

Patient Satisfaction with Care Provided by Dental Therapists in Minnesota

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Bethany Ann Palmstein

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Christine M. Blue, DHSc, MS, BSDH

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ABSTRACT

Objectives: Patient satisfaction is a commonly used indicator for measuring quality of care within medical and dental facilities. The purpose of this study was to quantify the level of patient satisfaction with care received from dental therapists (DT) in Minnesota.

Methods: Three Minnesota dental clinics employing dental therapists, a private dental practice in Southern rural Minnesota, a Twin Cities urban group practice, and a federally-qualified health center (FQHC) located in St. Paul were recruited to participate in the study. A convenience sample of 116 patients, 18 years or older, who received dental treatment from a DT consented to complete a thirty-two-question paper survey immediately following care.

Results: The level of patient satisfaction was found to be high in the areas of interpersonal skills, convenience, trust, and care quality. The majority of survey participants agreed they are likely to recommend the dental therapist to others.

Conclusions: The results of this study found patients in Minnesota were very satisfied with the care received by a dental therapist.

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SECTION ONE

Introduction

In 2009, Minnesota became the first state in the U.S. to license dental therapists (DTs) and advanced dental therapists (ADTs). (1, 2) Dental therapists were created to expand access to care to the underserved, especially rural populations lacking an adequate dental workforce. Dental therapists provide basic restorative treatment and preventive services, including health education to people of all ages. (Figure 1) A dental therapist may be viewed as analogous to a physician's assistant or nurse practitioner in the medical setting with the scope of practice lying between that of a dental hygienist and a dentist. Blue and Lopez stated, "the clinical effectiveness of nonphysician clinicians has been demonstrated in terms of expanding access to care, quality of care, cost-effectiveness, patient outcomes and patient acceptance and satisfaction." (3) Therefore, the implications of these findings are relevant to the implementation of the role of the dental therapist.

The introduction of dental therapy in Minnesota was surrounded by controversy. Consequently, early research studies focused on the acceptance of DT's by dental students, dental school faculty and dental practitioners. (4-6) Additional studies have described the development of a professional identity among dental therapists themselves. (2, 3) Given dental therapists have only been in the workforce since 2011, only two studies have investigated the role of dental therapists in practice. (1, 7) Early evidence suggests dental therapists are providing a full range of services to patients and expanding access to care in Minnesota. (1, 2, 7) However, lacking in the literature is a formal investigation of patients' satisfaction with the care provided by a dental therapist.

Purpose of the Study

The purpose of this study was to quantify the level of patient satisfaction with care received from a dental therapist in Minnesota.

Statement of the Problem

Patient satisfaction is a commonly used indicator for measuring quality of care within medical and dental facilities. (8, 9) Patient attitudes and opinions concerning treatment received have become a benchmark for organizations seeking to improve their technical, personal and professional services. (8, 9) Patient satisfaction is a reflection of the patient-provider relationship, timelines of care, and perceived health outcomes. (8) Currently, the knowledge of patient satisfaction with care provided by dental therapists in Minnesota has yet to be investigated.

Significance of the Study

Early evidence supports dental therapy is expanding access to care as intended. The Minnesota Department of Health reported dental therapists have improved healthcare by reducing emergency room visits and increased access to care for patients in rural or underserved area. (1) Blue & Kaylor found dental therapists were working full-time and their employers delegated procedures reflecting the full scope of dental therapy practice, indicating dentists have a high trust and acceptance level of dental therapists. (7) However, if dental therapy is to fulfill its goal of expanding care to the underserved, patient satisfaction is a key metric needed for the sustainability of this new profession. (8) The medical literature underscores the relationship between patient satisfaction and the delivery of quality health care. (7) Therefore, the results of this study will inform both

public and professional communities of patients' perceptions and opinions of care received from dental therapists.

Research Question

What is the level of patient satisfaction with care provided by a dental therapist in Minnesota?

Pre-Study Limitations

Because dental practices will be responsible for administering the surveys, there is a potential for selection bias. Selection bias is a limitation, as the study sample obtained may not be representative of the target population.

SECTION TWO

Importance Of Patient Satisfaction In Relation To Quality Of Care

Patient satisfaction is a reflection of the patient-provider relationship, timelines of care, and perceived health outcomes. (8) Patient satisfaction as a quality of care indicator is an important metric for providers for numerous reasons including: patient loyalty, improved patient retention, increased staff morale, risk management, and increased personal and professional satisfaction. (8, 10, 11) Patient satisfaction can also affect business profitability; it is estimated the loss of patients due to their dissatisfaction, can result in the loss of over \$200,000 over the lifetime of a medical practice in the United States. (8) Studies suggest a positive clinical outcome is dependent on compliance, which in turn, is dependent on patient satisfaction (12). Therefore, the latter is considered a legitimate health care goal and therefore a prerequisite of quality care. (12)

The Donabedian Model of Quality of Care suggests quality of care is rooted in three major areas: structure, process and outcomes. (13) The first area, *structure*, is defined as the physical and organizational aspects of care settings. For example, the facilities, equipment, personnel, operational and financial processes supporting medical care. Second, the *process* of patient care sits in the middle of the model, because it relies on the structures to provide resources and mechanisms for participants to carry out patient care activities. *Processes* are performed in order to improve patient health through recovery, functional restoration and survival. Finally, patient satisfaction is considered an *outcome measure* of medical care; referring to the effects of care on the health status of the patient. (10-12) Patient satisfaction is at the heart of patient-centered-care. Boulding et al., found an association between patient perceptions of care and better outcomes. (14)

Patient Satisfaction with Nurse Practitioners and Physician's Assistants

Because the development of dental therapy parallels the development of non-physician clinicians in the medical field, patient satisfaction with care provided by nurse practitioners and physician assistants was a primary focus in the literature search. Current research on patient satisfaction with these health care providers has employed both quantitative and qualitative methods. The majority patient satisfaction studies are descriptive in nature and employed Likert-scale type surveys. (15-23) Pinkerton and Bush used two standardized survey instruments to collect data on patient satisfaction with nurse practitioners: the SF-20 Health Survey and the Nurse Practitioner Satisfaction Instrument. (24) The results of their study found no statistically significant difference in perceived health and satisfaction, whether a nurse practitioner or a primary care physician (MD) provided the care. (22) However, the majority of literature suggests there is a

higher level of patient satisfaction when a nurse practitioner or physician's assistant provided care. (13-21) The high level of satisfaction with NPs was associated with the amount of time spent during appointments. The average time spent with PA's and NP's, is forty-five minutes per appointment, whereas MD visits averaged around twenty-five minutes. (15-23) Patients preferred longer appointment times for various reasons including: more time to ask questions, more individualized preventive care, etc. Roblin et al, found patients' overall perceptions of an appointment experience did not vary among practitioner type, meaning patients felt their care experience was not affected by provider-type. (22) A limitation of Roblin's study was the three-year administration of the survey. The long study period may have resulted multiple survey responses and variations in answers from the same patients due to changing viewpoints.(22)

Dill, Pankow, Erikson and Shipman surveyed patients' opinions of care delivered by a NP and/or PA vs. a physician in an emergency department. Findings revealed study participants were initially less willing to be seen by a PA, NP, and/or resident than by a physician (MD). (17) However, when presented with the scenario of a worsening cough and given a choice between seeing a PA or NP the same day, or a MD the following day, nearly sixty percent of respondents preferred to be seen by a PA or NP the same day, with only twenty-five percent preferring to wait a day to see a physician. (15) This finding was higher among patients who have never visited a PA or NP. (17)

Patient preference for shortened appointment wait-times over the credential of the health care provider is repeatedly demonstrated in the literature. Counselman, Graffeo and Hill found over 95% of patients were satisfied with the care they received from PAs in an emergency department. (25) Of the 111 patients surveyed after care, only 13 patients stated they would prefer to wait longer in the future to see an emergency

physician over a PA. (25) A study of patient satisfaction in a retail health care clinic that employed NPs and/or PAs found over sixty percent of patients preferred a retail health clinic compared to seeing a physician at an urgent care or other clinic. Reasons included: convenient location (61%), no appointment necessary (59%), and shorter wait times (52%).(19) An overwhelming 96% of respondents surveyed stated they experienced no wait times, or less than what they expected, and 95% of all patients indicated that they were very satisfied or satisfied with their treatment by a PA or NP. (19) Ninety-eight percent of all respondents stated that they would return again for their healthcare needs. (19) Only 4% of respondents reported a negative experience. (19)

A plethora of research studies have investigated patient satisfaction with care provided by NP's as compared to care provided by a MD. Stanik-Hutt et al., conducted a systematic review of 27,993 articles published between 1990 and 2009. Data was separated into eleven aggregated outcomes that summarized the *Quality, Safety* and *Effectiveness* of NP's. (26) In addition to summarizing data on current articles, the researchers compared their findings to previous systematic reviews to better qualify findings. On the subject of *quality*, researchers found conclusive evidence demonstrating health outcomes and physical function did not differ regardless of whether cared for by an NP or an MD. (26) The *effectiveness* of NP's was found to be similar; however, the literature was inconclusive on whether NP care was superior to care provided by a MD. Lastly, NP *safety* was the most difficult to measure, as mortality was the only tangible measurement for patient safety noted. (26)

Patient Satisfaction With Dental Therapists

Fifty-four countries have some form of dental therapy, including the United States. Dental therapists are a significant part of the oral care workforce in New Zealand,

Australia, and the United Kingdom. (27) Recent legislation has expanded the number of dental therapists trained in the UK, and allowed DTs to take on more responsibilities in dental practice. (28) Given dental therapists expanded role, Sun, Burnside and Harris investigated whether there were any differences in patient satisfaction after a visit to a therapist compared to a dentist and found that patients seeing dental therapists were found to have a significantly higher level of overall satisfaction. (23) The results showed higher satisfaction levels in the areas of information-communication, understanding-acceptance and technical competence. (21) It is important to note that the response rate for patients of dental therapists was lower than for dentists, and it was not possible to conclude if non-responders were less satisfied. Because the reasons for these findings were unclear, more research is required. (23) General dental practitioners in Great Britain also hold a favorable view of dental therapists. A survey of dentists in 2003 found over 70% of dentists considered a dental therapist to be a valued member of the dental team and expressed they would employ a dental therapist in their practice. (28)

Dental Therapy in the United States

At the time dental therapy was created, the addition of a dental therapist provider was viewed as a means to optimize the skill-mix within a dental team, resulting in improved access and cost effectiveness. Because of the unmet need for dental care, it was hypothesized that dental practices would be able to employ a dental therapist full-time, increase the number of patients seen, and increase access to care in underserved communities. A dentist would be able to take on more complex procedures, as a dental therapist could perform basic restorative and preventive services. Beazoglou et al., found that dentists directly relate a practice's productivity and efficiency to the amount of delegation to allied providers. Based on this study, entrustment of oral health care to

dental therapists would contribute to overall practice efficiency and patient care.(4, 5, 16)

Early evidence appears to support this hypothesis. A 2013 study by the Minnesota Department of Health and the Minnesota Board of Dentistry found nearly one-third of all patients surveyed experienced a reduction in wait times for an appointment and a general decreased amount of travel time, to get to the dental appointment with a dental therapist.

(1) In that same study, two thirds of the dental clinics surveyed reported substantial savings in personnel costs when employing a dental therapist compared to a dentist, as DT salaries are typically half that of a DDS. (1, 7) It should be noted that this study sample was limited to very small numbers of dental therapists (n=32) and patients served (n= 1,382). (1) The clinics employing DT's reported the versatility and flexibility of DT's has led to an overall increase in productivity and that this provider aids in permitting the dentist to focus on more complex procedures. (1, 5)

To inform the study of dental therapy in the US, Blue created a theoretical framework to identify the key factors and variables needed to test these hypotheses. (7) (*Figure 2*). (7) A dentist's acceptance and trust level of a dental therapist was identified as an intervening variable in the literature. As posited by social identity theory, professional culture influences the roles and practice patterns of team members. Given the newness of dental therapists, the culture of a practice setting may influence the optimization of a dental therapist's skill-set. (29) Dentists may not embrace a substitutive skill-mix or lack trust in a DT's skills and unknowingly create boundaries through delegation practices hindering dental therapists from achieving the goals for which the role was created. Similarly, patients' satisfaction with care provided by dental therapists will impact their acceptance in dental practice. Patient satisfaction can affect many

aspects of dental care including quality of care, profitability, acceptance and loyalty.

(29) Additionally, patient satisfaction with care provided by a dental therapist may influence a dentist's decision to employ a dental therapist or may impact the range of procedures delegated to an employed dental therapist. Therefore, patient satisfaction is a key variable in whether dental therapy will achieve the goal for which it was created, and for this reason, it was added to the theoretical framework. Given patient satisfaction with the care provided by dental therapists has yet to be studied in Minnesota, the purpose of this study is to determine the current level of patient satisfaction of dental therapists in Minnesota. The findings of this study will inform both dental education and practice, and ultimately fulfill the goal of increasing access to quality oral health care in Minnesota.

SECTION THREE

MANUSCRIPT

Abstract

Objectives: Patient satisfaction is a commonly used indicator for measuring quality of care within medical and dental facilities. The purpose of this study was to quantify the level of patient satisfaction with care received from dental therapists (DT) in Minnesota.

Methods: Three Minnesota dental clinics employing dental therapists; a private dental practice in Southern rural Minnesota, a Twin Cities urban group practice, and a federally-qualified health center (FQHC) located in St. Paul; were recruited to participate in the study. A convenience sample of 116 patients, 18 years or older, who received dental treatment from a DT consented to complete a thirty-two-question paper survey immediately following care.

Results: The level of patient satisfaction was found to be high in the areas of interpersonal skills, convenience, trust, and care quality. The majority of survey

participants agreed they are likely to recommend the dental therapist to others.

Conclusions: The results of this study found patients in Minnesota were very satisfied with the care received by a dental therapist.

Introduction and Literature Review

At the time dental therapy was introduced in Minnesota, the addition of a mid-level provider was viewed as a means to optimize skill-mix within a dental team resulting in improved access and cost efficiency. A dentist would be able to take on more complex procedures while a dental therapist delivered basic and restorative care. It was hypothesized dental practices would be able to employ a dental therapist full-time, increase the number of patients, mitigate the effect of low reimbursement rates, and therefore, increase access to care in underserved communities. To inform the study of dental therapy in the US, Blue created a theoretical framework to identify the key factors and variables needed to test these hypotheses. (7)

Within the framework, an intervening variable was a dentist's acceptance and trust level of a dental therapist. As posited by social identity theory, professional culture influences the roles and practice patterns of team members. (28) Given the newness of dental therapists, the culture of a practice setting may influence the optimization of a dental therapist's skill-set. (29) Dentists may not embrace a substitutive skill-mix or lack trust in a DT's skills and unknowingly create boundaries through delegation practices hindering dental therapists from achieving the goals for which the role was created.

Similarly, patients' satisfaction with care provided by dental therapists will impact their acceptance in dental practice. Patient satisfaction can affect many aspects of dental care including quality of care, profitability, acceptance and loyalty. Additionally, patient satisfaction with care provided by a dental therapist may influence a dentist's

decision to employ a dental therapist or may impact the range of procedures delegated to an employed dental therapist. Therefore, patient satisfaction is a key variable in whether dental therapy will achieve the goal for which it was created, and for this reason, it was added to the theoretical framework.

Patient satisfaction as a measure of quality of care is important for numerous reasons including: patient loyalty, improved patient retention, increased staff morale, risk management, and increased personal and professional satisfaction. (8, 10, 11) High levels of patient satisfaction resulted in nurse practitioners and physician clinicians becoming an integral part of our health care system. Within Donabedian's theoretical model of quality of care, the addition of a dental therapist is a structural change in oral health care delivery with patient satisfaction is viewed as an *outcome* of care. (11-13) Patient satisfaction is a reflection of the patient/provider relationship, timelines of care, and perceived health outcomes. (8) Studies suggest a positive clinical outcome is dependent on compliance, which in turn, is dependent on patient satisfaction. Therefore, the latter is considered a legitimate health care goal and therefore a prerequisite of quality care. (12)

Early evidence suggests dental therapists are providing a full range of services to patients and expanding access to care in Minnesota. (1, 2, 7) Blue & Kaylor found dentists were "optimizing the skill-set of the DT" as "delegated procedures reflected the full scope of dental therapy practice". (7) This finding suggests dentists appear to have a high trust level of dental therapists. (7) The results of a program evaluation of Alaskan dental health aide therapists (DHATs) revealed the level of patient satisfaction derived from surveys was generally high and did not vary among age groups or location.(30)

Therapists were rated as explaining things clearly, listening carefully, and treating patients with courtesy and respect. (30)

Knowledge of patient satisfaction with care provided by a dental therapist is a quality of care metric needed for this emerging profession. If patient satisfaction with a Minnesota DT is found to be high, it may lead to greater acceptance of this new provider, encourage dentists to hire DTs and facilitate the growth of this profession. Therefore, the purpose of this study is to determine the current level of patient satisfaction with care provided by dental therapists in Minnesota. The findings may inform both dental education and practice and ultimately achieve the goal of improving access to quality oral health care in Minnesota.

Methods and Materials

This design of this quantitative study was descriptive. Survey questions queried patient satisfaction with a dental therapist immediately after patient care. The study took place from January to April 2017.

Subjects

Patients in Minnesota dental offices that employed DTs comprised the study sample. Dental practices were selected from a list of licensed DT's employed in Minnesota. An email about the study and an invitation to participate was sent to dentists in nine dental practices representing various geographic locations throughout Minnesota. Three dental practices agreed to participate in the study.

The first office (office A) is a private practice clinic located in the Southern rural Minnesota town of Montevideo, which is about 140 miles directly west of the Twin Cities metropolitan area. The second office (office B) is a federally qualified health

center (FQHC) in St. Paul, in a large metro/urban area of Minnesota. Third, is office C, which is an urban group private practice with clinics, located in both St. Paul and Savage. (Table 1)

A cover letter providing study information and letter of consent was sent via email to either the clinic manager or the primary dentist in each office. (Appendix A, B and C) Upon receiving participation agreement, one front office staff member in each office was designated as the survey collector (SC). The principal investigator had email and phone correspondence with each SC to review the study's purpose and explain the survey administration protocol. The SC's functions included recruitment, survey distribution, and ensuring secure storage of the surveys. Any questions or concerns about the survey were directed to the PI. A subject recruitment script was provided to the SC to standardize communication (Appendix E).

A convenience sample of 116 patients 18 years or older, who received treatment from a DT at the participating clinics were recruited for research participation. Participants were asked by the SC to complete a paper survey immediately after they completed the appointment with the dental therapist. Surveys were coded for tracking purposes; all patient data were de-identified. No designation or coding was given as to whether an ADT or DT provided treatment. As an incentive to participate, the names of participants were placed in a lottery; at the end of the study one participant from each practice was awarded a \$50 Visa gift card. To be entered into the lottery, participants must have completed the separate and optional contact information portion of the survey. The SC in each participating office was responsible for the lottery and had access to the winner's name.

Instrument

The Nurse Practitioners Satisfaction Survey (NPSS) was used to assess participant satisfaction with care received from a DT. (31) The NPSS was developed using Cox's Interactional Model of Client Health Behavior and has been found to be valid and reliable. (31) The author of the survey reported a high overall reliability with Cronbach's alpha for the factors of general satisfaction (0.98), communication (0.83), and accessibility & convenience (0.76). (31) Participants evaluated statements on a five point Likert-type scale from strongly agree to strongly disagree, or not applicable. Of the twenty-eight questions in the original NPSS, eighteen items were focused on general satisfaction, six on communication, and four on accessibility and convenience (scheduling with preferred provider, scheduling at preferred time), trust and care quality. For the purposes of this study, the survey was modified for the dental environment (Appendix D). Specific modifications added by the principal investigator included professional terminology, additional questions pertaining to patient demographics, office coding, and space for the addition of patients name for lottery entry purposes (optional). Examples of terminology changes included removing all identifying information of 'Nurse Practitioner' and modifying it to read 'Dental Therapist' and adjusting 'health care' to 'dental care'. Lastly, the order of the questions was adjusted slightly to better suit the flow of a dental appointment, and the middle 'Neutral' response option was removed based on recent research on survey validity. The modified instrument consisted of 32 items designed to elicit information about the patient's satisfaction including their perception of the DT's interpersonal skills, convenience, trust and care quality related to dental therapy treatment provided that day.

The modified survey was pilot tested before study implementation in two ways. First, a survey expert from the University of Minnesota served as an initial pilot test to aid in the validity of the modified survey. Second, the survey was distributed to patients receiving treatment from DT students at the University of Minnesota School of Dentistry Dental Clinic. This second method of validation served as a final method of survey modification, as it best related to the research methodology and most approximated the subjects studied. This study was deemed exempt from review by the University of Minnesota Institutional Review Board. (Study #1610E96341)

Data Analysis

Descriptive statistics were used for data analysis. Wilcoxon rank sum tests or Kruskal-Wallis tests were used to compare satisfaction scores between age groups, gender, and education levels. Cronbach coefficient alphas were calculated to assess the internal consistency of the items included in the four types of satisfaction scores. SAS V9.3 (SAS Institute Inc., Cary, NC) was used for the analysis. Statistical significance was determined at the 0.05 level.

Results

Three dental practices representing diverse geographic locations and practice settings in Minnesota participated in the study. Patients (n=116) who received care from a dental therapist in the three dental practices comprised the sample. The characteristics of the participating dental practices are listed in Table 1. The Cronbach coefficient alphas for the themes of interpersonal, convenience, trust, and care quality scores are 0.94, 0.72, 0.69, and 0.87, respectively. These indicate acceptable to excellent reliability and internal consistency among the items included in each theme score.

During the study period, a total number of 116 patients completed a survey after receiving care from a dental therapist. Clinic A had a 53.5% response rate (N=62); clinic B had a 34.5% response rate (N=40); and clinic C, a 12.1% response rate (N=14). Incomplete survey questions were reported as missing data collected for each survey question. The overall survey results can be found in Table 3. Demographic information on participants from all clinics is provided in Table 2. Of the 116 participants, 34.8% were male and 60.9% were female (6 chose not to disclose). The average participant was 35-45 years of age (25%) and of white race (57%). The majority of the patients (N=81) were patients of record and traveled 0-10 minutes to the clinic. These patients had been seen at a dental clinic a median of three times in the past year and had seen a DT for treatment one (26.6%) of those visits. Of the patients who answered that they have a regular dental care provider (N=70), 14.5% stated that provider was a DT, 22.6% a dentist and 32.3% a dental hygienist.

For the purpose of data analyses, survey data were categorized according to four major themes: interpersonal skills (N=5), convenience (N=2), trust (N=4), care quality (N=6) with a final category of overall satisfaction. A breakdown of themes with associated questions can be found in Tables 4 through 7. Patients were highly satisfied with dental therapists' interpersonal skills (3.8/4.0). The option to have an appointment with a dental therapist was reported to be more convenient (3.5/4.0). Patients had a high level of trust in the dental therapist (3.5/4.0) and in the quality of the care they received (3.7/4.0).

Overall satisfaction with care provided by a DT did not vary by gender (mean=3.7) or education level (mean=3.8). Women were slightly more satisfied in relation to the themes of interpersonal skills, convenience, trust, and care quality than

men. The patient age group with the highest degree of satisfaction was the 35-45 year age bracket. (M=3.9) Patients aged 18-25 were the least overall satisfied with care (M=3.3) also ranking lowest in themes of interpersonal skill (M=3.4), convenience (M=3.3) and care quality. (M=3.5)

Patients agreed (94.7%) that the DT spent an adequate amount of time with them and were respectful (94.8%) during their visit. Eighty percent strongly agreed that the dental therapist explained the care to them; including treatment plans and oral health recommendations in way that they could readily understand.

Overall patient satisfaction level was 3.7 out of a maximum of 4.0, with the majority (90.4%) of survey participants agreeing that they are likely to recommend the dental therapist to others.

Discussion

This study sought to quantify the level of patient satisfaction with care received from dental therapists in Minnesota. The study findings indicate patients are highly satisfied with care provided by dental therapists in Minnesota (90.4%). Participants perceived the DT to be professional, knowledgeable and believed dental therapists provided quality care. Participants indicated that they were able to schedule an appointment time that was convenient for them (88.6%) and that they were able to schedule in a timely manner (87%). Similar to findings for nurse practitioners and physicians assistants, (17, 21, 22, 32) , high levels of satisfaction were associated with the interpersonal skills of dental therapists. (15,19,20,30) Participants reported that dental therapists took time to listen and address needs and concerns (94.7%). Patients valued the longer appointments, as it allowed more time for questions and more individualized preventive care. (20) Ninety-one percent reported they could easily talk about their oral

health concerns with the DT. Over eight-four percent of patients stated they would return to the DT in the future with only 4% reporting dissatisfaction.

These results are similar to findings in the PA and NP literature. The finding that good communication is associated with higher patient satisfaction is consistent with previous studies that found a positive association between effective provider–patient communication and health outcomes. (14) According to Donabedian's model of health care quality, improvements in the structure of care should lead to improvements in clinical processes resulting in improved patient outcome (13) . Within Donabedian's model, *process* denotes the transactions between patients and providers throughout the delivery of healthcare. The introduction of a new dental provider was a structural change which, in turn, modified the *process* of oral health care delivery. An improved patient outcome was the opportunity to receive care in a timely manner from a knowledgeable and trusting provider. Participants highly valued their interactions with the dental therapist, and in turn, perceived care received to be of high quality. The high level of patient satisfaction found is an important outcome measure for the future of dental therapy. Positive findings will aid in propelling the profession into the future as a valued and trusted provider to both patients and other healthcare providers. Because these findings help to validate DT's position as an important healthcare provider, oral health and access to care will potentially be improved through trust and acceptance. The more DT's who are employed and attending to the needs of patients throughout the state is necessary in improving access and care to all.

Based on study findings, patient satisfaction does not appear to be significantly influenced by the type of dental provider. In fact, the majority of study participants preferred to see a dental therapist rather than a dentist, however, it is hard to quantify due

to the studies small sample size. Participants' positive experience and acceptance of dental therapists will allow dental therapy to evolve and expand. Study findings suggest patient satisfaction will facilitate the achievement of dental therapy goals as posited by Blue's theoretical framework. If patient perceptions' of care had been found to be negative, it no doubt would hinder the acceptance of dental therapists by patients and dentists.

Although dental therapy is in the early stages of its development, findings suggest dental therapists in Minnesota may follow the path of NP's and other non-physician clinicians and become integral members of the oral health care team. Participants in this study were accepting of this new dental provider. Patient's feel the quality of care provided by the DT's is at the level of DDS. There was agreement that the majority surveyed patients would rather see a dental therapist than a dentist and are likely to schedule a future appointment with the dental therapist. Based on the results of this study, patients' perceptions of dental therapists have the potential to hasten the adoption of dental therapists in other Minnesota practices.

Limitations in this study included a limited number of participating clinics and the small patient sample. Through interviews with participating clinic personnel both during and after the survey period, it was a common for patients not wanting to take the time to complete the survey. The survey was given to patients after treatment was completed and due to a variety of factors either patients did not stay to complete the survey or failed to deliver the completed survey after leaving. The short survey period of four months was also a limiting factor, as a decline in survey distribution was noted in each clinic.

The greatest limitation in this study was in finding clinics and dental therapists themselves willing to participate in the study. Anecdotal information suggests many DT's in Minnesota feel over researched, and there is resistance to participate in research due to fear the findings will have a negative bias. Many individuals, non-profit organizations and insurance companies have contacted DT's throughout the state asking for participation in research of various types, some with negative or hidden agendas. Because of the DT's reluctance to participate in research, this could negatively affect the growth of the profession. Research data is important to analyze the evolution of the dental therapy, specifically the implementation in practice, as research findings facilitate continued improvement in oral health delivery models and reveal issues or barriers to be addressed. Having limited data of dental therapy may prevent dentists from employing DTs and limit funding for expansion of educational programs nationwide. Left with only anecdotal information, people around the country may hear only the loudest voices that may be spreading a negative or false narrative.

Larger longitudinal studies in the area of patient satisfaction are needed in the future. The larger sample size would allow for a better representation of dental therapists and Minnesotans as a whole. Additionally, particular aspects of patient satisfaction that could be studied in greater detail include: health outcomes, care quality, and cost effectiveness.

Conclusion

The results of this study found patients in Minnesota were very satisfied with the care received by a dental therapist. Specifically, patients liked the convenience of scheduling and perceived dental therapists to have good interpersonal skills, and had trust in the quality of care provided.

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SECTION FOUR**Figures and Tables**

Figure 1	Minnesota Dental Therapy Credential and Supervision Requirements, and Scope of Practice
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Table 2	Demographic Information of Participants
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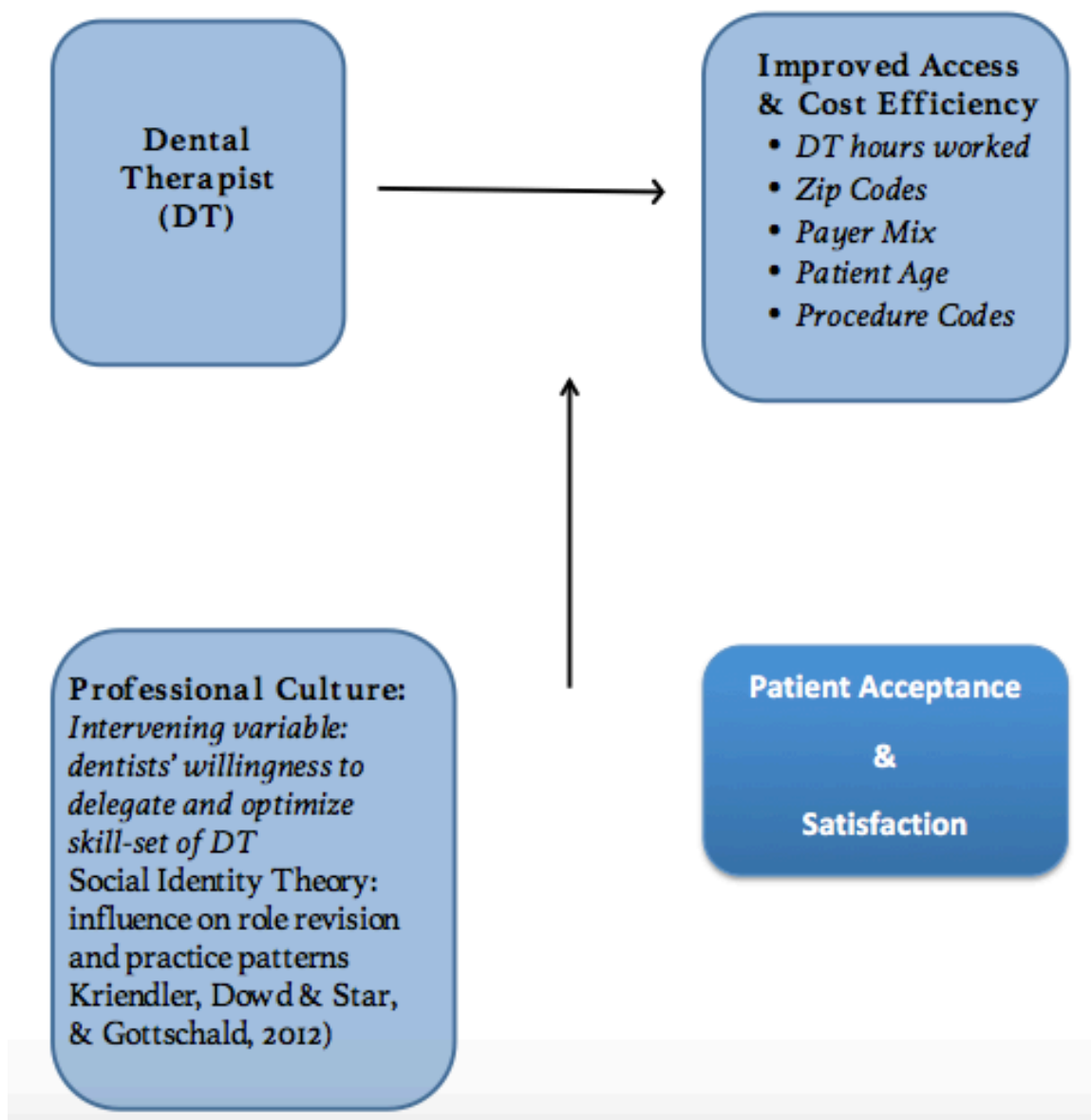
Figure 1 - Minnesota Dental Therapy Credential and Supervision Requirements, and Scope of Practice

	Educational / Credential Requirements	Level of Supervision	Scope of Practice
Dental Therapist	<ul style="list-style-type: none"> • Bachelor's degree in dental therapy • Competency and licensure exam • Jurisprudence examination 	<p>Practices under the supervision of a dentist, with whom they must have a collaborative management agreement. Some DT services can be provided under “indirect supervision” (Dentist is on-site and authorizes procedures) and others under “general supervision” (Dentist is not necessarily on-site during the procedure but does authorize its performance).</p>	<p>A licensed dental therapist may perform the following services under general supervision:</p> <ul style="list-style-type: none"> • Oral health instruction and disease prevention education, including nutritional counseling and dietary analysis • Preliminary charting of the oral cavity • Take radiographs • Mechanical polishing • Application of topical preventive or prophylactic agents, including fluoride varnishes and pit and fissure sealants • Pulp vitality testing • Application of desensitizing medication/resin • Fabrication of athletic mouthguards • Placement of temporary restorations • Fabrication of soft occlusal guards • Tissue conditioning and soft reline • Atraumatic restorative therapy • Dressing changes; • Tooth reimplantation • Administration of local anesthetic and administration of nitrous oxide. • Dispense and administer analgesics, anti-inflammatories, and antibiotics as permitted by the collaborative management agreement. <p>A licensed dental therapist may perform the following services under indirect supervision:</p> <ul style="list-style-type: none"> • Emergency palliative treatment of dental pain • Placement and removal of space maintainers • Cavity preparation • Restoration of primary and permanent teeth • Placement of temporary crowns • Preparation and placement of preformed crowns • Pulpotomies on primary teeth • Indirect and direct pulp capping on

			<p>primary and permanent teeth</p> <ul style="list-style-type: none"> • Stabilization of reimplanted teeth • Extractions of primary teeth • Suture removal • Brush biopsies • Repair of defective prosthetic devices • Recementing of permanent crowns
Advanced Dental Therapist	<ul style="list-style-type: none"> • Dental therapist license • Master's degree in advanced dental therapy • 2,000 hours of clinical practice • Certification exam for advanced practice 	<p>Like a DT, the ADT practices under the supervision of a dentist, with whom they must have a collaborative management agreement, but all ADT services can be provided under "general supervision." The Dentist does not need to see the patient first or be on-site during the procedure.</p>	<p>An advanced dental therapist may perform the following services under general supervision:</p> <ul style="list-style-type: none"> • Oral evaluation and assessment of dental disease and the formulation of an individualized treatment plan authorized by the collaborating dentist • All services and procedures described under the Dental Therapist scope of practice section 150A.105, subdivision 4 (See Above) • Make appropriate referrals to dentists, physicians, and other practitioners in consultation with the collaborating dentist. • Extraction of periodontally diseased permanent teeth with mobility of +3 to +4 as permitted by the collaborative management agreement. Not to include unerupted, impacted, fractured, or need for sectioning. • Dispense and administer analgesics, anti-inflammatories, and antibiotics as permitted by the collaborative management agreement. Advanced Dental Therapist may provide, dispense and administer.

Early Impacts of Dental Therapists in Minnesota [Internet]. Minnesota Department of Health; Minnesota Board of Dentistry March 12, 2014 cited October 12, 2015]; [39]. Available from: <http://www.health.state.mn.us/divs/orhpc/workforce/dt/>

Figure 2 – Theoretical Framework for New Dental Delivery Model



Blue CM, Kaylor MB. Dental therapy practice patterns in Minnesota: A baseline study. Community Dentistry and Oral Epidemiology. In Press; [Doctoral Dissertation](A.T. Still University)

Table 1 - Characteristics of Dental Practices

Practice Type	Location	Number of Patients Served	HRSA Designation	Number of Dentists	Number of Dental Therapists
Office A Private Practice	Montevideo	~7,954	Greater/Rural	3	4
Office B Federally Qualified Health Center (FQHC)	St. Paul	~3,000	Metro/Urban	4	3
Office C Group Private Practice	St. Paul & Savage	~ 25,000	Metro/Urban	8	2

Table 2 - Demographic Information of Participants

Demographic Information of Participants		
(N=116)		
Item	N	Percent
Gender		
Female	70	60.87
Male	40	34.78
Choose Not to Respond	5	4.35
Frequency Missing	1	-
Age		
18-25	10	8.93
25-35	21	18.75
35-45	28	25.00
45-55	19	19.96
55-65	9	8.04
65-75	5	4.46
>76	1	0.89
Choose Not to Respond	19	16.96
Frequency Missing	4	-
Race		
Asian or Asian American	4	3.51
American Indian or Alaska Native	5	4.39
Black or African American	23	20.18
Native Hawaiian or other Pacific Islander	0	0
White	65	57.02
Other	3	2.63
Choose Not to Respond	14	12.28
Frequency Missing	2	-
Education		
High School Diploma or GED	46	41.44
College Degree	38	34.23
Masters Degree	5	4.50
Doctoral Degree	2	1.80
Choose Not to Respond	20	18.02
Frequency Missing	5	-
Employment Status		
Employed for wages	46	40.35
A homemaker or stay-at-home parent	10	8.77
Self-employed or farmer	7	6.14
A student	9	7.89
Unemployed or out of work	7	6.14
Retired	4	3.51
Unable to work because of a disability	14	12.28
Choose Not to Respond	17	14.91
Frequency Missing	2	-
Health Insurance		
Private	16	14.68
Public	19	17.43
Medicare/Medicaid	60	55.05
Sliding Fee/Self Pay	3	2.75
Other	2	1.83
Choose Not to Respond	9	8.26
Frequency Missing	7	-
Marital Status		
Single	46	42.20

Never Married	4	3.67
Married/Cohabiting	27	24.77
Separated or Divorced	17	15.60
Widowed	2	1.83
Choose Not to Respond	13	11.93
Frequency Missing	7	-
Yearly Net Income		
Less than \$25,000	39	36.11
\$25,001 - \$50,000	21.30	21.30
\$50,001 - \$75,000	6.48	6.48
\$75,001 - \$100,000	2.78	2.78
More than \$100,001	1.85	1.85
Choose Not to Respond	34	31.48
Frequency Missing	8	-
Travel Distance to Clinic		
0-10 minutes	30	27.52
11-20 minutes	26	23.85
21-30 minutes	16	14.68
31-40 minutes	12	11.01
41-50 minutes	11	10.09
Over 1 hour	14	12.84
Choose Not to Respond	0	0
Frequency Missing	7	-

Table 3 - Survey Responses

Question	Frequency	Percent	Frequency Missing
Do you have a regular dental care provider?			
No	45	39.13	
Yes	70	60.87	1
Which dental provider do you see most often?			
Dentist	14	22.58	
Dental Therapist	9	14.52	54
Dental Hygienist	20	32.26	
Unsure	19	30.65	
I am likely to recommend the Dental Therapist I saw today to others.			
Strongly Disagree	9	7.83	
Somewhat Disagree	2	1.74	1
Somewhat Agree	18	15.65	
Strongly Agree	86	74.78	
How likely are you to schedule future appointments with the DT you saw today?			
Very Likely	85	74.56	
Somewhat Likely	11	9.65	
Somewhat Unlikely	4	3.51	2
Very Unlikely	11	9.65	
Not Applicable	3	2.63	
I would rather see the Dental Therapist than a Dentist.			
Strongly Disagree	11	9.73	
Somewhat Disagree	9	7.96	
Somewhat Agree	47	41.59	3
Strongly Agree	28	24.78	
Not Applicable	18	15.93	
I was able to schedule an appointment at a time convenient for me with the Dental Therapist.			
Strongly Disagree	6	5.26	
Somewhat Disagree	4	3.51	
Somewhat Agree	22	19.30	2
Strongly Agree	79	69.30	
Not Applicable	3	2.63	
When I feel the need to see a dental care provider, I can get an appointment with the Dental Therapist without a problem.			
Strongly Disagree	2	1.77	
Somewhat Disagree	7	6.19	
Somewhat Agree	36	31.86	3
Strongly Agree	63	55.75	
Not Applicable	5	4.42	
I am satisfied with the dental care I received from the Dental Therapist today			
Strongly Disagree	3	2.61	
Somewhat Disagree	2	1.74	
Somewhat Agree	18	15.65	1
Strongly Agree	88	76.52	
Not Applicable	4	3.48	
I was satisfied with the amount of time the Dental Therapist spent with me today.			
Strongly Disagree	2	1.75	
Somewhat Disagree	4	3.51	
Somewhat Agree	15	13.16	2
Strongly Agree	93	81.58	
Not Applicable	0	0	
My Dental Therapist was professional during today's visit.			
Strongly Disagree	2	1.75	
Somewhat Disagree	2	1.75	2

Somewhat Agree	16	14.04	
Strongly Agree	94	82.46	
Not Applicable	0	0	
My Dental Therapist is knowledgeable about oral problems.			
Strongly Disagree	2	1.77	
Somewhat Disagree	3	2.65	
Somewhat Agree	17	15.04	3
Strongly Agree	87	76.99	
Not Applicable	4	3.54	
I trust my Dental Therapist.			
Strongly Disagree	3	2.63	
Somewhat Disagree	1	0.88	
Somewhat Agree	20	17.54	2
Strongly Agree	90	78.95	
Not Applicable	0	0	
My Dental Therapist knows when to consult with the Dentist.			
Strongly Disagree	3	2.68	
Somewhat Disagree	7	6.25	
Somewhat Agree	5	4.46	4
Strongly Agree	40	35.71	
Not Applicable	57	50.89	
The Dental Therapist treated me with respect at today's visit.			
Strongly Disagree	2	1.74	
Somewhat Disagree	1	0.87	
Somewhat Agree	12	10.43	1
Strongly Agree	97	84.35	
Not Applicable	3	2.61	
I can easily talk to the Dental Therapist about my oral health concerns.			
Strongly Disagree	2	1.74	
Somewhat Disagree	2	1.74	
Somewhat Agree	15	13.04	1
Strongly Agree	90	78.26	
Not Applicable	6	5.22	
The Dental Therapist explained my care to me; including my treatment plan and oral health recommendations in way that I could readily understand.			
Strongly Disagree	3	2.61	
Somewhat Disagree	1	0.87	
Somewhat Agree	16	13.91	1
Strongly Agree	92	80.00	
Not Applicable	3	2.61	
I understood what the Dental Therapist told me to do at today's visit.			
Strongly Disagree	2	1.75	
Somewhat Disagree	0	0	
Somewhat Agree	20	17.54	2
Strongly Agree	90	78.95	
Not Applicable	2	1.75	
How comfortable did you feel asking the Dental Therapist questions at today's visit?			
Very Comfortable	78	69.03	
Somewhat Comfortable	12	10.62	
Somewhat Uncomfortable	13	11.50	3
Very Uncomfortable	8	7.08	
Not Applicable	2	1.77	
Who do you feel has provided you with the best dental education?			
Dental Therapist	21	18.75	
Dentist	6	5.36	
Both	74	66.07	4
Not Applicable	11	9.82	

Overall I was satisfied with my visit today with the Dental Therapist.

Strongly Disagree	3	2.61	
Somewhat Disagree	2	1.74	
Somewhat Agree	17	14.78	1
Strongly Agree	87	75.65	
Not Applicable	6	5.22	

Table 4 - Survey Themes

Theme	N	N Missing	Mean	Standard Deviation	Median	Minimum Likert scale	Maximum
Interpersonal	114	2	3.8	0.5	4.0	1.0	4.0
Convenience	112	4	3.5	0.7	4.0	1.0	4.0
Trust	115	1	3.5	0.6	3.7	1.0	4.0
Care Quality	113	3	3.7	0.6	4.0	1.0	4.0
Overall Satisfaction	109	7	3.7	0.6	4.0	1.0	4.0

Table 5 - Gender Themes

Gender	N Obs	Variable	N	N Miss	Mean	Std Dev	Median	Minimum	Maximum
Male	40	Interpersonal	39	1	3.7	0.4	4.0	2.8	4.0
		Convenience	38	2	3.4	0.7	3.5	1.5	4.0
		Trust	40	0	3.4	0.6	3.6	1.7	4.0
		Care Quality	39	1	3.6	0.5	4.0	2.0	4.0
		Overall Satis	38	2	3.7	0.6	4.0	2.0	4.0
Female	70	Interpersonal	69	1	3.8	0.6	4.0	1.0	4.0
		Convenience	68	2	3.6	0.7	4.0	1.0	4.0
		Trust	69	1	3.5	0.6	3.7	1.0	4.0
		Care Quality	68	2	3.8	0.6	4.0	1.0	4.0
		Overall Satis	65	5	3.7	0.7	4.0	1.0	4.0
Choose Not to Respond	5	Interpersonal	5	0	3.9	0.2	4.0	3.6	4.0
		Convenience	5	0	3.9	0.2	4.0	3.5	4.0
		Trust	5	0	3.3	0.5	3.0	2.7	4.0
		Care Quality	5	0	3.9	0.1	4.0	3.7	4.0
		Overall Satis	5	0	3.8	0.4	4.0	3.0	4.0

Table 6 - Age Group Themes

Age Group	N Obs	Variable	N	N Miss	Mean	Std Dev	Median	Minimum	Maximum
18-25	10	Interpersonal	9	1	3.4	1.0	3.8	1.0	4.0
		Convenience	8	2	3.3	1.0	3.5	1.0	4.0
		Trust	9	1	3.4	0.9	3.7	1.0	4.0
		Care Quality	9	1	3.5	0.9	3.8	1.3	4.0
		Overall Satis	9	1	3.3	1.0	4.0	1.0	4.0
25-35	21	Interpersonal	21	0	3.8	0.4	4.0	2.8	4.0
		Convenience	21	0	3.7	0.6	4.0	2.0	4.0
		Trust	21	0	3.3	0.7	3.7	1.7	4.0
		Care Quality	21	0	3.8	0.4	4.0	2.7	4.0
		Overall Satis	18	3	3.8	0.5	4.0	2.0	4.0
35-45	28	Interpersonal	27	1	3.9	0.3	4.0	3.0	4.0
		Convenience	27	1	3.5	0.6	3.5	2.0	4.0
		Trust	28	0	3.6	0.5	3.7	2.0	4.0
		Care Quality	27	1	3.8	0.4	4.0	2.0	4.0
		Overall Satis	27	1	3.9	0.5	4.0	2.0	4.0
45+	34	Interpersonal	34	0	3.8	0.5	4.0	1.0	4.0
		Convenience	33	1	3.5	0.8	4.0	1.0	4.0
		Trust	34	0	3.5	0.5	3.7	1.7	4.0
		Care Quality	33	1	3.8	0.7	4.0	1.0	4.0
		Overall Satis	32	2	3.8	0.8	4.0	1.0	4.0

Table 7 - Educational Level Themes

Education Level	N Obs	Variable	N	N Miss	Mean	Std Dev	Median	Minimum	Maximum
HS or GED	46	Interpersonal	45	1	3.8	0.4	4.0	2.8	4.0
		Convenience	44	2	3.6	0.7	4.0	2.0	4.0
		Trust	45	1	3.4	0.6	3.7	1.7	4.0
		Care Quality	45	1	3.8	0.4	4.0	2.0	4.0
		Overall Satis	46	0	3.8	0.5	4.0	2.0	4.0
College Degree or Higher	45	Interpersonal	44	1	3.9	0.5	4.0	1.0	4.0
		Convenience	44	1	3.5	0.7	4.0	1.0	4.0
		Trust	45	0	3.5	0.5	3.7	1.0	4.0
		Care Quality	43	2	3.8	0.5	4.0	1.3	4.0
		Overall Satis	40	5	3.8	0.7	4.0	1.0	4.0

SECTION FIVE

Appendix A	Consent Form
Appendix B	Office Participation Letter
Appendix C	Survey Information Sheet
Appendix D	Patient Satisfaction Survey
Appendix E	Office Instruction/Narrative
Appendix F	IRB Application Form
Appendix G	Comprehensive List of References

APPENDIX A - Consent Form

Patient Satisfaction With Treatment After A Dental Visit With A Dental Therapist In Minnesota.

You are invited to take part in a research study designed to determine patient satisfaction with treatment after a dental visit with a dental therapist in Minnesota. Please read this form and ask any questions you may have before agreeing to be in this study. Participation in this study is voluntary. The principal investigator of this study is Bethany Palmstein RDH, BASc, REF

Background Information

Because you have received care from a dental therapist, you are invited to take part in a research study designed to measure patient satisfaction. The purpose of this study is to determine patient satisfaction with treatment after a dental visit with a dental therapist in Minnesota. The results of this study will give both the public and professional communities information on the level of patient satisfaction with the care provided by a dental therapist. Knowledge of patient satisfaction is a quality of care metric needed for this emerging profession. This study is the first in the area of quality of care with Minnesota dental therapists.

Procedures

If you agree to be in this study, we would ask you to take a survey that will ask you about your experience receiving care from a dental therapist as well as demographic information.

Risks and Benefits of Being in the Study

The study has very minimal risks. Some questions may make you uncomfortable. If this happens, feel free to withdraw from the survey or not to respond to any question without any repercussion.

The benefits of the study will be knowledge of patient satisfaction of treatment provided by a dental therapist in Minnesota. This study is the first in the area of quality of care with Minnesota dental therapists.

Confidentiality

You will not be personally identified in the study. A code or identifier will be used to determine which surveys came from which clinic. All data will be kept in a secure location. Data will only be reported in aggregate fashion.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with your dental practice. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions

The principal investigator of this study is Bethany Palmstein RDH, BAsC, REF. You may ask any questions you have now. If you have questions later, you are encouraged to contact her at 218-464-2962 or email at bergs407@d.umn.edu.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher, you are encouraged to contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware St. S.E., Minneapolis MN 55455; telephone 612-625-1650.

You will be given a copy of this information to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I understand the rules and consent to participate in the study.

Signature _____ Date _____

APPENDIX B - Office Participation Letter

<name>
 <address>
 <city>, <state> <zip>

Dear Dr. <name>,

I am writing to ask your help in a study of patient satisfaction of treatment provided by dental therapists in the State of Minnesota. This study is part of an effort to determine if patients are satisfied with care they are receiving from the dental therapists employed in your practice. As you may be aware the state legislature approved the Dental Therapist provider classification in 2009 and the first class of Dental Therapists graduated from Metropolitan State University in June of 2011. This study is the first in the area of quality of care with Minnesota dental therapists.

As a Dentist practicing in Minnesota, your patients views about expanding allied scopes of practice and newly emerging non-dentist providers such as the Dental Therapist and their potential impact on dental care provided to the public is critical for dental workforce planning. You were randomly selected from all licensed dentists in the state of Minnesota who employ dental therapists. Your practices participation in this survey is important in ensuring that the study accurately reflects all providers in the state.

Please be assured that your patients' answers are confidential: protecting your confidentiality is very important to us. Names will never be associated with the answers you give. This questionnaire has an identification number on it for mailing purposes only. This is so that we can remove your name from the mailing list once your questionnaire is returned. If for some reason you prefer not to respond, please let us know by returning the blank questionnaire in the enclosed stamped envelope.

In closing I would like to emphasize your importance to this research, your opinions toward expanding roles of non-dentist providers is critical for workforce planning in our state and critical to a successful evaluation of dental practice in Minnesota. Please do not hesitate to contact me at 218-464-2962 with questions or concerns about this study.

Sincerely,

Bethany Palmstein RDH, BASc, REF
 Graduate Student, Dental Hygiene Education

What do you need to do?

Distribute and collect this survey from patients receiving care from the DT's in your practice.

Who is participating?

Clinics who employ Dental Therapists in their practice.

What will patients get?

At the end of the study a drawing will be held at EACH participating clinic and the winner will receive a \$50 Visa Gift Card.

University of Minnesota School of Dentistry

APPENDIX C - Information Sheet for Research

INFORMATION SHEET FOR RESEARCH

What is the level of patient satisfaction after a dental visit with a dental therapist in Minnesota?

You are invited to be in a research study of patient satisfaction after a dental visit with a dental therapist. You were selected as a possible participant because you have received treatment from a dental therapist at your dental clinic. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: Bethany Palmstein RDH, BASc, REF, University of Minnesota School of Dentistry, Division of Dental Hygiene.

Procedures:

If you agree to be in this study, we would ask you to do the following things: Completion of a survey asking questions about your perception of the Dental Therapist's interpersonal skills, convenience, trust and care quality related to dental therapy treatment provided

Confidentiality:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota or your care at this, or another dental clinic. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:

The researcher(s) conducting this study is (are): Bethany Palmstein RDH, BASc, REF. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact them at the University of Minnesota School of Dentistry, Division of Dental Hygiene, 218-464-2962, bergs407@d.umn.edu. Advisor: Christine Blue DHSc, MS, Associate Professor and Director of the University of Minnesota School of Dentistry, Division of Dental Hygiene, 612-625-5954, blux005@umn.edu.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455; (612) 625-1650.

You will be given a copy of this information to keep for your records.

What is the level of patient satisfaction with care provided by a dental therapist in Minnesota?

APPENDIX D - Patient Satisfaction Survey

This office is conducting a study of patient satisfaction regarding care provided by dental therapists. The survey is completely confidential and only summary information will be reported in the study results. Thank you in advance for your help with this research study.

Please rate your experience with the following:



Strongly Disagree



Somewhat Disagree



Somewhat Agree



Strongly Agree



Not Applicable

1. **Do you have a regular dental care provider?**
 No (Go to Question #3) Yes (Go to Question #2)
2. **Which dental provider do you see most often?**
 Dentist Dental Therapist Dental Hygienist Unsure
3. **I am likely to recommend the Dental Therapist I saw today to others.**
 Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree
4. **How likely are you to schedule future appointments with the DT you saw today?**
 Very Likely Somewhat Likely Somewhat Unlikely Very Unlikely
 Not Applicable
5. **I would rather see the Dental Therapist than a Dentist.**
 Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable
6. **I was able to schedule an appointment at a time convenient for me with the Dental Therapist.**

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

7. When I feel the need to see a dental care provider, I can get an appointment with the Dental Therapist without a problem.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

8. I am satisfied with the dental care I received from the Dental Therapist today.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

9. I was satisfied with the amount of time the Dental Therapist spent with me today.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

10. My Dental Therapist was professional during today's visit.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

11. My Dental Therapist is knowledgeable about oral problems.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

12. I trust my Dental Therapist.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

13. My Dental Therapist knows when to consult with the Dentist.

Not Applicable Strongly Disagree Somewhat Disagree
 Somewhat Agree Strongly Agree

14. The Dental Therapist treated me with respect at today's visit.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

15. I can easily talk to the Dental Therapist about my oral health concerns.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

16. The Dental Therapist explained my care to me; including my treatment plan and oral health recommendations in way that I could readily understand.

Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

17. I understood what the Dental Therapist told me to do at today's visit.

- Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

18. How comfortable did you feel asking the Dental Therapist questions at today's visit?

- Very Comfortable Somewhat Comfortable Somewhat Uncomfortable
 Very Uncomfortable

19. Who do you feel has provided you with the best dental education?

- Dental Therapist Dentist Both Not Applicable

20. Overall I was satisfied with my visit today with the Dental Therapist.

- Strongly Disagree Somewhat Disagree Somewhat Agree
 Strongly Agree Not Applicable

21. Number of times in the past year that you have been seen in a dental clinic.

- _____ Visits Unsure

22. Number of times in the past year that you have seen the Dental Therapist in this clinic:

- _____ Visits Unsure

23. What is the highest level of education attained?

- High School Diploma or GED
 College Degree
 Masters Degree
 Doctoral Degree
 Choose Not To Respond

24. Gender

- Male Female Choose Not To Respond

25. Age

- _____ years Choose Not To Respond

26. Race (Please choose only one response)

- Asian or Asian American
 American Indian or Alaska Native
 Black or African American
 Native Hawaiian or other Pacific Islander
 White
 Other (please specify): _____
 Choose Not To Respond

27. Employment Status

- Employed for wages

- A homemaker or stay-at-home parent
- Self-employed or farmer
- A student
- Unemployed or out of work
- Retired
- Unable to work because of a disability
- Choose Not To Respond

28. Health Insurance

- Private
- Public
- Medicare/Medicaid
- Sliding Fee / Self-Pay
- Other (please specify): _____
- Choose Not To Respond

29. Marital Status

- Single
- Never Married
- Married/Cohabiting
- Separated or Divorced
- Widowed
- Choose Not To Respond

30. Your yearly net (take home) income

- Less than \$25,000
- \$25,001 - \$50,000
- \$50,001 - \$75,000
- \$75,001 - \$100,000
- More than \$100,001
- Choose Not To Respond

31. Approximate travel distance to the clinic:

- 0-10 minutes
- 11-20 minutes
- 21-30 minutes
- 31-40 minutes
- 41-50 minutes
- Over 1 hour

32. Have you received dental care from this clinic before?

- Yes No

To thank you for your participation, a lottery will be held at the completion of the study. One patient from each participating dental clinic will be entered into a drawing to win a

\$50 Visa gift card. Participants wanting to be entered into the lottery must complete the contact information portion below.

Full Name: _____

Address: _____

Phone Number: _____

APPENDIX E - Office Instruction/Narrative

<name>

<address>

<city>, <state> <zip>

Dear <name>,

Thank you and your clinic for agreeing to participate in this landmark study of patient satisfaction with care provided by dental therapists (DT) in Minnesota!

Enclosed you will find printed copies of the survey intended for completion by patients after they have received care from the dental therapist in your clinic. It will be left to the discretion of your clinic as to how you would prefer to disperse the surveys – for example: completed in chair, after the appointment in the reception area, etc. Just so long as the survey is completed **AFTER** the DT provides care.

Please collect surveys from the date you receive this package until **April 1st, 2017**. If you run out of survey copies and would like more, please contact me as soon as possible and more copies can be mailed to you.

I have included a brief narrative and information sheet on how to present the survey to patients or answer patient questions as needed. Please contact me with any additional questions or concerns that may arise during the survey period.

Very excited to be working with you and your clinic, have a great start to 2017!

Sincerely,

Bethany Palmstein RDH, BASc, REF

Graduate Student
School of Dentistry Division of Dental Hygiene
University of Minnesota
PH: 218-464-2962
Email: bergs407@d.umn.edu

Survey Presentation Narrative

1. Our office is participating in a study being conducted by a graduate dental hygiene student at the University of Minnesota School of Dentistry. The purpose of the study is to measure your satisfaction with the treatment provided to you today by our dental therapist.
2. This survey is optional and your individual results will remain confidential and not be shared with your dental office. All data will be reported in aggregate fashion only. Results will be reviewed by the graduate student conducting the study and her faculty advisor. Declining to participate in the study will not harm your relationship with our dental office. Completion of the survey will indicate your consent to participate in the study.
3. This survey consists of 32 questions and takes about 10-15 minutes to complete.
4. The results of this survey will in no way effect the relationship with our office or the treatment provided to you at our clinic. When taking the survey, you may choose to not answer any questions and may withdraw at any time. We thank you for taking the time to complete this survey.

APPENDIX F - IRB Application Form

Submit this application, along with all required appendices and supplemental documents to the University of Minnesota IRB.		IRB Use Only IRB Study # Click here to enter text.
Electronic Submission (preferred): Submit to: rspperev@umn.edu PI must submit request using University of Minnesota e-mail Account.	U.S. Mail Address: Human Research Protection Program MMC 820 420 Delaware St. SE Minneapolis, MN 55455-0392	For more information please visit our website http://www.research.umn.edu/irb/index.html Contact our office Phone: 612-626-5654 Email: rspperev@umn.edu Fax: 612-626-6061
Project Title If the project is funded, the Sponsored Project Administration (SPA) project title must match the IRB project title. If the project is funded by multiple grants, provide all grant titles below:		
What is the level of patient satisfaction with care provided by a dental therapist in Minnesota?		
Section 1 Principal Investigator		
Name Bethany Palmstein RDH, BASc, REF	Highest Earned Degree: Bachelor of Science - Public Health Education	
Preferred contact information: bergs407@d.umn.edu Preferred email or phone number at which the PI may be contacted by IRB staff or reviewers to resolve questions or concerns.		
Affiliation and contact information <input checked="" type="checkbox"/> University of Minnesota (complete contact info section 1 only) <input type="checkbox"/> Fairview (complete contact info section 2 only) <input type="checkbox"/> Gillette (complete contact info section 2 only)		
Required Contact information Section 1 - U of M only	U of M Internet ID (x.500):	bergs407
	U of M Employee/student ID Number:	3343577
	University Department:	School of Dentistry, Department of Primary Dental Care, Division of Dental Hygiene
Required contact information Section 2 Non-U of M only	Address: 110 Grove Street	Phone number: 218.464.2962

Proctor, MN 55810		<input checked="" type="checkbox"/> Mobile <input type="checkbox"/> Pager <input type="checkbox"/> Office Email address: bergs407@d.umn.edu
Occupational Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Physician <input type="checkbox"/> Staff <input checked="" type="checkbox"/> Student - Students must complete the faculty academic advisor section below and submit Appendix J <input type="checkbox"/> Other:		
Conflict of Interest: Does the PI have a reportable conflict as defined in Section 9 of the application? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Required CITI Human Subjects Training Date (Month/Year) CITI completed (either initial or refresher course): 7/2016 Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training		HIPAA TRAINING Check box below if HIPAA training is required. <input checked="" type="checkbox"/> HIPAA Required – Data contains PHI HIPAA Training completed through: <input checked="" type="checkbox"/> UMN <input type="checkbox"/> Other:
<i>For information regarding human subjects and HIPAA training requirements please go to http://www.irb.umn.edu/training.html</i>		
As Principal Investigator of this study, I assure the IRB that the following statements are true: <ul style="list-style-type: none"> • The information provided in this form is correct. • I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment. • I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. • I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. • I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. • I will not begin my research until I have received written notification of final IRB approval. • I will comply with all IRB requests to report on the status of the study. • I will maintain records of this research according to IRB guidelines. • The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. • If these conditions are not met, I understand that approval of this research could be suspended or terminated. 		
Bethany Palmstein	RDH, BAsC, REF; Master of Science in Dental Hygiene Candidate	8/14/2016

Signature/Digital signature/x.500 of PI	Title of PI	Date
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Faculty Academic Advisor – Student-led Research	
Appendix J filled out by the faculty advisor must be submitted with this application. Academic advisors must be cc'ed on all correspondence between the student PI and the IRB.	
Student research requires the approval of a faculty academic advisor. As academic advisor to the student investigator, the advisor assumes responsibility for ensuring that the student complies with University policies and federal regulations regarding the use of human subjects in research.	
Faculty Academic Advisor Name (Last name, First name MI): Blue, Christine M.	University Department: Primary Dental Care
U of M Employee ID: 0948682	U of M x.500 ID (ex. smith001): bluex005
Conflict of Interest: Does this person have a reportable conflict as defined in Section 9 of the application? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Human Subjects Training: CITI – Date completed (either initial or refresher course): 8/2016 Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	HIPAA TRAINING Check box below if HIPAA training is required. <input type="checkbox"/> HIPAA Required – Data contains PHI HIPAA Training completed through: <input type="checkbox"/> UMN <input type="checkbox"/> Other:
bluex005	8.15.16
Signature/ x.500 of Advisor	Date

Additional Study Personnel? Download and attach the Additional Study Personnel form found in the appendices section of the [IRB forms page](#)

Section 2 Summary of Activities
The following questions must be answered in lay language or language understood by a person unfamiliar with your area of research.
2.1 What is your research question? State hypothesis or primary objective and the rationale for conducting the study.
What is the level of patient satisfaction with care provided by a dental therapist in Minnesota?

Statement of the Problem: Minnesota was the first state in the nation to authorize the licensing and practice of a mid-level Dental Therapist (DT) provider in 2009 (1, 2). Dental therapists were created to expand access to care to underserved populations and rural populations lacking dental providers in their area while providing basic preventative and restorative treatment to people of all ages, including education, clinical and therapeutic services. Since the first DT went into practice in 2011, baseline studies have investigated the characteristics of the first dental therapists, the acceptance of dental therapists by dentists, the impact on emergency room usage for dental care; practice patterns and cost to the public health care system. However, there has been no formal investigation on patient satisfaction with treatment received from dental therapists. Early evidence suggests dental therapists have improved healthcare by reducing emergency room visits and increased access to care for patients in rural or underserved areas.

Significance of the Study: The results of this study will give both the public and professional communities information on the level of patient satisfaction with the care provided by a dental therapist. Knowledge of patient satisfaction is a quality of care metric needed for this emerging profession.

2.2 Indicate which of the following will be included in your research. Note required supplemental materials that must be included when application is submitted for review

Be aware that no personal or sensitive information can be sought under exempt research guidelines.

Tasks - check all that apply	Required Supplemental Materials
<input type="checkbox"/> Psychological test	A copy of the test(s) must be submitted
<input type="checkbox"/> Educational test(s)	A copy of the test(s) must be submitted
<input type="checkbox"/> Evaluation instrument	The evaluation instrument must be submitted
<input type="checkbox"/> Interviews	Interview questions must be submitted
<input type="checkbox"/> Focus Groups	Focus group questions must be submitted

The activity required to complete the research is not listed above, describe the activity below

Complete an electronic survey of experience during a dental appointment.

2.3 What is the frequency of the tasks the subjects will be asked to perform?

Once

More than once. Indicate expected frequency:

2.4 What is the anticipated duration of the task?

2.5 Will the research occur in an education setting?

No Yes. If yes, describe the activities non-participants will do during this period and how these activities will be supervised.

Not applicable. All students will participate.

Anticipated start date: 10/1/2016 Anticipated end date: 12/15/2016

Exempt research is generally considered short-term in nature. This office routinely inactivates exempt applications after five years from the time it was determined to meet the exempt criteria. If you think your project will extend beyond five years, contact the IRB office (612-626-5654 or irb@umn.edu).

Section 3 Participant Population

Describe the participant population below.

NOTE: Research involving PRISONERS or other incarcerated individuals (or their existing data and/or specimens) do not qualify for exemption.

3.1 What is the expected number of participants?

Total: 300	Of the total requested indicate how many will be	Male 150	Female 150
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3.2 What is the age range of the subjects?

Exact Age Range: 18 to 90+ *See information below for required supplemental materials.*

If age range includes

0-17 years

Submit [Appendix Y](#) Research with subjects younger than 18 years old may be conducted under Exempt category 2 only if the research procedures do not include surveys or interviews. Researchers may observe public behavior of children but **MAY NOT** participate in the activity or behavior.

3.3 What are the inclusion criteria for this study?

Dental practices participating in the study must employ and provide services from dental therapists. Patients in these practices who participate in the study must be age 18 years of age or older, with the only requirement of having received care from a DT during their care at the participating clinic.

3.4 What are the exclusion criteria for this study?

Participants who are 0-17 years of age are excluded from the study.

NOTE: Research that includes participants considered vulnerable is not eligible for exempt review.

2.6 What are the anticipated start and end dates for the study?

Section 4 Location of Subjects during Research Data Collection	
4.1 Check the box(es) below to indicate where research activities will occur or where subjects will be when the data is collected. Note that some locations require submission of appendices or additional documentation.	
LOCATION – check all that apply	Required Supplemental Materials
<input type="checkbox"/> Elementary/Secondary Schools*	Submit Appendix M “Research in Schools” and appropriate documentation of approval from school district
<input type="checkbox"/> Community Center. Specify:	Submit an approval letter from the community center
<input type="checkbox"/> University Campus (non-clinical) <ul style="list-style-type: none"> <input type="checkbox"/> Twin Cities <input type="checkbox"/> Duluth <input type="checkbox"/> Morris <input type="checkbox"/> Rochester <input type="checkbox"/> Crookston 	
<input type="checkbox"/> Subject’s home	
<input type="checkbox"/> International location	Submit Appendix K “International Research”
<input checked="" type="checkbox"/> Other. Describe: Dental Clinics in Minnesota	
*NOTE: It is the PI’s responsibility to contact each school district to determine if separate school IRB approval or district approval is required (e.g. Minneapolis Public Schools and St. Paul Public Schools require approval from their Research, Evaluation, and Assessment departments)	

Section 5 Recruitment & Compensation
5.1 Which of the statements below describes the recruitment strategy? If both apply, select both.
<input checked="" type="checkbox"/> Statement A. Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling. If ONLY statement A selected, go to question 5.2

Statement B. Potential subjects will be recruited based on information contained in private/protected records (medical records, student records). This also includes subjects who will be recruited from the PI or Co-I's patient population.

If statement B is selected, answer question 5.1.1.

Recruitment from records

5.1.1 Are the records publicly available?

- Yes, go to question 5.2**
- No - Answer questions 5.1.2-5.1.4**

5.1.2 What type of records will be accessed?

Medical - Indicate the mechanism the PI will use to confirm that the patient has agreed to release their PHI contained in their medical record for research purposes; for example, the patient has documented consent to research on their treatment, intake or hospital admitting form. (MN Statue 144.334 Subd. 3; Access to Medical Records for Research)

- Academic Health Center Information Exchange (AHC-IE)
- Other. Describe:
- Educational**
- Employment**
- Other:**

5.1.3 Does the researcher have legitimate access to these records (i.e. through a job, volunteer work, internship, etc.)

- Yes, explain how the researcher has access:**
- No**
If you answered "No" ...
 - If you do not have permissible access to the records, the fact that the custodian will give you the list does not create permissible access.
 - You must ask the custodian of the record to make initial contact with potential subjects for you
 - Attach a letter of cooperation from the custodian of the record indicating that they will make initial contact on your behalf.
 - Describe how the custodian will do this in question 5.1.2 below.
 - You must let potential subjects contact you if they are interested. You may not make initial contact. This remains true even if the custodian is willing to give you the private list.

5.1.2 Identify who will make initial contact with potential subjects.

5.2 Provide a brief narrative to describe the recruitment process. Include in the description how potential subjects will be informed of the research.

A purposive sample of five dental practices in MN who employ a dental therapist will be selected to participate in the study. Dental practices will be selected to represent different practice models in diverse locations across the State of Minnesota. An email about the study and invitation to participate will be sent to the principal dentists in each dental practice. If a practice agrees to participate, one employee in the practice will be designated

the study coordinator. The study coordinator will be responsible for patient recruitment. The study coordinator(SC) will provide information about the study and extend an invitation to participate to all patients who received dental treatment from a dental therapist and who meet inclusion criteria. If a patient agrees to participate, the study coordinator will obtain informed consent and administer the survey. The principal investigator will meet with each SC to explain the study protocol. Patients who agree to be a part of the study will be asked to complete an electronic survey using a laptop computer immediately after completing an appointment with a dental therapist. Surveys will be coded for tracking purposes; all patient data will be de-identified. As an incentive to participate, the names of participants in each dental office will be placed in a lottery, and at the end of the study, one participant from each practice will be awarded a \$50 Target gift card. To be entered into the lottery, subjects must complete the contact information portion of the survey.

5.3 Describe with whom and how you will make initial contact with the subjects; will contact be in a classroom setting, by mail, e-mail, etc.

Contact will occur in the patients' dental office/clinic. Initial Contact will be made by a designated study coordinator who will be of a member of the dental office staff.

5.4 Indicate if any of the recruitment methods described below will be utilized. Note that some selections require you to submit additional documentation.

	Required Supplemental Materials
Section 6 Confidentiality	
See Protecting Private Data Guideline from the Office of Information Technology (OIT) for information about protecting the privacy of research data.	
6.1 Where will the data be stored?	
6.2 How long will the data be stored?	
6.3 What security provisions will be taken to protect and maintain the confidential data (password protection, encryption, etc.)? See the University of Minnesota's Safe Computing Recommendations .	
<p>6.4 Will the PI have a link to identify subjects?</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

6.5 Will identifiable data be made available to anyone other than the PI?

No

Yes **Explain who will have access and why access is required.**

Section 7 Informed Consent Process

Even though the IRB may determine that some research is exempt from the federal regulations, adequate provisions still need to be in place to protect research participants.

In making its consideration of exempt status, the HRPP/IRB office still has to determine that:

- a) The research involves no more than minimal risk to participants
- b) Selection of participants is equitable
- c) If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
- d) **If there are interactions with participants, there will be a consent process that will disclose such information as:**
 - **that the activity involves research**
 - **a description of the procedures**
 - **that participation is voluntary**
 - **name and contact information for the investigator**
- e) There are adequate provisions to maintain the privacy of participants.

For exempt category 2 research, it is not necessary to obtain signed documentation of consent (i.e. a signature). Please submit a 'consent information sheet' which does not include a signature line. The IRB office reserves the right to require that you obtain signatures, but in most cases it is not necessary.

If you are mailing a survey to subjects and asking them to return it to you, or doing a phone interview, you must send or read a consent statement which includes the same information as the consent information sheet form.

An information sheet template is available on the IRB forms page in the "templates" section.

7.1 Who will conduct the consent process?

7.2 How will consent be obtained?	
7.3 Describe what will be said to subjects to introduce the research. <i>Do not say "see consent form".</i>	
Method	
<input type="checkbox"/> Flyers	Submit flyer(s) with application
<input type="checkbox"/> Newspaper ads	Submit draft of ad with application
<input type="checkbox"/> Radio or television ads	Submit script with application
<input type="checkbox"/> Social networking sites	Submit text, page mock up or description of posting including any images or videos Indicate site(s):
<input type="checkbox"/> Letters or emails	Submit letter(s) or email(s) with application
<input type="checkbox"/> Phone call	Submit phone script with application
<input type="checkbox"/> Group or class presentations	Submit outline of

	presentation and any materials provided to participants with application
<input type="checkbox"/> Other method not described above	Specify:
<input checked="" type="checkbox"/> None of the above	
5.5	<p>Will the subjects receive gifts, payment, compensation, reimbursement, services without charge or extra credit in exchange for participation?</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Yes, describe the compensation type and value: Subjects completing the survey will be entered in a lottery. One winning patient from each participating clinic will receive a \$50 Visa gift card.</p>

Section 8 Funding	
8.1 Has funding for this project been applied for, requested or received or do you intend to request/apply for funding?	
<input checked="" type="checkbox"/> No	Explain how the research will be conducted without funding: The principal investigator will fund the study with personal funds and with assistance from a scholarship awarded by the Division of Dental Hygiene in the School of Dentistry.
<input type="checkbox"/> YES	Indicate in the table below who will provide/manage funds.
Funds provided/managed by	Required Supplemental Materials
<input checked="" type="checkbox"/> Internal University of Minnesota (departmental funds, internal grant program, etc.)	none
<input type="checkbox"/> University of Minnesota Sponsored Project Funding	Appendix A required
<input type="checkbox"/> Non-University of Minnesota source or management	Appendix A required

Section 9 Conflict of Interest
<p>Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. Reporting of financial interests is required from all individuals responsible for the design, conduct or reporting of the research. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IRB.</p> <p>Examples of conflicts of interest may include, but are not limited to:</p>

- A researcher participating in research on a technology, process or product owned by a business in which the researcher or family member holds a significant financial interest or a business interest.
- A researcher participating in research on a technology, process or product developed by that researcher or family member.
- A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researcher's University responsibilities.
- A researcher or family member serving on the Board of Directors of a business from which that member receives University supervised Sponsored Research Support.
- A researcher receiving consulting income from a business that funds his or her research.
- A researcher receiving consulting income from a business that could benefit from the results of research sponsored by a federal agency (i.e. NIH).

9.1 Do any of the Investigators or personnel listed on this research project have a business interest or a financial interest of \$10,000 or more (\$5,000 or more if research is funded by a Public Health Service (PHS) agency or researcher is involved in clinical health care) associated with this study when aggregated for themselves and their family members?

No.

Yes. List the investigator(s) with conflicts:

9.2. Do any of the investigators or personnel (when aggregated for themselves and their family members) listed on this research have:

9.2.1 Ownership interests more than \$10,000 (\$5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of interest could be affected by the outcome of the research?

No

Yes List the investigator(s) with conflicts:

9.2.2 Ownership interests exceeding 5% interest in any one single entity (or any equity interest in a non-publicly traded entity if research is funded by PHS or researcher is involved in clinical health care)?

No

Yes List the investigator(s) with conflicts:

9.2.3 Compensation greater than \$10,000 (\$5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of the

compensation could be affected by the outcome of the research?	
<input checked="" type="checkbox"/>	No
<input type="checkbox"/>	Yes List the investigator(s) with conflicts:
9.3 Have all business or financial interests indicated above been reported?	
<input type="checkbox"/>	No.
<input checked="" type="checkbox"/>	Yes.
<ul style="list-style-type: none"> • University of Minnesota researchers need to report business or financial interest online via the Report of External Professional Activities (REPA) • Fairview Health System researchers need to complete the Fairview Health Services Conflict of Interest Disclosure forms and submit the completed forms to the Fairview Office of Research. • Gillette Children's Specialty Healthcare researchers must contact the Director of Research Administration, at 651-229-1745. <p>The IRB will verify that a management plan is in place with the Conflict of Interest (COI) Program. If the COI Program does not have an approved management plan in place for this research, they will contact the individual(s) for additional information.</p> <p>Final IRB approval cannot be granted until the IRB has reviewed the management plan and all potential conflict matters are settled. The IRB receives a recommendation from the Conflict of Interest Review Committee regarding disclosure to subjects and management of any identified conflict. The convened IRB determines what disclosure language should be in the consent form.</p>	

Section 10 Research Services, Assessment and Oversight

Section 10.1 RESEARCH COLLABORATIONS

10.1.1 Does this research project involve collaborations with any sites or personnel outside of the University of Minnesota, its coordinate campuses, the Fairview Health Systems or Gillette Children's Specialty Healthcare?

No

Yes **Briefly describe the collaboration (with whom and for what purpose):**

Dental practices in Minnesota who employ dental therapists. The purpose of this collaboration is to access patients in dental practice settings who have received dental treatment from a dental therapist.

10.1.2 Is this research proposal being reviewed by any other institution or peer review committee?

No

- Yes** **It is the responsibility of the PI to secure the appropriate approval from these committees and to provide documentation of approval to the IRB. List the committee(s) below and attach copies of documentation of approval**

Additional requirements for ensuring appropriate IRB oversight may apply. These requirements are often dependent on whether or not the site/personnel is considered “engaged” in human subjects research according to federal definitions. Contact the UMN IRB office (irb@umn.edu) to determine how IRB oversight of the research activity with the external site/personnel should be addressed.

Section 10.2 AFFILIATED ENTITIES WITH OVERSIGHT RESPONSIBILITIES

10.2.1 Will this research use services, resources, or funding from the **Clinical and Translational Science Institute**? Examples include pilot funding, career development awards, biostatistics support, facilities, staffing, project management, regulatory assistance, or informatics consultation and support

- No** **Go to question 10.2.2**
- Yes** Provide CRT Portal ID#:

10.2.2 Does this research require [Masonic Cancer Center Protocol Review Committee \(CPRC\)](#) review?

The CPRC is required to evaluate, approve or reject, monitor, and re-review on an annual basis all University of Minnesota clinical cancer research protocols including those with non-therapeutic intent.

- No** **Go to question 10.2.3**
- Yes** Documentation of approval must be provided to receive final IRB approval.

10.2.3 Will this research utilize Gillette Children’s Specialty Healthcare resources or medical records?

- No**
- Yes** If using Gillette resources, please contact:
- Joyce Trost, PT
Research Administration Manager
- Gillette Children's Specialty Healthcare
651-325-2339/651-312-3182/jtrost@gillettechildrens.com