AN INTROSPECTIVE CASE STUDY EXAMINING THE BARRIERS FACED BY HEALTHCARE PROVIDERS WHEN REPORTING ADVERSE EVENTS TO MEDWATCH

BY

ANSLEY ALICIA BOOKER
(Under the Direction of Paul Brooks)

ABSTRACT

The Food and Drug Administration's MedWatch is the program for reporting serious adverse events. Due to several barriers, there is a gap between the number of self-reported events and the actual number of events that occur. The aim of this research was to gauge the perspective of varying healthcare providers regarding barriers that prevent effective reporting of adverse events to MedWatch. Interviews were conducted with physician assistants, pharmacists, nurses, and physicians. Data analysis was performed during this qualitative case study utilizing interviews and focus groups. Barriers identified included: difficulty in linking ADEs to a specific drug, lack of education, lackadaisical attitude toward reporting, lack of time, lack of knowledge of reporting vehicles, fear of punitive retribution, cumbersome paperwork, and failure to know which ADEs to report. The objectives of this research were to improve healthcare provider adverse event reporting as well as to improve the current educational directives and vehicles for reporting.

INDEX WORDS: MedWatch, Barriers, Food and Drug Administration (FDA), Adverse event reporting, Adverse Drug Event (ADEs)

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ANSLEY ALICIA BOOKER

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ANSLEY ALICIA BOOKER

Major Professor: Paul Brooks

Committee: David Mullis
Randall Tackett

Electronic Version Approved:

Maureen Grasso
Dean of the Graduate School
The University of Georgia
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DEDICATION

I dedicate this thesis to my family for nurturing my dreams and for providing continued love and support.

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CHAPTER 1

INTRODUCTION

Purpose of the Study

The purpose of this qualitative study was to examine barriers faced by healthcare providers when reporting adverse events to the Food and Drug Administration's MedWatch. To investigate barriers, which may affect adverse event reporting, this study raised four interrelated questions:

1. Who is reporting to MedWatch?
2. What should be reported?
3. How should events be reported?
4. How can adverse event reporting be improved?

How This Study is Original

This study evaluated a small population of healthcare providers ranging from 18 to 65 years of age. The target population was unique because it was conducted with healthcare providers (HCPs) in the Middle Georgia Area. The study population was recruited from healthcare facilities, pharmacies, and academic institutions from several cities and towns in the geographic locations of middle and southeastern parts of Georgia (USA). The researcher chose middle and southeast Georgia because of proximity to subjects selected. The area was also chosen because there was no known prior research in the area that contained several medical institutions and research facilities.

This study was comprised of a subset of diverse healthcare providers such as physician assistants, pharmacists, physicians, and nurses. The target population contained a broad range of years of experience within multiple healthcare settings. This study included a variety of healthcare professionals that have operated in several different occupations as well as venues. The study population also contained a very large gradient in the years of practice of the participants. With this diverse population a variety of potential barriers could be explained. Barriers from various healthcare prospectives including those of newly graduated professionals as well as experienced veterans were explored. The study also contributed to prior research by supporting barriers previously identified in the literature review. By examining barriers faced by healthcare providers, this study identified some solutions to reporting problems.

Expected Results

Expected barriers were fear of reporting, failure to know where or how to report, lack of education on adverse event reporting, and an apathetic attitude toward reporting. From the literature, some of the barriers identified included lack of time, lackadaisical attitude toward reporting, fear of malpractice or punitive retribution, lack of knowledge of reporting vehicles, lack of education on reporting Adverse Drug Events (ADEs), failure to know which ADEs to report, difficulty in linking ADEs to a specific drug, lack of patient history, duplicative reporting requirements, cumbersome forms, lack of compensation and limited support from employers, and mistrust of the Food and Drug Administration.

Potential Benefits

The primary benefit of this research was to identify barriers that may prevent healthcare workers from reporting adverse events through the FDA's MedWatch system. Gathering situational and personal perspectives from various healthcare practitioners provided a contextual

description that may assist in improving awareness of common reporting barriers to MedWatch. Furthermore, if barriers were identified and reported to HCPs, more healthcare professionals may acknowledge the importance of reporting and the barriers that confront them. If the importance of adverse event reporting and their role in reporting was ingrained in them, they may then want to take a more active role in reporting as well as asking for help with reporting from other healthcare professionals such as pharmacists and nurses. They might even encourage more consumer reporting to alleviate some of the stress from reporting. Healthcare providers may encourage consumer reporting by introducing MedWatch and adverse event reporting to the consumer. The consumer may then consult the doctor about reporting, but ultimately be able to complete the voluntary forms themselves. The FDA could also become more aware of the time commitment to reporting and would therefore, refine the instrument used for reporting adverse events making for a more systematic and convenient method.

CHAPTER 2

RELATED RESEARCH

Post-Marketing Surveillance

While the United States has one of the most rigorous drug device approval processes in the world, adverse events can still result from the use of manufacture's approved products. Medical product studies, ranging from preclinical animal testing and medical device bench testing to final tests in humans have inherent limitations no matter how well they are designed or conducted. These limitations may include hidden side effects not determined during clinical testing. The need for post-marketing surveillance is a direct result of these limitations. [1] Medical product safety monitoring is an ongoing process accomplished through the Food and Drug Administration's (FDA) Post-marketing Surveillance System. The system monitors the safety of drugs [or any other medical product] once they are marketed to the general population. This process encompasses adverse event reports evaluation, generation of safety-related hypotheses, and use of techniques to evaluate these hypotheses. One of the early attempts at post-marketing surveillance was the Adverse Event Reporting System.

A. Adverse Event Reporting System

The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The FDA uses AERS to monitor for the frequency of new adverse events and medication errors that might occur with these marketed products. The

structure of AERS complies with the International Safety Reporting Guidance (ICHE 2B) issued by the International Conference on Harmonization. [14]

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

- Death – Report if the death was suspected as an outcome of the adverse event, and include the date if known.
- Life-threatening – Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.
- Hospitalization (initial or prolonged) – Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).
- Disability or Permanent Damage – Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions (i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life).
- Congenital Anomaly/Birth Defect – Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

- Required Intervention to Prevent Permanent Impairment or Damage (Devices) – Report if that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, situation suspected to be due to the use of a medical product.
- Other Serious (Important Medical Events) – Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.[15]

B. MedWatch Reporting System

In order to track the post-marketing surveillance activities, the FDA initiated a new program called MedWatch in June 1993. MedWatch has two interconnected goals: to educate both healthcare providers and their patients about the importance of reporting serious adverse events into the FDA, and to facilitate that reporting. MedWatch is the program for reporting serious adverse events, product quality problems, therapeutic equivalence/failure, and product use errors with human medical products, such as drugs and medical devices, and problems with different manufacturers of the same medicine.

However, patient safety reached the forefront of public awareness with the 1999 Institute of Medicine's report, "To Err Is Human," shortly after the new incentives presented by MedWatch for reporting adverse events were implemented. That report suggested that at least 7,000 deaths annually were due to medication errors.[2] Another 1.5 million people suffered from

adverse drug events annually at a cost of approximately 3.5 billion dollars.[3] Between 5% and 25% of hospitalized adult patients experienced a serious adverse drug reaction at some point during their hospitalization. A study published in 2011 in the *Journal of Health Affairs* reported that care mistakes were more common than previously thought.[4] A report entitled *An Apology's Healing Power* suggested that one in three hospital patients experienced an "adverse event" such as a preventable infection or the wrong medication or surgical procedure.[4] As a result, many were admitted for expensive treatments to fix mistakes, and tens of thousands died. One leading expert has said our healthcare system is putting up with an error-related death rate equivalent to three jumbo-jet crashes every two days.[4]

Another estimate indicated that the FDA received less than 1% of suspected serious Adverse Drug Reactions by direct report.[5] This meant that cases spontaneously reported to any surveillance program, which comprised the numerator, generally represented only a small portion of the number that has actually occurred. Dr. Peter Kilbridge of Duke University reported that in their adverse event detection system, even with strong encouragement to report adverse events, approximately one out of every six events is logged into the voluntary reporting system. In comparison, estimates were that the ratio in community hospitals was 1 in every 80 events. This data from Duke University illustrated how voluntary reporting falls short of accurately reflecting the numbers of adverse events experienced by patients since 5 out of 6 events were missed.[6] The effect of underreporting can be somewhat lessened if submitted reports, irrespective of number, were of high quality.[5]

A recent study of serious adverse drug reactions in an elderly ambulatory population showed that these events were common and often preventable and that the more serious adverse drug events were more likely to be preventable. Some of these known adverse reactions were

expected and unavoidable in patient care, while others may be prevented and avoided by either careful monitoring or management. Other adverse reactions that have not yet been recognized or identified occur unexpectedly and were therefore not yet preventable or avoidable. These unexpected adverse reactions still are the cornerstone that supports the FDA's post-marketing safety surveillance activities.[10]

C. US Federal Government ADEs Reporting System

Medication errors in the American medical community have always been at the forefront of debate. However, the problem is so severe now that the Obama administration recently announced a billion-dollar initiative to combat errors. It seeks to bring together hospital executives, employers, insurers, physicians, nurses, patient advocates, and government to find ways to make care safer. It aims to reduce avoidable errors by 40% and hospital readmissions by 20%.[4]

Kathleen Sebelius announced on April 12, 2011 that the Health and Human Services Department will spend $1 billion dollars on a new program designed to reduce medical mistakes, preventable injuries and infections in American hospitals.[43] The new program, called Partnership for Patients, was made public following on a report released earlier that said as much as much as 90 of all hospital mistakes, injuries and infections go unreported and that one in three Medicare patients would likely experience one of the three when admitted for treatment.

"Americans go to the hospital to get well, but millions of patients are injured because of preventable complications and accidents," Sebelius said. She also said the Partnership could save 60,000 lives over the next three years and up to $35 billion in health care costs if so many mistakes were not made.[43]

Funding for the Partnership will be made available through the new federal health care reform law. Hospitals with high re-admission rates and large numbers of mistakes will be able to apply for grants from a $500 million program to create pilot projects to reduce those problems.[43]

Background

I. Medication Errors

In 1992, the FDA began monitoring medication error reports that were forwarded from the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). The agency also reviewed MedWatch reports for possible medication errors. Currently, medication errors are reported to the FDA as manufacturer reports (adverse events resulting in serious injury and for which a medication error may be a component), direct contact reports (MedWatch), or reports from USP or ISMP.

The National Coordinating Council for Medication Error Reporting and Prevention defines a 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. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."[12]

The American Hospital Association lists the following as some common types of medication errors:

- incomplete patient information (not knowing about patients' allergies, other medicines they are taking, previous diagnoses, and lab results, for example);
- unavailable drug information (such as lack of up-to-date warnings);

- miscommunication of drug orders, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units, and inappropriate abbreviations[13];
- lack of appropriate labeling as a drug is prepared and repackaged into smaller units; and
- environmental factors, such as lighting, heat, noise, and interruptions that can distract health professionals from their medical tasks.

The FDA receives medication error reports on marketed human drugs (including prescription drugs, generic drugs, and over-the-counter drugs) and non-vaccine biological products and devices.

The Division of Medication Errors and Technical Support includes a medication error prevention program staffed with pharmacists and support personnel. The program staff reviews medication error reports sent to the USP Medication Errors Reporting Program and MedWatch, evaluates causality, and analyze the data to provide feedback to others at the FDA.[12]

II. Mandatory versus Voluntary Reporting

Even though post-marketing safety surveillance activities are duties performed by the FDA, they strongly rely on adverse event reports that are submitted by healthcare providers. The FDA receives a significant number of adverse events from manufacturers, distributors, and packers of drug, biologics and devices because they have mandatory reporting requirements. User-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both the FDA and manufacturers utilizing Mandatory Reporting Form FDA 3500A.[10]

Mandatory Reporting Form, FDA 3500A, is required for health providers who work in a hospital or another user facility such as a nursing home, ambulatory surgical facility, outpatient treatment facility or outpatient diagnostic facility. Risk managers and other personnel within the user facility are legally required to report suspected medical device-related deaths and serious injuries. However, physician's offices are excluded from the user facility definition and are therefore exempt from mandatory reporting requirements as are dentists, nurses, optometrists, pharmacists, and nurse practitioners.[11]

The FDA recognizes the valuable role that hospitals play in the detection of adverse events and problems with medical products and views every active hospital-monitoring program as a vital component of the national post marketing surveillance system. Hospital reporting of adverse events, both within and outside an individual facility, is a mixture of voluntary and mandatory reporting. Adverse event monitoring by hospitals is linked to standards of The Joint Commission (TJC), formerly called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). TJC requires each hospital to monitor for adverse events involving pharmaceuticals and devices. TJC standards indicate that medical product adverse event reporting should be done per applicable law/regulation, including those of state/federal regulatory bodies.[5]

Reporting of adverse events from the point of care is voluntary in the United States. The FDA receives some adverse event and medication error reports directly from health care professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others). Physicians and pharmacists are the healthcare providers who submit reports to the FDA the most frequently. Other healthcare providers include nurses and dentists. The agency receives over 600,000 reports each year. According to

the Adverse Event Reporting System as of June 30, 2012, reports by healthcare provider physicians accounted for 161,543; healthcare provider pharmacists 27,395; other healthcare providers110,645; total healthcare providers 299,583; and lastly consumers, 272,021.[2]

Individual healthcare providers and consumers may also report these events to the products' manufacturers. If a manufacturer receives an adverse event report, it is required to send the report to the FDA as specified by regulations. The manufacturer may also submit adverse event reports via periodic summary reports. Typically, reports related to side effects that are already discussed on a drug's label can be submitted through periodic safety-summary reports while reports that are unexpected or serious are required to be filed as so-called 15-day reports that are filed into FDA's AERS system.[1]

Experts differ regarding the most effective reporting system. Some suggest that voluntary systems combined with strict confidentiality may be the best method to encourage health professionals to report mistakes. Others argue that mandatory systems are most effective, given research showing that hospitals report fewer care-related injuries in states with voluntary systems than in states that mandate reporting.[44]

Prior to the IOM report, 15 states had mandatory reporting systems. These states varied in their definitions of adverse events. [44] The IOM report defined an adverse event as a serious injury resulting from medical management, and not from the underlying condition of the patient. Numerous bills dealing with these issues remain deadlocked in state legislatures. Currently, 22 states have mandatory reporting systems, covering 63% of the U.S. population.[44] If reporting was made mandatory, it may be assumed more accurate and detailed reports would be received which may result in a reduction in medical errors.

Reporting by facilities, practitioners, and patients to the FDA or to manufacturers – known as voluntary reporting when involving medical devices and spontaneous reporting when involving drugs and biologic products – is voluntary at the Federal level, but has increased greatly in recent years. In addition to voluntary reporting, there is limited mandatory reporting required at the Federal level. Manufacturers who receive a drug, biological, or device report must submit it to the FDA. Moreover, healthcare facilities must file reports of deaths and serious injuries involving medical devices only.[18]

A. Mandatory Report Due Date

The mandatory report due dates are listed below. They are listed by user facilities, manufacturers, and distributors after each event type.

User Facilities:

- Deaths (to FDA and manufacturer within 10 Days)
- Serious injuries/illnesses (to manufacturer within 10 days; to the FDA if manufacturer is unknown, also within 10 days)
- Semiannual Reports (to the FDA) of all reports sent to the FDA and/or manufacturer (due January 1 and July 1)

Manufacturer:

- Deaths, serious injuries, malfunctions **(**to the FDA within 30 calendar days of becoming aware of event)
- "5-day Report" [to the FDA if become aware of (1) event(s) necessitating "remedial action to prevent an unreasonable risk of substantial harm to the public health" or (2) reportable event for which the FDA has requested a 5-day report]
- Annual Certification of number of reports

Distributor:

- Deaths (to the FDA and manufacturer within 10 days)
- Serious injuries/illnesses (to the FDA and the manufacturer within 10 days)
- Malfunctions (to FDA and manufacturer within 10 days) [5,11]

B. How to Report to MedWatch

MedWatch is used to report any adverse event that occurs while using the FDA regulated healthcare products such as:

- Human drugs (both prescription and over-the-counter)
- Medical devices (e.g., contact lenses, glucose tests, pacemakers, and medical x-rays)
- Blood products, human cell and tissue products, and other biologics (except vaccines, which are reported to another system)
- Special nutritional products (dietary supplements, infant formulas, and medical foods such as nutritional supplements used under medical supervision)
- Cosmetics.[16]

Since 1998, the MedWatch website, www.fda.gov/medwatch, has offered an online reporting form as an alternative to reporting by mail or fax. In addition, a toll free 800 number is available for answers to reporting questions and to submit a report. Reporting consists of a one-page paper form that can be returned to the FDA by pre-paid mail or fax.

- Mail Download the pre-addressed postage-paid form or call 1-800-FDA-1088 to request the form.
- Fax Get the form (as above) and fax to 1-800-FDA-0178.
- Phone Call 1-800-FDA-1088 Mon-Fri between 8:00 a.m. and 4:30 p.m. EST.

The four core elements of the report include a reporter's name, a suspect drug or device product, a narrative report of the adverse event or problem and an identifiable patient. The FDA, however, holds the identity of patients in strict confidence, protected by federal law and regulation. Patients are encouraged to take this form to their healthcare provider so that the report contains information that is more detailed; however, patients may submit reports directly to the FDA.[9] Consumers may obtain this form from the MedWatch website. Submitters are encouraged to report using the online form FDA Form 3500 because it is the quickest and most direct route (see Appendix A).

The process of filling out and submitting the voluntary form is relatively simple. However, some language seems too advanced for the average user or consumer. Terms such as "dose frequency," "medical pathway," and "event abated" are complicated and possibly intimidating for a lay person. Alternatively, the forms are brief and the user interface is basic, with big buttons, spacious form fields, and large font sizes. The form takes anywhere from ten to twenty minutes to complete, depending on how much detailed information the user wishes to provide.[2]

C. What Happens After Reporting to MedWatch?

FDA staff members enter the report into a database so that it is available for review and used for comparison to other reports. An FDA safety evaluator, often a pharmacist, doctor, or nurse, reviews the report and examines the database for similar reports. The FDA monitors the data for trends and conducts an investigation if appropriate.[6] The FDA takes the necessary action to protect the public health, however not all of these actions maybe timely. FDA actions may include:

- issuing safety alerts advising the public and health care professionals to monitor a product's use, adjust the way it is used, or stop using it;
- updating the product label to reflect new warnings;
- requiring a product to have a Medication Guide—a consumer-friendly instruction sheet provided to patients each time they fill a prescription to help them use the drug safely;
- requesting a change in the product's design, manufacturing process, packaging, or distribution;
- requesting a company to recall a product or requiring a manufacturer to conduct further studies to demonstrate the product's safety prior to allowing the product back on the market.[16]

Each year, the FDA compiles the data received from these adverse event reports and releases safety alerts. These safety alerts are posted on the website (www.fda.gov/medwatch); however, an email notification is sent to all 170-partner organizations, which includes healthcare providers. The individual e-list subscribers total over 54,000.[9] These subscribers include the Academy of Managed Care Pharmacy, Advanstar Communication of All Nurses, the Consumer Healthcare Products Association, American Medical Student Association, American Association of Colleges of Pharmacy, American Association of Colleges of Nursing, the American Academy of Family Physicians, and The Joint Commission. [17]

D. Mandatory vs. Voluntary Reporting from a state governmental level

Seventeen states have formed, or are developing, statewide public/private patient safety coalitions. These programs focus on disseminations of best practices, mandatory and voluntary error reporting, education of policymakers and consumers, professional accountability,

development of information technology, and systems improvement. Of the states with patient safety coalitions, Massachusetts and Florida have made notable progress toward medical error reduction and patient safety.[44] In 1998, Massachusetts founded the first state patient safety coalition, the Massachusetts Coalition for the Prevention of Medical Errors. The Coalition has been in the forefront of national activities to promote a systems-oriented approach to improving patient safety. The Massachusetts Department of Public Health (MDPH) was awarded a three-year, $4.5 million grant from the Agency for Health Care Research and Quality to study the root causes of medical errors and devise appropriate prevention strategies.[44]

Currently, 27 of 50 U.S. states including the District of Columbia have mandatory reporting systems. These states are: Georgia, Florida, South Carolina, Tennessee, California, Nevada, Utah, Colorado, Kansas, Wyoming, Maine, Vermont, Massachusetts, Rhode Island, New York, Connecticut, Pennsylvania, Maryland, New Jersey, South Dakota, Washington, Oregon, Minnesota, Illinois, Indiana, Ohio, and District of Columbia. [58] If the FDA would like to see progress toward more statewide public/private patient safety coalitions, the federal government must pass a mandate. The model can be taken from pre-existing coalitions such as in Massachusetts and funded through Health and Human Services called Partnership for Patients. The coalition would serve to help determine barriers and eradicate the nine types of medical mistakes occurring in hospital settings nationwide. However, do to previous limitations in funds these coalitions are not being formed.

III. Alternative Reporting Vehicles

A. MedWatch Plus

The government does understand the need to implement some sort of expansive national wide system for reporting and is making strides to improve this problem. Since 1993, all adverse

event reports were submitted on paper and were transcribed by the FDA into an electronic format for usability and analysis. The FDA recognized that in order to effectively meet the needs of the consumers in regulated industries and to ensure product safety, there was a need for a fully automated, web-based system that could seamlessly submit information to the Agency without the use of paper-based methods.

As such, the FDA began developing in 2008 a new electronic system for collecting, submitting and processing adverse events reports. The MedWatch Plus Portal, which the FDA expects could be ready for use by all of its centers by fiscal year 2011, will enable companies to submit both voluntary and mandatory adverse event reports for drugs, medical devices and other FDA- related products to a single point of entry through the Agency's electronic submissions gateway. However, MedWatch Plus is still not completely integrated as of 2013. The Agency believes a one point of entry will better enable organizations to submit information.[52]

MedWatch Plus allows the FDA's Health Level 7 Individual Case Safety Report (HL7 ICSR) standard for receiving reports on adverse events. It is a compilation of the current MedWatch system, and integrates the 3500 and 3500A forms into the FDA adverse event reporting systems (FAERS) database, which will allow the Agency to more effectively analyze and identify safety reports.[52]

Using the MedWatch Plus portal, the time between submission and FDA acknowledgement will be significantly reduced according to the FDA. The FDA and National Institutes of Health worked collaboratively to build into MedWatch Plus a "rational questionnaire" software, which is a data collection tool that helps the user determine the data that is needed to be included for each individual report. The reporter can use the online questionnaire or gateway-to-gateway access. The questionnaire's reporting time is one hour and gateway-to-

gateway time is ten minutes. Current reports estimate that in the future about 80% of reports will be submitted via gateway-to-gateway.[52]

Building a software solution around MedWatch Plus will require significant development resources. For example, a custom-developed MedWatch Plus solution that integrates with existing business systems can cost between $200,000 to $350,000 to implement. MedWatch Plus also enhances the communication process with the FDA and eliminates or reduces "crossover emails." Those who use MedWatch Plus will benefit from an immediate receipt and acknowledgement-within six to 12 minutes-as opposed to waiting days or longer with the manual reporting process. Use of MedWatch Plus will result in cost savings, as it will eliminate the need for the FDA administrative overhead incurred from traditional communication.[52]

MedWatch Plus is designed to enhance AER by enhancing functionality for both the reporter and the FDA. The FDA will benefit from time savings, increased collaboration and electronic retrieval of MedWatch Plus data. Similarly, companies will benefit from a web-based, central point of entry, resulting in significantly shorter wait time between submissions and less chance of the human error factor that often accompanies manual processes.[52] If the MedWatch Plus system is implemented, it should streamline reporting and bring major improvements to post-market surveillance and reporting.

Another alternative solution to reporting AERS barriers is to develop a comprehensive electronic adverse event reporting system in an academic health center. In January 2001, an interdisciplinary team was convened with the goal of creating a comprehensive approach to patient safety reporting and resolution. A secure, Web-based system, the MUHC Patient Safety Network System (PSN), was created that allows staff, physicians, patients, families, and visitors to report comments, adverse events, and near-miss events from any computer in the hospital and

from home, using the department managers responsible for resolution; managers are alerted to the presence of a report by e-mail. Anonymous reporting is an option for near-miss events. Near miss-events are those adverse events that almost occurred. Reports are immediately available to department managers responsible for resolution and managers are alerted to the presence of a report by e-mail. As a result, a pilot study performed in two MUHC intensive care units documented dramatic reductions in resolution time using the PSN. [53]

The pilot also demonstrated an increased willingness to report by physicians and respiratory therapists. Training was accomplished in the fall of 2001, and the PSN was successfully implemented throughout the hospital on January 1, 2002.[53] An implementation such as this may increase reporting rates because of efficiency, accountability, and speed. Healthcare professionals would not have to be burdened with extensive reports, but could immediately upload data to this system. This patient safety network could bring about much needed improvements to reporting as well. A combination of this system and the MedWatch Plus system would allow for increase in ADE reporting because it will allow for anonymous reporting for near-miss events. These records would also be made immediately accessible to department managers and the FDA. Since these systems are less time consuming, healthcare providers may feel more urgency to report.

B. MedStream

Currently, MedWatch offers a FREE MedStream channel for any mobile device. It provides information from the FDA Safety Information and Adverse Event Reporting Program. It serves both healthcare providers and the medical product-using public. MedWatch provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting

devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas). Medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans are quickly disseminated to the mobile devices of the medical community via Med Stream. MedWatch safety alerts delivered to PDA's include:

- clinically important medical product safety alerts for use at the point of care;
- concise, timely information about the drugs and devices, prescribed, or dispensed every day, directly from the U.S. Food and Drug Administration; and
- a summary of the safety alert. When more information is needed, a web address provides more detailed information.[50]

MedStream channels provide healthcare providers with current data pertaining to safety alerts and medication treatments. MedWatch is a free channel that has been included with every download of MedStream. Additional free channels include CDC Spotlights, Preventing Chronic Disease and Connections.[50]

Information in MedWatch is easily and dynamically integrated via smARTlink™ with other Skycape-powered channels and references and is updated whenever users synchronize their PDAs, providing medical professionals with the most current source of clinical and drug information in context at the point-of-care. For example, if a physician in the course of treating a patient were to consider warfain as potential treatment and then smARTlinks, he would be automatically informed about all of the latest information and news flashes about warfain that have flowed into the MedStream channels.

However, this educational tool must be advertised to all public and private sector healthcare providers. The healthcare providers must be trained on how to manipulate this

software and must be able to readily access it. Once these goals are achieved, this channel will be imperative in combating ADE prevention.

C. MedSun

MedSun is another avenue to report adverse events for medical devices. The Medical Product Surveillance Network known as MedSun is a pilot program started in 2002 in response to the FDA Modernization Act of 1997 (FDAMA) mandate. This means implementation of a national surveillance network to provide critically important data on medical devices. Critical design aspects include:

- confidentiality through the use of a neutral third party;
- affording incentives for participation;
- lessening the burden of participation; and
- communicating timely feedback to the participants.

The Safe Medical Devices Act (SMDA) already required mandatory reporting and MedSun goes even further. Patterned and mirrored after Form 3500A, MedSun provides options for recording additional information to help improve the safety and design of medical devices. Center for Devices and Radiological Health (CDRH) contracted with a research organization called Coda to manage this web-based program. Hospitals, nursing homes and other healthcare facilities that participate receive several benefits including feedback and experience sharing among the other participating facilities; special database analyses as well as dispensing with the requirement to complete a paper Form 3500A. Confidentiality remains a priority in terms of protecting the identity of both the person who submits the report as well as the reporting facility.[11]

D. MedWatchLearn

The FDA is currently celebrating the 20th anniversary of its MedWatch program. With this celebration came some new improvements, one of them being MedWatchLearn. MedWatchLearn is a new web-based learning tool. This tool is designed to educate students, healthcare professionals and consumers on how to report. MedWatchLearn also provides examples of quality reports that include critical information to help the FDA evaluate the event or product quality complaint. Consumers also have the opportunity to practice filling out FDA Form 3500B, the new MedWatch consumer reporting form. [54] MedWatchLearn is a practice site only. Consumers have to return to the MedWatch site to report an actual problem.

The MedWatchLearn portal also has a section used to educate consumers. In the consumers section, they have provided case studies for four categories of problems with medical products. The case studies are based on actual reports received by the FDA. The case studies provided include unexpected side effects, problems with different manufacturers of the same medicine, product use error, and product problems.

Research concerning barriers to reporting healthcare

With increased medication usage and number of patients, there has been a steady increase in adverse event reporting on behalf of healthcare providers. [2] However, it has been speculated that due to several barriers that there is a gap between the numbers of self-reported events and the actual number of events that occur. [7] Subsequently, healthcare providers for this study had their reporting practices examined through individual interviewing or a focus group.

Although the FDA accepts MedWatch reports directly from consumers, it prefers that consumers have their healthcare provider complete the form because they will be able to provide clinical information based on the patient's medical record that could help the FDA better

evaluate the report. However, the doctor is not required to complete the form nor is he/she required to report to the FDA. Therefore, in these situations the patient may complete the Online Reporting Form.[8] "Health care providers have the test results and other clinical information that will help us to better evaluate the report," says Norman Marks, MD, Medical Director of the FDA's MedWatch program.[9] Lastly, having healthcare providers report more often would increase the amount of quality data reports.

A. Pharmacists

Pharmacists have also cited many barriers that impede the reporting of Adverse Drug Events. An adverse drug event has been described as "an injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy)." Adverse Drug Events may result from medication errors but most do not.[19] Barriers with reporting ADE's include a lack of time, failure to know which ADEs to report, difficulty in linking the ADE to a specific drug, lack of patient history, lack of compensation, fear of malpractice suits, limited support from employers and mistrust of the FDA, lackadaisical attitude toward reporting, and lack of education on reporting.

Pharmacists believe that reporting serious adverse events is time consuming and disrupted the normal workflow. In one study that measured the attitudes of pharmacists, about 90% of the pharmacist believed that reporting serious ADEs would improve patient safety. However, 72.6% indicated that reporting serious adverse events was time consuming and over half (55.5%), of the respondents believed that reporting serious ADEs disrupted the normal workflow.[20] Pharmacists have recommended continuing education and training to raise awareness on ADE reporting and streamlining the report process to enhance pharmacists

reporting behavior.[21] Consumers often consult with pharmacists about adverse events entailing over-the-counter and prescription medications when their primary physicians are not available leaving the duty to report to their pharmacist. Pharmacists may also be asked to report adverse events by doctors in a clinical setting as well.

B. Nurses

The third largest healthcare group to report ADEs includes nurses, dentists, and others. Many of the reports that MedWatch receives from nurses are on behalf of doctors as well. In reality, nurses, staff or nurse managers, most frequently report cases through their incident reporting systems, and case managers/medical records staff files cases in the charts or other records. In all instances, staff who identify adverse events, whether state-reportable or not, are required to call or notify their designated superiors or department heads, or fill out incident reports, depending on the particular hospital's system. Once an event is reported, the responsible department often conducts follow-up with staff involved in the event to gather more information and to complete both internal and state-mandated reports.[22] Nurses may also report directly to the Director of Nursing, pharmacists, or doctor and then to family of the patient depending upon the facility.

Another obstacle associated with reporting on behalf of nurses is the level of training and importance given to staff pertaining to adverse event reporting. Reporting practices differ from practice to practice as well as funding level. The organizations in which nurses practice, dictate the level of attention given to reduction of health care errors. For example, some hospitals have very sophisticated error reporting, infection control and risk management programs. By comparison, ambulatory and community based care settings have generally employed less sophisticated approaches, relying on education and training, policies and procedures. There are

many reasons cited for the differences between hospital and ambulatory institutions and their efforts to address patient safety. Chief contributors to these disparate approaches include significant differences in the number of staff and resources available, as well as lack of technical knowledge about effective quality improvement methods or related infrastructure and lack of recognition of errors due to short patient stay and lack of data. With the rise in outpatient and office-based patient procedures, including surgery, attention to patient safety is increasing in all settings.[51]

C. Physicians

There are several reasons that are attributed to under-reporting by physicians. Physicians have to determine if the event is related to the cause of the disease itself, not necessarily a product of the drug or device. This is especially relevant to physicians who observe patients with unique or rare diseases. Second, it is not an ingrained practice for physicians to notify the FDA about adverse events or product problems. This may be due to the historically bureaucratic nature of reporting procedures.

D. Other Hospital Staff

As a group, hospital staff may not report adverse events because they do not believe reports lead to improvement, do not have time, or fear punitive action. Hospital managers indicated that hospital staff members do not report all adverse events, although estimates of how many adverse events are not reported vary widely. In interviews, hospital managers gave estimates as low as 5% of adverse events reported to as high as "nearly 100 percent," attributed to focused training on identifying adverse events. Stakeholders reported the following reasons for not reporting in order of prominence. [23]

- lack of follow-up by responsible staff when reports are made;

- lack of time to complete incident reports and documentation;
- fear of punitive action against self or a colleague;
- assumption that other involved staff will report;
- failure to track care as patients move through multiple departments and caregivers, and
- difficulty in distinguishing adverse events from harm caused by underlying disease.

The importance of hospitals taking action to encourage staff to report adverse events through such measures as strengthening enforcement, streamlining procedures, and training staff on reporting procedures, and ensuring confidentiality when possible cannot be stressed enough. Allowing anonymous reporting or ensuring confidentiality of reporters has been shown to increase reporting, but can limit the usefulness of reports because those analyzing the adverse events are not able to follow up to clarify the event and possible causes.[23]

IV. Barriers revealed in previous research

A. Barrier: Reporting Duplicative Reporting Requirements

According to a study conducted by the Department of Health and Human Services by the Office of the Inspector General, detailed and duplicative reporting requirements may also lead to underreporting. Hospitals are often required to report adverse events—sometimes the same event—to several different entities, which hospital staff indicated takes considerable staff time and effort. For example, in one state, a single adverse event involving a medication error may require reporting to eight different entities, each with different reporting mechanisms and standards. Further, some oversight entities require substantial information for each reported event, such as a root cause analysis, a corrective action plan, staff surveys, and medical records.[23]

B. Barrier: Cumbersome Forms

The FDA reports that MedWatch captures only a small percentage of the total burden of adverse events (Dr. Anne Trontell of the FDA, 2004). Richard Platt of Harvard Medical School and Harvard Pilgrim Health Care stated that completing and filing forms for MedWatch (and the Vaccine Adverse Event Reporting System [VAERS]) requires clinicians to recognize that a medical problem may be an adverse reaction to a drug, remember how and where to obtain the forms, and then invest substantial time in providing the required information. These steps lead to substantial underreporting and incomplete reporting. In 2004, physicians and pharmacists (according to Trontell, predominantly pharmacists, with a lesser percentage from physicians) provided 48% of reports regarding adverse events to the FDA through MedWatch. Consumers contributed only 17%.[6]

C. Barrier: Lack of knowledge of reporting vehicles

Another concern about MedWatch is the variability of report quality. Although MedWatch is available to health-care professionals, these professionals are not necessarily taught how to use the system.[6] According to Mr. Troy, the FDA "generally assumes that only 1 in 10 adverse events are reported." However, utilization of other reporting methods, such as registries, can result in higher reporting rates. One issue with voluntary reporting is that clinicians report only when they think something is both significant and drug related. The large majority of adverse events are either not recognized or not reported, and there are unknown biases in the reporting that does occur, according to Dr. Platt. [6]

D. Barrier: Fear of punitive retribution

There have been suggestions that anonymity of reporting and perhaps overcoming the barrier of liability concerns would motivate people to file more adverse event reports, said Dr.

Trontell.[6] Most respondents also attribute low reporting among physicians to fear of a punitive response from the hospital or state, or the belief that reporting is unnecessary and ineffective. [22] Marchev (41) suggested reasons for fear of punitive retribution by healthcare providers. Earlier research studies have shown that healthcare providers especially physicians are the most resistant to reporting ADEs to any agency or system because of fear of punitive responses from state or hospitals boards. [41] In this context, a question for states is whether the specter of possible malpractice litigation is hampering the effectiveness of their error reporting systems by creating resistance on the part of providers to freely report medical errors and adverse events. Earlier this year, the National Academy for State Health Policy (NASHP) completed a survey of 19 of the 21 states with mandatory reporting systems. Almost all of the states participating in the survey reported that facilities often cite concerns about possible medical malpractice litigation as a factor in under reporting of adverse events. While the fear of litigation is undoubtedly real, it remains an open question whether reporting of medical errors with or without legal protection actually leads to a dramatic increase in litigation, especially since most data are disclosed in aggregate form.[41]

Law states that any healthcare provider must be found negligent after a complete investigation. Therefore, any healthcare provider should not fear punitive response for reporting an ADE. Laws and malpractice insurance are in place to combat problems that may arise. Furthermore, another study revealed that only 37% of doctors believe that resulting ADEs in a hospital setting were directly attributed to them.

The health care system needs to transform the existing culture of blame and punishment that suppresses information about errors and adverse events into a culture of safety that focuses on openness and information sharing to improve health care and prevent adverse outcomes.[42]

E. Barrier: Lackadaisical attitude toward reporting & Barrier #6 Lack of education on reporting ADEs

The final barrier associated with reporting is that some healthcare professionals have expressed feelings of not having the desire to report. The data will reveal at what point healthcare providers are exposed to or educated on reporting adverse events. It is hypothesized that an earlier exposure period (i.e., in a healthcare training facility) will increase MedWatch reporting on behalf of healthcare providers. Healthcare providers would be familiar with reporting and would have a better understanding of its significance. Finally, they would have a more clearly defined role as a reporter.

V. Previous research studies associated with reporting adverse events

Study 1: Adverse drug reaction and medication error reporting by pharmacy students. By: Sears EL, and Generali JA.

A study was conducted at Baylor Institute for Rehabilitation to determine pharmacy students' knowledge of and ability to report ADRs and medication errors. The study demonstrated that students were becoming familiar with ADR and Medication Error Reporting programs via the college curriculum; however, there was an opportunity for greater exposure and understanding. Lastly, pharmacy programs should continually seek methods to strengthen the education provided to pharmacy students regarding these programs.[24]

Summary: This study has provided insight into adverse drug reaction and medication error reporting by pharmacy students. It noted that students were becoming more familiar with ADR and Medication Error Reporting. However, this study was conducted at one institution. Students responded positively to learning the curriculum. If pharmacy and other healthcare students were exposed to adverse drug reaction and medication error reporting programs and

practices more often, there may be an increase in the level of knowledge concerning adverse event reporting.

Study 2: Improving the quality of adverse drug reaction reporting by 4th-year medical students. By: Rosebraugh CJ.,Tsong Y., Zhou F., Chen M., Mackey AC., Flowers C., Toyer D., Flockhart DA., Honig Pk.

The United States Food and Drug Administration conducted a study in 2003 that indicated that as little as a 15-minute intervention could significantly improve the quality of adverse drug reaction reporting by 4th-year medical students. Academic medical centers should consider incorporating adverse drug reaction reporting curriculum into the clinical training of medical students.[25]

Summary: The previous study supported the idea that at least a 15- minute intervention could lead to improving the quality of adverse drug reaction reporting. This study was conducted using 4th-year medical students. The lack of education barrier could also be removed by improving the level of education of medical students. The FDA recommended that medical centers consider incorporating adverse drug reaction reporting into the clinical training of medical students. This thesis research also supports the idea that if students are provided with information for adverse event reporting during their training curriculum adverse event reporting may increase.

Study 3: Patient safety: helping medical students understand error in healthcare. By: Patey, Rona. Flin, Rhoa., Cutherbertson, Brain., McDonald, Louise., Mearns, Kathyrn., Cleland, Jennifer., Williams, David.

A study entitled, "Patient Safety: Helping medical students understand errors in healthcare," was conducted at the United Kingdom Medical School in England. During this study, 110 final year students were enrolled in a research study designed to test the knowledge level of healthcare errors reporting. A 5-h evidence-based module on understanding errors in healthcare was designed with a preliminary evaluation using self-report questionnaires. Participants completed two questionnaires. The first questionnaire was designed to measure students' self-ratings of knowledge, attitudes and behavior in relation to patient safety and medical error, and was administered before and approximately 1 year after the module. The second formative questionnaire was on the teaching process and how it could be improved and was administered after completion of the module. Before attending the module, the students reported they had little understanding of patient safety matters. One year later, only knowledge and the perceived personal control over safety had improved. The students rated the teaching process highly and found the module valuable.[26]

Summary: The above study mentioned above was conducted in England also suggests that there can be improvements in knowledge and perceived personal control through educational modules. The study was conducted within one year of the teaching modules. The students were also very receptive to the teaching process and found it very valuable. This study also demonstrated that improvements in education could lead to improvements in adverse event reporting and knowledge of reporting vehicles. Lack of knowledge of reporting vehicles and lack of education as reported above are common barriers listed by healthcare providers when

reporting adverse events to MedWatch. Lastly, healthcare providers' barrier of a lackadaisical attitude toward reporting may also be improved with these educational modules as reported in the above study.

Study 4: Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior. By: Coyle, YM., Mercer, SQ., Murphy- Cullen, CL., Schneider, GW., Hynan, LS.

Study participants were U.S. family practice postgraduate residencies of 3 years duration. This study included all 30 graduate trainees in the UT Southwestern Family Medicine Residency Program; with 10 from each of the three postgraduate residency years. They developed the program using the human error in medicine teaching approach of Gosbee and Stahlhut. [27] The program consisted of six 1-hour conferences on patient safety and near misses held monthly from July to December 2002, preceded by a 1-hour introductory lecture on medical error given by two of the study investigators (Coyle and Mercer) in July 2002.[27]

The content of the program's lecture included a brief overview of the impact of medical error on patient safety and had five educational objectives: (1) to define medical error; (2) to define medical event; (3) to describe the conditions that promote medical events; (4) to describe the process (root cause analysis) used to identify causes of medical events; and (5) to state the purpose of a medical event reporting system.[27]

Past studies have shown that medical events involving graduate medical trainees have the potential for causing harm to healthcare recipients. Incorporating patient safety education into graduate medical training programs offers the opportunity to improve patient safety. The study indicated that attending a patient safety educational program was key for promoting a positive

change in the attitude and behavior to graduate medical trainees to medical event reporting at the 6 month follow up. The study indicated that major barriers to medical event reporting were lack of time, extra paper work, and concerns about career and personal reputation. Faculty need to be role models for their graduate medical trainees by reporting medical events themselves, encouraging their trainees to report medical events, and providing emotional counseling and support to those trainees touched by medical events or participating in the medical event disclosure analysis process.[27]

Summary: This study revealed major barriers in medical event reporting which were lack of time, cumbersome paper work, and concerns about career and personal reputation. The above study suggested improvements in emotional counseling and healthcare provider reporting would also encourage trainee physician reporting.

Study 5: House staff and Medical Student Attitudes toward Medical Errors and Adverse Events. By: Vohra, Pamela D.; Johnson, Julie K.; Daugherty, Christopher K.; Wen, Ming; Barach, Paul.

A lack of formal patient safety curricula has contributed to the suboptimal training of medical students and house staff. Attitudes of physician trainees regarding medical errors and adverse events were surveyed in a pilot study. Five hundred sixty-three physician trainees were surveyed at an urban teaching hospital. Five domains were evaluated using a factor analysis as they relate to patient safety: knowledge, self-efficacy, awareness of safety culture, barriers/ facilitators, and awareness of human factors.[28]

One hundred fifty-eight (28%) trainees completed the survey, with 22% (n = 35) describing exposure to at least one adverse medical event. The survey showed good internal

validity and reliability. Respondents who reported exposure to adverse events demonstrated a lower awareness of human factor errors and lower awareness of the hospital's approach to safety. Older respondents scored higher on measures of self-efficacy than younger trainees. Self-efficacy is the measure of one's own ability to complete tasks and reach goals. [59] Exposure of physician trainees to errors and adverse events can have a negative effect on their attitudes and competencies. Exposure to adverse events and the institution's response may decrease both error reporting and the willingness to adopt safety practices. The results support the need for implementing a sustained patient safety curriculum that promotes learning regarding adverse events.[28]

Summary: The above study demonstrated a low awareness of medical adverse event reporting, a low awareness of human factor error, and low awareness of the hospital's approach to safety. Older physicians scored higher than newer trainees. This particular hospital did not have a standard safety curriculum to promote learning regarding adverse events. This research has revealed similar findings. Trainees are not aware of reporting procedures or adverse event reporting vehicles in their current hospitals. The older physicians interviewed in the author's research study were more aware of adverse event reporting vehicles and agencies as well. The research in this study suggests a sustained patient safety curriculum. The author's research would also suggest a patient safety curriculum to improve adverse event reporting practices.

Study 6: Attitudes and barriers to incident reporting: a collaborative hospital study. By: S M Evans, J G Berry, B J Smith, A Esterman, P Selim, J O'Shaughnessy, and M DeWit.

This study was designed to assess the awareness and use of the current incident reporting system and to identify factors inhibiting reporting of incidents in hospitals. The anonymous survey included 186 doctors and 587 nurses from diverse clinical settings in 6 South Australian hospitals (response rate = 70.7% and 73.6%, respectively). Most doctors and nurses (98.3%) were aware that their hospital had an incident reporting system. Nurses were more likely than doctors to know how to access a report (88.3% v 43.0%; relative risk (RR) 2.05, 95% CI 1.61 to 2.63), to have ever completed a report (89.2% v 64.4%; RR 1.38, 95% CI 1.19 to 1.61), and to know what to do with the completed report (81.9% v 49.7%; RR 1.65, 95% CI 1.27 to 2.13).[29]

Staff members were more likely to report incidents, which are habitually reported, often witnessed, and usually associated with immediate outcomes such as patient falls and medication errors requiring corrective treatment. Near misses and incidents, which occur over time such as pressure ulcers and deep vein thrombosis (DVT) due to inadequate prophylaxis, were less likely to be reported. The most frequently stated barrier to reporting for doctors and nurses was lack of feedback (57.7% and 61.8% agreeing, respectively).[29]

Summary: The previous study suggested that nurses were more likely to have access to a report, have completed a report, or know what to do with a completed report. Both healthcare providers did report having knowledge of the incident reporting system. The FDA states that doctors, pharmacists, and nurses report in that order respectively. This contradicts the above studies numbers about reporting. However, the authors' research suggests that knowledge of most adverse events was handled most often by pharmacists and nurses. Protocol, in most

incidents, states that all incidents are reported to a doctor. Therefore, this may account for why doctors report most often. Furthermore, this study suggested barriers to reporting for doctors and nurses were a lack of feedback and agreeing. The authors' research did not identify these barriers but doctors did report not asking nurses and pharmacists to report on their behalf.

Study 7: Assessing Hospitals' Use of State-Mandated Adverse Event Reporting Data. Final Report to the National Patient Safety. By: Kimberley Fox, M.P.A., Amy M. Tiedemann, Ph.D., Denise Davis Dr.P.H., M.P.A., Joel C. Cantor, Sc.D.

In 2002, Rutgers Center for State Health Policy conducted an exploratory study funded by the National Patient Safety Foundation to assess hospitals' use of state-mandated medical error and adverse event data in New York State, which has one of the oldest and largest state mandated hospital reporting systems in the country. Based on semi-structured telephone interviews with over 100 administrative and clinical leaders from a stratified random sample of 20 hospitals throughout New York State, the study investigated hospital leaders' awareness and perceived purpose of the state-mandated reporting system, the process by which hospitals collect and use this data, the barriers to use, and perceived value by hospital leaders and its impact on patient safety.[22]

The study also sought to identify key factors that either facilitated or limited the use of data from the mandatory reporting system within New York State hospitals. This report presents the findings and highlights "best practices" for collecting and utilizing such data as well as barriers that may limit its usefulness. Despite efforts by facilities to move towards a non-punitive "systems" approach to addressing medical errors, the primary barrier to reporting cited by nearly

all respondents was that reported errors would be used for punitive purposes either within the hospital or by the state. Physicians were identified as most resistant to reporting.[22]

Summary: The above study has identified fear of punitive retribution as a barrier to reporting. It also identified physicians as the most resistant to reporting. In the author's research, healthcare providers have identified fear of punitive retribution as a barrier to reporting. Punitive retribution barrier may have caused a decrease in adverse event reporting. Physicians and other healthcare providers would be held responsible for negligence if found falsely reporting adverse events.

Study 8: Residents Report on Adverse Events and Their Causes. By: Reshma Jagsi, MD, DPhil; Barrett T. Kitch, MD, MPH; Debra F. Weinstein, MD; Eric G. Campbell, PhD; Matthew Hutter, MD; Joel S. Weissman, PhD.

A study entitled, "Residents Report on Adverse Events and Their Causes," surveyed trainees at 2 teaching hospitals about experiences with adverse events (AEs), mistakes, and near misses, as well as the potential causes. Responses were obtained from 821 (57 %) of 1440 eligible trainees. Analysis was restricted to 689 clinical trainees. More than half (55 %) reported ever caring for a patient who had an AE. The most common types of AEs were procedural and medication related. More than two thirds of AEs were considered significant. Of the most recent AEs, 24% were attributed to mistakes. The most common reasons for mistakes, as perceived by residents, were excessive work hours (19 %), inadequate supervision (20 %), and problems with handoffs (15 %). In the last week, 114 respondents (18 %) reported having a patient with an AE; of these, 42 (37%) reported AEs involving a mistake for which they considered themselves

responsible. In addition, 141 (23 %) reported near-miss incidents in the last week for which they considered themselves responsible.[30]

In multivariate analyses, significant predictors of AEs in the last week were inpatient rotation, duty hours in the last week, and procedural specialty. Predictors of near-miss errors in the last week were inpatient rotation, days of fatigue in the last month, and postgraduate year 1 status. Conclusions: These findings support the perception that AEs are commonly encountered by physicians and often associated with errors. Causes of errors in teaching hospitals appear to be multi-factorial, and a variety of measures are necessary to improve safety. Eliciting residents' perspectives is important because residents may perceive events, actions, and causal relationships that medical record reviewers or observers cannot.[30]

Summary: This data suggested that adverse events were most commonly experienced by physicians. However, causation of errors included inpatient rotation, duty hours in last week, and procedural specialty. The author's research identified lack of time as a barrier to reporting. The correlation to lack of time to report ADEs experienced and excessive work hours was identified.

Study 9: Voluntary Electronic Reporting of Medical Errors and Adverse Events an Analysis of 92,547 Reports from 26 Acute Care Hospitals. By: Catherine E. Milch MD, N. Salem MD, Stephen G. Pauker MD, Thomas G. Lundquist MD, MMM' Sanjaya Kumar MD, MSc, Jack Chen BM, BS.

A descriptive study of reported events was conducted using the same electronic reporting system (e-ERS) between January 1, 2001 and September 30, 2003. During this study**,** twenty-six acute care nonfederal hospitals throughout the U.S. voluntarily implemented a web-based e-ERS for at least 3 months. Participants included hospital employees and staff. A secure, standardized, commercially available web-based reporting system intervention was utilized to collect data. Median duration of e-ERS use was 21 months (range 3 to 33 months). A total of 92,547 reports were obtained during 2,547,154 patient-days. Reporting rates varied widely across hospitals (9 to 95 reports per 1,000 inpatient-days; median=35). Registered nurses provided nearly half of the reports; physicians contributed less than 2 %. Thirty-four percent of reports were classified as non-medication-related clinical events, 33% as medication/infusion related, 13% were falls, 13% as administrative, and 6% other. Among 80 % of reports that identified level of impact, 53% were events that reached a patient ("patient events"), 13% were near misses that did not reach the patient, and 14% were hospital environment problems. Among 49,341 patient events, 67 % caused no harm, 32 percent temporary harm, 0.8 percent life threatening or permanent harm, and 0.4% contributed to patient deaths.[31]

Summary: The study noted that nurses reported nearly half the reports, while physicians only contributed to less than 2 percent. This study also utilized a standardized e-ERS to collect data about adverse event reporting. The authors' research also suggested a more standardized

method to collect adverse event data. The electronic-ERS system could also be used to collect data from other healthcare providers.

CHAPTER 3

METHODOLOGY

This was an exploratory qualitative case study from a theoretical perspective. The aim was to gauge the prospective on reporting adverse events from healthcare providers via focus groups and individual interviewing. The qualitative interviewing techniques were adapted from the text entitled *Interviews: An Introduction to Qualitative Research Interviewing* by Steinar Kvale, Sage Publications, Thousand Oaks California, 1996[32] and *Qualitative Interview Design: A Practical Guide for Novice Investigators* by Daniel W. Turner III.[33]

Sample

This study required that all eligible participants demonstrate a level of knowledge of and/or have experience utilizing an adverse event reporting system. Eligible participants were determined by using the inclusion and exclusion criteria. Eligible subjects included physicians, nurses, physician assistants, and pharmacists in the healthcare field. Physician assistants were also included because of the low enrollment of physicians. In the state of Georgia, physician assistants operate under the direct supervision of physicians and follow their reporting practices. Participants also had to be healthy male and female volunteers between the ages of 18-65.

The total population in the target area included enrolling 30 participants. In order to achieve, a 95% confidence level with a confidence interval of +/- 4, the researcher had to sample at least 28 participants.[34, 35] Due to conflicting enrollment schedules, only 28 participants were enrolled. The sampling method utilized was nonrandom or convenience sampling. The researcher utilized focus groups to reduce variation, simplify analysis, and facilitate group

interviewing. The study population was recruited from healthcare facilities, pharmacies, academic institutions, and governmental agencies. The researcher also utilized snowball or chain sampling to recruit and/or identify subjects of interest from sampling people who could refer other potential subjects to the study.[34]

Criteria for Inclusion

- Subject must be a registered and/ or licensed Nurse, Pharmacist, Physician Assistant, or Physician.
- Subject must be able to provide written consent (see Appendix E).
- The subject must also have prior knowledge and/or use of an adverse event reporting system.

Criteria for Exclusion

- A subject will be excluded from the study if they are not a licensed and/or practicing healthcare provider.
- A subject will be excluded from the study if they do not have prior knowledge and/or use of an adverse event reporting system.
- A subject will be excluded from the study if they would be labeled as a Consumer by the FDA. *Consumer* refers to any reporter who is not a healthcare provider.
- A subject will be excluded if they are a healthcare student enrolled at a healthcare facility.
- A subject will be excluded if they are a healthcare administrator.

Recruitment

The study population was recruited from healthcare facilities, pharmacies, and academic institutions from several cities and towns in the geographic locations of middle and southeastern parts of Georgia (USA). In addition, FDA personnel who were recruited for the study were from the Atlanta District and were contacted by phone. The researcher chose middle and southeast Georgia because of proximity to subjects selected. The area was also chosen because there was no prior research in the area that contained several medical institutions and research facilities.

Snowball or chain sampling was used to recruit and/or identify subjects from sampling people who knew people that would be good sources of information for study and/or good interview participants. The recruited participants suggested other healthcare providers who would be eligible to participant in the study. Nurses were recruited from a rehabilitation nursing home in a city in middle Georgia. Pharmacists were enlisted from three local private community pharmacies in middle Georgia. Physician assistants were recruited from a university in Savannah, GA. Moreover, physicians were obtained from a local hospital in and private practices in the same general area. Lastly, FDA personnel were contacted via the Consumer Complaint System (Consumer Complaint Coordinator) located in Georgia. All recruitment procedures were handled by the principal researcher via letter, email (see Appendix D), or phone call. Procedures were directed towards eligible study participants based upon information received in the initial interview.

These healthcare providers were chosen to gather a more comprehensive prospective of the barriers associated with reporting adverse events. Currently, physicians are the largest group to report. Pharmacists were chosen because they have the second largest reporting group. The population of registered nurses represents the third largest population for reporting. FDA

personnel where obtained to provide insight on behalf of the current regulatory reporting system. Even though consumers were also a large reporting population for MedWatch, they were excluded from the study because the aim of the study was to determine barriers experienced by healthcare providers. The consumers would not be able to provide enough insight into the healthcare profession for this particular study. The following provides a breakdown of participants according to classification of their profession: three pharmacists, six physicians, three physician assistants, and 16 nurses. These numbers were not chosen proportionally. They were simply chosen out of convenience. During recruitment, the researcher received the largest response from nurses from a single facility; however, it was harder to recruit doctors and pharmacists because of their inflexible schedules. Physicians and pharmacists were recruited from private individual practices.

Risk/Benefit Analysis

All information was confidential used only by the principal researcher. Any risk to subjects was negligible and all documentation was stored in a secure facility with all identifiers removed. Specific links to individual subjects and the data were not included. Responses were later reported as aggregate results. There were no foreseeable discomforts.

The primary benefit to this research was to identify barriers that may prevent health care workers from reporting adverse events through the FDA MedWatch system. If barriers were identified, more healthcare providers may acknowledge the importance of reporting and the barriers that confront them if given the opportunity through education. They may then want to take a more active role in reporting as well as asking for help with reporting from other healthcare providers such as pharmacists and nurses. Healthcare providers may also encourage consumer reporting to alleviate some of the stress from reporting due to barriers. Consumers can

now be properly educated on how to complete an adverse event report form by their healthcare provider and MedWatch Learn. So that they can begin providing the FDA with more quality reports. The FDA may also become more aware of the time commitment to reporting and would therefore develop a more systematic and convenient method of reporting. Healthcare facilities may also spend more time focusing on creating an environment conducive to adverse event reporting. This may be achieved by supporting healthcare providers in these endeavors and by encouraging reporting utilizing proper techniques and vehicles for reporting. This research may increase the overall knowledge of consumers, manufacturers, and healthcare providers.

Initial Contact

The researcher made initial contact with participants via phone, email, or letter. The estimated timeline to enroll study participants was two days starting October 9-11, 2011. To generate interest, possible participation and confirm inclusion criteria participants were notified by email, telephone, and/or mail. Based upon an agreed date, the participants reported to the principal researcher via phone or in-person for an individual interview according to the assigned schedule. The interview dates were scheduled between October 13-28, 2011 from 8 a.m. to 5 p.m. Prior to the interview, subjects were briefed on the study and presented with the Informed Consent (see Appendix E) documents. If the subjects chose to participate, they were fully enrolled in the study. Informed consent was obtained after the initial visit on October 13, 2011 by the principal researcher. The study was reopened with the IRB at UGA for increased enrollment. The enrollment process for part II of the study took place November 9-11, 2012 and March 3-5, 2013. Interview dates were November 13-18, 2012 from 8-5 p.m. However, due to scheduling conflicts, subjects were interviewed March 6, 7, & 15, 2013. The aim was to add additional subjects.

Disclosure

A potential bias was presented because the sample population members included members of the researcher's networks and/or organizations. However, the subjects were not encouraged to provide any particular answers nor were they compensated for their interviews. Healthcare providers were enlisted from a captive homogenous, snowball/chain, and convenience sample population. Most behavioral and social science studies use convenience samples consisting of students, paid volunteers, patients, prisoners, or members of friendship networks or organizations. Studies with such samples were useful primarily for documenting that a particular characteristic or phenomenon occurs within a given group or, alternatively, demonstrating that not all members of that group manifest a particular trait. Such studies were also very useful for detecting relationships among different phenomena.[37] The FDA personnel were not a part of this captive sample. Careful attention was allotted for this bias and generalizations gathered from this research can only be applied to this population and not necessarily the overall population of all healthcare providers.

Interview guide Design and Testing

The interview guide (see Appendix B) was developed by the researcher utilizing information gathered from literature about the barriers associated with reporting adverse events to MedWatch by healthcare personnel.[36] To help improve construction and readability, the instrument was pretested using two practicing registered nurses of three years and was revised based on these findings. All corrections were then accounted for, including bias and clarity of questions. During pretesting, the nurses had trouble defining adverse events. Therefore, the definition was included in the interview guide, based on definition in literature. A standardized, open-ended interview approach was used because the same open-ended questions are to be asked

to all interviewees of each subgroup. This approach facilitates faster interviews that can be more easily analyzed and compared.[38] Eligibility was determined based upon self-report via a screening questionnaire.

Survey Content

Participants were asked to report on healthcare adverse events. Questions were focused on the occurrence of adverse events, mechanisms used to report, sentiments towards reporting, and lastly opinions on how reporting could be improved. Data was gathered regarding barriers that might affect the likelihood of healthcare provider reporting adverse events. Each interview or focus group was planned to last no more than two hours.

Data Collection

Data collection instruments included an inclusion questionnaire (see Appendix B), a registration form (see Appendix B), an interview guide (see Appendix B) and a debriefing document (see Appendix C). Interviewing was recorded on an audio device Memorex Audio Recorder. To help ensure data security and privacy, all names were stripped from the audio records. Patients were required to give their identifier (i.e., subject one and background/working history). The subject's real name was only documented on the informed consent form, which was not being published. All identifying materials were locked in a secure file cabinet that only the principal researcher had access to. The retention period for the audio recordings was until research was complete in May 2013. Audiotapes were destroyed after analysis, based on the IRB approval process.

Data Analysis

The data collected during the interview was analyzed utilizing a data analysis process for analyzing qualitative data that was developed by John V. Seidel in 1998. This process focused on "noticing, collecting, and thinking about things."[39]

Noticing included making observations, writing field notes, and tape recording interviews to produce a record of the patterns, ideas or phrases that the researcher noticed during interviews with subjects. Once the researcher produced a record; she focused her attention on that record and noticed interesting things in the record. The researcher completed this by reading over the transcript several times. As she noticed things in the record, she named, or "coded," them.[39]

After transcribing the interview data, the researcher "noticed" to find similar thoughts on reporting, needs for improvement, and attitude towards reporting. Noticing also included noting the overall knowledge of adverse events, reporting mechanisms and protocols, and lastly overall sentiments toward reporting. Commonalities were coded using the A, B, C, D, E, F scheme. They were recorded into a research notebook and later into a Microsoft Office Document.

The coded data was then separated into categories. The data was broken into several elements based upon commonalities. The researcher sorted and sifted through the data and looked for types, classes, sequences, processes, or wholes to connect the data to the research. The aim of this process was to assemble or reconstruct the data in a meaningful or comprehensible fashion.[39] The goals were to: (1) collate and organize the data in way to effectively initiate a qualitative analysis, (2) look for patterns and relationships both within a collection, and across collections, and (3) make general discoveries about the phenomena being researched.[39]

A similar idea was expressed by Charmaz in 1983.[39] For Charmaz, who works in the "grounded theory" tradition, the disassembling and reassembling occurs through the "coding" process.[39] Codes serve to summarize, synthesize, and sort many observations made of the data. Coding becomes the fundamental means of developing the analysis. The researcher used codes to pull together and categorize a series of otherwise discrete events, statements, and observations, which were identified in the data.[39]

The researcher then categorized and coded the responses to all questions in the six domains by common themes and subthemes. The themes were developed by a consensus approach because the researcher reviewed responses to questions within each domain and developed a typology of themes to be shared and agreed upon. The data was then coded by theme and verified by audiotapes. A coding Mechanism was adapted from *Assessing Hospitals' Use of State-Mandated Adverse Event Reporting Data June 2004.*[22]

Lastly, the Michael Agar approach to analyzing data was employed to achieve triangulation. In 1991, Michael Agar described an inductive research process where the researcher reads and "notices many things" in the data record. By focusing on one portion of the "coded" data record at a time, the researcher began to construct general propositions about the data. Using Agar's approach, each portion was chosen at random and deliberately. The analytic process was not focused on gross analysis and summarization of a category of the data. Rather, it emerged out of preliminary coding and followed Agar's prescription of working with "a little bit of data, and a lot of right brain."[39] The analysis of each segment was investigated using a printed transcript of the interview, the actual audio transcript, and notes were coded onto the transcript when patterns were noticed.

Triangulation is a process of verification [checking for truth] that increases validity by incorporating three different viewpoints and methods. Triangulation was implemented by incorporating different research techniques. In this study, interviews, focus groups as well as multiple theories were used to analyze the data collected. This technique was implemented to achieve triangulation. In 1988, Wolcott suggested that triangulated techniques were helpful "for cross-checking or for ferreting out varying perspectives on complex issues and events" (p. 192).[40] Finally, these ideas, whether similar or different, were translated into the research. All findings were presented with detail. Limitations were also included.

Proposed Budget: No proposed funding

Figure 1. Proposed Budget.

IRB referral	September 8, 2011 October 30, 2012
Study investigation (subject recruitment)	October 9-11, 2011
Subject enrollment	October 12, 2011 November 9-11, 2012 March 3-5, 2013
Subject interview dates	October 13-November 4, 2011 November 13-18, 2012 March 6,7,&15, 2013
Data analysis/transcript encoding	November 1-5, 2011 March 16, 2013
Proposed writing	September 12-June 13, 2013

Figure 2. Timeline.

CHAPTER 4

RESULTS

The researcher surveyed healthcare providers from the Central Georgia area. The healthcare providers were interviewed individually and in focus groups. The participants enrolled in the study included three pharmacists, six physicians, three physician assistants, and 16 nurses. In summary, the barriers identified in this research were: difficulty in linking ADEs to a specific drug, lack of education, lackadaisical attitude toward reporting, cumbersome paperwork, lack of time, lack of knowledge of reporting vehicles, fear of punitive retribution, and failure to know which ADEs to report.

Barrier 1: Difficulty in Linking ADE to Specific Drug

A number of respondents found difficulty in linking an ADE to a specific drug as a barrier to reporting to MedWatch. In particular, nurses reported barriers with determining which medication caused an adverse event due to the patient population being on multiple medications. This finding was supported by Abelson (13), who noted that physicians have difficulty in determining whether an event was related to the cause of the disease itself or the result of the use of a product of the drug or device. The following respondents stated:

> Subject 12 (nurse, oral communication, Oct. 2011) stated, "Sometimes it is multiple medications working together to produce an event. So you have to kind of cross one out to get to the next to see what is actually the cause of the problem."

> Ten out of 16 nurses identified difficulty in linking an ADE to specific drugs as a barrier to reporting.

Barrier 2: Lack of Education

Several subjects identified lack of education as a barrier to reporting adverse events. In particular, they suggested that educating staff as well as patients would help the improvement of reporting practices. This echoes the findings of Rosenbraugh et al (25) who found that a 15-minute intervention can significantly improve the quality of adverse event reporting. The following respondents suggested that:

> Subject 17 (Director of Nursing, oral communication, Oct. 2011) concluded and said, "I think it is a knowledge barrier as far as the residents reporting an adverse event. I think it is an educational as well as a knowledge barrier in this rural area. A lot of residents do not understand the importance of reporting. You also have some nurses that do not take the time to educate residents on the side effects to look for."

> Subject 31 (Dentist, oral communication, March 2013) agreed that educating the patient is important. Subject 31 concluded with sentiments toward lack of education as a barrier by saying, "There needs to be more education especially in the dental profession. There are no continuing education courses. If I would have a question, I would contact the pharmacology department at the dental school."

Several subjects identified lack of education and a lack of knowledge of who to report to as a barrier for reporting adverse events. This is similar to the findings of Patey (26) who demonstrated that improvements in education could lead to improvements in adverse event reporting and knowledge of reporting. Garvaza et al (21) revealed that pharmacists have recommended continuing education and training to raise awareness on ADE reporting and that streamlining the reporting process may enhance pharmacists reporting behavior. Vohra (28) found that a lack of formal patient safety curricula contributed to the suboptimal training of medical students and house staff. The study suggested a sustained patient safety curriculum. The respondents concluded with the following:

> Subject 32 (Physician, oral communication, March 2013) also reported on the lack of education and stated, "I think we should have required medical education in the reporting process, and it should include who to report to."
>
> Subject 20 (Physician Assistant, oral communication, Oct. 2011) stated that there was no formal training on reporting adverse events. The statement is as follows, "No, there was no formal training at least not where I work anyway. For reporting adverse events, I learned about it from the pharmaceutical reps. There is no formal training. I would say that most of the adverse events are events that I have researched on my own or been familiar with or drugs that I prescribe on regular bases."
>
> Subject 20 also alluded to education as a solution to under reporting by physician assistants. Subject 20 stated, "I believe that training programs should teach students, medical students, nursing students, and PA students the proper channel that they should go about reporting these things. Employers should say before you begin work this is the system we utilize to report medical adverse event reports whether it be pharmaceutical representative event reporting whether it be a website or contact the pharmaceutical company directly. I believe there should be better training involved."

Barrier 3: Lackadaisical Attitude toward Reporting

A number of respondents found that they have a lackadaisical attitude toward reporting ADEs. In particular, they found it not necessary to report an event if the patient was deemed stable. Fox et al (22) attributed low reporting to the belief that reporting is unnecessary and ineffective. In a similar study by Sears et al (23), data revealed that hospital staff may not report events because of a failure to track care as patients move through multiple departments and caregivers.

> Subject 10 (Nurse, oral communication, Oct. 2011) said, "I think the reason a lot of nurses do not report is because as a traveling nurse or agency nurse we are not in the same facility all the time. They may feel like they may not have to report an incident that happened to a person because they will not be around to see the end result of what they have done. And it is shameful and it is embarrassing that not everyone is meant to be a nurse or caregiver. It can be very detrimental to the patient."
>
> Subject 19 (Nurse, oral communication, Oct. 2011) also agreed that not reporting if the patient was deemed stable. Subject 19 said, "I don't think they are reported as often as they should be. Out of 100 about 45% are reported. Usually nurses that I know of if a patient is okay. They don't report it."

Barrier 4: Cumbersome Paperwork

A few respondents cited cumbersome paperwork as a barrier to reporting. Drazen et al (6), stated that completing and filing forms for MedWatch (and VAERS Vaccine Adverse Event Reporting System) requires clinicians to adhere to several rational and systematic steps including recognizing that a medical problem may be an adverse reaction to a drug, remembering how and where to obtain the forms, and then investing substantial time needed in providing the required information. These multiple steps in addition to regular duties appear to contribute to substantial underreporting. The following subjects suggested:

> Subject 27 (Pharmacist, oral communication, March 2013) stated, "Sometimes it is the amount of information they are asking, and it is the time it takes to go through all of it. Some solutions include limiting the reporting form, the amount of information that is being asked, and the time it takes to do it."
>
> Subject 30 (Physician, oral communication, March 2013) stated, "They are more designed to give you an academic answer than for treating the patient. From my stand point, I am more concerned with treating the patient than statistics."

Barrier 5: Lack of Time

Several subjects listed lack of time as a major barrier to reporting adverse events. Coyle et al (27) found that physicians identified lack of time as a barrier to reporting. Jagsi et al (30) revealed a correlation between the lack of time to report ADEs and excessive work hours. Physicians in this study had a strenuous work load and were therefore limited in the amount of time to report ADEs. The respondents supported the previous research by stating the following:

> Subject 1 (Nurse, oral communication, Oct. 2011) said, "Time consuming you have to stop what you are doing. There is a procedure you have to follow. Nurses feel there is not enough time. If you feel like it is not going to cause a major problem then you do not report it."
>
> Subject 7 (Nurse, oral communication, Oct. 2011) stated, "In several incidents of giving medications or vaccines, you are so busy you do not have time to stop at that moment and put it down. This leaves room for error in remembering to do it or just having that time to

> go put it down where you see it. Time is a factor. Time is a factor in not reporting vaccine or medication reportable problems."
>
> Subject 28 (Physician, oral communication, March 2013) said, "It takes time to see the patient and/or call to report. You have more and more patients to see with less reimbursement."

Barrier 6: Lack of Knowledge of Reporting Vehicles

In previous research by Vohra et al (28) house staff and medical students' attitudes toward medical error reporting were examined. They demonstrated a low awareness of medical adverse event reporting, a low awareness of human factor error, and a low awareness of hospital approach to safety. Trainees were not aware of reporting procedures or adverse event reporting vehicles in their current hospitals. The results supported the need for implementing a sustained patient safety curriculum that promoted learning regarding adverse events. The current study found a low awareness of MedWatch with a variety of other possible reporting agencies when asking respondents about the knowledge of reporting vehicles. The responses were as follows:

> Subject 18 (Pharmacist, oral communication, Oct. 2011): "Probably knowing the best way to report and the right person to contact or the right agency."
>
> Subject 23 (Pharmacist, oral communication, Nov. 2011): "I have heard of MedWatch, but didn't know you could report directly to them. If it were a serious adverse event, we would forward it to the State Board of Pharmacists."
>
> Subject 28 (Physician, oral communication, March 2013): "I heard of the term. I didn't know there was an organization that I could report adverse events too. It would not be the place, I would go to report. I would report to poison control."
>
> Subject 30 (Physician, oral communication, March 2013):"I've heard of MedWatch, but I didn't know that I could report directly to them. I would report to CDC or a drug manufacturer if there was a drug reaction."
>
> Only 6 out of 28 subjects were aware of MedWatch including two nurses, two pharmacists, and two physicians. This accounts for only 21.5 % of the total population of this study.

Barrier 7: Punitive Retribution

According to Drazen et al (6), there have been suggestions that the anonymity of reporting and perhaps overcoming the barrier of liability concerns would motivate people to file more adverse events reports. In a study by Fox et al (22), the data suggested that the primary barrier cited by nearly all respondents was that reported errors would be used for punitive purposes either within the hospital or by the state. One of the respondents made special note of punitive retribution as a barrier to reporting, while others alluded to the fact of having to have malpractice insurance as a precautionary action. The response from the subject was as follows:

> Subject 23 (Pharmacist, oral communication, Nov. 2011) stated, "I think reporting is a very good. I think it is good as long as it does not led to punitive stipulations. That is the only way we will get better. But when you read articles about other adverse events, you will be on the lookout for these things. It will make you a better pharmacist because you will be able to counsel people about what they may or may not take.

Barrier 8: Failure to Know which Adverse Events to Report

The last barrier identified by this study included failure to know which adverse events to report. According to Abelson et al (13), it can be difficult to determine whether or not an adverse event has occurred or whether it should be reported. In some instances, an adverse event may not be considered until it has surfaced a second or third time, or until another physician has encountered it as well. In a similar study, Drazen (6) stated one issue with voluntary reporting is that clinicians report only when they think something is both significant and drug related. The large majority of adverse events are either not recognized or not reported, and there are unknown biases in the reporting that does occur. There were similar findings in this study. Several respondents did not know what events were considered severe enough to report or where to report it. There was a lack of knowledge of the parameters that constituted an adverse event. A few of the healthcare professionals did mention other medical resources and agencies, however,

few of them had heard of Medwatch as a reporting vehicle. The respondents' quotes were as follows:

> Subject 23 (Pharmacist, oral communication, Nov. 2011) stated the following about barriers to reporting, "I guess I just did not know. I do not know that much about MedWatch. Their needs to be more education on having an adverse event and defining what are adverse events.
>
> Subject 28 (Physician, oral communication, March 2013) stated that a large part of the problem is knowing what to report. She said, "For example a rash from antibiotics." She noted that you must make a judgment call on whether an event is adverse or a normal side effect.

Alternative Reporting Vehicles

As stated above in the last barrier to reporting, few healthcare professionals had heard of or used MedWatch as a reporting vehicle. Several of the practitioners used alternative reporting vehicles to report or document adverse events in their practices.

One alternative to reporting ADEs is the electronic-ERS system. In a study completed by Milch et al (31), 26 acute care nonfederal hospitals throughout the U.S. used this voluntary web-based system to report events. This study concluded with a significant number of adverse events recorded. The research also suggested a more standardized method to collect adverse event data. The electronic-ERS system could also be used to collect data from other healthcare providers. Subject 28 also reported utilizing electronic record systems as a way to improve adverse event reporting from a healthcare provider prospective.

Other respondents listed several alternatives for reporting in adverse events regarding their different facilities.

> Subject 4 (Physician, oral communication, Oct. 2011) has been a (physician) for six months. She stated that she would report adverse events to the attending physician, the

charge nurse, and to the online reporting system at her job called Prometheus. Subject 4 did have trouble identifying the correct name for the reporting system at her job.

Subject 14 (Nurse, oral communication, Oct. 2011) works at a state mental facility. At this facility the nurses report to the Medication Surveillance Committee. "I can't tell you how many we actually had. There were quite a few because I am on the medication surveillance committee and once a month we have to meet and all the medication errors and advertences are brought to the table. We discuss them and determine how they are going to be resolved and what type of resolution should be appropriate." "Once an adverse event is reported it is determined by the Medication Surveillance Committee what type of reprimand is warranted whether it is verbal, written, reeducation or reassignment."

Subject 18 (Pharmacist, oral communication, Oct. 2011) Subject 18 has been a pharmacist for 34 years and had not heard of MedWatch. He has never had an adverse event. When asked about reporting barriers, the pharmacist said, "There shouldn't be any barriers. They would come and tell us and we would know what needs to be done and contact the Pharmacy Association. It could be done. It is just a matter of knowing who to tell."

Subject 19 (Nurse, oral communication, Oct. 2011) Subject 19 reported having a medical compliance office in their facility for reporting. "We have a compliance office in our facility. So you have to do it on the computer and you put in your name, the patient name, when it occurred and what adverse event happened to the patient. It is like corporate compliance online."

Subject 20 (Physician assistant, oral communication, Oct. 2011) said that she has had to report two adverse events. In both instances, they were with medications where the patients experienced side effects and she had to report it to the pharmaceutical representative. The physician assistant stated, "And in both instances, I reported this information to the pharmaceutical representative that comes by the office periodically to ask about the medication and give us samples of the medication and give us information about the medications."

Subject 21(Physician assistant, oral communication, Oct. 2011) reported a diabetes medication with a GI side effect about a year ago. The event was reported to pharmaceutical representatives.

Subject 27 (Pharmacist, oral communication, March 2013) said, "General adverse events we report to a doctor. A pharmacist can also report to MedWatch."

Subject 28 (Physician, oral communication, March 2013) stated, she reported to the local poison control of Center for Disease Control and Prevention.

Subject 30 (Physician, oral communication, March 2013) stated reporting to alternative sites such as the CDC or drug manufacture to report adverse events.

In conclusion, the adverse events were being reported. However, there seems to be an inconsistency across professions and practices as to where they are reported. Few healthcare professionals had knowledge of the largest adverse event collecting vehicle, which is MedWatch. Furthermore, none of them had even used the site to report. It has been hypothesized that with an increase in knowledge of what constitutes adverse event reporting is and where to report may also increase reporting practices and the number of quality reports from healthcare professionals.

Overall Sentiments toward Reporting

The following statements gathered from this study reflect the sentiment toward reporting ADEs from this population. One integral part when determining barriers faced by healthcare professionals is to determine their attitudes toward reporting. The practitioners' attitude may be one of the key factors in determining whether to report or not. In a study conducted by Gavaza (20), the findings determined the overall attitudes towards reporting by pharmacists. The research determined that about 90 % of pharmacists believed that reporting serious ADEs would improve patient safety. However, 72.6% indicated that reporting serious adverse events was time consuming and over half 55.5 % of the respondents from this study believed that reporting serious ADEs disrupted the normal workflow. The following responses support the previous research findings toward the belief that reporting ADEs would improve patient safety.

> Subject 22 (Physician assistant, oral communication, Oct. 2011) stated, her sentiments towards reporting included, "I think it is something that is underutilized. It is something that is very important. As a result of having this interview, I think I will take it more seriously. An adverse effect could be death. I do not think a lot of time practitioners do not think about that. If there is a medication, especially a newer one, it is your responsibility as a practitioner to report these things to possibly prevent death in patients. It is something that is not taken seriously or at least in the realm I work in. A lot of practitioners should be educated on more than what they have been. It is not something that I learned in my school. I can tell you that. In my training, I was never taught the proper channel to report adverse events. I would definitely say that it is something that practitioners need to be educated on."

> Subject 21 (Physician assistant, oral communication) her sentiments towards reporting included," I think it is important. It is something that needs to happen so that we can try to cut down on the amount of adverse events that occur.
>
> Subject 29 (Physician, oral communication, March 2013) stated her sentiments toward reporting, "I think it is a good thing. As a medication has gone through its first set of trials, drugs can be recalled."

In conclusion, the study population did reflect overall good sentiments towards reporting with the belief that it would improve patient safety. However, due to the barriers revealed earlier, many have had trouble reporting as effectively as possible.

Adverse Event Reporting Improvements

In this research study, all healthcare providers were asked ways to improve adverse event reporting from a healthcare provider prospective. Many stated improvements in communication, record keeping, paperwork, and education would help. The following respondents ended with these insightful conclusions:

> Adverse event reporting could be improved as the subject 22 (Physician Assistant, oral communication) stated, "I think everybody needs to communicate a little bit better. Because communication is always the problem especially in a hospital when so many people are involved in one patient's care. Communication breaks down and once that communication breaks down it is a big problem. There should be little bit better protocol for making sure patients are taking the medication they are supposed to be taking."
>
> Subject 27 (Pharmacist, oral communication, March 2013) stated barriers for reporting were, "Complicated terms, format, or tools. It may be difficult for consumers to report. I would say the way of communication the event is the biggest barrier. It requires you to use technology. Not everyone is tech savvy."
>
> Subject 31 (Physician, oral communication, March 2013) suggested, "Advertise to the different societies. Use commercials to get the word out. Contact the general organizations: the American Dental Association, the National Dental Association, or the American Medical Association. Inform them and form a partnership with those specialties because they have a membership base to send out electronic information."

Reporting Responsibility

According to the survey in this study, physicians were the least likely of all staff to report adverse events. This is mainly because, within most hospital quality improvement processes, physicians are not expected to be the primary reporters of adverse events. This responsibility most frequently lies with nurses. Physicians are encouraged by administrators to report any events that they are involved in or aware of, but the ultimate responsibility for reporting is rarely theirs. Evans et al (29) suggested that nurses were more likely to have access to a report, have completed a report, or know what to do with a completed report. Knowledge of most adverse events was handled most often by pharmacists and nurses. However, the protocol in most incidents states that they report all incidents to doctors. This explains why doctors report most often. The FDA states that doctors, pharmacists, and nurses report ADEs in that order respectively. The FDA does recommend that doctors complete the reporting paperwork because it improves the quality of the report and provides insight into the patient history as well as the ADE.

This study's subject population supported the findings that nurses were the first line of defense in facilities such as hospital settings. They were the first to recognize an adverse event; however, they had to use the chain of command for reporting to the Director of Nursing and the attending physician. Pharmacists interviewed admitted they advised their patients, who reported experiencing side effects and possible adverse events from medications to consult their personal doctor for a follow-up. Pharmacists did not report any ADEs directly to MedWatch. The physician assistants that were interviewed stated that they reported directly to attending physicians or pharmaceutical representatives. It was noted that other hospital staff including nurses, physician assistants, and pharmacists do understand the chain of command for reporting

to a direct supervisor or attending physician, however, legally reporting for them is not mandatory. It is hypothesized that it must become an engrained practice for all healthcare providers to understand the responsibility and importance in reporting. If reporting was made mandatory or encouraged from other healthcare providers, such as nurses, pharmacists, and physician assistants, there may be an increase in reports received on their behalf from the FDA involving ADEs. The following statements pertain to reporting from a pharmacist or physician assistant prospective.

> When ask about where to report an adverse event, Subject 18 (Pharmacist, oral communication, Oct. 2011) stated: "Well I would say that I would have to report somewhere on the computer. I do not know that name; No.
>
> When asked about where to report adverse events and training, Subject 21 Physician Assistant, oral communication, Oct. 2011) stated, "It not something that I have been informed on or instructed in my job so far. I would report to my attending and they would probably report to the hospital. I am assuming because I have not really experienced any of that in my profession yet."
>
> When asked about where to report and training, Subject 23(Pharmacist, oral communication, Nov. 2011) responded, Yes, to having reported and reported to the State Board of Pharmacists. "I have heard of MedWatch; did not know you could report directly to them. Pharmacists are trained during school obviously and continuous online training."
>
> When asked about where to report and training, Subject 27 (Pharmacist, oral communication, March 2013) Yes, I have reported. I am not sure of the date. It has not been recently. Within the last month, I had to report to a patient's doctor that they were having one. I am aware of MedWatch. I was trained when I got my doctorate from the University of Georgia concerning MedWatch, and I learned that you can report adverse events to MedWatch. In obtaining my license when I went to school in New York, I learned to report to a doctor.
>
> When asked about where to report and training, Subject 19 (Nurse, oral communication, Oct. 2011) stated, "We have a compliance office in our facility. So you have to do it on the computer and you put in your name, the patient name, when it occurred and what adverse event happened to the patient. It is like a corporate compliance online. I have never heard of MedWatch before."
>
> When asked about chain of command for reporting, Subject 17 (Director of Nursing, oral communication, Oct. 2011) stated, "The chain of command for reporting: When an

> adverse event is found, they are automatically sent to the director of nursing. This is after the physician and family member have been notified."
>
> When asked about chain of command for reporting and reporting practices, Subject 14 (Nurse, oral communication, Oct. 2011) responded, "I can't tell you how many we actually had. There were quite a few because I am on the medication surveillance committee and once of month, we have to meet and all the medication errors and advertence are brought to the table. We discuss them and determine how they are going to be resolved and what type of resolution should be appropriate. Chain of Command reporting: charge nurses must review the MAR every day. We have medication nurses does the medication. The charge nurses have to review the MAR and they have cross-checking at the end of each shift. Someone from another unit will come and check your MAR so it is actually double checked twice. Most of our errors occur at night. Rarely do we any occur during the day, but they are always reported. There is a nurse administration on duty 24-7. There is an on call nurse administration at night that makes rounds."

Reporting Accuracy Levels

The accuracy levels of reporting varied greatly across the study population. All healthcare providers agreed that the ADEs were not reported as accurately or as often as they occurred. Of the 28 healthcare providers interviewed, only two said that they were reporting at a 100%. All other subjects were in the range of 5% to 80%. In a study by Dr. Levinson, Inspector General (23), various conclusions were reported. Hospital managers indicated that hospital staff members do not report all adverse events, although estimates of how many adverse events are not reported vary widely. In interviews, hospital managers gave estimates as low as 5% of adverse events reported to as high as "nearly 100 percent," attributed to focused training on identifying adverse events. Healthcare providers reported the following reasons for not reporting in order of prominence:

- Lack of follow-up by responsible staff when reports are made
- Lack of time to complete incident reports and documentation
- Fear of punitive action against self or a colleague
- Assumption that other involved staff will report

- Failure to track care as patients move through multiple departments and caregivers
- Difficulty in distinguishing adverse events from harm caused by underlying disease

Lastly, these reasons are reflective of the barriers experienced by the study population when reporting ADEs to the FDA.

Reporting at Federal Institutions vs. Privatized

In a study conducted by Drazen (6), Dr. Peter Kilbridge of Duke University reported that in their adverse event detection system, even with strong encouragement to report adverse events, approximately one out of every six events is logged into the voluntary reporting system. In comparison, estimates are that the ratio in community hospitals is 1 in every 80 events.

The study population contained 16 nurses that worked at privatized nursing facilities as well as those that were employed at federal institutions. The reporting agencies were completely different for each institution. The federal institutions provided for pharmacists to accompany staff nurses during med-pass visits to ensure accuracy of dosage as well as to help eliminate medication errors. The pharmacists also provided literature on adverse event reporting as well as educated the staff on reporting to MedWatch.

In another federal facility, the staff received quarterly training from the medical surveillance team. In contrast, the privatized institutions received educational training during school. Furthermore, they received no future training on adverse event reporting or medication error reporting once employed. All training practices and techniques were established by the individual nurses themselves.

This disparity in the dissemination of information may be to blame for inaccurate reporting levels as seen in the above research. It may be hypothesized that consistent training and

education directives should be addressed to all healthcare providers regardless of the ownership status of the facility.

Collective Conclusion across All Populations

The following statements were determined using the study population. Most of the interviews conducted were face-to-face with a few being conducted via the telephone. Only 21.5% of subjects had heard of MedWatch. Study data further demonstrates the barrier of a lack of knowledge of reporting vehicles. All of the physician assistants and pharmacists found it necessary to improve healthcare provider education in order to impact reporting practices. Only a few healthcare providers knew of the adverse event reporting system used at or by their facility. Furthermore, even fewer were trained on adverse event reporting.

- The most common form of reporting was verbal or face-to-face reporting followed by telephone and internet. Verbal was not listed during my research answers.
- Subject 3 (nurse), Subject 14 (nurse), Subject 23 (pharmacist), Subject 27 (physician), Subject 28 (physician), and Subject 32 (physician) all had knowledge of the FDA MedWatch system. Three out of 22 subjects enrolled knew of MedWatch, which accounts for 21.5% of participants.
- Six out of 6 physician assistants and pharmacists agreed that education and training is the best way to improve adverse event reporting. They all found it a necessary pursuit to improve adverse event reporting.
- Seven out of 28 healthcare providers knew of a different adverse event reporting system at their healthcare facility. However, three could not accurately identify the name of the system used. These systems were Prometheus, INN, and a compliance facility office.

- Eleven out of 28 healthcare providers have experienced an adverse event, which represented 39.5% of the total population.
- Only 5 of 28 healthcare providers had formal training on reporting adverse event reporting.

Limitations with Results

There were a few limitations with the collection of data and reporting of results. The audio device used to record the subject interview did malfunction twice. The interviews were either re-recorded or transcribed to the best of the researcher's ability. This may provide a potential bias because the transcript was not transcribed by a creditable second party. The initial target recruitment population called for 30 total subjects; however, due to time constraints and hectic schedules of healthcare providers, fewer subjects were enrolled. There was no impact on the study, however it did change the statistical confidence interval. Another limitation to this study was that the MedWatch personnel could not be reached after several attempts. There were a few questions the researcher wanted to ask to help with the clarification of the reporting practices. Several of the statements given by the healthcare providers were in fragments and grammatically incorrect; therefore, the researcher rearranged the statements without altering the content of the answers. Lastly, all conclusions drawn from this study must only be used on this population. Generalizations may not be placed on larger groups of healthcare providers. This is due to the potential bias of using convenience sampling to recruit participants. Participants were not encouraged to provide any answers nor were they compensated for their interviews.

- Subject 22 recording was not accurately recorded due to a malfunction in equipment.
- Subject 29 recording was not accurately recorded due to a malfunction in equipment, however it was re-recorded.

- Only 28 out of 30 projected participants were enrolled due to time constraints.
- MedWatch personnel couldn't be reached during initial contact for interviewing.
- Some answers were recorded in fragments and had to be rearranged grammatically for use in the paper.
- All conclusions drawn from this study population cannot be generalized to larger populations. They may only be applied to the sample population at hand.

Barriers Not Identified

During this study, there were several barriers that were not identified. They are listed below. These initial barriers were observed in previous research studies; however, they were not mentioned by healthcare providers during this study. The lack of patient history was reported in previous studies by pharmacists as a barrier for not being able to accurately diagnose an adverse event and subsequently report it. In previous studies, the barrier of a lack of compensation and limited support from employers was observed by doctors who were not compensated for their time and efforts. Several healthcare providers listed limited support from employers as a barrier to reporting. Lastly, mistrust of the Food and Drug Administration was not identified as a barrier. Furthermore, most of the healthcare providers did not list the Food and Drug Administration as a vehicle for reporting.

Barriers not identified:

1. Lack of patient history
2. Lack of compensation and limited support from employers
3. Mistrust of Food and Drug Administration

CHAPTER 5

CONCLUSIONS

After examination of this study's healthcare population, the data revealed several barriers to reporting ADEs to the FDA's MedWatch. The barriers that were identified included difficulty in linking ADEs to a specific drug, lack of education, lackadaisical attitude toward reporting, cumbersome paperwork, lack of time, lack of knowledge of reporting vehicles, fear of punitive retribution, and failure to know which adverse events to report. The study was original because the target population contained a broad range of years of experience within multiple healthcare settings in a particular geographic area. Gathering situational and personal perspectives from these various health care practitioners provided a contextual description that may assist in improving awareness of common reporting barriers to MedWatch.

Why reporting ADEs is Important?

Reporting to the FDA such "adverse events" as unexpected, serious side effects, accidental exposure, and product quality issues can prompt the agency to act- and it can also bring new safety information forward and help the FDA take appropriate actions, including;

- Making necessary changes on the label for a medication to better describe how the product should be used;
- Influencing how a patient receiving the product should be monitored; and,
- Issuing product recalls, warnings, corrections, or safety messages which FDA issues through MedWatch[57]

How can adverse event reporting be improved based upon the Researcher's Interview Data

1. Opportunities for Healthcare Professionals especially Nurses to Improve Patient Safety with MedWatch

Traditionally, nurses and other professionals have been educated and health care organizations have focused on independent action, personal responsibility and error free performance. This has led to a culture of hierarchy and authority in decision-making and a belief that mistakes made by health professionals represent personal failures. The IOM report also speaks to the need for developing a working culture where communication flows openly regardless of the authority gradient.[51]

Based upon the researcher's interview data, nurses have stated that if they were not afraid to report adverse events for fear of backlash from administration more adverse events may be reported. The subjects stated that most reports are not filed if the patient is deemed okay. Attitudinal adjustments may also change now that healthcare providers may see the importance of reporting. If the Director of Nursing would encourage reporting practices and implement training courses at privatization institutions, reporting practices may also improve here as well. Team training with new hires and once an error is committed is not adequate anymore. Training quarterly from the Department of Health Services or MedWatch can be given via a Podcast with a certification process at the end.

2. Advice to Healthcare Professionals for Improving Reporting Practices

The researcher's data has shown that continuing education programs are concerns for healthcare providers. Multiple healthcare providers suggested improvements in reporting practices as well as the attitudes if adverse event reporting was engrained through professional graduate training programs. The educational directives may be achieved through continuing education courses in conjunction with renewal of licensure or curriculum during graduate studies

that serve as an introduction to ADE reporting. Another way to better communicate and educate practicing healthcare professionals is to communicate with them through medical societies that they may be privy too. Several of the researcher's healthcare providers subscribe to these societies for current medical information. Why not utilize them as a resource for disseminating information periodically? One of the physicians in the researcher's study population suggested advertising to different medical societies. He suggested contacting the general organizations such as the American Dental Association, National Dental Association, and the American Medical Association. His rational included utilizing this partnership with

Several of the healthcare providers in the research were concerned with their careers and the stigma associated with reporting severe adverse events. However, if the FDA can ensure these healthcare providers that making the FDA aware is the best practice, it may lead to more reports on unsafe medications and practices.

According to research data there is a great disparity between federal and privatized institutions concerning resources and training information. There also needs to be a change in reporting practices based upon funding (i.e. federal vs. privatized reporting). Regardless of whom funds the institution the level of continued educational training and staff members dedicated to reporting should be somewhat equal. One federally funded program should not have the luxury of continued free education while the others such as the privatized intuitions have continued educational training with trained personnel. Finally, if government could support funding to increase continued education training classes for all, it would be much more beneficial.

How can adverse event reporting be improved based upon the literature review

1. Manufacturer Advertising

Further improvements in advertising can be made by working with manufactures to reach consumers. According to Fredric Cohen, M.D. on behalf of Consumers Union Advocacy group, the recent law passed to require print drug ads to provide a 1-800 number and website (FDAAA-P.L. 110-85) is a step in the right direction, but should be extended to include TV ads, which are viewed far more frequently and with a greater command of the viewing audience.[46]

A citizen advocacy group, Consumers Union, has requested that the FDA require all television advertisements for prescription drugs and over-the-counter drugs to include a toll-free number and a website address for the public to report side effects to the agency. All television advertisements for prescription drugs should include the following, "You are encouraged to report adverse effects of prescription drug medication. Log onto www.fda.gov/Medwatch or call 1-800-FDA-1088." The FDAAA (P.L. 110-85) required all print advertisements to include this statement, but this should be expanded to include TV advertisements. Statement for Grounds include all too often, drug advertisements fail to present the benefits and risks of using prescription drugs in an accurate and balanced way. It is often the newest drugs that are the most heavily advertised, and these drugs have the least known side effects.

Hence, 1.5 million people suffered from adverse drug events annually at a cost of approximately 3.5 billion dollars. [3] Including a toll-free number and a website to report side effects will increase the information the FDA has on drug risks and would increase awareness to consumers. Furthermore, television drug ads run far more frequently than print ads. Consumers are repeatedly faced with TV ads, with their pictorial power, compared to what is generally a

one-time scan in the print media. Including this number and website in TV ads would reach far more Americans than through print ads.[47]

Lastly, if the Code of Federal Regulations required all advertisements regardless of media to have information pertaining to reporting adverse event reporting such as the contact information above. It may be assumed with the influx in consumer involvement in reporting to MedWatch, that there might be an increase in reporting practices from consumers. This would only strengthen the consumer knowledge and reporting base.

2. Media Outlets

Media outlets and commercials have revolutionized the way manufacturers market to consumers. However, this research shows that this can also be used to educate the consumers on adverse event reporting. Americans are watching more videos online, on their cell phones, and on television, according to the Nielsen Company's latest "three screen" report. The report was covered the last three months of 2008 and showed that the average American television viewer watched more than 151 hours of television per month -- an "all-time" high -- up from more than 145 hours during the same period the previous year, Nielsen said. The increase in television watching is part of a long-term trend, said Nielsen spokesperson Gary Holmes.[48] If manufacturers and the FDA utilize television marketing to educate the consumers on the importance of reporting adverse events, the number of events reported by consumers annually may increase.

A current example of this educational programming included a series entitled MedWatch Today website launched in 2007. This television broadcast was produced on a local scale in 2009. The Community Health Care Centers Network continues to produce its health care advocacy web site (www.medwatchtoday.com), which saw more than 7,600 visitors a month last

year and gets e-mail feedback from regular readers from as far away as North Carolina and even China. The site, launched in 2007, is updated regularly with health news, videos, feature stories and leadership blogs. It also offers access to a medical library and other 25 resources designed specifically for residents of central California. More than 120 health-related stories and 65 health-related videos were produced and posted on the site during the past year.[49]

If the FDA utilized television broadcasting to produce an educational program about adverse event reporting, it may improve consumer education and as a result would increase consumer education. This would allow for an increase in knowledge pertaining to how to report adverse events and how to recognize when you are experiencing an adverse event.

3. **Multi-media Advertisements Improvements**

Currently**,** to spread awareness of the reporting mechanism, FDA is using social media including Twitter, email lists, and electronic newsletters. It is also getting help in this effort from librarians, consumer organizations, patient advocacy groups, health professional organizations and schools of medicine, pharmacy, and nursing. [54] These all are good means of communication; however, it is the belief of this researcher that a vast majority of the general public understands or knows what MedWatch is or what it is doing. Their needs to be information sent out through commercial advertising to explain what MedWatch is and how it can be beneficial to consumer's lives.

In conclusion, information regarding healthcare recalls and product safety must reach the consumer market as well as the busy healthcare professional. What better way to advertise than through healthcare professional societies, social media, and the manufacturers of the medication. In order to effectively attack the barrier of lack of knowledge on reporting practices, the government must pool together its resources to provide important information.

4. A further look at foreign government for solutions to reporting

While MedWatch has been considered the best voluntary system in the world, it still does not appear to be enough. [45] Raymond Woosley, a professor of pharmacology at Georgetown University in Washington D.C., thinks that to look at France in comparison to the U.S. shows that improvements can definitely be made. Woosley says, "In France, they have 30 centers around the country with people trained to look for adverse drug effects. They go into hospitals, look at charts, talk to patients, talk to doctors, fill out forms and enter them in a database." [45] If more personnel were hired by the FDA, this type of post marketing surveillance design could be implemented in the U.S. and may provide a solution to our problems with suspected underreporting. The responsibility would not solely be on the individual sometimes-overworked health professional. This solution could also be realized through the implementation of Consumer Advocacy groups in hospitals that were trained to look for adverse events. They would be able to compile a report and submit it to the FDA.

Future Implications for Research

Future research should focus on consumer reporting and the barriers experienced by that population. Consumers are the smallest reporting group; however they take the largest amount of risk with medication. The consumer's role in reporting is also very critical for detecting serious side effects from medicines given to children. These trials usually involve a very small study population and problems might not be detected until medicines have been used by a large number of children of different ages.[54] MedWatch has two interconnected goals to educate both the healthcare provider and their patients about the reporting of serious adverse events into the FDA and to facilitate that reporting. It is only logical that new educational directives be focused on that population.

With MedWatch's new initiatives, they created a consumer friendly volunteer reporting form (Form FDA 3500 B *See Appendixes A pg. 88*). The new consumer-friendly MedWatch reporting form launched the week of June 17, 2013 responded to consumer concerns that the form is too technical. FDA worked with groups such as AARP, Consumers Union, and the National Women's Health Network to develop a new consumer Form. [54] However, further research must exam this populations reporting practices as well as patient consumer knowledge of understanding adverse events and reporting vehicles such as MedWatch. It is hypothesized with the increase in knowledge adverse event reporting may increase from the consumer population.

Final thoughts

There were some limitations to this study however there were a few things the researcher would do differently. She would compile a larger study population thru better advertisements of the recruiting process. She would also vary my subject's demographics and not use the snowball approach for recruiting. Most of the subjects were nurses from the middle Georgia area. The researcher would like to include more physicians, pharmacists, and physician assistants. This would increase their ability to more accurately assess barriers faced by healthcare professionals.

Finally, given the clinical importance of post marketing surveillance, all healthcare providers (physicians, pharmacists, nurses, dentists and others) should look upon adverse event reporting as part of their professional responsibility. The American Medical Association and American Dental Association advocate (respectively) physician and dentist participation in adverse event reporting systems as an obligation. Further, the *Journal of the American Medical Association* instructed its authors that adverse drug or device reactions should be reported to the appropriate government agency, in addition to submitting such information for publication.[5]

Reporting can be increased if staff members are encouraged to report adverse events through such measures as strengthening enforcement of reporting, streamlining procedures, and ensuring confidentiality when possible. Procedures must be streamlined to educate healthcare providers on the chain of command for reporting, how to report and what to report. Confidentiality must be ensured so that healthcare providers will report without a fear of punitive actions or malpractice. However, all healthcare providers must realize through self-examination or education that they are the backbone of post-marketing surveillance system. The FDA needs their participation in order for post-marketing surveillance to thrive.

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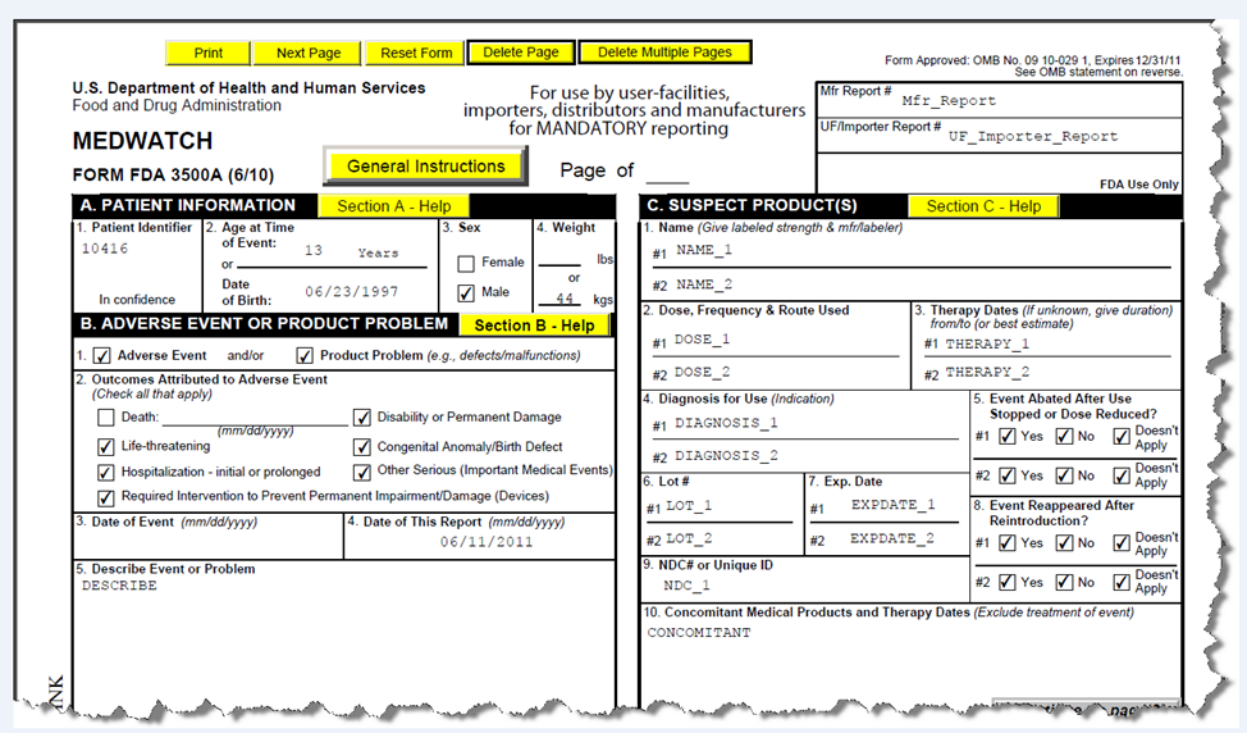
APPENDIX A

FDA FORM 3500



Print | Next Page | Reset Form | Delete Page | Delete Multiple Pages

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # Mfr_Report
UF/Importer Report # UF_Importer_Report

MEDWATCH

FORM FDA 3500A (6/10)

General Instructions

Page of ____

FDA Use Only

A. PATIENT INFORMATION Section A - Help

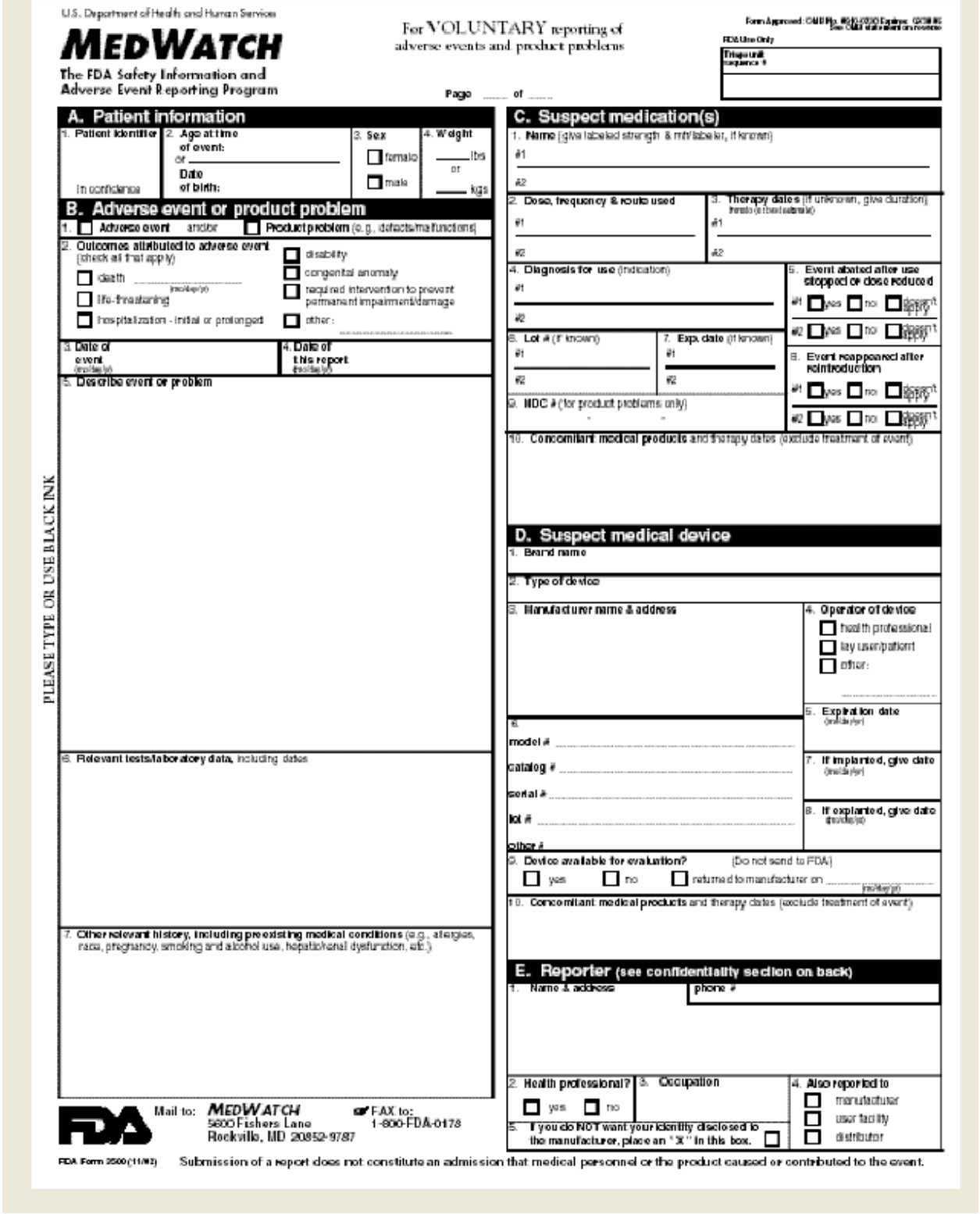
1. Patient Identifier: 10416 (In confidence)
2. Age at Time of Event: 13 Years or ____ Date of Birth: 06/23/1997
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or 44 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM Section B - Help

1. ☑ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*
2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☑ Life-threatening
   - ☑ Hospitalization - initial or prolonged
   - ☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☑ Disability or Permanent Damage
   - ☑ Congenital Anomaly/Birth Defect
   - ☑ Other Serious (Important Medical Events)
3. Date of Event *(mm/dd/yyyy)*:
4. Date of This Report *(mm/dd/yyyy)*: 06/11/2011
5. Describe Event or Problem: DESCRIBE

C. SUSPECT PRODUCT(S) Section C - Help

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 NAME_1
   - #2 NAME_2
2. Dose, Frequency & Route Used
   - #1 DOSE_1
   - #2 DOSE_2
3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
   - #1 THERAPY_1
   - #2 THERAPY_2
4. Diagnosis for Use *(Indication)*
   - #1 DIAGNOSIS_1
   - #2 DIAGNOSIS_2
5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☑ Yes ☑ No ☑ Doesn't Apply
   - #2 ☑ Yes ☑ No ☑ Doesn't Apply
6. Lot #
   - #1 LOT_1
   - #2 LOT_2
7. Exp. Date
   - #1 EXPDATE_1
   - #2 EXPDATE_2
8. Event Reappeared After Reintroduction?
   - #1 ☑ Yes ☑ No ☑ Doesn't Apply
   - #2 ☑ Yes ☑ No ☑ Doesn't Apply
9. NDC# or Unique ID: NDC_1
10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*: CONCOMITANT



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 02/28/05 See OMB statement on reverse

FDA Use Only

Triage unit

Page ____ of ____

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier — In confidence

2. Age at time of event: or Date of birth:

3. Sex: ☐ female ☐ male

4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
model #
catalog #
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address

phone #

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

FAX to: 1-800-FDA-0178

FDA Form 3500 (11/02)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement on preceding general information page)

MedWatch Consumer Voluntary Reporting (FORM FDA 3500B)

Section A – About the Problem

What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(including new or worsening symptoms)*
- ☐ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm *(for medical devices only)*
- ☐ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(Include date)*:_____
- ☐ Other serious/important medical incident *(Please describe below)*

_____
_____
_____

Date the problem occurred *(mm/dd/yyyy)*

Tell us what happened and how it happened. *(Include as many details as possible)*

_____
_____
_____ Continuation Page

List any relevant tests or laboratory data if you know them. *(Include dates)*

_____
_____
_____ Continuation Page

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

For more information, visit *http://www.fda.gov/MedWatch*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

APPENDIX B

RESEARCH INTERVIEW GUIDE FOR PHYSICIANS, NURSES, PHARMACISTS, AND MEDWATCH ADMINISTRATION

Research Interview Guide

Subject Identifier: _____

Date: _____ Time: _____

Research Survey Interview Guide:

Directions: Please fill out the personal information below.

Gender
Male
Female

Age
18-34
35-44
45-54
55-64
65+

Employment
Employed full time
Employed part time
Retired
Not Employed

Employment as:
Pharmacist
Nurse
Physician Assistant
Physician
Administrative

Race
White/ Caucasian
Black/African-American
Asian/Asian-American/Pacific Islander
Hispanic or Latino
American Indian
Other _____

Interview Guide for Physicians/Physician Assistants

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

- Death
  Report if you suspect that the death was an outcome of the adverse event, and include the date if known.

- Life-threatening
  Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.

- Hospitalization (initial or prolonged)
  Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
  Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).

- Disability or Permanent Damage
  Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

- Congenital Anomaly/Birth Defect
  Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

- Required Intervention to Prevent Permanent Impairment or Damage (Devices)
  Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

- Other Serious (Important Medical Events)
  Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.[13]

1. Does the above definition change your idea of an adverse event?
2. Have you ever had to report an adverse event and if so when?
3. To whom or where did you report this event?
4. Have you ever heard MedWatch and if so did you know that you can report directly to them?
5. Are staff members trained on adverse events for different prescription or over-the-counter drugs? When were you trained on reporting adverse events?
6. What are some common adverse events that have been reported or occurred?
7. How often do you believe they are reported?
8. What is the chain of command for reporting?
9. What form of communication do you use to report an adverse events telephone, internet form, fax, or mail?
10. How often do patients complain about side effects from medications?
11. After a patient complains of side effects, do you follow-up with research into that specific medication or into their patient history to determine if they are having an adverse event?
12. What are the follow-up procedures after reporting an adverse event?
13. Have you ever asked a nurse or pharmacist to report an adverse event?
14. What are some barriers that you have experienced when reporting an adverse event?
15. What are you sentiments towards adverse event reporting?
16. What do you believe can be done to improve adverse event reporting from a healthcare provider prospective?

Interview Guide for Nurses

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

- Death
  Report if you suspect that the death was an outcome of the adverse event, and include the date if known.

- Life-threatening
  Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.

- Hospitalization (initial or prolonged)
  Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
  Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).

- Disability or Permanent Damage
  Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

- Congenital Anomaly/Birth Defect
  Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
  Required Intervention to Prevent Permanent Impairment or Damage (Devices)
  Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

- Other Serious (Important Medical Events)
  Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.[13]

1. Does the above definition change your idea of an adverse event?
2. Have you ever had to report an adverse event and if so when?
3. How many adverse events have you had this year?
4. To whom or where did you report this event?
5. Have you ever heard of MedWatch? And if so did you know that you can report directly to them?
6. Are staff members trained on adverse events for different prescription or over-the-counter drugs?
7. What are some common adverse events that have been reported or occurred?
8. How often do you believe they are reported?
9. What is the chain of command for reporting?
10. What form of communication do you use to report an adverse events telephone, internet form, fax, or mail?
11. How often do patients complain about side effects from medications?
12. After a patient complains of side effects, do you follow-up with research into that specific medication or into their patient history to determine if they are having an adverse event?
13. Have you ever had trouble pin-pointing an adverse event due to patients being on multiple medications?
14. Has a doctor or pharmacist ever asked you to report an adverse event?
15. What are the follow-up procedures after reporting an adverse event?
16. Why doesn't the elderly population in a closed environment such as a nursing home report medical adverse events themselves?
17. What are some barriers in your opinion for reporting adverse events?
18. What do you believe can be done to improve adverse event reporting from a healthcare provider prospective?

Interview Guide for Pharmacists

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

- Death
  Report if you suspect that the death was an outcome of the adverse event, and include the date if known.

- Life-threatening
  Report if suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.

- Hospitalization (initial or prolonged)
  Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
  Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).

- Disability or Permanent Damage
  Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

- Congenital Anomaly/Birth Defect
  Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

- Required Intervention to Prevent Permanent Impairment or Damage (Devices)
  Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

- Other Serious (Important Medical Events)
  Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

1. Have you ever had to report an adverse event and if so when?
2. To whom or where did you report this event?
3. Have you ever heard MedWatch and if so did you know that you can report directly to them?
4. Are staff members trained on adverse events for different prescription or over-the-counter drugs? And when were you trained on how and when to report adverse events?
5. What are some common adverse events that have been reported or occurred?
6. How often do you believe they are reported?
7. What is the chain of command for reporting?
8. What form of communication do you use to report an adverse events telephone, internet form, fax, or mail?
9. How often do patients complain about side effects from medications?
10. After a patient complains of side effects, do you follow-up with research into that specific medication or into their patient history to determine if they are having an adverse event?
11. What should I do if I am experiencing an unexpected side effect from a prescription or over-the-counter medication?
12. Where should I report an adverse event?
13. Will I be able to report an adverse event through you?
14. How often do you have patients to come in and ask you to report an adverse event?
15. What are some of the barriers in your opinion for reporting adverse events to the FDA using MedWatch from a pharmacist's prospective?
16. What are some of the barriers in your opinion for reporting an adverse event to the FDA using MedWatch for a consumer?
17. What are your sentiments towards reporting?

Interview Guide for MedWatch Administration

1. How many adverse events do you experience each year?
2. How often do you receive calls from the Consumer Complaint System?
3. What products are mostly reported?
4. Do most consumers experience the desire to speak with a physician?
5. Do they ask what will happen next or about a follow-up visit?
6. Do you ask how they found this number, website, etc.?
7. I have noted some improvements to the MedWatch System including the e-submitter software, what are some of your other future indications for consumer reporting?
8. What challenges do your foresee manufactures facing?
9. What challenges do most consumers face when reporting?
10. What improvements towards consumer education on adverse event reporting are slated for the future?
11. What are some of the barriers that healthcare professionals have cited in response to reporting Adverse Events to the FDA?

Interview Answers

Subject 1 Nurse 40 years

1. No
2. Yes, I had to report an adverse event on several occasions medication errors have been made. You report to your Director of Nursing, he in then reports to pharmacist to fill out a medication error sheet.
3. Probably only one.
4. To DON
5. No, I did not know that.
6. Yes
7. Mostly medication not given properly. Medications might interact with another one. Allergy to medications that the doctor is not aware of.
8. Not as often as they should. Time consuming you have to stop what you are doing. There is a procedure you have to follow. Nurses feel there is not enough time. If you feel like it is not going to cause a major problem then you do not report it.
9. Director of Nurses; if not available notify pharmacists and then doctor
10. All
11. A lot. A lot of time, we do not recognize them as side effects. Usually until after they complain several times then we recognize it might be a side effect of the medication.
12. Both
13. Yes, that is the problem.
14. No
15. Check nurses notes. You check the patient to see if patient is doing better. Check with DON to see what happened as far as recommendations.
16. They are afraid. Sometimes they are not aware that it may be from a medication. I think mostly just the fear. A lot of them tolerate a lot of discomfort. They do not realize it may from the medication.

Subject 2 Nurse 20 years

1. No
2. No
3. One
4. DON
5. No
6. Yes
7. Had some adverse to medications that had to be reported.
8. During a year's time, probably about three times during the year.
9. We have to report to supervisor. Then our supervisor sends it in to the state.
10. Telephone and fax
11. Not often
12. Yes, we look at resident history and physical conditions and follow from there on.
13. No
14. No
15. Monitor patient for any other reactions

16. We have a lot of dementia residents. Who are not able to report and a lot of them are not aware of what to report with or what is going on with that medicine. What they are looking for?

Subject 3 Nurse 28 years

1. No
2. No
3. None that I know of.
4. No where
5. Yes. How did you hear about MedWatch? From the pharmacists that comes in and makes rounds with you. You have to do a med pass with the pharmacists. He also is doing research. Then he makes sure you are doing it correctly. They send you a pamphlet on different medication if a new one comes out. How often do they come around? Mostly once a month or every two weeks according to whatever schedule they have. We have regular pharmacists that come around to check the cart to make sure we do not have any outdated meds. They do a med pass with each nurse.
6. Yes
7. Adverse reactions to different antibiotics.
8. Rarely
9. Notify DON and then physician of any adverse reactions to any prescription or medication.
10. Telephone
11. Very rarely
12. Yes
13. Yes
14. Yes
15. First of all, you take a patient's vital signs to make sure they are easy and unlabored. Then you notify doctor and DON.
16. Mainly a lot of elderly people do not know about different medication or nursing homes. So they tell their families and you are the last to know really.

Subject 4 Physician 6 months

1. No
2. No, I have not.
3. To my attending physician, the charge nurse, and to online reporting system at my job. Prometheus online reporting system; not sure.
4. No, I have not heard of them.
5. No
6. That I have heard of, wrong site surgeries. Once of month.
7. Fifty to 60% of the time
8. You would tell your immediate supervisor, which would be an attending. Then you would tell your charge nurse and then report on online reporting system.
9. Telephone and internet
10. Daily
11. Yeah
12. That I am not actually sure.

13. No, I have not.
14. I have not reported one. No, barriers.
15. I think no matter how big or small. They should all be reported.
16. People can be more careful and pay attention to what they are doing .Sometimes it is usually because people are in a rush and they are impatient. Physicians from doing their job.

Subject 5 Nurse 28 years

1. No
2. No, Never had.
3. None that I know of.
4. You would report to the DON and doctor.
5. No
6. Yes
7. Medication Errors
8. Not often enough.
9. DON therefore she reports to doctor.
10. You use all of the above. Maybe telephone.
11. Not often
12. Yes
13. Yes
14. No
15. You have to monitor the patient. You have to notify his or her family. You also have to let the doctor know of any changes in his condition.
16. A lot of times, they are not aware because of their condition.

Subject 7 Nurse 40 years

1. No
2. Yes, approximately five years ago
3. None
4. VARS: allergic reactions to medications; vaccines.
5. No
6. Not in my field. Other than the VARs and reportable accidents.
7. Hives and swelling of the arms of legs; fever and temperature
8. Approximately in my incident about 50% of time.
9. I report to my lead nurse and then she instructs me on what to do. Sometimes the lead nurse is the first one to see the problem.
10. Telephone usually
11. Maybe 25% of the time
12. Our rule is to check the patient and problem with patient. Tell the patient if the site of the injection is swollen and varied over a 24- hour period. We tell them they can go to M.D and the let them check or continue to follow our protocol.
13. No
14. No
15. Follow up procedure is to check back with patient have them to call us and let us know if they needed any medical attention or any further attention pass coming to us.

16. In those incidents they are older and do not understand. Some that are informed and know what to do and do report it. Several really do not know what is going on in nursing home. The elderly lots of time do not understand.
17. In relation to public health versus hospital, nursing, nursing homes, and prison systems in our reporting when given vaccines we have to write on our computers lot numbers. Especially in the computer if we have them. These lot numbers can be referred back to in result of these incidents whether several children come in with irritate or joints or hives or any type reactions. Instead of the vaccine preventing the vaccine, they come up with the illness. These lot numbers will be referred back too. Hospitals do not the nurses are not required to put in lot numbers. Prison systems are not required to put in lot numbers. Lot numbers are very valuable in the incidents of reactions. These particular problems as chicken pox, measles not be contained; this is a way of going back referring to what lot number were used and that something did go wrong with this medication or vaccine.
18. In several incidents of giving medications or vaccines, you are so busy you do not have the time to stop at that moment and put it down leaving room for error in remembering to do it or just having that time to go put it down where you see it. Time is a factor. Time is a factor in not reporting vaccine or medication reportable problems.

Subject 8 Nurse 2 years

1. Nope
2. Nope
3. I am unsure.
4. You report it online and tell your supervisor. Where would you report it online? We have this website. I think we fill out an incident report. I think it goes to inspection employers and other layers. What is the name of the website? IN
5. Yes: nope
6. Yes
7. Increase heart rates due to certain medications and sometimes a prescription will be written for a drug the patient is allergic too and you have to report that.
8. Rarely
9. Go to IN fill it out. Tell your supervisor and I think from them I don't know. I think they report it to someone over them. Who is your supervisor? Director of Nursing
10. Internet and I think they are supposed to mail out consent or contact the family. So telephone and internet.
11. 1 out of 10 people
12. A patient will use any excuse why not to take a medication. And after they take it if they don't like it. Will make up an excuse to say I don't like it because so forth and so forth.
13. Yes
14. Nope
15. We were just told to report and they would follow-up. They said we and I am assuming managers or directors.
16. They don't report because I guess they probably want you buy the drug.

Subject 9 Nurse 25 years

1. No
2. No
3. None
4. DON
5. No have never heard of it
6. Yes
7. Most common wrong medication.
8. I don't believe they are reported that often. It is just from working in that environment and seeing things and working in that environment.
9. Being a nurse if you were to make a medication error, you would tell your supervisor, your supervisor would tell your DON and from their call the doctor.
10. Telephone
11. Hardly ever
12. No
13. Yes
14. No
15. Discontinue medication or whatever they think caused the adverse event.
16. Being elderly they usually don't know. They usually don't think that this medication is making me sick.

Subject 10 Nurse 4 years

1. No
2. No, I have not.
3. This particular facility that we are currently in; I am not sure.
4. I have not reported.
5. No, I have not heard of MedWatch.
6. Yes, they are.
7. In this particular facility, I am not aware. In other facilities, where I work the one that stands out the most is an incident with a Heparin drip which is a blood thinner. The rate of which was not set appropriately. The patient died as a result. They had too much of that medicine.
8. I believe they are reported often, but not as often as they should be.
9. In general nurses, well any particular individual there is a chain of command. If it is a CNA (Certified Nurse Assistant), they should contact a nurse or any other licensed individual to help with the procedure. You know to report that incident. If it were a nurse, themselves then they would get right to business to correct the incident. If it were a result of medication error, then they would report to physician. But, initially they take charge of the situation themselves. If it something that can be corrected such as stopping a particular drip of a medication. You would realize that medication is being over administered or under administered. Then you would need to do what you need to do immediately. Then follow the chain of command for reporting to the physician and risk management and your facility.
10. None of those in general. I imagine if anything was to go beyond what you would do verbally as far as telling someone else and then recording that incident down in writing. If

anything needs to go fax or outside of the facility for any reason risk management or upper echelon hospital or nursing home would take care of that.

11. Patients complain a lot about side effects but it is difficult to determine whether or not those side effects are coming from that medication or the reason they are taking that medication. Sometimes it is hard to decipher.
12. We actually do both. Initially you would interview that person concerning the side effects asking questions that would further give you information about what causes, when, where, how, And what lessens? Then go to that person chart and review their history as well the medications they are taking and then do a background advertisement.
13. It is hard to determine whether or not the multiple medications make it difficult to pinpoint what causes an adverse reaction. Is it something totally, outside what the patient is taking, is it the reason this incident has occurred or it is a combination or medication that should not have been mixed.
14. Yes, doctors what to know not necessarily adverse events because that is something you would do naturally, but adverse reactions definitely.
15. Follow-up procedures after an adverse event would be to monitor that patient. Stop any medications or any actions that you believe would be harmful to that patient.
16. The nursing home patients are generally elderly and have problems with dementia and Alzheimer's. Some may just be reluctant for fear some kind of retribution. You never know what people are thinking. You can never be quite sure unless it is yourself. How people are being treated outside of the immediate care you are giving them and they may be reluctant to report for fear of being mistreated or not being paid attention too.
17. I think the reason a lot of nurses do not report and not necessarily just nurses do not report incidents because as traveling nurses or agency nurses are not in the same facility all the time. They may be in a facility one day and working in another facility in another state two or three days later. They may feel like they may not have to report an incident that happened to a person because they will not be around to see the end result of what they done. And it is shameful and it is embarrassing that not everyone is meant to be a nurse or caregiver. It can be very detrimental to the patient.

Subject 11 Nurse 13 years

1. An adverse event can be different things not necessarily caused by medication or something of its properties. It is according to the resident and what to expect. That we have to note it. (subject 11)
2. No subject 10, 11, and 12
3. None
4. Subject 11 since we did not have any to report. Had something have happened we would report to our Director of Nursing and nursing home administrator and they would report to doctor. Second interview> you would go through the channels and report to DON, then call doctor and family and physician. Then DON would handle it.
5. Never heard of them.
6. Yeah
7. Nausea, vomiting diarrhea. If on Coumadin could have a bleed out. Bruising, respiratory distress.
8. I don't really how often they are reported, but for me they are reported every time.
9. DON, Doctor

10. Reported to DON and then do paperwork. Then I call Doctor on phone to report it.
11. You can really determine because sometimes they don't know their side effects because they have dementia or Alzheimer's and they just don't know what side effects are. So the Certified Nurse Assistants and nurses look for side effects and report to doctor.
12. Yes, because you can go to the chart look and see what is in the chart or you can go to the drug book to look up the drug that they are on and especially if it is a new one you can see what their side effects are.
13. N/a
14. Yes, because if you have a new order that sometimes we have an order for Coumadin at the same time. You have to be careful to make sure they don't clash.
15. Report and turn over to DON and doctor. Your part is through unless they ask you to do something.
16. Because at a nursing home situation as I said you have dementia, Alzheimer's, confusion, they don't know what to look for or feel in an adverse event and they can't tell you how they feel. You have to have nurses and CNAs look for those adverse events and then you handle them.

Subject 12 Nurse 1 year

1. Yes
2. I have never had to report one.
3. None. None have been reported.
4. If we were to have one, we would go up the chain of command as a charge nurse then to DON then to Doctor.
5. I have not.
6. Yes
7. Common ones; adverse events nausea vomiting from antibiotics. Bleeding from Coumadin and heparins and aspirins. And things like that.
8. I hope they would be reported every time. With the time it takes you; you never know.
9. n/a
10. Verbal to DON or doctor to see if there is anything you can do right then to fix the problem. Then there would be some type work file or follow up with.
11. Sometimes often depends on the medicine. A lot of more medicines are more apt to different side effects. Depending on what the side effects are. If it is nausea not reported. If it is diarrhea and vomiting or bleeding bring that forward.
12. Yes, we go through and make sure there is no history or nausea whatever it may be then we would go to a drug book or call the MD to see what could be going on and how we could step in to fix it.
13. Sometimes. Sometimes it is multiple medications working together to produce an event so you have to kind of cross one out to get to the next to see what is actually cause of the problem.
14. Yes, they do quite often when a lot of different medicines that cause a lot of different side effects such as Coumadin and bleeding medications. They ask you to watch the bleeding closely. Things like that.
15. Just watch the resident and follow any medications orders that the doctor may order. If they order any medications, that my counter-act something be on the watch for the counteraction and more reactions that come from the new med.

16. Some of them don't have the mental capacity to report. They are not there. They aren't oriented to their name. Or the situation going on. They don't have it in themselves to do it. It is important in nursing homes for nurses to step up and be the advocate for the patient.

Subject 13 LPN Nurse 21 years

1. No
2. No
3. Very few if any
4. To my Director of nurses
5. Never of heard of them
6. We are trained.
7. Not very many if any. Basic side effects on meds. Reported to the doctor.
8. I have no idea.
9. Chain of command for reporting is to go to the Director of Nurses and then she will take it to the administrator.
10. Telephone
11. Very few; rarely
12. You have to do both.
13. No trouble
14. No
15. Follow up if medication has been changed or whatever. Daily for seven days.
16. They can't do it. Nurses have to do it.

Subject 14 Registered Nurse 36 years

1. No
2. Yes, I have reported one in 2010. It was situation where the client got the wrong dose of medication at my job we call that a medication advertence.
3. I can't tell you how many we actually had. There were quite a few because I am on the medication surveillance committee and once of month, we have to meet and all the medication errors and advertence are brought to the table. We discuss them and determine how they are going to be resolved and what type of resolution should be appropriate.
4. Well the committee chairperson actually does the reporting to the state. I have to report to my manager who she reports to Dr. Sanders.
5. Yes, I heard of MedWatch and I did know you could report directly to them but I have never done so.
6. Yes
7. Medications that have a specified date start and stop time not being stopped in time. Missed doses, doses not being put on Medication Administration Records, wrong doses and wrong time.
8. Every time
9. Chain of Command reporting: charge nurses must review the MAR every day. We have medication nurses does the medication. The charge nurses have to review the MAR and they have cross-checking at the end of each shift. Someone from another unit will come and check your MAR so it is actually double checked twice. Most of our errors occur at

night. Rarely do we any occur during the day, but they are always reported. There is a nurse administration on duty 24-7. There is an on call nurse administration at night that makes rounds.

10. Medication Adverse Form
11. Rarely
12. Yes
13. Yes
14. No
15. Once an adverse event is reported it is determined by the Medication Surveillance Committee what type of reprimand is warranted whether it is verbal, written, reeducation, or reassignment.
16. Most of the time they are not capable. I don't think and most of time in those type of situations I don't think, those people are on so many medications it is hard to pin-point if whatever is going on is a medication adverse event.

Subjects 15 Nurse 7 years /Subject 16 Nurse 32 Years

1. Subject 15: no subject 16: no
2. Subject 15 and 16 no
3. Subject 15: I don't know. Subject 16: I am not aware of any adverse event occurring this year.
4. Subject 15: Doctor, MD. Subject 16: Physician and leave documentation for administrative staff.
5. Subject 16: No
6. Subject 15: Yes Subject 16: Yes
7. Subject 15: Rashes. Subject 16: In the past couple occasions some minor reactions to medications that were reported to the physicians with no serious outcome.
8. Subject 15: not sure. Subject 16: As far as I know, I am concerned it is always reported.
9. Subject 16: Physician and administrative staff. Subject 15: Physician, administrative staff and family.
10. Subject 15: Telephone Subject 16: Telephone and written documentation to administration staff.
11. Subject 16: Occasionally minor complaints.
12. Subject 16: I believe so. Subject 15: I do.
13. Subject 15: No. Subject 16: Yes, there has been some difficulty in the past. The elderly population being on multiple medications.
14. Subject 15 and 16: no
15. Subject 15: I would monitor the patient closely and send to hospital so they can have IV fluids or whatever they need. Subject 16: I am not aware of what. I know that I report to the doctor and that written documentation and that the report is completed and given to the administrative staff. Subject 15: Would you observe their ABCs? Their airways, breathing, and circulating so that the event does not lead to death. Subject 16: Sure you would do that but as far as reporting.
16. Subject 15: Most of them have cognitive difficulties. Most of them have Alzheimer's and dementia and do not know themselves. Subject 16: I would agree. Their ability to understand to understand medications and side effects.

Subject 17 Director of Nursing 20 years

1. No
2. Yes, probably about a month ago. Had a resident to receive some extra doses of medication that they should not have.
3. On average probably about five.
4. We report it on an adverse event form. We kept it in a folder here at the nursing home. The report also goes to notify the doctor and family members of the adverse event.
5. No
6. Yes they are.
7. Some adverse events not necessarily medication administration. Not doing blood sugars. Not transferring medication correctly on the MAR. Having the medication over the advised ordered date.
8. They are reported when they are found. Out of the five that we have had each time.
9. The chain of command for reporting: When an adverse event is found, they are automatically sent to the director of nursing. This is after the physician and family member have been notified.
10. Telephone
11. We really do not have a lot of residents that complain about side effects. We may have to talk them to identify side effects. Our population is an older population and we have to ask them questions about certain side effects to find out whether or not they had them.
12. Yes, we used the desk PBR, The Drug Handbook. To find out if they if there complaint is legitimate for that medication. Well patient history, make nurses note about that side effect.
13. Sometimes
14. No
15. Family education on the occurrence.
16. I think it is a knowledge barrier as far as the residents reporting an adverse event. I think it is an educational and well as a knowledge barrier in this rural area. A lot of residents do not understand the importance of reporting. You also have some nurses that do not take the time to educate residents on the side effects to look for.

Subject 18 Pharmacists 34 years

1. The answer is no. Not that I can recall.
2. Well I would say that I would have to report somewhere on the computer.
3. I do not know that name no.
4. Pharmacists and technicians yes trained. Trained every year.
5. Basic ones listed in the literature. Obviously not happened that frequently. Basic side effects when they get the drug. Skin reactions to the sun.
6. Seldom
7. Tell me and doctor
8. Telephone
9. Rarely
10. Absolutely
11. If you ask me about it, I would look to see if the side effect was common in the literature. If it were indeed something, I would suggest that you tell your doctor about it so that they could change your medication.

12. Pharmacists and doctor
13. Absolutely
14. They do not.
15. Probably knowing the best way to report and the right person to contact or the right agency.
16. There shouldn't be any barriers. They would come and tell us and we would know what needs to be done and contact the Pharmacy association. It could be done. It is just a matter of knowing who to tell.
17. I am fine with it. The reality is it that the side effects and most of the things people ask us about is documented in the literature and it not something they don't really know. If it is something undocumented, then we would probably call the manufacturer themselves to see if they have knowledge of it.

Subject 19 Nurse 3 years

1. No not necessarily. We have been taught that adverse events at this point definitely cause potential harm. Your definition was valid.
2. Yes I have. My first month of nursing, I had a nurse that was over me and she told me to go take something and instead of ordering it with an attending. It turned out to be potassium. I gave like a dose of potassium because it could have been harmful and caused cardiac issues. I had to report that. The patient was fine though.
3. I don't necessarily know an accurate number. We had a few where the patient resulted in death. Not having them hooked up to telemetry when they are supposed to be hooked up to telemetry. Medical errors. I don't know the number, but we have had a few this year.
4. We have a compliance office in our facility. So you have to do it on the computer and you put in your name, the patient name, when it occurred and what adverse event happened to the patient. It is like a corporate compliance online.
5. I have never heard of MedWatch before.
6. Sure, we are responsible for knowing actually what we are giving. There are certain medications that will call for us to give more medications to counter-act. For example Narcan which counter-acts barbiturates. As far as site down education on a particular drug no.
7. Patient was sent to a room and the nurse was told that for some reason or another that the patient was supposed to be on telemetry done, but by the time they found the patient they had died. Medication errors. Heparin Medication Errors. You usually report adverse events that you have done it are anonymous.
8. I don't think they are reported as often as they should. Out of 100 about 45% are reported. Usually nurses that I know of if the patient is okay they don't report it.
9. First you would tell your charge nurse and make sure they know what is going on and then you go to corporate compliance (policy adverse on staff) to alert them. Then you would tell the doctor. Now if the patient is fine then you would tell the charge nurse, the director of unit would be notified and house clearing room. When you say director? Director of the unit. Each unit has a director and assistant director.
10. Internet. The form is online.
11. Not often but of course with pain medications diarrhea and constipation. I have got itching with Benadryl but it is usually treatable.

12. With different medications you observe medications and sister drugs that they are allergic too and research it. We try to find a solution and then we alert the doctor because sometimes medications are different for that patient. I do if I give a medication and they start to complain of burning in there and ringing in their ears. I always research the medication are those possible side effects for that medication.
13. Yes, I have. I had a patient that was having severe headaches. Since he came on to the hospital with several medications and the doctor had given him many medications at once. I had to start one at a time. It was very hard to determine which medications were causing the headaches. So I had to do a process of elimination and take him off one by one.
14. The pharmacists and doctors are not responsible for reporting or asking nurses to report it. It is the nurse's jobs to be able to identify an adverse event and be able to alert the pharmacists and doctor. That is not there responsibility. They expect us to alert them.
15. Making sure that if it is a medication that we mark allergy on the chart. Educating the patient on what medications they are allergic too. Education is the key.
16. I think in the elderly environment as a nursing home. They are not able not mentally functional to report it. I think that goes back to the nurses. The nurse should be able to do an assessment. Whenever you give a medication you ask, how do you feel? are you in any pain? They should be suspicious of adverse event or medications all the time. You are always suspicious and investing. They are not always mentally capable to let you know everything or that they are hurting. You have to educate them on adverse events so they will be able to vocalize that to you.

Subject 20 Physician Assistant 5 months

1. No
2. Yes, I have reported an adverse event more than once. In both instances they were with medications where the patients experienced a side effect and I had to pharmaceutical representative for that particular medication. The Medication was called Humira it is an anti-TMF therapy. It is used in patients who have an auto- immune disorder. Both patients had rheumatoid arthritis. Both patients experienced a site reaction. The medication is administered subcutaneously. Both patients experienced an injection site reaction. One patient experienced pain from injecting the medication which deterred them from using it. The other experienced a rash at the site in which she injected the medication.
3. And in both instances, I reported this information to the pharmaceutical representative that comes by the office periodically to ask about the medication and give us samples of the medication and give us information about the medicine.
4. No, I have never heard of that.
5. You mean like a formal training. No there is no formal training at least not where I work anyway. For reporting adverse events, I learned about it from the pharmaceutical reps. There is no formal training involved in that. I would say that most of adverse events are events that I have researched on my own or been familiar with or drugs that I prescribe on regular bases.
6. Itching is the most common that I encounter. That medication made me itch. Like I said before injection site reactions and that can range from itching, redness, infection or pain and I encountered all of those. Another big one is GI upset. Stomach ache or nausea,

heartburn or acid reflux. Dependence is another one. I have had patients become dependent on certain medications. I also seen patients develop different anemia s as a result of medication and I have also increase in liver function enzyme and also a decline in kidney function.

7. By practitioners not as often as they should be. Adverse events are reported 50 to 60% of the time.
8. From my experience, the patient will come they say to me I experienced this and this. I will let the pharmaceutical representative know for that medication and if that one is not available then it is not reported to anyone.
9. In-person or if I have the pharmaceutical reps business card or phone number then sometimes I will shot them an email or give them a call on the telephone.
10. All the time. Some patients if they have an allergic reaction to something. They don't know what a true allergic reaction. An adverse event is something they didn't expect to occur anyway. Patients report adverse events all the time. Very common.
11. Yes, because sometimes patients will admit to having adverse events to every medication they take because they don't want to take the medication or for other reasons. They are trying to prevent you from prescribing this type of medication so that they can get this type. I will give you an example. So patients that drug seek for instance. They will say that they are allergic to this medication and that medication so that you can prescribe them a stronger medication. Yes, I would look at that patient charts and look at previous encounters with that patient to determine if they are actually having an adverse event or if this is just one of their ways of getting out of taking a medication or so on and so forth. Yes I do. I don't necessarily research the medication in every instance because most of the medication I prescribe I am pretty familiar with so I know what to expect and I know the adverse events. Usually the first thing I do is refer to that patients chart when a person comes to me to say they had an adverse event when taking a certain medication.
12. Nothing. Usually I report it.
13. NO
14. I don't know the proper contact person. I don't have the time to contact the company myself. I don't know the proper channel to take. Like you said the MedWatch I am not familiar with that.
15. I think it is something that is underutilized. It is something that is very important. As a result of having this interview, I think I will take it more seriously. An adverse effect could be death. I don't think a lot of time practitioners don't think about that. If there is a medication, especially a newer one, it is your responsibility as a practitioner to report these things to possibly prevent death in patients. It is something that is not taken seriously or at least in the realm I work in. A lot of practitioners should be educated on more than what they have been. It is not something that I learned in my school I can tell you that. In my training I was never taught the proper channel to report adverse events. I would definitely say that it is something that practitioners need to be educated on.
16. I believe that training programs should teach students medical students, nursing students, pa student's proper channel/proper ways they should go about reporting these things. Employers should say before you begin work this is the system we utilize to report medical adverse event reports whether it be pharmaceutical representative event reporting whether it be a website or contact the pharmaceutical company directly. I believe there should be better training involved.

Subject 21 Physician Assistant 3 years

1. No
2. Yes, one year ago a diabetes medication had a GI side effect.
3. Pharmaceutical representative
4. No
5. No
6. Diarrhea
7. Not very often
8. No answer based on skewed recording. Not applicable.
9. No answer based on skewed recording. Not applicable.
10. rarely
11. Yes
12. Having them come back for a two week follow-up
13. No
14. No barriers
15. No answer based on skewed recording. Not applicable.
16. No answer based on skewed recording. Not applicable.

Subject 22 Physician Assistant 8 months

1. No
2. No
3. My attending physician.
4. No
5. Somewhat. I just once one happens, in my experience discuss it. It not something that I have been informed on or instructed in my job so far.
6. Pulmonary emboli, from people that were not properly anticoagulated. I work with orthopedic trauma. So a lot of it after surgery we get pulmonary emboli a lot of times in our patients. Nosocomial infections from them being in the hospital to long like pneumonia.
7. Not as often as they occur.
8. I would report to my attending and they would probably report to the hospital. I am assuming because I have not really experienced any of that in my profession yet.
9. Actually face-to-face
10. Not often
11. Well it is usually brought to my attending attention and he takes it over from there. If it is an, then we discuss it in conference every morning. I have not had since I have been there in the past three and half months had any adverse events taken into account and discussed.
12. I do not know.
13. No
14. I have had any yet.
15. I think it is important. It is something that needs to happen so that we can try to cut down on the amount of adverse events that occur.
16. I think everybody needs to communicate a little bit better. Because communicate is always the problem especially in a hospital when so many people are involved in one

patients care. Communicate breaks down and once that communication breaks down it is big problem. There should be a little bit better protocol for making sure patients are taking the medication they are supposed to be taking. We put almost everybody on Lovenox after their orthopedic surgery. And a lot of times, they will not take it, somehow leave the hospital without it, or discontinue it after leaving the hospital when they supposed to be on it for at least another two weeks. I think there needs to be a better system in place to make sure that every patient that comes into the hospital leaves the hospital is on their proper medicine regimen.

Subject 23 (Pharmacists) 8 years

1. Yes
2. State Board of Pharmacists
3. Have heard of MedWatch; did not know you could report directly to them.
4. Pharmacists are trained during school obviously and continuous online training.
5. Dry mouth, constipation, and nausea
6. 10 percent of the time
7. Typically, if a patient calls in and says they are having a problem with the medication the technician will pass them off to the pharmacists.
8. Telephone
9. I would probably say about 20% of the time you have someone complain about side effects.
10. Sometimes
11. You would want to let your pharmacists know. Your pharmacists can decide if it is due to the medication, if it is due to how you are taking the medication. Maybe you need to take it with food. Morning time versus nighttime. First of all if you are having a life threatening emergency like your throat is closing up you would want to 911 if it is not life threatening then call your pharmacists and they can kind of let you know whether or not it is due to the drug or if it is coincidence. Then you would follow up with your physician and let him know if you can or cannot take the medication.
12. Not a 100% where a patient should report an adverse event but the FDA website has something.
13. Yes, like I said if it were a serious adverse event, we would forward it to the State Board of Pharmacy, but if it is something like talking to you to change your medication or talking to your doctor. It will not be forwarded.
14. Never, or no One time
15. I guess I just did not know. I do not know that much about MedWatch. If we had some more training on MedWatch.
16. Like me not knowing who to tell. Had you said more education on if you are having an adverse event. Actually defining an adverse event. Do you want every time some takes a pain pill and have constipation should they call in. Or are you talking about life serious that kind of thing.
17. I think reporting is very good. I think as long as it does not led to punitive stipulations. That is the only way we will get better. I know that you know when you read articles about mistakes other people have made not necessarily, because they are mistakes, but are adverse events. But when you read articles about other adverse events. You will be

on the look- out for these things. It will make you a better pharmacist because you will be able to counsel people about what they may or may not take.

Subject 27 Pharmacist 24 years

1. Yes, I have. I am not sure of the date. It has not been recently. Within the last month, I had to report to a patient's doctor that they were having one.
2. Patient's doctor.
3. I am aware of MedWatch. Yes.
4. No, other than the pharmacist. I was trained when I got my doctorate from the University of Georgia concerning MedWatch, and I learned that you can report adverse events to MedWatch. In obtaining my license when I went to school in New York, I learned to report to a doctor.
5. Simple rash, difficulty swallowing, tongue swelling from taking an ace inhibitor.
6. I'm not sure. Pharmacists report to doctors all the time. How often are they reported directly to MedWatch? Rarely.
7. General adverse event: We report to a doctor. A pharmacist can also report to MedWatch. There is not a specific chain of command because of retail pharmacy.
8. Telephone only because I only reported to the physician of the patient.
9. Patients complain a lot. I don't think we get the right number. About 25% of the time, it's not accurate. Some patients don't come back to pharmacists; they go to a doctor.
10. I look into their medication profile. I look at the disease based on the medication. Then I check the medication to see if they can cause them. (symptoms)
11. The consumer, customer, or patient contacts the pharmacist or doctor. More than likely, you will be able to contact your pharmacist first. Consumers should stop taking medications and go to the emergency room.
12. Report to pharmacist or doctor. I am sure MedWatch has a section to report. Not sure overall.
13. Yes, you can give that information to me. Pharmacists can give that information to doctors or tell patients to go to a doctor instead of using the MedWatch system to do it.
14. Rarely asked to report. They just tell me that they are experiencing one.
15. Sometimes it is the amount of information they are asking, and it is the time it takes to go through all of it. Some solutions include limiting the reporting form, the amount of information that is being asked, and the time it takes to do it. The pharmacist's duty is to report to the physician. The physician should report it for sure. Then the company sends the information that the doctor or pharmacist has to fill out and then it goes to MedWatch.
16. I am not sure. I do not know if any. Barriers: Complicated terms, format, or tools. It may be difficult for consumers to report. I would say the way of communicating the event is the biggest barrier. It requires you to use technology. Not everyone is tech savvy.
17. I think we should report. Physicians should for sure. It is not a bad thing that pharmacists should also report. Some pharmacists do not go that extra step because they report to physicians. Some pharmacists do not go the extra step to report to MedWatch. So it is good to do it. The fact that we are obligated to the patient, we assume physicians are going to do it.

Subject 28 Physician 13 years

1. No
2. Yes
3. Several years ago. It was an adverse reaction to a vaccine.
4. I heard of the term. I didn't know there was an organization that I could report adverse events to. It would not be the place I would go to report.
5. Prescription, yes. I am not sure about over-the -counter drugs. In my line of work, we usually report them to poison control. This is for accidental ingestion. If they are having side effects from it, they have to come into the office.
    a. Not a specific training. I am a pediatrician. I am trained to report problems with vaccines or medications we give. Then I know the route for doing that. Not a lot of the over- the- counter medications are recommended for children. I don't I have any.
6. A child getting too much of a medicine. Report it to the CDC or poison control. There is a number we call to report a vaccine. Did not call MedWatch. That would not be my first choice.
7. Not as often as they occur. Small percentage: 10-15%.
8. Not really a chain of command. If it is something I note, I will report it. The nurse tells the doctor. Then the doctor reports it. The nurse could still report. She may not know. For example, a rash to antibiotics. I think that is a big part of the problem. Must make judgment calls on whether an event is adverse or a normal side effect.
9. In the past, I have done a phone call.
10. They complain about side effects quite often. A lot of the time, you get side effects but not all the time are they adverse. Antibiotics cause diarrhea. You get them all the time but you have to weigh the risks versus the benefits. Which gives you the most benefit with the least amount of risks? Side effects versus adverse events.
11. Amoxicillin rash. Allergic to penicillin perceived adverse events. Have patients to come in. Judgment call.
12. Follow-up: how is the patient doing? Once reported, I don't follow up with the agency unless I get a phone call to give more information. I don't have time to do it.
13. No
14. Time constraint
15. Don't have a problem reporting. It is a judgment call. Don't have time to follow-up. That is why reporting is so low. If it is going to be detrimental. Not a matter of not wanting to report.
16. I went into medicine to help people. It was less about reimbursement. Take time to see patient or call to report. More and more work to see patients. Physicians have to do more.

Subject 29 Physician 3 years

1. No
2. No
3. To attending physician
4. No. No.
5. Yes, doctors trained on adverse events. We weren't really trained on adverse events just on how to do it.

6. Some common adverse events are patient code blues. Patient death is sudden and unexpected. What could have been done differently to prevent it from happening again?
7. Daily.
8. Report to direct supervisor or your attending physician. They will report it then report to resident director then to CEO of hospital.
9. Telephone (verbal)
10. Daily. Anytime we are in clinic.
11. Yes
12. Return back to clinic to reevaluate the patient.
13. No. We receive calls from them about patients they have seen. That would be risking their jobs.
14. None
15. I think it is a good thing. As medication has gone through its first set of trials, drugs can be recalled.
16. For medications to report to pharmaceutical companies to have interactive electronic medical records. So that it is interchangeable.

Subject 30 Physician 30 years

1. Yes
2. No
3. CDC or drug manufacturer if there is a drug reaction.
4. No. I have not heard of it.
5. No
6. Allergic reactions, rashes, nausea, vomiting those kinds of things.
7. Those kinds of events, rarely.
8. I would do the reporting.
9. Probably fax or telephone.
10. Probably 5 percent.
11. My response is to treat symptoms of the adverse event. I have not had to report an adverse event.
12. Usually follow-up with the patient to see if the symptoms have resolved.
13. No
14. Well some of the barriers are paperwork requirements. They are more designed to give you an academic answer than for treating the patient. From my stand point, I am more concerned with treating the patient than statistics.
15. Well, looking at the paperwork requirements, I can understand why there would be a lot of details required to make the statistics mean anything. But for instance, they would prefer if I cultured wounds so they would know what organism we were dealing with. If I wait until I have a disease to culture, I would be further down the line with treating the patient. I would rather go ahead and treat with an antibiotic. I think there is a built in tension between providers and statisticians. Treatment versus statisticians.

Subject 31 Physician 25 years

1. No
2. No
3. Not applicable

4. No. Never heard of it.
5. Yes. Training received: General CPR and Emergency Protocol from the local American Heart Association.
6. Adverse events experienced: Delayed Hypersensitivity Reaction. Acta Cardio-I gave a topical anesthetic, Lidocaine. I had three patients with swelling of the mouth the next day. We also had an event with a vaso constrictor and a local anesthetic epinephrine. It sometimes will cause acta cardiac. Another patient went out because of nitrous oxide. With overweight patients, even the small amount of nitrous oxide will incorporate in the fatty tissue. It will cause them to sedate to a different plane rather than conscious sedation.
7. In my profession, general dentistry is probably rare. Out of a year, we had a patient volume of 4500. Out of that volume, we had two cases of acta cardiac.
8. We have not had to report to the FDA. We have not experienced anything but an acute reaction. We had to call EMT (911).
9. Telephone for emergencies. We have not had anything we deemed necessary to report to the FDA.
10. Fifty percent of patients. Different side effects from allergic reactions. Educate the patients and give them a bit of an antigen. You have just got to educate the patient.
11. Definitely. Patient history is really important. We see quite a few patients on different medications, so it is important for us to discern how they take the medication. Did they take it full or on an empty stomach? When you have a conjugation of medicine, the efficacy levels definitely decrease.
12. Just follow-up. Normally triage them somewhere. Make contact with specialists.
13. No
14. I can't say that I have. I never had a barrier. I am a little conservative than most. I give the minimum amount of medication that works. I am comfortable with a few drugs.
15. There is a need. It needs to be more education especially in the dental profession. There are no continuing education courses. If I would have a question, I would contact the pharmacology department at the dental school.
16. Advertise to the different societies. Use the internet, advertisements, and commercials to get the word out. Contact the general organizations: the American Dental Association, National Dental Association, and the American Medical Association. Inform them and form a partnership with those specialties because they have a membership base to send out electronic information.

Subject 32 Physician 25 years

1. No
2. No
3. No. I do not know.
4. I have heard of MedWatch, but I did not know that I could report directly to them.
5. No
6. Allergic Reactions and GI bleeds.
7. Probably less than 5 percent of the time.
8. I do not have one.
9. I do not have one.
10. Fifteen percent of the time.

11. Yes
12. I do not report adverse events. I have not reported an adverse event.
13. No
14. I have not reported any.
15. I think it should be done. It is a good thing.
16. I think we should have required medical education in the reporting process and include who to report to.

APPENDIX C

INCLUSION FORM AND DEBRIEF DOCUMENT

Inclusion Form 1-1

Institution Code _____	Participant ID _____	Visit Type _____	Visit Date (MM/DD/YYYY) _ _/_ _/_ _ _ _

Answers to questions 1-3 must be yes for the subject to be eligible.

1. Are you a registered and/ or licensed as a Nurse, Pharmacist, Physician Assistant, or Physician?
   Yes or No

2. Are you willing and able to provide written consent?
   Yes or No

3. Do you have prior knowledge and/or use of an adverse event reporting system?
   Yes or No

Does the participant satisfy all of the eligibility criteria? _____Yes _____No

Source: Forms adapted from textbook by Gallin JI and Ognibene FP, *Principles and Practice of Clinical Research*. 2nd edition. *Forms*. pp. 72-73.

Debrief Document 1-4

Institution Code _____	**Participant ID** _____	**Visit Type** _____	**Visit Date** ____/____/_____ ***(MM/DD/YYYY)***

APPENDIX D

RECRUITMENT EMAIL

Greetings,

My name is Ansley Alicia Booker and I am a graduate student at the University of Georgia. I am currently enrolling participants to become subjects in my thesis research. The aim of this research is to gauge the perspective of varying healthcare providers regarding barriers that prevent effective healthcare provider reporting of adverse events to the Food and Drug Administration's MedWatch program.

The enrollment process will take place November 9-11, 2012 and March 3-5, 2013. The data will be gathered through individual interviews of healthcare professionals. Healthcare professionals to be used as subjects are physician assistants, nurses, and pharmacists. Interview dates are November 13-18, 2012 and March 6-7, & 15, 2013 from 8 to 5 p.m.

The principal investigator for this study is Paul J. Brooks, Pharm.D, Ed.D. He also serves as my thesis advisor and chair.

Dr. Brooks contact information:
Assistant Dean, Division of Nontraditional Education & Outreach
Graduate Coordinator, Pharmaceutical & Biomedical Regulatory Affairs
University of Georgia College of Pharmacy; Athens, GA 30602
pbrooks@rx.uga.edu; 706-542-5343

To be eligible for this study, you must meet the following inclusion criteria:

- Subject must be a registered and/ or licensed as a Nurse, Pharmacist, Physician Assistant, or Physician;
- Subject must be able to provide a written consent.
- The subject must also have prior knowledge and/or use of an adverse event reporting system

If you are interested in participating in this study, please contact me using the information below no later than November 11, 2012 before 9 p.m. at ansleybkr@gmail.com or 706-473-1128.

Sincerely,

Ansley Booker
University of Georgia
Master of Science
ansleybkr@gmail.com
(706) 473-1128

APPENDIX E

PROTOCOL CONSENT FORM

I, _____, agree to participate in a research study entitled "An Introspective Case Study examining the barriers faced by Healthcare Providers when reporting adverse events to MedWatch" conducted by Ansley Booker from the Pharmaceutical & Biomedical Regulatory Affairs Department at the University of Georgia College of Pharmacy (706-473-1128) under the direction of Dr. Paul Brooks, Assistant Dean, Division of Nontraditional Education & Outreach Graduate Coordinator, Pharmaceutical & Biomedical Regulatory Affairs, University of Georgia College of Pharmacy (542-5343). I understand that my participation is voluntary. I can refuse to participate or stop taking part at any time without giving any reason and without penalty or loss of benefits to which I am otherwise entitled. I can ask to have all of the information that can be identified as mine returned to me, removed from the research records, or destroyed.

The reason for this study is to understand the barriers faced by Healthcare Providers when reporting adverse events to MedWatch. If I volunteer to take part in this study, I will be asked to do the following things:

Answer questions about my occupation, race, gender, and age
Answer a research questionnaire about adverse event reporting
Participate in an audio-recorded interview about adverse event reporting
Someone from the study may call you to clarify my information

The primary benefit to this research is to identify barriers that may prevent healthcare providers from reporting adverse events through the FDA MedWatch system. If barriers are identified, more healthcare professionals will acknowledge the importance of reporting and the barriers that confront them. They may then want to take a more active role in reporting as well as ask other healthcare professionals such as pharmacists and nurses more often. They may also encourage consumer reporting to alleviate some of the stressors involved with reporting. The FDA may also become more aware of the time commitment to reporting and will therefore develop a more systematic and convenient method for reporting. Healthcare facilities may also create an environment more conducive to adverse event reporting by encouraging healthcare professionals to use proper vehicles for reporting.

No risk is expected. The only potential disadvantage is the time spent in answering the questions. The anticipated duration of participation is about two hours.

I will not receive any monetary compensation for my participation in this study.

No individually-identifiable information about me, or provided by me during the research, will be shared with others without my written permission, unless except unless required by law. I will be assigned an identifying number and this number will be used on all of the questionnaires I fill out. The audio recordings will be destroyed after transcription.

The investigator will answer any further questions about the research, now or during the course of the project.

I understand that I am agreeing by my signature on this form to take part in this research project and understand that I will receive a signed copy of this consent form for my records.

_____	_____	_____
Name of researcher	Signature	Date
_____	_____	
Telephone number	Email	
_____	_____	_____
Name of Participant	Signature	Date

Please sign both copies, keep one and return one to the researcher.

Additional question or problems regarding your rights as a research participant should be addressed to The Chairperson, Institutional Review Board, University of Georgia, 629 Boyd Graduate Studies Research Center, Athens, Georgia 30602; Telephone (706) 542-3199; Email Address IRB@uga.edu.