ASSOCATIONS AMONG ORAL HEALTH KNOWLEDGE, LOCUS OF CONTROL, AND PERIODONTAL RISK STATUS

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A thesis submitted to the Faculty of the
Comprehensive Dentistry
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
in partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology

June 2019

Distribution Statement

Distribution A: Public Release.

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2019

ABSTRACT

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Introduction: Patient intervention plays an important role in the management of chronic oral diseases such as periodontal disease. Understanding the dynamics of a person's behavior is a complex area of study that if better understood could result in increased oral health. Oral Health Knowledge (OHK) and Locus of Control (LOC), a predictor for behavior specific health conditions, are two measureable determinants that may affect periodontal risk status. The Survey of Oral Health Knowledge in Adults (SOHKA) was developed to comprehensively assess OHK. To date, no study has been performed to evaluate if LOC and OHK have any effect on periodontal risk status.

Objective: To determine if there is a correlation between LOC, OHK and periodontal risk status in an active duty military population.

Methods: Surveys were completed by 312 participants at the Walter Reed National Military

Medical Center's Primary Care Dental Clinic. The survey had specifically designed questions to determine OHK and LOC specific for oral disease. Dental records for 191 survey respondents were reviewed to determine risk for periodontal disease, which was classified into low (n= 136), moderate (n=39), or high (n=16).

Results: Oral health knowledge was not associated with periodontal risk status ($p>0.05$). There were no differences in number of correct items on the SOHKA by periodontal risk status group ($p>0.05$). Periodontal risk status was associated with 'powerful others' and 'doctors' LOC ($p's<0.05$).

Conclusion: The SOKHA was not associated with periodontal risk status, thus this survey may need additional refinement before use in clinical practice. Moderate and high periodontal risk status were associated with attributing LOC to powerful others and doctors suggesting that participants with higher risk status tend to rely more on the care of their clinicians for oral health needs instead of their own oral self-care activities.

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CHAPTER I: INTRODUCTION

The thought that "the doctor knows best" had been a firmly held belief of both health professionals and the general public through the 20th century. That perception continues to persists, but over the last several decades, it has gradually been changing from a model where the physician will diagnose and treat disease towards a model that promotes prevention as a key component in healthcare. The process of prevention has become a major facet in the delivery of health care, from lifestyle changes that include diet and exercise modification to shifting responsibility of preventative care from the providers to the patients.

In oral health, periodontal disease is a chronic disease that, if left untreated can result in the loss of multiple teeth and even the patient's complete dentition. The American Academy of Periodontology (AAP) describes periodontal disease as the leading cause of tooth loss and may be associated with other chronic diseases such as diabetes (Kiran et al. 2005, Mealey, Oates, and American Academy of 2006), heart disease (Liccardo et al. 2019), and most recently dementia and cognitive impairment (Sung et al. 2019). In an analysis of nationally collected data from the Center for Disease Control and Prevention (CDC), Eke and colleagues found that approximately 47% of adults over the age of 30 have some form of periodontitis (Eke et al. 2012). To successfully treat periodontal disease the patient is expected to be an active participant.

The common habit of brushing and flossing teeth is essential to maintaining periodontal health. The importance of good daily oral health care is magnified for patients diagnosed with periodontitis. Some of the risk factors of periodontal disease may be unavoidable and uncontrollable such as age (Abdellatif and Burt 1987) and genetics (Nibali et al. 2019). Other

modifiable risk factors that will impact periodontal health include diet and bodyweight (Gorman et al. 2012), tobacco use (Leite et al. 2018), and poor daily oral health care (Zimmermann et al. 2015). To better understand the impact of patient choices and behavior, different psychological theories have been developed and studied such as the Health Literacy theory (citation?), Social Cognitive Theory (Bandura 2004), the Transtheoretical Model (Prochaska and DiClemente 1982), and the Health Belief Model (Rosenstock 1974).

The challenge to make the patient part of their own health care provider team is different for each individual. Education and knowledge are areas affecting all patients. Education and knowledge for health matters is known as 'health literacy.' The Patient and Affordable Care Act of 2010, Title V defines health literacy as follows: "The term 'health literacy' means the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services in order to make appropriate health decisions." In a March 2011 publication (Berkman, Sheridan, Donahue, Halpern, Viera, et al. 2011) the Agency for Healthcare Research and Quality linked low health literacy to higher risk of death and more emergency room visits and hospitalizations. With that in mind the pursuit to increase oral health literacy is one direction to follow that could lead to improved oral health status. An Institute of Medicine committee in 2011 identified the following guiding principles for the Human Health Services that will foster growth in this field of dentistry: (1) emphasize disease prevention and oral health promotion; (2) improve oral health literacy and competence; and (3) expand oral health research and improve data collection (Krugman et al. 2011).

Another aspect to investigate that applies to all patients is motivation. If a person's behavior was better understood this could lead to better oral health. This is not a novel concept and has been well studied. Several Health Belief Theories exist with each taking a different

approach to describing how a patient understands and processes information along with their source of motivation in regards to their health. Human behavior is complex and there has been progress in understanding the relationship between health literacy, behavior and general health. There is significantly less information when only oral health is considered. The concept of Locus of Control can be applied to investigate the factors that influence oral health status.

That low health literacy would be associated with more unfavorable outcomes seems to be a logical assumption as was mentioned above by the AHQR. It is unknown if these findings are applicable to oral health; that low oral health literacy will lead to lower oral health. However, within oral health literacy studies, knowledge provides the "weakest relationship" to oral health outcomes (Berkman, Sheridan, Donahue, Halpern, Viera, et al. 2011). This weak relationship may be due to the methods by which oral health knowledge is measured (Sabbahi et al. 2009). Prior studies measuring oral health knowledge either measured attitude, or the questionnaire was not inclusive enough to properly assess knowledge (citation from the CITRO thesis here). A new measure, the Survey of Oral Health Knowledge in Adults (SOHKA) was developed for use in this study. The 28-question SOHKA focuses on specific knowledge of disease prevention and progression. Along with this an 18 question Multidimensional Health Locus of Control (MHLC) specific for oral health was used to assess source of motivation. If we can better understand the interaction between knowledge, motivation, behavior and oral health status, the opportunity to better educate patients exists and can lead to improved oral health.

CHAPTER II: REVIEW OF LITERATURE

Health Literacy is a relatively new construct, one that is evolving and not consistently applied (Berkman et al. 2004). Groups ranging from the AMA to Zarcadoolas have attempted to define health literacy over the past 20 years. The definition developed by Berkman and colleagues (2010) was based on a modification of the Ratzan and Parker 2000 definition and stated, "The degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions." (Berkman, Sheridan, Donahue, Halpern, and Crotty 2011). While the exact meaning of health literacy has been difficult to gain agreement on, the concept has been applied in numerous studies.

With the measurement of health knowledge being a goal, the concept that a higher health literacy rate could translate to improved health knowledge and lead to better general and oral health has been frequently investigated. The opposite result has been seen in China where oral health status, oral health knowledge and behaviors among the village children was poor (Gao et al. 2014). Similarly, Wehmeyer and colleagues found that despite a high level of education among study participants, low levels of oral health literacy (OHL) were found in one-third of the study population seen in a university periodontology clinic. They went on to conclude a lower OHL was associated with more severe periodontal disease among new and referred patients (Wehmeyer et al. 2014). In another study, low oral health literacy, independent of education and

other socioeconomic determinants, was found to be a predictor for poor self-reported oral health (Sistani et al. 2013). An additional study by Baskaradoss found that periodontal status was significantly associated with the OHL scores in 150 patients seen at a university dental clinic. Participants in this study with limited OHL levels had poorer periodontal health (Baskaradoss 2018).

Education is considered to be pivotal for improving health literacy. A study of the effectiveness of oral health education (OHE) found that the frequency of brushing increased significantly from baseline after receiving OHE instruction. This study also noted the education was more effective when supporting materials were available to the group during the study such as information handouts (Eden, Akyildiz, and Sonmez 2019). From the position that healthy practices adopted at an early age are more sustainable, Blaggana and colleagues stated "as school age is the right time when behavior can still be molded, secondary level students would be the appropriate target group to receive the first organized intervention leading towards correct knowledge along with a positive attitude which is essential to bring about change in their oral health behavior." They went on to point out that for improved efficacy the education should take into account various socio-economic and environmental factors (Blaggana et al. 2016).

There is agreement amongst researchers that more and better education is a key component to improving health literacy, oral health knowledge, and oral health. Health literacy is generally agreed upon as a means to find, understand, analyze and use information that will lead to better decision making regarding health. However, there is not much agreement on what type of education is best. The complexity of human behavior doesn't allow a one-size-fits-all approach (Pleasant and Kuruvilla 2008). Attempting to positively influence a patient's behavior requires some understanding of behavioral theory, models that suggest how people respond to

information. The guiding principles found in health behavior models provide useful methods to oral health providers in promoting effective individual patient behaviors.

BEHAVIORAL HEALTH THEORIES

Public health workers in the 1950's began to discuss the importance of individuals taking part in their own health. The Health Belief Model (Rosenstock 1974) was one of the first theories to gain attention. Other theories have since followed and have been applied to various health conditions. Theories often associated with oral health are the Health Belief Model, Locus of Control (Wallston et al. 1976), Social Cognitive Theory (Bandura 2004), Transtheoretical Model (Prochaska and DiClemente 1982), and Theory of Reasoned Action (Madden, Ellen, and Ajzen 1992).

Health Belief Model

First proposed by Hockbaum in the 1950's (Hochbaum 1970), the core principle of the Health Belief Model (HBM) is that individuals with better information will make better health decisions (Hollister and Anema 2004). Hockbaum proposed that having an open mind and being prepared to accept new concepts will lead to a better understanding of self. When individuals have a better understanding of how and why they make decisions, they are able to make health care decisions intelligently, independently, and maturely.

The HBM is composed of stages, where each step in the decision making process is dependent on the previous decision or belief. For example, to achieve good health when faced with a health challenge, an individual must believe they are susceptible to a condition; believe the condition is serious; believe an intervention to resolve the condition exists; and believe they can overcome any barriers using the intervention. In a dental setting the theory could be applied

as follows: the patient believed they are susceptible to periodontal disease, believe that periodontal disease is a serious threat to their oral health; believe that periodontal disease can be treated; and be willing to follow through with the instructions given with the dentist assisting the patient with therapy and support.

Locus of Control

Locus of Control, as a construct framed within health behavior, was developed by Wallston & Wallston in the mid 1970's (Wallston and Wallston 1978). This model focused on the perception of personal control over health issues. Internal locus of control (LOC) occurs when individuals think their personal actions determine their health status. Having an external locus of control means these individuals perceive others in control of health decisions and health status. External sources may be fate, chance, luck, God, or powerful others such as physicians or dentists (Wallston, Stein, and Smith 1994).

If a person has an internal locus of control, that person attributes success to their own efforts and abilities. A person who expects to succeed will be more motivated and more likely to learn. A person with an external locus of control, who attributes success to luck or fate, will be less likely to make the effort needed to learn. People with an external locus of control are more likely to experience anxiety since they believe that they are not in control of their lives (Galvin et al. 2018).

The Locus of Control theory is considered to have a global orientation to health behavior. The scales first introduced have been modified to measure more specific conditions. Wallston (1978) developed the Multidimensional Health Locus of Control scale to provide researchers with the capability to subdivide externals into subgroups and study disease-specific expectancies

utilizing “Form C’ (Wallston, Stein, and Smith 1994). The three dimensions MHLC scale divides locus of control into: (1) internal (IHLC), (2) powerful others (PHLC), and (3) chance (CHLC). Form C further subdivides PHLC into doctors (DHLC) and others (OHLC) as a more specific external expectancy.

Self-Efficacy

Self-efficacy is a construct of Social Cognitive Theory which was developed and proposed by Bandura. This theory states that individuals do not learn or change behavior in a linear fashion. Rather, change takes place bi-directionally; environment, information, and behavior all affect one another. As an individual learns more, behaviors and environment may change, causing more knowledge to be gained, which reinforces behavior and healthy environments. Lapses are a part of the learning process as the individual employs personal choices to develop behaviors consistent with individual choice and lifestyle (Bandura 2001). Self-efficacy is a person’s belief that s/he has the capacity to execute behavior needed to attain a goal (Bandura 1977).

Theory of Reasoned Action

The importance of attitudes and intentions in changing behavior are stressed in the Theory of Reasoned Action (Fishbein and Ajzen 1977). According to this theory, the most important determinant of behavior is intention. People make rational decisions based on their knowledge, personal values and attitudes. Therefore, a person’s intent to perform a certain action is the most immediate and relevant predictor of carrying out that action. Behavioral beliefs and normative beliefs are two kinds of beliefs that shape intentions (Montano and Kasprzyk 2015).

Chapter III: MATERIALS AND METHODS

Methodology

This study involved participants completing a questionnaire to determine the level of their knowledge of oral health using a Survey of Oral Health Knowledge (SOHKA) and correlating that information with (1) their self-reported oral health-related behaviors, (2) their recent history of periodontal disease, and (3) their current risk of periodontal disease. The US Navy Bureau of Medicine and Surgery Instruction 6600.16a (Oral Disease and Risk Management Protocols in the Navy Medical Healthcare System, Appendix A) was the basis for determining a subject's individual risk status for periodontal disease.

The questionnaire also inquired on subject's health locus of control and correlated this with (1) their level of oral health knowledge, (2) their oral health-related behaviors, (3) their recent history of periodontal disease, and (4) their current risk of periodontal disease.

This study is the completion of Phase I of a planned two phase study. The first phase is a pilot testing of the SOHKA to test the reliability and validity. The second phase is looking to psychometrically validate the SOHKA. The first phase involvee 312 participants. In the first part of Phase I, 201 volunteers were interviewed. In current report, an additional 111 participants were recruited to complete Phase I data collection.

Participants were selected from the Primary Care Dental Clinic (PCDC) when they came in for their annual dental exam. The participants completed a 15 question survey which included demographic and self-reported behaviors (Appendix B), a 28 question (SOHKA) (Appendix C),

and an 18 question Multidimensional Health Locus of Control (MHLC) survey specific for oral health (Appendix D). All three surveys were bundled together. The survey generally took about 20-25 minutes to complete.

Dental records for 89 participants were then examined to determine if any of the surveys accurately predicted current oral health status using the periodontal diseases risk management protocol.

Study Design

In the testing of the SOHKA to determine reliability and validity a total of 312 participants were surveyed to complete the study plan as outlined above. From the 312 surveys collected, 191 participant dental records were reviewed and data collected for disease status/risk. The other participants' surveys were collected for SOHKA and MHLC data. The data was evaluated and the SOHKA survey questions will be reviewed for modification or deletion with possible new questions created prior to entering Phase II.

Participants were invited to participate in this study while they were in the Dental Readiness clinic, awaiting their dental appointments. Potential participants were asked if they might be interested in participating in this study, provided with a description the study and requested to answer all questions. To avoid coercion, surgical scrubs and laboratory coats were worn, rather than military uniforms. Participants were assured that participation in the survey is voluntary, and that declining to participate would, in no way, affect their eligibility for dental care.

Study Population, Inclusion and Exclusion Criteria

The eligibility criteria to participate in this study was that participants be active duty male or female patients of WRNMMC PCDC who had their dental records maintained by this clinic.

a. Inclusion Criteria

1) All male and female military active duty personnel whose dental records are held at WRNMMC PCDC.

2) Participants dental records must contain documentation of at least three annual dental examinations.

b. Exclusion Criteria

1) Participants whose dental records are not held at WRNMMC Primary Care Dentistry.

2) Participants whose dental records do not contain documentation of at least three annual dental examinations.

Sample Size

To complete Phase I (pilot test, the present phase): A sample size of 312 participants completed the SOHKA. The data was collected (the periodontal risk status from the dental record) for 191 subjects that completed the survey.

Phase II will be performed to validate the SOHKA. Interpreting the data from Phase I, the SOHKA questions will be rewritten or eliminated if there were not significant distinctions among the risk status groups. Once the SOHKA is validated, a second group of participants will be surveyed. The sample size is expected to be at least 556 in order to meet the statistical power requirements. This number is expected to include

a high risk status of 50 participants (10% of sample size) and allow for a potential 10% loss rate due to drop outs or incomplete records.

Phase II (SOHKA validation, next phase of study to be completed at a future date): To estimate the minimum number of participants needed to detect an association between survey results and periodontal disease risk (rated as low, moderate, or high), the following distribution of participants in risk categories is assumed based on past clinic experience.

	High Risk	**Moderate Risk**	**Low Risk**
Periodontal	10% (conservative estimate)	60%	30%

A sample size of 85 participants would have 80% power to detect a correlation coefficient of at least r = 0.30 between the SOHKA and risk status, however with a sample of 194 participants statistical power rises to 90%. The outcome category with the fewest number of potential participants is the periodontal high risk category. The expectation is that at least 10% of the sample will fall into this category allowing exploration of multiple factors that may be associated with high risk status. This number will be robust enough to use a logistic regression analysis to test for predictors of high risk of periodontal disease. A properly developed model needs 10-20 participants per predictive variable. A sample of 500 participants would therefore provide 50 high risk participants, allowing the assessment of at least 4-5 independent variables in a multivariate model for periodontal risk.

To allow for dropouts or incomplete medical records (e.g. ~10% loss rate), up to 556 participants will be recruited for Phase II of this protocol (SOHKA validation, next phase of study to be completed at a future date). Based on current clinic caseload, there will be between 40-50

eligible participants per clinic day, and therefore accruing up to 868 participants (312 in Phase I + 556 in Phase II = 868 total participants) is feasible.

Data Analysis Plan

1. For each phase (Phase I and Phase II) of the study, demographic and clinical characteristics of the participants in each Phase will be collected and reported using means with standard deviations, medians with ranges or counts with proportions.

2. Phase I:

a. Data for the MHLC-Form C and SOHKA surveys were examined using binary linear regression; internal consistency was examined using Cronbach's alpha, and the range, mean and standard deviations are presented. Subscales for the SOHKA were explored (i.e. behavioral subscales and knowledge subscales) as well as a total score.

b. The MHLC-Form C survey results were scored for each subject on a scale from 6-36 for each of the three subscales for this survey: the IHLC, the CHLC and the PHLC. The PHLC is further categorized into two subscales scored from 3-18. These subscales for the PHLC are the OHLC and the DHLC. (see Appendix F for scoring methodology). Scores were summarized using means with standard deviations or medians with interquartile ranges.

c. Association of the MHLC-Form C subscales and SOHKA subscales with periodontal disease risk status was explored using analysis of variance.

3. Phase II:

a. The MHLC-Form C and SOHKA surveys will be scored (subscales or a total score for the SOHKA will be determined from Phase I). Descriptive statistics will be generated (mean, median, range) for each score by demographic characteristics (age groups, gender, race, and education), tobacco use, and periodontal disease risk status.

b. Each most recent periodontal risk category (Low, Moderate, High) will be described as follows:

Mean (± SD) and highest PSR sextant score at each annual examination;

Mean (± SD) three-year PSR sextant score and mean (± SD) three-year highest PSR sextant score; PSR scores will be evaluated for missing data and consistency of results after Phase I to determine if this data will continue to be collected in Phase II.

Mean (± SD) MHLC-Form C subscale scores and SOHKA survey scores (total, behavioral subscale and knowledge subscale). Scores in the three risk groups will be compared using analysis of variance.

Additional outcomes are the number of caries at the current visit and the total number of caries over the past 3 years. These outcomes will be correlated with the 6 questions regarding behavior using Kruskal Wallis analysis of variance.

The demographic and clinical characteristics of the subjects were summarized using measures of frequency. The information about the pattern of missing data for Locus of Control and SOHKA questionnaire were provided. Measures of frequencies were used to summarize the

answers to the SOHKA and Locus of Control questionnaire, as well as the correct/incorrect answers to SOHKA questionnaire. The association of Locus of Control subscales and SOHKA total correct score was explored using Spearman rank correlation. The association of the Locus of Control subscales and correct/incorrect answers to SOHKA questionnaire with periodontal disease risk status was explored using Wilcoxon rank-sum test and Fisher's exact tests. Statistical levels were set as alpha = 0.05. All statistical analyses were completed using SPSS Version 24 (IBM, Inc.) and R Studio Version 1.1.383 (R Foundation for Statistical Programming).

Study Limitations: Given the fixed order of the surveys, it is possible that the last survey may have less complete responses. Also, generalizability of this research is limited based on the specific characteristics of the study population**.**

CHAPTER IV: RESULTS

Study participants completed 312 surveys and 191 dental records were reviewed. The study population consisted of 210 males and 102 females. The largest group of surveys came from the enlisted ranks of E4-E6 (n=123, 39%) and officer ranks O1-O3 (n=87, 28%). Overall, there were 173 enlisted (55%) and 138 officers (45%) that completed the survey. The grouping of ages 25-39 made up 65% (n=204) of the collected surveys. Only 38 (12%) of participants currently used tobacco products, while 54 (17%) reported being former tobacco users, and 218 (70%) reported no history of tobacco use. Brushing and flossing behavior for the entire study sample is shown in Table 1.

Table 1

	<1 time per week	1-2 times per week	Most days but not everyday	At least 1 time per day	More than 1 time per day
How often do you brush your teeth?	0 (0%)	2 (1%)	13 (4%)	115 (37%)	180 (58%)
How often do you floss your teeth?	74 (24%)	76 (24%)	86 (27%)	68 (22%)	5 (2%)

Upon record review, 136 participants were categorized as low periodontal risk while 55 participants were categorized as moderate or high periodontal risk. In general there was no differences in oral health knowledge between the high and low periodontal risk patients as measured by the SOHKA. The mean score for the low periodontal risk group (n=136) was 19.6 questions answered correctly with a mean of 8.4 incorrect answers, whereas the moderate/high caries risk group (n=55) had a mean 19.6 correct answers and 8.4 mean incorrect answers.

(Asymptomatic Wilcoxon Rank Sum Test for correct questions: 3859, p=0.730; Asymptomatic Wilcoxon Rank Sum Test for incorrect questions: 4087.5, p=0.804).

The scores on the Locus of Control subscales are shown in Table 2 for all participants and for the participants in the periodontal risk groups.

Table 2

	Full Study Sample (n=312)	Periodontal Group only (n=191)
MHLC_Internal	29.08 (5.5)	28.88 (5.5)
MHLC_Chance	10.58 (4.8)	10.66 (4.8)
MHLC_Powerful	23.41 (4.0)	23.29 (3.7)
MHLC_Doctors	15.87 (2.6)	15.83 (2.4)
MHLC_OtherPeople	7.53 (3.2)	7.45 (3.0)

Means and (Standard Deviations) are shown.

To determine if there were any significant differences in Locus of Control subscales between the periodontal risk groups, a Wilcoxon Rank Sum Test was completed for each subscale. These results are shown in Table 3

Table 3

	Low Periodontal Risk Group (n=136)	Mod/High Periodontal Risk (n=55)	W	p
MHLC_Internal	28.95 (5.3)	28.72 (6.0)	3645.5	0.8706
MHLC_Chance	10.51 (4.7)	11.04 (4.9)	3421.0	0.6647
MHLC_Powerful	23.05 (3.5)	23.89 (4.1)	2892.0	0.03629
MHLC_Doctors	15.76 (2.3)	16.00 (2.8)	2863.5	0.02636
MHLC_OtherPeople	7.29 (2.9)	7.87 (3.2)	3199.5	0.2402

Means and (Standard Deviations) are shown. W: Wilcoxon Rank Sum Test statistical value.

As can be seen in Table 3, the two groups were significantly different on the Powerful Others subscale and the Doctors subscale with participants in the moderate/high periodontal risk group scoring higher on these subscales. There were no statically significant differences among previous or current tobacco users and periodontal risk group (Chi-square = 2.048, p=0.152).

CHAPTER V: DISCUSSION

Periodontal disease is prevalent in both the military population and the general population. The correlation between smoking and a higher risk status for periodontal disease was noted in this and previous studies. This message appears to be understood by a large percentage of our study population with 94% of all respondents making this link. There has been a prolonged public information campaign that smoking is harmful to your health for over 30 years and to have 94% of respondents make that connection is a positive sign that information is being received and processed. We were not able to determine if this knowledge provided enough motivation or established a cause and effect relationship to get people to change their behavior and stop smoking.

There was no association with the SOHKA and an increase periodontal risk status. There was similarity in most responses from all the groups on most of the SOHKA questions which precluded making any association between the patient's response and their periodontal risk status. There were 6 questions where 90% or more of all groups responded similarly. There were also 2 questions where less than 25% of the participants answered correctly. These results suggest that the current SOHKA is not a reliable indicator of risk status and may need to be modified.

One result of this study indicated that a statistically significant indicator of periodontal risk status could be made for individuals who had an External Locus of Control. Those individuals influenced by Powerful Others or Doctors were more likely to be associated with a higher periodontal risk status. Powerful Others and Doctors are subsets of External Locus of Control and are indicators that participants with these beliefs feel their oral health is determined by someone other than themselves, such as the dentist.

Although there was not a significant statistical difference between the high and low risk status groups, a trend was noted where lower risk participants had a slightly higher level of oral health knowledge.

CHAPTER VI: CONCLUSION

There is a great effort being made to address oral health issues in the general and military populations. Part of the solution to improve oral health is to recruit the patient as part of the care giving team. To educate the patient effectively and motivate the patient sufficiently, health belief models have been researched and developed. Further research into these theories may provide more effective methods of educating and motivating patients to alter their behavior toward more positive oral health habits which translate to better oral health.

The attempt made here to associate Locus of Control, Oral Health Knowledge and Periodontal Risk Status provided some evidence that subject's with an External Locus of Control associated with Powerful Others and Doctors are at a higher risk status for periodontal disease. This is an indicator that the message the oral health care profession and care takers promote can have direct consequences on patient behavior.

At this time additional research is necessary to further refine the survey and elucidate the link between oral health knowledge, locus of control, and periodontal health status.

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APPENDIX A: BUMED INSTRUCTION 6600.16A-Caries/Periodontal Risk

DENTAL CARIES RISK MANAGEMENT PROTOCOL

1. A Caries Risk Assessment will be performed on all active duty dental patients during the annual and periodic oral examination and recorded on the NAVMED 6600/13 Oral Exam. Patients will be classified as low, moderate, or high risk for future caries experience per the following Tri-Service criteria:

a. Low Caries Risk patients exhibit the following (must satisfy all criteria below):

(1) No new incipient or cavitated primary or secondary carious lesions during current exam.

(2) No factors that may increase caries risk. Factors increasing risk of developing caries may include, but are not limited to:

(a) Poor oral hygiene.

(b) Cariogenic diet.

(c) Presence of exposed root surfaces.

(d) Enamel defects or genetic abnormality of teeth.

(e) Many multisurface restorations.

(f) Restoration overhangs or open margins.

(g) Active orthodontic treatment.

(h) High titers of Cariogenic bacteria.

(i) Chemotherapy or radiation therapy.

(j) Eating disorders.

(k) Physical or mental disability with inability or unavailability of performing proper oral health care.

(l) Suboptimal fluoride exposure.

b. Moderate Caries Risk patients exhibit the following (demonstration of any single criterion necessitates an assessment of Moderate Caries Risk):

(1) One or two new incipient or cavitated primary or secondary carious lesions during current exam.

(2) No incipient or cavitated primary or secondary carious lesions during current exam but presence of at least one factor that may increase caries risk as outlined in paragraphs 1a(2)(athrough 1a(2)(l) above.

c. High Caries Risk patients exhibit the following (demonstration of any single criterion necessitates an assessment of High Caries Risk):

(1) Three or more new incipient or cavitated primary or secondary carious lesions during current exam.

(2) Presence of multiple factors that may increase caries risk as outlined in paragraphs 1a(2)(a) through 1a(2)(l) above.

(3) Xerostomia (medication-, radiation- or disease-induced).

2. Determination of caries risk classification will prompt treatment protocols specific to the risk category. Required educational and treatment protocols for each caries risk category are summarized in the following table on the next page, and must be uniformly implemented throughout Navy Dentistry.

CARIES RISK MANAGEMENT PROTOCOL FOR NAVY DENTISTRY

Low Caries Risk	Moderate Caries Risk	High Caries Risk
1. Oral hygiene Instruction. 2. Fluoride Dentifrice.	1. Oral hygiene instruction and oral disease education using this instruction, enclosure (7) as an outline. 2. Fluoride dentifrice. 3. Caries elimination a. Sealants for pits and fissures judged at risk. b. Incipient caries remineralization. 4. Identification of patient specific dietary modification (nutritional counseling). 5. Professional topical fluoride treatment (at 6 month interval); may be accomplished concurrently with restorative treatment). 6. Home fluoride rinses (OTC) or home fluoride treatments using prescription dentifrices, gels or pre-fabricated trays. 7. Discuss benefits of Xylitol chewing gum and provide a sample if available.	1. Oral hygiene instruction and oral disease education using this instruction, enclosure (7) as an outline. 2. Fluoride dentifrice. 3. Caries elimination a. Sealants for pits and fissures judged at risk. b. Incipient caries remineralization. 4. Identification of patient specific dietary modification (nutritional counseling). 5. Professional topical fluoride treatment (four applications over 6-12 months; may be accomplished concurrently with restorative treatment). 6. Home fluoride rinses (OTC) or home fluoride treatments using prescription dentifrices/gels or pre-fabricated trays. 7. Discuss benefits of Xylitol chewing gum and provide a sample if available. 8. Antibacterial mouth rinses. 9. Bacterial testing (if available). 10. Evaluation of salivary flow.
One Year Recall	6-12 Month Recall	3-Month Recall

PERIODONTAL DISEASES RISK MANAGEMENT PROTOCOL

1. A Periodontal Disease Risk Evaluation will be performed on all active duty dental patients during the annual or periodic oral examination and recorded on the NAVMED 6600/13. Patients will be classified as low, moderate, or high risk for development of periodontal disease per the following risk factors:

a. Periodontal Screening and Recording (PSR) Score. Among clinical parameters, probing depths of 3.5 mm or more (PSR 3 or 4) may be predictive of subsequent attachment loss. Therefore, PSR scores are the primary indicator of future periodontal diseases risk.

b. Tobacco Use. Smokers are four to five times more likely to have periodontal diseases than non-smokers. Spit tobacco use (sometimes referred to as smokeless tobacco) increases the risk of localized gingival recession, caries, and oral cancer.

c. Genetic Susceptibility. Assessed by asking the patient if any of his or her immediate family have lost teeth at an early age, have had treatment for periodontal disease, or has a history of diabetes.

d. Oral Hygiene. Inadequate oral hygiene is predictive of gingivitis and mild to moderate chronic periodontitis.

e. Past history of periodontal treatment.

2. Determination of periodontal risk classification will prompt treatment protocols specific to the risk category. Required educational and treatment protocols for each

periodontal risk category are summarized in the table below, and must be uniformly implemented throughout Navy Dentistry.

PERIODONTAL DISEASES RISK MANAGEMENT PROTOCOL

LOW PERIO RISK	MODERATE PERIO RISK	HIGH PERIO RISK
• *PSR 0, 1, or 2*	• *PSR 3* • Less than two additional risk factors.	• *PSR 4* • *PSR 3* (Plus any two of the following) - Tobacco user. - Inadequate oral hygiene. - Family history of tooth loss or diabetes. - Past history of periodontal treatment.
RISK MANAGEMENT	**RISK MANAGEMENT**	**RISK MANAGEMENT**
• Annual exam by general dentist and prophylaxis as needed by trained auxiliary.	• Annual exam by a general dentist and prophylaxis by a dental hygienist. • Recall based on individual patient needs. • Evaluation and discussion of periodontal disease risk factors.	• Referral for comprehensive exam by a periodontist or equivalent and prophylaxis by a dental hygienist. • Recall based on individual patient needs. • Evaluation and discussion of perio-dontal disease risk factors.

DEMOGRAPHIC AND BEHAVIOR QUESTIONS

1) Currently Active Duty?
    a. Yes
    b. No

2) Continuously Active Duty for the past 36 months or longer?
    a. Yes
    b. No

3) Branch of service:
    a. Army
    b. Navy
    c. Air Force
    d. Marines
    e. Coast Guard
    f. Public Health Service
    g. National Guard
    h. N/A

4) Rank (or final rank if retired)
    a. E1-E3
    b. E4-E6
    c. E7-E10
    d. O1-O3
    e. O4-O6
    f. O7-O10
    g. Non military

5) Age:
    a. 16-18
    b. 19-24
    c. 25-39
    d. 40-49
    e. 50-64
    f. 65 and older

6) Educational level:
    a. Less than high school
    b. Some high school
    c. High school graduate
    d. GED or high school equivalency

e. Some college, less than 2 years
f. Associates degree
g. Some college, 2 or more years, no degree
h. Bachelors degree
i. Some postgraduate training, no degree
j. Postgraduate degree

7) Gender:
   a. Male
   b. Female

8) What is your race/ethnicity? Please choose one or more a.
   a. White
   b. Black or African-American
   c. Hispanic or Latino
   d. Asian
   e. Native Hawaiian or other Pacific Islander
   f. American Indian or Alaska Native
   g. Other

9) Reason for today's visit:
   a. Annual exam
   b. Hygiene appointment
   c. Dental filling or other dental procedure appointment
   d. Walk-in or sick call

10) How often do you brush your teeth?
   a. Less than 1 time per week
   b. 1-2 times per week
   c. Most days but not everyday
   d. At least 1 time every day
   e. More than 1 time every day

11) How often do you floss your teeth?
   a. Less than 1 time per week
   b. 1-2 times per week
   c. Most days but not everyday
   d. At least 1 time every day
   e. More than 1 time every day

12) Do you use tobacco products?
   a. Yes. I smoke cigarettes or cigars or a pipe
   b. Yes. I use smokeless tobacco
   c. No. I quit using tobacco products more than 3 months ago
   d. No. I quit using tobacco products less than 3 months ago
   e. No. I have never been a regular user or tobacco products

13) How often do you drink regular soda or eat sugary snacks between meals?
   a. Less than 1 time per week
   b. 1-2 times per week
   c. Most days but not everyday

d. At least 1 time every day
e. More than 1 time every day

14) Is your dental knowledge today greater than it was 3 years ago?
a. Yes
b. No
c. I don't know

15) Is your oral hygiene better that it was 3 years ago?
a. Yes
b. No
c. I don't know

SOHKA QUESTIONNAIRE

SURVEY OF ORAL HEALTH KNOWLEDGE IN ADULTS

The following survey is designed to help us understand what people know about their dental health.

All of the questions are true and false or multiple-choice. Please answer all questions and it is appropriate to answer with the choice "I don't know".

16) Bacteria that cause dental cavities can be spread from mother to child through contact with the mother's saliva by sharing food or kissing.
a. True
b. False
c. I don't know

17) Stimulating saliva flow protects your teeth.
a. True
b. False
c. I don't know

18) Snacks that are low in carbohydrates are less likely to cause dental cavities.
a. True

b. False
c. I don't know

19) Snacks like carrots and apples are as likely to cause dental cavities as snacks such as cake and cookies.
a. True
b. False
c. I don't know

20) Dry mouth, a side effect of many medications and chronic diseases, is a factor in developing dental cavities.
a. True
b. False
c. I don't know

21) Carbonated beverages that do not contain sugar (like Diet Coke) have no effect on teeth.
a. True
b. False
c. I don't know

22) Which of the following does not cause dental cavities?
a. table sugar
b. fruit juice
c. milk
d. artificial sweetener
e. corn syrup
f. I don't know

23) Dental cavities usually grow beneath the surface of the teeth before becoming a hole on the surface.
a. True
b. False
c. I don't know

24) Dental caries refers to
a. The decay (carious) process
b. The lesion that results from the decay process
c. both a and b
d. neither a and b
e. I don't know

25) Which of the following practices most increases your risk of getting dental cavities?
a. Sipping from a sugary soft drink all afternoon

b. Drinking a sugary soft drink at a meal
c. Both practices are equally risky
d. I don't know

26) Drinking tap water containing _____ may protect your teeth from getting dental cavities.
a. Fluoride
b. Iron
c. Vitamin C
d. Vitamin D
e. I don't know

27) Dental sealants prevent:
a. food particles from getting in between the teeth
b. teeth from getting stained
c. gum disease
d. dental cavities
e. I don't know

28) The ideal time to get dental sealants is:
a. When baby teeth first appear in the mouth
b. When enamel on permanent teeth is fully visible above the gum line
c. When enamel on permanent teeth has been visible above the gum line for 3-5 year
d. I don't know

29) Tooth brushing reduces dental cavities by breaking up plaque above the gum line.
a. True
b. False
c. I don't know

30) Tooth brushing with more force is a good practice because it leaves the teeth cleaner.
a. True
b. False
c. I don't know

31) Flossing controls gum disease by breaking up plaque below the gum line.
a. True
b. False
c. I don't know

32) If flossing makes your gums bleed, you should not floss.
a. True
b. False
c. I don't know

33) The same kind of plaque that causes dental cavities causes gum disease.
a. True
b. False
c. I don't know

34) Smoking tobacco affects oral cancer but not gum disease.
a. True
b. False
c. I don't know

35) Smokeless tobacco has no effect on gum disease or dental cavities.
a. True
b. False
c. I don't know

36) Gum disease may make it more difficult for a diabetic patient to control their blood sugar.
a. True
b. False
c. I don't know

37) Gum disease may be more severe in people with poor nutrition.
a. True
b. False
c. I don't know

38) Some orally transmitted viruses may cause oral cancer.
a. True
b. False
c. I don't know

39) Stress may contribute to dental disease and mouth sores.
a. True
b. False
c. I don't know

40) Expert tooth brushing is enough to prevent dental cavities and gum disease.
a. True
b. False
c. I don't know

41) Skin replaces itself every 30 days. Soft tissue covering the inside the mouth replaces itself in 15 days.
a. Both statements are true
b. The first statement is true, the second statement is false
c. The first statement is false, the second statement is true
d. Both statements are false
e. I don't know

42) Sinus congestion can cause toothaches.
a. True
b. False
c. I don't know

43) Jaw muscle pain can cause toothaches.
a. True
b. False
c. I don't know

MHLC FORM C-ORAL HEALH QUESTIONNAIRE

Instructions: Each item below is a belief statement about your health condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to select the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you select. The more you disagree with a statement, the lower will be the number you select. Please make sure that you answer **EVERY ITEM** and that you select **ONLY ONE** number per item. This is a measure of your personal beliefs; there are no right or wrong answers.

Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
1	2	3	4	5	6

Score 1-6

44	If my oral health worsens, it is my own behavior, which determines how soon I will get better again.	

45	As to my condition, what will be, will be.	
46	If I see my dental professional regularly, I am less likely to have problems with my oral health	
47	Most things that affect my oral health happen to me by chance.	
48	Whenever my oral health worsens, I should consult a dentally trained professional.	
49	I am directly responsible for my oral health getting better or worse.	
50	Other people play a big role in whether my oral health improves, stays the same, or gets worse.	
51	Whatever goes wrong with my oral health is my own fault.	
52	Luck plays a big part in determining how my oral health improves.	
		Score 1-6
53	In order for my oral health to improve, it is up to other people to see that the right things happen.	
54	Whatever improvement occurs with my oral health is largely a matter of good fortune.	
55	The main thing, which affects my oral health, is what I myself do.	
56	I deserve the credit when my oral health improves and the blame when it gets worse.	
57	Following dentist's orders to the letter is the best way to keep my oral health from getting any worse.	
58	If my oral health worsens, it's a matter of fate.	
59	If I am lucky, my oral health will get better.	
60	If my oral health takes a turn for the worse, it is because I have not been taking proper care of myself.	

61	The type of help I receive from other people determines how soon my oral health improves.	

APPENDIX G: INFORMED CONSENT

WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Research Study Entitled:
Correlations between Oral Health Knowledge, Locus of Control, and Oral Health Status

Principal Investigator: CAPT Andrew J. Avillo, DC USN
Comprehensive Dentistry Department
andrew.j.avillo2.mil@mail.mil

Study site: X WRNMMC, __ FBCH, __USUHS, ___WRAIR, ___NMRC, ___JPC, ___OTHER

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you are active duty military and have had at least 3 annual dental exams in the military.

Taking part in this study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. Leaving the study will not affect your medical care. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.

If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

2. PURPOSE OF THE STUDY:

The purpose of this study is to explore any associations of oral health knowledge and oral health beliefs with oral health status. In other words, this research will help us learn more about what our patients know about oral health and if our patients think that self- care or professional care is more important for keeping our mouths healthy. To be in this study you must be active duty and have had at least 3 annual dental exams in the military.

Other studies have shown that knowledge and locus of control (how much control over your health you have or think you have) are associated with behavior and potentially oral health status. No studies to date have looked at these factors utilizing an oral health disease specific questionnaire for locus of control.

3. PROCEDURES TO BE FOLLOWED:

If you decide to participate, please answer all 61 questions on the Survey of Oral Health Knowledge in Adults, the Locus of Control survey plus some questions on gender, age, education, rank, time in the military, etc. It takes about 20 minutes to answer all 61 questions on the computer or paper copy survey.

Please do not ask other people for answers, or look up answers on your portable devices or share the questions with friends and colleagues. For this survey to benefit everyone, we need to know the baseline knowledge people have about these questions and not have anybody complete the survey twice.

After the survey, we will look in your dental record for information about your past dental cavity and gum disease experience. That is why at the end of the consent we ask you for your name and last 4 digits of your social security number. This information will be matched with your study ID number on a master list, and then it will be removed from your consent document that the investigators keep. After the cavity and gum disease information is collected, your name and last 4 digits of your social security number will be saved on the master list until all participant data has been collected. Then the master list will be destroyed.

You can elect to only complete the survey and not have your dental decay and gum disease risks assessed in your dental record. Your participation in the research will be finished following completion of the online or paper copy survey.

4. ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study (completing the questionnaire) is your alternative to participating for the study.

5. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

You will be finished with this study following completion of the online survey. After you consent, completing the survey takes about 20 minutes.

6. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

A total of 868 patients will be enrolled in this study. It is only being conducted here at Bethesda.

7. POSSIBLE RISKS AND DISCOMFORTS FROM BEING IN THIS STUDY

There is no known health risk associated with completing the survey. There is a possible privacy risk if master list that links your name and last 4 digits of your social security number were compromised. To prevent this from happening, the list containing this information will be protected by being kept in locked cabinets and on a password protected file on a CAC-enabled computer in the PI's office.

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY:

You may benefit from taking part in this study because your participation may increase your health knowledge. And your answers may help design future dental education programs that could improve dental health, reduce need for treatment, and save money. The information we collect may help us learn about further interventions to prevent and manage patients with dental disease.

However, no benefit can be guaranteed.

9. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the Walter Reed (WRNMMC) Department of Research Programs, the Walter Reed (WRNMMC) Institutional Review Board (IRB), the DoD Higher Level Review, and other government agencies.

These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations

and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your research records may be disclosed outside of WRNMMC, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you lose your right to receive dental care at a military hospital.

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the study investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator, Department of Research Programs, at Walter Reed National Military Medical Center at 301-295-8273.

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the study investigator as soon as possible. By leaving this study

at any time, you in no way risk losing your right to medical care and there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled.

Should you choose to withdraw, you must tell the investigators that you do not want to complete the survey.

15. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you. We are required to advise you how your PHI will be used. This authorization is effective until the end of the research study.

(1) What information will be collected?

For this research study, we will be collecting your name, the date of your enrollment on this study, and the last 4 digits for your social security number in order to retrieve the correct dental record, and match your dental decay and gum disease information (if any) from your dental record and the answers you provide on the survey.

(2) Who may use your PHI within the Military Healthcare System?

The members of the research team will use your PHI to review your dental records to collect information about your oral health status, including your dental decay and gum disease information, if any. Additionally, your PHI may be made available to groups such as the WRNMMC Department of Research programs and the WRNMMC Institutional Review Board.

(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?

No data is expected to be shared.

(**4) What is the purpose for using or disclosing your PHI?**

PHI will be used to collect information about oral health status from your dental records.

(5) How long will the researchers keep your PHI?

The master list, linking your study number and personal identifying information, will be destroyed as soon as data collection is completed. This action de-identifies the data so that it cannot be linked to you. The individual study files will be destroyed 6 years after completion of the study or after the research has been published whatever comes first.

This consent form and HIPAA authorization and individual data files will be maintained for a period of six years after the study is completed and then destroyed.

(6) Can you review your own research information?

You may look at your personal research information at any time before your identifiers are permanently removed from the data.

(7) Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The study information collected prior to this cancellation will be used by the research team. No further data will be collected. If you want to cancel your Authorization, please contact the Principal Investigator in writing:

Andrew J. Avillo
Naval Postgraduate Dental School
Walter Reed National Military Medical Center Building 1, 2nd Deck
8955 Wood Road
Bethesda, MD 20889-5628

(8) What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10) Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775.

Your signature at the end of this document acknowledges that you authorize WRNMMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

16. CONTACTS FOR QUESTIONS ABOUT THE STUDY:

If you have questions about the study, or if you think you have a study-related injury you should contact CAPT Andrew J. Avillo at 301-295-0552 or CDR Ling Ye at 301-295-0565. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at 301-295-8273 or WRNMMC Staff Judge Advocate Office at 301-295-2215.

A signed copy of this consent form will be given to you.

SIGNATURE OF SUBJECT

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

_____ Yes, I give study team permission to access my dental record to assess my dental decay and gum disease risks. Initial ._____

_____ No, I DO NOT give study team permission to access my dental record to assess my dental decay and gum disease risks. Instead I will only complete the survey. Initial ._____

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____

Printed Name of Subject

_____

Signature of Subject **Date** **Time**

SIGNATURE OF RESEARCH TEAM MEMBER OBTAINING CONSENT

My signature is intended to attest that the information in the consent document and any other information was explained to and apparently understood by the subject that questions and concerns were addressed and that informed consent was freely given.

_____

Printed Name of Person Obtaining Consent **Date (must be same as subject)**

_____

Signature of Person Obtaining Consent **Time**

****

This sentence and the identifiers below will be removed from your consent as soon as the identifiers are entered on the master list.

Study #: _____

Your Name (please print): _____

Last 4: _____