Experiences with the Streptococcus mutans in Lakota Sioux (SMILeS) Study: Risk Factors for Caries in American Indian Children 0-3 Years

Journal of Health Disparities Research and Practice

Volume 8
Issue 3 *Summer 2015*

Article 7

2014

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Abstract

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Keywords

oral bacteria; caries; children

Cover Page Footnote

This study was supported by RO1 DE017736 from the National Institute for Dental and Craniofacial Research.

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Journal of Health Disparities Research and Practice
Volume 8, Issue 4, Fall 2015, pp. 123 – 132

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ABSTRACT

Severe Early Childhood Caries (S-ECC) is a terribly aggressive and devastating disease that is all too common in lower socio-economic children, but none more so that what is encountered in American Indian Tribes. Nationwide, approximately 27% of 2-5 year olds have decay while 62% percent of American Indian/Alaska Native children in the same age group have a history of decay (IHS 2010, NHANES 1999-2002). We have conducted a study of children from birth to 36 months of age on Pine Reservation to gain a better understanding of the variables that come into play in the development of this disease, from transmission and acquisition of Streptococcus mutans genotypes from mother to child to multiple dietary and behavioral components. This article describes how we established a direct partnership with the Tribe and the many opportunities and challenges we faced in performing this 5-year field study.

Keywords: oral bacteria, caries, children

INTRODUCTION

The overall goal of this research initiative is to identify risk factors for ECC among AI/AN infants and toddlers. We are focusing on the determination of the role of the mutans streptococci overall and specific genotypes of Streptococcus mutans in combination with behavioral and dietary factors to ascertain how these interacting variables increase a child's risk of caries (Albino and Orlando, 2010; Cheon et al., 2013; Evans et al., 2013; Klein et al., 2004; Maupome et al., 2010; Palmer et al., 2012; Qin et al., 2013; Vann et al., 2010; Zhou et al., 2011).

Dental caries is the most prevalent chronic disease of childhood, occurring five to eight times as frequently as asthma, the second most common chronic disease in children. Early childhood caries (ECC) is a particularly virulent form of caries that affects infants, toddlers and preschool children (Congiu et al., 2014). The manifestations of ECC go beyond pain and infection. It may affect a child's ability to eat and grow properly, speak and communicate, and may impair the child's ability to learn. American Indians and Alaska Natives (AI/AN) are the population group with the highest level of ECC (Albino and Orlando, 2010; American Academy of Pediatrics and Metis, 2011; Irvine et al., 2011; Phipps et al., 2012; Psoter et al., 2006; Schroth et al., 2005). Nationwide, approximately 27% of 2-5 year olds have decay while 62% percent of AI/AN children in the same age group have a history of decay (Phipps et al., 2012).

The specific goals of this report are to describe our experiences in conducting this study, and to describe the specific opportunities and challenges we encountered. We believe that there are important findings to be gained in the study of high-risk populations, and that studies in these populations serve to identify information that will help resolve specific serious public health problems. A study on a dental intervention with an Alaskan Native population described problems encountered and lessons learned (Riedy, 2010). These investigators made several assumptions prior to the initiation of the study, including that dental care was a perceived benefit, having a central location for child delivery would facilitate recruitment efforts, and that studying and reading about the people would provide adequate information on their culture. However, procedures based upon these assumptions failed to address all difficulties. Perhaps the most problematic procedural omission may have been the failure to talk directly with the communities in the beginning to build trust and their participation in the study. We encountered some of these challenges as well as additional ones. We hope that by sharing the "lessons learned" through our experiences we can also help prepare the way for future investigations.

METHODS

General Overview

The recruitment goal for this study was 250 mother-child dyads which, given an estimated loss to follow-up of 20%, would result in 200 dyads completing the study. The sample size of 200 mother-child dyads was selected based upon both the feasibility for longitudinal follow-up and available power afforded by these numbers. For proposed analyses to detect relationships between two quantitative variables from among the measures to be collected, for either mothers or their infants, a sample size of 200 subjects would permit us to detect correlations that are 0.23 or greater in magnitude (positive or negative) with at least 90% power, and correlations that are about 0.20 or greater in magnitude with at least 80% power. We therefore anticipated having high levels of power to detect even relatively modest correlations, e.g., between the number of carious surfaces at the end of follow-up and variables reflecting such quantities as microbial burden and dietary intake measures. This sample size therefore assured adequate power to discern key associations of interest. (In reality, power was actually greater, since attrition was considerably less than anticipated, as seen in Table 1.)

Table 1. Participation and Retention of Subjects

Visit	N	Cumulative Exams	Retention	Target Age in Months	Mean	Med.	Min. Age in Months	Max. Age in Months	Within window +/- 1 month	Within +/- 35 days of target	Within +/- 45 days of target
1	239	239	100.00%	1	0.94	0.66	0.00	4.41	89.96%	92.47%	95.40%
2	233	472	97.49%	4	3.89	3.85	2.30	5.66	92.27%	95.28%	97.85%
3	233	705	97.49%	8	7.84	7.80	5.53	9.41	90.99%	94.42%	99.14%
4	235	940	98.33%	12	11.65	11.51	10.56	13.13	94.89%	98.30%	100.00%
5	232	1172	97.07%	16	15.43	15.33	14.08	17.07	91.38%	99.57%	99.57%
6	234	1406	97.91%	22	21.23	21.12	20.23	23.03	80.77%	99.15%	99.15%
7	227	1633	94.98%	29	28.26	28.16	27.11	31.81	87.22%	99.12%	99.12%
8	229	1862	95.82%	36	35.41	35.23	34.14	43.46	88.21%	95.63%	98.25%

Mother-child dyads were enrolled in the SMILES Study when the child was approximately 1 month old. Mothers were eligible for the study if they had a biological child 0-60 days old, lived with their child at the baseline visit, were able to provide informed consent, and lived on or near the Pine Ridge Reservation. Mothers that planned on leaving the community before the child was 36 months were excluded.

Between June 2009 and June 2010, we enrolled 239 AI/AN women. When the child was 1 month old (+30 days), the mother-child dyad was enrolled and baseline data were collected including plaque samples from the dyad, a caries exam of the mother, plus detailed information regarding childcare, feeding practices, maternal nutrition, child nutrition, oral hygiene, and other caries-related variables. If someone living in the home, other than the mother, cared for the child 20 or more hours per week we collected plaque samples, dental caries status and basic demographic information from the caregiver.

Our initial design was to have follow-up visits every four months until the children reached 36 months of age. However, due to unforeseen costs and logistical issues with the number of visits across the Reservation, we spread the final visits out and eliminated one. Our final design was follow-up visits were at 4, 8, 12, 16, 22, 29, and 36 months of age, with a window of +30 days allowed for each visit. At each of the follow-up visits we collected plaque from the mother and child. If the child had teeth, the follow-up visit included a dental examination. We collected plaque samples from caregivers other than the biological mothers at the 4, 8, and 12 month visits. We limited the sampling of the caregivers again due to cost and logistical issues. Once scheduled, we did not experience any problems in collecting plaque samples from the caregivers. A research team consisting of a research assistant and dental hygienist collected all information and specimens during in-home or in-office study visits.

Community Recruitment

Prior to the funding of the SMILeS Study, the investigators participated in a three year community-based participatory research (CBPR) project to identify and nurture tribal communities interested in conducting early childhood caries research (NIH/NCMHD, Using CBPR to Improve Oral Health in Northern Plains Indian Children, R24MD001658). One of the tribes that participated in the CBPR project was the Oglala Sioux Tribe (OST) based on the Pine Ridge Reservation in South Dakota. We approached OST and requested a collaborative effort based on four general criteria; our working relationship with the Tribe, an annual birth cohort of

400 or more children, availability of pediatric and general dentists for the provision of dental services to study participants, and a high rate of ECC.

Successfully recruiting AI/AN study participants requires cultural awareness along with an understanding of tribal policies, the Indian Health Service (IHS), tribal health care systems and the IRBs of record. To facilitate the process, our study established a subcontract directly with the Oglala Sioux Tribe. Moreover, two consultants with extensive experience working with and conducting research in tribal communities were hired to help with study implementation. The Tribe, in consultation with the study PI, was responsible for hiring study staff and completing day-to-day study tasks. Study staffs were members of the Tribe, apart from one who was a longtime community member. Having Native personnel on the field team proved to be invaluable, particularly in working closely with the mothers. Having members of their own Tribe coming to their homes appeared to be much more acceptable to participants than utilization of non-native study staff from outside the Reservation. The consultants were the primary liaison between the University and the tribal organizations and worked with the PI in obtaining all levels of approval. Before starting any research study in a tribal community, the support and approval of three different entities is required: the tribal health board or health committee, the tribal council and the IRB of record. The first step is to obtain approval from the tribal health board or committee that is delegated authority by the tribal council to review tribal health issues. Once the tribal health board approved the project, it was forwarded to the tribal council for review and approval. The final step was to obtain approval from the IRB. We obtained approval from two separate IRBs – from the Aberdeen Area IRB, which was the IRB of record, as well as the University of Iowa IRB. Approval from both was required. The Aberdeen Area IRB was the IRB on record overseeing studies within this particular region and the University of Iowa IRB was required since the PI of the study is a faculty member and the parent RO1 grant was awarded to the university. This aspect of the process was time consuming, both in terms of the development of the formal contract between the Tribe and the University, and because each step of the process generally required at least one in-person presentation by the PI.

Participant Recruitment and Retention

On the Pine Ridge Reservation, IHS is the primary health care provider and most pregnant women receive their prenatal care and deliver at the local IHS hospital. We implemented a multi-pronged recruitment approach that included a media campaign), community presentations, and presentations at prenatal classes and WIC clinics. In addition, women were informed of the study by the maternity support nurses and physicians during their prenatal visits. Initial recruitment was slow, but once the community became aware of the study, recruitment increased and we were able to shorten our recruitment window from 24 to 13 months. Posters were placed in all public meeting places and the native staff had booths setup at all tribal events. Also, word-of-mouth from the staff helped considerably in people becoming aware of our study.

The mean annual per capita income for the Reservation is less than $6,000 and based on previous experience we knew that traditional retention incentives such as birthday cards, newsletters, and small gifts were not sufficient to maintain high-risk families for a three-year period. For this reason, we opted to give monetary incentives. Mother/child dyads received $90 for the first mother/child visit, $35 for each visit two through seven, and $105 for the final visit for a total of $405 per dyad if they completed all visits.

Young families on the reservation move frequently and many do not have telephones, but they can usually be located through family and friends. Because of this, we asked each study

participant to provide contact information for three individuals that we could call if we were unable to contact them. Having a local community member as the recruitment and retention coordinator enabled us to maintain contact with the study participants. Another important aspect of our participant retention efforts is that we gave every participant the option of having the visit completed in their home or at the study's office. Pine Ridge is a very large reservation (nearly 3,500 square miles) and families are spread out over long distances, making travel difficult. By traveling to the participant's home, we reduced participant burden and increased long-term retention.

RESULTS

The SMILeS study has been successful in its implementation. Markers of this success include meeting our recruitment goal and a low number of dropouts and missed visits. We enrolled 239 unique mother-child pairs into the study. The OST team visited these families every 4-7 months, with the vast majority of visits taking place in the participants' homes. Table 1 summarizes participation at each visit and provides the percentages of children that are considered in window for each follow-up visit. As indicated in Table 1, we were quite successful in keeping within the 30-day window at each target age of follow-up and in maintaining participation over the longitudinal course; retention rates exceeded those anticipated at the time of study planning. In Table 2, we show the frequency distribution of categorical maternal demographic variables. Of particular interest was the level of education and family income that was reported, both important characteristics that have been linked to greater susceptibility to ECC (Borges et al., 2012; Finlayson et al., 2007). In Table 3, the frequency distribution for categorical maternal oral health-related variables is shown. These variables were chosen as previous studies have shown that socio-economic status and the level of education appear to be associated with oral health outcomes of children (Borges et al., 2012; Brandao et al., 2006; Congiu et al., 2014; Finlayson et al., 2007; Psoter et al., 2006; Vann et al., 2010). Note the finding that the most common dental visit frequency on the Reservation was that subjects only see a dentist "when they have a problem". Seventeen percent of mothers reported never or rarely in terms of being seen by a dentist.

Table 2. Frequency distribution for categorical maternal demographic variables in an American Indian population

Maternal Descriptive Statistics at Visit 1	**number**	**percent**
Race/ethnicity		
• not American Indian	1	0.42
• American Indian and other	14	5.86
• American Indian only	224	93.72
Highest level of education		
• 8^{th} grade or less	9	3.77
• some high school	98	41.00
• high school diploma/GED	49	20.50
• some college	71	29.71
• 2-year college degree	7	2.93
• 4-year college degree or more	5	2.09

Education in 2 categories		
• high school diploma/GED or lower	156	65.27
• some college or higher	83	34.73
Annual family income		
• $0-$10,000	95	39.75
• $10,001-$20,000	21	8.79
• $20,001-$30,000	26	10.88
• $30,001-$40,000	17	7.11
• $40,001+	11	4.60
• unknown/refused	69	28.87
Income in 2 categories; no unknown/refused		
• $0-$10,000	95	56.21
• $10,001+	74	43.89

Table 3. Frequency distribution for categorical maternal oral health-related variables in an American Indian population

Categorical maternal oral health-related variables	**number**	**percent**
Currently smoke cigarettes		
• no	173	72.69
• yes	65	27.31
Currently chew tobacco		
• no	200	97.56
• yes	5	2.44
Any d_2 surfaces		
• no	28	11.72
• yes	211	88.28
Any $d_2$mfs		
• no	4	1.67
• yes	235	98.33
Toothbrushing frequency		
• >once/day	130	54.62
• once/day	87	36.55
• every few days	18	7.56
• every few weeks	2	0.84
• never	1	0.42
• I don’t have any teeth	0	0
Dental visit frequency		
• > once/year	24	10.08
• once/year	71	29.83
• every few years	28	11.76
• rarely/never been	17	7.14
• when I have a problem	98	41.18

DISCUSSION

We were very successful in conducting this study even though we experienced many issues and challenges. We were able to attain recruitment, retention and data collection goals in a complex field study involving dietary assessments, behavioral assessments, oral health exams of the mothers and children, and taking/processing multiple plaque samples for shipment. Moreover, we were able to keep track and maintain contact with our cohort spread across a large Reservation. Below we address the challenges we encountered and how we dealt with them.

Specific Challenges

The first major challenge was to establish a sub-contract to support the work of the field team. We were the first University to establish a research contract directly with the Tribe; therefore no precedent existed. Steps in the establishment of this contract included multiple in-person meetings with tribal leadership to discuss terms of this contract and develop a protocol invoicing and fund transfers. Negotiations on the indirect cost rate and other aspects of the contract were lengthy. We had to recognize the importance of autonomy and involvement in decision making if we were to be successful in directly partnering with the Tribe. Moreover, the importance of face-to-face meetings cannot be underscored when working with American Indian Tribes. Abiding by their salary structures, classification of employees, and timelines for interviewing and hiring the field team staff created a strong sense of partnership.

Coinciding with this was submission of the research protocol and human subjects' information to the Aberdeen Area (IRB, the Iowa IRB, and the OST Research Review Board. While not necessarily problematic, it was a challenge to deal with three entities and to ensure all was in order per their different submission formats and regulations. Submission to the Iowa IRB was entirely web-based whereas at the time, submission to the Aberdeen Area IRB and the Tribal Research Review Board was mostly paper-based. In addition, the Tribal Research Review Board required the PI to be present at the meeting when our proposed research study was being discussed. As part of the contract agreement, all potential publications and presentations had to be approved by this Research Review Board prior to them being submitted. A component of that is the Tribe would decide the level of their identification. This was in line with learning cultural sensitivity issues and acting accordingly in good faith.

Following the establishment of the sub-contract and approval from the IRBs, the next important steps were to assemble the field team. As part of the agreement, all staff members would be Tribal members and hiring would be based on Tribal policies and procedures. Advertisement and interviews comprised a lengthy and involved process, with the study PI participated in interviews via conference call. Staff were eventually hired and the research team at Pine Ridge was assembled.

The Tribe provided office space in the old IHS hospital building, which was home to many of the health-associated programs of the Tribe. Upon visiting, we identified a number of infrastructure issues that needed to be resolved before the study could begin. First and foremost, we needed to purchase new computers and a printer for the office, and obtain internet service for the team. This was of paramount importance for recruitment, scheduling, and communication with the Iowa personnel. We also purchased cell phones for the team as they would be traveling over the Reservation and needed to be able to communicate with other team members.

Later in the study, a major infrastructure issue developed. The building where the OST team had their field office was condemned and scheduled for demolition. We were given short-

notice, which meant that the entire operation had to move to a new, undetermined location in a short period of time. The Tribe did not have additional space; therefore, the study director was instructed to find new office space for the study. Upon finding potential space, an agreement was reached with the tribe regarding monetary support for costs to be incurred with the new office location, and the move was conducted by the field team. A major lesson learned here. Take nothing for granted about infrastructure at the Tribe. It is imperative that investigators have a clear understanding of what the Tribe can provide in support of an investigation in the early design phase so appropriate items can be addressed in a contract budget.

Another challenge was the process of seeing the mothers and children. We decided that it would be best to meet the majority of the mothers and children in their homes. Most young mothers have limited means of transportation and to ask all of them to come to the field office for visits would have been a major burden. Therefore, the field team traveled considerable distances across the Reservation on a daily basis. Bad weather and road conditions were a consistent issue. We had a number of study subjects who were not home when the field team visited, even though they had confirmed their appointments. We also experienced subjects moving to a new location on the Reservation and not informing us of this change. As with any study, there were missed appointments that had to be rescheduled, which created a complex, ongoing logistical planning that was necessary for us to see all of the subjects within the timeframe of when their visits were due. When one adds in all of these various issues, it is easy to see that the field team faced many challenges throughout the study.

CONCLUSION

Keys to Success

From these experiences, we learned that one MUST carefully determine infrastructure needs before establishing a field study in tribal communities. Most Tribes do not have a research infrastructure and have limited abilities to absorb new study teams into their physical plant. Communication upfront – and a lot of it – face-to-face – is critically important in the successful establishment of a new study. Meeting the Tribal Leadership (and more than just once) is not only important as a sign of respect, it fosters a recognition and level of communication that will help a PI and team in establishing a study.

Having a study director and a dental hygienist that are Native has been a key factor in the success of the study. While we have had some turnover on the field team, each person has been outstanding in the performance of their duties, and our final team is very experienced and quite adept at getting the job done as evidenced by the status of our family visits and low dropout rate. Maintaining regular communication via conference calls and onsite visits with the field team is of paramount importance. In any complex field study, regardless of where it is conducted, there are many issues and things that come up that need to be resolved quickly.

The success of our study began with establishing a good relationship with the Tribe and respecting their rules and operations. Communication has been a key factor, as well as having a Director of the study onsite with a field team under her guidance that showed commitment, perseverance, and excitement about the study. Having this commitment from an outstanding team onsite is of paramount importance for a successful study such as ours**.**

ACKNOWLEDGEMENTS

This study was supported by RO1 DE017736 from the National Institute for Dental and Craniofacial Research.

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