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Sepsis: Do the Clinical Criteria Support the Medical Coding?

April M. Insco

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Abstract

Background: Sepsis is a condition that can be very costly and very deadly. Diagnosing sepsis can be challenging as there is not one specific test that will identify whether a patient has sepsis and there are varying opinions as to the true definition of sepsis. The definition of sepsis used for this research is a combination of System Inflammatory Response Syndrome (SIRS) with an identified infection. Medical Coders must review the documentation provided in a medical record to accurately assign an ICD-10-CM code. Administrative data is then used to provide statistical information for research purposes. When coded data is not accurate, this leads to errors in administrative data and inaccuracies in research. Objectives: The main goal of this study was to identify the accuracy of medical coding for sepsis patients. There were six research questions that guided the research. These included 1) Are cases coded as sepsis that are not clinically supported as sepsis; 2) Are infection cases not coded as sepsis clinically supported as sepsis; 3) Are there any variances for certain physicians; 4) Are there any variances for certain physician specialties; 5) Are there any variances for certain payers; 6) Are there any variances for certain medical coders? Methods: We used a convenience sampling of patient records from 4th quarter 2019 from Erlanger Health Systems that were coded as sepsis and a sampling that were coded as an infection without sepsis. Research Design and Study Procedures: Following Institutional Review Board (IRB) approval from both Erlanger Health Systems and the University of Tennessee Health Science Center (UTHSC), a chart review was conducted. Clinical indicators identified in the created data abstraction tool were abstracted from the patient records. Results: Data analysis concluded that the accuracy rate of medical coding for the sepsis patient records based on the clinical documentation was 98.5%. Physician specialty and payer type had no impact on the accuracy of medical coding on these records. Data analysis concluded the accuracy rate of medical coding for the infection patient records based on clinical documentation was 59%. Logistical regression also identified there were no variances in the coding for the infection patients based on the payer type, medical coder years of inpatient coding experience and the medical coders education level. Analysis determined there was a variance in coding accuracy of the infection patients group based on physician specialty.

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DEDICATION

This dissertation is dedicated to my husband and best friend, Corbin, and my son, Brandon, both of whom have always supported me.

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ABSTRACT

Background: Sepsis is a condition that can be very costly and very deadly. Diagnosing sepsis can be challenging as there is not one specific test that will identify whether a patient has sepsis and there are varying opinions as to the true definition of sepsis. The definition of sepsis used for this research is a combination of System Inflammatory Response Syndrome (SIRS) with an identified infection. Medical Coders must review the documentation provided in a medical record to accurately assign an ICD-10-CM code. Administrative data is then used to provide statistical information for research purposes. When coded data is not accurate, this leads to errors in administrative data and inaccuracies in research.

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LIST OF ABBREVIATIONS

AAPC	American Academy of Professional Coders
AHIMA	American Health Information Management Association
AKI	Acute Kidney Injury
ARF	Acute Respiratory Failure
BERD	Biostatistics, Epidemiology Research Design Unit
CAHIIM	Commission on Accreditation for Health Informatics and Information Management
C&M Committee	ICD-10 Coordination and Maintenance Committee
CCS	Certified Coding Specialist
CCS-P	Certified Coding Specialist – Physician Based
CDI	Clinical Documentation Improvement
CMS	Centers for Medicare and Medicaid Services
CPC	Certified Professional Coder
D/C disposition	Discharge disposition
E. coli	Escherichia Coli
HIM	Health Information Management
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICD-10-CM	International Classification of Diseases, Clinically Modified, 10th Revision
ICU	Intensive Care Unit
IRB	Institutional Review Board
LOS	Length of Stay
MAP	Mean Arterial Pressure
MS-DRG	Medicare Severity Diagnosis Related Group
NCHS	National Center for Healthcare Statistics
OCG	Official Guidelines for Coding and Reporting
OIG	Office of Inspector General
PDX	Principal Diagnosis
RN	Registered Nurse
RHIT	Registered Health Information Technician
SIRS	Systemic Inflammatory Response Syndrome
UTHSC	University of Tennessee Health Science Center
WBC	White Blood Count
WHO	World Health Organization

CHAPTER 1. INTRODUCTION

Statement of the Problem

Sepsis is a potentially life-threatening condition with variances in the clinical presentations and symptoms and yet it remains difficult to define (Seymour et al., 2016). This makes diagnosis of sepsis sometimes challenging and requires clinical judgment to accurately diagnose the condition (Teng & Wilcox, 2020). ICD-10-CM codes identify patients with documentation of sepsis in medical records. These codes are assigned by medical coders based on review of the provider documentation in the medical record. Medical coders must follow the *ICD-10-CM Official Guidelines for Coding and Reporting* when assigning codes to documentation in medical records. It is generally accepted that all sepsis cases are accurately and consistently assigned to the correct medical codes. However over the years, the numbers of reported patients with sepsis have increased, and part of this increase has been attributed to medical coding (Rhee et al., 2014). It is important to accurately collect data on patients with sepsis for public health reporting, future research, and reimbursement. Understanding the potential variance in medical coding can help determine the quality of medical coding of cases of sepsis. The goal of this research is to assess accuracy of medical coding of sepsis in medical records based on the clinical indicators for sepsis in the medical record.

Research has indicated that "more than 1.7 million individuals are diagnosed with sepsis annually in the United States and has a one in three mortality rate" (Teng & Wilcox, 2020). As the number of sepsis patients continues to rise, the cost of treating sepsis also continues to rise. One article stated more than $24 billion was spent in 2013 caring for patients with sepsis (Teng & Wilcox, 2020). According to a 2018 article in Healthcare Journal, "The cost of sepsis and postsepsis care continues to be a serious healthcare burden" (Hajj et al., 2018, p. 6)**.**

Physicians use specific clinical criteria to diagnose a patient as being septic. The clinical criteria used is dependent upon which definition of sepsis is used. Medical coders use the *ICD-10-CM Official Guidelines for Coding and Reporting*, which is published annually, to assign diagnosis codes to patient encounters. These guidelines and the clinical criteria used to diagnosis a patient with sepsis are not always the same. This makes the assignment of medical codes for sepsis both challenging as well as unclear. In this study, the following two questions will be explored: Do medical records coded as sepsis have documentation to clinically support the diagnosis of sepsis in the medical record? Does the documentation in the medical record support the diagnosis of sepsis when it is not coded as sepsis? The purpose of this study is to identify the accuracy of medical coding for sepsis patients based on the clinical documentation contained within the medical record.

Background of the Problem

Sepsis can be challenging for both the provider to diagnose and for the medical coder to assign a diagnosis code to the condition. Sepsis is a combination of symptoms and conditions that when presented together lead to the presumption of this diagnosis. Sepsis is assigned using various combinations of these indicators as well as several different clinical criteria. Many providers currently use sepsis 2 criteria, however there are some medical providers that utilize sepsis 3 criteria (Simpson, 2018). Additionally, the myriad of terms that may be used to describe sepsis or sepsis-like conditions including urosepsis, severe sepsis, septic shock, and sepsis syndrome adds to the confusion in regard to defining the diagnosis of sepsis.

Sepsis has been defined previously in 1991 and 2001 at the International Consensus Conferences (Seymour et al., 2016). The Third International Consensus Definitions Task Force met in 2014 and 2015 and changed the definition of sepsis for a third time as it was determined the current definition was outdated (Singer et al., 2016). They did not seek to change the definition of infection; however they "recommended elimination of the terms sepsis syndrome, septicemia, and severe sepsis and instead defined sepsis as "life-threatening organ dysfunction due to a dysregulated host response to infection" (Seymour et al., 2016, p. 763). While the new definition of sepsis, which has been termed Sepsis 3 was established by the Task Force, it has not been widely accepted. Currently the Centers for Medicare and Medicaid Services (CMS) uses sepsis 2, but some private insurance companies have changed over to sepsis 3.

There is not a single defined test that a provider can give a patient to make the determination of whether the patient does or does not have sepsis. According to the 2020 CDI Pocket Guide, the sepsis 2 definition is Systemic inflammatory response syndrome (SIRS) due to an infection (Pinson & Tang, 2020). The clinical indicators for SIRS include an elevated temperature (≥101 F) or hypothermia (<96.8 F), white blood count (WBC) >12,000 or <4,000 per µl, lactate >1.0 mmol/L, tachycardia (pulse >90 beats per minute), tachypnea (respiratory rate >20 breaths per minute), elevated procalcitonin, elevated c-reactive protein, altered mental status, mottling of the skin or prolonged capillary refill, and non-diabetic hyperglycemia or evidence of other acute organ dysfunction. If a patient has an infection and has two or more of the previously listed criteria that are not easily explained by another condition, then the patient has met sepsis 2 criteria.

Patients would be considered in septic shock if they have sepsis as well as >4.0 lactate and refractory hypotension (SBP <90, or MAP <70). These patients often require vasopressor therapy. Severe sepsis includes septic shock, but a patient may also have severe sepsis without septic shock. If a patient has sepsis as well as organ dysfunction, such as acute respiratory failure (ARF), acute renal failure, also known as acute kidney injury (AKI), encephalopathy, or other types of acute failure due to sepsis, then that patient would meet criteria for severe sepsis.

Sepsis 3 is "defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. For clinical operationalization, organ dysfunction can be represented by an increase in the Sequential [sepsis-related] Organ Failure Assessment score of 2 points or more" (Singer et al., 2016, p. 801). The sepsis 3 definition includes the presence of organ dysfunction whereas the definition of sepsis 2 does not. Studies show that identifying sepsis early can improve patient outcomes. "Ideally, patients at risk for sepsis should be identified before organ dysfunction is established" (Sartelli et al., 2018, p. 4). At the time of this study, sepsis 3 is not widely accepted by all physicians and payers, for this reason the definition and clinical criteria for sepsis 2 was used in this research.

Medical Coding of Sepsis

Medical Coders review clinical documentation in the patient medical record and assign an ICD-10-CM diagnosis code(s) based on *ICD-10-CM Official Guidelines for Coding and Reporting*. The documentation that medical coders can code from includes documentation from the medical provider, such as the history and physical, daily progress notes, consultation reports, procedure notes, and discharge summary. The International Classification of Diseases (ICD) 10th revision was published by the World Health Organization (WHO) in 1990. "The United States has used ICD-10-CM to code mortality since 1999. Since 1994, the NCHS has been developing the clinical modifications for use in the United States" (Cartwright, 2013, p. 589). The Health Insurance Portability and Accountability Act (HIPAA) mandates the use of the ICD-10-CM coding systems for electronic transactions and coding standards. The ICD-10-CM coding system includes many coding conventions that medical coders must follow to be compliant with HIPAA and prevent fraud and abuse (*Code Sets Overview*, 2020). The United States officially adopted the ICD-10-CM coding System and ICD-10-CM Official Guidelines for Coding and Reporting for use with discharges effective October 1, 2015.

Just as the clinicians meet and discuss various definitions of medical conditions; a similar process happens with review and updates to the ICD-10-CM coding system and the *ICD-10-CM Official Guidelines for Coding and Reporting*. Twice a year the Coordination and Maintenance committee, also known as the cooperating parties, reviews public comments on proposed changes to the medical codes and coding guidelines. The *ICD-10-CM Official Guidelines for Coding and Reporting* are published for use on October 1 each year. The cooperating parties include the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), the Centers for Medicare and Medicaid Services (CMS) and the National Center for Healthcare Statistics (NCHS), so there is input from a wide range of stakeholders on the coding definitions and guidelines.

The *ICD-10-CM Official Guidelines for Coding and Reporting* has four different sections. Section I is separated into 3 subsections. These include: section IA which includes guidance on the conventions of ICD-10-CM; section IB includes the General coding guidelines; section IC includes the chapter specific coding guidelines. Section II

identifies the guidelines for selection of a principal diagnosis. Section III identifies the guidelines for reporting additional diagnoses, and Section IV is for diagnostic coding and reporting guidelines for outpatient services.

In section IA of the Official Coding guidelines, guideline number 19 states: "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis." Based on this specific guideline, medical coders can sometimes find themselves with a dilemma on how to assign a sepsis code for a medical record. *ICD-10-CM Official Guidelines for Coding and Reporting* state it is sufficient that the physician documents the condition, but if the patient did not clinically meet sepsis criteria, there is a greater likelihood that the medical claim will be denied by the payer retrospectively.

The importance of accurate documentation and medical coding is best stated in the *ICD-10-CM Official Guidelines for Coding and Reporting*:

> A joint effort between the healthcare provider and the medical coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. These guidelines have been developed to assist both the healthcare provider and the medical coder in identifying those diagnoses that are to be reported. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated (2020, p.1)

Purpose of the Study

The purpose of this study is to identify the accuracy of medical codes assigned to patients with sepsis documented in their medical records. To assess the accuracy of medical coding of sepsis, researchers designed a data abstraction tool which includes key clinical indicators and other pertinent clinical information. This data abstraction tool will be used to abstract data from the medical records in the study sample. The coded data will then be compared to the clinical data for each record. Analysis of the abstracted data will determine if there are variances between the documentation and medical coding of sepsis with the clinical criteria to support the diagnosis. The researcher believes there are cases that are not properly coded as sepsis based on Sepsis 2 criteria. As such, the number of sepsis cases reported is not a good representation of the total population of patients with sepsis. Identifying these discrepancies will allow for education to health care providers, medical coders, and researchers about how sepsis codes are assigned and later used for research. This may also inform policy makers for the need to review and change *ICD-10-CM Official Guidelines for Coding and Reporting* for sepsis.

Significance of the Study

This study will generate empirical data on medical coding and sepsis. In addition, it will identify if there are any discrepancies with coded data and the clinical data in the medical records that supports the diagnosis of sepsis. Recognizing these issues will help providers to improve documentation to support sepsis when it is clinically present. Identifying these issues will help medical coders to determine the need to clarify any conflicting documentation in the medical record. Determining these issues will help researchers to recognize there are limitations in data sets. In future studies, the data abstraction tool could be utilized to evaluate more medical records and include other geographical regions on the United States.

Conceptual Frame of Reference

Currently, there are not any existing instruments that could be used for this type of study. A data abstraction tool included separately from this document as a supplemental file titled Data Abstraction Tool was developed in Excel based on the 2020 CDI Pocket Guide clinical indicators for sepsis. The data abstraction tool was reviewed by a panel of coding experts and adjustments were made to the tool based on the feedback collected. The data abstraction tool includes the clinical criteria used in the diagnosis of sepsis. In addition to the criteria included in the CDI Pocket Guide, the patient's account number, the medical coder, the length of stay (LOS), payer, physician, physician specialty, principal diagnosis code (PDX), the infection code, any identified organ failure, whether the patient has severe sepsis and/or shock, and whether or not positive blood cultures were present were included on the data abstraction tool. The only identifying patient information on the abstraction tool will be the account number and that is to prevent duplication. The medical coder and the physician identification number along with their specialty is included on the data abstraction tool. The purpose of those data points is to identify any trends or variances with the coding accuracy of sepsis. Coder and physician identities will not be reported as part of the research findings.

Research Questions

The researcher hypothesizes that the accounts coded as sepsis will be coded accurately less than 95% of the time. The second hypothesis is that the accounts coded as infections will be coded accurately less than 95% of the time. While the coding standard is 95% accuracy, previous studies have indicated a "median diagnostic accuracy" rate of 80.3 (Burns et al., 2012, p. 141). The researcher hypothesizes that the documentation does not always support sepsis even when it is coded as sepsis. The researcher hypothesizes that accounts coded as infections could have been clarified by the medical coder with the provider to obtain additional provider documentation to support sepsis based on the clinical indicators documented in the medical record.

The research questions used to guide this study pertain to the concepts of medical coding and whether the documentation supports the diagnosis of sepsis 2 with the clinical indicators. The research questions are:

1. Are cases coded as sepsis that are not clinically supported as sepsis?
2. Are infection cases not coded as sepsis clinically supported as sepsis?
3. Is there any variance for certain physicians?
4. Is there any variance for certain physician specialties?
5. Is there any variance for certain payers?
6. Is there any variance for certain medical coders?

Limitations of the Study

Some potential problems or limitations to the study could be the use of sepsis 3 criteria by the provider treating the patient. Another possibility could be that the provider thought the patient had a diagnosis of sepsis, but it was not documented accurately enough for the medical coder to code as sepsis.

Other limitations could be the experience of the medical coder. Medical coders may have different skill levels and experience that could hinder their ability to code accurately. Medical coders may also have different levels of formal education.

Several other factors may influence the results of the study. A convenience sample of medical records will be used. A sample of medical records with a principal diagnosis of sepsis will be obtained and a sample of medical records with a principal diagnosis of an infection without sepsis will be obtained. The ICD-10-CM diagnosis codes will be limited to specifically identified codes that are routinely associated with sepsis.

The geographical location of the facility used is also a limitation to the study. The study is limited to one health system in eastern Tennessee. The study was limited to discharges from Erlanger Health Systems for 4th quarter 2019. If additional studies are done at other facilities in other geographical regions, the outcome may be different.

Chapter Summary

As stated previously, sepsis is a condition that can be difficult to diagnose and difficult to code. This study will identify if there are any discrepancies with coded data and the clinical data in the medical record that supports the diagnosis of sepsis. The researcher will review the medical records to determine if the documentation supports the coding of sepsis. Identifying these issues will help providers to improve documentation to support sepsis when it is clinically present by identifying the missing documentation needed. It will also help medical coders to identify the need to clarify any conflicting documentation in the medical record.

A review of the literature supporting the research above will be presented in chapter two.

CHAPTER 2. LITERATURE REVIEW

Introduction

This chapter will examine the relevant literature for the proposed study including medical coding guidelines and sepsis coding criteria. Medical coding guidelines are utilized to report medical conditions in the United States and throughout the world to share information about mortality and morbidity globally. The review of the literature is organized by presenting an overview of the following sections: (a) Sepsis, (b) Sepsis Defined, (c) Medical Coding, (d) Limitation of Administrative Data, (e) Coding accuracy, (f) Summary.

Sepsis Defined

Sepsis can be very costly and deadly if not detected early or treated properly. Some studies estimate the cost of sepsis is over $20 billion annually (Hajj et al., 2018; Jafarzadeh et al., 2016; Torio & Andrews, 2013). Research has shown that sepsis has been identified as a condition that has one of the highest mortality rates (Gale & Hall, 2020; Zuick et al., 2016). The cost of treatment does depend on the patient's overall presentation. If the patient has severe sepsis, then the expected cost would be higher. The patients underlying comorbidities could also play a part in the overall cost of the hospital encounter. "Sepsis is generally remarkably expensive to treat and has been associated with high readmission rates" (Hajj et al., 2018, p. 1). Other studies have shown that the cost of sepsis is as high as $23 to $24 million and is one of the most costly conditions in the United States (Rudd et al., 2020; Torio & Moore, 2015). Additional potential costs could be incurred due to organ damage as a result of sepsis (Jafarzadeh et al., 2016).

According to Arefian et.al, many factors are considered when attempting to identify the cost of sepsis (Arefian et al., 2017). Some factors include the patient's comorbidities, whether the patient was in the intensive care unit (ICU), and the treatment provided. After the study was conducted, the conclusion was still that "despite all of the limitations of these original reports, sepsis treatment is still consistently extremely expensive" (Arefian et al., 2017, p. 115). Facilities have different protocols for treating sepsis patients and these would be a factor in identifying the true cost of a sepsis patient. A facility may place a patient in the intensive care unit (ICU) if they suspect sepsis, while other facilities may treat the patient on a regular patient unit unless they require critical care. Other factors may be the patient's wishes regarding their healthcare. One patient may be willing to be placed on a mechanical ventilator if acute respiratory failure develops, while others may refuse mechanical ventilation.

Rubens et.al, identified not only an increase in the cost of sepsis, but an increase in the rates of sepsis from 2005 to 2014 (2018). Additional findings in this study identified that sepsis accounts for 2% of all hospital admissions and that "the total cost of hospitalization due to sepsis increased significantly from U.S. $22.2 to U.S. $38.1

billion" (p. 860). Another study suggests that the incidence of sepsis has increased by 10% annually (Jafarzadeh et al., 2016). And yet another study has found that there are estimates of up to 300 cases per 100,000 population of patients with sepsis (Inada-Kim et al., 2017).

Several factors are attributed to the increasing number of sepsis cases. One factor is the increased focus on sepsis awareness as indicated in the Surviving Sepsis Campaign. The Surviving Sepsis Campaign is a joint collaboration of the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care Medicine (ESICM) committed to reducing mortality and morbidity from sepsis and septic shock worldwide (Society of Critical Care Medicine, n.d.). The Surviving Sepsis Campaign provides guidance, bundles, tools, and education for facilities to use to identify and treat sepsis patients (Rhodes et al., 2017).

In addition to the increased cost of sepsis and increased incidence of sepsis, there is also support for increased mortality of sepsis patients. According to a previous study, "Mortality related to sepsis was up to 140% higher compared to annual estimates of mortality form other causes" (Hajj et al., 2018, p. 5). Other studies show that in the United States, sepsis kills approximately 250,000 people per year (Epstein et al., 2016; Rhee et al., 2017; Simpson, 2018).

Even though the incidence of sepsis has been increasing, it continues to be a difficult condition to diagnose. There is not a specific test that determines if a patient has a diagnosis of sepsis or not. This makes differentiating sepsis as a cause of multiple organ dysfunction from other acute systemic inflammatory conditions difficult for providers to recognize and distinguish (Jolley, Sawka, et al., 2015). Sepsis is also made up of symptoms that can be seen with other conditions (Gale & Hall, 2020). Since there is not a universally identified test for sepsis, providers use established criteria to determine whether a patient has sepsis. However, not all providers agree on the best clinical criteria to use to diagnose sepsis.

The definition of sepsis has continued to evolve. The initial definition of sepsis, established in 1991, by a consensus panel convened by the American College of Chest Physicians (ACCP) and the Society of Critical Care Medicine (SCCM) (Sartelli et al., 2018). During this conference, sepsis was defined "as a systemic inflammatory response syndrome (SIRS) due to an infection" (Sartelli et al., 2018, p. 1). The clinical definitions of sepsis were updated in 2001 providing more clarification of what signs and symptoms are included in sepsis (Jolley, Quan, et al., 2015; Sartelli et al., 2018). This definition is currently still used to define sepsis, but it is now considered sepsis 2 criteria. In the 2020 CDI Pocket Guide by Pinson and Tang, the definition of sepsis is "SIRS due to an infection" (Pinson & Tang, 2020, p. 192). A proposal for a new definition of sepsis was published in the Journal of American Medical Association in February 2016 (Sartelli et al., 2018).

The Society of Critical Care Medicine and the European Society of Intensive Care Medicine appointed a task force that created the new definitions and criteria (Sartelli et

al., 2018). The sepsis 3 definition is a "life-threatening organ dysfunction caused by a dysregulated host response to infection" (Pinson & Tang, 2020, p. 192; Singer et al., 2016, p. 804). However, not all providers adhere to the new definition of sepsis 3 to diagnose their patients. According to a published article by Steven Simpson, although there was consensus in the development of sepsis 3 criteria, there is not consensus with the providers that diagnose and treat patients (Simpson, 2018). Another contributing factor to physicians continuing to use the Sepsis 2 definition is the fact that The Centers for Medicare and Medicaid Services (CMS) continues to support this definition (*Report on Medicare Compliance*, 2017). This makes defining sepsis challenging and may lead to confusion when reviewing coded data on sepsis.

Patients with sepsis may present with varying clinical signs and symptoms and some of the signs and symptoms are nonspecific. This creates a challenge for providers to determining whether or not patients are infected, particularly in the early stages of presentation and this is not something that can be addressed in definition of sepsis (Kuye & Rhee, 2018). Other studies support that sepsis is a complex condition and that makes it difficult to diagnosis (Gul et al., 2017; Iskander et al., 2013). Due to the vague and nonspecific symptoms, the complexity of the diagnosis process and no standard test to identify sepsis, all makes it a difficult condition to diagnose (Gul et al., 2017; Iskander et al., 2013; Kuye & Rhee, 2018).

Medical Coding

Medical coding is the first step in the medical billing and coding process in healthcare facilities. Medical coding is essentially the transformation of clinical documentation of healthcare diagnoses, procedures, medical services, and equipment from the patient health record into universal alphanumeric codes using the ICD-10-CM, ICD-10-PCS, CPT and HCPCS code sets. Medical coders must adhere to the *ICD-10-CM Official guidelines for Coding and Reporting* to ensure accurate medical coding. These coding guidelines are updated annually for implementation on October first which corresponds to beginning of the federal calendar and budget. The ICD-10-CM Official Guidelines for Coding and Reporting should be used as a companion document to the official version of ICD-10-CM as published on the NCHS website (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019). The Health Insurance Portability and Accountability Act (HIPAA) mandates the use of ICD-10-CM for the assignment of diagnosis codes (Administrative Simplification, n.d.). Adherence to the ICD-10-CM Official Guidelines for Coding and Reporting when assigning ICD-10-CM diagnosis codes is required under the Health Insurance Portability and Accountability Act (HIPAA) (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019).

In addition to the ICD-10-CM Official Guidelines for Coding and Reporting, medical coders must understand the coding hierarchy. Coding conventions take precedence over all other coding guidelines. If there is an instructional note in the tabular listing, then this would be followed before following the ICD-10-CM Official Guidelines for Coding and Reporting. Within the ICD-10-CM Official guidelines for Coding and

Reporting, there are guidelines for determination of principal diagnosis (PDX) selection as well as chapter specific guidelines. Section I.C includes the chapter specific guidelines. Chapter one includes Certain Infectious and Parasitic Diseases which includes the coding guidelines for sepsis.

The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care" (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019). There are additional guidelines for selection of PDX when there is more than one diagnosis that equally meets the definition of PDX. There is also a guideline that states:

> If the diagnosis documented at the time of discharge is qualified as "probable," "suspected," "likely,' "questionable," "possible," or "still to be ruled out," "compatible with," "consistent with," or other similar terms indicating uncertainty, code the condition as if it existed or was established (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019, p. 108).

Understanding these guidelines is key to identifying the principal diagnosis for an encounter and assigning the accurate medical code. Based on the previous coding guidelines, if sepsis is listed only as a possible diagnosis, and is not identified as still possible at discharge, the medical coder should not assign a code for sepsis without clarification from the provider. A query to the provider would then be required for clarification. A query tool is used to ask the provider a question for clarification about the documentation in the medical record. The American Health Information Management Association (AHIMA) developed guidelines for achieving a compliant query practice. Within these guidelines, AHIMA has established criteria for when it is appropriate to query a provider about a medical coding question (Bossoondyal et al., 2019). One instance is "to support documentation of medical diagnoses or conditions that are clinically evident and meet Uniform Hospital Discharge Data Set (UHDDS) requirements when the corresponding diagnoses or conditions stated is not stated" (Bossoondyal et al., 2019, p. 2).

Sepsis and severe sepsis have specific guidelines for sequencing as a principal diagnosis. The severe sepsis guideline states: "If severe sepsis is present on admission, and meets the definition of principal diagnosis, the underlying systemic infection should be assigned as the principal diagnosis" (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019, p. 25). When sepsis is the reason for admission, it should be sequenced as the PDX with the code for the identified infection as a secondary code. If the reason for admission is a localized infection and sepsis develops after admission, then the localized infection code would be first, followed by a sepsis code that was not present on admission.

Medical records should include documentation from the provider that validate the diagnosis of sepsis with clinical criteria. However, according to the ICD-10-CM Official

Guidelines for Coding and Reporting, it is not necessary for that documentation to be present for a medical coder to assign a specific code. According to guideline I.A.19,

> The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis (*ICD-10-CM Official Guidelines for Coding and Reporting*, 2019, p. 13).

Facilities may establish guidelines that require medical coders to review the medical record for clinical criteria to support the diagnosis of sepsis, but based on the previously stated guideline, it is not a requirement from the ICD-10-CM Official Guidelines for Coding and reporting (Sartori, 2018).

Limitation of Administrative Data

Many studies rely on administrative data to identify patients with sepsis for research purposes (Jolley, Sawka, et al., 2015; Martin et al., 2003; Nunnally et al., 2021; Rhee et al., 2015). In a 2015 study, it was stated "a reasonable conclusion is that sepsis is largely undercoded in administrative data using ICD-9 or ICD-10 coded case definitions" (Jolley, Sawka, et al., 2015, p. 6). Accuracy of medical coding provides valid reliable administrative data; however, physician documentation plays a role in the capture and reporting of administrative data.

To ensure administrative data is accurate, physician documentation must be complete, accurate and reliable. A qualitative study by Tang et al was conducted to determine if any barriers to high quality administrative data existed. There were five emerging themes. These themes were:

1. Coders are limited in their ability to add to, modify or interpret physician documentation, which supersedes all other chart information.
2. Physician documentation is incomplete and nonspecific.
3. Chart information tends to be replete with errors and discrepancies.
4. Physicians and coders use different terminology to describe clinical diagnoses.
5. There is a communication divide between coders and physicians, such that questions and issues regarding physician documentation cannot be reconciled (Tang et al., 2017, p. E617).

Medical coders can only code from a provider's documentation in the patient health record. If the provider documentation is incomplete or nonspecific, then it would be the medical coder's responsibility to send a provider query to clarify the documentation. This can be a complex process as some providers do not like responding to coder queries and some medical coders may lack the experience or confidence to send a query to a physician. When providers do not respond to a medical coder query to clarify the documentation, or the medical coder does not initiate the query then the docu-

mentation can continue to remain unclear. It will also prevent a medical coder from assigning accurate ICD-10-CM diagnosis codes to the encounter.

Administrative coding of sepsis is affected by the combination of the quality and completeness of physician documentation and the ability of the professional medical coder to identify the diagnosis of sepsis in the medical record (Jafarzadeh et al., 2016). This supports the need to have complete physician documentation to ensure accurate code assignment which results in accurate administrative data reporting. An initiative aimed at improving the accuracy and quality of physician documentation is identified as clinical documentation improvement (Thomas et al., 2015).

Clinical documentation improvement (CDI) professionals are medical coders or nurses that review documentation in medical records while a patient is still in the hospital. One of the goals of the CDI professional is to ensure that accurate documentation is recorded in the medical record before the patient is discharged from the hospital. One way that a CDI professional does this is through the query process. A query is a communication tool used to clarify clinical documentation by asking the provider to clarify documentation in the medical record. A query can be written when the documentation in the medical record is unclear, ambiguous, or incomplete (Bossoondyal et al., 2019). If a query is not written while the patient is still in the hospital, a medical coder can write a post-discharge query. This simply means the query was written after the patient was discharged from the hospital.

When a patient meets the clinical sepsis criteria, but sepsis is not documented in the medical record, the medical coder can send a post-discharge query to clarify with the provider if the patient has sepsis. The Guidelines for Achieving a Compliant Query Practice (2019 update), published by the Association of Clinical Documentation Improvement Specialists (ACDIS) and the AHIMA, is the recommended industry best standard for making documentation queries (Bossoondyal et al., 2019). Queries are useful tools to increase the accuracy of clinical documentation and create an accurate description of the episode of care.

As stated previously, administrative data is used in a variety of ways regarding sepsis. One way that administrative data is used for sepsis is by comparing the costs. Another is by comparing the mortality rates of individuals diagnosed with sepsis. These studies are conducted using the administrative data that are provided to databases. This data comes from the assignment of ICD-10-CM codes by the medical coders. The administrative data must be accurate to ensure results using this data is correct (Paoli et al., 2018).

Previous studies have reviewed patient records with sepsis, but none have used a combination of a medical coder and a physician for the validation. These studies compare the administrative data with the coded data. There are no comparisons of the clinical indicators of sepsis in the documentation with the accuracy of medical coding (Balamuth et al., 2015; Fleischmann-Struzek et al., 2018; Iwashyna et al., 2014).

Coding Accuracy

Medical coders must ensure they are assigning ICD-10-CM codes accurately based on the documentation in the medical record. Potential issues with accurate medical coding can stem from illegible documentation; incorrect or missing information; lack of clarity or precision, unbundling, upcoding; undercoding and duplicate billing. Accurate medical code assignment ensures that hospitals are reimbursed appropriately, but it also ensures the data is accurate for public reporting and other secondary data usage such as quality outcomes measures, regulatory compliance risk management and ensuring medical necessity (Wernhoff, 2021). Coded information is used to ensure quality of care for patients as well as providing accurate statistical data. Individual hospitals may have various accuracy expectations for medical coders; however, the industry standard for medical coders to accurately assign diagnosis and procedure codes is currently at 95% accuracy rate (3M Health, 2019). This accuracy rate is the gold standard for medical coders. Coded information is used to ensure quality of care for patients as well as providing accurate statistical data.

Medical coders must review the entire medical record to ensure they are coding the patient's diagnoses, conditions, and procedures appropriately and based on current guidelines. This review includes all documentation from the provider, including the history and physical examination, progress notes, consultations, emergency room documentation, procedure notes and discharge summary. In addition to the documentation from the provider, it may also be necessary for the medical coder to review pertinent laboratory and radiology data. After all the documentation has been reviewed, the medical coder then determines the accurate principal diagnosis based on the UHDDS definitions of principal diagnosis and assigns the appropriate ICD-10-CM diagnosis code.

Medical coders must adhere to ICD-10-CM Official Guidelines for Coding and Reporting to ensure they are coding accurately. These guidelines are updated each year for use with October 1 discharges. It is imperative that medical coders remain up to date on these code changes each year. Medical coders must maintain continuing education to ensure that they remain current with pertinent guidelines, CMS directives and coding changes. In addition to these guidelines, medical coders must also be familiar with and adhere to guidance from Coding Clinic for ICD-10-CM and ICD-10-PCS to ensure accounts are coded accurately. Coding Clinic is published each quarter by the American Hospital Association and provides expert advice on different coding scenarios. CMS also declared Coding Clinic as the official source for coding information (Office of the Federal Register, 2009).

Medical coders must also ensure they are coding patient records accurately to ensure the reimbursement provided to the hospital stays intact. When the documentation does not support the diagnosis of sepsis by explicitly stating sepsis, there could be a payer denial. Based on ICD-10-CM Official Guidelines for Coding and Reporting, a medical coder should never code a diagnosis that is not explicitly stated by the provider. A diagnosis of sepsis may still be denied by the payer if clinical criteria is not indicated in

the chart to support a diagnosis of sepsis. Other denials may come from payers based on the use of different clinical criteria (*Report on Medicare Compliance*, 2017).

Summary

In summary, diagnosing sepsis can be challenging since there is no standard test to identify if a patient has sepsis. This is further complicated by the lack of standard criteria for identifying the clinical factors indicating a patient has sepsis. Research has shown that the cost of sepsis continues to rise as does the incidence of sepsis. Even with the rising cost and incidence of sepsis, research shows that the mortality rate of sepsis does appear to be decreasing.

Although diagnosing sepsis can be challenging, there are very specific guidelines that a medical coder must follow to ensure medical records are coded accurately and appropriately. A physician query can and should be sent to a medical provider if the documentation is not clear, confusing, or ambiguous. Accurate code assignment and consistent, clear, and complete documentation ensures the accuracy of administrative data. This administrative data is used in research and to further enhance quality protocols and processes. When the data is not accurate, results of research studies are not accurate.

CHAPTER 3. METHODOLOGY

This chapter examines the research methods used to determine the accuracy of cases coded as sepsis and cases not accurately coded as sepsis as measured by clinical criteria captured in the data abstraction tool. This instrument includes measures of sepsis criteria from the CDI Pocket Guide and CMS standards and was validated by an expert panel. The chapter includes the following sections: (a) Research Design, (b) Medical Record selection, (c) Instrumentation, (d) Variables, (e) Data Acquisition and (f) Research Questions (g) Data Analysis Procedures (h) Limitations (i) Summary.

Research Design

The research design is a retrospective chart review utilizing convenience sampling. The data abstraction tool was used to gather patient data to compare with sepsis 2 clinical criteria. The data abstraction tool was adapted from the CDI Pocket Guide. According to the CDI Pocket Guide, sepsis is defined as "SIRS due to an infection. SIRS due to an infection is (either suspected or confirmed) is manifested by two or more of the following criteria, not easily explained by another co-existing condition"

- Temperature ≥101°F/> 38.3°C or <96.8° F/<36°C
- WBC >12,000 or <4,000 per µl
- Lactate > 1.0 mmol/L
- Tachycardia (pulse > 90 beats per minute)
- Tachypnea (respiratory rate >20 breaths per minute)
- Elevated Procalcitonin
- Elevated C - reactive protein
- Altered Mental Status
- Non-diabetic hyperglycemia (blood sugar >140 mg/dl)
- Other evidence of acute organ failure (severe sepsis) (Pinson & Tang, 2020, p. 192).

Important issues to address when developing the data abstraction tool include the length of the data abstraction tool, the interpretation of wording in the data abstraction tool, minimizing respondent bias and enhancing reliability. The data abstraction tool must be clear to the medical coders and providers. Since the data abstraction tool is adapted, with little modification, from variables in the CDI Pocket Guide, the researcher believes the instrument has validity to measure the key variables for this study. In order to identify any problems with the data collection tool, a review was performed by a panel of Health Information Management experts and a physician advisor so that any necessary changes could be made before conducting the study. The panel of Health Information Management experts was selected based on their background in medical coding and clinical documentation improvement and included practitioners from West Tennessee Healthcare, Baptist Memorial, Sweetwater Hospital Association and Erlanger Health Systems.

The suggestions from the experts included additional diagnoses to be used in the sample selection. This included the use of A02.1, A22.7, A26.7, A32.7 and A54.89 in the sepsis sample and N30.00, N30.01, L89 and L97 in the infection sample. One of the panel members suggested using the clinical indicator of significant edema or positive fluid balance (>20ml/kg over 24 hours) as an additional indicator on the data abstraction tool. However, after discussion with the physician advisor, it was determined that this indicator would not likely be documented specifically enough to determine its value for research purposes and for this reason, it was not included on the data abstraction tool.

Medical Record Selection

The medical records for this study consist of medical records from patients discharged from Erlanger Health System from the 4th quarter of 2019. There is no significance to this timeframe, this just happened to be the most recently completed quarter at the time the details of the research study were being fleshed out. These include patients discharged from October 1, 2019, through December 31, 2019, and only include inpatient encounters. All other types of patient encounters were excluded from the study. The HIM Coding Manager generated a report from Epic (the electronic health record) that included all patients with a principal diagnosis code of sepsis discharged during the 4th quarter of 2019. The ICD-10-CM medical codes utilized to identify the patients with sepsis to be included are A02.1, A22.7, A26.7, A32.7, A40.0, A40.3, A40.8, A40.9, A41.01, A41.02, A41.1, A41.2, A41.3, A41.4, A41.50, A41.51, A41.52, A41.53, A41.59, A41.81, A41.89, A41.9 and A54.86. These codes and the code descriptions are displayed in **Table 3-1**. These codes were selected as they are the sepsis codes included in the Specifications Manual for National Hospital Inpatient Quality Measures. This list also includes the additional diagnosis codes as suggested by the medical coding experts. A second report generated from Epic by the HIM Coding Manager, identified patients with a principal diagnosis code(s) for an infection, without a principal diagnosis of sepsis. The ICD-10-CM infection codes utilized to generate this report include codes from the following categories and subcategories: N10, N12, N13.6, N30.00, N30.01, N39.0, J09, J10, J11, J12, J13, J14, J15, J16, J18, J69.0, L02, L03, L89, and L97. These codes and descriptions are listed in **Table 3-2**. The category and subcategories include infections such as urinary tract infections, pneumonia, influenza, cellulitis, pressure, and non-pressure ulcers. Obstetrical and pediatric sepsis and infection cases were excluded from the study.

This research study is a retrospective review of electronic medical records. A convenience sample is being used for the research study. In order to determine a valid sample size for the study, the industry standard for medical coding is 95% accuracy (3M Health, 2019). The industry standard was chosen to calculate the sample size for this study. A valid sample will be determined for each population. The first population will be the accounts with sepsis listed as the principal diagnosis. The second population will be the accounts with an infection listed as the principal diagnosis.

Table 3-1. ICD-10-CM Sepsis Diagnosis Codes with Description.

ICD-10-CM Sepsis Diagnosis Code	ICD-10-CM Sepsis Diagnosis Code Description
A02.1	Salmonella Sepsis
A22.7	Anthrax Sepsis
A26.7	Erysipelothrix Sepsis
A32.7	Listerial Sepsis
A40.0	Sepsis due to streptococcus, group A
A40.3	Sepsis due to streptococcus pneumoniae
A40.8	Other streptococcal sepsis
A40.9	Streptococcal sepsis, unspecified
A41.01	Sepsis due to Methicillin susceptible staphylococcus aureus
A41.02	Sepsis due to Methicillin resistant staphylococcus aureus
A41.1	Sepsis due to other staphylococcus
A41.2	Sepsis due to unspecified staphylococcus
A41.3	Sepsis due to Hemophilus influenzae
A41.4	Sepsis due to anaerobes
A41.50	Gram-negative sepsis, unspecified
A41.51	Sepsis due to Escherichia coli [E. coli]
A41.52	Sepsis due to Pseudomonas
A41.53	Sepsis due to Serratia
A41.59	Other Gram-negative sepsis
A41.81	Sepsis due to Enterococcus
A41.89	Other specified sepsis
A41.9	Sepsis, unspecified organism
A54.86	Gonococcal sepsis

Table 3-2. ICD-10-CM Infection Diagnosis Category with Description.

ICD-10-CM Infection Diagnosis Category	ICD-10-CM Infection Diagnosis Category Description
N10	Acute Pyelonephritis
N12	Tub-interstitial nephritis, not specified as acute or chronic
N13.6	Pyonephrosis
N30.00	Acute cystitis without hematuria
N30.01	Acute cystitis with hematuria
N39.0	Urinary tract infection, site not specified
J09	Influenza due to certain identified influenza viruses
J10	Influenza due to other identified influenza virus
J11	Influenza due to unidentified influenza virus
J12	Viral pneumonia, not elsewhere classified
J13	Pneumonia due to Streptococcal pneumoniae
J14	Pneumonia due to Hemophilus influenzae
J15	Bacterial pneumonia, not elsewhere classified
J16	Pneumonia due to other infectious organisms, not elsewhere classified
J18	Pneumonia, unspecified organism
J69.0	Pneumonitis due to inhalation of food and vomit
L02	Cutaneous abscess, furuncle and carbuncle
L03	Cellulitis and acute lymphangitis
L89	Pressure ulcer
L97	Non-pressure chronic ulcer of lower limb, not elsewhere classified

Although the industry coding accuracy standard is 95%, there is an expectation that one number could be higher or lower, for this reason two-tailed tests will be used to determine whether the findings are statistically significant. Faculty from the UTHSC Biostatistics, Epidemiology Research Design Unit (BERD) were consulted to determine an appropriate sample size for each population within the study. After discussion with the committee and BERD statisticians, it was determined that 200 patient accounts should be reviewed from each of the reports generated for an adequate sample size.

Instrumentation

The data abstraction tool was adapted from the CDI Pocket Guide and reviewed by an expert panel comprised of health information management professionals. According to the Libman Education website, the Pinson and Tang CDI Pocket Guide is recognized as "the best resource for coding and clinical documentation integrity" (2020, p. 1). The data abstraction tool contains the following data elements including patient account number, medical coder identification number, LOS, discharge disposition, payer, physician, physician specialty, principal diagnosis code, infection code, severe sepsis/shock, identified organ failure, MS-DRG assigned, maximum temperature, minimum temperature, max systolic blood pressure, minimum systolic blood pressure, maximum heart rate, maximum respiratory rate, maximum WBC, minimum WBC, maximum lactate, maximum procalcitonin, maximum C-reactive protein, AMS documented, positive blood culture, and maximum glucose in a non-diabetic which will be collected by the researcher during the retrospective medical record review.

A **supplemental file** entitled Data Abstraction Tool is included separate from this document. The medical coder identification number will be collected during abstraction. This will allow the researcher to explore whether there are differences based on the medical coder. The physician's name and specialty of the physician will be collected. This will allow analysis to determine if there are any trends or variances based on the medical provider or the provider's specialty.

The principal diagnosis ICD-10-CM code will be collected. Based on Uniform Hospital Discharge Data Set (UHDDS) definitions, the principal diagnosis code is what identifies the reason, after study that the patient was admitted to the facility. If the patient presents and is admitted for sepsis, the sepsis code should be the principal diagnosis code based on the ICD-10-CM Official Guidelines for Coding and Reporting. The definition of sepsis requires an infection. For that reason, the infection code will also be abstracted. Some patients with sepsis will also have severe sepsis and/or septic shock. Severe sepsis is indicated by an associated organ dysfunction. Both severe sepsis and septic shock as well as the associated organ dysfunction will be abstracted. The Medicare Severity diagnosis related group (MS-DRG) for each patient will be included in the data abstraction. Abstracting the MS-DRG will allow the researcher to quickly know whether the patient has a principal diagnosis of sepsis or another infection.

Sepsis is present when a patient has an infection and meets the SIRS criteria. As noted in **Table 3-3**, the additional variables to be abstracted include temperature, systolic blood pressure (BP), heart rate, respiratory rate, WBC, lactate, procalcitonin, C-reactive protein, AMS, blood cultures and non-diabetic hyperglycemia. The variables will be abstracted to determine if the patient meets SIRS criteria. If a patient meets two of the preceding diagnostic criteria not easily explained by another condition, they will meet criteria for SIRS (Pinson & Tang, 2020). If a patient has a positive blood culture, it means they have a bacterium in the blood, which can indicate an infection. A positive blood culture may also be an indicator of sepsis. The physician advisor determined that the clinical data will only be abstracted if it occurred within the first 24 hours of admission for the patient.

Variables

The variables, values and descriptions of the clinical data elements included in the study are provided in **Table 3-3**. The variables and descriptions of the non-clinical data elements included in the study are provided in **Table 3-4**.

Data Acquisition

Medical records from the 4th quarter of 2019 at Erlanger Health System are selected as the research population for this study. The HIM Coding Manager generated a preliminary report and determined there were 478 patient medical records with sepsis as the principal diagnosis and 427 accounts with a principal diagnosis identified as an infection, but not sepsis. After discussion with the committee and statisticians, it was determined that 400 patient accounts should be reviewed for an adequate sample size. The HIM Coding Manager provided the researcher with two separate reports from which to select the medical records. The researcher will choose 200 randomly selected patient accounts from the report with sepsis patients and 200 randomly selected patient accounts from the patients not identified as sepsis.

The Institutional Review Boards (IRBs) at the University of Tennessee Health Science Center (UTHSC) in Memphis and The University of Tennessee Health Science Center (UTHSC), College of Medicine in Chattanooga both approved the proposed research study. These approvals are included in the **Appendix** (**Figures A-1** and **A-2**).

Each patient medical record will be manually reviewed by the researcher to gather each data element on the data abstraction tool. Each patient medical record may have multiple laboratory values for the WBC, lactate, procalcitonin, C - reactive protein and glucose level. Each patient medical record will likely have multiple vital signs documented, including the temperature, systolic blood pressure, heart rate and respiratory rate. After discussion with the physician advisor, it was determined that the only data collected would be vital sign values that were obtained within 24 hours of patient admission to the facility. Lab values over 24 hours would not be abstracted.

Table 3-3. Variables, Values, and Descriptions of Clinical Data Elements.

Variable	Value	Description
Temperature	≥101°F/>38.3°C or <96.8°F/<36.0°C	Fever or hypothermia
Systolic BP	<90 mm Hg	Persistent hypotension is an indicator of septic shock
Heart Rate	Pulse >90	Elevated heart rate
Respiratory Rate	Respirations >20	Elevated breathing rate
WBC	>12,000 or <4,000 per µl	Elevated or low white blood cell count
Lactate	>1.0 mmol/L	Elevated in heart failure or a severe infection or shock
Procalcitonin	≥0.25 ng/ML	Elevated in response to bacterial infections
C-Reactive Protein	>0.8 MG/DL	A marker of inflammation
AMS		Altered mental status – changes in brain function, can be due to infection
Blood Culture	Positive culture	Organisms present in the blood can indicate an infection
Glucose	>140 mg/dl	High blood sugar in a non-diabetic patient

Table 3-4. Variables and Descriptions of Non-clinical Data Elements.

Variable	Description
Coder Number	Number assigned by researcher to identify the medical coder
LOS	Length of stay identifies the number of days that the patient is in the facility
Discharge Disposition	Patients anticipated location or status at discharge
Payer	Responsible party for hospital bill
Physician Number	Number assigned to identify the physician
Physician Specialty	Branch of medicine to which the physician specializes
PDX Code	The diagnosis after study that is the reason the patient was admitted to the facility
Infection Code	Identified infection code diagnosed by the physician
Severe	Severe sepsis is sepsis with an identified organ dysfunction.
Septic/Shock	Septic shock is severe sepsis with hypotension or an elevated lactated above 4
Identified Organ Failure	Failure of s system in the body, such as respiratory failure, acute kidney failure or encephalopathy
MS-DRG	Medicare Severity diagnosis related groups is identified by the patients PDX, secondary diagnoses, discharge disposition, age and procedures

After each sepsis record is abstracted, the researcher will analyze the data to determine if the patient met SIRS criteria and had an infection to validate the diagnosis of sepsis. The patient medical records that do not have an identified infection code will be submitted to the physician advisor for review to determine whether there was an infection. The researcher will then determine if the patient met SIRS criteria based on the abstracted laboratory findings and documented vital signs. If the patient meets at least three criteria, it will be identified as meeting sepsis criteria and will be assigned an outcome measure of 1. If the patient has one or zero criteria, it will be identified as not meeting sepsis criteria and will be assigned an outcome measure of 0. Each patient that only meets on two criteria or the researcher is unsure, will be submitted to the physician advisor for review. The physician advisor will then use his clinical expertise to make the determination if the patient met sepsis criteria. The outcome measure will be assigned accordingly based on the physician advisor's recommendation.

The non-sepsis records will be abstracted utilizing the same data abstraction tool and process. Once these records have been abstracted, the researcher will analyze the data to determine if the patient meets SIRS criteria. These records each have an infection as the principal diagnosis, so they have met that portion of sepsis criteria. If the patient meets on three or more additional criteria, they will be identified as meeting sepsis criteria. If the patient meets zero or one criteria, it will be identified as not meeting sepsis criteria. Each patient that only meets two criteria or the researcher is unclear on will be submitted to the physician advisor for review. Again, the physician advisor will use his clinical expertise to determine if the patient met sepsis criteria.

Research Questions

The first two research questions proposed by the researcher are:

Are cases coded as sepsis that are not clinically supported as sepsis?
Are infection cases not coded as sepsis clinically supported as sepsis?

Some research has shown coding accuracy as low as 80.3% for diagnosis coding (Burns et al., 2012). However, the industry standard for medical coding accuracy is 95%. The Office of Inspector General identifies the error rate as 5% or less identifying the 95% accuracy rate for medical coding (Focus on Compliance: The Next Generation of Corporate Integrity Agreements, 2012). The researcher hypothesizes that the coding accuracy for the coded sepsis cases will be less than 95%. The researcher also hypothesizes the coding accuracy for infection cases will be less than 95%.

The next questions proposed by the researcher, which apply to both the sepsis cases and the infection cases are:

Are there any variances for certain physicians?
Is there any variance for certain physician specialties?

Since providers utilize different diagnostic criteria to diagnose a patient with sepsis. The researcher wants to establish whether this variance, if it exists, is specific to a certain physician specialty or if it is limited to certain providers.

The next question proposed by the researcher, which applies to both the sepsis cases and the infection cases is:

Is there any variance for certain payers?

Although a medical record should be coded based on the documentation in the patient record and the diagnosis of a patient with sepsis should be specific to the diagnostic criteria established for the diagnosis, the researcher is also reviewing the payer types to determine if there are any variances based on the patient's type of insurance.

The last question proposed by the researcher, which also applies to both the sepsis cases and the infection cases is:

Is there any variance for certain medical coders?

Medical coders have different levels of education and experience that impact their knowledge of coding guidelines and disease processes. Medical coders may also hold different coding credentials that may impact their skillset and knowledge base.

Data Analysis Procedures

Once the researcher was prepared to abstract the data, the HIM Coding Manager generated a final report to which the charts would be selected. The final report did include a total of 480 patients on the sepsis report and 423 on the infection report. Some of the patient records were excluded from the study. These exclusions included patient records that were coded during the 4th quarter 2019 but were not discharged during this timeframe. Pediatric and obstetrical patient records were also excluded. Only inpatient records were reviewed for the study, so any patient records that were previously changed to observation status were excluded. Patient accounts with a Swing Bed status were also excluded as they are not considered inpatient accounts. At the conclusion of the data abstraction, to protect patient privacy, the patient accounts were numbered as patient one to patient 200 on the infection patient records and patient 201 to patient 400 on the sepsis patient records. The hospital assigned account number was removed from the data set. The researcher analyzed the data to determine if each patient met sepsis criteria.

On the sepsis report, if the patient met on three or more clinical criteria, they were assigned as meeting sepsis criteria. If the patient met on one clinical criterion, they were assigned as not meeting sepsis criteria. Accounts where patients only met two clinical criteria were sent to the physician advisor to determine if the patients clinically met sepsis. On the infection report, if the patient met on three or more clinical criteria, they were assigned as meeting sepsis criteria. If the patient met on only one or no criteria, they

were assigned as not meeting sepsis criteria. Accounts on the infection report that only met on two criteria, or the researcher was uncertain if the account met sepsis criteria were sent to the physician advisor for review.

In **Table 3-5** there is an overview of the types of laboratory (lab) tests performed and the outcomes of each test for the sepsis patient records. Every lab test was not performed on every patient, therefore the overall total performed was not equal to 200 for each type of lab test. The lab tests included below were identified in chapter 3 as clinical indicators for sepsis. **Table 3-5** shows that a WBC was performed on each of the 200 patient records identified as sepsis, however the other lab tests were not performed on every patient.

Table 3-6 provides an overview of the types of lab tests performed and the outcomes for each test for the infection patient records. Not all lab tests were performed on each patient on this report, therefore the total number of tests performed does not equal 200. Two of the infection patient records had noninfectious SIRS documented and one patient record had the diagnosis of bacteremia. 80 patient records were coded with an identified organ failure, such as acute respiratory failure, acute kidney injury or encephalopathy.

The physician specialties were combined into the most common specialty groups. These groups included Internal Medicine, Family Medicine, Hospitalist, Surgical Critical Care, and Critical Care Medicine. Physicians not identified as one of those specialties were placed in the other group.

The insurance providers, also known as the payer, were grouped into four payer types. The payer types included Commercial, Government, and Self-pay. Insurance providers not identified as one of those payer types were grouped to the other group.

Data was collected as to the level of education, years of inpatient coding experience and credentials that each medical coder had as of January 1, 2020. At the time the data was gathered, only 18 of the 20 medical coders were still employed at Erlanger. Two of the medical coders were no longer at Erlanger and therefore the researcher was unable to obtain their specific information.

Once the data was cleaned in Excel, the results were entered into SPSS version for 27 Windows. Chi square tests were used to compare proportions of categorial variables for the patient records. Pearson product moment correlation was performed on the medical coders to determine if there was a correlation between coding accuracy and years of inpatient coding experience. The unadjusted odds ratio was calculated for the physician specialty group, the payer group and the medical coders' education level. Logistic regression was then used to examine the effect of the independent variables on the expected outcome. These variables included the physician specialty group, payer group, and the medical coder's education level. The years as an inpatient coder was

Table 3-5. Outcomes of Tests Performed on Sepsis Patients.

Type of Test Performed	Abnormal Range	Normal Range	Total Performed
WBC	74%	26%	200
Lactate	78%	22%	156
Procalcitonin	82%	18%	82
CRP	96%	4%	79
Blood Culture	20%	80%	177
Glucose in a Non-diabetic	36%	64%	89

NOTES: WBC – white blood count >12,000 or <4,000 per µl. Lactate >1.0 mmol/L. Procalcitonin ≥0.25 ng/ML. CRP – C-Reactive Protein >0.8 mg/dl. Glucose >140 mg/dl.

Table 3-6. Outcomes of Tests Performed on Infection Patients.

Type of Test Performed	Abnormal Range	Normal Range	Total Performed
WBC	36%	64%	195
Lactate	49%	51%	99
Procalcitonin	34%	66%	32
CRP	84%	16%	49
Blood Culture	7%	93%	130
Glucose in a Non-diabetic	18%	82%	87

NOTES: WBC – white blood count >12,000 or <4,000 per µl. Lactate >1.0 mmol/L. Procalcitonin ≥0.25 ng/ML. CRP – C-Reactive Protein >0.8 mg/dl. Glucose >140 mg/dl.

included as this provides the details regarding the medical coder's experience. Receiver operating characteristic (ROC) curve was used to test the goodness-of-fit of the logistic regression model, in other words, how well the logistic regression model fits the dataset. The Hosmer-Lemeshow test was also performed to determine the goodness of fit for the logistic regression model. Confidence intervals were calculated to determine the expected ranges for each of the calculated Odds Ratios. P values below 0.05 were considered statistically significant.

Limitations

This study is limited to an academic health system geographically located in the southeastern United States. While results of this study may be typical for this type of health system, they may not be indicative of other facilities in the area or other regions of the United States.

Other limitations to the study include the use of sepsis 2 criteria. Although CMS uses Sepsis 2 criteria, some providers have started using Sepsis 3 criteria and therefore not all patients would be identified as sepsis 2. Currently the "Sepsis-3 definitions are inconsistent with the *ICD-10-CM Official Guidelines for Coding and Reporting* (OCG)" (Pinson, 2016). Currently in ICD-10-CM, the sepsis codes identify severe sepsis with organ dysfunction and severe sepsis without organ dysfunction. Sepsis 3 criteria includes organ dysfunction and therefore would not need to have an option for coding without organ dysfunction. At this time, the ICD-10-CM coding system is not designed to properly code Sepsis 3. If a provider uses sepsis 3 criteria to diagnose the patient, they could still meet sepsis 2 criteria, but may not have been diagnosed as sepsis based on the providers clinical judgment.

Other limitations of the study could be the documentation. Some physicians may feel their documentation is sufficient to support the coding of sepsis, however, that may not be the case based on *ICD-10-CM Official Guidelines for Coding and Reporting*. Previous studies have found that medical coders report that three of the five main barriers to coding include the fact that "physicians and coders use different terminology to describe clinical diagnoses" and "that there are communication divide between coders and physicians" (Tang et al., 2017). Providers do not always like to document and may think the documentation is enough for a medical coder to code sepsis, when in fact, it may not be sufficient (Tang et al., 2017).

Medical coders may not code accurately if they are not well versed in the *ICD-10-CM Official Guidelines for Coding and Reporting* of sepsis. Some medical coders are word coders and code exactly what is documented without using critical thinking skills to question what they are reading or what might be missing. There are many guidelines regarding ICD-10-CM coding that a medical coder may not utilize that can cause errors. There is also Coding Clinic references that provide guidance for coding issues. Coding Clinic is designed to clarify coding issues that may be ambiguous or challenging. Although available, some medical coders do not use Coding Clinic or refer to *ICD-10-*

CM Official Guidelines for Coding and Reporting when they are uncertain of how to code a specific diagnosis. Some medical coders fail to follow the *ICD-10-CM Official Guidelines for Coding and Reporting* that states:

> If the diagnosis documented at the time of discharge is qualified as "probable," suspected," "likely," "questionable," "possible," or "still to be ruled out," "compatible with," "consistent with," or other similar terms indicated uncertainty, code the condition as if it existed or was established. The bases for these guidelines are the diagnostic workup, arrangements for further workup or observation, and initial therapeutic approach that correspond most closely with the established diagnosis.
>
> Note: This guideline is applicable only to inpatient admissions to short-term, acute, long-term care and psychiatric hospitals (2019, p. 108).

Medical providers might identify that a patient may have sepsis on admission, but eventually rule out the diagnosis. The medical coder may code a medical record as sepsis even if the diagnosis is considered an uncertain diagnosis. This would only be appropriate if the diagnosis was still considered a possibility at discharge based on the *ICD-10-CM Official Guidelines for Coding and Reporting*. However, an inexperienced medical coder could code it inaccurately.

The experience and knowledge of the medical coder may be a limitation. Coding credentials have different educational requirements. The Registered Health Information Technician (RHIT) provided by the American Health Information Management Association (AHIMA) requires a person to have an Associate Degree in Health Information Management from a CAHIIM (Commission on Accreditation for Health Informatics and Information Management) Accredited Program. However, a Certified Coding Specialist (CCS) does not require an educational component. The American Academy of Professional Coders (AAPC) also provides a coding credential. The Certified Professional Coder (CPC) offered by the AAPC also does not require an educational component. Medical coders with a formal education possess knowledge about coding, medical terminology, and disease processes that a medical coder without a formal education may not have.

Summary

This chapter examines the research methodology used within this research project. The research will identify any discrepancies in coded data and documented clinical data. Determining if these variances exist will help medical coders to use critical thinking skills to identify what might be missing when assigning codes to the documentation in a medical record. It will help them to determine what types of questions they need to ask the physician prior to completion of the coding to ensure accurate and consistent documentation supports the diagnosis coded by the medical coder.

Results will help advance research initiatives as it will provide researchers with the knowledge that there are variances in provider documentation and coding guidelines that may not completely identify all patients with sepsis. Therefore, data sets that are used to conduct research may be inaccurate. Determining if there are clinical indicators in the medical record that support sepsis but without a sepsis diagnosis will help physicians to understand what documentation needs to be in the medical record from a coding standpoint to ensure the diagnosis is coded appropriately and accurately based on the documentation. Providers know exactly how to diagnose a patient, however, sometimes the documentation is not complete and that prevents the medical coder from being able to accurately assign an ICD-10-CM code for the diagnosis. Medical coders can only assign ICD-10-CM codes for diagnoses that are documented by the physician or his representative. Medical coders cannot code diagnoses from other documentation, such as nursing, physical therapy, or dieticians, unless the diagnosis has been established by the provider.

The chapter included a review of the research design for the proposed study, an overview of the data abstraction tool, a review medical record inclusion criteria and proposal for data acquisition, a proposal for the analysis of data based on the research questions and hypotheses and the expected outcomes from this study.

CHAPTER 4. STUDY RESULTS

The purpose of this study was to determine the coding accuracy of sepsis in medical records. This chapter will discuss how the data was abstracted. The data analysis will then be discussed. Then the statistical analysis and hypothesis evaluation will be discussed. Lastly, the researcher will summarize the findings of the data and statistical analyses.

Data Abstraction

The researcher obtained reports of patient records for analysis. The first report included all patients that had a principal diagnosis of sepsis based on the preselected diagnosis criteria. The preselected criteria were presented in chapter 3. The second report included all patients that had a principal diagnosis of an infection based on the preselected diagnosis criteria. The reports included all patient records that were coded for these diagnoses during 4th quarter 2019.

A systematic sample of 200 patients per report was used for the study. The sepsis patient report was analyzed. There was a total of 480 patient accounts on the sepsis report. The researcher started with the first patient record on the list and chose every other patient record that met criteria until the systematic sample of 200 was identified. There were some patient records excluded from the study. Three pediatric patient records were excluded. One record was excluded because it was a swing bed account. One patient record was excluded because after the account was coded it had been converted to an observation account. Seven patient records were excluded because although they were coded in the 4th quarter, the patients were discharged prior to 4th quarter 2019.

The report with infection as the principal diagnosis was analyzed. The infection report had 432 patient accounts. The researcher started with the first patient record on the list and chose every other patient record until the systematic sample of 200 was identified. There were 44 pediatric patient records that were excluded from the study. Five patient records were also excluded as they had been converted to an observation account. Twelve additional patient records were excluded because they were discharged prior to 4th quarter 2019.

Statistical Analysis and Hypothesis Evaluation

Analysis of the sepsis patient records reveals that only three patient records did not meet sepsis criteria based on the clinical documentation in the medical record. 197 patient records were coded accurately as sepsis based on the clinical findings in the medical record. Three patients were coded as sepsis that were not clinically supported as sepsis in the medical record. The coding accuracy rate based on this finding is 98.5%,

which is above the identified standard 95% accuracy rate. The standard deviation was 0.122 and the confidence interval was CI: 0.97 - 1.00.

The researcher reviewed the accounts to identify the medical coders who coded these records. The patient records were coded by three different medical coders. There were also three different physicians for these patient records. The commonality for the physicians was that all three were internal medicine physicians. Two of the patients were Medicare, but the third patient had United Healthcare. Each of these three patient records only met on one diagnostic criteria. One patient had an elevated heart rate, one patient had an elevated white blood count, and the third patient had an elevated respiratory rate.

Analysis of the infection patient records revealed that 82 patient records met sepsis criteria on three or more of the identified clinical indicators. Ten of the patient records had provider queries that ruled out sepsis as a diagnosis. Of those ten patient records, seven met sepsis criteria. There were two patient records that were coded with sepsis as a secondary diagnosis that was present on admission. These two patient records were coded by different medical coders. The coding accuracy rate based on this finding is 59% which is significantly lower than the identified standard of 95% accuracy rate. The standard deviation was 0.493 and the confidence interval was CI: 0.34 – 0.48.

Analysis of the data on the sepsis report identified 66 different providers for the 200 patient records reviewed. The infection report identified 55 different providers for the 200 patient records reviewed. There were 16 different physician specialties responsible for the 400 patients on the combined two reports. There was a combined total of 30 different insurance groups for the 400 patient records that were reviewed.

Table 4-1 presents the count and the percentage of patient records identified for each defined specialty physician group for both the sepsis patient records and the infection patient records. Overall, 41% of the patients on the infection report met sepsis criteria based on the clinical indicators in the medical record. 51% of the patients were seen by the Internal Medicine Group, with 27% seen by Family medicine, 13% were seen by a Hospitalist and that last 9% were seen by physicians that were in the Other group. There were no critical care medicine or surgical critical care providers on the infection report.

For the sepsis records, seven different coders had only coded 6 patient records or less and 11 coders had coded as least 7 or more patient records. For the infection group, there were five coders that had coded six accounts or less and 12 medical coders that had coded seven or more patient records.

There was a total of 20 different medical coders identified as assigning the ICD-10-CM codes for the patient records that were included in the study. 17 of the 20 medical coders coded the infection patient records. Of those 17 medical coders, 15 were still employed at Erlanger as of the time of the data abstraction. The medical coders had different coding and educational backgrounds. The education level ranged from no degree to a Master's degree. One of the medical coders had a master's degree, three had

Table 4-1. Physician Specialty Groups and Payer Groups Data.

	Sepsis Patients		Infection Patients	
Variable	**Count**	**Percentage**	**Count**	**Percentage**
Physician Specialty Groups				
Critical Care Medicine	12	6%	0	0%
Family Medicine	37	18.5%	54	27%
Hospitalist	17	8.5%	26	13%
Internal Medicine	107	53.5%	102	51%
Other	17	8.5%	18	9%
Surgical Critical Care	10	5%	0	0%
Payer Groups				
Commercial	54	27%	60	30%
Government	90	45%	90	45%
Other	31	15.5%	18	9%
Self-Pay	25	12.5%	32	16%

NOTES: The sample size for the sepsis patients was 200 medical records. The sample size for the infection patients was 200 medical records.

a bachelor's degree and nine of the medical coders had a minimum of an associate degree. Only two of the medical coders did not have any additional degrees. The credentials held by the medical coders included RHIA, RHIT, CCS, CCS-P, CPC, and one medical coder holds and RN licensure, but no specified coding credential. The length of time employed at Erlanger ranged from one year to 33 years. The length of experience coding ranged from four years to 35 years. Lastly, the length of experience coding inpatient records ranged from four years to 33 years. **Table 4-2** shows the degree held by the medical coder, the credential as well as the coding accuracy for the infection cases based on the clinical indicators of sepsis documented in the medical record. Medical coders cannot code sepsis without the documentation explicitly stating sepsis, so this is not a coding accuracy rate based on the current identified diagnosis. However, this would have been an opportunity for a post discharge query to clarify the documentation.

The coding accuracy by medical coder including length of time at Erlanger and length of experience as a medical coder and more specifically as an inpatient coder is included in **Figure 4-1**. As previously stated, the number of patient records completed by each medical coder varied from two medical records to 31 medical records. The coding accuracy rate based on the clinical indicators of sepsis ranged from 33% to 100%. Further studies should be conducted to compare a larger sample of records coded by each medical coder.

Pearson product moment correlation was performed to determine if there was a correlation between the coding accuracy and the years of inpatient coding experience. The years of inpatient coding experience ranged from four years to 33 years. The average years of inpatient coding experience was 12.80 years. Pearson product moment correlation indicated a weak and not statistically significant negative correlation between the years of inpatient coding experience and the coding accuracy. The Pearson product moment correlation is provided in **Table 4-3.**

A Chi-Square test was performed to compare the proportions of each of the physician specialty groups and each of the payer groups. The p value for the physician specialty groups for the sepsis patients was 0.754. This indicates that the physician specialty group did not contribute to the difference in coding accuracy for the sepsis group. This meant that whether the patient was coded as sepsis was not dependent upon the physician specialty group treating the patient. The p value for the physician specialty groups for the infection patients was 0.023. This indicates that the physician specialty group contributed to the difference in coding accuracy for these patient records. A patient may not be diagnosed as sepsis depending upon which specialty group treated the patient. A Chi-Square test was performed to test the statistical significance of the payer group. The p value for the payer group for the sepsis patients was 0.749. The p value for the infection patients was 0.302. The p value for the payer group for both the sepsis patients and the infection patients are above 0.05, therefore, neither are considered statistically significant, indicating that the payer group did not contribute to the difference in coding accuracy for either the sepsis or the infection group. This meant that whether the patient was coded as sepsis was not dependent on the patient's payer type.

Table 4-2. Coding Accuracy, Education Level and Credential by Coder of Infection Cases.

Coder Number	Degree	Credential	Number of Accounts Coded	Coding Accuracy
1	AS	RHIT, CCS	2	50%
3	AS	RN	7	43%
4	N/A	CCS, CPC	18	44%
6	AS	RHIT, CCS	9	89%
8	BS	RHIT, CCS	2	100%
9	AS	RHIT, CCS, CCS-P	14	57%
10	AS	RHIT, CCS	3	33%
11	AS	RHIT, CCS	15	60%
12	BS	RHIA, CCS	7	43%
14	N/A	CCS, CCS-P	12	67%
15	BS	RHIT, CCS	6	83%
16	AS	RHIT, CCS	27	63%
17	MS	RHIT, CCS	15	73%
18	AS	RHIT	31	58%
20	AS	RHIT, CCS	18	50%

NOTES: AS is an Associate of Science Degree. BS is a Bachelor of Science Degree. MS is a Master of Science Degree. RHIT is a Registered Health Information Technician. CCS is a Certified Coding Specialist. CCS-P is a Certified Coding Specialist, Physician based. CPC is a Certified Professional Coder. RN is a Registered Nurse. RHIA is a Registered Health Information Administrator. This includes the 15 medical coders still employed at Erlanger at the time of the analysis that coded medical records on the infection patients.

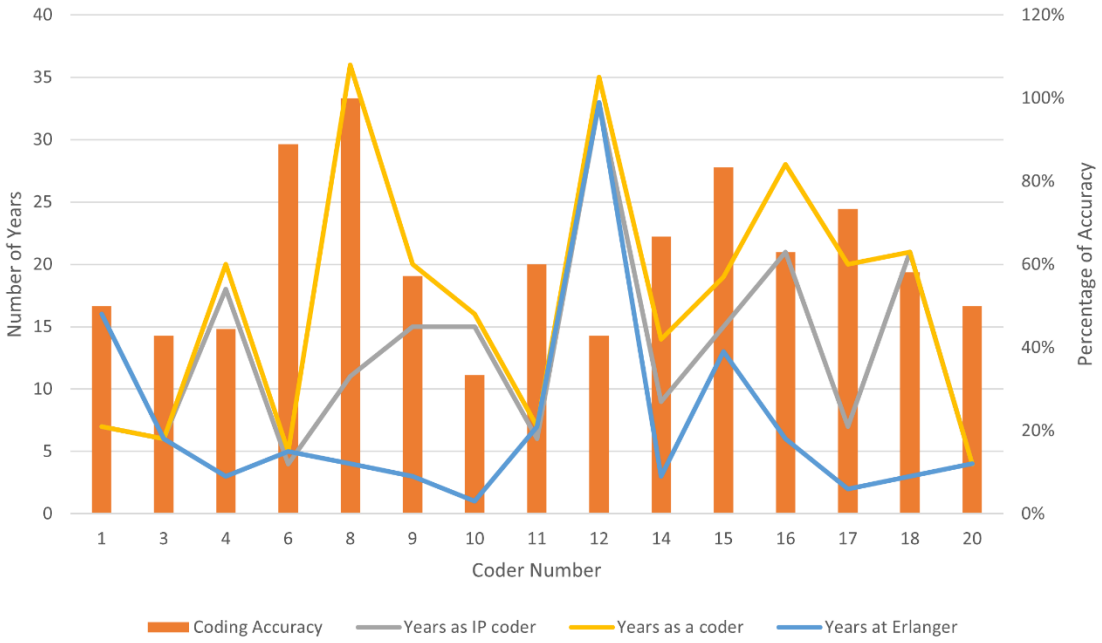

Figure 4-1. Coder Accuracy with Years of Coding Experience, Inpatient Coding Experience and Length of Time at Erlanger.

Table 4-3. Pearson Correlation Between Medical Coder Accuracy with Years of Inpatient Coding Experience.

Variable	Mean	Pearson Correlation
Years as Inpatient Coder	12.80	-0.281

A comparison of accuracy was performed for the physician specialty groups and the payer group for the sepsis patients. This is shown in **Table 4-4**. For the physician specialty groups on the sepsis patients, all physician specialties were at 100% coding accuracy, except for Internal Medicine which was at 97.2% accuracy.

A Chi Square for comparison of accuracy was performed for the physician specialty groups and the payer groups for the infection patients. The p-value for the physician specialty groups was 0.23. The p-value for the payer group was 0.302. The coding accuracy rate for both the physician specialty group and the payer group is shown in **Table 4-5**. For the physician specialty groups, the highest accuracy rate was at 73.1% for the Hospitalist group and the lowest accuracy rate was at 27.8% for the other group. When comparing the payer group, the highest rate of accuracy was for the other group at 66.7%. The lowest rate of accuracy was for the Commercial group at 50%. These numbers indicate the physician specialty impacted the documentation in the medical record therefore affecting what was coded by the medical coder.

Logistic regression was not performed on the sepsis patients due to the high percentage of accuracy in the coding of the sepsis cases. Logistic regression was performed on the infection patients and was calculated for the physician specialty group, payer group and the level of coder education separately to determine the unadjusted odds ratio. A patient that was treated by a hospitalist physician was 0.25 times as likely to have sepsis and be inaccurately coded as a patient treated by a physician in the family medicine group (OR=0.25; 95% CI: 0.08 – 0.79). A patient treated by an internal medicine physician was 0.14 times as likely to have sepsis and be inaccurately coded as a patient treated by a physician in the family medicine group (OR=0.14; 95% CI: 0.04 – 0.55). A patient treated by a physician in the other group was 0.26 times as likely to have sepsis and be inaccurately coded as a patient in the family medicine group (OR=0.26; 95% CI: 0.09 – 0.78). Since the number 1 is not included within the upper and lower limits of the confidence interval, it is interpreted that the physician specialty group is statistically significant.

A patient in the government payer group was 1.29 times as likely to have sepsis and be inaccurately coded as a patient in the commercial group (OR=1.29; CI 95% .54 – 3.05). A patient in the other payer group was 0.71 times as likely to have sepsis and be inaccurately coded as a patient in the commercial group (OR=0.71; 95% CI: 0.31 – 1.61). A patient in the self-pay payer group was 0.64 times as likely to have sepsis and be inaccurately coded as a patient in the commercial group (OR=0.64; 95% CI: 0.19 – 2.14). Since the number 1 is included within the lower and upper limits of the confidence interval, it is interpreted that the payer type is not statistically significant.

The number of patient records included in the logistic regression was only 186. As indicated previously, there were 2 medical coders that coded a total of 14 medical records that were no longer employed at Erlanger at the time of the analysis. A patient coded by a medical coder with no degree was 0.44 as likely to have sepsis and be inaccurately coded as a patient coded be a medical coder with an associates degree (OR=0.44; 95% CI: 0.12 – 1.70). A patient coded by a medical coder with a master's

Table 4-4. Percentage of Coding Accuracy of Sepsis Patients by Physician Specialty and Payer.

Sepsis Patients	Coding Accuracy
Physician Specialty Group	
Critical Care Medicine	100%
Family Medicine	100%
Hospitalist	100%
Internal Medicine	97.2%
Surgical Critical Care	100%
Other	100%
Payer Group	
Commercial	98.1%
Government	97.8%
Other	100%
Self-Pay	100%

NOTE: Sample size is 200 medical records with sepsis as a principal diagnosis.

Table 4-5. Percentage of Coding Accuracy of Infection Patients by Physician Specialty and Payer.

Infection Patients	Coding Accuracy
Physician Specialty Groups	
Critical Care Medicine	N/A
Family Medicine	61.1%
Hospitalist	73.1%
Internal Medicine	59.8%
Surgical Critical Care	N/A
Other	27.8%
Payer Group	
Commercial	50%
Government	64.4%
Other	66.7%
Self-Pay	56.3%

NOTE: Sample size is 200 medical records with an infection as the principal diagnosis.

degree was 0.68 as likely to have sepsis and be inaccurately coded as a patient coded by a medical coder with an associate degree (OR=0.68; 95% CI 0.18 – 2.48). A patient coded by a medical coder with a bachelor's degree was 0.853 as likely to have sepsis and be inaccurately coded as a patient coded by a medical coder with an associate degree (OR=0.85; 95% CI: 0.39 – 1.88). The number one was included within the lower and upper limits of the confidence interval, indicating the education level of the medical coder is not statistically significant.

Logistic regression was calculated with the patient met sepsis criteria as the dependent variable and physician specialty group and payer group as the independent variables. This is model one. Results of this model and the following models are provided in **Table 4-6**. The base model was created by the initial data that was entered into the model. This provided the baseline of 59.7% coding accuracy on the infection group. The new model was created using the independent variables of payer group and physician specialty group. This new model was created to identify if the data elements included would predict the probability of the patient having sepsis and not being coded as sepsis. To accept that the new model is statistically significant when compared to the base model, this p value would need to be less than 0.05. Since the p value is 0.05, this is on the line as to whether or not the new model is statistically significant. The Hosmer and Lemeshow test was also performed to identify whether the data was a good fit for the model. The p-value was 1.000 indicating the data is a good fit for the model.

The classification table of the base model identified that model was correct 59.7% of the time. With the independent variables added, the model was correct at predicting whether a patient would have sepsis 65.6% of the time.

The lower and upper limits of the confidence interval for the physician specialty group did not include the number one. Therefore, these findings were found to be statistically significant for the physician specialty groups while controlling for the payer group. A patient that was treated by a hospitalist physician was 0.24 times as likely to have sepsis and be inaccurately coded as a patient treated by a physician in the family medicine group (OR=0.24; 95% CI: 0.07-0.85). A patient treated by an internal medicine physician was 0.19 times as likely to have sepsis and be inaccurately coded as a patient treated by a physician in the family medicine group (OR=0.19; 95% CI: 0.03-0.51). A patient treated by a physician in the other group was 0.24 times as likely to have sepsis and be inaccurately coded as a patient treated by a physician in the family medicine group (OR=0.29; 95% CI: 0.07-0.83).

The odds ratio was 1 for the commercial group. After adjusting for physician specialty government group payers had 1.54 times higher odds of inaccurately coding a record when compared to the self-pay group (OR=1.54; 95% CI: 0.60-3.99). The other payers group had 0.83 times higher odds of inaccurately coding a record when compared to the commercial group (OR=0.83; 95% CI: 0.35-1.98). The self-pay payer group had 0.73 times higher odds of inaccurately coding a record when compared to the commercial group (OR=0.73; 95% CI: 0.21-2.56). The lower and upper limits of the confidence

Table 4-6. Logistic Regression Models with Varied Variables for Infection Patients.

Variable	Model 1 OR (95% CI)	Model 2 OR (95% CI)	Model 3 OR (95% CI)
Physician Specialty Group			
Family Medicine	1	1	1
Hospitalist	0.24 (0.07-0.85)	0.25 (0.70-0.89)	0.22 (0.06-0.82)
Internal Medicine	0.19 (0.03-0.51)	0.11 (0.03-0.50)	0.10 (0.02-0.45)
Other	0.24 (0.07-0.83)	0.24 (0.07-0.83)	0.22 (0.06-0.77)
Payer Group			
Commercial	1	1	1
Government	1.54 (0.60-3.99)	1.51 (.58-3.90)	1.51 (0.58-3.96)
Other	0.83 (0.35-1.98)	0.82 (0.34-1.96)	0.86 (0.35-2.08)
Self-pay	0.73 (0.21-2.56)	0.72 (0.21-2.49)	0.73 (0.21-2.59)
Years as an Inpatient Coder		1.02 (0.98-1.06)	1.02 (0.98-1.07)
Medical Coder Education Level			
Associate degree			1
Bachelor's Degree			0.88 (0.38-2.04)
Master's Degree			0.51 (0.12-2.24)
No Degree			0.44 (0.10-1.92)

NOTES: This table shows a comparison of the different logistic regression models used. As noted in red, the physician specialty group had statistically significant findings for each of the models.

interval for the payer group included the number one, therefore the odds ratio was determined not to be statistically significant for the payer group. (Hicks, 2013).

Model two is a logistic regression model with the dependent variable as patient met sepsis criteria and physician specialty group, payer group and years as an inpatient coder as the independent variables. When adjusting for the payer group and the years as an inpatient coder, the hospitalist group had 0.25 higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.25; 95% CI: 0.70-0.89). The internal medicine group had 0.11 higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.11; 95% CI: 0.03-0.50). The other physician group had 0.24 higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.24; 95% CI: 0.07-0.83). Each of the odds ratios for the physician specialty groups was considered statistically significant.

When adjusting for physician specialty group and years as an inpatient coder, the government group had 1.51 higher odds of inaccurately coding a medical record as sepsis than the commercial group (OR=1.25; 95% CI: 0.58-3.90). The other payer group had 0.82 higher odds of inaccurately coding a medical record as sepsis than the commercial payer group (OR=0.82; 95% CI: 0.34-1.96). The self-pay payer group had 0.72 higher odds of inaccurately coding a medical record as sepsis than the commercial group (OR=0.72; 95% CI: 0.21-2.49). Each of the odds ratios for the payer group were considered not statistically significant.

When adjusting the physician specialty group and the payer groups, the years and an inpatient coder odds ratio was 1.02 (OR=1.02; 95% CI: 0.98-1.06). This value for the years as an inpatient coder was not statistically significant.

For model three, logistic regression was calculated again with the dependent variable as patient met sepsis criteria and physician specialty group, payer group, years as an inpatient coder and medical coder education level as independent variables. When analyzing for these variables, there were 14 missing cases with a final sample of 186 cases.

The predicted classification for identifying whether or not a patient would be in the sepsis category was 66.7% accurate. When adjusting for years as an inpatient coder, education level and payer group, the hospitalist group had 0.22 times higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.22; 95% CI: 0.06-0.82). The internal medicine group had 0.10 times higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.10; 95% CI: 0.02-0.45). The other group had 0.22 times higher odds of inaccurately coding a medical record as sepsis than the family medicine group (OR=0.22; 95% CI: 0.06-0.77). Each of the physician specialty odds ratios were identified as statistically significant.

When adjusting for years as an inpatient coder, education and physician specialty group, government payer group had 1.51 higher odds of inaccurately coding a medical record as sepsis than the commercial group (OR=1.51, 95% CI: 0.58-3.96). The other payer group had 0.86 times higher odds of inaccurately coding a medical record as sepsis

than the commercial group (OR=0.86; 95% CI: 0.35-2.08). The self-pay payer group had 0.726 higher odds of inaccurately coding a medical record as sepsis than the commercial group (OR=0.73; 95% CI: 0.21-2.59). Each of the odds ratios identified for the payer groups were not statistically significant.

When adjusting for education level, physician specialty group and the payer group, the years as an inpatient coder had an odds ratio of 1.02 (OR=1.02; 95% CI:0.98-1.07). This value was not considered statistically significant.

When adjusting for physician specialty group, years and an inpatient coder and the payer group, the bachelor's degree had 0.88 times higher odds of inaccurately coding a medical record as sepsis than the medical coders with an associate degree (OR=0.88; 95% CI: 0.38-2.04). The medical coders with master's degree had 0.51 higher odds of inaccurately coding a medical record as sepsis than a coder with an associate degree (OR=0.51; 95% CI: 0.12-2.24). The medical coder with no degree had 0.44 times higher odds of inaccurately coding a medical record as sepsis than a medical coder with an associate degree (OR=0.44; 95% CI: 0.10-1.92). Each of the odds ratios identified for the medical coder education level were determined not to be statistically significant.

ROC curve (receiver operating characteristic curve) analysis was performed to measure the goodness-of-fit for each of the logistic regression models based on the simultaneous measure of sensitivity and specificity. For model 1, the area under the curve was 0.664 with 95% confidence interval (0.562, 0.726) as seen in **Figure 4-2**. For model 2, the area under the curve was 0.663 with 95% confidence interval (0.583, 0.744) as seen in **Figure 4-3**. For model 3, the area under the curve was 0.663 with 95% confidence interval (0.583, 0.743) as seen in **Figure 4-4**. For all three models, the area under the curve was significantly different from 0.5 since the p-value was 0.001 for model 1 and 0.000 for both models two and three. Based on these values, logistic regression classifies the groups significantly better than by chance, although the model has a lower discrimination ability.

Summary

The established coding accuracy rate is 95%. In this study, the overall accuracy rate for patients coded as sepsis when the documentation supports sepsis was 98.5% which is above the identified coding accuracy rate standard. The overall accuracy rate of patient's not coded as sepsis when the documentation supported sepsis was 59%. This puts the coding accuracy for the infection patients below the established standard. The logistical regression model was not performed on the sepsis patients due to the 98.5% coding accuracy rate. A logistic regression model was created for the infection patients. The base rate of the logistic regression model identified an accuracy rate of 59.7% based on the data that was input into the model. A new model was created with the physician specialty groups and the payer groups as independent variables. The new

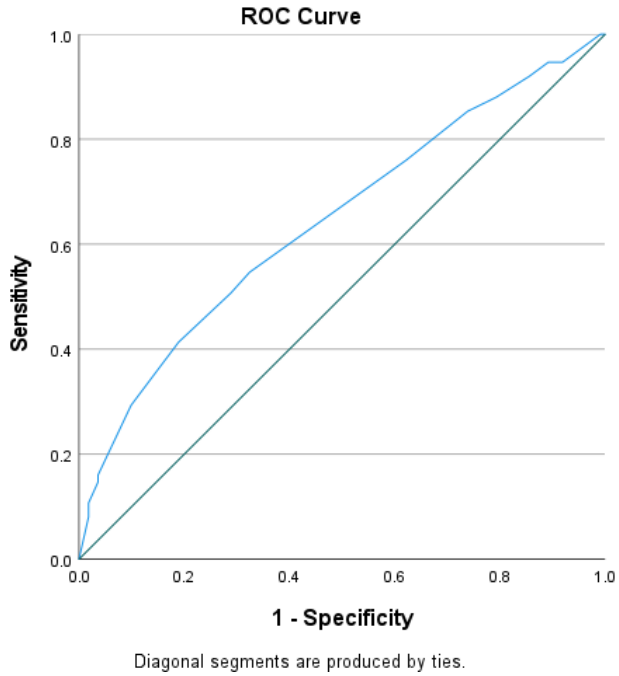

Figure 4-2. ROC Curve for Logistic Regression Model One.

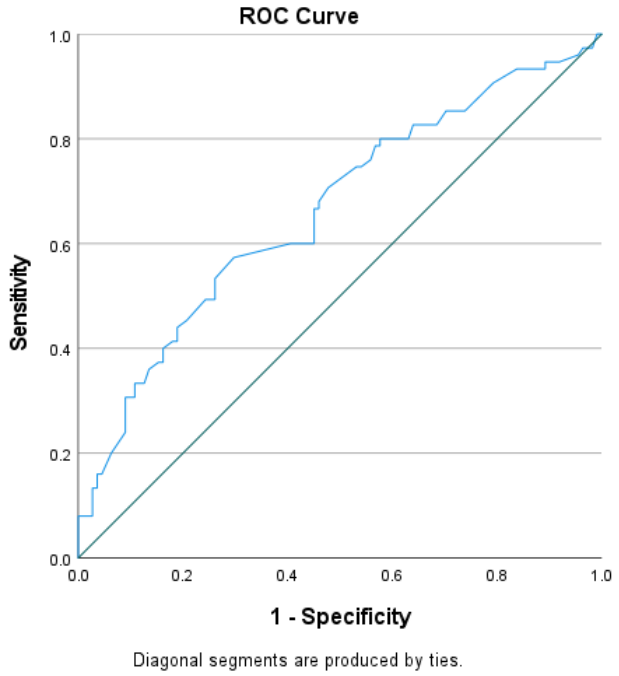

Figure 4-3. ROC Curve for Logistic Regression Model Two.

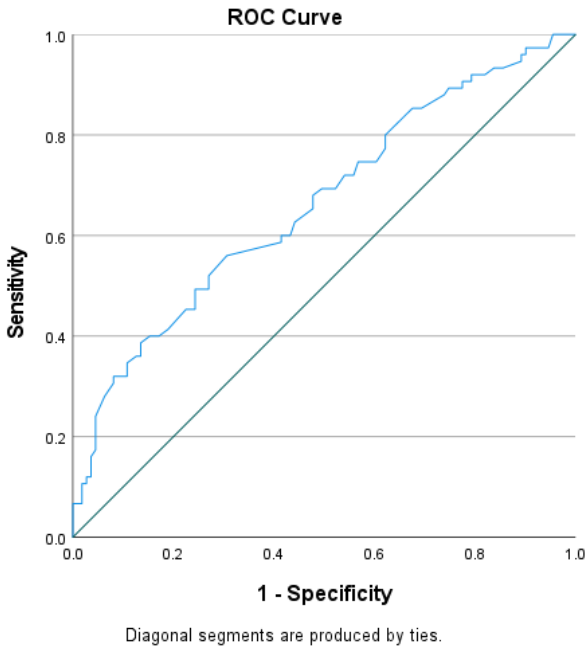

Figure 4-4. ROC Curve for Logistic Regression Model Three.

model predicted whether a patient would be coded as sepsis 65.6% of the time. The Hosmer and Lemeshow test indicated the data used was a good fit for the model.

When analyzing the unadjusted odds ratio, it was determined that the physician specialty group was statistically significant when reviewed by itself. The unadjusted odds ratio for the payer group and medical coder education level were determined to not be statistically significant. Model 1, which included both the physician specialty group and the payer groups as independent variables, showed the physician specialty group was statistically significant and the payer group was not statistically significant. Model 2, which included the physician specialty group, the payer group and the years as inpatient coder as independent variables, showed the physician specialty group as statistically significant and the payer group and years as an inpatient coder were not statistically significant. Model 3, which included the physician specialty group, payer group, years as an inpatient coder and coder education level, showed the physician specialty group as statistically significant. Payer group, years and an inpatient coder and education level were not statistically significant. Regardless of which model was used, the physician specialty group continued to be statistically significant.

CHAPTER 5. DISCUSSION

Summary

Sepsis is a serious condition that many people are diagnosed with each year. Sepsis can be very expensive to treat and is a leading cause of death in the United States (Hajj et al., 2018; Jafarzadeh et al., 2016; Society of Critical Care Medicine, n.d.; Torio & Andrews, 2013). Sepsis is challenging to diagnosis as there is no gold standard test to identify whether a patient has sepsis. There are also challenges in defining sepsis and what clinical criteria supports the diagnosis. Medical coders must follow specific guidelines to ensure the accuracy of coded data. Coded data is used for research purposes for many reasons. Accuracy of the medical codes is paramount to ensure the administrative data is also accurate. The purpose of this study was to assess the accuracy of medical coding of sepsis in medical records.

Conclusions

A study was conducted reviewing 400 medical records from Erlanger Health Systems from 4th quarter 2019. 200 of the records were identified with a principal diagnosis of sepsis. The other 200 were identified as having an infection routinely associated with sepsis, however with the diagnosis of sepsis. The medical records were reviewed for clinical indicators associated with the sepsis 2 definition. The sepsis 2 definition was used for this study as CMS continues to support the definition (*Report on Medicare Compliance*, 2017). The researcher explored six research questions in this study.

The first question was:

Are cases coded as sepsis that are not clinically supported as sepsis?

200 patient records were abstracted with the diagnosis of sepsis. 197 of the 200 were clinically supported as sepsis in the medical record. Three of the patient records did not support the diagnosis of sepsis based on the clinical indicators in the record. Based on these findings, it was determined that medical records diagnosed as sepsis are accurately coded and clinically supported in the medical record 98.5% of the time.

The second research question was:

Are infection cases not coded as sepsis clinically supported as sepsis?

200 patient records were abstracted with an infection diagnosis. 118 of the 200 were clinically supported as an infection without sepsis. 82 of the patient records met sepsis criteria based on the established and documented clinical criteria. Based on these findings, it was determined that patients with an infection code without a diagnosis of

sepsis were coded accurately 59% of the time. Leaving 41% meeting sepsis criteria without a diagnosis of sepsis.

The third and fourth research questions were:

Is there any variance for certain physicians?
Is there any variance for certain physician specialties?

There were 66 different physicians identified on the sepsis patient records and 55 different physicians identified on the infection patient records. There was a total of 16 different physician specialties between the 121 different physicians. The majority of the physicians were grouped into five of the most common physician specialties. Physicians that did not fit into one of those five common groups, were grouped into the "other" category. The physician specialty group accuracy rate for the sepsis patient records ranged from 97.2% for the Internal Medicine group to 100% for all other physician specialty groups. The physician specialty group accuracy rate for the infection patient records ranged from 27.8% for the other group to 73.1% for the hospitalist group. Statistical analysis of the sepsis patient records identified the p value as 0.754 indicating there was no variance in these patient records based on the physician specialty. Analysis of the infection patient records identified the p value as 0.023 indicating there is a variance in coding accuracy of these patient records based on the physician specialty.

For the infection group, three separate logistic regression models were created. In the first model, physician specialty remained associated with the coding accuracy even when adjusting for the payer variable. In model two, the physician specialty remained associated with the coding accuracy when adjusting for the payer and the years as an inpatient coder variables. In model three, the physician specialty remained associated with the coding accuracy when adjusting for payer, years and an inpatient coder and the education level of the medical coder variables.

The fifth research question was:

Is there any variance for certain payers?

When comparing the payer group, the sepsis patient records ranged from 97.8% for the government payer group to 100% for both self-pay and other. The payer group for the infection patient records ranged from 50% for the commercial group to 66.7%f or the other group. Statistical analysis identified a p value for both the sepsis patient records and the infection patient records that was not statistically significant. The odds ratio identified in logistic regression also identified the payer groups as not statistically significant. Based on these findings, there are not coding variances of sepsis based on payer type.

The sixth research question was:

Is there any variance for certain medical coders?

There were 20 different medical coders for the 400 medical records that were reviewed. Each medical coder coded a varying number of the medical records. There was not an even distribution of medical records to medical coder. Some medical coders only coded one patient records, whereas other medical coders coded up to 31 patient records. Logistic regression was performed to determine if there was any correlation between the medical coders and the number of years, they have been an inpatient coder and also the education level of the medical coder. There was a positive correlation with the education level of the medical coder. As the education level increased, so did the accuracy level. There was a weak negative correlation between the years of inpatient experience and the coding accuracy. Although weak, the coding accuracy did decrease as the years of experience decreased.

Limitations

The medical coder and the provider of the medical care and clinical documentation may impact some of the findings from the study. The medical coders have different levels of education. Some of the medical coders have Health Information Management degrees, while others may have a degree from another area, and others may not have a degree. The medical coders also have different coding credential. Some medical coders have the Certified Coding Specialist (CCS) available through the American Health Information Management Association (AHIMA), while others have a Registered Health Information Technician (RHIT) also available through AHIMA. Some medical coders may have both the CCS and the RHIT. One medical coder did not hold a coding credential but was a Registered Nurse (RN). Some of the medical coders may have had less than five years of inpatient coding experience where others may have 20 or more years of coding experience.

Some physicians use sepsis 3 criteria and may not have diagnosed the patient with sepsis even when they met sepsis 2 criteria. Other physicians may not diagnose a patient without a positive blood culture, whiles others may require an intensive care unit (ICU) stay before they are willing to assign the diagnosis. Some of the identified clinical indicators that support the diagnosis of sepsis 2 may have been due to other underlying causes.

Additional limitations of the study are that the reviewed medical records came from one health system in one geographical location. Additional studies from other locations may yield different results. Another limitation could be the timeframe of the study. The study was limited to the fourth quarter 2019. The timeframe could be expanded to include a longer time period. This study was also conducted with one medical coder as the data abstracter and reviewed with the assistance of one physician advisor.

Implications

This research demonstrates that administrative data used regarding sepsis patients may not be accurate. The coding accuracy rate for the infection patient records was 59%. This suggests that 41% of the patient records were diagnosed inaccurately based on the clinical documentation in the patient record. These research findings demonstrate there may be a need to educate medical coders on the clinical indicators used to diagnose sepsis. This would provide the required knowledge for a medical coder to send a physician query to clarify the patient's diagnosis to ensure that the documentation is complete. Additional education may need to be provided to the physicians to ensure the documentation in the patient record is complete. This research also demonstrates the need to have an identified definition of sepsis that is supported and used by all physicians to ensure that patient data is coded appropriately and accurately.

The researcher has been unable to locate any studies performed as this study was. This study included a manual abstraction of the clinical indicators documented within the medical record to determine if the patient met sepsis 2 criteria. There have been many studies that have been conducted to determine the accuracy of medical coding for sepsis patients, but those studies were based on administrative data and the specific codes. There were no comparisons of the clinical indicators of sepsis with the accuracy of medical coding. One study aimed at identifying incidence, trends and outcomes of infection sites among hospitalizations of sepsis used sepsis-3 and Martin GS et al as their criteria for selection of patients for their study. They identified cases using specific ICD-9-CM diagnosis codes and the presence of an organ dysfunction. This study was dependent upon the accuracy of medical coding for sepsis patients (Chou et al., 2020).

Additional studies have been performed to identify the incidence of sepsis and the accuracy of the documentation, but the research has been performed by utilizing administrative data. While this data is readily available, it does not provide the opportunity to review the clinical information within the medical record and compare it to the ICD-10-CM codes on the medical record (Rhee & Klompas, 2020).

A German study compared the validity of different ICD coding abstraction strategies for sepsis case identification in German claims data, however they did not compare the coding accuracy based on the clinical indicators in the medical record (Fleischmann-Struzek et al., 2018). The findings in this study indicate using specific codes might underestimate the true incidence of sepsis whereas using "implicit coding overestimates the sepsis cases" (Fleischmann-Struzek et al., 2018). These studies further identify the need for accurately coded data.

Recommendations

The researcher found limited published studies of validation of previously coded medical records where a medical coder validated the previous code assignment. Other studies looked at claims data and reported codes, but none investigated the coding of

sepsis by a medical records review process. Further studies should be conducted to determine if there are specific reasons as to the variances of diagnosing sepsis based on physician specialty. Additional studies should be conducted to see if there is a variance based on the medical coder. Medical coders with more experience and education may have been able to determine the need to query the physician more than one with less experience. These studies could also look at the medical record to see if there was a query sent to the provider for clarification. This data could be useful in developing training materials for both the medical coders the providers.

Additional studies could be done that would include more than one geographical region or health system. Additional studies could also be conducted utilizing a longer time period than one quarter. The researcher also suggests further studies with a larger sample size, this may provide a better analysis of the variables and whether or not there is a correlation between the coding accuracy and those variables.

The importance of accurate and complete documentation in patient records cannot be understated. Identifying issues in medical record documentation will help medical coders identify when a coding query for clarification is necessary. Identifying these issues with help researchers identify that there are limitations to data sets. Identifying these issues will help medical providers understand the need for accurate, complete, and consistent documentation.

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APPENDIX. INSTITUTIONAL REVIEW BOARD APPROVALS

THE UNIVERSITY OF TENNESSEE
HEALTH SCIENCE CENTER.

Institutional Review Board
910 Madison Avenue, Suite 600
Memphis, TN 38163
Tel: (901) 448-4824

October 07, 2020

April Marie Insco
UTHSC - COGHS - Coll of Grad Hlth Sci

Re: 20-07573-XM
Study Title: Sepsis: Does the clinical criteria support the medical coding?

Dear Ms. Insco:

The Administrative Section of the UTHSC Institutional Review Board (IRB) has received your written acceptance of and/or response dated October 07, 2020 to the provisos outlined in our correspondence of August 17, 2020 concerning the application for the above referenced project.

The IRB determined that your application is eligible for **exempt** review under 45 CFR 46.104(d) (4). Your application has been determined to comply with proper consideration for the rights and welfare of human subjects and the regulatory requirements for the protection of human subjects. The use of children as subjects is approved under 45 CFR 46.404. In accord with 45 CFR 46.104(d) (4), informed consent is not required. Therefore, this letter constitutes full approval of your application (version 1.1) as submitted including:

- Data Collection Tool

All of the above were stamped IRB-approved October 07, 2020. You must use the date-stamped versions of the study documents. Date-stamped materials are available in the *Informed Consent* and *Other Project Documents* folders in iMedRIS.

The UTHSC IRB acknowledges receipt and review of the following:

- The Institutional Review Board of the University of Tennessee College of Medicine at Erlanger Health System dated September 25, 2020.

In addition, the request for waiver of HIPAA authorization for the collection of data for the study is approved in accord with the criteria and review procedures specified at 45 CFR 164.512(i) (2). The waiver applies to the medical records of all patients admitted to Erlanger Medical Center between October 01, 2019 and December 31, 2019.

In the event that volunteers are to be recruited using solicitation materials, such as brochures, posters, web-based advertisements, etc., these materials must receive prior approval of the IRB.

Any alterations (revisions) in the protocol must be promptly submitted to and approved by the UTHSC Institutional Review Board prior to implementation of these revisions. In addition, you are responsible for reporting any unanticipated problems, including reportable adverse events, involving risks to subjects or others in the manner required by the local IRB policy. Lastly, you must request to close your project when

Figure A-1. University of Tennessee Health Science Center, Memphis Institutional Review Board Approval.

you have completed data analysis. All of the above should be submitted to the IRB via the appropriate form in iMedRIS.

Please note that while the UTHSC IRB is still processing IRB submissions during the COVID-19 pandemic, you must follow UTHSC IRB's COVID-19 policy located on our website here: https://uthsc.edu/research/compliance/irb/-covid-19.php . You must review the policy and adhere to it as it relates to any and each of your UTHSC IRB-approved studies

Sincerely,

Donna Stallings

Signature applied by Donna L Stallings on 10/07/2020 01:15:18 PM CDT

Donna Stallings, CIM
IRB Administrator
UTHSC IRB

Figure A-1. Continued.

THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
COLLEGE of MEDICINE Chattanooga

Institutional Review Board
960 East Third Street
Suite 100
Chattanooga, Tennessee 37403
T (423) 778-3818
F (423) 778-4170

Knoxville
Chattanooga
Nashville

September 25, 2020

Roger Deversa, M.D.
University Hospitalists
975 East Third Street - Box 251
Chattanooga, TN 37403

RE: Your application dated 8/26/2020 regarding study number 20-088: Sepsis: Does the clinical criteria support the medical coding

Dear Dr. Deversa:

The Chairman of the UT College of Medicine Institutional Review Board has reviewed your request for expedited approval of the new study listed above. Your study is eligible for expedited review under FDA and DHHS (OHRP) 5. Materials collected for non research purposes designation.

This is to confirm that he has approved your application effective 9/18/2020. The protocol is approved through the version dated August 26, 2020. The data set associated with this study is considered identifiable. The requirement for obtaining informed consent is waived.

You are granted permission to conduct your study as described in your application effective immediately. The study is NOT subject to continuing review; however, any revisions must be approved by the IRB prior to initiation and a final approval must be submitted once the study has finished. . Approval is granted based on the understanding that the study will be performed as outlined in the approved protocol and that the study will be conducted at the one of Erlanger Medical Center's campus, or in the office of members of its medical staff or members of the University of Tennessee faculty.

Please refer to the UTCOMC Policy and Procedure 017: REPORTING UNANTICIPATED PROBLEMS INCLUDING ADVERSE EVENTS at the following link: http://www.utcomchatt.org/docs/IRB_PP_20116.pdf to determine events that require reporting to the IRB.

The Institutional Review Board of the University of Tennessee College of Medicine at Erlanger Health System operates in accordance with all applicable laws, regulations and guidelines for clinical trials. We maintain compliance with the FDA Code of Federal Regulations, International Conference of Harmonization (ICH and Good Clinical Practice (GCP) guidelines.

Please note that all changes made such as protocol amendments and/or consent form revisions and final closure must be submitted to the Institutional Review Board for approval prior to enrolling patients. Some changes may be approved by expedited review; others require full board review.

Contact Stacey Hendricks (423-778-3818; fax 423-778-3673; email: stacey.hendricks@erlanger.org) if you have any questions or require further information.

Sincerely,

Stacey Hendricks

Stacey Hendricks, CIM
IRB Administrator

Figure A-2. University of Tennessee Health Science Center College of Medicine, Chattanooga Institutional Review Board Approval.

VITA

April Insco (inscoam@roanestate.edu) born in 1978 is a Doctoral Candidate at the University of Tennessee Health Science Center, Memphis in Health Outcomes and Policy Research, with a concentration in Health Informatics and Information Management. She obtained her Masters in Health Informatics and Information Management and a Bachelor of Science in Health Informatics and Information Management from the University of Tennessee Health Science Center, Memphis. April currently has her Registered Health Information Administrator (RHIA), Certified Health Data Analyst (CHDA), Certified Professional in Health Informatics (CPHI), and Certified Coding Specialist (CCS), from the American Health Information Management Association (AHIMA). She is currently a program director and associate professor at Roane State Community College in Harriman, Tennessee. April expects to receive her Ph.D. degree in July 2022.