project Manager, Christina Pacheco at 913-945-7047 or [tctabs@kumc.edu](mailto:tctabs@kumc.edu).*

Name (print): \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Appendix D**

Moderator's Guide Kansas Focus Groups

## Smokeless Tobacco Cessation Project Smokeless Tobacco Use Moderator Guide

Prior to the start of the focus group, all participants will be given information about the study and will be asked to sign informed consent forms. They will be provided with answers to any questions they may have and all aspects of participation and informed consent will be explained. Anyone who does not wish to participate or will not sign a consent form will not be permitted to participate. All focus groups will be led by a moderator, assisted by an assistant moderator. The assistant moderator will take notes while the moderator leads the group.

This is intended as a guide for the focus group moderator. As each focus group progresses, follow-up questions may be asked on any of the topics discussed. Questions will flow from one to the next guided by the group. Participants will be informed that they may choose not to answer any questions that they are uncomfortable answering prior to the start of the focus group. Topics not included in this guide will not be brought up by the focus group moderator. This guide is intended for use by community members and will focus on smokeless tobacco, with an emphasis on what current users would like to see in a quit smokeless program. Focus groups will be stratified as follows, and questions about smokeless tobacco will be modified as appropriate for each stratum.

Smokeless Tobacco Focus Group	
Age 18-29	Age 30+
3 groups of 5 individuals	3 groups of 5 individuals
N=15	N=15
Total: 6 groups (30 participants)	

Focus group participants will each receive a \$25 gift card to a local store, i.e. Target.

\*\*\*\*\*

*Thanks again for agreeing to participate in this study. As we talked about before, we're audio-taping this focus group and we will be transcribing it. We won't put your name on the transcript and we won't use your name in conjunction with any quotes we may use. We are very interested in finding out about smokeless tobacco use. Our ultimate goal is to figure out what current and former SLT users would like in a quit using program and to learn about knowledge, attitudes and beliefs about SLT.*

*Before we start the focus group, we would like each of you to fill out our demographic questionnaire. It asks you questions about basic demographic information, like your age, tribal affiliation, and history of smokeless tobacco use. I will go through the questionnaire and as I go along, please ask me any questions that you may have.*

**PARTICIPANTS WILL BE GIVEN DEMOGRAPHIC QUESTIONNAIRE**

.....

## QUESTIONS FOR CURRENT AND FORMER SLT USERS

*Now I'd like all of you to come together so we can talk as a group. The group discussion should last approximately one hour. First we'll talk about smokeless tobacco use. Then we'll break for a few minutes and when we come back together, we will talk about what people want in a quit using smokeless tobacco program. Does anyone have any questions before we get started?*

### **2. Smokeless Tobacco Use:**

- **How do you define a “smokeless tobacco user”?**
- **Why did you start using smokeless tobacco?**
  - Why do other people start using smokeless tobacco? Why do they continue?
  - How does smokeless tobacco relate to cigarettes?
- **Do you consider yourself to be addicted to smokeless tobacco?**
  - If so, when did you first consider yourself to be addicted?
  - Why do you consider yourself to be addicted?
- **What are the benefits to using smokeless tobacco?**
- **Do you want to quit using smokeless tobacco? Why or why not?**
  - Do you think you could quit smoking if you wanted to? Why or why not?
  - Why do you think it's so hard to quit using smokeless tobacco? Is it harder or easier than quitting cigarettes?
  - How many of your close friends and family members use smokeless tobacco?
- **Do you/did you ever smoke cigarettes? Other tobacco or nicotine products?**
  - What is the difference between cigarettes and smokeless tobacco?
  - Did you use cigarettes and smokeless tobacco at the same time as or one after the other?

*Now we'll take our quick break. When we come back in about 10 minutes, we'll talk about what students want in a quit using smokeless tobacco program. Are there any questions before we break?*

### ***BREAK FOR ABOUT 10 MINUTES***

*Welcome back. Did anyone think of anything during the break that they want to bring up? Now we will talk about quit using smokeless tobacco program.*

## 2. Quit Smokeless Tobacco Program:

- **What kind of program would help people quit using smokeless tobacco (*Phone based, in-person individual, in-person group based, via website*)? Why?**
  - How often should people make contact with the program? Why?
  - How important is it that the facilitator is American Indian?
  - How long would you like the program to be?
  - Would you prefer a group based program or individual program?
  - What information would you specifically want included in the program?
- **What types of incentives/aids would you want to help you quit using?**
  - Some examples of what we provide for our quit smoking program are: stress balls, relaxation CDs to help with stress, workout videos to counter potential weight gain, etc.
  - Should the program provide similar medications used to help people quit smoking?

*Before we finish, I'm going to ask our assistant moderator to give us a brief summary of what was said. If we got anything wrong or you want to clarify, please tell us.*

*(Note: Assistant moderator will give a brief summary and participants will modify as needed.)*

*Once again, thanks so much for your time today. Through these focus groups, we hope to learn more about smokeless tobacco among tribal college students. We have some information about the health effects of smokeless tobacco and about our quit smoking program, All Nations Breath of Life, if you would like. Does anyone have anything they want to ask us? Thanks again!*

**Appendix E**

Consent Form Kansas Focus Groups

## **Consent for Quit Chewing Tobacco Project**

### **Group Discussion Participation**

As an eligible person (age 18 or older, a former or current chewing tobacco user who self-identifies as American Indian), you are invited by Principal Investigator Christine M. Daley, PhD, SM, MA from the University of Kansas Medical Center, to take part in the Quit Chewing Tobacco project. The purpose of this project is to study chewing tobacco use among American Indians to determine what influences people to start using chewing tobacco and keep it, as well as the best way to develop a program to help American Indians quit using chewing tobacco. Group discussions and surveys will gather information that will be used to design future programs to help individuals stop using chewing tobacco. This project will run for three (3) consecutive years. Your participation is voluntary. You can choose to quit at any time or refuse to answer certain questions. If you have questions, we will answer them prior to your participation in this project.

If you decide to participate in this portion of the project, you will be asked to take part in a group discussion. The group discussion will address knowledge, attitudes and beliefs about chewing tobacco and the creation of a quit chewing tobacco program. The group discussion will last 60-90 minutes and will be digitally recorded. The recordings will be transcribed. We will not use your name on the transcript and we will not use your name in conjunction with any quotes we may use. Participants in group discussions will be grouped by age (18-29 and 30+). You will be asked to provide basic demographic information (gender, age, tribal affiliation, chewing tobacco status, etc.).

You will be given information about chewing tobacco use. You may or may not benefit from the information provided. Care will be taken to safeguard the information you provide but under rare circumstances confidentiality breaches may occur.

There are no costs associated with taking part in this project. You will receive a \$25 gift card for participating in the group discussion. The KUMC Research Institute will be given your name, address, social security number, and the title of this study to process payments to research subjects. Payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are \$600 or more in a calendar year.

If you think that you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director of Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas State law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

If you decide to participate in this project, the information collected about you will be kept confidential. The other participants in the group will be asked keep what we talk about private, but this cannot be assured. Basic demographics, contact information, and your responses are the only personal information collected about you. This information is kept at KUMC until the project is finished and a report is written. Digital recordings are retained for six (6) years in accordance with

KUMC's Research Records Retention Policy. Once the recordings have met the retention requirements, they will be destroyed per KUMC's policies. Only the people who oversee research will be able to look at your information. Nothing that can identify who you are will be published with the results of this project. If you change your mind, you can cancel the permission to use your personal information by writing to Dr. Christine M. Daley, University of Kansas Medical Center, Center for American Indian Community Health, Mail Stop 1030, 3901 Rainbow Blvd., Kansas City, KS 66160. If you do not want your information used in this project, you should not participate in the group discussion.

*I have read the information about the Quit Chewing Tobacco project and I agree to participate. If I have any questions, I can contact the Principal Investigator, Dr. Christine Daley at 913-588-0866 or [cdaley@kumc.edu](mailto:cdaley@kumc.edu) or the Project Manager, Dr. Melissa Filippi at 913-588-2654 or [mfilippi@kumc.edu](mailto:mfilippi@kumc.edu).*

Name (print): \_\_\_\_\_  
Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**Appendix F**

Draft 1 of the Program Curriculum: Friends and Family Session Example

**TOPIC: FRIENDS AND FAMILY AND QUITTING CHEWING TOBACCO****Page 1: Cover**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

**Page 2**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

**Friends and Family as Support for Quitting**

Support from the people around you when you are trying to quit chewing can be very important. Friends and family can provide encouragement, distraction, humor, and warmth when you need it.

Many tobacco users find it helpful to have family members or friends involved in the quitting process. AND many friends and family members really want you to succeed and would love to help in any way that they can!

List 3 people that you think could be supportive of you while you quit chewing tobacco and try to stay quit.

- 1.
- 2.
- 3.

Remember this list of people whenever you feel like you need to chew. Call them instead of chewing. Maybe you can meet them somewhere so you can talk!

**Page 3**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

When friends and family members aren't so helpful...

Sometimes there are people around you who don't help you quit. In fact, sometimes they may make it harder! Friends and family members who smoke may feel angry or threatened when you try to quit. Sometimes they worry that you won't want to be around them anymore. Other times they may be jealous of you if you succeed and they can't.

- When someone around you is hurting your attempt to quit, you need to try and do something about it!
- Try and talk to the person about it.
- If they are a tobacco user, tell them that you still care about them just as much, even if you are not chewing.
- If they are a tobacco user tell them that you will help them if they want to quit.
- Try to get them involved with helping you quit or stay quit in a positive way. If you can't do that, think about how you can minimize the negative effect that they are having on you.

**Unfortunately, not everyone supports your efforts to quit. Don't let those people who don't support you stop you from doing what you want!**

#### **Page 4**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

#### Communicating with Friends and Family

Sometimes we need to ask the people around us for help or to stop doing something that is hurting us. This can be very hard to do! Here are some tips to make talking to someone easier:

1. Respect others – treat them like you want to be treated.
2. Listen to the other person
  - Ask questions when you're unsure what they said
  - Repeat what you hear if there is confusion
  - Let the person know that you hear them and understand them
  - Think about their feelings and how you would respond in their situation
3. Think before you speak.
4. Avoid gossip.

#### **Page 5**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

Communicating with Friends and Family (*continued*)

5. Make sure you tell them your needs or requests in a clear and friendly way.
6. How you speak is important! Make sure you are not misunderstood because of your tone of voice or body language.
7. Recognize and respect how the other person is different from you.
8. Give the other person praise!

**Page 6**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

Communicating with Friends and Family (*continued*)

There are also some things that make communication harder. You should try to avoid these!

1. Don't insist that you are right and the other person is wrong.
2. Don't blame problems on the other person.
3. Don't claim that you are the innocent victim.
4. Don't put the other person down.
5. Don't give up.
6. Don't say that you aren't upset when you are.

**Page 7**

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

Communicating with Friends and Family (*continued*)

7. Don't avoid the issue.
8. Don't blame yourself.
9. Don't just try to solve someone else's problem the way YOU want it solved – listen to them.
10. Don't refuse to admit that you can be wrong.
11. Don't criticize.
12. Don't change the subject.

**Page 8**

Header: Quit Chewing Tobacco Program for Native People

## Friends and Family and Quitting Chewing Tobacco

What are your strengths in communicating with others?

What are your weaknesses?

### Page 9

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

How Chewing Harms Infants and Children

- When used during pregnancy it can increase the risk for early delivery and stillbirth. Nicotine in smokeless tobacco can also affect how a baby's brain develops before birth.
- Can cause nicotine poisoning in children.

### Page 10

Header: Quit Chewing Tobacco Program for Native People

Friends and Family and Quitting Chewing Tobacco

Youth and Chewing:

- AI/AN youth often get smokeless tobacco from family members and they tend to start using smokeless tobacco at a young age.
- AI/AN youth are more likely to use smokeless tobacco than youth from other race/ethnicities.
- Teens want to be like their friends.
- Some teens may want to be like their parents or other family members who chew.
- Some teens will chew just to do something their parents don't want them to do.
- Young people downplay the harm chewing can do or think they will not be harmed.

### Page 11

Notes:

**Appendix G**

Cultural Review Consent Form

**Interview for Cultural Appropriateness of Materials: All Nations SOS****Consent Letter****Principal Investigator: Christine M. Daley, PhD, MA, SM**

The goal of this research is to gather your views and ideas on the cultural appropriateness of education materials for our quit chewing program, All Nations SOS. We are interested in knowing what you think about our materials and what you would change to make them better tailored for American Indian communities. We hope the results of this research will lead to better materials and help those individuals who enter our quit chewing program.

Participation in this study is voluntary. You can choose not to participate, to quit at any time, or refuse to answer any study questions without any penalty or loss. You understand that not participating or quitting will have no effect upon the medical care or treatment you receive now or in the future at the University of Kansas Medical Center.

If you are at least 18 years of age and decide to participate in this study, your participation will involve taking a short survey and being part of an interview. The survey may last up to 5 minutes and the interview may last up to 30 minutes.

If you decide to participate, the information we collect about you will be kept confidential. Your health information is protected by government laws on privacy, and we are required to get your permission to use information about you for the study. The only personal information we collect about you is your initials and place you grew up, along with your answers to the survey. We'll keep this information at KU Medical Center until we finish our study and write our report. Only people doing the study, or people who oversee research, will be able to look at your information. When we publish the results of our study, we won't share anything that identifies you, so your information will stay protected.

The interview will be led by the project staff. The interview will be audio-recorded. After the interview, the recording will be transcribed. Any names used during the interview will appear as a series of "X's" wherever a person's name should be. Audio recordings will be kept in a locked cabinet for five years after the study ends, as required by federal law. Any time we present information from these discussions, we will not use any information that will identify you.

Do you have any questions?

Do you consent to be part of this research?

If you have any more questions, concerns, or complaints after agreeing to participate, you may contact Dr. Christine M. Daley or one of her associates at 913-588-0866. If you have any questions about your rights as a research participant or other concerns, you may call (913) 588-1240 or write the Human Subjects Committee, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.



KUMC IRB # STUDY00001122 | Approval Period 7/7/2015 – 7/6/2016 | FWA# 00003411

**Appendix H**

Cultural Review Survey



## All Nations SOS

### Demographic Questions



ID: \_\_\_\_\_

1. What is your gender?      Male                      Female                      Other
  
2. What is your age?      18-29              30-39              40-49              50-59              60+
  
3. Where did you grow up?      Reservation      Rural area      Urban area      Other
  
4. What is your current relationship status?  
 Married/Living with a partner      Never married      Divorced/Separated      Widowed      Other
  
5. Do you have children?      No              Yes              How many? \_\_\_\_\_
  
6. Education Level      Some high school or less      High school graduate/GED  
 Some college      College graduate      Graduate degree
  
7. Profession (please list) \_\_\_\_\_
  
8. Have you ever used chewing tobacco?      No              Yes
  
9. Do you currently use chewing tobacco?      No              Yes

**Appendix I**

Cultural Review Interview Guide

## Interview Guide—All Nations SOS

*Prior to the interview, all participants will be given information about the study and will be asked to read an informed consent letter. They will be provided with answers to any questions they may have and all aspects of participation and informed consent will be explained. Anyone who does not wish to participate will not be interviewed.*

*This is intended as a guide for interviews. As each interview progresses, follow-up questions may be asked on any of the topics discussed. Questions will flow from one to the next guided by the person being interviewed. Participants will be informed that they may choose not to answer any questions that they are uncomfortable answering prior to the start of the interview. Topics not included in this guide will not be brought up by interviewers.*

\*\*\*\*\*

*Thanks again for agreeing to participate in this study. As we talked about before, we're audio-taping this interview and we will transcribe it. We won't put your name on the transcript and we won't use your name in conjunction with any information that we may use. The results will be de-identified and incorporated into our materials. The goal of this interview is to gain a better understanding of how our quit chewing tobacco materials should be tailored. Your participation will provide data that will assist us with developing educational materials.*

1. Do you use or have you ever used chewing tobacco?
2. What is your gut reaction when looking at this material? What comes to mind when you see this?
3. What images would you want to see in these materials?
4. What kinds of activities would you want to see in these materials?
5. Should we include graphic images, like pictures of mouth cancer? Do you like shock value? Would the community?
6. What colors do you prefer?
7. Are there any other facts regarding American Indians and chewing tobacco you would like to see?
8. Are there any other facts regarding American Indians and tobacco use, including both traditional and recreational use, you would like to see?
9. Are we missing any topics?
10. What don't you like?
11. What is offensive?
12. Is there anything else you would like to add?