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The Association of Foreign PHI on AME & Death

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BY

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A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

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Abstract of Dissertation Presented to the

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Background: Recent data shows at least 1.5 million people are affected by adverse medication events (AME) every year. The purpose of this study is to see if increased use of FPHI is associated with lower instances of AME's and lower mortality rates for hospitals.

Methods: Using a retrospective analysis and logistic regression, this study examines the relationship between IT use and quality. Specific metrics include AMEs and mortality rates in hospitals in the United States. Demographic data are used to control for confounders, CPT, DRG, and AHRQ questions are used as classifying variables for High IT utilization.

Results: Unadjusted rates of AME's were higher among high-IT hospitals than non-high-It hospitals (27.8% vs. 15.8%; $p<0.0001$). Unadjusted rates of mortality were similar between high-IT hospitals and non-high-IT hospitals (0.1 vs. 0.1; $p=0.1706$). The adjusted odds of suffering an AME for patients seen in ED that is a high IT use department are 36% lower than similar patients seen in low IT use Eds (OR:0.64, CI:0.60 – 0.67: $p<0.0001$). There was no direct association between increased use of FPHI and mortality rates.

Conclusions: There is a clear association between the increased use of FPHI and lower adverse medication events (AME) rates. Studies have shown that of all the AME's yearly 50% are preventable and the finding presented here show that high use of FPHI could potentially lower the odds of an AME by 36%. Given these findings, hospitals may want to consider incentivizing the utilization of FPHI in their Eds.

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CHAPTER I INTRODUCTION

1.1 Background and Need

Our healthcare system is intended to improve a patient's quality of life. Physicians take an oath to "Do No Harm" yet adverse medical events happen all over the country. In a systematic literature review of 8 studies with a total of 74,485 patients in the United States, the average for adverse events (AE) in hospitals is 9.2% with a median percentage rate of preventable events at 43.5% (de Vries, E., Ramrattan, M., Smorenburg, S., Gouma, D., & Boermeester, M., 2008). Recent data shows at least 1.5 million people are affected by an adverse medication event (AME), which is an AE alongside many other medical errors, every year (AMCP, 2019). In one scoping review on global AME rates that included 25 studies the authors write that approximately 10% of patients had at least one AME with approximately 7.3% of those resulting in mortality (Schwendimann, R., Blatter, C., Dhaini, S., Simon, M., & Ausserhofer, D., 2018).

Adverse medication events could be decreased if the medical team took precautions, for example, checking foreign patient information for details such as allergies or currently prescribed medications. In addition to the benefits to the patient, reducing medical errors will also benefit healthcare systems through financial gains, better patient outcomes, and potentially reducing/mitigating malpractice lawsuits. The Institute of Medicine released a report in 2007 that shows the additional medical cost to treat in hospital AME's to be approximately $3.5 billion dollars a year (IOM, 2007). A 1999 study, which included lawsuit settlements found preventable AE's cost the healthcare industry between $17 billion and $29 billion annually (de Vries, E., Ramrattan, M., Smorenburg, S., Gouma, D., & Boermeester, M., 2008). In an article from 2019, the authors looked at malpractice settlements from 2007 – 2016 (Zhao, B., Cajas-Monson, L. C., & Ramamoorthy, S., 2019). They found 2,353 cases of malpractice involving resident physicians

with total indemnity paid of $831.7 million with amounts ranging from $9,000 to $743,214. The second most common accusation was improper management of surgical patients at an average payout of $275,044, which would include medications administered during the hospital stay. Preventing just one event could cover the expense associated with taking the time to check foreign patient health information (FPHI) before prescribing medications.

A literature review was performed, for this research project, related to mortality, adverse medication events, electronic health record, and electric health record (EHR) interoperability that yielded 824,665 independent articles. Narrowing the search to include only articles that include all four topics yielded only 118 results. However, there have been very few studies that look directly at the clinical use of FPHI. All literature reviewed described the seriousness of AME and the aftermath of these events including mortality. In most cases the authors noted that this is an area that needs additional research.

In *Medication Dispensing Errors and Prevention*, a book looking at AME lists an obvious AME, allergies (Tariq, R., Vashisht, R., Sinha, A., & Scherbak, Y. 1970). The authors attribute this to failure to communicate with the patient, something not possible for unresponsive patients. Another issue found was not reviewing FPHI due to a lack of technical interface skills. A journal article discussing adverse medication events states that just over half of AE happen during hospital admission or transfer of care (Laatikainen, O., Sneck, S., & Turpeinen, M., 2021).

This literature review found considerable information about AME or mortality and the aftermath to patients, families, and providers. Despite the amount of research available, there is limited available research into clinical use of FPHI. This literature review found no research that looked at using FPHI and its impact on AME and mortality. Annually, 10% of all hospital

patients experience an adverse medication event (AME) and 50% of those are potentially preventable, could increasing the use of FPHI lower AME (Schwendimann, R., Blatter, C., Dhaini, S., Simon, M., & Ausserhofer, D., 2018)?

1.2 AIM

What is the association of the use of FPHI on the rates of AME and death? This research proposal hypothesizes increasing the clinical use of FPHI is associated with lower instances of AME's and lower mortality rates for hospitals.

For the perspective of this project the interface is the clinical user interfacing with available data. One of the potential solutions to reduce adverse medication events is increased use of electronic health data from foreign sources. Combining data from multiple sources and the increased use of machine learning could have a large impact on this issue.

The insights gained from a study such as this, focusing on preventable medication events could have a profound impact on patient outcomes as well as hospital finances. All patients presenting to a hospital can benefit from the clinical staff reviewing all available foreign PHI. The potential for improving patient outcomes is even greater for unresponsive trauma patents. Not only would reducing medication events save hospitals money it would also have an impact on staff morale. For people dedicated to saving lives the impact of losing a patient carries a heavy weight that can be hard to overcome.

CHAPTER II SCOPING LITERATURE REVIEW

2.1 Introduction

The concept of quality improvement in healthcare encompasses all aspects of patient care emphasizing process improvements to achieve better outcomes. These improvements cover everything from admissions to discharges. Issues occur in hospitals daily despite the best efforts of the entire healthcare team. One devastating aspect of this is harming a patient, which is called an adverse event (AE). Adverse events can take many forms, one if which is the adverse medication event (AME).

These often-preventable events are devastating to both patient/families and the clinical staff involved. Medication errors can result in lasting harm to the patient and in the worst-case, death. The long-term effects often shatter lives and destroy careers. The aftermath can range from mild depression to PTSD and in severe cases suicide (Ozeke, O., Ozeke, V., Coskun, O., & Budakoglu, I. I., 2019).

There have been many regulations enacted over the years to address the issue of AE's and will likely continue to be a part of government actions in the future. Part of this regulatory focus has been on healthcare interoperability or the ability to share patient health data. This has included all aspects of exchanging data from incentives to implement computer systems, creation of data sharing standards, incentives for successful implementation of electronic health records as well as penalties in the way of lowered reimbursements for failure to comply (HealthIT.gov., 2022). Health information exchanges are an ideal way to share patient data, but issues such as information blocking have hindered its adoption (Pai, R., Rajan, B., & Chakraborty, S., 2021). This is an area that needs addressing in the future.

2.2 Adverse Events (AE)

Each year there are at least 1.5 million people, in the United States, affected by an AME, which is considered an adverse event (AE) alongside many other medical errors (AMCP, 2019). In one scoping review article on global AME rates that included 25 studies the authors wrote that approximately 10% of patients had at least one AME with approximately 7.3% of those resulting in mortality (Schwendimann, R., Blatter, C., Dhaini, S., Simon, M., & Ausserhofer, D., 2018). The number of preventable AME's ranged between 34.3% and 83% with a median of 51.2%. This equates to approximately 10% of inpatient stays involved an AME and roughly 50% of those are preventable.

2.3 Mortality Rates

The number of deaths attributed to AME's in 1995 were 198,000 with a population estimate of 266,600,000 (0.074%) which increased to 218,000 with a population estimate of 281,400,000 (0.077%) in 2000 (AMCP, 2019). Based on these numbers there was an increase in population of 5.4% and a 0.003% increase in AME related deaths nationally. In 2018 the United States HCUP data shows a total of 123,392,577 emergency room visits and a 0.15% mortality rate (HCUP, 2019). This means that in 2018 there were 185,089 deaths associated with emergency room visits. If 10% of the total emergency room visits suffered an AME, 7.3% of those resulted in death, and if 51.2% of those AME's were preventable then 4612 (2.5%) of those patient deaths could have been prevented.

Information from an early longitudinal mortality study shows mortality rates increasing higher than the number of hospital visits increased between 1983 - 1993 (Phillips, D. P., Christenfeld, N., & Glynn, L. M.,1998). The increase in mortality rates was thought to be related

to the increased difficulty in the continuity of care and the quality of the relationships between patient and physician. This is an early indication of the need for accurate data sharing and ensuring that that data is used to improve patient care and outcomes. In their 2016 article on medical errors Makary & Daniel discuss the difficulty in finding accurate data on medical errors and the impact on mortality (Makary, M. A., & Daniel, M., 2016). They mention a lack of ICD-10 codes that are specifically related to mortality and errors in all forms. They conclude that one method of lowering medical errors is the widespread use of patient data sharing between providers and institutions. Since that article there have been many additions to the ICD-10 code such as the inclusion of an entire group of codes dedicated to medication errors and another group for mortality reasons including special cause of death codes. The detailed list of codes is:

ICD-10 Codes

- T36 – T50 ICD codes for adverse medication effects (15 codes)
- T88.7 ICD code for unspecified adverse effect of drug or medication
- Z88 ICD code for allergy status to other drugs
- Y40 – Y59 Cause of death ICD code for AME in therapeutic use (20 Codes)
- Y88 ICD code for Sequelae, the aftereffect of medications

DRG Codes

- DRG 915 Allergic reactions with multiple chronic conditions
- DRG 916 Allergic reactions without multiple chronic conditions

These codes allow hospitals to be more transparent with issues related to AME's. The concern is that there may be inconsistencies with the way different institutions code certain events.

2.4 Costs to the Healthcare System

The Institute of Medicine released a report in 2007 that shows the additional medical cost to treat in hospital AME's to be approximately $3.5 billion dollars a year (IOM, 2007). More recently in a 2020 systematic review of the impact of medication error to the healthcare system of England found the costs of preventable AME's to be £98,462,582 or in U.S. dollars $105,221,670. The Office of the Insurance Commissioner for Washington State releases a yearly report about medical malpractice payouts (Kreidler, 2022). In the most recent publication, 2021, the average indemnity payment compensation for malpractice suits was $2.7 million. The result of these lawsuit payouts are increased premiums to providers and institutions which then causes the cost of care to increase. When added to the already high liability costs directly to the healthcare system, cost alone should be reason enough to invest in increasing access to and use of all available patient data.

2.5 AE Aftermath

After a traumatic event there can be devastating consequences to surviving patients, family members, and even clinicians. This can range from financial issues to mood and anxiety issues and in some cases post-traumatic stress disorder (PTSD) (Gries, C. J., Engelberg, R. A., Kross, E. K., Zatzick, D., Nielsen, E. L., Downey, L., & Curtis, J. R., 2010). PTSD is a disorder that occurs in some people when they endure a serious or frightening event (U.S. Department of Health and Human Services, n.d.). Life threatening adverse medical events, such as a medication error, would undoubtedly qualify as scary. A diagnosis of PTSD requires the patient to exhibit four specific criteria for at least one month.

- At least one re-experiencing symptom such as flashbacks of the trauma which can include a racing heart or sweating, bad dreams, or dreadful thoughts.
- At least one avoidance symptom like staying away from things that trigger remembering the experience. This can be locations, events, or things.
- At least two arousal or reactivity symptoms like being startled easily, feeling on edge or tense, trouble sleeping, or angry outbursts. These symptoms typically are constant rather than being triggered by an event or place and can impact concentration, eating, or sleeping.
- The last symptom is at least two cognition or mood symptoms. This includes not being able to remember details of the event, negative feelings about themselves or others, feeling a sense of guilt or blame, or a loss of interest in normal activities.

2.5.1 Aftermath for Patients

Patients depend on healthcare providers and institutions to help in times of need. No one makes a trip to a hospital with the expectation of incurring additional harm as part of the care provided. Unintentional errors do happen and are exacerbated when the error is preventable, especially when the incident is not disclosed immediately, or the provider does not acknowledge their role in the event. An example is if a patient presents to the ER with no history of allergic reactions to a medication and then develops complications from that medication it is tragic but not to be blamed on the providers. If the patient's records do show an allergy and the medication is administered due to providers not checking the patients record it is even more traumatic.

The long-term impact to patients of an AE was the subject of a study that appeared in a 2021 edition of the Journal of Patient Safety (Ottosen, M., Sedlock, E., Aigbe, A., Bell, S.,

Gallagher, T., & Thomas, E., 2021). The researchers involved in this study broke out the effects based on years since the incident which gives a detailed look at the differences felt be patients and families over a longer period. This shows the evolution of symptoms and their severity. The inclusion of patient quotes also allows the patient to be heard, validating their feelings. This richness and depth of details lets the reader see through the eyes of those most effected by medical harm. The study included 72 volunteers which met the criteria of being either a patient who suffered an AE or family member of the patient. The participants were grouped into three groups based on the time that passed since the event: less than 5 years, 5-9 years, and 10+ years. Each person participated in a telephone interview that lasted between 60 and 90 minutes. After transcribing the audio recordings 4 common themes were discovered: social or behavioral, psychological, financial, and physical. Social or behavioral issues were the most common in all groups. This included sharing the experience with the public to help prevent future events. More than half felt that their lives would never be the same and considered themselves to be victims and that others had difficulty relating to or empathizing with their experience. New behaviors in searching for healthcare were reported by approximately one third of the patients due to the event and the way it was handled by the hospital staff. They cited poor communication, a perceived absence of concern, and a refusal to make an apology or even admit the error. Participant 25 said, “I’d rather croak in my own bed than go to a hospital”, (p. 1147). Among the psychological impacts, 50% said they felt anger or frustration in the way the hospital managed the situation, feeling that hospital administration should have stepped in instead of paying no attention to the issue. Loss of trust in the healthcare system and feeling let down was another prevalent issue. Feeling that hospital administration or providers appeared egotistical or dishonest further reenforced the loss of trust. Many used terms such as “terrifying”, “horrifying”,

and the “worst week of my life” when describing the vivid memories, they continued to experience. Some felt they were to blame, feeling that they knew something was wrong but did not trust in that feeling. Grief, sadness, and feelings of vulnerability and desertion were also reported by patients and families. About a third of the participants talked about psychological scars, depression, paranoia, and even suicidal thoughts. One of the most telling quotes from participant 71 was “they would not talk to me…they didn’t care that they had hurt me. This has been about, I don’t know, 5 years ago, I guess. I mean I’ve been suicidal over this.” (p. 1148).

The remaining two themes are physical impacts and financial impacts. Sixty-six percent of patients had lasting physical injuries resulting from AE’s. These injuries can be a loss of limbs, organs, or senses such as sight. Participant 22 stated “As an outcome of that [surgical error] …I was totally and irreversibly blind very early into the first recovery period after the first morning surgery. And to date, I am 100% blind in both eyes…I have no light perception.” Thirty-one percent of patients were hampered by financial issues well after the adverse event. Most of the financial burdens were directly related to the physical impact due to impairment causing lost jobs, health insurance, as well as large medical bills. Clearly these patients suffered tremendous burdens after an AE and may suffer permanently.

2.5.2 Aftermath for Family

While families will suffer many of the same issues that surviving patients do there is one aspect of AE’s that is solely felt by the families. Death whether from an AE or normal circumstances is something that impacts families, in some cases PTSD can be the result and knowing that it could have been prevented only makes things worse. The journal *Chest* published an article in 2010 that looked at the predictions of PTSD for families that lost a loved one in a hospital (Gries, C. J., Engelberg, R. A., Kross, E. K., Zatzick, D., Nielsen, E. L., Downey, L., &

Curtis, J. R., 2010). There were 226 families, partially from a randomized control trial (RCT) and part from a patient health questionnaire. The response rates were 46% in the RCT and 82% in the patient health questionnaire. The RCT results found PTSD or depression in 14% and in the patient health questionnaire the results were 18.4%. The study found PTSD was more prevalent in female family members, having a relationship with the patient, not including spouse or adult child, as well as knowing the patient for a shorter time period. Depression was found to be more prevalent in females, knowing the patient for shorter times, and a lower educational level.

2.5.3 Aftermath for Clinical staff

Clinicians are human. A simple fact but one often forgotten in the case of AE's. Patients or families are likely to lash out at someone that harms them and in the healthcare setting that is usually a physician or nurse. No one goes to a hospital thinking that the staff will do their best, they expect perfection. Yet when errors occur the patients and family are not the only ones to suffer. The term second victim was coined by Albert Wu to describe the impact of errors on the healthcare providers (Wu AW., 2000). While there has been discussion about discontinuing the use of the term as being insensitive to the patient, the term second victim is known around the world as describing healthcare providers that are involved in an AE (Ozeke, O., Ozeke, V., Coskun, O., & Budakoglu, I. I., 2019). The expectation of perfection is not just from the patients and families, physicians also expect perfection from themselves. This article goes on to say that medical schools do not prepare future physicians to deal with the impact of medical errors. A physician caught in the expectation of perfection has a chance of losing self-confidence leading to work inefficiency, concern about being judged by their peers, depression and even thoughts of suicide (Robertson, J. J., & Long, B., 2018). Two studies included in an article in the *Journal of American Medical Association* discuss the results of interviews with physicians that have been

involved in an AE. The reoccurring theme was feelings of anxiety, guilt, unhappiness, and fear, which lasted from days to months after the event (Gallagher, T. H., Waterman, A.D., & Ebers, A.G., 2003). One physician said in an interview “It is a crime. I am not sure why or how it gets translated that way, but it is. Medicine has always had this very high ethical standard and to fail that standard is to be guilty”.

Physicians are not the only clinical staff that suffers after an AE. Nurses have more direct contact with the patient than physicians do. This makes them more sensitive to the impact of an AE (Kim, S.-A., Kim, E.-M., & Lee, J.-R., 2022). Additionally, nurses are more prone to be participating in AME’s. One study discussed in this earlier article found that 63.6% of Korean nurses participated in an AME more than once a month but only approximately 28.3% of events were officially reported (KIM, K., KWON, S., KIM, J., & CHO, S., 2011). This implies that the under reporting could be due to the disciplinary culture in healthcare. Reporting these events would allow their peers to offer support and allow the nurse to get professional help to deal with the feelings of guilt and remorse.

2.6 Health Information Exchange

The concept of the health information exchange (HIE) as an organization to facilitate data exchanges has been part of healthcare legislation for many years, going back to the HITECH Act of 2009. HIE’s are organizations that facilitate the sharing of protected health information (PHI). This is of particular use to private medical practices and institutions that do not have sophisticated software systems to provide this functionality. A single provider can choose to participate in an HIE to both share internal PHI as well as retrieve foreign PHI from other providers. Larger organizations can choose to participate in government HIE’s, or if they have certain EHR systems they can participate in a vendor controlled HIE. Starting back in 1996, PHI

has been an important aspect of healthcare legislation. There have been many pieces of legislation passed by congress to both protect patients' rights, as well as improve patient care by sharing data between providers. Considering the potential for improved patient care and mitigating the prospective risk of litigation from AE's the clinical use of this shared data is still very low.

2.6.1 What is an HIE

An HIE is described as the electronic transfer of clinical data across varied and often rival health care organizations (Dixon, B. E.,2016). The term HIE is typically used to describe a method of sharing patient data but can be used as both a noun and a verb. When used as a verb HIE refers to the transmission of patient health information both within an organization and with foreign organizations. When used as a noun it means an organization that facilitates the transmission of health information.

These organizations are entrusted with a tremendous responsibility to safeguard all patient information and ensure that it is readily available. There are 4 forms of HIE organizations (Dixon, B. E.,2016):

- The first form is the private HIE which is operated by an organization to facilitate the sharing of information internally with associated locations. The HITECH Act of 2009 not only provided enticements to the healthcare industry to adopt electronic health record (EHR) systems but also funded the Office of the National Coordinator for Health Information Technology (ONC) to promote HIE. The funding was to assist states with the creation of the next form of HIE.

- The second form is the government facilitated HIE. This form is when state governments authorized an entity to be a single health information organization (HIO). An HIO is a group of healthcare resources established to provide secure sharing of PHI (HealthCurrent, 2017). Most however, chose to authorize a government agency to act as the HIE.
- The third form of HIE is the community based HIE. This is where community healthcare organizations share data between other local healthcare systems that are not affiliated. These entities agree to share information to provide enhanced care to the local population. These are enabled by using an HIO that operates in the same physical area.
- The fourth form of HIE is the vendor facilitated HIE. The main issue with this form of HIE is that all providers need to be on the same EHR vendor. When discussing this type of HIE, Dixon (2016) points to Care Everywhere by Epic Systems which allows customers to access outside records from within the patient's local record. This allows the provider to search other locations that also use this system for patient data.

2.6.2 EMR vs EHR

The terms electric medical record (EMR) and electronic health record (EHR) are often used to signify the same thing, a patient's health information. While this is technically true, there are significant differences. The ONC website Health IT Buzz discussed this difference back in 2011 but it is still happening today (Garrett, P., & Seidman, J.,2011).

Early on the ONC defined EMR as a digital form of the patient's paper charts (Garrett, P., & Seidman, J., 2011). EMR's allow a provider to follow a patient's health over time, check to

see when preventive tests are due, follow specific measurements such as blood pressure, and ensure high quality care for the patient.

An EHR is a broader record of patient data. It is designed to facilitate sharing of data. As such it contains information from multiple sources such as different providers, laboratories, pharmacies, and other medical data sources. EHR's are a central part of the "meaningful use" term in healthcare legislation such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Meaningful use is the Centers for Medicare and Medicaid Services (CMS) program to incentivize the adoption of qualified EHR technology. The American Recovery and Reinvestment Act of 2009 listed the three main parts of meaningful use that are used in the Meaningful Use program (Anumula, N., & Sanelli, P. C., 2012), specifying EHR's must:

- First be used in a meaningful use like clinical decision making or e-prescribing.
- Second electronically share healthcare information to improve quality of care.
- Third submit measures for monitoring the meaningful use of the system to CMS.

The criteria for meeting meaningful use as referred to in the Meaningful Use incentive program consisted of two stages that were to be implemented over a 5-year period from 2011 to 2015 (Anumula, N., & Sanelli, P. C., 2012).

- Stage 1 creates a baseline for electronic data capture and information sharing. This stage has 25 objectives comprised of 15 core objectives and 10 menu objectives. To meet the incentive requirements of this stage an organization must meet all 15 core objectives and 5 of the menu objectives.
- Stage 2 focuses on promoting the use of health IT for quality improvement and the exchange of health information in a structured format.

While the Meaningful Use incentive program requirements of stage 1 discuss the core and menu requirements it is not written in such a way that the specifics can be easily determined. Clinical staff need the ability to understand the requirements in order to fully comply with the intent of the legislation. The CMS website lists the core and menu objectives for providers (CMS, 2010).

- **15 Core Objectives**
    1. Computer provider order entry (CPOE)
    2. E-Prescribing (eRx)
    3. Report ambulatory clinical quality measures to CMS/States
    4. Implement one clinical decision support rule
    5. Provide patients with an electronic copy of their health information, upon request
    6. Provide clinical summaries for patients for each office visit
    7. Drug-drug and drug-allergy interactions checks
    8. Record demographics
    9. Maintain an up-to-date problem list of current and active diagnoses
    10. Maintain active medication list
    11. Maintain active medication allergy list
    12. Record and chart changes in vital signs
    13. Record smoking status for patients 13 years or older
    14. Capability to exchange key clinical information among providers of care and patient-authorized entities electronically
    15. Protect electronic health information

- **10 Menu Objectives**
    1. Drug-formulary checks
    2. Incorporate clinical lab test results as structured data
    3. Generate lists of patients by specific conditions
    4. Send reminders to patients per patient preference for preventive/follow up care
    5. Provide patients with timely electronic access to their health information
    6. Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate
    7. Medication reconciliation
    8. Summary of care record for each transition of care/referrals
    9. Capability to submit electronic data to immunization registries/systems*
    10. Capability to provide electronic syndromic surveillance data to public health agencies*

    * At least 1 public health objective must be selected

The CMS website allows the user to learn about the individual items and what each one is intended to accomplish.

Just as there are financial incentives to meet the qualifications of meaningful use, there are also payment reductions for failing to meet those same qualifications. These reductions in payments ranged from 1% to 5% from 2011 to 2019, respectively.

2.6.3 Healthcare IT Legislation

The federal government has a vested interest in promoting the use of healthcare technology. In addition to improving the quality of care, the use of healthcare technology is seen

as another way to lower the costs of healthcare in the United States (HealthIT, 2022). The ONC website HeathIT.gov lists the timeline of IT related healthcare legislation shown below:

- Health Insurance Portability and Accountability Act (HIPAA) of 1996. Created standards of healthcare data transmission, established national identifiers for providers (NPI). The security aspects of this legislation protect patient IT information and set safeguards on who can use or share protected health information (PHI).
- Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 is one of the key technology acts in healthcare. It was designed to improve healthcare through the advancement of health IT. A major aspect if this act was to promote EHR's and secure HIE's.
- American Recovery and Reinvestment Act of 2009 allocated $27 billion dollars to be used for investments in certified EHR systems. It also detailed the three primary components of using EHR's for meaningful use.
- Affordable Care Act of 2010 further reinforced the need for EMR's and budgeted incentives to adopt EMR systems as well as CMS penalties for failure to meet the deadline of 2015 (Encinosa, W. E., & Bae, J., 2011). They show data from a 2007 AHRQ dataset that showed hospitals using EMR's have an event rate of 5.1% with an average spending per event of $55,810 versus non-EMR hospitals with an AE rate of 5.0% and an average spending per event of $60,093.
- Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 was enacted to provide a framework for healthcare technology for things such as medical devices. It creates standards for measuring data and conformance requirements for

transmitting data from devices to associated software and for that software to send the data to EHR systems.

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) instituted the new Quality Payment program (QPP). This program switches CMA reimbursement towards a quality-based payment system with increased reimbursement for high quality/value providers and reductions in reimbursement for providers that do not meet the new standards. The use of EMR's and EHR's are a large part of meeting those standards.
- 21st Century Cures Act of 2016 was implemented to increase sharing of patient information through secure and reliable methods. This act clearly defined healthcare interoperability as "the ability exchange and use electronic health information without special effort on the part of the user and as not constituting information blocking" (HealthIT, 2022).

Healthcare information technology has been at the forefront of legislative actions for many years. The continuing enhancements to existing acts will likely continue for many years to come.

2.6.4 Clinical Use

Patient information from foreign sources can be used to lower costs and improve patient outcomes. Even with the potential benefits, physician use of this data is still low, and this low usage diminishes the value of these data (Esmaeilzadeh, 2022). A recent study looked at the clinical use of HIE data in Australia showing how often foreign data were accessed and by whom (Mullins, Skouteris, Rankin, Morris, Hatzikiriakidis, & Enticott, 2022). Looking at data from 2019 to 2021 an ED for a non-profit hospital in Australia found that HIE data was accessed in only 17.4% of patients in the ED. Pharmacists were the primary users at 15.6% with other

clinical specialties making up the remaining 84.4% of users accessing this information. These numbers look high for clinical use but is low considering that use is out of only 17.4% of patients.

A study of clinical use at the U.S. Veterans Hospital system found usage as low as 5% (Herout, J., Baggetta, D., Cournoyer, A., Dietz, A. S., Robbins, J., Maddox, K., & Dobre, J., 2019). This study listed four main reasons for such a low usage rate.

- First is information overload, where so much information is presented that it is difficult for users to find what they need.
- Second is workflow related. Even though total system integration is the goal of EHR vendors there can still be instances where users must log into multiple systems.
- Third are technical issues such as speed of access. As healthcare IT increases its capabilities the hardware that is used to access these systems must be updated regularly.
- Fourth are the constantly changing standards used to share PHI. The use of acronyms by one healthcare specialty may have a different meaning for another specialty. Also, there are many fields in EHR's that allow free text entries by clinicians. This can make data mining difficult based on how issues are reported.

While most studies of HIE usage focus on the organizational capability and usage, a rare look into HIE usage by end users was documented in an article in *The Journal of the American Medical Informatics Association* (JAMIA). This study utilized actual access log files from the Indiana Network for Patient Care (INPC), which is a statewide HIE, to determine the true clinical usage of HIE data (Rahurkar, S., Vest, J. R., Finnell, J. T., & Dixon, B. E., 2020). This retrospective study of user log files from 2011 to 2017 and included 1,159,144 inpatient,

14,932,164 outpatient, and 3,006,972 ED encounters. The results of this study should be alarming to the healthcare industry. They found that of all the encounters viewed the percentage of access was only 4.7%. When looking further, of the 4.7% of encounters inpatient cases were viewed 17.6%, ED cases were viewed 4.4% and outpatient cases were viewed 3.7% of the time. Over the years these numbers increased by 29% for inpatients, 3.5% for outpatients, and 9% for ED visits. This trend shows improvement which may be attributed to advancements in EHR capabilities and internet infrastructure. However, these are still alarmingly low rates of access to HIE data.

A more recent study looked at the effect of implementing a Fast Healthcare Interoperability Resources (FHIR) application called Health Dart in the Indiana Network for Patient Care (INPC) focused on increased usage of foreign patient data (Hosler, H., Jang, J., Schaffer, J., Price, J., Schleyer, T., & Rivera, R., 2022). They found that INPC use increased by 131% (from an estimated 3.6% to 8.3%) after the implementation of Health Dart. This study shows the increased use of HIE data when it has been integrated into the EHR. This integration makes it easier for clinicians to view data without going to a separate system. Despite the increasing implementation of HIE capable systems, clinical use of foreign PHI is still low.

2.6.5 Opposing opinion of interoperability's impact

Looking at a study in released in 2021 there is an opposing opinion regarding the impact of HIE and EHR integration. In this study of the Pennsylvania healthcare system, the authors found that EHR and HIE usage is not optimal (Pai, R., Rajan, B., & Chakraborty, S., 2021). The authors found that HIE's have a positive association with hospital cost savings and EHR's have a positive association with lowering mortality. Their data also pointed to HIE's increasing mortality. Their findings show that the slow acceptance and integration of technology

enhancements cause integration issues that impact clinical access of foreign data in a timely manner. They found that only one third of all hospitals were connected to the regional health information organization (RHIO) which is a group of healthcare organizations created to facilitate HIE expansion across the region. They list several impediments to HIE use.

- A lack of integration standards across all EHR's, particularly related to the incorporation of test results from differing systems into the patients EHR.
- Issues with continuation of care due to limited ability to link episodes of care across different organizations. This likely is related to the issue with standards.
- Patient privacy is another concern. HIPAA addressed this issue, but the reality is that secure transmission of patient health information (PHI) is both costly and difficult to do. It requires both dedicated equipment and personnel to create secure transmission methods and to monitor for any issues as well as keeping the technology up to date.
- There is also the issue of competition between both healthcare organizations and EHR vendors.

A lack of successful integration has a dramatic impact on HIE usage as seen between this study and the Indiana study discussed earlier.

2.7 Conclusion

Preventable AME's are a serious issue. The impact can be felt in the healthcare industry by the cost of these events and with malpractice settlements in the millions of dollars the cost of properly implementing and using foreign data could have a profound effect to overall healthcare and patient outcomes. Patients and clinicians are also exposed to the long-term effects of AME's particularly when the result is death. The aftermath to patients and families can include mild to

severe depression, financial setbacks, and in some cases PTSD (Gries, C. J., Engelberg, R. A., Kross, E. K., Zatzick, D., Nielsen, E. L., Downey, L., & Curtis, J. R., 2010). Clinicians, or second victims as they are called, are just as prone to these problems when coming to terms with the realization that they caused harm to a patient (Robertson, J. J., & Long, B., 2018).

There was a reoccurring theme mentioned in every article, the need for additional research in the areas of HIE usage and EHR implementation. The article by Pai, R., et al, mentions the need for additional research in these areas many times throughout the article. Their study was the only study found in this literature review that looked at the relationship between HIE usage and mortality. While there are thousands of articles that discuss HIE and EHR implementation, no studies were found that looked for statistical data related to clinical HIE usage and the effects on both adverse medication errors and mortality. Considering the potential of saving 4,612 lives per year, there is a need for research into the relationship between using patient heath information from all sources internal and external to lower AME's and mortality.

CHAPTER III METHODOLOGY

3.1 Research Aim and Hypotheses

The overarching research question is, "What is the association between the use of foreign PHI (FPHI) on the rates of AME and mortality?" Current research shows that approximately 10% of emergency room visits suffer an AME and that approximately 7.3% of AME's result in mortality. Considering that all research into the topic agrees that approximately 51.2% of AME's are preventable, there is clearly a need to research the impact of using FPHI on lowering those rates and saving lives.

Question 1

What is the association between accessing FPHI (independent variable) and AME's (dependent Variable)?

Hypothesis

Increasing the clinical use of FPHI is associated with lower rates of AME's.

Question 2

What is the association between accessing FPHI (independent variable) and Mortality (dependent variable)?

Hypothesis

Increased use of FPHI will be associated with a decrease in mortality rates.

3.2 Research Method

This is a retrospective study looking at historical data related to AME's, mortality, and the impact of foreign PHI. The dataset is used to determine if the use of foreign PHI lowered the percentage of preventable AME's and associated deaths resulting from these events. Available literature on the related aspects of this issue all discuss the same need for further research in this area. The lack of research into the impact of clinical use of foreign data use on AME and mortality suggests a need to study these relationships. Pertinent literature that looks at either AME's, hospital mortality rates, or interoperability availability and clinical use have all used a retrospective design. A prospective study into this topic would be complex, requiring an extended length of time and considerable expense making it unfeasible for this project.

3.3 Dataset Description

The hospital, demographic, and outcome dataset used in this study will come from the Comparative Effectiveness & Data Analytics Research Resource (CEDAR) source. This will be the 2018 HCUP State Emergency Department Databases (SEDD) Florida data which is comprised of emergency department visit data. This includes clinical and nonclinical data from all visits that do not result in a hospital admission (AHRQ, ND).

Statistical analysis was performed using SAS software developed by the SAS Institute. The data included in the dataset is grouped using demographic data, CPT and DRG codes for AME and mortality counts. Demographic data includes the Charlson Comorbidity score (Quan, H., et al., 2005). This is a method predicting death within 1-year based on the weighted score of several specific medical conditions. As this score increases the risk of death within 1-year increases (Charlson, M. E., Pompei, P., Ales, K. L., & MacKenzie, C. R., 1987).

The Agency for Healthcare Research and Quality (AHRQ) Information Technology questionnaire is used to determine the availability of and clinical use of foreign PHI. This questionnaire allows hospitals to self-report information technology levels in multiple areas. The area of interest for this research is whether clinicians search for FPHI and how often they use this FPHI for patient care decisions. Question 9 related to provider searching for FPHI is a binary yes/no question. Question 11A, which addresses provider use of FPHI, is a Likert scale from 1 Never to 5 Always. This research considers a score of 3 and above to indicate provider use of FPHI. MUSC has a current data use agreement in place for all data used in this study. The data from the AHRQ IT survey will be linked to the HCUP SEDD data using two unique identifiers. First is the data source number for identifying hospitals (DSHOSPID) which is assigned by the hospital (AHRQ, N.D.). The second is the American Hospital Association number (AHAID). The difference between the two identifiers is that the AHAID number is assigned to a hospital or hospital group and can include multiple facilities. The DSHOSPID number is assigned to a single facility.

3.4 Sample Selection

The data collection method chosen for this research project will be convenience. The state of Florida has been selected for this research. Hospitals reporting high levels of clinical use, as determined by a score of 3 or above on AHRQ question 11A, of FPHI will be compared to hospitals reporting low clinical levels of FPHI use. These two groups will be used for comparison of associated factors associated with lower AME and mortality rates. The AME and mortality data will be aggregated to the state level. Hospital level factors, demographic data, CPT, DRG, and AHRQ questions will be used as control variables to adjust for AME and mortality rates.

3.5 Independent and Dependent Variables

Outcome

- AME
    - T36.xx – T50.xx ICD codes for adverse medication events
    - T88.7 ICD code for unspecified adverse effect of drug or medication
    - Z88 ICD code for allergy status to other drugs
    - Y40.xx – Y59.xx Cause of death ICD code for AME in therapeutic use
    - DRG 915 Allergic reactions with multiple chronic conditions
    - DRG 916Allergic reactions without multiple chronic conditions

- Mortality
    - Y40.xx – Y59.xx Cause of death ICD code for AME in therapeutic use
- Demographic Data
    - Age
    - Sex
    - Race/Ethnicity
    - Charlson score
- Hospital level factors
    - Rural/Urban
    - Hospital bed count
    - Teaching hospital status
    - Payer
    - ED Volume

- Main Independent variables
    - 9 – Do providers query for PHI from foreign sources
    - 11A – How frequently do providers use PHI from outside sources

3.6 Conceptual Model

To discover the relationship between provider use of FPHI and rates of AME or mortality this research uses the Donabedian model of structure-process-outcome (Donabedian A., 1966). When considering healthcare outcomes, all aspects of patient care need to be considered. This means that the structure, which would include the staff and associated electronic equipment, must be considered as well as the workflow or process that is in place for managing the patient.

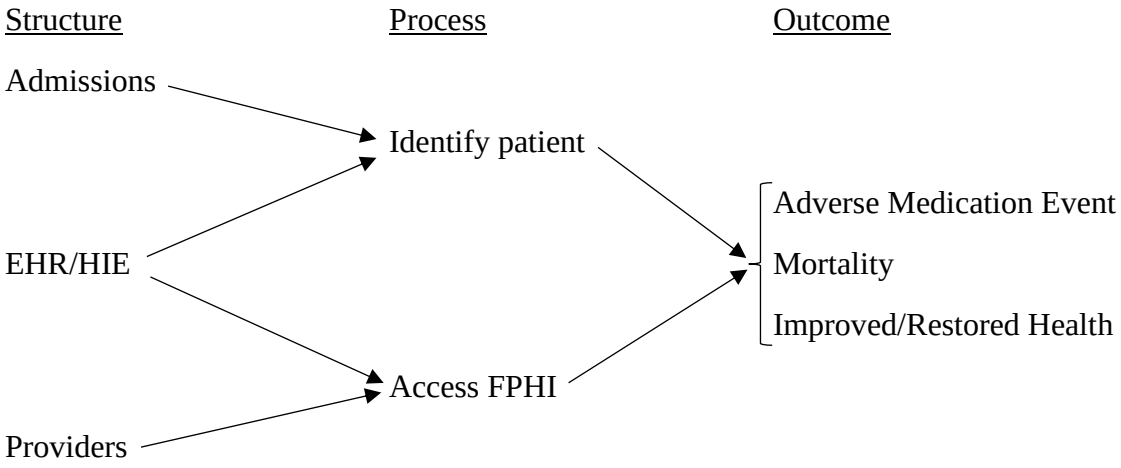


Figure 1. Conceptual model to assess FPHI relationship to AME & Mortality

The structure will include the admissions staff, the providers, and the EHR or HIE participation (Figure 1). The structure also needs to consider the EHR training provided to the staff as well as whether the EHR has the capability of automatically sending a request for data to an HIE when a patient is admitted to the ED. The process will be

identifying the patient, if possible, and admitting to the ED. Do staff request information from outside sources if the system does not automatically do it upon registration? Providers use of the EHR or an HIE portal will be the focal point to consider when assessing the outcome. If the providers use FPHI is there an associated lowering of instances of AME's or mortality?

3.7 Data Analysis

This is a retrospective analysis using logistic regression. Demographic data is used to control for confounders. Mortality rates will likely vary, drastically increasing as the population age increases. Likewise, Charlson scores may increase as the population ages. Adjusting for rural vs. urban will limit the impact of hospital variation due to population size while bed count and ED volume will group hospitals into similar groups. After controlling for the demographic differences, the data from the CPT, DRG, and AHRQ data will be less susceptible to bias. Analysis will be performed using SAS version 9.4 and STAT version 15.1.

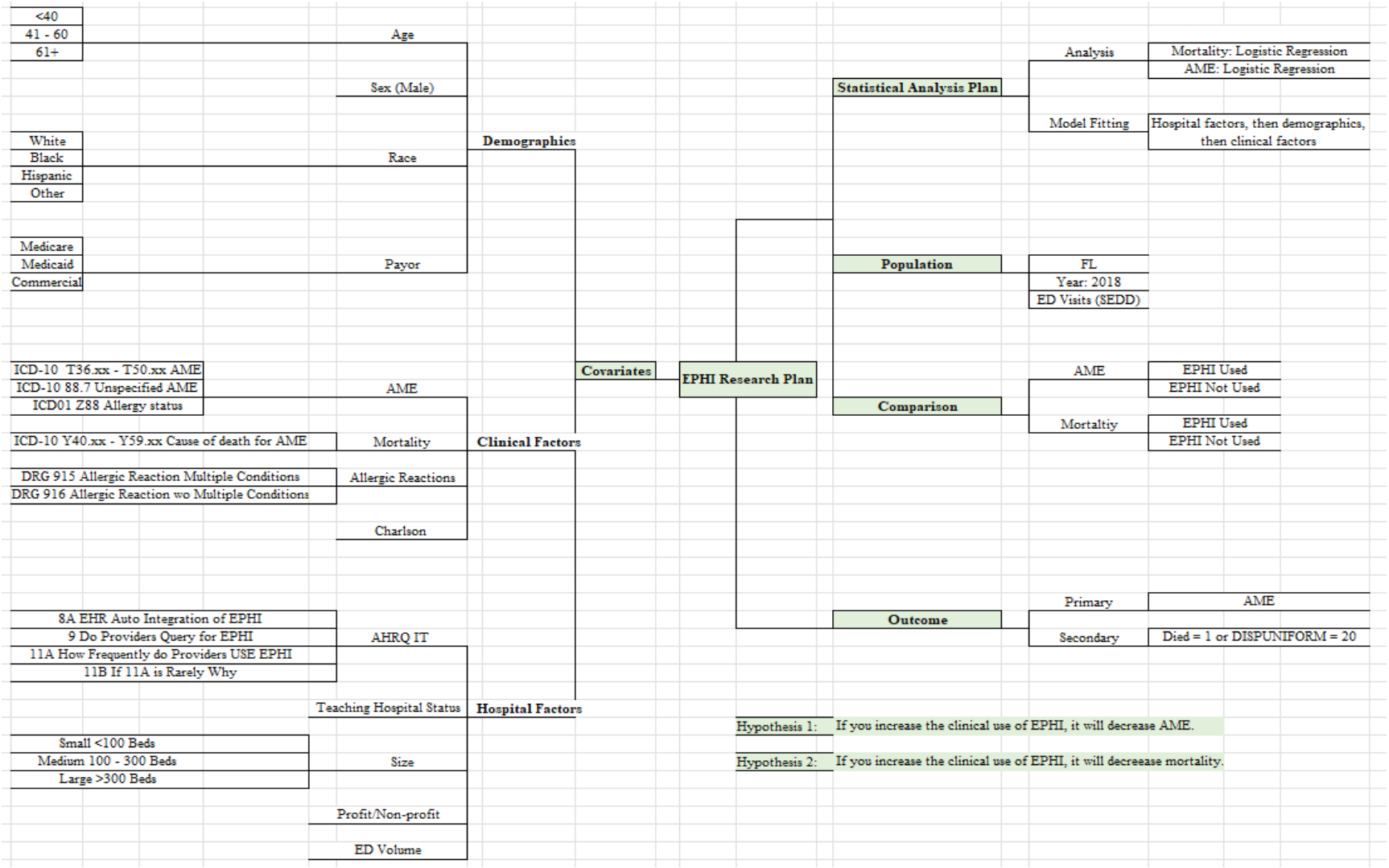
3.8 Protection of Human Subjects

This study uses aggregated, deidentified data and is therefore exempt.

3.9 Assumptions and Limitations

The AHRQ IT data is self-reported information which may be subject to response bias. Question 9 will be assumed to be no if no response is given. Question 11A will be assumed to be Never if no response is given. The clinical use and reporting of Current Procedural Terminology (CPT) and Diagnosis Related Group (DRG) codes as well as a lack of response to availability and use of foreign PHI could be limitations to this study. Patients that are admitted to the hospital from the ED visit are excluded from the SEDD dataset.

3.10 Research Plan



Chapter IV Journal Manuscript

Abstract

Background: Recent data shows at least 1.5 million people are affected by adverse medication events (AME) every year. The purpose of this study is to see if increased use of FPHI is associated with lower instances of AME's and lower mortality rates for hospitals.

Methods: Using a retrospective analysis and logistic regression, this study examines the relationship between IT use and quality. Specific metrics include AMEs and mortality rates in hospitals in the United States. Demographic data are used to control for confounders, CPT, DRG, and AHRQ questions are used as classifying variables for High IT utilization.

Results: Unadjusted rates of AME's were higher among high-IT hospitals than non-high-It hospitals (27.8% vs. 15.8%; $p<0.0001$). Unadjusted rates of mortality were similar between high-IT hospitals and non-high-IT hospitals (0.1 vs. 0.1; $p=0.1706$). The adjusted odds of suffering an AME for patients seen in ED that is a high IT use department are 36% lower than similar patients seen in low IT use Eds (OR:0.64, CI:0.60 – 0.67: $p<0.0001$). There was no direct association between increased use of FPHI and mortality rates.

Conclusions: There is a clear association between the increased use of FPHI and lower adverse medication events (AME) rates. Studies have shown that of all the AME's yearly 50% are preventable and the finding presented here show that high use of FPHI could potentially lower the odds of an AME by 36%. Given these findings, hospitals may want to consider incentivizing the utilization of FPHI in their Eds.

Information

The U.S. healthcare system is intended to improve patients' quality of life. Physicians take an oath to "Do No Harm" yet adverse medical events happen all over the country. Each year there are at least 1.5 million people, in the United States, affected by an AME, which is considered an adverse event (AE) alongside many other medical errors (AMCP, 2019). In one scoping review article on global AME rates that included 25 studies the authors wrote that approximately 10% of patients had at least one AME with approximately 7.3% of those resulting in. The number of preventable AME's ranged between 34.3% and 83.0% with a median of 51.2%. This equates to approximately 10% of inpatient stays involved an AME and roughly 50% of those are preventable. mortality (Schwendimann, R., Blatter, C., Dhaini, S., Simon, M., & Ausserhofer, D., 2018).

The Institute of Medicine released a report in 2007 that shows the additional medical cost to treat in hospital AME's to be approximately $3.5 billion dollars a year (IOM, 2007). In an article from 2019, authors looked at malpractice settlements from 2007 – 2016 (Zhao, B., Cajas-Monson, L. C., & Ramamoorthy, S., 2019). They found 2,353 cases of malpractice involving resident physicians with total indemnity paid of $831.7 million with amounts ranging from $9,000 to $743,214. The second most common accusation was improper management of surgical patients at an average payout of $275,044, which would include medications administered during the hospital stay.

Aftermath of AME's

A traumatic event has devastating consequences to surviving patients, family members, and even clinicians. These can range from financial issues to mood and anxiety issues and in

some cases post-traumatic stress disorder (PTSD) (Gries, C. J., Engelberg, R. A., Kross, E. K., Zatzick, D., Nielsen, E. L., Downey, L., & Curtis, J. R., 2010).

The long-term impact to patients of an AE was the subject of a study that appeared in a 2021 edition of the Journal of Patient Safety (Ottosen, M., Sedlock, E., Aigbe, A., Bell, S., Gallagher, T., & Thomas, E., 2021). The study included 72 volunteers which met the criteria of being either a patient who suffered an AE or family member of the patient. The participants were grouped into three groups based on the time that passed since the event: less than 5 years, 5-9 years, and 10+ years. Each person participated in a telephone interview that lasted between 60 and 90 minutes. After transcribing the audio recordings 4 common themes were discovered: social or behavioral, psychological, financial, and physical. Social or behavioral issues were the most common in all groups. This included sharing the experience with the public to help prevent future events. More than half felt that their lives would never be the same and considered themselves to be victims and that others had difficulty relating to or empathizing with their experience. They cited poor communication, a perceived absence of concern, and a refusal to make an apology or even admit the error. Participant 25 said, “I’d rather croak in my own bed than go to a hospital”. Among the psychological impacts, 50% said they felt anger or frustration in the way the hospital managed the situation, feeling that hospital administration should have stepped in instead of paying no attention to the issue. Loss of trust in the healthcare system and feeling let down was another prevalent issue.

The journal *Chest* published an article in 2010 that looked at the predictions of PTSD for families that lost a loved one in a hospital (Gries, C. J., Engelberg, R. A., Kross, E. K., Zatzick, D., Nielsen, E. L., Downey, L., & Curtis, J. R., 2010). There were 226 families, partially from a randomized control trial (RCT) and part from a patient health questionnaire. The response rates

were 46% in the RCT and 82% in the patient health questionnaire. The RCT results found PTSD or depression in 14% and in the patient health questionnaire the results were 18.4%.

The term second victim was coined by Albert Wu to describe the impact of errors on the healthcare providers (Wu AW., 2000). The expectation of perfection is not just from the patients and families, physicians also expect perfection from themselves (Ozeke, O., Ozeke, V., Coskun, O., & Budakoglu, I. I., 2019). This article goes on to say that medical schools do not prepare future physicians to deal with the impact of medical errors. A physician caught in the expectation of perfection has a chance of losing self-confidence leading to work inefficiency, concern about being judged by their peers, depression and even thoughts of suicide (Robertson, J. J., & Long, B., 2018). Physicians are not the only clinical staff that suffers after an AE. Nurses have more direct contact with the patient than physicians do. This makes them more sensitive to the impact of an AE (Kim, S.-A., Kim, E.-M., & Lee, J.-R., 2022). Additionally, nurses are more prone to be participating in AME's.

Clinical Use

Patient information from foreign sources can be used to lower costs and improve patient outcomes. Even with the potential benefits, physician use of this data is still low, and this low usage diminishes the value of these data (Esmaeilzadeh, 2022). A recent study looked at the clinical use of HIE data in Australia showing how often foreign data were accessed and by whom (Mullins, Skouteris, Rankin, Morris, Hatzikiriakidis, & Enticott, 2022). Looking at data from 2019 to 2021 an ED for a non-profit hospital in Australia found that HIE data was accessed in only 17.4% of patients in the ED. Pharmacists were the primary users at 15.6% with other clinical specialties making up the remaining 84.4% of users accessing this information. These

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- Second is workflow related. Even though total system integration is the goal of EHR vendors there can still be instances where users must log into multiple systems.
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- Fourth are the constantly changing standards used to share PHI. The use of acronyms by one healthcare specialty may have a different meaning for another specialty. Also, there are many fields in EHR's that allow free text entries by clinicians. This can make data mining difficult based on how issues are reported.

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While there are thousands of articles that discuss HIE and EHR implementation, no studies were found that looked for statistical data related to clinical HIE usage and the effects on both adverse medication errors and mortality.

Methods

The overarching research question is, “What is the association between the use of foreign PHI (FPHI) on the rates of AME and mortality in an Emergency Department setting?” In this study foreign patient health information (FPHI) is any patient medical information that comes from a source outside the current providers electronic system. This is done electronically through an independent health information exchange (HIE) or a vendors HIE portal using technology called interoperability. Interoperability is the ability of different computer systems to exchange data in a useable form, allowing providers to see what has occurred in other institutions for a given patient.

Current research shows that approximately 10% of emergency room visits suffer an AME and that approximately 7.3% of AME’s result in mortality. Considering that all research into the topic agrees that approximately 51.2% of AME’s are preventable, there is clearly a need to research the impact of using FPHI on lowering those rates and saving lives.

Question 1

What is the association between accessing FPHI (independent variable) and AME’s (dependent Variable)?

Hypothesis

Increasing the clinical use of FPHI is associated with lower rates of AME’s.

Question 2

What is the association between accessing FPHI (independent variable) and Mortality (dependent variable)?

Hypothesis

Increased use of FPHI will be associated with a decrease in mortality rates.

This retrospective study looks at historical data related to AME's, mortality, and the association of foreign PHI.

These hypotheses were made upon review of previous literature and through the application of Donabedian's structure, process, outcome model. According to this model, access to information through a structure can impact both the process and outcome of care. Thus, with more and better information about patients, we hypothesize that patient care quality and outcome will improve. This model is further explained later in this section.

The hospital, demographic, and outcome dataset used in this study came from the Comparative Effectiveness & Data Analytics Research Resource (CEDAR) source. This is the 2018 HCUP State Emergency Department Databases (SEDD) Florida data which is comprised of emergency department visit data. This includes clinical and nonclinical data from all visits that do not result in a hospital admission (AHRQ, ND).

Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). The data included in the dataset was grouped using demographic data, CPT and DRG codes are used for AME and mortality counts. For comorbid burden, we calculated the Charlson Comorbidity score (Quan, H., et al., 2005). This is a method predicting death within 1-year based on the weighted score of several specific medical conditions. As this score increases the risk of death within 1-year increases (Charlson, M. E., Pompei, P., Ales, K. L., & MacKenzie, C. R., 1987).

The Agency for Healthcare Research and Quality (AHRQ) Information Technology questionnaire data was used to determine the availability of and clinical use of foreign PHI. This questionnaire allows hospitals to self-report information technology levels in multiple areas. The area of interest for this research was whether clinicians search for FPHI and how often they use this FPHI for patient care decisions. Question 9 related to provider searching for FPHI is a binary yes/no question. Question 11A, which addresses provider use of FPHI, is a Likert scale from 1 Never to 5 Always. A score of 3 and above is used to indicate provider use of FPHI. The data from the AHRQ IT survey is linked to the HCUP SEDD data using two unique identifiers. First was the data source number for identifying hospitals (DSHOSPID) which is assigned by the hospital (AHRQ, N.D.). The second is the American Hospital Association number (AHAID). The difference between the two identifiers is that the AHAID number is assigned to a hospital or hospital group and can include multiple facilities. The DSHOSPID number is assigned to a single facility.

The variables used in this research were:

- AME
    - T36.xx – T50.xx ICD codes for adverse medication events
    - T88.7 ICD code for unspecified adverse effect of drug or medication
    - Z88 ICD code for allergy status to other drugs
    - Y40.xx – Y59.xx Cause of death ICD code for AME in therapeutic use
    - DRG 915 Allergic reactions with multiple chronic conditions
    - DRG 916Allergic reactions without multiple chronic conditions

- Mortality

    - Y40.xx – Y59.xx Cause of death ICD code for AME in therapeutic use
- Demographic Data
    - Age
    - Sex
    - Race/Ethnicity
    - Charlson score
- Hospital level factors
    - Rural/Urban
    - Hospital bed count
    - Teaching hospital status
    - Payer
    - ED Volume
- Main Independent variables
    - 9 – Do providers query for PHI from foreign sources
    - 11A – How frequently do providers use PHI from outside sources

To discover the relationship between provider use of FPHI and rates of AME or mortality this study uses the Donabedian model of structure-process-outcome (Donabedian A., 1966). When considering healthcare outcomes, all aspects of patient care need to be considered. This means that the structure, which would include the staff and associated electronic equipment, must be considered as well as the workflow or process that is in place for managing the patient.

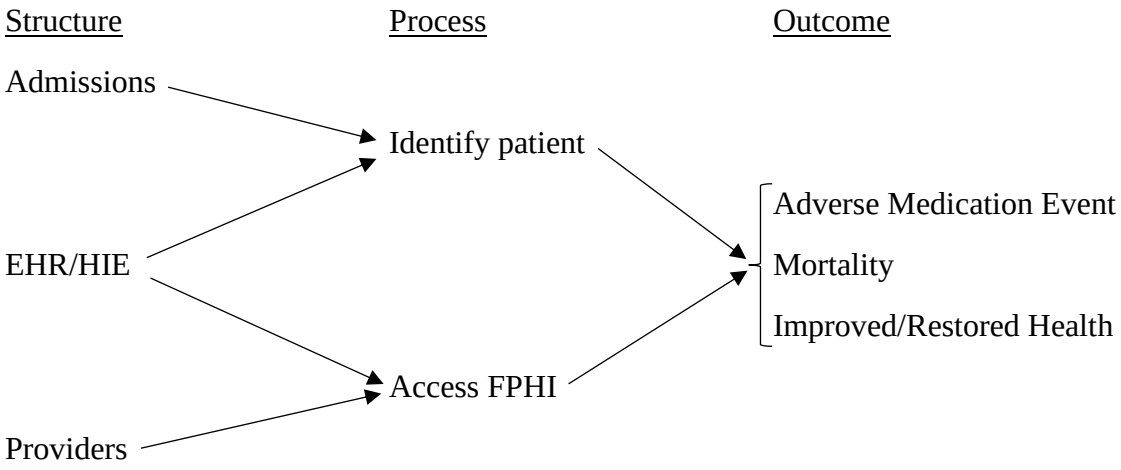


Figure 1. Conceptual model to assess FPHI relationship to AME & Mortality

The structure includes the admissions staff, the providers, and the EHR or HIE participation (Figure 1). The structure also needs to consider the EHR training provided to the staff as well as whether the EHR has the capability of automatically sending a request for data to an HIE when a patient is admitted to the ED. The process will be identifying the patient, if possible, and admitting to the ED. Do staff request information from outside sources if the system does not automatically do it upon registration? Providers use of the EHR or an HIE portal will be the focal point to consider when assessing the outcome. If the providers use FPHI is there an associated lowering of instances of AME's or mortality?

Analysis

Table 1 shows the results for a comparison of patient demographics between patients seen at high vs. low IT utilizing EDs. Charlson score, age, race, allergy to medications (a common source of AME), and sex were not significantly different. Hospital size was categorized as Small, Medium, and Large. The respective composition was qualitatively different between hospitals that were and were not high-IT utilizers; the largest proportion of hospital sizes (50%) were medium hospitals among high-IT users, whereas the largest proportion of hospital sizes (54%) were large hospitals for non-high-IT hospitals. ED visit volume was broken into quartiles, Q1 <3,892 was 5,067 (11.0) for Low IT usage locations and 16,297 (7.0) for high IT locations, Q2 3892 – 8081 was 8,193 (17.8) for Low IT locations and 49,646 (21.4) for high IT usage locations, Q3 8082 – 13,272 was 9,064 (19.7) for Low IT locations and 85,091 (36.7) for high IT usage locations, Q4 13,273+ was 23,710 (51.5) for Low IT locations and 80,818 (34.9) for high IT locations.

Table 1: Population characteristics of ED patients in a Low IT usage ED's vs those that at High IT usage ED's.

Patient Characteristics	Low IT n = 46,034	High IT n = 231,852
Charlson Score		
0	36,456 (79.2)	189,419 (81.7)
1	6,385 (13.9)	28,719 (12.4)
2	2,144 (4.7)	9,304 (4.0)
3+	1,049 (2.3)	4,410 (1.9)
Chalrson Score	0.3 ±0.8	0.3 ±0.7
Age		
<41	20,322 (44.1)	98,570 (42.5)
41 – 60	13,125 (28.5)	66,295 (28.6)
61+	12,587 (27.3)	66,987 (28.9)
Race		
White	31,959 (69.4)	161,940 (69.8)
Black	8,594 (18.7)	38,099 (16.4)
Hispanic	4,083 (8.9)	26,165 (11.3)
Other	1,398 (3.0)	5,648 (2.4)
Allergy to medications	39,196 (85.1)	169,570 (73.1)
Sex		
Female	30,603 (66.5)	151,410 (65.3)
Male	15,431 (33.5)	80,442 (34.7)
Hospital Size		
Small <100 Beds	10,809 (23.5)	49,401 (21.3)
Medium 100 – 300 Beds	10,347 (22.5)	115,880 (50.0)
Large 300+ Beds	24,878 (54.0)	66,571 (28.7)
ED Visit Volume		
Q1 <3,892	5,067 (11.0)	16,297 (7.0)
Q2 3,892 - 8081	8,193 (17.8)	49,646 (21.4)
Q3 8082 – 13,272	9,064 (19.7)	85,091 (36.7)
Q4 13,273+	23,710 (51.5)	80,818 (34.9)

Values expressed as n (%) or mean ±SD

Table 2 shows the percentage outcomes of the two variables being researched. Unadjusted rates of AME's were higher among high-It hospitals than non-high-It hospitals (27.8% vs. 15.8%; p<0.0001). Unadjusted rates of mortality were similar between high-IT hospitals and non-high-IT hospitals (0.1 vs. 0.1; p=0.1706).

Table 2. Unadjusted rates of Outcomes

Patient Characteristics	Low IT n = 46,034	High IT n = 231,852	p-value
Adverse Medication Events	7,262 (15.8)	64,412 (27.8)	<0.0001
Died during ED Visit	48 (0.1)	299 (0.1)	0.1706

Values expressed as n (%)

Our logistic regression model adjusted for ED volume, an interaction between ED volume and the primary predictor of High IT use, age, sex, race, Charlson score, and hospital size. A qualitative interaction was found to be small, yet significant (p<0.0001)—wherein the joint effect of being a low IT utilizing ED the rates of AMEs increase as ED volume increases, whereas among high IT utilizing ED the rates of AMEs decrease as ED volume increases. See Appendix A for the adjusted OR and 95% confidence intervals.

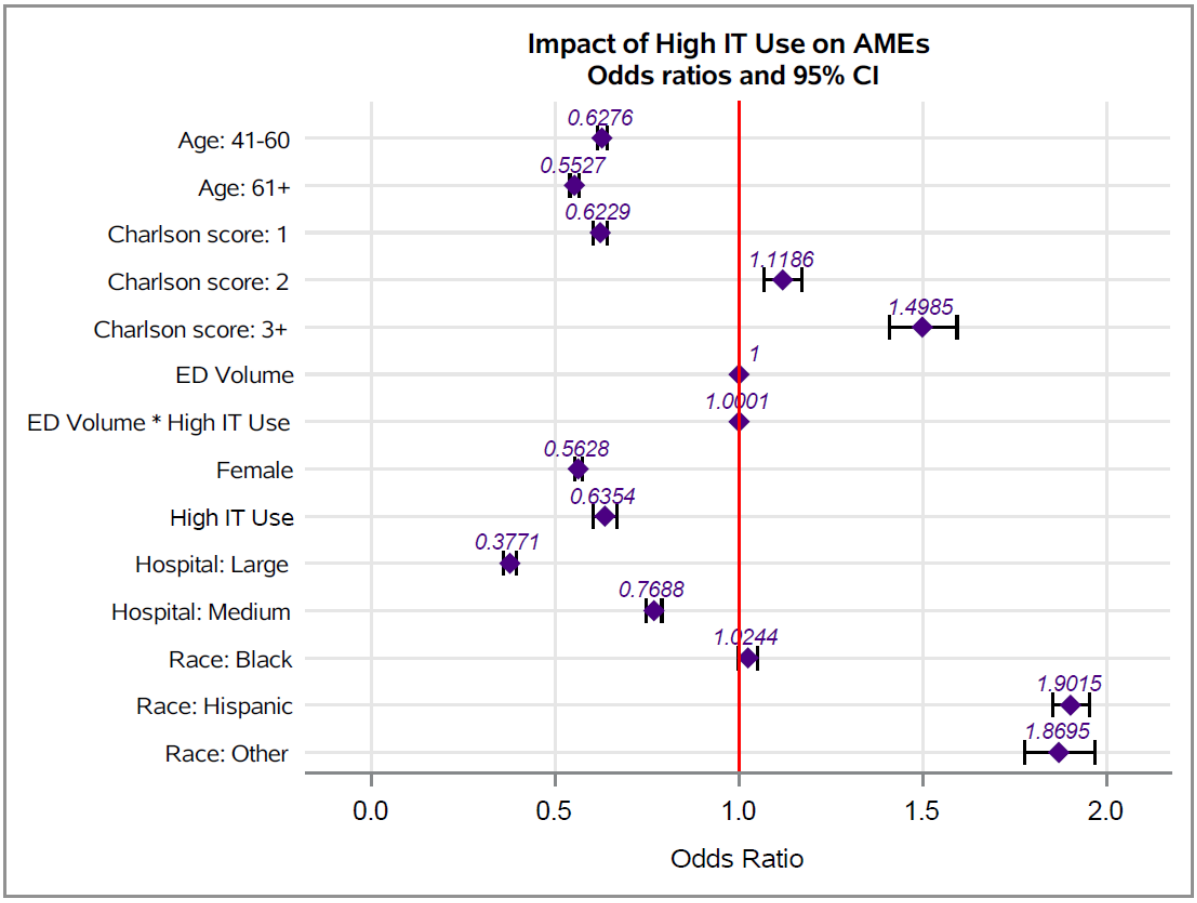
Discussion

This study examines the association between the use of FPHI and rates of AMEs and mortality. Despite the hypotheses, there was no significant association found between the use of FPHI and rates of mortality when comparing high IT use ED's with low IT use ED's with a p-value of p=0.1706.

Looking at the demographics shows a couple of key findings. First is that Low IT use locations appear to have experienced a sharp increase in ED volume during the 4th quarter, 51.5% of the yearly total, of 2018 while High IT use locations were consistent in the 2nd, 3rd, and 4th quarters. The second finding is that medium size hospitals, 100 – 300 beds, have the highest ED volume in the High IT use group while large hospitals, 300+ beds, have the highest ED volume in the Low IT use group. These findings should be considered for future research with implications for IT funding and staffing.

When looking at the association between high IT use and AME rates there is a statistically significant difference with a p-value of p<0.0001. This was only apparent after considering the interaction between the ED Volume and High IT Use variables. As seen in Graph 1 below, there is a small but predictive interaction between these two.

Graph 1. Odds ratio of High IT Use on AME's



The small 0.01% increase in the odds of an AME based on ED Volume has an impact on the actual association with High IT use which has 36% lower odd of an AME. Providers are human and as the ED volume increases the potential for AME's increases. Logistic regression modeling shows an increase in ED volume for low IT ED's resulted in increased rates of AME's while increased ED volume in high IT ED's resulted in decreased rates of AME's. As the volume increases the use of IT to gather FPHI helps to give providers insight to the best options for the patient. There are several other demographic data points that impact the odds of an AME, but these are all beyond the control of the healthcare staff.

The Donabedian model shows how this use of FPHI could impact the patient and help prevent an AME. In a High IT Use ED, a patient is presented and identified. Admissions staff can access patient records through an HIE. The data from the HIE is added to the patient record so that when the providers look at the patient record, they see an allergic reaction noted. The provider can consider alternative medications, thereby avoiding and AME. In a Low IT Use ED, a patient is presented to the ED. The admissions staff enters the information that is available from the patient. The provider only knows what is available in the record and prescribes a medication that the patient is allergic to, and the patient suffers an AME. Clearly this would not impact the treatment of unresponsive patients that cannot be identified.

In 2018 the United States HCUP data shows a total of 123,392,577 emergency room visits and a 0.15% mortality rate (HCUP, 2019). This means that in 2018 there were 185,089 deaths associated with emergency room visits. If 10% of the total emergency room visits suffered an AME, 7.3% of those resulted in death, and if 51.2% of those AME's were preventable then 4612 (2.5%) of those patient deaths could have been prevented.

While this study did not look at the association of lower AME's on hospital mortality, this is an area that needs further research. Additional areas of future research should consider why there are quarterly increases in low IT use Ed volume and why there are higher ED volumes at large hospitals with low IT yet there are higher volumes at medium high IT locations. These findings could help influence future staffing and funding to increase IT use.

Conclusion

Despite the best attempts and legislation to improve healthcare through the expansion of healthcare data interoperability provider use of foreign patient health information (FPHI) remains low. There is a clear association between the increased use of FPHI and lower adverse medication events (AME) rates. Studies have shown that of all the AME's yearly 50% are preventable and the finding presented here show that high use of FPHI is associated with lowering the odds of an AME by 36%.

There are some limitations to this study. The AHRQ IT data is self-reported information which may be subject to response bias. Question 9 was assumed to be *No* if no response is given. Question 11A was assumed to be *Never* if no response is given. The clinical use and reporting of International Classification of Diseases v.10 (ICD-10) and Diagnosis Related Group (DRG) codes as well as a lack of response to availability and use of foreign PHI could be limitations to this study. There is some clinical discretion involved with the choice and use of ICD-10 codes and the use of codes not included in this list could result in events that were not counted in this study. The annual AHRQ Information Technology questionnaire is voluntary, and some institutions may choose to skip questions 9 and 11A, these were counted as negative responses for this study and may affect the results. Patients that are admitted to the hospital from the ED visit are excluded from the SEDD dataset. Patients that presented to an ED and were unidentifiable at the time of admission yet suffered an AME were not excluded even though they may have been identified later.

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Appendix A

Adjusted Odds ratios and 95% confidence intervals of suffering an AME and mortality.

Predictor	**OR (95% CI)**	**p-value**
High_IT_Use	0.64 (0.60 - 0.67)	<.0001
ED_Volume	1.00 (0.99 - 0.99)	<.0001
ED_Volume*High_IT_Use	1.00 (1.00 – 1.00)	<.0001
Mortality	1.18 (0.86 – 1.62)	0.299