

COMPARISON OF ARNP AND PHYSICIAN MALPRACTICE IN STATES WITH AND
WITHOUT CONTROLLED SUBSTANCE PRESCRIBING AUTHORITY

by

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ABSTRACT

Florida is one of two states that do not allow ARNPs to prescribe controlled substances. The Florida Legislature has expressed concern regarding the safety of ARNPs prescribing controlled substances. The purpose of this study was to compare malpractice rates of ARNPs and physicians in states with and without controlled substance prescribing.

The design was a direct comparison of malpractice rates in states with and without ARNP controlled substance prescriptive authority. Comparison of malpractice claims was made between physicians (MDs and DOs collectively) and ARNPs in the United States and by state ARNP prescribing authority. Comparison of malpractice claims was also made between Florida and states that were demographically similar.

The results showed that ARNPs have significantly less malpractice than physicians in the United States. In addition, there were no significant differences in malpractice, whether or not the ARNP was allowed to prescribe controlled substances. Finally, ARNPs working in states that are demographically similar to Florida, but allowed to prescribe controlled substances had no significant increase in malpractice.

This study showed that there is no increase in malpractice rates in states where ARNPs prescribe controlled substances, either fully or partially, supporting the hypothesis.

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CHAPTER 1: INTRODUCTION/SCOPE OF THE PROBLEM

Nurse practitioners have been in clinical practice for over 40 years and have experienced expanded privileges to their practice. A total of 48 states now allow Advanced Registered Nurse Practitioners (ARNPs) at least partial controlled substance prescribing privileges and 34 states grant ARNPs full prescriptive privileges for Class II-V controlled substances without restrictions (Byrne, 2008). Full prescriptive privileges have promoted practice autonomy for ARNPs and access to care and services for clients. While the advances in prescriptive practices have occurred in 48 states, the State of Florida has not permitted its ARNPs to practice at their full potential (Miller, 2005). The purpose of this study is to compare malpractice rates of ARNPs and physicians in states with and without controlled substance prescribing.

Definition of Terms

For the purposes of this study, each term will be defined by their conceptual and operational meanings. Conceptual definitions express the idea of the term (Rogers & Knafl, 2000). Walker and Avant's meaning of an operational definition (as cited in Rogers, 2000) are ways in which the concept can be measured.

Malpractice

Conceptual: Any act or omission by a provider during patient treatment that deviates from accepted standards of care and causes injury to a patient (Bal, 2009).

Operational: Physician or ARNP who have committed an error and declared responsible for the error, such as delay of appropriate care.

Malpractice Rate

Conceptual: Number of occurrences that providers have been accused of malpractice.

Operational: Rates listed in the National Practitioner Data Bank (NPDB) which indicates the number of malpractice payment reports by state.

Incident

Conceptual: Events in healthcare which may cause unanticipated harm to a patient (Farlex, 2009).

Operational: Inappropriate medication prescribed, illegal dispensing of controlled substances, or an incident which did not involve medications, such as an incorrect or missed diagnosis.

Controlled Substances

Conceptual: Those medications which have a certain degree of addictive properties and are regulated by the DEA (Drug Enforcement Administration).

Operational: Medications such as narcotics, barbiturates, and sedatives.

Full Prescriptive Authority

Conceptual: ARNPs are allowed by law to prescribe Class II-V controlled substances independent of physician involvement. Physicians may be involved in terms of collaborative or supervisory practice in general terms.

Operational: Patient requires a Class II medication such as Methylphenidate for Attention Deficit Hyperactivity Disorder and the ARNP prescribes for the patient without involving the physician.

Partial Prescriptive Authority

Conceptual: ARNPs are limited by law in prescribing Class II-V controlled substances. This may be a limitation by class, indication, or quantity.

Operational: The ARNP is allowed to prescribe only a seven-day supply of a Class II medication. Patients who require controlled substances may need a physician involved in their care.

No Prescriptive Authority

Conceptual: ARNPs are not allowed to prescribe controlled substances medications.

Operational: Patients who require medications such as a medication for sleep must have a physician involved in their care.

Supervising Physician

Conceptual: physician (Medical Doctor or Doctor of Osteopathic Medicine) that has a collaborative protocol agreement with an ARNP (Florida Department of Professional Regulation Board of Nursing, 1990).

Operational: A physician that accepts responsibility to oversee an ARNPs practice.

Controlled substances are grouped into the following five classes by the Drug Enforcement Administration (DEA) (Drug Enforcement Administration, 2008). Class I

prescriptions are highly addictive and highly abusive substances, and are illegal to prescribe in the United States (U.S.). Class II prescriptions are those which have a high potential for abuse and physical dependence. Included in this group are prescriptions for Attention Deficit Hyperactivity Disorder and severe pain. Class III prescriptions can cause moderate or low physical dependence or high psychological dependence. Class III medications are generally prescribed for moderate to severe acute pain. Class IV prescriptions have a low abuse potential and limited potential for physical or psychological dependence. Class IV medications are generally prescribed for sleep and anxiety. Class V medications have a low abuse potential, and may or may not require a prescription. Class V medications include certain cough medicines, seizure medicines, and anti-diarrheal medications.

CHAPTER 2: SYNTHESIS OF THE RESEARCH EVIDENCE

In 1977, the first proposal for a Scope of Practice for Advanced Practice Nurses in Florida was created by a Joint Committee of members from the Florida Department of Health Boards of Medicine and Nursing (Lumpkin, 2004). In 1979, the Advanced Registered Nurse Practitioner (ARNP) was defined and added to the Florida Nurse Practice Act. Included in the act was the requirement that each ARNP would have a supervising physician who would also be legally responsible for the care and treatment provided by the ARNP. This supervising physician would establish protocols with the ARNP that delineate the scope of practice with the supervising physician. The protocols are then submitted to the Boards of Nursing and Medicine, with bi-annual updates (Florida Department of Professional Regulation Board of Nursing, 1990). Florida was one of the first states to pass legislation to regulate advanced nursing practice. In 1987, the Joint Committee again convened and authorized ARNPs to prescribe non-controlled substances (Lumpkin, 2004).

By 1988, ARNPs were working with their supervising physicians to update protocols to include non-controlled substance medications. In 1995, an ARNP task force was assembled to develop a bill which would allow nurse practitioners the ability to prescribe controlled substance medications. The bill was opposed by both the Florida Pharmacy Association and the Florida Medical Association and was defeated (Lumpkin, 2004). There were several issues which contributed to the bill's defeat. One of the issues identified was the allowance of nurse

practitioners to gain ARNP licensure through a certificate without additional education. In addition, there was a nursing movement nationally to standardize basic as well as advanced educational preparation. The Florida Nurses Association (FNA) began working on minimum education requirements to facilitate a future bill for advancing ARNP scope of practice. In 1996 a law was passed that changed the minimum education requirement of ARNPs to be a master's degree in advanced practice nursing beginning in 1998 (Lumpkin, 2004).

In 1997, the Florida Legislature mandated the creation of a task force appointed by the Agency for Healthcare Administration to include pharmacists, nurses, physicians and doctors of osteopathy, as well as a Florida Hospital Association representative. The Prescribing of Controlled Substances task force was developed to evaluate the risk and benefits of ARNPs prescribing controlled substance medications in Florida. Their study concluded that ARNPs are safe to prescribe controlled substance medications (Prescribing of Controlled Substances Task Force, 1997). This conclusion was based on the findings that the potential for harm to patients or increase in substance abuse by ARNPs was very limited. In addition, trends of malpractice payments indicated that in the three years following the Drug Enforcement Agency (DEA) authorization of "mid-level providers" [*sic*] to be granted DEA numbers, there was a 5% increase in malpractice claim awards payments for physicians but a 22% decrease in malpractice claim awards payments for ARNPs (Prescribing of Controlled Substances Task Force, 1997). There was dissent, however among the physicians in the group, who wrote a Minority Report, expressing four primary concerns. The first concern was that there were no studies available

regarding the safety of controlled substance prescribing by ARNPs. The second concern was that many states had limitations on controlled substance medication prescribing. The third concern was that education was lacking in specific pharmacology training. The fourth and final concern was that to have ARNPs prescribing controlled substance medications would result in an increase in the liability exposure for the supervising physician. At the time of the 1997 study, 32 of 50 states had passed legislation to allow ARNPs to prescribe at least some form of controlled medications. Unfortunately, between 1997 and 2001, the Florida Legislature continued to oppose allowing ARNPs to prescribe controlled substance medications (Lumpkin, 2004). As recently as December, 2008, the Florida Senate's Committee on Health Regulation met to hear Interim Report 2009-117 which was a report reviewing ARNP prescriptive authority (The Florida Senate, 2008). The Senate professional staff recommended extending controlled substance prescribing authority to Florida licensed ARNPs who have attained national certification. One senator again brought up the safety of ARNPs prescribing controlled substances and directly asked about malpractice rates in other states that allow ARNPs this authority. No study to-date had occurred. Of the seven senators present, Senators Michael Bennett, Dennis Jones and Minority Leader Alfred Lawson were in favor of moving the bill forward, Senator Dave Aronberg was in favor of allowing ARNPs to prescribe class III-V, Senators Eleanor Sobel and Thad Altman were opposed, questioning whether there were any studies on the safety of ARNPs prescribing controlled substances, and Senators Andy Gardiner and Don Gaetz were silent on the matter. Since consensus could not be reached, the bill was put

forth by Senators Bennett and Jones, but the bill was never heard on the floor (Senate Committee on Health Regulation, 2008). Then in the 2010 legislative session the head of the House of Representatives Health Care Regulation Policy Committee, Representative Nick Thompson stated that he would not accept any scope of practice bills this session (Small, 2010).

Patients, ARNPs, and physicians in the state of Florida are faced with many challenges as a direct result of ARNPs not having full prescriptive authority. Challenges include lost productivity of the ARNP waiting for a physician to write a prescription, delay of care for the patient, lost productivity of the physician to leave his own patient to care for the ARNPs patient's needs, and increased liability for the physicians to write prescriptions for patients with whom they are less familiar (Kaplan & Brown, 2004). If the physician is not available, the patient must arrange a second appointment specifically with the physician to obtain the appropriate medication. The cost for a patient to make a return visit impacts the patient by increased time taken from other activities and delay of treatment. A return visit also impacts the insurance providers, as there will be a second office visit charge (Kaplan, 2004). Patients in rural areas are most vulnerable to these types of consequences, due to physician shortages (Ricketts & Holmes, 2007; Hill, 2008; Millson, 2008). ARNP managed clinics in rural and underserved areas cannot provide patients appropriate services without the ability to prescribe the medications needed for treatment of the condition. ARNPs also have obstacles when practicing in specialty practices such as palliative care and pain management, negatively impacting the patient's quality of life and comfort. In addition, ARNPs prescribing trends are not

accurately reflected when a physician must write a prescription for the ARNP's patient. For example, an ARNP's patient requires a medication for anxiety prior to a procedure (such as a Magnetic Resonance Imaging [MRI]). The protocol for the office is lorazepam, a Class IV controlled substance. The physician must write the order, making the number of controlled substances for his/her patient population falsely high, while the ARNP's record shows none. Regulations which limit the ARNPs scope of practice, including prescribing controlled substances, reduce their ability to meet patient's health care needs (Lugo, O'Grady, Hodnicki, & Hanson, 2007).

The Florida Legislature has expressed concern regarding the safety of ARNPs being given the privilege of prescribing controlled substances. This is in direct opposition to the report written by the professional staff of the Committee on Health Regulation, which stated that ARNPs pose no greater risk to patients by prescribing more inappropriately than other providers who have this authorization. Two Senators expressed their own concerns. One concern was increased prescription drug abuse in Florida and the other is that there is no evidence on malpractice incidence in controlled substance prescribing (The Florida Senate, 2008). A recent study evaluated the extent of illicit drug use in the U.S. Drugs included categories of both illegal substances (heroin, marijuana, and cocaine) and prescription substances used for non-medical purposes (narcotic pain relievers, tranquilizers, sedatives and stimulants). The Table I shows the rate of illicit drug use in 2007 comparing U.S. regions (Substance Abuse and Mental Health Service Administration, 2008).

Table 1: Illicit Drug Use in Persons over 12

U.S. Region	Percent of persons older than age 12 using illicit drugs
West	9.3%
Midwest	7.9%
Northeast	7.6%
South	7.4%

Substance Abuse and Mental Health Service Administration, 2008

There have been over 50 studies which have evaluated outcomes, patient satisfaction, and differences in practice patterns between ARNPs and physicians, but in no study has malpractice, negative licensure actions, civil judgments, or criminal convictions data been compared for physicians and ARNPs (Action for Sick Children, 1999; Chumbler, Geller, & Weier, 2000; Shell, 2001; Jacobs, 2005; CIPHER, Hooker, & Guerra, 2006). Therefore this study seeks to address whether the actual difference in the scope of practice of controlled substance prescribing of ARNPs affects malpractice judgments, negative licensure actions, civil judgments, and criminal convictions.

Cumulative Index to Nursing and Allied Health Literature (CINAHL) and MEDLINE databases were used to complete the literature review for this study. Initial search terms included Prescribing *and* Malpractice and ARNP. This produced no results. The second search included Prescribing Controlled Substances *and* ARNP *or* Advanced Practice Nurse. Restrictions were then placed to include English only. This search produced a yield of 2,167 articles. The third search included the terms Nurse Practitioner and Prescribing *or* Malpractice. This produced a

yield of 137 articles. There were no peer reviewed data-based research articles which compared the prevalence of malpractice between ARNPs and physicians. Included in the literature review were those articles which evaluated the safety of care provided by ARNPs in comparison to physicians, articles identifying barriers to ARNP practice, including controlled substance prescribing and articles assessing whether care provided by ARNPs is cost-effective.

Table 2: Controlled Substance Prescribing Literature Review
CINAHL and MEDLINE Database

Key Words/Limits	Articles
Prescribing, ARNP, Advanced Practice Nurse; Limitations: English Only; No Limit to Dates of Articles	2167
Prescribing, ARNP, Advanced Practice Nurse. Date Limits set from 2006 to 2008	1,650
Prescribing Controlled Substances, ARNP, Advanced Practice Nurse. Date Limits 2006-2008	940
Nurse Practitioner, Prescribing or Malpractice	137

There have been over 50 studies comparing care and treatment of patients between ARNPs and Physicians. These studies consistently support that care and outcomes are similar between the providers (Haider, 2008; Horrocks, Anderson & Salisbury, 2002; Brown and Grimes, 1995). In a review of prescriptive practices of psychiatrists and psychiatric nurse practitioners, there were no significant differences in patient adherence to medications (Jacobs, 2005). Significant differences were found in physician's utilization of more second generation antidepressants and anxiolytics than the ARNPs who provided more first generation and generic medications when appropriate.

In terms of time spent with the patients, the ARNPs had increased face-to-face visit time with patients and they used more integrated therapy, such as biofeedback and psychotherapy (Jacobs, 2005). One study found that patients perceived nurses to be more approachable when

medications were needed and that since the ARNP could prescribe the medicine, treatment could be started sooner rather than waiting for a physician to prescribe. Specifically, patients stated that they had established a relationship with their nurse, and felt that the ARNP knew more about their condition than a physician who didn't know their background (Luker, 1998). ARNPs and physicians also experience similar difficulties ensuring patient safety in prescribing whether prescriptive authority is limited or full, such as patient expectations regarding medication, self adjusting medication and abuse (Jacobs, 2005). Since the ARNP has been shown to provide patients with more education regarding care and treatment, the risk should not increase, but be equivalent or possibly decrease (Little, 2001).

In a study by Cipher (2006), there were increases in the amount of controlled substance prescribing among ARNPs from 1996-2002, compared to the seven years prior, however over the time of the study more and more states were passing laws allowing ARNPs to either prescribe controlled substances, or expand the degree to which they were allowed to prescribe controlled substances.

The Florida Medical Association in its Minority Report to the Florida Legislature brought up the concern of increased liability exposure to the supervising physician if ARNPs are allowed to prescribe controlled substances (The Joint Committee Task Force, 1997). The term "supervising physician" can allow a lawsuit to expand, and even those with appropriate practice can receive a lawsuit, but if the physician has never seen the patient, nor been asked his/her advice, then the physician as a defendant in the suit would be most likely dropped (Buppert,

2001). The case, however, becomes more complicated with current restrictions on prescribing for ARNPs. Consider that the ARNP's patient requires a controlled medication, such as a refill on a Class II drug for Attention Deficit Hyperactivity Disorder (ADHD). The nurse practitioner must obtain the controlled substance prescription from the physician and give it to the patient. The physician did not evaluate the patient and yet the physician's name must be on the prescription for the medication. This leads to not only increased liability for the physician who is now responsible for the outcome, but inappropriate tracking of prescribing trends in all states with limitations (Lebo, 2007). Poor outcomes alone, however, are not the only reason that persons bring about a lawsuit, but lapse in communication following the occurrence is a major issue (Baum & Dowling, 2009). Communication is one area that nurse practitioners have improved skills compared to physicians. In a meta-analysis by Haider, surveys indicated patients preferred ARNPs due to the increased time spent in communication with the patient (Shum, Humphreys, Wheeler, Cochrane, Skoda, & Clement, 2000; Haider, 2007). In the same meta-analysis, mothers of sick children expressed that family physicians made them feel anxious, and gave them vague instructions for care (Haider, 2007, Action for Sick Children, 1999). More recently, a nurse practitioner managed cardiac clinic at the Cleveland Clinic was designed to address the needs of heart patients in terms of improving health outcomes as well as preventive care. Surveys were conducted monthly to assess the quality of the program as this was originally managed by physicians. After one year, the clinic was found to be cost-effective, had improved patient satisfaction scores in the areas of communication and spending enough time with the patient, and

improved outcomes including significant reductions in total cholesterol, triglycerides, high-density lipoprotein, low-density lipoprotein, blood pressure, and C-reactive protein (Gambino, Planavsky, & Gaudette, 2009). Studies consistently show that ARNPs can effectively reduce healthcare costs while maintaining quality, improving communication and improving outcomes.

In *Barriers to Autonomous Practice*, Kaplan (2004) studied specific barriers to prescriptive authority with controlled substances II-V and grouped ARNPs into those with full authority and those without authority in the State of Washington. The study questioned the ARNPs before the law authorizing prescriptive authority for Class II-IV was in place and again soon after the law was enacted. Findings revealed that the ARNPs primary reason for not pursuing DEA registration and prescriptive authority were lack of expertise in prescribing specific Schedule II-IV drugs. The author continued to follow the same ARNPs over a two year period and found that by year two, two-thirds of the ARNPs had obtained DEA licenses and were prescribing controlled substances. One premise as to why the ARNP did not wish to prescribe controlled substances reported a concern regarding patients with drug-seeking behavior (Kaplan, 2004). These findings both support the requirement for pharmacology education for ARNPs with regards to controlled substance prescribing (Kaplan, 2004).

State limitations have also imposed barriers to practice, limiting the ARNP's ability to practice to their fullest capacity (Pan, Straub & Geller, 1997). Rankings of states related to ARNP autonomous practice (including prescriptive authority) were published to show the

disparity of scope, despite standardized training. In this study, Florida ranked 49th out of 51 states including the District of Columbia (Lugo, 2007, Phillips, 2009).

Recently, several national advanced practice nursing groups have united to create a Consensus Model for Advanced Practice Registered Nurse (APRN) regulations: Licensure, Accreditation, Certification and Education (Trossman, 2008). This document was created and endorsed by several advanced practice specialist or specialty groups, including nurse-midwives, clinical nurse specialists, and nurse practitioners to standardize the education and regulatory processes for APRN practice and promote APRNs independent function, including prescriptive authority (Trossman, 2008).

Cost savings is another advantage to allowing ARNPs full prescriptive authority. In a recent cost-benefit analysis, a net benefit of \$32 million dollars in the state of Florida per year was estimated (Chandler, 2007). Cost estimates included time for the practitioner to find the physician, the physician to stop his patient flow to prescribe the medication, and those instances where a second office visit would be required, should the physician not be in the office at the time (Chandler, 2007). Nurse practitioner managed clinics (NMCs) are also a way to improve the cost of healthcare. Coddington & Sands (2008) conducted a meta-analysis describing five NMCs as having significant impact on reduced emergency department, urgent care centers and hospitalization visits. This is enhanced by providing preventive services to persons who could otherwise not afford treatment. In one study, Schroeder (1993) estimated over \$750,000 in savings was found by ARNP care in reducing the number of HIV patients hospitalizations and

the following year, over one million dollars savings was realized. Another study evaluated a NMC, and found that some months after opening, the local emergency department found that the NMC's clients were only making up 0.3% of overall visits (Helvie, 1999). A thirteen million dollar savings occurred in another hospital following a NMC opening, by a 25% reduction in emergency department visits (Smith-Campbell, 2005).

In conclusion, there are over 50 studies which compare care and treatment between ARNPs and Physicians but none which specifically look at comparing the prevalence of malpractice claims in states with and without ARNP controlled substance prescribing privileges regulation.

CHAPTER 3: PROJECT IMPLEMENTATION

The purpose of this study was to identify any difference in malpractice rates among ARNPs and physicians in states with either full or partial controlled substance prescriptive authority. The data was reported from the National Practitioner Data Bank as cumulative malpractice claims for each state (Pearson, 2010). Specific data regarding malpractice rates secondary to controlled substance prescribing was not available. The physician's rates were calculated as Medical Doctor (MD) malpractice rates and Doctor of Osteopathic Medicine (DO) malpractice rates combined. This design was chosen to provide a direct comparison of malpractice rates in states with and without ARNP controlled substance prescriptive authority. Various studies have been conducted that compare outcomes, practice patterns, and cost effectiveness of ARNPs utilizing a full scope of practice, but no studies have specifically looked at prescriptive authority and malpractice rates.

The population for this project included all ARNPs and physicians in all of the U.S. and the District of Columbia. Data regarding total population for each classification was derived from the Pearson Report (Pearson, 2010). Rates of malpractice were obtained from the National Practitioner Data Bank Summary Report and the National Practitioner Data Bank 2006 Annual Report (Pearson, 2010). Information regarding adverse action reports, civil judgments, and criminal conviction reports was obtained from the Healthcare Integrity and Protection Data Bank (Pearson, 2010). For this study, several sources were evaluated for the most accurate

determination of malpractice data. The closest data set to reflect malpractice data in the United States is the National Practitioner Data Bank. This information, however, is not complete in itself. Actions restricting clinical privileges and professional society membership sanctions are mandatorily reported for physicians and dentists but are voluntarily reported for other providers to include ARNPs (National Practitioner Data Bank, 2006). Malpractice reports are also skewed in that some providers may have had two or more malpractice suits which inappropriately worsen rates for the entire provider group. In addition, the National Practitioner Data Bank reports cumulative data from 1990-2008, and not annual rates. Finally, states have granted controlled substance prescriptive authority to ARNPs in various years, which may make some states malpractice rates with earlier legislation related to controlled substance prescribing more accurate than those states that have changed prescriptive authority in more recent years. Therefore, other sources for data were included and are presented in the following table.

Table 3: Sources for Data Collection

Agency	Data to be Collected
Federal Drug Enforcement Agency (DEA)	Case reports of DEA intervention against providers who have been sanctioned in some way related to controlled substance prescribing.
Health Integrity Protection Data Bank	Number of reports concerning individuals by professional type and by Federal Licensure and DEA Action
Kaiser Foundation	State health facts concerning number of practitioners in each state and demographic characteristics of the professions in the state.
National Practitioner Data Bank	Number of malpractice cases by provider type and state which resulted in payment.
Pearson Report	Overall prevalence of malpractice rates in each state by professional type.

Design

This study was conducted as a secondary analysis of collected data regarding malpractice rates among ARNPs and physicians. The design was chosen after an extensive search of other sources for specific information regarding malpractice related to controlled substance prescribing. The Drug Enforcement Administration tracks and presents specific cases of misuse of controlled substances rather than aggregate data. The Health Integrity Protection Data Bank tracks the number of adverse events, criminal convictions and civil judgments against practitioners, but is only mandated for MDs and DOs and voluntarily reported by ARNPS. There was also investigation of insurance companies that carried malpractice insurance for physicians

and ARNPs to assess whether controlled substance prescribing increased the risk, and therefore the rate of insurance, versus a provider that did not prescribe controlled substances. It was discovered, however, that controlled substance prescribing was only a small part of a larger complex formulation in determining annual malpractice insurance rates. No source was found that monitored malpractice as it relates to controlled substance prescribing by state. The closest source that monitored overall malpractice by state was the National Practitioner Data Bank.

Human Subjects

There was no risk to human subjects. All of the data collected was public domain and has been reviewed by other methods to describe specific trends. The University of Central Florida Institutional Review Board reviewed this study and determined that the proposed study was not human research and thereby exempt from IRB review (see Appendix).

Data Analysis

Data was analyzed using the SPSS Database system. Frequency distributions were performed for each of the research questions.

In this study, each state was listed in the data spreadsheet. All 50 states including the District of Columbia were coded according to the level of ARNP controlled substance prescribing regulations: full, partial, or none. Each state then had listed the total number of ARNPs practicing in the state as well as the total number of MD's, DO's and combined physicians practicing in the state. Finally, malpractice rate by provider type (ARNP, MD, and DO) for each state was analyzed.

The research questions for this study included the following:

- What was the rate of malpractice claims by state against ARNPs compared to physicians in the U.S.?
- What was the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs have full controlled substance prescribing privileges?
- What was the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs have partial controlled substance prescribing privileges?
- What was the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs do not have controlled substance prescribing privileges?
- Was there a difference in the rate of malpractice among ARNPs based on prescriptive authority?
- Was there a difference in ARNP malpractice rates in Florida compared to states demographically similar to Florida but allowing controlled substance prescribing?

Statistical evaluation included frequency distributions, mean distribution, one-sample t-test, Wilcoxon Signed Ranks test, and the Kruskal-Wallis test. Graphic representation of the data was also utilized. Independent variables included the number of ARNPs nationally and in each state, the number of physicians nationally and in each state, and ARNP prescribing privileges. Dependent variables included the rate of malpractice per 1000 per discipline, and the rate of malpractice in each state. States were then coded as determined by the level of autonomy nurse practitioners have to prescribe controlled substances (full prescribing, partial prescribing and no

prescribing). The hypothesis was that there was no statistically significant difference in the malpractice rates of ARNPs and physicians in states with and without controlled substance prescribing.

There are a number of limitations inherent in this study. Data collected regarding malpractice was not equal among providers. There were only two professions that required mandatory reporting for malpractice incidents with the National Practitioner Data Bank, physicians and dentists. In addition, malpractice rates do not specifically represent malpractice related to controlled substance prescribing. Malpractice payment reports also do not distinguish those providers who have had one malpractice claim or several. This can affect the overall rate of malpractice as well. The available data can only be interpreted as to whether there is evidence that ARNPs in states with controlled substance prescribing have overall significantly more malpractice judgments against them compared to ARNPs in states without controlled substance prescribing.

CHAPTER 4: RESULTS

In this chapter, the findings of the data analysis are presented. The sample for the study included data for the 50 United States and the District of Columbia. Data collected from each state included numbers ARNPs, DOs and MDs by state, malpractice rates by state, adverse actions, civil judgments and criminal convictions reports, and level of state ARNP prescribing privileges. For malpractice rates, data was analyzed by malpractice rate per 1000 providers for each set and then compared. Comparison results to address the research questions were as follows:

Question 1: What was the malpractice rate for ARNPs compared to physicians in the United States?

There were 156,958 ARNPs in the U.S, (mean [M] = 3,078 per state; Median [Mdn] = 2,319 per state). The average or mean rate of malpractice for every 1000 ARNPs was 6.29. There were over 978,672 physicians in the U.S (M = 19,190 per state, Mdn = 11,829 per state). The average or mean rate of malpractice for every 1000 physicians was 249.75. The results of the Wilcoxon signed rank test indicated that nurse practitioners (Mdn = 5.28) have statistically significant lower malpractice rates than physicians (Mdn = 247.75) ($p < .001$).

Malpractice Rates for ARNPs and Physicians based on Prescribing Authority

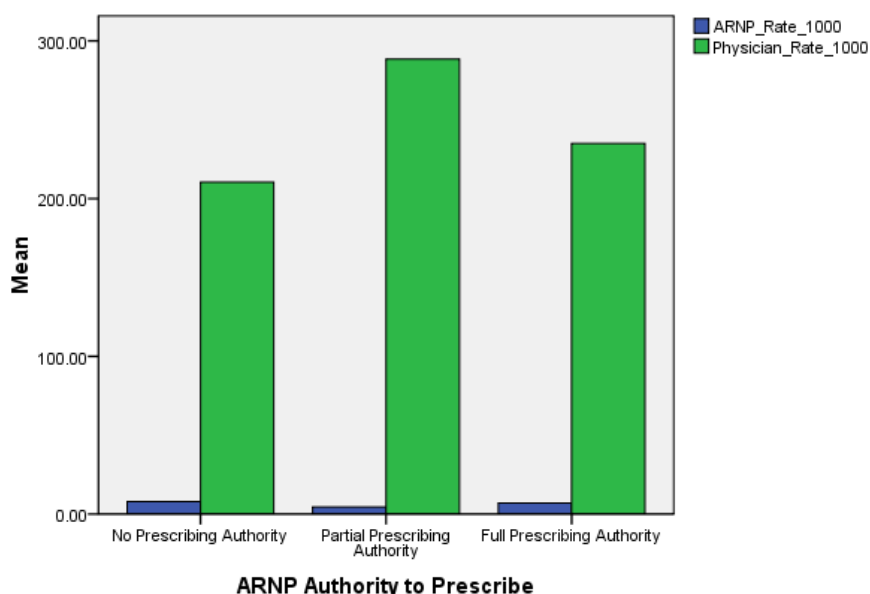


Figure 1. Comparison of Malpractice Rates for Physicians and ARNPs

Question 2: What was the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs have full controlled substance prescribing privileges?

There were 34 states including the District of Columbia that allow ARNPs full prescriptive authority. The number of ARNPs in states with full prescriptive authority totaled 93,083. In the same states there were 565 malpractice claims. The average or mean rate of malpractice for every 1000 ARNPs in states with full prescriptive authority was 7.00. The number of physicians in states where ARNPs have full prescriptive authority was 552,461. In those same states there were 133,995 malpractice claims against physicians. The average or mean rate of physician

malpractice in states with ARNP full prescriptive authority for every 1000 physicians was 234.97. The results of the Wilcoxon signed rank test indicated that malpractice rates against ARNPs in states with full prescriptive authority ($Mdn = 6.21$) have statistically significant lower malpractice rates than physicians ($Mdn = 222.63$) in those states ($p < .001$).

Question 3: What is the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs have partial controlled substance prescribing privileges?

There are 15 states that allow ARNPs partial prescriptive authority. The number of ARNPs in states with partial prescriptive authority was 50,804. The average or mean rate of malpractice for every 1000 ARNPs in states with partial prescriptive authority was 4.48. The number of physicians in states where ARNPs have partial prescriptive authority was 356,136. In those same states there were 107,439 malpractice claims against physicians. The average or mean rate of physician malpractice in states where ARNPs have partial prescriptive authority for every 1000 physicians was 288.47. The results of the Wilcoxon signed rank test indicated that malpractice rates against ARNPs in states with partial prescriptive authority ($Mdn = 3.73$) have statistically significant lower malpractice rates than physicians ($Mdn = 262.74$) in those states ($p < .001$).

Question 4: What is the rate of malpractice claims against ARNPs compared to physicians in states in which ARNPs do not have controlled substance prescribing privileges?

There are two states that did not allow controlled substance prescriptive authority. The number of ARNPs in states that do not allow controlled substance prescriptive authority was 13,071. The average or mean malpractice rate for every 1000 ARNPs in states that do not have controlled substance prescriptive authority was 7.94. There were 70,075 physicians in states in which ARNPs do not have controlled substance prescriptive authority. The average or mean malpractice rate for every 1000 physicians in states where ARNPs do not have controlled substance prescriptive authority was 210.46. The results indicate that ARNPs have lower malpractice rates than physicians in states that do not allow ARNP controlled substance prescribing.

Question 5: Is there a difference in the rate of malpractice among ARNPs based on prescriptive authority?

Statistical analysis was performed using the Kruskal-Wallis test to evaluate significant differences in malpractice rates for ARNPs in states with full, partial and no prescriptive authority. The average or mean malpractice rate for every 1000 ARNPs in states with full prescriptive authority was 7.00. The average or mean malpractice rate for every 1000 ARNPs in states with partial prescriptive authority was 4.48. The average or mean malpractice rate for every 1000 ARNPs in states without controlled substance prescriptive authority was 7.94. The results of the Kruskal-Wallis one-way ANOVA by ranks indicated that there were no statistically

significant differences among the three prescribing privilege categories ($\chi^2_{K-W}=4.304$, $df=2$, $p=.116$).

Table 4: Summary of Malpractice Rate/1000 by ARNP Prescribing Privileges

Controlled Substance Prescribing Authority	Number of States (n)	Number of ARNPs	Mean/ Median Per State	Number of Physicians	Mean/ Median Per State
Full Prescriptive Authority	34	93,083	7.00/6.21	552,461	234.97/222.63
Partial Prescriptive Authority	15	50,804	4.48/3.73	356,136	288.47/262.74
No Prescriptive Authority	2	13,071	7.94/7.94	70,075	210.46/210.46

Question 6: Was there a difference in ARNP malpractice rates in Florida compared to states demographically similar to Florida but that allow ARNP controlled substance prescribing?

Two criteria were used to compare states that were demographically similar to Florida, the state population size and number of uninsured residents. From this criteria, three states were found comparable to Florida; Illinois, New York, and Texas. The following table provides a comparison of the states, controlled substance prescribing authority and individual malpractice rates.

Table 5: ARNP Malpractice Rate Comparisons to Florida

State	Population Size	Number of State Uninsured	Prescriptive Authority	ARNP Malpractice Rate/1000
Florida	18,029,897	3,738,230	No Controlled Substance Prescribing	14.24
Illinois	12,642,143	1,737,876	Partial Controlled Substance Prescribing	3.78
New York	19,046,037	2,590,364	Full Controlled Substance Prescribing	5.28
Texas	23,406,068	5,832,884	Partial Controlled Substance Prescribing	8.47

Table 5 indicates that ARNPs with full and partial prescribing authority in states that are demographically similar have lower malpractice rates compared to Florida which does not allow controlled substance prescribing.

CHAPTER 5: DISCUSSION

ARNPs have been providing cost-effective, comparable care for over forty years. This study was completed to evaluate malpractice rates in states where ARNPs have full prescriptive authority to those ARNPs with limited or no prescriptive authority to demonstrate that there was no increased risk of malpractice to the ARNP or the physician when allowing ARNPs to prescribe controlled substances.

The average or mean rate of malpractice among ARNPs and physicians varied by state and by discipline. Average or mean malpractice rates for every 1000 physicians varied between 94.27 (Alabama) and 486.72 (Montana) with *Mdn* = 247.75. Malpractice rates for every 1000 ARNPs varied between zero (Hawaii and Vermont) and 26.56 (New Mexico) with *Mdn* = 5.28. This data was included to provide a baseline for the results of the questions that followed. There are several possible explanations for the variance. Laws in each state regarding malpractice were not evaluated for this study, but could have an impact on the overall rate. ARNPs have not been in practice as long as physicians and do not typically provide care in some settings that pose greater risks for lawsuits (such as a neurosurgery, high-risk obstetrics, etc.). This may partially explain the disparity between ARNP malpractice rates and physician malpractice rates.

There are 34 states that allow ARNPs full controlled substance prescriptive authority. In states where ARNPs are allowed to fully prescribe, physicians had no significant difference in malpractice claims as compared to physicians in states where ARNPs are not allowed to fully

prescribe. This is significant in that the Florida state legislature has had concerns that ARNPs who were able to fully prescribe controlled substances would increase the supervising physician's malpractice rates. This study does not support that finding. In the fifteen states that allow ARNPs partial controlled substance prescriptive authority, the findings again concurred that there was no increase in physician malpractice rates. ARNPs in states with partial controlled substance prescriptive authority had the lowest malpractice rates overall (4.48/1000 ARNPs), but not significantly different from ARNPs in states with full prescriptive authority (7.00/1000 ARNPs) or the national mean (6.29/1000 ARNPs). This is noteworthy in that it appears that increasing the scope of practice by allowing ARNPs to prescribe controlled substances will not likely increase the supervising physician's liability, nor the ARNPs liability.

In reviewing the two states that do not have any level of controlled substance prescribing, the malpractice rate for physicians and ARNPs are higher than in states with partial or full controlled substance prescriptive authority, although not significantly. One possible explanation for the higher malpractice rates are the state rules surrounding controlled substance prescribing. For example, ARNPs who do not have the ability to write for a controlled substance when one is clearly indicated potentially can be accused of delay of care, or inappropriate treatment because the most appropriate medication cannot be prescribed. If the physician is not at the site of service, the patient is frequently asked to secure another appointment to see the physician so that they can evaluate the patient and prescribe the medication. In this situation, care has been delayed.

The disparity of the number of states with full prescribing (34), partial prescribing (15) and no controlled substance prescribing (2) may have abnormally skewed the data. Florida ARNPs alone had more malpractice claim reports ($M = 14.24$) than any other state, and twice the number as the next highest state (Texas $M = 8.47$). There is no data base available which looks specifically at malpractice claims related to controlled substance prescribing. What can be shown is that ARNPs who have the authority to prescribe controlled substances show no greater preponderance for having a lawsuit brought against them than ARNPs without controlled substance prescribing.

To provide a comparison to the NPDB information, data was also gathered from the HIPDB. In comparing the three groups of states, those with full, partial and no controlled substance prescriptive authority, ARNPs in those states with no controlled substance prescribing had considerably more adverse actions, civil judgments, and criminal convictions than ARNPs in states with partial or full controlled substance prescriptive authority. Specifically, however, Alabama had the greatest number of HIPDB reports (175) compared to Florida (42). Florida's individual number of HIPDB reports was not much different from other states regardless of prescribing privileges. In evaluating physician adverse actions, criminal convictions and civil judgments, there were no significant differences throughout the United States, regardless of ARNP prescribing authority.

As noted above, there are several factors which could contribute to malpractice rates. The final evaluation was to see if states that were demographically similar to Florida had similar

malpractice rates. Three states were chosen that most closely matched Florida in terms of total state resident population and number of persons uninsured. States that were demographically similar included Illinois, New York and Texas with Illinois and Texas allowing partial prescriptive authority and New York allowing full prescriptive authority. The results show that malpractice rates for ARNPs remain appreciably lower in states demographically similar to Florida even when allowed partial or full prescriptive authority.

There are several limitations to this study and the interpretation of the data. The National Practitioner Data Bank requires mandatory reporting for MDs and DOs but voluntary reporting for ARNPs. This could lessen the accuracy of the data. In addition, there is no data set available which looks specifically at malpractice claims related to controlled substance prescribing. Developing a monitoring tool to track malpractice claims as they are related to controlled substance prescribing would provide the State of Florida with accurate information regarding the nature of the malpractice (inappropriate dose prescribed, adverse outcome, drug trafficking, etc) and provide information to use to address inappropriate prescribing.

In conclusion, there are currently 48 states and the District of Columbia that allow some form of controlled substance prescribing. No state has ever rescinded a law granting ARNP controlled substance prescribing. There have been many studies which show that ARNPs provide care comparable to physicians, and that overall, ARNPs prescribe less medications than physicians (Haider, 2008, Horrocks, 2002; Brown and Grimes, 1995). In December, 2008, the Florida Senate's Committee on Health Regulation was given a recommendation based on

extensive study to grant controlled substance prescribing authority to Florida licensed ARNPs who have attained national certification. One senator again brought up the safety of ARNPs prescribing controlled substances and directly asked about malpractice rates in other states that allow ARNPs this authority. This study showed that there is no increase in malpractice rates, adverse actions, criminal convictions or civil judgments in states where ARNPs prescribe controlled substances, either fully or partially, supporting the hypothesis. In fact, states that do not have controlled substance prescriptive authority have increased malpractice rates or increased criminal convictions, civil judgments, and adverse actions than states that do not.

There are two implications for this study. This study has implications for nursing practice in that ARNPs who are allowed to prescribe fully can provide comprehensive, cost-effective care (Kaplan & Brown, 2004). Patients who can be treated fully by ARNPs spend less time in the office and have less return visits to have their needed prescriptions (Chandler, 2007). This study also shows the need for a comprehensive data base that tracks specifically controlled substance errors. There are other tracking systems including the Health Integrity Protection Data Bank, and this does delineate medication errors, but does not separate RN medication errors from ARNP prescribing errors. In addition, national requirements for mandatory reporting to the National Practitioner Data Bank for all providers would help to provide more accurate data.

Recommendations for future studies would include a concurrent study in a controlled setting, such as a healthcare facility, to monitor ARNP and physician controlled substance

prescribing errors to compare to the national NPDB rates. This would provide more accurate data of the state of controlled substance prescribing errors.

APPENDIX: NOT HUMAN RESEARCH DETERMINATION



University of Central Florida Institutional
Review Board

NOT HUMAN RESEARCH DETERMINATION Office of Research & Commercialization

From : UCF Institutional Review Board #1
FWA00000351, IRB00001138

To : Deborah C. Chandler, ARNP

Date : February 4, 2010

Dear Researcher:

Thank you for sending the description of your proposed research to the IRB office. After reviewing this information and discussing your plans on the phone, the IRB determined that the following proposed activity is not human research as defined by DHHS regulations at 45 CFR 46 or FDA regulations at 21 CFR 50/56:

Type of Review:	Not Human Research Determination
Project:	Analysis of nurse practitioner and physician malpractice in all fifty states – publically available data, as well as previously published in medical journals; no personal identifiers.
Investigator:	Deborah Chandler
Research ID:	N/A

University of Central Florida IRB review and approval is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are to be made and there are questions about whether these activities are research involving human subjects, please contact the IRB office to discuss the proposed changes.

On behalf of the IRB Chair, Joseph Bielitzki, DVM, this letter is signed by:

Joanne Muratori
IRB Coordinator

cc: Dr. Elizabeth Rash

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