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Improving Patient Comfort in the Primary Care Waiting Area Using Evidence-Based Design

by

Elizabeth Elmore, MSN, CRNP

A DNP PROJECT

Submitted in partial fulfillment of the requirements for the Degree of Doctor of Nursing Practice to

The School of Graduate Studies of

The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA 2019

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Student Signature Date 710/19

DNP PROJECT APPROVAL FORM

Submitted by Elizabeth Elmore in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

College of Nursing, Dean

Graduate Dean

Graduate Dean

Graduate Dean

Graduate Dean

ABSTRACT

The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice		College: Nursing
Name of Candidate:	Elizabeth Elmore	

Title: Improving Patient Comfort in the Primary Care Waiting Area Using Evidence-Based

Design

The majority of healthcare visits occur in the primary care setting; therefore, the environment directly affects comfort and ultimately, patient satisfaction. A large part of the patient's time at a primary care office is spent in the patient waiting area. Aesthetics of the office have been found to affect patient comfort in their healthcare visit. A project was conducted using cost-effective, evidence-based design strategies to determine if making aesthetic changes to a waiting room would improve patient comfort. Wall color, live plants, and local artwork were used in a Plan-Do-Study-Act (PDSA) project. Patients were administered a survey related to the waiting area environment before and after the intervention. The purpose of the quality improvement project was to determine if cost-effective, evidence-based design strategies will improve patient comfort within the primary care waiting environment. After the intervention, there was no statistically significant change in patient comfort; however, there was a mean increase from pre-test (M=14.93, SD=1.639) to the post-test (M=15.00, SD=1.66), t=-.563, p < 0.05. There was also an increase in the mean from the pre-test (M= 3.57) to the post-test (M=3.71) in the question regarding attractiveness, indicating an improvement in the patient's perception of the attractiveness of the waiting area. A larger sample size would be needed to determine the statistical significance of how aesthetic changes impact patient comfort.

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Improving Patient Comfort Using Evidence-Based Design in Primary Care Waiting Areas

Introduction

It is difficult to separate the built environment from the care provided within the healthcare environment (Ulrich, Berry, Quan, & Parish, 2010). More and more facilities are being developed as the demand for greater access to healthcare increases. There must be close attention taken to the design of the facility to benefit both the patient and staff populations (Kotzer, Zacharakis, Raynolds, & Buenning, 2011). The design of a healthcare facility plays a vital role in the care of patients as well as the comfort level of both patients and staff alike.

Evidence-based design is the process of basing decisions about the built environment of a healthcare facility to achieve the best possible outcomes. There are several steps included in this process. The eight steps of the evidence-based design process and are as follows: define evidence-based goals, find sources for relevant evidence, critically interpret relevant evidence, create and innovate evidence-based design concepts, develop a hypothesis, collect baseline performance measures, monitor implementation of design and construction and measure post-occupancy performance results (The Center for Health Design, 2018). With the implementation of evidence-based design, facilities can make decisions regarding the physical aspect of the care environment to reduce stress, improve safety and productivity, reduce resource waste and strengthen the sustainability of the healthcare environment (Ulrich et al., 2010). As identified by Cesario (2009), three outcome categories can be impacted by the use of evidence-based design. These three categories are stress reduction, safety, and overall health care quality and ecology. By creating a healthcare environment that addresses each of these areas of concern, all participants involved have the opportunity to benefit from the intervention.

The purpose of this scholarly quality improvement (QI) project was to implement evidence-based design strategies in a primary care waiting area to determine the impact on patient comfort related to the primary care environment. The PICOT question for this DNP QI project is as follows:

In the primary care practice setting, does a healthcare facility implementing an evidencebased design concept increase patient comfort related to the built environment as compared to a healthcare facility not based on evidence-based design concepts?

The objectives for this DNP scholarly QI project will be as follows:

- 1. Increase patient comfort concerning waiting area design and characteristics.
- 2. Obtain an adequate sample size of approximately 30 patients or more.
- 3. Implement evidence-based design concepts while being cost-effective.

Identification of Need

It is estimated that nearly 20 billion dollars are spent per year in the United States for healthcare construction (Berry, Parker, Coile, Hamilton, O'Neill, and Sadler, 2004). Each aspect of the patient environment influences the care the patient receives. These aspects can range from the equipment, furnishings, color of the walls, landscaping, or even the building's structure in general (Ulrich et al., 2010). The design of healthcare facilities impacts not only patient outcomes but also the nurses and other health care workers. It can affect both staff recruitment and staff retention (Cesario, 2009). According to Zborowsky and Hellmich (2011), in order to create an optimal healing environment, three aspects contribute to healing. Creating this optimal healing environment is a multifaceted process and incorporates people, place, and environment. When addressing the patient holistically, an optimal healing environment is created.

It is estimated that knowledge in healthcare doubles every 18 months (Nagle, Sermeus, & Junger, 2017). Therefore, since healthcare has continued to change dramatically, so do the factors that drive the design of healthcare facilities. There is now a more competitive nature in healthcare. Hospital and outpatient facilities are expected to provide quality care as well as hospitality in a pristine healthcare environment (Zborowsky & Hellmich, 2011). The pressure can be especially felt with the use of the Merit-based Incentive Program System (MIPS) that the Centers for Medicare Services has implemented over the last several years. In the MIPS program, physicians are reimbursed based on several grading criteria. Areas of grading include quality, promoting interoperability, improvement activities, and cost (CMS, 2018). Evidence-based design can not only affect quality and improvement activities but also help to reduce cost by improving patient outcomes (Kotzer et al., 2011).

The CDC (2017) reported 990.8 million physician office visits in the year 2015, with over 50% being primary care visits. With primary care accounting for such a large percentage of physician visits, there is an unprecedented opportunity to make a difference in this population. Also, within the primary care environment, there is a great deal of time that patients spend in the waiting area. Data reveals that the average time spent in the waiting area between registration and seeing the provider is approximately 41 minutes (Ahmad, Khairatul, & Farnaza, 2017). While the concept of evidence-based design could be applied to a variety of patient populations, this scholarly project will focus on the primary care patient population within the waiting area setting.

The primary care setting in which this scholarly QI project took place has been in the same location for approximately 11 years. This facility is privately owned by the practicing family medicine physician. There have not been any changes made to the facility since the

original construction. By using evidence-based design, there is a potential to reduce discomfort in this area, and therefore improving the patient experience of this population. By improving the patient experience, there is the potential to improve patient outcomes.

Review of the Literature

An extensive literature review was performed to obtain data related to evidence-based design and its relationship to the patient experience. The databases used for this literature review included Pubmed, CINAHL, OVID, and ScienceDirect. Several keywords were used, including evidence-based design, healthcare facility, patient satisfaction, family medicine, patients, nurses, staff retention. Limitations used to narrow the search included peer-reviewed, English language, research article, and published date within the last 15 years. The results revealed 158 articles from CINAHL, 40 articles from Pubmed, 91 articles from OVID, and 2,985 articles from Science Direct. This review of the literature was then narrowed further to the use of approximately 40 articles.

Throughout the literature review, there was support for the use of evidence-based design to improve outcomes for both patient and staff populations. In the primary care setting, by enhancing the physical environment in which the healthcare is provided, there is an opportunity to reduce the stress of patients and staff members (Ulrich et al., 2010). Several areas of the built environment can help to reduce the stress on patient and staff population. These areas may include aspects such as the layout of the patient room, natural light, storage, writing surfaces, comfort, and appeal (Kotzer et al., 2011). Even areas of the practice environment such as the acoustics, floor material, and natural light affect the stress of the population involved. A study performed by Harris (2015), compared three different types of flooring and how each type of flooring affected sound levels, healthcare worker responses as well as Hospital Consumer

Assessment of Healthcare Providers and Systems (HCAHPS) ratings over 42 weeks. The study found that a flooring that provided a reduction in sound and was more comfortable under foot resulted in an increase in satisfaction of both staff and patient populations. While most of the past research has been done in inpatient settings, there has been a recent push towards outpatient facilities. A research study done by Ajiboye, Dong, Moore, Kallail, and Baughman (2015) indicated that even the layout of a patient exam room can determine the patient's willingness to discuss health concerns. By replacing the typical exam table with a pedestal table, the patient felt more comfortable and were able to communicate more effectively. These are just a few examples of how evidence-based design can be applied to a variety of setting and patient populations.

Research has shown that the perceived attractiveness of the waiting area increased both the appraisal of the wait and the satisfaction with the service provided (Pruyn & Smidts, 1998). A study performed by Haddox (2018), revealed that the design of the healthcare facility as perceived by the patient influenced the patient participation, which in turn influenced patient outcomes. By patients becoming more actively involved in the healthcare experience, health outcomes have the potential to improve. The three areas of focus for this scholarly project that included design aspects of the waiting area intending to improve patient satisfaction. These three interventions included changing of the wall color from yellow to a light blue, the use of live greenery and replacing generic artwork with local artwork from an art gallery within the same town as the practice location for a more personalized touch. These three areas of evidence-based design research will be discussed further.

Wall Color

Numerous research studies show how color affects mood. Patients react to various colors in specific ways, and it has been found that cool colors such as blue and green seem to have a

relaxing effect (Ayas, Eklund, & Ishihara, 2008). The use of color has also been assessed within the pediatric environment. Research indicates that even the pediatric population responded better to blue and green hues on the wall (Park, 2009). The use of the color blue has been linked to positivity, harmony, peace, calm, and tranquility. By using this color, it has the potential to have an anti-depressive effect on the patient population, which can lead to improving patient outcomes (Call & Jantzen, 2012). Within healthcare environments the use bland colors can deprive the senses and can ultimately be detrimental to healing. Research has shown that the color blue is beneficial in the waiting area to soothe anxious patients (Baughan-Young, 2001)

Use of Greenery

The use of indoor plants provides a positive distraction for patients, especially green, palm-like plants. Indoor plants have been shown to reduce physical discomfort and perceived stress (Ayas, et al., 2008). Studies have shown that healthcare environments with higher satisfaction ratings included design aspects such as the use of live plants (Rice et al., 2008). Lee et al. (2015) found that active interaction with live indoor plants can reduce both physiological and psychological stress. Plants function to reduce physiological stress by producing oxygen as well as clean the toxins in the air (Wolverton, 1997). By reducing both physiological and psychological stress, the use of live plants have been linked to improvement in clinical outcomes such as reducing pain medication and shortening hospital stays (Ulrich, 2002). Plants also function to help produce oxygen as well as clean the toxins in the air.

Artwork Displayed

As mentioned above, the design of the healthcare environment affects patient satisfaction, including small details such as the artwork displayed on the walls. Local, more personalized artwork has shown to help improve the aesthetic of the facility. Patients have voiced the desire

for local artwork rather than "generic store art" to improve the healthcare environment (Haddox, 2018). A study completed by Nielsen et al. (2017) noted that the use of artwork in the healthcare setting aided patients in feeling safe and free to socialize while in the healthcare office. The use of artwork works to introduce a harmonious and uplifting environment for the patient population. Therefore, the incorporation of artwork is no longer looked at as frivolous but as an integral part of the healthcare design (Markoff, 2015). The researchers also concluded that the use of artwork improved satisfaction, which in turn improved patient outcomes.

Theoretical Framework

The theoretical framework applicable to the impact of the evidence-based design of the healthcare facility is the middle-range comfort theory by Katherine Kolcaba. Comfort Theory contains three intuitive components that can be applied separately or as a whole. The first component states that comforting interventions result in increased comfort for the recipient.

These comfort interventions address basic human needs and view the patient holistically. The second component reports that by increasing the comfort level of patients, this results in an increase in strength towards health-seeking behaviors. The third component of comfort theory states that increase engagement in health-seeking behaviors results in increased institutional integrity. Having enhanced institutional integrity strengthens the institution, or facility, and the ability of the facility to gather evidence for best practice and best policies. In turn, best practice and policies lead to better quality care for both patients and staff. By applying comfort theory to the daily practice in a healthcare facility, staff provide individualized care that is efficient, creative, and satisfying to both themselves and patients who receive said care (Smith & Parker, 2015).

Subsequently, this theory applies to most patient populations and focuses on basic, holistic care. Comfort theory lends itself to the concept of evidence-based design in the primary care setting. Primary care serves a wide variety of patients. Providing comfort is an essential component of good nursing care. It confirms what is essential to patients, families, and factors that facilitate healing. If healthcare providers have such a strong knowledge base, but the facility is prohibiting them from providing the best care, there is a severe disservice to the patient population. By using this theory to guide the concept of evidence-based design, the patient will experience enhanced comfort as well as higher productivity (Smith & Parker, 2015). A relationship diagram has been provided to demonstrate the relationship of Kolcaba's comfort theory to the use of evidence-based design. (see Figure 1)

Conceptual Framework

The conceptual framework used for this scholarly QI project was the Plan-Do-Study-Act (PDSA) model. A QI project is a systematic and continuous process that leads to measurable improvement in healthcare services and the health status of the targeted population (Moran, Burson, & Conrad, 2017). This framework aligns consistently with the purpose and clinical focus of this scholarly QI project. Use of the PDSA model allows for a structured process to design, implement, measure, and disseminate the QI project (Hall & Roussel, 2017). The PDSA cycle can be used as both an implementation tool and evaluation tool. By using the PDSA model as an evaluation tool, there is an opportunity to modify and refine the intervention before a second implementation cycle (Agency for Healthcare Research, 2008). This methodology helps to enable an attitude of continuous improvement. An additional strength of the use of the PDSA model is that the concept of the cycle implementation is simple to understand and can be used by a large number of professionals (Sokovic, Pavletic, & Pipan, 2010).

During the planning phase, the essential tasks were identified, and a timeline was agreed upon among members. This phase lasted approximately four weeks. The focus was on the specific improvement activity and how it connects to the daily environment of the healthcare facility. In this scholarly project, the planning phase included key stakeholders such as the primary care office staff consisting of one nurse, three clerical personnel, one nurse practitioner, and one physician. A cause and effect analysis and pre-test data were collected for comparison. The pre-test data included a patient satisfaction survey to serve as a baseline for comparison after the intervention was implemented.

The do phase of the scholarly QI project included the implementation of the intervention of the project. This phase lasted approximately four weeks. The intervention defined in the planning phase was executed, and an evaluation of the intervention was performed. After the implementation of all defined changes was completed, the post-test was administered to evaluate the effectiveness of the QI project and potential improvement in patient comfort.

The study phase incorporated an evaluation of the impact of the implementation on the healthcare environment. This phase determined the successfulness of the QI project. The data analysis was completed that compared and analyzed pre- and post-implementation data related to patient comfort. The summary report was created, and the PICOT question created during the planning phase was compared to the outcome. The total time allotted for this phase was four weeks.

The act phase was the final phase of the scholarly project and lasted approximately four weeks. This phase involved dissemination and determination of the next steps for broader distribution of the QI project. This phase helped to decide whether the PDSA cycle needed to be modified for implementation at the microsystem or macrosystem level.

SECTION II: DNP PROJECT PRODUCT

Professional Journal Selection

The journal of choice will be the Health Environments Research and Design Journal (HERD). This journal is a quarterly interdisciplinary, peer-reviewed journal that works to enrich knowledge and practice of evidence-based healthcare design by disseminating research findings, discussing issues and trends, and translating research to practice. Articles within the journal feature healthcare innovations and design (The Center for Health Design, 2018). This journal aligns with the core aspects of this scholarly project and would fit well the attributes of the journal. A query letter has been sent to the editor with positive feedback for journal submission.

Scope of Journal

This journal features a variety of evidence-based articles that focus on the use of designrelated outcomes associated with safety, clinical results, organizational performance, economics,
and human experience. There are several disciplines displayed throughout the journal that
includes both professionals in the healthcare realm and design industry. These professionals
include nurses, physicians, healthcare administrators, architects, engineers, interior decorators,
and graphic designers. There is also a tie into fields such as behavioral and environmental
psychology, neuroscience, art, music, and other complementary fields. This journal uses all of
the above to encompass a common goal to improve patient outcomes by displaying knowledge
about healthcare innovations and design while also addressing significant industry challenges
(SAGE, 2019).

Aims of Journal

The goal and vision of HERD are to enhance healthcare environments to improve the outcomes for both those receiving care and providing care within the healthcare environment.

HERD serves as a translational journal and features both rigorous research and application to practice for all professionals. Every submission, whether from a scholar or practitioner, are held to high standards (SAGE, 2019).

Improving Patient Comfort in the Primary Care Waiting Area Using Evidence-Based

Design

by

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Keywords: Evidence-Based Design, Cost-effective, Family Medicine, Waiting Room, Quality Improvement Project

ABSTRACT

Title: Improving Patient Comfort in Primary Care Using Evidence-Based Design in Waiting

Areas

The majority of healthcare visits occur in the primary care setting; therefore, the environment directly affects comfort and ultimately, the patient experience. A large part of the visit is spent in the patient waiting area. Aesthetics of the office have been found to affect patient satisfaction in their healthcare visit. A project was conducted using cost-effective, evidencebased design strategies to determine if making aesthetic changes to a waiting room would improve the patient experience. Wall color, live plants, and local artwork were used in a Plan-Do-Study-Act (PDSA) project. Patients were administered a survey related to the waiting area environment before and after the intervention. The purpose of the quality improvement project was to determine if cost-effective, evidence-based design strategies will improve patient comfort within the primary care waiting environment. After the intervention, there was no statistically significant change in patient comfort; however, there was a mean increase from pre-test (M=14.93, SD=1.639) to the post-test (M=15.00, SD=1.66), t=-.563, p<0.05. There was also an increase in the mean from the pre-test (M=3.57) to the post-test (M=3.71) of the question regarding attractiveness, indicating an improvement in the patient's perception of the attractiveness of the waiting area. A larger sample size would be needed to determine the statistical significance of how aesthetic changes impact patient comfort.

Improving Patient Comfort in Primary Care Using Evidence-Based Design in Waiting Areas

Introduction

It is difficult to separate the built environment from the care provided within the healthcare environment (Ulrich, Berry, Quan, & Parish, 2010). More and more facilities are being developed as the demand for greater access to healthcare increases. There must be close attention taken to the design of the facility to benefit both the patient and staff populations (Kotzer, Zacharakis, Raynolds, & Buenning, 2011). The design of a healthcare facility plays a vital role in the care of patients as well as the satisfaction level of both patients and staff alike. Evidence-based design is the process of basing decisions about the built environment of a healthcare facility to achieve the best possible outcomes. There are several steps included in this process. The eight steps of the evidence-based design process and are as follows: define evidence-based goals, find sources for relevant evidence, critically interpret relevant evidence, create and innovate evidence-based design concepts, develop a hypothesis, collect baseline performance measures, monitor implementation of design and construction and measure postoccupancy performance results (The Center for Health Design, 2018). With the implementation of evidence-based design, facilities can make decisions regarding the physical aspect of the care environment to reduce stress, improve safety and productivity, reduce resource waste and strengthen the sustainability of the healthcare environment (Ulrich et al., 2010). As identified by Cesario (2009), three outcome categories can be impacted by the use of evidence-based design. These three categories are stress reduction, safety, and overall health care quality and ecology. By creating a healthcare environment that addresses each of these areas of concern, all participants involved have the opportunity to benefit from the intervention. The purpose of this

scholarly quality improvement (QI) project was to implement evidence-based design strategies in a primary care waiting area to determine the impact on patient comfort.

Significance

With the increased rate of construction of health care facilities, more and more facilities are focusing on creating an optimal physical environment to accomplish optimal outcomes for patients, families, and staff (Kotzer et al., 2011). Both existing structures and new facilities are being built to meet the need for increasing healthcare growth. It is estimated that nearly 20 billion dollars are spent per year in the United States for healthcare construction (Berry, Parker, Coile, Hamilton, O'Neill, and Sadler, 2004). Each aspect of the patient environment influences the care the patient receives. These aspects can range from the equipment, furnishings, color of the walls, landscaping, or even the building's structure in general (Ulrich et al., 2010). The design of healthcare facilities impacts not only patient outcomes but also the nurses and other health care workers. It can affect both staff recruitment and staff retention (Cesario, 2009). According to Zborowsky and Hellmich (2011), to create an optimal healing environment, three aspects contribute to healing. The creating of this environment is a multifaceted process and incorporates people, place, and environment. When addressing the patient holistically, an optimal healing environment is created.

It is estimated that knowledge in healthcare doubles every 18 months (Nagle, Sermeus, & Junger, 2017). Therefore, since healthcare has continued to change dramatically, so do the factors that drive the design of healthcare facilities. There is now a more competitive nature in healthcare. Hospital and outpatient facilities are expected to provide quality care as well as hospitality in a pristine healthcare environment (Zborowsky & Hellmich, 2011). The pressure can be especially felt with the use of the Merit-based Incentive Program System (MIPS) that the

Centers for Medicare Services has implemented over the last several years. In the MIPS program, physicians are reimbursed based on several grading criteria. Areas of grading include quality, promoting interoperability, improvement activities, and cost (CMS, 2018). Evidence-based design can not only affect quality and improvement activities but also help to reduce cost by improving patient outcomes (Kotzer et al., 2011).

The CDC (2017) reported 990.8 million physician office visits in the year 2015, with over 50% being primary care visits. With primary care accounting for such a large percentage of physician visits, there is an unprecedented opportunity to make a difference in this population. Also, within the primary care environment, there is a great deal of time that patients spend in the waiting area. Data reveals that the average time spent in the waiting area between registration and seeing the provider is approximately 41 minutes (Ahmad, Khairatul, & Farnaza, 2017). While the concept of evidence-based design could be applied to a variety of patient populations, this scholarly project will focus on the primary care patient population within the waiting area setting.

The primary care setting in which this scholarly QI project took place has been in the same location for approximately 11 years. This facility is privately owned by the practicing family medicine physician. There have not been any changes made to the facility since the original construction. By using evidence-based design, there is a potential to reduce discomfort in this area, therefore improving the patient experience in this population. By improving the patient experience, there is the potential to improve patient outcomes.

Aim or Purpose

The purpose of this scholarly project was to implement evidence-based design strategies in a primary care waiting area to determine the impact on patient comfort. The PICOT question for this DNP project is as follows:

In the primary care practice setting, does a healthcare facility implementing an evidence-based designed concept increase patient comfort as compared to a healthcare facility not based on evidence-based design concepts over three months? The purpose of this scholarly quality improvement (QI) project was to implement evidence-based design strategies in a primary care waiting area to determine the impact on patient comfort, therefore relating to patient satisfaction.

Theoretical Framework

The theoretical framework applicable to the impact of the evidence-based design of the healthcare facility is the middle-range comfort theory by Katherine Kolcaba. Comfort Theory contains three intuitive components that can be applied separately or as a whole. The first component states that therapeutic interventions result in increased comfort for the recipient. These comfort interventions address basic human needs and view the patient holistically. The second component reports that by increasing the comfort level of patients, this results in an increase in strength towards health-seeking behaviors. The third component of comfort theory states that increase engagement in health-seeking behaviors results in increased institutional integrity. Having enhanced institutional integrity strengthens the institution, or facility, and the ability of the facility to gather evidence for best practice and best policies. In turn, best practice and policies lead to better quality care for both patients and staff. By applying comfort theory to the daily practice in a healthcare facility, staff provide individualized care that is efficient,

creative, and satisfying to both themselves and patients who receive said care (Smith & Parker, 2015).

Subsequently, this theory applies to most patient populations and focuses on primary, holistic care. Comfort theory lends itself to the concept of evidence-based design in the primary care setting. Primary care serves a wide variety of patients. Providing comfort is an essential component of good nursing care. It confirms what is vital to patients, families, and factors that facilitate healing. If healthcare providers have such a strong knowledge base, but the facility is prohibiting them from providing the best care, there is a severe disservice to the patient population. By using this theory to guide the concept of evidence-based design, the patient will experience enhanced comfort as well as higher productivity (Smith & Parker, 2015). A relationship diagram has been provided to demonstrate the relationship of Kolcaba's comfort theory to the use of evidence-based design. (see Figure 1)

Review of the Literature

An extensive literature review was performed to obtain data related to evidence-based design and its relationship to the patient experience. The databases used for this literature review included Pubmed, CINAHL, OVID, and ScienceDirect. Several keywords were used, including evidence-based design, healthcare facility, patient satisfaction, family medicine, patients, nurses, staff retention. Limitations used to narrow the search included peer-reviewed, English language, research article, and published date within the last 15 years. The results revealed 158 articles from CINAHL, 40 articles from Pubmed, 91 articles from OVID, and 2,985 articles from Science Direct. This review of the literature was then narrowed further to the use of approximately 40 articles.

Throughout the literature review, there was support for the use of evidence-based design to improve outcomes for both patient and staff populations. In the primary care setting, by enhancing the physical environment in which the healthcare is provided, there is an opportunity to reduce the stress of patients and staff members (Ulrich et al., 2010). Several areas of the built environment can help to reduce the stress on patient and staff population. These areas may include aspects such as the layout of the patient room, natural light, storage, writing surfaces, comfort, and appeal (Kotzer et al., 2011). Even areas of the practice environment such as the acoustics, floor material, and natural light affect the stress of the population involved. A study performed by Harris (2015), compared three different types of flooring and how each type of flooring affected sound levels, healthcare worker responses as well as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) ratings over 42 weeks. The study found that a flooring that provided a reduction in sound and was more comfortable under foot resulted in an increase in satisfaction of both staff and patient populations. While most of past research has been done in inpatient settings, there has been a recent push towards outpatient facilities. A research study completed by Ajiboye, Dong, Moore, Kallail, and Baughman (2015) indicated that even the layout of an outpatient exam room can determine the patient's willingness to discuss health concerns. By replacing the typical exam table with a pedestal table, the patient felt more comfortable and was able to communicate more effectively. These are just a few examples of how evidence-based design can be applied to a variety of setting and patient populations.

Research has shown that the perceived attractiveness of the waiting area increased both the appraisal of the wait and the satisfaction with the service provided (Pruyn & Smidts, 1998). A study performed by Haddox (2018), revealed that the design of the healthcare facility as

perceived by the patient influenced the patient participation, which in turn influenced patient outcomes. By patients becoming more actively involved in the healthcare experience, health outcomes have the potential to improve. The three areas of focus for this scholarly project that included design aspects of the waiting area intending to improve patient satisfaction. These three interventions included changing of the wall color from yellow to a light blue, the use of live greenery and replacing generic artwork with local artwork from an art gallery within the same town as the practice location for a more personalized touch. These three areas of evidence-based design research will be discussed further.

Wall Color

Numerous research studies show how color affects mood. Patients react to various colors in specific ways, and it has been found that cool colors such as blue and green seem to have a relaxing effect (Ayas, Eklund, & Ishihara, 2008). The use of color has also been assessed within the pediatric environment. Research indicates that even the pediatric population responded better to blue and green hues on the wall (Park, 2009). The use of the color blue has been linked to positivity, harmony, peace, calm, and tranquility. By using this color, it has the potential to have an anti-depressive effect on the patient population, which can lead to improving patient outcomes (Call & Jantzen, 2012). Within healthcare environments the use bland colors can deprive the senses and can ultimately be detrimental to healing. Research has shown that the color blue is specifically beneficial in the waiting area to soothe anxious patients (Baughan-Young, 2001)

Use of Greenery

The use of indoor plants provides a positive distraction for patients, especially green, palm-like plants. Indoor plants have been shown to reduce physical discomfort and perceived stress (Ayas, et al., 2008). Studies have shown that healthcare environments with higher

satisfaction ratings included design aspects such as the use of live plants (Rice et al., 2008). Lee et al. (2015) found that active interaction with live indoor plants can reduce both physiological and psychological stress. Plants function to reduce physiological stress by producing oxygen as well as cleaning the toxins in the air (Wolverton, 1997). By reducing both physiological and psychological stress, the use of live plants has been linked to improvement in clinical outcomes such as reducing pain medication and shortening hospital stays (Ulrich, 2002).

Artwork Displayed

As mentioned above, the design of the healthcare environment affects patient satisfaction, including small details such as the artwork displayed on the walls. Local, more personalized artwork has shown to help improve the aesthetic of the facility. Patients have voiced the desire for local artwork rather than "generic store art" to improve the healthcare environment (Haddox, 2018). A study completed by Nielsen et al. (2017) noted that the use of artwork in the healthcare setting aided patients in feeling safe and free to socialize while in the healthcare office. The researchers also concluded that the use of artwork improved satisfaction, which in turn improved patient outcomes. The use of artwork works to introduce a harmonious and uplifting environment for the patient population. Therefore, the incorporation of artwork is no longer looked at as frivolous but as an integral part of the healthcare design (Markoff, 2015).

Methodology

After obtaining approval from the Institutional Review Board at the University of Alabama in Huntsville, informed consent was obtained from each participant, and the implementation process began. The conceptual framework used for this scholarly QI project was the Plan-Do-Study-Act (PDSA) model. This framework aligns consistently with the purpose and clinical focus of this scholarly QI project. Use of the PDSA model allows for a structured

process to design, implement, measure, and disseminate the QI project (Hall & Roussel, 2017). The PDSA cycle can be used as both an implementation tool and evaluation tool. By using the PDSA model as an evaluation tool, there is an opportunity to modify and refine the intervention before a second implementation cycle (Agency for Healthcare Research, 2008). This methodology helps to enable an attitude of continuous improvement and will be discussed throughout each section below.

Setting

The setting in which this QI project took place was a primary care office in a suburban area of north Alabama. The office was privately owned by a family practice physician who has been in the same location for the past 11 years. The building was original construction designed by the physician. The average number of patients seen per day range from 40-45 patients per day. The office sees approximately 2650 total patients from two months to 97 years of age. The planning phase incorporated the focus on the specific improvement activity and how it connects to the daily environment of the healthcare facility setting. The intervention agreed upon was the changing of the wall color and artwork on the wall, as well as the addition of live plants to the waiting area environment. In this scholarly project, the planning phase included key stakeholders within this particular healthcare setting such as the primary care office staff consisting of one nurse, three clerical personnel, one nurse practitioner, and one physician.

Participants

A convenience sample was used to determine participants for this QI study in the planning phase of the project. The participants were chosen from patients seen for monthly B12 injections due to the increased likelihood of a quick return visit after the intervention was complete. The inclusion criteria for the QI study was that the patient must be between the ages of

20 – 80 and be an established patient in the B12 clinic for a minimum of six months. The exclusion criteria included any patient who had not been an established patient at the facility in the past six months and an age of less than 20 or older than 80. Both male and female participants of any race were considered equally. The anticipated number of participants was a total of 30 participants; however, only 15 participants were collected for pre-test data with attrition of one for post-test data collection.

Tools

The tool used for assessment of the intervention in this QI project was a Likert scale survey provided by the Massachusetts Medical Society. Permission was granted from the Massachusetts Medical Society before using the survey (See Appendix D). The medical society has utilized this survey since 2004. The Likert scale survey used for this scholarly project included questions regarding comfort, convenience, and attractiveness. Participants were asked to rank their contentment on a scale of 1-4, with one being poor and four being excellent (See Appendix A).

Intervention

The do phase of the scholarly QI project included the implementation of the intervention of the project. This phase lasted approximately four weeks. The intervention defined in the planning phase was executed, and an evaluation of the intervention was performed. The implementation phase of the QI project consisted of making changes to the current waiting area at the healthcare facility and distributing post-test surveys for evaluation. The changes to the waiting area included painting the walls with a softer tone of color, replacing the artwork on the wall and including live indoor plants to the waiting room environment. (See Appendix B). The changes made to the waiting area over a weekend after the pre-test surveys were collected over

four weeks. Once adjustments were made, post-test surveys were administered to the participants on their return visit to determine the effectiveness of the intervention.

Budget

The total cost for this QI project was approximately \$600.00. This budget covered the price of 3 gallons of paint, paint supplies, live indoor plants, and administrative supplies. A local art gallery donated the artwork displayed on the walls. The manual labor for the intervention was done by the DNP student at no cost. See Table 1 for visual representation and breakdown of the budget for the project.

Data Analysis Methods

The study phase of the QI scholarly project included the interpretation and comparison of pre- and post-test data to determine if the intervention implemented was successful. This study phase lasted approximately four weeks to allow for adequate evaluation and interpretation. The Likert-type scale surveys were evaluated using both parametric and non-parametric test. It has been shown that the use of parametric tests is sufficient for assessing ordinal data and are generally more robust than non-parametric tests (Sullivan & Artino, 2013). However, since there was a low number of participants, non-parametric tests were used as well. The specific parametric test to be used in this scholarly project will be the paired t-test. The non-parametric test used was the Wilcoxon Test. These tests help to determine the significance between the responses of patients on pre- and post-test surveys. The statistical analysis system used to formalize the results was the SPSS data management system (IBM Corp., 2017). Also during the study phase, a summary report was created and the PICOT question created during the planning phase was compared to the outcome.

Findings

The paired t-test was performed, and the pretest criterion was satisfied by determining a normal curve on the histogram. There was no statistical significance noted from the pre-test (M=14.93, SD=1.639) to the post-test (M=15.00, SD=1.66), t=-.563, p<0.05. There was; however, an increase in the mean from the pre-test (M=3.57) to the post-test (M=3.71) of question four indicating and improvement in the patient's perception of the attractiveness of the waiting area. Therefore, the results were statistically insignificant, and we would reject the alternative hypothesis and accept the null hypothesis. However, in two of the surveys that the pre- and post-test scores were the same, there was an increase in the patient's perception of the attractiveness of the waiting area.

Limitations

Limitations to this QI project included a small sample size, which would be considered as a change within the act phase of the PDSA model. Although the B12 population is ideal for the pre- and post-evaluation due to a return visit within a month timeframe, the number of patients in this group is relatively small. Also, the size of the primary care office is approximately 3,000 square feet, so there is not much room for structural growth. This presented a limitation in the fact that the intervention planned had to be cosmetic. However, with the intervention being cosmetic, there was less money spent, therefore allowing a smaller budget. It was difficult to determine the length of time patients spent in the waiting room, which can also present a barrier. The amount of time spent in the waiting area may alter the patient's perspective. Of note, this particular population presented as an already satisfied group; therefore, there was very little room for improvement of satisfaction. All of these limitation were considered within the act phase of the QI scholarly project for future implementation cycles.

Conclusions

In conclusion, an evidence-based design intervention has the potential to impact the primary care population and improve patient outcomes. There is anticipation that this QI project will create an opportunity for implementation in other areas of healthcare and a variety of different environments. By implementing evidence-based design strategies, patient outcomes and comfort may be improved while remaining cost-effective. Although no statistical significance was found in patient comfort, there was an increase in the mean indicating an improvement in patient's perceptions of the change. By using the PDSA framework, there are further plans to reevaluate the population in order to have a larger impact. The QI project was completed without any potential harm to the patient or healthcare professional population while maintaining a strict budget. Therefore, this project has the potential to be implemented in a variety of areas.

Recommendations for Future Results

The act phase was the final phase of the scholarly project and involved dissemination and determination of the next steps for broader distribution of the QI project. This phase lasted approximately four weeks and helped to decide whether the PDSA cycle needed to be modified for implementation at the microsystem or macrosystem level. It was determined during this phase that a larger sample size would be needed for further evaluation as mentioned earlier. There are several environments and populations evidence-based design can help to improve. Throughout this project, several employees noted an improvement in the patient experience with the waiting area. There are areas of research that states there can be an improvement in staff satisfaction as well (Cesario, 2009). There are also opportunities to implement this type of research into an outpatient or even long-term care setting as well. With an evidence-based design foundation, the sky is the limit to improve future patient outcomes.

Implications for Practice

Patient comfort regarding the physical environment continues to be a growing issue in healthcare. Studies have been shown to correlate an increase in patient satisfaction with improved health outcomes. By improving patient comfort within the healthcare environment, there is a potential to improve patient satisfaction with their overall healthcare experience. Several techniques can be used to enhance patient comfort in the environment. The methods included in this scholarly project included paint color, greenery, and artwork. However, other tactics proven to improve patient comfort can consist of indoor changes such as flooring and furnishings or outdoor changes such as landscaping and exterior presence (Ulrich et al., 2010). Therefore, the use of evidence-based design can create a reduction in the practice gap by improving healthcare environments for both patients and staff. Although the cost of the unprecedented healthcare growth continues, the use of evidence-based design can help to reduce healthcare costs by improving patient outcomes and staff retention (Kotzer et al., 2011; Laursen, Danielsen, & Rosenberg, 2014). Another strength of the use of the evidence-based design in the practice setting is the easy low-risk implementation. The improvement of patient satisfaction related to the healthcare environment with minimal risk makes evidence-based design feasible in most healthcare settings (Laursen et al., 2014). The use of evidence-based design allows the doctorally prepared nurse to collaborate with other non-healthcare professionals, such as designers and architects so that both patients and healthcare staff benefit (Rabner, 2012). Unfortunately, deficits occur in the design of healthcare facilities due to the focus of designers. the way designers are trained, as well as the way design knowledge is shared and disseminated (Dickerman & Barach, 2008). The doctorally prepared nurse can help to influence the design from a healthcare and leadership knowledge base while working to create a common ground with interprofessional relationships (Redden & Evans, 2014). During the QI project, office staff liked the changes and requested the project be implemented in the patient care/work areas. Staff satisfaction related to evidence-based design strategies lends itself to future projects.

As previously discussed, there is an unprecedented opportunity for inter-collaborative practice with the implementation of evidence-based design strategies. The doctorally prepared nurse has a chance to determine the needs of both patients and staff, to be an effective communicator and participate in design teams. These design teams are multi-professional and can include architects and interior designers (Cesario, 2009). Nurses and healthcare professionals provide insight to help impact the design of healthcare delivery as well as design solutions for the supporting environment (Evans, 2014). There is also an opportunity to complete a certification course in evidence-based design. This certification will help to incorporate the knowledge a healthcare provider possesses with the field of architecture and physical design to obtain better outcomes (The Center for Health Design, 2018).

References

- Agency for Healthcare Research and Quality. (2008). *Plan-do-study-act (PDSA) cycle*. Retrieved from https://innovations.ahrq.gov/qualitytools/plan-do-study-act-pdsa-cycle
- Ahmad, B. A., Khairatul, K., & Farnaza, A. (2017). An assessment of patient waiting and consultation time in a primary healthcare clinic. *Malaysian Family Physician*, 12(1), 14-21.
- Ajiboye, F., Dong, F., Moore, J., Kallail, K. J., & Baughman, A. (2015). Effects of revised consultation room design on patient-physician communication. *HERD*, 8(2), 8-17. doi:10.1177/1937586714565604
- Ayas, E., Eklund, J., Ishihara, S. (2008). Affective design of waiting areas in primary healthcare. *The TQM Journal*, 20 (4), 389-408
- Baugham-Young, K. (2001). Healing power of color as cheap as a coat of paint. *Managed Care*, 10(11), 40-1.
- Berry, L. L., Parker, D., Coile, R. C., Jr., Hamilton, D. K., O'Neill, D. D., & Sadler, B. L. (2004). The business case for better buildings. *Healthcare Financial Management*, 58(11), 76-78, 80, 82-74 passim.
- Call, P., & Jantzen, K. (2012). Does your color scheme ireally matter? *Behavioral Healthcare*, 32(3), 14-16.
- Centers for Disease Control. (2017). Ambulatory care use and physician office visit. onRetrieved from https://www.cdc.gov/nchs/fastats/physician-visits.htm.
- Center for Health Design (2018). *About*. Retrieved from https://www.healthdesign.org/certification-outreach/edac/about

- Center for Medicare and Medicaid Services. (2018). *MIPS overview*. Retrieved from https://qpp.cms.gov/mips/overview
- Cesario, S. K. (2009). Designing health care environments: Part I. Basic concepts, principles, and issues related to evidence-based design. *Journal of Continuing Education in Nursing*, 40(6), 280-288.
- Dickerman, K. N., & Barach, P. (2008). Designing the Built Environment for A Culture and System of Patient Safety A Conceptual, New Design Process. In K. Henriksen, J. B. Battles, M. A. Keyes, & M. L. Grady (Eds.), Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign). Rockville (MD).
- Evans, J. (2014). Evolving leadership in healthcare design. *Health Environments Research and Design Journal*, 7(4), 9-12.
- Haddox, J. C. (2018). Impact of Design on Patient Participation in Healthcare in a Rural Health
 Clinic in Appalachia: A Qualitative Pilot Study. Health Environments Research and
 Design Journal, 11(1), 31-39. doi:10.1177/1937586717696701
- Hall, H. & Roussel, L. (2017). Evidence-based practice: An integrative approach to research, administration, and practice (2nd ed.). Burlington, MA: Jones and Bartlett.
- Harris, D. D. (2015). The influence of flooring on environmental stressors: a study of three flooring materials in a hospital. *HERD*, 8(3), 9-29. doi:10.1177/1937586715573730
- IBM Corp. (2017). IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY IBM Corp.
- Kotzer, A. M., Zacharakis, S. K., Raynolds, M., & Buenning, F. (2011). Evaluation of the built environment: Staff and family satisfaction pre- and post-occupancy of the Children's Hospital. *Health Environments Research and Design Journal*, 4(4), 60-78.

- Laursen, J., Danielsen, A., & Rosenberg, J. (2014). Effects of environmental design on patient outcome: a systematic review. *Health Environments Research and Design Journal*, 7(4), 108-119.
- Lee, M. S., Lee, J., Park, B. J., & Miyazaki, Y. (2015). Interaction with indoor plants may reduce psychological and physiological stress by suppressing autonomic nervous system activity in young adults: a randomized crossover study. *Journal of Physiological Anthropology*, 34, 21. doi:10.1186/s40101-015-0060-8
- Markoff, B. (2015). Art in healthcare is an integral part of the design plan. *Manhattan Arts International*. Retrieved from https://www.healing-power-of-art.org/art0in-healthcare-is-an-integral-part-of-the-design-plan/
- Moran, K. J., Burson, R., & Conrad, D. (2016). The doctor of nursing practice scholarly project:

 A framework for success. Burlington, Massachusetts: Jones and Bartlett Learning.
- Nagle, L. M., Sermeus, W., & Junger, A. (2017). Evolving Role of the Nursing Informatics Specialist. Studies in Health Technology and Informatics, 232, 212-221.
- Nielsen, S. L., Fich, L. B., Roessler, K. K., & Mullins, M. F. (2017). How do patients actually experience and use art in hospitals? The significance of interaction: a user-oriented experimental case study. *International Journal of Qualitative Studies on Health and Well-being*, 12(1), 1267343. doi:10.1080/17482631.2016.1267343
- Park, J. G. (2009). Color perception in pediatric patient room design: healthy children vs. pediatric patients. *Health Environement Research and Design Journal*, 2(3), 6-28.
- Pruyn, A., & Smidts, A. (1998). Effects of waiting on the satisfaction with the service: Beyond objective time measures. *International Journal of Research in Marketing*, 15(4), 321-334.

- Rabner, B. S. (2012). How to help hospitals achieve their mission through good design. *Health Environment Research and Design Journal*, 5(3), 7-11.
- Redden, P. H., & Evans, J. (2014). It takes teamwork... the role of nurses in ICU design. *Critical Care Nursing Quarterly*, 37(1), 41-52. doi:10.1097/CNQ.00000000000000000
- Rice, G., Ingram, J., & Mizan, J. (2008). Enhancing a primary care environment: a case study of effects on patients and staff in a single general practice. *British Journal of General Practice*, 58(552), 465-470. doi:10.3399/bjgp08X319422
- SAGE Publishing (2019). HERD: Health environments research & design journal. Retrieved from https://us.sagepub.com/en-us/nam/journal/herd-health-environments-research-design-journal-3#submission-guidelines
- Sokovic, M., Pavletic, D., & Pipan, K. (2010). Quality improvement methodologies PDCA cycle, RADAR matrix, DMAIC, and DFSS. *Journal of Achievements in Materials and Manufacturing Engineering*. 43(1), 476-483.
- Smith, M. C., & Parker, M. E. (2015). *Nursing Theories and Nursing Practice* (4th ed.). Philadelphia, PA: F. A. Davis Company.
- Sullivan, G. M., & Artino, A. R., Jr. (2013). Analyzing and interpreting data from likert-type scales. *Journal of Graduate Medical Education*, *5*(4), 541-542. doi:10.4300/JGME-5-4-18
- Ulrich, R. S., Berry, L. L., Quan, X., & Parish, J. T. (2010). A conceptual framework for the domain of evidence-based design. *Health Environments Research and Design Journal*, 4(1), 95-114.

- Ulrich, R. S. (2002). *Health benefits of gardens in hospitals*. Paper presented at Plants for People at the International Exhibition Floriade. Retrieved from https://greenplantsforgreenbuildings.org/new/health-benefits-of-gardens-in-hospitals/
- Wolverton, B. C. (1997). How to grow fresh air: 50 Household plants that purify your home or office. New York, New York: Penguin Books.
- Zborowsky, T., & Hellmich, L. B. (2011). Impact of place on people and process: the integration of research on the built environment in the planning and design of critical care areas.

 Critical Care Nursing Quarterly, 34(4), 268-281. doi:10.1097/CNQ.0b013e31822c3831

TABLES

Table 1

Budget Allotment Item Chart

Budget Item	Work Hours	Total Cost
Live Indoor Plants	2	\$300.00
Oil Paint Local Artwork (donated)	2	\$0.00
Paint supplies – Paint Brushes, Rollers, Paint Trays, drop cloths, tape (purchase)	2	\$100.00
Paint – 3 gallons (purchase)	2	\$125.00
Administrative Supplies (paper, ink and pens)	1	\$75.00
Total		\$600.00

FIGURES

Figure 1 Concept map pairing Kolcaba's Comfort Theory and Evidence-Based Design



APPENDIX A

Scholarly Project Pre- and Post-test Survey - First Population

Dear Patient:

I am interested in finding out how you feel about various aspects of my office practice. Please take a minute to complete this questionnaire about your visit to my office today. Your responses are confidential and are greatly appreciated. Thank you.

Please rate each of the following:	Excellent Good Fair Poor			
1. The convenience of the office location. (Consider travel time, access by public transportation, and parking.)	4	3	2	1
2. The accessibility of the office. (Is the office easy to find, are stairs or elevators readily available, is handicapped entrance adequate, etc.)	4	3	2	1
3. The comfort of the reception area.	4	3	2	1
4. The attractiveness of the reception area.	4	3	2	1
5. If you could change one thing about the waiting area, what would y	ou change	?		

APPENDIX B

Before and After Pictures





APPENDIX C

IRB Approval Letter



February 1st 2019

Elizabeth Elmore Department of Nursing University of Alabama in Huntsville

Dear Mrs. Elmore.

$\boxtimes E$	xpedited (see pg 2)
Е	xempted (see pg 3)
F	ull Review
_ E	xtension of Approval

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Use of Evidence Based Design Strategies in a Primary Care Setting to Improve Patient Satisfaction*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Bruce Stallsmith

IRB Chair

Professor, Biological Sciences

Jua thomile

Expedited:
Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
Collection of data from voice, video, digital, or image recordings made for research purposes.
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Exempt
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject's responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagno specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.
Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, an which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.
Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approve by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

¹ Surveys, interviews, or observation of public behavior involving children cannot be exempt.

Appendix D

Approval for Use of Instrument

Carly Redmond (Massachusetts Medical Society)

Dec 10, 3:31 PM EST

Hello Elizabeth,

I have discussed your request with the PPRC team and you are welcome to use the Patient Satisfaction survey you found at no cost, we just ask for proper attribution.

We find it important to point out to you that this informational packet was published in 2004 with the understanding that the Massachusetts Health Quality Partnership (MHQP) would be developing an in-depth program covering these topics. Because this did in fact end up happening and that program is now implemented within the state, the PPRC has not found it pertinent to update our resource, so please keep that in mind. Additionally, we do not have information at this time regarding the reliability/validity date you inquired about for questions 1-4.

Thank you for contacting the Physician Practice Resource Center at the Massachusetts Medical Society.

Regards,

Carly Redmond

Physician Practice Resource Assistant

Massachusetts Medical Society

ELIZABETH ELMORE

401 Dominion Drive Hartselle, AL 35640 | 256-898 5030 | erc0002@uah.edu

December 10, 2018

Dr. K. Eric Mashburn, MD Clinical Mentor Family Health of Hartselle 1006 Hill Street Hartselle, AL 35640

Dear Dr. K. Eric Mashburn, MD:

Thank you for the opportunity to access your facility for a quality improvement scholarly project. I really appreciate your willingness to help and I look forward to working with you. If you will, please sign the agreement below stating that you agree with the use at your facility for the quality improvement scholarly project.

Sincerely.

Elizabeth Elmore

(please print name)

permission to use my facility. Family Health of Hartselle, for the use of a quality improvement scholarly project.

(Please sign here)