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ANALYZING THE ASSOCIATION OF CERTIFICATE OF NEED REGULATIONSON VOLUME AND QUALITY INDICATORS FOR HEART AND KIDNEY TRANSPLANTATION

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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DEDICATION

It is with love and respect that I dedicate both the efforts and product of this Dissertation to my brother, Jack, who has inspired me throughout my life. He was available for specific help and support on my dissertation and many other challenges in my life. He has shared his family with me, his beach trips and his exceptional fine mind which I will be forever grateful.

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ANALYZING THE ASSOCIATION OF CERTIFICATE OF NEED REGULATIONS ON VOLUME AND QUALITY INDICATORS FOR HEART AND KIDNEY TRANSPLANTATION

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States have historically used Certificate of Need (CON) regulations to regulate cost, quality, and access to healthcare services. Federally mandated in 1974, the regulation required the states to review requests for new healthcare construction and services. In theory, community-level planning backed by the state-level CON review and health planning process would prevent unnecessary duplication of services and the accompanying costs (Smith-Mellot, 2004). However, none of the published studies have examined the association of CON regulation on volume and outcomes of solid organ transplants.

In 1984, the federal mandate ended, and each state was allowed to determine whether or not to maintain its CON programs; more than one-third of the states eliminated them (Altman & Ostby, 1991). Currently, 37 states including the District of Columbia

have CON programs (American Health Planning, 2010). Of those states, 21 include organ transplant as a reviewable, regulated service.

Although several studies have investigated whether CON regulation has affected healthcare cost, to date very little has been written about the impact of CON on volume and quality of care; the data that does exist is contradictory. In 1988, investigators studied the effects of CON regulation on mortality and observed that greater regulatory stringency was a positive and significant predictor of hospital mortality rates (Shortell & Hughes, 1988). In contrast, DiSesa et al (2006) found no significant difference in risk-adjusted mortality for cardiac surgery patients in states with and without CON regulations. The gap between evidence and decision-making and the large number of states that use CON to regulate healthcare services indicate a need for a study on the quality of healthcare services. Solid organ transplantation is a complex, high-cost treatment that was performed over 27,000 times in 2008.

The purpose of this study is to assess the association of solid organ transplant CON regulations using clinically rich data available from the Scientific Registry of Transplant Recipients (SRTR). This study tests the hypotheses that states with solid organ transplant CON regulations have fewer transplant centers, higher volumes of heart and kidney transplants per center, lower graft failure rates and lower patient mortality rates per center. In addition, this study assesses these hypotheses using two different transplant procedures (heart and kidney). This study provides additional information for transplant centers to use in their strategic decision making. Moreover, with the presence of minimum volume standards for transplant procedures mandated by the Centers for Medicare and Medicaid

(CMS) now, the policy implications of continuing or repealing CON regulations should be examined.

CHAPTER I
INTRODUCTION

Within the last year a major healthcare bill was passed that will reform the U.S. healthcare system and it was one of the President's top legislative priorities. Policy makers and providers seek to ensure the provision of high-quality healthcare while restraining cost growth. Many states pursue these two goals by enforcing Certificate of Need (CON) programs. CON is a regulatory system that requires healthcare providers to obtain prior authorization from the state for major capital expenditures and the offering of new or expanded services (Hyman, 1977). CON regulations are intended to contain healthcare costs, ensure equal access and quality. When CON regulation was first implemented, healthcare providers were reimbursed based on the cost of the services they provided, no matter how high that cost. Their charges incorporated overhead expenses and the other costs of doing business, as well as the necessary profit margin. Under this system overbuilding was costly because the expenses of inefficiency were built into reimbursement. The regulatory mechanism of CON regulations was designed to control costs by limiting the expansion and duplication of services.

Now, some thirty years later, the competitive forces of managed care have transformed healthcare. Provider payments are determined by capitation, fixed fees for services, and fee schedules that are the product of negotiation and have little or no bearing on the underlying costs. Today's providers compete on price and quality of care – not costs—and are neither rewarded for nor bailed out when they overspend on facilities or technology. Given these fundamental shifts, it is particularly important to

examine the effect of CON regulations. Is CON relevant in today's healthcare environment?

Regulation of healthcare resources began in 1948, with the passage of the Hospital Survey and Construction Act (PL 79-725), commonly known as the Hill-Burton Act. The Act was intended to encourage the development of hospitals in rural areas because of a perceived shortage of healthcare facilities (Dunham, 1981). The Act required states to institute health policy planning in order to receive federal funding for hospital construction (Sloan, 1988).

Additional concerns were duplicated services and excess supply of equipment. Under fee-for-service insurance, hospitals would be fully reimbursed for the amount spent on patients. Hospitals were also paid their total costs for services rendered to the elderly and the poor after the introduction of Medicare and Medicaid in 1966. The extensive coverage of hospital services from third-party payers had two effects: it removed patients' incentive to look for the best offer, and hospitals being assured of profit by the payment methods had no incentive to be concerned with efficiency and the costs of treatment.

Small hospitals emulated medical centers by adopting the latest technology and expensive equipment, disregarding the economy of scale. The larger the number of hospitals in a community, the greater the need for each hospital to invest in expensive equipment to attract physicians and patients. This non-price competition is termed as "medical arms race" (McGinley, 1995). In addition, since hospitals were fully reimbursed, they could increase the capacity by adding more beds even when the occupancy rates were

low. As a result, excess capacity and "medical arms race" contributed to the ever-rising healthcare costs.

As an attempt to control the supply side of the healthcare market to contain costs, in 1974, Congress passed the National Health Planning and Resources Development Act (PL 93-641), which mandated each state to designate health planning agencies for CON reviews to determine whether the proposed projects were necessary for the needs of local communities. Despite its intended purpose of restraining healthcare costs, the medical bill reached $332 billion in 1982, the first time the cost of healthcare exceeded 10% of the gross domestic product (GDP) (McGinley, 1995). Subsequently, Congress repealed the mandate for state CON regulations in January, 1987. Each state, however, was free to continue regulating healthcare facilities.

Since then, 14 states have dropped CON regulations. Conover and Sloan (1998) proposed several reasons why some states have chosen to abandon CON regulations. In addition to CON, two other types of regulations were implemented to hold down costs. In the late 1980s, Medicare adopted the Prospective Payment System (PPS), which greatly weakened hospitals' incentive to inflate costs and the growth of Health Maintenance Organizations (HMOs) that pressured hospitals to lower costs by negotiating discounted rates. Taken together, many policy makers believed that these regulations and market pressures would control healthcare costs, without CON laws.

Today, the 37 states (and the District of Columbia) (see Appendix 1) that retain CON regulations have made them more flexible by raising review thresholds and limiting the scope of the regulations (Conover & Sloan, 1998).

The coverage and review thresholds vary considerably across these states. According to the 2010 National Directory State Certificate of Need Programs published by the American Health Planning Association (AHPA) (see Appendix 2), Vermont covers 30 types of healthcare services and equipment, the highest coverage rate of all states. Ohio has the lowest coverage: only for nursing home and long-term care beds. Only 21 of the 37 states that still have CON regulations include organ transplant services.

While CON laws are a result of federal legislation, CON programs, where they exist, are based on state statutes, rules and regulations which designate an agency or board to administer the process of reviewing CON applications and authorize the CON regulatory review board or commission to promulgate regulations specifying the criteria by which CON applications are evaluated. These criteria are commonly required to be created in conjunction with the state's long-term health plans and goals. In the states where CON regulations are still in effect, CON programs constitute the most frequently used form of state health planning (Madden, 1999).

The original intent of CON statutes was to control costs by regulating major capital expenditures and changes in healthcare services capacity (Chayer & Sonnenreich, 1978). CON regulations were designed to prevent duplication of healthcare services. CON regulations are based on the theory that in an unregulated market, healthcare providers will provide the newest, most costly technology and equipment, regardless of duplication or need (Feldstein, 2005). According to Ameringer (2008), if policy makers thought that government regulation in the 1970s would "stem rising costs of healthcare, they were

mistaken" (p. 57). Although CON regulations were intended to reduce healthcare costs by preventing duplication of services, healthcare costs continued to rise.

The use of CON programs as a means of ensuring quality of care has been a matter of debate (Conover & Sloan, 1998). Vaughan-Sarrazin et al. (2006) supported the contention that CON laws both increase coronary artery bypass graft (CABG) volumes and improve patient outcomes. This analysis was limited to elderly patients, did not control for regional factors and, due to its reliance on an administrative database, did not adjust fully for clinical factors. DiSesa (2006) found that CON states have higher hospital volumes but not better outcomes for coronary artery bypass grafting. Supporting this finding, Ho (2004) and Popescu, Vaughan-Sarrazin and Rosenthal (2006) both concluded that CON states have higher hospital cardiac procedure volumes but not better outcomes than do states without CON regulations.

The association between volume and outcomes appears to be strong. Several studies (Birkmeyer et al., 2002; Ho, 2004; Schrag et al., 2003) base their conclusions that increased volume decreases mortality among patients in high- and low-volume hospitals. Mortality rate, the likelihood to survive the procedure, is not the best or even the only indicator of quality outcomes. Other indicators are likelihood of experiencing complications (complication rate), probability that a patient may be readmitted to the hospital (readmission rate), and length of stay. In addition, patient data in the volume studies are often not "risk-adjusted." Risk adjustment takes into account the severity of a patient's illness upon admission to the hospital, and is necessary for an apple-to-apple comparison.

CON regulations also were intended to ensure quality of care and clinical proficiency by limiting the number of healthcare facilities performing complex medical procedures. More than 100 studies have established a strong relationship between higher provider procedure volume and better outcomes (Conover & Sloan, 1998). Luft, Bunker, and Enthoven conducted the pioneering study noting this link in 1979. After another decade of research, Luft et al. (1990) reviewed the literature and concluded that there was a link between volume and quality. Because CON is not associated with substantially lowering healthcare costs (Conover & Sloan, 1998; Sloan & Steinwald, 1980), the reluctance to eliminate CON regulation may be partly attributable to the impact on quality.

The Institute of Medicine's (IOM) reports, *To Err is Human; Building a Safer Health System* (Kohn, Corrigan & Donalson,1999) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) gave the healthcare industry a charge to make healthcare in America safer and of consistently high quality. All stakeholders in care are to be held accountable. The second report outlines six aims for improving the healthcare system: all healthcare should be safe, effective, patient-centered, timely, efficient, and equitable. Multiple stakeholders have a significant interest in using legislation or other regulatory means to ensure affordable and high quality healthcare for everyone. This is especially true for treatments like coronary artery bypass grafting, in which differences in procedural quality can have a direct impact on patient outcomes. New York and Pennsylvania were among the first states to require all hospitals and practitioners performing CABG surgery to report case volumes and outcomes annually. Other states have followed. Although the results of these surveys are available to the

public, their effects on quality of care have been difficult to measure (Birkmeyer, 2002). Other stakeholders, such as the Centers for Medicare and Medicaid Services (CMS) and industry consortia of high-volume purchasers of healthcare services (the Leapfrog Group, for example) have proposed volume and/or outcome criteria for certification of and payment for expensive services such as CABG surgery.

There is growing interest in the quality of healthcare and in the use of quality measures to direct patients to hospitals and providers offering high quality, low cost healthcare (Epstein, 1995; Clinton, 1993; Enthoven & Kronick, 1989). Although tremendous strides in the development of quality measures have been made, there is still little agreement on what constitutes "quality," how it should be measured, and how quality information should be used. Some experts predict that it may be another 10 years before highly reliable and valid quality measures will be widely available (IOM, 2001). The dilemma is that, while there is an increasing need for quality indicators as a result of a changing healthcare environment, this new environment has important implications for the use of these measures.

Since the 1970s, a growing body of research in the U.S. has addressed the empirical relationship between the number of surgical procedure and the outcomes after treatment in a particular hospital or by a particular physician ("volume-outcome" studies). Virtually all of the studies examining the relationship between volumes and outcomes have been conducted in the U.S. (a few have been conducted in Canada) (Banta, Engel & Schersten, 1992). One reason is that European countries routinely regulate the number of facilities that are allowed to perform certain procedures, and thus there are fewer

institutions with low volumes. The ready availability of routinely collected data on procedures, diagnoses, and outcomes in the U.S. also facilitates such research (Banta, Engel & Schersten, 1992).

The use of volume information in a regulatory context emerged from a healthcare market in the U.S. where cost-based reimbursement was still the norm, hospitals were the center of healthcare delivery, and the "medical arms race" drove hospitals to compete for physicians and their patients by offering more services and possibly better quality, although the latter was rarely measured explicitly. Today, the driving market factors are a focus on consumer decision-making, the increasing dominance of managed care organizations, the consolidation of health plans and facilities, and the use of selective contracting through negotiations with purchasers. This changing environment has added new complexities in using volume information, as well as other quality indicators, within both regulatory and market-oriented environments.

Despite this growing interest in assessing surgical quality, there remains controversy about how best to identify high-quality hospitals for individual procedures. Hospital procedure volume is currently among the most widely used quality indicators. There remains little doubt that volume is inversely related to mortality with many procedures (Birkmeyer et al., 2002; Dudley et al., 2000; Halm et al., 2002). But critics state that volume is a crude surrogate for quality and a poor predictor of individual hospital performance (Christian et al., 2003; Hannan, 1999; Rathore et al., 2004). Instead, many think that surgical quality is best judged by direct outcome measures, including mortality.

Overview of Study

Because of the lack of research for transplant procedures and the questions related to the best measures of quality, this study examines structure measure (centers and center's volume) as well as outcome measures (graft failure and patient death). The question under examination by this study is whether or not solid organ transplant CON regulations for heart and kidney transplants makes a differences in the number of transplant centers and volume per center as well as the quality outcomes for transplant centers in states with and without solid organ transplant CON regulations. Previous studies have examined the impact of CON on volume and quality for coronary artery bypass grafts and coronary interventions but no studies have been done for the transplant populations. This study would add to that knowledge and provide additional information for transplant centers to use in their strategic decision making. With the presence of minimum volume standards for transplant procedures mandated by CMS, the policy implication of continuing or repealing CON laws should be examined.

The next chapter provides an overview of the history of Certificate of Need, the theoretical basis for CON laws, and the intent and structure of CON regulations. The third chapter explores the relevant research. Studies of the quality, access, cost and expenditures of CON are reviewed.

Following the literature review, the study question and methodology utilized for this study are explained. This study will use a clinically-rich database available from the Scientific Registry of Transplant Recipients (SRTR) on 101 adult heart transplant centers and 208 adult kidney transplant centers within the United States. The years of study will

be 2006 through 2008, when the number of states with CON regulations for heart and kidney transplantation remained stable. The variables of interest will be the number of transplant centers per state, the volume of transplants per center and the risk-adjusted graft failures and patient deaths per transplant center. This study question is: What is the association of solid organ transplant CON regulations on the number of transplant centers per state and the volume and outcomes at heart and kidney transplant centers?

CHAPTER II
CERTIFICATE OF NEED

In 1964, local businesses and Blue Cross in Rochester, New York established a community health planning council composed of payers, consumers and providers to evaluate the need for hospital beds. The council concluded that there was a surplus. This work led to the passing of the nation's first Certificate of Need (CON) regulations by the State of New York in 1966 (Dunham, 1981). State and federal involvement in planning for health facilities has an extensive and well-documented history. The regulation of healthcare resources began after World War II, with the passage of the Hospital Survey and Construction Act (Dunham, 1981), commonly known as the Hill-Burton Act (PL 79-725), in 1946. The enactment of federal CON regulations was the genesis of government-mandated health policy planning. While federal regulations provided legislation and enforcement provisions, most program development and implementation has taken place on the state or local level (McGinley, 1995).

The objective of CON regulations was to control costs by restricting provider capital expenditures. The principle behind CON regulations is that excess capacity (in the form of facility overbuilding) directly inflates healthcare prices. When a hospital cannot fill its beds, fixed costs must be met through higher charges for the beds that are used.

CON regulations originated to regulate the number of beds in hospitals and nursing homes, and to prevent overbuying of expensive equipment. Mandatory regulation through health planning agencies determined the most urgent healthcare needs, contributed to solutions for these needs, and attempted to manage the fluctuations in prices often caused

by a competitive market. The idea was that new or improved facilities or equipment would be approved based only on a genuine need in a community. Statutory criteria often were created to help planning agencies decide what was necessary for a given location. By reviewing the activities and resources of hospitals, the agencies made judgments about what needed to be improved. Once need was established, the applicant organization (corporation, not-for-profit, partnership or public entity) was granted permission to begin a project.

Development of Federal Regulations

The passage of the Hill-Burton Act marked the beginning of more than forty years of federally funded health policy planning (Sloan, 1988). It was intended to encourage the development of hospitals in rural areas because of a perceived shortage of healthcare facilities after the Depression and World War II (Dunham, 1981). The Act required states to institute health policy planning in order to receive federal funding for hospital construction (Sloan, 1988). In addition to producing a plan delineating their healthcare needs, states were required to inventory existing healthcare facilities and designate a single agency for health policy planning (Dunham, 1981). Between 1946 and 1971, the Hill-Burton program provided financial assistance for the construction of new facilities to 60% of American hospitals (Dunham, 1981).

In 1964, New York became the first state to enact a statute authorizing the state government to determine whether or not there was a need for a new hospital or nursing home before it was approved for construction. Four years later the American Hospital

Association (AHA) expressed an interest in CON regulations, and started a national campaign for states to generate their own CON regulations.

By 1974, 24 states had enacted CON regulations in response to the passage of Section 1122 of the 1972 Social Security Amendments (Hyman, 1977). Section 1122 allowed the Secretary of Health, Education, and Welfare to enter into agreements with states with a "designated planning agency" responsible for determining whether healthcare facilities could make capital expenditures (Chayer & Sonnenreich, 1978). Mandatory federal health policy planning did not exist before Section 1122 was passed and only five (5) states had health policy planning regulations. Similar to CON regulations, Section 1122 forced states to review capital expenditures exceeding $100,000, bed capacity changes, or "substantial" changes in services (Mendelson & Arnold, 1993). It was much more comprehensive than existing state CON regulations and covered all major healthcare institutions (Hyman, 1977). States failing to institute health policy planning programs would lose their eligibility for Medicare and Medicaid reimbursement. Because Medicare and Medicaid reimbursement is a significant source of revenue for most healthcare facilities, healthcare facilities would comply with state CON regulations. "Two years after the passage of the '1122' amendments 37 states had opted to establish an agency for the purpose of implementing the federal law" (Hyman, 1977, p. 31).

The 1972 Amendments also established Professional Standards Review Organizations (PSRO) to control utilization of services and to review procedures (Ashby, 1984). PSROs preceded Professional Review Organizations (PROs), established in the mid-1980s to evaluate the reasonableness and necessity of inpatient services provided to

Medicare patients (Sloan, 1988). Although advocates of PSROs argue that they have improved the quality of healthcare, the majority of evidence indicates that PSROs were used primarily to control costs, not to promote quality (Sloan et al., 2001). A 1979 PRSO Program Evaluation study found that each dollar spent by states on reviewing CON applications yielded approximately 90 cents in reimbursement savings, a savings-to-cost ratio of about 0.9-to-1 (Congressional Budget Office, 1988). However, in 1978, data indicated that only 40% of the costs of PSRO reviews were recouped (Congressional Budget Office, 1988).

The National Health Planning and Resource Development Act (NHPRDA), enacted in 1974, pushed CON regulations to the forefront of government healthcare cost containment efforts. The Act was designed to develop a "national health planning policy" (National Health Planning and Resource Development Act, 1974) in response to the "lack of uniformly effective methods of delivering healthcare, the substitution of ambulatory and intermediate care for inpatient hospital care, and the lack of basic knowledge regarding personal healthcare and methods for effective use of available services" (Rubel, 1976, p. 4). The Act required federal agencies to pass health policy planning guidelines and establish specific goals, priorities, and success criteria (Sloan, 1988). It prompted states to enact CON statutes by guaranteeing federal funding for state CON review programs and conditioning the receipt of certain healthcare funding on enacting CON regulations (McGinley, 1995). It required all 50 states to have a structure in place that involved the submission of proposals and obtaining approval from a state health planning agency before beginning any major capital projects such as building expansions or ordering new high-

tech devices. Many states implemented CON regulations in part because of the incentive of receiving CON federal funds. As enacted, this federal oversight plan created disincentives for noncompliance with the mandated establishment of CON review programs. In 1974, 23 states had CON statutes, and by 1983, all states except for Louisiana had a CON law (Louisiana passed CON regulations in 1991).

In the 1980s, however, the deregulation movement set the stage for the elimination of federal CON regulations. Federal support for CON regulations ended in 1986 with the repeal of the National Health Planning and Resources Development Act of 1974 (Madden, 1999). After the Act's repeal, state CON statutes were no longer federally subsidized (McGinley, 1995). Legislators were concerned that CON regulations "failed to reduce the nation's aggregate healthcare costs, and it was beginning to produce a detrimental effect in local communities (McGinley, 1995). Ameringer (2008) states that an "important reason why government planning and regulation failed to stem costs concerned weak financial incentives." He goes on to state that the retrospective payment method established by Congress in 1965 gave "physicians carte blanche to maximize fees and medical services. Physicians enhanced their income by doing more rather than less – by seeing more patients, by ordering more tests, and by performing more procedures." The federal mandate was repealed in 1987, and its federal funding was withdrawn.

In the decade that followed, 14 states abolished their CON regulations. However, 36 states currently maintain some form of CON regulation, and even the 14 that repealed their state CON regulations still retain some mechanisms intended to regulate costs and duplication of services. Puerto Rico and the District of Columbia also have CON

regulations. States that have retained CON regulations tend to concentrate their activities on outpatient facilities and long-term care. This is largely due to the trend toward free-standing, physician-owned facilities that now constitute an increasing segment of the healthcare market.

While current CON regulations were modeled upon federal legislation, CON regulation is based on state statutes and rules and regulations which designate an agency or board to administer the approval process of reviewing CON applications and give authority to the CON regulatory review board or commission to promulgate regulations specifying the criteria by which CON applications are evaluated. These criteria must usually be created in conjunction with the state's long-term health plans and goals. In the states where CON is still regulated, CON statutes constitute the predominant form of state health planning. State CON regulations generally have two functions: to develop a health plan that promotes equitable access to healthcare services; and, to review CON applications submitted by healthcare providers (Morrissey, 2001).

The Theoretical Basis for CON

Roemer and Shain (1959) have argued that hospital beds would be intentionally filled by providers who induce ill-informed patients into hospital stays; this has been termed the "Roemer effect." They stated that an increase in the number of hospital beds per capita increased hospital utilization rates (Roemer and Shain, 1959), and this was an important underpinning of efforts to control hospital construction through health planning (Madden, 1999). Attempts to measure the magnitude of the effect have yielded results

ranging from no effect to a one-to-one relationship and thus the research has been inconclusive. One study (Ginsburg & Koretz, 1983) restricted its inquiry to Medicare patients and used a unique data base, thus avoiding many of the shortcomings of earlier studies. This study concluded that a 10% increase in hospital beds per capita would increase hospital utilization by Medicare enrollees by about 4%. While the basis of the argument might have been valid during the "cost-plus reimbursement era", it is widely asserted that it has not been demonstrated to be the case today, an era characterized by the shifting of financial risk to providers (Morrisey, 2001).

In response to rising healthcare costs, the Centers for Medicare and Medicaid Services (CMS) have transitioned from reimbursing providers on a cost-plus or fee-for-service basis to the prospective payment system (PPS), under which reimbursement is set before the service is provided (Madden, 1999). CMS originally paid for hospital services using a "cost plus" reimbursement basis, where hospitals were paid for all their costs and more. Under this reimbursement system, hospital profits were directly linked to patient volumes. In 1983, "cost-plus" reimbursement was replaced by a prospective payment system defined by "diagnosis-related groups" (DRGs) based on the patient's primary diagnosis. Under this reimbursement system, hospitals have the financial risk of providing services efficiently under a set fee scale for a given diagnosis.

The premise of CON regulations was simple: lower costs by reducing duplication, The term "duplication" is often called "excess capacity" and it is used in the assertion that societal costs increase when there are "too many" providers of the same health service (Madden, 1999). Madden (1999, p 1651) summarized studies of excess capacity saying,

"Without a clear statement of this standard (e.g., the correct number of hospital beds), we cannot determine what constitutes too many." The research literature provides no clear statement (Madden, 1999).

Arguments For and Against CON

Advocates of CON regulations say that healthcare is not a "typical" economic product. They argue that many "market forces" do not obey the same rules for healthcare services as they do for other products. In support of this argument, it is often pointed out that, since most health services (like an x-ray) are "ordered" for patients by physicians, patients do not "shop" for these services as they do for other commodities. This makes hospital, lab and other services insensitive to market effects on price, and suggests a regulatory approach based on public interest.

The American Health Planning Association (AHPA) is the professional group of state agencies responsible for regulation and planning. They identify three factors that suggest the need for CON regulations. The primary argument is that CON regulations limit healthcare spending. CON regulations can promote appropriate competition while maintaining lower costs for treatment services. The AHPA argues that by controlling construction and purchasing, state governments can oversee what expenditures are necessary and where funds will be used most effectively. This helps eliminate projects that detract attention from more urgent and useful investments and reduces excessive costs. AHPA also asserts that CON regulations have a valuable influence on the quality of care. When facilities and equipment are monitored, hospitals and other treatment centers

can ascertain what sort of services are in demand and how well patients are being taken care of.

Supporters also contend that the programs distribute care to areas that new medical centers are likely to ignore. CON regulations are a resource for policymakers. CON regulations are described as a reliable way to implement planning policies and practices, and to distribute healthcare to all populations. The CON process can call attention to underserved areas in need because planners can track and evaluate the requests of hospitals, doctors and citizens and see which areas need improvement and development.

CON regulations also have been subject to wide criticism. To start, opponents argue that it is not clear that these state-sponsored programs actually controlled healthcare costs. For example, by restricting new construction, CON regulations not only reduce price competition among facilities, but may actually keep prices high. Barriers to new building are seen as unfair restrictions, sometimes by both existing facilities and by potential new competitors. There is little compelling proof that overcapacity or duplication leads to higher charges. In 2004 the Federal Trade Commission (FTC) and the Department of Justice both claimed that CON regulations actually *contribute* to rising prices because they inhibit competitive markets that should be able to control the costs of care and guarantee quality and access to treatment and services (FTC & DOJ, 2004).

Some opponents believe that changes in the Medicare payment system (such as paying hospitals according to Diagnostic Related Groups or DRGs) would obviate the need for external regulatory controls, because healthcare organizations would be more subject to market pressures. Some critics have pointed out that the CON regulations are not

consistently administered. A “flexible” program could allow development, to the dismay of competitors. A “restrictive” program could limit competition, with the same effect. Many argued that health facility development should be left to the economics of each institution, in light of its own market analysis, rather than being subject to political influence.

Some evidence suggests that lack of competition has paradoxically *encouraged* construction and additional spending. Some opponents of CON regulations believe an open healthcare market, based on quality rather than price, might be the best means of containing rising costs. Proponents of CON regulations disagree. This debate rests on the same arguments as many other “Regulated market” vs. “Open market” discussions.

In theory, CON regulations are granted based on objective analysis of community need, rather than the economic self-interest of any single facility. However, opponents of CON regulations claim that the programs have not worked this way. They cite cases in which CON regulations were apparently enacted on the basis of political influence, institutional prestige or other factors apart from the interests of the community. Furthermore, it is sometimes a matter of debate what sort of development is actually in the community’s interest, with people of good will sharply divided.

A central argument against CON regulatory policy is that by intervening in the market, natural market forces are disrupted and is significantly anti-competitive (Feldstein, 2005). As a result, CON regulations are often barriers to new market entrants and many healthcare economists see them as a strong disincentive to reaping the benefits of new technologies. Porter et al. (1994) states:

> In industry after industry, the underlying dynamic is the same: competition compels companies to deliver increasing value to customers. The fundamental driver of this continuous quality improvement and cost reduction is innovation. Without incentives to sustain innovation in healthcare, short-term cost savings will soon be overwhelmed by the desire to widen access, the growing health needs of an aging population, and the unwillingness of Americans to settle for anything less than the best treatments available. Inevitably, the failure to promote innovation will lead to lower quality or more rationing of care—two equally undesirable results. (p. 131)

Furthermore, there is consensus among researchers that competition among providers drives quality-of-care, patient outcomes, and cost efficiency (Smith-Mello, 2004). According to Madden (1999, p. 1659), "there is . . . agreement across all perspectives of [health economics theory] on one issue: the negative consequence of too much concentration of economic power." Hospitals in more competitive markets have been demonstrated to have average costs below those of less competitive markets (Zwanziger & Melnick, 1996). Competition appears to give economic power to patients and payers by creating choices for consumers and raising quality standards as providers compete for patient loyalty. When patient choice is diminished, decisions about access, quality, and beneficial outcomes become the purview of oligopolistic market players who, as decision makers acting in the absence of healthy competition, are free to ignore patient demands and needs (Brown et al., 1992).

CON regulations are an example of a governmental regulatory policy that is often in conflict with the goals of antitrust enforcement, and have been regularly denounced by the Federal Trade Commission (FTC). Seeking to preserve competition in healthcare markets, the FTC has opposed CON regulations in a 2004 joint study with the Department of Justice (DOJ). The agencies believe that CON regulations are not successful in containing healthcare costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits (FTC & DOJ Report, 2004). Market incumbents can too easily use CON procedures to forestall competitors from entering an incumbent's market. The vast majority of single-specialty hospitals—a new form of competition that may benefit consumers—have opened in states that do not have CON regulations.

Two important factors determine the number of hospitals competing in a given market: economies of scale and barriers to entry. Entry barriers increase the market power—hence profitability—of those hospitals currently in the market (Feldstein, 2005). CON regulations restrict the healthcare market by preventing healthcare providers from choosing the types and amounts of care they will offer – and even whether they may enter the market at all. Economic theory predicts that providers already in the market will react to CON regulations in two ways: altering their labor and capital mix, and raising prices (Saikever & Bice, 1976).

To produce goods, firms employ a mix of capital and labor. CON regulations restrict capital investments – especially beds – but not labor. Consequently, firms that want to expand or retain their market shares will shift investment from categories that are

under intense scrutiny, like enhancing facilities and adding beds, to those that are less closely monitored by CON regulations, such as labor and perhaps equipment.

By restricting entry and exit, CON regulations grant firms monopoly power. Under CON regulations, then, healthcare providers are monopolists that will charge higher prices because they do not face competition from other firms. CON regulations encourage prices to rise by limiting the amount of certain healthcare services that monopolists may provide to patients. These caps make services more valuable to consumers at the margin, further pushing up prices. This effect is especially likely in healthcare, since insurance decreases the price sensitivity of most consumers. At the same time, though, price increases might not reach their full potential because managed care firms make great efforts to lower costs. Although a thorough literature review revealed no studies that examine the association of CON regulations on pricing, economic theory strongly predicts that such regulations would raise prices. Capping prices through mandated rate-setting would be the only way to ensure that prices do not rise under CON regulations.

Another likely effect of monopoly power is that a healthcare provider will have fewer incentives to improve or maintain efficiency and quality. Kessler and McClellan (2000) offered some support for this argument. The researchers found that after 1990, high levels of hospital competition both lowered costs and improved outcomes for Medicare beneficiaries. In states with CON regulations, the healthcare market is further distorted because CON regulations do not apply to all healthcare services. Services such as magnetic resonance imaging (MRI), which are exempt from CON regulations, are free to proliferate. Such uneven application of CON regulations gives an advantage – and

incentive – to firms and individual providers to supply more unregulated services, which are not necessarily needed more by the community.

Intent and Structure of CON Regulations

The assumption underlying CON regulations is that excess capacity (in the form of facility overbuilding) directly inflates healthcare prices. When a hospital cannot fill its beds, fixed costs must be met through higher charges for the beds that are used. Larger institutions have higher costs, so supporters of CON regulations claim that it makes sense to limit facilities by building only enough capacity to meet actual needs.

CON statutes were intended to regulate the number of beds in hospitals and nursing homes, and to prevent overbuying of expensive equipment. Mandatory regulation through health planning agencies determined the most urgent healthcare needs, contributed to solutions for these needs, and attempted to manage the price fluctuations that are often caused by a competitive market. The idea was that new or improved facilities or equipment would be approved based only on a genuine need in a community. Statutory criteria often were created to help planning agencies decide what was necessary for a given location. By reviewing the activities and resources of hospitals, the agencies made judgments about what needed to be improved. Once such a need was established, the applicant organization (corporation, not-for-profit, partnership or public entity) was granted permission to begin a project. These approvals generally are known as "Certificates of Need."

CON regulations are now established by state law. CON regulations prohibit identified health facilities, services or equipment from being initiated, upgraded or modernized, expanded, relocated or acquired without a certificate from that state determining that the facility, service or equipment is needed. Criteria for the approval or denial of a CON application are established by law or regulation as review standards and include cost, quality and access considerations. Covered facilities, services or equipment, like review standards, vary from state to state.

The latest data available indicates that 37 states including the District of Columbia have CON regulations applying to at least one service or medical procedure and 14 states do not (Appendix 2). Ten CON-regulated states do not include acute care hospitals in their program, but all 36 include long-term care. The number of services covered by any one state program varies from 1 to 30 and there are wide variations in how the programs are administered. Transplant services are covered in 21 states.

Since the inception of CON programs, many changes occurred in healthcare financing and delivery rendering most of the fiscal benefits expected from CON obsolete in today's market place. A significant change is the shift from cost-based reimbursement methodologies toward service-based payment methodologies. Many private healthcare insurance companies as well as large public programs such as Medicare and Medicaid adopted service based payments methods such as inpatient prospective payment system, diagnostic related groups, resource utilization groups, outpatient prospective system, ambulatory payment classification system, and managed care capitation rates over the last two decades. The trend toward service-based payments reduced

provider incentives to build excess capacity or take on unneeded capital investment projects, as they cannot directly recover the cost of their investments. Thus, this concern does not seem to have validity in today's healthcare market as it did 30 years ago.

With the changes in the healthcare environment it is important that CON regulations are examined for relevancy and usefulness. This study examines specifically the association of solid organ transplant CON regulations on the number of transplant centers per state, the volume and the outcomes for heart and kidney transplant centers.

CHAPTER III
LITERATURE REVIEW

This chapter reviews the literature on the association of Certificate of Need (CON) regulations on healthcare in addition to the literature on volume and quality. Three major areas of healthcare delivery are discussed here – quality, access, and costs -- in relationship to CON regulations. An interactive relationship exists among the cost of healthcare, people's ability to obtain needed healthcare services, and the quality of services. This review of literature focuses on the studies of volume and quality and the influence of CON regulations since this is the main focus of this study.

The literature on the influence of CON regulations on access, quality and costs is mixed. Empirical research does not appear to support the claim that CON regulations reduce healthcare costs. CON regulations have not been found to be effective in controlling overall per capita healthcare spending because many factors affecting costs such as labor and physician services are beyond the scope of the CON regulations. Nor has CON regulations been found to be effective in controlling hospital costs because (a) not all services are regulated under CON regulations, (b) CON regulations are not always effective in controlling supply, and (c) when bed supply was controlled, expenditures per bed have been found to increase (Arnold & Mendelson, 1992; Conover & Sloan, 1998: Custer, 1997; Delaware Health Commission, 1996; Lanning et al., 1991; Mendelson & Arnold, 1993; Salkever, 1978).

The empirical evidence on the access impact of CON regulations is limited and contradictory. In some studies, CON regulations have been found to protect inner city

facilities and enhance healthcare access while in other studies CON regulations are shown to have restricted needed services. The effects of access seem to vary by state and by service. Finally, there appears to be lack of empirical evidence on the rural access effects of CON regulations (Arnold & Mendelson, 1992; Brown et al., 1992; Delaware Healthcare Commission, 1996; Hackey, 1993; Kiel, 1993; McGinley, 1995; Mendelson & Arnold, 1993; Rettig, 1992; Sloan, 1988; Weaver, 1995).

Evidence is inconclusive regarding the ability of CON regulations to improve quality by forcing high utilization of equipment or services even though high utilization rates have been found to improve outcomes. There is some evidence that CON regulations protect quality in the home health sector by filtering out unprepared or unqualified providers. CON regulations effect on preventing for-profit providers from participating and the resulting effect on quality are mixed. Finally, findings indicate that CON regulations do not provide an ongoing mechanism for monitoring quality (Arnold & Mendelson, 1992; Brown et al., 1992; Burling, 1998; Collins & Keane, 1997; Conover & Sloan, 1998; Delmez et al., 1992; Delaware Healthcare Commission, 1996; Federal Trade Commission, 1986; Griffiths et al., 1994; Irvin, 1998; Lanning et al., 1991; Luft et al., 1990).

Access

In theory, CON regulations improve access to healthcare (a) by limiting entry of new providers who may limit the ability of incumbents to provide unprofitable services, (b) by restricting expansion of facilities in overbuilt areas leading providers to expand

services in underserved areas, and (c) by requiring providers to serve all patients needing care in a particular area.

Sloan and Steinwald (1980) found a 1.4% additional increase in bed supply in the year prior to CON regulations implementation and attributed this to the anticipatory effects of CON laws implementation. After CON regulations implementation, providers shifted investments to those areas not covered by CON regulations, such as hospital equipment. In addition, empirical analysis of labor inputs indicated that CON regulations tend to increase labor employment as an unintended, although compensatory effect of CON regulations (Sloan & Steinwald, 1980). The study observed 1,228 U.S. hospitals from 1969 to 1975, including labor inputs and simultaneous assessment of several concurrent regulatory programs in an attempt to isolate the effects of CON regulations from those of other regulatory programs in place (Sloan & Steinwald, 1980).

However, opponents of CON regulations point out that the remaining firms would be unable to raise prices to monopoly levels because competitors could easily enter the market. "Attempts by providers to reduce costs, gain efficiencies of scale, and position themselves aggressively in the marketplace have results in the formation of vertical integrated delivery systems of such providers" (Montesino, 1996).

Studies suggest that specialty hospitals and ambulatory surgery centers (ASCs) – which most frequently arise in the absence of CON regulations – have the potential to drain nonprofit providers' financial resources and provide less charity care. The U.S. GAO (2003) discovered that most specialty hospitals focus on highly profitable services and often are not located in geographic areas of medical need. Mitchell (2005), who compared

specialty and general hospitals in Arizona, a state without CON regulations, found evidence to support the GAO's conclusions. She found that physicians with ownership stakes in specialty hospitals treated higher percentages of profitable cases, less severe cases, and better-insured patients. Further suggesting that specialty hospitals might harm access, Gruber (1994) found that less charity care was provided in California after it abandoned CON regulations.

Other research, however, concludes that the absence of CON regulations do not necessarily lead to more services, abandonment of cities or charity care, or a proliferation of for-profit hospitals. Anderson, Heyssel, and Dickler (1993), comparing the presence of CON regulations in Baltimore and their absence in Minneapolis-St. Paul did not find clear differences in service offerings. However, a study that compares the effect of CON regulations on services in cities to that of suburbs would be more useful, since most supporters of CON regulations are concerned that free exit will leave inner cities bereft of healthcare as services are shifted to more lucrative suburbs. This question was addressed qualitatively by Bazzoli, Gerland, and May (2006). They reviewed recent facilities construction in many markets and concluded that CON regulations do not influence whether construction occurs in cities or suburbs. Regardless of CON regulations, more ambitious projects were launched in affluent suburbs than in poor cities.

Shortell et al. (1986) asserted that the provision of charity care would not be threatened by eliminating CON regulations because the proportion of uncompensated care does not differ between non- and for-profit hospitals. Another study, though, found that

those results are not meaningful, because the number of for-profit hospitals is unlikely to greatly increase upon the removal of CON regulations (Conover & Sloan, 1998).

Costs and Expenditures

The initial driving force for the CON regulations, in addition to the 1974 federal mandate, was the concern that excess capacity and capital investment contributed to higher publicly funded healthcare costs, as early 1970s healthcare payments were based on cost-based reimbursement methodologies. Under these methodologies, providers were reimbursed for their capital costs and had incentives to build excess capacity. Since the inception of CON regulations, many changes have occurred in healthcare payment methodology, rendering most of the fiscal benefits expected from CON regulations obsolete in today's marketplace. A significant change is the shift from a cost-based reimbursement methodology to service-based methodologies. Most private healthcare insurance companies and large public programs such as Medicare and Medicaid have adopted services- based payment methods such as prospective payment systems, diagnostic related groups, outpatient prospective payment over the last two decades. The trend toward service-based payments reduced provider incentives to build excess capacity or take on unneeded capital investment projects as they cannot directly recover the cost of their investments.

Salkever and Bice (1979) demonstrated that CON regulations from 1968 to 1972 had no appreciable effect on total hospital investment but did result in a decrease in the rate of growth in bed supply and an increase in investment in quality enhancing projects.

Additionally, analyses based on all states combined, from 1968 to 1972, found that CON regulations applied to a typical state would have reduced the number of inpatient days, a small increase cost per inpatient days, and a very modest reduction in hospital costs per capita (Salkever & Bice, 1979). Moreover, no significant savings in hospital costs were achieved through CON regulations as any savings from lower admission rates and hospital stays resulting from control over bed growth were approximately offset by higher than average per diem costs resulting from upgrading the level of care (Salkever & Bice, 1979).

Anderson and Kass (1986) examined the justification for requiring CON approval before new firms could begin providing home healthcare services. Like studies of the impact of CON regulations on hospitals, this study found no evidence that CON regulations contribute to lower costs for the provision of home healthcare services and, if anything CON regulations are associated with on average two percent higher costs for firms operating in regulated states (Anderson & Kass, 1986). Moreover, operating under CON regulations was more costly due to administrative in addition to the seeming lack of cost containment benefits (Anderson and Kass, 1986).

Noether (1987) reported that CON regulations significantly limit entry into the hospital market. While for-profit institutions were once subject to more stringent CON regulations than non-profit institutions, non-profits no longer have this advantage (Noether, 1987). Studies show that where entry into the market is regulated by CON regulations, both prices and expenses are higher than in areas without such regulation. Despite CON regulations' function as a potential entry barrier, its primary effect is less efficient resource utilization which is then passed on in the form of higher prices (Noether,

1987). Noether estimated that states with CON regulations on average have higher prices and expenses averaging 1.8 to 2.6% and 1.2 to 2.4% higher, respectively, than those without. Nor did he find evidence that CON regulations produced the resource savings they were designed to provide. It concludes that plans and decisions to repeal CON regulations in some states should, in theory, increase consumer welfare (Noether, 1987).

Sherman (1988) analyzed data from 1983 to 1984 from the “1984 Annual Survey of Hospitals” conducted by the American Hospital Association, using data from approximately 6,300 short-term general acute care hospitals. Output costs were measured by five variables: total number of inpatient days spent in acute care; total number of inpatient days spent in intensive care; patient days spent in sub-acute care or other departments; all visits to hospital emergency departments; and, clinic and other outpatient visits made to hospital (Sherman, 1988).

Results of the study indicated that as states review fewer hospital expenditures, hospital costs do not increase (Sherman, 1988). Rather, hospital costs are lower in states that have set higher review thresholds for all types of hospital expenditures. Moreover, it was estimated that if states were to significantly relax their regulatory constraints by doubling the thresholds at which hospital expenditures were subject to CON regulations, total hospital costs would decline by 1.4% (Sherman, 1988). The study posits that the reason for increased costs despite CON regulations are because CON regulations assume that by reducing the amount of capital and equipment available to hospitals, the total cost of resources will decrease (Sherman, 1988).

Sloan et al. (1988) evaluated several of the arguments made by proponents of CON regulations. One argument in support of CON regulations was that "in the absence of regulation, firms will drop prices so low that most will fail, leaving the market to a monopolist or a few oligopolists" (Sloan et al., 1988). Providers have been shown to accelerate investments in facilities and equipment in anticipation of the implementation of CON regulations (Sloan et al., 1988). Such behavior is cited as demonstrating the willingness of providers to "play the system." Thus, existing providers support CON regulations to prevent competition.

A 1992 study by Anderson examined the effect of CON regulations on hospital capital investment and operating expenditures. Previous studies had found that hospital capital investments significantly raised operating costs. However, a 1987 assessment of prior studies found that although current capital expenditures increased future operating expenditures, it estimated that the overall effect was much less than previously reported (Anderson, 1992). The study advised, "As Congress debates whether to incorporate capital into the Medicare Prospective Payment System, our results suggest that controlling the rate of increase in operating expenses may only negligibly deter capital expansion by hospital administrators" (Anderson, 1992).

Most evidence suggests that CON regulations do not substantially reduce or contain healthcare expenditures. Neither CON regulations nor other types of regulation are associated with lower costs, according to an econometric analysis of 22 years of data by Antel, Ohfeld, and Becker (1995). As previously discussed, Salkever and Bice's early (1976) study of the financial effects of CON regulations found that these regulations did

not suppress overall hospital investment but exacerbated the medical arms race. Although CON regulations slowed bed expansion, they more substantially sped up investment in new services and technologies, substituting a growth in labor and services for a growth in beds (Salkever & Bice, 1976). Similarly, Conover and Sloan (1998) found that CON regulations slightly lowered acute care spending but neither slowed the diffusion of hospital-based technologies nor reduced total spending. Bazzoli, Gerland, and May (2006) noted that some markets are developing duplicative services and technologies, despite the presence of CON regulations.

Feldman's 2000 meta-analysis of CON regulations and government market process concludes that the "empirical literature on CON regulations is extensive, and virtually unanimous in its consensus that CON regulations have neither controlled hospital costs nor restrained service diffusion" (Feldman, 2000, p. 245). The studies reviewed by Feldman indicated that CON regulations have resulted in higher profits for for-profit hospitals, and have prevented entry of new providers into the market to the benefit of existing providers (Feldman, 2000). This restriction into the market is described as especially significant given the increased competitiveness due to the spread of managed care entities. Moreover, recent studies indicate that CON regulations tend to increase costs, rather than achieve their designed purpose of controlling costs, with hospitals in states regulated by CON regulations having costs 20.6% higher than those in states with no CON regulations (Feldman, 2000).

The empirical literature reviewed in the Feldman meta-analysis also suggests that CON regulations have not been effective in restricting the diffusion of new technologies,

including open-heart surgery, renal dialysis programs, and CT scanner (Feldman, 2000). Case studies from Policy Analysis-Urban Systems (1980), cited by Feldman, suggest this lack of effectiveness resulted from hospitals being able to avoid CON regulations by leasing CT scanners, purchasing mobile units, or purchasing units right below CON regulatory threshold (Feldman, 2000).

In 1998, the Joint Legislative and Audit Review Committee and the Health Policy Analysis Program of the University of Washington's School of Public Health and Community Medicine conducted a study of the CON Program in Washington State, examining the effects of CON regulations and its effect on the cost, quality, and availability of healthcare services, as well as CON regulations' effect on charity care and access to health services in rural areas (State of Washington JLARC, 1999). Results based on a literature review, interviews and information from healthcare providers and healthcare economic experts in the state, in addition to the analysis of states that completely or partially repealed their CON regulations, found strong evidence that CON regulations are not effective either in controlling healthcare spending or in controlling supply (State of Washington JLARC, 1999). This study found that while CON regulations can slow the expansion of some healthcare services, other factors that CON regulations do not control also affect healthcare costs.

Further, the evidence gathered in this study, regarding the effect of CON regulations on quality, and the ability of CON regulations to improve quality by concentrating volume of specialized services is weak and inconclusive, with only some indirect evidence suggesting that CON regulations may protect quality in home health and

hospice by keeping out unprepared or unqualified providers, mainly due to the fact that CON regulations do not provide an ongoing mechanism to monitor quality (State of Washington JLARC, 1999).

This study found conflicting evidence regarding the effect of CON regulations or its repeal on access to health services, particularly in rural areas. Although CON regulations have been used to protect existing facilities in inner cities or to encourage providers to locate to those areas, CON regulations appear to restrict access by preventing the development of new facilities (State of Washington JLARC, 1999). In addition, the relationship between CON regulations and access varies by service and by state, with no ongoing mechanism to monitor access (State of Washington JLARC, 1999).

Finally, while some states are more likely to grant a CON to facilities offering more charity care, the CON regulations in Washington and most other states do not include monitoring for compliance. No studies were identified that measured the effect of CON regulations on levels of charity care, while the study reported that financial and market pressures make it increasingly difficult for all types of providers to offer charity care (State of Washington JLARC, 1999).

The study determined that the available evidence did not support making a recommendation as to whether Washington should repeal or retain its CON regulations. However, the study did provide specific options for policy makers depending on their decision as to the CON regulations' future. Should Washington decide to reform the program, the study suggested reassessing legislative and regulatory goals in relation to new conditions and needs in healthcare system; establishing policy oversight or an advisory

board to make CON regulations more responsive to changes in the healthcare system; and improving data collection to allow for ongoing monitoring and oversight of quality, access, and community benefits, including charity care (State of Washington JLARC, 1999). Should the program be repealed, the study suggested identifying policy goals for cost, quality, access and accountability along with alternative methods of attaining these goals; strengthening data collection and reporting to monitor the effects of repeal on quality, access and community benefits; and conducting economic analysis to estimate the effects of deregulation and to guide the policy changes (State of Washington JLARC, 1999).

An empirical study by Conover and Sloan (1998) examined health spending between the late 1970s and 1993, including spending prior to and directly after state CON regulations were repealed, stated:

> The major findings about CON regulations can be summarized as follows: first, we found no surge in expenditures after CON regulations were lifted; second, despite a statistically significant reduction by mature programs on acute spending per capita, there was no corresponding reduction in total per capita spending (apparently due to offsetting expenditures on non-hospital services). We found that mature CON regulations reduced hospital bed supply per capita population, but could detect no increase in bed supply following the removal of CON (p. 474).

Furthermore, the study found that established CON regulations increased cost per adjusted patient day and also cost per admission (Conover & Sloan, 1998).

The only way in which research indicates CON regulations might generate cost savings is through lowering the number of procedures. Popescu, Vaughan-Sarrazin, and

Rosenthal (2006) and Ho (2004) all found that states with CON regulations have lower coronary procedure rates for patients with cardiac problems. The authors suggested that this is because fewer providers are certified to perform such procedures, relative to states without CON regulations. However, the difference in procedure rates is slight; suggesting both that the effects of supplier-induced demand for these services and the potential benefit of cost savings is small.

In a 2002 study of CON regulatory policy, hospital financial and utilization data for states with CON regulations and states without CON regulations were analyzed for the years 1989, 1994, and 1999 (Cimasi, 2002). The study fell within the parameters of CON theory, which asserts that the management and implementation of CON regulations on inpatient care supply should reduce the cost of care. The objectives of the study were to: (a) describe characteristics of the U.S. healthcare system, stratified by the CON policy; and (b) compare inpatient costs, utilization, and capital indicators between states with and without CON regulations.

Case definitions for the 2002 HCC CON Regulations study included: the term "CON state," which was any state that had acute care CON regulations in effect during the analysis period years 1989 through 1999; the term "non-CON state," which was any state that did not have acute care CON regulations in effect during the analysis period years 1989 through 1999; the term "included states," defined as the 47 states and the District of Columbia, whose status related to whether CON regulations were in effect did not change during the analysis period years 1989 through 1999; and, the term "excluded states," which

referred to the states of Indiana, North Dakota, and Pennsylvania, which were excluded because of significant changes to their CON regulations between 1989 and 1999.

The methodology for the 2002 HCC CON study was based on a statistical analysis, employing a one-way analysis of variation (ANOVA), comparing each of the study variables, i.e.: beds per 1,000; admissions per 1,000; average length of stay (ALOS); expenses per admission; expenses per capita; cost per 1,000; total profit margins; average age of plant; and debt per bed, by state CON law status, across three points in time—1989, 1994, and 1999. Confidence p-values were calculated for each variable for each variable pair (CON regulations and no CON regulations) for each year. A standard statistical significance cut-off of .05 was utilized.

Data selected and analyzed for the 2002 HCC CON Study was derived from three (3) recognized sources, i.e.: (a) Hospital Statistics published by the American Hospital Association (AHA), which compiles hospital data derived from replies to the AHA Annual Survey, sent to all AHA-registered and non-registered hospitals in the U.S.; (b) The Almanac of Hospital Financial and Operating Indicators, published by The Center for Healthcare Industry Performance Studies (CHIPS), which annually reports the financial position of the hospital industry; and (c) *The Comparative Performance of U.S. Hospitals: The Sourcebook*, published and produced by Healthcare Investment Analysts (HCIA) and Deloitte & Touche, which presents current and historical information on the financial performance of the U.S. hospital industry.

Several limitations of the 2002 HCC CON Study were disclosed:

(a) the complexity of the healthcare economy, subject to the impact of multiple variables, complicates efforts to isolate CON regulations as the driving variable in the analysis of health system costs, utilization, or access amid market forces such as the impact of government policy and managed care on reimbursements; evolving technology, and, shifting patient population demographics and expectations;

(b) CON is not a 'Yes/No' variable because states subject to CON regulations are also subject to other significant variations including facilities and services regulated; CON geographic market definitions; CON review thresholds and criteria; demographic and epidemiological characteristics; and CON administrative processes; and,

(c) the accuracy, validity, and efficacy of the study's statistical analysis was dependent upon the accuracy, validity, and scope of the reported data utilized (p. 24).

Among the several conclusions drawn from the 2002 HCC CON Study Analysis, based on comparing data from states with CON and states with no CON regulations during the analysis period years of 1989, 1994, and 1999, was that:

(a) the data examined indicated that CON regulations do not reduce *beds per 1,000; admissions per 1,000; ALOS, expenses per admission; or expenses per capita*;

(b) there is no evidence that states with CON regulations have achieved greater total profit margins at less *cost per 1,000*;

(c) there is no statistically significant evidence that states with CON regulations have achieved a lower average *age of land* as an indicator of acceleration in new construction activity or retirement of existing, aging facilities; and

(d) there is statistically significant evidence that states with CON regulations have higher *debit per bed* than states without CON regulations in 1999 as an indicator of increased cost due to debt load. (p. 32)

CON regulations proponents have cited assertions by the “big three automakers”, that the employee healthcare costs for these automobiles are less on states with CON regulations than in states without CON regulations where they operate (Missouri Health Facilities Review Committee, 2004). These purported results have been provided in legislative hearings on CON regulations in Indiana, Missouri, and Ohio (Hawkins, 2004). Nonetheless, CON regulations proponents have not yet published or otherwise submitted the underlying empirical data or methodology for peer review (Hawkins, 2004). From the information that has been made publicly available on the Missouri CON website, these studies include the following characteristics, some of which have been challenged by CON regulations opponents. Only eight states are sampled: three of which are states without CON regulations (Wisconsin, Ohio, and Indiana) and five states with CON regulations (Delaware, Kentucky, Missouri, Michigan, and New York). The survey data was limited to healthcare expenses for employees of automakers which may not be representative of the total healthcare expenses in these states.

As a review of the automakers’ claims, Health Capital Consultants (HCC) evaluated a data sample that includes hospital expenses per capita for states with CON

regulations as compared to states without CON regulations, and also selected states with CON regulations and states without CON regulations including all of the states included in the automakers' study. The results of the HCC analysis indicated that hospital expenses per capita for states without CON regulations are considerable less than hospital expenses per capita for states with CON regulations. Furthermore, hospital expenses per capita for all of the five (5) states with CON regulations selected in the automakers' study, were higher than in states without CON regulations overall (HCC, 2002).

Volume and Quality

CON regulations are intended to ensure that providers maintain high volume by limiting the number of service providers. More than 100 studies have established a strong relationship between higher provider procedure volume and better outcomes (Conover & Sloan, 1998). Luft, Bunker, and Enthoven conducted the pioneering study noting this link in 1979. After another decade of research, Luft et al. (1990) reviewed the literature and concluded that there was a link between volume and quality. Later studies have supported the hypothesis that provider volume is negatively associated with mortality and other negative outcomes for a variety of cancer resections (Birkmeyer et al. 2002; Ho, 2004; Ho et al., 2006; Schrag et al. 2003) and coronary procedures (Birkmeyer et al., 2003; Hannan et al., 1998). Whether the relationship is stronger for hospital or surgeon volume is unclear, although Birkmeyer et al. (2003) found that surgeon volume accounts for a substantial proportion of hospital volume's effect on mortality. However, Shahian (2004),

noted that surgeon data may not be a reliable indicator of quality because, unlike hospitals, surgeons can choose to operate on less difficult cases.

The literature indicates that the presence of CON regulations influences volume, but not always in a way that also improves outcomes. Di Sesa et al. (2006) found that states with CON regulations have higher hospital volumes but not better outcomes for coronary artery bypass grafting. They used the Society of Thoracic Surgeons' (STS) National Cardiac Surgery Database to examine isolated CABG surgery volume, operative mortality, and complications for the years 2000 to 2003. The presence of CON regulations for open heart surgery was ascertained for each state in this study. Results were analyzed nationally, by state, and by region (West, Northeast, Midwest, South) and were adjusted for clinical factors and both population density and region with mixed-effects hierarchical logistic regression models. From 2000 to 2003, 314,710 isolated CABG surgeries were performed at 294 STS hospitals in states with CON regulations (n=27, including Washington, DC) and 280,512 procedures at 343 STS hospitals in states without CON regulations (n=24). Patient clinical characteristics were similar among states with CON regulations and states without CON regulations. States with CON regulations tended to have higher population densities and had significantly higher median hospital annual CABG volumes in each year from 2000 to 2003 ($p < 0.005$). This difference remained significant after adjustment for region and population density. Operative mortality was 2.52% for states with CON regulations versus 2.62% for states without CON regulations ($p = 0.32$). There was a significant association between CON regulations and operative mortality in the South. After adjustment for patient risk factors and region, there was a

marginally significant reduction of mortality risk in states with CON regulations (adjusted OR 0.92, 95% CI 0.86 to 1.00). However, this difference was not statistically significant when a revised model accounted for random state effects. Similar volume and outcomes results were seen when the analysis was repeated with data from Medicare database.

Supporting this finding, Ho (2004) and Popescu, Vaughan-Sarrazin, and Rosenthal (2006) concluded that states with CON regulations have higher hospital cardiac procedure volumes but not better outcomes, compared to states without CON regulations. Ho (2004) studied data from the AHRQ Nationwide Inpatient Sample (NIS) database to compare hospital procedure volumes and costs for PTCA and CABG in states with and without cardiac CON regulations. The NIS contains patient-level clinical and resource use information and the data was analyzed for the years 1988 to 2000. Regression estimates were used for the determinants of hospital PTCA and CAGB procedure volume and mortality. The conclusions for this study suggest that substantial declines in average hospital PTCA and CABG procedure volume have resulted in states which repealed cardiac CON regulations. Reductions in average hospital volume associated with the absence of CON regulations have a detrimental impact on mortality rates for CABG patients. For the 29,294 patients who received CABG surgeries in states that have repealed CON regulations in 2000, the results suggest that 29 fewer inpatient deaths could have been avoided with CON regulations. In addition, the results yield no evidence that the volume effects associated with CON regulations led to reduced mortality for patients undergoing PTCA.

A retrospective cohort study of 1,139,792 Medicare patients aged 68 years and older with acute myocardial infarction (AMI) who was admitted to 4,587 U.S. hospitals during 2000 to 2003 was performed by Popescu et al. (2006). Their findings were that patients in states with CON regulations were less likely to be admitted to hospitals with coronary revascularization services (321,573 {51.5%] vs. 323,695 [62.8%]; $p < .001$) or to undergo revascularization at the admitting hospital (163,120 [26.1%] vs. 163,877 [31.8%]; $p < .001$) than patients in states without CON regulations but were more likely to undergo revascularization at a transfer hospital (73,379 [11.7%] vs. 45,907 [8.9%]; $p < .001$. They concluded that patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality.

Shortell and Hughes (1988) found that states that have CON regulations, rate-setting programs, or high HMO penetration actually have higher mortality, but their study has not been replicated. They examined the influence of the regulation of hospital rates, state CON regulations, competition, and hospital ownership on mortality rates among inpatients receiving care under Medicare. Data were obtained from the records of 214,839 patients who received care in 981 hospitals in 45 states from 1983 to 1984. They found significant associations between higher mortality rates among inpatients and the stringency of state programs to review hospital rates ($p < 0.05$), and the intensity of competition in the marketplace, as measured by enrollment in health maintenance organizations ($p < 0.05$). They found hospitals in the states with the most stringent procedures for reviewing

applications for certificate of need had ratios of actual to predicted death rates that were 5 to 6% higher than those of hospitals in states with less stringent CON regulations ($p < 0.05$).

Another study by Ross et al. (2007) was conducted to examine whether rates of appropriate catheterization after admission for acute myocardial infarction varied between states with and without CON regulations of cardiac catheterization. Their hypothesis was that CON regulations would be associated with lower rates of catheterization among patients with equivocal and weak indications but equal or higher rates among those with strong indications. This study performed a retrospective analysis of chart-abstracted data for 137,279 Medicare patients admitted for acute myocardial infarction between 1994 and 1996 at 4,179 US acute-care hospitals. Using 3-level hierarchical generalized linear modeling adjusted for patient sociodemographic and clinical characteristics and physician and hospital characteristics, they compared catheterization rates within 60 days of admission for states (and the District of Columbia) with (n=32) and without (n=19) CON regulations in the full cohort and stratified by catheterization appropriateness. They found that CON regulations were associated with a borderline-significant lower rate of catheterization overall (45.8% versus 46.5%; adjusted risk ratio [RR] 0.91, 95% confidence interval 0.82 to 1.00, $p = 0.06$). After stratification by appropriateness, CON regulations were not associated with a significantly lower rate of catheterization among 68,823 patients with strong indications (49.9% versus 50.3%; adjusted RR 0.94, 95% confidence interval 0.86 to 1.02, $p = 0.17$). However, CON regulations were associated with significantly lower rates of catheterization among 65,077 patients with equivocal

indication (45.0% versus 46.0%; adjusted RR 0.88, 95% confidence interval 0.78 to 1.00, $p = 0.05$) and among 8,379 patients with weak indications (19.8% versus 21.8%; adjusted RR 0.84, 95% confidence interval 0.71 to 0.98, $p = 0.04$).

Researchers consistently find that when controlling for volume and case severity, specialty and for-profit hospitals do not have better outcomes than general hospitals. The GAO (2003) concluded that specialty hospitals see patients who are less ill, a finding that has been confirmed by Winter (2003) and Mitchell (2005). Specialty hospitals' larger share of less-severe cases appears to influence their outcome data. In a study of coronary artery bypass grafting (CABG), Cram, Rosenthal, and Vaughan-Sarrazin (2005) found that outcomes do not differ between specialty and general hospitals, controlling for volume and case severity. The ownership of a hospital – another potential difference between general and specialty hospitals – appears to have no bearing on outcomes, cost, or efficiency (Shortell & Hughes, 1988; Sloan et al., 2001).

Luft, Bunker and Enthoven (1979) were the first to suggest a relationship between procedural volume and outcome. Since that time, many studies have supported their results. However, a consensus about the significance of high volume and its association with lower in-hospital mortality still does not exist and the use of volume as a "quality indicator" continues to be debated (Birkmeyer, 2003; Halm et al., 2000). Despite the lack of agreement, many policymakers and some physicians advocate the use of volume as an indicator of quality and as the basis for such policies as selective patient referral.

Research by Birkmeyer et al. (2002) was undertaken to be the definitive study of the relationship between volume and outcome. Using information from the national

Medicare claims database and the Nationwide Inpatient Sample, they examined the mortality associated with six types of cardiovascular procedures and eight types of major cancer resections between 1994 and 1999 (total number of procedures in the sample was 2.5 million). Regression analysis was used to determine the relationship between hospital volume (total number of procedures performed per year) and mortality (in-hospital or within 30 days), with adjustments for characteristics of the patients. Mortality decreased as volume increased for all 14 types of procedures, but the relative importance of volume varied markedly according to the type of procedure. Absolute differences in adjusted mortality rates between very-low-volume hospitals and very-high-volume hospitals ranged from over 12% (for pancreatic resection, 16.3% vs. 3.8 %) to only 0.2% (for carotid endarterectomy, 1.7% vs. 1.5 %). They concluded that in the absence of other information about the quality of surgery at the hospitals near them, Medicare patients undergoing selected cardiovascular or cancer procedures can significantly reduce their risk of operative death by selecting a high-volume hospital (Birkmeyer et al, 2002).

The Leapfrog Group, a consortium of healthcare purchasers and providers representing approximately 33 million patients and $56 billion in healthcare revenue, is perhaps the best-known promoter of volume-based selective referrals (Birkmeyer et al., 2002). The Leapfrog Initiative plans to use market forces to promote improvement in the quality of healthcare. One of its initial guidelines calls for selective referral to high-volume hospitals for five invasive procedures, and for high-risk neonatal care. The annual volume thresholds were set at 500 coronary artery bypass graft (CABG) procedures per year, 400 coronary angioplasties, 30 abdominal aortic aneurysm (AAA) repairs, 100

carotid endarterectomies (CEA), and 7 esophagectomies (Hannan, Popp & Tranmer, 1998). The Leapfrog Group based these thresholds on expert opinion and a critical review of the literature. Several of these studies used geographically limited databases with few high-volume institutions and may not be generalizable (Sollano & Moskowitz, 1999; Khuri, Daley & Henderson, 1999). More importantly, these analyses were not intended to determine thresholds but were primarily designed to validate the existence of volume-outcome correlations. Finally, more recent studies of the same populations failed to show a relationship between volume and mortality for two of these procedures, AAA and CABG. The Leapfrog Group revised its suggested volume thresholds in April 2003, removing CEA from the list of procedures and adding major pancreatic resections. In addition, they altered the thresholds for the remaining three procedures (450 CABG, 50 AAA, and 13 esophagectomies). This amendment illustrates that despite the consistent evidence of a relationship between volume and outcome in the literature, it is still not clear how to proceed to policy changes. Although selective referral may be a viable option, it is still not clear where the threshold should be set and if a single threshold is even reasonable.

The relationship between volume and outcome is likely a proxy for other structural and process components of care, which more accurately predicts quality than volume alone. Many of these suggested structural and process characteristics, such as the presence of house staff or more specialized attending staff, dedicated operating rooms, or better nurse staffing, are more prevalent in academic institutions. The importance of process measures has been recognized by the Leapfrog Group, which recently proposed a set of process measures for each of its index procedures to be used as an adjunct to volume;

however, until these process measures are better defined and institutions are able to document their performance based on these indicators, volume will continue to be used in quality measurement.

Khuri et al. (1998) failed to show a relationship between surgical volume and outcome using the Veterans Affairs National Surgical Quality Improvement Program database (VA NSQIP). This large, multi-institutional national database (includes 68,631 operations from 123 institutions between October 1, 1991, and September 30, 1997) was used to investigate eight common surgical procedures and failed to find a relationship between volume and outcome for any of them. This study included prospective assessment of presurgical risk factors, process of care during surgery, and outcomes 30 days after surgery; development of multivariable risk-adjustment models; identification of high and low outlier facilities by observed-to-expected outcome ratios; and generation of annual reports of comparative outcomes to all surgical services in the Veterans Health Administration (VHA).

Thiemann et al. (1999) conducted a retrospective cohort study of the relation between the number of Medicare patients with myocardial infarction that each hospital in the study treated (hospital volume) and long-term survival among 98,898 Medicare patients 65 years of age or older. They used proportional-hazards methods to adjust for clinical, demographic, and health-system-related variables, including the availability of invasive procedures, the specialty of the attending physician, and the general area of residence of the patient (rural, urban, or metropolitan). They concluded that patients with acute myocardial infarction who are admitted directly to hospitals that have more

experience treating myocardial infarction, as reflected by their case volume, are more likely to survive than are patients admitted to low-volume hospitals.

Although Thiemann et al. (1999) reported a significant relation between hospital volume and mortality in the case of acute myocardial infarction, the findings of another study (Chen et al. 1999) suggested that the relation between volume and mortality may be related to differences in the processes of care. Using the same database but not all the same patients or hospital groupings, Chen at al. (1999) found that one group of high-volume hospitals (those included on the list of "America's Best Hospitals," published annually by *U.S. News & World Report, 1997*) had significantly lower rates of 30-day mortality than did two other groups of hospitals. One of the other groups consisted of high-volume hospitals that had on-site facilities for cardiac catheterization, angioplasty, and coronary-artery bypass graft surgery, and the other group was composed of mostly low-volume hospitals that did not have these facilities. The differences in mortality rates were no longer significant after adjustment for the higher use of aspirin and beta-blockers in hospitals listed in "America's Best Hospitals."

Summary

CON regulations emerged during 1970s as a response to a federal mandate introduced by the National Health Planning and Resources Development Act (NHPRDA) and to healthcare cost containment concerns associated with cost-based reimbursement methodologies. In today's environment, none of these original reasons seem to have validity as they did three decades ago. In 1988, when NHPRDA expired, CON regulations

were no longer federally mandated. Also, the trend toward service-based payment methodologies coupled with expansion of managed care significantly mitigated the original cost containment concerns that existed when cost-based payment methodologies were being used.

There is limited literature on CON regulations effects on volume and quality. Most studies conclude that the absence of CON regulations do not necessarily lead to more services, abandonment of cities or charity care, or to a proliferation of for-profit hospitals. High procedural volume has been strongly associated with better outcomes but the literature indicates that the presence of CON regulations impacts volume, but not in a way that improves outcomes. Lastly, most of the evidence suggests that CON regulations neither substantially reduce nor contain healthcare expenditures. Solid organ transplantation is a complex, high-cost treatment that in 2008 was performed over 27,000 times. However, none of the published studies have examined the association of CON regulation on volumes and outcomes for solid organ transplants.

CHAPTER IV
METHODOLOGY

Following the overview and development of the Certificate of Need (CON) regulations and the review of the literature, this study examines the regulation and its impact on heart and kidney transplant centers. Historically, CON was meant to regulate cost, quality, and access to healthcare services. The objectives of this study are to understand the association of CON regulations on number of centers, volume and outcomes of transplant centers in states with and without solid organ transplant CON regulations. This chapter provides a detailed account of the study design, hypotheses, and the study population; it also defines and describes the variable used in this study. As previously discussed, this study tests the relationships between CON regulation the number of centers per state, transplant volume and quality indicators (graft and patient failure).

The study assesses the association of solid organ transplant CON regulations using a clinically-rich database available from the Scientific Registry of Transplant Recipients (SRTR). The study will answer the question: What is the association of solid organ transplant CON regulations on the number of centers, the transplant volume and outcomes for heart and kidney transplant centers?

Data Source

The Organ Procurement and Transplantation Network (OPTN) is the unified transplant network established by Congress under the National Organ Transplant Act (NOTA) of 1984 to be operated by a private, non-profit organization under federal

contract. The United Network for Organ Sharing (UNOS) was awarded the first OPTN contract on September 30, 1986, and has continued to administer the OPTN under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services (HHS) for more than 20 years and four successive contract renewals. The OPTN is a public-private partnership that links all of the professionals involved in the donation and transplantation system. The goals of the OPTN are to:

- increase and ensure the effectiveness, efficiency and equity of organ sharing in the national system of organ allocation.
- increase the supply of donated organs available for transplantation.

"As part of the OPTN contract, UNOS has:

- established an organ sharing system that maximizes the efficient use of organs through fair and timely allocation.
- established a system for the collection, storage, analysis and publication of data pertaining to the patient waiting list, organ matching, and transplants.
- provided information, consultation and guidance to persons and organizations concerned with human organ transplantation in order to increase the number of organs available for transplantation." (UNOS, 2010)

UNOS members include transplant hospitals, organ procurement organizations and independent histocompatibility laboratories in the United States, as well as voluntary health organizations, such as the American Diabetes Association; ethicists and families of donors; and medical professional and scientific organizations, such as the American Medical Association. "Membership means that upon completion of the prescribed

application process and satisfaction of applicable requirements, the organization or individual has demonstrated compliance with all applicable UNOS membership criteria." (UNOS, 2010)

Representing the largest group of UNOS membership, transplant centers are the medical institutions that operate organ transplant programs. As of October 11, 2009, 250 transplant centers in the United States were operating one or more organ transplant programs. Transplant centers are required to submit data to at the time of recipient registration include transplant center information, recipient demographics, organ type transplanted (heart, lung, or heart-lung combination), patient description, pre-transplant serology, and factors that increase the patient's risk for a poor transplant outcome.

Kidney data collected on the Transplant Recipient Registration Form include transplant date, patient status (at time of transplant), primary renal diagnosis, pre-transplant serology, organ preservation description, and surgical information. Additional data collected as part of the Transplant Recipient Follow-Up Form include patient status (at time of follow-up), information about organ rejection, immunosuppressive medication, graft status, cause of graft loss, patient status, and cause of death (OPTN, 2010).

Thoracic data collected at the time of recipient registration include transplant center information, recipient demographics, organ type transplanted (heart, lung, or heart-lung combination), patient description, pre-transplant serology, and factors that increase the patient's risk for a poor transplant outcome. This data is submitted to The Scientific Registry of Transplant Recipients (SRTR) is a national database of statistics related to solid organ transplantation (kidney, liver, pancreas, intestine, heart, and lung). The

Registry covers the full range of transplant activity, from organ donation and waiting list candidates to transplant recipients and survival statistics. The purpose of the Registry is to support the development of sound policy, to encourage research on issues of importance to the transplant community, and to facilitate responsible analysis of transplant programs and Organ Procurement Organizations (OPOs).

Data in the Registry are collected by the Organ Procurement and Transplantation Network (OPTN) from transplant centers and organ procurement organizations (OPOs) across the country. Transplant centers are medical institutions within the United States that operate an organ transplant program. The database captures clinical information from transplant centers. Centers enter patient data using uniform definitions. A series of quality checks are performed before a site's data are aggregated into the national sample. The SRTR is administered by the Arbor Research Collaborative for Health with the University of Michigan.

Patient Population

Data from the SRTR for 309 transplant centers (101 heart transplant centers and 208 kidney transplant centers) from 2006 through 2008 will be examined. Volume of transplants performed per center as well as their risk-adjusted graft failure and patient deaths will provide the variables of interest.

Information about states' CON regulations was obtained from the 2006 and 2008 annual reports published by the National Directory of the American Health Policy Association.

Variables

The independent variable for the study is the presence or absence of solid organ transplantation CON regulations within a state. For transplant-center level analyses, the outcome variables of interest were graft failure and patient death as measured by the risk-adjusted observed to expect graft failure ration and observed to expected patient death ratio report through SRTR for each transplant center. For state-level analyses, the outcome variable of interest were the number of transplant centers, the average transplant center volume and the total number of transplant procedures performed during the study period in a given state.

Graft failure is reported by SRTR at the 1-month, 1-year, and 3-year reporting time points for each center, with corresponding rates for the U.S. This study uses the 1-year data. For the 1-year statistics, transplants occurring between January 1, 2006 and December 31, 2008 were included. Statistics reported by SRTR for adults (age 18 and older) were used. Additional data from the Social Security Death Master File (SSDMF) and Centers for Medicare & Medicaid Services (CMS) were incorporated by SRTR into the graft survival rates.

Graft failure is defined differently for different organs. For all organs, deaths are considered to be graft failures. Once the patient has died, it cannot be determined how long the graft would have functioned had the patient lived. The SSDMF and CMS data are used in conjunction with OPTN data to identify deaths. In the case of conflicting deaths dates from various sources, the OPTN death date takes precedence. If there is no OPTN

death date but conflicting dates from SSDMF and CMS, the SSDMF date takes precedence.

A graft is considered to have failed when follow-up information indicates that one of the following occurred prior to the reporting time point: graft failure (except for heart and liver where retransplant dates are used instead), retransplant, or death. OPTN follow-up forms are used to identify graft failure and retransplant dates. Transplants that occurred in the last six months of the accrual period for the 1-year reporting time point are only followed for six months after transplant because the 1-year follow-up information is not available in the current OPTN data. The reporting time point for this subset of transplants is six months after transplantation.

The "Expected Graft Failure" is the fraction of grafts that would be expected to fail at each reported time point, based on the national experience for patients similar to those at this center. The national experience was analyzed using data for all grafts at all facilities in the United States. A Cox proportional hazards regression model for time to graft failure (Cox, 1972) was fitted to the national data, which yielded the probability of graft failure for each patient, based upon the characteristics of each patient and the reporting time point. The expected survival is the average of these computed probabilities. The characteristics accounted for in these calculations are reported by SRTR in their model description. Models are fit separately by age group (adult and pediatric) and cohort (1-month/1-year and 3-year). For kidney and liver transplants, models are also fit separately for living and deceased donor transplants. The "Expected Graft Failure" for each organ was adjusted for the patient characteristics as listed in the Risk-Adjustment Models.

Patient death is reported by SRTR at the 1-month, 1-year, and 3-year reporting time points for each center, with corresponding rates for the U.S. Only those transplants that occurred between January 1, 2006 and December 31, 2008 were eligible for inclusion in the analyses. Patients who had previously received a transplant of this type, whether this previous transplant occurred during the accrual period or not, were not included. For this reason, the eligible procedures for inclusion may be smaller than the transplant count used in the volume model. Statistics were used for adults (age 18 and older). SRTR used additional data from the SSDMF CMS for inclusion in the patient death rates.

The SSDMF and CMS data are used in conjunction with OPTN data to determine whether each patient is alive or dead at the end of the follow-up period. A patient is counted as having died when OPTN follow-up information, SSDMF data, or CMS data indicates that a death has occurred prior to the reporting time point. In the case of conflicting deaths dates from various sources, the OPTN death date takes precedence. If there is no OPTN death date but conflicting dates from SSDMF and CMS, the SSDMF date takes precedence. If the patient is not reported to have died in any source, the patient is assumed to be alive.

The national experience was analyzed using data for all accrued transplants at all facilities in the United States. A Cox proportional hazards regression model for time to death (Cox, 1972) was fitted to the national data, which yielded the probability of survival to the reporting time point for each patient, based upon the characteristics of each patient and the reporting time point. The expected death is the average of these computed probabilities. The characteristics accounted for in these calculations are reported by SRTR

in their model description. Models are fit separately by age group (adult and pediatric) and cohort (1-month/1-year and 3-year). For kidney and liver transplants, models are also fit separately for living and deceased donor transplants. The "Expected Patient Death" for each organ was adjusted for the patient characteristics as listed in the SRTR Risk-Adjustment Models. For statistical comparisons, it is appropriate to compare the number of deaths observed during follow-up (which is shorter than the reporting time point for censored patients) to the number of deaths that would be expected during follow-up, rather than by comparison of observed and expected survival rates at the reporting time points. The ratio of observed to expected deaths compares the entire survival curve up to the reporting time point to the curve expected for patients with the same characteristics based on the national experience rather than just the survival at the reporting time point. A ratio greater than 1.00 indicates that there were more deaths at the center than would have been expected based on the national experience, while a ratio less than 1.00 indicates that there were fewer deaths at the center than would have been expected based on the national experience. For example, a ratio of 1.20 indicates that the death rate at the center was, on average, 20% higher than the national rate. A ratio of 1.00 indicates that the death rates at the center are the same as the national death rates.

Hypotheses

This study will be a non-experimental, descriptive and correlational research design.

Based on the objective to examine CON regulations on heart and kidney transplant centers, the following hypotheses are proposed:

1. States with CON regulations for solid organ transplant services will have fewer transplant centers than states without a solid organ transplant CON regulation.
2. States with CON regulations for solid organ transplant services will perform more heart and kidney transplant procedures than states without CON regulation for solid organ transplant services.
3. States with CON regulations for solid organ transplant services will have better quality outcomes (graft failures and patient deaths) than states without CON regulation for solid organ transplant services.

As the healthcare environment has changed over time from cost-based reimbursement to capitation and fixed fees for service, CON regulations effectiveness should be critically examined. Heart and kidney transplantation are complex procedures that have been regulated by CON but never studied for volume differences or improved outcomes.

CHAPTER V
DATA ANALYSIS

This chapter will outline the results of the study of 309 transplant centers during the years 2006 through 2008. First, a descriptive analysis of the data will be presented. Then the results of the independent samples *t*-test and univariate analysis of variance for each hypothesis will be presented.

Descriptive Analysis – States

Currently 37 states and the District of Columbia (DC) have a CON regulation and of those 37, 21 have a specific solid organ transplant CON regulation. Fourteen (14) states have no CON regulation and 30 states have no solid organ transplant CON regulation.

Figure 1. States with CON regulations compared to States with Transplant CON Regulations

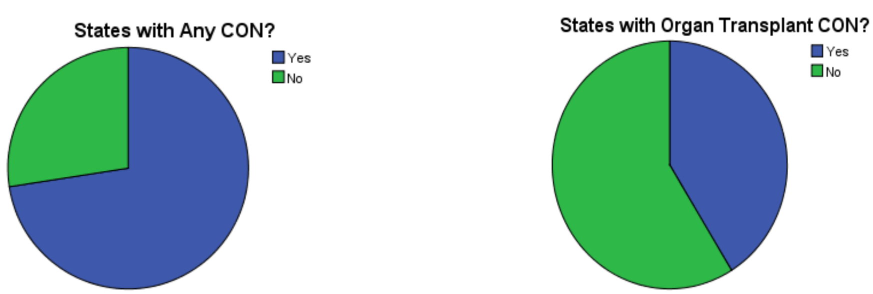


Table 1. States with CON Regulations and States with Transplant CON Regulations

State CON?

	Frequency	Percent
Yes	37	72.5
No	14	27.5
Total	51	100.0

Organ Transplant CON?

	Frequency	Percent
Yes	21	41.2
No	30	58.8
Total	51	100.0

Descriptive Analysis – Transplant Centers

Active transplant centers (performed at least 1 transplant procedure each year for 2006, 2007 and 2008) for adult heart and kidney transplants numbered 309 for the 50 United States including the District of Columbia. The number of transplant centers per state ranged from 0 to 30 (Table 3). Four states have no transplant centers: Alaska, Idaho, Montana and Wyoming.

Figure 2. Number of Heart and Kidney Transplant Centers by Transplant CON

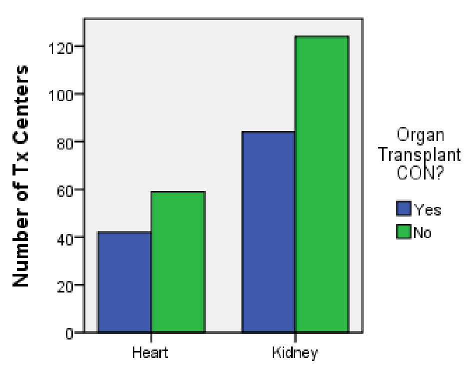


Table 2. Transplant Centers by Transplant CON and Organ

			Organ Transplant CON?		Total
			Yes	No	
Organ	Heart	Count	42	59	101
		% within Organ	41.6%	58.4%	100.0%
	Kidney	Count	84	124	208
		% within Organ	40.4%	59.6%	100.0%
Total		Count	126	183	309
		% within Organ	40.8%	59.2%	100.0%

In 96 hospitals, both heart and kidney transplant were performed; in 213 hospitals only one type of transplant was performed – either heart or kidney. For the purpose of this study, centers are counted separately even when a hospital performs both type of transplants (heart and kidney). Typically, there are different transplant surgeons and nursing staffs caring for the different organ types.

Hypothesis # 1 - Transplant Centers Analysis

One purpose of CON regulations is to limit the number of providers or services in order to prevent duplication of services. The first hypothesis of this study proposes that states with a CON regulation for solid organ transplant services will have fewer heart and kidney transplant centers than a state without a CON regulation for solid organ transplant services. The null hypothesis is that there are no differences or more transplant centers in

states with a solid organ transplant CON regulation than states without a CON regulation for solid organ transplants.

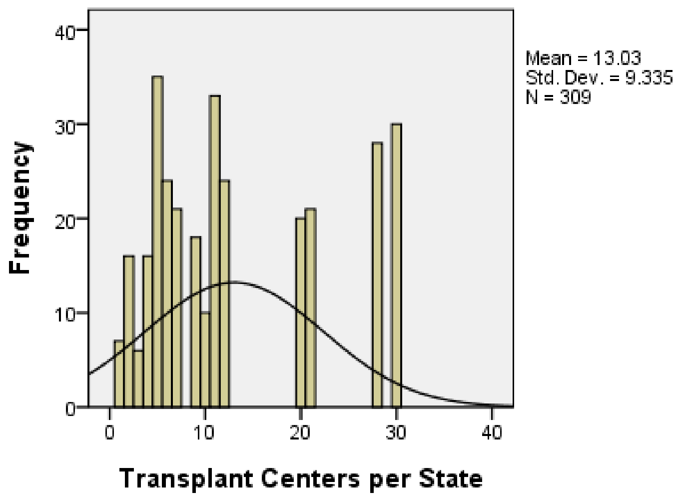
To test this hypothesis, the explanatory variable of the presence of a solid organ transplant CON regulation for the state in which the centers are located was used and the number of transplant centers per state was tested. Table 3 shows the results and as expected states with a solid organ transplant CON regulation had fewer transplant centers (126 versus 183). A difference in the mean number of transplant centers per state was identified. States with a solid organ transplant CON regulation had 4.94 fewer transplant centers than states without a solid organ transplant CON regulation.

Table 3. Transplant Centers per State

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	13.03	10.10	15.04
Median	11.00	10.00	11.00
Standard Deviation	9.335	5.275	10.877
Minimum	1	1	1
Maximum	30	20	30
Skewness	.699	.573	.283
Std. Error of Skewness	.139	.216	.180
Kurtosis	-.929	-.265	-1.657
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 3 indicate that the measure was not normally distributed. This is illustrated in Figure 3.

Figure 3. **Histogram Transplant Centers per State**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 4. Figure 4 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for transplant centers per state to determine if there was a statistically significant difference in the mean number of transplant centers in the states with and without a solid organ transplant CON regulation. Table 5 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is not equal variance in both groups (p = .000) and the t (306) = -2.397, p = .017. This analysis found that as hypothesized states with a CON regulation for solid organ transplant services had fewer transplant centers than those without a solid organ transplant CON regulation.

Table 4. Log Transformation Transplant Centers per State

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean of Log	.9847	.9289	1.0230
Median of Log	1.0413	1.0000	1.0414
Standard Deviation of Log	.3623	.2891	.4014
Minimum of Log	.0000	.0000	.0000
Maximum of Log	1.4771	1.3010	1.4771
Skewness of Log	-.463	-1.297	-.387
Std. Error of Skewness of Log	.139	.216	.180
Kurtosis of Log	-.222	2.414	-.988
Std. Error of Kurtosis of Log	.276	.428	.357

Figure 4. **Histogram Log Transformation Transplant Centers per State**

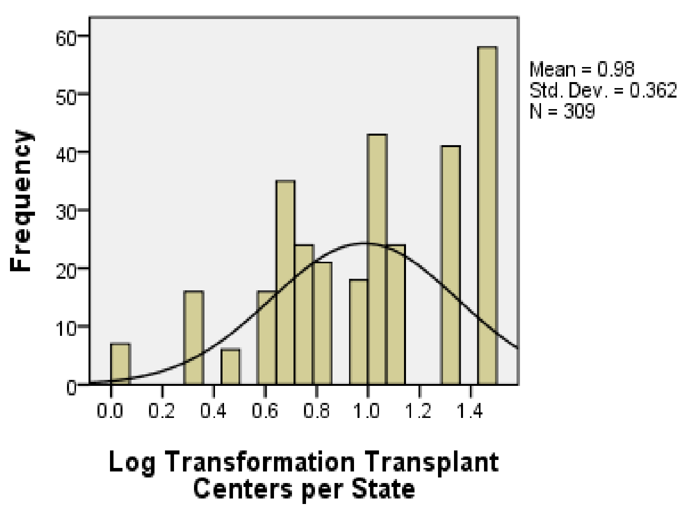


Table 5. T-Test Log Transformation Transplant Centers per State

		Transplant Centers per State	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	38.362	
	Sig.	.000	
t-test for Equality of Means	*t*	-2.260	-2.397
	df	307	306.358
	Sig. (2-tailed)	.025	.017
	Mean Difference	-.0942	-.0942
	Std. Error Difference	.0417	.0393
	95% Confidence Interval of the Difference		
	Lower	-.1761	-.1715
	Higher	-.0122	-.0169

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 6 shows the results of that test. This analysis demonstrates a significant difference [F (1, 307) = 5.108, p = .025] in the mean number of transplant centers in the states with and without a solid transplant CON regulation.

Table 6. ANOVA Log Transformation Transplant Centers per State

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.662	1	.662	5.108	.025
Within Groups	39.779	307	.130		
Total	40.441	308			

The above analysis is consistent with hypothesis that CON regulations control or restrict the total number of centers. One concern is that this relationship could be an artifact of the population of the state. If states with a solid organ transplant CON

regulation are smaller in population size, on average, they may have fewer centers per state because population needs would be lower.

A first review of the state population size for states with and without a solid organ transplant CON regulation shows that both groups contain at least some states with large populations. Table 7 shows that of states with populations over 10 million, there are 4 with a solid organ transplant CON regulation and 4 without a solid organ transplant CON regulation.

Table 7. States with Average Populations greater than 10,000,000 Residents

State	Average Population Estimate 2006-2008	Current CON for Solid Organ Transplant	Active Heart Transplant Centers	Active Kidney Transplant Centers
California	36,261,900	No	9	19
Texas	23,837,005	No	9	21
New York	19,415,710	Yes	6	14
Florida	18,263,424	Yes	4	8
Illinois	12,780,127	Yes	5	7
Pennsylvania	12,520,014	No	7	14
Ohio	11,513,794	No	3	8

A better test would control for "transplant needs" in each state in order to evaluate if access to transplant centers is restricted in states with a solid organ transplant CON regulation relative to states without a solid organ transplant CON regulation. As a rough proxy for this idea, a test for differences between the numbers of centers per state was performed by creating a new variable (Transplant Centers per 100,000 Residents). This variable was created using the number of transplant centers per state normalized to the state average population for 2006 through 2008. Table 8 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation.

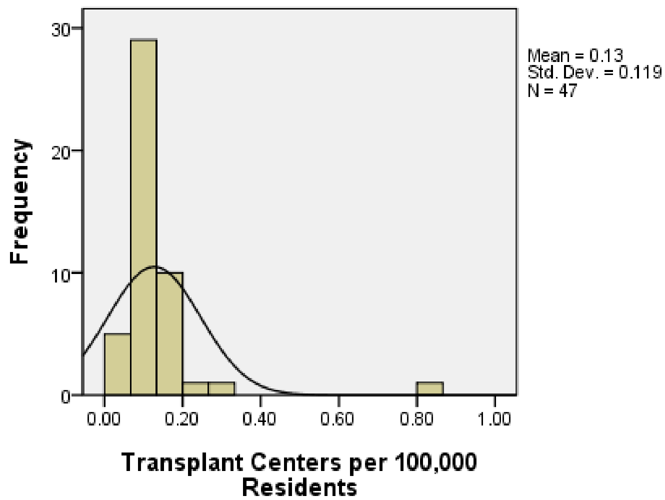
A difference in the mean number of transplant centers per state was identified but in the opposite direction once population was taken into account. The mean difference was 0.0132 more centers for states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation.

Table 8. Transplant Centers per 100,000 Residents

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	.1262	.1340	.1208
Median	.1030	.0993	.1259
Standard Deviation	.1013	.1497	.0436
Minimum	.0431	.0431	.0452
Maximum	.8520	.8520	.3131
Skewness	6.034	4.463	1.144
Std. Error of Skewness	.139	.216	.180
Kurtosis	40.782	19.171	3.104
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 8 indicate that the measure was not normally distributed. This is illustrated in Figure 5.

Figure 5. **Histogram Transplant Centers per 100,000 Residents**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 9. Figure 6 illustrates that the transformed variable is normally distributed. An independent *t*-test was then performed on the transformed data for transplant centers per 100,000 residents to determine if there was a statistically significant difference in the mean number of transplant centers per 100,000 residents in states with and without a solid organ transplant CON regulation. Table 10 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .590) and the t (307) = -.847, p = .398. This analysis found that states with a solid organ transplant CON regulation did not have fewer transplant centers than those without a solid organ transplant CON regulation. So when normalized by the rough measure of population, the hypothesis is not supported.

Table 9. Log Transformation Transplant Centers per 100,000 Residents

	All Transplant Centers	Transplant Centers in States *with* Transplant CON Regulation	Transplant Centers in States *without* Transplant CON Regulation
Number	309	126	183
Mean of Log	-.9521	-.9627	-.9447
Median of Log	-.9872	-1.0031	-.9000
Standard Deviation of Log	.18360	.21976	.15408
Minimum of Log	-1.37	-1.37	-.34
Maximum of Log	-.07	-.07	-.50
Skewness of Log	1.691	2.573	-.092
Std. Error of Skewness of Log	.139	.216	.180
Kurtosis of Log	7.030	8.790	-.075
Std. Error of Kurtosis of Log	.276	.428	.357

Figure 6. **Histogram Log Transformation Transplant Centers per 100,000 Residents**

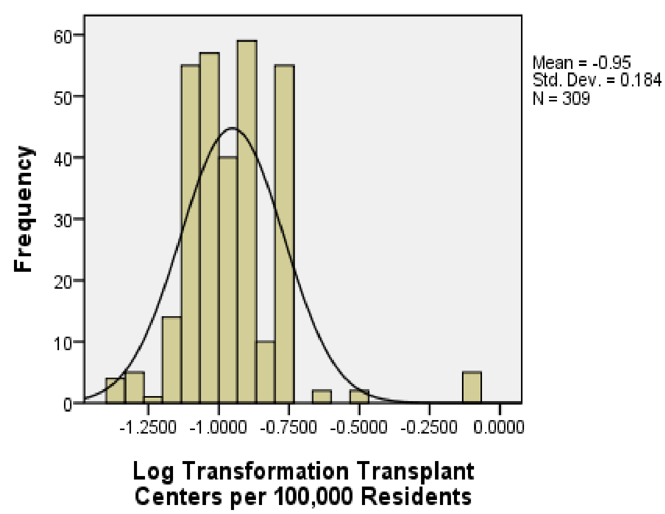


Table 10. *T*-Test Transplant Centers per 100,000 Residents

		Transplant Centers per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	.291 .590	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference	-.847 307 .398 -.01801 .02126	-.795 207.604 .428 -.01801 .02265
	Lower	-.05985	-.06266
	Higher	.02383	.02665

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. This analysis demonstrates [F (1, 307) = .717, p = .398] that there is no significant difference in the mean number of transplant centers per 100,000 residents in the states with and without a solid organ transplant CON regulation.

Table 11. ANOVA Log Transformation Transplant Centers per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.024	1	.024	.717	.398
Within Groups	10.358	307	.034		
Total	10.382	308			

Type of Transplant

The next step was to see if a significant difference existed between the two types of organ transplants under study – heart and kidney transplants. Even though the procedures are both complex surgical procedures, the process of procurement of the organs are quite different between heart and kidney transplants. Heart transplants are dependent on the death of a donor in order to have a heart to use in the transplant procedure. Kidneys, on the other hand, can be procured from deceased donors or from living donors. Because of the extreme differences in procurement, both were analyzed separately to determine if one played a larger role or not.

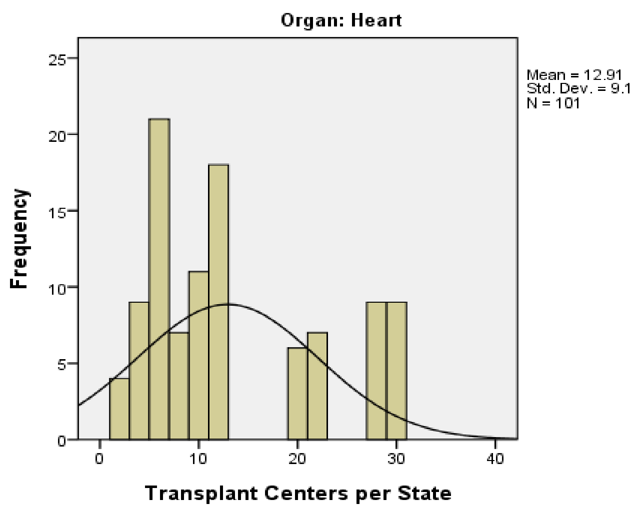
Table 12 shows the descriptive statistics for heart transplant centers and as expected states with a solid organ transplant CON regulation had fewer heart transplant centers (42 versus 59). A difference in the mean number of heart transplant centers per state was 4.62. States with a solid organ transplant CON regulation had, on average, fewer heart transplant centers than states without a solid organ transplant CON regulation.

Table 12. Heart Transplant Centers per State

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean	12.91	10.21	14.83
Median	10.00	10.00	11.00
Standard Deviation	9.100	4.941	10.793
Minimum	2	2	2
Maximum	30	20	30
Skewness	.792	.715	.351
Std. Error of Skewness	.240	.365	.311
Kurtosis	-.802	.056	-1.668
Std. Error of Kurtosis	.476	.717	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 12 indicate that the measure was not normally distributed. This is illustrated in Figure 7.

Figure 7. **Histogram Heart Transplant Centers per State**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 13. Figure 8 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for heart transplant centers per state to determine if there was a statistically significant difference in the mean number of heart transplant centers in the states with and without a solid organ transplant CON regulation. Table 14 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is not equal variance in both groups (p = .000) and the t (96.951) = -1.206, p = .231. This analysis found that states

with a CON regulation for solid organ transplant services had no fewer heart transplant centers than those without a solid organ transplant CON regulation.

Table 13. Log Transformation Heart Transplant Centers per State

	All Heart Transplant Centers	Heart Transplant Centers in States with Transplant CON Regulation	Heart Transplant Centers in States without Transplant CON Regulation
Number	101	42	59
Mean of Log	.9979	.9552	1.0283
Median of Log	1.0000	1.0000	1.0414
Standard Deviation of Log	.3248	.2298	.3773
Minimum of Log	.3010	.3010	.3010
Maximum of Log	1.4771	1.3010	1.4771
Skewness of Log	-.093	-.569	-.171
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	-.843	.344	-1.319
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 8. **Histogram Log Transformation Heart Transplant Centers per State**

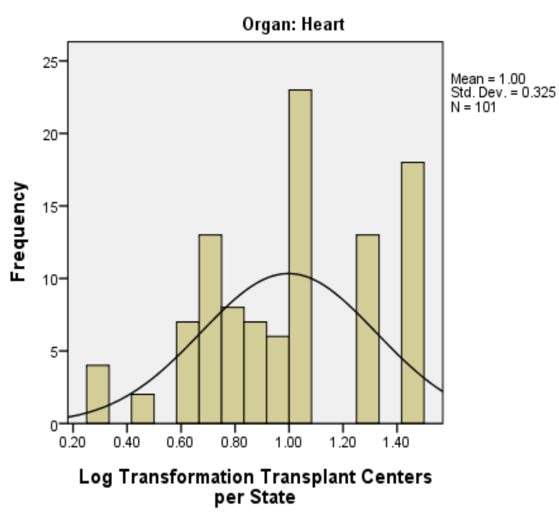


Table 14. *T*-Test Log Transformation Heart Transplant Centers per Sate

		Heart Transplant Centers per State	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	26.281 .000	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	-1.116 99 .267 -.0731 .0655 -.2030 .0569	-1.206 96.951 .231 -.0731 .0606 -.1933 .0471

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 15 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = 1.245, p = .267] in the mean number of heart transplant centers in the states with and without a solid transplant CON regulation.

Table 15. ANOVA Log Transformation Heart Transplant Centers per State

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.131	1	.131	1.245	.267
Within Groups	10.421	99	.105		
Total	10.552	100			

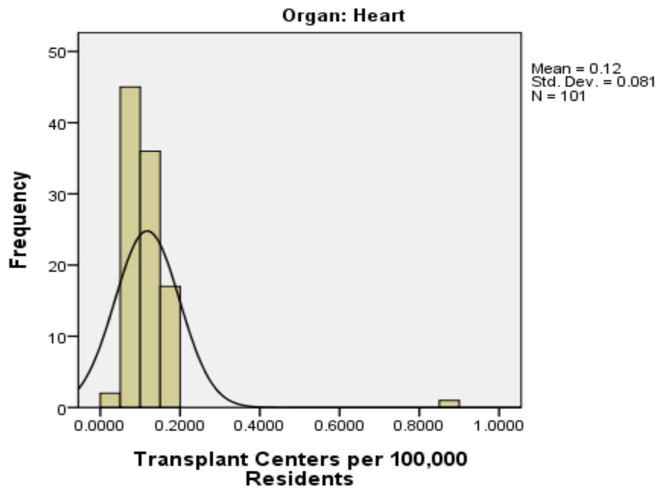
For reasons previously discussed, the data was normalized to population by creating a new variable: heart transplant centers per 100,000 residents. Table 16 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation. A slight difference in the mean number of heart transplant centers per 100,000 residents was identified but in the opposite direction once population was taken into account. The mean difference was 0.006 more centers for states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation.

Table 16. Heart Transplant Centers per 100,000 Residents

	All Heart Transplant Centers	Heart Transplant Centers in States with Transplant CON Regulation	Heart Transplant Centers in States without Transplant CON Regulation
Number	101	42	59
Mean	.1176	.1211	.1151
Median	.1030	.0993	.1185
Standard Deviation	.0812	.1189	.0368
Minimum	.0431	.0431	.0452
Maximum	.8520	.8520	.1784
Skewness	7.522	5.923	.107
Std. Error of Skewness	.240	.365	.311
Kurtosis	67.962	37.038	-1.054
Std. Error of Kurtosis	.476	.717	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 20 indicate that the measure was not normally distributed. This is illustrated in Figure 9.

Figure 9. **Histogram Heart Transplant Centers per 100,000 Residents**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 17. Figure 10 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for heart transplant centers per state to determine if there was a statistically significant difference in the mean number of heart transplant centers in the states with and without a solid organ transplant CON regulation. Table 18 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = -.434) and the t (99) = -.510, p = .611. This analysis found that states with a CON regulation for solid organ transplant services had no fewer heart transplant centers than those without a solid organ transplant CON regulation.

Table 17. Log Transformation Heart Transplant Centers per 100,000 Residents

	All Heart Transplant Centers	Heart Transplant Centers States with Transplant CON Regulation	Heart Transplant Centers in States without Transplant CON Regulation
Number	101	42	59
Mean of Log	-.9698	-.9797	-.9627
Median of Log	-.9871	-1.0030	-.9262
Standard Deviation of Log	.1650	.1866	.1491
Minimum of Log	-1.3655	-1.3655	-1.3449
Maximum of Log	-.0696	-.0696	-.7486
Skewness of Log	1.362	2.751	-.440
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	7.814	13.624	-.539
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 10. **Histogram Heart Transplant Centers per 100,000 Residents**

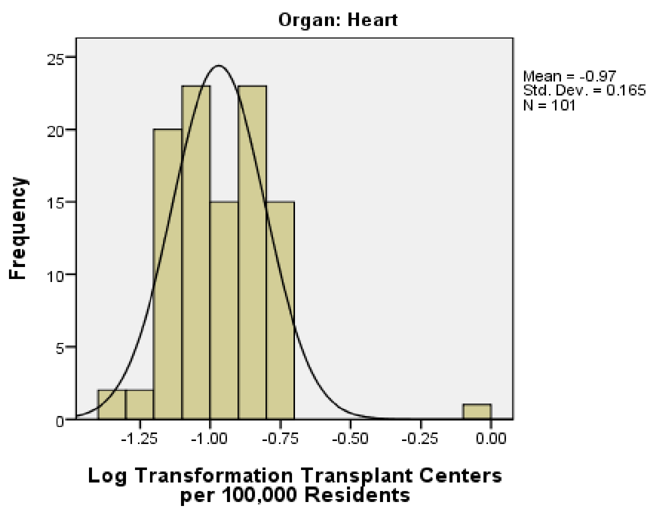


Table 18. *T*-Test Log Transformation Heart Transplant Centers per 100,000 Residents

		Heart Transplant Centers per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.618	
	Sig.	.434	
t-test for Equality of Means	*t*	-.510	-.491
	df	99	75.709
	Sig. (2-tailed)	.611	.625
	Mean Difference	-.0170	-.0170
	Std. Error Difference	.0334	.0347
	95% Confidence Interval of the Difference		
	Lower	-.0834	-.0862
	Higher	.0493	.0521

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 19 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = .260, p = .611] in the mean number of heart transplant centers in the states with and without a solid transplant CON regulation.

Table 19. ANOVA Log Transformation Heart Transplant Centers per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.007	1	.007	.260	.611
Within Groups	2.717	99	.027		
Total	2.724	100			

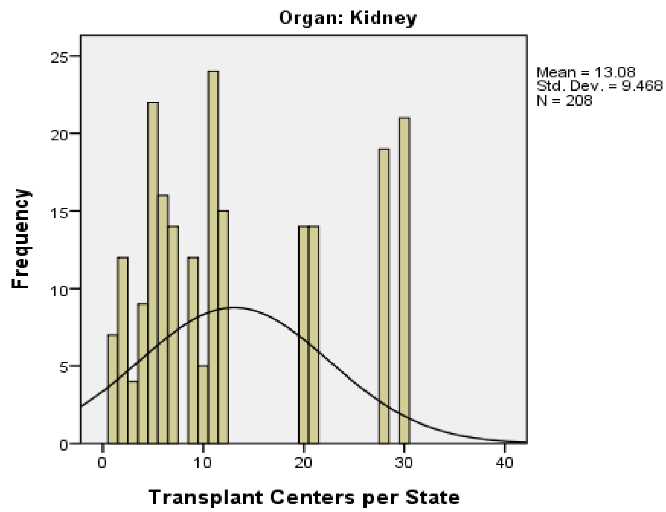
To continue testing the first hypothesis, the explanatory variable of the presence of a solid organ transplant CON regulation for the state in which the centers are located was used and the number of kidney transplant centers per state was tested. Table 20 shows the results and as expected states with a solid organ transplant CON regulation had fewer kidney transplant centers (84 versus 124). A difference in the mean number of kidney transplant centers per state was identified. States with a solid organ transplant CON regulation had on the average 5.11 fewer kidney transplant centers than states without a solid organ transplant CON regulation.

Table 20. Kidney Transplant Centers per State

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	13.08	10.04	15.15
Median	11.00	9.50	11.00
Standard Deviation	9.468	5.463	10.959
Minimum	1	1	1
Maximum	30	20	30
Skewness	.662	.535	.255
Std. Error of Skewness	.169	.263	.217
Kurtosis	-.978	-.354	-1.669
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 20 indicate that the measure was not normally distributed. This is illustrated in Figure 11.

Figure 11. **Histogram Kidney Transplant Centers per State**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 21. Figure 12 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for kidney transplant centers per state to determine if there was a statistically significant difference in the mean number of kidney transplant centers in the states with and without a solid organ transplant CON regulation. Table 22 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is not equal variance in both groups (p = .000) and the t (203.144) = -2.071, p = .040. This analysis found that as hypothesized states with a CON regulation for solid organ transplant services had fewer kidney transplant centers than those without a solid organ transplant CON regulation.

Table 21. Log Transformation Kidney Transplant Centers per State

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	.9782	.9157	1.0206
Median of Log	1.0414	.9771	1.0414
Standard Deviation of Log	.3798	.3151	.4139
Minimum of Log	.0000	.0000	.0000
Maximum of Log	1.4771	1.3010	1.4771
Skewness of Log	-.558	-1.354	-.462
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	-.153	2.203	-.909
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 12. Histogram Log Transformation Kidney Transplant Centers per State

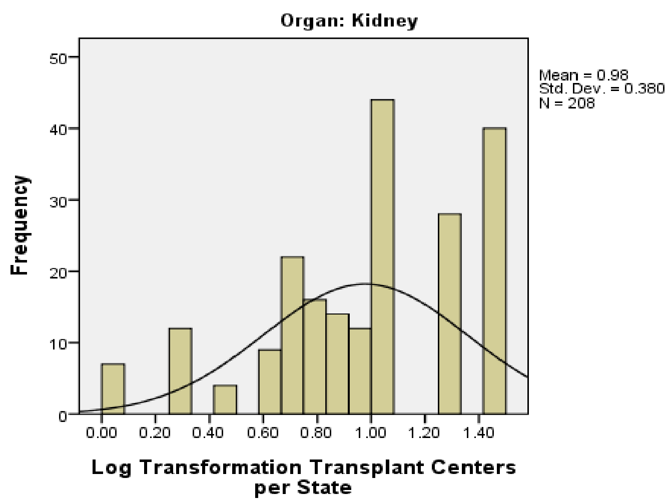


Table 22. *T*-Test Log Transformation Kidney Transplant Centers per State

		Kidney Transplant Centers per State	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	18.858	
	Sig.	.000	
t-test for Equality of Means	*t*	-1.967	-2.071
	df	206	203.144
	Sig. (2-tailed)	.051	.040
	Mean Difference	-.1048	-.1048
	Std. Error Difference	.0533	.0506
	95% Confidence Interval of the Difference		
	Lower	-.2099	-.2047
	Higher	-.0002	-.0050

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 23 shows the results of that test. This analysis demonstrates a significant difference [F (1, 206) = 3.870, p = .051] in the mean number of kidney transplant centers in the states with and without a solid transplant CON regulation.

Table 23. ANOVA Log Transformation Kidney Transplant Centers per State

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.551	1	.551	3.870	.051
Within Groups	29.311	206	.142		
Total	29.862	207			

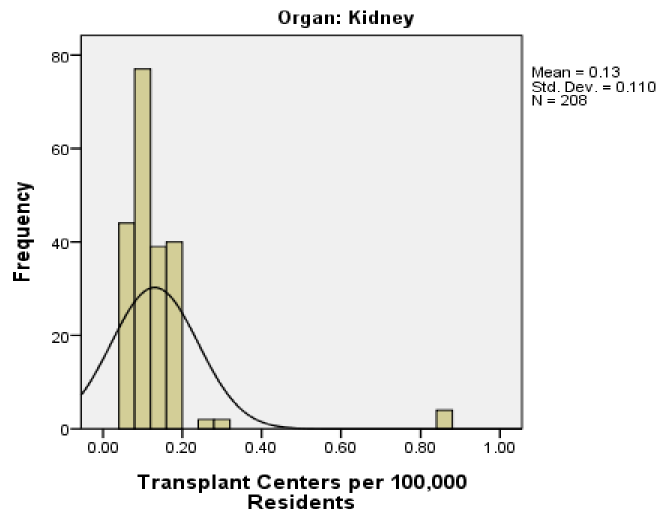
For reasons previously discussed, the data was normalized to population by creating a new variable: kidney transplant centers per 100,000 residents. Table 24 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation. A difference in the mean number of kidney transplant centers per 100,000 residents was identified but in the opposite direction once population was taken into account. The mean difference was 0.0169 more centers for states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation.

Table 24. Kidney Transplant Centers per 100,000 Residents

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	.1304	.1404	.1235
Median	.1030	.0993	.1259
Standard Deviation	.1096	.1631	.0463
Minimum	.0431	.0431	.0452
Maximum	.8520	.8520	.3131
Skewness	5.585	4.067	1.324
Std. Error of Skewness	.169	.263	.217
Kurtosis	34.428	15.647	3.428
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 24 indicate that the measure was not normally distributed. This is illustrated in Figure 13.

Figure 13. **Histogram Kidney Transplant Centers per 100,000 Residents**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 25. Figure 14 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for kidney transplant centers per 100,000 residents to determine if there was a statistically significant difference in the mean number of kidney transplant centers in the states with and without a solid organ transplant CON regulation. Table 26 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .257) and the t (206) = -.665, p = .507. This analysis found that states with a CON regulation for solid organ transplant services did not have fewer kidney transplant centers per 100,000 residents than those without a solid organ transplant CON regulation.

Table 25. Log Transformation Kidney Transplant Centers per 100,000 Residents

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	-.9435	-.9542	-.9362
Median of Log	-.9872	-1.003	-.8999
Standard Deviation of Log	.1917	.2352	.1562
Minimum of Log	-1.3655	-1.3655	-1.3449
Maximum of Log	-.0696	-.0696	-.5043
Skewness of Log	1.764	2.483	.031
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	6.655	7.584	.037
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 14. Histogram Log Transformation Kidney Transplant Centers per 100,000 Residents

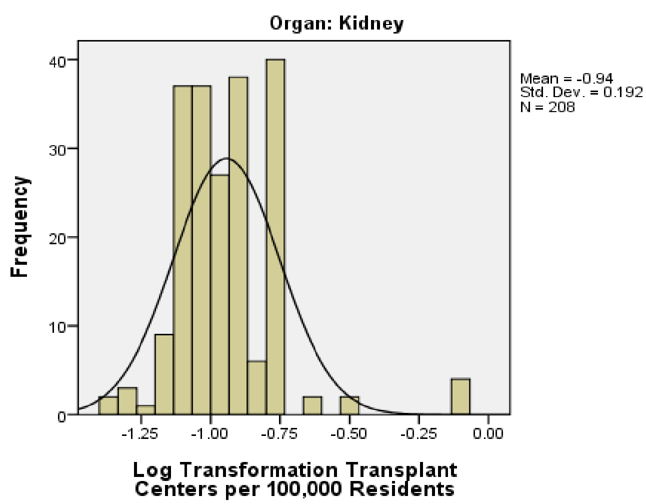


Table 26. *T*-Test Log Transformation Kidney Transplant Centers per 100,000 Residents

		Kidney Transplant Centers per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	1.290	
	Sig.	.257	
t-test for Equality of Means	*t*	-.665	-.617
	df	206	132.080
	Sig. (2-tailed)	.507	.538
	Mean Difference	-.0180	-.0180
	Std. Error Difference	.0271	.0292
	95% Confidence Interval of the Difference		
	Lower	-.0715	-.0759
	Higher	.0354	.0398

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 27 shows the results of that test. This analysis demonstrates no significant difference [F (1, 206) = .443, p = .507] in the mean number of kidney transplant centers per 100,000 residents in the states with and without a solid transplant CON regulation.

Table 27. ANOVA Log Transformation Kidney Transplant Centers per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.016	1	.016	.443	.507
Within Groups	7.594	206	.037		
Total	7.611	207			

The number of transplant centers per state were statistically lower (p = 0.17) in states with a solid organ transplant CON, as expected. Of the 308 transplant centers studied, 126 centers were in states with solid organ transplant CON regulations while 183 were in states without solid organ transplant CON regulations (see Table 2). In summary, for heart and kidney transplant centers together, the number of transplant centers per state was impacted by the presence of a solid organ transplant CON regulation. The hypothesis is supported in that states with a solid organ transplant CON regulation in place have fewer transplant centers than states without a solid organ transplant CON regulation.

When the type of transplant center (heart or kidney) was examined separately, only the number of kidney transplant centers per state remained statistically significant for states with a solid organ transplant CON in place. The number of heart transplant centers per state with and without solid organ transplant CON regulations were not found to be statistically different.

In an attempt to account for the differences in population between states, a different variable was created and tested (Transplant Centers per 100,000 Residents); no significance is found between states with and without CON regulations for solid organ transplants using this measure.

Hypothesis #2: Transplant Volume Analysis

CON regulations were also intended to ensure improved quality and clinical proficiency by limiting the number of healthcare facilities performing complex medical procedures and thus increasing the volume of procedures performed at approved facilities.

The second hypothesis of this study is that transplant center in states with a solid organ transplant CON regulation will perform more heart and kidney transplant procedures than transplant centers in states without a solid organ transplant CON regulation. The null hypothesis is that there is no difference in the number of heart and kidney transplant procedures performed by transplant centers in states with or without a solid organ transplant CON regulation.

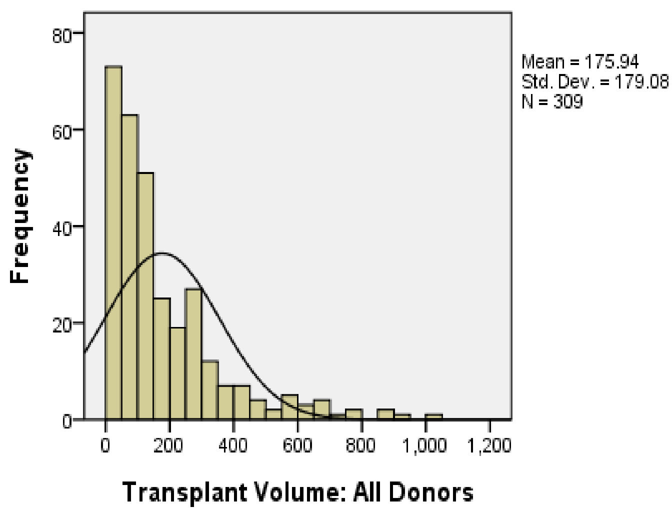
To test this hypothesis, the explanatory variable of the presence of a solid organ transplant CON regulation for the state was used and the total number of transplant procedures performed by every center in the state was tested. Table 28 shows the results and as expected transplant centers in states with a solid organ transplant CON regulation performed on the average more transplants (185 versus 170). A difference in the mean number of transplant procedures was identified. Transplant centers in states with a solid organ transplant CON regulation performed 15.4 more transplant procedures than transplant centers in states without a solid organ transplant CON regulation.

Table 28. Transplant Volume per Center

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	175.94	185.06	169.66
Median	116.00	130.00	107.00
Standard Deviation	179.080	185.614	174.676
Minimum	4	4	4
Maximum	1,008	867	1,008
Skewness	1.917	1.728	2.080
Std. Error of Skewness	.139	.216	.180
Kurtosis	4.051	2.686	5.380
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 28 indicate that the measure was not normally distributed. This is illustrated in Figure 15.

Figure 15. **Histogram Transplant Volume per Center**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 29. Figure 16 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for transplant volume per center to determine if there was a statistically significant difference in the mean number of procedures performed by transplant centers in states with and without a solid organ transplant CON regulation. Table 30 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in

both groups (p = .708) and the t (307) = .565, p = .572. This analysis found that transplant centers in states with and without a solid organ transplant CON regulation did not perform a significantly different number of transplant procedures. This does not support the hypostasis and the null hypothesis is accepted.

Table 29. Log Transformation Transplant Volume per Center

	All Transplant Centers	Transplant Center in States ***with*** Transplant CON Regulation	Transplant Center in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean of Log	2.0293	2.0474	2.0169
Median of Log	2.0645	2.1139	2.0294
Standard Deviation of Log	.46578	.47699	.45880
Minimum of Log	.60	.60	.60
Maximum of Log	3.00	2.93	3.00
Skewness of Log	-.356	-.413	-.324
Std. Error of Skewness of Log	.139	.216	.180
Kurtosis of Log	-.102	-.161	-.015
Std. Error of Kurtosis of Log	.276	.428	.357

Figure 16. Histogram Log Transformation Transplant Volume per Center

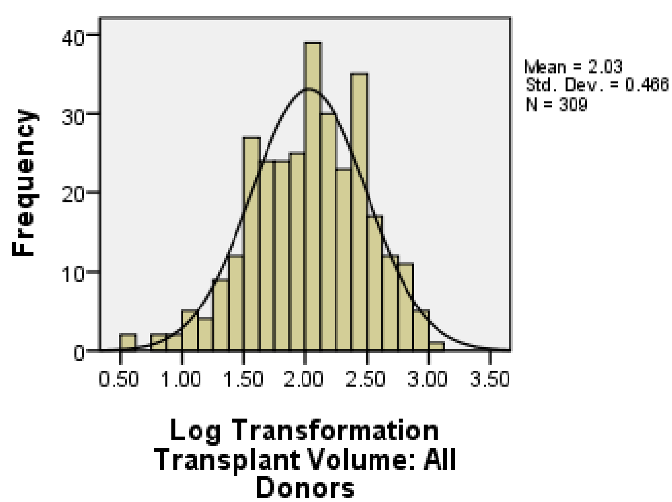


Table 30. *T*-Test Log Transformation Transplant Volume per Center

		Transplant Volume per Center	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.141	
	Sig.	.708	
t-test for Equality of Means	*t*	.565	.561
	df	307	261.967
	Sig. (2-tailed)	.572	.575
	Mean Difference	.03050	.03050
	Std. Error Difference	.05398	.05437
	95% Confidence Interval of the Difference		
	Lower	-.07571	-.07655
	Higher	.13672	.13756

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 31 shows the results of that test. This analysis demonstrates no significant difference [F (1, 307) = .319, p = .572] in the mean number of transplant procedures performed by transplant centers in states with and without a solid transplant CON regulation.

Table 31. ANOVA Log Transformation Transplant Volume per Center

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.069	1	.069	.319	.572
Within Groups	66.751	307	.217		
Total	66.820	308			

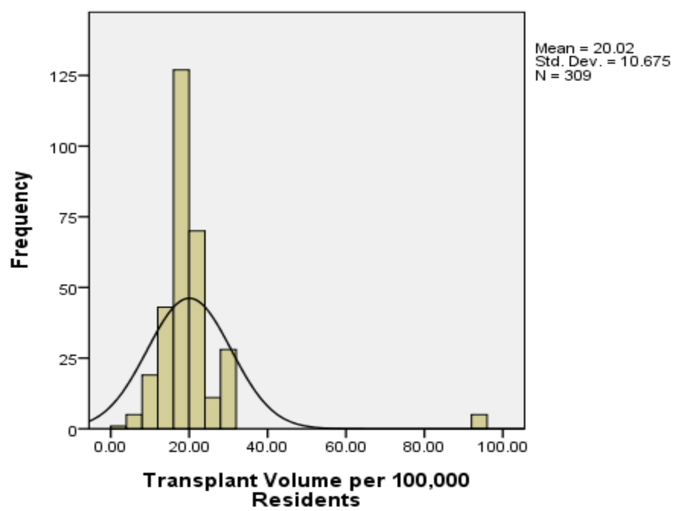
The above analysis does not support the hypothesis that CON regulations increase volume per center by restricting the number of facilities that perform procedures. As with the first hypothesis, one concern is the differences in state populations. As a rough proxy for this idea, a test for differences between the state volumes was performed by creating a new variable (Transplant Volume per 100,000 Residents). This variable was created using the number of transplant procedures performed in the state normalized to the state average population for 2006 through 2008. Table 32 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation. A difference in the mean volume of transplants performed per state was identified. The mean difference was 2.0764 more transplants were performed per 100,000 residents in states with a solid organ transplant CON regulation than in states without a solid organ transplant CON regulation.

Table 32. Transplant Volume per 100,000 Residents

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	20.0228	21.2525	19.1761
Median	18.2773	18.5641	17.3902
Standard Deviation	10.6749	15.0714	5.9219
Minimum	3.8163	7.9510	3.8163
Maximum	93.2142	93.2142	31.9843
Skewness	5.235	4.381	.400
Std. Error of Skewness	.139	.216	.180
Kurtosis	33.733	18.766	-.105
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 32 indicate that the measure was not normally distributed. This is illustrated in Figure 17.

Figure 17. **Histogram Transplant Volume per 100,000 Residents**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 33. Figure 18 illustrates that the transformed variable is normally distributed. An independent *t*-test was then performed on the transformed data for transplant volume per 100,000 residents to determine if there was a statistically significant difference in the mean number of transplants performed per 100,000 residents in states with and without a solid organ transplant CON regulation. Table 34 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .347) and the t (307) = 1.187, p = .236. This analysis

found that states with a solid organ transplant CON regulation did not perform more transplant procedures per 100,000 residents than those without a solid organ transplant CON regulation. So when normalized by the rough measure of population, the hypothesis continues to be not supported.

Table 33. Log Transformation Transplant Volume per 100,000 Residents

	All Transplant Centers	Transplant Center in States ***with*** Transplant CON Regulation	Transplant Center in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean of Log	1.2691	1.2817	1.2605
Median of Log	1.2619	1.2687	1.2403
Standard Deviation of Log	.15410	.16612	.14508
Minimum of Log	.58	.90	.58
Maximum of Log	1.97	1.97	1.50
Skewness of Log	.897	2.558	-.853
Std. Error of Skewness of Log	.139	.216	.180
Kurtosis of Log	6.896	9.825	2.421
Std. Error of Kurtosis of Log	.276	.428	.357

Figure 18. **Histogram Log Transformation Transplant Volume per 100,000 Residents**

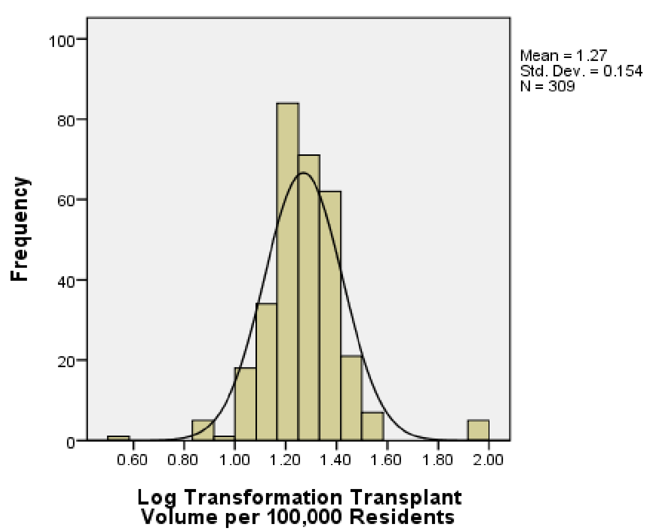


Table 34. *T*-Test Log Transformation Transplant Volume per 100,000 Residents

		Transplant Volume per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's test for Equality of Variances	*F* Sig.	.887 .347	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	1.187 307 .236 .02115 .01783 -.01393 .05623	1.157 244.460 .248 .02115 .01828 -.01485 .05715

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 35 shows the results of that test. This analysis demonstrates no significant difference [F (1, 307) = 1.408, p = .236] in the mean number of transplant procedures per 100,000 residents performed in the states with and without a solid transplant CON regulation.

Table 35. ANOVA Log Transformation Transplant Volume per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.033	1	.033	1.408	.236
Within Groups	7.281	307	.024		
Total	7.314	308			

Type of Transplant

The next step, as with the first hypothesis, was to see if a significant difference existed between the two types of organ transplants under study – heart and kidney transplants. Table 36 shows the descriptive statistics for heart transplant volume for transplant centers in states with and without a solid organ transplant CON regulation. Transplant centers in states with a solid organ transplant CON regulation performed on the average fewer heart transplant procedures (56.79 versus 58.63). A difference in the mean number of transplant procedures was identified. Transplant centers in states with a solid organ transplant CON regulation performed 1.84 fewer heart transplant procedures than transplant centers in states without a solid organ transplant CON regulation.

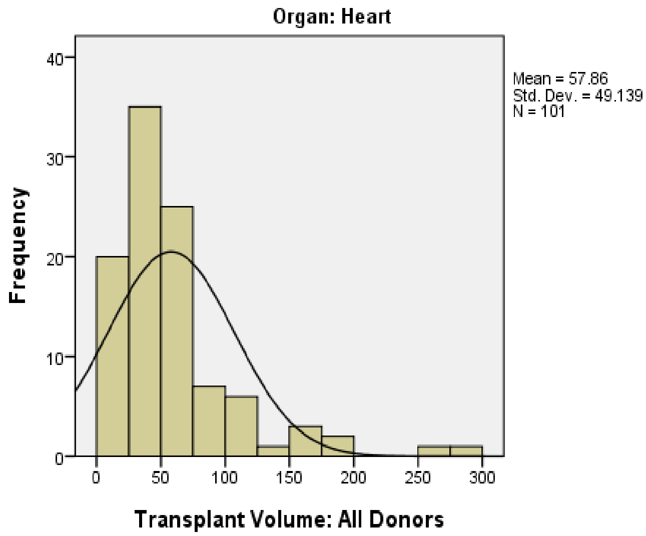
Table 36. Heart Transplant Volume per Center

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean	57.86	56.79	58.63
Median	44.00	42.50	44.00
Standard Deviation	49.139	49.314	49.424
Minimum	4	8	4
Maximum	281	281	268
Skewness	2.314	2.652	2.141
Std. Error of Skewness	.240	.365	.311
Kurtosis	6.855	9.773	5.637
Std. Error of Kurtosis	.476	.717	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness

and kurtosis statistics shown in Table 36 indicate that the measure was not normally distributed. This is illustrated in Figure 19.

Figure 19. **Histogram Heart Transplant Volume per Center**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 37. Figure 20 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for heart transplant volume per center to determine if there was a statistically significant difference in the mean number of heart transplant procedures performed by transplant centers in states with and without a solid organ transplant CON regulation. Table 38 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .964) and the t (99) = -.022, p = .983. This analysis found that transplant centers in states with and without a solid organ transplant CON regulation did not perform a significantly different number of heart

transplant procedures. This does not support the hypothesis and the null hypothesis is accepted.

Table 37. Log Transformation Heart Transplant Volume per Center

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean of Log	1.6323	1.6314	1.6329
Median of Log	1.6435	1.6269	1.6435
Standard Deviation of Log	.3512	.3314	.3675
Minimum of Log	.60	.90	.60
Maximum of Log	2.45	2.45	2.43
Skewness of Log	-.378	-.004	-.576
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	.553	-.003	.872
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 20. **Histogram Log Transformation Heart Transplant Volume per Center**

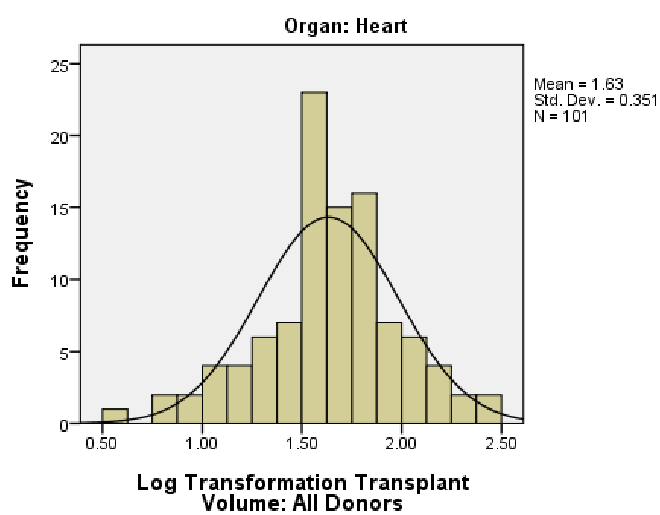


Table 38. *T*-Test Log Transformation Heart Transplant Volume per Center

		Heart Transplant Volume per Center	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.002	
	Sig.	.964	
t-test for Equality of Means	*t*	-.022	-.022
	df	99	93.535
	Sig. (2-tailed)	.983	.982
	Mean Difference	-.0015	-.0015
	Std. Error Difference	.0712	.0700
	95% Confidence Interval of the Difference		
	Lower	-.1429	-.1406
	Higher	.13987	.1375

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 39 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = .000, p = .983.] in the mean number of transplant procedures performed by heart transplant centers in states with and without a solid transplant CON regulation.

Table 39. ANOVA Log Transformation Heart Transplant Volume per Center

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.000	1	.000	.000	.983
Within Groups	12.338	99	.125		
Total	12.338	100			

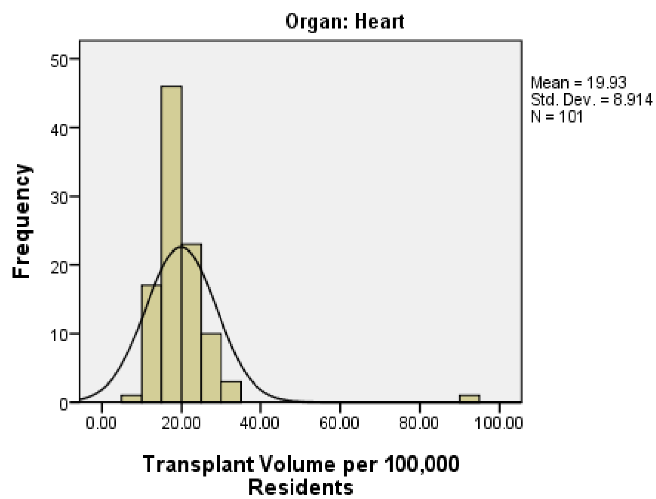
The above analysis is not consistent with the hypothesis that CON regulations increases volume per center by restricting the number of facilities that perform those procedures. As with the first hypothesis, one concern is the differences in population per state. As a rough proxy for this idea, a test for differences between the state volumes was performed by creating a new variable (Heart Transplant Volume per 100,000 Residents). This variable was created using the number of heart transplant procedures performed by transplant centers in the state normalized to the state average population for 2006 through 2008. Table 40 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation. A difference in the mean volume of heart transplants performed per state was identified. The mean difference was 0.4333 more heart transplants were performed per 100,000 residents for states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation.

Table 40. Heart Transplant Volume per 100,000 Residents

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean	19.9316	20.1847	19.7514
Median	18.5288	18.5995	17.7288
Standard Deviation	8.9143	12.0013	5.9258
Minimum	7.6378	10.7180	7.6378
Maximum	93.2142	93.2142	31.9843
Skewness	5.697	5.723	.508
Std. Error of Skewness	.240	.365	.311
Kurtosis	45.740	35.522	-.383
Std. Error of Kurtosis	.476	.717	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 36 indicate that the measure was not normally distributed. This is illustrated in Figure 21.

Figure 21. **Histogram Heart Transplant Volume per 100,000 Residents**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 41. Figure 22 illustrates that the transformed variable is normally distributed. An independent *t*-test was then performed on the transformed data for heart transplant volume per 100,000 residents to determine if there was a statistically significant difference in the mean number of heart transplants performed per 100,000 residents in states with and without a solid organ transplant CON regulation. Table 42 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .163) and the t (99) = -.071, p = .944. This

analysis found that states with a solid organ transplant CON regulation did not perform more heart transplant procedures than those without a solid organ transplant CON regulation. So when normalized by the rough measure of population, the hypothesis continues to not be supported.

Table 41. Log Transformation Heart Transplant Volume per 100,000 Residents

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean of Log	1.2753	1.2742	1.2761
Median of Log	1.2678	1.2695	1.2487
Standard Deviation of Log	.1346	.1385	.1329
Minimum of Log	.88	1.03	88
Maximum of Log	1.97	1.97	1.50
Skewness of Log	1.094	2.866	-.270
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	6.546	15.467	.254
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 22. Histogram Log Transformation Heart Transplant Volume per 100,000 Residents

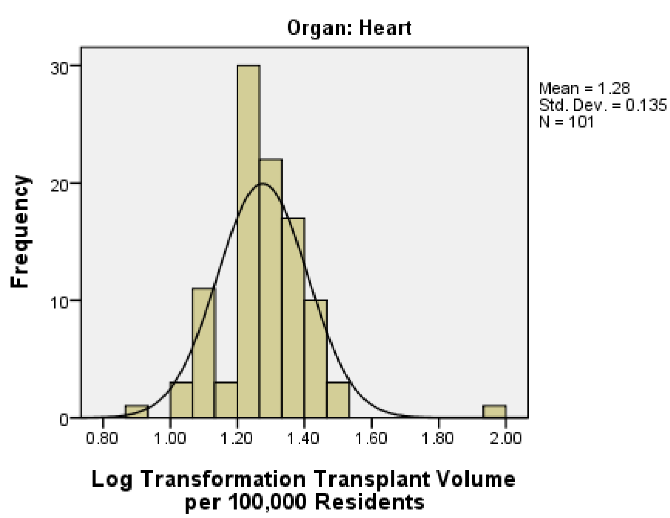


Table 42. *T*-Test Log Transformation Heart Transplant Volume per 100,000 Residents

		Heart Transplant Volume per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	1.974	
	Sig.	.163	
t-test for Equality of Means	*t*	-.071	-.070
	df	99	86.223
	Sig. (2-tailed)	.944	.944
	Mean Difference	-.0019	-.0019
	Std. Error Difference	.0273	.0275
	95% Confidence Interval of the Difference		
	Lower	-.0561	-.0566
	Higher	.0522	.0527

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 43 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = .005, p = .944] in the mean number of heart transplant procedures per 100,000 residents performed in the states with and without a solid transplant CON regulation.

Table 43. ANOVA Log Transformation Heart Transplant Volume per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.000	1	.000	.005	.944
Within Groups	1.812	99	.018		
Total	1.812	100			

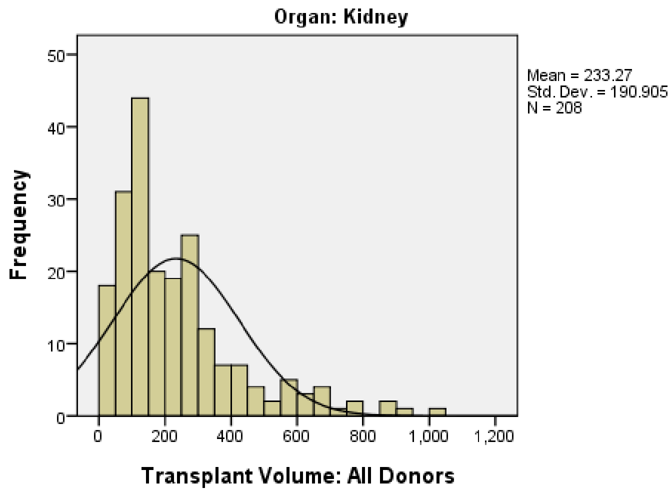
To continue testing the second hypothesis, the explanatory variable of the presence of a solid organ transplant CON regulation for the state in which the centers are located was used and the number of kidney transplant procedures performed by transplant centers was tested. Table 44 shows the results and, as expected, transplant centers in states with a solid organ transplant CON regulation performed on the average more kidney transplant procedures (249 versus 222). A difference in the mean number of kidney transplant procedures was identified. Transplant centers in states with a solid organ transplant CON regulation performed 26.72 more kidney transplant procedures than transplant centers in states without a solid organ transplant CON regulation.

Table 44. Kidney Transplant Volume per Center

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	233.27	249.20	222.48
Median	170.00	170.50	169.00
Standard Deviation	190.905	195.436	187.800
Minimum	4	4	12
Maximum	1,008	857	1,008
Skewness	1.582	1.392	1.751
Std. Error of Skewness	.169	.263	.217
Kurtosis	2.566	1.339	3.762
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 44 indicate that the measure was not normally distributed. This is illustrated in Figure 23.

Figure 23. **Histogram Kidney Transplant Volume per Center**



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 45. Figure 24 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data for kidney transplant volume per center to determine if there was a statistically significant difference in the mean number of procedures performed in centers located in states with and without a solid organ transplant CON regulation. Table 46 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .551) and the t (206) = 1.024 , p = .307. This analysis found that kidney transplant centers in states with and without a solid organ transplant CON regulation did not perform a significantly different number of kidney transplant procedures. This does not support the hypothesis and the null hypothesis is accepted.

Table 45. Log Transformation Kidney Transplant Volume per Center

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	1.2661	1.2854	1.2531
Median of Log	1.2619	1.2678	1.2403
Standard Deviation of Log	.1629	.1790	.1504
Minimum of Log	.58	.90	.58
Maximum of Log	1.97	1.97	1.50
Skewness of Log	.855	2.437	-1.018
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	6.793	8.469	2.896
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 24. **Histogram Log Transformation Kidney Transplant Volume per Center**

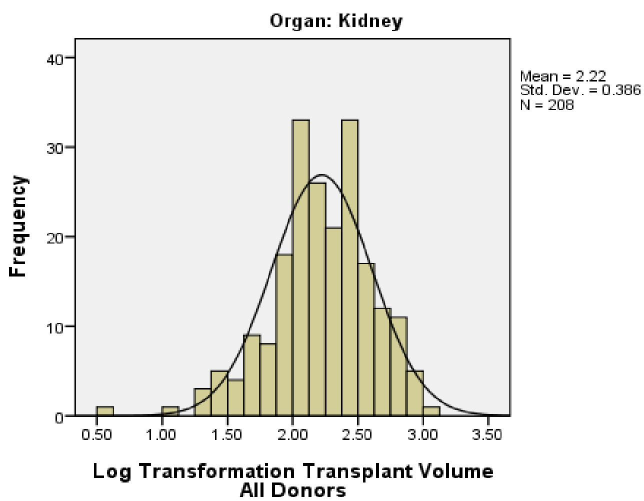


Table 46. *T*-Test Log Transformation Kidney Transplant Volume per Center

		Kidney Transplant Volume per Center	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.356	
	Sig.	.551	
t-test for Equality of Means	*t*	1.024	1.015
	df	206	172.828
	Sig. (2-tailed)	.307	.312
	Mean Difference	.0558	.0558
	Std. Error Difference	.0545	.0550
	95% Confidence Interval of the Difference		
	Lower	-.0516	-.0527
	Higher	.1633	.1644

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 47 shows the results of that test. This analysis demonstrates no significant difference [F (1, 206) = 1.048, p = .307] in the mean number of kidney transplant procedures performed by kidney transplant centers in states with and without a solid transplant CON regulation.

Table 47. ANOVA Log Transformation Kidney Transplant Volume per Center

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.156	1	.156	1.048	.307
Within Groups	30.675	206	.149		
Total	30.831	207			

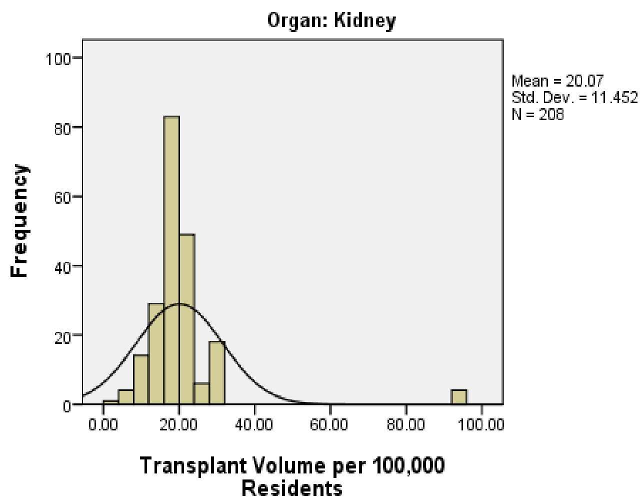
The above analysis is not consistent with hypothesis that CON regulations improve volume by restricting the number of facilities that perform procedures. As with the previous tests, one concern is the state's population. As a rough proxy for this idea, a test for differences between the state volumes was performed by creating a new variable (Kidney Transplant Volume per 100,000 Residents). This variable was created using the number of kidney transplant procedures performed in the state normalized to the state average population for 2006 through 2008. Table 48 shows the descriptive statistics for this new variable for states with and without a solid organ transplant CON regulation. A difference in the mean volume of kidney transplants performed per state was identified. The mean difference was 2.884 more kidney transplants were performed per 100,000 residents for states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation.

Table 48. Kidney Transplant Volume per 100,000 Residents

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	20.0670	21.7864	18.9024
Median	18.2773	18.5288	17.3902
Standard Deviation	11.4524	16.4340	5.9243
Minimum	3.8163	7.9510	3.8163
Maximum	93.2142	93.2142	31.9843
Skewness	5.038	4.009	.360
Std. Error of Skewness	.169	.263	.217
Kurtosis	30.208	15.403	.036
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 48 indicate that the measure was not normally distributed. This is illustrated in Figure 25.

Figure 25. Histogram Kidney Transplant Volume per 100,000 Residents



Using a log transformation, a new variable was created with the resulting descriptive statistics shown in Table 49. Figure 26 illustrates that the transformed variable is normally distributed. An independent *t*-test was then performed on the transformed data for kidney transplant volume per 100,000 residents to determine if there was a statistically significant difference in the mean number of kidney transplants performed per 100,000 residents in states with and without a solid organ transplant CON regulation. Table 50 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .778) and the t (206) = 1.407, p = .161. This

analysis found that states with a solid organ transplant CON regulation did not perform more kidney transplant procedures per 100,000 residents than those without a solid organ transplant CON regulation. So when normalized by the rough measure of population, the hypothesis continues to not be supported.

Table 49. Log Transformation Kidney Transplant Volume per 100,000 Residents

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	1.2661	1.2854	1.2531
Median of Log	1.2619	1.2678	1.2403
Standard Deviation of Log	.1629	.1790	.1504
Minimum of Log	.58	.90	.58
Maximum of Log	1.97	1.97	1.50
Skewness of Log	.855	2.437	-1.018
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	6.793	8.469	2.896
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 26. **Histogram Log Transformation Kidney Transplant Volume per 100,000 Residents**

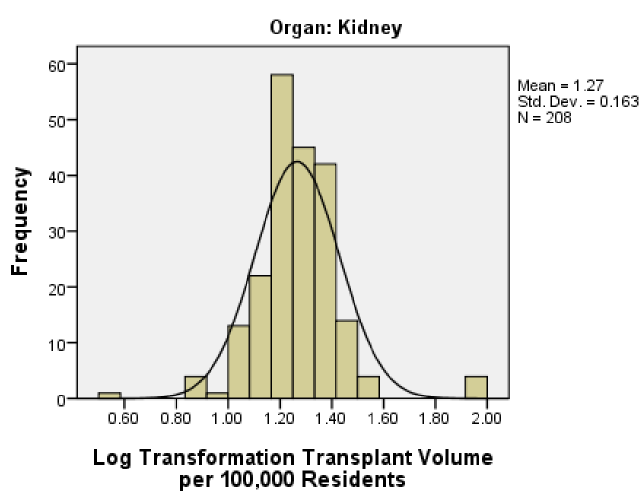


Table 50. *T*-Test Log Transformation Kidney Transplant Volume per 100,000 Residents

		Kidney Transplant Volume per 100,000 Residents	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	.080 .778	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	1.407 206 .161 .0323 .0229 -.0129 .0776	1.361 157.155 .175 .0323 .0237 -.0146 .0792

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 51 shows the results of that test. This analysis demonstrates no significant difference [F (1, 206) = 1.980, p = .161] in the mean number of kidney transplant procedures per 100,000 residents performed in the states with and without a solid transplant CON regulation.

Table 51. ANOVA Log Transformation Kidney Transplant Volume per 100,000 Residents

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.052	1	.052	1.980	.161
Within Groups	5.444	206	.026		
Total	5.496	207			

No statistical differences were found in the transplant center volume between states with and without a solid organ transplant CON regulation. Even though the number of centers was fewer for states with a solid organ transplant CON regulation, the volume per center did not prove to be higher for centers in states with a solid organ transplant CON regulations. This requires that the null hypothesis be accepted. Even though CON regulations were established to increase volume by limiting providers that does not prove correct for heart and kidney transplant center volume. Differences in volume may be affected by other factors such as supply of organs for transplantation. The demand for solid organ transplantation, as measured by the number of registrants on the waiting list on December 31st of each year, increased by 250 percent from 1995 to 2005. However, the number of transplants performed grew only by 52 percent over the same period (UNOS, 2010). This disparity between utilization and potential demand could be due to the limited organ supply rather than the capacity of transplant centers.

As with the first hypothesis, another variable was created in an attempt to account for the differences in population between states. There was no difference in transplants per 100,000 residents between states with and without a solid organ transplant CON regulations.

Heart and kidney transplant center volumes were examined separately. There was no difference found in transplant center volume in states with and without solid organ transplant CON regulations.

Analysis - Hypothesis #3

The third hypothesis tests whether the presence of a solid organ transplant CON regulation is associated with lower graft failures and mortality. It is has been stated previously that the intent of CON was to restrict the number of healthcare providers, leading to higher procedural volume per center. Higher procedural volume has been associated with lower mortality rates in previous studies cited in this literature review (Hannan et al, 1989; Begg et al., 1998). The third hypothesis states that there fewer graft failures and patient deaths in transplant centers that reside in states with a solid organ transplant CON regulation. The null hypothesis is that there is not a relationship between a solid organ transplant CON regulation and graft failures or patient deaths for that transplant center. For organ transplantation, two outcomes are used – the failure of the transplanted organ and/or the patient's death.

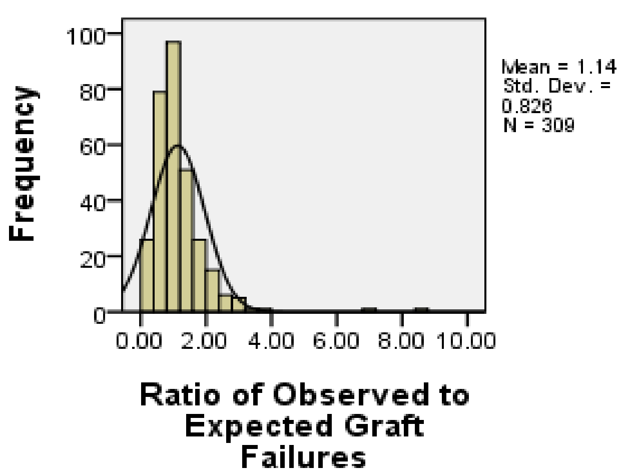
To test this hypothesis, the explanatory variable of a solid organ transplant CON regulation for the state where the centers resides was used and the ratios for the observed to expected (O/E) graft failures and patient deaths were tested. Table 52 shows descriptive statistics for observed to expected ratio for graft failures. As expected, states with a solid organ transplant CON regulation had a lower observed to expected ratio for graft failures (1.0471 versus 1.1972). A difference in the mean observed to expected ratio for graft failures was identified. Centers in states with a solid organ transplant CON regulation had a 0.15 lower observed to expected ratio than states without a solid organ transplant CON regulation.

Table 52. Ratio of O/E Graft Failures

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	1.1360	1.0471	1.1972
Median	1.0200	.9250	1.0400
Standard Deviation	.82565	.76948	.85892
Minimum	0.00	0.00	0.00
Maximum	8.64	7.11	8.64
Skewness	4.035	4.095	4.038
Std. Error of Skewness	.139	.216	.180
Kurtosis	30.030	30.137	30.501
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 52 indicate that the measure was not normally distributed. This is illustrated in Figure 27.

Figure 27. Histogram Ratio of O/E Graft Failures



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 53. Figure 28 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of transplant centers in the states with and without a solid organ transplant CON regulation. Table 54 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .715) and the t (307) = -1.841, p = .067. This analysis found transplant centers in states with a solid organ transplant CON regulation did not have a lower observed to expected ratio for graft failures than centers in states without a solid organ transplant CON regulation. The direction of effects on quality was as expected on all tests, although the magnitude of effects did not reach statistical significance using a two-tailed test at the .05 level, suggesting that the magnitude of difference may be due to chance.

Table 53. Log Transformation Ratio of O/E Graft Failures

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean of Log	1.1178	1.0910	1.1362
Median of Log	1.1053	1.0733	1.1119
Standard Deviation of Log	.21287	.20516	.21665
Minimum of Log	.69	.69	.69
Maximum of Log	2.36	2.21	2.36
Skewness of Log	1.268	1.260	1.286
Std. Error of Skewness of Log	.139	.216	.180
Kurtosis of Log	5.377	6.138	5.195
Std. Error of Kurtosis of Log	.276	.428	.357

Figure 28. Histogram Log Transformation Ratio of O/E Graft Failures.

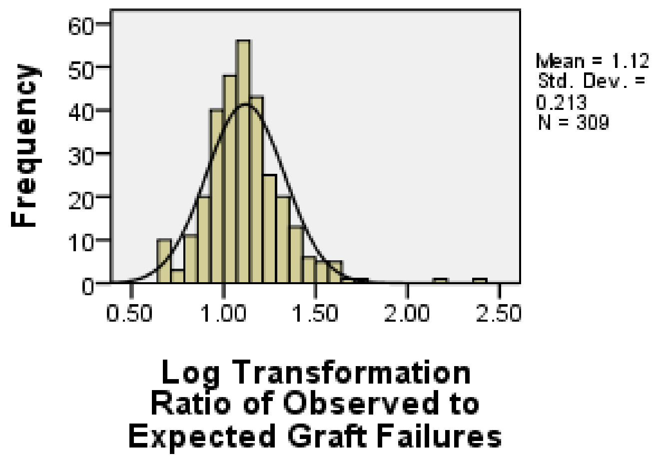


Table 54. *T*-Test Log Transformation Ratio of O/E Graft Failures

		Ratio Observed to Expected Graft Failures	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.133	
	Sig.	.715	
t-test for Equality of Means	*t*	-1.841	-1.860
	df	307	278.058
	Sig. (2-tailed)	.067	.064
	Mean Difference	-.04520	-.04520
	Std. Error Difference	.02455	.02430
	95% Confidence Interval of the Difference		
	Lower	-.09350	-.09304
	Higher	.00310	.00264

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 55 shows the results of that test. This analysis demonstrates no significant

difference [F (1, 307) = 3.390, p = .067] in the mean ratio of observed to expected graft failures for transplant centers in the states with and without a solid transplant CON regulation.

Table 55. ANOVA Log Transformation Ratio of O/E Graft Failures

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.152	1	.152	3.390	.067
Within Groups	13.804	307	.045		
Total	13.956	308			

Type of Transplant

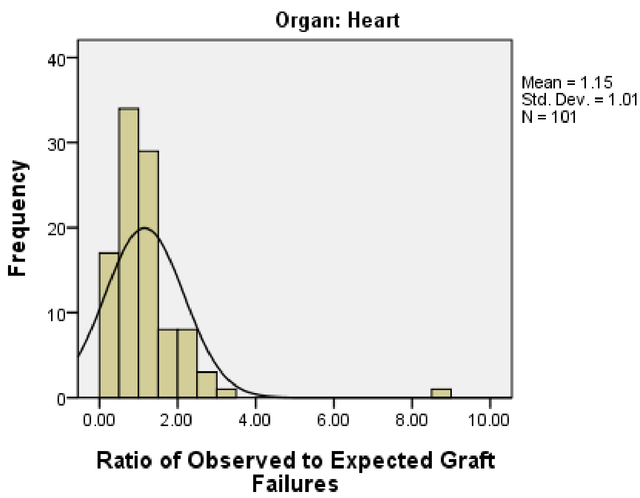
To continue testing this hypothesis, the explanatory variable of a solid organ transplant CON regulation for the state where the centers resides was used and the ratio for the observed to expected (O/E) graft failures by transplanted organ were tested. Table 56 shows descriptive statistics for observed to expected ratio for graft failures for heart transplants. As expected, states with a solid organ transplant CON regulation had a lower observed to expected ratio for graft failures (.9752 versus 1.2824). A difference in the mean observed to expected ratio for graft failures was identified. States with a solid organ transplant CON regulation had a 0.3072 lower observed to expected ratio than states without a solid organ transplant CON regulation.

Table 56. Ratio of O/E Graft Failures for Heart Transplant Centers

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Center in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean	1.1547	.9752	1.2824
Median	.9900	.8600	1.0500
Standard Deviation	1.0097	.6374	1.1960
Minimum	.00	.00	.00
Maximum	8.64	2.68	8.64
Skewness	4.288	.6375	4.208
Std. Error of Skewness	.240	.644	.311
Kurtosis	29.649	.365	24.608
Std. Error of Kurtosis	.476	.120	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 56 indicate that the measure was not normally distributed. This is illustrated in Figure 29.

Figure 29. Histogram Ratio of O/E Graft Failures for Heart Transplant Centers



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 57. Figure 30 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of heart transplant centers in the states with and without a solid organ transplant CON regulation. Table 58 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is not equal variance in both groups (p = .542.) and the t (99) = -1.590, p = .115. This analysis found heart transplant centers in states with a solid organ transplant CON regulation did not have a statistically significant lower observed to expected ratio for graft failures than centers in states without a solid organ transplant CON regulation. The hypothesis #3 is not supported since there is no statistically significant difference in the observed to expected ratio for graft failures.

Table 57. Log Transformation Ratio of O/E Graft Failures for Heart Transplant Centers

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean of Log	1.1145	1.0686	1.1472
Median of Log	1.0953	1.0508	1.1151
Standard Deviation of Log	.2467	.2101	.2667
Minimum of Log	.69	.69	.69
Maximum of Log	2.36	1.54	2.36
Skewness of Log	1.343	.152	1.664
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	5.529	-.372	6.435
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 30. Histogram Log Transformation Ratio of O/E Graft Failures for Heart Transplant Centers

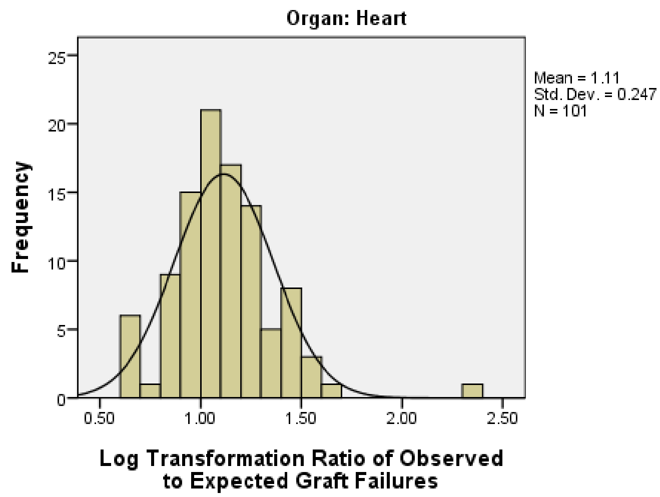


Table 58. *T*-Test Log Transformation Ratio of O/E Graft Failures for Heart Transplant Centers

		Ratio Observed to Expected Graft Failures	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.374	
	Sig.	.542	
t-test for Equality of Means	*t*	-1.590	-1.655
	df	99	97.930
	Sig. (2-tailed)	.115	.101
	Mean Difference	-.0786	-.0786
	Std. Error Difference	.0494	.0475
	95% Confidence Interval of the Difference		
	Lower	-.1767	-.1729
	Higher	.0195	.0156

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any significant differences between the means. Table 59 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = 2.528, p = .115] in the mean ratio of observed to expected graft failures for heart transplant centers in the states with and without a solid transplant CON regulation.

Table 59. ANOVA Log Transformation Ratio of O/E Graft Failures

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.152	1	.152	2.528	.115
Within Groups	5.935	99	.060		
Total	6.087	100			

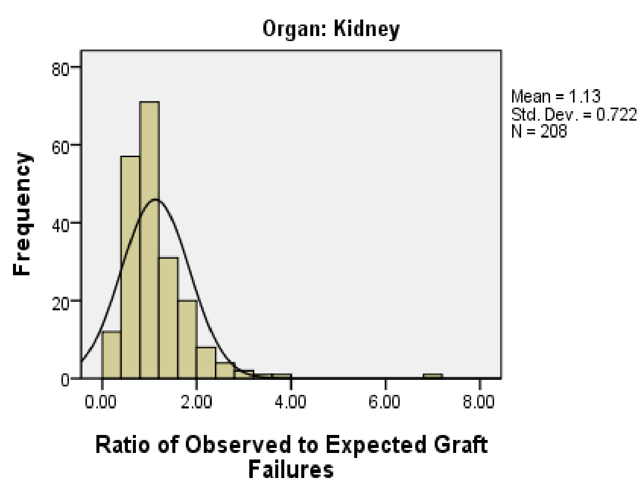
To continue testing this hypothesis, the explanatory variable of a solid organ transplant CON regulation for the state where the centers resides was used and the ratios for the observed to expect graft failures and patient deaths were tested for kidney transplants. Table 60 shows descriptive statistics for observed to expected ratio for graft failures. As expected, states with a solid organ transplant CON regulation had a lower observed to expected ratio for graft failures (1.0831 versus 1.1567). A difference in the mean observed to expected ratio for graft failures was identified. States with a solid organ transplant CON regulation had on the average a .0736 lower observed ratio than states without a solid organ transplant CON regulation.

Table 60. Ratio of O/E Graft Failures for Kidney Transplant Centers

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	1.1270	1.0831	1.1567
Median	1.0200	1.0050	1.0350
Standard Deviation	.7222	.8289	.6418
Minimum	.00	.00	.00
Maximum	7.11	7.11	3.69
Skewness	3.362	4.777	1.319
Std. Error of Skewness	.169	.263	.217
Kurtosis	22.786	33.561	2.410
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 60 indicate that the measure was not normally distributed. This is illustrated in Figure 31.

Figure 31. Histogram Ratio of O/E Graft Failures for Kidney Transplant Centers



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 61. Figure 32 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of kidney transplant centers in the states with and without a solid organ transplant CON regulation. Table 62 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .949) and the t (206) = -1.044, p = .298. This analysis found kidney transplant centers in states with a solid organ transplant CON regulation did not have a lower observed to expected ratio for graft failures than centers in states without a solid organ transplant CON regulation. The hypothesis #3 is not supported since there is no statistically significant difference in the observed to expected ratio for graft failures.

Table 61. Log Transformation Ratio of O/E Ratio Graft Failures for Kidney Transplant Centers

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	1.1194	1.1023	1.1310
Median of Log	1.1053	1.1003	1.1102
Standard Deviation of Log	.1949	.2030	.1892
Minimum of Log	.69	.69	.69
Maximum of Log	2.21	2.21	1.74
Skewness of Log	1.176	1.903	.632
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	4.598	9.746	.843
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 32. Histogram Log Transformation Ratio of O/E Graft Failure for Kidney Transplant Centers

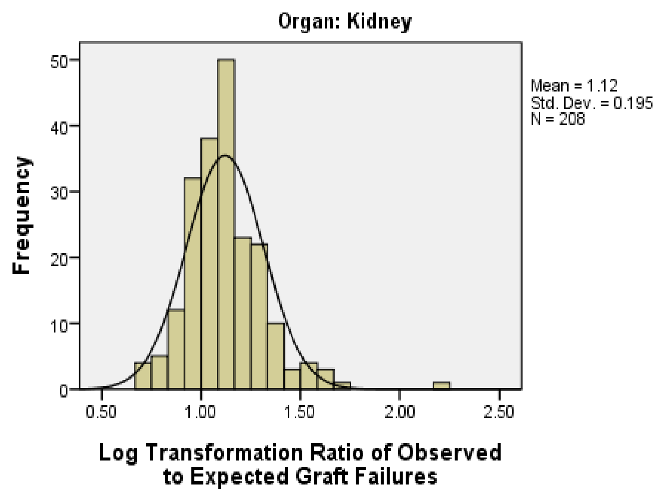


Table 62. *T*-Test Log Transformation Ratio of O/E Graft Failures for Kidney Transplant Centers

		Ratio Observed to Expected Graft Failure	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F*	.004	
	Sig.	.949	
t-test for Equality of Means	*t*	-1.044	-1.030
	df	206	169.797
	Sig. (2-tailed)	.298	.304
	Mean Difference	-.0287	-.0287
	Std. Error Difference	.0275	.0279
	95% Confidence Interval of the Difference		
	Lower	-.0830	-.0838
	Higher	.0255	.0263

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 63 shows the results of that test. This analysis demonstrates no significant difference [F (1, 206) = 1.091, p = .298] in the mean ratio of observed to expected graft failures for kidney transplant centers in the states with and without a solid transplant CON regulation.

Table 63. ANOVA Log Transformation Ratio of O/E Graft Failures for Kidney Transplant Centers

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.041	1	.041	1.091	.298
Within Groups	7.827	206	.038		
Total	7.868	207			

The second part of the test for quality is patient deaths (mortality). If CON meets its intention, centers in states with a solid organ transplant CON regulation would have fewer observed to expected patient deaths. To test this portion of the hypothesis, the explanatory variable of transplant CON regulation for the state where the centers resides was used and the observed to expected ratio for patient deaths was tested. Table 64 shows descriptive statistics for observed to expected ratio for patient deaths. As expected, states with a solid organ transplant CON regulation had a lower observed to expected ratio for patient deaths (1.0326 versus 1.1831). A difference in the mean observed to expected ratio for graft failures was identified. States with a solid organ transplant CON regulation had a

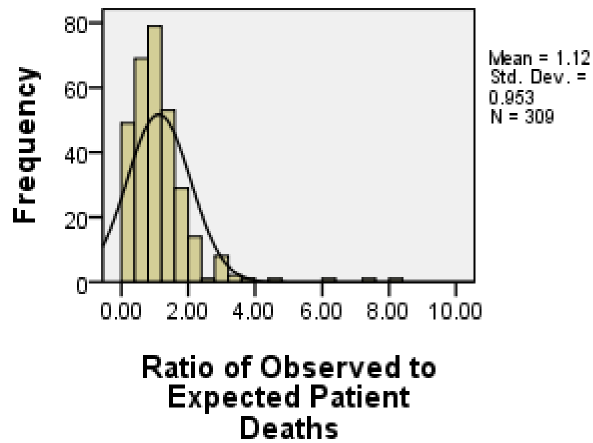
0.15 lower observed to expected ratio than states without a solid organ transplant CON regulation.

Table 64. Ratio of O/E Patient Deaths

	All Transplant Centers	Transplant Centers in States ***with*** Transplant CON Regulation	Transplant Centers in States ***without*** Transplant CON Regulation
Number	309	126	183
Mean	1.1217	1.0326	1.1831
Median	.9300	.9050	.9600
Standard Deviation	.95335	.68707	1.09753
Minimum	0.00	0.00	0.00
Maximum	8.35	3.91	8.35
Skewness	3.241	1.031	3.335
Std. Error of Skewness	.139	.216	.180
Kurtosis	18.409	2.309	16.590
Std. Error of Kurtosis	.276	.428	.357

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 64 indicate that the measure was not normally distributed. This is illustrated in Figure 33.

Figure 33. Histogram Ratio of O/E Patient Deaths



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 65. Figure 34 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of patient deaths in the states with and without a solid organ transplant CON regulation. Table 66 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p =.160) and the t (307) = -1.068, p = .287. This analysis found transplant centers in states with a solid organ transplant CON regulation did not have a lower observed to expected ratio for patient deaths than centers in states without a solid organ transplant CON regulation. Hypothesis #3 continues to not be supported since there is no statistically significant difference in the observed to expected ratio for patient deaths.

Table 65. Log Transformation Ratio of O/E Patient Deaths

	All Transplant Centers	Transplants Center in States with Transplant CON Regulation	Transplant Center in States without Transplant CON Regulation
Number	309	126	183
Mean	1.1038	1.0855	1.1164
Median	1.0750	1.0664	1.0852
Standard Deviation	.25056	.21803	.27056
Minimum	.69	.69	.69
Maximum	2.34	1.78	2.34
Skewness	1.035	.209	1.273
Std. Error of Skewness	.139	.216	.180
Kurtosis	3.262	.286	3.681
Std. Error of Kurtosis	.276	.428	.357

Figure 34. **Histogram Log Transformation Ratio of O/E Patient Deaths**

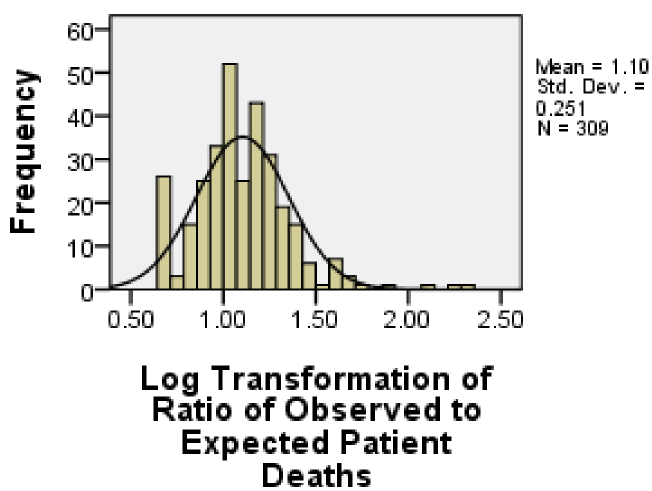


Table 66. *T*-Test Log Transformation Ratio of Observed to Expected Patient Deaths

		Ratio of Observed to Expected Patient Deaths	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	1.982 .160	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	-1.068 307 .287 -.03096 .02900 -.08802 .02611	-1.110 299.416 .268 -.03096 .02788 -.08582 .02391

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 67 shows the results of that test. This analysis demonstrates no significant difference [F (1, 307) = 1.140, p = .287] in the mean ratio of observed to expected patient deaths for transplant centers in the states with and without a solid transplant CON regulation.

Table 67. ANOVA Log Transformation of Ratio of O/E Patient Deaths

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.072	1	.072	1.140	.287
Within Groups	19.265	307	.063		
Total	19.337	308			

To continue testing this hypothesis, the explanatory variable of a solid organ transplant CON regulation for the state where the centers reside was used and the ratio for the observed to expected (O/E) patient deaths by transplanted organ were tested. Table 68 shows descriptive statistics for observed to expected ratio for patient deaths for heart transplants. As expected, heart transplant centers in states with a solid organ transplant CON regulation had a lower observed to expected ratio for patient deaths (.9695 versus 1.278). A difference in the mean observed to expected ratio for patient deaths was identified. Transplant centers in states with a solid organ transplant CON regulation had a .3086 lower observed to expected ratio for patient deaths than states without a solid organ transplant CON regulation.

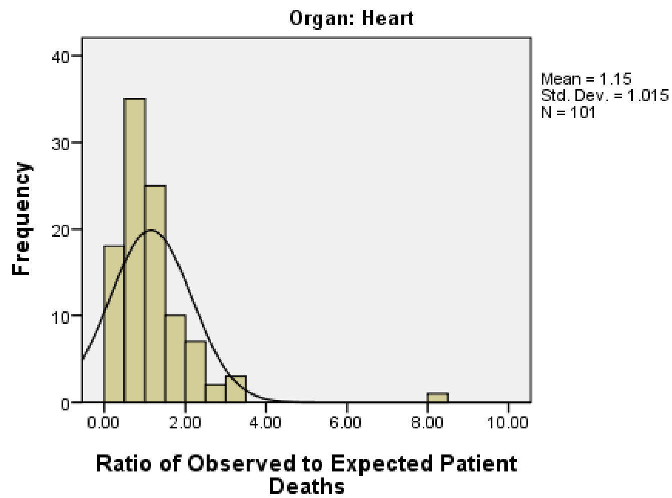
Table 68. Ratio of O/E Patient Deaths for Heart Transplant Centers

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Center in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean	1.1498	.9695	1.2781
Median	.9000	.8650	1.0900
Standard Deviation	1.0145	.6649	1.1924
Minimum	.00	.00	.00
Maximum	8.35	2.97	8.35
Skewness	3.868	.798	3.842
Std. Error of Skewness	.240	.365	.311
Kurtosis	24.781	.873	21.053
Std. Error of Kurtosis	.476	.717	.613

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness

and kurtosis statistics shown in Table 68 indicate that the measure was not normally distributed. This is illustrated in Figure 35.

Figure 35. **Histogram Ratio of O/E Patient Deaths for Heart Transplant Centers**



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 69. Figure 36 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of heart transplant centers in the states with and without a solid organ transplant CON regulation. Table 70 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is not equal variance in both groups (p = .239) and the t (99) = -1.517, p = .133. This analysis found heart transplant centers in states with a solid organ transplant CON regulation did not have a statistically significant lower observed to expected ratio for patient deaths than centers in states without a solid

organ transplant CON regulation. Hypothesis #3 is not supported since there is no difference in the observed to expected ratio for patient deaths.

Table 69. Log Transformation Ratio of O/E Patient Deaths for Heart Transplant Centers

	All Heart Transplant Centers	Heart Transplant Centers in States ***with*** Transplant CON Regulation	Heart Transplant Centers in States ***without*** Transplant CON Regulation
Number	101	42	59
Mean of Log	1.1115	1.0650	1.1445
Median of Log	1.0647	1.0526	1.1282
Standard Deviation of Log	.2533	.2179	.2727
Minimum of Log	.69	.69	.69
Maximum of Log	2.34	1.60	2.34
Skewness of Log	1.239	.175	1.538
Std. Error of Skewness of Log	.240	.365	.311
Kurtosis of Log	4.543	-.055	5.252
Std. Error of Kurtosis of Log	.476	.717	.613

Figure 36. Histogram Log Transformation Ratio of O/E Patient Deaths for Heart Transplant Centers

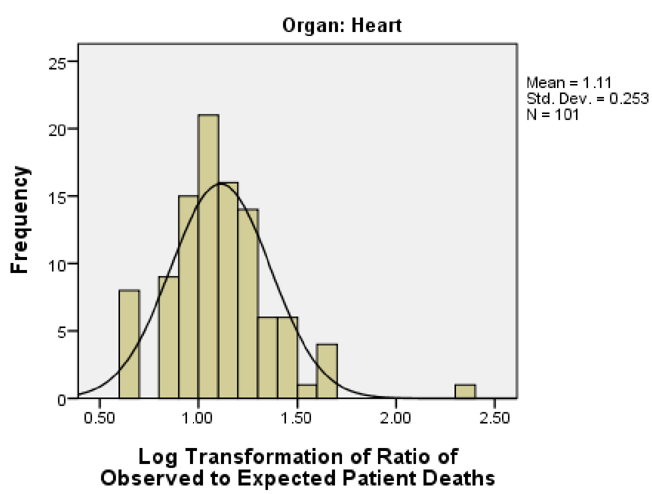


Table 70. *T*-Test Log Transformation Ratio of O/E Patient Deaths for Heart Transplant Centers

		Ratio Observed to Expected Patient Deaths	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	1.403 .239	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	-1.517 99 .133 -.3086 .2035 -.7124 .0952	-1.659 94.288 .101 -.3086 .1861 -.6780 .0608

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 71 shows the results of that test. This analysis demonstrates no significant difference [F (1, 99) = 2.457, p = .120] in the mean ratio of observed to expected patient deaths for heart transplant centers in the states with and without a solid transplant CON regulation.

Table 71. ANOVA Log Transformation Ratio of O/E Patient Deaths

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.155	1	.155	2.457	.120
Within Groups	6.262	99	.063		
Total	6.417	100			

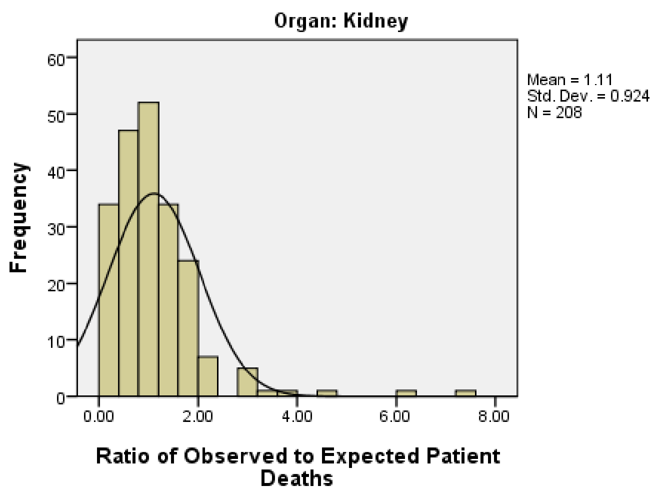
To continue testing this hypothesis, the explanatory variable of a solid organ transplant CON regulation for the state where the centers resides was used and the ratios for the observed to expected patient deaths was tested for kidney transplants. Table 72 shows descriptive statistics for observed to expected ratio for patient deaths. As expected, states with a solid organ transplant CON regulation had a lower observed to expected ratio for patient deaths (1.0642 versus 1.1379). A difference in the mean observed to expected ratio for patient deaths was identified. Kidney transplant centers in states with a solid organ transplant CON regulation had on the average a .0737 lower observed ratio than kidney transplant centers in states without a solid organ transplant CON regulation.

Table 72. Ratio of O/E Patient Deaths for Kidney Transplant Centers

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean	1.1081	1.0642	1.1379
Median	.9450	1.0550	.8950
Standard Deviation	.9244	.6996	1.0515
Minimum	.00	.00	.00
Maximum	7.32	3.91	7.32
Skewness	2.852	1.137	3.010
Std. Error of Skewness	.169	.263	.217
Kurtosis	14.312	2.949	13.619
Std. Error of Kurtosis	.336	.520	.431

In order to test for a difference between the means, a review was completed to assure the assumptions for normal distribution of the measure were held. The skewness and kurtosis statistics shown in Table 72 indicate that the measure was not normally distributed. This is illustrated in Figure 37.

Figure 37. Histogram Ratio of O/E Patient Deaths for Kidney Transplant Centers



Using a natural log +2, a new variable was created with the resulting descriptive statistics shown in Table 73. Figure 38 illustrates that the transformed variable was normally distributed. An independent *t*-test was then performed on the transformed data to determine if there was a statistically significant difference in the mean observed to expected ratio of patient deaths for kidney transplant centers in the states with and without a solid organ transplant CON regulation. Table 74 provides results from the independent *t*-test and Levine's Test for Equality of Variances. There is equal variance in both groups (p = .123) and the t (206) =-.564, p = .574. This analysis found kidney transplant centers in states with a solid organ transplant CON regulation did not have a lower observed to expected ratio for patient deaths than centers in states without a solid organ transplant CON regulation. Hypothesis #3 is not supported since there is no difference in the observed to expected ratio for patient deaths.

Table 73. Log Transformation Ratio of O/E Ratio Patient Deaths for Kidney Transplant Centers

	All Kidney Transplant Centers	Kidney Transplant Centers in States ***with*** Transplant CON Regulation	Kidney Transplant Centers in States ***without*** Transplant CON Regulation
Number	208	84	124
Mean of Log	1.1001	1.0957	1.1030
Median of Log	1.0801	1.1168	1.0630
Standard Deviation of Log	.2497	.2186	.2696
Minimum of Log	.69	.69	.69
Maximum of Log	2.23	1.78	2.23
Skewness of Log	.941	.229	1.174
Std. Error of Skewness of Log	.169	.263	.217
Kurtosis of Log	2.722	.521	3.129
Std. Error of Kurtosis of Log	.336	.520	.431

Figure 38. Histogram Log Transformation Ratio of O/E Patient Deaths for Kidney Transplant Centers

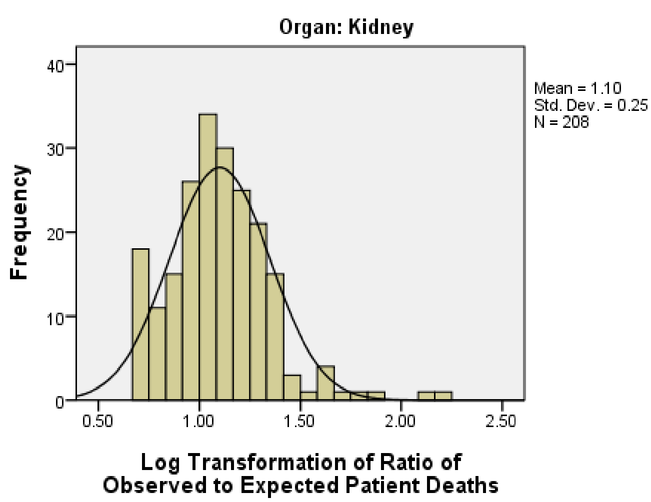


Table 74. *T*-Test Log Transformation Ratio of O/E Patient Deaths for Kidney Transplant Centers

		Ratio Observed to Expected Patient Deaths	
		Equal variances assumed	Equal variances not assumed
Levene's Test for Equality of Variances	*F* Sig.	2.393 .123	
t-test for Equality of Means	*t* df Sig. (2-tailed) Mean Difference Std. Error Difference 95% Confidence Interval of the Difference Lower Higher	-.564 206 .574 -.0737 .1308 -.3317 .1842	-.607 205.950 .544 -.0737 .1214 -.3131 .1657

As a further check, a one-way analysis of variance (ANOVA) was also used to determine whether there are any statistically significant differences between the means. Table 75 shows the results of that test. This analysis demonstrates no significant difference [F (1, 206) = .043, p = .836] in the mean ratio of observed to expected patient deaths for kidney transplant centers in the states with and without a solid transplant CON regulation.

Table 75. ANOVA Log Transformation Ratio of O/E Patient Deaths for Kidney Transplant Centers

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.003	1	.003	.043	.836
Within Groups	12.908	206	.063		
Total	12.911	207			

Graft and patient survival after transplant are used as measures of quality for this study. Both graft failures and patient deaths showed somewhat better outcomes per center in states with solid organ transplant CON regulations compared to those without solid organ transplant regulations but these outcomes were not found to be statistically significant at the 0.05 level. When heart and kidney outcomes were examined separately, the relationship between solid organ transplant CON states and quality of outcomes was stronger for heart transplants (p = .115 than it was for kidney transplants (p = .133). The direction of effects on quality was as expected on all tests, although the magnitude of effects did not reach statistical significance using a two-tailed test at the .05 level, suggesting that the magnitude of difference may be due to chance. .

Summary of Analysis

One of the oldest forms of governmental health regulations is represented by state certificate of need programs. One of the original purposes of CON regulations were to concentrate expensive healthcare services within a limited number of institutions by requiring prior approval before these services can be offered (DiSesa et al, 2008). These programs have been applied to services such as solid organ transplantation. Such CON laws affecting transplantation are in effect in 21 states. The purpose of this study was to assess the association of state CON regulations using clinical data available from the SRTR.

The first hypothesis supports one of the original intents of CON to restrict providers. The presence of a solid organ transplant CON regulation restricted the number of transplant centers in that state. This study shows, as expected, that in states with a solid organ transplant CON regulation in place there are fewer transplant centers than states without a solid organ transplant CON regulation. The difference was statistically significant at the .05 level. When studied separately, this pattern held for kidney transplant centers but not for heart transplant centers. There were fewer kidney transplant centers in states with a solid organ transplant CON regulation than for states without a solid organ transplant CON regulation. For heart transplant centers, there was no statistically significant difference in the number of centers in states with and without solid organ transplant CON regulations. A possible explanation for the lack of statistical significance for heart transplant centers is that the time to transplant of a harvested heart is significantly less (4 to 6 hours for hearts compared to 24 hours for kidneys. This difference may account for more heart transplant centers. (A summary of the statistical differences for each test conducted is shown in Appendix 3).

When a new variable was created and tested in order to account for differences in population size per state (Transplant Centers per 100,000 Residents), no significance is found between states with and without CON regulations for solid organ transplants. This pattern held for both heart and kidney centers when studies separately. There was no difference in the number of transplant centers per 100,000 residents between states with and without solid organ transplant CON regulations. This new variable was only a rough attempt to explain differences in need for solid organ transplants per state. It did not take

into account other factors that may impact the number of centers per state such as risk factors of the population (obesity, cigarette smoking, diabetes) and market characteristics (e.g., percent uninsured, per capita personal income, proximity to bordering state centers)..

The second hypothesis tests whether the presence of a solid organ transplant CON regulation is associated with higher procedural volumes for transplant centers. As previously stated, one of the original intents of CON laws were to reduce duplication of services which would lead to fewer facilities performing more procedures. This intent was not supported in the current study. The study found that the volume of transplants per center was not significantly higher in states with a solid organ transplant CON regulation. This remained the case when the specific organs were studied separately. Neither heart nor kidney transplants volumes per center were statistically significantly different in states with and without solid organ transplant CON regulations. This pattern held for the transplant volume per 100,000 residents for heart and kidney transplants combined and separated. Thus, the second hypothesis was rejected.

One possible explanation for this outcome is the lack of availability of organs for transplantation. In spite of improvements in graft and patient survival rates, the number of available organs for transplants continues to lag far behind the need. The lack of organ donation has been cited as a major limiting factor in transplantation (Cameron & Forsythe, 2009). Thus, tests of procedural volume per center may need to account for the availability of organs for transplant.

The third hypothesis looked at the quality of patient outcomes. Past studies have found a strong association between quality of outcomes and center volume. Thus, CON

laws intended to increase volume may also affect outcome quality. Although the transplant volume was not found to be statistically significant between states with and without solid organ transplant CON regulations, graft failures and patient deaths were both lower for states with a solid organ transplant CON regulation; however these differences did not reach statistical significance at the 0.05 level.. When studied separately, it appears that the heart transplant centers performed better than the kidney transplant centers for both graft failures and patient deaths. However, differences between outcomes in centers operating with CON regulations and those without was not statistically significant at the .05 level for either kidney or heart transplants. Thus, the third hypothesis was not supported.

CHAPTER VI
CONCLUSIONS AND POLICY IMPLICATIONS

The purpose of this study was to determine if the original intent of Certificate of Need (CON) regulations are still being met when applied to specific, complex surgical procedures like heart and kidney transplantation. The study question was:

> What is the association of solid organ transplant CON regulations on the number of transplant centers per state, the transplant volumes and the quality outcomes of the transplant centers?

CON regulations, as previously outlined, is a regulatory program, administered by states, that requires providers to obtain approval before establishing certain services, such as solid organ transplant services. Eventually CON regulation were seen as a means to control healthcare costs and improve quality of care in part by limiting the number of facilities providing complex medical care. One original intent of CON was "to control costs by regulating major capital expenditures and changes in healthcare services capacity." (Chayet & Sonnenreich, 1978). As presented in the literature review for this study, most evidence suggests that CON regulations do not substantially reduce or contain healthcare costs. For this reasons, an analysis of costs for heart and kidney transplant services was not part of this study. This analysis represents the first evaluation of the potential impact of CON regulation on transplant centers volume and outcomes.

The first hypothesis, states with CON regulations for solid organ transplant services will have fewer transplant centers than states without solid organ transplant CON regulations was found to be significant at the 0.5 level. Using clinically-rich data for heart

and kidney transplant procedures that took place between 2006 and 2008, this study found that the number of transplant centers per state were lower, as expected, for states with CON regulations. However, there was no significant difference in the volume of transplants performed per center in states with a solid organ transplant CON regulation and those without a solid organ transplant CON regulation. The second hypothesis was found to not be significant at the 0.5 level. The quality transplant outcomes (the third hypothesis) for centers in states with and without solid organ transplant CON regulations showed a weak tendency to better outcomes for states with CON regulations than those without CON regulations, particularly for heart transplants, but this was not a statistically significant difference..

The importance of the current findings is that while solid organ transplant regulations may restrict the number of transplant centers in a state it has no impact of the volume of transplants performed at these centers or the quality outcomes. This finding differs from previous findings in the published studies on volume and quality.

Luft et al (1970) reported that the number of procedures performed at a hospital and mortality rates for many surgical procedures were inversely related. Since then, this relation has been documented many times (Halm & Chassin, 2000). For example, in studies of the Medicare population, high-volume centers were associated with significantly lower odds of perioperative mortality, ranging from 12% for carotid endarterectomy to 80% for pancreatic resection (Birkmeyer et al, 2002). Several possible explanations may be offered for the no volume increase for transplant centers in this study. First, unlike the Medicare analysis, the current analysis used clinical data from the SRTR rather than

relying upon claims data or other administrative data sources. The ability to perform detailed risk adjustment using clinical data has been reported to reduce the measured effect of volume on outcome in other studies (Halm et al, 2002). Second, the subset of American hospitals where transplantation is performed is small and select. In general, these hospitals must demonstrate skilled anesthesia, radiology, and intensive care capabilities in order to establish a transplant program (Pronovost et al, 2002). Many of the process variables that contribute to volume differences across a more diverse group of hospitals performing less scrutinized and regulated surgical procedures may not vary to the same degree among transplant centers. Third, transplant centers are subject to a legislatively mandated review process, administered by a government contractor, which is designed to ensure high quality care. Center performance that is significantly worse than expected is flagged for audit, review, and remediation.

Organ transplantation outcomes reflect the influence of many factors: patient and donor selection, case mix, timeliness of donor availability, operative technique, and postoperative medical management and immunosuppression which any one could explain the reason differences in outcomes and the acceptance of the null hypotheses in this study.

The SRTR database used in this study provides clinical and outcome information that is not available in administrative databases and provides risk-adjusted outcomes data. This is a difference from analysis of data derived from administrative sources such as CMS MedPAR. The SRTR database has the advantages of years of peer-reviewed development, refinement, and validation of its risk models, as well as national scope of representation. Unlike other databases, the SRTR database is not voluntary. Any transplant center

performing transplants is required to submit data in order to participate in United Network of Organ Sharing (UNOS).

Limitations of Study

The results in this study should be interpreted in the context of the following limitations. The associations, or lack of associations, between CON regulations and transplant services in this study can suggest, but cannot prove a causal effect of CON on the delivery of transplant care. It is possible that factors not accounted for in this study may also be important in understanding the relationship between CON regulations and volume. These factors may include managed care penetration; regional physician practice variation; efforts to report outcomes data to hospitals, clinicians, third-party payers, and the public; ownership of facility as well as organization characteristics; and differences in population and physician density. The degree to which CON status is related to these factors has not been study or established for heart and kidney transplant programs.

A more specific analysis of population would add a level of analysis. This study used the population of the state as a rough attempt to explain differences in need for solid organ transplants per state. Organ supply and organ demand vary by geographic locations and organ procurement organizations (UNOS, 2010). Residents of a state are not bound to receive transplants only within their own state. In many cases, due to proximity, physician referral or patient preference, a patient may receive their transplant outside of the state they reside.

The epidemiologic planning model was not employed in this research to analyze the population at risk for heart disease or end-stage renal disease. This model is a process to "define, measure, and forecast the community served and its needs" (Griffith & White, 2007) and could have offered additional insight into the populations served by the transplant centers studies. If there is a higher concentration of disease that leads to the need of transplantation in a particular state or region, one would expect differences in the number of centers and the volume of transplants performed at those centers. The present study does not consider an evaluation of costs, an important component of the value equation (DiSesa et al, 2006). Although charge data is available for hospitals cost information is not readily available. The use of the SRTR data merged with a cost analysis, if it were available, would address the value question.

The differences in the administration of CON regulation state to state also suggest limitation to this study. There is likely heterogeneity in the character of CON regulations for transplant services across individual states, which may lead to differences in the scope and stringency of regulation (Vaughan-Sarrazin, 2002). Furthermore, states without CON regulations may have other types of healthcare regulatory mechanisms, such as licensure that impacts transplant services.

Future Research

While this study added to the knowledge related to the association of CON programs and transplantation, it also leaves more questions to be addressed in future research. For CON and transplant center outcomes, continued data analysis using the

SRTR database would provide interesting study. This study used only 3 years of data but expanding that to more years might provide additional insight as well as expanding the outcomes to 3-month and 3 year instead of just the 1year used in this study.

This study lacked information on the prevalence of diabetes, hypertension, cardiac disease, and end-stage renal disease, all of which may influence the need for heart and kidney transplantation. Future research should take these factors into consideration in analyzing the volume at transplant centers.

States with solid organ transplant CON programs may differ in their enforcement, and states without solid organ transplant CON programs may regulate transplant procedures through other means. The study of the differences in use of CON or other means of regulation could offer significant insight.

Implications of Study

Despite these limitations, the current study has several important implications for healthcare research and policy. Currently, efforts are under way to concentrate surgical procedures with significant volume-outcome effects to large-volume centers (Birkmeyer et al., 2003). The adoption of such a policy for heart and kidney transplantation would not be straightforward even if it were desirable, particularly in the case of deceased donor transplantation. As with HLA matching, the benefit of high-volume center performance must be carefully weighed against the increased risk of graft loss associated with the increased cold ischemia time which would likely accompany increased regionalization of transplant services (Mitropoulos et al., 2005). Furthermore, the frequent follow-up visits

necessary after transplantation might prove to be an added hardship if patients were forced to travel great distances. Because patients may be more compliant with follow-up visits if appointments are convenient, compliance may also be an important determinant of outcome.

As previously noted, the volume-outcome relationship appears to be particularly important for highly complex procedures that require a significant commitment of resources and highly specialized teams (Lin et al. 1998). Organ transplantation is a clear example of this type of procedure. One caution in using volumes as "indicators" of quality is that studies of the association between volumes and outcomes examine patterns across many hospitals, but the inference may not be true for individual hospitals or providers. There can be a number of reasons, other than poor quality, to explain why specific hospitals or providers may have low volumes, such as the start-up of new services, rural location, or a procedure performed by a high-volume surgeon in several low-volume hospitals. Furthermore, hospitals may have high volumes and quality for some procedures but low volumes and quality for others, or volumes and quality may fluctuate over time. Therefore, low volumes cannot be used as an overall "indicator" of poor quality, volume standards will vary by procedure and disease, and it would be useful to have multiple measures and longitudinal data. However, in the past one could reasonably say that in the absence of other quality measures, one would probably have a higher likelihood of better outcomes with a high volume provider than a low-volume provider (Hannan et al., 1999).

One of the controversial issues about volumes is whether an observed association between higher volumes and better outcomes is a result of more experience leading to

better outcomes, the "Practice-Makes-Perfect" hypothesis, or whether patients are attracted to hospitals with better outcomes, thereby increasing their volumes, the "Selective-Referral" hypothesis (Luft et al., 1990). That is, if increased volume is sufficient to achieve better outcomes, then increases in volumes at selected sites will improve outcomes (ignoring other problems such as access to care). However, if the observed volume-outcome relationship reflects selective referrals to better quality providers, regulatory and other "steering" strategies would need at least as effective indicators of quality and means to choose the best providers. There is some evidence that both hypotheses may be true to varying degrees for different procedures (Khuri, Daley & Henderson, 1999).

Higher levels of nurse staffing have also been associated with improved quality of care in hospitals (Needleman, 2002). Teaching status and its relationship to quality of care and outcomes have been examined across illnesses and procedures (Allison et al., 2000). Many of these studies suggest that teaching hospitals have more favorable clinical outcomes. Levels of expertise and staffing may be an underlying explanation for the observed volume-outcome link; this could be modified to improve outcomes in low-volume hospitals. Although procedure volume may be a convenient proxy for quality of care, questions have been raised about the ramifications of policy making based on volume. Although there appears to be a statistical link between volume and quality of care, the nature of this link is still poorly understood. For example, recent studies have compared morbidity and mortality at low- and high-volume centers for esophagectomy, pancreatic resection, and carotid endarterectomy and suggest that volume alone is not a sufficient signal of quality (Padmanabhan et al., 2002). These studies point to at least two

additional factors that influence outcomes: surgeons' skill and experience, and the presence of an organizational structure for assuring high quality of care, such as treatment protocols. It is possible that for the most complex procedures, whether frequent or infrequent, the hospitals providing them must maintain a certain level of staffing and technology. In addition, a few specialized surgeons might perform these procedures at more than one hospital, so an individual hospital's volume, whether high or low, is a poor proxy for outcomes. Individual surgeon volume, staffing, or measures of the presence of key technologies or practices, such as protocols, may be better measures. Such factors should be further examined so in order to understand how best to improve quality and to provide the basis for quality improvement initiatives. The link between volume and outcome for high-technology, complex procedures is likely to be indirect and complex, reflecting at least the organization of healthcare services and the skill and experience of staff.

Policy Implications

When CON regulations were introduced, healthcare providers were reimbursed based on the cost of the services they provided, no matter how high that cost. Their charges incorporated overhead expenses and the other costs of doing business, as well as the necessary profit margin. "Under that scheme overbuilding was costly to everybody because the expenses of inefficiency were built into the reimbursements. The regulatory mechanism of CON regulations was developed to control costs by limiting the expansion of services in a geographic area" (Conover & Sloan, 1998). Now, some thirty years later, the competitive forces of managed care have altered healthcare. Provider payments are

determined by capitation, fixed fees for services, and fee schedules that are the product of negotiation and have little or no bearing on the underlying costs. Today's providers compete on price and quality of care-not costs-and are neither rewarded for nor bailed out when they overspend on facilities or technology (Porter & Teisberg, 2004). Thus, CON regulations may no longer be an appropriate tool to regulate healthcare costs. The free market – as with virtually every other business endeavor - should be allowed to determine need and encourage healthy competition based on price and quality of care (Porter & Teisberg, 2004).

Although CON may be effective in limiting the expansion of some services (transplant centers in this study), the role of CON programs on a national level should be debated in the context of research evidence of the association of CON on the quality outcomes. Thus, the findings in this study are important, despite the limitations, for the ongoing debate regarding the lack of benefits of CON programs. This study found no significant difference in transplant center volume or outcomes in states with and without solid organ transplant CON regulations. This conclusion would lead one to ask: what is the purpose of the continued presence of CON regulations for transplant services? In a time when patient safety, medical errors, and patient outcomes as well as access and cost are coming under greater scrutiny, CON regulations may not be an important and effective regulatory mechanism for ensuring higher quality care and better patient outcomes.

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Appendix 1: CON Regulations by State

State/District	Current State CON?	Current Organ Transplant CON?	Dates of Regulations
Alabama	Yes	Yes	1979-present
Alaska	Yes	Yes	1976-present
Arizona	No		1971-1985
Arkansas	Yes	No	1975-present
California	No		1969-1987
Colorado	No		1973-1987
Connecticut	Yes	Yes	1973-present
Delaware	Yes	No	1978-present
District of Columbia	Yes	Yes	1977-present
Florida	Yes	Yes	1973-present
Georgia	Yes	No	1979-present
Hawaii	Yes	Yes	1974-present
Idaho	No		1980-1983
Illinois	Yes	Yes	1974-present
Indiana	No		1980-1996, 1997-1999

State/District	Current State CON?	Current Organ Transplant CON?	Dates of Regulations
Iowa	Yes	Yes	1977-present
Kansas	No		1972-1985
Kentucky	Yes	Yes	1972-present
Louisiana	Yes	No	1991-present
Maine	Yes	Yes	1978-present
Maryland	Yes	Yes	1968-present
Massachusetts	Yes	Yes	1972-present
Michigan	Yes	Yes	1972-present
Minnesota	No		1971-1985
Mississippi	Yes	No	1979-present
Missouri	Yes	No	1979-present
Montana	Yes	No	1975-present
Nebraska	Yes	No	1979-present
Nevada	Yes	No	1971-present
New Hampshire	Yes	No	1979-present
New Jersey	Yes	Yes	1971-present

State/District	Current State CON?	Current Organ Transplant CON?	Dates of Regulations
New Mexico	No		1978-1983
New York	Yes	Yes	1966-present
North Carolina	Yes	Yes	1978-present
North Dakota	No		1971-1995
Ohio	Yes	No	1975-present
Oklahoma	Yes	No	1971-present
Oregon	Yes	No	1971-present
Pennsylvania	No		1979-1996
Rhode Island	Yes	Yes	1968-present
South Carolina	Yes	No	1971-present
South Dakota	No		1972-1988
Tennessee	Yes	No	1973-present
Texas	No		1975-1985
Utah	No		1979-1984
Vermont	Yes	Yes	1979-present
Virginia	Yes	Yes	1973-present

State/District	Current State CON?	Current Organ Transplant CON?	Dates of Regulations
Washington	Yes	Yes	1971-present
West Virginia	Yes	Yes	1977-present
Wisconsin	Yes	No	1977-1987, 1993-present
Wyoming	No		1977-1989

Appendix 2: CON Services by State 2010	Alabama	Alaska	Arizona	Arkansas	California
	AL	AK	AZ	AR	CA
Air Ambulance	1				
Ambulatory Surgical Centers (ASC)	1	1			
Burn Care	1				
Cardiac Cath	1	1			
Business Computers					
Computed Tomography (CT) Scanners		1			
Gamma Knives	1	1			
Home Health	1			1	
Hospice	1			1	
Hospitals/Beds	1	1			
ICF/MR				1	
Lithotripsy		1			
Long Term Acute Care (LTAC)	1	1			
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners		1			
Mobile Hi Technology (CT/MRI/PET, etc)		1			
Nursing Home/Beds	1	1		1	
Neonatal Intensive Care (NICU)	1	1			
Obstetrical	1	1			
Open Heart Surgery	1	1			
Solid Organ Transplant	1	1			
Positron Emission Tomography (PET Scanners)		1			
Psychiatric Beds	1	1		1	
Radiation Therapy/LinearAccelerator	1	1			
Rehabilitation	1				
Renal Dialysis	1	1			
Residential Care/Assisted Living				1	
Subacute Care		1			
Substance Abuse	1				
Swing Beds	1				
Ultra Sound					
Other	1	1		1	
Total	**21 Yes**	**20 Yes**	**No CON**	**7 Yes**	**No CON**

Appendix 2: CON Services by State 2010	Colorado	Connecticut	Delaware	District of Columbia	Florida
	Colorado	CT	DE	DC	FL
Air Ambulance		1		1	
Ambulatory Surgical Centers (ASC)		1	1	1	
Burn Care		1		1	
Cardiac Cath		1	1	1	
Business Computers					
Computed Tomography (CT) Scanners		1		1	
Gamma Knives		1		1	
Home Health				1	
Hospice		1		1	1
Hospitals/Beds		1	1	1	1
ICF/MR					1
Lithotripsy		1	1	1	
Long Term Acute Care (LTAC)		1	1	1	1
Medical Office Buildings				1	
Magnetic Resonance Imagining (MRI) Scanners		1		1	
Mobile Hi Technology (CT/MRI/PET, etc)		1		1	
Nursing Home/Beds		1	1	1	1
Neonatal Intensive Care (NICU)		1		1	1
Obstetrical		1		1	
Open Heart Surgery		1		1	
Solid Organ Transplant		1		1	1
Positron Emission Tomography (PET Scanners)		1	1	1	
Psychiatric Beds		1		1	1
Radiation Therapy/LinearAccelerator		1	1	1	
Rehabilitation				1	1
Renal Dialysis				1	
Residential Care/Assisted Living					
Subacute Care				1	1
Substance Abuse		1		1	1
Swing Beds				1	
Ultra Sound				1	
Other			1		
Total	**No CON**	**21 Yes**	**9 Yes**	**28 Yes**	**11 Yes**

Appendix 2: CON Services by State 2010	Georgia	Hawaii	Idaho	Illinois	Indiana
	GA	HI	ID	IL	IN
Air Ambulance					
Ambulatory Surgical Centers (ASC)	1	1		1	
Burn Care		1			
Cardiac Cath	1	1		1	
Business Computers					
Computed Tomography (CT) Scanners		1			
Gamma Knives	1	1			
Home Health	1	1			
Hospice		1			
Hospitals/Beds	1	1		1	
ICF/MR	1	1		1	
Lithotripsy	1	1			
Long Term Acute Care (LTAC)	1	1		1	
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners		1			
Mobile Hi Technology (CT/MRI/PET, etc)		1			
Nursing Home/Beds	1	1		1	
Neonatal Intensive Care (NICU)	1	1		1	
Obstetrical	1	1		1	
Open Heart Surgery	1	1		1	
Solid Organ Transplant		1		1	
Positron Emission Tomography (PET Scanners)	1	1			
Psychiatric Beds	1	1		1	
Radiation Therapy/Linear Accelerator	1	1			
Rehabilitation	1	1		1	
Renal Dialysis		1		1	
Residential Care/Assisted Living					
Subacute Care		1		1	
Substance Abuse	1	1			
Swing Beds		1		1	
Ultra Sound		1			
Other	1			1	
Total	**18 Yes**	**27 Yes**	**No CON**	**16 Yes**	**No CON**

Appendix 2: CON Services by State 2010	Iowa	Kansas	Kentucky	Louisiana	Maine
	IA	KS	KY	LA	ME
Air Ambulance					1
Ambulatory Surgical Centers (ASC)	1		1		1
Burn Care					1
Cardiac Cath	1		1		1
Business Computers					
Computed Tomography (CT) Scanners					1
Gamma Knives					1
Home Health			1		
Hospice			1		
Hospitals/Beds	1		1		1
ICF/MR	1		1	1	
Lithotripsy					1
Long Term Acute Care (LTAC)	1		1		1
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners			1		1
Mobile Hi Technology (CT/MRI/PET, etc)			1		1
Nursing Home/Beds	1		1	1	1
Neonatal Intensive Care (NICU)			1		1
Obstetrical					1
Open Heart Surgery	1		1		1
Solid Organ Transplant	1		1		1
Positron Emission Tomography (PET Scanners)			1		1
Psychiatric Beds			1		1
Radiation Therapy/Linear Accelerator	1		1		1
Rehabilitation			1		1
Renal Dialysis					1
Residential Care/Assisted Living				1	
Subacute Care					
Substance Abuse			1		1
Swing Beds					1
Ultra Sound					1
Other			1		
Total	**9 Yes**	**No CON**	**19 Yes**	**3 Yes**	**24 Yes**

Appendix 2: CON Services by State 2010	Maryland	Massachusetts	Michigan	Minnesota	Mississippi
	MD	MA	MI	MN	MS
Air Ambulance		1	1		
Ambulatory Surgical Centers (ASC)	1	1	1		1
Burn Care	1				
Cardiac Cath	1		1		1
Business Computers					
Computed Tomography (CT) Scanners			1		
Gamma Knives		1	1		1
Home Health	1				1
Hospice	1				1
Hospitals/Beds	1		1		1
ICF/MR	1				1
Lithotripsy		1	1		
Long Term Acute Care (LTAC)	1		1		1
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners		1	1		1
Mobile Hi Technology (CT/MRI/PET, etc)			1		
Nursing Home/Beds	1	1	1		1
Neonatal Intensive Care (NICU)	1	1	1		
Obstetrical	1				
Open Heart Surgery	1	1	1		1
Solid Organ Transplant	1	1	1		
Positron Emission Tomography (PET Scanners)		1	1		1
Psychiatric Beds	1	1	1		1
Radiation Therapy/Linear Accelerator		1	1		1
Rehabilitation	1	1			1
Renal Dialysis					1
Residential Care/Assisted Living					
Subacute Care					
Substance Abuse	1	1			1
Swing Beds			1		1
Ultra Sound					
Other	1	1	1		
Total	**17 Yes**	**15 Yes**	**19 Yes**	**No CON**	**18 Yes**

Appendix 2: CON Services by State 2010	Missouri	Montana	Nebraska	Nevada	New Hampshire
	MO	MT	NE	NV	NH
Air Ambulance					
Ambulatory Surgical Centers (ASC)		1		1	1
Burn Care					
Cardiac Cath	1				1
Business Computers					
Computed Tomography (CT) Scanners	1				
Gamma Knives	1				
Home Health		1			
Hospice					
Hospitals/Beds	1			1	1
ICF/MR	1	1		1	
Lithotripsy	1				
Long Term Acute Care (LTAC)	1				1
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners	1				1
Mobile Hi Technology (CT/MRI/PET, etc)	1				1
Nursing Home/Beds	1	1	1	1	1
Neonatal Intensive Care (NICU)					
Obstetrical					
Open Heart Surgery					1
Solid Organ Transplant					
Positron Emission Tomography (PET Scanners)	1				1
Psychiatric Beds					1
Radiation Therapy/Linear Accelerator	1				1
Rehabilitation	1	1	1		1
Renal Dialysis					
Residential Care/Assisted Living	1				
Subacute Care		1			
Substance Abuse		Y			1
Swing Beds		1			
Ultra Sound					
Other	1				
Total	**15 Yes**	**7 Yes**	**2 Yes**	**4 Yes**	**13 Yes**

Appendix 2: CON Services by State 2010	New Jersey	New Mexico	New York	North Carolina	North Dakota
	NJ	NM	NY	NC	ND
Air Ambulance					
Ambulatory Surgical Centers (ASC)			1	1	
Burn Care	1		1	1	
Cardiac Cath	1		1	1	
Business Computers					
Computed Tomography (CT) Scanners			1	1	
Gamma Knives				1	
Home Health	1		1	1	
Hospice			1	1	
Hospitals/Beds	1		1	1	
ICF/MR	1			1	
Lithotripsy			1	1	
Long Term Acute Care (LTAC)	1			1	
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners			1	1	
Mobile Hi Technology (CT/MRI/PET, etc)			1	1	
Nursing Home/Beds	1		1	1	
Neonatal Intensive Care (NICU)	1		1	1	
Obstetrical			1		
Open Heart Surgery	1		1	1	
Solid Organ Transplant	1		1	1	
Positron Emission Tomography (PET Scanners)				1	
Psychiatric Beds	1			1	
Radiation Therapy/Linear Accelerator			1	1	
Rehabilitation	1		1	1	
Renal Dialysis			1	1	
Residential Care/Assisted Living				1	
Subacute Care				1	
Substance Abuse				1	
Swing Beds					
Ultra Sound					
Other				1	
Total	**12 Yes**	**No CON**	**18 Yes**	**26 Yes**	**No CON**

Appendix 2: CON Services by State 2010	Ohio	Oklahoma	Oregon	Pennsylvania	Rhode Island
	OH	OK	OR	PA	RI
Air Ambulance					
Ambulatory Surgical Centers (ASC)					1
Burn Care					
Cardiac Cath					1
Business Computers					
Computed Tomography (CT) Scanners					1
Gamma Knives					1
Home Health					
Hospice			1		1
Hospitals/Beds					1
ICF/MR		1			
Lithotripsy					
Long Term Acute Care (LTAC)			1		1
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners					1
Mobile Hi Technology (CT/MRI/PET, etc)					1
Nursing Home/Beds	1	1	1		1
Neonatal Intensive Care (NICU)					1
Obstetrical					1
Open Heart Surgery					1
Solid Organ Transplant					1
Positron Emission Tomography (PET Scanners)					1
Psychiatric Beds		1			1
Radiation Therapy/Linear Accelerator					1
Rehabilitation					1
Renal Dialysis					
Residential Care/Assisted Living					
Subacute Care		1			1
Substance Abuse					1
Swing Beds			1		
Ultra Sound					
Other		1			
Total	**1 Yes**	**5 Yes**	**4 Yes**	**No CON**	**20 Yes**

Appendix 2: CON Services by State 2010	South Carolina	South Dakota	Tennessee	Texas	Utah
	SC	SD	TN	TX	UT
Air Ambulance					
Ambulatory Surgical Centers (ASC)	1		1		
Burn Care			1		
Cardiac Cath	1		1		
Business Computers					
Computed Tomography (CT) Scanners					
Gamma Knives	1				
Home Health	1		1		
Hospice	1		1		
Hospitals/Beds	1		1		
ICF/MR	1		1		
Lithotripsy	1		1		
Long Term Acute Care (LTAC)	1		1		
Medical Office Buildings					
Magnetic Resonance Imagining (MRI) Scanners	1		1		
Mobile Hi Technology (CT/MRI/PET, etc)	1				
Nursing Home/Beds	1		1		
Neonatal Intensive Care (NICU)	1		1		
Obstetrical					
Open Heart Surgery	1		1		
Solid Organ Transplant					
Positron Emission Tomography (PET Scanners)	1		1		
Psychiatric Beds	1		1		
Radiation Therapy/Linear Accelerator	1		1		
Rehabilitation	1		1		
Renal Dialysis					
Residential Care/Assisted Living					
Subacute Care	1		1		
Substance Abuse	1		1		
Swing Beds			1		
Ultra Sound					
Other	1		1		
Total	**21 Yes**	**No CON**	**21 Yes**	**No CON**	**No CON**

Appendix 2: CON Services by State 2010	**Vermont**	**Virginia**	**Washington**	**West Virginia**	**Wisconsin**	**Wyoming**
	VT	**VA**	**WA**	**WV**	**WI**	**WY**
Air Ambulance	1					
Ambulatory Surgical Centers (ASC)	1	1	1	1		
Burn Care	1		1			
Cardiac Cath	1	1	1	1		
Business Computers	1					
Computed Tomography (CT) Scanners	1	1		1		
Gamma Knives	1	1				
Home Health	1		1	1		
Hospice	1		1	1		
Hospitals/Beds	1	1	1	1		
ICF/MR	1	1		1	1	
Lithotripsy	1	1				
Long Term Acute Care (LTAC)	1	1	1	1		
Medical Office Buildings	1					
Magnetic Resonance Imagining (MRI) Scanners	1	1		1		
Mobile Hi Technology (CT/MRI/PET, etc)	1	1		1		
Nursing Home/Beds	1	1	1	1	1	
Neonatal Intensive Care (NICU)	1	1	1	1		
Obstetrical	1	1	1	1		
Open Heart Surgery	1	1	1	1		
Solid Organ Transplant	1	1	1	1		
Positron Emission Tomography (PET Scanners)	1	1		1		
Psychiatric Beds	1	1	1	1		
Radiation Therapy/Linear Accelerator	1	1		1		
Rehabilitation	1	1	1	1		
Renal Dialysis	1		1	1		
Residential Care/Assisted Living	1					
Subacute Care	1		1		1	
Substance Abuse	1			1		
Swing Beds	1		1			
Ultra Sound	1					
Other		1	1	1		
Total	**31 Yes**	**20 Yes**	**18 Yes**	**22 Yes**	**3 Yes**	**No CON**

Appendix 2: CON Services by State 2010	**Number of States with CON for Service**
Air Ambulance	**7**
Ambulatory Surgical Centers (ASC)	**27**
Burn Care	**12**
Cardiac Cath	**26**
Business Computers	**1**
Computed Tomography (CT) Scanners	**13**
Gamma Knives	**16**
Home Health	**17**
Hospice	**18**
Hospitals/Beds	**28**
ICF/MR	**22**
Lithotripsy	**16**
Long Term Acute Care (LTAC)	**27**
Medical Office Buildings	**2**
Magnetic Resonance Imagining (MRI) Scanners	**19**
Mobile Hi Technology (CT/MRI/PET, etc)	**16**
Nursing Home/Beds	**37**
Neonatal Intensive Care (NICU)	**23**
Obstetrical	**15**
Open Heart Surgery	**25**
Solid Organ Transplant	**21**
Positron Emission Tomography (PET Scanners)	**20**
Psychiatric Beds	**26**
Radiation Therapy/Linear Accelerator	**23**
Rehabilitation	**25**
Renal Dialysis	**12**
Residential Care/Assisted Living	**5**
Subacute Care	**14**
Substance Abuse	**18**
Swing Beds	**12**
Ultra Sound	**4**
Other	**18**

Appendix 3.

Hypothesis #1 Summary

Transplant Centers per State					
Independent Sample T-Test	Mean Diff = 4.94 NonCON > CON	df = 307	*t* = -2.397	Sig = .017	Significant
ANOVA		df = 1	F = 5.108	Sig = .025	Significant
Transplant Centers per 100,000 Residents					
Independent Sample T-Test	Mean Diff = 0.01317 CON > NonCON	df = 307	*t* = -.847	Sig = .398	Not Significant
ANOVA		df = 1	F = .717	Sig = .398	Not Significant
Heart Transplant Centers per State					
Independent Sample T-Test	Mean Diff = 4.62 NonCON > CON	df = 99	*t* = -1.206	Sig = .231	Not Significant
ANOVA		df = 1	F = 1.245	Sig = .267	Not Significant
Kidney Transplant Center per State					
Independent Sample T-Test	Mean Diff = 5.11 NonCON > CON	df = 206	*t* = -2.071	Sig = .040	Significant
ANOVA		df = 1	F = 3.870	Sig = .051	Significant
Heart Transplant Centers per 100,000 Residents					
Independent Sample T-Test	Mean Diff = 0.0059 CON > NonCON	df = 99	*t* = -.510	Sig = .611	Not Significant
ANOVA		df = 1	F = .260	Sig = .611	Not Significant
Kidney Transplant Center per 100,000 Residents					
Independent Sample T-Test	Mean Diff = 0.0169 CON > NonCON	df=206	*t* =-.665	Sig=.507	Not Significant
ANOVA		df=1	F=.443	Sig=.507	Not Significant

Hypothesis #2 Summary

Transplant Volume per Center					
Independent Sample T-Test	Mean Diff = 15.4 CON > NonCON	df = 307	*t* = .565	Sig = .572	Not Significant
ANOVA		df = 1	F = .319	Sig = .572	Not Significant
Transplant Volume per 100,000 Residents					
Independent Sample T-Test	Mean Diff = 2.0764 CON > NonCON	df = 307	*t* = 1.187	Sig = .236	Not Significant
ANOVA		df = 1	F = 1.408	Sig = .236	Not Significant
Heart Transplant Volume per Center					
Independent Sample T-Test	Mean Diff = CON > NonCON	df = 99	*t* = -.022	Sig = .983	Not significant
ANOVA		df = 1	F = .000	Sig = .983	Not Significant
Kidney Transplant Volume per Center					
Independent Sample T-Test	Mean Diff = CON > NonCON	df = 206	*t* = 1.024	Sig = .307	Not Significant
ANOVA		df = 1	F = 1.048	Sig = .307	Not Significant
Heart Transplant Volume per 100,000 Residents					
Independent Sample T-Test	Mean Diff = CON > NonCON	df = 99	*t* = -.071	Sig = .944	Not Significant
ANOVA		df = 1	F = .005	Sig = .944	Not Significant
Kidney Transplant Volume per 100,000 Residents					
Independent Sample T-Test	Mean Diff = CON > NonCON	df = 206	*t* = 1.407	Sig = .161	Not Significant
ANOVA		df = 1	F = 1.980	Sig = .161	Not Significant

Hypothesis #3 Summary

Ratio of Observed to Expected Graft Failures (1 year)					
Independent Sample T-Test		df = 307	*t* = -1.841	Sig = .067	Not Significant
ANOVA		df = 1	*F* = 3.390	Sig = .067	Not Significant
Ratio of Observed to Expected Graft Failures – Heart (1 year)					
Independent Sample T-Test		df = 99	*t* = -1.590	Sig = .115	Not Significant
ANOVA		df = 1	*F* = 2.528	Sig = .115	Not Significant
Ratio of Observed to Expected Graft Failures – Kidney (1 year)					
Independent Sample T-Test		df = 206	*t* = -1.044	Sig = .298	Not Significant
ANOVA		df = 1	F = 1.091	Sig = .298	Not Significant

Ratio of Observed to Expected Patient Deaths (1 year)					
Independent Sample T-Test		df = 307	*t* = -1.068	Sig = .287	Not Significant
ANOVA		df = 1	F = 1.140	Sig = .287	Not Significant
Ratio of Observed to Expected Patient Deaths – Heart (1 year)					
Independent Sample T-Test		df = 99	*t* = -1.517	Sig = .133	Not Significant
ANOVA		df = 99	F = 2.457	Sig = .120	Not Significant
Ratio of Observed to Expected Patient Deaths – Kidney (1 year)					
Independent Sample T-Test		Df = 206	*t* = -.564	Sig = .574	Not Significant
ANOVA		Df = 206	F = .043	Sig = .836	Not Significant

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