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Adverse Childhood Screening Among Adult Primary Care Patients

Elizabeth Aponté

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Adverse Childhood Screening Among Adult Primary Care Patients

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Abstract

**Background:** The prevalence of adverse childhood experiences (ACE) in the United States is estimated to be 60 percent of the population. A growing body of evidence unequivocally states the significant impacts of childhood adversity on chronic negative health outcomes and that the cumulative effects of adverse childhood experiences have profound public health and societal implications. Despite this overwhelming evidence, research suggests that a lack of effective ACE screening persists in the primary care setting. **Purpose:** The purpose of this project was to effectively translate the evidence of ACEs’ negative influence on overall health into a clinical practice, and to ultimately eliminate the gap between evidence-based ACE research and clinical practice. **Methods:** A screening intervention intended to assess for childhood adversity and the presence of chronic diseases was implemented among adult patients within the primary care setting. The selected clinical site of implementation was a nurse practitioner owned and operated primary care office that serves a large rural community. Adult patients with histories of gastrointestinal complaints, chronic pain, substance abuse, anxiety, depression, or a poorly managed chronic health condition were screened for ACEs. Adult patients who reside in high-risk settings or had high health care utilization were also screened. Additionally, a post-screening form was completed by the nurse practitioner student to collect information about screening process including patient responses, provider preparedness and comfort level, and patient-specific follow-up recommendations. Descriptive statistics were used to calculate total adults screened, prevalence of ACEs, and patient and provider responses to the screening intervention. **Results:** Of the convenience sample, 82% reported ACE. Despite the notably high ACE prevalence, only 24% of patients were receiving psychological counseling. Chronic diseases were found to be associated with higher ACE scores. Moreover, significant reports of additional chronic health problems were found which expanded upon those originally hypothesized. Additionally, the average ACE screening time was 8.5 minutes. An increase in provider comfort and knowledge had a strong positive correlation with decreased ACE screening time. Furthermore, providers that were more secure in knowledge and ability to screen for ACE were more comfortable with screening for ACE. **Conclusions:** The large volume of individuals with poorly managed chronic illnesses seen in the primary care setting affords a rich opportunity for identifying ACE. Furthermore, ACE is associated with significant chronic diseases often unrecognized by patients and providers. Evaluation of this ACE screening intervention suggests that ACE screening is feasible in the primary care setting, allowing for purposeful interventions to improve patient outcomes. Moreover, increasing knowledge and comfort in screening for ACE can help providers and patients improve well being and management of chronic disease.

**Keywords:** abuse, childhood, primary care, review, evidenced based practice, family history, screening, advanced practice nurse, child maltreatment, child trauma, child misfortune, adverse childhood experiences
Adverse Childhood Screening Among Adult Primary Care Patients

A growing body of evidence unequivocally states the significant impacts of childhood adversity on negative health outcomes and that the cumulative effects of adverse childhood experiences (ACE) have profound public health and societal implications. Adverse childhood experiences are prevalent and are experienced by approximately 60 percent of the United States’ population (Centers for Disease Control and Prevention, 2010). In addition to being common, adverse childhood experiences are destructive and often have an effect that lasts a lifetime. In fact, individuals with histories of childhood abuse are more likely to engage in health-risk behaviors (Dube, Cook, & Edwards, 2010; Ford et al., 2011) and have a greater risk of developing chronic physical and psychological illnesses in adulthood (Afifi et al., 2008; Felitti et al., 1998; Schafer & Ferraro, 2011). Despite this overwhelming evidence, healthcare systems continue to serve survivors of childhood adversity without treating them for the consequences of that adversity. Moreover, systems serve individuals without even being aware of the adversity that occurred (Fallot, 2001).

Sound research evidence has demonstrated an association between experiencing childhood adversity and multiple negative chronic health conditions that frequent the adult primary care setting (Felitti et al., 1998; Greenfield & Marks, 2009; Kalmakis & Chandler, 2015). Furthermore, the management of chronic diseases accounts for 86 percent of healthcare costs in the United States (Gerteis et al., 2014). This may be due, at least in part, to a healthcare approach focused on the long-term effects of adverse childhood experiences without recognizing the inextricable link between ACE and its sequelae. This approach leads to “troubling treatment failures and the frustration of expensive diagnostic quandaries where everything is ruled out but nothing is ruled in” (Felitti, 2002, p. 6). The risk factors of chronic diseases include tobacco use,
poor diet, low exercise levels, and excessive alcohol consumption (Bauer, Briss, Goodman, & Bowman, 2014). All of which are behavioral responses associated with multiple forms of childhood adversity (Kalmakis & Chandler, 2015). The primary care visit offers a key opportunity to identify a history of ACE and incorporate these social determinants of health into the healthcare continuum. This strategy will facilitate the timely recognition and efficient management of the emotional and physical sequelae of adverse childhood experience and is in correspondence with the major goals of Healthy People 2020 (Glowa, Olson, & Johnson, 2016; U.S. Department of Health and Human Services, 2010).

Nursing has been founded on care that considers the whole person and the promotion of health across the life span. Much of the challenge in the role of the nurse practitioner has been the negotiation of seemingly disparate worlds: the reconciliation of an essentially holistic nursing model with a health-care system still focused predominantly on disease-oriented care (Dunphy et al., 2015). It is precisely this nexus between more discrete diagnostic categories of disease and a more holistic view of the continuum between health and illness that gives nursing its identity, richness, diversity, and usefulness. Today’s primary care providers dwell in this nexus and must bridge these two realities, the world of disease and illness and the world of prevention and wellness, including the context of the patient’s life in all its complexity (Dunphy et al., 2015). The increasing and necessary placement of nurse practitioners within the primary care setting is well noted (American Association of Nurse Practitioners, 2013). Such demand provides nurse practitioners with the opportunity to effect change on both the micro and macro levels. That is, in the lives of individual patients and families, as well as in the well-being of communities, including the global community (Dunphy et al., 2015). This positive culture change can start with nurse practitioners implementing ACE screening within the primary care setting.
Problem Statement

The risk of chronic physical and psychological illness among the adult population is indicated by maladaptive coping behaviors, physical impairment, and or toxic stress and may result from a negligent lack of routine adverse childhood experience screening within the primary care setting. Nurse practitioners have demonstrated throughout history that they are well equipped to close the gap between ACE research and clinical practice, yet ACE screening continues to be overlooked (Kalmakis, Chandler, Roberts, & Leung, 2016; Glowa, Loson, & Johnson, 2016). Evaluating the skills, attitudes, and perceived barriers of the nurse practitioner students conducting a brief ACE screening intervention is essential to the establishment of an understanding as to why this gap persists. Such knowledge may contribute toward the facilitation of ACE screening as a standard of practice within the primary care setting, and therefore chronic disease management that is founded on quality patient care (Sarvet, 2017).

Review of Literature

A systematic review of literature was conducted using PubMed, CINAHL, and PsycINFO databases. The literature search included publications up to November 2015. The primary search term “adverse childhood experiences” was used. Similar terms (i.e. child neglect, child abuse, child trauma and childhood maltreatment) were also permitted. A snowball technique allowed the literature search to expand to additional pertinent literature. Specific criteria were used to help choose appropriate articles to be evaluated throughout this literature review. The criteria included research studies on the relationship between adverse childhood experiences and negative health outcomes and interventions directed at achieving ACE prevention. A specific emphasis was put on searching for healthcare literature that identified assessment and screening tools of childhood adversity and nursing-specific interventions. The
search successfully retrieved fourteen keeper studies published from 2003 to 2015 conducive to this literature review.

**Results**

Two main outcomes have resulted from this review of the literature about ACE: (1) there is significant evidence for the influence of adverse childhood experiences on negative health outcomes, and (2) there is consensus to recommend interventions to prevent ACE and or the effects of ACE. This evidence demonstrates the clinical demand for ACE screening. Additionally, the level of evidence used to support such recommendations was also evaluated to ensure applicable, reliable, and valid evidence. Throughout this literature review each study’s level of evidence was critiqued using the John Hopkins Evidence Rating Scale (2005) Model. According to the John Hopkins (2005) Model, the articles evaluated throughout this literature provided type I evidence as they were the meta-analysis of multiple, well-designed controlled studies. In addition, the strength and consistency of evidence is considered type A, as there there is type I evidence and consistent finding from multiple studies.

**ACE’s influence on negative health outcomes.** The prevalence of adverse childhood experiences in the United States is estimated to be 60 percent of the population (Centers for Disease Control and Prevention, 2010). Individuals with a history of adverse childhood experiences have a greater risk of acquiring negative health outcomes. These negative health outcomes can be physical or psychological in nature (Afifi et al., 2008; Felitti et al., 1998). Numerous studies have repeatedly linked adverse childhood experiences with measures of negative health outcomes including poor social functioning, mental health, sexual health, the presence of risk factors for prevalent chronic diseases (Garner, 2014).
A history of adverse childhood experiences has also been linked to higher likelihood of engaging in several health-risk behaviors (Dube, Cook, & Edwards, 2010; Ford et al., 2011). Health risk behaviors include but are not limited to smoking, overeating, promiscuity, substance abuse, and inflicting self harm. Individuals may begin practicing health risk behaviors as a means of coping with chronic stress in effort to build resilience against a history of childhood trauma. Negative physical and psychological health outcomes may occur as the direct result of chronic stress brought on by childhood adversity and or the practice of maladaptive coping mechanisms (Garner, 2014). Garner (2014) notes that stress becomes toxic when stress is “frequent, sustained, and severe in intensity, but is distinguished by the lack of sufficient levels of social-emotional buffering” (Garner, 2014, p. s68). Consequently, the physiological mediators of stress became toxic to brain development and alter the brain’s ability to regulate stress, learn, and adopt healthy coping skills. Altered developmental outcomes, such as engaging in health-risk behaviors as a means of coping, ultimately leads to noncommunicable diseases, poor economic productivity and the intergenerational propagation of health disparities (Garner, 2014).

Adverse childhood experiences can also result in biopsychosocial impairment symptoms (Chartier, Waler, & Naimark, 2010). Post traumatic stress disorder, anxiety, depression, shame, helplessness and disturbed sleep are examples of biopsychosocial impairment symptoms that may result from adverse childhood experiences. When biopsychosocial impairment symptoms are left undiagnosed and or untreated they can directly or indirectly lead to morbidity and mortality. For example, anxiety is linked to a hyper-responsive or chronically activated stress response (Lewis, 2007). If left untreated, anxiety can contribute to the inflammation and immune system changes that are seen in chronic, noncommunicable diseases such as, cardiovascular disease.
Additionally, many research studies have concluded that adverse childhood experiences increase the risk of many of the causes of premature death, disease and illness (Garner, 2013). Adverse childhood experiences can increase the risk of many of the causes of premature death, disease and illness either through maladaptive coping behaviors and or physical impairment (Flaherty et al., 2013). Adverse childhood experiences have been linked to sexually transmitted diseases (Dube & Felitti, 2003), human immunodeficiency virus, viral hepatitis, major depression, anxiety disorder, post traumatic stress disorder (Tanka & Wekerie, 2011), cirrhosis, obesity, cardiovascular disease, chronic obstructive pulmonary disease and diabetes (Garner, 2014).

**Current recommendations in ACE prevention.** It is clear that research exposes ACE as an undeniable health care concern. Thus, it is crucial that this review of literature expand to studies that will guide the development of an evidence-based solution addressing this concern.

Reynolds and Mathieson (2009) acknowledge the mounting evidence linking child maltreatment to enduring negative effects across a lifespan. The article further recognizes that this evidence challenges the traditional treatment focus of healthcare. As a result, Reynolds and Mathieson (2009) seek to evaluate whether early childhood primary prevention programs can reduce rates of child maltreatment by reviewing the empirical evidence provided by fifteen studies. The authors take a community-centered approach to adverse childhood experience prevention as it evaluates community-based programs that incorporate home visits, parent-education classes, or the provision of health services. According to the articles findings, there is limited evidence that early childhood intervention can prevent child maltreatment (Reynolds & Mathieson, 2009). Thus, some degree of childhood adversity is inevitable.
Foy, Kelleher, and Laraque (2010) recognizes that adverse childhood experiences affect a person’s mental health for a lifetime. The authors highlight that mental health services have been traditionally separated from medical care. The findings of the article suggest that this separation may contribute to the poor stigma associated with mental health services, poor coordination of care, and increased costs (Foy et al., 2010). In effort to counteract this negative cycle, it is recommended that medical practices establish a system that routinely collects information about adverse experiences. These experiences need to be documented in a person’s medical record (Foley et al. 2010). This system will allow “clinicians to view all future physical and mental health issues through the prism of the traumatic experience(s)” (Foy et al., 2010, p. S97).

Furthermore, Danese et al. (2009) and Brown et al. (2009), emphasize the high prevalence of ACE and significant impact of ACE across a lifespan. While Brown et al. (2009) concludes that ACEs are associated with an increased risk of premature disease, death, and healthcare costs, Danese et al. (2009) study uncovers specific abnormalities associated with poorly managed ACE victims. Abnormalities associated with poorly managed ACE victims include, enduring emotional, immune, and metabolic abnormalities that significantly contribute to an elevated risk of morbidity and mortality (Danese et al., 2009). Based on the results of their study, Danese et al. highlights the need for timely and effective ACE victim healthcare management.

To date, there have only been two studies focused on screening childhood abuse in adult patients. Weinreb et al. (2010) which focused on physician screening practices and Kalmakis et al. (2016) which examined nurse practitioner screening practices. Both studies found that the majority of providers did not routinely screen for for histories of adverse childhood experiences. Another common trend among both studies was the citation of multiple barriers. The most
frequently reported barriers to adverse childhood experience screening included: insufficient
time, lack of confidence, and inadequate knowledge (Weinreb et al., 2010; Kalmakis et al.,
2016). Findings suggested that the focus groups in both studies were more likely to screen for
adverse childhood experiences when they felt more confident in their abilities to screen.

**Discussion**

A growing body of evidence unequivocally supports the significant impacts of childhood
adversity on chronic negative health outcomes and that the cumulative effects of adverse
childhood experiences have profound public health and societal implications (Brown et al.,
2009). The articles evaluated throughout this literature review attest to such evidence. Despite
this extensive evidence, little attention has been given to the implementation of an evidence-
based screening practice that identifies adults at high risk for toxic stress, and therefore an array
of chronic negative health outcomes induced by adverse childhood experience(s). Additionally,
this literature review distilled five pieces of essential information: (1) Some degree of childhood
adversity is inevitable (Reynolds & Mathieson, 2009); (2) medical practices need to establish a
system that routinely collects information about adverse experiences in a person’s life (Foy et al.,
2010); (3) quality adverse childhood experience prevention requires an expansion in
responsibilities including: screening, assessment, and referrals (Danese et al., 2009); (4) early
identification of ACE may help reduce the cost of age-related diseases and mortality (Danese et
al., 2009) and (5) healthcare providers do not routinely screen for ACE and this may be linked a
number of barriers including insufficient time, lack of confidence, and inadequate knowledge
Ultimately, research reveals a significant gap between ACE research and practice. This gap
represents a desperate need for positive change regarding ACE intervention. The implementation
of ACE screening amongst an adult population in the primary care setting effectively addresses
this need by facilitating ACE identification and therefore patient-centered, timely, and efficient intervention.

**Theoretical Framework**

This research translation project has been driven by the theoretical underpinnings of the Lewin’s Change Theory (1951) (refer to appendix II). Lewin’s theory (1951) is a framework for planning, implementing, and evaluating change in the nursing field. Lewin’s theory suggests that change occurs in three stages: unfreezing, moving, and refreezing (Lee, 2006).

**Unfreezing**

Unfreezing, which is the first step in the change process, involves motivating individuals by getting them ready for change (Lee, 2006). This involves identifying what factors are working for (driving forces or facilitators) and against (restraining forces or barriers) the change (Lee, 2006). Strategies need to be devised to strengthen driving forces and weaken restraining forces.

**Moving**

Kurt Lewin states that change is not a single event, but rather a process (Huber, 2010). This process requires a transition or inner movement in reaction to change to be effective (Huber, 2010). This stage of Lewin’s Change Theory is arguably the most difficult because people are resistant to change by nature. As a result of change and uncertainty, fear and anxiety may manifest.

**Refreezing**

According to Lewin, the final stage of change is refreezing (Huber, 2010). Refreezing is the evaluation of the implemented change and adaption of the stakeholders (Huber, 2010). This final step is crucial to verifying appropriate integration and stability of the new change (Huber,
Lewin’s Change Theory Applied

The principle that each individual stakeholder needs to find meaning and express value within the process of change is well understood (Porter-O’Grady & Mallach, 2015). Lewin’s Change Theory is founded on this reality. In keeping with this principle, each stakeholder has been encouraged to complete these tasks throughout the phases of change initiated by the ACE screening intervention. The nurse practitioner student utilized motivation interviewing strategies to achieve this goal (refer to appendix III). Lewin’s Change Theory and the principles of motivational greatly intersect as both are founded on the importance of a participatory approach to change.

Behavior change is both a major goal and challenge in primary care. This challenge holds true in the context of adverse childhood experiences. Not only is ACE screening neglected in the primary care setting, but patients commonly do not understand that their childhood trauma may have a long-term effect on their adult health. All too often, patients remain stuck in a state of ambivalence regarding their adverse childhood experience(s). This state facilitates high-risk behaviors and toxic stress (Sullivan, 2017). One solution to this dilemma the incorporation of motivational interviewing in health promotion (Sargent, 2017).

The central conflict within the challenge of changing behavior may reside in an imbalance between responsibility and authority which relies heavily of several socialized aspects of traditional health care (Sargent, 2017). Motivational interviewing is an approach to care that challenges traditional healthcare by initiating a conversation about behavior change with a patient that establishes a collaborative relationship between the professional and the patient to address a shared concern; in this case the patient’s mental and physical health (Sargent, 2017).
Motivational interviewing is not a cynical effort to get the patient to do something the professional wants. To the contrary, motivational interviewing is genuinely collaborative and based on understanding the patient’s desires and goals and helping the patient to resolve ambivalence (Sargent, 2017). Thus, minimizing high-risk behaviors and buffering toxic stress with a safe, stable, and nurturing relationship and environment (Sullivan, 2017).

Lewin (1951) breaks down change into three phases. According to the principles of motivational interviewing, the process of change can be further divided into precontemplation, contemplation, preparation, action, and maintenance. The ACE screening intervention facilitates the process of change by using screening as an opening of a long term conversation between the patient and his or her primary care nurse practitioner. It initiates the primary care practice as a “medical home” for trauma-informed care through ongoing monitoring, continuity of relationships, and placing the patient as the unique center of the care plan (Sullivan, 2017).

**Project Design**

A mixed method translation-into-practice project has been conducted. This project design was deemed appropriate because adverse childhood experiences have been associated with chronic health outcomes, yet the evidence continues to have limited application in primary care practice. This fact generates two main questions: (1) What barriers may be contributing to this gap? and (2) How can these barriers be eliminated? Given the information yielded by the comprehensive review of literature, it is hypothesized that an increase in provider knowledge and comfort with ACE screening will have a positive correlation with decreased ACE screening time. Additionally, identifying trends between specific demographic data and ACE scores may help categorize high-risk patient populations and expand upon current ACE research. For example, if a specific disease is linked to higher ACE scores, adults presenting to their primary care office
with that disease should be considered a high-risk ACE population and specifically targeted for ACE screening. The concept of identifying high-risk patient populations for preventable adverse outcomes, and therefore tailoring their health care accordingly, is not a new practice in the primary care setting. Consider the way a patient with dyslipidemia is commonly understood to have a major risk factor for cardiovascular disease in the primary care setting. Given this patient-specific information, the primary care nurse practitioner would naturally begin a discussion to determine the best therapy for each unique patient situation in effort to prevent cardiovascular disease (Dunphy et al., 2015). Therefore, the question remains why is it common practice to identify high-risk populations for physical disease and yet, seemingly nonexistent in terms of ACE? This translation-into-practice project carefully considers this perplexing reality and seeks to apply an established primary care practice to the care of ACE victims.

ACE Screening Intervention

Throughout the course of this project, the nurse practitioner student conducted a brief ACE screening intervention with each individual patient making up the sample population. The screening intervention utilized a standardized interview process that was guided by the Screening, Brief intervention, and Referral for Treatment (SBIRT) model. The standardized interview process included a demographics questionnaire (refer to appendix IV), adverse childhood experiences questionnaire (refer to appendix V), and nurse practitioner student post intervention form (refer to appendix VI). Each phase of the standardized interview process was anticipated to generate data that may have addressed specified objectives. For example, the demographics questionnaire was expected to provide quantitative data regarding the intervention population and therefore affirm and or expand upon current ACE research. While the nurse practitioner student post intervention form was anticipated to provide qualitative data regarding
the screening intervention experience and provide insight into why the gap between ACE research and practice may exist.

In addition to the standardized interview process, the nurse practitioner student also maintained a three-phase approach to screening that was guided by evidence-based motivational interview skills. Motivational interview skills were especially helpful to the facilitation of sustainable change as outlined in Lewin’s Change Theory (1951). In keeping with Lewin’s (1951) sequential process of change, a three-phased approach facilitated change in each individual by first preparing or “unfreezing” the individual for change and then stimulating an inner movement of change. The three-phase approach to screening included providing information to the patient regarding the purpose of the screening (unfreezing), asking the patient about childhood adversity in a non-judgmental manner, and responding to patient with compassion (moving). In the circumstance that the patient did experience childhood adversity the final stage of change, refreezing was activated. Refreezing was accomplished by asking the patient how he or she thought these experiences affect their health. These same patients were also referred to their primary care nurse practitioner so they could benefit from a specific health plan that incorporated this pertinent patient history.

**Setting and Resources**

The selected clinical site of implementation is a nurse practitioner owned and operated primary care office that serves a large rural community. The office has been seamlessly operating for eight years and is committed to providing compassionate, professional health care that is founded on excellence and integrity. The health care team is made up of a nurse practitioner, two medical assistants, phlebotomist, office and billing manager, and a receptionist. The outpatient primary care office commonly cares for thirty patients a day. Although busy, the
office is well equipped with an experienced nurse practitioner with nearly twenty years of experience and a health care approach that is holistic and collaborative. In addition, the nurse practitioner specializes in primary care and family psychiatry. As a key stakeholder, she has expressed her commitment to the success of the ACE screening intervention. As a result, she has agreed to share her patient population and expertise without resistance.

**Population**

A convenience sample of 71 patients who are cared for by the selected outpatient primary care office represented the target population for this study. Patients were selected in adherence to specified inclusion criteria. Inclusion criteria was evidence-based and targeted patient populations that research has strongly linked to a history of ACE (Kalmakis & Chandler, 2015). The inclusion criteria were that subjects are at least 21 years of age and present with any one or combination of the following health problems: obesity, GI complaints, chronic disease(s) that are not well managed, post traumatic stress disorder (PTSD), anxiety, depression, or substance abuse disorder. Additionally, patients who reside in high-risk setting such as homeless shelter and women’s shelters were included. Patients with high health care utilization were also included. High health care utilization was defined as patients presenting with multiple complaints and or patients with at least three primary care visits in a six-month period. Patients were excluded if they did not meet the inclusion criteria listed previously or if they were unwilling to provide consent to the ACE screening intervention. It is important to note that subjects were not excluded based gender, race, ethnicity, martial status, and occupation as adverse childhood experience exposure does not discriminate.

**Ethics and Human Subjects Protection**

The ACE screening research project was reviewed and approved by the UMass Amherst
Institutional Review Board (IRB). In addition, all patient and provider communication and documentation adhered to the standards and practices of the Health Insurance Portability and Accountability Act of 1996 (HIPPA, 1996). Eligible subjects were educated regarding the informed consent and the opportunity to participate, refuse to participate, or terminate participation at any time. As part of the consent process, potential subjects were informed of their risks of participating in the study. Subjects were informed that they may experience emotional distress as a result of the questions asked during the interview, or while answering the questionnaire. Eligible subjects were, however, assured that should they become distressed immediate care from the primary care nurse practitioner will be provided. Furthermore, the ACE screening intervention did not in any way interfere with the patient’s scheduled health services. To ensure privacy and eliminate any potential violation in patient health confidentiality, subject consents and questionnaires were coded with unidentifiable coding.

**Organizational Analysis of Project Site**

Like so many adult primary care practices, the selected site of implementation does not routinely screen for adverse childhood experiences. To help prepare and engage the practice for this positive change, the nurse practitioner student presented staff education one month prior to the ACE screening intervention implementation. Within this education, current ACE research was summarized and the project purpose, design and timeline was outlined. In continued effort to engage the staff and avoid the impedance of daily office procedures, the nurse practitioner student also collaborated with the implementation site team to establish an appropriate time for the ACE screening intervention to take place. With the team’s collaboration, it was determined that the ACE screening intervention would take place before the patient’s planned visit. Outside of the ACE screening intervention, the practice’s established workflow would remain preserved.
**Cost-Benefit Analysis**

**Estimated Cost**

The nurse practitioner student conducted the ACE screening intervention without any monetary gains. The minimal monetary costs affiliated with this research project are limited to the cost of printing standardized interview forms and the patient and provider education pamphlet. Cost of all materials was approximately 120 dollars. All monetary costs were paid for by the nurse practitioner student which eliminated any responsibility of the implementation site to cover direct project costs.

**Estimated Cost Savings**

Research unequivocally states that ACE increases the risk of morbidity and mortality. Therefore, this initiative’s benefits go far beyond a value that can be represented by a dollar value. However, ACEs have been linked to many costly chronic adverse health outcomes (Dube, 2003; Garner, 2014; Tanka, 2011). In fact, the management of chronic diseases accounts for 86 percent of healthcare costs in the United States (Gerteis et al., 2014). As a result, the potential cost savings generated by ACE research and programs, like this translation-into-practice project, are estimated to be approximately $56 million every ten years (Hall, 2015).

**Results**

The ACE screening intervention adhered to the sequential project design previously outlined in detail. Throughout the course of the ACE screening intervention 71 patients were screened for ACE. In keeping with the project design, each patient completed a standardized demographics questionnaire and an adverse childhood experiences questionnaire through the facilitation of the nurse practitioner student. Additionally, the nurse practitioner student completed a post intervention form following each patient screening. In effort to eliminate
confounding variables, a standardized interview with a three phase SBIRT approach was uniformly utilized. Each sequence of the ACE screening intervention uncovered unique and pertinent data. Such findings significantly contributed to meeting and exceeding specified objectives.

**Demographics**

Among the seventy-one patients screened for ACE, there was a wide range of patient ages, martial statuses, and medical diagnoses. Patient ages ranged from twenty-one to eighty years of age and were well distributed (Table 1). Patient’s marital status also varied and included widowed (7.0%), divorced (18.3%), single (23.9%), and married (45.1%). Self-reported chronic diseases also included a wide variety of diagnoses (Table 2). Although patients’ ages, marital statuses, and medical diagnoses were diverse, more than half of patient participants were of the female gender. In fact, only twenty-two (31%) were males and forty-nine (69%) were females. Patient participants were also limited to one racial group, with 100% of patient participants identifying with a White or European race.

Table 1

*Participant demographics*

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<th>Answer Options</th>
<th>Response Percent</th>
<th>Response Count</th>
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<td>21-30</td>
<td>8.5%</td>
<td>6</td>
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<tr>
<td>31-40</td>
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<tr>
<td>61-70</td>
<td>18.3%</td>
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<tr>
<td>71-80</td>
<td>8.5%</td>
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Table 2

*Participant diagnoses*

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<tr>
<th>Diagnosis</th>
<th>Response Percent</th>
<th>Response Count</th>
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<tbody>
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<td>Depression</td>
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<td>28</td>
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<tr>
<td>Anxiety</td>
<td>38%</td>
<td>27</td>
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<tr>
<td>Cardiovascular disease</td>
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<td>Diabetes</td>
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<td>7</td>
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<tr>
<td>Chronic Pain</td>
<td>17%</td>
<td>12</td>
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<tr>
<td>Chronic Respiratory</td>
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<td>10</td>
</tr>
<tr>
<td>Obesity</td>
<td>11%</td>
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</tr>
<tr>
<td>PTSD</td>
<td>10%</td>
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<tr>
<td>Arthritis</td>
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<td>6</td>
</tr>
<tr>
<td>Bipolar</td>
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<tr>
<td>No Reported Diagnosis</td>
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<td>Substance Abuse</td>
<td>6%</td>
<td>4</td>
</tr>
<tr>
<td>ADHD</td>
<td>6%</td>
<td>4</td>
</tr>
</tbody>
</table>

**Adverse Childhood Experiences Questionnaire**

Of the seventy-one patients screened, fifty-eight (81.7%) reported at least one ACE experience; while only thirteen patients (18.3%) reported no perceived adverse childhood experiences. Despite this high percentage of ACE exposures, only 17 (24%) of subjects reported
that they were receiving psychological counseling; leaving 54 (76%) of subjects with no psychological care. The patients were also asked to self-report how many visits they had at the practice in the last year. Based on their reports, the mean number of annual patient visits was 9.2 visits from November 2015 to November 2016. It is important to note that although the patient reports of annual patient visits were well distributed overall, one patient outlier reported 200 annual patient visits within the specified time period. This report significantly differed from those of the other subjects, however, accuracy of the report was confirmed by the patient’s primary care nurse practitioner. The statistically significant patient diagnoses identified by the demographics questionnaire were also highlighted and the average ACE scores specific to patients with these diagnoses were recorded (Table 3).

Table 3
ACE Score and Diagnoses

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Average ACE Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTSD</td>
<td>10.4</td>
</tr>
<tr>
<td>Substance Abuse</td>
<td>7.2</td>
</tr>
<tr>
<td>Depression</td>
<td>6.0</td>
</tr>
<tr>
<td>Anxiety</td>
<td>5.4</td>
</tr>
<tr>
<td>Bipolar</td>
<td>5.2</td>
</tr>
<tr>
<td>Chronic Pain</td>
<td>4.9</td>
</tr>
<tr>
<td>Chronic Respiratory</td>
<td>4.9</td>
</tr>
<tr>
<td>ADHD</td>
<td>4.8</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4.3</td>
</tr>
<tr>
<td>Obesity</td>
<td>4.1</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>3.6</td>
</tr>
<tr>
<td>Arthritis</td>
<td>3.2</td>
</tr>
<tr>
<td>No Reported Disease</td>
<td>1.8</td>
</tr>
</tbody>
</table>
Nurse Practitioner Student Post Intervention Form

Information was also collected about the interview process based on the reports of the student nurse practitioner. This information was gathered following each patient interview and documented on the nurse practitioner student post intervention form. The nurse practitioner student post intervention form focused on the interview process from two crucial perspectives: (1) the patient, and (2) the provider.

The nurse practitioner student was asked to describe the patients’ responses to the ACE screening intervention. A variety of patient verbal and nonverbal cues were used to describe the patients’ responses. While some patients were open and emotional, others appeared to be more reserved and somewhat elusive. And yet others were their own unique combination of adjectives. Although there was a variety of patient responses to the ACE screening intervention, all seventy-one (100%) of the patients who originally agreed to participate in the intervention completed it in its entirety. At no time was a patient coerced into completing the ACE screening intervention but rather completed it on their own accord. Even when patients were emotionally triggered by the ACE intervention questions they remained open to continuing the full screening process. In fact, many of the patients who did have an emotion response to the screening process described a feeling of “relief” and or “healing” following the intervention. Many patients also described a sense of empowerment as many patients explained they had never heard of ACE and were unaware that experiences of their childhood could impact their physical and mental health today prior to the ACE screening intervention. Furthermore, the majority of patients appeared to be open to sharing and following-up with their primary care nurse practitioner regarding this significant patient history. Very few patients were reluctant to appropriate follow-up. In such cases, patients were encouraged to reflect on our conversation and share the experience with
their primary care nurse practitioner when they were ready; to which all patients were receptive. In addition to observing and recording patient responses to the ACE screening intervention, the nurse practitioner student also noted numerous patient specific ACE experiences. Among these experiences were many variations of domestic violence, feelings of abandonment, physical abuse, emotional abuse, sexual abuse, and neglect.

The nurse practitioner student was also asked to rate her comfort level during the ACE screening intervention as well as how secure she felt about her knowledge and ability to screen for ACE. Based on the nurse practitioner student report, there were no responses that indicated the nurse practitioner student felt any degree of discomfort or insecurity during the ACE screening intervention. For both comfort and security ratings, the nurse practitioner student reported 57 times (80%) feeling very comfortable during the interview and very confident about her knowledge and ability to screen for ACE. While the nurse practitioner student reported that she felt somewhat comfortable and somewhat confident in knowledge and ability to screen for ACE 14 times (20%). The nurse practitioner student was then asked to record the time it took to complete each patient ACE interview. The average interview time was 8.5 minutes long and ranged from 3 to 30 minutes. The nurse practitioner student was additionally asked to record if she felt the ACE intervention too longer than expected. The majority of the reports (89%) stated the ACE intervention did not take longer than expected, while 11% of reports stated the intervention did take longer than expected.

Data Analysis

All recorded data was reviewed using Excel and SPSS software. Data cleaning was diligently practiced by two people to ensure data accuracy and eliminate unnecessary bias. Descriptive statistics were used to evaluate the characteristics of the sample population. In
addition, correlational data analysis was conducted to evaluate correlations between number of visits per year, ACE score, provider comfort in screening, provider security in screening, and time used to perform screening SBIRT process. The correlation results show that provider’s perceived level of comfort during the ACE intervention and the provider’s security about knowledge and ability to screen for ACE demonstrate a moderately positive correlation (r=0.438) (p=0.000). Therefore, providers that were more comfortable with screening for ACE were also more secure in their knowledge and ability to screen for ACE. Another correlation revealed that an increase in provider comfort and knowledge had a moderately strong positive correlation with decreased ACE screening time. This data exemplifies that as providers became more comfortable with ACE screening, the time to complete screening became shorter. The final identified correlation demonstrated a strong positive correlation between ACE score and the length of time for ACE screening (r=0.445) (p=0.000). Thus, patients with higher ACE scores took more time to screen.

Table 4

*Descriptive Statistics*

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>#Visits yr.</td>
<td>9.246</td>
<td>23.3573</td>
<td>71</td>
</tr>
<tr>
<td>ACE</td>
<td>4.66</td>
<td>3.909</td>
<td>71</td>
</tr>
<tr>
<td>Provider Comfort</td>
<td>3.803</td>
<td>.4007</td>
<td>71</td>
</tr>
<tr>
<td>Provider Security</td>
<td>3.831</td>
<td>.3774</td>
<td>71</td>
</tr>
<tr>
<td>Time</td>
<td>8.479</td>
<td>3.7066</td>
<td>71</td>
</tr>
</tbody>
</table>

Table 5

*Correlations*

<table>
<thead>
<tr>
<th></th>
<th>#Visits yr.</th>
<th>ACE</th>
<th>Provider Comfort</th>
<th>Provider Security</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Discussion, Conclusion and Sustainability

Adverse childhood experiences are common, destructive and have an effect that often lasts a lifetime. A growing body of evidence unequivocally states the significant impacts of childhood adversity on chronic negative health outcomes and that the cumulative effects of adverse childhood experiences have profound public health and societal implications. Despite this overwhelming evidence, research suggests that a lack of effective ACE screening persists in the primary care setting. Primary care is a healthcare setting purposed to be the “medical home” where which chronic health issues are identified and managed through ongoing monitoring, continuity of relationships, and placing the patient as the unique center of the care plan. The
purpose of this project was to effectively translate the impactful evidence of ACEs’ negative influence on overall health into a responsible clinical practice focused on treating the whole person, and to ultimately eliminate the gap between evidence-based ACE research and clinical practice. Assessing the feasibility of ACE screening within an adult primary care setting is the preliminary step to a greater purpose of establishing ACE screening as a standard of care within the primary care setting. Results from the study have generated demographic information that has expanded upon an at risk ACE population and their needs, assessed the quantity and characteristics of ACE reports as well as provided information regarding provider screening times, comfort with screening, knowledge and ability to screen and how receptive patients were to the ACE screening process and patient-specific follow-up recommendations.

Observations drawn from this project attest to the fact that adverse childhood are common as 82% of the patient sample reported at least one adverse childhood experience. In addition, ACE effects people of varying ages, martial statuses, and medical diagnoses. In fact, results from this project identified additional chronic diseases associated with high ACE scores including cardiovascular disease, chronic pain, respiratory disease, arthritis, and ADHD. Findings suggest an expansion of recommendations to screen patients for ACE with the above mentioned health problems in addition to the chronic illnesses originally hypothesized. Additional outcomes revealed that screening time took less time than anticipated, however longer interview times were associated with higher ACE scores. It was however found that increased provider comfort and knowledge in ACE screening, decreased the time for the ACE screening as a whole.

Throughout the process of this project it was determined that an increase in ACE screening in the primary care setting is necessary. It was also discovered that ACE is associated
with significant chronic diseases often unrecognized by patients and providers. Despite these harsh realities, the results of this project suggest that increasing knowledge and comfort in screening for ACE can help providers and patients improve well being and effective management of chronic disease. The overall results provided insight into next steps to encourage nurse practitioner screening for ACEs in primary care to restore wellness in adult patients with chronic disease. To help address the identified patient knowledge deficit regarding ACE and how such experiences may be affecting or contributing to their chronic disease processes, a patient friendly pamphlet has been delivered to the primary care practice. This pamphlet has been organized with the overall goal of encouraging patients to self-reflect and discuss their ACE-related concerns with their primary care nurse practitioner.

Finally, the data analysis yielded by this translation-into-practice project uncovered provider and patient attitudes and responses to ACE screening which may contribute to expanded knowledge regarding barriers and facilitators to the implementation of ACE screening as a routine practice in the primary care setting. This knowledge can be used to eliminate preventable barriers and promote facilitators of ACE screening specific to the primary care setting. Thus, contributing to the generation of a standardized ACE screening system (ACE screening tool, provider education, and patient education) that is effective, efficient, and well received by providers and patients alike.
References


Appendix A

Key Stakeholder Agreement

8/27/16

To Whom It May Concern:

I am the Director of the DNP Program at the University of Massachusetts, Amherst, College of Nursing. I am writing this letter on behalf of __________________________, your student preceptor. Your student is planning to complete the pinnacle requirement for the Degree, a DNP Capstone Project, in your facility. Your student will be designing, implementing, and evaluating the impact of translating a programmatic intervention into your practice or setting. As these projects are considered performance improvement, quality improvement, or program evaluation projects and not research studies, the University does not require Institutional Review Board (IRB) permission for this student to actualize the project as outlined by the student and approved by preceptor/s within your facility. I am using this letter as a “Key Stakeholder” commitment letter for the student to use in the DNP Capstone Project Proposal. A Graduate faculty member of the College of Nursing will also be working directly with your student as Chair of the DNP Capstone Project Committee.

Thank you in advance for allowing this student to actualize the DNP Capstone Project in your facility. If you have any questions, please call me at 413-545-5089 or email paselton@nursing.umass.edu.

Key Stakeholder Signature: __________________________ Date: 8-29-2016

Student Signature: __________________________ Date: 8-30-2016

Sincerely,

Pamela Aselton

Pamela Aselton, PhD, FNP-BC
Associate Professor
Director DNP Program

The University of Massachusetts is an Affirmative Action/Equal Opportunity Institution
Appendix B

Lewin’s Change Model

Change Model – Kurt Lewin
Appendix C

Motivational Interview Framework

The Framework of Motivational Interviewing
Appendix D

Demographics Questionnaire

Demographics Questionnaire

Patient Study ID [NRCE 20160712]

1. Patient age: □ 21-30 □ 31-40 □ 41-50 □ 51-60 □ 61-70 □ 71-80 □ over 81

2. Patient gender (circle one): Male Female Transgendered

3. Patient race (circle one):
   a. Black or African American
   b. White or European
   c. American Indian
   d. Asian
   e. Native Hawaiian or Pacific Islander
   f. Middle Eastern/Arabic
   g. Other (please describe): __________________________

4. Patient ethnicity (circle one):
   a. Hispanic or Latino
   b. Not Hispanic or Latino

5. Patient marital status (circle one):
   a. Single
   b. Married
   c. Living with partner
   d. Separated
   e. Divorced
   f. Widowed
   g. Other (please describe): __________________________

6. Patient occupation ________________________________

7. Months/years patient of the practice/clinic _________

8. Number of visits in past year __________

9. Diagnosis
   1. _______________________________________________
   2. _______________________________________________
   3. _______________________________________________
   4. _______________________________________________

10. Currently receiving psychological counseling?
    Yes    No
Appendix E

Adverse Childhood Experiences Questionnaire

Adverse Childhood Experiences
Questionnaire

*Please put an X over the box that best answers the question*

**Prior to your 18th birthday:**

1. Did a parent or other adult in the household swear at you, insult you, put you down, or humiliate you?

2. Did a parent or other adult in the household act in a way that made you afraid that you might be physically hurt?

3. Did a parent or other adult in the household push, grab, slap, or throw something at you?

4. Did a parent or other adult in the household ever hit you so hard that you had marks or were injured?

5. Did an adult or person at least 5 years older than you touch or fondle you or have you touch their body in a sexual way?

6. Did an adult or person at least 5 years older than you attempt or actually have oral, anal, or vaginal intercourse with you?

7. Did you feel that no one in your family loved you or thought you were important or special?

8. Did you feel that your family didn’t look out for each other, feel close to each other, or support each other?

9. Did you feel that you didn’t have enough to eat, had to wear dirty clothes, and had no one to protect you?

10. Did you feel that your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

11. Did you witness your mother or stepmother or other adult women in your household being abused (ex. punched, slapped, kicked, bitten, or pulled by hair)?

12. Did you witness your mother or stepmother or other adult women in your household threatened with a gun or knife?
**Please circle your response**

13. Was a biological parent ever lost to you through divorced, abandonment, or other reason?  
   - Yes  
   - No

14. Did you live with anyone who was a problem drinker or alcoholic?  
   - Yes  
   - No

15. Did you live with anyone who abused drugs?  
   - Yes  
   - No

16. Was a household member depressed?  
   - Yes  
   - No

17. Was a household member diagnosed with a mental illness?  
   - Yes  
   - No

18. Did a household member attempt suicide?  
   - Yes  
   - No

19. Did a household member go to prison?  
   - Yes  
   - No

---

*4/26/12 KAK*
Appendix F

Nurse Practitioner Student Post Intervention Form

DNP Student Post intervention form

Patient Study ID ____  Date of intervention ____  ACE score ____

1. Write down the patient’s response to the ACE intervention (Example: Open and forthright, emotional).

__________________________________________________________________________

__________________________________________________________________________

2. Provide a patient quote, or a paraphrase of their words in response to the ACE intervention (do not include any names of people or places in the response).

__________________________________________________________________________

__________________________________________________________________________

3. Please indicate your comfort level during the ACE intervention with this patient? (Choose one response)
   □ Very uncomfortable
   □ Somewhat uncomfortable
   □ Somewhat comfortable
   □ Very comfortable

4. Please indicate how secure you felt about your knowledge and ability to screen for ACE intervention with this patient? (Choose one response)
   □ Very insecure
   □ Somewhat insecure
   □ Somewhat confidant
   □ Very confident

5a. How much time did you spend on this intervention?
   ____ minutes

5b. Did the visit take longer than you expected?
   Yes ____  No ____

6. Indicate the follow-up plan for this patient:
   □ Referred to primary care NP for follow-up
   □ Patient requests none at this time
   □ No follow-up needed

7. Notes about the interview: ________________________________________________
Appendix G

Protocol for ACE Screening

Screening for ACE among adult primary care patients

A. Who to screen?

1. Patients with the following health problems should be screened for ACE:
   - Obesity (current or past history)
   - GI complaints
   - Chronic diseases not well managed, or patient appears to be non-compliant with self-management
   - PTSD
   - Anxiety
   - Depression
   - Substance abuse disorder (includes alcohol, illicit drugs)

2. Patients in high-risk settings such as homeless shelters, women's shelters.

3. Patients with high health care utilization (Multiple complaints, 3 or more visits in 6 months).

B. How to screen.

We recommend a three-phase approach to screening:

Phase 1 – provide information about why we are screening:
   *We know that childhood experiences may have a long-term effect on adult health*

Phase 2 – ask about childhood adversity in a clear, concise, non-judgmental manner:
   *Did you experience hardship or abuse when you were a child? (e.g., living in poverty, living with a family who abused substances, physical, psychological abuse, and or neglect)*

Phase 3 – Respond with compassion.

   *I am sorry/sad this happened to you. How do you think this has affected your health? What can I do to help you? (Example: referral to counseling, schedule a follow-up visit, be available as needed in the future, etc.)*

   *You may want to use follow-up questions if the patient responds yes, but seems hesitant to talk about their childhood (e.g., Tell me more about your experiences. If you feel comfortable sharing your experiences. I am ready listen.)*

   *If the patient reports no childhood hardships or abuse, use the following response: Thank you for answering.*
Appendix H

Consent Form for Participation in Research Study

Consent Form for Participation in a Research Study
University of Massachusetts Amherst

Researcher(s): Kalmakis, K., Chandler, G., Roberts, S.

Study Title: Screening for Adverse Childhood Experiences among Adult Primary Care Patients

1. WHAT IS THIS FORM?
This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHO IS ELIGIBLE TO PARTICIPATE?
Subjects must be at least 21 years old to participate.

3. WHAT IS THE PURPOSE OF THIS STUDY?
We are conducting this research study to test a healthcare screening approach for childhood adversity.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?
The study will take place in a private room in the Health Center and will take approximately 5 to 10 minutes.

5. WHAT WILL I BE ASKED TO DO?
If you agree to take part in this study, you will be asked three questions as part of an interview with a nurse practitioner student and then to respond to a short questionnaire about your childhood experiences. Please note, you will be asked questions about childhood abuse, neglect and about family hardship. You may skip any question you feel uncomfortable answering.

This is a research study that involves questions related to sensitive topics that may cause distress. As nurse practitioner students training at this health center, we will be able to consult with your primary care provider immediately if needed, in order to refer you to appropriate support services that best fit your health needs. By signing this consent form, you are agreeing to allow the DNP student to share the information with your primary care provider in order to obtain appropriate health care services.
6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?
If you have experienced childhood adversity, such as abuse, neglect, or poverty, you will benefit from a specific health plan. Your health care provider will be able to provide you with services that will support you and assist you to cope with these past experiences.
If you do not have a history of childhood adversity, you may not directly benefit from this research, however, we hope that your participation in the study may result in improved care for those who have such these past experiences.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?
You may experience emotional distress as a result of the questions asked during the interview, or while answering the questionnaire. As noted above, should you become distressed, you will receive immediate care from the primary care nurse practitioner at the health center as well as follow-up and/or referrals as appropriate specific to your needs and wishes.

The interview will take place either before or after your planned visit at the Health Center, and will in no way interfere with your planned health services or visit with your health care provider.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?
The following procedures will be used to protect the confidentiality of your study records. Completed questionnaires and interview forms will not include your name, date of birth, or any other personal information that may be used to identify you. The researchers will keep all study records, including any codes to your data, in a secure locked file. Research records will be labeled with a code. A master key that links names and codes will be maintained in a separate and secure location. The master key will be destroyed three years after the close of the study.
There is always the remote possibility that someone other than the researchers may see study forms. We will strictly follow the safeguards described above to prevent this.
At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Information disclosed during the interview will be shared with your Health Center primary care provider if follow-up or referral is appropriate to ensure you receive optimum health care specific to your needs.

9. WHAT IF I HAVE QUESTIONS?
Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher(s), (Karen Kalmakis: 413 577-4763, or Genevieve Chandler 413 545-xxx.
If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu."

10. CAN I STOP BEING IN THE STUDY?
You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.
11. SUBJECT STATEMENT OF VOLUNTARY CONSENT
When signing this form I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language that I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. I understand that I can withdraw at any time. A copy of this signed Informed Consent Form has been given to me.

Participant Signature: ___________________________ Print Name: ___________________________ Date: ___________________________

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

Signature of Person Obtaining Consent ___________________________ Print Name: ___________________________ Date: ___________________________