2022

Factors Associated With Accidental Drug Exposure in U.S. Adults Over 65 Years of Age

Edwin Raj
Walden University

Walden University

College of Health Professions

This is to certify that the doctoral dissertation by

Edwin Raj

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Richard Jimenez, Committee Chairperson, Public Health Faculty
Dr. Mehdi Agha, Committee Member, Public Health Faculty
Dr. Loretta Shields, University Reviewer, Public Health Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2022

Abstract

Factors Associated With Accidental Drug Exposure in U.S. Adults Over 65 Years of Age

by

Edwin Raj

MBA, Kakatiya University, 2000

BSc, Kakatiya University, 1997

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health Epidemiology

Walden University

February 2022

Abstract

Medication errors are a major public health issue and a leading cause of fatalities in the United States and globally. Older adults who rely on medications to address age-related health issues are at higher risk of medication errors. Accidental exposure to drugs is a major type of medication error that impacts older people more than other age groups. The purpose of this quantitative correlational study was to examine the association between patient gender, age group, and reporter type and accidental exposure to drugs in older people. The ecological model was used to guide the study. Logistic regression analysis was used to examine archived data from the Food and Drug Administration's Adverse Event Reporting System. The sample size for this study was 239,716. Pearson chi-square analysis showed a statistically significant association between age group ($\chi 2(1) = 5.89$, $p < 0.05$), reporter type ($\chi 2(1) = 99.45$, $p < 0.001$), and gender ($\chi 2(2) = 56.40$, $p < 0.001$) and accidental exposure to drugs. The logistic regression model was statistically significant, $\chi 2(3) = 170.20$, $p < .001$. Age group ($p < .05$; 95 CI 1.020–1.252), gender ($p < .001$; 95% CI 1.353–1.666), and reporter type ($p < .001$; 95% CI 1.537–1.885) were found to be statistically significant predictors of accidental exposure to drugs. Understanding the associations between the variables and accidental exposure to drugs may help patients, health care providers, drug manufacturers, and regulators to implement measures to minimize the occurrence of medication errors, which may reduce health care spending, boost patients' trust in the health care system, and improve health outcomes in older people.

Factors Associated With Accidental Drug Exposure in U.S. Adults Over 65 Years of Age

by

Edwin Raj

MBA, Kakatiya University, 2000

BSc, Kakatiya University, 1997

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health Epidemiology

Walden University

February 2022

Dedication

I dedicate this project to my wife Bokyoung, my children Leo, Emma & Aiden, my parents, my siblings, and my friends. Bokyoung held the fort at home while I was busy on countless nights and weekends with my assignments and dissertation work. I thank her and my children for trusting me and helping me to achieve this dream. I thank my parents, siblings and friends for their constant support and encouragement. I could not have achieved this dream without their unconditional love and support.

Acknowledgements

I would thank my committee members Dr. Richard Jimenez, Dr. Mehdi Agha and Dr. Loretta Shields for their support in successfully completing my dissertation journey. I can't thank Dr. Jimenez enough for his excellent mentorship throughout this journey. I would like to thank the staff at Walden writing center, Walden library who helped me at various stages of my dissertation journey. I would like to thank the Walden professors who helped me get ready for my dissertation. I would like to thank my work colleagues and my managers for their support. This was certainly not an individual achievement. I could not have sustained and succeeded in this long journey without the support of everyone. Many thanks from the bottom of my heart to everyone who helped me.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Medication errors continue to be a serious public health problem and a leading cause of deaths in the United States and globally (Rodziewicz et al., 2020). Older adults are at higher risk of medication errors due to polypharmacy, increased use of therapeutic interventions, and age-related health issues (Fialová & Onder, 2009). Medication errors pose a significant financial burden on the health care system in additional treatment costs and lost productivity including the loss of trust in the health care system, which could prevent patients from seeking treatment, leading to unaddressed health concerns (Tariq et al., 2020). Medication errors are unintentional preventable errors that can occur at any stage between prescription of the medication by the clinician to the consumption of the medicine by the patient (Tariq et al., 2020). Though there is greater awareness about medication errors in clinicians and consumers, they remain a widespread public health concern impacting millions of patients and remain a leading cause of death in the United States and globally (Tariq et al., 2020). An estimated 44,000 to 98,000 Americans succumb to medication errors annually (Kohn et al., 2000). Kohn et al. (2000) estimated the annual cost of adverse events resulting from medication errors in the United States to be between $27.6 billion and $50 billion.

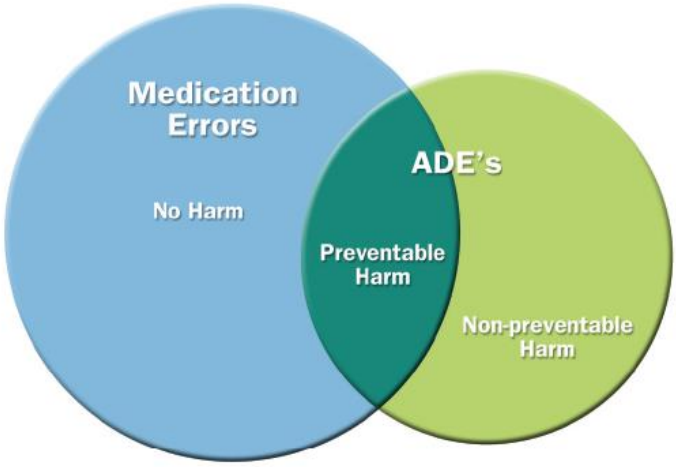
The World Health Organization (WHO) launched an initiative in 2017 to reduce severe medication-related harm globally by 50% over the next 5 years (WHO GPS Challenge, 2017). In this initiative, the WHO targeted weakness in the health care systems that result in medication errors leading to severe patient harm (WHO GPS Challenge, 2017). The WHO estimated that at least one person dies due to medication

errors every day and 1.3 million people in the United States are harmed annually due to medication errors (WHO GPS Challenge, 2017). According to the WHO, health worker fatigue, overcrowding, staff shortages, insufficient training, and incorrect information to patients are some of the causes for medication errors (WHO GPS Challenge, 2017).

The National Coordinating Council for Medication Error Reporting and Prevention defined medication error as "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" (NCCMERP, 2014). The National Coordinating Council for Medication Error Reporting and Prevention (07/23/2018, as cited in Falconer et al., 2019) divided medication errors into nine categories in which Categories A–D result in no harm and Categories E–I result in patient harm that could be preventable or nonpreventable. The relationship between medication errors and adverse drug events (ADEs) is show in Figure 1.

Figure 1

Relationship Between Medication Errors and ADEs



[1]Adapted from Figure 1 in Qual Saf Health Care 2004;13:306–314. doi: 10.1136/qshc.2004.010611

Accidental exposure to drugs is a significant cause of medication errors. The U.S. Poison Control Center receives reports of accidental exposure to drugs in older people because they are prone to forgetfulness, take the wrong drug dose, have an inappropriate schedule of drugs, and mix up drugs (Haselberger & Kroner, 1995). Additional factors such as polypharmacy, increased use of therapeutic interventions, and age-related health issues contribute to medication errors in older people (Fialová & Onder, 2009). The current study was aimed at examining the factors associated with accidental exposure to drugs in older people, specifically whether patient gender, age group, and reporter type were associated with accidental exposures to drugs. Despite significant advancements and research, there was a dearth of knowledge on factors associated with and contributing to accidental exposure to drugs in older people. Results of the current study may be used

to implement measures to educate the patients and providers to prevent these errors and contribute to positive health outcomes in older people.

Chapter 1 includes a description of the public health impact of medication errors and accidental exposure to drugs in older people. The chapter introduces some recently published peer-reviewed articles on this topic and indicates the gap in the literature. The chapter provides an overview of reasons for conducting this study and its impact on positive social change. I also describe the theoretical framework used in the study and how the theory aligned with the problem statement and research questions. The chapter lists the research questions and hypotheses that were addressed in this study. The chapter concludes with the assumptions in the study, its limitations and delimitations, and a summary transition to the next chapter.

Background

Since the publication of Kohn et al.'s (2000) research, there have been numerous publications highlighting the issue of medication errors in the United States and globally. Kohn et al. estimate that medication errors result in 44,000 to 98,000 U.S. deaths annually in hospitals. Medication errors add significant stress on the health care system. An estimated $37.6 billion to $50 billion is spent each year to address adverse events resulting from medication errors in the United States (Kohn et al., 2000). Medication errors continue to be a leading cause of death exceeding the combined number of fatalities due to road accidents, breast cancer, and AIDS (Kohn et al., 2000).

In England, Elliott et al. (2021) estimated that 237 million medication errors occur each year during the medication process. Around 28% (66 million) of medication errors

are considered clinically significant causing patient harm (Elliott et al., 2021). The financial burden including the stress on the health care system for addressing the adverse events resulting from medication errors is overwhelming with an annual cost of over £98 million, over 181,000 bed days, and over 1,700 deaths (Elliott et al., 2021). Advancement in therapeutics combined with increasingly complex medication needs are main causes for medication errors (Elliott et al., 2021).

According to a study by Tudor et al. (2016), the United Kingdom's National Health Service reported an estimated 2% of adult outpatients and 1.6% of adult inpatients are prone to medication errors costing the health system £770 million annually. According to Tudor et al., 3.7% of hospitalizations are due to medication errors that are largely preventable. According to Falconer et al. (2019), over 30% of U.S. adults in the consume five or more medications at a given time contributing significantly to medication errors and inappropriate use of medications. Due to hospitalizations, increased medical care, deaths, and significant morbidity, medication errors pose a significant burden to the health care system (Falconer et al., 2019). Although medication errors have been researched globally, there was a dearth of research on accidental exposure to drugs in older people. Through secondary data analysis of the Food and Drug Administration's (FDA's) Adverse Event Reporting System (FAERS) database, the current study was aimed at examining the factors of patient gender, patient age group, and reporter type and their association to accidental exposure to drugs in older people.

Problem Statement

Compared to other age groups, older adults rely on medications due to age-related health issues (Fialová & Onder, 2009). Medication errors occur at a higher rate in older adults compared to other age groups (Fialová & Onder, 2009). Accidental exposure to drugs is a major health concern in the older population. In 2011, an estimated 645,000 emergency department visits in the United States by older people were due to accidental exposure to drugs (Mattson et al., 2017). Understanding the factors that contribute to accidental exposure to drugs in older people is crucial to providing solutions for preventing their occurrence. Most older people who abuse prescription medication do so accidentally, and the risk of mistakes in this population is higher due to the increased number of medications taken by them and their high reliance on medications (Jones, 2021). There was very little research on accidental exposure to drugs among older people. This is an increasing public health challenge in the United States and globally, which needs to be addressed (Rodziewicz et al., 2020). Understanding the factors contributing to accidental exposures to drugs in older adults may help this population in safely taking the medications they rely on. This may help improve the health of older people and reduce the burden on the health care system, resulting in positive health outcomes and reduced health care cost.

Purpose of the Study

This study was a quantitative correlational study using secondary data analysis of the FDA's FAERS database with the aim of examining the factors associated with accidental exposure to drugs in older people, such as patient gender, patient age group,

and reporter type. The data in the FAERS database are collected globally though the FDA's MedWatch program for active surveillance of the risk–benefit profile of drugs marketed in the United States (MedWatch, 2020). The current study was aimed at examining the association between factors such as patient gender, patient age group, and reporter type and accidental exposure to drugs in older people. Patient gender, age group, and reporter type were the independent variables, and accidental exposure to drugs was the dependent variable.

Research Questions and Hypotheses

RQ1: Is there a statistically significant difference in accidental drug exposures between older adults and other age groups?

H_{01}: There is no statistically significant difference in accidental drug exposures between older adults and other age groups.

H_{a1}: There is a statistically significant difference in accidental drug exposures between older adults and other age groups.

RQ2: What is the association between reporter type and accidental drug exposures in older adults?

H_{02}: There is no association between reporter type and accidental drug exposures in older adults.

H_{a2}: There is an association between reporter type and accidental drug exposures in older adults.

RQ3: What is the association between gender and accidental drug exposures in older adults?

H_{03}: There is no association between gender and accidental drug exposures in older adults.

H_{a3}: There is an association between gender and accidental drug exposures in older adults.

RQ4: To what extent do reporter type, age group, and gender predict accidental exposure to drugs?

H_{04}: Reporter type, age group, and gender are not statistically significant predictors of accidental exposure to drugs.

H_{a4}: Reporter type, age group, and gender are statistically significant predictors of accidental exposure to drugs.

Theoretical Framework

The ecological model was used as the framework for this study. To examine the factors influencing patients characteristics and health care workers leading to medication errors, the ecological model is an ideal framework (Berben et al., 2012). In the current study, the ecological model was used to examine the factors such as patient gender, patient age group, reporter type and their association to accidental exposure to drugs in older people. It was essential to examine the factors at these levels to understand the causes for medication errors and implement measures for their prevention (see Berben et al., 2012). Chapter 2 provides more details on how the ecological model was used to examine the factors associated with accidental exposure to drugs in older people.

Nature of the Study

This study was a quantitative correlational study using secondary data with the aim of examining the association between the independent variables (patient gender, patient age group, and reporter type) and the dependent variable (accidental drug exposure) in older adults. According to the Medical Dictionary for Regulatory Activities (MedDRA , n.d.), the adverse events reported in the U.S. FAERs database were analyzed to assess whether older adults are disproportionally prone to accidental drug exposure and to examine the system and human factors that contribute to the errors. The MedDRA high-level term (HLT) "Accidental exposure to products" was used to search for reports of accidental drug exposure. Descriptive statistics were used to describe the study population and selected participant characteristics. Logistic regression at the bivariate levels was used to test the hypotheses and produce a predictive model for the outcome. Logistic regression was appropriate given that the dependent variable was a binary outcome (presence or not of accidental drug exposure).

Definitions

The following definitions for key terms and constructs were used in this study:

Accidental exposure to drugs: Accidentally taking a drug that was not intended for the patient; accidentally taking the drug more than prescribed; accidentally taking drug at the wrong time than intended; accidentally prescribing the wrong drug (Haselberger & Kroner, 1995).

Adverse event: According to the "FDA Adverse Event" (2020), an adverse event is defined as any undesirable experience associated with the use of a medical product in a patient.

Adverse reaction: An adverse event that is causally related to the drug taken ("FDA Adverse Event," 2020).

ASCII: An acronym for American Standard Code for Information Interchange. ASCII is a character encoding system that uses numeric codes to represent characters that include upper and lowercase English letters, numbers, and punctuation symbols (*ASCII Definition*, n.d.).

Medication errors: Medication errors are defined as any unintentional and preventable events that might lead to inappropriate use of medication and potential patient harm while the product is in the control of a health care provider, consumer, or patient (NCCMERP, 2014).

MedWatch: A platform used by the FDA to receive reports of adverse events and medication errors. Data received through the MedWatch program are stored in the FAERS (MedWatch, 2020).

Older people: Adults who are at least 65 years of age (Singh & Bajorek, 2014).

Reporter type: The person who is reporting the adverse event to the FDA through MedWatch. This could be a patient/consumer or health care provider ("FAERS Reporter Type," 2019).

SQL: An acronym for Standard Query Language. SQL is a programming language used to organize and retrieve information in relational databases (Knight, 2017).

Assumptions

The following assumptions were made in this study. I used secondary data analysis of FAERS data to perform analysis and answer the research questions. I assumed that the FAERS data were complete and accurate. I also assumed that there were no duplicates in the reports. Because the data did not contain any patient identifiers, it was not practically feasible to identify and remove duplicates. Next, I assumed that the originators of the database used scientifically sound methods to collect data. Finally, I assumed that the adverse events in the FAERS database were coded with the most recent version of MedDRA.

Scope and Delimitations

This study was aimed at examining the factors associated with accidental exposure to drugs in older people through quantitative secondary data analysis of FAERS data. The study included only the data fields from the FAERS database that were publicly available. I did not perform an in-depth review of medication errors caused by procedural errors (Level 3 of the ecological model) or policy errors (Level 4 of ecological model). Because the FDA does not require drug and biologic manufacturers to report medication errors without an adverse drug reaction, medication errors such as errors without harm (near misses), intercepted errors, and potential errors were excluded from this study.

Limitations

Although drug and biologic manufacturers are required to report adverse events that occur with the use of their products, the public (including health care providers) are not required to report adverse events occurring with the use of a drug. Although the

MedWatch program is the most reliable database for adverse event and medication error reports, due to the voluntary nature of reporting for the public there is significant underreporting (Berniker, 2001). Due to the spontaneous nature of reporting into FAERs, the data could be incomplete and prone to errors. The current study was limited to the data fields that were publicly accessible. Certain demographic data points such as ethnicity, which could have been useful for the study, were not included because they were not available in the publicly available data set. Despite these limitations of the FAERS database, which receives approximately 100,000 reports of medication errors annually, the current study contributed meaningful and significant conclusions to effect positive social change.

Presence of one or more outliers in observations could lead to a false sense of relationship in correlation analysis (Aggarwal & Ranganathan, 2016). Current study data were cleaned for outliers to avoid a potentially false sense of relationship. Correlational analysis could show a false relationship if the sample size is small (Aggarwal & Ranganathan, 2016). In the current study, the large amount of data present in the FAERS database was sufficient to avoid this issue. A true relationship between the independent and dependent variables cannot be taken as evidence for causation of the outcome (Aggarwal & Ranganathan, 2016). Through careful design, these limitations of correlational analysis were avoided.

Significance

Medication errors are a leading cause of death in the United States and continue to be a serious public health issue (Rodziewicz & Hipskind, 2020). The results of the

current study may help patients, pharmacists, and clinicians to take actions to prevent these errors from harming the patients and to reduce health care spending. The FDA and the drug manufacturers may use the insights obtained from this study to implement additional measures to prevent accidental drug exposures and enhance positive health outcomes in this population. Understanding how this issue impacts older adults is essential to ensure safe administration of needed medical interventions to ensure the health and well-being of this vulnerable population.

Summary

Chapter 1 introduced this important public health issue of medication errors (specifically accidental exposure to drugs) and emphasized the relevance of this study in examining this issue in the older population. It was apparent from the existing literature that the issue of accidental exposure to drugs is a significant and current public health issue. It was also apparent that there was a dearth of literature on this important topic. This chapter provided a compelling case for conducting this study to examine the factors contributing to accidental exposure to drugs in older people. The chapter highlighted the importance of using the FAERS database as a reliable resource for conducting this study. The research questions and the hypothesis that were tested as part of this study were listed in the chapter. Chapter 1 also provided the definitions for terms that were used throughout the study to ensure they were understood as intended. The scope of the study and its delimitations along with assumptions and limitations were provided in this chapter. Chapter 2 provides a detailed review of the relevant literature, as well as an overview of the theoretical model that was used to assist me in interpreting my findings.

Chapter 2: Literature Review

Medications developed in various forms and administered by various routes are the most common intervention in health care (Falconer et al., 2019). Over 30% of adults in the United States consume five or more medications at a given time (Falconer et al., 2019). Inappropriate use of medications poses a significant burden to the global health care system, resulting in hospitalizations, increased hospital visits, and significant morbidity and mortality (Falconer et al., 2019). Medication errors are a serious public health problem and a leading cause of death in the United States and globally (Rodziewicz et al., 2020). Although the impact of medical errors was brought to the forefront by Kohn et al. (2000), the issue of medication errors remains a significant cause of pain and suffering for patients and their families. Kohn et al. emphasized that to provide quality care, safety should be a crucial first step, and stated that health care is at least a decade behind compared to other high-risk industries in providing basic safety. Although there are multiple contributing factors to medication errors, understanding the errors and the contributing factors can help in implementing strategies for their prevention (Rodziewicz et al., 2020). Understanding the errors provides an opportunity to effect positive change and improve education in health care delivery (Rodziewicz et al., 2020).

The National Coordinating Council for Medication Error Reporting and Prevention defined *medication errors* as unintentional and preventable errors that could occur while the drug is in the possession of a health care professional, patient, or consumer and could lead to patient harm or result in inappropriate medication use

(NCCMERP, 2014). In the United States, an estimated 7,000 to 9,000 deaths are attributed to medication errors annually, including approximately $40 billion in additional health care spending (Tariq et al., 2020). Medication errors can occur during any stage of handling of the drug such as ordering/prescribing, documenting, transcribing, dispensing, administering, and monitoring by the pharmacist, health care provider, consumer, or caregiver (Tariq et al., 2020). Although medication errors were once believed to be caused by the individual, health care facilities have shifted their focus toward systematic causes for medication errors and are implementing measures to ensure the system does not fail (Tariq et al., 2020).

Adults over the age of 65 are at higher risk of medication errors compared to other age groups due to their increased reliance on therapeutic interventions that are needed to manage age-related health issues (Fialová & Onder, 2009). Polypharmacy, comorbidities, and enrollment in disease management programs including the quality of care are contributing factors for increased occurrence of medication errors in older people (Fialová & Onder, 2009). Although medication errors have been studied extensively, there was a dearth of research on medication errors in older people and the factors that contribute to medication errors in older people in the United States.

This literature review highlights the research that was available on medication errors globally and the initiatives undertaken by public health organizations such as the WHO to curb them. The prevalence of medication errors and their impact on public health are evident from the existing research, along with the lack of research on causes of medication errors in older people. This literature review starts with an overview and

epidemiology of medication errors, followed by typology of medication errors, impact of medication errors on public health, prevention of medication errors, accidental drug exposure in older people, and monitoring medication errors reported to the FDA's FAERS.

Literature Search Strategy

The literature search strategy included searching the CINAHL Plus, APA PsycINFO, and MEDLINE databases. The search results were restricted to peer-reviewed journal articles that were published in English between 2015 and 2021. Key literature such as the Institute of Medicine's report on medication errors (Kohn et al., 2000) and related publications were also included in the review. The search terms were developed through an iterative process. The initial search terms included *accidental ingest** or *accidental intake* or *unintentional drug poisoning* or *incorrect route of administration* or *mistaken identity of medication* or *improper storage* or *ingest extra dose* or *medication administration error* or *medication adherence* or *patient compliance* AND *elderly* or *aged* or *older* or *elder* or *geriatric* or *elderly people* or *old people* or *senior*. The reference lists of reviewed articles provided additional sources that were included in this review.

Theoretical Foundation

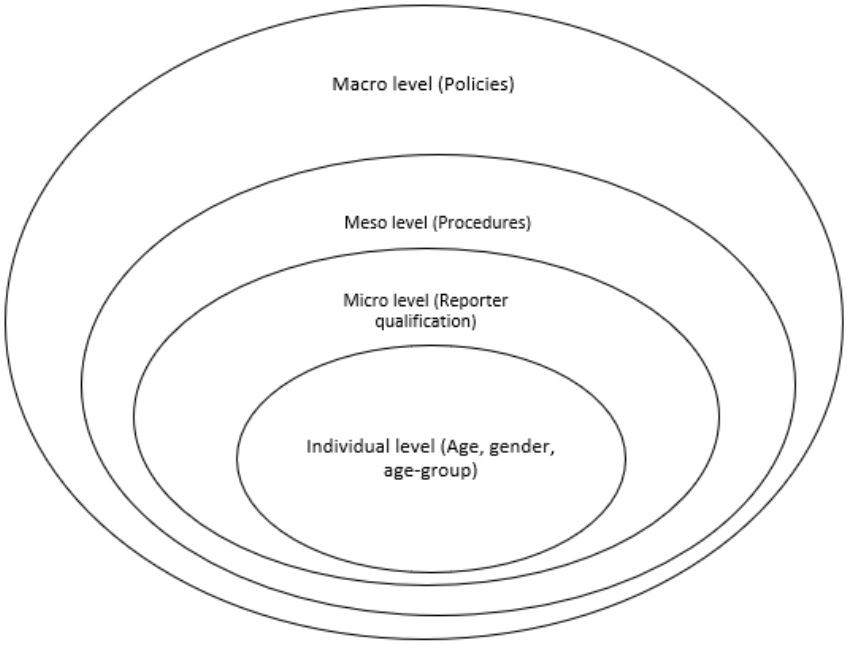
To explain the factors influencing behaviors of patients and health care workers leading up to medication errors, I used the ecological model as a framework (see Berben et al., 2012). There are different levels of factors that impact medication errors, such as the individual level, micro level (provider), meso level (health care organization), and

macro level (health policy; Berben et al., 2012). Factors at these levels should be considered to understand the causes for medication errors and implement measures for their prevention (Berben et al., 2012). The ecological framework, with its four levels, served as the theoretical framework for the current study. Bronfenbrenner (1981) described the ecological model as a nested structure within one another like a "set of Russian dolls" (p. 3). Bronfenbrenner, through the ecological model, provided a theory to study human development and provide perspectives of the developing individual, their environment, and the relationship between them.

Bronfenbrenner's (1981) theory can be applied to understand the factors contributing to medication errors. At the innermost level is the individual with factors such as gender, age, health literacy, and stress that could contribute to medication errors. The next level is the micro level with factors such as the surroundings (home or hospital) and product- or device-related issues that contribute to medication errors. The next level is the meso level with factors such as organizational protocols and procedures that could contribute to medication errors. The last level is the macro level with factors such as policies (government or product manufacturer) that could contribute to medication errors. Using relevant adverse events of medication errors in the FAERS database, I examined the association between individual, micro, meso, or macro level factors and accidental exposure to drugs (see Figure 2).

Figure 2

Ecological Model Used for This Study



Literature Review Related to Key Variables

Epidemiology of Medication Errors

According to the WHO (2018), preventable medication errors are a leading cause of injury and harm in health care systems around the world. An estimated 42 billion U.S. dollars are spent globally to address medication errors (WHO, 2018). Medication errors could occur during any stage of medication use and could be due to human factors or weak health care systems resulting in severe harm, disability, or death (WHO, 2018). The WHO launched a global patient safety challenge called Medication Without Harm to address severe medication errors with an aim to reduce harm by 50% between 2017 and 2022.

Adults over the age of 65 are at increased risk of ADEs due to a myriad of factors such as polypharmacy (use of at least 5 drugs), incorrect medication administration, and inappropriate prescriptions (Whittaker et al., 2017). In a survey conducted by the National Health and Nutrition Examination in 2011–2012 (as cited in Whittaker et al., 2017), 39% of older adults reported polypharmacy). ADEs lead to significant consequences in older adults resulting in an estimated 100,000 emergency hospitalizations and 177,500 emergency room visits annually (Whittaker et al., 2017). Approximately 66% of the hospitalizations are due to unintentional drug overdoses, and 37% of the emergency room visits result in hospitalizations in this population (Whittaker et al., 2017). Although these errors are largely preventable and unintentional, they have a profound impact on the health outcomes for older people and pose a significant financial burden on the national health system (Whittaker et al., 2017). Medication errors result in significant mortality and morbidity in the United States and globally (Tariq et al., 2020). An estimated 7 million patients are impacted due to medication errors in the United States, resulting in 7,000 to 9,000 fatalities annually (Tariq et al., 2020). Besides the hefty annual price tag of $40 billion, there is significant psychological and physical pain as a result of medication errors leading to the patient losing faith in the health system and patients deprived of therapeutic benefits (Tariq et al., 2020). Medication errors can occur at any stage of the process starting from the ordering/prescribing of the medicine to monitoring of the patients after the consumption of the medicine (Tariq et al., 2020). The most common stage for the occurrence of medication errors is the ordering/prescription stage (Tariq et al., 2020). Errors such as writing the wrong medication name or wrong

dose/route/frequency by the health care provider can occur during the ordering/prescribing stage and account for 50% of the medication errors (Tariq et al., 2020). Despite increased awareness and improvements, medication errors remain a widespread problem that needs to be addressed (Tariq et al., 2020). Poor system design and over expectation of human performance are seen a major contributors to medication errors (Tariq et al., 2020).

According to Tudor et al. (2016), the United Kingdom's National Health Service reported an estimated 2% of adult outpatients and 1.6% of adult inpatients are prone to medication errors costing the health system £770 million annually. In a review conducted by Tudor et al., 3.7% of hospitalizations were due to medication errors that were largely preventable. Hoeve et al. (2020) stated that stakeholders such as pharmaceutical companies, regulators, health care professionals, and patients along with their caretakers have an important role in the prevention of medication errors. At the product development and design stage, pharmaceutical companies can implement strategies to minimize medication errors (Hoeve et al., 2020). The European Medicines Agency published guidelines in 2015 describing common areas of risk to be considered by the industry and regulators to minimize medication errors prior to authorization of the product for marketing (Hoeve et al., 2020). Although these guidelines can minimize some risk of medication errors prior to the authorization of the product, the risk cannot be completely eliminated (Hoeve et al., 2020).

Elliott et al. (2021) estimated that 237 million medication errors occur annually in England during the medication process. Although 72% of these errors pose little or no

potential harm to patients, 66 million errors have the potential for being clinically significant (Elliott et al., 2021). The ADEs resulting from medication errors cost England over £98 million, over 181,000 bed days, and over 1,700 deaths annually (Elliott et al., 2021). Increasingly complex medication needs and greater availability of new medications are main causes for the medication errors (Elliott et al., 2021). Most of the errors (54%) were administration errors followed by prescribing errors (21% percent) and dispensing errors (16%), and 2% had the potential to severe harm (Elliott et al., 2021).

Kohn et al. (2000) estimated that between 44,000 and 98,000 Americans die due to medical errors each year in hospitals. In the lower estimate, the number of deaths by medical errors still exceeds those due to road accidents, breast cancer, and AIDS (Kohn et al., 2000). The national annual cost in the United States for adverse events resulting from medication errors is estimated to be between $37.6 billion and $50 billion (Kohn et al., 2000).

Typology of Medication Errors

The use of multiple terms and definitions has for a long time been a challenge for researchers, clinicians, and regulators (Falconer et al., 2019). Researchers have used various terms such as potential ADEs, adverse drug reactions (ADRs), ADEs, medication errors, and drug-related problems to describe medication errors (Falconer et al., 2019). To enable precise comparison of event rates and to enhance communication between patients, clinicians, researchers, and policymakers, there is a need for uniform terminology to describe medication errors (Falconer et al., 2019). The International Council for Harmonization created the MedDRA for standardizing the scientific and

technical aspects of drug regulation and provided multilingual terminology that can be used to communicate clinical data (Falconer et al., 2019). Regulators such as the FDA and European Medical Agency prefer to refer to medication errors as ADRs, aligning with the WHO (Falconer et al., 2019). Agencies such as the Agency for Research and Quality and the Canadian Patient Safety Institute prefer ADEs (Falconer et al., 2019). The Institute of Safe Medication Practices uses both ADEs and ADRs to describe harm due to medication errors (Falconer et al., 2019). There exists a lack of clarity on the harm resulting from medication nonadherence, misuse, untreated indications, and missed doses in which harm is caused by the unintentional nonuse of the drug (Falconer et al., 2019). In situations in which a patient is harmed and there is no direct drug association, the term adverse event can be used (Falconer et al., 2019). Quantifying, comparing, and extrapolating harm due to medication errors is limited due to lack of harmonized terminology (Falconer et al., 2019).

Impact of Medication Errors on Public Health

Studies have shown medication errors to be common and costly, resulting in tens of billions of dollars each year in additional health care expenditure around the world (Holmström et al., 2015). Elliott et al. (2021) conducted a study in the United Kingdom and found an estimated 237 million medication errors occurring in all stages of medication handling. Most of the medication errors occurred at the administration stage (54.4%), followed by the prescription stage (21.3%), dispensing stage (15.9%), and monitoring stage (7%). Of the 237 million medication errors, 72% had the potential to

cause minor harm, 26% had the potential to cause moderate harm, and 2% had the potential to cause severe harm.

Adults over 65 have increased medication needs due to age-related health issues and vulnerability for poor health outcomes (Kiel & Phillips, 2017). Over 33% of the total prescriptions filled are for older adults, and medications have a pronounced effect on older adults, including confusion, an increased risk of fall, and ADRs that could result in increased cost and increased reliance on the health care system (Kiel & Phillips, 2017). ADRs could decrease the quality of life of individuals and are known to be the reason for hospitalizations and mortality (Bukic et al., 2019). In addition to additional cost, patients are faced with psychological and physical pain as a result of medication errors, which could lead to decreased patient satisfaction and loss of trust in the health care system (Tariq et al., 2020).

Prevention of Medication Errors

Improvements in chain of communication between the various individuals involved in the stages of medication ordering to dispensing, administration and monitoring could help in reducing the occurrence of medication errors (Tariq et al., 2020). Enhanced patient education is a key factor in increasing adherence to medications and in reducing medication errors (Tariq et al., 2020). Distractions among healthcare workers are a major cause of medication errors, attributing to 75% of the errors (Tariq et al., 2020). Introducing measures to minimize distractions in hospitals can help prevent medication errors (Tariq et al., 2020). Distortions such as poor handwriting, use of abbreviations, use of symbols is another major cause for medication errors resulting from

improper filling of prescriptions (Tariq et al., 2020). A complete elimination of handwritten prescriptions, and orders was recommended by the Institute of safe medication practices to prevent errors resulting from illegible handwriting (Tariq et al., 2020).

Accidental Exposure to Drugs

Although majority of poisonings involve children under the age of 6 years, older adults are more prone to hospitalization and death due to drug poisoning, compared to younger people (Haselberger & Kroner, 1995). Drugs such as antidepressants, analgesics, cardiovascular medications, and other psychotropic medications are commonly responsible for death due to drug poisoning in older adults (Haselberger & Kroner, 1995). Accidental exposure to drugs in older adults is the most commonly reported issue in the poison control center calls (Haselberger & Kroner, 1995). Accidental exposure to drugs in older adults is primarily caused due to forgetfulness, mix-up of medications, incorrect route of administration, and improper storage of medications (Haselberger & Kroner, 1995). Between the years 2000 and 2012, the United States poison control centers received 67,603 reports of accidental exposure to drugs outside of a healthcare setting resulting in serious medical outcomes (Hodges et al., 2018). In a 13 year study of the poison control center data, the rate of medication errors increased in each age-group except for children under the age of 6 years of age (Hodges et al., 2018). The most commonly reported adverse events in the poison control center database are incorrect dose, inadvertently taking the medication twice, administering or consuming the wrong drug (Hodges et al., 2018).

The most commonly reported medication error was “Other incorrect dose” (19.8%) followed by “wrong medication taken / given” (18.4%) and “inadvertently took medication twice” (15.7% ; Hodges et al., 2018). Although the general management of drug poisoning is similar in younger and older patients, its management is complicated in older patients due to factors such as difficulties in the diagnosis of drug poisoning, age related pharmacokinetic and pharmacodynamic changes, increased use and reliance on medications, and increased occurrence of chronic illness (Haselberger & Kroner, 1995). Nearly 1 in 5 serious medication errors reported were with the use of cardiovascular drugs, followed by analgesics, and hormones / hormone antagonists (Hodges et al., 2018). More than one third of the 67,603 reported medication errors resulted in hospitalizations representing a significant burden on the healthcare system (Hodges et al., 2018).

Reviewing Accidental Exposure to Drugs in the FAERS Database

The FDA’s FAERS is a database that consists of adverse event reports, product quality complaints and medication errors which are reported by consumers, drug / device manufactures and healthcare providers through the MedWatch program (FDA’s Adverse Event Reporting System (FAERS), 2019). The data in the FAERS database meets the standards set forth by the International Conference of Harmonization for the collection of adverse events (FDA’s Adverse Event Reporting System (FAERS), 2019). Adverse events and medication errors reported in the FAERS database are coding using the MedDRA (FDA’s Adverse Event Reporting System (FAERS), 2019). Clinical reviewers and FDA’s Center for Drug Evaluation and Research and the Center for Biologics

Evaluation and Research evaluate the data submitted to the FAERS database for the active safety surveillance of drugs and devices that are approved by the FDA (FDA's Adverse Event Reporting System (FAERS), 2019). The data submitted to the FAERs database is publicly accessible through the FAERS dashboard which is a highly interactive web-based tool for querying the data, through downloadable data files and also through the Freedom of Information act request to the FDA (FDA's Adverse Event Reporting System (FAERS), 2019). The Institute of Safe Medication Practices encourages consumers and healthcare professionals to use the Medication Error Reporting Platform for reporting medication errors (Wang et al., 2018). The MedWatch program, which feeds the data to the FAERS database is the leading database for medication errors (Wang et al., 2018). The FAERS database contains essential information for each report such as a unique case ID, receipt date, list of drugs involved, seriousness of the events, outcome of the events along with patient's demographic information (Wang et al., 2018).

The adverse events reported to the FAERS database are coded using MedDRA Preferred Term (Fang et al., 2014). The MedDRA dictionary is organized as a hierarchy of terms as described in figure 3 below. The HLT "Accidental exposure to products" will be used in FAERS to retrieve the relevant records reported for medication errors specific to accidental exposure to drugs. The preferred terms "accidental device ingestion," "accidental exposure to product," "accidental exposure to product by child," "accidental exposure to product packaging," "accidental exposure to product packaging by child," fall under the HLT "accidental exposure to products" (see Figure 4).

Figure 3

Hierarchy of Terms in MedDRA

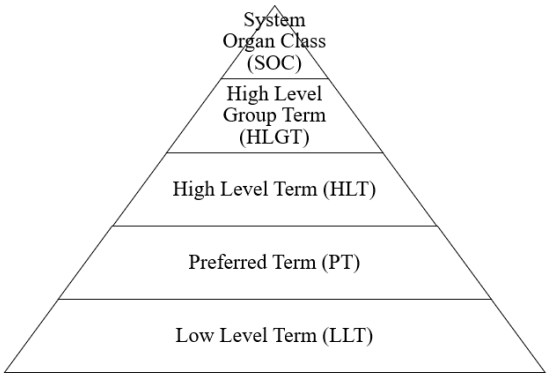
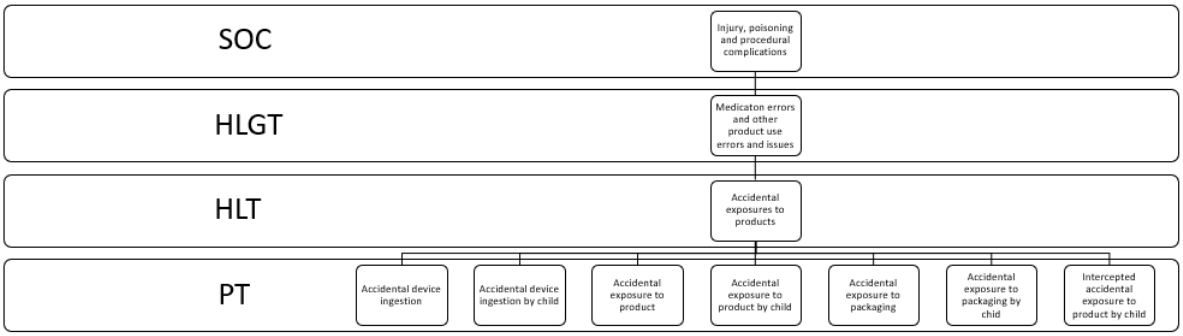


Figure 4

MedDRA Hierarchy for HLT Accidental Exposure to Products



Summary and Conclusions

Medication errors are any preventable events that could lead to inappropriate use of medication and potential patient harm while the product is in the control of a healthcare provider, consumer, or patient (*FDA - Medication Errors*, 2020). Medication errors continue to be a leading case of morbidity and mortality in the United States and Globally. The United States FDA and World Health Organization have established

several initiatives with the vision of reducing and eliminating medication errors. While causing significant emotional, physical, and financial burden, medication errors could also erode the patients and their families trust in the healthcare system. This could lead to patients not seeking medical attention potentially causing negative health outcomes.

Since the publication of "To Err is Human" by IOM, numerous publications have been published to understand the factors contributing to medication errors and find ways to minimize them. Despite of the heightened awareness and extensive research, medication errors remain a significant challenge for the healthcare industry. Older adults are at a higher risk of being impacted by medication errors due to polypharmacy, increased vulnerability, and age related health issues (Kiel & Phillips, 2017; Whittaker et al., 2017) . Although there is lot of literature on the impact of medication errors, there is a gap in understanding the specific factors that directly impact older adults. Accidental exposure to products has not been studied in older adults, though they are at a higher risk of poisoning due to forgetfulness, taking drugs twice, mixing medications and interactions between medications.

This study aimed to study the medication errors submitted to the FAERS database to understand the factors associated with the adverse events in older adults. The study with the aid of Bronfenbrenner's ecological model aimed to understand the relationship between the individual, the immediate surroundings, protocols used and the policies that exist to understand the factors contributing to mediation errors. By understanding the factors that contribute to medication errors, measures can be taken at different levels (Health policies, hospital procedures, surroundings, individual behaviors) to minimize

medication errors. These measures will ultimately lead to decreased burden on the healthcare system and improved health outcomes in older people. These measures also prevent the loss of trust in the healthcare system so patients and their families to continue to seek medical attention when needed.

Chapter 3 below describes the research methodology used by this study to determine the factors associated with medication errors in older people, strategy used for data extraction, and data analysis plan.

Chapter 3: Research Methodology

The purpose of this study was to conduct a secondary data analysis using the FDA's FAERS to examine factors associated with accidental exposure to drugs in older people. The study was aimed at examining whether patient gender, age group, and reporter type were disproportionately associated with accidental exposure to drugs in older people more than in other age groups. Patient gender, age group, and reporter type were the independent variables while accidental exposure to drugs was the dependent variable. Chapter 3 is divided into the following subsections: Research Design and Rationale, Research Questions and Hypotheses, Methodology, and Data Analysis Plan. The Data Analysis Plan includes a description of the structure of the FAERS output, query used for data extraction, variables, sampling methodology, statistical analysis, threats to validity and reliability, and ethical considerations.

Research Design and Rationale

This was a quantitative correlational study using secondary data analysis to examine the association between patient gender, age group, reporter type, and accidental drug exposure in older adults. Using the MedDRA dictionary, I examined the adverse events reported into the FAERs database to determine whether older adults were disproportionally prone to accidental drug exposure compared to other age groups. The MedDRA preferred terms "accidental device ingestion," "accidental exposure to product," "accidental exposure to product by child," "accidental exposure to product packaging," "accidental exposure to product packaging by child," fall under the MedDRA HLT "accidental exposure to products" were used to classify reports in the

FAERS database as accidental exposure to drugs. Descriptive statistics were used to describe the study population and selected participant characteristics. Logistic regression at the bivariate level was used to test the hypotheses and produce a predictive model for the outcome. Logistic regression was appropriate given that the dependent variable was a binary outcome (presence or not of accidental drug exposure).

The dependent variable accidental drug exposure contained a binary value of 1 (*yes*) or 0 (*no*) indicating the presence or absence of accidental exposure to drugs in the report. If the value in the field "Reactions" contained any of the five terms of interest ("accidental device ingestion," "accidental exposure to product," "accidental exposure to product by child," "accidental exposure to product packaging," "accidental exposure to product packaging by child"), it was assigned a value of 1; if not, it was assigned a value of 0. The independent variable age in years was a continuous variable that indicated the age in years of the consumer. Age in years was calculated based on the field "Patient age," which contained a numeric age followed by "YR" for years and "MTH" for months. The number portion of the records with "Patient age" containing "MTH" was multiplied by 12 for the Age column. The number portion of the records with "Patient age" containing "YR" was used as is for the Age column. The age-group column was a categorical variable with possible values of 1 (*older*) and 0 (*not older*). If age was greater than or equal to 65, the age-group field contained a value of 1, and if age was less than 65, the age-group field contained a value of 0. The field "Gender" was a categorical variable containing possible values of 0 (*male*), 1 (*female*), or 2 (*not specified*). The field

"Reporter type" contained possible values of 0 (*non-health-care professional*) for patient or 1 (*health care professional*) for provider (see Table 1).

Table 1

Variables Used in the Study

Field name	Description	Type	Possible value	Calculated from	Calculation
Case ID	Unique id for each reported adverse event	Continuous	Random incremental value	None	None
Accidental exposure to drug	Dependent variable which indicates if accidental exposure to drugs was reported	Dichotomous	Yes / No	Reactions	If Reactions contains "accidental device ingestion", "accidental exposure to product", "accidental exposure to product by

Field name	Description	Type	Possible value	Calculated from	Calculation
					child", "accidental exposure to product packaging", "accidental exposure to product packaging by child", then "Yes", otherwise "No
Age-group	Independent variable - age group of the patient	Categorical	Older / Not older	Age	If age is greater than or equal to 65, then "Older", otherwise "Not older".
Gender	Independent variable -	Categorial	Male / Female /	None	None

Field name	Description	Type	Possible value	Calculated from	Calculation
Reporter type	Gender of the patient Independent variable – Reporter of the adverse event	Categorical	Not specified Consumer / Healthcare professional	None	None

Methodology

Secondary Data Analysis

Primary data analysis is research conducted by the original research team that gathered the data as part of their research (Allen, 2017). Using existing data to answer additional research questions different from original research is known as secondary data analysis (TRIPATHY, 2013). Large scale surveys or data collected through surveys as part of a primary research are considered secondary data (TRIPATHY, 2013). Although there is general agreement about using large data sets for secondary data analysis, there is little agreement on using data collected as part of primary research (TRIPATHY, 2013). Secondary data analysis saves researchers a lot of time and resources and allows researchers to utilize the data for questions that were not in scope of the primary research (TRIPATHY, 2013). Besides saving the researcher time, secondary data analysis reduces

burden on participants for providing data on sensitive topics and collecting data from hard-to-reach populations (O'Connor, 2020). Secondary data analysis is fast becoming a preferred method for efficiently undertaking health research (Cheng & Phillips, 2014). Researchers often gather more information than needed to answer their original research question. Although these data are not always publicly available, researchers make the data available for further research (Cheng & Phillips, 2014).

Secondary data analysis can follow two approaches: research question driven and data driven (Cheng & Phillips, 2014). In the approach where the secondary data analysis is driven by the research question, the researcher needs to find an appropriate data source that can answer the research question(s) and also needs to make sure they can access the data source (Cheng & Phillips, 2014). In the data-driven approach, the researcher identifies a data source that they have access to or is publicly available. The researcher then formulates their research question(s) based on the data elements that exist in the database (Cheng & Phillips, 2014). If the researcher is unable to find an appropriate database to answer their research question in the research-question-driven approach, they adjust the research questions and variables based on data that they are able to find (Cheng & Phillips, 2014). Researchers should have a comprehensive understanding of the data set and the limitations of the data. Before conducting any analysis, researchers should define the operational definitions for dependent variables, independent variables, covariates, and confounders in the data set (Cheng & Phillips, 2014).

Cost and time are the most important advantages of using secondary data, though there could be a small fee to access the data. For new investigators who may not have the

time and funds to gather primary data, secondary data can be very useful in helping them to test the theories and conduct research (Cheng & Phillips, 2014). With advancements in technology and reduced cost for online storage, private and public organizations are making large data sets available for download to facilitate research (Cheng & Phillips, 2014). Statisticians can use these available real-life data sets to test new statistical methods (Cheng & Phillips, 2014).

Despite its increasing popularity and several advantages, secondary data analysis is not without limitations. One of the major limitations is that data are not collected to answer the current research question and could be missing important variables or populations that are necessary for the current research (Cheng & Phillips, 2014). Due to privacy concerns, data that are made available for secondary research are usually anonymized, causing potential confounding during secondary analysis (Cheng & Phillips, 2014). Another major limitation is the lack of understanding of nuances that were involved in primary data collection, which could lead to misinterpretation of variables (Cheng & Phillips, 2014). For data that are publicly available, it can be implicitly understood that the researcher has permission to use it for their research. However, if the data are not publicly available, for ethical clearance the researcher needs to get written permission to access the data for their use in secondary research (TRIPATHY, 2013). Researchers performing secondary data analysis should have special consideration for secure storage of the data to prevent unauthorized access during data storage (TRIPATHY, 2013).

Use of Logistic Regression

The statistical model to describe or examine one dependent variable on the basis of one or more independent variables is called regression (Hilbe, 2009). The dependent variable is the variable that is being examined or described while the independent variables are the variables that are used to predict the dependent variable (Hilbe, 2009). Logistic regression was used in the current study to examine the relationship between the dependent and independent variables and answer the research questions. Binary logistic regression was used to understand a binary dependent variable (accidental drug exposure) on the basis of one or more predictor variables (see Hilbe, 2009). The dependent variable could have had a value of 1 indicating the occurrence of accidental drug exposure or 0 indicating the absence of accidental drug exposure. The independent variables in this study were reporter type, age group, and gender.

Population

Main Study: FAERS

I conducted secondary data analysis using the FAERS database. The FAERS database contains millions of reports from device and drug manufacturers, patients, and health care professionals and facilitates the FDA's postmarketing drug safety surveillance efforts (Fang et al., 2014). The number of reports and the quality of data submitted to the FAERS database has increased significantly over the years making it an important source for regulatory science (Fang et al., 2014). The use of FAERS database in disease monitoring was examined by Fang et al. (2014). The FAERS database contains adverse events, medication errors, patient demographics (excluding personally identifiable data),

product information, therapy dates, indication for use, manufacturer information, and reporter information (Fang et al., 2014; Li et al., 2021). The FAERS database gets its data from the FDA's MedWatch program, which is used as a medical product safety reporting program for patients, consumers, health care professionals, and manufacturers (MedWatch, 2020). This program is also used to capture and monitor medication errors.

The FAERS database consists of adverse event reports from drug/device manufacturers, patients, and health care providers. The manufacturers are required to submit the reports to the FDA while the reporting is voluntary for patients and health care providers. The FAERS database is publicly accessible and used by the FDA's Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, and clinicians to monitor the benefit risk of the drugs and biologic products that are approved by the FDA (FDA's Adverse Event Reporting System (FAERS), 2019). The FAERS database complies with the informatic structure defined by the International Conference for Harmonization (FDA's Adverse Event Reporting System (FAERS), 2019). Based on the FDA's review of data in the FAERS database, the FDA can take actions such as updates to the product labeling information, communication of new safety information to the public, restricting the use of the drug, and in rare instances withdrawing a product from the market (FDA's Adverse Event Reporting System (FAERS), 2019). The FDA updates and posts the FAERS data files on its website quarterly.

The FAERs database contains adverse events and medication errors reported to the FDA using the MedWatch program (FAERs, n.d.). The FAERs database is a publicly accessible database that was designed to support the FDA's postmarketing surveillance of

drugs and biologics (FAERs, n.d.). The data from the FAERs database contains patients' demographic information such as age, height, weight, and gender, along with adverse reactions, drugs used, indications for the drug use, and outcomes of the adverse reactions such as hospitalization. The data are already deidentified. The ADRs reported by the reporter are already coded using the MedDRA dictionary.

The FAERS database is not without limitations. There are potential duplication of reporting from multiple sources when the same report was submitted by the consumer, healthcare professional and the manufacturer (FDA's Adverse Event Reporting System (FAERS*)*, 2019). The existence of adverse events should not be assumed to be causal to the drug and the reports are not always medically reviewed by a health care professional (FDA's Adverse Event Reporting System (FAERS), 2019). Since reporting is voluntary for patients and healthcare professionals, not all adverse events are reported to the FDA, leading to underreporting.

MedDRA

The International Conference for Harmonization along with World Health Organization developed MedDRA in the 1990s based on the terminology used by the United Kingdom's Medicines and Healthcare products Regulatory Agency (History | MedDRA, n.d.). MedDRA provides a globally followed, standard hierarchical structure for reporting adverse events (History | MedDRA, n.d.). The adverse events reported to the FAERS database are coded using MedDRA terminology (OpenFDA, n.d.). For this study, reports of accidental exposure will be extracted from the FAERS database by using the

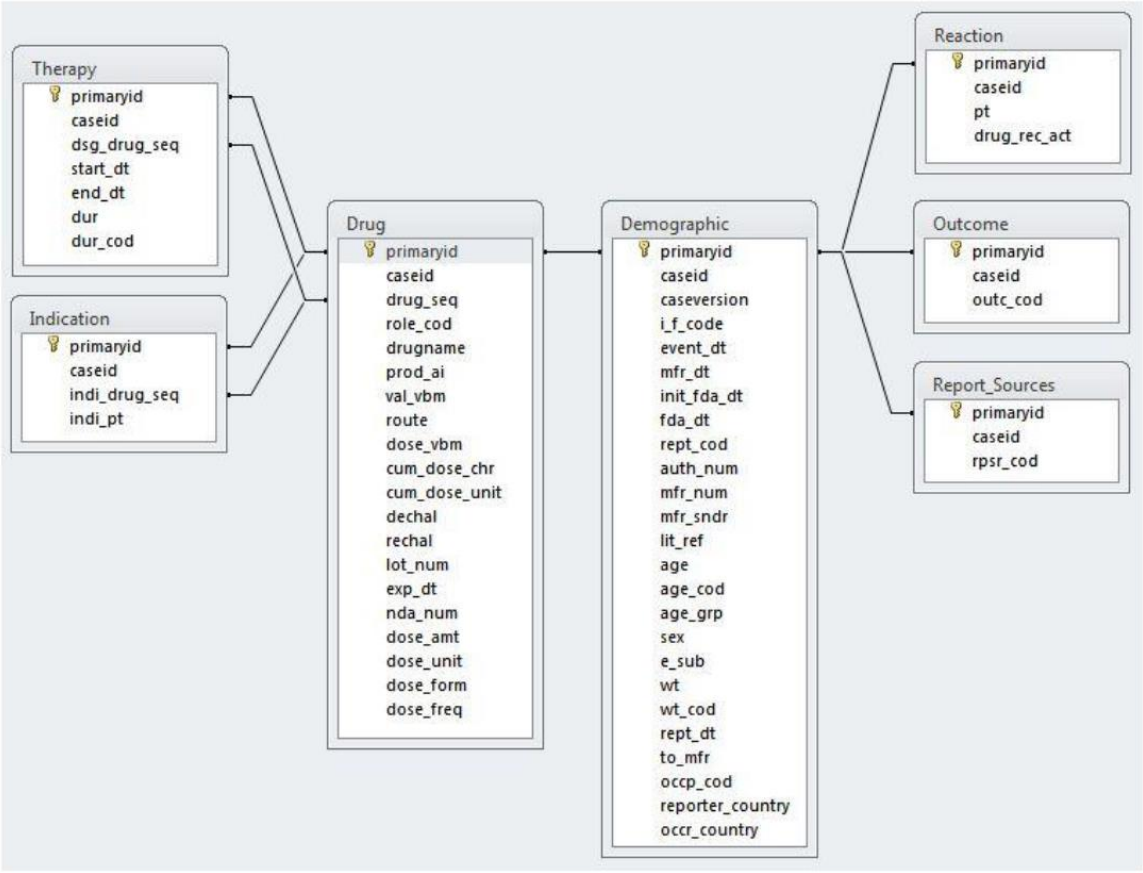
preferred terms that fall under the MedDRA High Level Term “accidental exposure to drugs”.

Description of FAERS Output

The FAERS data files can be downloaded in ASCII or XML formats. For the current study, the data files will be downloaded in ASCII format. The structure of the ASCII files and the relationship between the different tables is presented in Figure 5 below.

Figure 5

FAERS ASCII Data Files Structure



Sampling and Sampling Procedures

Population

The study population was not restricted to any age group, gender, or reporter type. All the data extracted from the FAERS database for the latest quarter was included in the analysis. Data was not sampled, and no sampling procedure was used.

Procedures for Recruitment, Participation, and Data Collection

The FAERS database contains adverse event reports that are reported by patients, healthcare providers, drug, and device manufacturers. Patients and healthcare providers report data voluntarily to the FAERS database through the MedWatch program (MedWatch, 2020). Drug and device manufacturers are required to have mechanisms in place to collect adverse events associated with the use of their products and report it to the FDA (FDA's Adverse Event Reporting System (FAERS), 2019). The FDA does not store or publish patient and reporter identifiers on the FAERS data. Data from the FAERS database was used for this study and no additional participants were recruited. Data in FAERS database is refreshed quarterly which could result in different results if the analysis were to be repeated in a different quarter.

Gaining Access and Permissions to FAERS

FAERS database is a publicly accessible database through the internet (FDA's Adverse Event Reporting System (FAERS), 2019). No additional permissions are required to access the data. Anyone with access to an internet browser and internet connection can search and download the data in Excel format. The latest quarterly data files from the FAERS database were used for this study.

Preparing Data for Analysis

The FDA publishes data from FAERS database on its website every quarter in ASCII and XML formats. Below steps were followed to download, clean, recode and prepare the data for analysis.

Step 1: Downloading FAERS Data

The most recent quarterly data files from the FAERS database was downloaded in ASCII format from the FDA's website (FAERs, n.d.). The downloaded ASCII files was saved on a secure folder on my OneDrive folder and a copy will be saved on my laptop.

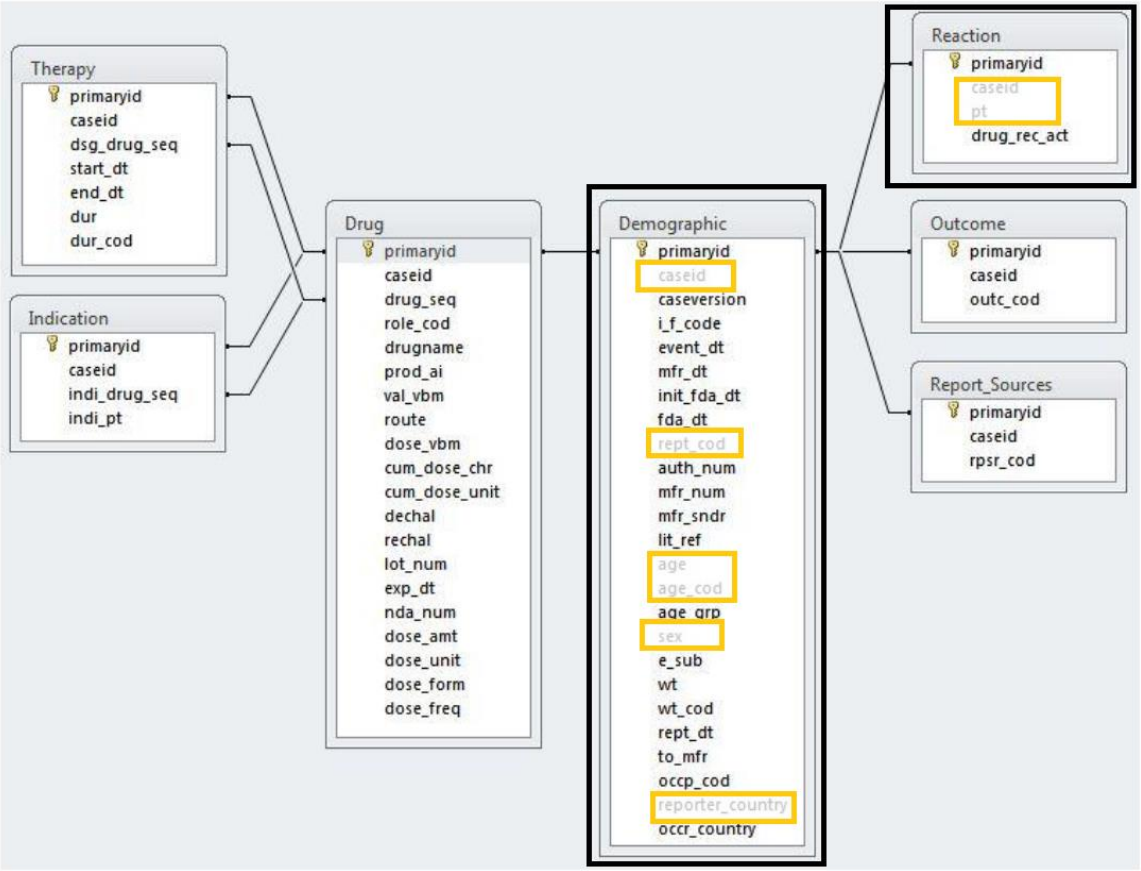
Step 2: Preparing the Data

The structure of the ASCII files along with their relationships is illustrated in Figure 9 below. Demographics table - DEMOyyQq.TXT contains patient demographic and administrative information, a single record for each event report. "yy" in the file name is replaced by the 2-digit year and "Qq" is replaced by the quarter for the download – 21Q2 for instance for 2021 quarter 2. REACyyQq.TXT contains all MedDRA terms coded for the adverse event (1 or more). For the purposes of this study, data from "demographic" table and "reaction" tables was used. Data from other tables were not relevant and was not used. Only the fields highlighted in Figure 6 were used for this study. Due to the high volume of data (> 400,000 records), Microsoft Access was used to prepare the data. A new Microsoft Access database was created and data from the DEMOyyQq.TXT ASCII file was imported into a table in the access database. Data from REACyyQq.TXT ASCII file was imported into another table in the access database. Each .TXT file also contains a table with "column name," "total count," and "missing

count" to show the number of records in each TXT file. The ASCII extract also contains a file named "ASC_NTS.pdf" which contains the details on organization and contents of each of the ASCII data files. This file describes the column names present in each ASCII file, their description, decodes for coded values and the entity relationship diagram (Figure 5).

Figure 6

Fields That Were Used From the FAERS Download



The following code (Table 2) was added to the Access database to facilitate calculations and coding of fields.

Table 2

Microsoft Access Module for Calculating and Coding Fields

Function	Purpose	Code
IsAccidentalExp	Return if accidental exposure was reported in a given case	Public Function IsAccidentalExp (strCaseID As String) As Integer On Error GoTo Err_Handler ‘Purpose: return if accidental exposure to drugs was reported for a given case id. ‘Return:1 if accidental exposure to drug is found; 0 if not found ‘Arguments: strCaseID = adverse event case id. Dim rs As DAO.Recordset Dim strSql As String Dim strOut As Integer strSql = “SELECT pt FROM REAC21Q1 where primaryid=“ & strCaseID & “ ORDER BY pt” Set rs = DBEngine(0)(0).OpenRecordset(strSql, dbOpenDynaset) strOut = 0 ‘ Default zero ‘Loop through the matching records Do While Not rs.EOF

Function	Purpose	Code

		If Not IsNull(rs(0)) And (rs(0) = “Accidental exposure to product” or rs(0) = “ Accidental device ingestion “ or rs(0) = “accidental exposure to product by child” or rs(0) = “accidental exposure to product packaging” or rs(0) = “accidental exposure to product packaging by child”) Then
		strOut = 1
		End If
		rs.MoveNext
		Loop
		rs.Close
		IsAccidentalExp = strOut
		Exit_Handler:
		‘Clean up
		Set rsMV = Nothing
		Set rs = Nothing
		Exit Function
		Err_Handler:
		MsgBox “Error “ & Err.Number & “: “ & Err.Description, vbExclamation, “IsAccidentalExp()”
		Resume Exit_Handler

Function	Purpose	Code
		End Function
AgeInYears	Return age in years	Public Function AgeInYears(iAge As Variant, strAgeUnit As Variant) As String On Error GoTo Err_Handler ‘Purpose: return age in years for a given age and age unit. ‘Return: age in years ‘Arguments: iAge (numeric portion of age) and StrAgeUnit (age unit code) If IsNull(iAge) Then intAgeInYears = ““ ElseIf strAgeUnit = “YR” Then intAgeInYears = iAge ElseIf strAgeUnit = “DY” Then intAgeInYears = Round(iAge / 365) ElseIf strAgeUnit = “DEC” Then intAgeInYears = iAge * 10 ElseIf strAgeUnit = “HR” Then intAgeInYears = Round(iAge / (365 * 24)) ElseIf strAgeUnit = “MON” Then intAgeInYears = Round(iAge / 12)

Function	Purpose	Code
		ElseIf strAgeUnit = “WK” Then intAgeInYears = Round(iAge / 52) End If AgeInYears = intAgeInYears Exit_Handler: ‘Clean up Exit Function Err_Handler: AgeInYears = “ERR :” & Err.Number Resume Exit_Handler End Function
AgeGroup	Return age group	Public Function AgeGroup(iAge As Variant, strAgeUnit As Variant) As String On Error GoTo Err_Handler ‘Purpose: return age group for a given age and age unit. ‘Return: 1 if age in years is >= 65 ; 0 if age is <65 ‘Arguments: iAge (numeric portion of age), strAgeUnit (age unit code). Dim strAgeInYrs As String strAgeInYrs = AgeInYears(iAge, strAgeUnit)

Function	Purpose	Code
		If strAgeInYrs = ““ Then
		AgeGroup = ““
		ElseIf (Int(strAgeInYrs) >= 65) Then
		AgeGroup = “1” ‘ Older
		ElseIf (Int(strAgeInYrs) < 65) Then
		AgeGroup = “0” ‘ younger than 65
		End If
		Exit_Handler:
		‘Clean up
		Exit Function
		Err_Handler:
		MsgBox “Error “ & Err.Number & “: “ &
		Err.Description, vbExclamation, “AgeGroup()”
		Resume Exit_Handler
		End Function
getGender	Return gender code	Public Function getGender(strGender As Variant) As Integer
		On Error GoTo Err_Handler
		If strGender = ““ Then
		getGender = 3
		ElseIf strGender = “M” Then

Function	Purpose	Code
		getGender = 0 ElseIf strGender = “F” Then getGender = 1 ElseIf strGender = “UNK” Then getGender = 3 End If Exit_Handler: ‘Clean up Exit Function Err_Handler: MsgBox “Error “ & Err.Number & “: “ & Err.Description, vbExclamation, “GetGender()” Resume Exit_Handler End Function
getReporterType	Return reporter type code	Public Function getReporterType (strRepCode As Variant) As Integer On Error GoTo Err_Handler If strRepCode = “MD” Then getReporterType = 1 ElseIf strRepCode = “CN” Then getReporterType = 2

Function	Purpose	Code
		ElseIf strRepCode = “HP” Then
		getReporterType = 3
		ElseIf strRepCode = “LW” Then
		getReporterType = 4
		ElseIf strRepCode = “PH” Then
		getReporterType = 5
		ElseIf strRepCode = ““ Then
		getReporterType = 6
		End If
		Exit_Handler:
		‘Clean up
		Exit Function
		Err_Handler:
		MsgBox “Error “ & Err.Number & “: “ &
		Err.Description, vbExclamation,
		“GetReporterType()”
		Resume Exit_Handler
		End Function

Step 3: Retrieve Data Relevant for This Study

A new query was created in the Access database with the below SQL script (Table 3) to retrieve only the relevant columns and rows for this study. The output of the above query was exported into an Excel file which was used by SPSS as source data for data analysis.

Table 3

SQL Code to Retrieve Relevant Columns and Rows for This Study

Purpose	SQL code
Retrieve relevant columns and records from demographics and reactions table	SELECT DEMO21Q1.primaryid, getGender(DEMO21Q1.sex) AS gender, IsAccidentalExp(Primaryid) AS IsAccidentalExposure, getReporterType(DEMO21Q1.occp_cod) as Reporter_code, occr_country, ageinyears (DEMO21Q1.age , DEMO21Q1.age_cod) AS AgeInYears, AgeGroup (DEMO21Q1.age,DEMO21Q1.age_cod) AS Age_Group FROM DEMO21Q1

Data Cleaning and Handling Missing Data

Due to the spontaneous nature of adverse event reporting into the FAERS database, the patient demographics data such as age, gender is sometimes missing (*FDA's Adverse Event Reporting System (FAERS)*, 2019). Records with missing age information

were excluded from the analysis. It is possible that the same report is reported by several parties (patient, healthcare provider, and drug manufacture) which could lead to duplicate records for the same adverse events for the same patient in the database (*FDA's Adverse Event Reporting System (FAERS)*, 2019). It was not possible to identify duplicates in the excel output due to lack of any patient identifiers or reporter information. The data was screened for outliers in 'Age' to avoid biased results. Records with age '0' were excluded as an outlier.

Calculating Age in Years

The 'Age' variable contains a numeric value, and the variable age code contains a two or three letter descriptor for age unit. The table below (Table 4) describes the various age codes used, their meaning and the formula used for calculating age in years.

Table 4

Age Unit Codes and Formula for Calculating Age in Years

Age code	Meaning	Calculation for age in years
HR	Hours old	(age) / (365 *24)
DAY	Days old	(age) / 365
Week	Weeks old	(age) / 52
MTH	Months old	(age) / 12
YR	Years old	age * 1
DEC	Decades old	age * 10

Power Analysis

A study with higher power is an ideal one and has the potential to identify the differences between the groups, if the difference exists and if the difference does not exist, the researcher can confidently conclude that there is no difference between the groups (Suresh & Chandrashekara, 2012). Sample size calculation is essential for the design of any study (Suresh & Chandrashekara, 2012). Increase in sample size increases the power of the study (Suresh & Chandrashekara, 2012). Minimum power required for a study is 80 % (Suresh & Chandrashekara, 2012). To calculate the sample size for this study, G*Power version 3.1.9.4 software was used. Sample size was calculated for Z test (logistic regression) based on the parameters below (Table 5). The minimum sample size was determined as 7202 with an actual power of 0.95 (Figure 6 and 7). The priori power analysis was recalculated once the final study data is downloaded and cleaned.

Table 5

*Parameters Entered in G*Power for Sample Size Calculation and Output*

	Parameter	Value	
Input:	Tail(s)	=	Two
	Odds ratio	=	1.2
	Pr(Y=1|X=1) H0	=	0.3
	α err prob	=	0.05
	Power (1-β err prob)	=	0.95
	R^2 other X	=	0
	X distribution	=	Binomial

	X parm μ	=	0
	X parm σ	=	1
Output:	Critical z	=	1.9599640
	Total sample size	=	7202
	Actual power	=	0.9500248

Figure 7

*Output From G*Power for Sample Size Calculation*

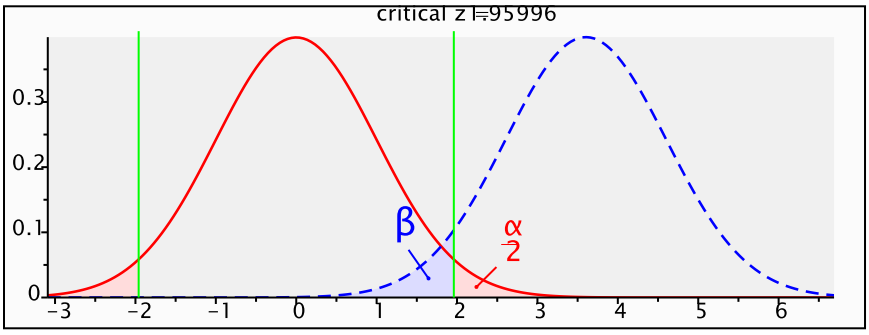
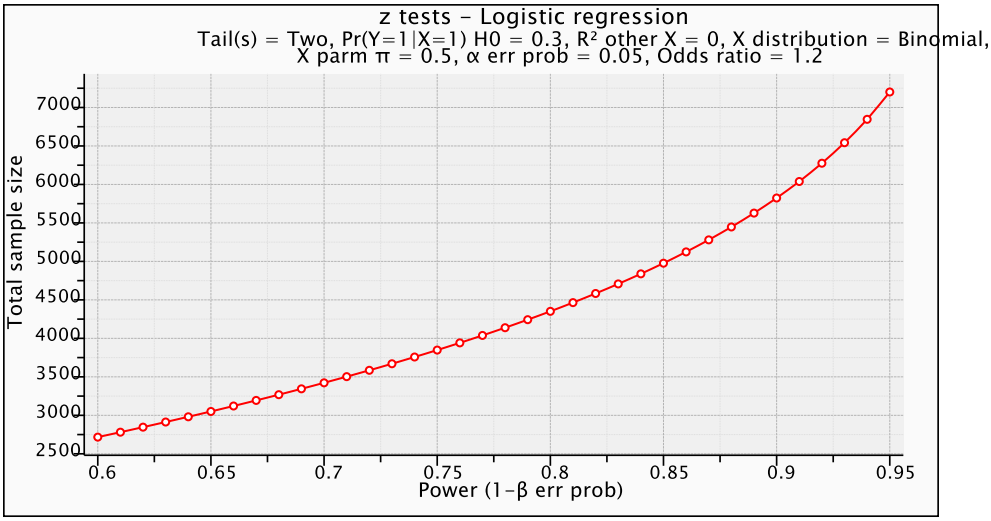


Figure 8

*Output From G*Power for Sample Size Calculation (X-Y Plot)*



Data Analysis Plan

IBM's SPSS Version 27 was used for all statistical analyses that are required for this study. Descriptive and inferential statistics were used to characterize the data extracted from FAERS and to test the hypotheses. SPSS was chosen due to its flexibility and superior functionality in performing statistical analysis.

FAERS database could contain incomplete data due to the spontaneous and voluntary nature of reporting. The same report could be made by different parties (consumer, manufacturer, and healthcare provider) resulting in duplicate reports. The reports contain at least one adverse event, at least one suspect drug or device, a reporter, and an identifiable patient. Details such as age and gender of the reporter and patient

could be missing, and reporter type could be unknown. Due to typographic errors, records could contain incorrect data. For the purposes of this study, no data corrections were made. Records with missing age were excluded. To minimize biased reports, outliers were removed.

Research Questions and Hypotheses

RQ1: Is there a statistically significant difference in accidental drug exposures between older adults and other age groups?

H_{01}: There is no statistically significant difference in accidental drug exposures between older adults and other age groups.

H_{a1}: There is a statistically significant difference in accidental drug exposures between older adults and other age groups.

RQ2: What is the association between reporter type and accidental drug exposures in older adults?

H_{02}: There is no association between reporter type and accidental drug exposures in older adults.

H_{a2}: There is an association between reporter type and accidental drug exposures in older adults.

RQ3: What is the association between gender and accidental drug exposures in older adults?

H_{03}: There is no association between gender and accidental drug exposures in older adults.

H_{a3}: There is an association between gender and accidental drug exposures in older adults.

RQ4: To what extent do reporter type, age group, and gender predict accidental exposure to drugs?

H_{04}: Reporter type, age group, and gender are not statistically significant predictors of accidental exposure to drugs.

H_{a4}: Reporter type, age group, and gender are statistically significant predictors of accidental exposure to drugs.

Descriptive Analysis

Descriptive statistics aid the researcher to examine the sample data without the need for inferring the larger population (Descriptive Statistics – APA Dictionary of Psychology, n.d.). Descriptive statistics such as mean, median, mode, along with range and standard deviation help the researcher to understand how widespread the scores are within the sample data and include charts and graphs such as frequency distribution and histogram (Descriptive Statistics – APA Dictionary of Psychology, n.d.). Descriptive analysis was performed using SPSS version 27 to examine the characteristics of the study population. Frequency statistics of “age in years” were calculated including Mean, Mode, Median, and standard deviation. Frequency statistics for gender, age-group, and reporter type were also calculated. Statistics table for Age in years (Table 6) provides information on the range of age in years from the reports. This helps to understand if the data is skewed and if it represents different age groups evenly. Frequency tables for age group, gender, and reporter type (Table 7,8,9) provide insights on distribution of data.

Table 6

Illustration of Statistics: Age in Years

		Age in years
N	Valid	X
	Missing	X
Mean		X
Median		X
Mode		X
Std. Deviation		X
Std. Error of Skewness		X
Range		X
Skewness		X

Table 7

Illustration of Frequency: Age Group

	Age group	
	N	%
Older	X	X%
Under 65	X	X%

Table 8

Illustration of Frequency: Reporter Type

Reporter type		
	N	%
Reporter type	X	X%

Table 9

Illustration of Frequency: Gender

Gender		
	N	%
Female	X	X%
Male	X	X%
Not Specified	X	X%

Inferential Analysis

Although descriptive analysis is used to understand the characteristics of the sample data, it cannot be used to make any generalizations (Taylor, 2020). Through inferential analysis, researchers can study the relationship between variables in a sample data and generalize the findings in larger populations (Taylor, 2020). Inferring a conclusion on a population based on logical reasoning on smaller sample data is known as inferential analysis (*Inferential Statistics – APA Dictionary of Psychology*, n.d.). Statistical hypothesis testing is an example of inferential analysis (*Inferential Statistics – APA Dictionary of Psychology*, n.d.). Since it is not practically possible to study the entire population, researchers use a smaller representative sample data to study the population and test hypothesis (Taylor, 2020). Techniques such as linear regression

analysis, ANOVA, logistic regression analysis, correlation analysis, are used by researchers to study the relationship between variables and create inferential statistics (Taylor, 2020). Test of significance such as chi-square, t-tests are used by researchers to determine whether the results are generalizable to the larger population (Taylor, 2020).

Bivariate Analysis

In this study, binary logistic regression analysis was used to understand the relationship between the variables and to test the hypothesis. Logistic regression was used to study the association between a categorical or continuous independent variable with a dichotomous dependent variable (Leon, 1998). The dependent variable "Accidental exposure to drugs" contained a value 1 or 0 to indicate the presence or absence respectively of accidental exposure to drugs in the record. The independent variables age-group, reporter type, gender were categorical variables. Assumptions such as linearity of the continuous variable, independence of errors, absence of multicollinearity, and absence of outliers must be met for logistic regression analysis (Stoltzfus, 2011).

Testing Assumptions

To be able to conduct a binary logistic regression analysis, the dependent variable should be a dichotomous variable with 2 values indicating the presence or absence of the property. In this study, the variable Accidental drug exposure has a value 1 or 0 indicating the presence of absence of accidental drug exposure in the report. The independent variables (age group, gender, and reporter type) were nominal (Table 8). The

dependent variable and the nominal independent variables were checked to ensure they are mutually exclusive and exhaustive.

Based on the above assumptions, a bivariate logistic regression was a right test to analyze the data.

Interpreting the Results

The data was checked for outliers and if found, the relevant records were removed from the data and regression analysis was re-run. Once the assumptions and outliers are addressed, regression analysis output were examined for statistical significance of the model. The Cox & Snell R Square and Nagelkerke R Square values was used to understand how the model explains the variation in the dependent variable. After model fit and variance explanation, the outcome was examined to check the estimated probability of occurrence of accidental exposure to drugs (dependent variable). If the probability is less than 0.5, we can classify that accidental exposure to drugs does not occur. Finally, the contribution of each independent variable to the model along with its statistical significance was examined using odd ratio, including confidence intervals of each independent variable.

Logistic Regression

Logistic regression was used in this study to examine if some of the independent variables (age, age group and gender) predict the dependent variable (accidental exposure to drugs). Logistic regression was also used to determine the overall fit of the model and understand the contribution of each independent variable to variance.

Testing Assumptions

Assumptions such as independence of errors, presence of linear relationship between the predictor variables and the dependent variable, presence of homoscedasticity of residuals, lack of multicollinearity, lack of significant outliers, were tested for conducting multiple logistic regression. The independent variables (age group, gender, and reporter type) were checked to ensure they are nominal along with being mutually exclusive and exhaustive.

Interpreting Results of Logistic Regression

Nagelkerke R square values of close to 1 describe how the addition of the independent variables explain variability in the dependent variable. The significance of the model was obtained by observing the significance column in the Omnibus Tests for model coefficients summary table. A significance value of less than .05 indicates a statistically significant result. The Variables in the Equation table was examined for independent variables that have a significance (Sig.) value of less than .05. The independent variables with a significance value of less than .05 are stated to be statistically significant predictors of the dependent variable. The extent of prediction is found by examining the value in Exp (B) column.

Table 10

Data Analysis Matrix

Variable	Type of variable	Research question tested	Statistical test type
Accidental exposure to drugs	Dependent variable (dichotomous)	RQ1, RQ2, RQ3, RQ4	Logistic regression; Chi-Square test
Gender	Independent variable (nominal)	RQ3, RQ4	Logistic regression; Chi-Square test
Reporter type	Independent variable (nominal)	RQ2, RQ4	Logistic regression; Chi-Square test
Age group	Independent variable (nominal)	RQ1, RQ4	Logistic regression; Chi-Square test

Threats to Internal Validity

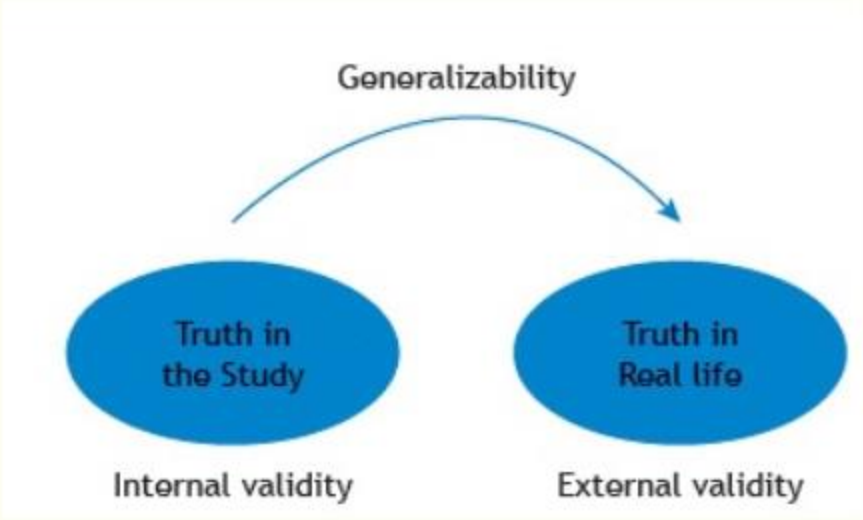
Researchers need to identify potential threats to validity of the study design and make sure the threats are eliminated or minimized (Creswell & Creswell, 2018). If a manipulated variable of interest affects an outcome and not some other factor, questions regarding validity of the research could be raised (Creswell & Creswell, 2018). In a quantitative study, validity is measured as the extent to which a concept is accurately measured (Heale & Twycross, 2015). Validity of a research refers to how well the results of the study can be representative of the characteristics of the general population outside of the study (Patino & Ferreira, 2018). Internal validity threat arises when the

experimental procedures, treatments, or participant experiences from the study are different from the population outside of the study (Creswell & Creswell, 2018). The extent to which the observed results in the study are representative of the results in population outside of the study is known as internal validity (Patino & Ferreira, 2018). Factors such as sampling methods, errors in measurements can threaten the internal validity of the study and researchers should address them (Patino & Ferreira, 2018). It is essential to establish internal validity to show that the results of the study do not deviate from reality and conclusions drawn are valid (Patino & Ferreira, 2018).

In the current study, the data selected was based on voluntarily reported adverse event terms that are relevant for the study. Data was not further filtered for any patient demographics or product. Since data represents all age groups and all products in which potential accidental exposure to drugs have occurred it did not pose threat to the internal validity of the study. Underreporting is a known limitation of FAERS data and will be a limitation of this study (Fang et al., 2014). All relevant data that has been reported to the FAERS database which meets the search criteria were used in the analysis. Although the main purpose of FAERS database is to help the US FDA and drug manufacturers monitor the benefit-risk profile of marketed drugs, this data can be used to study medication errors and does not pose a threat to the internal validity of the study. Once the researcher establishes that the study's internal validity is not threatened, the researcher can go on to ensuring external validity of the study.

Figure 9

Internal and External Validity (Patino & Ferreira, 2018)



Threats to External Validity

External validity is threatened when the results of the current study cannot be replicated in a different setting, past or future situations (Creswell & Creswell, 2018). External validity could be threatened due to the characteristics of individuals selected to be a part of the study, the unique characteristics of the study setting, and the timing in which the study was set (Creswell & Creswell, 2018). Lack of external validity could lead to low adoption of the study results by other researchers (Patino & Ferreira, 2018).

The current study used the secondary data from FAERS database which gathers data that are voluntarily reported from patients, healthcare providers and drug manufacturers. Due to this, it is possible that the results of this study cannot be replicated in a different setting. However, all the relevant data for accidental exposure to drugs that

were reported are included in the study without sampling. This could minimize the threats to external validity.

Ethical Procedures

This study used secondary data analysis which resolves the issue of obtaining informed consent from the participants. The data used for this study is from the FAERS database, which is a free and publicly accessible database. The FAERS database output is already de-identified and only contains patient's demographics data such as the patient's age, gender, and weight. This data is not sufficient to uniquely identify a person and does not pose an ethical issue. The IRB still will need to confirm that the data is void of personally identifiable information (TRIPATHY, 2013). Before performing any analysis of data, I obtained Walden university's IRB approval to ensure alignment with the IRB (IRB approval number 11-02-21-0971570). Permission to use secondary data that is free and publicly accessible is implied (TRIPATHY, 2013).

Researcher should ensure the data is kept in a secure location, prevent unauthorized access and store the data only for a limited amount of time (TRIPATHY, 2013). I extracted the FAERS data for this study and stored it on my Microsoft OneDrive folder and will not share with anyone except members of the dissertation committee. A copy of the data was also be saved on my desktop computer which is secured by a password known only to me. Once the data is no longer required (after 5 years), the data will be deleted from the OneDrive and desktop computer.

Summary

This study used secondary data analysis using data from the FAERS database to examine the association between accidental exposure to drugs and reporter type, age group, and gender in older population. FAERS database is a free publicly accessible database which contains reports of adverse events and medication errors from all over the World. The most recent quarterly data files from the FAERS database were downloaded for this study. Microsoft Access was used for coding, cleaning, and retrieving only relevant data from the FAERS data files for this study. There are no ethical considerations for the FAERS data as the output does not contain any patient identifiers. Data was cleaned to exclude records with missing data, and outliers. Additional columns were added to facilitate analysis. Upon receiving Walden IRB approval, data analysis was conducted using SPSS version 27. Binary Logistic regression was conducted to examine the dependent and independent variables and answer the research questions. Logistic regression was conducted to predict accidental exposure to drugs based on patient gender, age group, and reporter type.

Chapter 4 includes a description of the results and findings of the data collected and analysis performed for the study.

Chapter 4

The purpose of this study was to examine the factors associated with accidental exposure to drugs in older people. The study was a quantitative correlational study using secondary data analysis of the FAERS. The association between patient age group, gender, and reporter type to accidental exposure to drugs was examined in this study. Accidental exposure to drugs was the dependent variable while patient age group, patient gender, and reporter type were the independent variables. The study was conducted to fill the gap in the literature regarding understanding of the factors associated with accidental exposure to drugs in the older population. Research showed that older adults are at higher risk of medication errors, specifically accidental exposure to drugs (Fialová & Onder, 2009). According to logistic regression analysis on the data from FAERS, age group, gender, and reporter type were found to be statistically significant predictors of accidental exposure to drugs ($p < .05$). Chapter 4 provides an overview of data collection, results of the analysis, and a summary of the findings.

Data Collection

The latest quarterly ASCII files from the FEARS database were downloaded from the FDA's website. The latest available quarterly files were posted on the FAERS website in August 2021 for second quarter 2021 (April 2021 to June 2021). The August quarterly download contained 479,945 records of adverse events. After filtering for records with missing age, I determined there were 240,523 records. After initial analysis, I found outliers in age (800 records with age 0 and five records with age > 105). Because the number of records with age 0 was a small percentage (0.16%) of the total records, I

did not impute the value with the mean of age. Instead, these records were excluded. After excluding these records, I determined the remaining 239,716 records would be used for the analysis.

Overview of Results

Setting Up Data for Analysis

Data from the ASCII files were exported to Microsoft Access, and the SQL query was executed to extract the data for analysis. The output of the SQL query was exported to an Excel file, which was then used as the source for SPSS. In the variable gender, male was coded as O and female was coded as 1. For the variable accidental exposure to drugs, no accidental exposure to drugs was coded as 0 and accidental exposure to drugs was coded as 1. Age group under 65 years was coded as 0 and 65 years or older was coded as 1. Reporter type non-health-care professional was coded as 0 and health care professional was coded as 1.

Descriptive analysis was conducted using frequency tables for the relevant variables to understand the characteristics of the study population. Crosstabs and a chi-square test were used to perform bivariate analysis. The Phi Cramer's V measure of association was used to assess the strength of the relationship between the outcome variable and independent variables.

Binary logistic regression was conducted to explore the correlation of the dependent variable to the independent variables. Logistic regression was performed by selecting the variable accidental exposure to drugs as the dependent variable and variables age group, gender, and reporter type as covariates. Age group was defined as a

categorical variable with the last category as the reference category. The output of binary logistic regression included the omnibus tests for model coefficients, model summary, and variables in the equation tables.

Descriptive Analysis

SPSS Version 27.0 was used to perform the statistical analysis for this study. Table 11 presents the descriptive analysis of the study data. Of the 239,716 records, 62% were for patients under 65 years of age and 38% were for patients 65 years and older. Findings indicated that 42.5% of the reports were from male patients and 57.5% were from female patients, 48.3% of the adverse events were reported by health care professionals (medical doctors, pharmacists, other health care professionals), and 51.7% were reported by non-health-care professionals (consumers, lawyers). Of the total number of reports for Q2 2021, 99% of the adverse events had no presence of accidental exposure to drugs and 1% had presence of accidental exposure to drugs. The mean age of the patients was 55.61 years with a standard deviation of 19.9 (see Figure 10).

The difference between exposure groups by the variables is shown in Table 12. Of the 238,098 reports with no accidental exposure to drugs, 42.6% were from males while 57.4% were from females. Of the 1,618 reports of accidental exposure to drugs, 33.3% were from males and 66.7% were from females. Non-health-care professionals reported 48.4% of reports with no accidental exposure to drugs while 51.6% of reports were reported by health care professionals. Non-health-care professionals reported 36% of reports with accidental exposure to drugs while 64% were reported by health care professionals. Of the 238,098 reports with no accidental exposure to drugs, 62% were for

patients under 65 years of age while 38% were for patients 65 years or older. Of the 1,618 reports with accidental exposure to drugs, 65% were for patients under 65 years of age while 35% were for patients 65 years or older.

Table 11

*Descriptive Characteristics of Study Sample (*N *= 239,718)*

	N	%
Gender		
Male	101,902	42.5%
Female	137,813	57.5%
Unknown	3	0.0%
Age group		
Under 65 years	148,715	62.0%
65 years or older	91,003	38.0%
Reporter type		
Non-health-care professional	115,826	48.3%
Health care professional	123,892	51.7%
Reporter occupation		
Medical doctor	49,983	20.9%
Consumer	95,207	39.7%
Other health care professional	57,248	23.9%
Lawyer	15,756	6.6%
Pharmacist	16,661	7.0%
Unknown	4,863	2.0%
Accidental exposure to drugs		
No	238,098	99%
Yes	1,618	1%

Table 12

Difference Between Exposure Groups

		Accidental exposure to drugs		
		No	Yes	Total
		N = 238,098	*N = 1,618*	*N = 239,716*
Gender	Male	101,362 (42.6%)	539 (33.3%)	101,901 (42.5%)
	Female	136,733 (57.4%)	1,079 (66.7%)	137,812 (57.5%)
	Unknown	3 (0.0%)	0 (0.0%)	3 (0.0%)
Reporter type	Non-health care professional	115,244 (48.4%)	582 (36.0%)	115,826 (48.3%)
	Health care professional	122,854 (51.6%)	1,036 (64.0%)	123,890 (51.7%)
Age group	Under 65 years	147,663 (62.0%)	1,051 (65.0%)	148,714 (62.0%)
	65 years or older	90,435 (38.0%)	567 (35.0%)	91,002 (38.0%)

Chi-Square Analysis

A chi-square test for association was conducted between age group and accidental exposure to drugs. All expected cell frequencies were greater than five. There was a statistically significant association between age group and accidental exposure to drugs, $\chi 2(1) = 5.89$, $p < 0.05$, as shown in Table 13. There was a very weak association between age group and accidental exposure to drugs, $\varphi = 0.005$, $p < 0.05$, as shown in Table 14.

A chi-square test for association was conducted between reporter type and accidental exposure to drugs. All expected cell frequencies were greater than five. There

was a statistically significant association between reporter type and accidental exposure to drugs, $\chi 2(1) = 99.45$, $p < 0.001$, as shown in Table 15. There was a very weak association between reporter type and accidental exposure to drugs, $\varphi = 0.02$, $p < 0.001$, as shown in Table 16.

A chi-square test for association was conducted between gender and accidental exposure to drugs. All expected cell frequencies were greater than five. There was a statistically significant association between gender and accidental exposure to drugs, $\chi 2(2) = 56.40$, $p < 0.001$, as shown in Table 17. There was a very weak association between gender and accidental exposure to drugs, $\varphi = 0.015$, $p < 0.001$, as shown in Table 18.

Table 13

*Chi-Square Test: Age Group * Accidental Exposure to Drugs*

	Value	*df*	Asymptotic significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson chi-square	5.894[a]	1	.015		
Continuity correction[b]	5.770	1	.016		
Likelihood ratio	5.957	1	.015		
Fisher's exact test				.016	.008
Linear-by-linear association	5.894	1	.015		
N of valid cases	239716				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 614.23.

b. Computed only for a 2x2 table

Table 14

*Symmetric Measures: Age Group * Accidental Exposure to Drugs*

		Value	Approximate significance
Nominal by nominal	Phi	-.005	.015
	Cramer's V	.005	.015
N of valid cases		239716	

Table 15

*Chi-Square Tests: Reporter Type * Accidental Exposure to Drugs*

	Value	*df*	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson chi-square	99.459[a]	1	.000		
Continuity correction[b]	98.961	1	.000		
Likelihood ratio	101.063	1	.000		
Fisher's exact test				.000	.000
Linear-by-linear association	99.458	1	.000		
N of valid cases	239716				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 781.79.

b. Computed only for a 2x2 table

Table 16

Symmetric Measures: Reporter Type Accidental Exposure to Drugs*

		Value	Approximate significance
Nominal by nominal	Phi	.020	.000
	Cramer's V	.020	.000
N of valid cases		239716	

Table 17

Chi-Square Test: Gender Accidental Exposure to Drugs*

	Value	*df*	Asymptotic significance (2-sided)
Pearson chi-square	56.400[a]	2	.000
Likelihood ratio	57.854	2	.000
Linear-by-linear association	56.325	1	.000
N of valid cases	239716		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is .02.

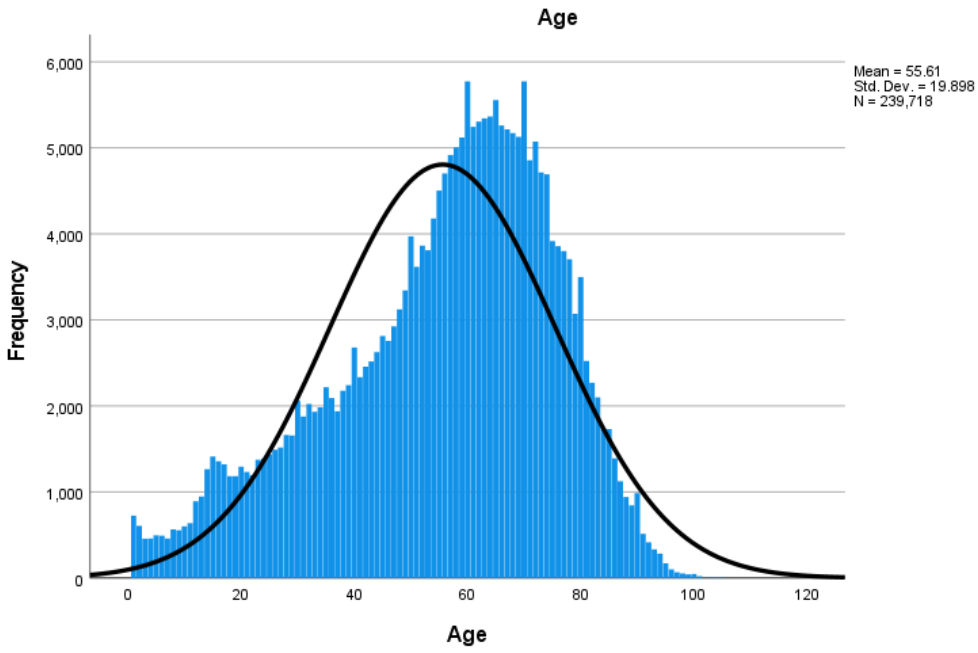
Table 18

Symmetric Measures: Gender Accidental Exposure to Drugs*

		Value	Approximate significance
Nominal by nominal	Phi	.015	.000
	Cramer's V	.015	.000
N of valid cases		239716	

Figure 10

Frequency Chart for Age



Inferential Analysis

Testing for Assumptions

The dependent variable for this study (accidental drug exposure) was checked to ensure it had a value of 1 or 0 indicating the presence of absence of accidental drug exposure in the report. The independent variables (age group, gender, and reporter type) were nominal. The nominal independent variables were checked to ensure they were mutually exclusive and exhaustive. Once the assumptions were met, the results were interpreted.

A binomial logistic regression was performed to ascertain the effects of gender, age group, and reporter type on the likelihood of accidental exposure to drugs. The logistic regression model was statistically significant, $\chi 2(3) = 170.20$, $p < .001$. The

model explained 9.0% (Nagelkerke R2) of the variance in reports of accidental exposure to drugs. All three predictor variables were statistically significant: gender, age group, reporter type, as shown in Table 21. Females had 1.5 times higher odds of reporting accidental exposure to drugs than males. Adults 65 years and older had 1.13 times higher odds of reporting accidental exposure to drugs compared to patients under 65 years. Health care professionals were 1.7 times more likely to report accidental exposure to drugs compared to non-health-care professionals.

Research Questions and Results of Analysis

Research Question 1 was the following: Is there a statistically significant difference in accidental drug exposures between older adults and other age groups? The Pearson chi-square test value, as shown in Table 13, showed a statistically significant association between age group and accidental exposure to drugs ($\chi2(1) = 5.89$, $p < .05$). I rejected the null hypothesis because there was a statistically significant association between age group and accidental exposure to drugs.

Research Question 2 was the following: What is the association between reporter type and accidental drug exposures in older adults? The Pearson chi-square test value, as shown in Table 15, showed a statistically significant association between age group and accidental exposure to drugs ($\chi2(1) = 99.45$, $p < .001$). I rejected the null hypothesis because there was a statistically significant association between reporter type and accidental exposure to drugs.

Research Question 3 was the following: What is the association between gender and accidental drug exposures in older adults? The Pearson chi-square test value as

shown in Table 17 showed a statistically significant association between gender and accidental exposure to drugs ($\chi 2(2) = 56.4$, $p < .001$). I rejected the null hypothesis since there was a statistically significant association between gender and accidental exposure to drugs.

Research Question 4 was the following: To what extent do reporter type, age group, and gender predict accidental exposure to drugs? Based on the output of the logistic regression analysis, the Exp (*B*) value (Table 21) for reporter type is 1.702 ($p < .001$; 95% *CI* 1.537–1.885) indicating that for every unit increase of reporter type (from non-health-care professional to health care professional), accidental exposure to drugs increased by 1.702 times. Reports of accidental exposure to drugs from health care professionals (such as medical doctors, pharmacists) are 1.702 times higher than reports from non-health-care professionals. The Exp (*B*) value for Age-group (Table 21) is 1.130 ($p < .05$; 95 *CI* 1.020–1.252) indicating that for every unit increase in age group (under 65 years to 65 and older), accidental exposure to drugs increased by 1.13 times. This shows that adults 65 years and older are 1.13 times more likely to experience accidental exposure to drugs compared to those younger than 65 years of age. The Exp (*B*) value (Table 21) for gender is 1.502 ($p < .001$; 95% *CI* 1.353–1.666) indicating that for every unit increase in gender (male to female) accidental exposure to drugs increased by 1.502 times. In other words, females are 1.5 times more likely to have accidental drug exposures compared to males. I rejected the null hypothesis as logistic regression analysis of the data showed that reporter type, age group, and gender were statistically significant predictors of accidental exposure to drugs.

Table 19

Omnibus Tests for Model Coefficients

		Chi-square	*df*	Sig.
Step 1	Step	170.207	3	.000
	Block	170.207	3	.000
	Model	170.207	3	.000

Table 20

Model Summary for Logistic Regression

Step	-2 Log likelihood	Cox & Snell R square	Nagelkerke R square
1	19229.230[a]	.001	.009

a. Estimation terminated at iteration number 8 because parameter estimates changed by less than .001.

Table 21

Logistic Regression Analysis: Variables in the Equation

						95% C.I. for EXP(B)	
		B	*df*	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Gender	.407	1	.000	1.502	1.353	1.666
	Age group (1)	.122	1	.020	1.130	1.020	1.252
	Reporter type	.532	1	.000	1.702	1.537	1.885
	Constant	-5.629	1	.000	.004		

a. Variable(s) entered on step 1: Gender, Age group, Reporter Type.

Summary

In summary, the study confirms with available research that adults over the age of 65 are at higher risk of accidental exposure to drugs compared to people younger than 65 years of age. In 2011 an estimated 645,000 emergency room visits by older adults in the

U.S. was as a result of accidental exposure to drugs (Mattson et al., 2017). Older adults are more likely to experience medication errors compared to other age groups due to their reliance on medications caused by age related health issues (Fialová & Onder, 2009). The current study showed that gender, reporter type, and age group are statistically significant predictors of accidental exposure to drugs. Understanding these factors helps in implementing measures to minimize accidental exposure to drugs.

Chapter 5 provides more details on the findings of the current study and highlight the limitations of the study along with providing further recommendations on future research and implications on potential social change.

Chapter 5

The purpose of this study was to examine the factors associated with accidental exposure to drugs in the older population (adults over the age of 65 years). Existing research showed that older adults are at higher risk of medication errors compared to other age groups (Fialová & Onder, 2009). There was a paucity of research on factors associated with accidental exposure to drugs in older people. Medication errors continue to be a leading cause of fatalities in the United States and exert undue stress on the health care system (Falconer et al., 2019). Besides reducing the burden on the health care system, minimizing medication errors also reduces hospitalizations and deaths, improves positive health outcomes, and improves patient trust in the health care system. The current study confirms that adults over the age of 65 are more likely to experience accidental exposure to drugs compared to other age groups. Factors such as patients' gender, age group, and reporter type were found to be statistically significant predictors of accidental exposure to drugs.

Interpretation of the Findings

Findings from the study showed that adults over the age of 65 were 1.130 times more likely to experience accidental exposure to drugs compared to patients younger than 65 years of age ($p < .05$; 95% CI 1.020–1.252). Females were 1.502 times more likely to experience accidental exposure to drugs compared to males ($p < .001$; 95% CI 1.353–1.666). Health care professionals were 1.702 times more likely to report accidental exposure to drugs compared to non-health-care professionals ($p < .001$; 95% CI 1.537–1.885). Beyond confirming that older adults are at higher risk of accidental exposure to

drugs, this study indicated that patient gender and reporter type were statistically significant predictors of accidental exposure to drugs. Using Bronfenbrenner's ecological model, I examined the factors contributing to accidental exposure to drugs using a multilayered approach. Patient age group and patient gender were individual characteristics at the innermost level (individual level), and reporter type was at the next level (micro level); all three variables were found to be statistically significant factors contributing to accidental exposure to drugs. The results of this study confirm existing research that older adults are at higher risk of accidental exposure to drugs, and the study expanded existing knowledge by showing that factors such as gender, reporter type, and age group are statistically significant predictors of accidental exposure to drugs.

Limitations of the Study

I conducted secondary data analysis of data from the FAERS database to answer the research questions. The FAERS database contains adverse events that are spontaneously reported by consumers, drug manufacturers, and health care professionals. Due to the spontaneous nature of reporting, there may have been significant underreporting of adverse events and there may have been concerns with the quality of data such as missing or incomplete data (see Fang et al., 2014). The FAERS database contains only reports of potential patient harm. Medication errors that do not result in patient harm are not reported to the FAERS database and were not a part of the current study. Medication errors such as near misses or prescribing errors that do not cause patient harm were not part of this study. The study was also limited to the variables that were available in the FAERS database. Other patient demographic information such as

patient race, literacy status, and drug status (prescribed versus over the counter) are important to understand in relation to medication errors but were not examined as part of this study because they were not captured in the FAERS database.

Recommendations

Despite significant research, medication errors continue to be a major public health issue. Understanding the factors contributing to medication errors may significantly improve the health outcomes of millions of patients and consumers. Further research using additional data sources (primary and secondary) may help improve understanding of the factors contributing to accidental exposure to drugs. Using additional MedDRA terms to examine the outer 2 levels of the ecological model may help to identify factors such as procedures at hospitals/clinics and policies that contribute to accidental exposure to drugs.

Implications

Medication errors are preventable errors that, if avoided, can save thousands of lives and billions of dollars in health care spending (Kohn et al., 2000). The results of this study enhanced the understanding of factors that contribute to accidental exposure to drugs. Through improved understanding of these factors, measures can be put in place to address concerns and prevent medication errors. The results of this study indicated that adults over the age of 65 are at higher risk of accidental exposure to drugs. The study also showed that females are at higher risk compared to males. Drug manufacturers should consider these factors in designing the packaging, marketing, and delivery of medicines to minimize accidental exposure to drugs. Pharmacies and clinics may use this

information to be extra careful when dispensing or administering medications to populations that are at higher risk.

Conclusion

Medication errors not only cause patient harm, but they also prevent lifesaving treatments from being safely consumed by patients who need them. This study revealed factors that contribute to accidental exposure to drugs. Although this is a promising start, further research should be conducted to examine additional factors that may contribute to accidental exposure to drugs. Patients, health care professionals, drug manufacturers, and regulators need to work together to better understand the factors causing medication errors and come up with strategies to minimize them. The WHO launched an initiative in 2017 to reduce medication errors in all countries by 50% by 2022 (WHO GPS Challenge, 2017). Countries, companies, consumers, and clinicians need to work together to make this a reality. Reducing medication errors will not only cuts down on health care costs, it also will significantly improve the quality of life for millions of patients.

References

Aggarwal, R., & Ranganathan, P. (2016). Common pitfalls in statistical analysis: The use of correlation techniques. *Perspectives in Clinical Research*, *7*(4), 187–190. https://doi.org/10.4103/2229-3485.192046

Allen, M. (2017). Primary data analysis. SAGE Publications, Inc. https://doi.org/10.4135/9781483381411.n456

ASCII Definition. (n.d.). Retrieved September 3, 2021, from https://techterms.com/definition/ascii

Berben, L., Dobbels, F., Engberg, S., Hill, M., & Geest, S. (2012). An ecological perspective on medication adherence. *Western Journal of Nursing Research*, *34*, 635–653. https://doi.org/10.1177/0193945911434518

Berniker, J. (2001). *Spontaneous reporting systems: Achieving less spontaneity and more reporting* [Text]. Harvard Law School Library. https://dash.harvard.edu/bitstream/handle/1/8846816/Berniker.html?sequence=2&isAllowed=y

Bronfenbrenner, U. (1981). *The ecology of human development: Experiments by nature and design*. Harvard University Press. http://ebookcentral.proquest.com/lib/waldenu/detail.action?docID=3300702

Bukic, J., Rusic, D., Mas, P., Karabatic, D., Bozic, J., Perisin, A. S., Leskur, D., Krnic, D., Tomic, S., & Modun, D. (2019). Analysis of spontaneous reporting of suspected adverse drug reactions for non-analgesic over-the-counter drugs from

2008 to 2017. *BMC Pharmacology & Toxicology*, *20*. http://dx.doi.org.ezp.waldenulibrary.org/10.1186/s40360-019-0338-2

Cheng, H. G., & Phillips, M. R. (2014). Secondary analysis of existing data: Opportunities and implementation. *Shanghai Archives of Psychiatry*, *26*(6), 371–375. https://doi.org/10.11919/j.issn.1002-0829.214171

Creswell, J. W., & Creswell, J. D. (2018). *Research design: Qualitative, quantitative, and mixed methods approaches* (5th edition). SAGE.

Descriptive statistics – APA Dictionary of Psychology. (n.d.). Retrieved July 13, 2021, from https://dictionary.apa.org/descriptive-statistics

Elliott, R. A., Camacho, E., Jankovic, D., Sculpher, M. J., & Faria, R. (2021). Economic analysis of the prevalence and clinical and economic burden of medication error in England. *BMJ Quality & Safety*, *30*(2), 96–105. https://doi.org/10.1136/bmjqs-2019-010206

FAERS Reporting by Healthcare Providers and Consumers by Year. (2019). *FDA*. https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/faers-reporting-healthcare-providers-and-consumers-year

Falconer, N., Barras, M., Martin, J., & Cottrell, N. (2019). Defining and classifying terminology for medication harm: A call for consensus. *European Journal of Clinical Pharmacology*, *75*(2), 137–145. https://doi.org/10.1007/s00228-018-2567-5

Fang, H., Su, Z., Wang, Y., Miller, A., Liu, Z., Howard, P., Tong, W., & Lin, S. M. (2014). Exploring the FDA Adverse Event Reporting System (FAERS) to

generate hypotheses for disease monitoring. *Clinical Pharmacology and Therapeutics*, *95*(5), 496–498. https://doi.org/10.1038/clpt.2014.17

FDA Adverse Event Reporting System (FAERS): Latest Quartely Data Files—Data.gov. (n.d.). Retrieved May 9, 2020, from https://catalog.data.gov/dataset/fda-adverse-event-reporting-system-faers-latest-quartely-data-files

FDA's Adverse Event Reporting System (FAERS). (2019, May 22). FDA; FDA. https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers

Fialová, D., & Onder, G. (2009). Medication errors in elderly people: Contributing factors and future perspectives. *British Journal of Clinical Pharmacology*, *67*(6), 641–645. https://doi.org/10.1111/j.1365-2125.2009.03419.x

Haselberger, M. B., & Kroner, B. A. (1995). Drug poisoning in older patients. Preventative and management strategies. *Drugs & Aging*, *7*(4), 292–297. https://doi.org/10.2165/00002512-199507040-00004

Heale, R., & Twycross, A. (2015). Validity and reliability in quantitative studies. *Evidence-Based Nursing*, *18*(3), 66–67. https://doi.org/10.1136/eb-2015-102129

Hilbe, J. M. (2009). *Logistic regression models*. CRC Press LLC. http://ebookcentral.proquest.com/lib/waldenu/detail.action?docID=1633158

History | MedDRA. (n.d.). Retrieved June 13, 2021, from https://www.meddra.org/about-meddra/history

Hodges, N. L., Spiller, H. A., Casavant, M. J., Chounthirath, T., & Smith, G. A. (2018). Non-health care facility medication errors resulting in serious medical outcomes.

Clinical Toxicology, *56*(1), 43–50. https://doi.org/10.1080/15563650.2017.1337908

Hoeve, C. E., Francisca, R. D. C., Zomerdijk, I., Sturkenboom, M. C. J. M., & Straus, S. M. J. M. (2020). Description of the risk management of medication errors for centrally authorised products in the European union. *Drug safety*, *43*(1), 45–55. https://doi.org/10.1007/s40264-019-00874-7

Holmström, A.-R., Laaksonen, R., & Airaksinen, M. (2015). How to make medication error reporting systems work – Factors associated with their successful development and implementation. *Health Policy*, *119*(8), 1046–1054. https://doi.org/10.1016/j.healthpol.2015.03.002

Inferential statistics – APA dictionary of psychology. (n.d.). Retrieved July 13, 2021, from https://dictionary.apa.org/inferential-statistics

Jones, K. B. (2021, February). *Prescription drug Abuse in the elderly*. Familydoctor.Org. https://familydoctor.org/condition/prescription-drug-abuse-in-the-elderly/

Kiel, W., & Phillips, S. (2017). Impact of pharmacist-conducted comprehensive medication reviews for older adult patients to reduce medication related problems. *Pharmacy*, *6*(1), 2. https://doi.org/10.3390/pharmacy6010002

Knight, M. (2017, August 21). What is structured query language (SQL)? *DATAVERSITY*. https://www.dataversity.net/structured-query-language-sql/

Kohn, L. T., Corrigan, J., & Donaldson, M. S. (2000). *To err is human: Building a safer health system*. National academy press. https://www.ncbi.nlm.nih.gov/books/NBK225182/?report=reader

Leon, A. C. (1998). 3.12—Descriptive and inferential statistics. In A. S. Bellack & M. Hersen (Eds.), *Comprehensive clinical psychology* (pp. 243–285). Pergamon. https://doi.org/10.1016/B0080-4270(73)00264-9

Li, H., Sun, X., Sun, D., Zhao, J., Xu, Z., Zhao, P., Ma, Z., & Zhang, Y. (2021). Thromboembolic events associated with immune checkpoint inhibitors: A real-world study of data from the food and drug administration adverse event reporting system (FAERS) database. *International immunopharmacology*, *98*, 107818. https://doi.org/10.1016/j.intimp.2021.107818

Mattson, M., lipari, R. N., Hays, C., & Van, S. L. (2017, May 11). *A day in the life of older adults: Substance use facts*. A day in the life of older adults: Substance use facts. https://www.samhsa.gov/data/sites/default/files/report_2792/ShortReport-2792.html

MedDRA |. (n.d.). Retrieved May 9, 2020, from https://www.meddra.org/

Medication errors related to CDER-regulated drug products. (2020, November 2). FDA; FDA. https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products

MedWatch: The FDA safety information and adverse event reporting program. (2020, January 27). FDA. http://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Nattino, G., Pennell, M. L., & Lemeshow, S. (2020). Assessing the goodness of fit of logistic regression models in large samples: A modification of the Hosmer-Lemeshow test. *Biometrics*, *76*(2), 549–560. https://doi.org/10.1111/biom.13249

NCCMERP. (2014, July 18). About medication errors. NCCMERP. https://www.nccmerp.org/about-medication-errors

O'Connor, S. (2020). Secondary data analysis in nursing research: A contemporary discussion. *Clinical nursing research*, *29*(5), 279–284. https://doi.org/10.1177/1054773820927144

OpenFDA. (n.d.). Retrieved june 13, 2021, from https://open.fda.gov/data/faers/

Patino, C. M., & Ferreira, J. C. (2018). Internal and external validity: Can you apply research study results to your patients? *Jornal Brasileiro de Pneumologia*, *44*(3), 183. https://doi.org/10.1590/S1806-37562018000000164

Rodziewicz, T. L., & Hipskind, J. E. (2020). Medical error prevention. In *StatPearls*. StatPearls publishing. http://www.ncbi.nlm.nih.gov/books/NBK499956/

Rodziewicz, T. L., Houseman, B., & Hipskind, J. E. (2020). Medical error prevention. In *StatPearls*. StatPearls publishing. http://www.ncbi.nlm.nih.gov/books/NBK499956/

Singh, S., & Bajorek, B. (2014). Defining 'elderly' in clinical practice guidelines for pharmacotherapy. *Pharmacy Practice*, *12*(4), 489.

Stoltzfus, J. C. (2011). Logistic regression: A brief primer. *Academic emergency medicine*, *18*(10), 1099–1104. https://doi.org/10.1111/j.1553-2712.2011.01185.x

Suresh, K., & Chandrashekara, S. (2012). Sample size estimation and power analysis for clinical research studies. *Journal of human reproductive sciences*, *5*(1), 7–13. https://doi.org/10.4103/0974-1208.97779

Tariq, R. A., Vashisht, R., Sinha, A., & Scherbak, Y. (2020). Medication dispensing errors and prevention. In *StatPearls*. StatPearls publishing. http://www.ncbi.nlm.nih.gov/books/NBK519065/

Taylor, C. (2020, February 17). *Descriptive vs. inferential statistics: What's the difference?* ThoughtCo. https://www.thoughtco.com/differences-in-descriptive-and-inferential-statistics-3126224

TRIPATHY, J. P. (2013). Secondary data analysis: Ethical issues and challenges. *Iranian journal of public health*, *42*(12), 1478–1479.

Tudor Car, L., Papachristou, N., Gallagher, J., Samra, R., Wazny, K., El-Khatib, M., Bull, A., Majeed, A., Aylin, P., Atun, R., Rudan, I., Car, J., Bell, H., Vincent, C., & Franklin, B. D. (2016). Identification of priorities for improvement of medication safety in primary care: A prioritize study. *BMC family practice*, *17*(1), 160. https://doi.org/10.1186/s12875-016-0552-6

Wang, J., Ali, E., & Gong, Y. (2018). An information enhanced framework for reporting medication events. *Studies in health technology and informatics*, *250*, 169–173.

What is a serious adverse event? (2020). *FDA*. https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

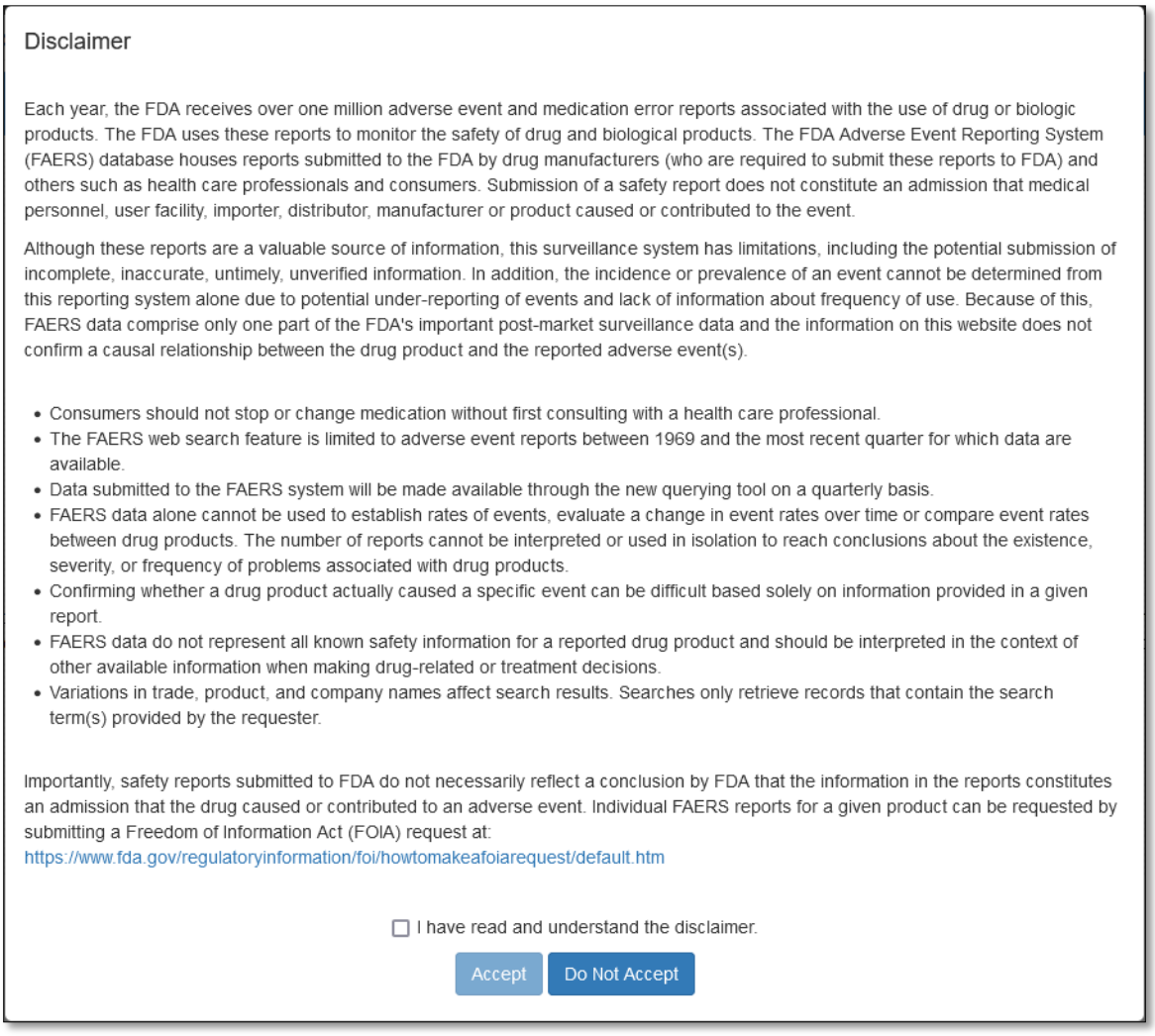
Whittaker, C. F., Tom, S. E., Bivens, A., & Klein-Schwartz, W. (2017). Evaluation of an educational intervention on knowledge and awareness of medication safety in older adults with low health literacy. *American journal of health education*, *48*(2), 100–107. https://doi.org/10.1080/19325037.2016.1271754

WHO | The third WHO global patient safety challenge: Medication without harm. (2018). WHO; World Health Organization. http://www.who.int/patientsafety/medication-safety/en/

WHO launches global effort to halve medication-related errors in 5 years. (2017, March 29). https://www.who.int/news/item/29-03-2017-who-launches-global-effort-to-halve-medication-related-errors-in-5-years

Working to reduce medication errors. (2019). *FDA*. http://www.fda.gov/drugs/drug-information-consumers/working-reduce-medication-errors

Appendix A: FAERS Access Disclaimer



Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

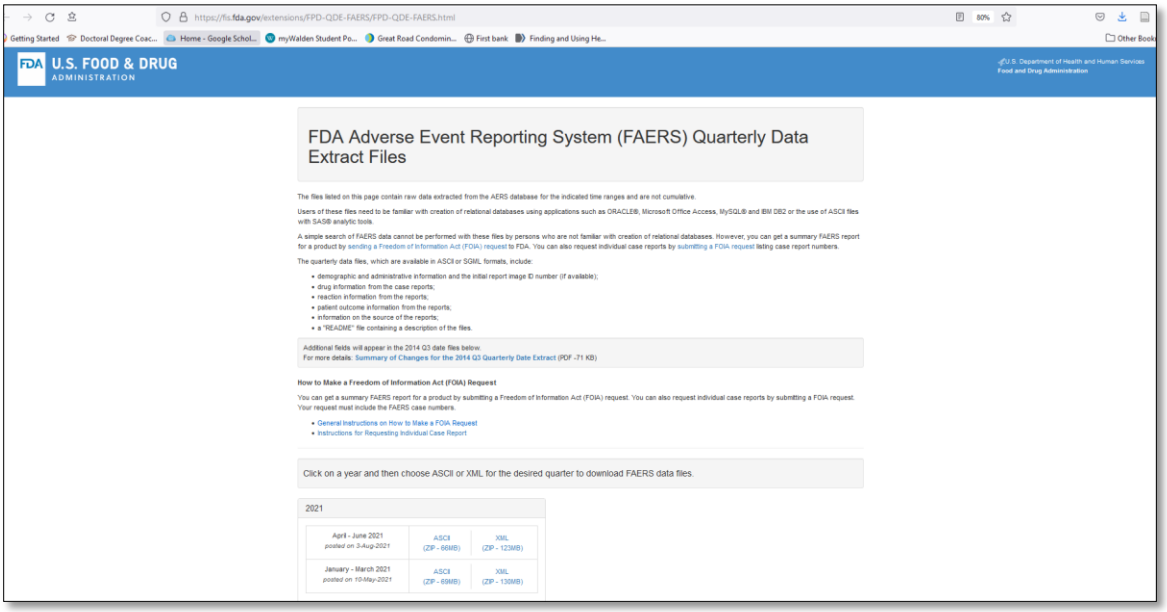
- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:
https://www.fda.gov/regulatoryinformation/foi/howtomakeafoiarequest/default.htm

I have read and understand the disclaimer.

Accept Do Not Accept

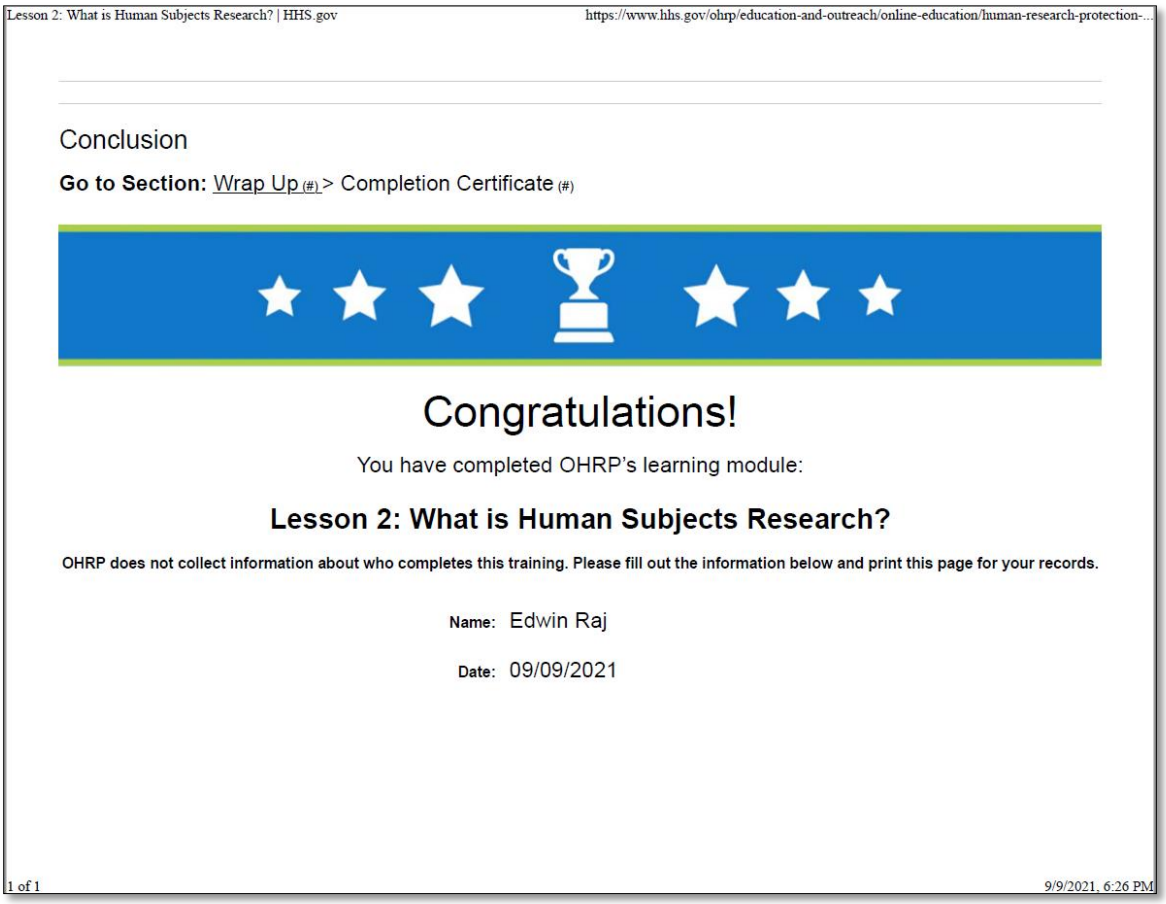
Appendix B: Screenshot of FAERS Quarterly Data Download Page



Appendix C: Original Coding of Variables of Interest From FAERS

FAERS variable	Description	Coding (Code – Meaning)
CASEID	Number for identifying a FAERS case.	
AGE	Numeric value of patient's age at event.	
AGE_COD	Unit abbreviation for patient's age	DEC - DECADE YR - YEAR MON - MONTH WK - WEEK DY - DAY HR - HOUR
AGE_GRP	Patient Age Group code as follows, when available:	N - Neonate I - Infant C - Child T - Adolescent A - Adult E - Elderly
SEX	Code for patient's sex	UNK - Unknown M - Male F - Female
OCCP_COD	Abbreviation for the reporter's type of occupation in the latest version of a case.	MD - Physician PH - Pharmacist OT - Other health-professional LW - Lawyer CN - Consumer
OCCR_COUNTRY	The country where the event occurred.	US - United States of America
PT	"Preferred Term"- level medical terminology describing the event, using the Medical Dictionary for Regulatory Activities (MedDRA). The order of the terms for a given event does not imply priority. In other words, the first term listed is not necessarily considered more significant than the last one listed.	

Appendix D: Human Subjects Research Training Certificate



Lesson 2: What is Human Subjects Research? | HHS.gov https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-...

Conclusion

Go to Section: Wrap Up (#) > Completion Certificate (#)

Congratulations!

You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

OHRP does not collect information about who completes this training. Please fill out the information below and print this page for your records.

Name: Edwin Raj

Date: 09/09/2021

1 of 1 9/9/2021, 6:26 PM