THE IMPACT OF COVID-19 ON THE WORK SYSTEM'S INFLUENCE ON CARE PROCESSES AND AMBULATION OUTCOMES

by

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Ambulation is one of the most frequently reported missed nursing care activities for hospitalized patients. The COVID-19 pandemic forced hospitals to make systems changes to minimize transmission of the disease and compromised the ability of hospitals to promote ambulation. The impact of systems changes on ambulation care processes was unknown, creating a gap in the literature. This study aimed to address this gap in knowledge by exploring hospital changes influencing ambulation from a systems perspective A single case study research design was used to explore the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes. A systems perspective of ambulation was achieved by using the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety to guide the study.

A large academic medical center located in the southeast region of the United States (U.S.) was selected as a critical case for this single case study research design. Purposeful sampling was used to select 12 leaders representing the following disciplines: nursing, physical therapy, occupational therapy, respiratory therapy, and epidemiology/infection prevention. The primary source of data was interviews, which were triangulated with documents and direct observations. Data analysis included first and second cycle coding for labels, sorting for patterns,

identifying outliers, and reflecting. Patterns were identified using Microsoft Word documents, drawings, matrices, and models/diagrams. Analysis revealed the patterns of influence of COVID-19 on ambulation care processes. The findings were categorized as the external environment, work system, and ambulation care processes.

Findings showed COVID-19 was a significant source of stress on the work system. This additional stress from the pandemic forced changes in the daily operations of the work system. Although changes were necessary, they were barriers to ambulation (staff shortages, visitor restrictions, and mask supply shortages) which disrupted usual care processes. When visitor restrictions removed family members from the work system, the value of informal ambulation care processes provided by family members was revealed.

This study is significant in providing new knowledge related to informal ambulation care processes and broadening the definition of external environment to include pandemics. Understanding how the external environment and work system influence informal care processes may help facilitate the design of system-level ambulation policies and programs. Future studies should further examine the value of informal care processes occurring in the hospital setting.

The Impact of COVID-19 on the Work System's Influence on Care Processes and Ambulation Outcomes

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DEDICATIONS

This dissertation is dedicated to my husband, Marke Hooker. I am forever grateful for your prayers and unconditional love. Thank you for your wisdom and unwavering belief in my ability to cross the finish line. I love you.

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The completion of this dissertation was truly a team effort that included the support of many people. To start, I give God praise for providing steadfast hope throughout this journey. I would also like to thank my family, Marke, Mom, Dad, and Kimberly, for always believing in me.

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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Infection
COVID-19	Coronavirus Disease 2019
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
PPT	PowerPoint
QUAL-qual	A qualitatively-driven mixed-method research design
QUAL	Qualitative method used as a core component
qual	Qualitative method used as a supplemental component
SEIPS	Systems Engineering Initiative for Patient Safety
μg/mL	Micrograms per milliliter

CHAPTER 1: INTRODUCTION

Missed, delayed, or incomplete nursing care are considered patient safety issues and errors of omission (Kalisch & Williams, 2009). According to a systematic review of 42 studies, approximately 55% to 98% of acute care nurses reported missing at least one item of nursing care during their shift (Jones et al., 2015). Research suggests that missed nursing care has been associated with adverse events (Kalisch et al., 2014; Palese et al., 2015; Simpson & Lyndon, 2017), readmissions (Brooks-Carthon et al., 2016; Carthon et al., 2015), infections (Nelson & Flynn, 2015), non-ventilator hospital-acquired pneumonia (Quinn et al., 2014; Tesora et al., 2018), post-surgical mortality (Ball et al., 2018), and decreased patient satisfaction (Lake et al., 2016). A recent scoping review of the literature confirmed the continued association between missed nursing care and negative patient outcomes (Kalankova et al., 2020).

In Kalisch's (2006) seminal work on missed nursing care, ambulation was identified as one of nine nursing care activities regularly missed by medical-surgical nursing staff. Reasons for missed ambulation included lack of time, staff shortages, and/or patient refusal. Ambulation continues to be one of the most frequently reported missed nursing care activities for hospitalized patients (Kalisch et al., 2011; Friese et al., 2013; Maloney et al., 2015; Smith et al., 2018; Winsett, et al., 2016). Even if ambulation alternatives are used (i.e., sitting in a chair), patients are at risk for negative outcomes, such as the inability to perform activities of daily living or even death (Brown et al., 2004).

Recent events have compromised the ability of hospitals to promote ambulation for patients. In particular, the world faced an unprecedented pandemic with the emergence of the coronavirus disease 2019 (COVID-19) which impacted the delivery of patient care activities. For example, hospitals were required to make systems changes to minimize the transmission of the

disease, which included policies and protocols limiting patient mobility, increasing the use of personal protective equipment, and decreasing visitors (Centers for Disease Control and Prevention, 2020). The impact of these systems changes on inpatient ambulation is unknown. Therefore, this dissertation study aims to address this gap in knowledge by exploring hospital changes influencing ambulation from a systems perspective. This chapter will provide a background on patient ambulation, the potential impact of the COVID-19 pandemic on ambulation, and the theoretical model guiding the design of the dissertation study.

Background to the Problem

While hospitalized, patients spend an average of 83% of their time lying in bed (Brown et al., 2009). Even if patients are willing and able to walk independently, medical inpatients can spend an average of 20 hours each day in bed (Brown et al., 2009). Research shows the length of time on bed rest is directly related to a patient's recovery from orthostatic intolerance (Fox et al., 2018). When patients are not ambulated complications may occur (Brown et al.,2004; Doherty-King et al., 2014; Pottenger et al., 2019).

Complications of Immobility

Complications of immobility include muscle weakness, orthostatic hypotension, deep vein thrombosis (DVT), and decreased cardiac reserve (Dittmer & Teasell, 1993; Teasell & Dittmer, 1993). Additional complications of immobility include decreased ventilation, atelectasis, decreased metabolic rate, constipation, decubitus ulcers, delirium, and increased walking dependence (Dittmer & Teasell, 1993; Teasell & Dittmer, 1993). Bed rest has been associated with a decline in activity of daily living, new institutionalization, and death (Brown et al., 2004).

Ambulation Facilitators and Barriers

Researchers have studied interventions designed to facilitate ambulation and decrease immobility. Examples of these interventions include the use of exercise programs (Brassil et al., 2014; Bryant et al., 2017), as well as mobility and ambulation programs (Brassil et al., 2014; Bryant et al., 2017; King et al., 2016; Teodoro et al., 2016). Additional facilitators include trained staff (i.e., mobility techs/aides, and restorative aides), and surveillance, such as nurse leader rounding (Doherty-King & Bowers, 2011). Devices used to facilitate ambulation include pedometers (Hamilton et al., 2019; Low et al., 2018; Teodoro et al., 2016), accelerometers (Brown et al., 2009; Sallis et al., 2015), and the ambulation platform apparatus (Henecke et al., 2015).

Despite efforts to facilitate ambulation, hospitalized patients often encounter barriers that influence ambulation. Research on ambulation barriers has been growing for over 15 years. Examples of these barriers include physician orders (Brown et al., 2009; Doherty-King & Bowers, 2013), acuity levels (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011), patient equipment (i.e., urinary catheter) (Brown et al., 2006), perceived support from nurses or physicians (So & Pierluissi, 2012), and resources (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011; Hamilton et al., 2018).

COVID-19 Pandemic and Missed Ambulation

The COVID-19 pandemic created an unprecedented time in history. This novel coronavirus was first identified in Wuhan, China in December 2019 and was officially named "COVID-19" on February 11, 2020 (World Health Organization, 2020). In July 2020, COVID-19 had infected approximately 3 million people in the United States (U.S.) (Center for Systems Science and Engineering, 2020). By March 2022, over 79 million people in the U.S. had been

infected with COVID-19 (Centers for Disease Control & Prevention, 2022). At the beginning of the pandemic, the most frequently reported symptoms included fever (83-99%), cough (59-82%), fatigue (44-70%), anorexia (40-84%), and shortness of breath (31-40%) (Centers for Disease Control and Prevention, 2020). Over the past two years, there have been opportunities to learn more about COVID-19; therefore, an abundance of research is now available about the most frequently reported symptoms, risk factors, prevention, and treatment of COVID-19.

Transmission of COVID-19 continues to spread through respiratory droplets when a person with COVID-19 speaks, coughs, sneezes, or spits. Depending on the proximity of the person, the droplets can be inhaled or simply land in the mouth, nose, or eyes of another person. To prevent the spread of the disease, the Centers for Disease Control and Prevention (CDC) provided recommendations for infection prevention. The initial recommendations included forced inactivity (Valenzuela et al., 2020) for hospitals, businesses, and people. For example, patient movement in the hospital setting was limited or restricted, requiring patients to stay in their rooms unless medically necessary (Centers for Disease Control and Prevention, 2020).

Existing research shows inpatient ambulation is medically necessary for patients with COVID-19. Researchers have shown that COVID-19 patients are subject to deep vein thrombosis (DVT) and pulmonary embolism (Marone & Rinaldi, 2020; Skeik et al., 2020). Studies have shown COVID-19 patients have an increased coagulation activity, evidenced by increased d-dimer concentrations greater than 1 μg/mL (Skeik et al., 2020; Zhou et al., 2020). Early ambulation was included as a prophylaxis strategy for COVID-19 patients at Minneapolis Heart Institute at Abbott Northwestern Hospital (Skeik et al., 2020); however, the logistics for sustaining an early ambulation program were not provided.

Missed ambulation during the COVID-19 pandemic is not only a safety issue but also an issue requiring critical input from operational leadership within the organization. During pandemic conditions, leaders were responsible for decisions about employee safety, as well as the delivery of patient care. These decisions were influenced by multiple factors related to infection prevention and safety requirements/mandates. It was important to explore how these factors interacted with each other as a system, and ultimately influenced patient ambulation.

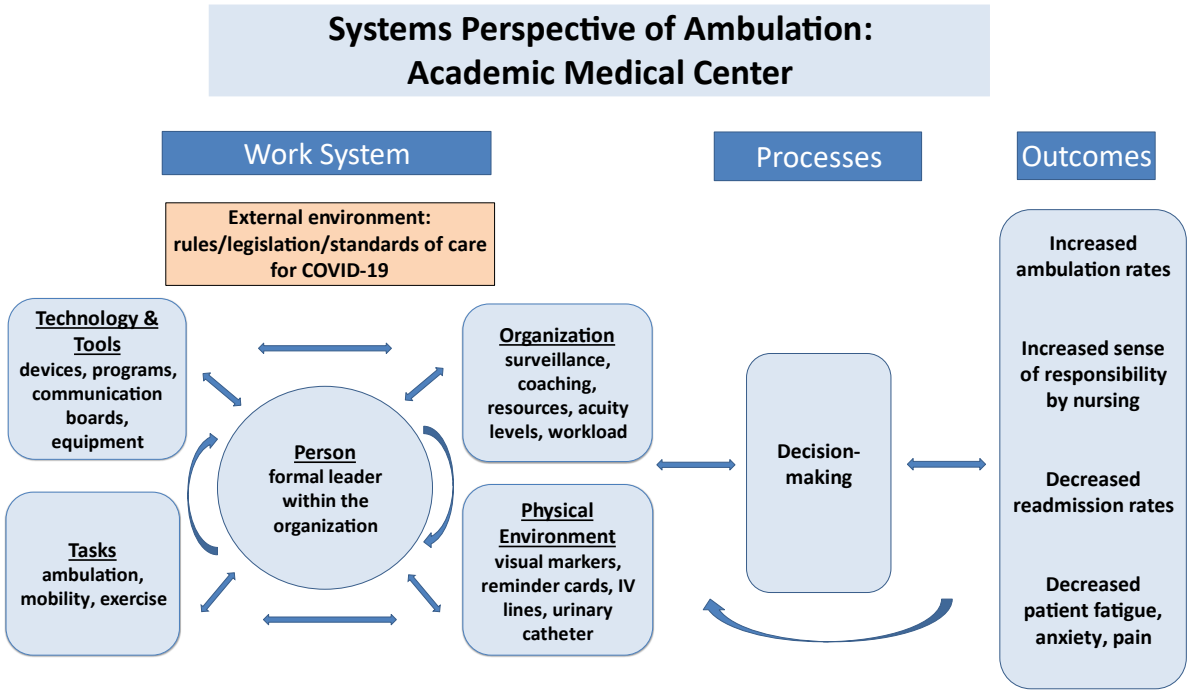
A systemic approach is congruent with suggestions from a 2014 study conducted by Kalisch and colleagues about the association between missed nursing care and patient-reported outcomes. When reviewing missed ambulation, they identified the need for system changes, such as nursing interventions and policies to increase mobility, as well as system improvements (i.e., staffing, checklists) (Kalisch et al., 2014). Because changes in the system can impact ambulation, a work system and patient safety model was selected to guide this study.

SEIPS Theoretical Model

The Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety was used to guide this study. The SEIPS model is based on the work system model developed by Smith and Carayon-Sainfort (1989), and Donabedian's (1988) structure-process-outcome (SPO) framework. The SEIPS model is one of the most widely used healthcare human factors models and has also been used in nursing research (Holden et al., 2013; Steege & Dykstra, 2016; King et al., 2016). There are feedback loops between the work system, processes, and outcomes that allow interactive, shared responsibility for systems issues such as ambulation (see Figure 1). The following components of the SEIPS model (Carayon et al., 2014) will be discussed: external environment, work system, processes, and outcomes.

Figure 1

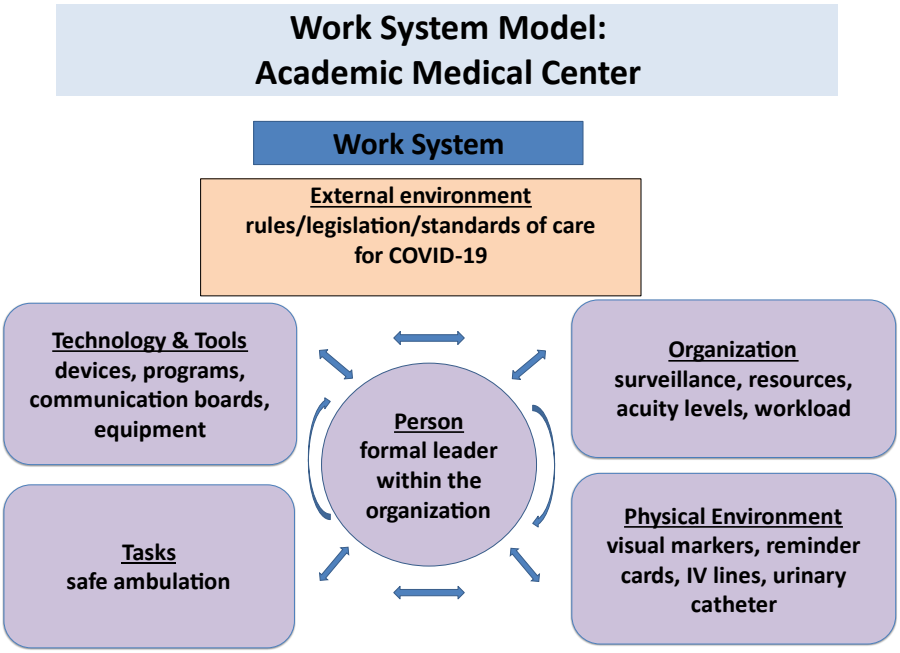
Theoretical Model: Systems Perspective of Patient Ambulation Based on a Review of the Literature



Note. Adapted with permission from "Human factors systems approach to healthcare quality and patient safety," by Carayon, P., Wetterneck, T. B., Rivera-Rodriguez, A. J., Hundt, A. S., Hoonakker, P., Holden, & R., Gurses, A. P., 2014, *Applied Ergonomics, 45*(1), p. 15. (https://doi.org/10.1016/j.aspergo.2013.04.023).

Figure 2

Research Model: Work System Model for Dissertation



Note. Adapted with permission from "Human factors systems approach to healthcare quality and patient safety," by Carayon, P., Wetterneck, T. B., Rivera-Rodriguez, A. J., Hundt, A. S., Hoonakker, P., Holden, & R., Gurses, A. P., 2014, *Applied Ergonomics*, *45*(1), p. 15. (https://doi.org/10.1016/j.aspergo.2013.04.023).

External Environment

The external environment includes any extra-organizational standards, legislation, or characteristics of the healthcare industry and/or workforce (Carayon et al., 2014). For this study, the *external environment* was defined as the rules, legislation, and/or standards of care for COVID-19 (see Figure 2).

There is limited research informing the systems effect of the external environment on ambulation. In the research available, the external environment is associated with standards of care and practice imposed by external organizations. For example, three studies (Brown et al.,

2006; Brown et al., 2009; Doherty-King et al., 2014) included extra-organizational standards, such as standards of care for mobility of older, hospitalized patients (Brown et al., 2009; Doherty-King et al., 2014) and standards of practice related to falls and restraints (Brown et al., 2006). These standards were not considered within the system; therefore, they did not influence the design or outcomes of the studies.

Work System

The work system is the structure of an organization in which patient care is provided (Carayon et al., 2006). The SEIPS work system includes the following components: person; organization; technology and tools; tasks; and physical environment (Carayon et al., 2006; Carayon et al., 2014). The work system model is dynamic, meaning changes within one component of the work system, will result in changes throughout the work system. For this study, the *work system* was defined as an academic medical center located in the southeastern region of the U.S.

Person

Within the SEIPS model, the person is the center of the work system. This means the work system should be designed to support and enhance the work of this person. Within the SEIPS model, person has been defined as a healthcare provider, health care team, and/or the patient. This definition has evolved to include people who interact with the patient, such as "family members and informal (lay) caregivers" (Carayon et al., 2014, p. 17).

For this study, *person* was defined as a formal leader at the manager level or higher who made decisions about policies and procedures related to patient ambulation during the COVID-19 pandemic. This definition of person was used because leadership knowledge and decision-making were critical to sustaining the work system during the COVID-19 pandemic. Focusing on

the leadership perspective of ambulation provided a systems-level, interdisciplinary view of ambulation in the work system.

Research shows leaders can influence patient ambulation by increasing awareness of a patient's pre-hospitalization walking ability with his/her staff (Doherty-King & Bowers, 2013). This awareness allows others to understand changes in functional status and set goals with patients. Leaders can also set clear expectations for their staff and enforce those expectations (Doherty-King & Bowers, 2013). These expectations included assigning responsibility for patient ambulation to various staff, such as nurses (Pottenger et al., 2019), nursing assistants (Abate et al., 2011; Hamilton et al., 2018), mobility teams (Pottenger et al., 2019), mobility techs (Hamilton et al., 2018), mobility aides (King et al., 2016), physical therapists (Pottenger et al., 2019), and physical therapy aides (Abate et al., 2011).

Tasks

In the literature, ambulation has been defined as a nursing task (Kalisch, 2006; Kalisch et al., 2009). Conceptually, ambulation is a form of mobility (Moulton et al., 2019). Evidence suggests mobility and ambulation are related concepts, where ambulation is a level or form of mobility. (Brown et al., 2009; Dermody & Kovach, 2017; Dermody & Kovach, 2018; Doherty-King et al., 2014; Hamilton et al., 2018; Pottenger et al., 2019; Yoon et al., 2014). For this study, *tasks* were defined as safe ambulation. Safe ambulation was defined as walking (with or without assistance) with the appropriate personal protective equipment (i.e., mask), in the appropriate location (i.e., hallway, patient's room), and with the appropriate resources (i.e., assistance, device).

There are several ways to measure ambulation, including step counts using accelerometers or pedometers (Abate et al., 2011; Sallis et al., 2015; Teodoro et al., 2016),

ambulation frequency (i.e., occurrences), or ambulation distance (i.e., distance measured in feet) (Henecke et al., 2015; King et al., 2016). Ambulation has also been associated with other factors that can be measured, including patient refusal rate (Abate et al., 2011), readmission rate (Low et al., 2018), length of stay (Henecke et al., 2015), resources needed for mobility (Pottenger et al., 2019), time-to-mobility (Pottenger et al., 2019), discharge disposition (Hamilton et al., 2018; Henecke et al., 2015), and staff needed for patient ambulation (Henecke et al., 2015).

Technology and Tools

According to the SEIPS model, technology and tools include any "health information technology, medical devices, and other tools and technologies" (Carayon et al., 2014, p. 16). For this study, *technology and tools* were defined as barriers and/or facilitators to ambulation, whether real or perceived, and either past or present. Technology and tools included mobility and ambulation programs (Brassil et al., 2014; Bryant et al., 2017; King et al., 2016; Teodoro et al., 2016), pedometers (Hamilton et al., 2019; Low et al., 2018; Teodoro et al., 2016), accelerometers (Brown et al., 2009; Sallis et al., 2015), and the ambulation platform apparatus (Henecke et al., 2015). The communication boards commonly referred to as "whiteboards," were another tool used by nurses and other healthcare professionals to communicate with the patient, family, and each other about questions, goals, and scheduled activities.

Research studies provided several barriers and facilitators to using technology and tools for patient ambulation. Barriers included cost (Henecke et al., 2015), reliability (Low et al., 2018), technical issues (Low et al., 2018; Sallis et al., 2015), and human factors (i.e., usability of device, loss of device). The use of technology and tools has improved ambulation refusal rates (Abate et al., 2011), increased nurse satisfaction with ambulation (Henecke et al., 2015),

increased ambulation occurrences and distance (King et al., 2016), and decreased length of hospitalization (Brassil et al, 2014).

Physical Environment

According to the SEIPS model, the physical environment is defined as "the physical layout, workstation design, noise, lighting, temperature, and humidity; air quality" (Carayon et al., 2014, p. 16). In this study, the *physical environment* was defined as restricted and non-restricted areas in the medical center for patient ambulation, including relevant signage and visual displays. Research shows the physical environment, such as the layout, lighting, noise, temperature, and workstation design can affect patient ambulation rates. There are objects in the physical environment that discourage ambulation (barriers) and objects that promote ambulation (facilitators) (see Figure 1). The presence of intravenous lines, use of a urinary catheter, use of restraints, and/or unfamiliarity with the hospital environment have been reported as barriers to patient ambulation (Brown et al., 2006). Adding visual markers on the floors to measure ambulation distance, communication boards, and ambulation pathways have been shown to improve the physical environment, increasing both ambulation frequency and ambulation distance (King et al., 2016). Using the patients' whiteboards for daily goals, providing walking reminder cards, and placing magnetic footprints on the patients' doors were environmental modifications that increased ambulation rates (Teodoro et al., 2016).

Organization

The organization includes the informal and formal organization, including culture, rules, procedures, and/or leadership structure (Carayon et al., 2014). In this study, *organization* was defined as informal and formal culture, such as changes, policies, or people. Evidence of organizational elements related to ambulation was obtained from a variety of sources, such as

documentation of ambulation programs, emails, and/or policies and training related to ambulation or mobility.

According to the literature, organizational elements are either a barrier or facilitator to ambulation (see Figure 1). Organizational barriers to ambulation include resources (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011; Hamilton et al., 2018); lack of out-of-bed mobility orders (Brown et al., 2009; Doherty-King & Bowers, 2013); acuity levels (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011); lack of support from nurses or physicians and/or active discouragement (So & Pierluissi, 2012). Organizations facilitated ambulation by using surveillance and increased accountability, such as nurse leader rounding and shift reports including updates on patient ambulation (Doherty-King & Bowers, 2011).

Processes

Processes include care processes and other processes supporting the delivery of safe patient care (Carayon et al., 2014). For this study, *processes* were specific to care processes and defined as supportive behaviors influencing ambulation. Research shows the behaviors of patients and nurses can be barriers to ambulation in the inpatient setting. For example, many patients are willing and able to walk independently; however, they decide to spend 90% of their hospitalization in bed (Brown et al., 2009). Patients decide to stay in bed due to weakness, fatigue, pain, or fear of falling (So & Pierluissi, 2012). One study suggested nurses do not consider a decline in walking ability a preventable complication, such as a hospital-acquired decubitus ulcer (Doherty-King & Bowers, 2011). If nurses encounter barriers to ambulation, they often select other strategies (i.e., sequential compression devices, sitting in the chair) to prevent mobility-related complications (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011).

Outcomes

According to the SEIPS model, outcomes of care include the following: patients, employees, and the organization (Carayon et al., 2006, Carayon et al., 2014). For this study, *outcomes* were defined as ambulation outcomes. Research shows positive patient outcomes associated with mobility and exercise programs. These outcomes include an increase in ambulation occurrence, distance, rates, increased social interaction, decreased fatigue, anxiety, and pain (Brassil et al., 2014; Bryant et al., 2017; King et al., 2016; Teodoro et al., 2016). Nursing outcomes include an increased sense of responsibility for ambulation, increased sense of nursing pride, improved clinical skills related to ambulation, and increased confidence (King et al., 2016). Organizational outcomes were mixed, with some research showing a decrease in length of stay (Brassil et al., 2014) and readmission rates (Low et al., 2018); while other studies did not show a significant decrease in the length of stay (Hamilton et al., 2018; Henecke et al., 2015).

COVID-19 and the Work System

COVID-19 resulted in many organizational changes in the work system which created barriers to patient ambulation. Examples of these barriers included decreased resources (Wu et al., 2021). Examples of these resources included masks (Sickbert-Bennett et al., 2020) and nursing staff (Lasater et al., 2020). Isolation orders related to COVID-19 influenced out-of-bed orders, resulting in inactivity (Centers for Disease Control and Prevention, 2020). In addition, patients may refuse ambulation efforts because of difficulties wearing a mask and/or fear of infection (Sugg et al., 2021).

COVID-19 also introduced a variety of technology and tools used to monitor and track the virus (i.e., dashboard), as well as monitor and track resources (i.e., supplies, staff) (Vaishya

et al., 2020). Hands-free, real-time voice communication devices were used as a way for members of the healthcare team to communicate with each other and minimize the number of people entering isolation rooms. Other examples of technology used during the pandemic include mobile devices (i.e., tablets), and robotics for mobile monitoring (Scott et al., 2020; Vaishya et al., 2020).

Statement of the Problem

Missed nursing care is the delay or omission of required patient care (Kalisch, 2006; Kalisch & Williams, 2009); however, the impact of COVID-19 on patient ambulation was unknown. Existing research provided individual interventions or programs focused on improving ambulation in a non-pandemic work environment. Although these findings inform nursing practice, there is a lack of information about how the pandemic influenced the work environment and ambulation care processes.

Central to the work system, leaders are able to influence systems-level changes within the organization related to patient ambulation. Due to the gap in missed care research and to further understand why missed ambulation is frequently cited, the dynamics between ambulation outcomes, the external environment, work system, and care processes were examined. To this student researcher's knowledge, this was the first study exploring the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes.

Purpose of the Study

The purpose of this single case study was to explore the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes.

Research Question

How did the COVID-19 pandemic impact the work system's influence on organizational care processes and ambulation outcomes?

Theoretical Propositions

A theoretical proposition is a statement suggesting the relationship between two or more variables (Johnson & Webber, 2015). These statements were used to guide data collection and analysis (Yin, 2018). For this study, propositions were based on the SEIPS model of work system and patient safety (Carayon et al., 2006). The following theoretical propositions are posited:

1. Ambulation is a form of mobility and is a frequently missed nursing care task in hospitals.
2. Missed nursing care, such as ambulation, is a systems issue involving components of the work system and external environment.
3. The work system influences care processes and ambulation outcomes.
4. The external environment impacts the work system, care processes, and ambulation outcomes.

Definitions

The conceptual definitions were operationalized to reflect the SEIPS model in a specific and measurable way (Johnson & Webber, 2015). The operational definitions used for this study are provided below.

External Environment

The external environment was operationalized as the extra-organizational rules or requirements imposed on the medical center due to COVID-19. The issues, rules, or

requirements were imposed by the CDC, the State Health Department, and/or other state, local, or federal organizations. Examples of requirements from the CDC included canceling elective procedures, limiting entry to the hospital, and screening everyone for COVID-19 symptoms.

Work System

The work system was operationalized as an academic medical center located in the southeastern region of the US. This medical center has over 950 beds, including multiple specialty hospitals.

Person

Person was operationalized as a formal leader at the manager level or higher who influenced policies and/or procedures related to patient ambulation during the COVID-19 pandemic. Examples of leaders include managers and directors from a variety of disciplines including nursing, physical therapy, respiratory therapy, and infection prevention.

Tasks

Tasks were operationalized as the leaders' experiences with inpatient ambulation. This student researcher developed the following definition for safe ambulation: walking (with or without assistance) with the appropriate personal protective equipment, in the appropriate location, and with the appropriate resources.

Technology and Tools

Technology and tools were operationalized as devices, programs, communication boards, and equipment available for safe ambulation. For example, tools included the patients' communication boards in their room, reminder cards, and/or magnetic footprint on the patients' doors (Teodoro et al., 2016).

Physical Environment

The physical environment was operationalized as areas for patients to ambulate within the hospital, such as medical units and surgical units. Visual markers on the floors or walls, as well as intravenous lines or urinary catheters that restrict mobility, were included in the physical environment. Due to COVID-19, the physical environment also included educational posters (i.e., visitor restrictions, masks) and restricted areas inside the hospital (i.e., patient rooms, COVID-19 units).

Organization

Organization was operationalized as informal and formal culture, such as changes, policies, and people. Organizational elements were measured using surveillance (i.e., interviews), and resources (i.e., documents).

Processes

Processes were operationalized as supportive behaviors influencing ambulation. Examples of these behaviors included decision-making by formal leaders regarding ambulation, such as responsibility, delegation, and prioritization.

Outcomes

Outcomes were operationalized as the leader's perspective and/or experience with ambulation outcomes during a pandemic.

Conclusion

This chapter describes a case study design to investigate the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes. For the hospitalized patient, there are several factors contributing to missed ambulation; therefore, leaders were asked to provide a systems-level perspective of ambulation. The SEIPS model provided a systems

framework for investigating the impact of COVID-19 on ambulation care processes and outcomes. The next chapter provides the results of a literature review completed to determine the state of the science regarding best practices for patient ambulation in the hospital setting.

This dissertation research study is presented using the College of Nursing's two manuscript option. Manuscript One presents a detailed account of the methodology based on the proposed use of a qualitatively-driven mixed-method design and replaces the traditional dissertation Chapter 4. Manuscript Two reports the findings from this dissertation and is a replacement for the traditional dissertation Chapter 5.

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CHAPTER 2: REVIEW OF THE LITERATURE

The purpose of this dissertation study was to explore the impact of the coronavirus disease 2019 (COVID-19) on the work system's influence on care processes and ambulation outcomes. This chapter provides the results of a review of the literature conducted to determine the state of the science regarding best practices for ambulation of patients in the hospital setting. Understanding best practices was important since ambulation continues to be reported as missed nursing care (Kalisch, et al., 2011; Friese et al., 2013; Maloney et al., 2015; Smith et al., 2018; Winsett, et al., 2016). Missed nursing care has been associated with negative patient outcomes, such as adverse events (Kalisch et al., 2014; Palese et al., 2015; Simpson & Lydon, 2017), infections (Nelson & Flynn, 2015), non-ventilator hospital-acquired pneumonia (Quinn et al., 2014; Tesora et al., 2018), post-surgical mortality (Ball et al., 2018), and decreased patient satisfaction (Lake et al., 2016). The review of the literature revealed a need for additional inquiry guided by the following research question: How did the COVID-19 pandemic impact the work system's influence on organizational care processes and ambulation outcomes? Whittemore and Knafl's (2005) methodology was used for this review of the literature and the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety (Carayon et al., 2014) was used to guide the analysis and organization of the findings.

Impact of COVID-19 on Research Question

The COVID-19 pandemic created an unprecedented time in history. This novel coronavirus was first identified in Wuhan, China in December 2019 and named "COVID-19" on February 11, 2020 (World Health Organization, 2020). To prevent the spread of the disease, the Centers for Disease Control and Prevention (CDC) provided recommendations for infection prevention. These recommendations limited and/or restricted patient movement in the hospital,

requiring patients to stay in their assigned rooms unless medically necessary (Centers for Disease Control and Prevention, 2020).

Research evidences that patient ambulation during hospitalization is medically necessary. There were multiple factors influencing patient ambulation, specifically restrictions related to infection prevention and safety. Interaction between these factors produced a systems response to the delivery of patient care, such as ambulation. To fully understand the impact of COVID-19 on systems-level decision-making, a systems approach was used based on a work system and safety model.

Theoretical Perspective

The SEIPS model of work system and patient safety was used to guide this literature review. The SEIPS model is based on the work system model developed by Smith and Carayon-Sainfort (1989) and Donabedian's (1988) structure-process-outcome (SPO) framework. This model is one of the most widely used healthcare human factors models and has also been used in nursing research (Holden et al., 2013; Steege & Dykstra, 2016; King et al., 2016). The SEIPS model includes the external environment, work system, processes, and outcomes (Carayon et al., 2014). The model is dynamic, meaning changes within one component will result in changes throughout the other components. Feedback loops between the work system, processes, and outcomes allow interactive, shared responsibility for systems issues such as ambulation.

Method

In consultation with a university librarian, a literature review was conducted using the methodology of Whittemore and Knafl (2005). The purpose of this review was to determine the state of the science regarding best practices for patient ambulation in the hospital setting. A comprehensive search, using PubMed, CINAHL, and PsychInfo with multiple search terms in

combination (walking OR ambulation OR ambulating OR exercise OR gait AND nurses OR nurse OR nursing personnel AND inpatients OR inpatient OR inpatients OR hospitalized OR hospitalization) was used.

Research studies with adult patients in non-intensive acute care units were included. The search was limited to studies conducted in the United States (U.S.) and published between 2006 and 2019, which provided information about patient ambulation in the hospital setting before the COVID-19 pandemic. Rehabilitation units were excluded from the search because they may have specific ambulation resources available. Quality improvement projects, literature reviews, and unpublished documents were also excluded.

Results

A total of 19 articles were included in this review: four qualitative studies, 14 quantitative studies, and one quantitatively-driven mixed methods study (King et al., 2016). Qualitative designs included grounded dimensional analysis (Doherty-King & Bowers, 2011; Doherty-King & Bowers, 2013) and qualitative descriptive (Bryant et al., 2017; So & Pierluissi, 2012). The quantitative designs included a single-blind randomized controlled trial (Hamilton et al., 2018); a comparison study (Abate et al., 2011); an observational cohort study (Low et al., 2018); three prospective cohort studies (Brown et al., 2006; Brown et al., 2009; Sallis et al., 2015); a prospective time and motion study (Pottenger et al., 2019); an exploratory study (Yoon et al., 2014); two descriptive correlational studies (Dermody & Kovach, 2017; Dermody & Kovach, 2018); a pretest/posttest, randomized, experimental design (Teodoro et al., 2016); a quasi-experimental design with non-random groups (Henecke et al., 2015); and a quasi-experimental repeated measures design (Brassil et al., 2014). Results of this review were organized based on the Systems Engineering Initiative for Patient Safety (SEIPS) model, which includes the external

environment, components of the work system (person; organization; technology and tools; tasks; physical environment), processes, and outcomes (Carayon et al., 2014).

Ambulation Outcomes

Research shows work system components and processes influence ambulation outcomes (see Figure 1 in Chapter 1). The following sections will describe the state of the science of each component of the work system as well as processes based upon a review of the literature. Ambulation outcomes will be included as barriers and facilitators of ambulation.

SEIPS Work System: Person

Within the SEIPS framework, person is defined as a single individual or group of individuals at the center of the work system (Carayon et al., 2014). The definition of person was a formal leader at the manager level or higher who influenced policies and/or procedures related to patient ambulation during the COVID-19 pandemic. Leaders were included in two studies (Doherty-King & Bowers, 2011; King et al., 2016). In the study by Doherty-King and Bowers (2011), three leaders were included and identified as nurse managers; however, no additional details or characteristics were provided about the leaders. In their study, King and colleagues (2016) included one leader, who was described as a nurse manager of a general medical unit. This nurse manager was a member of the research planning team, as well as a study participant. No additional details or characteristics (i.e., age, experience, educational level) were provided for this nurse manager (King et al., 2016).

Person Outcomes: Barriers

There was limited information in this review on ambulation barriers specifically associated with leaders. The findings from one study showed a lack of explicit leadership expectations for ambulation was a barrier (Doherty-King & Bowers, 2011). In particular, leaders

were a barrier when they did not hold staff accountable and did not provide "consequences" for missed ambulation (Doherty-King & Bowers, 2011, p. 793).

Person Outcomes: Facilitators

There was also limited information identifying how leaders facilitate ambulation. Research suggests leaders at the unit-level facilitated ambulation by enforcing unit-based expectations (Doherty-King & Bowers, 2011; Doherty-King & Bowers, 2013). Unit-based expectations were established by leadership rounding to observe ambulation and consistent accountability (i.e., coaching, or written counseling) for ambulating patients (Doherty-King & Bowers, 2011).

SEIPS Work System: Tasks

According to the SEIPS model, tasks are a "description and characteristics of tasks; variety, content, physical and psychological demands" (Carayon et al., 2014, p. 16). Studies from this review showed ambulation-related tasks can be conceptualized as *ambulation*, *mobility*, and/or *exercise* as concepts.

Concept: Ambulation

Within nursing research, ambulation has been defined as a nursing care task (Kalisch, 2006; Kalisch et al., 2009). *Ambulation* is a form or level of mobility and was included in nine articles (Abate et al., 2011; Brown et al., 2006; Doherty-King & Bowers, 2011; Doherty-King & Bowers, 2013; Henecke et al., 2015; King et al., 2016; Low et al., 2018; Sallis et al., 2015; Teodoro et al., 2016). The literature contained a variety of definitions for ambulation, including walking in the hall (Doherty-King & Bowers, 2011) or walking a minimum of 10 steps (Pottenger et al., 2019). Ambulation has also been described as various types of mobility events such as transferring, walking to and from the bathroom, walking within the patient room, and

walking in the hallway (Doherty-King et al., 2014; Yoon et al., 2014). These variations agreed with earlier qualitative findings where nurses revealed types of mobilizing, including ambulation (Doherty-King & Bowers, 2011).

Concept: Mobility

The concept of *mobility* (Moulton et al., 2019) was included in seven articles (Brown et al., 2009; Dermody & Kovach, 2017; Dermody & Kovach, 2018; Doherty-King et al., 2014; Hamilton et al., 2018; Pottenger et al., 2019; Yoon et al., 2014). Mobility is used to describe patient movement and has been defined as "the ability to move or be moved freely and easily" (Wald et al., 2019, p. 11). Findings from this review agree with evidence suggesting there are multiple uses and definitions of the concept of mobility (Smart et al., 2018). For example, mobility was described using levels (i.e., sitting, standing, walking) (Brown et al., 2009) or measured using mobility scales/instruments (Dermody & Kovach, 2017; Dermody & Kovach, 2018; Pottenger et al., 2019). Mobility was also described as four types of activities: transferring, walking to and from the patient's bathroom, walking in the patient's room, and walking in the hallway (Yoon et al., 2014). In one of the studies, a "culture of mobility" was associated with both ambulation and four exercise levels (sitting, standing, walking, and climbing stairs) (Hamilton et al., 2018, p. 273), confirming the use of multiple concepts in the literature.

Concept: Exercise

The concept of exercise is included in three articles (Brassil et al., 2014; Bryant et al., 2017; So & Pierluissi, 2012). Exercise is defined as a subcategory of physical activity that is structured and purposeful (Dasso, 2018); however, there are also many other definitions of exercise in the literature. For example, exercise has been described by patients as walking, "calisthenics" or climbing stairs; however, the majority (71%) defined exercise as walking (So &

Pierluissi, 2012, p. 715). Another study defined exercise as "mixed-modality," which included a combination of aerobic (walking or stationary bike) activity, resistance bands, and stretching (Bryant et al., 2017, p. 414). Exercise has also been a class offered to patients, including stretching, resistance, and muscle-strengthening activities (Brassil et al., 2014).

Task Measurement

Researchers used several quantitative methods to measure ambulation, such as step counts using accelerometers or pedometers (Abate et al., 2011; Sallis et al., 2015; Teodoro et al., 2016), ambulation frequency, or ambulation distance (Henecke et al., 2015; King et al., 2016). Researchers have also used quality measures with ambulation, such as patient readmission rate (Low et al., 2018), length of stay (Henecke et al., 2015), and discharge disposition (Hamilton et al., 2018; Henecke et al., 2015). In addition, ambulation has been measured using patient refusal rates (Abate et al., 2011), time-to-mobility (Pottenger et al., 2019), and resources needed (Henecke et al., 2015; Pottenger et al., 2019).

SEIPS Work System: Technology and Tools

Technology and tools include health information technology, medical devices, and any related human factors characteristics (Carayon et al., 2006; Carayon et al., 2014). The science of human factors focuses on the interactions among tools, technology, organization, persons, tasks, and the internal environment within the work system that impact ambulation (Carayon et al., 2006). In three studies (Hamilton et al., 2019; Low et al., 2018; Teodoro et al., 2016), researchers used tools such as pedometers (i.e., Fitbit, Fitbit Flex, Fitbit Charge, ShrinQ) to measure steps taken during ambulation. In two studies (Brown et al., 2009; Sallis et al., 2015) researchers used accelerometers (i.e., Tractivity) to measure a range of mobility activities, including ambulation. Only one study used a tool that helped patients during ambulation. The ambulation platform

apparatus (APA) provided stabilization of the patient and equipment during ambulation, so the patient and staff could focus on ambulation efforts (Henecke et al., 2015).

Researchers also used innovative, non-technological tools in their studies. One study used canine-assisted ambulation (i.e., therapy dog) with chronic heart failure patients (Abate et al., 2011). Communication tools, such as whiteboards (King et al., 2016; Teodoro et al., 2016) and educational videos (Teodoro et al., 2016) were used. Mobility and exercise programs were also used (Brassil et al., 2014; Bryant et al., 2017; King et al., 2016; Teodoro et al., 2016). One mixed-modality exercise program ("Motivated and Moving") included tools such as a stationary bike, yoga, exercise class, and/or the 6-minute walk (Brassil et al., 2014). Another study included an exercise program ("Exercise and Quality of Life in Leukemia Adults") with options of walking or use of a stationary bike along with resistance training (Bryant et al., 2017). King and colleagues (2016) used an investigator-developed, nurse-driven program ("Mobilizing Older Adult Patients Via a Nurse-Driven Intervention"), which included psychomotor skills training, whiteboards, and unspecified ambulation equipment.

Technology and Tools Outcomes: Barriers

There were several barriers documented in the literature with the use of technology and tools. Cost is suggested to be a barrier for the ambulation platform device ($4,000 to $5,000 each); however, the devices were provided free by the manufacturer for the study (Henecke et al., 2015). The use of reliable and valid technology for slow or assisted ambulation was mentioned in the literature (Low et al., 2018). Data could be inaccurate (underestimated) based on the way the pedometer or accelerometer is designed to calculate steps or movement. Other barriers include device failure (Low et al., 2018; Sallis et al., 2015); inability to wear the pedometer (allergy or swelling) (Low et al., 2018), and/or human factors, such as the loss of

devices (Sallis et al., 2015). For example, one study reported a loss of approximately 44% of the accelerometers due to a failure to remove them before the patient was discharged (Sallis et al., 2015).

Technology and Tools Outcomes: Facilitators

Tools, such as the canine-assisted ambulation, showed significant improvement ($p = .0002$) in ambulation refusal rates (Abate et al., 2011). The ambulation platform apparatus improved nurse satisfaction levels regarding ambulation (Henecke et al., 2015). Mobility and exercise programs were associated with positive patient ambulation outcomes, such as shorter lengths of hospital stay ($p = .005$) (Brassil et al., 2014); increase in ambulation occurrences ($p = .001$) and total ambulation distance ($p = .01$) (King et al., 2016); and increase ($p = 0.012$) in the amount of ambulation (Teodoro et al., 2016). Increased social interaction (i.e., personal trainers), as well as decreased fatigue, anxiety, and pain were perceived by patients participating in a mixed-modality exercise program (Bryant et al., 2017).

SEIPS Work System: Physical Environment

Within the SEIPS model, the physical environment includes factors such as the physical layout, lighting, temperature, noise, and workstation design (Carayon et al., 2014). There was limited detailed information available on the physical environment; however, there was general information about the type of unit. The physical environment included non-intensive acute care units, such as medical and surgical units. The studies showed nurses worked on units located in academic teaching hospitals (Doherty-King et al., 2014; Doherty-King & Bowers, 2011; Doherty-King & Bowers, 2013; Pottenger et al., 2019), and community hospitals (Dermody & Kovach, 2018; Dermody & Kovach, 2017). Within those hospitals, nurses worked in medical or surgical units (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011; Doherty-King &

Bowers, 2013; Doherty-King et al., 2014), a neuroscience unit (Pottenger et al., 2019), and a variety of non-intensive acute care units (neurology, cardiac, pulmonary, nephrology, oncology, and medical-surgical) (Dermody & Kovach, 2017).

Physical Environment Outcomes: Barriers

Research suggests that patient ambulation is hindered by environmental barriers. So and Pierluissi (2012) found that 43% of patients reported barriers such as intravenous lines or other devices, and/or unfamiliarity with the hospital environment. Urinary catheters and/or restraints have also been reported as environmental barriers (Brown et al., 2006). In addition, the findings from one study suggest a lack of ambulation pathways is also a barrier (King et al., 2016).

Physical Environment Outcomes: Facilitators

Research suggests modification to the physical environment improves ambulation. For example, King and colleagues (2016) conducted an intervention study with nursing staff on a 26-bed general medical unit of an academic teaching hospital. In the pilot study, Mobilizing Older Adult Patients Via a Nurse-Driven Intervention (MOVIN), visual markers were added on the floors to measure ambulation distance, communication boards, and "ambulation pathways that are interesting" (King et al., 2016, p. 2089). Researchers have also used the patients' whiteboards in their rooms for daily goals, provided walking reminder cards, and placed a magnetic footprint on the patients' doors (Teodoro et al., 2016). Time clocks have also been used to stamp patients' physical activity start and stop times (Brassil et al., 2014).

SEIPS Work System: Organization

According to the SEIPS model, the organization includes the informal and formal organization, including culture, rules, procedures, and/or leadership structure (Carayon et al., 2014). For this study, organization was operationalized as elements of culture (formal and

informal), such as leaders, resources, policies, expectations, workload, communication, and staffing.

Organization Outcomes: Barriers

Research evidences several organizational barriers to ambulation. The barriers include lack of nursing assistants (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011; Hamilton et al., 2018); lack of mobility technicians (Hamilton et al., 2018); ambiguous out-of-bed mobility physician orders (Brown et al., 2009; Doherty-King & Bowers, 2013); and high acuity levels (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011). The use of a dedicated mobility technician was not associated with a significant decrease in length of stay ($p = .62$) or readmission ($p = .89$) (Hamilton et al., 2018). Similarly, there was no significant increase in ambulation distance ($p = .595$) or decrease in length of stay ($p = .076$) when researchers used an ambulation platform apparatus (APA) to promote ambulation (Henecke et al., 2015). Even with the use of assistive devices, research shows ambulation requires the assistance of up to two staff members (Henecke et al., 2015; Pottenger et al., 2019).

One study showed the most frequently reported organizational barrier to ambulation was nursing workload (mean = 3.15, SD = 1.4) (Dermody & Kovach, 2018). For example, workload was increased when patients have medium or high levels of mobility limitations. Research shows 87% to 92% of patients required additional staff for mobility activities when the patient has medium or high levels of mobility limitations, respectively (Pottenger et al., 2019). Research suggests patient labeling occurs when nursing staff label a patient as high risk for falls, confused and/or requiring increased assistance with mobility (Doherty-King & Bowers, 2011). Patients also report organizational barriers such as perceived levels of support for ambulation from health care providers (i.e., nurses, physicians) (So & Pierluissi, 2012).

Organization Outcomes: Facilitators

Research suggests accountability is established by highly visible patient mobilization efforts (i.e., hallway ambulation), as well as updates written on the patients' whiteboard and included during end-of-shift report (Doherty-King & Bowers, 2011). Low and colleagues (2018) found that 100 additional steps per inpatient recovery day were associated with 17% lower risk of 30-day readmission and 18% lower risk of 60-day readmission. There is also research suggesting discharge disposition home is associated with at least 400 steps during hospitalization (Hamilton et al., 2018). In another study, patients accruing more points in a mobility program called "Motivated and Moving" had a decreased length of stay in the hospital ($p = .005$) (Brassil et al., 2014). However, there is research showing longer lengths of stay are not predictors of ambulation or increased steps (Sallis et al., 2015).

SEIPS: Processes

In the SEIPS model, processes include care processes and other processes supporting the delivery of safe patient care (Carayon et al., 2006). Findings from this review revealed processes were linked to decision-making between the nurse and patient. Ambulation was a complex decision-making process requiring patient involvement and often the involvement of multiple health care professionals (Doherty-King et al., 2014).

Processes: Barriers There was research suggesting nurses' and patients' decision-making about mobilization strategies could be a barrier to ambulation.

Barriers: Nurses' Decision-making. The literature showed a patient's phase (i.e., acute, recovery, discharge) of hospitalization (Doherty-King & Bowers, 2011) was considered by nurses when planning ambulation. For example, nurses were more likely to consider ambulation when the patient is recovering and more physiologically stable (Dermody & Kovach, 2017;

Doherty-King & Bowers, 2011). The literature also showed nurses make ambulation decisions based on an informal, risk assessment. An increase in perceived risk for injury to the nurse or patient was associated with a decreased likelihood of ambulation (Doherty-King & Bowers, 2011). In addition, there was evidence suggesting nurses do not consider a decline in walking ability a preventable complication, (Doherty-King & Bowers, 2011). If nurses encountered barriers to ambulation, they often decided to select other strategies (i.e., sequential compression devices, sitting in the chair) to prevent mobility-related complications (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011). This is concerning because sitting is an example of a low mobility task that has been shown to be an independent predictor of negative patient outcomes such as decreased ability to perform activities of daily living, new institutionalization, and death (Brown et al., 2004).

Barriers: Patients' Decision-making. Studies show patients are resistant to being mobilized and often refuse ambulation efforts by staff (Dermody & Kovach, 2017; Hamilton et al., 2018). More specifically, research shows patients often decline ambulation efforts due to symptoms, such as weakness, fatigue, pain, or fear of falling (So & Pierluissi, 2012). In a study with 45 participants, Brown and colleagues (2009) found that 77.8% were willing and able to walk independently; however, 33.3% of participants spent more than 90% of their hospitalization in bed. Doherty-King and colleagues (2014) found similar results in a time and motion study with 31.9% of 47 participants having no mobility events during an eight-hour observation period.

Processes: Facilitators There is limited information on specific processes that facilitate ambulation. One study suggests patients are initiating the majority of ambulation events, especially patients who require assistance (Doherty-King et al., 2013). Another study suggests

incentives are motivators for decision-making, such as competition and door markers for recognition (Brassil et al., 2014).

Implications for Research

The purpose of this literature review was to determine the state of the science regarding best practices for patient ambulation in the hospital setting; however, this was difficult to accomplish for many reasons. First, there was a lack of consensus on the best way to conceptualize and measure ambulation. For example, ambulation was considered a level of mobility, suggesting lower levels of mobility (i.e., lying, sitting) were acceptable for inpatients; however, adverse outcomes were associated with low mobility (Brown et al., 2009). Next, there are known barriers to ambulation that still exist within work systems. If nurses encounter barriers to ambulation, they often selected other strategies (i.e., sequential compression devices, sitting in the chair) to prevent mobility-related complications (Dermody & Kovach, 2018; Doherty-King & Bowers, 2011).

This literature review suggested individual components of the work system contribute to patient ambulation. Theoretically, changes in the work system will influence all work system components, as well as processes and outcomes within the organization. However, it is difficult to show this systems effect with the current ambulation research because these components have been studied as individual influences rather than collectively. A gap in knowledge exists in exploring the influence of the work system on patient ambulation using a systems approach. The SEIPS model offers a systems framework for the investigation of ambulation outcomes.

Lack of Systems Research

Existing studies were limited and focused on one of the following concepts: *ambulation, exercise,* and/or *mobility.* Although the use of multiple concepts made the comparison of studies

difficult, *exercise* and *mobility* were operationalized in the literature to include *ambulation*. By organizing the studies using the SEIPS model, this student researcher was able to identify a lack of systems research. Based on these findings, there was a need for additional research exploring the work system's (i.e., person; organization; technology and tools; tasks; and physical environment) influence on care processes and ambulation outcomes using a systems perspective.

The leaders' role in ambulation has been under-researched. Additional research is needed to explore ambulation of the hospitalized patient from an interdisciplinary leadership perspective. An interdisciplinary leadership perspective would provide a more comprehensive understanding of ambulation and workflows (Pottenger et al., 2019), ambulation barriers (Dermody & Kovach, 2017; Dermody & Kovach, 2018), responsibility (Doherty-King & Bowers, 2013; King et al., 2016), and decision-making (Doherty-King & Bowers, 2011). Understanding how patient ambulation [task] is accomplished using available resources [organization], such as mobility programs [technology and tools] within a hospital environment [physical environment] is needed to fully understand care processes.

Because the studies in this review did not use research designs that supported a systems approach, there was a lack of feedback between work systems, processes, and outcomes. There is a need for additional inquiry informing processes that facilitate ambulation, which is directly affected by the work system. The interdependency demonstrates a need for additional inquiry using the SEIPS model. There was one study suggesting a systems approach to ambulation research. King et al. (2016) completed a pilot study of an investigator-developed, nurse-led intervention called Mobilizing Older Adult Patients VIa A Nurse-Driven Intervention (MOVIN) to improve patient ambulation. In their study, King and colleagues (2016) developed the program using the SEIPS model as a framework, hypothesizing a change in ambulation must be

accompanied by a change in nursing practice and a change in ambulation culture (King et al., 2016). Quantitative results from the pilot study showed statistically significant changes in ambulation frequency ($p = .001$), ambulation distance ($p = .01$), and documentation.

Methodological Weaknesses

The use of multiple concepts (ambulation, mobility, exercise) makes comparison of studies difficult and may result in less rigorous research. For example, the concepts *ambulation* and *mobilization* are combined (ambulation/mobilization) in an updated version of the missed nursing care survey (MISSCARE survey) (Dabney et al., 2019) to reflect concepts used in the literature. Using ambulation and mobilization interchangeably will not allow nurse scientists to truly identify the levels of mobility patients may need to achieve prior to ambulation.

Other studies also had methodological issues. For quantitative studies, methodological weaknesses include a lack of comparison studies and/or control groups (Brassil et al., 2014; King et al., 2016), lack of randomization, and self-selection of subjects (Brassil et al., 2014). The use of validated tools, such as pedometers and accelerometers was inconsistent and not clearly stated. For example, one study was actually a validation study of a wireless accelerometer by AugmenTech, Inc.; however, this was not disclosed until the acknowledgment section (Brown et al., 2009). In a time and motion study, a dedicated mobility team was used to investigate resources needed to mobilize patients; however, time-to-mobilize data was not compared to usual care (Pottenger et al., 2019). Although there are always limitations to studies, these types of methodological weaknesses should be avoided if possible.

Conclusion

Finding from this review of the literature show there is a need for research using a systems approach to ambulation, particularly when environmental conditions differ (i.e.,

pandemic). As discussed in Chapter 1, ambulation is frequently reported as missed nursing care and has not been researched under pandemic conditions. Research studies suggest components of the work system contribute to missed ambulation; however, they do not show how the interdependence of components in the work system may negatively influence the care process of ambulation. Any change in the work system will influence all work system components, as well as processes and outcomes. Using the SEIPS model, the work system components (i.e., person; organization; technology and tools; task; and physical environment) guided the investigation of ambulation outcomes. For this reason and the reasons presented in this review, additional research was conducted to explore the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes. The next chapter will provide an overview of the methodology used for this dissertation study.

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CHAPTER 3: METHODOLOGY

Case study research method (Yin, 2018) was used during this study to provide an in-depth understanding of patient ambulation during pandemic conditions. A single-case study research design was used to answer the following research question: How did the coronavirus disease 2019 (COVID-19) pandemic impact the work system's influence on organizational care processes and ambulation outcomes? Investigation of the research question was guided by the Systems Engineering Initiative for Patient Safety (SEIPS) model described in Chapter 1. This chapter provides an overview of the methodology used for this single-case study research design.

Case Study Research Design

Over the years, case study research has developed into a "distinctive mode of social science inquiry" with a clear methodological path (Yin, 2018, p, 20). As a qualitative method of inquiry (Anthony & Jack, 2009; Stake, 1995; Yin, 2018), case study research requires systematic procedures, including a case study protocol for data collection and strategies for data analysis. Analytical strategies such as theoretical propositions, triangulation, and rival explanations promote rigor within case study research (Yin, 2018). The following sections will discuss important aspects of case study research design.

Methodology

Case study is a method of inquiry used for investigating a contemporary phenomenon in its real-world context, where the boundaries between the phenomenon (the case) and the context may not be clear (Yin, 2018). Case study research methods can be used to conduct in-depth investigations about complex issues without controlling behavioral events (Yin, 2018). This methodology has been used in nursing research to answer how or why questions (Anthony & Jack, 2009; Foley & Dowling, 2019; Hoonakker & Carayon, 2018).

According to Yin (2018), there are two types of case study research designs: single-case designs and multiple-case designs. Single-case study is appropriate when the case is critical, unusual, common, revelatory, or longitudinal (Yin, 2018). For this study, a single, critical case was investigated during the COVID-19 pandemic. This critical case will be described later; however, it justified the use of a single-case study design. Single-case study designs have recently been used to explore COVID-19 response activities (Holt et al., 2021), care strategies for COVID-19 patients (Tanzi et al., 2020), and virtual care technology (Shah et al., 2022).

Online Methods

Due to the COVID-19 pandemic, case study research methods had to be adapted to comply with infection prevention guidelines. The literature shows researchers created innovative methods for online data collection during pandemic conditions. For example, researchers in Brazil used virtual methods (i.e., phone calls, video conferencing) to study women infected by COVID-19 during pregnancy (Freitas-Jesus et al., 2020). Researchers also used field diaries as observational instruments, along with video or telephone interviews to record non-verbal communication such as body language, facial expression, patterns of speech, and/or emotions (Freitas-Jesus et al., 2020).

Additional innovative online methods were available on Harvard University's website, including Deborah Lupton's (2020) crowdsourced document entitled, *Doing Fieldwork in a Pandemic*. For example, there was an informative piece contributed by Alexia Maddox which provided information about scheduling and conducting online interviews (Maddox, 2020). The ideas in the crowdsourced document aligned with existing literature showing online focus groups, participant observation, and interviews have been used to inform qualitative

methodologies, such as ethnography (Tuncalp & Le, 2014) and grounded theory (Healy & McDonagh, 2013).

Defining the Case

A case is the unit of inquiry in case study research (Yin, 2018). This single case was a 950-bed academic medical center located in the southeastern region of the U.S. The academic medical center was a referral center for COVID-19 patients across the state. The case was part of a large healthcare system, which included hospitals providing specialized care. This academic medical center included multiple adult inpatient units dedicated to caring for medical patients, such as general medicine, pulmonary, nephrology, gastroenterology, family medicine, and infectious disease (i.e., COVID-19).

This medical center was a critical case for exploring the impact of COVID-19 on ambulation for the following two reasons: access to research and access to COVID-19 testing. It was critical to the future of nursing research that scholarly inquiry continued during the COVID-19 pandemic; however, gaining access to hospitals as research sites was challenging. This academic medical center allowed access for researchers, making this a critical case during pandemic conditions.

At the start of the pandemic, there was a critical need for diagnostic testing. This medical center was able to offer COVID-19 testing in addition to testing available by the state health department, making this a critical case. A researcher-developed COVID-19 diagnostic test was available and used in accordance with the U.S. Food and Drug Administration (FDA). Access to COVID-19 testing meant faster results for patients and healthcare providers. These results helped diagnose and manage the large number of COVID-19 cases experienced in the local region.

Bounding the Case

It was important for this case to have boundaries that limited the scope of the study, otherwise, the investigation could become too large and unmanageable (Yin, 2018). To avoid these potential issues, the investigation was bound by a case study research design and protocol, which provided structure and guidance for the student researcher. For example, a specific medical center was selected for the study, and data collection was focused on ambulation during pandemic conditions. In addition, the case was bound by a well-established work system and patient safety model. The SEIPS work system provided boundaries for the case investigation. The case was defined by the work system components, which provided structure to the investigation. The next section provides an overview of the SEIPS model.

Theoretical Perspective

As discussed in Chapter 1, the SEIPS model was used to guide this study. Components of the SEIPS model of work system and patient safety include the external environment, work system (person; organization; technology and tools; tasks; and physical environment), processes, and outcomes (Carayon et al., 2014). Theoretical propositions were established based on the SEIPS model and the concept of missed nursing care (Kalisch, 2006). These propositions were developed prior to the start of the study to theoretically predict patterns within the data, and these patterns were compared with empirical evidence from the study. The following theoretical propositions are posited:

1. Ambulation is a form of mobility and is a frequently missed nursing care task in hospitals.
2. Missed nursing care, such as ambulation, is a systems issue involving components of the work system and external environment.

3. The work system influences care processes and ambulation outcomes.
4. The external environment impacts the work system, care processes and ambulation outcomes.

Data Collection Procedures and Instruments

Systematic procedures were followed during data collection to increase the rigor and quality of the study. As previously discussed, the COVID-19 pandemic resulted in adaptations to data collection methods. These adaptations included the use of online methods such as virtual interviews and collection of documents. Data from online, semi-structured interviews was triangulated with documentation and direct observations to increase construct validity (Yin, 2018). All data collection was continuously evaluated in consultation with the dissertation chair. Table 1 provides the sources of data for this single-case study research design.

Table 1

Case Study Research Evidence

Interviews	Documentation	Direct Observation
L1 L2 L3 L4 L5 L6 L7 L8 L9 L10 L11 L12	• Ambulation pathways • CDC COVID-19 infection prevention and control recommendations • CDC press releases • COVID-19 medical management PPT • COVID-19 visitation PPT • COVID-19 visitation plan • Emails • ERAS nursing tip sheet • Executive orders from state government • Highly communicable diseases preparedness and response plan • Policies • Recovering from COVID-19 instructions	Visual cues for infection prevention, such as signs, physical barriers, and markings on the floor.

Note. L = Leader

Interviews

Semi-structured interviews provided the primary source of data for this single-case study. A total of 22 leaders were emailed about participating in the study and 12 agreed to participate. Purposeful recruiting was used to identify leaders who made decisions about policies and procedures related to patient ambulation during the COVID-19 pandemic. If leaders met the inclusion criteria, they were asked to participate in online, audio-recorded, semi-structured interviews. Leaders were invited to participate if they were a formal leader, defined as a manager-level or higher leadership position. In addition, leaders had to have knowledge of patient ambulation in the hospital during the COVID-19 pandemic, be employed by the medical center for at least one year, and work at least 24 hours each week in an inpatient position for at least six months. Newly hired leaders still in orientation, and/or leaders working with a pediatric population were excluded from the study. Guided by information power (Malterud et al., 2016), the final sample included 12 leaders from the following disciplines: nursing, physical therapy, occupational therapy, respiratory therapy, and epidemiology/infection prevention.

Before each interview, the student researcher emailed the participant instructions for the online interview and written consent. Participants were provided instructions to select a location for the online interview that would maximize privacy. The instructions also included a link to join the online interview, which was conducted using a HIPAA-compliant version of Zoom. The following demographic questions (see Table 2) were included on the interview guide and completed by participants using Qualtrics, an online survey platform approved by the university.

Table 2

Demographic Questions for Participants

Question
Pseudonym for interview
Gender
Age (provide in decade, 40's, 50's, 60's)
Degree(s)
Years' experience as a registered nurse
Years' experience as a formal leader
Professional certification(s)
Job Title

The goal of each interview was to have a "guided conversation," per Yin's (2018) recommendation (p. 118). Participants were asked a broad opening question, "Tell me how COVID-19 has influenced patient ambulation in your facility?" Based on the answer to the opening question, probing questions were focused on gaining a deep, rich understanding of the impact of COVID-19 on the work system's influence on ambulation care processes and outcomes. See appendix B for the interview instrument.

After each interview, the student researcher had steps in place to promote rigor and confidentiality of the interview data. First, the student researcher maintained the audio recordings until the transcription was complete. Secondly, a professional transcription service was used to transcribe the interviews verbatim. Next, each transcription was reviewed by this student researcher for accuracy and removal of any identifiable information. Once a transcription was reviewed, it was stored on a secure Pirate Drive, associated with East Carolina University College of Nursing. The Pirate Drive was specifically assigned for this research study and data will remain there for a period of five years. After five years, the data will be electronically erased per university policies and procedures.

Online Interviews

Due to the COVID-19 pandemic, the importance of online alternatives for interviews became a point of consideration. Similar to any qualitative technique, there were advantages and disadvantages to using online interviews. A scoping review of 11 studies reported the following advantages: convenience; ability to cover a sensitive topic; and recruiting (Davies et al., 2020). The challenges of online interviews included a concern for losing the richness of data and/or a personal connection; an increased participant satisfaction with face-to-face interaction (i.e., online answers to interview questions were shorter and less reflective than face-to-face); and technical skills needed by the participants. Time and cost can be an advantage or challenge, based on the study.

For this study, online interviews were advantageous because of infection and safety issues related to the pandemic. Conducting interviews in an online environment eliminated COVID-19 exposure risks, while still promoting a personal connection that may have been diminished or lost if telephone interviewing was used. During the online interviews, participants were asked open-ended questions about a topic within their own field, which has been shown to promote rich data (Davies et al., 2020).

Interview Guide. A semi-structured interview guide was created by this student researcher based on a review of the literature regarding patient ambulation with questions aimed to uncover the impact of COVID-19 on ambulation. See appendix B for the interview guide.

Documentation

Documentation included evidence related to ambulation during COVID-19. This evidence was obtained from a variety of sources (Yin, 2018), such as emails, ambulation programs/guidelines, policies, and infection prevention guidelines. As seen in Table 2,

documents were collected and used as evidence. This documentary evidence was collected before and/or after interviews and used to gather information when participants were no longer available (Bowen, 2009). Examples of the documentary evidence included unit-specific ambulation programs, policies, and infection prevention guidelines. These documents were used to corroborate evidence from direct observations and interview data (Higginbottom et al., 2013; Yin, 2018). Because of the potential for bias and inaccuracies, documentary evidence was used with caution and objectivity (Yin, 2018).

Documentation Instrument

A documentation instrument was used to collect and organize the documents. See appendix C for the documentation instrument.

Observations

As an employee within the study setting, it was impossible to deny or separate direct observations occurring from a researcher and employee lens. Thus, direct observations occurred while the student researcher was working at the medical center. During data collection, the student/employee worked over 300 hours in the research setting. Visual cues served as reminders about infection prevention guidelines and social distancing. For example, observations included signs and posters on the walls and doors. The signage provided details about mask-wearing and use of other personal protective equipment, such as gowns and eye protection. Signs were reminders to employees and non-employees to comply with infection prevention guidelines. In addition to signs, there were physical barriers limiting and/or restricting access to certain areas of the medical center. The barriers included stanchions, which were portable posts used to divide the units into high-risk and low-risk areas. Other areas, such as retail shops and the cafeteria contained six-foot distance markings on the floors to remind people about social distancing.

Observation Tool

An observation tool was used to promote objectivity and decrease bias (Fusch et al., 2017). See appendix D for the observation tool.

Sample Size: Information Power

Due to the difficulties predicting and evaluating sample sizes needed for qualitative research, information power has been suggested as a method of determining sample size in qualitative studies (Malterud et al., 2016). “Information power indicates that the more information the sample holds, relevant for the actual study, the lower number of participants is needed” (Malterud et al., 2016, p. 1759). The sample size was determined by information power; however, approximation was used for planning (Malterud et al., 2016). The estimated sample size was 10 participants, and 12 participants were interviewed.

The final sample size (n = 12) was informed by the five dimensions of information power: study aim, sample specificity, established theory, quality of dialogue, and analysis strategy (Malterud et al., 2016). The aim of the study was narrow (case study research design) and there was a specificity to the sample (formal leaders in an academic medical center). Quality of dialogue was supported by specific questions (semi-structured interviews) aimed to answer the research question. The analysis strategy focused on a single case (academic medical center) and a single topic (ambulation during a pandemic). In addition, an established work system and safety model (Carayon et al., 2014) were used to guide data collection and analysis.

Data Analysis

Data analysis was a collaborative effort, which included this student researcher and two nurse researchers who were experienced in qualitative research. One nurse researcher had

expertise in leadership within a teaching hospital. Data analysis included three sources of case study evidence: interviews, documents, and direct observations (Yin, 2018).

Interview Analysis

Transcripts from 12 semi-structured interviews were coded by this student researcher and the dissertation chair from March 2021 to May 2021. Exploratory, holistic coding methods were used during first and second cycle analysis of the interview data (Saldana, 2021). We each conducted an independent review of every transcript, then compared our coding to achieve internal consistency. To differentiate between first and second cycle coding, colored pencils were used to label key words, issues, and/or phrases. As additional interview information was available from the transcripts, codes were added, and/or differences in coding were discussed and resolved. First cycle coding resulted in 21 codes, which were further analyzed during second cycle coding.

In preparation for second cycle coding, this student researcher and the dissertation chair reviewed each of the 21 codes for similarities, differences, and emerging patterns. The emerging patterns informed the development of new categories, which corresponded with a component of the SEIPS work system and patient safety model. These SEIPS categories included the following: external environment; organization; technology and tools; person; task; and physical environment (Carayon et al., 2014).

Using the SEIPS-based coding was an iterative process, resulting in several revisions (i.e., expanding, collapsing, deleting) and refinement of the codebook. Second cycle coding was completed in May 2021 and resulted in 22 codes. Table 3 shows the first cycle codes, second cycle codes, rationale for changes, and the new SEIPS-based code. At the conclusion of second

cycle coding, the student researcher prepared for team analysis, which is described in the next section.

Table 3

Rationale for SEIPS-Based Coding

1st Cycle Code(s)	Rationale for SEIPS-Based Coding	2nd Cycle Code(s) (SEIPS-based)
Communication	Renamed to capture the organizational component of the SEIPS model. This code describes communication on a micro and macro level, regarding ambulation.	Organization Communication Micro (OCommMicro) Organization Communication Macro (OCommMacro)
COVID barrier and COVID precautions[1]	Collapsing the two codes and renaming to capture the external environment. It is important to code policies/procedures from the CDC or other sources outside the organization.	External environment: external rules
COVID barrier and COVID precautions[2]	Collapsing the two codes and renaming to capture the organizational component of the SEIPS model. During the pandemic, it is important to identify COVID versus non-COVID factors.	Organizational Internal Rules (OIR)
Critical care	Deleted because this code described ambulation in critical care areas (i.e., medical intensive care unit, intensive care unit) and critical care not included in this study.	Deleted
Disconnect	Collapsed and renamed to align with SEIPS model. Description of any real or perceived disconnection between frontline staff and leadership impacting patient ambulation, such as expectations and/or culture.	OrgDisconnect
Facilitator	Renamed to capture the organizational component of the SEIPS model. During the pandemic, it is important to identify facilitators that are not specific to COVID-19. Resource facilitator (*expanded code – this is the definition of "facilitator" removing the COVID-related*): description of any facilitator to ambulation, whether real or perceived, related to non-human resources.	Organization Resource Facilitator (ORF)
Guidelines	Renamed to align with SEIPS model. OSGuide: description of ambulation guidelines designed to standardize care for surgical patients, such as ERAS. OMGuide: description of ambulation guidelines designed to standardize care for medical patients. ORNGuide: description of nursing practice and/or assessment(s) used in addition to ambulation guidelines.	OSurgGuide, OMedGuide, ORNGuide

1st Cycle Code(s)	Rationale for SEIPS-Based Coding	2nd Cycle Code(s) (SEIPS-based)
Help	Collapsed and renamed to align with SEIPS model Description of nonemployees who contribute to ambulation, such as students, volunteers, family members and/or visitors.	Technology and tools help (TTH)
Medicine	Collapsing this code and renaming to align with SEIPS model and physical environment. This code describes ambulation in medical units. Description of ambulation in the medical service and/or medical units, to include observation units, oncology and postpartum.	Physical environment (PEMed)
Outcomes: Negative	Deleted because this code described negative patient outcomes associated with ambulation. The research model is focused on the work system. According to the SEIPS model, this is an outcome, not a component of the work system.	Deleted
Outcomes: Positive	Deleted because this code described positive patient outcomes associated with ambulation. The research model is focused on the work system. According to the SEIPS model, this is an outcome, not a component of the work system.	Deleted
Patients	Deleted because this code described patient-driven decisions regarding ambulation during COVID-19. The research model is focused on the work system. According to the SEIPS model, this is a process, not a component of the work system.	Deleted
Prioritization	Collapse prioritization and renamed to align with SEIPS model. Task is defined as safe ambulation. Initial data shows ambulation is prioritized differently by staff members. Description of a real or imagined "to-do list" which includes ambulation and other patient care tasks sequenced by the health care provider; whether the health care provider is caring for one or multiple patients who are requiring individual or simultaneous tasks; description of trying to decide how to accomplish ambulation and other important tasks during any given shift for assigned patients.	Task prioritization (TP)
Project	Collapsing this code and renamed to align with SEIPS model, technology and tools facilitators. Initial data shows projects are used as ambulation tools. Description of any facilitator to ambulation, whether real or perceived (past or present), related to technology and tools, such as quality improvement or performance improvement project, intervention, or specific initiative focused on patient ambulation.	Technology and tools facilitator (TTF)
Resource barrier and financial barrier	Collapsing the two codes and renaming to capture the organizational component of the SEIPS model. Resource barrier: description of any barrier to ambulation, whether real or perceived, related to non-	Organization Resource Barrier (ORB)

1st Cycle Code(s)	Rationale for SEIPS-Based Coding	2nd Cycle Code(s) (SEIPS-based)
	human resources such as finances *(collapse financial barrier)*, time, processes, space, and/or supplies.	
Responsibility	Task is defined as safe ambulation. Initial data shows responsibility for patient ambulation includes various members of the health care team. Renamed to align with SEIPS model. Description of one's beliefs regarding professional responsibility for ambulation	Task responsibility (TR)
Staffing	Collapsing the code and expanding to capture the specific roles identified using the organizational component of the SEIPS model. Leader – description of a leader involved or contributing to patient ambulation Registered Nurse – description of a registered nurse involved or contributing to patient ambulation. Nursing Assistant – description of a nursing assistant involved or contributing to patient ambulation. Non-nursing – description of non-nursing staff involved or contributing to patient ambulation, including physical therapy, recreational therapy, respiratory therapy.	Organization Leader (OrgLeader) Organizational RN (OrgRN) Organizational NA (OrgNA) Organizational Non-Nursing (OrgNN)
Surgical	Collapsing this code and renamed to align with SEIPS model, physical environment. This code describes ambulation in surgical units. Description of ambulation in surgical units to include cardiac (heart and vascular), neuro and burn units.	Physical environment (PESurg)
Technological Barrier	Renamed to align with SEIPS model. Initial data shows a need to differentiate barriers and facilitators for this work system component. Description of any barrier to ambulation, whether real or perceived, related to technology.	Technology and tools barrier (TTB)

Data Analysis

Analysis included three content reviewers, this student researcher and two experienced nurse researchers, to promote rigor and increase reliability of qualitative findings. In preparation for analysis, this student researcher provided transcripts to each nurse researcher and presented an overview of first and second cycle coding. Analysis meetings started in July 2021 with an in-person meeting, followed by routinely scheduled Zoom meetings.

The process of analysis started with an independent review of each transcript for important, powerful, interesting, and/or unique quotes/passages. Prior to each analysis meeting,

each content reviewer selected three quotes or passages that best represented the assigned transcript(s). At the meetings, each reviewer had time to ask questions, participate in discussions and provide individual reflection on the transcript. An initial matrix was created showing the selected quotes and/or passages for each transcript, totaling 108 selected quotes/passages. In 67% (8 of the 12) of the transcripts, at least one duplicate quote/passage was selected by all three reviewers.

After initial team analysis of the transcripts, the selected quotes/passages were categorized by this student researcher using the work system components from SEIPS model. The SEIPS coding was discussed by all three researchers, and interpretative differences were identified and resolved. One example of an interpretive difference was the coding of non-employees who assisted or helped with ambulation. These "helpers"/people were coded as "technology and tools help" (TTH) because the data suggested they were being used as ambulation tools; however, further team analysis resulted in recategorizing helpers as "people" within the SEIPS model.

Document Analysis

Documents were analyzed using an inductive approach to content analysis (Elo & Kyngas, 2008; Graneheim et al.,2017). The inductive approach includes open coding, categories, and abstraction (Elo & Kyngas, 2007). With open coding, this student researcher freely generated notes and headings for the purpose of establishing categories. These categories were grouped under larger themes (Elo & Kyngas, 2007). Abstraction was used throughout the process to identify and place words in the most appropriate categories (Elo & Kyngas, 2007). The document tool (Appendix C) was used to organize data for analysis.

The unit of analysis aligned with each document and a holistic approach was used to code and categorize each document. Documents were independently analyzed by this student researcher, followed by a team review and discussion of the analysis. Analysis included reading to determine relevance to the research question and purpose of this study (Bowen, 2009). After determining relevance, this student researcher identified key words (i.e., ambulation), phrases, and/or information (present or missing) which were meaningful to the study. If the document was both relevant and meaningful, the document was categorized using the same codebook used for second cycle interview analysis. Because documentation data supplemented existing interview data, it was acceptable to use pre-defined codes for analysis (Bowen, 2009).

Direct Observations

Direct observations were independently analyzed by this student researcher, followed by a team review and discussion of the analysis. An inductive approach to content analysis was used to analyze the direct observations (Elo & Kyngas, 2008; Graneheim et al., 2017). This student researcher completed an initial analysis, followed by team review and discussion of the analysis. Direct observations that were both relevant to the study and meaningful (Bowen, 2009), were analyzed using the same codebook from second cycle interview analysis. The next section will describe the analytic strategies used during data analysis.

Analytic Strategies

According to Yin (2018), the analytic strategy should support the specific case study design (Yin, 2018). Because this was a single-case study, patterns found in the empirical data were compared to the predicted theoretical propositions. This analytical process began with this student researcher "playing with the data," looking for differences and themes (Yin, 2018, p. 167). The use of matrices, charts, and drawings helped this student researcher sort the data into a

variety of patterns. These patterns were used during team analysis, where emerging themes were further analyzed using the SEIPS model as a guide. These patterns were discussed and identified as main findings.

Ethical Considerations

This single-case study research design involved a focused investigation of ambulation during a pandemic, which exposed this student researcher to several ethical situations. Approval by the university and academic medical center was obtained prior to any research activities during pandemic conditions. Safety issues and risk for exposure were part of the ethical considerations, which are described in the sections below.

Protection of Human Subjects

During this pandemic, online qualitative techniques (i.e., online interviews) were used to promote the safety of this student researcher and the study participants. Efforts were made to mitigate any weaknesses associated with online techniques and limitations will be discussed. Participation in the study was voluntary and each participant provided informed consent prior to study participation. The informed consent process included an explanation of "minimum risk" to the participant, as the research was conducted online due to pandemic conditions.

Privacy and Confidentiality

Privacy and confidentiality of individuals and all data related to the case were protected. Interviews recordings and transcripts were recorded and immediately uploaded to PirateDrive, a secure drive managed by the university. Participants were asked to select a pseudonym to protect their identity, which was further deidentified using sequential labeling (L1, L2, etc.) prior to dissertation publication. Data was used only for the purpose of this research study, as documented in the research design.

Trustworthiness

Lincoln and Guba (1985) established four criteria for trustworthiness in qualitative inquiry: credibility, dependability, confirmability, and transferability.

Credibility

This student researcher conducted the study in a professional manner, following guidelines and restrictions set by the university and medical center. Credibility was enhanced by expert review (versus peer review) by two nurse researchers. Debriefing was available from the research mentor, and reflexivity was used to decrease any researcher bias.

Dependability and Confirmability

Dependability was achieved by triangulation of data from interviews, documents, and direct observations. Case study research methods (Yin, 2018) were described in detail and any differences in coding were resolved to achieve intercoder reliability. Detailed documentation and supervision by a research mentor optimized confirmability.

Transferability

One of the main goals of this student researcher was to produce rich, descriptive data which was transferable to other hospitals. Research findings will be disseminated through publication(s) and public presentation. Ultimately, the long-term goal is that ambulation outcomes will be improved by the development of an evidence-based, systemwide (all patients) ambulation protocol that can also be used during external events, such as pandemics.

Conclusion

The use of case study research was one way to explore ambulation during a pandemic. This design provided a framework to investigate contemporary “how” and “why” research questions that occurred within an uncontrollable, real-world situation (i.e., COVID-19). This

case study research allowed this student researcher to answer the question: How did the COVID-19 pandemic impact the work system's influence on organizational care processes and ambulation outcomes? The next chapter is a manuscript which further describes decision-making related to the methodology and lessons learned during this study.

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CHAPTER 4: DESIGNING A QUALITATIVELY-DRIVEN MIXED-METHOD STUDY: METHODOLOGICAL DECISION-MAKING AND LESSONS LEARNED MANUSCRIPT

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Abstract

This methods article is a reflection on the design of a qualitatively-driven mixed-method study from the perspective of a novice researcher and the research mentor. The methodological design included mixing case study research with focused ethnography. Challenges related to the implementation of design plans were a barrier to collecting observation data; therefore, data analysis was limited in capturing the cultural component. Lessons learned from this experience provide insights for collecting observation data, using reflexivity to guide decision-making, and considering a pilot study to refine processes. We trust this article will help guide your methodological journey.

Highlights

- Healthcare researchers often use case studies to explore real-world context.
- Focused ethnography can enhance cultural findings of case study research.
- Data collection should be intentional and address methodological requirements.
- Observation plans, reflexivity, and pilot studies may prevent methodological issues.

Introduction

Researchers in healthcare settings often use case studies to gain an in-depth understanding of contemporary issues in their real-world context (Yin, 2018). Case study research can be used to explain, describe, or explore issues, which makes this research design particularly useful in healthcare (Anthony & Jack, 2009). Researchers may want to enhance the design of case study research by including a cultural component aimed at identifying and/or explaining values, beliefs, or traditions influencing the case. When these situations arise, cultural context can be examined by using focused ethnography as the cultural component in a qualitatively-driven mixed-method design (Morse, 2017). A qualitatively-driven mixed method design (Morse, 2017) allows a researcher to use a primary qualitative method (QUAL) and enhance the study with a supplemental qualitative method (qual). More specifically, using case study research (QUAL) with focused ethnography as a supplemental method (qual) is a design in which to examine cultural context influencing healthcare issues such as nurse communication (Chien et al., 2022) and patient safety (Leslie et al., 2014).

This article represents the learning experiences of a novice researcher and research mentor. The lead author is a novice researcher and was a doctoral student in a Doctor of Philosophy nursing program during the conception of this article. The second author served as the research mentor during the dissertation and has experience mixing qualitative methods. We used a mentor-mentee pedagogical strategy (Ferrell et al., 2020; Wegener & Tanggaard, 2013) to facilitate knowledge development in both methodology and scholarly writing. The purpose of this article is to provide guidance to other researchers interested in exploring the use of case study research with focused ethnography in a qualitatively-driven mixed-method design.

Qualitatively-Driven Mixed-Method Design

When examining a health care issue where cultural context is warranted, researchers should consider using a qualitatively-driven mixed-method design (Morse, 2017). Using this mixed-method design, a core qualitative method can be mixed with a supplemental qualitative method. Specifically, this article describes a mixed-method design using case study research and focused ethnography. By definition, case study research is designed to investigate contemporary issues which are not easily separated from their context, making the boundaries between phenomenon and context difficult to separate (Yin, 2018). Adding a supplemental focused ethnography approach can offer researchers a cultural lens throughout the investigation.

The lead author and research mentor worked together to plan a QUAL-qual design mixing case study research and focused ethnography. Based on our experience developing the qualitatively-driven mixed-method design and reflecting on the data collected, using focused ethnography to strengthen case study research is an innovative way to design a study that includes cultural context. In this article, we will share valuable lessons learned that may help guide other researchers in future studies.

Use of Case Study Research

Although there are multiple approaches to case study research, key contributors include Yin (1989; 2018) and Stake (Stake, 1995). Yin has been developing case study research as a method since 1989 and has defined the components of case study research as (1) case study research - mode of inquiry, (2) case studies - method of inquiry, and (3) case(s) - unit of inquiry. The use of case study research is recommended when answering how or why questions about contemporary events outside the researcher's control (Yin, 2018). Once the how or why

questions are developed, a researcher should follow a clear methodological path, including formal written procedures for data collection and analysis (Yin, 2018).

Even with guidelines and strategies, case study methods can be intense and time-consuming. Some of the challenges associated with case study research include defining the case (Yin, 2018); managing and making sense of multiple sources of data (Yin, 2018); and navigating the role of the researcher (Yin, 2018 & Stake, 1995). Strategies to avoid these challenges include examining the research question and identifying *what* is being analyzed, as well as using a clear plan for data management, and a case study protocol for data collection (Yin, 2018).

Although researchers may minimize challenges, other people may confuse the use of case study research and other non-research case studies. The confusion is related to the use of "case study" for non-research purposes, such as an educational teaching tool to encourage discussion, problem-solving teaching, or practice case (i.e., student or patient case exemplar) (Yin, 2018). Although non-research case studies may be valuable, they cast a shadow of doubt when establishing credibility among research approaches.

Despite these challenges, case study research is frequently used for understanding issues in healthcare. The real-world environment of contemporary healthcare is dynamic, changing beyond the control of a researcher, and creating problems/issues that are not easily separated from their context. For the reasons mentioned above, case study research has been used to inform nursing research in acute care, public health nursing, and nursing education (Anthony & Jack, 2009). Although case study research may illuminate some aspects of the cultural context, the purpose of case study research is to gain a deep understanding of the entire case(s), not focus on the culture.

Use of Focused Ethnography

Focused ethnography is a specific ethnographic approach that allows focused inquiry on an existing phenomenon occurring in a culture or subculture of contemporary society (Higginbottom et al., 2013; Knoblauch, 2005). The basic tenets of focused ethnography are based on the identification of differences in shared knowledge or "communality" (Knoblauch, 2005, p. 4). When a researcher has background knowledge of a problem, this enables them to identify specific research needs and contexts to study (Higginbottom et al., 2013). The specificity of focused ethnography allows short, intermittent field visits and intense data collection from multiple sources (i.e., observations, interviews, documents, and field notes), unlike the lengthy field visits associated with conventional ethnography (Higginbottom et al., 2013; Knoblauch, 2005). Field visits are focused on understanding more about the decisions, behaviors, and/or customs of an individual, group, or organization. Participants are purposively selected to contribute specific knowledge or experience to the focused investigation (Higginbottom et al., 2013).

Healthcare is a complex research environment, benefiting from flexible and focused methodologies. Focused ethnography is useful in healthcare research because it provides a methodological framework for the investigation of specific healthcare issues within a cultural context (Higginbottom et al., 2013). Nursing researchers frequently use focused ethnography as a method of inquiry (Cruz & Higginbottom, 2013). For example, Bunkenborg et al. (2017) used observations and focus group interviews to understand nurses' experiences and perspectives during handoff/report for patients transferring from intensive care to a medical or surgical unit. Focused ethnography is also used more broadly in healthcare research (Higginbottom et al., 2013). Ghirotto and colleagues (2020) used observations, semi-structured interviews, and a focus

group to understand healthcare providers' attitudes related to a qualitative research methods training program offered at their place of employment.

Mixing Qualitative Methods

Once a baseline understanding of each qualitative method is achieved, the researcher needs to learn about mixing qualitative methods. The lead author began this educational process by becoming acquainted with the literature for mixing two qualitative methods. Upon initial review of the literature, it became evident researchers held strong opinions and conceptual differences about "blending" (Fusch et al., 2017), "merging" (Cote-Boileau et al., 2020), or mixing "method" (Morse, 2017) or "methods" (Fetters & Freshwater, 2015). Although this was confusing, it evidences researchers wanting and needing to mix qualitative methods to fully answer the research question(s).

In reviewing the literature, we sought to identify mixed-method designs as exemplars that adequately reflected the methodological standards from both approaches. Ultimately, we were drawn to the work of Janice Morse (2010; 2017), who provided a comprehensive perspective on mixed-method designs using qualitative research, called qualitatively-driven mixed-method design. According to Morse (2010), the QUAL-qual design contains a qualitative core method paired with a supplemental qualitative method. The core method provides the major findings for the study that is publishable as a complete method (Morse, 2017). The supplemental method adds depth and rich description to the inquiry that the core component is unable to contribute (Morse, 2017). This body of literature provided guidance on how to mix a supplemental qualitative method(s) with a core qualitative method (Morse, 2017; Morse & Niehaus, 2016; Richards & Morse, 2013).

Lessons Learned

Through this research journey, lessons were learned from both the novice researcher and research mentor. Challenges related to the implementation of design plans were a barrier to collecting participant observation data; therefore, observation data was not rigorous enough to fully understand the cultural component. This experience presented an opportunity to reflect on our challenges and uncover lessons learned. Based on our reflection we recommend the following methodological strategies for successfully implementing a qualitatively-driven mixed-method study using focused ethnography to enhance case study research: plans for observational data, reflexivity to guide decision-making, and a pilot study to refine processes.

Plans for Observation Data

Observations are a significant source of data for focused ethnography (Knoblauch, 2005). The value of observational data is gaining an increased understanding of a specific topic from the perspective of study participants within their environment (Knoblauch, 2005). Observational insights and knowledge can be used to corroborate findings from other sources, such as interviews and documents. Because multiple sources of data are essential for a rigorous analysis of culture, researchers should be intentional with plans for collecting observation data. For this study, the primary source of data collection plans was interviews (core method). While structured procedures (i.e., interview guide) were in place for conducting interviews, similar procedures for collecting observational data were challenging for the novice researcher to use. It was during the analytic phase that we discovered there was not enough observation data to support a rigorous analysis of culture.

Often when researchers are examining a familiar culture, such as nursing care, it can be challenging to separate personal experiences (etic perspective) from the experiences of others

(emic perspective) (Macnamara, 2021). Being an insider provided a high level of immersion in fieldwork (Dumont, 2022); however, observations were close and personal making the process more difficult. Part of the difficulty was being surrounded by observations; however, not "seeing" or considering the observations as research data. To avoid this challenge, it is recommended that researchers schedule time dedicated to immersion and fieldwork (Higginbottom et al., 2013). Additionally, routinely debriefing about fieldwork with an experienced researcher will provide a different perspective on observation data (Dumont, 2022; Eggeling, 2022).

The COVID-19 pandemic disrupted traditional observation strategies and likely impacted the ability to fully examine the values, beliefs, and traditions. The pandemic required researchers to rethink fieldwork and the concept of "being there" (Eggeling, 2022, p. 3). In a reflective piece, Howlett (2022) shared their experiences redefining the "field" using digital methods for research during the pandemic. They described developing an "online co-presence" (Howlett, 2022, p. 392) and "remote embeddedness" (Howlett, 2022, p. 394) during their study. Based on the experiences of the novice researcher, it is recommended that researchers plan for situations where "being there" may not mean an in-person observation. Applying ethical standards and protecting research participants can be more challenging with online platforms (Tuncalp & Le, 2014); therefore, strategies to maintain HIPAA compliance should be considered.

Even with specific protocols for observation, researchers should practice their observational skills. Pacheco-Vega (2019) recommended the use of draft field notes to practice writing observations and Morse (2017) recommended the use of an "armchair walkthrough" (p. 47). Using these strategies may help researchers identify potential methodological issues prior to beginning the study. Once the study has begun, it is important to receive feedback early in the

process of conducting fieldwork and observations. With early feedback, corrections and/or improvements to observations can be identified.

Reflexivity to Guide Decision-Making

Because the lead author was deeply embedded in the case, activities to promote reflexivity were recommended early in the research journey. Reflexivity started with drawings, journal entries, and dialogue with the research mentor (Berger, 2015; Finlay, 2002). The power of reflexivity was not truly appreciated until data analysis, when the lead author was able to reflect on gaps in data collection. Unfortunately, earlier attempts at reflexivity did not lead to decision-making about collecting observation data, nor did it "sound the alarm" to change observation methods. With practice, mentoring, and time, reflexivity started to reveal the lead author's positioning and reasoning (Berger, 2015).

Reflexivity was a topic revisited throughout the dissertation journey. The mentor-mentee discussions not only included reflexivity strategies, but also discussions about developing a conceptual stance (Cronenberg, 2020) and appreciating the emic perspective (Macnamara, 2021). The purpose of using reflexive strategies was to guide decision-making (Berger, 2015); however, reflexivity was a difficult process for the novice researcher. More structure may assist with reflexivity, such as the use of a documentation tool. Reflexivity can be documented by capturing: (1) participant statements; (2) potential meaning of the statements, and (3) researcher feelings about the statement and potential meaning (Berger, 2015).

Pilot Study to Refine Processes

We recommend using a pilot study to refine methodological processes and assess feasibility (Malmqvist et al., 2019). More specifically, consideration of a pilot study is recommended when using two qualitative methods. Mixed method designs are more advanced

and a smaller, preliminary study can assist with the refinement of methodological processes. It is recommended to include a pilot study in the research design (Malmqvist et al., 2019). By including a pilot study there will be opportunities to refine processes, such as data collection and analysis. Because data analysis has been shown to be a troublesome threshold concept for doctoral students (Kiley, 2009), the inclusion of mentored experiences (i.e., pilot study) with qualitative data analysis is recommended.

Conclusion

Our goal in writing this article was to provide guidance for researchers wanting to use focused ethnography within a qualitatively-driven mixed-method study to add a cultural component to strengthen the findings of case study research. Methodological lessons learned included systems for observation data, reflexivity to guide decision-making, and a pilot study to refine processes. Despite the methodological challenges, this experience presented an opportunity to reflect on lessons learned. We trust this article will help guide your methodological journey.

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CHAPTER 5: THE IMPACT OF COVID-19 ON CARE PROCESSES AND AMBULATION OUTCOMES: EXPLORATION OF A SINGLE-CASE MANUSCRIPT

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Abstract

Aim: To explore the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes.

Background: Missed nursing care is the delay or omission of required patient care. Ambulation is frequently reported as missed care for hospitalized patients; however, the impact of COVID-19 on systems impacting inpatient ambulation is unknown. The Systems Engineering Initiative for Patient Safety (SEIPS) model was used to guide this study.

Method: A single case study research design was used to investigate ambulation in an academic medical center. Data from 12 semi-structured interviews with interdisciplinary leaders, documents, and direct observations were analyzed using content analysis.

Results: The findings were categorized as the external environment, work system, and ambulation care processes. COVID-19 stressed the work system and revealed the value of informal ambulation care processes.

Conclusions: Findings contribute new knowledge related to informal ambulation care processes and extend knowledge specific to the external environment's influence on work systems and care processes.

Implications for Nursing Management: Policy development is needed to address missed ambulation from a systems level. Policies should minimize the removal of individuals who assist with ambulation care processes. In addition, alternative ambulation resources, such as students and volunteers, should also be explored.

Background

Missed, delayed, or incomplete nursing care (Kalisch, 2006) is a safety issue associated with adverse patient outcomes (Ball et al., 2018; Hessels et al., 2019; Kalankova et al., 2020). Multiple negative patient outcomes have been linked to missed nursing care, such as infections (Tesora et al., 2018), post-surgical mortality (Ball et al., 2018), and falls (Recio-Saucedo et al., 2018; Zhao et al., 2020). In Kalisch's (2006) seminal work on missed nursing care, patient ambulation was identified as one of nine regularly missed patient care activities. Ambulation continues to be associated with the nursing discipline as one of the most frequently reported missed nursing care activities for hospitalized patients (Smith et al., 2018; Winsett et al., 2016; Campbell et al., 2020).

Hospitalized patients spend an average of 83% of their time lying in bed (Brown et al., 2009). Even if willing and able to walk independently, medical inpatients can spend an average of 20 hours each day in bed (Brown et al., 2009). Additionally, research suggests hospitalized patients are being advised to stay in bed to avoid falls and need permission from staff to get out of the bed (King et al., 2021). These findings are concerning because the length of time spent lying in bed is directly related to complications, such as muscle weakness, orthostatic hypotension, deep vein thrombosis (DVT), decubitus ulcers, increased walking dependence, and even death (Brown et al., 2004; Dittmer & Teasell, 1993; Fox et al., 2018; Teasell & Dittmer, 1993).

The COVID-19 pandemic has compromised the ability of hospitals to deliver basic patient care, such as ambulation. The pandemic forced hospitals to make systems changes to minimize the transmission of the disease (Centers for Disease Control & Prevention, 2020a & 2020b). The impact of these systems changes on the ambulation of hospitalized patients is

unknown, which presented a gap in research. Therefore, this study aimed to explore the impact of COVID-19 on the work system's influence on care processes and ambulation outcomes. The Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety (Carayon et al., 2006; Carayon et al., 2014) provided a systems perspective of ambulation. This is the first study guided by the SEIPS model to investigate ambulation during pandemic conditions to answer the following research question: How did the COVID-19 pandemic impact the work system's influence on organizational care processes and ambulation outcomes?

To understand the significance of this research study, this article will provide a background on patient ambulation, the COVID-19 pandemic, and the theoretical model guiding the study.

Theoretical Model

This study was guided by the SEIPS model of work system and patient safety (Carayon et al., 2006; Carayon et al., 2014). This model was selected because it is a well-established work system and patient safety model that has been used for over 15 years (Carayon et al., 2006; Holden & Carayon, 2021). In addition, the SEIPS model provided a framework to investigate ambulation as a work system issue versus an issue specific to the nursing discipline. The SEIPS model includes the following components: external environment; work system (i.e., person; organization; technology and tools; tasks; and physical environment), processes, and outcomes (Carayon et al., 2014). For the purposes of this study, the external environment was defined as the rules, legislation, and/or standards of care for COVID-19. Processes were specific to care processes and defined as supportive behaviors influencing ambulation. The work system was defined as an academic medical center, which is further described in the next section.

Methods

Design, Setting, and Sample

A single-case study research design explored inpatient ambulation during pandemic conditions. Using a case study research design provided a "clear methodological path" (Yin, 2018, p. 3) for an in-depth investigation of ambulation within the context of the work system (Carayon et al., 2014). A case study protocol was used to increase reliability and a chain of evidence to increase construct validity (Yin, 2018). The chain of evidence included documentation of the data collection process, changes in coding, and steps taken to analyze the data. The components of the SEIPS model provided boundaries for the case.

This single case is a large academic medical center located in the southeast region of the U.S., which is defined as the work system. With over 950 beds and specialized services for all ages, this work system served as a regional referral center for COVID-19 patients and COVID-19 testing. Purposeful sampling was used to select formal leaders, defined as employees of the work system at a manager level or higher. These leaders provided an interdisciplinary perspective of ambulation from a systems level.

A total of 22 leaders were recruited using email, and 55% agreed to participate. Guided by information power (Malterud et al., 2016), the final sample included 12 leaders representing the following disciplines: nursing, physical therapy, occupational therapy, respiratory therapy, and epidemiology/infection prevention. Leaders participating in this study had an average of 21 years of experience in their profession and an average of 12 years of experience as a formal leader. Most of the leaders were female (75%) and had a master's degree (58%). See Table 4 for leader characteristics.

Table 4

Characteristics of Leaders

Characteristics	*n*	%
Gender		
Female	9	75
Male	3	25
Age in decade		
30's	3	25
40's	6	50
50's	3	25
Highest educational level		
Bachelors	3	25
Masters	7	58
Doctorate	2	17

Instruments Used

A semi-structured interview guide was created by the lead author based on a review of the literature regarding inpatient ambulation. Development and review of the interview guide included four additional researchers who had expertise in qualitative tool development or systems science. The interview guide contained the following broad opening question: "Tell me how COVID-19 has influenced patient ambulation in your facility?" Probing questions were used to understand ambulation barriers and facilitators within the work system.

Ethical Considerations

Approval from the university institutional review board was obtained, along with research approval from the medical center.

Data Collection

Data collection began in January 2021, approximately one year after the COVID-19 pandemic started. During this time, social distancing, isolation precautions, and other restrictions

were still in place to keep staff and patients safe during pandemic conditions. To comply with safety precautions, online methods were used for data collection. After written informed consent was obtained, each participant completed a demographic survey and was assigned an identifier (e.g., L1, L2) to protect their identity. Semi-structured interviews were conducted online, using a HIPAA-compliant version of Zoom. Interviews were transcribed verbatim by a university-approved, professional transcription service. In addition to interviews, fieldwork included documents and direct observations related to ambulation during the COVID-19 pandemic.

Data Analysis

An inductive approach to content analysis was used to analyze data from the three sources: interviews, documents, and direct observations (Elo & Kyngas, 2008; Graneheim et al., 2017). The primary source of data was 12 interviews, which were triangulated with the other data sources. Content analysis was guided by Elo and Kyngas (2008), including coding for labels, sorting for patterns, identifying outliers, and reflecting. The analysis included the second and third authors, who independently analyzed the data to address any potential threats to validity (Yin, 2018).

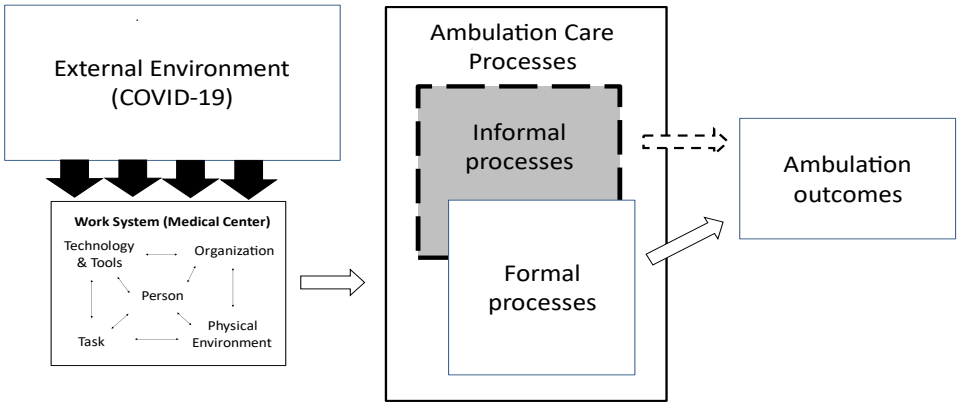
The analytic process started with a holistic or "broad brushstroke" (Saldana, 2021, p. 33) coding to select quotes/passages within each transcript. After first and second cycle coding (Saldana, 2021) was completed, any interpretative differences in the coding were identified and resolved. Patterns were identified using Word documents, drawings, matrices, and models/diagrams (Yin, 2018). Analysis revealed patterns showing the influence of COVID-19 on ambulation care processes. These patterns were organized using the following components of the SEIPS model: external environment, work system, and care processes.

Results

Findings showed COVID-19 was a significant source of stress on the work system. This additional stress from the pandemic caused changes in the daily operations of the work system. Although changes were necessary, they were barriers to ambulation which disrupted usual care processes. Part of this disruption resulted in the removal of visitors who had traditionally assisted with patient ambulation. As these people were removed from the work system, the value of informal ambulation assistance provided by visitors was exposed. (See Figure 3)

Figure 3

Exposing Informal Processes: The Impact of COVID-19 on Ambulation Care Processes



Note: Adapted with permission from "Human factors systems approach to healthcare quality and patient safety," by Carayon, P., Wetterneck, T. B., Rivera-Rodriguez, A. J., Hundt, A. S., Hoonakker, P., Holden, & R., Gurses, A. P., 2014, *Applied Ergonomics, 45*(1), p. 15. (https://doi.org/10.1016/j.aspergo.2013.04.023).

SEIPS External Environment: COVID-19

Guidelines, recommendations, and mandates related to COVID-19 were rapidly changing to keep up with the spread of COVID-19. The Centers for Disease Control and Prevention (CDC) provided guidance for businesses and employers that included COVID-19 screening, social distancing, and mask-wearing (Centers for Disease Control and Prevention, 2020a). The CDC recommended universal source control measures for everyone in a healthcare facility, which included mandatory mask-wearing and eye protection (Centers for Disease Control and Prevention, 2020b).

At the beginning of the COVID-19 pandemic, information about how to slow or stop the spread of COVID-19 was unknown. Participants described COVID-19 as "an unknown entity" (L6) and "a never event" (L4). One participant stated, "I think it was more a sense of the unknown and like how long was it [the COVID-19 pandemic] was gonna last initially." (L12) The uncertainties of COVID-19 are represented by the external environment in Figure 3.

Complying with COVID-19 mandates placed extraordinary stress on the work system, described as an "additional layer of hard" (L1) and represented as the bolded arrows in Figure 3. Because of the additional stress, many changes occurred in the work system that were abrupt and unexpected.

SEIPS Work System: Influence of COVID-19

To sustain operations during the COVID-19 pandemic, system changes were needed to promote staff and patient safety. Although these changes were necessary, participants described these changes as barriers to patient ambulation. The following sections will provide details on the ambulation barriers: staff shortages, mask supply shortages, and visitor restrictions.

Staff Shortages

Widespread, pandemic-level staffing shortages in the work system were described by participants as a barrier to ambulation. Emails regarding critical staffing differentials/rates, hiring travelers, and floating/cross-training confirmed the severe staffing shortages.

> *Staff is something else that's in short supply. And so, I think that that plays a role in being able to ambulate patients because I think staff is just a scarce resource at times. (L4)*

Staff shortages were intensified by COVID-related absences. CDC infection prevention guidelines and work system policies required staff to quarantine for 14 days after an exposure to COVID-19 and/or testing positive for COVID-19. As of December 31, 2021, the work system reported there was more than 530 staff were out due to COVID-19 exposures or testing positive. When multiple staff members were quarantined, this created a "devastating" (L6) shortage of staff, especially during peak months.

> *So, I think with the staffing, another thing we didn't account for would be our COVID-related absences. So, you know, when you're short-staffed already, and then all of a sudden, you got 14 people out for two weeks, I mean, it was devastating. (L6)*

While staff shortages in general negatively impacted ambulation, the shortage of nursing assistants was a significant barrier to ambulation. The shortage was significant because most participants (67%) referred to nursing assistants as the staff member responsible for patient ambulation. When there was a shortage of nursing assistants, it was difficult to provide ambulation assistance.

> *And so, our resources have been stretched a little bit. And so, we've had fewer assistive personnel, for instance. And fewer assistive personnel available to help with patient ambulation. (L5)*

Interview data and copies of unit-based ambulation protocols showed participants depended on nursing assistants to "drive" (L3) the operational side of ambulation, which included "owning" (L9) unit-based ambulation protocols. Nursing assistants were responsible for setting ambulation goals, prioritizing ambulation, documenting ambulation, and communicating results (i.e., patient refusal).

Mask Supply Shortages

Mask supply shortages were related to the unprecedented mandate for mask-wearing. When the CDC recommended universal mask-wearing and updated infection control policies required all staff, patients, and visitors to wear masks, this was a severe increase in usage that stressed the supply of masks within the work system. Public news updates from March 22, 2020, showed community donations were needed to supplement the work system's inventory of masks and other personal protective equipment.

Due to the shortage of masks, patient care activities were adjusted. For example, patients were asked to remain in their rooms and limit activities that would have required mask-wearing, such as hallway ambulation.

> *We were really discouraging people from getting up and walking. If they had to walk out of the room, [they had to] put on a mask, but we were really discouraging them from getting up and walking at all. (L7)*

Visitor Restrictions

The majority (83%) of participants referred to visitor restrictions as a barrier to ambulation. Although visitor restrictions were necessary to reduce the spread of COVID-19 and preserve the supply of masks, these restrictions resulted in the removal of people from the work system. These people were non-staff members, such as family members, students, and/or volunteers, who were usually available to assist patients with ambulation.

> *COVID-19 has impacted our visitation, so there's fewer people in the building. There's fewer family support members present for patients, and so, there are fewer people in the room with the patient who are able to help them ambulate safely. (L5)*

Effective March 23, 2020, visitors were not allowed in most inpatient areas. Information on the work system's website and emails from leaders showed visitation restrictions were updated six times in March 2020 to adjust to the spread of COVID-19 and mask supplies. As of May 2020, leaders at the work system had enforced more than 40 days of visitor restrictions. Darkened, closed waiting rooms, as well as empty lobbies, and a lack of visitor seating throughout the work system were constant reminders of these unprecedented restrictions.

SEIPS Care Processes: Formal and Informal

Care processes were supportive behaviors influencing ambulation. Participants described ambulation care processes in both a formal and informal context. Within the formal context, participants depended on the supportive behaviors of staff for patient ambulation. When barriers within the work system disrupted formal ambulation processes, this disruption exposed the value of visitors as an informal resource needed for patient ambulation.

Formal Care Processes

Participants described formal care processes as supportive ambulation behaviors of staff, more specifically, the behaviors of nursing assistants. Nursing assistants had formal training and guidance, as represented by the solid outline for the formal process box in Figure 3. As the work system experienced a shortage of nursing assistants, ambulation was a basic care task that dropped to the "wayside" (L5, L11) or was "pushed to the bottom of the list" (L1).

> *So, as we've had staffing challenges, with nurses and support staff, some of the basics, including ambulation, have been, you know, put to the wayside. You know, there are certain other things that we want to make sure happen. And ambulation might be one of those, that does get missed to our, just, staffing struggles that we've had. (L11)*

Because formal care processes were particularly dependent on nursing assistants, when nursing assistant support was "withdrawn" (L11) or "gone" (L7), patient ambulation was frequently missed.

Informal Care Processes

Participants described informal care processes as supportive ambulation behaviors of non-staff, such as family members, students, and volunteers. The value of these behaviors was revealed when formal care processes were disrupted, and ambulation was compromised. It became apparent to participants that informal care processes were needed for the formal care processes to be successful.

> *Having those visitors at the bedside, they could not only help and provide extra hands, but they would also speak up and be an advocate for the patient, when something needs to happen. (L7)*

Although students and volunteers assisted with patient care, participants referred to the support of family members most frequently. Participants referred to family members as a "second pair of hands" (L8) and "extra hands" (L7) to help provide safe ambulation. According to ambulation protocols and direct observation, supportive ambulation behaviors of family members included reinforcing safe ambulation instructions, holding ambulation equipment (i.e., walker, wheelchair), and rolling intravenous poles.

When family members were not at the bedside providing help, this exposed a “gap” (L5) or “missing link” (L7) in patient care processes.

> *We're used to our patients and families being trained on how to safely get patients up and move them around the unit and in their room safely, and because those people are not there, we... there's a gap there, because, we have not had ample, family support in order to do that. (L5)*

This “gap” (L5) revealed the value of informal ambulation behaviors by family members. The value to the work system was unpaid surveillance and additional ambulation support that promoted patient safety. When family members were restricted from the work system, participants perceived the lack of family assistance as partially responsible for negative patient outcomes, such as patient falls.

> *So we saw a high increase in falls with patients trying to ambulate on their own or patients who just didn’t want to ambulate because no one was there to help them.” (L7)*

This finding is limited to interview data only and should be corroborated with documentation from the work system, such as fall rates.

Discussion

In this study, we explored the impact of COVID-19 on the work system's influence on organizational care processes and ambulation outcomes. Guided by the SEIPS model (Carayon et al., 2014), our findings show the COVID-19 pandemic (external environment) caused stress on the medical center (work system) which resulted in three main barriers to ambulation: staff shortages, mask supply shortages, and visitor restrictions. Specifically, policies and procedures enforced restrictions that resulted in the immediate removal and ongoing limitation of visitors (i.e., family, students, and volunteers), revealing the value of informal care processes. The supportive ambulation behaviors of non-staff were needed for the formal care processes to be successful. Uncovering the value of informal care processes has implications for system-level policies and procedures, and consideration of how visitors might be included in the work system.

Results from our study suggest visitors are essential to the work system and informally contribute to the provision of safe ambulation. Our study adds to the existing knowledge on patient ambulation by providing an example of *how* these informal care processes are occurring in the hospital setting. According to participants, informal processes included surveillance and responding immediately to the patient's needs. These findings agree with research that shows supportive family members provide a "safety net" (Gandhi, 2022, p. 61) for hospitalized patients. In addition, supportive family members have significantly reduced adverse events, such as falls, pressure ulcers, and clinical deterioration (Giap & Park, 2021). When the COVID-19 pandemic restricted family members from hospitals, patients experienced a significant increase in patient safety events, such as falls and sepsis (Silvera et al., 2021).

Because most of the research on in-hospital care has been conducted outside the U.S., our findings fill a gap in the literature. Existing research from other countries shows it is common for family members to have active roles and responsibilities in the provision of basic care for

hospitalized patients, such as bathing, feeding, and administering medications (Lavdaniti et al. 2011; Sapountzi-Krepia et al., 2008; Stavrianou, 2018). Family members are often explicitly used to compensate for staffing shortages (Ambrosi et al., 2017; Amiresmaili et al., 2018; Bergerød et al., 2018; Lavdaniti et al., 2011; Lilleheie et al., 2020). Family members have been described as "staff extenders" (Ambrosi et al., 2017, p. 91) and "in-hospital informal caregivers" (Lavdaniti et al., 2011, p. 1). These trends occurring outside the U.S. are concerning and suggest the absence of family members may be a barrier to the provision of safe ambulation and basic in-hospital care.

Although our main findings show the value of assistance from family members, the informal assistance from other visitors (i.e., students and volunteers) should not be overlooked. Specifically, students were "extra hands" and assisted staff with complex patients and/or patients needing maximum assistance with ambulation. Our findings suggest students (e.g., nursing, nursing assistant, physical therapy, respiratory therapy, recreational therapy) may help relieve organizational staff shortages during usual operations, as well as during future pandemics. Research shows interdisciplinary healthcare students (i.e., medicine, pharmacy, nursing, dentistry, public health, and radiology) were willing to volunteer during the COVID-19 pandemic (Tran et al., 2022). In particular, research shows medical students and nursing students were willing to volunteer during COVID-19 (Al Gharash et al. 2021; Lazarus et al., 2021). In their study, Al Gharash and colleagues (2021) included second-year nursing students enrolled in a three-year Bachelor of Nursing program in Australia. The researchers purposefully selected second-year students because they possessed basic clinical skills that first-year students had not achieved (Al Gharash et al., 2021). Research suggests that although students may be a valuable resource, skill level and readiness to practice should be considered (Lazarus et al., 2021).

By broadening the definition of the external environment and outside forces that can pose a significant threat to usual care processes for hospitalized patients, this study adds to the body of knowledge on work systems. The external environment was added to the SEIPS model in 2014 due to "the major role of regulatory, professional and consumer/patient groups in healthcare delivery" (Carayon et al., 2014, p. 16). As the SEIPS model has been revised and updated, the definition of the external environment has developed to include specific examples, such as insurance companies, health care workforces, regulatory organizations, economic, and societal factors (Carayon et al., 2014; Carayon et al., 2020; Holden et al., 2013). Existing literature does not explicitly include pandemics and/or other disasters in the definition of the external environment (Carayon et al., 2014; Karsh et al., 2006; Kleiner, 2008); thus, our findings contribute to the understanding of how pandemics may add pressure on the organization and impact usual care processes.

Our findings suggest interactions between the external environment, work system, and care processes resulted in missed ambulation. Previous studies have not used a research design that supported a systems approach. By using the SEIPS model (Carayon et al., 2014), findings reflect a systems approach that shows an interdependency and shared responsibility between components for ambulation of the hospitalized patient. This is significant because missed ambulation has traditionally been a responsibility of the nursing discipline (Kalish, 2006) and a change in nursing practice (King et al., 2016). A shared responsibility (i.e., formal and informal care processes) for ambulation is the start of a systems-level solution that may provide a more comprehensive understanding of in-hospital ambulation.

Limitations of the Study

Several limitations of the study should be discussed. First, this study was conducted at a large academic medical center; therefore, the findings may not be transferable to other settings. Participants were interdisciplinary leaders who provided a systems-level perspective on ambulation; however, this purposeful sample excluded staff who were providing direct patient care and ambulation assistance during pandemic conditions. In addition, there were data limitations because patient ambulation processes were not observed, and outcome data were not collected. Future research should consider these types of data to corroborate findings and strengthen internal validity. Also, leaders were asked to recall ambulation activities that happened at the start of the pandemic. The passing of time and the stress of pandemic conditions may have affected their recall and accuracy of information during interviews. To minimize this limitation, interview data were triangulated with other sources of evidence. We also recognize the extreme staffing shortages may have influenced the leaders' perceived value of family members' supportive behaviors, and we realize family support during hospitalization varies greatly.

Conclusions

Missed ambulation is typically viewed as a nursing responsibility; however, findings from this study suggest missed ambulation is a systems issue involving interactions between the external environment, work system, and care processes. Unprecedented stress from the COVID-19 pandemic forced changes in the medical center. These changes were barriers to ambulation (staff shortages, visitor restrictions, and mask supply shortages) that disrupted usual ambulation care processes. More specifically, visitor restrictions removed family members and revealed the value of informal ambulation assistance. Understanding ambulation care processes may help

facilitate the design of system-level ambulation policies and programs that include informal, unpaid resources such as family members.

Implications for Nursing Management

Although this study was focused on ambulation during pandemic conditions, the findings can help reframe our thinking about missed ambulation from a systems perspective. As the COVID-19 pandemic forced changes in the hospital, there was a downstream effect that disrupted usual ambulation care processes. Policy development is needed to address missed ambulation, and decrease negative patient outcomes (Brown et al.,2004; Doherty-King et al., 2014; Pottenger et al., 2019). System-level policies should include pandemic plans that minimize the removal of individuals who may be able to provide valuable assistance with patient ambulation.

We recognize visitor restrictions may be unavoidable in high-risk situations; however, if appropriate, organizations should consider innovative solutions for the execution of safe ambulation. For example, one way to address the provision of ambulation is to provide system-level guidance (e.g., organizational communication, policies, workflows) to all patients and family members regarding *how* in-hospital, informal assistance can be provided. Research suggests there are "unique requirements" (Gur-Yaish, 2019, p., 266) for providing informal care in the hospital setting, and these requirements may be a knowledge barrier for family members. Due to unfamiliarity with hospital rules and regulations, family members may not understand how to actively participate in the provision of basic care unless they are provided guidance (Gur-Yaish et al., 2019; King et al., 2021). In addition, alternative ambulation resources, such as students and volunteers, should also be explored.

Notably, the medical center in this study developed a volunteer-based program to provide help with the provision of patient care. When visitor guidelines were updated in September 2021, the leaders at the medical center developed a program, referred to as “Helping Hands,” which provided opportunities for staff, students, retirees, and community members to volunteer to help with patient care activities such as COVID-19 testing, patient transportation, and ambulation. Documentation from news updates shows the program has enlisted over 400 volunteers as of October 2021. Leaders should consider developing a similar program that provides informal resources or “Helping Hands” to support ambulation care processes.

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APPENDIX A: UMCIRB

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** ·
rede.ecu.edu/umcirb/

Notification of Exempt Certification

From: Social/Behavioral IRB
To: Christa Jones-Hooker
CC: Deborah Tyndall
Date: 11/18/2020
Re: UMCIRB 20-001331
Exploring the Impact of COVID-19 on the Work System's Influence on Care Processes and Ambulation Outcomes

I am pleased to inform you that your research submission has been certified as exempt on 11/17/2020. This study is eligible for Exempt Certification under category # 2b.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

Document	Description
CJones-Hooker_DemographicInfo_9-23-20(0.01)	Surveys and Questionnaires
CJones-Hooker_DemographicInformation(0.01)	Data Collection Sheet
CJones-Hooker_DissertationProposalFinal(0.01)	Study Protocol or Grant Application
CJones-Hooker_Observation Tool(0.01)	Additional Items
CJones-Hooker_Participant Interview_9-23-20(0.01)	Interview/Focus Group Scripts/Questions
Revised Informed Consent_11-1-20(0.01)	Consent Forms
Revised Recruitment Email 11-2-20(0.01)	Recruitment Documents/Scripts
SEIPSModel_Permission(0.01)	Additional Items

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

APPENDIX B: INTERVIEW GUIDE

Please answer the questions below.

1. Pseudonym:

2. Gender:

3. Age: (provide in decade, 40's, 50's, 60's)

4. Degree(s):

5. Years' experience as a registered nurse:

6. Years' experience as a formal leader:

7. Professional certification(s):

8. Job Title: (i.e., Director, Manager)

Study Title: Exploring the Impact of COVID-19 on the Work System's Influence on Care Processes and Ambulation Outcomes

Opening Statement: I am interested in learning more about the work system influences on ambulation during a pandemic. As a leader in this organization, you are instrumental during these unprecedented times in influencing processes that impact patient outcomes related to ambulation. My questions are aimed to learn more about your perspective regarding the patient activity of ambulation during a pandemic.

Broad Opening Question: Tell me how COVID-19 has influenced patient ambulation in your facility?

Based on the answer to the broad opening question, the following probing questions **MAY** be used to further explore how the COVID-19 pandemic impacts the work system's influence on organizational care processes and ambulation outcomes.

Work system components ↓	**Facilitators** ↓	**Barriers** ↓	**Ambulation Outcomes** ↓
Because of the pandemic, have there been resources allocated for patient ambulation?	You have mentioned [polices, resources] that have been put into place since the pandemic. What factors helped these processes?	You mentioned [lack of resources, lack of polices, miscommunication] during the pandemic. What factors hindered these processes?	You have mentioned that ambulation of patients is often missed during the pandemic. What factors do you think are contributing to this?
Because of the pandemic, have any formal or informal policies been put into place to support patient ambulation?	Describe the influence of these _____ (facilitators) during COVID-19.	Describe the influence of these _____ (barriers) during COVID-19.	Tell me more about the factors (mentioned above) during COVID-19.
Were there challenges within the physical environment that impacted allocation of resources or implementation of policies?	Tell me more about any facilitators to ambulation.	Tell me more about any barriers to ambulation.	When ambulation of patients is missed, how is this handled (macro and micro)?
How were staff informed about new policies/protocols and or available resources? Were these methods effective? Why or why not?			

APPENDIX C: DOCUMENTATION INSTRUMENT FOR DATA COLLECTION

1	Type of Document
2	Physical Characteristics of the Document:
3	Title of Document
4	Date of Document
5	Author of Document: (committee/department/position/title)
6	Target Audience:
7	Purpose of Document:
8	Sources Provided
10	Solicited or Unsolicited

APPENDIX D: OBSERVATION TOOL FOR DIRECT OBSERVATIONS DURING FIELDWORK

Date **Purpose**	
Cue Column *Questions & Reminders will be recorded in this space*	**Notes** *This space will be used for descriptive, concrete, and detailed notes.* *Examples of field note data include:* *1. Setting* *2. Individuals present* *3. Physical setting* *4. Social interaction* *5. Activities* *This space will also be used to record the observer's own feelings, reactions, and reflections.*

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		Issue	1
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NEW WORK DETAILS

Title	The Impact of COVID-19 on the Work System's Influence on Care Processes and Ambulation Outcomes	Publisher imprint	N/A
		Expected publication date	2021-12-01
Author	Christa Jones-Hooker, MSN, RN, NE-BC	Expected size (number of pages)	5
Publication	Journal of Nursing Management	Standard identifier	N/A
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A) **Posting e-reserves, course management systems, e-coursepacks for text-based content,** which grants authorizations to import requested material in electronic format, and allows electronic access to this material to members of a designated college or university class, under the direction of an instructor designated by the college or university, accessible only under appropriate electronic controls (e.g., password);

B) **Posting e-reserves, course management systems, e-coursepacks for material consisting of photographs or other still images not embedded in text,** which grants not only the authorizations described in Section 14(b)(i)(A) above, but also the following authorization: to include the requested material in course materials for use consistent with Section 14(b)(i)(A) above, including any necessary resizing, reformatting or modification of the resolution of such requested material (provided that such modification does not alter the underlying editorial content or meaning of the requested material, and provided that the resulting modified content is used solely within the scope of, and in a manner consistent with, the particular authorization described in the Order Confirmation and the Terms), but not including any other form of manipulation, alteration or editing of the requested material;

C) **Posting e-reserves, course management systems, e-coursepacks or other academic distribution for audiovisual content,** which grants not only the authorizations described in Section 14(b)(i)(A) above, but also the following authorizations: (i) to include the requested material in course materials for use consistent with Section 14(b)(i)(A) above; (ii) to display and perform the requested material to such members of such class in the physical classroom or remotely by means of streaming media or other video formats; and (iii) to "clip" or reformat the requested material for purposes of time or content management or ease of delivery, provided that such "clipping" or reformatting does not alter the underlying editorial content or meaning of the requested material and that the resulting material is used solely within the scope of, and in a manner consistent with, the particular authorization described in the Order Confirmation and the Terms. Unless expressly set forth in the relevant Order Conformation, the License does not authorize any other form of manipulation, alteration or editing of the requested material.

ii) Unless expressly set forth in the relevant Order Confirmation, no License granted shall in any way: (i) include any right by User to create a substantively non-identical copy of the Work or to edit or in any other way modify the Work (except by means of deleting material immediately preceding or following the entire portion of the Work copied or, in the case of Works subject to Sections 14(b)(1)(B) or (C) above, as described in such Sections) (ii) permit "publishing ventures"

where any particular course materials would be systematically marketed at multiple institutions.

iii) Subject to any further limitations determined in the Rightsholder Terms (and notwithstanding any apparent contradiction in the Order Confirmation arising from data provided by User), any use authorized under the electronic course content pay-per-use service is limited as follows:

A) any License granted shall apply to only one class (bearing a unique identifier as assigned by the institution, and thereby including all sections or other subparts of the class) at one institution;

B) use is limited to not more than 25% of the text of a book or of the items in a published collection of essays, poems or articles;

C) use is limited to not more than the greater of (a) 25% of the text of an issue of a journal or other periodical or (b) two articles from such an issue;

D) no User may sell or distribute any particular materials, whether photocopied or electronic, at more than one institution of learning;

E) electronic access to material which is the subject of an electronic-use permission must be limited by means of electronic password, student identification or other control permitting access solely to students and instructors in the class;

F) User must ensure (through use of an electronic cover page or other appropriate means) that any person, upon gaining electronic access to the material, which is the subject of a permission, shall see:

- a proper copyright notice, identifying the Rightsholder in whose name CCC has granted permission,
- a statement to the effect that such copy was made pursuant to permission,
- a statement identifying the class to which the material applies and notifying the reader that the material has been made available electronically solely for use in the class, and
- a statement to the effect that the material may not be further distributed to any person outside the class, whether by copying or by transmission and whether electronically or in paper form, and User must also ensure that such cover page or other means will print out in the event that the person accessing the material chooses to print out the material or any part thereof.

G) any permission granted shall expire at the end of the class and, absent some other form of authorization, User is thereupon required to delete the applicable material from any electronic storage or to block electronic access to the applicable material.

iv) Uses of separate portions of a Work, even if they are to be included in the same course material or the same university or college class, require separate permissions under the electronic course content pay-per-use Service. Unless otherwise provided in the Order Confirmation, any grant of rights to User is limited to use completed no later than the end of the academic term (or analogous period) as to which any particular permission is granted.

v) Books and Records; Right to Audit. As to each permission granted under the electronic course content Service, User shall maintain for at least four full calendar years books and records sufficient for CCC to determine the numbers of copies made by User under such permission. CCC and any representatives it may designate shall have the right to audit such books and records at any time during User's ordinary business hours, upon two days' prior notice. If any such audit shall determine that User shall have underpaid for, or underreported, any electronic copies used by three percent (3%) or more, then User shall bear all the costs of any such audit; otherwise, CCC shall bear the costs of any such audit. Any amount determined by such audit to have been underpaid by User shall immediately be paid to CCC by User, together with interest thereon at the rate of 10% per annum from the date such amount was originally due. The provisions of this paragraph shall survive the termination of this license for any reason.

c) ***Pay-Per-Use Permissions for Certain Reproductions (Academic photocopies for library reserves and interlibrary loan reporting) (Non-academic internal/external business uses and commercial document delivery).*** The License expressly excludes the uses listed in Section (c)(i)-(v) below (which must be subject to separate license from the applicable Rightsholder) for: academic photocopies for library reserves and interlibrary loan reporting; and non-academic internal/external business uses and commercial document delivery.

i) electronic storage of any reproduction (whether in plain-text, PDF, or any other format) other than on a transitory basis;

ii) the input of Works or reproductions thereof into any computerized database;

iii) reproduction of an entire Work (cover-to-cover copying) except where the Work is a single article;

iv) reproduction for resale to anyone other than a specific customer of User;

v) republication in any different form. Please obtain authorizations for these uses through other CCC services or directly from the rightsholder.

Any license granted is further limited as set forth in any restrictions included in the Order Confirmation and/or in these Terms.

d) ***Electronic Reproductions in Online Environments (Non-Academic-email, intranet, internet and extranet).*** For "electronic reproductions", which generally includes e-mail use (including instant messaging or other electronic transmission to a defined group of recipients) or posting on an intranet, extranet or Intranet site (including any display or performance incidental thereto), the following additional terms apply:

i) Unless otherwise set forth in the Order Confirmation, the License is limited to use completed within 30 days for any use on the Internet, 60 days for any use on an intranet or extranet and one year for any other use, all as measured from the "republication date" as identified in the Order Confirmation, if any, and otherwise from the date of the Order Confirmation.

ii) User may not make or permit any alterations to the Work, unless expressly set forth in the Order Confirmation (after request by User and approval by Rightsholder); provided, however, that a Work consisting of photographs or other still images not embedded in text may, if necessary, be resized, reformatted or have its resolution modified without additional express permission, and a Work consisting of audiovisual content may, if necessary, be "clipped" or reformatted for purposes of time or content management or ease of delivery (provided that any such resizing, reformatting, resolution modification or "clipping" does not alter the underlying editorial content or meaning of the Work used, and that the resulting material is used solely within the scope of, and in a manner consistent with, the particular License described in the Order Confirmation and the Terms.

15) **Miscellaneous.**

a) User acknowledges that CCC may, from time to time, make changes or additions to the Service or to the Terms, and that Rightsholder may make changes or additions to the Rightsholder Terms. Such updated Terms will replace the prior terms and conditions in the order workflow and shall be effective as to any subsequent Licenses but shall not apply to Licenses already granted and paid for under a prior set of terms.

b) Use of User-related information collected through the Service is governed by CCC's privacy policy, available online at www.copyright.com/about/privacy-policy/.