Early Identification of Sepsis in Adults in Primary Care: A Pilot Project

By

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Abstract

Problem: Sepsis is a nocuous host response to infection that leads to organ dysfunction and hypotensive shock. Now deemed a public health burden, sepsis is predicted to increase as the population in the United States ages. Recent research conducted by the Centers for Disease Control and Prevention concluded that 80 percent of sepsis begins outside of the hospital setting and that seven out of every ten patients diagnosed with sepsis recently used healthcare services. Because early identification helps to decrease mortality, it is imperative that family practice providers increase their awareness and recognition of sepsis so that treatment may be expedited. The problem is that primary care providers often lack knowledge and competence in recognizing the signs and symptoms of sepsis as well as the clinical judgment necessary to detect sepsis in its early stages. Clinical comprehension of sepsis has improved using simulation, a teaching modality with a long history in medical education.

Purpose: The purpose of this project was to compare the knowledge and competence of primary care practitioners in the early recognition of sepsis using either high-fidelity simulation (HFS) or computer-based learning (CBL) with Kolb's Learning Theory as the framework. Simulation has been shown to increase critical thinking and self-confidence through re-creation and reflection in a safe environment.

Method: Family nurse practitioners (FNP) and advanced FNP students (FNPS) in the greater Kansas City area were recruited and randomly placed into CBL or HFS groups for this quasi-experimental design that included a clinical scenario, a 10-question pretest/posttest and a competence scale.

Conclusion: Although this pilot lacked statistical significance, the results may be of use to inform future studies or other advanced simulation experiences.

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Sepsis is a nocuous host response to infection that leads to organ dysfunction and hypotensive shock (Dellinger et al., 2013; Li et al., 2012; Rhodes et al., 2016). Unfortunately, there is no biomarker or diagnostic test to confirm sepsis and no anti-sepsis treatment (Cohen et al., 2015; Epstein, Dantes, Magill & Fiore, 2016). Therefore, management relies on early recognition, which has been shown to decrease mortality (Baker, 2016; Blackburn, Harkless, & Garvey, 2014; Cohen et al., 2015; Delaney, Friedman, Dolansky, & Fitzpatrick, 2015; Dellinger et al., 2012; Hansel et al., 2012; Li et al., 2012; Rhodes et al., 2016; Singer et al., 2016). Accordingly, family practice providers need to increase their awareness and recognition of sepsis in the primary care environment (Baker, 2016). The purpose of this paper is to present a project to aid in the early identification of sepsis in the primary care environment. This includes a literature synthesis on the use of simulation in sepsis. This project serves to supplement existing literature and add to evidence-based practice in this area.

Background

Although sepsis is a modern term to many of us, Hippocrates is credited with the first use of the word. It originates from the Greek term “sipsi” meaning to make rotten (German Sepsis Society, n.d.). Sepsis is not new; we have just put a name to it. In 1989 a physician named Roger Bone defined the term “sepsis syndrome” to describe the body’s systemic response to infection (Bone et al., 1989). His hope was that the definition would expedite the detection and treatment of sepsis (Bone et al., 1989). Over the years, experts in critical care have debated the definitions of sepsis, severe sepsis, and septic shock, and continue to work to find an agreeable approach in order to accurately screen for, diagnose, and manage this disease (Angus & van der Poll, 2013; Bone et al., 1992; Marshall, 1997; Rhodes et al., 2016; Singer et al., 2016). Although the patient populations in the various guidelines are characterized differently, The Surviving

Sepsis Campaign (Rhodes et al, 2016) and the Sepsis Definition Task Force (Singer et al., 2016) agree that sepsis is a dysfunctional host response to infection that leads to life-threatening organ dysfunction. Inconveniently, most of the published studies and guidelines are directed at recognition and management of sepsis in the acute care environment.

Significance

There is no standard approach to diagnosing sepsis, making the incidence difficult to estimate (Tsertsvadze et al., 2016). Regardless, mortality is as high as 50 percent once hypotensive shock commences (Cohen et al., 2015). Despite collaborative inpatient methodologies including protocols, bundles and algorithms (Angelelli, 2016), the cost and incidence of sepsis has risen and is predicted to increase as the U.S. population ages (American Association of Critical Care Nurses [AACN], 2012; Baker, 2016; Hansel et al., 2012; Shen et al., 2017; Tsertsvadze et al., 2016). The cost of treating sepsis has increased to over $20 billion annually, and this is considered to be an underestimation (Angelelli, 2016; Singer et al., 2016). Torio and Moore (2016) reported septicemia as the single most expensive condition treated in United States hospitals. Septicemia also led the list for the most expensive condition billed to Medicaid and was the second-most expensive condition billed to Medicare (Torio & Moore, 2016).

Problem Statement

Recent research conducted by the Centers for Disease Control and Prevention (CDC) concluded that 80 percent of sepsis begins outside of the hospital setting and that seven out of every ten patients diagnosed with sepsis recently used healthcare services (Novosad et al., 2016). As a result, the government’s focus on sepsis has shifted to a comprehensive population health approach (Angelelli, 2016; CDC, 2016). This approach positions primary care providers as key in recognizing sepsis and initiating early treatment (Baker, 2016; Delaney et al., 2015). The problem is that primary care providers often lack knowledge and competence in recognizing the signs and symptoms of sepsis as well as the clinical judgment necessary to detect sepsis in its early stages (Baker, 2016; Ibrahim, 2008; Li et al., 2012; Nguyen et al., 2009; Seymour et al., 2012). This project provides an initial step towards increasing provider awareness and knowledge of sepsis with the goal of early intervention and treatment. This aligns with the CDC's "Think Sepsis" awareness program (CDC, 2016).

Purpose Statement

Sepsis is a complex syndrome, requiring knowledge and clinical acumen for diagnosis (Englert & McDermott, 2016; Rhodes et al., 2016; Singer et al., 2016). This type of expertise is termed competence, and is attained when knowledge, insight, and clinical skills are applied within a given context (Blackburn et al., 2014). Simulation is a teaching technique that replicates reality and allows for interaction, which validates learning (Blackburn et al., 2014; International Nursing Association for Clinical Simulation and Learning, 2013). Simulators are objects or representations of humans or human systems that respond to the actions of a user and imitate real patient scenarios (Blackburn et al., 2014; Huang, Rice, Spain, & Palaganas, 2015). Some examples of simulators are mannequins, task trainers, virtual patients, and standardized or live patients. Simulation has been shown to increase critical thinking and self-confidence through re-creation and reflection in a safe environment (Blackburn et al., 2014; Conrad, Guhde, Brown, Chronister, & Ross-Alaolmolki, 2010; Englert & McDermott, 2016; Haut, Fey, Akintade, & Klepper, 2014; Littlewood, Shilling, Stemland, Wright, & Kirk, 2013; National League for Nursing [NLN] Board of Governors, 2015). The specific goal of this project was to determine if simulation might be an answer in terms of educating healthcare providers in the primary care environment. Therefore, the following PICO question was proposed: In FNP and FNPS (population), does the use of simulation (intervention), as compared to computer-based learning (comparison), improve knowledge and competence in the early recognition of sepsis (outcomes)?

Gap in the Literature

A literature search revealed that a pre-hospital approach to identifying sepsis has been addressed in recent years (Bayer et al., 2015; Hunter et al., 2016; Seymour et al., 2012). However, the primary focus of these studies is emergency service providers. Although the CDC recently advocated for increased recognition and expedited intervention in the primary care environment, there is a paucity of information on this topic (Novosad et al., 2016). Similarly, simulation has not been used extensively as a teaching method in the outpatient setting. However, there is a multitude of data on the benefits of simulation training for sepsis in the inpatient setting, and the concepts may be applicable for providers in primary care. There is a need for documentation on the value of simulation in nurse practitioner providers (Haut et al., 2014).

Search Strategy and Criteria

A search for quantitative evidence published between 2011 and 2016 was conducted using PubMed, CINAHL complete, ProQuest, and Cochrane Library. The broad search terms “sepsis” with “simulation” resulted in 315, 40, 1143, and 10 results, respectively. The search was further limited to human studies written in English. The search in ProQuest was narrowed using search terms appearing in the abstract. “Knowledge” and “competence” were individually explored with the search terms “sepsis” and “simulation” in the above-mentioned sites as well. A preliminary review of abstracts and related searches was completed. Twenty-two empirical studies determining the effects of simulation on knowledge, competence or skills, and confidence in diagnosing sepsis were selected and saved in EndNote. The reference lists from the selected studies were also explored. These articles were critiqued and the eight articles that met the above inclusion criteria were organized into a literature review matrix (Appendix A – Literature Review Matrix). The CDC website on sepsis, the current Surviving Sepsis Campaign International Guidelines (Rhodes et al, 2016) and The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) (Singer et al., 2016) were also accessed for current statistical data and national recommendations. Additional articles on the use of and support for simulation were retained but not included in the literature review matrix. The literature review matrix provides the citation, study design and strength, participants, instruments, interventions, as well as key findings and limitations for the eight pertinent studies. The articles included in this matrix were used to summarize the current literature. Really Simple Syndication (RSS) feeds from multiple sites were established to ensure constant updates on the topic and these studies were added to the contents of the proposal at a later date.

Critique and Synthesis of Existing Articles

Critique

Eight studies, ranging from a single descriptive project (Blackburn et al., 2014) to a randomized, prospective controlled study (Hansel et al., 2012) were reviewed for this synthesis Delaney et al., 2015; Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009; Wilson, Klein and Hagler, 2014). Of these studies, one was level VI, two were level IV, one was level III, and four were level II (Appendix B – Hierarchy of Study Design). Approval from the appropriate Institutional Review Board (IRB) or ethics board was noted in seven of the studies (Delaney et al., 2015; Hansel et al., 2012; Wilson et al., 2014), most of which qualified as exempt (Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009).

The populations involved healthcare providers with various training. Two studies utilized nurses or nursing students (Delaney et al., 2015; Wilson et al., 2014) and two additional studies used advanced practice (AP) providers or AP students (Blackburn et al., 2014; Haut et al., 2014). The other four studies involved residents or medical students (Hansel et al., 2012; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). All populations were employed in or training for emergency or critical care positions.

Simulation was executed using diverse methods. High-fidelity mannequins were used most commonly (Hansel et al., 2012; Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009), while two studies engaged in human patient simulation (Delaney et al., 2015; Wilson et al., 2014). Additionally, Wilson et al. (2014) provided computer-based study as a comparison group. Blackburn et al. (2014) did not specify the type of simulator but mentioned that the study was carried out in a high-fidelity simulation center.

The selected studies incorporated a didactic component, simulation, and measured knowledge and/or competence (Blackburn et al., 2014; Delaney et al., 2015; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). Didactic was in the form of a classroom lecture or presentation, online module or video vignette (Blackburn et al., 2014; Delaney et al., 2015; Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). Simulation ranged from 20 minutes (Nguyen et al., 2009) to 30 minutes (Li et al., 2012) to four hours (Blackburn et al., 2014) to 1½ days (Hansel et al., 2012). Delaney et al. (2015) and Littlewood et al. (2013) discussed debriefing. Additionally, four of the studies asked participants to evaluate the experience using a Likert-type scale (Hansel et al., 2012; Haut et al., 2014; Li et al., 2012; Nguyen et al., 2009). Knowledge acquisition was measured using various tools, testing methods, or exams in all but one study (Blackburn et al., 2014; Delaney et al., 2015; Hansel et al., 2012; Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). Some of the tools used to measure knowledge also gauged skill and/or attitude (Blackburn et al., 2014; Haut et al., 2014). Additionally, skill and/or competence were frequently measured using a clinical performance checklist or competence survey specific to the scenario (Blackburn et al., 2014;

Delaney et al., 2015; Hansel et al., 2012; Haut et al., 2014; Li et al., 2012; Nguyen et al., 2009; Wilson et al., 2014). Wilson et al. (2014) used an SBAR (situation, background, assessment, recommendation) report as a measurement of critical thinking.

Results were dependent on the study and the measured outcomes. Blackburn et al. (2014) reported higher than average scores on the critical care knowledge test (92%) and the completion of 27 of 30 interventions on a competency skills checklist for a septic patient. Delaney et al. (2015) found statistically significant improvement ($p < 0.0001$) in knowledge posttest scores in the staging of sepsis and in nurse competence scores ($p < 0.05$), suggesting an improvement in the ability to care for patients with sepsis. In the Hansel et al. study (2012) the SAGAT (Situational Awareness Global Assessment Tool) score rose from 10.6±2.3 to 11.9±1.7 (P=0.04) in the sepsis simulation group, as compared to no significant change in the group experiencing situational awareness only or the control group. However, the clinical performance scores in the pretest and posttest did not differ (Hansel et al., 2012). Haut et al. (2014) showed no statistical significance in comparing classroom lecture on sepsis and HFS ($p = 0.09$). Lecture followed by simulation (78.8 + 10.6%) proved more effective than simulation followed by lecture (71.6 +12.6%, $p<0.01$) in Li et al. (2012). Additionally, task performance in a sepsis scenario was higher (90.8% > 83.8%) in this order, demonstrating significant improvement in the confidence level ($p<0.01$) of providers. Littlewood et al. (2013) reported that scores after simulation were superior for all comparisons between HFS and case-based discussion on shock which included sepsis. Nguyen et al. (2009) completed a cohort study including lecture, skills workshops and a sepsis scenario. Difference between the pretest scores and each posttest score (57.5 ± 13.0, 85.6 ± 8.8, and 80.9 ± 10.9%) were found to be statistically significant. Task performances during the sepsis scenario and confidence levels were also improved. Lastly, in Wilson et al. (2014), performance was significantly better with human simulation, 7.88 (SD=2.21), over computer-based education, 6.04 (SD = 2.39).

Most of the studies were forthcoming in the limitations that may have impacted the study results. Small sample size and sample bias was cited as a weakness in several of the studies (Delaney et al., 2015; Hansel et al., 2012; Haut et al., 2014; Nguyen et al., 2009). An additional weakness cited was the lack of a control or comparison group (Haut et al., 2014; Nguyen et al., 2009). Delaney et al. (2015) and Haut et al. (2014) felt that the results were not generalizable. Validated inpatient tools were used in many of the studies but Littlewood et al. (2013) created their own oral exam which they found to be quite successful in terms of measuring knowledge and competence. Delaney et al. (2015) expressed that a self-reported score for competence was a limitation. Other limitations reported included the order of the components of the study, lack of blinding, facilitator involvement and breach in fidelity due to computer malfunction (Littlewood et al., 2013; Nguyen et al., 2009; Wilson et al., 2014).

Summary by Topic

Sepsis is a complex, emerging issue that is increasing in incidence (Delaney et al., 2015; Hansel et al., 2012) and the role of the advance practice professional must continue to evolve (Blackburn et al., 2014; Delaney et al., 2015). These individuals are crucial to early recognition and expedited therapy (Delaney et al., 2015), which has been shown to improve outcomes (Blackburn et al., 2014; Hansel et al., 2012). Unfortunately, early therapy is limited by a lack of knowledge, skills and experience in providers and the education they receive (Li et al., 2012; Nguyen et al., 2009). Traditional methods of learning are not always sufficient in complex patients, such as those with sepsis. Traditional instruction lacks validation of competence which requires knowledge as well as the ability to use it in appropriate situations (Blackburn et al., 2014; Haut et al., 2014).

Historically, simulation has been used in aviation and the military (Hansel et al., 2012; Littlewood, et al., 2013). It has also been used for over 50 years in medical education (Li et al., 2012; Littlewood et al., 2013) and has recently been introduced in colleges of nursing (Blackburn et al., 2014). However, there is a paucity of documentation on the use of simulation with nurse practitioners (Haut et al., 2014). The realistic approach provided by simulation allows for the application of knowledge and clinical skills in a risk-free environment (Blackburn et al., 2014; Delaney et al., 2015; Haut et al., 2014; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). Several authors indicated that simulation was a possible solution in teaching early identification and management of sepsis (Blackburn et al., 2014; Li et al., 2012; Nguyen et al., 2009). Four of the studies in this literature synthesis included surveys to evaluate the simulation experience, which was rated high regardless of the results (Blackburn et al., 2014; Hansel et al., 2012; Haut et al., 2014; Li et al., 2012). Littlewood et al. (2013) stated that the advantages of simulation are countless.

The studies also expressed negatives in using simulation. Simulation is resource intensive in terms of cost, space, and staffing (Hansel et al., 2012; Littlewood et al., 2013; Wilson et al., 2014). Haut et al. (2014) described the benefits as conflicted. Hansel et al. (2012) cautioned that simulator training thus far has not improved sepsis management, and although participants tend to positively accept simulation, it might not always be necessary.

Surprisingly, debriefing was not discussed in depth in the studies. Debriefing allows participants to examine how they made clinical decisions and self-reflect on the events that occurred during the simulation. Haut et al. (2014) called the discussion and feedback given during this time “critical to learning” and expressed that debriefing may be the most important part of the experience (p. e89).

Literature Synthesis

The rising incidence, mortality and cost of sepsis to the U.S. healthcare system suggest that we must focus on early identification (AACN, 2012; Angelelli, 2016; Baker, 2016; Delaney et al., 2015; Hansel et al., 2012; Singer et al., 2016; Torio & Moore, 2016; Tsertsvadze et al., 2016). Unfortunately, sepsis has a very complex and insidious pathophysiology that lacks a single biomarker or test for diagnosis (Cohen et al., 2015; Epstein, Dantes, Magill & Fiore, 2016; Shen et al., 2017; Tsertsvadze et al., 2016). Therefore providers must use knowledge of the disease process along with patient risk factors and clinical judgment in order to detect sepsis in the early stages (Baker, 2016; Blackburn et al., 2014; Cohen et al., 2015; Delaney et al., 2015; Dellinger et al., 2012; Englert & McDermott, 2016; Hansel et al., 2012; Li et al., 2012; Singer et al., 2016). Signs and symptoms are likely to manifest prior to hospital admission, positioning primary care providers, especially family nurse practitioners, in vital roles (Baker, 2016; Novosad et al., 2016).

Simulation is not new (Hansel et al., 2012; Littlewood, et al., 2013). It is a method of learning in which a clinician applies pedagogy, psychomotor skills and critical thinking to a realistic scenario (Gore & Thomson, 2016; Haut et al., 2014; Marin, 2013). Simulation as a teaching adjunct has shown some promise when applied to complicated disease processes, improving medical education (Li et al., 2012; Littlewood et al., 2013). However, literature on the use of simulation in advanced practice is severely lacking (Haut et al., 2014). Additionally, this instruction has been conducted primarily in the hospital setting with critical care providers or students, not in primary care (Hansel et al., 2012; Li et al., 2012; Littlewood et al., 2013; Nguyen et al., 2009). There remains a need to obtain additional data on the use of simulation and the effectiveness of this intervention in practice. Additionally, the use of simulation in multifarious processes such as sepsis is essential.

Pilot Project

A pilot project was completed in December of 2016 with Kelsey Kelly, MD, MPH, at the University of Kansas Medical Center (KUMC). Twenty-four family medicine residents participated in the pilot project (Appendix C – Pilot Simulation Planning Template - Part 1). Half of the participants' experienced human simulation and the others participated in high-fidelity mannequin simulation using the same scenario (Appendix D – Pilot Simulation Planning Template – Part 2). Observers utilized a clinical skills checklist to monitor objective attainment in both groups. Debriefing included discussion about the early recognition of sepsis and the tools available to a provider in an outpatient clinic setting. This project was used to evaluate the facility, the realism of the simulated clinical environment, the timing necessary for the scenario and debriefing, and feedback regarding the fidelity of live versus mannequin simulation for sepsis identification. Contrary to the priori assumptions, the students were divided evenly between the use of a high-fidelity mannequin and human simulator. Based on this result, the current project remained as it began, comparing computer-based learning with a high-fidelity mannequin simulation.

Theoretical Framework

Kolb's Learning Theory was used as the theoretical framework for this project (Figure 1). Kolb stated, "Learning is the process whereby knowledge is created through the transformation of experience" (as cited in McLeod, 2013, ¶ 4). This cyclic process includes four stages and four learning styles: concrete experience occurs in a new situation or when an old experience is reinterpreted; reflective observation is how we absorb and make sense of the new experience; abstract conceptualization is our analysis of the experience leading to a conclusion that is new or modified from an existing one; active experimentation is when the learner tests what was learned (McLeod, 2013). Effective learning, according to Kolb, occurs when all four stages are completed. Nguyen et al. (2009) found this theory to be effective in the recognition and treatment of severe sepsis and septic shock, and Li et al. (2012) used the theory to better understand and explain their results.

Figure 1: Kolb's Learning Theory

Note. Source: Chemers & Cronin, 2015

Author's Assumptions

Simulation allows for all four of Kolb's stages. Therefore, the following priori assumptions were made: (1) The pilot program will reveal that using human simulation will result in better recognition of sepsis; (2) HFS will result in increased knowledge and competence of FNP and FNPS when compared to CBL; (3) the new or reinterpreted experience may lead into extensive reflection and even better comprehension of the topic (McLeod, 2013).

Analysis of Concepts and Variables

This project investigated the knowledge and competence of family nurse practitioners (FNP) and family nurse practitioner students (FNPS) in the early recognition of sepsis after experiencing either computer-based learning or high-fidelity simulation. Primary care nurse practitioners are becoming foundational in patient care, and are therefore key in the early identification of patient de-compensation (Blackburn et al., 2014). The knowledge and competence of these professionals served as the dependent variables in this project. Computer-based learning and high-fidelity simulation were explored in this project and served as the independent variables.

Theoretical Definitions of Variables

Knowledge and competence are theoretically continuous. Knowledge has a typology of its own, but for the purposes of this project it was defined according to Drucker (as cited in Clark, 2015) as *content* that makes an individual capable of new or more effective action. The American Nurses Association (2016) defines competence as purposeful performance at an expected level. Delaney et al. (2015) adds that competence is a professional responsibility of nurses. The concepts of knowledge and competence are representative of different domains of learning (Clark, 2015). While they are quite different from one another, they are often congruent.

Computer-based learning includes the use of clinical cases that are either real or based on real events. Relevant history as well as pictures, graphs, or charts may be included in these scenarios. This project employed a case study delivered via a PowerPoint presentation and served as the comparison group. The simulation for this project utilized a computerized high-fidelity, full-body mannequin designed to mimic a realistic physiologic scenario. Computer-based learning requires knowledge, while simulation requires cognitive, affective and psychomotor skills, promoting a summative learning process (Gore & Thomson, 2016; Haut et al., 2014; Marin, 2013). Wilson et al. (2014) described the addition of simulation to computer-based learning as multisensory realism.

Debriefing typically follows simulation. Through use of a discussion, feedback from the participants is shared and ruminated. Haut et al. (2014) defines debriefing as a reflective period where learners discuss and absorb the experience offered in the scenario. The objective is to connect experience with learning.

Operational Definitions of Variables

For the purpose of this project, the outcomes of knowledge and competence were defined as discrete variables. Knowledge was measured using pretest and posttest exam scores. Increased knowledge was indicated by an increase in the posttest score. Competence was measured using a short, 8-item questionnaire specific to the performance expected. This variable was evaluated before and after the intervention. Additionally, those experiencing HFS had competence measured with a clinical skills checklist.

Definitions of Other Concepts

Sepsis has multiple etiologies and must therefore be approached in its entirety. According to the most recent guidelines, sepsis is a dysregulated host response to infection that leads to organ dysfunction (Rhodes et al., 2016; Singer et al., 2016). Because these guidelines focus on early management of sepsis in the hospital setting, and the focus of this project was on early identification, measureable and concrete parts of this definition were utilized.

Methods

Design and Rationale

The design for this project was a quasi-experimental comparison group pretest/posttest (Polit & Beck, 2012) designed to correlate to the framework. This was based on the randomization of FNP or FNPS into two groups, one experiencing computer-based learning (CBL), and the other, high-fidelity simulation (HFS). The rationale for this project design was based on limited data available on the comparison between these two teaching modalities and the lack of this type of teaching with nurse practitioners. This project sought to compare these two modalities using Kolb's model for learning, and determine which was more effective in the early identification of sepsis. This project proposal was approved by the KUMC Internal Review Board (IRB) before the collection of the data for the project (Appendix E – Human Subjects Approval Document)

This project was conducted in the Clinical Skills Lab located in the School of Nursing at KUMC in Kansas City, Kansas. Permission was requested and formally granted by the director of the lab. A team was organized to administer the pretest and posttest as well as run the simulation and debriefing. Local experts in their respective fields were recruited for the project team. The timeline (Appendix F – Proposed Project Timeline) and budget (Appendix G – Proposed Project Budget) for this project were included.

Sample

The population for this project was FNP and FNPS in the greater Kansas City area. Eligibility criteria included licensed family nurse practitioners currently practicing on a full or part-time basis, and FNP students at KUMC who had passed their FNP national certification examination. This assured that the clinical component of their graduate education was completed and they would soon be entering practice.

Selecting the Sample

The sample size of this pilot project was determined by response rather than power analysis. The population sample was purposive and biased in favor of scholarly providers. Healthcare providers are educated on infection, inflammation, coagulation and fibrinolysis, the major components of the cascade of sepsis (Angus & van der Poll, 2013). Therefore, this population had knowledge about the topic under study (Polit & Beck, 2012).

Recruitment and Informed Consent Process

The participants in the project were recruited using email, local professional organizations and snowballing. A participant recruitment letter was drafted for this purpose (Appendix H – Participant Recruitment Letter). Participation was clearly explained and bulleted. There was a signature line on the letter and participants were asked to respond to the principal investigator or project director via email. The participants were assigned a participant identifier number (PIN) on arrival. All data collected during the project was recorded under the PIN and was not identifiable to the participant.

Data Collection Materials

Unfortunately, data collection materials for use in the primary care environment are lacking. Therefore, the project director developed the 10-question pretest/posttest and the clinical skills checklist, based on review of the literature. Five national-level experts in sepsis and family care were recruited for the purpose of providing content validity for the above-mentioned materials. The competency scale and the screening tool for sepsis were previously validated tools. Other materials required for this project included a PowerPoint presentation on sepsis, a case-based clinical scenario, a clinical simulation scenario, and debriefing questions.

Expert consultation. Expert consultation on this project was requested and provided by the following individuals: Steven Q. Simpson, MD, Professor of Medicine and Acting Director of the Division of Pulmonary and Critical Care Medicine at the University of Kansas, Kansas City, Kansas; Dawn Carpenter, DNP, ACNP-BC, Assistant Professor, Coordinator Adult Gerontology Acute Care Nurse Practitioner track, University of Massachusetts, Worcester, Massachusetts; Teresa Rincon RN, BSN, CCRN-E, FCCM, eICU and CareConnect Operations

Director, Enterprise Critical Care Champion, HER Design Team, UMass Memorial Health Care, Worcester, Massachusetts; Lori Harmon, RRT, MBA, Director of Quality, Society of Critical Care Medicine, Mount Prospect, Illinois; and Aroop Pal, MD, FACP, FHM, Associate Professor of Medicine at the University of Kansas, Kansas City, Kansas.

Perceived competence scale. The Perceived Competence Scale (PCS) is a validated tool with a Cronbach's alpha score of 0.8 (Appendix I – Perceived Competence Scale). It is a Likert-type test that is adaptable to the topic being studied (Self Determination Theory, 2017). All participants completed the pretest and posttest on Apple iPads owned by the Clinical Skills Lab. A link was provided to the university Research Electronic Data Capture (REDCap) system for this purpose.

Pretest/posttest. The 10-question pretest/posttest was developed through research and review of the literature, and reviewed by experts for validity. All participants completed the multiple-choice exams on the Clinical Skills Lab Apple iPads using a link to REDCap (Appendix J – Pretest/Posttest Exam Questions). The use of this application assured the security of the participants' responses.

Sepsis education. Family nurse practitioners receive education across the lifespan of a patient. However, sepsis is not a common topic for primary care as the most vulnerable populations are the very old and the very young (Epstein et al., 2016). An educational PowerPoint was developed to improve the participants' knowledge of sepsis.

Clinical scenario data. Unidentified data on patients presenting to the KUMC emergency department from 7/22/2013 through 1/18/2017 was collected via the Organizational Improvement department. The total number of patients was 8,438. Data was extracted using age, gender, ethnicity, race, and sepsis as a primary diagnosis. Initial vital signs including respiration rate, temperature, pulse, mean arterial pressure, and blood pressure were elicited as well. The information in the workbooks was combined and filtered to create the most likely and valid case scenario for this project. Although the presentation of a patient to the emergency department and to primary care will not be the same, the extrapolated data helped to create a "typical patient" in terms of age, gender, ethnicity and race as well as the vital signs that are most likely to be altered in the early stages. Although slightly more females than males presented to KUMC during this window, a male was selected to help with fidelity of the simulation, as the mannequin in the lab setting is male. Novosad et al. (2016) found that males slightly outranked females 127:119 in the data used for the CDC's comprehensive campaign to reduce sepsis. After the "typical patient" was created in terms of vital signs, the data set was filtered to extract only Caucasian, non-Hispanic males aged 66-76. The top three non-sepsis diagnoses for these patients were counted to reveal the most frequent non-sepsis diagnosis for the age group. This "typical patient" data was used to create the patient for the simulation.

Simulation and debriefing. A Clinical Simulation Planning Template from the Zamierowski Institute for Experiential Learning (ZIEL) at KUMC was utilized to structure the simulation. This two-part document provided a template to plan, organize and develop the simulation. Part one of the template (Appendix K – Project Simulation Planning Template - Part 1) included the project logistics, justification, goals and objectives. Part two detailed the set-up including the patient data, details of the event day, the case progression, and the debriefing questions (Appendix L – Project Simulation Planning Template - Part 2).

Screening tool. Current guidelines and recommendations include screening criteria applicable in the hospital environment, including intensive care units and emergency departments (Dellinger et al., 2012; Rhodes et al., 2016; Singer et al., 2016). Additionally, early warning tools such as the shock index, Prehospital Early Sepsis Detection (PRESEP) score, Modified Early Warning Score (MEWS), Robson and BAS 90-30-90, have been developed for emergency medical responders or nurses to screen for sepsis (Baker, 2016; Bayer et al., 2015; Bayez, Hanudel, & Wilcox, 2013; Gyang, Shieh, Forsey & Maggio, 2015; Hunter et al., 2016; Roney et al., 2015; Wallgren, Castren, Svensson, & Kurland, 2014). However, most of these tools were designed to assist with the identification of clinical deterioration in the inpatient setting and require a clinical team for follow up when the criteria are met. Tools are lacking for use in the primary care environment. The Sequential Organ Failure Assessment Score (SOFA) is a score that was validated to characterize clinical sepsis in intensive care (Singer et al., 2016). Quick SOFA (qSOFA) was then developed using multivariable logistic regression of the data to determine predictive validity of three clinical variables: altered mentation (evidenced by a Glasgow Coma Scale <15), a systolic blood pressure of <100 mmHg, and respirations of 22 per minute or greater (Singer et al., 2016). qSOFA has been recommended by the Sepsis Definitions Task Force as bedside criteria by which to identify adult patients who are likely to experience poor outcomes (Singer et al., 2016). When two of three values are present, it is prudent for the provider to monitor, further investigate, possibly initiate therapy and consider transfer of the patient (Singer et al., 2016).

The Glasgow Coma Scale (GCS) is not commonly used in the outpatient setting, as it is a tool originally designed for use in assessing head injury. Practitioners working in the outpatient environment may not be familiar with the components of or proper use of this tool. However, a GCS of <15 would indicate any mental status change including confusion, disorientation, amnesia or changes in a person's level of consciousness. Altered mental status should be recognizable by any trained provider; therefore the GCS is appropriate for use as a component of qSOFA in the outpatient setting.

Clinical skills checklist. The clinical skills checklist was used with the HFS simulation group only. Clinical performance checklists are common in simulation, however most are geared toward the acute setting (Hansel et al., 2012). Therefore, the project director created this tool based on review of the literature and experts reviewed it for validity. A template was used to assure that the actions of the participants, which were embedded in the simulation template as expected learner actions, met the goals and the objectives of the simulation (Appendix L – Project Simulation Planning Template - Part 2). HFS observers utilized this clinical skills list as an objective measure of the participants' performance.

Data Collection Methods

The participants were asked to present to the Clinical Learning Lab at KUMC where they received brief instruction and information about the project. Two time slots were offered for participants, one morning and one afternoon. The anticipated time commitment was two hours.

Data collected. Consent was verified on arrival using the signed letter of recruitment. Additionally a PIN number was assigned along with an Apple iPad for use during the project. Demographic data including gender, age and degree last completed were obtained from each participant within the pretest (Appendix M - Demographic Data).

Participation. All participants were asked to complete the PCS (Appendix I – Perceived Competence Scale) and a 10-question exam (Appendix J – Pretest/Posttest Exam Questions) prior to any education on sepsis. Following the pretest, a provider-appropriate PowerPoint presentation on the early signs and symptoms of sepsis was presented. Because one FNP and one FNPS signed up to participate in each time group, randomization was determined by a coin flip. The morning group experienced CBL and the afternoon group participated in HFS.

CBL group. The CBL group was provided with the case scenario via a computer-based PowerPoint presentation. This served as a concrete experience for the learner, one where a new experience is encountered (McLeod, 2013). The providers were asked to consider a diagnosis, applicable diagnostic tests or interventions, treatments, and a plan of care for the patient. The case review was followed by a team discussion about the scenario. This allowed the learner to reflect on and learn from the experience, fulfilling the next two components of the learning theory, reflective observation and abstract conceptualization. Following the discussion, the PCS (Appendix I – Perceived Competence Scale) and the 10-question posttest (Appendix J – Pretest/Posttest Exam Questions) were administered. The computer case-based group did not have the opportunity to apply what they learned at this time.

HFS group. The HFS group experienced the same scenario using a high-fidelity mannequin simulation. Using a number-selection process, one participant was the provider and the other participant was the clinic nurse. Those not involved in the scenario observed the simulation via audio-visual transmission from another room. These observers were given a clinical skills checklist as a means of objective measurement of the active participants' performance (Table 3). A team debriefing enabled the participants to cycle back to the initial experience following active experimentation. This allowed for completion of the learning cycle described by Kolb (Figure 1). All participants and observers participated in a debriefing session following the simulation. The posttest followed.

Data Analysis

No power analysis was completed for this project, as it was exploratory. There were three outcomes measured: perceived competence, knowledge, and clinical skills. Competence and knowledge were measured using a PCS (Appendix I – Perceived Competence Scale) and a 10-question multiple-choice exam (Appendix J – Pretest/Posttest Exam Questions), respectively. Clinical skills were measured using a checklist of 19 possible actions in the simulation group (Table 3). The differences in the pretest and posttest scores for competence and knowledge, as well as the checklist completion percentage were calculated in REDCap. All scores were exported from REDCap into an Excel spreadsheet for consideration of results.

Data Security

All data was stored within the REDCap database to assure the security of the participants' responses. The collected data included demographic information (Appendix M - Demographic Data), pretest/posttest scores, and clinical skills checklist results. All scores were recorded using a non-identifiable PIN to ensure that paired scores were accurately matched.

Results

Due to the limited number of participants, no statistical conclusions could be made regarding the increased knowledge and competence of FNP and FNPS when using HFS versus CBL. However, competence in recognizing and managing sepsis increased in all participants and clinical skills completion was high. Additionally, debriefing following the simulation showed evidence of extensive reflection and comprehension of the topic.

Four participants contributed to the results of this project. This sample size rendered statistical analysis impracticable. However, some quantitative analysis and qualitative reflection is acceptable when placed in the context of the project. The PCS consisted of eight Likert-type questions scored on a scale of 1 (not true at all) to 7 (very true). The first four questions were directed at general competence and the final four were specific to competence regarding sepsis (Table 1).

The group scores for general competence increased for all participants. While the pretest scores were high at 13/14 or 14/14, the posttest scores all increased to 14/14. More significantly, there was a greater increase for all participants in the scores regarding competence with sepsis. Pretest scores for the last four questions ranged 8/14 – 12/14, while posttest scores rose to 13/14 – 14/14. However, there was no observable difference between the CBL and HFS group scores.

Similarly, the posttest exam scores were increased by 35 percent over the pretest exam scores (Table 2). The CBL exam score totals increased by 45% as compared to the HFS exam score increase of 25%. However, the CBL scores were lower initially, so comparisons are not necessarily meaningful.

Table 1: *Perceived Competence Group Scores*

Perceived Competence Scale Questions	CBL Pretest	CBL Posttest	HFS Pretest	HFS Posttest
Confidence in the ability to learn the material	13/14	14/14	13/14	14/14
Capability of learning the material	13/14	14/14	13/13	14/14
Ability to achieve goals of the project	13/14	14/14	13/14	14/14
Ability to meet the challenge of performing well	13/14	14/14	13/14	14/14
Confidence in the ability to manage sepsis	8/14	12/14	10/14	13/14
Capable of understanding risk factors for sepsis	9/14	13/14	12/14	14/14
Ability to identify sepsis symptoms, SIRS, and organ dysfunction criteria	9/14	13/14	11/14	14/14
Ability to identify sepsis in the outpatient setting	9/14	13/14	11/14	14/14

Note. The Perceived Competence Scale was used with permission for purposes of research only (Self Determination Theory, 2017). All rights are reserved by selfdeterminationtheory.org. Individual participants were asked to rate their level of competence from 1-7 for each of the following items using the scale: *1="Not true at all"; 4="Somewhat true"; 7="Very true".*

Observers used a checklist of 19 expected actions to evaluate the participants' clinical skills (Table 3). The participants completed an average of 79% of the anticipated actions in the simulation.

Following the simulation, the HFS group participated in a session led by a team member trained in debriefing. Five topics were addressed during this session including how the simulation felt to the participants, the use of screening tools when sepsis is suspected in a patient, the steps to take when sepsis is suspected, what is available in an outpatient clinic setting to treat sepsis, and how teamwork affects low volume, high acuity situations.

Table 2: *Pretest/Posttest Exam Scores and Differences*

Pretest Exam Scores			
Group	PIN	Total Points	Score
CBL	11	20/40	50%
CBL	22	12/40	30%
HFS	33	28/40	70%
HFS	44	24/40	60%
Average Pretest Total CBL			40%
Average Pretest Total HFS			65%
Average Pretest Total CBL & HFS			52.5%
Posttest Exam Scores			
Group	PIN	Total Points	Score
CBL	11	36/40	90%
CBL	22	32/40	80%
HFS	33	36/40	90%
HFS	44	36/40	90%
Average Posttest Total CBL			85%
Average Posttest Total HFS			90%
Average Posttest Total CBL & HFS			87.5%

Exam Score Differences				
Group	PIN	Pretest % Score	Posttest % Score	% Difference
CBL	11	50%	90%	+40%
CBL	22	30%	80%	+50%
HFS	33	70%	90%	+20%
HFS	44	60%	90%	+30%

Note. Using REDCap, correct values were assigned a value = 4. Each exam had 40 possible points.

The participants had not experienced simulation in a controlled setting during their training with the exception of minor tasks such a suturing. They were first asked how they felt during the scenario. Both used the terms “natural” and “comfortable” to describe their experience. One subject shared that the simulation room set up as an outpatient clinic looked very real. When asked about their performance, the participants expressed that they felt they stepped into their roles quickly during the simulation and did what came naturally to them. They appeared oblivious that there were observers. Consequently, those watching witnessed a level of calmness and confidence in the participants. When asked what they believed was happening to the patient in the scenario, the participants acknowledged that the patient’s mental status declined during the simulation. When this symptom was combined with the patient’s history of influenza and the leading differential of pneumonia, sepsis onset was suspected. The observers added that the participants did not allow the change in the patient’s mental status to distract their treatment. Instead, they assessed the patient’s history more fully, by seeking information from the patient’s daughter. The participants denied feeling anxious or nervous when the patient’s condition declined.

Sepsis was suspected in the patient and verbalized by the providers, who proceeded to complete clinical skills that were expected as a result of the patient’s presentation. A focused history and physical exam were completed. Vitals were repeated three times during the simulation and the participants acknowledged abnormal values. Oxygen was applied when the patient’s saturation decreased. An intravenous line was placed and a fluid bolus given based on the sepsis guidelines shared in the presentation. Baseline labs were ordered including a lactate level and antibiotics were administered. Additionally, immediate transfer of the patient to an acute care facility was requested. Discussion during the debriefing included reviewing the steps to take when sepsis is a differential diagnosis and the tools that are or may be available for use in a clinic setting. Additionally, the participants emphasized the lack of protocols for such an encounter in the outpatient setting. One contributor, a FNP currently working in acute care, added that she would not have thought to take any of these steps in an outpatient clinic.

Table 3: *Clinical Skills Checklist Results*

	PIN 33		PIN 44	
Expected Actions/Clinical Skill Completed	Yes	No	Yes	No
Take history	Yes		Yes	
Perform focused physical exam	Yes		Yes	
Recognize initial vital signs as abnormal	Yes		Yes	
Asks for vitals to be repeated in 5 minutes	Yes		Yes	
Recognize second vital signs as abnormal	Yes		Yes	
Verbalize altered mental status	Yes		Yes	
Verbalize screening for sepsis and use of qSOFA screening tool		No		No
More thorough H&P to search for infection		No	Yes	
Request O2 at 4L/min	Yes		Yes	
Verbalize suspicion of sepsis	Yes		Yes	
Request vitals every 5 minutes	Yes		Yes	
Request to report any further change in mental status		No	Yes	
Continue O2 at 4L/min	Yes		Yes	
Check body for sources (wounds, indwelling devices)		No		No
Request IV placement and fluid bolus (30 mg/kg NS)[a]	Yes		Yes	
Request lab (CBC, CMP, PT/INR, FBS, lactate)[b]	Yes		Yes	
Request urinalysis, place catheter, I&O[c]		No		No
Request ceftriaxone 1g IV[d]	Yes		Yes	
Verbalize need to transfer to acute care	Yes		Yes	
Total	14	5	16	3
Total Possible	19	19	19	19
% Score (correct only)	74%		84%	

Note. H&P = history and physical; O2 = oxygen; L/min = liters per minute; IV = intravenous; mg/kg = milligrams per kilogram; NS = normal saline; CBC = complete blood count; CMP = comprehensive metabolic profile; PT/INR = prothrombin time/international normalized ratio; FBS = fasting blood sugar; I&O = intake and output; g = gram
[a,b,c,d] These interventions may not be available or advisable in all outpatient settings

When questioned about the use of screening tools such as qSOFA, the participants conveyed that, although they were "thinking about" and "aware" of the components of the tool, namely altered mental status, elevated respirations, and low systolic blood pressure, they did not actually verbalize use of the tool. However, they "recognized" the patient's condition as sepsis and felt as if they applied the tool instinctively. One participant shared that Systemic Inflammatory Response Syndrome criteria had been a large part of her training in the past and she felt as if she relied more on that criteria than qSOFA to evaluate the patient's condition.

Interprofessional teamwork is intrinsic to treating sepsis and this was discussed as well. The participants agreed that this was "very important" in doctoring patients with sepsis. The observers witnessed clear communication between participants, which led to efficient and effective interventions in this simulation. The participants did not appear to lose composure during the scenario, but instead spoke in calm, clear voices when addressing the patient, daughter, or one another. Although satisfaction was not measured as an outcome in this project, the participants and team members expressed a high amount of satisfaction with the simulation experience.

Limitations

One potential source of bias in this project was selection bias. Scholarly providers, motivated to improve their skills in their employment setting, were more likely to participate. These providers may have had more knowledge on the recognition and treatment of sepsis. This is a difficult problem to minimize; a larger, randomized sample would have been more meaningful. The recruitment of nurse practitioners and nurse practitioner students was chosen based on the lack of documentation on the use of simulation specific to that population (Haut et al., 2014; Mompoint-Williams et al., 2014).

This project had limited generalizability due to the small sample size. A small sample can inflate the effect of an intervention and prevent proper estimation of the population from which the sample was taken. Four participants volunteered for the project, including two practicing FNPs and two FNPS. A larger sample would have improved generalizability. However, this was a pilot project intended to evaluate feasibility, cost, and time, as well as statistical variability.

Discussion

Because this project had known limitations, it was a challenge to determine if the results had any applicability or usefulness in clinical decision-making. Simulation is known to be an intensive teaching method in terms of staff and cost (Solymos, O'Kelly, & Walshe, 2015). However, safety has been the focus of healthcare since the release of the Institute of Medicine (IOM) report on patient safety in 2000 (Kohn, Corrigan, & Donaldson). This report recommended increased use of simulation with providers in a "non-jeopardy environment" in order to practice skills, promote team management, and produce meaningful feedback (Kohn et al., 2000, p.177). Although this project did not provide a clear link to improved knowledge and competence with simulation, research has demonstrated that knowledge, critical thinking, and skill performance improves with simulation for medical professionals (Boling & Hardin-Pierce, 2016; Shin, Park & Kim, 2015).

A systematic review of studies using HFS with nurse practitioners found that simulation was generally favored as a learning experience (Warren, Luctkar-Flude, Godfrey, & Lukewich, 2016). In this review, simulation was found to be a superior tool to evaluate knowledge when compared to traditional methods of teaching, while also increasing satisfaction (Warren et al., 2016). Solymos et al. (2105) conducted a pilot study comparing simulation with didactic learning with medical students using a sepsis scenario. Although simulation was found to be intensive in terms of cost and staff, students ranked the simulation experience high with regard to relevance, interest and enjoyment. However, multiple-choice scores on knowledge were not statistically significant between groups. Lastly, Chung, Medina, and Fox-Robichaud (2016) conducted a pilot study using interprofessional simulation with physicians, nurses and respiratory therapists. Significant results in this mixed methods study showed increased knowledge, retention, and collaborative behaviors.

This project was completed in the KUMC Clinical Skills Lab facility, which had an existing simulation lab and staff including graduate teaching assistants. Therefore, there was no financial implication for the simulation or for the didactic learning component. The project required less than two hours of time for each group. This facility also had an in-house expert in debriefing. The team that conducted the didactic study and the simulation consisted of four employees of the university.

Acknowledging the limitations of this project, the merits of simulation proved applicable and worthy of additional exploration. Future considerations should consider a mixed methods study involving a larger sample of nurse practitioners and a control group comparing simulation and lecture-based learning in the early identification of sepsis.

Significance to Nursing

In October 2015, Centers for Medicare and Medicaid Services (CMS) and The Joint Commission identified sepsis as a core measure to reduce morbidity and mortality (Bennett, 2016). This designation required acute care facilities to report to CMS a minimum set of actions directed toward the treatment of sepsis. Additionally, the CDC has emphasized that providers need to improve the identification of sepsis in its early stages (Novosad et al., 2016). Simulation may be a solution. While this project demonstrated the use of simulation in a controlled environment, it can also be extended to any healthcare setting where it can be utilized with any type of provider, including nurses, physicians, students and medical aides. In this respect, the implications reach beyond the walls of the clinic to affect population health, and may have epidemiologic impact as well.

Conclusion

The incidence of sepsis is increasing and is costing the U.S. healthcare system billions of dollars annually (American Association of Critical Care Nurses, 2012; Angelelli, 2016; Baker, 2016; Hansel et al., 2012; Singer et al., 2016; Tsertsvadze et al., 2016). Until recently, efforts focused on treating sepsis using protocols and bundles in early goal-directed therapy (Angelelli, 2016). However, the governmental focus has now changed to prevention, increasing the FNP's role in early identification (Angelelli, 2016; CDC, 2016). Sepsis is a difficult diagnosis due to the ambiguity of the cause and the lack of a specific marker or diagnostic test (Cohen et al., 2015; Epstein et al., 2016). Frequently, providers lack knowledge and competence in recognizing sepsis (Baker, 2016; Ibrahim, 2008; Li et al., 2012; Nguyen et al., 2009; Seymour et al., 2012). Simulation has been shown to increase critical thinking skills in complex disease processes, including sepsis (Blackburn et al., 2014; Conrad et al., 2011; Englert & McDermott, 2016; Haut et al., 2014; Littlewood et al., 2013; NLN Board of Governors, 2015). This project was designed to investigate the effects of simulation on the knowledge and competence of FNP and FNPS in identifying sepsis at an early stage.

While this pilot project lacked statistical significance, HFS was found to be feasible for use in NP education. The project was practical, cost effective and refined the competence of the participants. The benefits of using simulation as a tool for educating healthcare providers is well-documented, and is recommended by the IOM. With the classification of sepsis as a core measure by CMS, facilities should make greater efforts to utilize simulation whenever possible to train their providers in the early identification of sepsis.

Competing interests

The authors declare no competing interests.

Authors' contributions

HC participated in the concept, design, and writing of the project. CB participated as faculty chairperson.

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Appendix A – Literature Review Matrix

Citation	Study Design & Strength	Participants	Instruments used	Intervention	Limitations	Key Findings
Blackburn, L. M., Harkless, S., & Garvey, P. (2014). Using failure-to-rescue simulation to assess the performance of advanced practice professionals. Clinical Journal of Oncology Nursing, 18(3), 301-306. doi: 10.1188/14.CJON.301-306	Descriptive project Level VI	14 Advance Practice Profession-als (APP)	Competency self-assessment BKAT -8S® Competency checklist	4-hour HFS & classroom	Oncology patients unique in presentation. Mannequins have mechanical limitations for respiratory distress	Competence in taking care of failing patients rated high. All scores on BKAT at or above level of critical care nurse with 1-year experience. 27/30 anticipated inter-ventions were enacted by all APPs
Delaney, M. M., Fried-man, M. I., Dolansky, M. A., & Fitzpatrick, J. J. (2015). Impact of a sepsis educational program on nurse competence. *The Journal of Continuing Education in Nursing, 46*(4), 179-186. doi:10.3928/00220124-20150320-03	QES Level IIb	82 Registered nurses	Exam scores NCS + 3 specific sepsis statements	TSEP (Four interactive online learning modules on bundles, clinical content, health literacy & cultural, communica-tion & teamwork)	Purposive sample Similar education and background Self-assessment instrument used Limited generaliza-bility	Statistically significant improve-ment for knowledge in bundles, clinical content and communica-tion & teamwork No statistical significance for NCS (total or individual domains) Statistically significant increases in NCS

						(competence in sepsis)
Hansel, M., Winkelmann, A. M., Hardt, F., Gijselaers, W., Hacker, W., Stiehl, M., . . . Muller, M. P. (2012). Impact of simulator training and crew resource management training on final-year medical students' performance in sepsis resuscitation: A random-ized trial. *Minerva Anestesiolog-ica, 78*(8), 901-909. Retrieved from http://www.minervamedica.it/en/journals/minerva-anestesiolog-ica/article.php?cod=R02Y2012N08A0901	RCT Level IIa	61 Medical student volunteers randomized into three groups: SIM CRM CG	Skills checklist SAGAT score	CG: no training SIM: HFS CRM: course on situational awareness	Sample comprised of volunteers	SAGAT score increased significantly in the SIM group only
Haut, C., Fey, M. K., Akintade, B., & Klepper, M. (2014). Using high-fidelity	NES Level IV	10 Nurse practitioner students	SMARTER Exam scores	Classroom lecture and HFS	Small convenience Sample No comparison between groups	An average of 67% of targeted responses were met Difference in exam

simulation to teach acute care pediatric nurse practitioner students. *The Journal for Nurse Practitioners, 10*(10), e87-91. doi:10.1016/j.nurpra.2014.09.012					SMARTER tool not validated	scores was not significant
Li, C. H., Kuan, W. S., Mahadevan, M., Daniel-Underwood, L., Chiu, T. F., & Nguyen, H. B. (2012). A multinational randomized study comparing didactic lectures with case scenario in a severe sepsis medical simulation course. *Emergency Medicine Journal, 29*(7), 559-564. doi: 10.1136/emermed-2011-200068	RES (crossover) Level IIa	98 subjects 2 experimental groups: lecture-first (51) and SIM-first (47)	Exam scores Standard-ized checklist Confidence evaluation	EG: lecture-first EG: SIM-first	No follow-up data on actual clinical practice	Posttest2 scores were significantly higher for all No difference between groups in pretest or posttest2 scores Lecture-first had significantly higher posttest1 score Task performance higher in lecture-first group
Littlewood, K. E., Shilling, A. M.,	NES Level IV	85 Third-year medical students 2 groups:	OE	$SIM_{cardiac}$: HFS cardiogenic shock, CBD	Study done retrospec-tively Chronology	Both groups showed statistically better

Stemland, C. J., Wright, E. B., & Kirk, M. A. (2013). High-fidelity simulation is superior to case-based discussion in teaching the management of shock. *Medical Teacher, 35*(3), e1003-1010. doi: 10.3109/0142159x.2012.733043		$SIM_{cardiac}$ (42) SIM_{sepsis} (43)		in sepsis SIM_{sepsis}: HFS in sepsis, CBD in cardiogenic shock	may have been a confounding factor No randomi-zation Non-blinded examiners OE instrument not validated	performance on SIM as compared to CBD
Nguyen, H. B., Daniel-Underwood, L., Van Ginkel, C., Wong, M., Lee, D., Lucas, A. S., . . . Clem, K. (2009). An educational course including medical simulation for early goal-directed therapy and the severe sepsis resuscitation bundle: An evaluation for medical student training. *Resuscitation, 80*(6), 674-679.	Prospective cohort study Level III	63 medical students 4 groups: divided by year in school	Exam Simulation task checklist Survey	Lecture followed by SIM	Facilitator-guided tasks No control group or comparison	Differences between pre-scores and each posttest score statistically significant Task perfor-mances during sepsis scenario improved Confidence levels improved

doi:10.1016/ j.resuscitation .2009.02.021						
Wilson, R. D., Klein, J. D., & Hagler, D. (2014). Computer-based or human patient simulation-based case analysis: Which works better for teaching diagnostic reasoning skills? *Nursing Education Perspectives, 35*(1), 14-8. doi: 10.5480/11-515	QES Crossover design Level IIb	54 nursing students 3 groups:	SBAR format synthesis Coding sheet	Computer SIM followed by human SIM	Participants were requested to think aloud Fidelity was disrupted by computer issues	Performance was significantly better with human simulation over computer-based education

Note. APP – Advanced Practice Professionals; QES – Quasi-experimental study with one-group pretest/ posttest; BKAT - Basic knowledge assessment tool; HFS – High fidelity simulation; TSEP – Taming Sepsis Educational Program; NCS – Nurse Competence Scale; RCT – Randomized controlled trial; SAGAT - Situation Awareness Global Assessment Tool; SIM – Simulation; CRM - Crew Resource Management; CG – Control group; SMARTER - Simulation Module for Assessment of Resident Targeted Event Responses; NES – non-experimental study; RES – Randomized experimental study with pretest/posttest1/posttest2; EG – Experimental group; OE – oral exam; CBD – case-based discussion; SBAR – Situation, background, Assessment, Recommendation

Appendix B – Hierarchy of Study Design

Level of Evidence	Sub-level	Type of Study
I	a.	Systematic review of randomized clinical trials
	b.	Systematic review of non-randomized clinical trials
II	a.	Individual randomized clinical trial
	b.	Non-randomized trail
III		Systematic review of correlational/observational studies
IV		Individual correlational or observational study
V		Systematic review of descriptive, qualitative, physiological studies
VI		Individual descriptive, qualitative, or physiological study
VII		Expert opinion or expert committees

Note. Source: Polit & Beck, 2012.

Appendix C – Pilot Simulation Planning Template - Part 1

Section 1: Tentative Course Logistics	
Course Title	Family Medicine Residency
Scenario Title	Early Identification of Sepsis Outpatient Simulation using HAL ® Simulator Model
Course Director	Kelsie Kelly, MD, MPH
Participants	Family Medicine Residents
Event	Terry Brown Scenario
Approximate event duration	1 hour
Goals and Objectives	
Define the goal(s) for the simulation	
Early Identification of Sepsis in Outpatient	
Define 2-4 learning objectives for the simulation case Recognize early signs of sepsis in outpatient setting, specifically qSOFA Perform initial management of sepsis Effectively communicate and work in a clinic team Residents to communicate ISBAR handoff to RRT and disposition of patient	
Objective 1: Following this activity, participants will be able to…	
Recognize early signs of sepsis in outpatient setting, specifically qSOFA	
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.	
Obtain vital signs and verbalize abnormal values Evaluate mental status using the GCS Calculate patient risk of poor outcome using qSOFA (verbalize 2/3 present)	
Objective 2: Following this activity, participants will be able to…	
Perform initial management of sepsis	
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.	
Request vital signs every 5 minutes Request neurological checks every 15 minutes using GCS Complete thorough history and physical exam to determine possible infection Fixed fluid resuscitation bolus with 30 mL/kg of crystalloid solution Laboratory assessment (if available) to include lactate Antimicrobial therapy within 1 hour using available pharmacotherapy Bedside electrocardiogram (if available) Initiate rapid response	

Objective 3: Following this activity, participants will be able to…
Effectively communicate and work in a clinic team
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Seek input from the team Clearly communicate plan Support and respect one another
Objective 4: Following this activity, participants will be able to…
Residents to communicate using ISBAR during handoff to rapid response team
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Report to RRT and physician using ISBAR format

Note. qSOFA = quick Sequential Organ Failure Assessment; ISBAR = introduction, situation, background, assessment, recommendation; RRT = rapid response team; GCS = Glasgow Coma Scale; mL/kg = milliliters per kilogram.

Appendix D – Pilot Simulation Planning Template – Part 2

Section 1: Set-Up	
Environment/Personnel	
Clinical Setting/Room Type	Outpatient Clinic Exam Room
Pre-brief Room(s) Needed	Yes, for 4 participants plus 3 team members
Debrief Room(s) Needed	Yes, for 4 participants plus 3 team members
Embedded Simulation Persons	Yes, one family member in mannequin simulation
Standardized Patients	Gaumard HAL® high-fidelity mannequin
Patient Voice	Team member to portray voice
Video Recording	Yes
Video Streaming	No, students will observe from observation room
Record Debriefing	No
Debrief Assistance	Yes, team member to lead debrief
Mannequin(s) and Accessories	
Mannequin(s)	Adult male
Bed type/patient position	Outpatient exam table
Mannequin gender/attire/wig	Gym shorts, t-shirt, black socks, tennis shoes
Monitor display	Temperature HR NIBP RR O2
Medical Equipment	
Supply carts	Standard Med-Surgical Nursing Supply Cart Code Cart with manual defibrillator available in hall
Vitals monitor	Welch Allyn mobile vital signs unit
Oxygen	Rolling oxygen tank and tubing available
Pharmacy (Meds and Doses)	Ceftriaxone sodium 1g IV, 1000 mL normal saline 0.9%, Normal saline 0.9% vials for IV infusion
IV Pump(s)	Allaris /Carefusion IV pump
Yankauer/suction	No
Consumable equipment	Standard supplies in nursing care including personal protective

available	equipment, rainbow lab tubes, intravenous supplies and tubing, syringes, flushes, blood glucose monitor
Patient Data	
Patient gender and age	Caucasian male age 76 (mannequin) or Caucasian female age 76 (live)
Patient name	Terry Brown
Past Medical History	HTN, Dyslipidemia, DMII, Osteoarthritis
Home Medications	Amlodipine, atorvastatin, metformin, glyburide, aspirin
Allergies	Sulfa (rash reaction)
Vital Signs	B/P 110/76, T 37.3 C, P 92, RR 22, SaO2 94% RA
Lab Values	None available
Radiology Data	None available
Integrate EHR (Y/N)	No
Need paper chart	Yes
Section 2: Event Day	
Pre-Brief Plan	
Location	University of Kansas School of Nursing Clinical Learning Laboratory
Time Allotted	10 minutes
Faculty presenter	Dr. Kelsie Kelly
Pre-brief: Treat the scenario as real as possible Request assistance if needed Ignore the camera Verbalize your thought process Roles will be assigned (can have learners pick a number between 1 and 6) RN Resident Recorder of task completion Orient residents to HAL® and simulation bay Mannequin Vitals display Supplies Oxygen Code cart Phone Structure of the session Questions?	

Case Overview for Instructors/Facilitators
Overview of the case to serve as background when preparing for simulation and debriefing. This should include the history of present illness, as well as relevant past medical history etc. Part A: Terry Brown is a 72 y/o M/F who came to your clinic for 10 am appointment, brought by the granddaughter, for changes in mentation over past few days. Mr./Ms. Brown has become more confused. Mr./Ms. Brown has not been eating and drinking as much, c/o some abdominal pain and has had some incontinence episodes, which is new. The granddaughter was worried. PMH: Former smoker, DM type 2 controlled, HTN, Dyslipidemia, Osteoarthritis Meds: Amlodipine, atorvastatin, metformin, glyburide, aspirin SH: lives alone in the same house for 40 years Clinic appointment vitals: T-99.6, HR-102, RR-22, BP-108/70, SaO2-93% During the clinic visit it is determined that the patient has a UTI by UA with positive for leukocytes and nitrates and needs to be admitted for IV antibiotics and further monitoring given confusion. There are no beds available and the patient stays in FM clinic for the duration of the morning awaiting a bed. Fast-forward 3 hours: The resident and RN/LPN are returning from lunch to check on Mr./Ms. Brown. The resident and RN are given Part A of Clinical Scenario prior to entering room Part B: Resident physician and LPN come back after lunch to check on Mr./Ms. Brown, who is noticeably more confused and not responding to questions. At this point the patient will begin to deteriorate from developing sepsis, becoming more lethargic and RRT should be called. LPN and/or resident should recheck vitals; ask for POC glucose at minimum. However, if at any point the team decides to give antibiotics then the progression of deterioration can be slowed.
Case Stem for Learners
This is the background information provided about the patient to the learners before they enter the room. Terry Brown is a 72 y/o M/F with h/o former smoker, DM type 2 controlled, HTN, dyslipidemia, Osteoarthritis who presented to clinic at 10 am for confusion, brought by granddaughter. You diagnosed patient with a UTI by UA and are admitting them for IV antibiotics and further monitoring. There are no beds available in the hospital currently and so he/she is waiting. It has been 3 hours so you come back after lunch to check on Mr./Ms. Brown. Vitals in clinic at 10:00am: T-99.6 HR-102 RR-22 BP-108/70 SaO2-93%
Information for Patient Voice
Please include information about past history and present illness that the patient should be prepared to provide. Please use layperson language. Terry Brown is a 72 y/o M/F with h/o former smoker, DM type 2 controlled, HTN, dyslipidemia, Osteoarthritis who came to clinic for 10 am appointment, brought by granddaughter, for changes in mentation over past few days. Mr./Ms. Brown has become more confused. Ms. Brown has not been eating and drinking as much, c/o some abdominal pain and has had some incontinence episodes which is new. The granddaughter is worried about her.

PMH: Former smoker, DM type 2 controlled, HTN, Dyslipidemia, Osteoarthritis Meds: Amlodipine, atorvastatin, metformin, glyburide, aspirin SH: lives alone in the same house for 40 years Mr./Ms. Brown is being admitted for UTI and confusion, he/she is awaiting a bed in the hospital. Fast forward 3 hours: The resident physician and LPN come back after lunch to check on Mr./Ms. Brown, who is noticeably more confused and not responding to questions. At this point the patient will begin to deteriorate from developing sepsis, becoming more lethargic. Mr./Ms. Brown will c/o abdominal pain, decreased appetite, nausea, only oriented to person.
Information for ESP - Patient's granddaughter
Please provide the information the ESP should be prepared to provide to learners if queried. Consider the recent history, apparent symptoms, or physical exam findings that may need to be provided. Terry Brown is a 72 y/o M/F with h/o former smoker, DM type 2 controlled, HTN, HLD, Osteoarthritis who came to clinic for 10 am appointment, brought by granddaughter, for changes in mentation over past few days. Mr./Ms. Brown has become more confused. Mr./Ms. Brown has not been eating and drinking as much, c/o some abdominal pain and has had some incontinence episodes, which is new. The granddaughter is worried about her. PMH: Former smoker, DM type 2 controlled, HTN, HLD, Osteoarthritis Meds: Amlodipine, atorvastatin, metformin, glyburide, ASA SH: lives alone in the same house for 40 years Mr./Ms. Brown is being admitted for UTI and confusion, she is awaiting a bed in the hospital. Fast forward 3 hours: The resident physician and LPN come back after lunch to check on Mr./Ms. Brown, who is noticeably more confused and not responding to questions. At this point the patient will begin to deteriorate from developing sepsis, becoming more lethargic. Mr./Ms. Brown will c/o abdominal pain, decreased appetite, nausea, only oriented to person. The granddaughter will become increasingly concerned about Mr./Ms. Brown as the patient becomes more confused. Can continue to ask resident physician what is going on. Role of granddaughter is to add distracter to case.
Section 3: Case Progression

Baseline										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	B/P	Pulse	SaO2	RR
Open	Clear to auscultation	Regular	Normal	100.1	120	No monitor	106/68	Normal	93% RA	24

Expected Learner Actions	Mannequin Operator		Patient Vocalizations
Resident to gather more history	Response: Patient is only oriented to self, more abdominal	Prompts	"My name is Terry Brown" " I don't feel very well"

	pain, generally not feeling well		"My stomach hurts"
Resident asks RN/LPN to come in, get vitals			
Asks for vitals to be repeated in 5 minutes			
Transition to next state: 2 minutes			

State 1 (only need to note features that change)										
Eyes Closed	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	SaO2	RR
Trend time (to state vitals) –					1 min		1 min		1 min	1 min

Expected Learner Actions	Mannequin Operator		Patient Vocalizations
Resident assesses/examines the patient		Prompts: If confusion not recognized and assessed increase comments	Makes comment about location or needing to go somewhere. Feeling lethargic and sleepy.
Resident and RN/LPN should consider giving O2 at 4L, starting IV, IV fluids, draw blood, POC glucose, electrocardiogram, antibiotics	Response: SaO2 increase 96% Glucose 102 Sinus tachycardia		ESP: States that he wasn't himself on phone. Granddaughter increasingly concerned and anxious
Give resident and RN/LPN time to discuss/verbalize plan of care			
Transition to next state: 3 minutes			

State 2 (only need to note features that change)										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	SaO2	RR
				100.1	140		92/55		92%	24
Trend time (to state vitals) –					1 min		1 min		1 min	1 min

Expected Learner Actions	Mannequin Operator	Patient Vocalizations

Repeat Vitals	Response: Patient will start to become minimally responsive, slump over	Prompts: Granddaughter: does he need to go to the hospital? I haven't seen him/her like this	Lethargic
Resident should ask for Rapid Response, IV and IV fluids (if not already started), IV antibiotic (1 gram Ceftriaxone IV in clinic)	HR will improve to 120 if fluids given	If fluids or antibiotics not given, HR continues to be 140 and patient becomes more unresponsive	ESP: Daughter helpful with questions but very concerned and anxious.
Verbalize need for transfer to acute care			
Transition to next state: 4 minutes			

State 3 (only need to note features that change)										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	SaO2	RR
Trend time (to state vitals) –					1 min		1 min		1 min	1 min

Expected Learner Actions	Mannequin Operator		Patient Vocalizations
Rapid Response Team arrives			Lethargic
Resident should give ISBAR handoff to RRT			

Section 4: Debriefing Plan
Reactions Phase: The purpose of this section is to clear the air so a learning conversation can occur. Try to avoid discussions of how it went, but rather given participants a chance to vent about how they feel.
Thanks, everyone, for participating. I'd like to start by hearing how you were feeling during the case?
Facts: Provide the basic facts about the case so participants don't spend time debating or wondering what was going on with the patient. Should be no more than 2-3 sentences.
Before we dig into the debriefing, I just want to clarify the medical facts of this case. Mr./Mrs. Brown was a Caucasian male/female who, as he/she sat in the clinic, began to

have increased respirations and confusion due to sepsis. Any questions?
Preview: Provide an outline of the topics (usually 2-3) you would like to discuss during the debriefing, which will help put participants at ease and encourage them to follow your lead. These topics will likely relate to your learning objectives, but sometimes to unexpected events that occurred and will make great teaching points.
I know these cases can be very challenging, and that things may not have gone exactly as you would have liked. I think that is ok, and that we can learn a lot from the experience. The topics that I'd like to discuss during this debriefing are screening tools that are available to us when we suspect sepsis in a patient, the steps we need to take if we suspect that a patient in the clinic is developing sepsis, what we have available to us in the clinic setting that might help this patient if we think they are developing sepsis, and teamwork in the clinic setting. Does that sound okay?
Explore/Understand Objective #1: For each objective, start with an introduction such as, "First I'd like to talk about closed-loop communication." Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
First, I'd like to discuss the early signs of sepsis in the outpatient setting, specifically qSOFA
Explore/Understand Objective #2: Clear transition to next objective. Then, consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
Next, I'd like to discuss the initial management of sepsis
Explore/Understand Objective #3: Clear transition to next objective. Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
Now, I'd like to discuss how we can effectively communicate and work in a clinic team
Explore/Understand Objective #4: Clear transition to next objective. Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
Lastly, I would like to discuss the use of ISBAR in hand-offs
Summary: Ask Learners to summarize their "take-away."

Note. HR = heart rate; NIBP = non-invasive blood pressure; RR = respiratory rate; O2 = oxygen; IV = intravenous; HTN = hypertension; DMII = diabetes mellitus type 2; B/P = blood pressure; T = temperature; P = pulse; SaO2 = oxygen saturation; RA = room air; RN = registered nurse; UTI = urinary tract infection; UA = urinalysis; LPN = licensed practical nurse; RRT = rapid response team; POC = point of care; ESP = embedded simulation person.

Appendix E – Human Subjects Approval Document

Type of Review:	Initial Study
FWA#:	00003411
IRB#:	STUDY00140724
Title:	Early Identification of Sepsis in Primary Care: A Pilot Project
Investigator:	Diane Ebbert
IRB ID:	STUDY00140724
Funding:	Name: University of Kansas
Exemption Category:	(1) Educational settings
Documents submitted for the above review:	Early Identification of Sepsis in Primary Care with expert edits.docx Revised Summary Document.docx Grant Proposal for STTI - Chaney.docx Summary Document as requested by reviewer Heide Chaney Letter of Recruitment Early Identification of Sepsis in Primary Care for Project.pptx Revised Letter of Recruitment.docx Exempt Project Description

Note. The IRB approved this submission as of 5/23/2017. This "exempt" approval is based upon the assurance that you will notify the HSC prior to implementing any revisions to the project. The HSC must determine whether or not the revisions impact the risks to human subjects, thus affecting the project's "exempt" status. Projects that do not meet the "exempt" criteria must comply with all federal regulations regarding research.

Appendix F – Proposed Project Timeline

February 17, 2017	Proposal Defense
March 10, 2017	Submit Project to IRB
March 24, 2017	Send documents to experts for review
April 1, 2017	Begin recruiting for participants, assemble team, formal letter for facility
April 15, 2017	Meet with DNP Project Committee
April 29, 2017	Project and data collection
May 15, 2017	Submit abstract to GAPNA for public presentation at national convention 2018
June 1, 2017	Draft results section of project
July 15, 2017	Revised draft to Andres Rodriguez
August 20-25, 2017	Finalize project with DNP Project Chair and committee, begin PowerPoint for presentation
October 15, 2017	Final draft due/PowerPoint completed

Appendix G – Proposed Project Budget

Budget Item	Estimated Cost	Estimated Total	Actual Total
Parking	$5 per participant/team member	$100	Free on Saturdays
Breakfast and/or lunch	$7.50 per participant/team member	$150	7 for breakfast at $9 ea. 10 for lunch @ $10 ea.
Total	$250	$250	$167

Appendix H – Participant Recruitment Letter

I am writing to let you know about an opportunity to participate in a DNP project about the early recognition of an acute care problem in primary care. Heide Chaney, a graduate nursing student at the University of Kansas School of Nursing is completing this project. The goal is to increase the knowledge and competence of family nurse practitioners in the early recognition of an acute care problem that may present in primary care. Additionally, the project results would supplement existing literature and add evidence-based practice in this area.

Participation will consist of the following:

- Verify signed recruitment letter as consent and provide demographic data (age, gender, degree of last completion)
- Complete a 10-question pretest/posttest and a perceived competence evaluation using REDCap
- View an educational PowerPoint presentation
- Participate in a clinical scenario either using a computer-based study or as a simulation with debriefing (placement into the computer-based study or the simulation group will be randomized)

No identifiable information will be collected for this project and the outcome data will be de-identified using a personal identification number. There are no personal benefits or risks to participating in this project and participation is voluntary. Agreement to be contacted or a request for further information does not obligate you to participate in the project.

All advance practice registered nurses in family care in the greater Kansas City area and all family nurse practitioner students that have passed their national certification exam are eligible to participate in this project. Licensing must be current and the participant must not be involved a disciplinary process.

The project will take place at the University of Kansas School of Nursing, 3901 Rainbow Boulevard, Kansas City, Kansas, on Saturday, June 10, 2017. If you would like to participate, please join us at the Clinical Learning Laboratory on the second floor of the School of Nursing at 9:00 am or 1:00 pm. A map of the campus and location of the school of nursing can be found at http://www.kumc.edu/about-us/kumc-auditoriums-and-meeting-locations.html. Parking is available in the Olathe II Public Parking garage. Access to the school is located on the west side along Rainbow Avenue. The University of Kansas School of Nursing Clinical Learning Laboratory is located on the first floor in Office 1020. This project will require approximately two hours. Parking will be validated and a continental breakfast or a light lunch will be served.

Thank you for considering this opportunity,

Heide Chaney DNP-FNP Candidate 2017

Please respond with the signed form below by June 1, 2017 to: Heide Chaney, (620) 242-2343, hchaney@kumc.edu . Any questions may be directed to the above emails. For questions about the rights of research participants you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or humansubjects@kumc.edu. Reference study ID # 00140724/FWA# 00003411.

I plan to participate in Early Identification of Sepsis in Adults in Primary Care:

(Please check one)

9:00 am 1:00 pm

Printed name:

Signature:

Appendix I – Perceived Competence Scale

Question	Competence Level						
I feel confident in my ability to learn this material.	1	2	3	4	5	6	7
I am capable of learning the material in this project.	1	2	3	4	5	6	7
I am able to achieve my goals in this project.	1	2	3	4	5	6	7
I am able to meet the challenge of performing well in this project.	1	2	3	4	5	6	7
I feel confident in my ability to manage sepsis.	1	2	3	4	5	6	7
I am capable of understanding factors that place certain patients at high risk for developing severe sepsis.	1	2	3	4	5	6	7
I am able to identify sepsis symptoms, SIRS, and organ dysfunction criteria.	1	2	3	4	5	6	7
I feel able to meet the challenge of identifying sepsis in the outpatient setting.	1	2	3	4	5	6	7

Note. The Perceived Competence Scale was used with permission for purposes of research only (Self Determination Theory, 2017). All rights are reserved by selfdeterminationtheory.org. Individual participants were asked to rate their level of competence from 1-7 for each of the following items using the scale: *1="Not true at all"; 4="Somewhat true"; 7="Very true"*.

Appendix J – Pretest/Posttest Exam Questions

1) A patient presents to the clinic after discharge from a post acute care facility. She is complaining of watery diarrhea. What sign might indicate that she could be developing sepsis from clostridium difficile?

A. Temperature of 36.7ºC

B. Altered mental status

C. Respirations of 20 per minute

D. Oxygen saturation of 94%

Rationale: A Glasgow Coma Score < 15 represents altered mentation and is a component of qSOFA. This should prompt clinicians to further investigate for organ dysfunction (Singer et al., 2016).

2) Which patient would you screen for sepsis?

A. A patient on steroids for a COPD exacerbation

B. Anyone with an infectious process

C. A patient with a central line to complete an antibiotic course

D. A patient on a second round of antibiotics for diverticulitis

Rationale: Any patient with an infectious process should be screened for sepsis.

3) Which of the following patients is the most likely to develop sepsis?

A. 25-year-old with urinary tract infection

B. 45-year-old with cellulitis

C. 50-year-old with intestinal obstruction

D. 76-year-old with right lower lobe pneumonia

Rationale: The most common illnesses leading to sepsis are pneumonia 35%, urinary tract infections 25%, gastrointestinal infections 11%, and skin/soft tissue infections 11% (Novosad et al., 2016). Additionally, approximately 49% of those who die from sepsis are aged 65–84 (Epstein et al., 2016).

4) What combination of assessment findings indicates a positive qSOFA score?

A. Temperature ≤ 36ºC, heart rate ≥90 bpm, respiratory rate ≥20 per minute

B. Mean arterial pressure < 65, Glasgow Coma Scale ≤13, heart rate ≥90 bpm

C. Respirations >22 per minute, systolic blood pressure ≤100 mmHg, Glasgow Coma Scale <15

D. Heart rate ≥90 bpm, respiratory rate ≥20 per minute, systolic blood pressure ≤100 mmHg

Rationale: qSOFA (quick SOFA) incorporates altered mentation (evidenced by a Glasgow Coma Score of < 15), systolic blood pressure of 100 mm Hg or less, and respiratory rate of 22/min or greater, and provides simple bedside criteria to identify adult patients with suspected infection who are likely to have poor outcomes (Singer et al., 2016).

5) Which of the following represents effective source control in a patient with an abscess

A. Blood cultures

B. Fluid resuscitation

C. Incision and drainage

D. Placement of central venous catheter

Rationale: The principles of source control in the management of sepsis and septic shock include rapid diagnosis of the specific site of infection and determination of whether that infection site is amenable to source control measures, specifically the drainage of an abscess, debridement of infected necrotic tissue, removal of a potentially infected device, and definitive control of a source of ongoing microbial contamination (Rhodes et al., 2016)

6) What approach should be taken in fluid resuscitation in an adult patient with suspected sepsis?

A. Fixed fluid resuscitation of 20 mL/kg crystalloid solution

B. 2 liters of crystalloid solution given wide open

C. Normal saline at 500 ml/hr

D. Initial fluid resuscitation of 30 mL/kg crystalloid solution

Rationale: Early effective fluid resuscitation is crucial for stabilization of sepsis-induced tissue hypoperfusion or septic shock, therefore, initial fluid resuscitation should begin with 30 mL/kg of crystalloid within the first 3 hours (Rhodes et al., 2016).

7) Which of the following statements regarding cultures and antibiotics is *false*?

A. Broad-spectrum antibiotics are used until the causative source is identified

B. Failure to initiate antibiotics early can lead to poor outcomes

C. Antibiotics may be administered if it is not feasible to obtain blood cultures

D. "Pan cultures" should be obtained prior to the administration of antibiotics

Rationale: "Pan culture" of all sites that could potentially be cultured should be discouraged because this practice can lead to inappropriate antimicrobial use (Rhodes et al., 2016).

8) According to the Centers for Disease Control and Prevention, what percentage of patients has developed sepsis outside of the hospital (includes all settings that are not acute care)

A. 20%

B. 40%

C. 60%

D. 80%

Rationale: Sepsis begins outside of the hospital for nearly 80% of patients (CDC, 2016).

9) The most common pathogens that lead to septic shock are:

A. Fungal

B. Bacterial

C. Viral

D. Protozoal

Rationale: The most common pathogens that cause septic shock are gram-negative bacteria, gram-positive, and mixed bacterial microorganisms (Rhodes et al., 2016).

10) Which is the most important principle of effective teamwork

A. Establishing roles

B. Seeking input from the team

C. Clear communication

D. Supporting and respecting one another

Rationale: Communication is necessary for all members to contribute to an effective team and may be considered the basis for effective teamwork (Gluyas, 2015).

Appendix K – Project Simulation Planning Template - Part 1

Section 1: Tentative Course Logistics	
Course Title	NRSG 980
Scenario Title	Early Identification of Sepsis in Primary Care: A Pilot Project
Course Director	Dr. Carol Buller
Additional Instructors	Dr. LaVerne Manos, Dr. Lisa Ogawa
Participants	Approximately 16 FNP and FNPS from the greater Kansas City Area
Event	Date to be determined. Two events total, one at 9:00 am and one at 1:00 pm.
Approximate event duration	Total event duration approximately 2 hours each
Section 2: Project Justification	
What would you like to prepare your participants to do?	
The purpose of this project is to compare the knowledge and competence of primary care practitioners in the early recognition of sepsis using either HFS or CBL with Kolb's Learning Theory as the framework.	
Please describe the health care problem this training will address.	
Sepsis is a nocuous host response to infection that leads to organ dysfunction and hypotensive shock whose cost and incidence will continue to increase as the population in the United States ages. Because early identification helps to decrease mortality, it is imperative that family practice providers increase their awareness and recognition of sepsis so that treatment may be expedited.	
Why is training on this topic important for your participants at this time?	
The cost and incidence of sepsis has and is predicted to increase as the population in the United States ages. Additionally, the cost of treating sepsis has increased to over $20 billion dollars annually, and this is considered to be an underestimation.	
Section 3: Goals And Objectives	
Define the goal(s) for the simulation. Goals are the broad educational aims.	
Increased knowledge of primary care practitioners in the early recognition of sepsis Increased competence of primary care practitioners in the early recognition of sepsis	
Define 2-4 learning objectives for the simulation case. Assess the patient and recognize possible sepsis Apply the qSOFA screening tool and calculate risk Prioritize care and generate a plan to monitor, further investigate, possibly initiate therapy and consider transfer of the patient Utilize effective teamwork in caring for an emergent patient	

Objective 1: Following this activity, participants will be able to…
Assess a patient using the qSOFA screening tool
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Obtain vital signs and verbalize abnormal values Evaluate mental status using the GCS Calculate patient risk of poor outcome using qSOFA (verbalize 2/3 present)
Objective 2: Following this activity, participants will be able to…
Recognize the need to monitor and further investigate the patient's status
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Request vital signs every 5 minutes Request neurological checks every 15 minutes using GCS Complete thorough history and physical exam to determine possible infection
Objective 3: Following this activity, participants will be able to…
Initiate therapy appropriate to a primary care clinic setting and consider transfer of the patient
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Fixed fluid resuscitation bolus with 30 mL/kg of crystalloid solution Laboratory assessment (if available) to include urinalysis and culture, complete blood count, comprehensive metabolic panel, PT/INR, blood glucose, and lactate Antimicrobial therapy within 1 hour using available pharmacotherapy (consider risk-benefit if inability to draw blood cultures) Insert urinary catheter and monitor intake/output Bedside electrocardiogram (if available) Consider removal of devices such as urinary catheters, central venous lines (if indicated after other vascular access obtained) Assess incision and drainage Arrange transfer of patient to acute care facility
Objective 4: Following this activity, participants will be able to…
Use effective teamwork to manage the emergent care of a patient
Observable Actions: Create a list of steps or actions that could be used during a simulation to determine if participants have met the objective.
Seek input from the team Clearly communicate plan Support and respect one another

Note. NRSG = nursing; qSOFA = quick Sequential Organ Failure Assessment; GCS = Glasgow Coma Scale.

Appendix L – Project Simulation Planning Template - Part 2

Section 1: Set-Up	
Environment/Personnel	
Clinical Setting/Room Type	Outpatient Clinic Exam Room
Prebrief Room(s) Needed	Yes, for 4 participants plus 3 team members
Debrief Room(s) Needed	Yes, for 4 participants plus 2 team members
Embedded Simulation Persons	Yes, one family member
Standardized Patients	Gaumard HAL® high-fidelity mannequin
Patient Voice	Team member to portray voice
Video Recording	No
Video Streaming	No, students will observe from observation room
Record Debriefing	No
Debrief Assistance	Yes, team member to lead debrief
Mannequin(s) and Accessories	
Mannequin(s)	Adult male
Case title if programmed in mannequin.	Not programmed
Bed type/patient position	Outpatient exam table
Mannequin gender/attire/wig	Gym shorts, t-shirt, black socks, tennis shoes
Moulage/Wounds/Dressing	None
Pt ID band(s)/code status	None
IV access	None
Supplemental O2	None
Patient on monitor	No
Monitor display	Temp HR NIBP RR O2
Medical Equipment	
Supply carts (Nursing supply, Code Cart,	Standard Med-Surgical Nursing Supply Cart Code Cart with manual defibrillator available in hall

Intubation Box…)	
Vitals monitor	Welch Allyn mobile vital signs unit
Oxygen	Rolling oxygen tank and tubing available
Pharmacy (Meds and Doses)	Ceftriaxone sodium 1g IV, 1000 mL normal saline 0.9%, Normal Saline 0.9% vials for IV infusion
IV Pump(s)	Allaris /Carefusion IV pump
Yankauer/suction	No
Consumable equipment available	Standard supplies in nursing care including PPE, rainbow lab tubes, intravenous supplies and tubing, syringes, flushes, blood glucose monitor
Patient Data	
Patient gender and age	Caucasian male age 76
Patient name	Terry Brown
Past Medical History	HTN, BPH, Dyslipidemia
Home Medications	Lisinopril 20 mg PO daily, chlorthalidone 12.5 mg PO daily, atorvastatin 40 mg PO daily, tamsulosin 0.4 mg PO daily
Allergies	Sulfa (rash reaction)
Vital Signs	B/P 110/76, T 37.3 C, P 92, RR 22, SaO2 94% RA
Lab Values	None available
Radiology Data	None available
Integrate EHR (Y/N)	No
Need paper chart	Yes
Section 2: Event Day	
Pre-Brief Plan	
Location	University of Kansas School of Nursing Clinical Learning Laboratory
Time Allotted	10 minutes
Faculty presenter	Dr. Diane Ebbert / Heide Chaney, DNP Candidate 2017
Plan (Suggested outline below): Welcome and Logistics (timeline, restrooms, pagers/phones) Overall Session Goal Confidentiality, Basic Assumption/Safe Learning Environment, Request for Buy-In Introduction to the Simulation Environment and Equipment Structure of the Session (Number of cases, participant plan, debrief plan)	

Questions?
Case Overview for Instructors/Facilitators
Overview of the case to serve as background when preparing for simulation and debriefing. This should include the history of present illness, as well as relevant past medical history etc. Mr. Brown is a 76 y/o male with a history of hypertension, hyperlipidemia, and benign prostatic hypertrophy presenting for shortness of breath. He was diagnosed with Influenza A two weeks ago and was prescribed Tamiflu. He has not been able to get back to his baseline. He has had a lingering cough and was coughing up yellow-colored sputum until two days ago. This morning, he felt a little more short of breath and called his daughter to ask her to bring him in to the clinic. She is concerned that he seems "not quite himself" today. This is a case of sepsis due to pneumonia.
Case Stem for Learners
This is the background information provided about the patient to the learners before they enter the room. Mr. Brown is a 76 y/o male with a history of hypertension, hyperlipidemia, and benign prostatic hypertrophy presenting for shortness of breath. He had Influenza A two weeks ago and we called in Tamiflu for him. He has been coughing up yellow sputum and just can't get back to his normal self. His daughter called for the appointment and brought him in. His vitals are on the chart and his medications are on the counter.
Information for Patient Voice
Please include information about past history and present illness that the patient should be prepared to provide. Please use layperson language. History of high blood pressure. Take two medications but can't remember the names. Takes a cholesterol medicine as well. Oh yes, and something to help you pee. Had that flu that has been going around two weeks ago. You called some medicine into the pharmacy for me. Have never felt so bad before. Glad that it is over. Was so sick. Started feeling better a week ago. Review of Systems (only if participants ask): Feels chilly. Still coughing. Not sleeping well because of cough. Was coughing up yellow gunk. Can't seem to catch breath today. Quit smoking 20 years ago. Some chest tightness. Feels fatigued. No vaccines, don't believe in them.
Information for Embedded Simulation Person (ROLE: Patient's daughter)
Please provide the information the ESP should be prepared to provide to learners if queried. Consider the recent history, apparent symptoms, and physical exam findings that may need to be provided. He was really sick with the flu but did better after the medicine was started. Lives alone. Wife passed five years ago from heart attack. Brought meals over for him. Did not visit him during illness as she and husband both work and couldn't afford to get sick and miss work. Talked on the phone every day. Gets around well for age. Called this morning. Said he just isn't getting better like he expected, breathing a bit harder. Ask to come to clinic. Maybe to get something for cough. Funny on the phone. Some comment about mom saying something. She has been gone

for five years. Laughed it off like it was a mistake. Not like him to do that. Memory is very good.
Takes medicines for hypertension and cholesterol. Brought bag with medicines. Used to smoke but quit about 20 years ago. Unsure if had any recent vaccines.

Section 3: Case Progression										
Baseline										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	Sa O2	RR
Open	Crackles in LLL	Regular	Normal	99.2	92	No monitor	110/76	Normal	94% RA	22

Expected Learner Actions	Mannequin Operator		Patient Vocalizations
Take history	Response	Prompts	In denial about evolving illness. Downplaying breathlessness. Focused on getting something for cough. Reluctantly admits to symptoms when asked.
Perform focused physical			
Recognize abnormal vital signs			
Asks for vitals to be repeated in 5 minutes			ESP: He was really sick with the flu, better medicine. Brought meals over, called every day. He called today, just isn't getting better. Asked for ride, maybe something for cough.
Transition to next state: 4 minutes			

State 1 (only need to note features that change)										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	Sa O2	RR
				99.2	99		100/74		90%	30
Trend time (to state vitals) –					1 min		1 min		1 min	1 min

Expected Learner Actions	Mannequin Operator	Patient Vocalizations

Reassess vitals	Response	Prompts If students not picking up on infection, increase coughing by patient If confusion not recognized and assessed increase comments	Makes comment about location or needing to go somewhere. Feeling lethargic and sleepy.
Verbalize altered mental status			
Verbalize screening for sepsis and use of qSOFA tool			
More thorough H&P to search for infection			ESP: States that he wasn't himself on phone. Some comment about mom. Daughter increasingly concerned and anxious
Request O2 at 4L/min	Improve SaO2 to 94%.		
Verbalize suspected sepsis			
Transition to next state: 4 minutes			

State 2 (only need to note features that change)										
Eyes	Lung	Heart	Bowel	Temp	HR	Rhythm	BP	Pulse	Sa O2	RR
				99.4	108		95/74		94%	30
Trend time (to state vitals) –					1 min		1 min		1 min	1 min

Expected Learner Actions	Mannequin Operator		Patient Vocalizations
Request vitals repeated every 5 minutes Request monitoring further change in mental status	Response	Prompts Daughter: does he need to go to the hospital? I haven't seen him like this	Continued lethargy and sleepy.
Continue O2 at 4L/min	SaO2 remains at 94%		ESP: Daughter helpful with questions but very concerned and anxious.
Check body for sources (wounds, indwelling devices)			
Request IV placement and fluid bolus (30 mL/kg NS) if available			

Request lab (CBC, CMP, PT/INR, FBS, lactate)			
Request urinalysis, place catheter, I&O Request ceftriaxone 1g IV if available Verbalize need for transfer to acute care			
Transition to next state: 4 minutes			
Section 4: Debriefing Plan			
Reactions Phase: The purpose of this section is to clear the air so a learning conversation can occur. Try to avoid discussions of how it went, but rather given participants a chance to vent about how they feel.			
Thanks, everyone, for participating. I'd like to start by hearing how you were feeling during the case?			
Facts: Provide the basic facts about the case so participants don't spend time debating or wondering what was going on with the patient. Should be no more than 2-3 sentences.			
Before we dig into the debriefing, I just want to clarify the medical facts of this case. Mr. Brown was a Caucasian male who, as he sat in the clinic, began to have increased respirations and confusion due to sepsis. Any questions?			
Preview: Provide an outline of the topics (usually 2-3) you would like to discuss during the debriefing, which will help put participants at ease and encourage them to follow your lead. These topics will likely relate to your learning objectives, but sometimes to unexpected events that occurred and will make great teaching points.			
I know these cases can be very challenging, and that things may not have gone exactly as you would have liked. I think that is ok, and that we can learn a lot from the experience. The topics that I'd like to discuss during this debriefing are screening tools that are available to us when we suspect sepsis in a patient, the steps we need to take if we suspect that a patient in the clinic is developing sepsis, what we have available to us in the clinic setting that might help this patient if we think they are developing sepsis, and teamwork in the clinic setting. Does that sound okay?			
Explore/Understand Objective #1: For each objective, start with an introduction such as, "First I'd like to talk about closed-loop communication." Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.			
First, I'd like to discuss the screening tools that are available to us when we suspect sepsis in a patient.			
Explore/Understand Objective #2: Clear transition to next objective. Then, consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and			

then generalize from this simulation to other patient scenarios.
Next, I'd like to discuss the steps we need to take if we suspect that a patient in the clinic is developing sepsis.
Explore/Understand Objective #3: Clear transition to next objective. Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
Now, I'd like to discuss what we have available to us in the clinic setting that might help this patient if we think they are developing sepsis.
Explore/Understand Objective #4: Clear transition to next objective. Then consider an Advocacy-Inquiry Statement to uncover participant frames. Consider the "I saw / I think / I wonder" structure. Once you uncover a frame, explore further, provide discussion/input, and then generalize from this simulation to other patient scenarios.
Lastly, I would like to discuss teamwork in situations like this one.
Summary: Ask Learners to summarize their "take-away."

Note. HR = heart rate; NIBP = non-invasive blood pressure; RR = respiratory rate; O2 = oxygen; IV = intravenous; PPE = personal protective equipment; HTN = hypertension; BPH = benign prostatic hypertension; B/P = blood pressure; T = temperature; P = pulse; SaO2 = oxygen saturation; RA = room air; LLL = left lower lobe; ESP = embedded simulation person; mL/kg = milliliters per kilogram; CBC = complete blood count; CMP = comprehensive metabolic panel; PT/INR = prothrombin time/international normalized ratio; FBS = fasting blood sugar.

Appendix M - Demographic Data

PIN	Age	Gender	Degree Last Completed
11	37	Female	APRN
22	30	Female	BSN
33	29	Female	BSN
44	52	Female	APRN