A Proposal for a Best-Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury

A PROPOSAL FOR A BEST-PRACTICE PROTOCOL FOR THE MANAGEMENT OF PATIENTS WITH SUSPECTED CERVICAL SPINE INJURY

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Kasey D. Cross entitled "A Proposal for a Best-Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury" and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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ABSTRACT

Background: Research suggests that cervical spine CT examination is over used for potential injury due to blunt trauma. Education of emergency providers regarding evidence-based guidelines can help reduce the over-use of CT examination, and the development of an evidence-based protocol for the management of patients with suspected cervical spine trauma may help promote more appropriate clinical use of radiologic imaging for cervical spine clearance.

Purpose: The ultimate goal of this project is to develop a best-practice, evidence-based protocol for the management of patients with suspected cervical spine injury, in order to promote safe and efficient clinical clearance, as well as promote judicious and appropriate use of diagnostic imaging for suspected cervical spine injury.

Methods: A retrospective chart review of emergency radiographic imaging studies obtained over a three-month timeframe for suspected cervical spine injury at a 300-bed hospital in Tucson, Arizona was performed to compare ordering practices with the ACR-AC. Descriptive statistics were used for data analysis. A web-based survey was conducted of facility stakeholders including emergency physicians, nurse practitioners and physician assistants regarding their views about clinical guidelines and protocols for radiographic and clinical clearance of cervical spine injury. Descriptive statistics and thematic analysis was used for survey responses.

Results: Analysis of 263 imaging studies over a three-month timeframe demonstrated that 24.3% of cervical spine imaging studies obtained in three-month timeframe would be considered not appropriate based on the ACR-AC. The survey of emergency clinicians revealed that none of those who responded have a preference for referring to the ACR appropriateness criteria, and the

majority of respondents did not support the implementation of a hospital protocol for the management of patients with suspected cervical spine trauma.

Recommendations: An institutional protocol for suspected cervical spine injury developed from the ACR-AC with incorporation of clinical clearance criteria is recommended. To promote clinician acceptance, overcome resistance to implementation, and promote individualized patient care, the protocol should also include provider education and should allow for variance based on individual patient circumstances.

CHAPTER I: INTRODUCTION TO THE PROBLEM

Background

The prevalence of CT (computed tomography) scanning in emergency settings for trauma-related injuries has doubled over the last 10 years, without a corresponding increase in the prevalence of life threatening injuries or hospital admissions (Sheikh, Belfi, Sharma, Baad, & Sanelli, 2012). There is a concern that this increase may reflect unnecessary use of imaging studies, resulting in increased radiation exposure as well as increased health care costs (Berdahl, Vermeulen, Larson, & Schull, 2013; Crownover & Bepko, 2013; Owlia et al., 2014).

Principles of Computed Tomography

Traditional radiography and Computed Tomography (CT) both use ionizing radiation to generate images (United States Food and Drug Administration [FDA], 2014). The basic mechanism is that an X-ray beam is emitted by a source and passed through the body, where the X-rays are absorbed or scattered by various anatomical structures, and the remaining pattern is transmitted to a detector and recorded as an image. While traditional radiography (often referred to simply as an X-ray) consists of a single X-ray image, CT consists of many X-ray images, which are recorded as the detector moves around the patient. A computer reconstructs the individual images into cross-sectional slices of the structure being examined, producing a three-dimensional image (FDA, 2014). The ionizing radiation emitted during radiography and CT is a form of energy that interacts with atoms to remove bound electrons from their orbit, causing the atom to become charged or ionized (World Health Organization, 2014).

The absorbed dose of ionized radiation are measured in grays (Gy), which is the dose of energy deposited per unit mass (Lin, 2010). Since not all types of radiation produce the same biological effect, a dose equivalent or effective dose is often used for radiation measurement. Equivalent dose is the product of the absorbed dose and a radiation-weighting factor specific to the particular type of radiation emitted, and is expressed in Sieverts (Sv). The radiation-weighting factor for x-rays is 1.0, so for the use of medical imaging, 1 Gy is equivalent to 1 Sv (Lin, 2010). Most types of radiation exposures encountered by the average person can be measured in millisieverts (mSv), with the average annual background radiation dose being approximately 3 mSv (Armao & Smith, 2014). Average annual background radiation dose includes exposure from cosmic radiation, air, soil, food and medical imaging (United States Nuclear Regulatory Commission, 2015).

Risks of Ionizing Radiation to Health

Radiation exposure from medical imaging such as CT scanning is termed the effective dose of radiation and is measured in Sieverts (Sv) or millisieverts (Faynhersh & Passero, 2009). The biological effects of ionizing radiation can be categorized as either deterministic or stochastic (Armao & Smith, 2014). Deterministic effects are those that produce an immediate and predictable change to tissues, and occur once radiation dose exceeds a certain threshold. These effects include the development of cataracts, cardiovascular disease, ulcerative lesions, alopecia or a burning sensation in response to radiation. Deterministic effects are uncommon with the low doses of radiation associated with noninvasive imaging. Stochastic effects are the main concern associated with medical imaging, as these effects occur with low radiation doses and typically take years to decades to manifest (Armao & Smith, 2014). Stochastic effects are caused by radiation-induced mutations to DNA. Ionizing radiation causes ionization of DNA water molecules, which creates hydroxyl radicals that cause strand breaks or base damage in

DNA. Misrepair of this damage leads to point mutations, gene fusions and chromosome translocations, which are all linked to cancer induction (Lin, 2010). These effects are not definite; they occur with a probability that is thought to be dependent on the radiation dose received (Armao & Smith, 2014). The damage caused by ionizing radiation is therefore linear, with increased cumulative doses representing an overall increased risk of biologic damage.

Direct evaluation of the full extent of long-term cancer risks due to medical imaging would require extremely large-scale research studies with lifelong patient follow up (Berrington de Gonzalez et al., 2009). Accordingly, risk estimates are used to determine the risks associated with various levels of ionizing radiation. Risk estimates currently used by national and international governing bodies such as the United Stated Environmental Protection Agency (EPA) and the International Commission on Radiological Protection (IRCP), rely on epidemiological data on cancer and other diseases that are obtained from various radiation-exposed populations (Preston et al., 2013; Lin, 2010). These populations include atomic-bomb survivors and people with known or estimated radiation doses from medical, environmental or occupational exposures (Armao & Smith, 2014; Berrington de Gonzalez et al., 2009). The data collected from studies of these populations have produced substantial evidence supporting a link between low-dose radiation exposure and the development of solid cancers and leukemia (Armao & Smith, 2014). Based on this evidence, the National Academy of Sciences has developed a lifetime risk model, which predicts that a single 10mSv dose of ionizing radiation carries a 1 in 1000 lifetime risk of developing cancer (Armao & Smith, 2014). This effective dose is the equivalent of dose estimates for one chest CT or 769 traditional posteroanterior chest radiographies (Crownover & Bepko, 2013).

Radiation dose estimates for CT examination can vary, depending on patient size and various techniques of imaging (Lin, 2010). In addition, there are wide variations in the radiation doses that are delivered by individual CT scanners, based on the type of scanner used, as well as the technique of imaging used, the quality or level of detail chosen for the study, and the patient's size or body habitus (Richards, Summerfield, George, Hamid, & Oakley, 2008; Richards, George, Metelko, & Brown, 2010). As a result, the actual effective dose delivered to a particular patient may be significantly different from the median effective dose for a given examination (Armao & Smith, 2014; Richards et al., 2008). Even with this potential variance, the effective dose of ionizing radiation delivered during any type of CT scan is significantly greater than that of X-ray. For instance, a CT of the chest delivers an effective dose that is 100 to 1000 times greater than that delivered during a traditional chest x-ray (Armao & Smith, 2014).

Significance

Overutilization of Computed Tomography

Medical imaging is the largest contributor to radiation dose for the United States (Faynhersh & Passero, 2009). Studies estimate that although CT examinations account for only 15% of diagnostic imaging studies, they make up 75% of the radiation dose to the total population (Griffith, Bolton, Goyal, Brown, & Jain, 2011). In the United States alone, the estimated number of annual CT examinations increased from 2.8 million in 1981, to 20 million in 1995 and to greater than 62 million in 2006(Sun, Ng, & Vijayananthan, 2010). Advancements in technology such as the development of helical and multi-slice scanners, have led to this rapid increase in the clinical use of CT due to improved quality and resolution of CT images, reduced procedure time, and greater versatility and range of clinical applications (Perlin, Mower, & Bushe, 2013; Schonfeld, Lee, & Berrington de Gonzalez, 2011).

A study conducted by Korley, Pham and Kirsch (2010) found a three-fold increase in the use of CT or MRI studies during emergency department visits for injury-related complaints between 1998 and 2007, without a proportional increase in the prevalence of life-threatening conditions or changes in patient disposition (Korley, Pham, & Kirsch, 2010). The majority of this increase was due to increased use of CT examinations. The researchers also found that patients presenting to academic emergency departments were more likely to receive a CT scan than those presenting to nonacademic emergency departments. In 2007 alone, nearly 15% of patients who presented to U.S. emergency departments with injury-related conditions received a CT scan (Korley et al., 2010). The fact that the use of CT has increased without a corresponding increase in the number of injury diagnoses, as well as the variance between teaching and non-teaching facilities indicate a component of overuse of the imaging modality. One study by Owlia et al. (2014) estimates that as many as 30-40% of CT scans performed are done so unnecessarily.

Although the individual lifetime risk of cancer development from CT radiation exposure may seem relatively small, the large number of people exposed to radiation from medical imaging creates a potentially large burden of future cancer development (Crownover & Bepko, 2013). Based on current radiation risk estimates, a projected 29,000 future cancers could develop incident to CT scan use in the United States from the year 2007 alone (Crownover & Bepko, 2013). Given the estimated amount of unnecessary CT examinations performed annually, a small reduction could produce drastic effects in reducing future cancer development.

In addition to the risk of adverse health effects, each CT examination has an associated financial cost as well, and overuse may contribute to unnecessary financial burden (Berdahl et al., 2013). An estimated 5% of the U.S. gross national product is spent on unnecessary tests and procedures that do not improve patient outcomes (Owlia et al., 2014). Other negative consequences associated with unnecessary CT scan use includes contrast-media complications and the discovery of incidental findings that may lead to over-diagnosis and treatment (Owlia et al., 2014). Furthermore, unnecessary CT use places an increased demand on imaging departments and personnel, and may result in an increased length of visit and the potential for slowing in patient care and workflow (Bairstow et al., 2010; Korley et al., 2010).

There are many potential reasons for the overutilization of CT in emergency department settings, including lack of knowledge regarding the appropriate use of imaging methods, diagnostic uncertainty, patient demand, or a clinician's practice of defensive medicine (Armao & Smith, 2014b; Owlia et al., 2014). Fragmentation of care is also a contributing factor to overuse of CT examination. Patients who lack long-term relationships with their provider, or who receive care from multiple providers may receive repetitive imaging that has little to no impact on changing their course of treatment (Owlia et al., 2014). Various strategies that have been suggested to reduce inappropriate imaging include the use of decision-support systems, education for clinicians about the risks of radiation exposure, and facility promotion of recommended guidelines and imaging appropriateness criteria (Bairstow et al., 2010; Korley et al., 2010; Owlia et al., 2014). The effectiveness of these strategies is not well documented in clinical research; however, the research that does exist shows some promise. For instance, Griffith et al. were able to demonstrate reductions in the rate of CT overutilization, following implementation of a clinician educational program (Griffith et al., 2013). While many hospitals have chosen to adopt evidence-based protocols for diagnostic imaging, evidence is lacking regarding the scope of the benefits to their implementation.

Computed Tomography for Cervical Spine Injury

Spinal complaints such as acute and chronic neck pain and possible injury to the spine are common in the emergency setting (Friedman, Chilstrom, Bijur, & Gallagher, 2010; Griffith et al., 2011). Over 1 million patients in the U.S. are treated annually for blunt trauma with potential cervical spine injury (Griffith et al., 2011). Actual cervical spine injury only occurs in an estimated 2-10% of these cases; however, given the potentially serious consequences of such injury and delays in their treatment, clinicians in the emergency setting frequently have a low threshold for ordering diagnostic imaging of the cervical spine (Griffith et al., 2011). The preferred method of imaging for possible cervical spine injuries is the CT scan (Theologis, Dionisio, Mackersie, McClellan, & Pekmezci, 2014). CT scanning has been shown to be more sensitive for detecting cervical spine injuries and is potentially more cost-effective than plain radiography due to fewer missed injuries and lower settlement costs. Accordingly, CT scan from the occuput to first thoracic vertebrae is the recommended imaging modality for patients requiring imaging for possible cervical spine injury (Theologis et al., 2014).

Cervical spine CT exams not only require large radiation doses, but studies have also shown that these studies often miss ligamentous injuries (Richards et al., 2008). Furthermore, radiography of the spine and abdomen carries substantially higher radiation doses than studies of the extremities or the chest (Richards et al., 2008). Traditional radiography of the cervical spine carries an estimated effective radiation dose of 0.05 mSv, whereas CT of the cervical spine carries an average dose of 5 mSv, or the equivalent of 385 chest radiographies (Crownover & Bepko, 2013; Richards et al., 2010). The effect of this radiation depends on the area exposed and the sensitivity of the tissue within the area (Richards et al., 2010). The recommended imaging technique of occiput to first thoracic vertebrae has been shown to emit a high dose of radiation to the thyroid, which is a highly radiosensitive organ, and is susceptible to conditions such as hypothyroidism or cancer (Richards et al., 2010).

The over-utilization of CT imaging in the setting of potential cervical spine injury has been suggested in multiple studies. For instance, Oguz et al. found that ease of ordering and proximity of the CT device was related to increased use of CT examination (2002). Specifically, the authors were able to demonstrate a 21% increase in the rate of CT use one year following installation of CT equipment within the department. This increase in use interestingly correlated with a decrease in the rate of positive cervical spine studies, indicating that an increased rate of utilization does not necessarily correspond to increased detection of abnormalities (Oguz et al., 2002). A study by Morrison and Jeanmonod (2014) found that 30% of the cervical spine imaging performed in a level 1 trauma center was potentially inappropriate, as the imaging studies were ordered for patients who were at low risk for cervical spine injury based on clinical criteria. Similarly, Griffith et al. (2011) found that up to 25% of cervical spine CT examinations performed in a level 1 trauma facility were unnecessary, and could have been eliminated if the ordering clinician had adhered to cervical spine clearance criteria for appropriate use of CT. Other research has suggested that 20-40% of overall CT scans could be avoided if clinical criteria and guidelines were appropriately followed (Armao, Semelka & Elias, 2012). Given the risks and costs associated with unnecessary medical imaging, it would behoove clinicians and facilities to implement evidence-based protocols, particularly for cervical spine injury, to reduce unnecessary examinations. Additionally, regulatory agencies such as the U.S. Government Accountability Office have already begun to target the overuse of medical imaging in order to promote quality of patient care and reduce costs (Sheikh et al., 2012). Changes to clinician or facility reimbursement are just one way agencies may try to influence ordering practices.

Existing Guidelines for Cervical Spine Imaging

There have been multiple guidelines recommended for cervical spine clearance in the setting of blunt trauma or possible cervical spine injury. Among hospitals with self-reported cervical spine protocols in place, the most commonly used guideline is the National Emergency X-Radiography Utilization Study (NEXUS) criteria for cervical spine clearance (Theologis et al., 2014). The NEXUS criteria were developed to help identify patients with a low probability of cervical spine injury, who would therefore receive no benefit from cervical spine imaging (Griffith et al., 2011). Low-risk patients are those who have no posterior midline cervical spine tenderness, no evidence of intoxication, no focal neurologic deficit, no painful distracting injury and a normal level of alertness (Sheikh et al., 2012). Cervical spine imaging is indicated when one or more of these low-risk criteria are not fulfilled (Sheikh et al., 2012). A clinical algorithm based on the NEXUS criteria may be found in Figure 1.

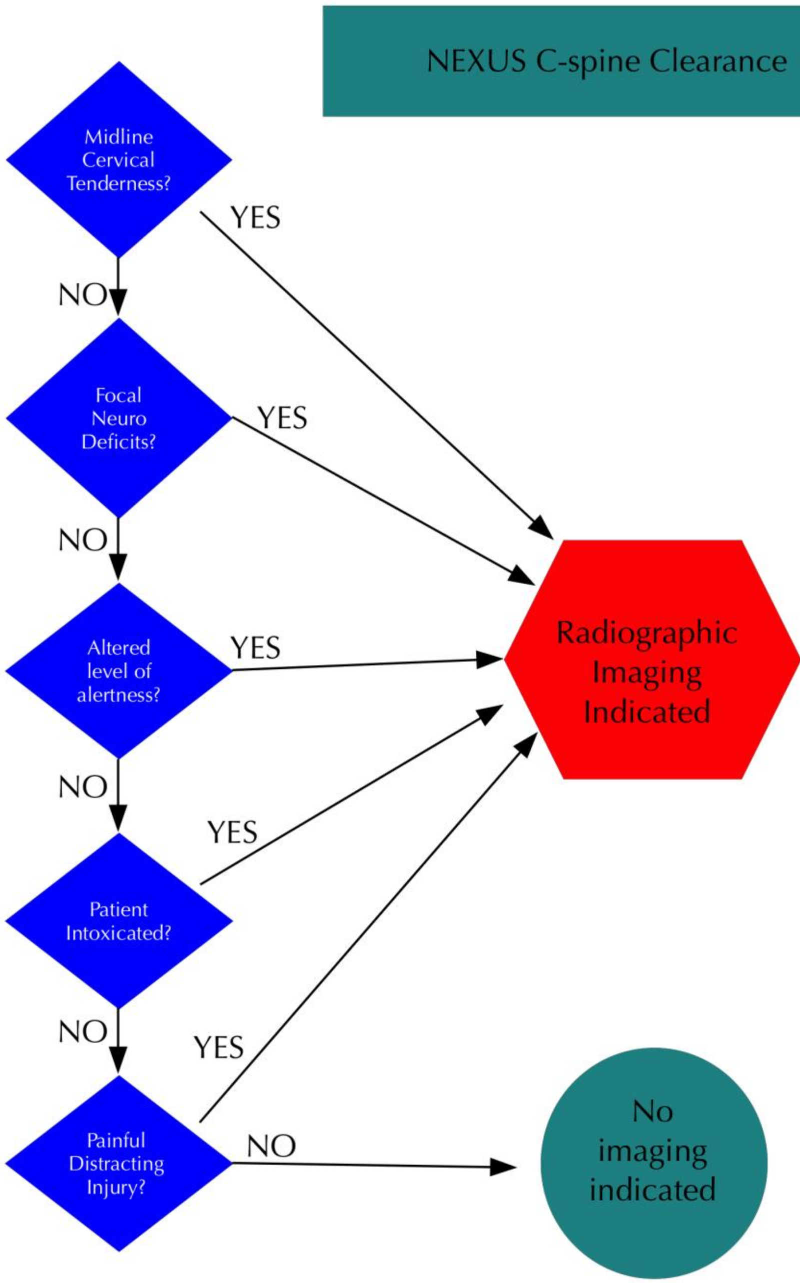

FIGURE 1. NEXUS Criteria Clinical Algorithm. (Adapted from the NEXUS criteria developed by Hoffman and colleagues, 2000).

The NEXUS criteria have been evaluated by multiple studies, and have been found to consistently have high sensitivity for cervical spine injury, meaning a negative test result is valuable in excluding cervical spine injury and the need for diagnostic imaging (Michaleff, Maher, Verhagen, Rebbeck, & Lin, 2012). Since the criteria does recommend imaging for all patients with positive criteria indicators, it carries a low specificity and high false positive rate, which means that many people without injury will still undergo diagnostic imaging unnecessarily (Michaleff et al., 2012). In addition, the criteria does not recommend a specific imaging modality for patients who do meet imaging criteria, so there does exist the potential for inconsistencies regarding the mode of imaging, and therefore the radiation dose received by NEXUS positive patients.

Another clinical decision rule for cervical spine clearance is the Canadian Cervical-Spine Rule (CCR) (Stiell et al., 2003). This rule may be used with alert patients in stable condition presenting with possible cervical spine injury due to blunt trauma. A clinical flowchart of the CCR may be found in Figure 2. The CCR contains three high-risk criteria and five low-risk criteria, in conjunction with active range of motion. The presence of one or more high-risk factors, including age greater than or equal to 65 years, a dangerous mechanism of injury or paresthesias in the upper extremities automatically mandates a radiographic study. A patient who has no high-risk criteria, fulfills any of the low risk criteria that allow range of motion and maintains full and active range-of-motion is considered low risk for injury, and therefore does not require imaging or immobilization (Stiell et al., 2003; Clement et al., 2016). Studies have demonstrated that the CCR maintains a consistently high sensitivity for indicating clinically important cervical spine injury (Michaleff et al., 2012). Similar to the NEXUS criteria, however, the rule carries a low specificity. This means that even with strict clinical application of the CCR, many patients will continue to receive unnecessary imaging (Michaleff et al., 2012).

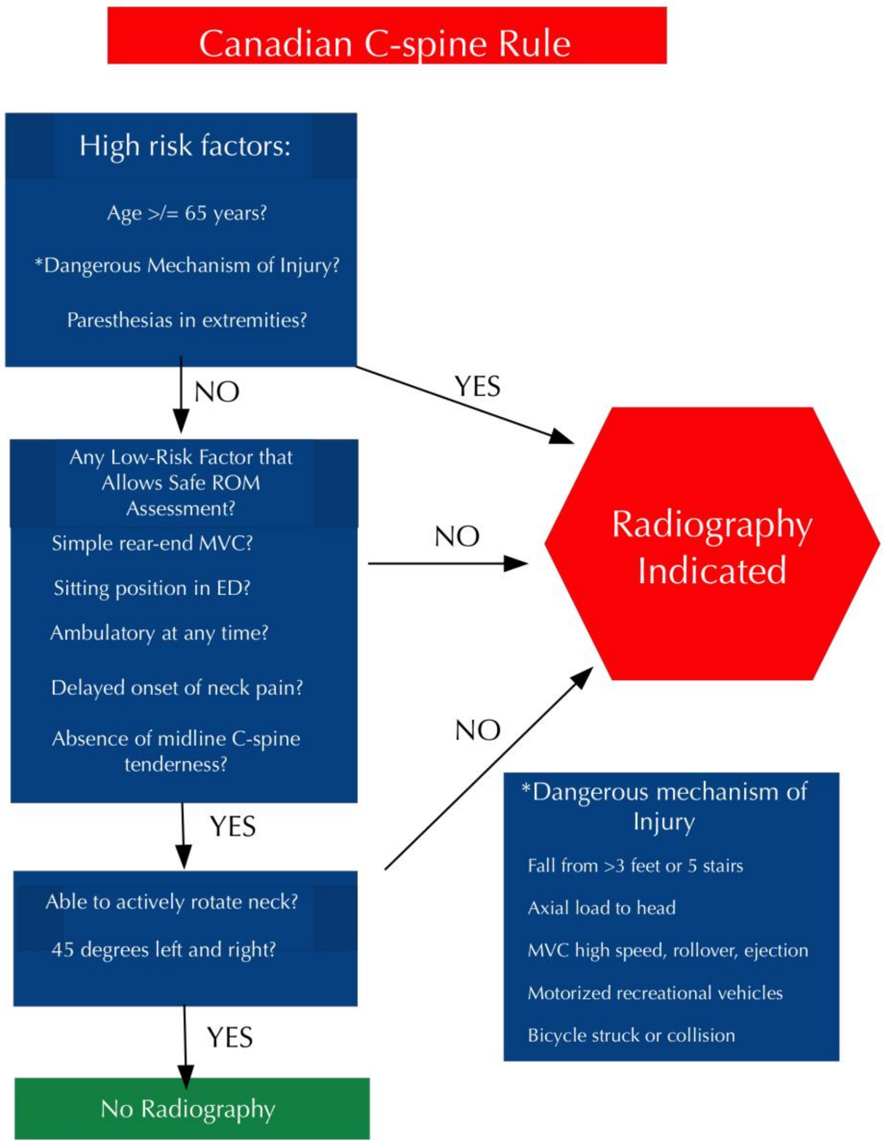

FIGURE 2. The Canadian C-Spine Rule Algorithm. (Adapted from Stiell and colleagues' Canadian C-spine Rule (Stiell et al., 2001).

The American College of Radiology Appropriateness Criteria (ACR-AC) are evidence-based guidelines that have been developed to help providers make appropriate radiologic imaging decisions for various given clinical conditions (American College of Radiology, 2017a). The goal of the criteria is to eliminate the inappropriate use of radiologic imaging services, thereby improving quality of care and safety to patients. The criteria address more than 178 clinical topics and 875 variants of these topics. They also provide appropriateness ratings for various imaging procedures under specific clinical circumstances. The ACR-AC for suspected spine trauma includes 14 situational variants with corresponding appropriateness ratings for various radiologic procedures such as simple X-ray, CT and MRI (Daffner et al., 2012). In addition, the criteria provide information regarding the relative radiation level associated with each type of diagnostic test (Daffner et al., 2012). One of the benefits of the ACR-AC is that they have been developed based on multidisciplinary clinical judgment as well as substantial research evidence. The guidelines incorporate clinical examination, recommending implementation of either NEXUS criteria or the CCR to first determine if imaging is necessary (Daffner et al., 2012).

In a survey of the 191 designated level 1 trauma centers in the United States, 57% reported having a protocol in place for cervical spine imaging after blunt trauma (Theologis et al., 2014). The most commonly used protocol reported is based on the NEXUS criteria, or modified NEXUS criteria with additional range of motion evaluation (Theologis et al., 2014). In a survey of 126 physicians at a university medical center, only three reported using the ACR-AC as a resource when choosing appropriate imaging techniques for their patients (Bautista et al., 2009).

Due to the potentially devastating consequences of missed or untreated cervical spine injury, the fact remains that many clinicians will choose to perform CT examination on all patients with potential cervical spine injury, regardless of their risk level. For instance, Duane et al. maintain that is it reasonable to perform a cervical spine CT on all significantly injured blunt trauma patients, regardless of their predictive risk for cervical spine injury, as they assert this the only way to maintain near 100% sensitivity for injury identification (2007).

Despite the fact that the ACR-AC and NEXUS criteria have been shown to be valuable in clearing the cervical spine without the need for imaging, there continues to be liberal use of diagnostic imaging in clinical practice, even in facilities with protocols in place (Michaleff et al., 2012). This may be reflective of uncertainty of the usefulness or application of clinical decision rules and guidelines, physician or patient preference, fear of litigation, or gaps in knowledge (Michaleff et al., 2012). Greater education of clinicians may help improve knowledge about and adherence to evidence-based guidelines for imaging and clearance of cervical spine injury.

Problem Statement

The use of CT examinations has increased drastically over the last several decades, to the point that medical imaging has become the largest contributor to individual radiation dose in the U.S. (Faynhersh & Passero, 2009). Furthermore, the over-use of cervical spine CT examination for potential injury due to blunt trauma has been suggested in multiple research studies (Griffith et al., 2011). Greater education of clinical staff and providers regarding evidence-based guidelines can help reduce the over-use of CT examination (Kruger et al., 2012). Additionally, the development and implementation of evidence-based protocol for the management of patients with suspected cervical spine trauma may help promote more appropriate clinical use of radiologic imaging for cervical spine clearance, thereby reducing unnecessary radiation exposure as well as health care expenditures (Sheikh et al., 2012).

Purpose and Specific Aims

The ultimate goal of this project is to develop a best-practice, evidence-based protocol for the management of patients with suspected cervical spine injury. To accomplish this goal, this project will consist of three specific aims, as follows:

1) Identify the type and frequency of radiographic imaging obtained for suspected cervical spine injury in the emergency room of a 300-bed urban hospital in northwest Tucson over a three-month timeframe, in order to determine the scope of the problem within the chosen facility.
2) Assess the potential barriers to the implementation of an evidence-based institutional protocol for the management of cervical spine injury and clearance among key stakeholders.
3) Using the information gained from Specific Aims 1 and 2, develop an evidence-based protocol for the management of patients with suspected cervical spine injury to be implemented in the emergency department of the studied hospital facility.

Significance to Advanced Nursing Practice

Healthcare research, practice, and policy development are focused on improving healthcare delivery and outcomes of care for patients (Gagliardi & Brouwers, 2012). Evidence-based practice is guided by the principles of identifying the best available research evidence available and reconciling this research evidence with clinical expertise to care for patients (Sanders et al., 2014). High quality clinical practice guidelines are developed using this research evidence, and are packaged in a way that is concise and useful for clinicians. The purpose of clinical practice guidelines may not necessarily include generalization to all patient populations, however they may be intended to assist the nurse practitioner or other provider in treating the average patient. Provider expertise and individual patient characteristics and preferences must also help to guide decision-making. Clinical practice guidelines can also help nurse practitioners improve the quality and consistency of care provided to their patients, decrease morbidity, and reduce costs through the delivery of consistent and optimized standards of care (Gracias et al., 2008; Sanders et al., 2014).

The role of the acute care nurse practitioner involves not only research development and utilization, but also performance and quality improvement (Gracias et al., 2008). In addition, nurse practitioners may also play an administrative or legislative role in healthcare, and may be actively involved in policy and procedure development for individual hospital facilities. Accordingly, nursing leaders can play an important role in the development and implementation of clinical practice guidelines, such as the ACR-AC as protocols for clinical practice.

CHAPTER II: LITERATURE REVIEW

Conceptual Framework

There are many complexities and variables associated with the development and transformation of research-based knowledge into healthcare practice. The knowledge translation process itself is complicated, and involves multiple steps including knowledge synthesis, dissemination, and application to healthcare delivery (Field, Booth, Ilot, & Gerrish, 2014). In addition, healthcare delivery occurs within a complex adaptive system that includes several independent and interacting components, which makes it difficult to predictably and effectively translate research evidence to widespread practice (Braithwaite, Marks & Taylor, 2014). A structured approach to the implementation of evidence-based knowledge can be useful in preparing for the variables that may affect the process, and may increase the likelihood of changed practice (Field et al., 2014). This can be accomplished through the use of a conceptual framework, which provides a roadmap of the steps involved, and potential barriers or facilitators that may arise during the process (Meyers, Durlak, & Wandersman, 2012).

The underlying basis of this project is the translation and application of evidence-based guidelines to a clinical practice setting. Practice guidelines are developed from a synthesis of the best available research evidence as a means to inform decision-making and promote the use of evidence-based knowledge in clinical practice (Gagliardi et al., 2011). For guidelines to be successful in this endeavor, they must be accepted and consistently used by the involved stakeholders. Gagliardi et al. (2011) point out that the adoption and use of guidelines is associated with the complexity of the included recommendations, and modification of guidelines to fit a local context may improve their acceptance and adherence. Accordingly, an appropriate conceptual framework for the implementation of practice guidelines would address the process of adapting knowledge synthesis for use in a specific practice setting.

The Knowledge-To-Action (KTA) conceptual framework provides the basis for this project. The framework was developed by Graham et al. (2006) as a means to describe the key elements of knowledge-to-action process. The framework incorporates two components of knowledge translation: knowledge creation and its application to practice. These components and their corresponding elements are dynamic, and may overlap or interact with one another at any point in the cycle (Field et al., 2014). Knowledge creation can refer to the development of raw data as well as the development of knowledge tools from research evidence such as guidelines and protocols (KT Clearinghouse, 2014). The action cycle outlines the processes and activities necessary for knowledge to be adapted and applied in practice. The term ‘action’ is used to describe the use of knowledge by practitioners, policymakers, patients and the general public (Field et al., 2014).

As shown in Figure 3, knowledge creation is portrayed as a “knowledge funnel,” which represents the process of refining, distilling and tailoring knowledge to the needs of health care professionals or policy makers (Graham et al. 2006). The first step in this process is Knowledge Inquiry, which refers to first generation knowledge such as clinical trials, randomized controlled trials, and other types of research studies. The second step, Knowledge Synthesis refers to second-generation knowledge such as systematic reviews of scientific evidence. The third step in the funnel is Knowledge Tools and Products, which represents the knowledge synthesis in the form of recommendations, practice guidelines, and decision aids. This step consists of tailoring second-generation knowledge to the needs of the end-user, such as healthcare practitioners or administrative (Graham et al., 2006). This step does not involve tailoring or adapting the knowledge to a local context or a specific setting, but rather to a broad context that may be further tailored to fit a specific organization, such as a local hospital. The NEXUS criteria, CCR and ACR-AC are examples of the type of knowledge tools created in this step. For this study, the ACR-AC serves as the knowledge tool that will be incorporated into the action cycle of the KTA framework, as this tool incorporates both clinical evaluation and recommendations for specific imaging.

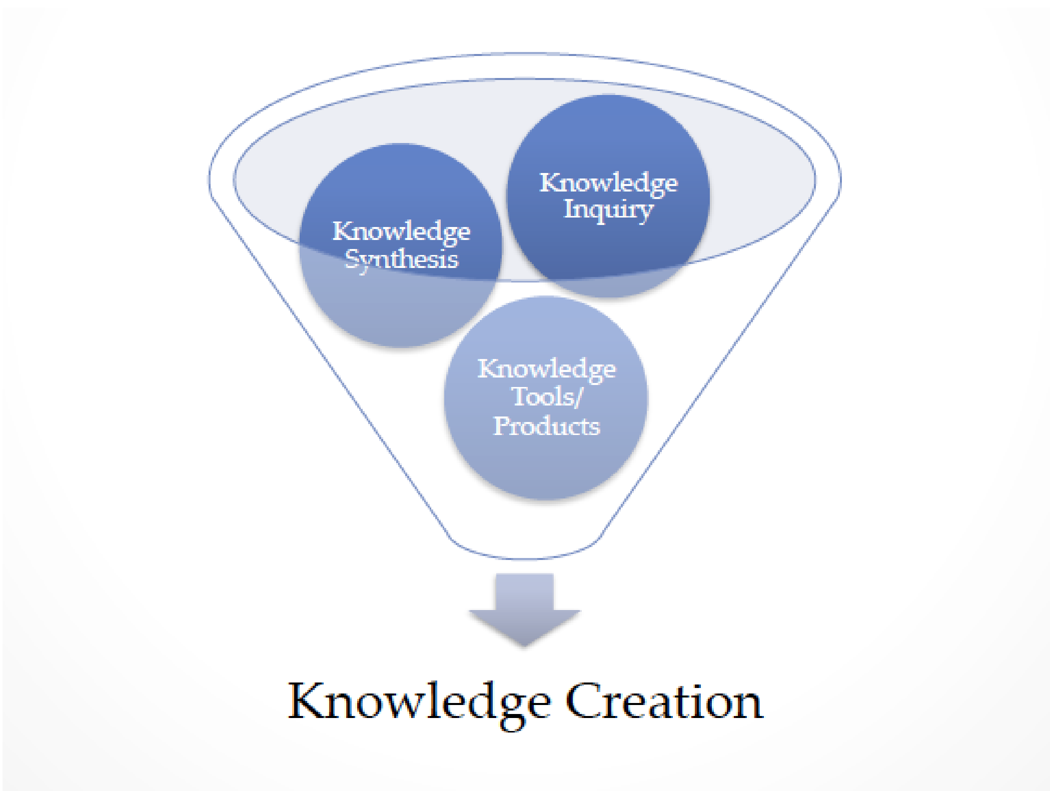

FIGURE 3. The Knowledge-to-Action Framework Knowledge Funnel. (This funnel represents the non-linear process of refining, distilling and tailoring knowledge to the needs of health care professionals or policy makers. Figure has been adapted from Graham et al., 2006).

As seen in Figure 4, the action cycle of the framework describes the process necessary for knowledge tools to be successfully implemented (Graham et al., 2006). The steps involved in the process may take place simultaneously or sequentially, and may impact or interact with one another (Field et al., 2014). These steps include:

1) Identify the Knowledge-to Action Gaps,
2) Adapt Knowledge to Local Context,
3) Assess Barriers to Knowledge Use,
4) Select, Tailor, Implement Interventions,
5) Monitor Knowledge Use,
6) Evaluate Outcomes,
7) Sustained Knowledge Use. (KT Clearinghouse, 2014).

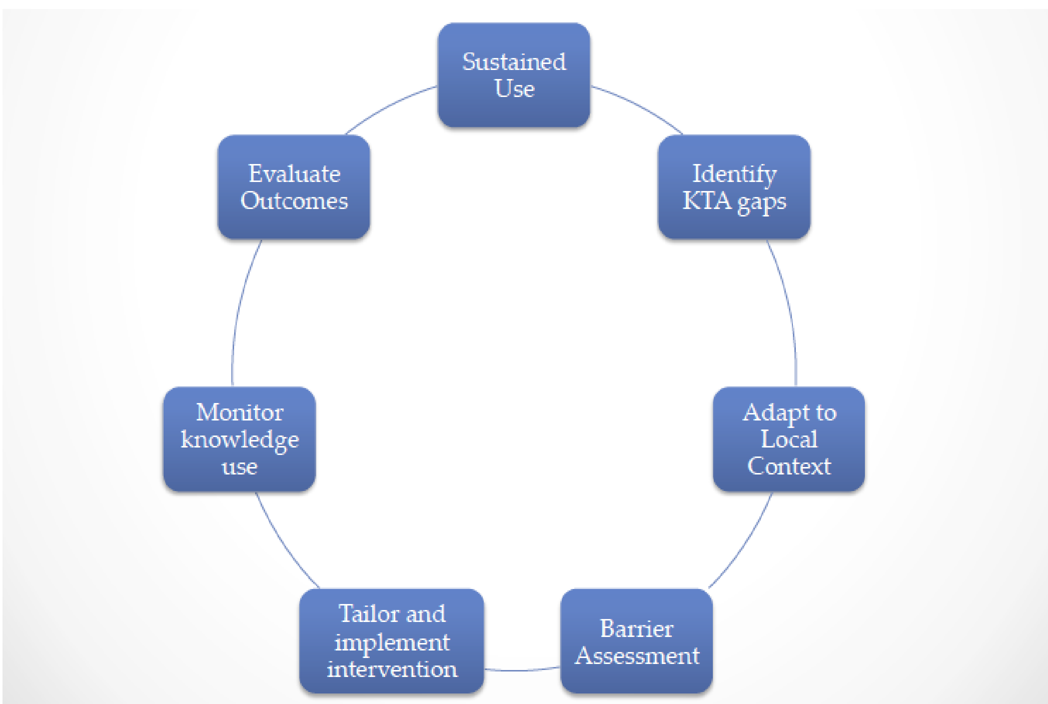

FIGURE 4. The Knowledge-to-Action Framework Action Cycle. (This portion of the framework describes the process necessary for knowledge tools to be successfully implemented. The steps may take place simultaneously or sequentially. Figure adapted from the Knowledge-to-Action cycle as outlined by Graham et al., 2006).

The first step of the action cycle, the identification of knowledge-to-action gaps, is the starting point of knowledge implementation (Graham et al., 2006). This step incorporates two phases: the identification of a problem, and the identification and selection of appropriate knowledge to solve the problem (Graham et al., 2006). This step also includes the involvement of relevant stakeholders in a needs assessment to identify problems, which may be characterized as gaps between knowledge and practice (KT Clearinghouse, 2014). These gaps may occur at various levels including that of the population, organization or healthcare providers. Methods that may be used to measure knowledge-to-action gaps at the organizational level include health records and chart audits, while surveys or questionnaires are commonly used to measure gaps at the provider level (KT Clearinghouse, 2014). For the purposes of this study, needs assessment will take place at both the organizational and provider levels, through the use of a retrospective chart audit and a clinician survey. A thorough needs assessment will enable the development of a clinical protocol based on ACR-AC that may be implemented in a way that is customized to the culture and needs of the clinical site.

The second step of the action cycle, the adaptation of knowledge to local context uses the knowledge gained from the needs assessment to customize guidelines and their implementation to fit the context of the organization (Graham et al., 2006). This customization can help improve acceptance and adherence to the new guidelines. This step may consist of several phases such as the identification of resources and assets, development of an adaptation plan, assessment of the guideline content, appropriateness and applicability to the local context, review of the guideline by local target audiences, and the development of a plan for future review and update of the guideline (Graham et al., 2006).

The third step of the action cycle consists of an assessment of the potential and actual barriers to use of the knowledge (Graham et al., 2006). Intervention strategies can then be developed in order to target and ideally overcome or diminish these barriers (Graham et al., 2006). Examples of potential barriers might include lack of familiarity or motivation on the part of the end-users, time limitations for implementation, lack of applicability to clinical context or insufficient organizational support. Assessment should also include identification of facilitators and supporting variables that may be taken advantage of during the implementation process (Graham et al., 2006).

The fourth step in the action cycle includes the planning and execution of interventions to implement the desired change (Graham et al., 2006). This typically involves tailoring interventions to the target audience and setting based on the variables identified in step three. Strategies that may be employed during this step include educational interventions, reminder systems or electronic decision support tools (Graham et al., 2006).

The next step in the action cycle consists of monitoring the use of the knowledge or intervention (Graham et al., 2006). This may include monitoring conceptual use of the knowledge, as demonstrated by changes in attitudes, knowledge or understanding on the part of the end users. Instrumental use of the knowledge describes changes in behavior or practice as a result of the knowledge. In order to monitor the use of the knowledge, those responsible must first identify what type of knowledge is to be measured, and next define how it will be measured (Graham et al., 2006).

The sixth step in the action cycle is dedicated to outcome evaluation (Graham et al., 2006). The impact of the new knowledge is evaluated in terms of its impact on variables such as health outcomes, practitioner behavior, or system outcomes. The purpose of this step is to assess the impact of the knowledge intervention in order to determine if implementation was successful, and if the intervention was useful in practice (Graham et al., 2006).

The final step in the action cycle is dedicated to sustaining the use of the knowledge in practice (Graham et al., 2006). Sustainability should include initiation of a feedback loop that cycle through one or several of the seven steps of the action cycle (Graham et al., 2006). An example of promoting sustainability includes the periodic update of policies and procedures based on new research evidence or changes in organization culture or practice standards.

The objectives of this project are grounded in the first three steps in the action cycle of the KTA framework. These steps include a needs assessment, involvement of stakeholders, adaptation of the ACR-AC to the context and needs of the hospital and end-users and an assessment of barriers and facilitators (Field et al., 2014). The remaining steps of the cycle, planning and execution of the intervention, monitoring the use of the intervention, evaluation of outcomes, and sustainability will not be addressed. The purpose of this project is to propose a feasible protocol based on the ACR-AC cervical spine clearance guidelines that could be implemented in the emergency department of a 300-bed hospital in Tucson, Arizona.

Review of the Literature

The objectives of this literature review include:

1) To discuss provider perception and awareness of the radiation risks from diagnostic imaging,
2) Explore the use of institutional protocols for cervical spine clearance,

3) Explore trends in provider adherence to established evidence-based cervical spine clearance guidelines,
4) Review the use of evidence based protocols and guidelines, including the development, implementation and benefits.

During the time period from January 2014 and October 2017, PubMed and CINAHL were used to identify pertinent research studies related to clinical practice guidelines and protocols, cervical spine clearance protocols commonly used in practice, provider adherence to cervical spine protocols, and provider attitudes toward patient radiation risk attributed to diagnostic imaging. Key search terms included “clinical practice guidelines,” “clinical protocols,” “cervical spine clearance,” “cervical spine imaging,” “cervical spine clearance protocol,” “radiation risk and providers,” “provider awareness of radiation risk,” as well as “protocol development.” Inclusion criteria included articles published within five years, human subjects, English language, and availability of the article as full-text online. In addition, articles with pediatric research subjects were excluded. These combined searches yielded over 1500 articles related to cervical spine protocols, and over 13,000 articles related to clinical protocols and guidelines in general. Articles that were relevant to the topics of protocol development, cervical spine clearance protocols, adherence to these protocols and provider attitudes toward radiation risks were reviewed. Since the main purpose of this literature review is to explore trends in provider adherence to cervical spine protocols and provider attitudes toward radiation risks of cervical spine CT, relevant literature may include various levels of research evidence such as observational, descriptive, qualitative or systematic reviews. Accordingly, the literature search and this review were not limited to specific levels of research evidence.

Provider Perception of Diagnostic Imaging Risks

In a qualitative study, Kruger et al. (2014) assessed clinician beliefs, attitudes and practices related to radiation exposure and their ordering of diagnostic imaging studies. Researchers conducted focus groups with specialty and primary care clinicians including physicians, nurse practitioners and physician assistants who delivered outpatient care in the San Francisco area (Kruger et al., 2014). Researchers conducted semi-structured focus groups, where participants were asked questions regarding their beliefs, attitudes and practices related to incorporating radiation exposure information in their clinical decision-making when ordering diagnostic imaging studies. The participants' answers were coded and grouped into major themes and relationships. Researchers found that most clinicians believed the provision of radiation exposure information related to diagnostic imaging studies would be useful in helping inform provider decision-making as well as patient-provider discussions. Clinicians indicated that while an electronic clinical decision tool that tracked a patient's cumulative radiation exposure might be useful, the use of such an intervention at the point of clinician order entry might not be useful. Specifically, their application of the information provided would be likely be limited due to time constraints. Clinicians also indicated that educational tools aimed at patients and clinicians alike may be helpful in fostering patient-clinician discussions regarding risks and benefits of imaging studies (Kruger et al., 2014).

The results of this study support the notion that educational support might be useful in helping clinicians make informed decisions regarding diagnostic imaging. While clinicians in the study felt that time constraints may serve as barriers to realistic use of electronic decision support, they were receptive to the idea of educational tools aimed at informing clinician decision making and patient education (Kruger et al., 2014).

In a cross-sectional study by Puri et al. (2012), researchers set out to assess the level of awareness emergency department providers had regarding patients' lifetime cancer risk attributable to radiation from diagnostic imaging. Researchers also aimed to explore how this awareness might be associated with providers' behaviors and attitudes toward risk-benefit analysis prior to ordering diagnostic imaging (Puri et al., 2012). An anonymous, multiple-choice questionnaire was sent to physicians, physician assistants and nurse practitioners in two hospital emergency departments in Rochester, New York. Providers were asked questions to assess their knowledge regarding lifetime cancer risk related to radiation, and were asked if they incorporated risk-benefit analyses into their imaging ordering practices. Risk-benefit analyses included exploring the patient's history of imaging studies, outlining the risks of radiation to the patient, and considering the radiation dose prior to ordering a study. The researchers found that only 12 of the 65 participants had accurate knowledge regarding lifetime cancer risk attributable to radiation from imaging, while 27 participants over-estimated the risk, 11 under-estimated the risk and 15 did not know the risk. Researchers also found an inverse relationship between the knowledge of lifetime cancer risk and the likelihood that the provider would conduct a risk-benefit analysis prior to ordering an imaging study. Furthermore, clinicians with greater clinical experience were more likely to conduct risk-benefit analyses prior to ordering imaging studies than were inexperienced clinicians (Puri et al., 2012). The results also indicated that physicians surveyed had a better level of knowledge and awareness of radiation risk due to CT studies than did nurse practitioners or physician assistants. The results from this study suggest that any educational intervention aimed at increasing knowledge of radiation risk and appropriateness of imaging should involve not only physicians, but also nurse practitioners and physician assistants.

A benefit of this study is that researchers included nurse practitioners and physician assistants in the study population. Given the role these providers often have in the emergency setting, they are frequently responsible for the diagnosis and management of patients who may require imaging studies, so it is appropriate to include them in any assessment of ordering practices (Puri et al., 2012).

Use of Cervical Spine Clearance Guidelines

In an observational, cross-sectional study, Theologis et al. (2014) evaluated the degree of incorporation of evidence-based guidelines into hospital protocols among trauma centers in the United States. Researchers contacted the 191 registered trauma centers via email or phone, and requested each facility's cervical spine clearance protocol, if available (Theologis et al., 2014). These protocols were then reviewed and compared with 2009 evidence-based guidelines issued by the Eastern Association for the Surgery of Trauma (EAST). The EAST guidelines recommend a combination of the NEXUS criteria with painless cervical range of motion for clearance of potential cervical spine injury. Based on these guidelines, imaging is indicated when NEXUS criteria are not met or in the presence of painful range of motion (Theologis et al., 2014).

Of the 191 designated Level 1 trauma centers in the United States, 167 (87%) responded to the survey (Theologis et al., 2014). The results showed that 57% of Level 1 trauma centers do have a protocol in place for patients presenting with possible cervical spine injury. Although the specific protocol used varied among the responding institutions, the most widely used protocol was the NEXUS criteria. Nearly half (43%) of those using the NEXUS criteria also incorporated painless range of motion (ROM) into the criteria for clinical clearance of cervical spine injury, which is the recommended practice according to 2009 EAST guidelines. Of the responding trauma centers, those with academic affiliation were more likely to have a protocol in place, as were facilities that had been verified by the American College of Surgeons (ACS). The response rate for this particular study was 87%, which suggests that the results are likely an accurate representation of the prevalence of cervical spine guidelines among Level 1 trauma centers (Theologis et al., 2014). Since only Level 1 trauma centers were surveyed, it is difficult to translate these results to other types of facilities.

In another observational, cross-sectional study by Bautista et al. (2009), an online survey method was used to examine the prevalence of ACR appropriateness criteria use versus other clinical decision resources by clinicians in large university medical center. Study participants included hospital physicians, who were asked to select the top three resources they used for assistance in determining what type of imaging to order for their patients (Bautista et al., 2009). Among the available options were Google, UpToDate, ACR appropriateness criteria, PubMed, and a radiologist consult. A total of 126 physicians, 59 of whom were residents and 67 attending physicians, completed the survey. Results of the survey indicated that only two of the responding physicians used ACR appropriateness criteria as their first choice resource, while only one used the criteria as their second choice resource. The most commonly used resource for decision-making regarding radiologic imaging was a radiologist consultation. Researchers noted that there seemed to be a general lack of awareness of ACR criteria among providers, both residents and attending physicians. The fact that physicians in the study were more inclined to use Google over evidence-based appropriateness resources and ACR appropriateness criteria suggests that accessibility and ease of use may be important influences for the selection of clinical decision aids by physicians (Bautista et al., 2009). Furthermore, since provider awareness of the ACR criteria was limited among both residents and attending physicians in this study, it is possible that improved provider education may be an important first step in establishing the ACR criteria as a valid and useful tool.

There are several limitations to this study. For instance, the researchers only surveyed hospital physicians, and did not include other provider groups such as physician assistants or nurse practitioners (Bautista et al., 2009). Furthermore, they chose to exclude emergency department physicians from the survey, citing the availability of previous research of this group (Bautista et al., 2009). Given that these groups do comprise a portion of the population responsible for ordering diagnostic imaging, it would be appropriate to include them when assessing ordering practices. Although the results of this study illustrate a lack of awareness or inconsistent use of clinical guidelines regarding appropriate imaging among those surveyed, it is difficult to translate these results to other facilities or healthcare as a whole. There may be wide variation based on facility location or type. For instance, the culture of a large university medical center may be vastly different from that of a small community hospital in the same geographical area.

Provider Adherence to Cervical Spine Clearance Guidelines

Sheikh et al. (2012) conducted a retrospective review of all radiographs and CT imaging of the cervical spine in the emergency setting of a Level 1 trauma center from July 2009 to July 2010. The study included adult patients with suspected acute cervical spine injury following a blunt trauma who received cervical spine radiographs and/or cervical spine CT scan. Clinical history and imaging indication were obtained via a medical record review. A resident and an attending radiologist evaluated the appropriateness of each imaging study based on the ACR Appropriateness Criteria. A total of 1325 imaging studies of the cervical spine were obtained during the designated time period, of which 433 (32.7%) were radiographic examinations and 892 (67.3%) were CT examinations. Per ACR recommendations, CT is indicated as the initial imaging study of choice for ruling out cervical spine injury, and providers should only obtain cervical spine radiography for a lateral view if images from the CT are deemed technically inadequate. According to this guideline, 100% of the 433 cervical spine radiographies obtained in this study were deemed inappropriate (Sheikh et al., 2012). Furthermore, cervical radiography alone was insufficient in the identification of actual cervical spine injury, and follow-up CT scan had to be obtained for the three individuals with possible abnormalities on radiography. In total, 28 of the 1245 patients in the study suffered an acute cervical spine injury, all of which were detected using CT.

Due to the retrospective nature of the study and limited clinical documentation, researchers were unable to report whether any of the 892 cervical spine CT examinations were inappropriately ordered, based on ACR criteria (Sheikh et al., 2012). The assumption was made that all patients who received cervical spine imaging did not satisfy the low-risk criteria for cervical spine clearance, and therefore required imaging. In addition, ordering clinicians at the facility were not required to indicate whether they followed any type of criteria when choosing to order diagnostic imaging (Sheikh et al., 2012). These factors make it difficult to truly assess what type of role the ACR criteria or any other imaging criteria played, if any, in the ordering practices of the clinicians involved. Researchers indicate that the data would be useful for the development of a quality improvement project that may include education of physicians about radiation dose associated with imaging, and the creation of an institutional protocol to coincide with ACR Appropriateness Criteria (Sheikh et al., 2012). While the results of this study are not necessarily indicative of clinician practices in other facilities, the study does help to illustrate how frequently inappropriate ordering may occur.

In a prospective, observational study, Morrison and Jeanmonod (2014) examined the use of NEXUS criteria among emergency medicine providers in a Level 1 trauma center who had received mandatory education regarding the use of appropriate imaging guidelines and NEXUS criteria. Providers were given the option of including their patients in the study by answering a questionnaire for each patient who presented to the ED in a years' time with complaints of blunt injury such as falls, car accidents or direct trauma (Morrison & Jeanmonod, 2014). Clinicians were able to order diagnostic testing of their choosing without intervention. The provider indicated on the survey whether the patient met NEXUS criteria for imaging, and the rationale for their decision to obtain imaging or not to obtain imaging for each patient. From November 2011 to September 2012, 300 patients were enrolled in the study, of who 128 met NEXUS criteria for a possible cervical spine injury and 172 of who did not. Patients who were negative for NEXUS criteria accounted for 31% of the 168 patients who received cervical spine imaging. In addition, 30% of the NEXUS negative patients received cervical spine imaging despite their low risk for cervical spine injury. Ultimately, this lead to the diagnosis of two cervical spine injuries, which would have been missed had the provider followed NEXUS guidelines and abstained from ordering diagnostic imaging for the patients. The most commonly cited reasons for ordering diagnostic imaging when it was not indicated by NEXUS criteria were advanced patient age, followed by mechanism of injury (Morrison & Jeanmonod, 2014).

In this study, there was no relationship between the providers' level of training and their adherence to the NEXUS protocol (Morrison & Jeanmonod, 2014). In addition, since all providers in this study received mandatory training regarding the NEXUS criteria, and since the NEXUS criteria had been used for all patients involved, the results indicate that provider knowledge of the criteria or even consistent use of the criteria may not be enough to prevent unnecessary imaging. Given that the NEXUS criteria are not 100% sensitive to identifying cervical injuries, there exists a risk of false negatives and potentially unidentified cervical spine injuries with the use of the criteria alone. As a result, providers may not strictly adhere to the criteria in every circumstance. Individual provider decision-making will always be an uncontrollable variable in the implementation of any protocol. Although a protocol may be developed to assist with efficient and effective diagnostic and treatment decisions, the experience and clinical judgment of the provider are invaluable for individual circumstances. For instance, two cervical spine injuries that would have otherwise been missed were identified via imaging that was not indicated according to NEXUS criteria (Morrison & Jeanmonod, 2014). In addition, populations such as the elderly, these results indicate providers may continue to have a low threshold for ordering diagnostic imaging, whether or not the patient meets NEXUS imaging criteria. The fact that other guidelines such as the CCR make specific recommendations for radiographic imaging in elderly populations may also have an impact. Previous training or knowledge of these guidelines and their established validity may influence clinicians' ordering practices, regardless of the development of a NEXUS-based protocol.

In a study by Griffith et al., (2013) researchers set out to determine whether a clinical education program would be successful in promoting clinician adherence to ACR AC guidelines for cervical spine clearance in an emergency department of a Level 1 trauma center. This was part three of a three-phase study, in which Phase 1 consisted of a retrospective evaluation of cervical spine CT and clinician documentation of diagnostic criteria (Griffith et al., 2011). Phase 2 was a prospective study that assessed utilization of cervical spine diagnostic criteria after the implementation of a clinician survey that asked ordering clinicians to indicate whether or not diagnostic criteria were consulted prior to ordering imaging (Griffith et al., 2013). Data from Phase 2 indicated that the rate of overutilization of CT imaging based on NEXUS criteria decreased from 23.9% to 16.1% following the implementation of the survey (Griffith et al., 2013). Following Phase 2, researchers implemented a clinical education program for clinicians responsible for ordering imaging studies in the emergency department (Griffith et al., 2014). The education program consisted of a 45-minute presentation reviewing the ACR AC for cervical spine imaging for suspected trauma. The presentation also addressed NEXUS and CCR criteria. Data from Phases 1 and 2 were also presented, including the incidence of cervical spine injury in patients meeting and not meeting ACR appropriateness criteria. Following this educational program, enrollment for Phase 3 of the study began (Griffith et al., 2014).

Between March 2012 and October 2012, all adult patients who presented to the emergency department at the Level 1 trauma center and received CT imaging of the cervical spine for evaluation of possible blunt trauma were enrolled in the study (Griffith et al., 2014). For all enrolled patients, clinicians were instructed to document the mechanism of injury, indications for ordering imaging, clinical suspicion for cervical spine injury, and the patient's risk classification based on NEXUS or CCR criteria. Researchers found that the overutilization of imaging, based on NEXUS or CCR guidelines, decreased from 16.1% to 13% following the implementation of the educational program (Griffith et al., 2014).

The results of this three-phase study indicate that increasing provider awareness of evidence-based guidelines for imaging criteria can produce a similar result as an educational program designed to reduce the rate of inappropriate imaging use. In this study, provider awareness of imaging guidelines and cervical spine criteria was addressed via optional surveys to be filled out for each patient with possible cervical spine injury as well as posted reminders throughout the emergency department (Griffith et al., 2014). The fact that these interventions produced an improvement in appropriate use of imaging for indicates that simple interventions to increase awareness can produce changes in ordering practices. A limitation of this study and the described interventions was low patient enrollment (26.9%) due to the fact that physician surveys and documentation in both phase two and phase three were optional (Griffith et al., 2014). As a result, it is difficult to state whether the survey or educational intervention had a significant impact on the overall ordering practices of all clinicians at the facility. It is possible that the clinicians who were more diligent about completing the surveys and documenting imaging indications may be more receptive to the provided interventions.

Background of Clinical Guidelines and Protocols in Healthcare

The history of clinical guidelines and protocols. Clinical guidelines allow for a systematic approach to patient care through use of evidence-based algorithms that have been designed to assist with decision-making (Prasad et al., 2010). The use of clinical guidelines in healthcare has become widespread, and their use is believed to contribute to improved quality of care (Kredo et al., 2016). Although the terms “clinical practice guidelines” and “protocols” are often used interchangeably, clinical practice guidelines generally refer to best-practice statements regarding the diagnosis, monitoring, or management of a specific health condition or concern (Kredo et al., 2016). Protocols, on the other hand, typically consist of a set of rules or instructions about how to complete a specific process, based on best-practice recommendations synthesized from research evidence (Kredo et al., 2016). For example, an individual hospital may develop a protocol for the determination of brain death; however, this protocol should be consistent with well-established guidelines, such as those outlined by the American Academy of Neurology (AAN) (Cohen, Steinberg, Singer, & Ashkenazi, 2015).

Clinical guidelines are thought to have first originated in the early 1900’s (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011). At that time, they were primarily developed by experts within the field, and were not yet based on the synthesis of scientific evidence. The first randomized controlled trial was published in 1948, and in the years following, the amount of available medical research evidence grew rapidly. As research evidence became more abundant, the verification of the validity of such evidence became more difficult. In 1990, the term “evidence-based medicine” was born, and not long after, evidence-based practice became the standard in healthcare. This evolution in clinical practice and the growing abundance of research evidence created the need for a tool that could provide a synthesis of critically appraised research, thereby allowing clinicians to stay abreast of the most up-to-date, valid, and relevant research evidence. This contributed to the development of the Agency for Healthcare Policy and Research (AHCPR), a government agency whose responsibility was the development of clinical practice guidelines, based on the synthesis of scientific evidence. In 1995, this role was terminated and the agency was renamed the Agency for Healthcare Research and Quality (AHRQ). This organization continues to support the production of systematic reviews that may be used in the development of clinical practice guidelines. Currently, the National Guideline Clearinghouse (NGC), a database within the AHRQ, houses a web-based collection of global clinical practice guidelines. This searchable database allows end-users to access clinical practice guidelines, facilitating their dissemination and use. By 2011, the NGC housed a total collection of 2,700 accepted clinical guidelines within the database (IOM, 2011).

To ensure the trustworthiness of the guidelines the NGC currently refers to the Institute of Medicine 2011 report entitled "Clinical Practice Guidelines We Can Trust" (National Guideline Clearinghouse, 2017). The report was published by the IOM with the intention of providing standards for the development of trustworthy clinical guidelines (Roman & Feingold, 2014). The authors assert that not only guidelines be developed based on a systematic review of the best-available evidence, but also the development process itself should adhere to trustworthy standards (IOM, 2011). Eight standards are recommended for the development of rigorous and trustworthy practice guidelines. These standards include: transparency, management of conflicts of interest, a heterogeneous and multidisciplinary composition of the guideline development group, the use of systematic reviews in the development of guidelines, an adequate explanation of the strength of the available evidence, a clear articulation of the recommended actions, an external review of the recommendations by key stakeholders and experts, and updating of the guidelines as pertinent research evidence is published (IOM, 2011).

The NGC uses the IOM definition of a clinical practice guideline, as well as their eight standards for the development of guidelines to inform its inclusion criteria for publication to the database (NGC, 2017). The NGC developed The National Guideline Clearinghouse Extent Adherence to Trustworthy Standards (NEATS) Instrument as a tool to allow NGC staff to perform simplified assessments of clinical practice guidelines based on the IOM recommendations. By performing these assessments, the NGC can work to improve the quality and trustworthiness of guidelines published within their database, thereby improving their likelihood of successful adoption into clinical practice (NGC, 2017).

In addition to the quality of the guidelines, research suggests that the adoption of clinical practice guidelines is also dependent upon how the guidelines interact with the end-users, the practice setting, and how they are communicated to the end-users (IOM, 2011). Since communication with end-users is an important factor, measures that promote communication also facilitate successful implementation. This can include quick reference guides, reminders, and electronic clinical decision support systems (IOM, 2011). The use of hospital or facility protocols can also help facilitate the implementation of evidence-based guidelines and treatments in clinical settings (Prasad et al., 2010).

Benefits of protocols. Studies have shown that implementation of facility-based protocols can reduce both hospital costs and hospital stays, as well as reduce morbidity and mortality (Theologis et al., 2014). A recent retrospective cohort study examining outcomes following the implementation of a primary stroke center protocol for patients with suspected stroke due to large vessel occlusion found that implementation of the protocol was associated with both increased efficiency of care as well as improved patient outcomes (McTaggart et al., 2017). Specifically, complete implementation of the protocol was associated with reduced time between hospital arrival and interventional angiography, as well as improved patient outcomes, as demonstrated by a greater reduction in National Institute of Health Stroke Scale score at the time of discharge, when compared to only partial or no execution of the protocol (McTaggart et al., 2017).

The benefits of evidence-based hospital protocols have been demonstrated with other medical conditions, and in other settings as well. For instance, the use of ventilator weaning protocols and sedation protocols that include daily interruption or light sedation have been shown to improve outcomes in critical care settings (Sevransky et al., 2015). Research has also shown acute respiratory distress syndrome (ARDS) ventilation protocols to be associated with decreased mortality when compared to historical control data (Sevransky et al., 2015).

In the case of cervical spine clearance protocols, Rosati et al. (2015) found that implementation of a clinical clearance protocol for pediatric patients in a level I trauma center produced a 13% total decrease in the number of CT scans of the cervical spine over a 12 month period. Additionally, no patient required follow-up imaging for a clinically apparent injury of the cervical spine during the two-year timeframe of the study (Rosati et al., 2015). This indicates that the use of the protocol not only reduced the amount of CT scans obtained, but also did so without a corresponding increase in missed cervical spine injuries (Rosati et al., 2015).

Disadvantages of protocols. Despite the potential benefits of protocol implementation, there are some possible disadvantages as well, such as the failure of the protocol to produce the produce the desired effects of improving patient care and outcomes. This may be a particular risk if the protocols were developed from guidelines that are inherently flawed, outdated, or lack clinical applicability to the target population (IOM, 2011). The potential benefits of protocols can also depend on how well they are implemented in the practice setting (Sevransky et al., 2015). In an observational study of intensive care units across 59 hospitals in the United States, the authors found no difference in mortality, hospital length of stay, and other critical care outcomes between facilities with a large number of protocols versus facilities with fewer protocols. The authors theorize that the benefits of hospital-based protocols may depend on factors such as compliance with recommendations, provider education, communication, and unit or facility culture (Sevransky et al., 2015).

Cervical spine clearance guidelines have been developed to provide a standardized approach to safely clearing the cervical spine after blunt trauma, ideally improving efficiency and reducing the number of unnecessary imaging studies while avoiding the possibility of a missed cervical spine injury (Pekmezci, Theologis, Dionisio, Mackersie, & McClellan, 2015). Multiple studies have demonstrated the utility of cervical spine clearance protocols such as the NEXUS, CCR, and ACR-AC, specifically demonstrating their sensitivity in detecting likely cervical spine injuries (Michaleff et al., 2012). Conversely, there is also research suggesting that clinical examination alone can be unreliable in diagnosing or excluding cervical spine injury in patients with recent blunt trauma (Duane et al., 2007).

A prospective study by Duane et al. (2007) found low reliability of clinical examination alone in clearing possible cervical spine injury after blunt trauma. The authors used cervical spine CT to examine the accuracy of clinical examination, and found that for patients who fit the EAST criteria for clearance of potential cervical spine injury based clinical examination alone (n=320), there were seven fractures identified on CT that were not identified on clinical examination. Given the potential consequences of a cervical spine injury, any missed injury can be significant both physically and economically. As a result, the authors of the study argue that contrary to EAST guidelines, clinical examination of potential cervical spine injury should be accompanied by a CT examination, even when clinical examination indicates a low probability of fracture (Duane et al., 2007). As new clinical data is published, and as new technologies are developed, clinical guidelines should be adjusted to reflect the new research evidence (IOM, 2011). This can help improve the efficacy of the guidelines, and prevent their failure when applied to practice (IOM, 2011). For instance, the EAST guidelines for cervical spine clearance have been updated twice since their creation, based on the publication of literature citing cost inefficiency, safety concerns and general inadequacy of previous guidelines (Pekmezci et al., 2014).

Conclusions

Clinical guidelines provide best-practice recommendations for the diagnosis, and management of a specific health conditions (Kredo et al., 2016). The use of evidence-based guidelines and their implementation via hospital-based protocols can reduce unnecessary hospital costs and improve morbidity and mortality (Theologis et al., 2014). The research indicates that there may be a general lack of provider awareness and use of clinical guidelines and evidence-based recommendations for cervical spine clearance (Bautista et al., 2009; Morrison & Janmonod, 2014; Sheikh et al., 2012). The research also indicates that increasing provider awareness regarding clinical guidelines can promote better adherence to evidence-based recommendations (Griffith et al., 2014b). Furthermore, educational support can be helpful in influencing clinician decision-making regarding diagnostic imaging (Griffith et al., 2014b;

Kruger et al., 2012). Theologis et al. (2014) demonstrated that although many hospitals in the United States have implemented protocols for the management of cervical spine injury, less than half of the protocols in place are consistent with evidence-based recommendations for best-practice. These results suggest that there remains a gap between the research evidence and clinical practice regarding the management of patients with suspected cervical spine injury. Further research should be aimed at narrowing this gap, and promoting more widespread use of evidence-based recommendations for clinical practice. This literature review supports the proposal of an evidence-based, best-practice protocol for clearance of suspected cervical spine trauma that may be implemented in the emergency department of a local hospital facility.

CHAPTER III: PROJECT AIMS AND DESIGN

This chapter will describe the aims and design of a study with the overall goal of developing an evidence-based cervical spine clearance protocol for proposed implementation in the emergency department of a 300-bed medical center in Tucson, Arizona.

Purpose and Specific Aims

The overall purpose of this project was to develop a best-practice protocol for the management of patients with suspected cervical spine injury, based on ACR appropriateness criteria. This aim was developed based on a review of the literature, which indicates that cervical spine clearance protocols such as the ACR-AC are underutilized in practice. To accomplish the main goal, specific aims have been addressed, consistent with the steps delineated within the conceptual framework. The specific aims of this project include:

Specific Aim 1: Identify the type and frequency of imaging studies obtained for suspected cervical spine injury in the emergency room of a local, urban hospital in northwest Tucson over a three-month timeframe to compare with ACR recommendations.

Specific Aim 2: Assess the potential barriers to the implementation of an evidence-based institutional protocol for the management of cervical spine injury and clearance among key stakeholders.

Specific Aim 3: Using the information gained from Specific Aims 1 and 2, develop an evidence-based protocol based on ACR-AC for the management of patients with suspected cervical spine injury to be implemented in the emergency department of the studied hospital facility.

Study Design

Data collection for this project consisted of two stages. To accomplish Aim 1, a retrospective descriptive design was used. This included a retrospective review of clinical data and imaging studies from hospital radiology information systems. For Aim 2, a prospective qualitative design was utilized. This consisted of a web-based survey, which was delivered to key stakeholders via email. The goal of this phase was to collect qualitative, subjective data regarding clinicians' use of clinical clearance criteria for suspected cervical spine injury, as well as their perceptions of potential barriers to the implementation of a facility-based cervical spine clearance protocol. The data gathered for aims 1 and 2 informed the development of a best-practice protocol for institutional implementation, which is Aim 3 of this project. The following section explains the study design and methods in detail.

Specific Aim 1

Setting and population. The primary setting of this project was the emergency department of Northwest Medical Center, a 300-bed trauma level III hospital in Tucson, Arizona. Utilized resources included the primary investigator's personal computer, the hospital computer system, the hospital computer network, the electronic medical record, the hospital email service, and the hospital's picture archiving and communication system (PACS).

For Specific Aim 1 of this project, the sample included all adult patients seen in the emergency department within a three-month timeframe, from November 2016 through January 2017, who received a cervical spine radiography (X-ray) and/or CT scan for possible cervical spine injury due to blunt trauma. Patient specific exclusion criteria included penetrating trauma and children less than 17 years of age. Other exclusion criteria included ordering locations other than the emergency department or emergency department overflow areas, and facilities other than the Northwest Medical Center main campus.

Data collection. To accomplish the first specific aim, a retrospective review of imaging data from the hospital PACS was conducted. Search criteria were entered into the system to identify all cervical spine exams to include X-ray and CT, obtained within the designated three-month timeframe. This process allowed a search by imaging type, body location, and timeframe. The time frame was separated into individual days within the three-month timeframe to improve the ease of the search and documentation. All cervical CT scans and X-rays obtained during the time period were reviewed to identify the studies fitting inclusion criteria. The purpose of the review was to assess the quantity of suspected cervical spine injuries presenting to the emergency department that received diagnostic imaging, what type of imaging study was ordered, and to determine how the ordering practices compare with the ACR appropriateness criteria.

Northwest Medical Center does not currently have a protocol or policy in place regarding cervical spine clearance, nor is documentation of clinical criteria for cervical spine clearance required. As a result, no objective data was obtained regarding the use of the ACR-AC, CCR or NEXUS criteria in clinical decision-making, as this information is not documented. It was assumed that all patients who received any type of cervical spine imaging could not be cleared by clinical criteria, and thus required imaging. The data that was collected was chosen based on current ACR-AC criteria for suspected spine trauma, specifically the variant that applies to suspected cervical spine trauma in the emergency department setting (Daffner et al., 2012). Only Variants 1 and 2 of the ACR-AC for suspected spine trauma was used. Variant 1 applies to patients for whom imaging is not indicated, based on clinical clearance using either the CCR or NEXUS criteria. Variant 2 applies to adult patients with suspected acute cervical spine injury on initial clinical evaluation in an emergency setting, for whom imaging is clinically appropriate (Daffner et al., 2012). Variant 3 was not included, because this variant then includes patients with possible myelopathy who may require MRI examination (Daffner et al., 2012). The scope and focus of this study is primarily CT and conventional radiography due to their use of ionizing radiation, so use of MRI imaging was not examined. Variants 4 through 14 were not used, as these variants do not apply to the target population of adults with suspected cervical spine injury on initial clinical evaluation in an emergency department setting (Daffner et al., 2012).

The specific data that was collected included:

- The total number of cervical spine CT examinations ordered alone, and the total number of conventional cervical spine radiographs (X-rays) ordered alone
- The total number of CT scans and X-rays obtained for the same patient during a single encounter within a 24-hour timeframe, and the chronology of the studies obtained.
- The type of cervical spine X-ray, including the number and type of anatomical views, obtained for patients who received both CT examination and X-ray.
- The indications and clinical history for all included studies.
- The number of identified cervical spine fractures or acute bony abnormalities identified on imaging, and the corresponding imaging modality.

Patients were first identified using the facility identification number (FIN), in order to track individual emergency department encounters and corresponding imaging studies obtained. After identification and documentation of the imaging data was completed, the patients were then assigned chronologic numerical identifiers by the primary researcher for documentation purposes and to remove any potential patient identification. No personal identifiers were documented. The FINs were used to assist with data collection, and were not tracked or otherwise documented thereafter. All data was obtained from the information provided in the PACS, including the imaging data and radiology report for each imaging study. The patient charts were otherwise not accessed or viewed. The indication for the completed diagnostic studies was recorded, to ensure that only the target population of patients with suspected cervical spine trauma was included in the study. This required viewing the radiology report for each study. The imaging study type, the date and time the study/studies were ordered, and indication for the study was documented for each patient who received cervical spine imaging. Clinical indications that were consistent with suspected cervical spine trauma were identified by the presence of key words or diagnoses such as *fall, motor vehicle accident, head trauma*, or *neck trauma,* and *neck injury*, among others. Clinical indications were found in two categories within the radiology reports: *Reason for Exam* and *Clinical History*. The reason for exam is the documented indication as chosen by the ordering clinician within the imaging order itself. There are several drop-down options for the reason for exam, including an *Other* option that requires a free-text comment by the ordering clinician. The clinical history is a brief synopsis of the patient's clinical history, and is obtained and documented by clinical staff, such as the transporting nurse, the radiology technician or the triage nurse (personal communication, radiology technologist D. Higuera, 2017).

Specific Aim 1 has been adapted from a prior study by Sheikh et al., (2012) who set out to assess the appropriateness of cervical spine imaging based on the ACR-AC in a large level 1 trauma center. Sheikh et al. (2012) used similar data collection and interpretation methods, and demonstrated that 422 of the 433 cervical spine X-rays performed over the course of a year were ordered “inappropriately,” based on ACR-AC.

Data analysis. Descriptive statistics were used for data analysis. The frequency of imaging ordered was calculated for each variable. The total number and percentage of studies performed that were not consistent with ACR-AC was calculated.

Specific Aim 2

Setting and population. For Specific Aim 2, the stakeholder survey, the desired sample included all emergency department physicians, physician assistants and nurse practitioners.

Data collection. For this aim, web-based surveys were emailed to 50 stakeholders for completion. These stakeholders included 37 physicians and 13 nurse practitioners or physician assistants. A commonly used internet-based service, SurveyMonkey Inc., was used to develop the survey that was sent via email link to participants. The survey consisted of five questions designed to assess providers’ self-identified use of clinical criteria for cervical spine clearance, their perception of potential over-use of CT examination for suspected cervical spine injury, their perception of the utility of a facility protocol for clinical clearance of suspected cervical spine injury, and potential barriers to its use. An outline of the survey is found in Appendix A. Participants were given three weeks to respond to the emailed survey. One week after the initial email invitation was sent, a reminder email was sent to all clinicians. A lack of response to both the first and second emails was considered “no response” (Appendix B).

The benefit of this survey method is that it was believed to be convenient for clinicians, as it allowed them to complete the survey as their schedule permits. Since it was limited to five questions, the survey could also be completed quickly. A three-week timeframe for survey completion was chosen to provide adequate time for the participants, and to also maximize overlap with the various work schedules of the participants. These strategies were used to encourage clinician participation. The professional designation (MD, DO, PA, NP) of each participant was obtained at the conclusion of the survey, however further identifiers were not included, in order to maintain anonymity for the participants.

Data analysis. Responses to the survey questions were analyzed using descriptive statistics. Free-text data collected during the clinician survey was analyzed thematically.

Specific Aim 3

For Aim 3, the information gained from Aims 1 and 2 has been used to develop an evidence-based protocol for the management of patients with suspected cervical spine injury, which could be implemented in the emergency department of the studied hospital facility. The specific aims of this project are grounded in the first three steps in the action cycle of the KTA framework. These steps include a needs assessment, involvement of stakeholders, assessment of barriers and facilitators, and adaptation of the ACR-AC to the context and needs of the hospital and end-users (Field et al., 2014). Accordingly, the data collected for specific aims 1 and 2 are used to assess the need for a protocol, assess the culture and barriers of clinicians working at the target hospital, and finally, to develop an evidence-based protocol tailored to the needs of the stakeholders and facility.

Risk/Benefit Assessment

This study was of minimal risk. Data was collected in a manner that protected patient privacy and prevented any breaches in confidentiality. No direct patient contact took place, and the intervention had no known significant impact on patient care. A potential source of impact on patient care may include changes in provider awareness of cervical spine clearance protocols, and subsequent changes in clinical practice.

Ethics and Human Subjects Protection

Prior to any data collection, approval was obtained from the Northwest Medical Center Institutional Review Board (IRB). A ceded IRB approval from the University of Arizona was subsequently obtained. The approval letters from each IRB committee are located in Appendix C. Research methods included only retrospective chart review and physician surveys, and there was no direct patient involvement. No patient identifiers were used during data storage. All de-identified data were obtained and electronically stored by the primary researcher.

Timeline and Budget

The anticipated timeline for the data collection portion of this project was approximately two months, including two weeks dedicated to retrospective chart review, and two to three weeks dedicated to the distribution, collection and interpretation of the physician surveys. The actual timeline for data collection and analysis was approximately four weeks. The retrospective chart review took place over a period of three weeks and was performed simultaneously with survey distribution and collection. Three weeks were allotted for participant completion of the physician survey.

There were no budgetary needs associated with this project. The clinician survey was developed on a commonly used web-based platform, free of charge (Appendix A). The PI personally conducted all data collection and analysis.

CHAPTER IV: RESULTS

This chapter presents the results of the data collection for Specific Aim 1 and 2. For Specific Aim 1, data was documented and analyzed using Microsoft Excel 2011 for Mac software. For Specific Aim 2, data was collected and analyzed using the SurveyMonkey web service.

Specific Aim 1

Identify the type and frequency of imaging studies obtained for suspected cervical spine injury in the emergency room of a local, urban hospital in northwest Tucson over a three-month timeframe to compare with ACR recommendations.

Imaging Modality

The imaging study type, the date the study/studies were ordered, and indication for the study was documented for each patient who received cervical spine imaging.

Data collection included the total number of cervical spine CT studies ordered alone, total number of cervical spine conventional radiographs (X-rays) ordered alone, the total number of CT studies and X-rays obtained for the same patient during a single encounter within a 24-hour timeframe, and the chronology of the obtained studies. The type of X-ray obtained for patients who received both CT and X-ray, including the number and type of anatomical views. The indications and clinical history was documented for all included studies.

TABLE 1. *Imaging Studies by Month and Modality*

Month	CT	XR
November 2016		
Total	158	186
Included	67	17
Excluded	91	169
December 2016		
Total	131	164
Included	64	24
Excluded	67	140
January 2017		
Total	158	166
Included	68	23
Excluded	90	143
Total Included	199	64

Note. Exclusion criteria included patient age<17 years, ordering location other than emergency department or emergency department ancillary areas, ordering facility other than Northwest Medical Center, and order indication not consistent with trauma.

The total cervical spine imaging studies obtained by month and modality are displayed in Table 1. Between November 1, 2016 and January 31, 2017, there were 963 imaging studies of the cervical spine ordered in the emergency department of Northwest Medical Center. Of those, 46.4% (447/963) were CT, and 53.6 % (516/963) were X-rays. From the total number of CT examinations performed, 44.5% (n=199) fit the inclusion criteria. A total of 248 CT studies were excluded. Of the 516 X-rays performed, 12.4% (n=64) fit the inclusion criteria, while 452 were excluded.

TABLE 2. *Distribution of Cervical Spine Imaging by Modality*

Month	All XR and CT	CT only	XR only	CT + XR	CT →XR	XR →CT
November, 2016	84	66	16	1	0	1
December, 2016	88	62	22	2	0	2
January, 2017	91	64	19	4	0	4
Total	263	192	57	7	0	7

Note. XR X-ray or conventional radiograph, *CT + XR* Total number of patients who received both CT and X-ray, *XR →CT* Total number who received a C-spine X-Ray before a C-spine CT, *CT→XR* total number who received a C-spine CT prior to X-ray.

A total of 263 examinations (257 individual patient encounters) were included in data analysis for this study, and are summarized in Table 2. CT studies accounted for 75.6% (199/263) of all included cervical spine studies, whereas X-rays accounted for 24.3% (64/263) of all included examinations. Data revealed that 74.7% (192/257) of patients who received imaging for possible cervical spine injury received only a CT scan, while 22.2% (57/257) received only X-ray.

Approximately 2.7% (7/257) of patients received both CT and X-ray of the cervical spine within a 24-hour timeframe of the same encounter. Of these patients, 100% (n=7) first received an X-ray, followed by a CT of the cervical spine. There were no patients that received a cervical spine CT examination followed by an X-ray.

Of the 64 X-ray studies, 89.1% (57/64) were performed alone, and without prior or subsequent CT examination. Of the patients who received only an X-ray, 100% (n=57) included three or more views, and none of these examinations included flexion and extension views. Of the patients who received both CT and X-ray, 100% (n=7) received three or more views, with no flexion and extension views. There were no X-rays that included only a single lateral view.

Approximately 3% (8/257) of patients who received cervical spine imaging were found to have a probable acute spine injury. Of these eight patients, seven received only CT examinations, and one received only an X-ray. There were no patients with an identified acute cervical spine injury who received both X-ray and CT studies. Of the seven patients who received both an X-ray and a CT, four had a questionable cervical spine injury identified on the initial X-ray, necessitating a follow-up CT for further evaluation. However, all four of these follow-up CT studies were negative for an acute injury. The remaining three patients had no acute injury identified on either the X-ray or subsequent CT.

Imaging Indications

As noted in Chapter III, clinical indications for the imaging studies were found in two categories within the radiology reports: *Reason for Exam* and *Clinical History*. The reason for exam is the documented indication as selected by the ordering clinician from a list of options. Seven documented indications were identified during this data collection. These included "pain, neck;" "injury, neck;" "injury, face & neck;" "spinal injury;" "fractured cervical vertebrae;" "cervicalgia;" and "other."

TABLE 3. *Stated Indication of Imaging Studies*

Reason for Exam	**Total**	**CT only**	**XR only**	**XR+CT**
Other*	31	28	2	1
Pain, neck	131	81	48	2
Injury, neck	80	76	0	4
Injury, face & neck	7	0	7	0
spinal injury	3	3	0	0
spinal injury; pain, neck	1	1	0	0
fractured cervical vertebrae	1	1	0	0
cervicalgia	1	1	0	0

Note. *Other* free text indications included in Table 4.

The distribution of imaging type by reason for exam is displayed in Table 3. The most common reason for exam was neck pain, accounting for 49.8% (131/263) of the included studies. Of the studies ordered for neck pain, 36.7% (48/131) were X-rays alone, while 61.8% (81/131) were only CT studies. There were two patients who received both CT and X-ray for neck pain. Of the seven patients who received both an X-ray and CT, 57% (4/7) were imaged for an indication of "injury, neck." The clinical history was examined for all seven patients who received both imaging modalities, which revealed that 71% (5/7) suffered a fall. The other 29% (2/7) were involved in a motor vehicle accident.

TABLE 4. *"Other" Indication Comments*

Free-Text Comment	**CT**	**XR**
Fall	10	0
Pain	0	1
Fall/eval fracture	1	0
Neck pain, MVA	0	1
Fall, syncope	1	0
Altered mental status, MVA	1	0
Fall, wound right scalp	1	0
Eval fracture*	1	1
Neck pain s/p fall	1	0
Head injury	1	0
Unwitnessed fall	1	0
Please also eval soft tissues	1	0
Possible head injury, +EtOH	1	0
Fall, RUQ and RLQ abdominal pain, +EtOH, +SI	1	0
MVA	1	0
Struck top of head with metal fence pounder 1/18/17	1	0
Fall from motorcycle, pain, 1/15/17, +LOC	1	0
Fall from standing, hit right head, right kneepain	1	0
Syncope	1	0
Fall, pain in face, head, neck, L chest wall	1	0
Syncope, forehead abrasion, R elbow abrasion	1	0
MVA, h/o carotid abnormality, + HA, neck pain, back pain	1	0
Total	29	3

Note. *Comment for both studies during same patient encounter

A choice of other during the ordering process requires a free-text comment in a separate field. The comments found for "other" reasons for exam are found in Table 4. Of these, 19 included mention of a fall within the comment field. A motor vehicle accident was included in five comment fields. One comment field included a fall from a motorcycle. Three comments included "syncope," one of which also included "fall." When the clinical history was also taken into account, 21 patients had a history of fall, including the patient with a fall from a motorcycle.

The clinical history portion of the radiology report was reviewed for order indications that did not suggest blunt trauma, including neck pain and cervicalgia. Examinations with a clinical history consistent with blunt trauma were considered to have met inclusion criteria. Examples of clinical history statements indicating blunt trauma included “MVA with neck pain,” “neck pain after fall,” “neck pain after trauma,” or “assault,” among others. Specific indications of trauma were extracted from these statements. Within the clinical history, falls and motor vehicle accidents were the most common reasons for the exams ordered for neck pain. A clinical history of fall was indicated in 53.4% (70/131) of the studies ordered for neck pain. Of those, 80% (52/70) were CT studies, while 20% (14/70) were X-rays. Motor vehicle accident was documented in the clinical history for 39.7% (52/131) of the examinations obtained for neck pain. Of those, 40.4% (21/52) were CT studies, while 59.6% (31/52) were X-rays.

TABLE 5. *Distribution of Imaging by Clinical History and/or Reason for Exam*

Clinical History	**All XR**	**All CT**	**XR only**	**CT only**	**XR +CT**
MVA	37	41	35	39	2
Fall	19	122	14	117	5
Assault	2	1	2	1	0
Other Injury	1	10	1	10	0
Syncope	2	8	2	8	0
Trauma	3	5	3	5	0
Found Down	0	3	0	3	0
Seizure	0	2	0	2	0

Note. Other Injury includes injuries from all other causes.

A history of fall was the most common overall reason for all cervical spine imaging, when both the reason for exam and clinical history were accounted for. The distribution of imaging by overall indication, as determined from the documented reason for exam and the clinical history, is depicted in Table 5.

A total of 141 patients received imaging for a clinical history of a fall or with “fall” included in the reason for exam. Of those 141 patients, 89.1% (122/141) received only a CT examination. Only 9.9% (14/141) received X-ray alone, and 3.5% (5/141) received both CT and X-ray. Of the total patients who received both CT and X-ray, the majority (71.4%; 5/7) of the patients had a clinical history indicating a fall. Other indications including a seizure, syncope, and “found down,” are suggestive but not conclusive for a history of fall, and were not included in the calculations for proportion of exams due to falls.

Motor vehicle accident (MVA) was the next most common reason for imaging, based on the clinical indications and clinical histories. There were 76 patients who received cervical spine imaging after a motor vehicle accident, two of whom received both CT and X-ray. The number of CT examinations and X-rays for MVA was comparable, with 37 total radiographs for MVA, and 41 total CT examinations.

Of the eight identified acute cervical spine injuries, the most common (75%; 6/8) reason for examination was neck pain. The remaining two reasons included “fractured cervical vertebrae” and “other: fall.” When the clinical history was taken into account, most of the patients with an acute cervical spine injury (87.5%; 7/8) had a history of a fall. The remaining one patient with a cervical spine injury was involved in a motor vehicle accident.

Specific Aim 2

The purpose of Specific Aim 2 was to assess the potential barriers to the implementation of an evidence-based institutional protocol for the management of cervical spine injury and clearance among key stakeholders. A clinician survey was used for this purpose. The survey was sent via email to a total of 50 emergency clinicians, including 37 physicians and 13 nurse practitioners or physician assistants. A total of 7 (14%) clinicians responded to the survey. Of those who responded, 57.1% (4/7) were physicians, one was a nurse practitioner, and 28.6% (2/7) were physician assistants (Appendix A).

Question 1. For patients presenting with suspected cervical spine trauma, are you familiar with clinical clearance guidelines such as the Canadian C-Spine Rule, NEXUS criteria, or the American College of Radiology (ACR) Appropriateness Criteria?

Of the seven who responded, 100% indicated that they were familiar with the CCR, NEXUS criteria or ACR-AC.

Question 2. For patients presenting with suspected cervical spine trauma, do you refer to a clinical guideline to assist with determining whether imaging is appropriate or necessary?

Of the participants, 100% (7/7) indicated they refer to a clinical guideline to assist them in determining if imaging is appropriate or necessary for patients with suspected cervical spine trauma.

Question 3. If you answered 'yes' to question 2, which guideline do you prefer, or refer to most often?

The NEXUS criteria were indicated as the most commonly referred to guideline, with 57.1% (4/7) respondents indicating this as their preference. The remaining 42.8% (3/7) chose the Canadian C-spine Rule (CCR). There were no responses indicating a preference for the ACR appropriateness criteria.

Question 4. Please indicate your agreement or disagreement with the following statements.

For Question 4, the participants were asked to indicate a level of agreement or disagreement with a series of questions regarding the use and potential overutilization of CT examination. The responses to question 4 are presented in Table 6.

TABLE 6. *Responses to Question 4 of Clinician Survey*

	Strongly Disagree	**Disagree**	**Neither Agree nor Disagree**	**Agree**	**Strongly Agree**
CT is overutilized in the workup of patients with suspected cervical spine trauma.	0%	71.4% (5/7)	0%	28.6% (2/7)	0%
CT is generally appropriately utilized in the workup of patients with suspected cervical spine trauma.	0%	14.3% (1/7)	14.3% (1/7)	71.4% (5/7)	0%
The possibility of a missed fracture often leads to the use of CT for patients with possible cervical spine trauma	0%	14.3% (1/7)	0%	42.9% (3/7)	42.9% (3/7)
If a patient is low-risk for cervical spine injury, based on clinical criteria, I may still consider a CT to avoid missing a fracture.	14.3% (1/7)	28.6% (2/7)	28.6% (2/7)	28.6% (2/7)	0%

The majority of respondents (71.43%; 5/7) disagreed that CT is overutilized in the workup of patients with suspected cervical spine injury, of whom 28.6% (2/7) were physicians, 28.6% (2/7) were Physician's Assistants, and one was a nurse practitioner. There were two (28.6%) who agreed that CT is overutilized, both of whom were physicians, and no responses indicating strong agreement or strong disagreement that CT is overutilized.

Most respondents (6/7) indicated agreement that the possibility of a missed fracture often leads to the use of CT for patients with possible cervical spine trauma. Three (42.9%) agreed with this statement, and the same number strongly agreed. Only one respondent disagreed that the possibility of a fracture leads to the use of CT examination.

Two of the participating clinicians, both Physician's Assistants, indicated agreement that they would still consider ordering a CT for a patient who is at a low-risk for injury based on clinical criteria. Two indicated neither agreement nor disagreement, and three indicated disagreement.

Question 5. Would you support the implementation of an evidence-based hospital protocol for management of suspected cervical spine trauma? Why or why not?

Five clinicians (four physicians and one physician assistant) answered question 5, which was open-ended and allowed for a written response from the clinicians. The responses to this question, and the participants' corresponding professional designation are presented in Table 7.

TABLE 7. *Clinician Written Responses to Question 5*

Professional Designation	Would you support the implementation of an evidence-based hospital protocol for management of suspected cervical spine trauma? Why or why not?
MD	I have a personal preference for NEXUS + clinical gestalt
MD	Patient expectation, the result of patients making complaints if they do not receive the testing they want, the burden of administration managing patient complaints in order appease patients, can lead to the over ordering of testing. Regardless of explanations to patients, they often have an expectation.
MD	Unlikely to be useful as a hospital protocol as multiple clinical factors often cause clinicians to do something outside the protocol
MD	No, I feel that EM providers are using clinical decision rules appropriately
Physician Assistant	No

Note. There were two participants with no response to question 5.

Specific Aim 3

The purpose of Specific Aim 3 is to use the information gained from Specific Aim 1 and 2 to develop an evidence-based protocol based on ACR-AC for the management of patients with suspected cervical spine injury that could be implemented in the emergency department of the studied hospital facility. The algorithm for this protocol is presented in Figure 5.

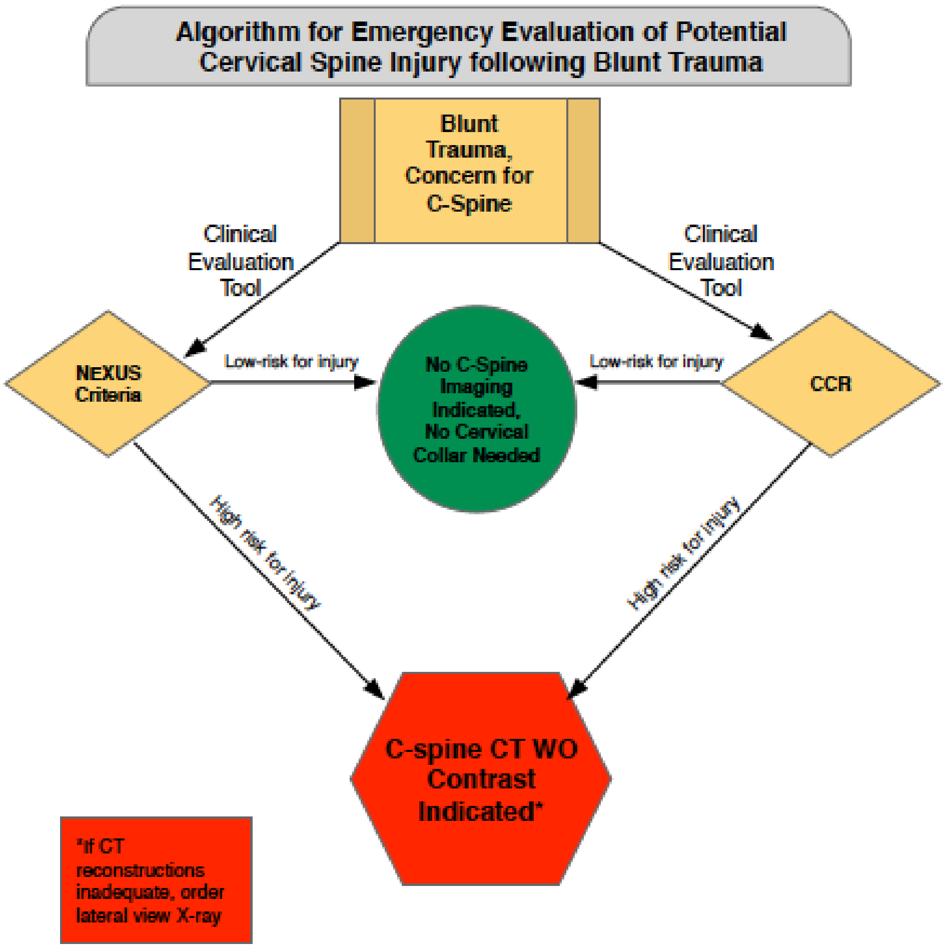

FIGURE 5. Algorithm for Proposed Evidence-Based Protocol. (This has been adapted from Stiell and colleagues' Canadian C-spine Rule (Stiell et al., 2001), the NEXUS criteria developed by Hoffman and colleagues (2000), and the ACR Appropriateness criteria for suspected cervical spine trauma (Daffner et al., 2012).

To facilitate hospital implementation and promote adoption among providers, a hospital policy related to the protocol has also been developed. This policy is outlined as follows:

Hospital Protocol for Suspected Cervical Spine Trauma Evaluation

Background. The American College of Radiologists Appropriateness Criteria (ACR-AC) are evidence-based guidelines developed by a multidisciplinary team that can aid providers in making appropriate decisions regarding diagnostic imaging for specific conditions, such as potential cervical spine injury.

Purpose of protocol. To improve patient safety, improve quality, and reduce potentially unnecessary imaging for patients presenting with suspected cervical spine injury.

Scope of protocol.

Sites, facilities:	*Departments included:*	*Persons affected:*
Northwest Medical Center	Emergency Department and supportive units (ancillary ED, behavioral ED units)	All providers (physicians, nurse practitioners, physician assistants

Personnel education. All persons affected by the protocol are required to attend an educational in-service regarding the current clinical recommendations and guidelines, including the NEXUS criteria, CCR, and ACR-AC.

Protocol initiation criteria. Patient >17 years of age presents to ED with a clinical history of blunt trauma, with concern for possible cervical spine injury.

Recommended procedure.

1. Clinical evaluation by provider (MD, DO, NP, PA, etc.) using either CCR or NEXUS criteria.
    a. If patient is low-risk for cervical spine injury:
        i. No imaging is indicated.
        ii. No rigid cervical collar is needed.
    b. If patient is high risk for cervical spine injury:
        i. Imaging is indicated:
            1. CT of cervical spine WO contrast preferred

a. 3-view X-ray may be appropriate if access to CT is unavailable, however this is not preferred.

2. If CT reconstructions are inadequate, a single lateral view X-ray is indicated.

ii. Rigid cervical collar is needed until cervical spine injury ruled out by diagnostic imaging.

CHAPTER V: DISCUSSION

To combat the over-use of radiographic imaging including CT and to promote safe clinical practice, several recommendations and guidelines have been developed to assist clinicians in determining whether imaging is necessary prior to clearance of cervical spine precautions. Previous studies have demonstrated a lack of awareness regarding guidelines such as the ACR Appropriateness Criteria (ACR-AC) and their limited use in clinical practice (Bautista et al., 2009; Puri et al., 2012; Sheikh et al., 2012). The goals of this study were to conduct a retrospective review of imaging studies obtained for suspected cervical spine injury and compare ordering practices with the ACR-AC, as well as conduct a survey of emergency physicians, nurse practitioners and physician assistants regarding their views about clinical guidelines and protocols for radiographic and clinical clearance of cervical spine injury, in order to propose an institutional protocol for cervical spine clearance. Analysis of 263 imaging studies over a three-month timeframe demonstrated that although the majority of included cervical spine imaging obtained for blunt trauma was consistent with the ACR recommendations, all of the 64 radiographic examinations obtained in that timeframe would not be considered appropriate, based on the ACR-AC. The survey of emergency clinicians revealed that none of those who responded have a preference for referring to the ACR appropriateness criteria when determining if imaging is necessary for patients with possible cervical spine injury. Additionally, the majority of respondents did not support the implementation of a hospital protocol for the management of patients with suspected cervical spine trauma.

Specific Aim 1

Cervical spine injuries are potentially devastating, physically and financially (Duane et al., 2007). Although clinical clearance carries a high sensitivity for ruling out a serious cervical spine injury, CT examination is the most sensitive study available for this purpose, which has contributed to it growing use in practice (Sheikh et al., 2012). Research has suggested that CT examinations have actually become over-utilized for the diagnosis and clearance of potential cervical spine injury (Griffith et al., 2011; Oguz et al., 2002). Both CCR and NEXUS criteria have demonstrated a high sensitivity for identifying patients at high risk for cervical spine injury, and research indicates that their use in clinical practice can help minimize unnecessary imaging (Daffner et al., 2012). The target hospital of this study, Northwest Medical Center (NWMC) does not currently have a protocol in place for potential cervical spine injury following blunt trauma, and there are no requirements regarding the use or documentation of clinical clearance guidelines for these patients. As a result, no objective data could be obtained regarding clinician adherence to clinical guidelines and the potential over-use of CT examination. Instead, the primary aim of the retrospective review portion of this study was to identify the frequency and imaging modalities used for suspected cervical spine injury, and compare these findings with ACR recommendations for imaging of these patients.

Imaging Frequency and Modality

Although the majority (75.6%) of the examinations obtained for suspected cervical spine injury were CT, consistent with ACR appropriateness criteria recommendations, nearly one-quarter (64/263) of all imaging studies were X-rays, and would not be considered appropriate. The ACR-AC provides a rating scale for the various imaging studies that may be ordered for the specific condition in question (Daffner et al., 2012). The scale includes three ratings: *usually not appropriate*, *may be appropriate* and *usually appropriate.* The criteria state that radiographs may be appropriate for patients with possible cervical spine trauma if they are obtained following an initial CT examination, when the CT reconstructions are suboptimal. In this circumstance, only a single lateral view is necessary (Daffner et al., 2012). In this retrospective review, no X-rays were obtained for this reason, and no lateral only view radiographs were obtained. The other circumstance where X-ray may be appropriate is if CT imaging is not possible, such as in an outpatient clinic or urgent care setting (Daffner et al., 2012). Access to CT and the ability to order CT imaging is available to all emergency clinicians at this studied facility. No documentation was identified within the imaging reports that would indicate a loss of access to CT, such as with technical malfunction or maintenance. When this information is taken into account, 100% of the cervical spine X-rays ordered for blunt trauma would not be considered appropriate, based on Variant 2 of the ACR appropriateness criteria for suspected cervical spine injury.

In their study, Sheikh et al. (2012) similarly found that 100% of the 433 X-ray exams obtained for blunt cervical spine trauma during a one year review at a level 1 trauma center would not be considered appropriate based on the ACR-AC. The authors found a slightly higher proportion of X-rays to CT in their study, with 32.7% (433/1325) of imaging studies being X-rays, and 67.3% being CT examinations (2012). By comparison, CT accounted for 75.6% (199/263) of all included cervical spine examinations reviewed in this study, whereas conventional radiographs accounted for 24.3% (64/263). Sheikh et al. (2012) also found a higher percentage of patients received both CT and X-ray in their study, with 6.4% (80/1245) of patients receiving both examinations, compared to 2.7% (7/257) of patients in this study at Northwest Medical Center. The percentage of identified cervical spine injuries among imaged patients in this study was similar to the findings of Sheikh et al., (2012) with approximately 3% (8/257) compared to 2.2% (28/1,245), respectively. These results are also comparable to the 2.4% incidence of fracture identified in the NEXUS study.

The results of data collection for the frequency and modality of imaging studies reveal that although the majority of imaging studies ordered for cervical spine trauma appeared to be consistent with the ACR-AC recommendations, nearly one-quarter of the performed imaging studies were not. X-ray continues to be ordered to evaluate for possible cervical spine injury following blunt trauma, despite significant data suggesting that CT is a superior examination to X-ray for this purpose (Daffner et al., 2012). For example, a meta-analysis by Holmes and Akinepalli (2005) found the sensitivity of CT to be 98%, compared to only 53% with X-ray (as cited in Daffner et al., 2012). In addition to lower sensitivity and therefore the increased possibility of a missed injury, the use of X-ray can result in unnecessary follow-up imaging due to false-positive results. In this study, there were a small percentage of patients (1.6%; 4/257) who received a traditional radiographic exam and subsequently required a CT examination for better evaluation. In all four circumstances, the follow-up CT ruled out a possible fracture. This further illustrates that CT would have been a more appropriate examination initially, or no imaging at all, if the patient was low-risk based on clinical examination.

Possible reasons clinicians continue to order conventional X-ray exams despite this evidence might include knowledge gaps, level of experience or years of experience, availability of imaging modalities, or other contributory clinical information. For example, clinicians with longer years of experience may be more familiar with older recommendations for cervical imaging in blunt trauma, while newer clinicians may be more familiar with the recent guidelines, as their training may have been based on them. Previously, a three-view series of radiographs including posteroanterior, lateral and odontoid views were recommended to allow for exclusion of a fracture radiographically (Graber & Kathol, 1999). This remained the recommended initial imaging modality for cervical spine injuries when both the CCR and NEXUS criteria were developed, largely due to low cost and better availability as compared to CT (Sheikh et al., 2012). It has only been within the past 10-15 years that CT has replaced X-ray as the imaging modality of choice, as a result of evidence demonstrating greater sensitivity of CT, and improved time efficiency (Daffner et al., 2012; Sheikh et al., 2012). Another possible reason for the continued use of X-ray might be the availability of radiography versus CT in certain situations such as emergency department saturation. This cannot be determined as a contributing factor for this study, as no data was collected regarding how imaging modality corresponded with the volume of total patient encounters or the overall quantity of imaging studies ordered.

Clinician decision-making may also be influenced by patient preferences and expectations. Within the clinician survey, one physician noted that patient expectations and complaints might influence the “over-ordering” of certain diagnostic testing. The implication is that imaging may be ordered to appease the patient’s desire for imaging to be done or to prevent a complaint, even if that patient is at low risk for injury based on the clinician’s examination.

Imaging Indication

In addition to the type and frequency of imaging study ordered, the indications for the imaging studies was also documented. Interestingly, the most commonly documented reason for exam after blunt trauma contained no indication of injury or trauma. Neck pain was documented as the reason for exam in 49.8% (131/263) of the included studies. The information provided in the clinical history provided the only indication that a blunt trauma had taken place. The most common reasons for examinations obtained for neck pain were falls and motor vehicle accidents, accounting for 53.4% and 39.7%, respectively. Falls accounted for 53% (141/263) of all imaging studies, when both order indication and clinical history were factored. Motor vehicle accidents remained the second most common cause of trauma, accounting for 29.7% (78/141) of all imaging studies.

Another interesting finding was that CT examination was performed more often than an X-ray for patients who suffered a fall, with 89.1% of these patients receiving a CT. Conversely, the number of CT studies versus X-rays was more equally distributed for patients involved in a motor vehicle accident, with 41 total CT examinations for MVA and 37 X-rays. The probable demographics of the corresponding patient populations might provide an explanation for this difference. For instance, although patient demographics including age were not obtained in data collection, individuals younger than 65 years of age account for the overwhelming majority of persons injured in motor vehicle accidents, with individuals aged 25-34 disproportionately affected (The Arizona Department of Transportation, 2017). Younger individuals may be seen as being lower risk for cervical spine injury than elderly patients, due to the increased prevalence of conditions such as osteoporosis among elderly populations. For example, postmenopausal women are at a significantly higher risk for fracture than their male counterparts or younger individuals, due to their increased risk for developing osteoporosis (Tella & Gallagher, 2014). Clinicians may also be less inclined to order CT imaging for younger patients due to the increased radiation emitted with such imaging, and the increased potential for future cancer development.

The characteristics of patients who present to the emergency department after a fall may contribute to their associated higher rate of CT imaging. It is possible that patients who received imaging after a fall were more likely to be elderly and/or women, and thus viewed as being at higher risk for serious injury such as fracture. Advanced age is an important risk factor for falls, and falls are the leading cause of injury in older American adults (World Health Organization, 2017). Future studies would benefit from the inclusion of demographic information in data collection. This would allow for a more thorough evaluation of ordering practices, including the type and frequency of imaging for various patient populations.

The goal of Specific Aim 1 was to provide an assessment of the scope of the problem within the target hospital. This goal was developed based on the first step of the action cycle of the KTA framework, the identification of knowledge-to-action gaps (Graham et al., 2006). This retrospective review demonstrated that despite clinical recommendations supported by research knowledge, there continues to be a gap in the application of these recommendations to practice among emergency clinicians, as it relates to imaging modality for suspected cervical spine injury.

Specific Aim 2

For guidelines to be successfully implemented as an evidence-based protocol, they must be accepted and adhered to by end-users (Gagliardi et al., 2011). An important aspect of promoting acceptance and successful implementation is the involvement of key stakeholders in the development process (IOM, 2011). This would include input from key stakeholders during the needs assessment, as well as for an assessment of the potential and actual barriers to implementation (Graham et al., 2006). Potential barriers might include provider resistance to the change, lack of familiarity with the evidence or guidelines, lack of applicability to clinical context or practicality (Graham et al., 2006). The purpose of the second aim of this project was to use a web-based survey of emergency department providers to assess potential barriers to the implementation of an evidence-based protocol for the management of cervical spine injury.

The questionnaire was sent to all 50 clinicians contracted with the NWMC emergency department, including 37 physicians and 13 nurse practitioners or physician assistants. A response rate of 14% (7/50) was obtained. This was lower than what was hoped for. Although a response rate of at least 50% is typically desired for most survey research (Draugalis, Coons, & Plaza, 2008), response rates for email surveys may only reach 25% to 30%, particularly without reminders or follow-up emails (Fincham, 2008). As a result of the low response rate, the reliability of quantitative data such as the reported use of clinical guidelines among clinicians may be somewhat limited. Qualitative data such as the free-text comments is still useful for informing the potential barriers and facilitating factors to implementation of a protocol.

Of the clinicians who responded to the survey, 57.1% (4/7) were physicians, one was a nurse practitioner, and 28.6% (2/7) were physician assistants. All of the participants indicated they refer to a clinical guideline to assist them in determining if imaging is appropriate or necessary for patients with suspected cervical spine trauma, however none indicated a preference for the ACR-AC as a clinical guideline or reference, instead selecting the NEXUS (4/7) or the CCR (3/7). Although both guidelines provide guidance for clinical clearance, neither provides a recommendation regarding imaging modality. The preference of NEXUS or CCR over ACR-AC among the survey participants may provide further explanation for the continued use of X-ray for possible cervical spine trauma. When both of these guidelines were developed, three-view X-ray was the diagnostic study of choice for possible cervical spine injury, and as previously mentioned, it has only been in recent years that CT has surpassed X-ray as the imaging modality of choice for this indication. Clinicians may not be aware of the current recommendations for CT over X-ray, or may not be well versed with the specific variants of the ACR-AC for possible cervical spine injury.

Given the wide acceptance of the ACR-AC among multiple medical specialty organizations and government entities including the Centers for Medicare & Medicaid Services (Farley, 2016), it is somewhat surprising that none of the respondents prefer the ACR-AC. These results are consistent, however, with a study by Bautista et al., who also used a survey method to evaluate clinicians' use of the ACR-AC versus other clinical decision resources (2009). The authors found that only 1.5% (2/126) physicians used the ACR-AC as their first choice resource, and only one used the ACR-AC as their second choice resource. The study also suggested a general lack of awareness of the ACR-AC among providers (Bautista et al., 2009). In examining the survey responses for Specific Aim 2, it is difficult to determine awareness versus preference among the clinicians. In retrospect, the survey should have included separate questions regarding familiarity and clinical application of the three individual clinical guidelines. The format of the questions made it difficult to determine whether the clinicians were familiar with the ACR-AC and just had a preference for the others, or if they were entirely unfamiliar with the ACR-AC.

The majority of respondents (71.43%; 5/7) disagreed that CT is over utilized in the workup of patients with suspected cervical spine injury, and two respondents agreed that CT is over utilized. Most respondents (6/7) indicated agreement that the possibility of a missed fracture often leads to the use of CT for patients with possible cervical spine trauma. It is understandable that clinicians would be inclined to order diagnostic imaging to avoid the risk of a missed diagnosis. A missed cervical spine injury could have potentially devastating consequences for the patient, clinician and facility (Griffith et al., 2014). From a cost-effectiveness standpoint, the potential financial loss associated with a missed diagnosis of cervical injury is substantial, particularly when compared to the cost associated with a potentially unnecessarily used resource such as radiography or CT (Duane et al., 2007).

Five of the seven participants responded to the question of whether they would support the implementation of an evidence-based hospital protocol for management of suspected cervical spine trauma. All five respondents appeared to have generally unfavorable views regarding this. Two participants referenced other factors that may influence ordering practices despite the presence of a protocol, including clinical factors and patient expectations. Another participant indicated a preference for the application of NEXUS criteria and “clinical gestalt.” Clinical gestalt is the theory that even in the absence of a complete picture, practitioners can make clinical decisions based on pattern recognition and generalizations developed through clinical experience (Cook, 2009). The benefit of this type of decision-making is that is allows for an efficient interpretation of the data, which can be particularly valuable in settings such as emergency medicine. The drawback in this form of decision-making is the potential for the clinician to make one of the errors inherent to it, such as overconfidence in decision-making, confirmatory bias, or illusory correlation. Clinical decision tools, guidelines, and protocols are all methods of predictive modeling, which can help to marginalize decision-making errors that can occur during diagnosis or intervention (Cook, 2009). As indicated by the survey respondent's stated preference for incorporating NEXUS criteria with clinical gestalt, clinical guidelines and gestalt are not mutually exclusive. An institutional protocol that incorporates evidence-based guidelines while allowing the clinician to still rely on their own clinical reasoning may be better received by the end-users, and might improve the likelihood of adoption. Furthermore, by allowing the patient's individual circumstance to be taken into account, the determined treatment can be individualized and patient-centered.

The results of the clinician survey are beneficial in providing a basic idea of provider preferences, however the low response rate might limit the reliability and validity of the results. One possible reason for the low response includes an uninterested sample group. The clinicians emailed may not have had an interest in completing the survey. Although measures were taken to promote participation including reminder surveys, brevity of the survey, and a user-friendly survey platform, there was no incentive offered for completion. In the future, participation could be encouraged through the inclusion of an incentive such as a raffle entry for a gift card.

The low response rate could also indicate a nonresponse bias, which occurs when respondents to the survey differ from non-respondents in a way that could influence the results (Draugalis, Coons, & Plaza, 2008). These potential differences could limit the representativeness of the responding sample to that of the overall target population. In the case of this clinician survey, some clinicians may not feel comfortable responding to questionnaires regarding their clinical decision-making and preferences. It is also possible that those who responded to the survey are more familiar with clinical clearance for cervical spine injury and are therefore more inclined to participate in a survey related to the topic. As an example, 100% of the respondents indicated that they refer to a clinical guideline to assist with clinical clearance of patients with suspected cervical spine injury. This percentage may not be reflective of the entire target population of emergency department clinicians; it may be that those who responded were more familiar with the guidelines, more likely to refer to them, and therefore more comfortable participating in the survey.

One method for potentially reducing nonresponse bias for surveys is pretesting to identify potential issues with the survey method, questions, or instructions (Draugalis et al., 2008). The survey for Specific Aim 2 was not pretested with a focus group prior to implementation. In the future, pretesting could help identify problems and improve the quality and reliability of the questionnaire to hopefully produce a better response rate (Draugalis et al., 2008).

Specific Aim 3

The overall goal of this project was to use the information gained from Specific Aim 1 and 2 to develop a best-practice, evidence-based protocol based on ACR-AC for the management of patients with suspected cervical spine injury that could be implemented in the emergency department of the studied hospital facility. The intention of this goal is to ultimately reduce unnecessary imaging and therefore radiation exposure to patients. Research indicates that educational support and interventions can help increase clinician knowledge regarding radiation risk and imaging appropriateness (Kruger et al., 2012; Puri et al., 2012). Furthermore, the development and implementation of evidence-based protocol for the management of patients with suspected cervical spine trauma may help promote more appropriate clinical use of radiologic imaging for cervical spine clearance, thereby reducing unnecessary radiation exposure as well as health care expenditures (Sheikh et al., 2012).

The specific aims of this study were selected and developed based on the first three steps of the Knowledge-to-Action framework. These steps include a needs assessment, the involvement of stakeholders, and adaptation of the knowledge to the local context, and an assessment of barriers and facilitators (Field et al., 2014). The findings of Specific Aim 1 and 2 present the needs assessment, barrier assessment, and involvement of involved stakeholders. This information is used to inform Specific Aim 3, the adaptation of the ACR-AC to the local context. The results of Specific Aim 1 illustrate that despite research evidence indicating that CT is the most appropriate imaging modality for suspected cervical spine trauma, nearly 25% of patients who presented to the studied facility received conventional X-ray as the sole or initial imaging modality. Furthermore, the results of Specific Aim 1 indicate that ordering practices regarding imaging modality may be influenced by the patient's clinical history, with patients suffering a fall being more likely to receive a CT than a conventional X-ray. These findings demonstrate possible areas for quality improvement through the implementation of a facility evidence-based protocol adapted from the ACR-AC. These findings could also be used to for comparison with data obtained after intervention of such a protocol, to determine its potential effects on imaging utilization.

The results of Specific Aim 2 further demonstrate a possible knowledge or practice gap among ED providers regarding the ACR Appropriateness Criteria for suspected cervical spine injury. The results of Specific Aim 2 also suggest that implementation of a hospital protocol for the management of patients with suspected cervical spine injury may be met with some resistance from the providers. Specific provider criticisms of an institutional protocol included the need for variation from the protocol based on individual patient circumstances, such as patient preferences or clinical characteristics, as well as the belief that clinicians already use clinical decision tools appropriately. Several strategies may be used to mitigate this resistance. For example, education of all emergency providers regarding ionizing radiation, radiation dose associated with the various imaging modalities, and the evidence indicating potential overuse of CT may help to promote clinician buy-in with the concept that there are areas for improvement with how imaging studies are chosen and ordered. Additionally, provider education regarding the current state of the research evidence as well as current recommended guidelines including the NEXUS criteria, the CCR, and the ACR-AC may improve their understanding and use of such guidelines in practice. This has been successfully demonstrated in some clinical settings already. For instance, Griffith et al. found that the overutilization of imaging decreased from 16.1% to 13% following the implementation of an education program reviewing the ACR-AC for suspected cervical spine injury (2014).

Allowing for some flexibility in decision-making within the protocol may also lessen provider resistance. Any proposed protocol should provide support to clinician decision-making by presenting clinical recommendations that are based on the best available evidence, but should also allow for variation and clinical judgment for each individual patient. As stated in the Institute of Medicine's report, 'Clinical Practice Guidelines We Can Trust'

> '*Rather than dictating a one-size-fits-all approach to patient care, clinical practice guidelines are able to enhance clinician and patient decision-making by clearly describing and appraising the scientific evidence and reasoning behind clinical recommendations, making them relevant to the individual patient encounter*' (2011).

Hopefully, the development of a protocol that still allows for clinical gestalt and variation will facilitate clinician support for implementation within the hospital facility. One way to allow for variation and individual decision-making is to avoid mandatory changes to provider workflow and documentation. For instance, a study by Blackmore et al. found that implementation of a computerized clinical decision support tool helped decrease unnecessary imaging (as cited in Sheikh et al., 2012). This tool required clinicians to indicate a utilized clinical clearance support tool when ordering any cervical spine imaging (Sheikh et al., 2012). Given the potential interruptions to regular workflow for clinicians as well as the potential for perceived limitations to their own decision-making, this type of tool would likely be met with increased resistance among providers, and will not be used.

Another method for overcoming the barrier of provider resistance is to limit drastic changes to workflow. One of the benefits of the ACR-AC is that it incorporates the CCR and NEXUS criteria; two well known and widely accepted clinical clearance guidelines (Daffner et al., 2012). Although none of the physicians who responded to the survey indicated a preference for the ACR-AC, all seven indicated that they refer to either the CCR or NEXUS criteria for evaluation and clearance of patients with potential cervical spine injury. The introduction of a protocol based on the ACR-AC that allows the clinician to continue using the clearance recommendation of their choice may help improve buy-in. This should also improve the ease of use for clinicians, as the only real change would be the inclusion of specific imaging recommendations.

Prior to implementation of the protocol, further involvement of key stakeholders would take place. Hospital administration and other clinical staff including nursing staff, radiologists, neurosurgeons and orthopedic spine surgeons would be invited to participate in interdisciplinary meetings or an open forum to discuss the proposed protocol, and related topics. This may include such topics as radiation risks and exposure, use of diagnostic imaging, diagnosis and treatment of cervical spine injuries, budgetary concerns, as well as any other topics viewed pertinent or necessary by the stakeholders. Involvement of the various stakeholders in the process would allow for adaptation of the protocol to the local needs, and would also facilitate planning for implementation of the protocol.

The proposed protocol would include a clinician education program as well as a hospital algorithm that provides recommendations for patients presenting to the emergency department with possible cervical spine injury after blunt trauma. The educational program would consist of an in-service that would discuss trends in CT use and overuse, the current state of research evidence related to clinical clearance of potential cervical spine injury, and the ACR-AC. This would also include a discussion of the clinical clearance tools incorporated within the ACR, the NEXUS criteria and CCR. Review of these clinical clearance tools would address potential knowledge gaps regarding clearance of cervical spine injury based on clinical criteria, hopefully facilitating the reduction of unnecessary imaging for cervical spine injury. Discussion of the clinical clearance criteria within the context of the ACR-AC would provide further education regarding the appropriate imaging modalities for patients who are do not fulfill low-risk criteria, and therefore require diagnostic imaging.

Future Directions

The overall goal of this study was to propose a best-practice protocol for the management of potential cervical spine injury, in an effort to reduce unnecessary diagnostic imaging and associated ionizing radiation exposure to patients. The Knowledge-to-Action framework provided the underlying basis for this project. The specific aims of the project were grounded in the first three steps of the framework including the identification of knowledge or practice gaps, the adaptation of knowledge to a local context, and a barrier assessment. The remaining steps of the KTA framework including planning and execution of the intervention, monitoring the use of the intervention, evaluation of outcomes, and sustainability were outside the scope of this study and were therefore not addressed. Future research in this area may include the development of an implementation plan for such a protocol, including the subsequent evaluation and sustainability steps.

Further examination of the scope of the problem might include an assessment of the economic impact of various imaging modalities and ordering practices. A cost assessment that includes direct, indirect, and contingent costs would provide further information about the potential economic benefits or risks of an institutional protocol. This may also help to promote buy-in for the implementation of a protocol among stakeholders such as hospital administration and providers.

Additionally, future research may include a greater scope of evaluation for the needs assessment. For instance, data collection only included the main campus of the target hospital, and did not include associated secondary facilities including one freestanding rural emergency department and a rural hospital emergency department. These facilities share an administrative connection with the target hospital of this study, and imaging data for both facilities is accessible through the same PACS network. In addition, the surveyed emergency providers are contracted and serve all three facilities. Further research might include data from all three facilities to provide a more complete picture, including variances between the urban and rural facilities.

One of the major limitations of this study was the inability of the retrospective design to include an objective assessment of providers' use of clinical clearance criteria prior to their ordering of cervical spine imaging. It was therefore not possible to determine whether the CT examinations ordered would be considered appropriate, based on the ACR-AC. The assumption was made that all patients who received a cervical spine CT for trauma were considered at high risk for injury, and therefore required imaging. Documentation of whether a clinical clearance criteria was used to assist with imaging orders would be helpful for future research, as it would provide somewhat of an objective measurement of this information. Mandatory documentation of this information would not likely be well received by providers, however, as it could affect workflow and possibly give the impression of undermining clinician's decision-making. Despite possible resistance, this type of documentation is likely to become a mandatory requirement for the treatment of Medicare patients presenting to the emergency department. Under the Protecting Access to Medicare Act (PAMA), consultation of appropriate use criteria developed by a "qualified Provider-Led Entity" (qPLE) for advanced diagnostic imaging will soon be required by CMS, and must be documented in order for rendering provider to be reimbursed (American College of Radiology, 2017b). Although this is most applicable in outpatient settings and some examinations ordered in the emergency department will be exempt, this will only include emergent conditions defined under EMTALA. As a result, many conditions and imaging tests ordered in emergency department settings will not be exempt from this requirement, and emergency clinicians may be required to document reference to appropriate use criteria for advanced imaging as soon as January 1, 2018 (ACR, 2017b). The ACR-AC have been accepted as qPLE a by CMS, meaning clinicians can fulfill reimbursement conditions by consulting the ACR-AC prior to ordering advanced diagnostic imaging such as CT (Farley, 2016). Provider education regarding the conditions covered within ACR-AC would be beneficial not only for the potential reduction in unnecessary imaging and associated radiation, but would also be prudent in anticipation of future reimbursement requirements.

DNP Essentials

The American Association of Colleges of Nursing developed the 'Essentials of Doctoral Education for Advanced Nursing Practice' to articulate the necessary competencies for nurse practitioners practicing at the doctorial level (AACN, 2006). The 'DNP Essentials' indicate that doctoral education is distinguished by the completion of a research project that provides demonstration of a synthesis of doctoral work and knowledge, as well as proficiency in the use of research evidence to work toward the improvement of clinical practice or patient outcomes (AACN, 2006).

This study demonstrates synthesis of the knowledge and foundational competencies gained from the doctoral program through the development and presentation of an institutional protocol for the management of patients with suspected cervical spine injury. The AACN 'DNP Essential I: Scientific Underpinnings for Practice' indicates that the DNP graduate should possess the ability to translate research knowledge to practice, and should be prepared to develop new practice approaches based on research knowledge and theories (AACN, 2006). This competency was demonstrated within this research paper through the development and presentation of the clinical protocol based on research evidence and existing practice guidelines.

'DNP Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice' addresses the integration of knowledge from various sources and disciplines, as well as the application of such knowledge to improve patient care and outcomes (AACN, 2006). A review of the literature provided the scientific foundation for this study, and the research evidence was then contextualized using the data collected from a retrospective chart review and clinician survey. This information was used to accomplish underlying goal of translating evidence-based guidelines for the management of suspected cervical spine injury to an institutional protocol, in order to improve clinical practice and patient outcomes. This also demonstrates competency with ‘DNP Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking’ as well as ‘Essential V: Health Care Policy for Advocacy in Health Care.’ Essential II indicates that the DNP should be prepared to lead quality improvement and patient safety initiatives, working with interdisciplinary teams and adapting to a variety of organizational situations. Consistent with Essential V, the DNP should also be prepared to participate and lead in the process of policy development to address various needs in health care. Although policy change often takes place at the governmental level, it may also occur at the institutional level (AACN, 2006). As outlined in this study, the development of an institutional clinical practice protocol is one method of advocating for policy change at the institutional level.

Finally, as outlined in ‘Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes,’ the delivery of healthcare is dependent on the contributions of professionals from various healthcare disciplines, and the delivery of high-quality healthcare is dependent upon their effective collaboration with one another (AACN, 2006). The DNP should therefore be prepared to effectively collaborate with other healthcare professionals, occasionally providing leadership of the multidisciplinary team when needed. As demonstrated by this research project, collaboration may take the form of initiating policy or practice changes, identifying and presenting areas for practice improvement, and the development of institutional protocols to assist healthcare providers in delivering quality care (AACN, 2006).

Conclusions

This study has identified the use of diagnostic imaging for the clearance of cervical spine injury as an area amenable to quality improvement. A review of the literature provided evidence that CT imaging if often over utilized in practice, posing potentially significant risks to long-term health, and producing greater economic burden to health care. A retrospective review of imaging studies performed over a three-month timeframe in a local hospital demonstrated that a minority of imaging studies ordered for possible cervical spine injury following blunt trauma are not consistent with the most current research evidence and the American College of Radiology clinical guidelines. A survey of emergency clinicians was consistent with these findings, specifically indicating that the participants did not indicate a preference for the ACR guidelines. This survey, although limited in the response rate, provided information regarding potential barriers to the development of a. With the information gained from the retrospective review and clinician survey, a best-practice protocol for the management of patients with suspected cervical spine injury has been presented.

APPENDIX A:

CLINICIAN SURVEY

Clinical Clearance of Suspected Cervical Spine Trauma

1. For patients presenting with suspected cervical spine trauma, are you familiar with clinical clearance guidelines such as the Canadian C-Spine Rule, NEXUS criteria, or the American College of Radiology (ACR) Appropriateness Criteria?

- ◯ Yes
- ◯ No

2. For patients presenting with suspected cervical spine trauma, do you refer to a clinical guideline to assist with determining whether imaging is appropriate or necessary?

- ◯ Yes
- ◯ No

3. If you answered 'yes' to question 2, which guideline do you prefer, or refer to most often?

- ◯ Canadian C-spine rule
- ◯ NEXUS criteria
- ◯ ACR Appropriateness criteria

Clinician Survey. Image of the clinician survey as portrayed on SurveyMonkey website. This was accessible by participants via hyperlink.

4. Please indicate your agreement or disagreement with the following statements.

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly Agree
CT is over-utilized in the workup of patients with suspected cervical spine trauma.	◯	◯	◯	◯	◯
CT is generally appropriately utilized in the workup of patients with suspected cervical spine trauma	◯	◯	◯	◯	◯
The possibility of a missed fracture often leads to the use of CT for patients with possible cervical spine trauma.	◯	◯	◯	◯	◯
If a patient is low-risk for cervical spine injury, based on clinical criteria, I may still consider a CT to avoid missing a fracture.	◯	◯	◯	◯	◯

5. Would you support the implementation of an evidence-based hospital protocol for management of suspected cervical spine trauma? Why or why not?

6. Please indicate which of the following best applies to you.

◯ MD

◯ Nurse Practitioner

◯ Physician Assistant

◯ Other

Clinician Survey - *Continued*. Continuation of the clinician survey as portrayed on SurveyMonkey website. This was accessible by participants via hyperlink.

APPENDIX B:

CLINICIAN SURVEY EMAILS

Subject: Survey of clinicians regarding cervical spine injury

Hello,

I am currently enrolled in the College of Nursing at the University of Arizona, and am in the process of writing my doctoral research paper. The research study is entitled *A Proposal for a Best-Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury*.

As part of this research project, I am looking at clinical and radiographic clearance of cervical spine trauma in the emergency department. Part of this research includes a brief survey of clinician's preferences and practices regarding clinical clearance of potential cervical spine injury.

I am writing you to request your participation in this survey. The survey is very brief and will only take 5 minutes to complete. Participation is voluntary. You may decline altogether or leave blank any questions you do not wish to answer. All answers are anonymous, and the results of the survey will only be published within the doctoral research paper.

If you are willing to complete the survey, please click the link below, which will take you to the Survey Monkey website. The survey will be accessible for a period of three weeks, and an email reminder of the survey will be sent out in 1 week.

https://www.surveymonkey.com/r/9TQHN8T

If you have any questions regarding this project, please feel free to contact Kasey Cross at the email address below. Thank you for your time, and for your assistance in the completion of this research project.

Sincerely yours,

Kasey Cross, MSN, ACNP-BC
DNP student, the University of Arizona
kpinson@email.arizona.edu

Reminder Email:

Subject: Reminder of Survey of clinicians regarding cervical spine injury

Hello,

This is a friendly reminder that you are invited to participate in a research study entitled *A Proposal for a Best-Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury*.

As a reminder, I am currently enrolled in the College of Nursing at the University of Arizona, and am in the process of writing my doctoral research paper. I am looking at clinical and radiographic clearance of cervical spine trauma in the emergency department. Part of this research includes a brief survey of clinician's preferences and practices regarding clinical clearance of potential cervical spine injury.

The survey is very brief and will only take 5 minutes to complete. Participation is voluntary. You may decline altogether or leave blank any questions you do not wish to answer. All answers are anonymous, and the results of the survey will only be published within the doctoral research paper.

Please follow the link below if you are willing to complete the survey. Thank you again for your time, and for your assistance in the completion of this research project.

https://www.surveymonkey.com/r/9TQHN8T

Sincerely yours,

Kasey Cross, MSN, ACNP-BC
DNP student, the University of Arizona
kpinson@email.arizona.edu

APPENDIX C:

IRB APPROVALS

NORTHWEST MEDICAL CENTER

June 19, 2017

Kasey D. Cross, ANPC
5860 N. La Cholla Blvd. #100
Tucson, Arizona 85741-3537

Dr. Ms. Cross:

Thank you for submitting the HIPAA Authorization as requested for the study, "A Proposal for a Best Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury". I have been authorized to approve the study on behalf of the IRB. The verification of the modifications has been confirmed. This letter is to inform you that you are now being provided with final IRB approval and you may implement this study.

Please contact me at 469-8553 if you have questions or concerns. The IRB looks forward to progress reports of the research findings. Thank you for your interest and commitment to the research process.

Sincerely,

Jan Kern

Jan Kern
IRB Chairman

DATE: 6-19-17 EXPIRES: 3-21-18
APPROVED BY:
NORTHWEST MEDICAL CENTER IRB
THIS STAMP MUST APPEAR ON ALL DOCUMENTS USED TO CONSENT PATIENTS

Northwest Medical Center – Tucson, AZ

APPLICATION FOR WAIVER OF HIPAA AUTHORIZATION

[This form is to be used in conjunction with the Application for IRB Review]

Title of Study: A PROPOSAL FOR A BEST-PRACTICE PROTOCOL FOR THE MANAGEMENT OF PATIENTS WITH SUSPECTED CERVICAL SPINE INJURY

The HIPAA Privacy Standard requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information (PHI, i.e., individually identifiable health information held by a health care provider or health plan covered by HIPAA). Northwest Medical Center's (NMC) Notice of Privacy Practices notes that PHI may be used for research purposes. This study requires a Health Insurance Portability and Accountability Act (HIPPA) waiver from the IRB, since it will evaluate the data of already ongoing interventions to improve NMC standard of care.

This request is for:

☒ **TOTAL WAIVER**
When you request a total waiver of the HIPAA Authorization, you are requesting permission to access, use or disclose a research subject's PHI for your research study without seeking the subject specific authorization for that use or disclosure.

☐ **PARTIAL WAIVER**
When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study. [For instance, you may request a waiver for subject identification or recruitment purposes but not for enrollment purposes. For example, you may request a waiver of the HIPAA authorization requirement so that a treating physician may obtain verbal permission from the patient/parent so that the physician can notify the study coordinator of the patient's/parent's interest in the study. Once the study coordinator has discussed the study with the interested patient and parent, they will consent the participant and parent and obtain a full authorization.]

---

1. Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on the presence of the following:
   a. An adequate plan to protect the identifiers from improper use and disclosure.
   b. An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
   c. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

☒ **YES** ☐ **NO**

2. Describe the plan to protect the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure?

> For every cervical spine CT or XR ordered on any given day, the patient's facility identification number will be noted by the primary investigator, in order to keep track of multiple studies ordered for single patients. Facility identification numbers will only be identified by the primary investigator during the collection of data and will not be saved or otherwise published. In order to encrypt PHI and protect privacy, each patient will be assigned a unique nominal identification number, which will be documented on an electronic spreadsheet. This electronic spreadsheet will be saved on a password-protected computer in order to ensure confidentiality. No other PHI will be collected or documented

3. Describe the plan to destroy identifiers at the earliest opportunity, or provide justification for retaining the identifiers?

> Patient identifiers, to only include facility identification numbers, will be eliminated during the data collection process. Once all relevant imaging studies have been identified for a specific FIN, the FIN will then be assigned a separate and unique identification number for the study, and the FIN will be eliminated. Identifiers will only be retained for as long as the data is being collected.

DATE: 6-19-17 EXPIRES: 3-21-18

APPROVED BY:
NORTHWEST MEDICAL CENTER IRB

THIS STAMP MUST APPEAR ON ALL DOCUMENTS USED TO CONSENT PATIENTS

4. Will a waiver adversely affect the privacy rights of the individual?
☐ YES ☒ NO

5. Could the research practicably be done without access to, use or disclosure of the PHI identified below?

☐ YES ☒ NO

Please identify the PHI that will be used under this waiver request.

Patient facility identification number, the type of cervical spine imaging study ordered for each hospital encounter, including the specific imaging study and the ordinal number for each cervical spine study ordered for a specific patient.

6. Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the individuals? *(Please describe your risk/benefit analysis relating to the waiver request below.)*

☒ YES ☐ NO

The information provided will help determine whether current ordering practices are consistent with ACR appropriateness criteria. This information will be used as an assessment to inform the development of an evidence-based protocol for the management of patients with suspected spine injury that could feasibly be implemented in the emergency department of a local hospital. This is to be done for academic purposes, and for the completion of a doctoral research study by the primary investigator. Patients will continue to receive that standard medical care at Northwest Medical Center with no expected interference or harm from this study.

7. Will the Principal Investigator be the only member for the research team who will access, use or disclose PHI?

☒ YES ☐ NO

If no, please name all of the individuals who will have access to PHI during the research study, including students.

Name	Job Description/Role on Study
	.

INVESTIGATORS AGREEMENT:
As Principal Investigator of this study, I assure that the following statements are true:

The information that is provided in this form is true and accurate. I will seek and obtain prior written approval from the IRB for any substantive modifications to the proposal, including but not limited to, changes in procedures and co-investigators.

I will report in writing any significant new findings tha t develop during the course of this study that may affect the risks and benefits to the individuals whose PHI is being obtained.

I will not begin my research, including subject identification or recruitment, until I have received written notification of IRB. I will comply with all IRB requests to report on the status of the study.

I will not reuse or disclose any PHI to any other person or entity other than the study investigators, except as required by law, for the authorized oversight of research or for other permitted research.

I will conduct the research in compliance with all applicable federal and state laws and regulations.

Kasey C. (signature) 5/31/2017

Signature of Principal Investigator Date

Research
Office for Research & Discovery

Human Subjects
Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	September 12, 2017
Principal Investigator:	Kasey D Cross
Protocol Number:	1708746174
Protocol Title:	A PROPOSAL FOR A BEST-PRACTICE PROTOCOL FOR THE MANAGEMENT OF PATIENTS WITH SUSPECTED CERVICAL SPINE INJURY
Level of Review:	Administrative Review
Determination:	Approved
IRB of Record:	NWMC

Documents Reviewed Concurrently:

Data Collection Tools: *Clinician survey questions NWMC IRB.pdf*
Data Collection Tools: *Data Abstraction.xlsx*
Data Collection Tools: *Survey.docx*
HSPP Forms/Correspondence: *F107 Verification of training.doc*
HSPP Forms/Correspondence: *NWMC.PDF*
HSPP Forms/Correspondence: *Signature page.pdf*
HSPP Forms/Correspondence: *U of A IRB ceded review.doc*
Other: *NWMC IRB utilization form.doc*
Other Approvals and Authorizations: *Agreement for hospital research services.pdf*
Other Approvals and Authorizations: *Application for Waiver of HIPAA Authorization.docx*
Protocol: *IRB abstract for CROSS_KASEY.docx*
Protocol: *NWMC IRB study form 1.docx*
Recruitment Material: *Survey Email.docx*
Regulatory Documentation: *NWMC IRB Approval Letter.pdf*

Institution Designated the IRB of Record: When an institution is the designated IRB of record, the UA IRB will not review the project. The University of Arizona agrees that it will rely on the review, approval, and continuing oversight by the institution IRB of those protocols approved by the institution pursuant to the terms of the Institutional Review Board Authorization Agreement (if applicable) and as outlined in the HSPP files.

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).
- All documents referenced in this submission have been reviewed and are filed with the HSPP.
- The Principal Investigator should notify the IRB immediately:
  - Any proposed changes that affect the LOCAL protocol.
  - Reports any LOCAL unanticipated problems involving risks to participants or others.
  - Continuing Review by the IRB of record has been completed.
  - When the study is complete at the LOCAL site.
- Please refer to the Guidance Ceded IRB Review for more information on local PI responsibilities. All research procedures should be conducted according to the approved protocol and the policies and guidance of the IRB of record.

This project has been reviewed and approved by an IRB Chair or designee.

NORTHWEST MEDICAL CENTER

October 18, 2017

Kasey D. Cross, ANPC
5860 N. La Cholla Blvd. #100
Tucson, Arizona 85741-3537

Dr. Ms. Cross:

Thank you for submitting your clarification that you want to collect fracture versus no fracture information for the study, "A Proposal for a Best Practice Protocol for the Management of Patients with Suspected Cervical Spine Injury". I have provided expedited approval of this request at this time and will take for full IRB approval at their next meeting.

Approval is granted with the understanding that no modifications will be made to the procedures or consent form without knowledge and approval of the IRB.

Please contact me at 469-8553 if you have questions or concerns. The IRB looks forward to progress reports of the research findings. Thank you for your interest and commitment to the research process.

Sincerely,

Jan Kern

Jan Kern
IRB Chairman

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