A MEDICARE BENEFIT EXPANSION: INPATIENT CLINICAL AND ECONOMIC OUTCOMES IN DEEP BRAIN STIMULATION FOR PARKINSON'S DISEASE

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by
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A MEDICARE BENEFIT EXPANSION: INPATIENT CLINICAL AND ECONOMIC OUTCOMES IN DEEP BRAIN STIMULATION FOR PARKINSON'S DISEASE

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ABSTRACT

Background: The Centers for Medicare and Medicaid Services, (CMS) implements National Coverage Decisions (NCD) to expand access or eliminate regional reimbursement differences. Policymakers may estimate clinical and economic consequences through short term pilots or demonstration projects.

Objective: Examined whether short term outcomes mirror longer term outcomes for a CMS NCD for Deep Brain Stimulation (DBS) in Parkinson's Disease (PD).

Methods: This observational study examined the inpatient clinical and economic outcomes associated with a CMS NCD for DBS in PD using Health Care Utilization Project (HCUP) retrospective data from 1999 through 2007. The Healthcare Utilization Project (HCUP) data, is supported by CMS. HCUP is the largest collection of all-payer, uniform, state-based inpatient surgery administrative data and covers the years of interest. Short-term cross-sectional analysis examined 12 months pre NCD (January 1, 1999 to March 31, 2003); and 12 months post NCD (April 1, 2003 to March 30, 2004). Long–term, cross-sectional analysis examined the three years, three months prior to the the short term pre period (January 1, 1999 to March 31, 2002); and the three years, nine months after the short term post period (April 1 2004 to December 31, 2007).

Results: A patient who had DBS surgery in the 12 months post NCD is more likely to be discharged to long or short term care rather than home (OR 3.671, p=0.0249); is associated with longer lengths of stay (0.2888, p=0.0001); and is positively associated with the log of total charges (0.19985, p=0.0240). A patient who has DBS surgery more than 12 months post NCD compared surgery more than 12 months pre NCD, was less likely to have complications (OR 0.376, 0.0004) , was associated with a shorter length of stay (-0.2857, p=0.0093), and is positively associated with the log of total charges (0.33875, p<0.001).

Conclusions: These results suggest that after the benefit expansion, outcomes worsened in the short term, and improved in the long term. Policymakers may benefit from a longer term view when forecasting before--or interpreting outcomes after--a benefit design change. Differences in populations served may cause temporary or long term shifts in health outcomes and resource utilization.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Graduate Studies, have examined a dissertation titled, "A Medicare Benefit Expansion: Inpatient Clinical and Economic Outcomes in Deep Brain Stimulation for Parkinson's Disease," presented by Jane Castelli Haley, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION AND PROBLEM STATEMENT

Introduction

Medicare was enacted in 1965 through an amendment to the Social Security Act (SSA). This amendment established the Medicare program; defined individuals eligible for services and defined broad categories of health care services to be funded. The amendment also outlined the process by which subcategories of clinical services would be evaluated for funding. This progress is known as the National Coverage Determination (NCD).

While the NCD process has evolved since its inception, the guiding principles of the original process remain intact. First, a request for a new NCD can be make by any individual or other party. Second, all coverage decisions will be made only after through deliberation of the all scientific, clinical and economic evidence supporting the requested technology. In instances where the body of evidence is not sufficient, Medicare may fund pilot programs to gather additional evidence to inform the coverage determination. After review of the evidence, Medicare will make the decision either to cover the technology or not. Such coverage decisions, however, are not easy given the mandate of Medicare to ensure adequate deliberation while balancing conflicting goals so inherent in health care decision making: cost, access, quality, service delivery models, financing and payment (CMS Application Guidelines, 2009).

When funding is available, implementation of the NCD requires the agency to define the targeted patient population through specific inclusion/exclusion criteria and standardize insurance coding to facilitate reimbursement. Ensuring transparency in the process is a top priority for Medicare and public comment is welcome at multiple steps in the process. After implementation, Medicare may monitor and report the outcomes of national coverage decisions specific to changes in access, cost and quality. At other times, however, such data are not available.

Problem Statement

The purpose of the current evaluation is to address one gap in the literature specific to the impact of a NCD change that occurred in 2003—Medicare's decision to fund deep brain stimulation (DBS) in patients with advanced Parkinson's disease. The evaluation reported below focused on short and long term changes in access, cost and quality for patients undergoing deep brain stimulation. The short term analysis compares 12 months prior to the NDC vis-à-vis 12 months after the decision. The longer term compared the three years, three months prior the short term to the three years, nine months after the short term. Both the short and long term analysis will investigate if the NCD was a key determinant of (1) the number of patients receiving DBS; (2) patient characteristics before and after NCD; (3) changes in provision of DBS by both hospital and physicians; and (4) changes in patient outcomes. The outcomes reported below provide data to support future decision making by multiple stakeholders in both the public and private arena.

CHAPTER 2

LITERATURE REVIEW

Introduction

Medicare started in 1965 after much debate and political wrangling. Central to the debate surrounding the implementation of Medicare was the fundamental question over who should receive coverage. Some believed that government benefits should be means tested and delivered only to the needy. Others believed that funding of public assistance should be the responsibility of individuals in all socioeconomic brackets. At the end of the debate, Medicare evolved through a compromise of all perspectives. First, all entities agreed that the elderly were deserving of federally funded health insurance. Second, those worried about wealth transfer were assuaged by two features of Medicare: payroll taxes on all workers would fund the program; and everyone, rich and poor, had the promise of their own Medicare entitlement in old age (Marmor, 2003, pp. 10-11).

Since 1965, the breadth of Medicare coverage has expanded incrementally with funding occurring through the Part A and Part B programs. More substantive change has been enacted in the past few years. In 2003, a prescription drug benefit passed in the Medicare Modernization Act (Part D) with implementation of the program beginning in 2006. With this change, Medicare now covers inpatient care, outpatient care, some aspects of home health, and prescription drugs. Further expansion is proposed to occur in the future. The Patient Protection and Affordability Act passed in March of 2010 is designed to cover an additional 40 Million uninsured Americans beginning in 2014 (The Patient Protection and Affordability Act, 2010).

Parallel to these extensive Medicare benefit expansions, citizens and policymakers have cautioned that the unrestrained growth of benefits would lead to insolvency. For example, less than four months after the prescription drug program was enacted, a report forecasting Medicare insolvency by 2019 appeared in the press (Pear, 2004, pp. 1-3).

Several initiatives to respond to the concern of insolvency have been proposed. One option gives the Secretary of Health and Human Services more regulatory authority to implement needed change as budgetary constraints relax or tighten. The recently passed Patient Protection and Affordability Act provide a number of areas of discretion for the Secretary of Health and Human Services. Such discretion is embodied in language included in the act such as "the Secretary shall…":

> "develop standards…;" (p. 14)
> "review and update, as appropriate, the standards developed in this section…;" (p.14)
> "establish a formula for determining the amount of any grant to a State…;" (p. 22)
> "establish a temporary high risk health insurance pool program…;" (p. 23)
> "negotiate rates for the reimbursement of health care providers for benefits covered under a community health insurance option…;" (p. 76)
> "prescribe rules setting forth the methods by which calculations of family size and household income…;" (p. 100)
> "Secretary shall identify and publish a recommended core set of adult health quality measures…;" (p. 199)
> (Patient Protection and Reimbursement Act, 2010)

Other initiatives focus on generation of new data to guide medical decision making by both public and private entities. In 2009, the American Recovery and Reimbursement Act allocated $1.1 billion dollars to comparative effectiveness research that would reveal the best interventions in various therapeutic areas. In the Patient Protection and Affordability Act, the

Patient Centered Outcomes Research Institute was created to evaluate which interventions, patient education programs, and integrated service models worked the best in various disease states. Although these results are not intended to influence Medicare's reimbursement decisions, the private companies that Medicare contracts with to provide care can use these research results, as well as their own, to make reimbursement decisions.

Alternative reimbursement strategies to align payment with quality outcomes have also been considered by Medicare. Some evidence supports a correlation between the number of procedures performed by a clinician and the outcome. This literature, frequently known as the volume effect literature, has demonstrated that surgeons and/or hospitals with less experience in a given procedure are more likely to have worse patient outcomes (Chernow, 1999; Eiseman, 1965; Eskander, Flaherty, Cosgrove, Shinobu & Barker, 2003; Halm & Chassin, 2002; Heidenreich & McClellan, 2001; Kim, Song, Lee, Han, Hyung & Cho, 2008).

The final options available to Medicare are very politically charges. Such initiatives support either (1) raising taxes; (2) means testing; (3) reducing the number of beneficiaries served by Medicare or (4) reducing the number and types of services each beneficiary receives. National Coverage Determinations guide the number and type of services available to Medicare beneficiaries. Denying needed services to patients does little to help the Medicare agenda of advancing access and quality even though it does assist with budget considerations. The research present below evaluates whether the 2003 NCD for DBS in patients with Parkinson's Disease (PD) achieves the health care goals of Medicare. In the literature, there are no studies assessing the clinical and economic outcomes of Parkinson's patients who undergo surgery for deep brain stimulation before and after the National Coverage Decision (NCD) by Medicare in 2003. Evaluation of this change in coverage decisions is important for several reasons: (1) access; (2) concerns related to cost given the aging of the United States population and inherent increases in the incidence and prevalence of Parkinson's Disease as Medicare beneficiaries; and (3) patient outcomes.

Policy Analysis and Program Evaluation: Models and Theory

Policy analysis and program evaluation for Medicare has concentrated on a number of models. Sometimes a timeline is used to reveal the incremental nature of expansion as described above. Other times, organizational, administrative, or economic theories or models are used to explain the public policy of Medicare.

Marmor describes the origins of Medicare as a less controversial initiative than national health insurance. Marmor posits that Truman chose this approach because he concluded that insurance for the aged had the best chance of getting passed because the public would not object to a program for the elderly. This view of the government as a rational actor assumes that some purposeful description of the issues at hand takes place, that explanations of those issues and their consequences are proposed, and that policy outcomes are then predicted and measured over time (Marmor, 1970/1973/2003).

One limitation of this approach is that it focuses on the political imperatives in place at the time a strategy is taken, and does not consider the possible intransigence of the circumstances that form those imperatives. For example, if the political imperatives were a result of an unstable or narrow majority in Congress, more thought might be given to how the political imperatives might change with the next election.

From an organizational perspective, however, one would spend less time understanding why choices were made in a rational fashion and more time trying to understand the pattern of decision-making. That is, how did concerned lobbying groups shape the discussion regardless of the policy issue at hand. Marmor contends that this model is more attuned to the behavior of the polar camps comprised of the American Medical Association (opposed to Medicare) and the AFL-CIO (supported Medicare) because it was the needs of these two organizations that shaped the debate and the ideological positions each had on social insurance initiatives (Marmor, 1970/1973/2003).

While this approach addresses the limitation of the rational actor model, it seems too simplistic to explain today's state of Medicare. True, Congress may be polarized at times with opposing views of health care reform. This situation, however, will most likely not be changing in the near term. Even in the presence of divisive political discourse about Medicare, two Presidents have expanded Medicare in unprecedented ways over the last seven years through the passage of the Medicare Modernization Act and the Patient Protection and Affordability Act. Neither the rational actor model nor the organizational process model seems particularly useful in describing recent events.

In a bureaucratic politics model, Medicare policy would be viewed as the outcome of bargaining between actors in decentralized organizations. In this approach, the policy outcome is not the solution to a pressing social problem, but rather the result of the bargaining between organizations with varying power. Predicting the future policy would include efforts to keep the power of the bargaining parties the same and would not, for example, include periodic discussions about whether new, additional social needs had arisen that need attention (Marmor, 1970/1973/2003).

It seems that this model would include internal bureaucratic bargaining over discretionary powers of government agencies. As such, it might include the perspective of

Richard Nixon when, after failed attempts at change through legislative victory, turned to influencing change by controlling the administrative branch. Nixon concluded, 'operations is policy,' (Randall, 1979, p. 808). The recent large expansions in Medicare have included many areas for discretion in implementation. And, in fact, the research outlined below in benefit expansion policy evaluation focuses on applied measurement of the outcomes of a discretionary expansion in Medicare benefits. This model is appropriate for the given research hypothesis and lends itself to empirical testing.

Jonathan Oberlander (2003) contends that no one institutional theory can explain Medicare's political existence. Instead, Oberlander recommends assessing the actual experience of Medicare, rather than trying to model it with any single framework. Oberlander asserts that the politics of Medicare from 1965 to 1994 was one of consensus as evidenced by bipartisan support for hospital and physician payment reforms; and a general recognition that healthcare for those over 65 years of age should be operated as a single payer system. Oberlander summarizes by pointing out that Medicare is again in an era with a discussion about ideas, and not just solvency.

Oberlander's acceptance of multiple theories is appealing; however, his explanation of sequential uses for these models implies that multiple models are not appropriate simultaneously. Medicare is a large organization with many pieces: administrative discretion, Congressional oversight, interaction with a privatized healthcare delivery system, and the discerning eyes of entitled beneficiaries. This complex organization may need more than one theory to fully understand. Further, this complexity may lend credence to Oberlander's suggestion that the actual experience of Medicare be examined rather than predicted or explained by theory.

From the economist's perspective, the DBS benefit expansion may be evaluated against the Medicare goal of improved access to this surgery as measured by the utilization of the procedure before and after the NCD. Conceptually, the coverage decision reduced the price of surgery to patients who were previously uncovered by insurance. At the same time, increase in reimbursement to physicians may encourage more utilization of the procedure in the targeted patient population. Through the traditional supply-demand model one would predict that there would be an increase in the quantity demanded for surgery because the price to the patient would be reduced (Nicholson & Snyder, 2005). A fundamental tenet of this model assumes that all players have perfect information which may not be true in the case of DBS in patients with advanced PD. It would be inherent, in most cases, that the physician would need to provide the information that the patient needs to form a rationale decision. If reimbursement increases, more physicians may be inclined to provide such information and encourage utilization of the procedure. Economists may suggest that changes in the NCD provide the ideal scenario for supplier-induced-demand implications. The potential for supplier-induced-demand is limited by the strict inclusion/exclusion criteria that exist for patient selection and funding. With the precertification of procedures that exists in health care markets, it is unlikely that patients who do not meet the strict inclusion/exclusion criteria will be admitted for the procedure. As such, the inclusion/exclusion constraint as well as the precertification process may reduce the physician ability to supply the procedure.

Jones (1996) asserts that Medicare influences private insurance markets. Medicare's coverage and administration "…has helped fund a large tertiary care and teaching establishment, an expansion of hospital beds, an increase in the number of physicians (especially specialists) and health professionals, the growth of the for-profit sector, and a burgeoning home health and independent laboratory industry. As noted previously, the constraints placed upon patient selection for DBS may limit its utilization.

Edward Lawler, in his book entitled, *Redesigning the Medicare Contract: Politics, Markets, and Agency*, applies agency theory to Medicare to illustrate nature of inter-relationships between enrollees, doctors, hospitals, administrators and Congress. Lawler defines agency in this way:

> In a simple agency relationship between a single principal and an agent, an individual or organization is delegated to act on behalf of the principal. An agent is supposed to do what the principal wants to have done. A perfect agent performs exactly as if the principal were acting, except that the principal does not have sufficient information, time, or other capabilities to perform the service in question (2003, p. 56).

Consider the doctor-patient relationship: the patient is the principal and the doctor is the agent. The patient hires, or contracts, the doctor to make decisions that the patient herself would make if she had the knowledge to make them herself. But physicians today also serve as agents for equity partnerships. Sometimes the incentives, or contracts, used by these firms encourage behavior that is contradictory to the best interests of the patient. For example, the physician may have caps on the number of tests he or she can order. Exceeding these caps may have a negative impact on the physician's income but also may be in the best interest of the patient. In other words, to be a perfect agent for the patient, the physician may sub-optimally serve as agent for the equity partnership; and to be a perfect agent for the equity partnership, the physician may sub-optimally treat his other agent, the patient. (Lawler, 2003).

Lawler meets his objective of explaining how agency theory can help Medicare policy analysis by exploring the array of contracts involved in delivery of care. Layered in these contracts between the patients, physicians, claims administrators and private firms (durable medical equipment manufacturers, medical device manufacturers, etc.) are contradictory or competing incentives that influence behavior. The web of double-agents is complex understanding these complexities can help policymakers to understand how ongoing changes to Medicare may improve one aspect of care delivery, but create an unintended incentive for something that detracts from other aspects of Medicare.

In its application to Medicare, Agency theory may have more value as a heuristic device than as a basis for applied measurement. Teasing out what consequences are due to a physician optimizing their behavior for one principal over another would be extremely challenging empirically.

Costs and Effectiveness in Medicare

The ongoing concerns about the fiscal health of Medicare have matured from warnings about insolvency to a commitment to measuring costs and outcomes of care. The Medicare Modernization Act, which sets forth the Part D benefit for prescription drugs, recognizes the role of this research. The following sections of the Medicare Modernization Act (2003) specifically recommend or require cost effectiveness research on delivered health care:

1. Sec. 1860D-4 (B) Formulary Development. In developing and reviewing the formulary, the committee shall—(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, *pharmacoeconomic studies, outcomes research data*, and on such other information as the committee determines to be appropriate; (p. 20)

2. Sec. 1860D-4 (C) Cost and Utilization Management; Quality Assurance; Medication Therapy Management Program—(1) In general the PDP [Prescription Drug Plan] sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following: (A) *A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs* (as defined in section 1927(k)(u)(A)(k)). (p. 20)

3. Sec. 641. Demonstration Project for Coverage of Certain Prescription Drugs and Biologicals. (e) Report—Not later than July 1, 2006, the Secretary shall submit to Congress a report on the project. *The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to the reduced physicians' services and hospital outpatient departments services for administration of the biological.*
(p. 256 [emphasis mine])

This statutory recognition of the need for cost-effectiveness research reveals that in the future, Medicare reimbursement decisions may increasingly depend on the economic performance of an intervention. Economic evaluations of health care delivery in Medicare fit into two broad categories. The first is programmatic; that is, examinations of the performance of the entire program as a whole. The second is disease or treatment specific; that is, the performance evaluation of an individual condition or the intervention for that condition. Numerous evaluations have been published in the literature that supports both types of studies.

Foote and coauthors have contributed to the literature a number of scholarly articles that examine programmatic features of the delivery of care in Medicare. For example, Foote examined: the politics of preventative care in Medicare (Foote & Blewett, 2003); the implications of a new initiative to care for the chronically ill (Foote, 2006); the variation in coverage policies by geographic location (Foote, Wholey, Rockwood, & Halpern, 2004;

Foote; Halpern & Wholey, 2005) and the consequences of Medicare modernization reform (Foote & Neumann, 2005).

Others examined Medicare from other perspectives: the consequences of longevity in Medicare (Miller, 2001); decision theory and Medicare coverage choices (Hanoch & Rice, 2006); pricing transparency (DoBias, 2006); and the effect of prospective payment on staffing and quality of care in skilled nursing facilities (White, 2005, 2006).

The former head administrator for CMS, Mark McClellan, has published widely both on programmatic themes and individual disease states. On programmatic topics, McClellan has published on Medicare reform (McClellan, 2000); Medicare Part D (McClellan, 2005; Bach & McClellan, 2005); and Medicare abuse, (Becker, Kessler, & McClellan, 2005). On treatment or disease specific topics, McClellan has published on: treatment trends for Medicare beneficiaries with ventricular arrhythmias (McDonald, et al, 2002); device use patterns and outcomes for cardioverter defibrillators for Medicare beneficiaries in California (Hlatky, Saynina, McDonald, Garber, & McClellan, 2002); costs associated with decedents in Medicare (Buntin, McClellan & Newhouse, 2004); trends in treatment and outcomes for myocardial infarction (Heidenreich & McClellan, 2001); and trends in inpatient treatment intensity for Medicare beneficiaries near death (Barnato, McClellan, Kagay, & Garber, 2004).

Others have explored diseases and interventions such as: the cost of smoking to Medicare (Zhang, Miller, Max, & Rice, 1999); the cost of colon resections (Sung, Wessel, Gallagher, Marcet & Murr, 2004); the reimbursement structure and its effect on chemotherapy treatment (Jacobson, et al, 2006); the cost of Alzheimer’s patients to Medicare (Taylor & Sloan, 2000);the cost of kidney transplants (Yen, et al, 2004); and the cost of defibrillators (Weiss, Saynina, McDonald, McClellan, & Hlatky, 2002). Finally, Katia Noyes and coauthors examined the costs associated with Parkinson's disease in elderly Medicare beneficiaries (Noyes, Liu, Li, Holloway, & Dick, 2006).

Specific to the purposes of this dissertation, in 2003 Medicare added reimbursement for the surgery and the device for deep brain stimulation (DBS) for advanced Parkinson's disease. Although regionally available prior to this time, a national coverage decision meant that this procedure would be covered in all regions. The DBS device, like other devices in development, is being studied for use in many other conditions--some of which are very common. DBS may be effective in treating depression, obsessive-compulsive disorder, chronic pain, epilepsy and multiple sclerosis (The Cleveland Clinic Health Information Center, 2001). The ability to assess the clinical and economic outcomes for DBS in Parkinson's disease is representative of the type of evaluation Medicare administrators will need to implement for other devices and biologics as they are approved.

In the literature, there are no studies assessing the clinical and economic outcomes of Parkinson's patients who undergo surgery for deep brain stimulation before and after the National Coverage Decision (NCD) by Medicare in 2003. Evaluation for this implantable device in Medicare is important for three reasons: (1) to learn whether reimbursement for this surgery and device improves access to the procedure; (2) to prepare for the aging of the population and the attendant increased prevalence of Parkinson's disease in the Medicare population; and (3) the device used in this surgery is being developed for more diseases and therefore the true burden on the Medicare budget will be many-fold the burden represented by Parkinson's disease.

Deep Brain Stimulation in Parkinson's Disease

Parkinson's disease is a progressive neurological disease affecting mostly older individuals. The burden of Parkinson's disease includes loss of independence and function for the patient, caregiving responsibilities on the part of spouses and children, the expense of walking aids and modifications to living quarters, and for some, use of long term care facilities. One recent study places the annual incremental direct and indirect costs of Parkinson's disease to society in the United States at $23 billion and this figure is expected to grow to at least $50 billion by the year 2040 (Huse, et al, 2005). Additionally, with the baby boomer cohort entering the years of typical diagnosis, the number of people with Parkinson's disease will grow at a rate faster than the growth of the general population (Lang & Lozano, 1998).

Parkinson's disease is incurable. The treatments available for Parkinson's disease are symptomatic and do not prevent progression of the disease. Over time, doses of appropriate medicines must be increased and additional agents added to adequately control the tremor, rigidity and slowness of movement associated with Parkinson's disease. Unfortunately, the medicines themselves can have unpleasant side effects including daytime sleepiness, nausea, hallucinations, and excessive gambling (Huse, Castelli-Haley, Orsini, Lenhart, & Abdalla, 2006). For some in the advanced stages of Parkinson's disease, there are unpredictable periods of poor mobility. Patients in this advanced stage of Parkinson's disease may be candidates for DBS surgery.

DBS surgery implants a wire in the brain connected to a small generator in the chest. When switched on with an external magnet by the patient, the wire stimulates the targeted area of the brain and Parkinson's symptoms diminish or stop. If patients have symptoms on one side of the body, they have one wire; if they have symptoms on both sides of the body (e.g. tremor in both left and right extremities) they have wires on both sides of the brain. When the device is implanted, the patient is usually under local anesthetic and awake. During the surgery, the probe is moved different parts of the brain until the surgeon observes that the patient's symptoms decrease or disappear. At this time the probe is permanently placed (Parkinson's Disease Society Information Sheet, 2003).

Although an expensive option, this surgical technique is effective for some Parkinson's patients. Randomized controlled trials are difficult to do with surgical interventions as they require a placebo surgery. However, in uncontrolled trials, DBS has reduced post-surgery doses of anti-Parkinson drugs (Charles, et al, 2004), and improved activities of daily living, mobility and other symptoms measured by the Unified Parkinson's Disease Rating Scale (Rodriguez-Oroz, et al, 2005). However, the device and procedure have risks as well. Although Parkinson's is a disease of the elderly, the device is not approved for implantation in patients 75 years of age or older. In the registration clinical trials, 96.3% of enrolled patients experienced one or more adverse events including: intracranial hemorrhage, 7.5%; device related infection, 10.6%; pain, 31.3%; confusion, 27.5%; abnormal thinking, 20.6%; and hallucinations, 6.9% (Medtronic Activa® Therapy, 2006).

Although costs for the DBS surgery can vary with lengths of stay in the hospital and adverse events, the manufacturer estimates procedure costs of $50,000 to $60,000. A number of studies examined the costs and effectiveness of DBS surgery in the United States, Germany, France and Italy. Economic and clinical outcomes are difficult to compare across countries and this difficulty is well documented: different cultural levels of stigma may influence diagnosis and recorded prevalence rates (Vernooij-Dassen, et al, 2005); the structure of healthcare delivery including collaboration patterns between nurses and physicians may differ (Hojat, et al, 2001); the mean, skewness and spread of the data collected may differ (Thomson, Nixon & Grieve, 2006); the available treatments and prices for treatments differ by country (van Mosseveld, 2005; Ridley, 2005); the incidence of diseases may differ by country (Nowak, et al, 2005); and socioeconomic status may influence the incidence of complications in certain diseases (Walsh, Zgibor, Songer, Borch-Johnsen, & Orchard, 2005).

Some of the DBS economic studies in the literature employ a set of research techniques that were developed in Canada and Europe to assist in allocating resources to health care services and/or to determine reimbursement for drugs and other interventions. Some of the assumptions underlying these techniques are inconsistent with neo-classical economics. A brief overview of the approaches and an explanation as to how these approaches may violate the assumptions of neo-classical economics is provided.

The most commonly used approaches for European resource allocation and/or reimbursement decisions are: (1) Cost-Effectiveness Analysis; and (2) Cost-Utility Analysis. Cost-Effectiveness Analyses typically assign a monetary value to a number of outcomes such as life-years gained, points of blood pressure reduced, or disability days saved. Cost-Utility Analyses assigns monetary value to a single output: Quality Adjusted Life Years (QALY's). It is the Cost-Utility Analysis that is based on an assumption that utility can be discretely measured—most frequently in healthcare described as a point on a continuum death at zero to the best possible health at 1 (Drummond, Sculpher, Torrance, O'Brien, & Stoddard, 2007).

One criticism from modern economists is that utilities are a theoretical construct that cannot be measured, only ordered (Nicholson & Snyder, 2005). Another criticism is from Economics Nobel Prize winning economist Daniel Khaneman. In Cost-Utility Analysis, utilities or health state preferences are measured by asking either patients or the general population hypothetical questions about preferences between possible combinations of risks, side-effects and death. Khaneman's research shows that respondents cannot accurately predict how they would respond to hypothetical scenarios "because affective forecasting is a task that people do not perform very well" (Khaneman, 2006, p. 65). Despite these criticisms of QALY measurement errors, European nations continue to use this approach to make reimbursement decisions in healthcare. Interestingly, the recent Patient Protection and Affordability Act expressly forbids use of QALY's in Medicare reimbursement decisions; however, the pharmacy benefit providers that Medicare contracts with can and do require and consider QALY's in formulary placement.

In Germany, Spottke and coauthors found that DBS surgery improved scores on the Unified Parkinson's Disease Rating Scale (UPDRS). A cost-effectiveness analysis comparing the DBS treatment to pharmacy treatment alone was performed. The incremental cost per unit decrease in the total score of the UPDRS compared to pharmacy treatment alone was €920 or about $940 in 2002 (Spottke, et al, 2002). Although this study had a 12-month follow up period, there were only 16 patients in the study and thus it is too small to be definitive or generalizable.

Later, Meissner and co-authors measured total costs over three years in Germany. Meissner examined the year before surgery, the year of surgery and the year after surgery. Total costs included drugs, in-patient costs and outpatient costs. Meissner found that on average, total costs for patients in the year before surgery were €15,991 (about $19,797); average total costs in the year of surgery were €21,082 (about $26,100); and average total costs were €7,223 (about $8,942) in the second year after surgery. Meissner concludes that beginning in the second year post surgery, patients are symptomatically improved and cost less to the health care system than they did prior to surgery (Meissner, et al, 2005). In a cost-effectiveness analysis, the incremental cost of decreasing the UPDRS III score in surgery patients compared to patients treated with pharmacy alone. The incremental cost per point on the UPDRS III was about €979 which is consistent with the € 920 in the Spottke research (Meissner, et al, 2005). This study improves upon Spottke's work in that it covers three years of treatment and in that it has 46 patients. However, the sample size is still rather small. Still, the confirmation of Spottke's estimates and the trend of lower costs over time reveals the possibility that this expensive surgery may provide value over time.

A Pre-Post design was employed by Fraix and co-authors (2006) in France. Fraix followed 95 Parkinson's patients who had DBS surgery. Costs were measured in the six months before surgery and the six months after surgery. Total direct medical costs before the surgery were €10,087 (about $12,492) and the total direct medical costs during the six months after surgery were €1,673 (about $2,072). The costs of the surgery itself were estimated to be €36,904 or about $45,702 (Fraix, et al, 2006). The decreases in costs after surgery are substantial. However, several limitations are important to consider: the costs associated with complications were not included nor were the costs of replacing the devices periodically. Another limitation of this study is the lack of longer follow up. The device does not does not prevent progression of the disease. Over time, symptoms will worsen and the incremental savings over pre-surgery costs will diminish.

In the United States, Tomaszewski and Holloway developed a cost-utility Markov model that estimates the cost per Quality Adjusted Life Year (QALY) for patients in the United States who receive DBS surgery. Tomaszewski and Holloway concluded that DBS is cost-effective (less than $50,000 per QALY) when quality of life measures are improved by 18% or more compared to patients without surgery. The authors argue that because post-surgery improvements on the Unified Parkinson's Disease Rating Scale exceed 18%, DBS surgery is cost-effective (Tomaszewski & Holloway, 2001).

Limitations of Tomaszewski and Holloway's study include the lack of long term data and the lack of quality of life measures. Improvements in quality of life were assumed to exactly correlate with improvements in the Unified Parkinson's Disease Rating Scale. There is no evidence in the literature to support using the Unified Parkinson's Disease Rating Scale as a substitute for a carefully constructed, valid and reliable quality of life questionnaire. This study also lacks a practical use because its societal perspective includes costs and benefits not experienced by the payer of the intervention (such as lost income and caregiver burden). As a result, Markov QALY studies rarely influence reimbursement decisions (Neumann, et al, 2006). Although the authors recommend randomized trials to more fully examine the clinical and economic differences between DBS and pharmacy treatment alone, this seems impractical. Sham surgeries for blinded trials are difficult, and DBS would be even more difficult to blind because of the adjustment to the device through magnets in the chest. Overall, the model has value as a theoretical exercise, but does not seem to have realistic assumptions, results, or recommendations.

Eskander and co-authors examined practice patterns, clinical outcomes and charges associated with DBS and other surgeries for Parkinson's disease from 1996 to 2000 using the

Nationwide Inpatient Sample from the Agency for Healthcare Research and Quality (AHRQ). Eskander found that the median total hospital charge for all patients was $14,300. For the subset of patients who received DBS, the median total hospital charge was $35,700 compared to $12,000 for the remainder of the procedures. This study reveals the practice shift toward DBS and its attendant expense. Additionally, Eskander found that mortality and morbidity were lower in hospitals that did PD surgeries more frequently (2003). This is a useful reminder that the cost-effectiveness of a surgical procedure can vary from institution to institution.

Eskander's research provides a foundation for my research because it uses the HCUP data, and the authors have shown the importance of controlling for the volume effect of surgical experience on outcomes. Unfortunately, the study included procedures other than DBS, and covers a period of time that encompassed a large change in treatment patterns. As discussed in Eskander, et al (2003), surgeries other than DBS were the mainstay in the early years of observation. This research will only look at DBS after the treatment patterns changed; and, will examine the consequences of a benefit expansion from Medicare on inpatient outcomes.

In response to increasing use of DBS surgery and to the emphasis on cost-effectiveness, Green and co-authors did a cost effectiveness study that measured the costs and outcomes associated with another brain surgery for Parkinson's disease: unilateral and bilateral pallidotomy. Unlike DBS, this surgery damages tissue in the brain whereas DBS only stimulates the tissue. Because no device is involved, this surgery is less expensive than DBS surgery.The outcome measure selected was Hoehn and Yahr. Green et al showed that a decrease in the Hoehn and Yahr scale of 0.87 resulted in an estimated savings to public expenditures of €3593 annually. Consequently, Green asserts, pallidotomy pays for itself through savings within six years post surgery. Additionally, Green recommends that pallidotomy continues to be considered as a viable surgical intervention because it improves outcomes and is less expensive than DBS surgery (Green, Joint, Sethi, Bain & Aziz, 2004).

Green does not address an element that is important to ongoing treatment of Parkinson's disease. Although pallidotomy appears cost-effective, this surgery permanently damages brain tissue and precludes the patient from undergoing DBS. Although pallidotomy is clinically appropriate for some patients, the subsequent loss of DBS as a treatment choice should be addressed as a "cost" in the cost analysis.

D'Ausilio and co-authors conducted a comparative economic study for advanced Parkinson's disease from the perspective of the National Health Service in Italy over a five year period. D'Ausilio measured costs and outcomes for traditional therapy, apomorphine therapy, and DBS. The five year direct medical cost total for traditional therapy was €58,065 (about $71,957); for subcutaneous apomorphine, €36,423 (about $45,145); and for DBS, €56,489 (about $70,015). D'Ausilio concludes that taking into consideration both costs and effectiveness, apomorphine treatment and DBS surgery are less expensive that traditional therapy (D'Ausilio, et al, 2003). Charles and co-authors followed 16 patients and measured their medication costs before and after DBS surgery in the United States. Before surgery, daily cost of medicine for Parkinson's disease was $19.53 and after surgery, the daily cost was $13.25. On an annualized basis, this represents an annual savings of $2,292 (Charles, et al, 2004). The small sample is problematic for generalization, but the trend shows that the decrease in medication costs may be non-trivial.

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Although the literature contains many studies assessing the costs and effectiveness of DBS surgery, none examines the consequences of expanding Medicare's benefit to reimburse DBS surgery for Parkinson's disease. Furthermore, the work provides insights as to whether improved inpatient clinical outcomes accompany the newly reimbursed DBS device and surgery and will provide a context for determining the importance of cost management in Medicare administration. The often competing goals of "excellent care" and "affordable cost" require research-driven policymaking that balances the price and promise of new intervention.

Hospital and Surgeon Volume Effect

Because this work will extend Eskander's work, it will be important to understand the surgical volume effect in more detail as it is an important element for policymakers to consider when examining treatment patterns and outcomes for surgical procedures.

Governmental expansion of health benefits through Medicare has occurred incrementally since its inception in 1966. The prescription drug benefit (Part D) enacted in 2006 is still causing substantial public discussion over benefit design, consumption patterns and costs. As big and expensive as the Medicare Prescription Drug program seems to be, other medical services delivered by Medicare consume much more of the budget. For example, the hospital insurance included in Part A is the single largest type of expense in Medicare and comprises 41% of expenditures whereas prescription drugs in Pard D comprise 18% of expenditures (Kaiser Family Foundation, 2009).

A subset of Part A inpatient services, surgically implanted medical devices, is a growing set of medical procedures that includes implanting drug eluting stents, pacemakers, defibrillators, deep brain stimulation probes for Parkinson's disease and cochlear implants. The success of companies like Medtronic demonstrates the growth of medical devices in diabetes, heart disease and Parkinson's disease. Evaluation of a benefit change for a medical device constitutes an interesting contribution to the program design and evaluation literature because it is a growing portion of Part A, the largest, single contributor to the Medicare budget. The recent comparative effectiveness priority topics from the Institute of Medicine

(IOM) are consistent with this: 14 of the top 50 (28%) research topics for comparative effectiveness research from the Institute of Medicine include surgical interventions (IOM priorities).

Evaluation of surgery poses special challenges that must be addressed when measuring whether a surgery meets its health policy goals. In 1965, Eisenman and Spencer coined the term “The Occasional Open-Heart Surgeon,” in their editorial published in *Circulation*. In the editorial, the authors compare open-heart surgeons to pianists where technique suffers from even one day without practice. An early study referenced in the editorial showed that 41% of hospitals who claimed to do open-heart surgeries did fewer than ten procedures annually. Eisenman and Spencer (1965) commented:

> Not revealed, of course, is the far more elusive figure relating operative mortality with the frequency of operation. Its correlation must be left to the imagination! (p. 162)

Over time, the literature has examined this relationship and found the correlation between volume of surgeries and mortality to be inverse. Facilities and surgeons with high volume practices have lower mortality rates than those with low volumes. For example, the relationship between the surgeon volume and facility volume to clinical and economic outcomes has been documented in many different types of surgeries. The literature reports higher facility volume was associated with lower mortality rates for the following surgeries: coronary artery bypass; pediatric cardiac surgery; carotid endarterectomy; surgery for unruptured abdominal aortic aneurysm; surgery to repair ruptured abdominal aortic aneurysm; lower-extremity arterial bypass surgery; pancreatic cancer surgery; esophageal cancer surger; breast cancer surgery; colorectal cancer surgery; lung cancer surgery; gastric cancer surgery; total hip replacement; total knee replacement; hip fracture repair; open prostatectomy; transurethral prostatectomy; surgery for ruptured cerebral aneurysm; surgery for unruptured cerebral aneurysm (Halm, Lee & Chassin, 2002).

Additionally, the literature reports higher surgeon volume was associated with lower mortality rates for the following surgeries: coronary artery bypass; pediatric cardiac surgery; carotid endarerectomy; surgery for unruptured abdominal aortic aneurysm; pancreatic cancer surgery; breast cancer surgery; colorectal cancer surgery; lung cancer surgery; gastric cancer surgery; and total hip replacement (Halm, Lee & Chassin, 2002).

Finally, the Halm, Lee and Chassin (2002) review article mentions that while volume and outcomes associations were documented in the vast majority of the literature, very few of the studies incorporated adjustments for patient characteristics such as age or co-morbidities. This is problematic because age and co-morbidity burden can also affect outcomes. This is well documented: Chernow (1999) found that age and gender affected outcomes in critically ill patients; Kim, et al, found that comorbidities could be a predictive risk factor in Laparoscopy-Assistive Distal Gastrectomy; Ory-Magne, et al (2007) found that the older the patient was for DBS surgery, the lower the improvement in quality of life as measured by mobility, activities of daily living and cognition; and Setoguchi, Solomon, Levin, and Winkelmayer (2008) found gender and age affect outcomes in Myocardial Infarction.

Elixhauser, Steiner, Harris and Coffey (1998) points out that work in healthcare by policy makers must include corrections for the heterogeneity in the patient population, including co-morbidities:

> Measures of the overall medical condition of patients are essential for health care research, whether collecting data prospectively or using data that have been collected for another purpose. This is true for testing new treatments, assessing established ones, evaluating health plans and providers, or studying the impact of health care

> policies….when using administrataive data, preexisting conditions, or comorbidities, should always be controlled. (pp. 8-9)

In addition to the medical implant surgeries discussed above, a study examining all surgeries for PD, including DBS, was conducted and the study assessed the volume/practice effect. Deep Brain Stimulation (DBS) was a subset of the population examined as part of a group of all PD surgeries by Eskander, et al (2003) using the Healthcare Cost & Utilization Project (HCUP) National Inpatient Sample (NIS). Only the DBS surgery involved a surgically implanted device. The study examined the effect of surgeon and facility volume on inpatient outcomes such as mortality, discharge to a short or long term care center, length of stay, and surgical complications. The results were consistent with that of other surgeries; that is, inpatient outcomes were better at facilities with higher volumes. However, during the time period of the study, there was dramatic change in the type of surgeries offered. The study covered surgeries from 1996 through 2000. In 1996, most PD surgeries were ablative (the burning of tissue without implantation of a device) and in 2000 most PD surgeries were surgically implanted medical devices for DBS. Further, the volume effect for just the DBS procedure was not reported separately (Eskander, et al, 2003). Therefore a new analysis would establish whether or not there was a facility/surgeon practice effect in DBS surgery specifically—and if so, the size of this effect.

The growth in the use of DBS surgery has expanded beyond PD and is being studied for: depression, epilepsy, Tourette's syndrome, pain (Coffey, 2008), hypertension (Pereira, Green, Nandi & Aziz, 2007), Obsessive Compulsive Disorder (Denys & Mantione, 2009), tinnitus (Shi, et al, 2009), and Schizophrenia (Mikell, et al, 2009). Some worry that these many potential uses may be the result of "Gizmo Idolatry" and that they may be adopted even when the evidence does not show any advantage over alternate interventions (Leff & Finucane, 2008). Leff and Finucane compare surgery to the activities of Veblen's Leisure Class:

> In *The Theory of the Leisure Class*, Veblen noted that in early societies, the upper leisure class performed high –prestige hunting and military exploits, while the lower classes performed menial work, such as agriculture, child-rearing, and cooking, which was arguably more important to survival of the society. Vestiges of this construct persist in medicine where surgical exploits are valued more highly than uneventful diligence or watchful waiting of primary care. (p. 1830)

There are two reasons why an evaluation in DBS would be informative for subsequent research or evaluations of DBS: (1) DBS is being applied to many new, disease states thereby exposing a much larger number of patients to the treatment; and (2) most of these new disease states have established pharmaceutical-based treatment regimes. When comparing routine pharmaceutical treatment to surgically implanted devices, the issues relating to volume and surgery are particularly problematic because one cohort will be subject to the volume effect, and one cohort will not. Any policy or comparative effectiveness that compares pharmaceutical treatment to surgical treatment with DBS will need to account for the surgical volume effect in outcomes.

On April 1, 2003 Medicare made a national coverage decision (NCD) for cover Deep Brain Stimulation (DBS) for Parkinson's disease (Leavitt, 2005). Generally, NCD's are not necessary. The Social Security Act does not provide a detailed list of covered procedures, services and treatments. Instead, the act prescribes coverage for services and treatments that are reasonable and necessary. It is the regional contractors decide to cover procedures and services if they deem them to be reasonable and necessary, in accordance with the guidelines in the Social Security Act. In fact, only 300 NCD's have been made over that last 30 years.

(Report to the Congress: Medicare Payment Policy, 2003). The public can formally request an NCD, or:

> ... CMS staff can initiate the process if they find that: (1) inconsistent local coverage policies exist; (2) the service represents a significant medical advance; (3) the service is the subject of substantial controversy; or (4) the potential for rapid diffusion or overuse exists. (p. 246)

Prior to 2003, DBS had local coverage in some places, but it was inconsistent. Some local providers considered the procedure reasonable and necessary whereas others did not. The NCD mandates that all local providers provide a particular service or procedure, and this made access to DBS universal for appropriate patients. This particular coverage decision is interesting to examine because 1) it is a Part A expansion and therefore is part of the biggest service type in the Medicare budget; and 2) Parkinson's disease is chronic and progressive and selection bias may be introduced because the patients who initially get this procedure as a result of the NCD may be older and sicker than their counterparts in regions where the procedure was already covered which may cause longer lengths of stay for some and death for others; 3) DBS is amongst a growing set of surgical interventions that the baby boomers entering Medicare will use in increasing numbers—implantable medical devices; 4) DBS is a surgical procedure and therefore may be subject to the physician and facility practice effect; 5) and the new disease states that will use DBS have established pharmaceutical treatments and therefore any comparison between the surgery and the pharmaceutical treatment must account for the surgery effect in the DBS.

These issues are important to examining whether health policy goals have been met because failing to recognize these complexities could lead to an incorrect assessment of the success or failure of the benefit expansion. In particular, surgically implantable devices in chronic, progressive disease states pose special problems that must be addressed. Failure to recognize and account for these issues can lead to incorrect conclusions in program assessment.

On its website, the Centers for Medicare and Medicaid (CMS) speaks directly to the beneficiary and explains Medicare's goal: "Medicare's goal is to make it easy for you to get the highest quality health care at the most affordable price. Medicare is transforming itself from a program which simply pays the bills to a program which actively supports a high quality health care system," (http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf, 2009, p. 2).

Therefore, measuring whether a Medicare benefit expansion reaches its goal includes three parts. Firstly, is access improved—that is, are more procedures consumed due to the benefit expansion? Secondly, are the outcomes high quality—that is, are lengths of stay, complications and mortality minimized? Lastly, are the outcomes affordable? In short, policy success is dependent upon the clinical and economic outcomes of the expanded benefit.

The DBS benefit expansion can be evaluated against the Medicare goal of improved access to this surgery by identifying the consumption of this health care surgery before and after the NCD. Overall, however, we should see more total surgeries, more physicians performing the procedures, and more facilities offering the surgery.

Increased consumption of the DBS procedure is only part of the evaluation. Medicare is also interested in "high quality" healthcare, and volumetric access alone does not measure quality. One approach to measuring high quality outcomes is to measure lengths of stay and mortality for the procedures. But, in doing this, we must check and possibly correct for a selection bias introduced by the kind of patients entering surgery post NCD.

Parkinson’s disease is a progressive disease; patients who waited until the NCD to have the surgery are older and may have developed more co-morbidities. This “backlog” of surgery candidates who have these risk factors may result in more deaths, more surgical complications, and longer lengths of stay. However, this effect may be temporary, and should subside over time as the “backlog” of older, sicker patients move through the system.

Other variables that may affect outcomes measures such as length of stay and mortality are the experience levels of the facility and/or surgeon doing the procedure. The literature shows that the more procedures a physician or facility does, the better the outcomes. Combined with the “backlog” of more complex patients, inexperienced surgeons and facilities may produce worse outcomes initially. Again, this effect should be temporary, and should subside over time as facilities and surgeons become more experienced with the surgery. Therefore, outcomes measures in the short term may differ from outcomes measures over time. Success in this kind of benefit expansion must take into consideration that the inpatient outcomes of a surgical benefit expansion may not be permanent, and a different, more positive outlook would be provided in evaluations that took into account some delay before inpatient outcomes improved.

The inexperience of facilities, surgeons, and the “backlog” of older, sicker patients may initially increase mortality rates, and may initially produce longer lengths of stay in the hospital for some patients. These longer lengths of stay may lead to higher hospital bills. Therefore, in the short term, it may appear that inpatient outcomes are worse, and charges are higher—a most uncomfortable result. However, over time, facilities and surgeons should improve with practice, and the backlog of sicker patients will move through the system. Subsequently, outcomes may improve while average charges decline in the longer term.

As discussed throughout this document, if a policy-maker were to only look at the initial expenses and outcomes of DBS surgery for Parkinson's disease, a grim picture of poorer outcomes and higher expenses might be observed. But this may be temporary. Over time, the effects of sicker patients and inexperienced facilities or surgeons diminishes and the more accurate effect of the policy on inpatient outcomes would be revealed.

These challenges for policymakers were the motivation for this study examining whether longer term outcomes mirror short term outcomes before and after an NCD for DBS in Parkinson's disease.

CHAPTER 3

METHODS AND HYPOTHESES

Introduction

This study retrospectively examined the consequences to inpatient clinical and economic outcomes of a benefit change at the national level for CMS. The years from 1999 to 2007 were used for this cross-sectional analysis. Because this is a pre and post design, only states that had data in at least two years pre and two years post were accepted into this observational analysis. The results are generalizable for the 24 states included in the study: Arizona, California, Colorado, Connecticut, Florida, Georgia, Iowa, Illinois, Kansas, Kentucky, Massachusettes, Maryland, Michigan, Minnesota, Missouri, North Carolina, New York, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, and West Virginia.

Short-term analysis examined 12 months before the benefit explantion (January 1, 1999 to March 31, 2003); and 12 months after the benefit expansion (April 1, 2003 March 30,2004). Long –term analysis examined the four years, three months prior to the benefit change (January 1, 1999 to March 30, 2003); and the four years, nine months post the benefit change (April 1, 2003 to December 31, 2007). The framework for the analysis is illustrated in Figure 1.

Data

The HCUP dataset is supported by the Agency for Healthcare Research and Quality (AHRQ), which is part of the Centers for Medicare and Medicate Services (CMS). The

Health Care Utilization Project National Inpatient Sample (HCUP NIS) data that Eskander, et al, used for their study of PD surgeries published in 2009 is the selected dataset for analysis. Policymakers use this dataset to track healthcare resource utilization, quality, access, charges and outcomes (HCUP NIS, 2009). Findings from this work are published and available on the HCUP website and they cover a range of topics including: the care of adults with mental health and substance abuse disorders; care of children and adolescents in U.S. hospitals; economic and health costs of Diabetes; and serving the uninsured. Additionally, this dataset is used by researchers nationwide and their results have been published in *The New England Journal of Medicine*, *The Journal of the American Medical Association* (JAMA), *Annals of Thoracic Surgery*, *Cancer, Health Services Research*, *Surgery*, *PharmacoEconomics*, *Health Affairs*, *Value in Health*, *Health Economics*, *Journal of the American Geriatric Society*, *The American Journal of Public Health*, *The American Journal of Managed Care*, *The Journal of Health Care for the Poor and Underserved*, and others (HCUP Website, 2009).

The HCUP NIS data is the best available data for an evaluation of whether Medicare policy goals are being met with the Medicare coverage of DBS surgery for PD. Steiner, Elixhauser, and Schnaier (2002) explains the attributes of the data; it is: the largest collection of all-payer, uniform, state-based inpatient surgery administrative data; the data covers the years of interest: 1999 through 2007; inpatient outcomes are available such as length of stay, complication rate, mortality, discharge to home, short term facility, or long term facility; patient characteristics are available such as race, sex, age, geographic region, and median household income for patient's zip code (in categories); hospital characteristics are available such as bed size, teaching status, urban/rural, ownership status and U.S. region; hospital surgery volume is available; physician level volume is available; the large size of the database allows analysis of relatively rare procedures such as DBS for Parkinson's disease; HCUP is the only hospital database with charge information on all patients regardless of their insurance carrier or insurance status including Medicare, Medicaid, private coverage, or no coverage; the dataset is representative for participating states and provides a generalizable sample of inpatient volume, outcomes and charges.

Steiner, et al, 2002, also articulates limitations of this dataset: disease-specific stage of disease is not always available (for some diseases, this is only available retrospectively through chart abstraction or through prospective collection); laboratory data is not available; patients cannot be tracked long term (the NIS sample provides information about inpatient outcomes through discharge status).

The HCUP NIS data has powerful advantages and some notable disadvantages. Overall, however, the dataset provided information about DBS inpatient clinical and economic outcomes as well as indications of benefit expansion policy success. This evaluation on DBS for Parkinson's disease informs policy makers as to what issues may need attention when examining results of demonstration projects to test benefit expansions and would inform administrators whether more expensive, longer-term, possibly prospective studies are necessary for PD patients receiving DBS in Medicare.

This study design and data was submitted to the University of Missouri—Kansas City Social Sciences Institutional Review Board (IRB) and received a waiver because the data is de-identified and publicly available.

Analysis Framework

Outcomes of interest were measured before and after the Medicare benefit expansion that made reimbursement for Deep Brain Stimulation a national requirement. The effective date of this reimbursement change was April 1, 2003. Additionally, outcomes in the short run and the long run will be examined. The short run will compare 12 months pre reimbursement decision to 12 months post the reimbursement decision. The long run will compare all data from 1999 to April 1, 2003 to the data from April 1, 2003 to December 31, 2007. This is illustrated in Figure 1 below.

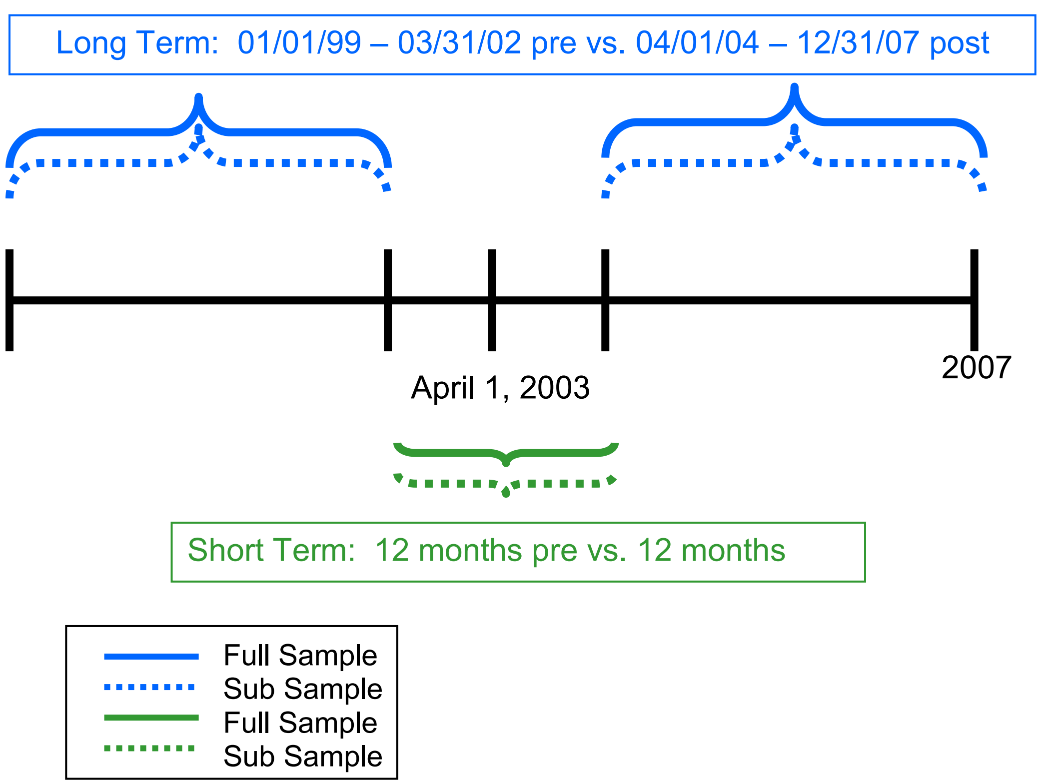

Figure 1. Analysis Framework--CMS National Coverage Decision
Enacted April 1, 2003

The HCUP sample of hospital discharges from 1999 through 2007 includes 70,052,217 inpatient hospital stays. Figures 2 and 3 describe the process that leads to the four samples examined in this study.

Sample Size – Full Sample

1999 through 2007 Hospital Discharges

N=70,052,217

↓

Diagnosed with Parkinson's Disease ICD-9: 332

N=564,527

↓

Had DBS Procedure Code: PR1-PR15

N=3,670

↓

Date of Surgery Known

N=3,370

Short-Term:	Long-Term
April 2002 – March 2004	January 1999 – March 2002 and April 2004 – December 2007
N=911	N=2,459

Figure 2. Inclusion / Exclusion Criteria and Sample Size for All Data Without Physician Variable

Sample Size – Subset

1999 through 2007 Hospital Discharges

N=70,052,217

Diagnosed with Parkinson's Disease ICD-9: 332

N=564,527

Had DBS Procedure Code: PR1-PR15

N=3,670

Date of Surgery Known

N=3,370

Doctor Volume Data Available

N=1,593

Short-Term:

N=460

Long-Term

N=1,133

Figure 3. Inclusion / Exclusion Criteria and Sample Size for Records where Physician Volume was Available

Hypotheses

The objective of this study is to evaluate whether patient characteristics receiving DBS after changes in the NCD are different than patient characteristics receiving DBS before the change. In addition, changes in the utilization of the procedure, physician characteristics or hospital characteristics will be assessed.

Patient and Service Characteristics in the Short Term

H_0 Patient Characteristics do not differ in the short term pre- and post- periods (age, sex, income, race, payer, Admission type, admission source, co-morbidities, length of stay, complications, disposition at discharge, per patient charges)

H_A Patient Characteristics differ in the short term pre- and post- periods (age, sex, income, race, payer, Admission type, admission source, co-morbidities, length of stay, complications, disposition at discharge, per patient charges)

Physician and Hospital Characteristics in the Short Term

H_0 Hospital and Physician Characteristics do not differ in the short term pre- and post- periods (bedsize, urban, teaching, ownership, state, region, number of facilities providing surgery, number of physicians associated with surgery, number of procedures per physician, number of procedures per hospital)

H_A Hospital and Physician Characteristics differ in the short term pre- and post- periods (bedsize, urban, teaching, ownership, state, region, number of facilities providing surgery, number of physicians associated with surgery, number of procedures per physician, number of procedures per hospital)

Longer term evaluations are also completed as noted in the short-term evaluation.

Patient and Services Characteristics in the Long Term

H_0 Patient Characteristics do not differ in the long term pre- and post- periods (age, sex, income, race, payer, Admission type, admission source, co-morbidities, length of stay, complications, disposition at discharge, per patient total charges)

H_A Patient Characteristics differ in the long term pre- and post- periods (age, sex, income, race, payer, Admission type, admission source, co-morbidities, length of stay, complications, disposition at discharge, per patient total charges)

Physician and Hospital Characteristics in the Long Term

H_0 Hospital and Physician Characteristics do not differ in the long term pre- and post- periods (bedsize, urban, teaching, ownership, state, region, number of facilities providing surgery, number of physicians associated with surgery, number of procedures per physician, number of procedures per hospital)

H_A Hospital and Physician Characteristics differ in the long term pre- and post- periods (bedsize, urban, teaching, ownership, state, region, number of facilities providing surgery, number of physicians associated with surgery, number of procedures per physician, number of procedures per hospital)

Hypotheses using multivariate analysis to assess whether having the procedure in the post period was a determinant of outcomes of interest: complications, discharge status, length of stay, and total charges (mean per patient).

H_O Having the procedure within the 12 months after the NCD is not a determinant of complications, discharge status, length of stay, and total charges.

H_A Having the procedure within 12 months after the NCD is a determinant of complications, discharge status, length of stay, and total charges.

Longer term evaluations are also assessed.

H_O Having the procedure beyond 12 months after the NCD is not a determinant of complications, discharge status, length of stay, and total charges.

H_A Having the procedure beyond 12 months after the NCD is a determinant of complications, discharge status, length of stay, and total charges.

Statistical Analysis

Variables derived from the HCUP dataset for the evaluation are provided in Appendix A. All dollar amounts used in these analyses were converted into 2003 U.S. dollars, the year of the benefit expansion. The following tests were completed: short term descriptive statistics and p-values using t-tests for continuous variables and chi square for the categorical variables; long term descriptive statistics and p-values using t-tests for continuous variables and chi square for the categorical variables; short run determinants of complications; long run determinants of complications; short run determinants of discharge disposition; long run determinants of discharge disposition; short run determinants of length of stay; long run determinants of length of stay .

Descriptive statistics (mean, standard deviation and p-values) were applied to the short and long term data. Each independent variable was tested to see if they differed pre- and post- NCD. Categorical variables will be tested with Chi Square tests and continuous variables were tested with t-statistics or for differences in distribution.

Multivariate analyses were applied to the short term and the long term data to identify determinants of complications (logistic regression), discharge location (logistic regression), length of stay (ordinary least squares) and total charges (ordinary least squares). In particular, the author was interested in whether the explanatory variable MEDREIMB (0 for before NCD, 1 for after NCD) was a determinant of these outcomes of interest. Explanatory variables were chosen to align with the theory and literature presented in Chapter 2 to test hypotheses.

Multivariate Hierarchical analyses were conducted to identify determinants of outcome variables of interest. As an alternate specification, hierarchical models were used to take into consideration inter-hospital variation. Hierarchical models are appropriate when there are nested classes of data (Houchens, Chu & Steiner, 2007). In these HCUP data, patients were nested within physicians, and physicians are nested within hospitals. Physician volume is not available the whole sample, so the analyses had patient nested within hospital for the full sample in both the long and short term; and it was planned that the subsample would have patient nested within physician nested within hospital for the short and long term subsample where physician volume is available. However, there was insufficient sample to perform this test. Instead, the two level testing was used on both the full and sub-sample.

When the dependent variable was binary as they were for the complications and mortality variables, logistic regression was applied. Fit was checked with the likelihood ratio (Kmenta, 2003/2004) and appropriate adjustments made, such as log transformations, if the fit was not good.

If the dependent variable was a count variable, such as length of stay, a negative binomial model was applied to both short and long term scenarios.

Statistical analysis will be completed using SAS v. 9.1. The [output/code/data analysis] for this paper was generated using SAS/STAT software, Version 9.1, SAS Institute, Inc., Cary, North Carolina, USA. An a priori alpha is set at 0.05.

CHAPTER 4

RESULTS

Study Cohort

Table 1 outlines the demographic characteristics of the study population. Three thousand four hundred twenty eight beneficiaries were included in the evaluation of DBS use in PD patients between 1999 and 2007. The population is predominantly male, greater than 63 years of age and had relatively low overall disease severity. Most procedures were elective and performed within large teaching hospitals located in either the south or western part of the United States. Total average hospital payments, per procedure were $47,000 (2003 US $$). Across all patient, payer and provider types, complications from DBS procedures were rare (<6%) with patients primarily discharged to home following the procedure and subsequent hospitalization.

Table 1

Demographics of the Study Population

VARIABLE	FREQUENCY	PERCENT	MISSING
Sex			
Male	2221	67.20	
Female	1084	32.80	
			65

Table 1 Continued

VARIABLE	FREQUENCY	PERCENT	MISSING
Income			
≤ $44,999	1362	41.83	
≥ $45,000	1894	58.17	
			114
Primary Payer			
Medicare	2157	64.04	
Medicaid	65	1.93	
Private	1083	32.75	
Self Pay/No Chg	21	0.03	
Other Ins.	42	1.25	
			2
Admission Source			
ER	23	0.71	
Another Hosp or Facility	34	1.05	
Routine	3189	98.24	
			124
Admission Type			
Emergency	99	3.96	
Urgent	93	3.72	
Elective	2310	92.33	
			868
Region for Hosp			
NEast	314	9.32	
Midwest	629	18.66	
South	1239	36.77	
West	1188	35.25	
			0
Teaching Hosp			
Non Teaching	494	14.66	
Teaching	2876	85.34	
			0

Table 1 Continued

VARIABLE	FREQUENCY	PERCENT	MISSING
Bedsize			
Small	147	4.36	
Medium	221	6.56	
Large	3002	89.08	
			0
Any Complications			
False	3174	94.18	
True	196	5.82	
			0
Discharge Loc.			
STC/LTC/Died	283	8.41	
Home	3082	91.59	
			5
Before or After NCD			
False (Before NCD)	1341	39.79	
True (After NCD)	2029	60.21	
			0

Table 2

Means for Descriptive Statistics

Variable	N	Min	Max	Mean	SD
Age	3340	19	89	63.46	10.11
Charlson (Range 0 = low severity to 6 = high severity)	3370	0	4	0.2228	0.5103
# Disch/Hosp	3370	3452	114163	29653.61	14587.94

Table 2 Continued

Variable	N	Min	Max	Mean	SD
#DBS/Hosp	3370	1	232	76.68	60.77
#DBS/MD	1593	1	58	26.61	17.75
LOS	3370	0	99	2.42	3.77
Total Charges/Patient	3152	551	357442	47565.56	30511.69

The data presented above describes the complete cohort of patient used in the evaluation. For the purposes of univariate and multivariate an inference, two additional types of analyses are completed. The first study reviews univariate and multivariates changes that occur 1 year before and 1 year after implementation of the NCD. For the first evaluation the pre/post period extends 1 year prior to the implementation of the NCD and includes data for 1 year after the implementation. The second evaluation considers a longer study period with the pre-assessment period defined as procedures completed between the periods of January 1, 1999 to March 31st, 2002 and the post-evaluation period occurring between the dates of April, 2004 to December, 2007.

Short Term (1 Year Pre & 1 Year Post) Descriptive Evaluation

Changes in patient characteristics and outcomes before and after the adoption of the NCD are presented in Table 3. Overall, patient specific variables were consistent across both periods. Temporal trends in patient age before and after implementation of NCD are also presented in Figure 1. Prior to the NCD, most patients receiving DBS were less than 65 years of age. After implementation of NCD, the average age of the patient population receiving DBS increased, but only incrementally (Table 3).

Table 3

Short Term (1 year Pre & 1 years Post) Evaluation Subsample

Variable	Pre (N=253) N or Mean	Pre (N=253) % or SD	Post (N=207) N or Mean	Post (N=207) % or SD	P Value
Patient Characteristics					
Female	80	31.62	76	36.71	0.2509
AGE	62.68	9.2571	63.831	10.11	0.2053
CHARLSON	0.2253	0.4636	0.2512	0.4973	0.5641
Income <$45,000	117	47.56	90	45.00	0.5896
Insurance Type					
Medicare	162	64.03	131	63.29	0.9589
Medicaid***					
Private/incl HMO	79	31.23	68	32.82	
Other Insurance***					
Admission & Hospital Characteristics					
Admission Source					
Emergency Room***					
Long Term Care & Other***					
Ambulatory	247	98.41	200	96.62	
Admission type					
Emergency***					
Urgent***					
Elective	243	96.05	199	96.14	
Region of Country					
Northeast	16	6.32	23	11.11	<0.0001*
Midwest	154	60.87	60	28.99	
South	82	32.41	111	53.62	
West***					
Teaching Hospital	230	90.91	179	86.47	0.1317
Hospital Size					<0.0001*
Small ***					
Medium	17	6.72	20	9.66	
Large	230	90.91	157	75.85	

Table 3 Continued

Variable	Pre (N=253) N or Mean	Pre (N=253) % or SD	Post (N=207) N or Mean	Post (N=207) % or SD	P Value
# PROC PER HOSP	79.245	34.73	62.903	35.92	<0.0001*
Mean Total Charges	43,577	25,562	41,400	24,004	0.3509
Physician Characteristics					
# PROC PER MD	33.356	17.22	22.473	14.68	<0.0001*
Patient Outcomes					
Complications***					
Discharge Location--Home	235	92.89	184	90.20	0.5816
LOS (Length of Stay)	2.071	1.8166	2.1449	1.8794	0.6865

* denotes statistically significant findings (P < 0.05)

***denotes a redaction to comply with HCUP requirements

NOTE: n=460

The number of procedures per physician declined after the implementation of the NCD (Figure 5). This could reflect either a reduction in the number of procedure performed by physician (i.e.if reimbursement for the procedure declined after the implementation of the NCD). Alternatively, in response to a new funding environment, physicians who had not previous performed DBS may have decided to begin seeing PD patients eligible for DBS and performing the procedure when warranted. For the entire pre period, there were 98 physicians; and for the entire post period, there were 152 physicians.

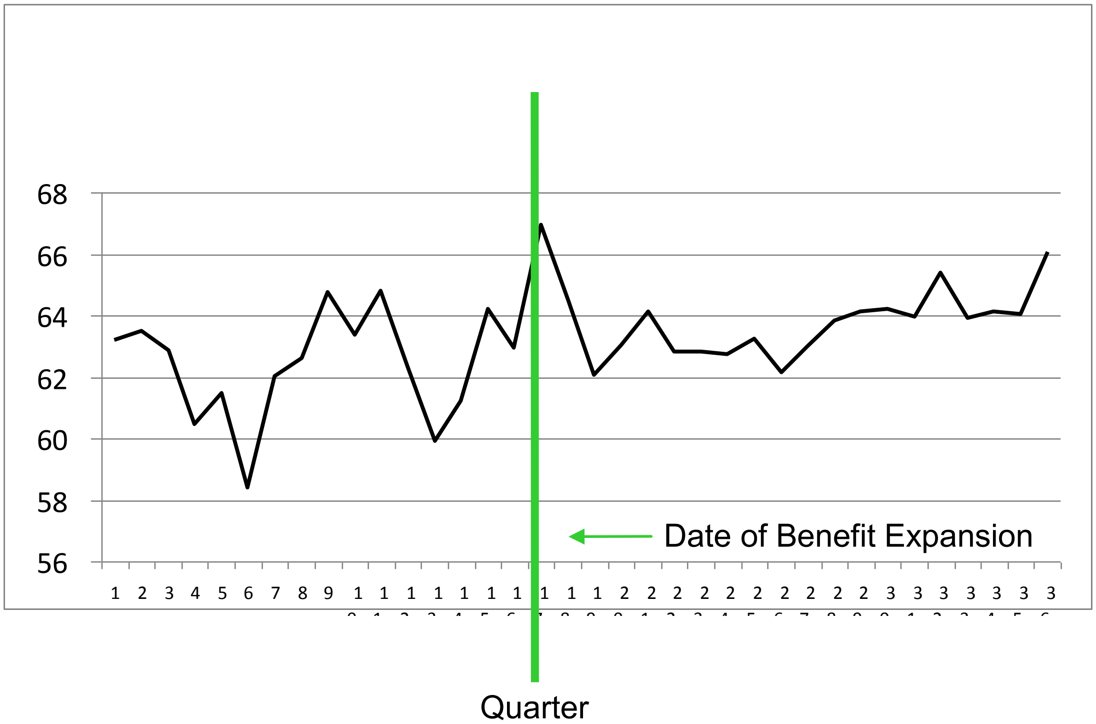

Figure 4. Temporal Trends in Age of Patients Receiving DBS

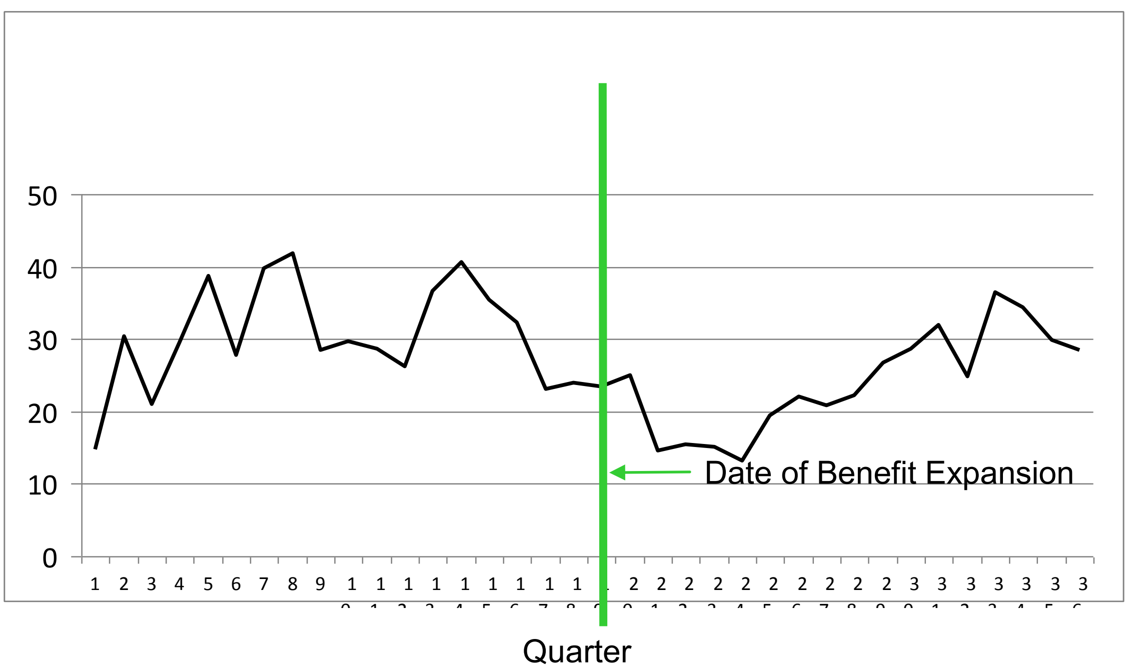

Figure 5: Average Number of Procedures Per Physician

No statistically significant differences were observed by admission types or hospital characteristics except the geographical region where procedures were most likely to be performed. A statistically significant increase in the number of procedures completed in the South was noted ($p < 0.001$). In contrast, fewer procedures were performed in the Midwest in the post period compared to the pre-assessment period. After implementation of the NDC, more procedures were performed in small hospitals compared to the pre-assessment period.

Short Term Multivariate Analysis

Univariate analysis provides limit insights into key determinants of a given outcome. In light of this, the author chose to perform multiple multivariate regression models to assess key determinants of various outcomes of interest. The four outcomes of interest included (1) complication rates post procedure; (2) patient disposition post procedure; (3) length of stay and (4) total charges.

Complication Rates

Multivariate logistic model were used to identify statistically significant factors influencing complication rate (1 = presence of any complication; 0 = no complication) and patient disposition coded to reflect the patient release to either home or long term/short term care. A negative binomial model was used to evaluate variations in patient's length of hospital stay. A negative binomial model was chosen because it does not assume that individuals randomly experience events as the Poisson distribution does (Ellison & Bauchner, 2007). Because of the skewed nature of distributions of cost data, variations in total charges were evaluated using an ordinary least squares model on log transformed cost data.

Data specific to the outcomes of the evaluation seeking a better understanding of factors influencing complication rates are provided in Table 4. It is not surprising that those patients whose baseline clinical characteristics imply greater disease severity as measured by the Charlson co-morbidity score were 1.629 times more likely to have a complication post procedure (OR=1.629, p=0.0369) than healthier counterparts. The Charlson co-morbidity score spans from 1 (low disease burden) to 6 (high disease burden). Dementia would earn one point, for example, whereas someone with a metasticized malignant tumor would earn six points. The scale predicts one year mortality. A score of 1 has an attendant 12% chance of 1 year mortality wheras as score of 5 or 6 has an attendant 85% 1 year mortality (Charlson, Pompei, Ales, & MacKenzie, 1987). A Patient whose surgery was performed in the Midwest also appeared to have about 78% lower chance of complications than patients treated in the Northeast region of the country (OR=0.219, p=0.0356). The data related to the number of procedures performed in a given institution support the "volume theory" discussed in a prior section of this paper. Individuals whose DBS surgery was completed in a high volume institution had better outcomes and slightly fewer—about 1%-- complications (OR=1.009, $p < 0.0039$).

Table 4

Complications – Short Run Full Sample

Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.010	0.976 – 1.045	0.5767
FEMALE	1.030	0.569 – 1.864	0.9231
INCOME ≤$44,999	0.765	0.409 – 1.434	0.4036
MEDICAID	3.934	0.741 – 20.895	0.1079
MEDICARE	1.145	0.556 – 2.360	0.7132
ERTYPE	3.971	0.637 – 24.766	0.1398
CHARLSON	1.629	1.030 – 2.576	0.0369*
MIDWEST	0.219	0.053 – 0.903	0.0356*
SOUTH	0.555	0.232 – 1.327	0.1855
TEACHING HOSPITAL	1.151	0.457 – 2.902	0.7649
BEDSIZE MEDIUM	0.860	0.099 – 7.479	0.8911
# TOTAL HOSP DISCH.	1.00	1.000 -- 1.000	0.2192
#DBS PROC IN HOSP	1.009	1.003 – 1.016	0.0039*
MEDREIMB	1.043	0.584 – 1.863	0.8870

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=911

Short term complication studies were also conducted on a data set that not only included the factors considered in the above study, but also included physician specific data related to the number of procedures a given physician performed over a specific period of time. Discussion exists as to whether a logistic model or hierarchical model is best to assess the influence of physician practice nested within a given institution. Therefore, the results of the logistic models are presented here and hierarchal models specifications are presented in a subsequent section of the paper.

Table 5 provides a summary of the outcomes of logistic data model when consideration is also given to physician procedure volume. Based upon the outcome of the assessment, three determinants of complication rates were revealed. These three determinants suggest that patients enrolled in the Medicaid program who undergo DBS are 10.541 times more likely to have complications (OR=10.541, p=0.0259) than those with private insurance. What is not known is whether the observed effect is due to the payer type or the underlying baseline clinical characteristics of the patient population. Medicaid by its mission is responsible for supporting the provision of can for underserved populations. Patients receiving care in institutions located in both the Midwest and South were about 87% and 83% less likely to have complications (OR=0.129, p=0.0251) and (OR, 0.168, p=0.0268), respectively.

Table 5

Complications - Short Run Including Physician Practice Volume

Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	0.966	0.907 – 1.030	0.2917
FEMALE	2.052	0.705 – 5.972	0.1872
INCOME ≤ $44,999	0.974	0.319 – 2.971	0.9628
MEDICAID	10.541	1.328 – 83.670	0.0259*
MEDICARE	1.344	0.346 – 5.226	0.6694
ERTYPE	1.379	0.090 – 21.196	0.8175
CHARLSON	0.580	0.153 – 2.196	0.4229
MIDWEST	0.129	0.022 – 0.774	0.0251*
SOUTH	0.168	0.035 – 0.815	0.0268*
TEACHING HOSPITAL	0.915	0.084 – 9.928	0.9420
BEDSIZE MEDIUM	2.848	0.217 – 37.439	0.4259
TOTAL DISCH PER HOSP	1.000	1.000 – 1.000	0.0272*
# DBS PER HOSP	0.979	0.957 – 1.002	0.0674
# DBS PER MD	1.015	0.975 – 1.056	0.4737
MEDREIMB	0.671	0.181 – 2.491	0.5515

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=460

Patient Disposition

The second outcome of interest in the evaluation was patient disposition. For this evaluation, categorical variables are used to define patients whose disposition post hospital stay is either to home or into a short term/long term facility. Like before the evaluation is conducted using data which does not take into account physician variables (Table 6) and then another that does consider physician effects (Table 7).

When physician effects are not considered, the results of the study reveal five factors related to the patient post hospital disposition (Table 6). The first factor identified was payer type. Medicaid beneficiaries are 9.97 times more likely to be released to care settings other than home (OR =9.967, p=0.0008). The same effects were observed with Medicare beneficiaries who were 2.7 times more likely to be released to care settings other than home (OR=2.704, p=0.0053). These results are intuitive given the fact that both Medicaid and Medicare programs funded rehabilitation type care as part of their beneficiary programs. Therefore, the cost to families for extended care services for individuals served by Medicaid and Medicare are relatively low. As seen previously, the patient's co-morbidity score is also correlated with a 1.63 times increased probability of the patient being discharge to an extended care facility (OR=1.626, p=0.0145). In contrast to trends observed in prior evaluations, patients receiving surgery in the West were also less likely by 84% to to be released to an extended care facility compared to someone in the Northeast (OR =0.159, p=0.0005.)

Table 6

Patient Disposition – Short Run Full Sample Without Physician Volume Variable

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.030	1.000 – 1.061	0.0517
FEMALE	0.923	0.561 -- 1.518	0.7530
INCOME ≤ $44,999	0.615	0.367 – 1.030	0.0648
MEDICAID	9.967	2.602 – 38.175	0.0008*
MEDICARE	2.704	1.343 – 5.444	0.0053*
CHARLSON	1.626	1.011 – 2.402	0.0145*
ANYCOMP	2.846	1.392 – 5.817	0.0041*
MIDWEST	0.412	0.159 – 1.065	0.0672
WEST	0.159	0.057 – 0.444	0.0005*
SOUTH	0.435	0.161 – 1.177	0.1010
TEACHING HOSP	1.744	0.785 – 3.728	0.1766
BEDSIZE SMALL	0.227	0.046 - 1.116	0.0681
BEDSIZE MEDIUM	0.585	0.162 – 2.112	0.4134
TOTAL DISCH / HOSP	1.000	1.000 - 1.000	0.03333*
# DBS / HOSP	1.000	0.995 – 1.005	0.9965
MEDREIMB	1.343	0.823 – 2191	0.2380

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=911

When physician variables were included in the model, discharge status outcomes (Table 7) remain consistent that those previously observed for Medicaid. That is, Medicaid beneficiaries were 50.35 times more likely to be released to extended care than those with private insurance as the primary payer (OR =60.348, p<0.0001); and Medicare beneficiaries were 4.12 times more likely to be released to extended care than those with private insurance as the primary payer (OR =4.115, p=0.0322). Region in which care is provided also influence patient discharge status with patients receiving care in the South 88% less likely to be discharged to home (OR=0.114, p=0.0139). Hospital characteristics were also observed to influence discharge disposition. As noted previously, the volume theory for hospitals is also implicated in the current analysis. Hospitals doing more procedures have patients who are more 2% more likely to be discharged to home and less likely to require additional care (OR= 0.981, p=0.0456). Patients were more 3.67 times more likely to be discharged to short/long term care after the implementation of the NCD (OR=3.671, p=0.0249); and patients who received care from physicians performing numerous procedures were 1.05 times more likely to be released to home (OR=1.051, p=0.0057). It is feasible that these to observations may be linked. If reimbursement increased after the NCD, more inexperienced physicians may elect to perform the procedure. If the physician is not experienced with the procedure, it is feasible that the outcomes could be less favorable.

Table 7

Patient Disposition – Short Run with Physician Variable

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.020	0.968 – 1.075	0.4487
FEMALE	1.339	0.627 —3.120	0.4126
INCOME ≤ $44,999	0.933	0.411 – 2.119	0.8686
MEDICAID	60.348	9.473 – 384.458	<0.0001*
MEDICARE	4.115	1.127 – 15.018	0.0322*
CHARLSON	0.874	0.3679 – 2.017	0.7523
ANYCOMP	0.908	0.149 – 5.555	0.9172
MIDWEST	0.985	0.275 – 3.524	0.9812
WEST	0.123	0.009 – 1.691	0.1172
SOUTH	0.114	0.020 – 0.643	0.0139*
TEACHING HOSPITAL	0.544	0.107 – 2.768	0.4634
BEDSIZE SMALL	0.819	0.074 – 9.083	0.8708
BEDSIZE MEDIUM	1.385	0.191 – 10.066	0.7477
TOTAL DISCH / HOSP	1.000	1.000 -- 1.000	0.2830
# DBS PER HOSP	0.981	0.963 – 1.000	0.0456*
# DBS PER PHYSICIAN	1.051	1.015 – 1.089	0.0057*
MEDREIMB	3.671	1.178 – 11.441	0.0249*

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=460

Length of Stay

The third outcome model evaluates variations in the average length of hospital stay for PD patients undergoing DBS. When physician variables are not considered (Table 8), several factors emerge as potential determinants of average length of hospital stay. Those positively associated with increased length of stay include patient age where a change in one year of age is associated with a 0.014 increase in length of stay (0.01404, p=0.0031); a Medicare beneficiary where Medicare as payer is associated with a 0.2142 day longer length of stay (0.2142,p=0.0045); a change of 1 in a patient's co morbidities score is associated with a 0.1684 day increase in length of stay (0.1684, p=0.0018); and a patient experiencing procedural complications is associated with a 0.613 day longer length of stay (0.6183, <0.0001); and receiving care at a teaching hospital is associated with a 0.7288 day longer length of stay (0.7288, p=0.0001) . Patients receiving care in the Midwest tended to have a shorter length of stay by .39 days (-0.3991, p=0.0035) as did those receiving DBS in small, by .67 days (-0.6706, p=0.0003) and medium, by .71 days, sized hospitals (-0.7103, p=<0.0001).

Table 8

Length of Stay – Short Run without Physician Variable

Variable	Estimate	Chi Square	P-Value
INTERCEPT	-0.1677	0.38	0.5379
AGE	0.01404	8.77	0.0031*
FEMALE	0.0513	0.71	0.4011

Table 8 Continued

Variable	Estimate	Chi Square	P-Value
INCOME ≤ $44,999	-0.0882	1.99	0.1583
MEDICAID	0.1396	0.39	0.5310
MEDICARE	0.2142	8.08	0.0045*
ERSOURCE	0.4794	0.36	0.5471
ERTYPE	-0.8401	1.38	0.2407
CHARLSON	0.1684	9.75	0.0018*
ANYCOMP	0.6183	34.35	<0.0001*
MIDWEST	-0.3991	8.55	0.0035*
WEST	-0.1459	1.13	0.2884
SOUTH	0.1607	1.29	0.2554
TEACHING HOSPITAL	0.7288	56.13	0.0001*
BEDSIZE SMALL	-0.6706	13.00	0.0003*
BEDSIZE MEDIUM	-0.7103	17.60	<0.0001*
TOTAL HOSP DISCH	0.0000	3.82	0.0506
# DBS PER HOSP	-0.0007	1.32	0.2507
MEDREIMB	-0.0154	0.06	0.7989

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=911

Table 9 describes the results for the length of stay variable in the short term when physician influence is considered. There are 10 determinants of length of stay: female, positively associated with length of stay where being femaile is associated with 0.1809 of a day longer stay in the hospital(0.1809, p=0.0123); Medicare as payer, positively associated with length of stay where the result is a 0.3462 of a day longer stay in the hospital (0.3462, p=0.0002); Emergency room as the admission source, positively associated with length of stay where the result is 1.9 more days in the hospital (1.9383, p=0.0235); Midwest region, negatively associated with length of stay where the result is 0.2954 fewer days in the hospital (-0.2954, p=0.0215); West region, negatively associated with length of stay where the result is 1.01 fewer days in the hospital (-1.0111, p=<0.0001); South region, negatively associated with length of stay where it is associated with 0.0588 fewer days in the hospital (-0.05882, p<0.0001); small bedsize, negatively associated with 0.7499 fewer days in the hospital (-0.7499, p=0.0001); number of procedures per physician, positively associated with a 0.0165 of a day longer length of stay (0.0165, p<0.001); and receiving the procedure after the benefit expansion, positively associated with a 0.2888 of a day longer length of stay (0.2888, p=0.0001).

Table 9

Length of Stay –Short Run with Physician Variable

Variable	Estimate	Chi Square	P-Value
INTERCEPT	1.2603	13.28	0.0003*
AGE	-0.0044	0.94	0.3317
FEMALE	0.1809	6.26	0.0123*
INCOME ≤ $44,999	0.0045	0.00	0.9504
MEDICAID	0.3420	3.03	0.0817
MEDICARE	0.3462	13.51	0.0002*

Table 9 Continued

Variable	Estimate	Chi Square	P-Value
ERSOURCE	1.9383	5.13	0.0235*
ERTYPE	-0.9464	1.49	0.2224
CHARLSON	0.0672	0.87	0.3522
ANYCOMP	0.2211	1.65	0.1989
MIDWEST	-0.2954	5.29	0.0215*
WEST	-1.0111	15.76	<0.0001*
SOUTH	-0.5882	17.85	<0.0001*
TEACHING HOSPITAL	0.0763	0.32	0.5732
BEDSIZE SMALL	-0.7499	14.81	0.0001*
BEDSIZE MEDIUM	-0.2624	2.62	0.1053
TOTAL HOSP DISCH	-0.0000	27.49	<0.0001*
# DBS PER HOSP	-0.0000	0.00	0.9931
# DBS PER PHYSICIAN	0.0165	41.93	<0.0001*
MEDREIMB	0.2888	10.68	0.0001*

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=460

The fourth outcomes model is the log of total charges. Table 10 reveals the results for this model in the short run full sample. Several variables were determinants of total charges. First, contrary to intuition, increased age was negatively associated with total charges where a one year change in age was associated with a 0.00769 decrease in the log of total charges (-0.00769, p=0.0161). The same negative effect was observed with the total number of discharges per hospital where one discharge was associated with a very small decrease in the log of total charges (-0.00001101, p<0.001). This later observation may again be related to the volume effect discussed in earlier sections of the paper. The remaining six variables were positively related to total charges and placed upward pressure on the log of total charges. Individuals who were sicker as defined by the Charlson co-morbidity index (0.12757, 0.0224), those admitted through the emergency department (1.21208, p=0.0495) and Medicaid beneficiaries (0.50769, 0.0078) were more likely to have high charges associated with their treatment program. Each of these variables may signal a high level of patient acuity prior to the procedure. Regional variations were also observed in an examination of total charges was conducted. Patients receiving care in the Midwest were associated with a 0.2471 increase in log of total charges (0.24718, p=0.0439); and in theWest were associated with a 0.8528 increase in the log of total charges (0.85280, p>0.0001) and thus all were more likely to have more expenses incurred in their treatment as defined by total charges. It is known, however, that total charges may not always be perfectly correlated with the total cost of care and are probably inflated in excess of the total actual cost. Patients receiving care through a teaching institution were also likely to have greater total charges than those receiving care elsewhere where teaching institution was associated with a 0.9586 increase in log of total charges (0.95688, <0.0001).

Table 10

Log Total Charges –Short Run Full Sample

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INTERCEPT	10.14	40.96	<0.0001*
AGE	-0.00769	-2.41	0.0161*
FEMALE	0.05881	1.04	0.2966

Table 10 Continued

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INCOME ≤ $44,999	-0.02737	-0.49	0.6222
MEDICAID	0.50769	2.67	0.0078*
MEDICARE	0.06968	1.07	0.2858
ER SOURCE	1.21208	1.97	0.0495*
ER TYPE	-0.44346	-0.82	0.4115
CHARLSON	0.12757	2.29	0.0224*
ANY COMPLICATIONS	0.06182	0.56	0.5728
MIDWEST	0.24718	2.02	0.0439*
WEST	0.85280	6.46	<0.0001*
SOUTH	-0.02885	-0.23	0.8187
TEACHING HOSPITAL	0.95688	11.3	<0.0001*
BEDSIZE SMALL	0.22712	1.45	0.1481
BEDSIZE MEDIUM	-0.16277	-1.23	0.2175
TOTAL DISCH / HOSP	-0.00001101	-3.96	<0.0001*
# DBS PER HOSP	0.00090568	1.75	0.0805
MEDREIMB	-0.05454	-1.00	0.3186

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=911

Table 11 reveals the results for the log of total charges model in the short term when physician influence is also considered. All of the variables included in the prior analysis with the exception of co-morbidities as measured by the Charlston index. In contrast to the prior evaluation, other factors seem to be related to overall total charges. Patients receiving care in small hospitals were associated with a 0.8720 decrease in log of total charges (-0.87200, p<0.001) and in medium hospitals were associated with 0.4908 decrease in log of total charges (-0.49083, p=0.0030) and thus these hospitals were less likely to incur additional charges compared to large hospitals. The number of DBS procedures per hospital were associated with a 0.0073 decrease in log of total charges (0.00738, p<0.0001); and number of DBS procedures per doctor were associated with a 0.0087 increase in log of total charges (0.00870, p=0.008) and thus were both positively associated with total charges which could indicate adverse selection of a sicker patient population for those hospitals and physicians who had reputations for doing DBS procedures. Total charges, in 2003 dollars, after the benefit expansion were also higher (0.19985, p=0.0240).

Table 11

Log Total Charges –Short Run With Physician Variable

Variable	Parameter Estimate	t-Statistic	P-Value
INTERCEPT	9.49785	25.92	<0.0001*
AGE	-0.01008	-2.17	0.0306*
FEMALE	0.07764	1.00	0.3155
INCOME ≤ $44,999	0.07651	1.02	0.3093
MEDICAID	0.36130	1.68	0.0936
MEDICARE	-0.03356	-0.36	0.7204
ER SOURCE	3.69375	4.08	<0.0001*
ER TYPE	-1.82052	-2.26	0.0242*
CHARLSON	0.13320	1.73	0.0846
ANY COMPLICATIONS	0.24265	1.21	0.2285
MIDWEST	0.45576	2.93	0.0035*
WEST	0.57981	2.29	0.0227*
SOUTH	0.19538	1.20	0.2299
TEACHING HOSPITAL	1.98962	13.84	<0.0001*

Table 11 Continued

Variable	Parameter Estimate	t-Statistic	P-Value
BEDSIZE SMALL	-0.87200	-4.15	<0.0001*
BEDSIZE MEDIUM	-0.49083	-2.98	0.0030*
TOTAL DISCH / HOSP	-0.00003660	-8.63	<0.0001*
# DBS PER HOSP	0.00738	5.30	<0.0001*
# DBS PER PHYSICIAN	0.00870	3.39	0.0008*
MEDREIMB	0.19985	2.26	0.0240*

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=911

Long Term Evaluation

The prior analysis looked at changes in key variables 1 year before and after the implementation of the NCD. The research question evaluated was to determine if patient demographic characteristics, hospital characteristics, physician characteristics, or patient outcome variables changed in the short run. Short-term patient outcomes were defined by complication rates, average length of hospital stay, disposition to care settings other than home and total charges in 2003 Dollars.

These overall study objectives are revisited in the following section of the paper. The primarily difference between the prior work and that which is about to be described can be found in the fundamental assumption that sometimes short term changes in patient outcomes are not consistent with the outcomes seen in the long term. Short term changes may be more or less positive as new hospitals and physicians enter into the market with less experience in conducting the procedures. The long term evaluation, which excludes the period assessed during the short term, could give a more reflective assessment of changes in patient outcomes when short term variances are removed.

As before, univariate statistics were used to evaluate any variations in the sample population before and after implementation of the NCD. Those results are presented in Table 12. While males in their middle sixties were still most likely to have DBS, the acuity of the patients receiving the procedure had significantly changes over time ($p < 0.0001$) and more procedures were being funded by Medicare and fewer procedures funded by private insurers ($p < 0.0010$). While regional variations did not reveal themselves to be important factors when comparing pre long term data to post long term data, there were significantly fewer cases performed in the long-term post period compared to the long-term pre period. This effect is not unexpected given the guidance provided into the NCD as to the inclusion and exclusion criteria that would be used to support the funding decision. In the longer term, complication rates improved ($p = 0.0267$) and the average length of stay declined (0.0065).

Table 12

Long Term Pre-/Post- Analysis Subsample

Variable	Pre (N=413)		Post (N=720)		P Value
	N or Mean	% or SD	N or Mean	% or SD	
Patient Characteristics					
Female	136	32.93	247	34.31	0.6375
AGE	62.605	11.025	64.603	10.321	0.0020*
CHARLSON	0.1477	0.4351	0.2903	0.5757	<0.0001*
Income <$45,000	198	49.62	312	44.70	0.1156
PAYER					0.0010*
Medicare	240	58.11	490	68.06	
Medicaid	11	2.66	14	1.94	

Table 12 Continued

Variable	Pre (N=413)		Post (N=720)		P Value
	N or Mean	% or SD	N or Mean	% or SD	
Patient Characteristics					
Private/incl HMO	153	37.05	196	27.22	
Other Insurance***					
Admission & Hospital Characteristics					
Admission Source***					
Emergency Room***					
Another Hosp***					
Long Term Care & Other***					
Ambulatory	401	97.80	688	97.31	
Admission type					
Emergency***					
Urgent	13	3.15	30	4.17	
Elective	396	95.88	678	94.17	
Region of Country					<0.001*
Northeast	62	15.01	112	15.56	
Midwest	93	22.52	79	10.97	
South	174	42.13	350	48.61	
West	84	20.34	179	24.86	
Teaching Hospital	331	80.15	566	78.61	0.5405
No. of Beds					<0.001*
Small	36	8.72	24	3.33	
Medium ***					
Admission & Hospital Characteristics					
Large (x-y beds)	368	89.10	623	86.53	
Hospital Discharges	30559	12498	35393	18669	<0.0001*
# Procedures/Hospital	50.867	29.662	40.165	26.696	<0.0001*
Mean Total Charges	44,671	30,811	44,415	30,811	0.8850
Physician Characteristics					
Number of Procedures/MD	29.777	17.91	23.607	17.685	<0.001*
Patient Outcomes					
Complications	35	8.47	37	5.14	0.0267*
Discharge to Home	381	92.25	664	92.22	0.9937
Average Length of Stay	2.8281	6.2835	1.9458	2.5059	0.0065*

denotes statistically significant findings (P < 0.05)
***denotes redaction to comply with HCUP requirements

Determinants of Short vs Long Term Complication Rates

One of the research questions originally proposed for the existing endeavor is whether variations were observed in the short run compared to the long run. Each of these tables below represents variations observed across time. The results of the long run statistical analysis are provided in the Appendices for reader review. Table 13 provides of summary of the variations observed over time specific to the analysis of changes in complication rates and key determinants of those complications. The second and third columns compare short term and long term analysis when physician variables are not included. Columns four and five should the outcomes of the results in physician variables are incorporated into the evaluation.

Table 13

Short Run vs Long Run Complications With and Without Physician Variance

	SR Without MD	LR Without MD	SR With MD	LR With MD
AGE				
FEMALE				
INCOME ≤$44,999				
MEDICAID			**	
MEDICARE				
ERTYPE				
CHARLSON	**	**		**
MIDWEST	**	**	**	**
SOUTH			**	**

Table 13 Continued

	SR Without MD	LR Without MD	SR With MD	LR With MD
TEACHING HOSPITAL				
BEDSIZE MEDIUM		**		
# TOTAL HOSP DISCH.			**	
#DBS PROC IN HOSP	**			
# Procedures/Physician				
MEDREIMB		**		**

** denotes statistically significant findings (P < 0.05)

Similarities were observed when comparing the short and long term. As would be anticipated patients with higher levels of acuity tend to have more complications with any procedure. While the improvements in care in Midwest institutions may be superior from a statistical standpoint, the actually improvement of Midwest institutions compared to the care provided in other region of the national may be clinically less meaningful. Addition research, however, to examine the geographic variations observed in this evaluation deserve merit of future consideration.

Determinants of Short vs Long Term Discharge Disposition Types

Most cases of DBS are done on patients who are admitted to the hospital voluntarily and whose disposition is to home for recovery. The comparison outline evaluates whether the short term disposition rates and significantly different than the long term rates. From a theoretical standpoint, Medicare funding post-acute care for beneficiaries and therefore in the Medicare population it is more likely that patients will be discharge to post acute care settings other than home. Table 14 presents these comparisons. The data used to populate the table can be found either in a prior section of the paper or in the Appendices.

Table 14

Short Run vs Long Run Disposition Rates With and Without Physician Variance

	SR Without MD	LR Without MD	SR With MD	LR With MD
AGE		**		**
FEMALE		**		**
INCOME ≤ $44,999				
MEDICAID	**	**	**	**
MEDICARE	**	**	**	
CHARLSON	**	**		
ANYCOMP	**	**		**
MIDWEST				
WEST	**			
SOUTH			**	
TEACHING HOSP				
BEDSIZE SMALL		**		
BEDSIZE MEDIUM				**
TOTAL DISCH / HOSP				**
# DBS / HOSP			**	
# Procedures/Physician			**	
MEDREIMB			**	

** denotes statistically significant findings ($P < 0.05$)

Across both time periods, payer type is a significant determinant of whether a patient is discharged home or not. Beyond this one finding, no other significant finding are immediately observable in the data presented related to discharge status.

Determinants of Short vs Long Term Length of Stay

Table 15 presents data related to variations between the average length of stay for patients undergoing DBS for PD. Appendix F and G provide data related to long term outcomes and short term outcome data are presented in prior sections of the paper, but summarized below.

Table 15

Short Run vs Long Run Length of Stay With and Without Physician Variance

	SR Without MD	LR Without MD	SR With MD	LR With MD
AGE	**	**	**	**
FEMALE		**		
INCOME ≤ $44,999				
MEDICAID			**	
MEDICARE	**		**	
ER TYPE				
CHARLSON				**
ANY COMPLICATIONS	**	**		**
MIDWEST	**	**	**	**
WEST	**	**	**	
SOUTH		**	**	**

Table 15 Continued

	SR Without MD	LR Without MD	SR With MD	LR With MD
TEACHING HOSPITAL		**		**
BEDSIZE SMALL	**	**	**	**
BEDSIZE MEDIUM	**	**		**
TOTAL DISCH / HOSP	**	**	**	
# DBS PER HOSP		**		**
#DBS per MD			**	**
MEDREIMB		**	**	**

** denotes statistically significant findings (P < 0.05)

Several factors were consistent with respect to increase the patient's length of stay in both the short run and the longer term. Such factors included items such as complication rates and patient age.

Determinants of Short vs Long Estimated Expenditures per Procedure

Table 16 presents data related to variations between the average expenditure for patient services in both the short and long term. While not ideal, expenditures are denoted in terms of patient charges. Actual costs per hospital stay are expected to be lower than the amounts provided below.

Factors in both the short run and long run that were related to changes in total hospital expenditures, defined as charges, included the patient presenting status to the hospital, hospitals located in western regions, teaching affiliation and bedside. Medicare reimbursement was also a consistent factor influencing the variations in patient expenditures in both times periods.

Table 16

Short Run vs Long Run Total Hospital Charges With and Without Physician Variance

	SR Without MD	LR Without MD	SR With MD	LR With MD
AGE	**		**	
FEMALE				
INCOME ≤ $44,999				
MEDICAID			**	
MEDICARE				
ER TYPE	**	**	**	
CHARLSON				
ANY COMPLICATIONS			**	
MIDWEST	**			
WEST	**	**	**	**
SOUTH			**	
TEACHING HOSPITAL	**	**		**
BEDSIZE SMALL	**	**	**	**
BEDSIZE MEDIUM	**			**
TOTAL DISCH / HOSP	**			**
# DBS PER HOSP	**		**	
#DBS per MD				
MEDREIMB	**	**		**

** denotes statistically significant findings ($P < 0.05$)

CHAPTER 5

HIERARCHICAL SPECIFICATION

Hierarchical Modeling of Nested Data

When patients or providers can be associated with a given hospital, the patient and/or provided is sometimes termed to be nested with the hospital. This can proposal some unique challenges to tradition statistical models. In light of this consideration, the author chose to summarize findings across hierarchical models that were used to assess key determinants of patient outcomes while taking into accounting that nesting is most likely occurring in the available data source. Several other reports of individuals statistical output when hierarchical models are apply to the short term sample with and without physician influence are available for the readers review in the Appendices of this research report. Table 17 shows descriptive statistics over four time periods with the time periods annualized for comparison. The information presented immediately below focuses on trends observed in the hierarchical models over time.

Table 17

Full Sample Annualized Frequencies and Means over Four Time Periods

Variable	PreLong		PreShort		PostShort		PostLong	
	Freq	% or Mean	Freq	% or Mean	Freq	% or Mean	Freq	% or Mean
Sex								
Male	200.00	67.49	426	94.25	294	65.33	272	67.24
Female	96.33	32.51	26	5.75	156	34.67	133	32.76
Income								
≤ $44,999	158.00	53.32	281	62.17	287	62.53	258	61.53
≥ $45,000	138.33	46.68	171	37.83	172	37.47	161	38.47
`Primary Payor								
Medicare	78.33	60.18	287	63.50	291	63.40	278	68.82
Other	118.00	39.82	165	36.51	159	34.64	127	31.18
Region for Hosp								
NEast	28.00	9.45	24	5.31	31	6.75	47	11.15
Midwest	74.00	24.97	162	35.84	70	15.25	47	11.15
South	96.33	32.51	135	30.00	212	46.19	161	38.40
West	98.00	33.07	131	28.98	146	31.81	165	39.29
Teaching Hosp								
Non Teaching	38.67	13.05	90	19.91	61	13.29	61	14.46
Teaching	257.67	86.95	362	80.09	398	86.71	358	85.54

Table 17 Continued

Variable	PreLong		PreShort		PostShort		PostLong	
	Freq	% or Mean	Freq	% or Mean	Freq	% or Mean	Freq	% or Mean
Any Complications								
False	275.33	92.91	426	94.25	429	93.46	398	95.10
True	21.00	7.09	26	5.75	30	6.54	21	4.90
Discharge Loc.								
STC/LTC/ Died	24.67	8.32	35	7.76	52	11.40	33	7.77
Home	271.67	91.68	416	92.24	404	88.60	386	92.22
Age	62.55	10.62	62.88	9.72	63.49	9.97	64	9.92
Charlson (Range 0 = low severity to 6 = high severity)	0.16	0.46	0.2079	0.46	0.2352	0.53	0.26	0.54
# Disch/Hosp	26030	10991.87	33531	16836.86	29552	14947.95	30618	15137.79
#DBS/Hosp	83	59.17	99.73	54.35	98.82	66.87	59	56.35
LOS	2.66	2.66	2.38	2.47	2.81	4.69	2.17	2.99
Total Charges/Patient	43361.87	26704.56	46709.03	31336.97	45628.02	25524.22	48196.61	29463.00

Determinants of Complication Rates

Table 18 describes the factors indicated as being statistically significant determinants of complication rates when the data were assessed using hierarchical logistic regression across all four time periods: prelong (January 1, 1999 through March 31, 2002); preshort (April 1, 2002 through March 31, 2003); postshort (April 1, 2003 through March 31, 2004); and postlong (April 1, 2004 through December 31, 2007). This data reflect the sample population that does not include physician variables.

Table 18

Complications—Full Sample with Four Time Periods

Hierarchical Logistic Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
INTERCEPT			0.0005
AGE	0.993	0.976—1.010	0.4306
FEMALE	1.263	0.928—1.719	0.1378
INCOME ≤ $44,999	0.923	0.668—1.276	0.6295
MEDICAID	2.550	1.082—6.009	0.0323*
MEDICARE	1.161	0.800—1.685	0.4320
ER SOURCE	3.787	0.958—14.960	0.0575
ER TYPE	1.449	0.567—3.708	0.4384

Table 18 Continued

Variable	Odds Ratio	95% Confidence Interval	P-Value
CHARLSON	1.624	1.286—2.050	<0.0001*
MIDWEST	0.296	0.159—0.552	0.0001*
SOUTH	0.434	0.246—0.766	0.0040*
WEST	0.505	0.291—0.875	0.0148*
TEACHING HOSPITAL	1.155	0.663—2.014	0.6111
BEDSIZE MEDIUM	1.781	0.917—3.461	0.0886
# DBS PER HOSP	1.003	1.000—1.006	0.0603
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.3850
PRESHORT	0.776	0.467—1.288	0.3264
POSTSHORT	0.724	0.455—1.152	0.1731
POSTLONG	0.817	0.508—1.313	0.4040

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=3370

Patient specific characteristics did not appear to be associated with changes in the patients complication rates other than co-morbidity levels as reported by the Charlson index where a one point increase in the Charlson was 1.624 times more likely to have complications (OR 1.624, p<0.0001). Variations in complication rates were observed across geographical regions of the country and tended to be about 70% less likely in the Midwest (OR 0.296, p=0.0001) and 57% less likely in the South South (OR 0.434, p=0.0040). Medicaid beneficiaries also tend to have more complications where Medicaid beneficiaries wehre 2.550 times more likely to have complications (OR 2.550, p=0.0323). The results of the analysis do not change dramatically when physician specific variables are included in the analysis (Table 19).

Table 19

Complications—Subsample with Four Time Periods

Hierarchical Logistic Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
INTERCEPT			0.2803
AGE	0.981	0.957—1.005	0.1164
FEMALE	1.574	1.001—2.475	0.0495*
INCOME ≤ $44,999	0.867	0.538—1.397	0.5577
MEDICAID	3.633	1.197—11.029	0.0228*
MEDICARE	1.732	0.966—3.105	0.0652
ER SOURCE	0.986	0.112—8.670	0.9900
ER TYPE	2.025	0.408—10.052	0.3880
CHARLSON	1.654	1.165—2.348	0.0049*
MIDWEST	0.317	0.143—0.705	0.0048*
SOUTH	0.294	0.143—0.603	0.0009*
WEST	0.626	0.304—1.288	0.2029

Table 19 Continued

Variable	Odds Ratio	95% Confidence Interval	P-Value
TEACHING HOSPITAL	0.910	0.401—2.065	0.8212
BEDSIZE MEDIUM	1.720	0.632—4.686	0.2884
# DBS PER HOSP	0.993	0.983—1.003	0.1775
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.0402*
NUMDOC	0.994	0.980—1.009	0.4502
PRESHORT	0.470	0.203—1.087	0.0776
POSTSHORT	0.967	0.421—2.225	0.9377
POSTLONG	0.382	0.164—0.889	0.0256*

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=1593

Determinants of Discharge Disposition

Models specific to assessing determinants of discharge disposition using hierarchical modeling techniques are presented in Tables 20 and 21. Eight determinants of discharge disposition were reported for the total sample not including physician specific influences (Table 21).

Table 20

Non Death Disposition - Full Sample With Four Time Periods

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
INTERCEPT			<0.001
AGE	1.038	1.020—1.055	<0.001*
FEMALE	1.172	0.894—1.535	0.2502
INCOME ≤ $44,999	0.717	0.540—0.952	0.0216*
MEDICAID	7.345	3.485—15.481	<0.001*
MEDICARE	1.983	1.338—2.940	0.0007*
ERSOURCE	5.367	1.525—18.886	0.0089*
ERTYPE	0.970	0.407—2.315	0.9458
CHARLSON	1.502	1.223—1.844	0.0001*
MIDWEST	0.946	0.527—1.697	0.8520
SOUTH	0.689	0.384—1.238	0.2129
WEST	0.556	0.312—0.993	0.0473*
ANYCOMP	3.388	2.269—5.059	<0.0001*
HTEACH	1.259	0.777—2.040	0.3489
BEDSIZE MEDIUM	1.062	0.592—1.905	0.8408
# DBS PER HOSP	1.000	0.996—0.003	0.8400
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.1595
PRESHORT	0.908	0.565—1.458	0.6892
POSTSHORT	0.681	0.459—1.010	0.0563*
POSTLONG	1.268	0.828—1.942	0.2749

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=3370

Like the results observe in the prior evaluations, discharge disposition is likely to be influenced by payer type. For example, Medicaid beneficiaries are 7.345 times more likely to be discharged to extended care compared to private payers (OR 7.345, $p<0.0001$); and Medicare beneficiaries are 1.083 more likely to be discharged to extended care compared to private payers (OR 1.983, $p=0.0007$). Also, like before, patients were 5.367 times more likely to be discharged to post acute care setting when the Emergency Department was the admission source (OR 5.367, $p=0.0089$); and 1.502 times more likely to be discharged to post acute care when the patient had more co-morbidities upon admission (OR 1.502, $p=0.0001$). Unlike data presented before, patients were also 1.038 times more likely to be discharged to longer term care if they were older (OR 1.038, $p<0.001$) and about 29% less likely to be discharged to longer term care if they had income less than $45,000 (OR 0.717, $p=0.0216$).

Table 20 describes the results for the subsample for non-death disposition using four time periods. There are four determinants for complications: more likely to be older (OR 1.046, $p=0.0008$); more likely to have Medicaid as payer(OR 10.349, $p<0.0001$); more likely to have been admitted through the ER (OR 12.724, $p=0.0101$); and more likely to have experienced complications (OR 4.013, $p<0.0001$).

Table 21

Non Death Disposition – Subsample with Four Time Periods

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
INTERCEPT			<0.001
AGE	1.046	1.019—1.074	0.0008*
FEMALE	1.478	0.986—2.217	0.0586
INCOME ≤ $44,999	0.827	0.542—1.262	0.3777
MEDICAID	10.349	3.972—26.963	<0.0001*
MEDICARE	1.245	0.693—2.236	0.4626
ERSOURCE	12.724	1.832—88.391	0.0101*
ERTYPE	0.524	0.071—3.867	0.5263
CHARLSON	1.247	0.894—1.738	0.1936
MIDWEST	1.360	0.598—3.095	0.4629
SOUTH	0.591	0.266—1.316	0.1976
WEST	0.887	0.388—2.024	0.7749
ANYCOMP	4.013	2.189—7.358	<0.0001*
HTEACH	0.993	0.496—1.987	0.9843
BEDSIZE MEDIUM	0.602	0.233—1.556	0.2949
# DBS PER HOSP	0.993	0.983—1.003	0.1528
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.2303
NUMDOC	1.009	0.993—1.025	0.2579
PRESHORT	0.929	0.448—1.927	0.8432
POSTSHORT	0.725	0.382—1.376	0.3258
POSTLONG	1.520	0.758—3.049	0.2382

* denotes statistically significant findings ($P < 0.05$)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=1593

Determinants of Length of Stay

Tables 22 and 23 describe the outcome length of stay (LOS) using a hierarchical negative binomial model. In table 23, there are five determinants of LOS in the full sample: age, where a one year change in age is associated with a 0.0095 of a day longer hospital stay (0.009513, p<0.0001); ER as source of admission, where this is associated with a 0.7274 of a day longer length of stay (0.7274, 0.0013); having surgery in the West is associated with a 0.3296 of a day shorter length of stay compared to the Northeast (-0.3296, p<0.001); the presence of any complications, where this is associated with a 0.7523 of a day increase in length of stay (0.7523, p<0.001); and having the surgery in the preshort period, 12 months prior to the benefit expansion, is associated with a 0.1215 of a day shorter length of stay (-0.1215, p=0.0486).

Table 23 describes LOS when physician influences are included. In addition geographical variation were observed with shorter lengths of stay in the South, which was associated with 0.3742 of a day shorter hospital stay compared to the Northeast (-0.3742, p=0.0305) and the West, which was associated with 0.4115 of a day shorter hospital stay than the Northeast (-0.4115, p<0.001). As before, complication rates also influence length of stay.

Table 22

Length of Stay - Full Sample with Four Time Periods

Hierarchical Negative Binomial Multivariate Model

Variable	Estimate	t Value	P-Value
INTERCEPT	0.2710	1.13	0.2612
AGE	0.009513	4.80	<0.0001*
FEMALE	0.03997	1.15	0.2515
INCOME $\leq$ $44,999	-0.06635	-1.85	0.0645
MEDICAID	0.2212	1.81	0.0703
MEDICARE	0.05691	1.36	0.1735
ERSOURCE	0.7274	3.22	0.0013*
ERTYPE	-0.2302	-1.62	0.1052
CHARLSON	0.05888	1.89	0.0584
MIDWEST	-0.1792	-1.00	0.3174
SOUTH	-0.2596	-1.48	0.1390
WEST	-0.3296	-1.85	0.0644
ANYCOMP	0.7523	12.39	<0.0001*
HTEACH	0.1397	1.11	0.2675
BEDSIZE MEDIUM	0.07601	0.69	0.4875
#DBS PER HOSP	0.000872	0.67	0.5031
TOTAL DISCHARGES	0.00000117	-0.35	0.7298
PRESHORT	-0.1215	-1.97	0.0486*
POSTSHORT	-0.1432	-2.47	0.0135*
POSTLONG	-0.05430	0.91	0.3646

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=3370

Table 23

Length of Stay –Subsample with Four Time Periods

Hierarchical Negative Binomial Multivariate Model

Variable	Estimate	t Value	P-Value
INTERCEPT	0.3883	1.36	0.1779
AGE	0.009786	3.23	0.0012*
FEMALE	0.05241	0.98	0.3264
INCOME $\leq$ $44,999	-0.01443	-0.27	0.7884
MEDICAID	0.1636	0.96	0.3367
MEDICARE	0.06296	0.95	0.3407
ERSOURCE	0.6926	2.10	0.0357
ERTYPE	-0.2661	-0.93	0.3518
CHARLSON	0.07150	1.49	0.1358
MIDWEST	-0.2462	-1.33	0.1831
SOUTH	-0.3742	-2.17	0.0305*
WEST	-0.4115	-2.13	0.0332*
ANYCOMP	0.7862	8.25	<0.001*
TEACHING HOSPITAL	0.08314	0.61	0.5421
BEDSIZE MEDIUM	0.05620	0.41	0.6807
# DBS PER HOSP	-0.00263	-1.22	0.2208
TOTAL HOSP DISCH	.00000251	-0.72	0.4707
NUMDOC	0.004778	1.95	0.0516
PRESHORT	-0.1801	-1.95	0.0519
POSTSHORT	-0.1334	-1.42	0.1556
POSTLONG	-0.06105	0.64	0.5245

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=1593

Determinants of Hospital Charges

Tables 24 and 25 describe the outcome log of total charges in the full sample and the subsample over four time periods. Table 24 reveals three determinants of log of total charges: Medicaid as the payer, where this was associated with 0.2241 increase in log of total charges (0.2241, p=0.0008); surgery in the West, which was associated with a 0.4297 increase in log of total charges (0.4297, p=0.0087); and teaching hospital status, which was associated with 0.1930 increase in log of total charges (0.1930, p=0.0318). Table 25 describes the outcome log of total charges in the subsample and reveals four determinants that were positively associated with total charges: Medicaid as payer, which was associated with a 0.3365 increase in log of total charges compared to private payers (0.3365, p=0.0003); surgery in the Midwest, which was associated with 0.06533 increase in log of total charges compared to the Northeast (0.06533, p=0.0172); surgery in the West, which was associated with a 0.5494 increase in log of total charges (0.5494, p=0.0391); and number of DBS procedures per physician, where one procedure was positively associated with a 0.0056 increase in long of total charges (0.005611, p=0.0002).

It is interesting to note that for three of the models, the intercept was not significant (complications in the subsample, length of stay in the full sample, length of stay in the subsample). Part of this may be the underlying construct of the data: discontinuous hospital data. Or, it could be that there is substantial stochastic error—which, ironically, the author was trying to decrease by using the hierarchy.

Table 24

Log Total Charges Full Sample with Four Time Periods

Hierarchical Ordinary Least Squares Multivariate Model

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INTERCEPT	10.2161	55.28	<0.001
AGE	-0.00141	-1.30	0.1935
FEMALE	-0.02691	-1.37	0.1708
INCOME ≤ $44,999	-0.01849	-0.93	0.3516
MEDICAID	0.2241	3.34	0.0008*
MEDICARE	0.03176	1.38	0.1667
ER SOURCE	0.1225	0.86	0.3923
ER TYPE	0.004741	0.06	0.9513
CHARLSON	0.02932	1.61	0.1078
MIDWEST	0.05098	0.32	0.0752
SOUTH	0.1320	0.84	0.4027
WEST	0.4297	2.63	0.0087*
ANYCOMP	-0.02787	-0.71	0.4787
TEACHING HOSPITAL	0.1930	2.15	0.0318*
BEDSIZE MEDIUM	-0.06606	-1.04	0.2967
# DBS PER HOSP	-0.00037	-0.29	0.7715
TOTAL DISCH / HOSP	0.000000997	0.39	0.6984
PRESHORT	0.01443	0.40	0.6898
POSTSHORT	0.04545	1.33	0.1847
POSTLONG	0.04646	1.32	0.1865

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=3370

Table 25

Log Total Charges -Subsample with Four Time Periods

Hierarchical Ordinary Least Squares Multivariate Model

Variable	Parameter Estimate	t-Statistic	P-Value
INTERCEPT	10.1633	36.24	<0.0001
AGE	-0.00282	-1.70	0.0901
FEMALE	-0.00348	-0.12	0.9065
INCOME ≤ $44,999	0.000899	0.03	0.9757
MEDICAID	0.3365	3.62	0.0003*
MEDICARE	0.02923	0.81	0.4159
ER SOURCE	0.3067	1.40	0.1604
ER TYPE	-0.1642	-0.94	0.3456
CHARLSON	0.06533	2.38	0.0172*
MIDWEST	0.08437	0.34	0.7324
SOUTH	0.2424	1.04	0.2997
WEST	0.5494	2.06	0.0391*
ANYCOMP	-0.07972	-1.30	0.1922
TEACHING HOSPITAL	0.1144	0.89	0.3716
BEDSIZE MEDIUM	-0.1319	-1.42	0.1546
# DBS PER HOSP	-0.00208	-0.76	0.4485
TOTAL DISCH / HOSP	0.000001143	0.34	0.7376
# DBS PER PHYSICIAN	0.005611	3.70	0.0002*
PRESHORT	0.00076	-0.01	0.9887
POSTSHORT	0.07408	1.34	0.1799
POSTLONG	0.03166	0.56	0.5762

* denotes statistically significant findings (P < 0.05)
NOTE: reference variable for region is the Northeast; reference for bedsize is bedsize large; reference for payers is private pay.
NOTE: n=1593

CHAPTER 6

DISCUSSION AND IMPLICATIONS

National Coverage Decisions implemented by CMS occur after extensive deliberation as to the costs and benefits that may occur to beneficiaries. With many NCDs either pilot programs are run to assesses such benefits or the NCD is implemented with subsequent evaluation of targeted outcomes assessed at a later date. One NCD implemented in 2003 expanded coverage to patients suffering from Parkinson's Disease who may benefit from Deep Brain Stimulation as part of the ongoing management of their disease. To the best knowledge of the author, no economic or clinical assessment as this decision has been reported in the literature. The effort presented in this work sought to address this gap in the literature.

These issues are important to examining whether health policy goals have been met because failing to recognize these complexities could lead to an incorrect assessment of the success or failure of the benefit expansion. In particular, surgically implantable devices in chronic, progressive disease states pose special problems that must be addressed. Failure to recognize and account for these issues can lead to incorrect conclusions in program assessment. This may be of increasing interest as DBS is being developed for more common diseases (such as depression), and this will put more patients, hospitals, physicians, and policymakers in the position of arguing for or against national coverage.

As discussed throughout this document, if a policy-maker were to only look at the initial expenses and outcomes of DBS surgery for Parkinson's disease, a grim picture of poorer outcomes and higher expenses might be observed. But this may be temporary. Over time, the effects of sicker patients and inexperienced facilities or surgeons diminishes and the more accurate effect of the policy on inpatient outcomes would be revealed. In part, this was confirmed by this study as outcomes worsened in the short term, and experienced some improvements in the long term.

Short Term and Long Term Descriptive Results
Full Sample and Subsample

The short term full sample revealed four variables that differed in the short term pre and post periods: region, teaching status, bedsize, and number of discharges. Generally, these are consistent with the hypotheses. That is, more or different hospitals began offering the procedure, and many of those were teaching hospitals. A greater percentage of hospitals in the post period were smaller. The number of discharges per hospital went down in the post period, which is consistent with smaller hospitals beginning to offer the procedure.

The short term subsample is largely consistent with differences shown above for region, teaching status, bedsize, and number of discharges. However, this sample shows that the post period number of procedures per hospital is lower whereas this was not significant in the full sample—although numerically the number of procedures was lower—it is not a large magnitude. Additionally, the subsample offers a variable not available in the full sample and that is the physician volume. This sample reveals that the mean number of procedures per physician is lower in the post period. This is consistent with more physicians entering into the DBS field thus putting downward pressure on the mean number of procedures per physician.

The variable for co-morbidity burden did not differ pre and post as expected, although in both samples the burden is numerically higher in the post period, although not significantly. Age also did not differ pre and post in either sample, although both samples showed numerically higher ages in the post period, which were not significant.

The long term full sample revealed 11 variables that differed pre and post: income (lower income post); payer, (greater percentage of Medicare post and smaller percentage of private payer post); more procedures in the south post; more medium sized hospitals and fewer large hospitals post; more complications post; older post; higher co-morbidity burden post; more hospital discharges post; fewer procedures per hospital post; and shorter length of stay post.

The long term subsample was largely consistent with the full sample except that income, admission source, and admission type no longer showed differences. All others were consistent with the full sample in direction and significance. Additionally, the subsample provides an additional variable, physician volume. This variable differs with fewer procedures per physician in the post period. This is consistent with the view that newer physicians would be attracted to the procedure, and they would do fewer procedures.

In general, it was expected that the long term analyses would reveal few differences. Instead, patients appear to remain older and sicker throughout the long term post period—probably due to the skewed age of the new Medicare eligible patients. Additionally, the length of stay variable went down over the same period. This may be due to changes in treatment patterns that shortened hospital stays for surgery, in general.

Original Specification Multivariate Results

The short term full sample and subsample offer relatively few determinants of complications, perhaps because complications are rare in this population. The largest magnitude predictor was in the short term and it was Medicare as the payer, which was over 10 times more likely to experience complications compared to privately insured. In general, Medicaid is generally for non-working people, and they may be non-working because they are disabled or too sick to work.

The long term full sample for complications reveals a patient is more likely to experience complications in the long term pre period. This was expected because, over time, physician and hospital experience may improve outcomes. The long term subsample, determinants included region and bedsize, but also included that the patient was more likely to have a higher co-morbidity burden, and less likely to have the procedure after the benefit expansion. This is consistent with the hypothesis that, over time, complication rates would drop after the first twelve months.

The short term full sample and subsample for non-death disposition reveals five determinants in the full sample and six determinants in the subsample. Region was a predictor for both samples, although West was significant in the full sample and South was significant in the subsample. The subsample revealed different hospital and physician variables to be predictive. For example, number of DBS procedures per hospital was less likely to result in discharge to a long or short term facility. However number of DBS procedures per physician was slightly more likely to be discharged to a long or short term facility. Lastly, if the surgery was performed in the 12 months after the benefit expansion, the patient was more likely to be discharged to long or short term care rather than home.

This is consistent with the hypothesis that outcomes may be worse in the immediate 12 months after a benefit expansion.

In the long run, although there are determinants of non-death disposition, having the surgery performed in the post period is no longer significant. That is, the discharge pattern is similar to the long term pre period. This is consistent with the hypothesis that, in the short run, after a benefit expansion, there may be more complications—but that this will subside over time.

For the short term outcome length of stay in the full sample, positive determinants included Medicare as payer, co-morbidity burden, teaching hospital status and complications. Negative determinants included region and small or medium bedsize. Having surgery in the post period was not associated with longer length of stay as hypothesized. In the short term LOS subsample, bedsize and region continued to be determinants of LOS. However, in this subsample where physician number of procedures is available, the number of procedures per physician is positively associated with length of stay, as is having the surgery in the 12 months after the benefit expansion. This confirms the hypothesis that outcomes may be worse in the immediate post period of a benefit expansion.

For the long run LOS full sample, surgery in a small or medium sized hospital was negatively related to length of stay, and hospital DBS volume was positively related to length of stay (although the coefficient was 0.008). Also, having the surgery in the long run post period was negatively related to the LOS. It was expected that there would be no differences between the long term pre and long term post—but long term improvements in technique and general trends for shorter hospital periods may have contributed to shorter and shorter stays in the long term. In the long term subsample, DBS per hospital is negatively associated with

LOS, and DBS per physician was positively associated with LOS. As in the full sample, surgery in the post period was negatively associated to LOS.

The fourth outcome variable is log of total charges in 2003 dollars (the year of benefit expansion). In the short term full sample, total discharges per hospital and age were negatively associated with the log of total charges. However, the coefficients were very small (-0.00001101 and -0.00769 respectively). Co-morbidity burden, West and Midwest regions (compared to the North East) and teaching hospital status were positively associated with log of total charges. Having surgery in the short term post period was not related to log of total charges. In the subsample, age, teaching hospital, regions, total number of discharges remained significant. However, in the subsample, the number of DBS procedures per hospital, the number of DBS procedures per physician, and having the surgery in the short term post period were positively associated with the log of total charges. This is consistent with the hypothesis that using constant dollars, surgery would be more expensive in the immediate post period.

In the long term full sample, region, teaching hospital and bedsize continue to be significant, and surgery in the post period is positively associated with log of charges. That is, log of total charges continues to rise. In the long term subsample, the data are broadly consistent.

Alternative Specification Hierarchical Results

Because patients are nested within physicians, who are nested within hospitals, it was suggested that hierarchical models be tried to more accurately assess the variability that hospitals and physicians separately contribute. The full samples do not have physician number of procedures, so only the hospital can be used as a class. The subsample has both physician ID and hospital ID, so each was to be a class. However, when attempting the physician and hospital as class models in the subsample, the models did not converge because the physician class ran out of degrees of freedom. Investigating this revealed the following: there is not strong correlation between the ID's of the pre and post physicians. Perhaps because in each state, for each year, a 20% sample is pulled, which is generalizeable to the DBS surgery in that state. But physician ID is unique only by hospital. So, unless the same hospitals are pulled every year, correlation between physician ID suffers which increases the number of unique ID's (thus using up sample). This is true for hospital ID as well, although to a lesser degree because full samples have many more degrees of freedom to accommodate the large number of unique hospitals.

Additionally, instead of the long run comparisons, it was suggested that a model that incorporated contiguous time periods be used. That is, instead of long term pre vs. long term post, develop a model that has four contiguous time periods (long term pre, short term pre, short term post, long term post) and use long term pre as the reference category.

In the complications short run full sample model, determinants were co-morbidity burden (increased likelihood); hospital in the Midwest or South (decreased likelihood); and total number of DBS procedures per hospital (decreased likelihood). In the short term subsample, only number of DBS procedures per hospital was significant (less likely).

In the four time-period full sample complications model, there were no significant differences due to the timing of the surgery. In the subsample complications model, the postlong period differed from the prelong period in that patients were less likely to experience complications in the long term post period than the long term pre period. This is consistent with the original specification long term results.

In the non death disposition short run full sample, patients who were older, who had Medicaid as payer, or medicare as payer, and had higher co-morbidity burdens were more likely to be discharged to long or short term care. Those having surgery in the West or had any complications were more likely to be discharged to home. In the short run subsample, Medicaid and Medicare were again determinants. However, having the procedure in the 12 months after the benefit expansion yielded a 4.474 times more likelihood of being discharged to a long or short term facility rather than home. This is consistent with the hypothesis that outcomes in the short post period would be worse.

In the full sample non death disposition model with four time periods, the post short period differs from the pre long period; however, this comparison was not identified in the hypotheses in the subsample, there are no time period differences. These results are consistent with the original specification long term results.

In the length of stay short run full sample, Medicare as payer, co-morbidity burden, and presence of complications were significant. In the subsample, Medicare was again significant. However, having the procedure in the post period was associated with a longer length of stay. This is consistent with the hypothesis that outcomes in the short post period would be worse.

In the full sample length of stay model with four time periods, none of the time periods are significant. In the subsample, preshort and post short differ from prelong. Neither of these comparisons were outlined in the hypotheses. In the subsample, no time periods were significant which is inconsistent with the original specification.

In the log of total charges model for the short term full sample, teaching hospital status, co-morbidity burden, and Medicare as payer were significant and the short term subsample was generally consistent. Using the four time periods model, no time periods showed a significant result. This is also true in the subsample. This is inconsistent with the long term results in the original specification but broadly consistent with the hypostheses that there would be differences in cost in the short run, that would dissipate in the long run.

Implications and Future Directions

These results suggest that there are differences in outcomes between the short and long term after an NCD for DBS. In the DBS field, replication of this result would strengthen its relevance. Because many demonstration projects are 2 years or fewer in length, implications for policy research are, that policymakers may need to interpret results of a benefit expansions carefully because there can be short term changes in outcomes that are temporary. On the other hand, long term, prospsective studies for the consequences of a benefit change could be cost prohibitive and impractical. Future policy research could contribute to the literature by exploring this conundrum and identifying ways to account for the risk of decision error based on misleading short term results.

Limitations

As with any inquiry, frequently more questions arise than those answered. Based upon the data presented, it does appear that patients meeting eligibility criteria did obtain the DBS and that outcomes improved over the long term, with fewer complication rates and shorter lengths of stay. Charges, as a surrogate marker of costs, also increased over time even though all costs were normalized to 2003 US dollars. Given these findings, expansion of funding for the evaluated services have improved patient outcomes over the longer term time period. In the short term, however, outcomes worsened.

There are some limitations with the data and the study. The data does not have a variable for disease-specific severity; instead, a measure for overall disease co-morbidity was used. The NIS HCUP data includes inpatient stays, and this is the unit of study; however, patients cannot be followed over time after their hospital discharge. Additionally, the data does not include laboratory values. Further, to support privacy of patients, CMS requires that no cell in a table reveal fewer than 10 observations so that there is no chance that patients can be identified. Therefore, any variable that has a cell with fewer than 10 observations will be redacted. Finally, the way the data is sampled may contribute to multicollinearity in the sample. In other words, the sampling method may insert correlations between explanatory variables that are not present in the entire population (Kmenta, 2003/2004).

As with all investigations, limitations exist in the existing work and are duly noted. First, the assessment was completed using retrospective data collected for other purposes. While it would have been ideal to have more specific physician data, access to this variable was not available for all records. Cost data was also limited in that it was charge data and the true cost of care are frequently less than charges. The exact overstatement in cost estimates in this evaluation is unknown. Geographical variations were observed but the data precluded a more through investigation of these variations and their implications for funding DBS in the alterative regions of the United States.

While the limitations are real, and so noted, the dataset can provided information about DBS inpatient clinical and economic outcomes as well as indications of benefit expansion policy success. The results of this study suggest that after the DBS benefit expansion, outcomes worsened in the short term, and improved in the long term. Policymakers may benefit from a longer term view when forecasting outcomes after a benefit design change—or interpreting short term results. Differences in populations served may cause temporary or long term shifts in health outcomes and resource utilization. This study shows that in the long term, the PD NCD does appear to improve patient care for those individuals suffering from PD.

CHAPTER 7

CONCLUSIONS

The Center for Medicare and Medicaid Services (CMS) is challenged each year with increasing beneficiary access to health care while working within multiple budget constraints. One mechanism for CMS to ensure patients receive care that is evidence based is through the National Coverage Decision (NCD) process.

One type of coverage decision that was implemented in 2003 was coverage for a procedure known as Deep Brain Stimulation in eligible candidates with Parkinson's Disease (PD). To ensure standardization in implementation of this expanded benefit, CMS issued guidance on types of patients who are eligible to receive their procedure based upon the patient clinical characteristics.

These issues are important to examining whether health policy goals have been met because failing to recognize these complexities could lead to an incorrect assessment of the success or failure of the benefit expansion. In particular, surgically implantable devices in chronic, progressive disease states pose special problems that must be addressed. Failure to recognize and account for these issues can lead to incorrect conclusions in program assessment.

As discussed throughout this document, if a policy-maker were to only look at the initial expenses and outcomes of DBS surgery for Parkinson's disease, a grim picture of poorer outcomes and higher expenses might be observed. But this may be temporary. Over time, the effects of sicker patients and inexperienced facilities or surgeons diminishes and the more accurate effect of the policy on inpatient outcomes would be revealed.

The purpose of the above evaluation was to assess changes in economic and clinical outcomes for patient undergoing the procedure before an after the implementation of the NCD in 2003. The outcome from the evaluation is designed to inform policy makers as to both the short run and long run outcomes of the NDC. To date, this analysis is not currently reported in the literature. Therefore, the efforts of this evaluation address an important gap and the understanding of key stakeholders about the outcomes of this benefit expansion.

The short and long term subsamples, where the important volume variable number of procedures per physician was available, revealed differences between short and long term outcomes.

The short and long term full sample, where physician volume was not available for all records, showed few differences due to the time surgery was delivered. This may be due to the lack of the important volume variable for the number of procedures per physician. The alternate specification using hierarchical models had consistencies with the short and long term subsample results; but could not accommodate two classes in the subsample analysis (hospital and physician) due to sample size restrictions.

The short run subsample reveals that having the procedure in the 12 months after the DBS benefit expansion is associated with discharges to long term or short term care rather than home; is positively associated with longer lengths of stay; and positively associated with the log of total charges. Having the surgery in the short run post period is not associated with complications. The long run subsample reveals that having the procedure over 12 months after the benefit expansion is associated with lower complications, negatively associated with length of stay, and positively associated with log of total charges.

In general, these results suggest that after the DBS benefit expansion, outcomes worsened in the short term, and improved in the long term, except for total charges. Policymakers may benefit from a longer term view when forecasting outcomes after a benefit design change—or interpreting short term results. Differences in populations served may cause temporary or long term shifts in health outcomes and healthcare resource utilization.

Appendix A

Data Dictionary

VARIABLE NAME	VARIABLE DESCRIPTION	HCUP DATABASE
KEY	HCUP Record (unique identifier for each hospitalization)	ALL
HOSPID	Hospital ID number (unique identifier for each hospital)	ALL
COHORT IDENTIFICATION		
PD	Diagnosed with Parkinson's Disease (based upon receipt of ICD-9 code of 332.xx in fields DX1-DX15)	CORE
DBS	Receipt of Deep Brain Stimulation (DBS) (based upon procedure codes – PR1-PR15 (ICD-9 procedures). See Appendix for codes for this variable	CORE
AMONTH	Month of admission (1-12)	CORE
YEAR	Year of admission (Note – this variable is not in any database BUT all data is collected by year)	CORE
PATIENT CHARACTERISTICS		
AGE	Patient age (in years) at time of hospitalization	CORE
FEMALE	1 if patient is female	CORE
PARK	Diagnosed with Parkinson's Disease	
INCOME	Median household income (based upon zipcode – found by variable ZIPINC_QRTL for years 2003-2006 and variable ZIPINC for years 1998 – 2002)	CORE
RACE	Patient race (1-white; 2-black; 3-Hispanic; 4-Asian or Pacific Islander; 5 Native American; 6-Other	CORE

ASIAN	If race=Asian then asian =True	
WHITE	If race=White then white=True	
BLACK	If race=Black then Black =True	
HISPANIC	If race=Hispanic then Hispanic = True	
NATAM	If race=natam then natam=True	
OTHRACE	If race=Othrace then Othrace = True	
PAY1	Primary payer (1-Medicare; 2-Medicaid; 3-Private including HMO; 4-Self-pay; 5-No charge; 6 other) based upon variable PAY1	CORE
MEDICARE	PAY1=1 then MEDICARE = True	
MEDICAID	PAY1=2	
PRIVINS	PAY1=3	
SELFINS	PAY1=4	
FREEINS	PAY1=5	
OTHERINS	PAY1=6	
MEDREIMB	If time period of medicare reimbursement is after benefit expansion, or from April 1, 2003 onwarad, MEDREIMB=1	
ATYPE	Admission Type – (1-Emergency; 2-Urgent; 3-Elective; 4-Newborn; 5-Trauma Center Beginning in 2003 data; 6-Other) based upon variable ATYPE	CORE
ASOURCE	Admission Source (1-ER; 2-Another hospital; 3-Another facility including long-term care; 4-Court/law enforcement; 5-Routine/birth/other) from variable ASOURCE	CORE
INC	Household income based on zipcode of patient residence: see approach to smooth categories over years in database	

INCOME	Income Categorization	
OUTCOMES		
TTREND	Time Trend by Month from 1/1/99 through 12/31/07	
LOS	Hospital LOS	CORE
DIED	1 if died during hospitalization	CORE
TOTCHG	Total charges (edited)	CORE
DISP	Disposition of patient (1-Routine; 2-Short-term hospital; 3-Skilled nursing facility; 4-Intermediate care facility; 5-Another type of facility; 6-Home health care; 7-Against medical advice; 20-Died)	CORE
DISPUNIFORM	If DISP=1 or 6 then DISPUNIFORM=HOME; If DISP=2 or 3 or 4 or 5 then DISPUNIFORM=ANOTHER HEALTH CARE FACILITY; If DISP=20 then DISPUNIFORM=DIED.	
SHRTRUN	1 year pre and post medicare reimbursement benefit change	
LONG RUN		
HOSPITAL CHARACTERISTICS		
HBEDSIZE	# Beds in hospital	HOSPITAL
BEDS	Hospital bedsize (1-small; 2-medium; 3-large) based upon variable HOSP_BEDSIZE	
BEDLG	If BEDS = 3 then Bedlg=True	
BEDMED	If BEDS=2 then Bedmed=True	
BEDSM	If BEDS=1 then Bedsm=True	
URBAN	Hospital location (0-rural; 1-urban) based upon variable HOSP_LOCATION	HOSPITAL
RURAL	If Urban = 0 then Rural = True and hospital in rural	

	region	
HURBRU	Hospital urban or rural	
HTEACH	Teaching status of hospital (0 – non-teaching; 1 teaching) based upon variable HOSP_TEACH	HOSPITAL
HCNTRL	Control/ownership of hospital (0-government or prive; collapsed category; 1-government, nonfederal public; 2-private, non-profit voluntary, 3-private invest-own; 4-private, collapsed category), based upon variable HOSP_CONTROL	HOSPITAL
HOSPST	State hospital is located in– can be rolled up to geographic regions	HOSPITAL
HREGION	Region of Hospital	
MIDWEST	Hospital in Midwest (list?)	
NEAST	Hospital in Northeast (list?)	
WEST	Hospital in West (list?)	
SOUTH	Hospital in South (list?)	
HDISCH	# Discharges from this hospital	
COMORBIDITIES / PATIENT SEVERITY		
AHRQSUM	Sum of 28 AHRQ comorbidities – see Appendix B (calculated using variables DX1-DX15)	CORE
APRDRG	All Patient Refined DRG score	SEVERITY
APRDRGM	APR-DRG Risk of Mortality Score (based upon variable APRDRG_Risk_Mortality)	SEVERITY
APRDRGS	APR-DRG severity of illness subclass (based upon variable APRDRG_Severity)	SEVERITY
CHLSON	Deyo-Charlson Comorbidity Score	SEVERITY
SARRAY	Receipt of Single Array Neurostimulator Pulse	

	Generator	
DARRAY	Receipt of Double Array Neurostimulator Pulse Generator	
COMPLICATIONS		
INF	Post-surgical infarction or hemorrhage (ICD-9-CM Diagnosis codes of 997.00-997.09)	CORE
HEM	Hematoma complicating a procedure (ICD-9-CM diagnosis codes of 998.1-998.13)	CORE
MECH NDCOMP	Mechanical complications related to a neurological device (996.2)	CORE
INFND ICND NDCOMP	Infectious complications related to a neurological device (996.63)	CORE
REM REMND	Removal of a previously implanted neurological device (01.22)	CORE
ANYCOMP	If INF or HEM or MECH or INFND or REM =1 then ANYCOMP = TRUE	
NEUR	Neurological complications (true false)	
PRDAY1	# of days from admission to primary procedure	
PHYSICIAN SPECIFIC VOLUME AND HOSPITAL VOLUME		
PPERFAC	Percentage of all facilities that provide DBS in the “pre-period”	
PPERDR	Percentage of all doctors that provide DBS in the “pre-period”	
PPERINPT	Percentage of all inpatient admissions that are DBS in the “pre-period”	
PDBSHOSP	Number of DBS procedures performed per hospital in the “pre-period”	

PERFAC	Percentage of all facilities that provide DBS in the "post-period"	
PERDR	Percentage of all doctors that provide DBS in the "post-period"	
PERINPT	Percentage of all inpatient admissions that are DBS in the "post-period"	
PDBSHOSP	Number of DBS procedures performed per hospital in the "post-period"	
PHYSID	Physician ID	
NUMDOC	Number of deep brain stimulations performed at physician level	
HNUMDB	Number of deep brain stimulations performed at hospital level	

Appendix B

Complications – Long Run Without Physician Variable

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	0.984	0.965—1.003	0.1032
FEMALE	1.434	1.002—2.052	0.0486*
INCOME ≤$44,999	0.933	0.640—1.358	0.7166
MEDICAID	1.764	0.648—4.797	0.2664
MEDICARE	1.088	0.709—1.672	0.6986
ERTYPE	2.162	0.963—4.856	0.0617
CHARLSON	1.643	1.255—2.150	0.0003*
MIDWEST	0.486	0.268—0.884	0.0181*
SOUTH	0.807	0.524—1.242	0.3294
TEACHING HOSPITAL	1.246	0.653—2.376	0.5046
BEDSIZE MEDIUM	2.144	1.068—4.303	0.0319*
# TOTAL HOSP DISCH.	1.000	1.000—1.000	0.0912
#DBS PROC IN HOSP	1.002	0.998—1.005	0.3383
MEDREIMB	0.577	0.393—0.846	0.0048*

*** denotes statistically significant findings (P < 0.05)**

Appendix C

Complications – Long Run with Physician Influence

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	0.980	0.955—1.006	0.1346
FEMALE	1.579	0.956—2.607	0.0745
INCOME ≤$44,999	0.773	0.456—1.312	0.3403
MEDICAID	2.533	0.644—9.964	0.1837
MEDICARE	1.854	0.975—3.524	0.0596
ERTYPE	2.135	0.541—8.424	0.2787
CHARLSON	1.873	1.299—2.702	0.0008*
MIDWEST	0.423	0.186—0.966	0.0411*
SOUTH	0.388	0.196—0.766	0.0064*
TEACHING HOSPITAL	0.872	0.367—2.072	0.7562
BEDSIZE MEDIUM	0.728	0.575—5.191	0.3299
# TOTAL HOSP DISCH.	1.000	1.000—1.000	0.0695
#DBS PROC IN HOSP	0.999	0.988—1.011	0.9250
NUMDOC	0.988	0.971—1.005	0.1570
MEDREIMB	0.376	0.218—0.649	0.0004*

*** denotes statistically significant findings (P < 0.05)**

Appendix D

Non Death Disposition - Long Run Full Sample

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.041	1.021—1.062	<0.001*
FEMALE	1.388	1.015--1.897	0.0401*
INCOME ≤ $44,999	0.723	0.519--1.005	0.0537
MEDICAID	4.776	1.9261—1.843	0.0007*
MEDICARE	1.638	1.050--2.555	0.0296*
CHARLSON	1.472	1.158--1.871	0.0016*
ANYCOMP	3.425	2.136--5.490	<0.0001*
MIDWEST	1.380	0.729--2.612	0.3224
WEST	0.898	0.495--1.629	0.7262
SOUTH	1.157	0.627--2.135	0.6406
TEACHING HOSP	1.438	0.850--2.435	0.1758
BEDSIZE SMALL	0.239	0.069--0.834	0.0248*
BEDSIZE MEDIUM	0.895	0.478—1.677	0.7295
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.1712
# DBS / HOSP	0.999	0.995—1.002	0.3621
MEDREIMB	0.885	0.629—1.245	0.4813

*** denotes statistically significant findings (P < 0.05)**

Appendix E

Non Death Disposition – Long Run with Physician Influence

Variable	**Odds Ratio**	**95% Confidence Interval**	**P-Value**
AGE	1.055	1.023—1.088	0.0007
FEMALE	1.662	1.037—2.663	0.0347
INCOME ≤ $44,999	0.674	0.408—1.113	0.1231
MEDICAID	6.186	1.744—21.937	0.0048*
MEDICARE	0.961	0.496—1.861	0.9050
CHARLSON	1.408	0.978—2.026	0.0656
ANYCOMP	4.955	2.580—9.517	<0.0001*
MIDWEST	1.530	0.607—3.859	0.3671
WEST	1.442	0.628—3.313	0.3882
SOUTH	1.184	0.504—2.783	0.6981
TEACHING HOSP	1.801	0.846—3.835	0.1269
BEDSIZE SMALL	<0.001	<0.001-- >999.999	0.9746
BEDSIZE MEDIUM	0.310	0.101—0.947	0.0398*
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.0451*
# DBS / HOSP	1.000	0.990—1.011	0.9408
# DBS / MD	0.990	0.974—1.006	0.2198
MEDREIMB	1.041	0.613—1.769	0.8808

*** denotes statistically significant findings (P < 0.05)**

Appendix F

Length of Stay–Long Run without Physician Influence

Variable	**PARAMETER ESTIMATE**	**Chi Square**	**P-Value**
INTERCEPT	0.1635	1.13	0.2884
AGE	0.0123	33.55	<0.0001*
FEMALE	0.0828	4.79	0.0287*
INCOME $\leq$ $44,999	-0.0650	2.90	0.0884
MEDICAID	0.2014	8	0.1153
MEDICARE	-0.0707	2.51	0.1132
ER TYPE	-0.1139	1.46	0.2271
CHARLSON	0.0486	2.15	0.1430
ANY COMPLICATIONS	0.7879	145.09	<0.0001*
MIDWEST	-0.1404	3.85	0.0499*
WEST	-0.3137	23.35	<0.0001*
SOUTH	-0.1635	5.83	0.0158*
TEACHING HOSPITAL	0.3226	25.66	<0.0001*
BEDSIZE SMALL	-0.4296	15.02	0.0001*
BEDSIZE MEDIUM	-0.1664	4.22	0.0399*
TOTAL DISCH / HOSP	-0.0000	11.92	0.0006*
# DBS PER HOSP	0.0008	4.39	0.0361*
MEDREIMB	-0.1306	10.73	0.0011*

*** denotes statistically significant findings (P < 0.05)**

Appendix G

Length of Stay–Long Run with Physician Influence

Variable	PARAMETER ESTIMATE	Chi Square	P-Value
INTERCEPT	0.1767	0.64	0.4242
AGE	0.0156	24.88	<0.0001*
FEMALE	0.0467	0.70	0.4035
INCOME $\leq$ \$44,999	-0.0110	0.04	0.4035
MEDICAID	-0.0992	0.25	0.8435
MEDICARE	-0.1161	2.96	0.6178
ER TYPE	0.4727	5.54	0.0853
CHARLSON	0.0940	3.88	0.0186*
ANY COMPLICATIONS	0.9358	107.71	0.0488*
MIDWEST	-0.1339	1.74	<0.0001*
WEST	-0.3730	17.63	0.1877
SOUTH	-0.2576	8.37	<0.0001*
TEACHING HOSPITAL	0.3389	14.44	0.0038*
BEDSIZE SMALL	-0.5111	11.37	0.0001*
BEDSIZE MEDIUM	-0.2172	3.36	0.0007*
TOTAL DISCH / HOSP	-0.000	13.15	0.0667*
# DBS PER HOSP	-0.0035	7.30	0.0003*
#DBS per MD	0.0053	6.76	0.0069*
MEDREIMB	-0.2857	22.17	0.0093*

*** denotes statistically significant findings (P < 0.05)**

Appendix H

Log Total Charges –Long Run Full Sample

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INTERCEPT	10.17789	89.51	<0.001
AGE	0.00006551	0.04	0.9668
FEMALE	-0.05399	-1.87	0.0611
INCOME ≤ $44,999	-0.01540	-0.54	0.5905
MEDICAID	-0.00316	-0.03	0.9744
MEDICARE	-0.02312	-0.69	0.4909
ER SOURCE	0.47813	02.75	0.0060*
ER TYPE	-0.19476	2.50	0.0126*
CHARLSON	0.00567	0.22	0.8279
ANY COMPLICATIONS	-0.07646	-1.30	0.1927
MIDWEST	-0.6909	-1.269	0.2062
WEST	0.27152	5.47	<0.001*
SOUTH	-0.00991	-0.19	0.8459
TEACHING HOSPITAL	0.28078	6.34	<0.001*
BEDSIZE SMALL	-0.32483	-4.13	<0.001*
BEDSIZE MEDIUM	-0.01775	-0.30	0.7619
TOTAL DISCH / HOSP	-0.00000112	-0.92	0.3595
# DBS PER HOSP	-0.00049607	-1.81	0.0708
MEDREIMB	0.33875	11.15	<0.001*

*** denotes statistically significant findings (P < 0.05)**

Appendix I

Log Total Charge – Long Run Subsample

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INTERCEPT	10.16751	57.14	<0.001
AGE	-0.00186	-0.74	0.4591
FEMALE	-0.00610	-0.13	0.8934
INCOME ≤ $44,999	-0.03294	-0.73	0.4653
MEDICAID	-0.09481	-0.62	0.5335
MEDICARE	-0.03420	-0.63	0.5305
ER SOURCE	0.32164	1.16	0.2459
ER TYPE	0.00193	0.01	0.9932
CHARLSON	0.05412	1.31	0.1889
ANY COMPLICATIONS	-0.05950	-0.67	0.5043
MIDWEST	-0.03047	-0.35	0.7267
WEST	0.20299	2.73	0.0065*
SOUTH	0.07260	0.99	0.3221
TEACHING HOSPITAL	0.32670	4.71	<0.0001*
BEDSIZE SMALL	-0.32641	-2.78	0.0055*
BEDSIZE MEDIUM	-0.24186	-2.55	0.0109*
TOTAL DISCH / HOSP	-0.00000511	-2.90	0.0038*
# DBS PER HOSP	0.00180	1.82	0.0690
#DBS per MD	0.00197	1.23	0.2201
MEDREIMB	0.41463	8.48	<0.001*

*** denotes statistically significant findings (P < 0.05)**

Appendix J

Complications – Short Run Full Sample

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.014	0.979—1.050	0.4432
FEMALE	1.038	0.567—1.893	0.9033
INCOME < $45,000	0.801	0.424—1.513	0.4935
MEDICAID	4.670	0.864—25.226	0.0733
MEDICARE	1.237	0.588—2.605	0.5746
ERSOURCE	0.225	0.004—11.505	0.4572
ERTYPE	10.838	0.543—216.473	0.1186
CHARLSON	1.709	1.074—2.719	0.0238*
MIDWEST	0.146	0.034—0.617	0.0090*
SOUTH	0.269	0.070—1.032	0.0556*
WEST	0.348	0.094—1.285	0.1133
TEACHING HOSPITAL	1.026	0.355—2.963	0.9627
BEDSIZE MEDIUM	0.854	0.094—7.791	0.8889
# DBS PER HOSP	1.009	1.002—1.015	0.0124*
TOTAL DISCHARGES/HOSP	1.000	1.000—1.000	0.4470
MEDREIMB	1.051	0.578—0.2581	0.8709

*** denotes statistically significant findings (P < 0.05)**

Appendix K

Complications - Short Run Subsample

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	0.973	0.907	0.4529
FEMALE	2.405	0.782	0.1256
INCOME ≤ $44,999	1.135	0.366	0.8259
MEDICAID	7.775	0.949	0.0559
MEDICARE	1.287	0.303	0.7319
ERSOURCE	<0.001	.	0.9996
ERTYPE	>999.999	.	0.9997
CHARLSON	0.769	0.199	0.7033
MIDWEST	0.152	0.023	0.0503
SOUTH	0.243	0.041	0.1174
WEST	<0.001	.	0.9992
NUMDOC	0.995	0.952	0.8288
TEACHING HOSPITAL	0.797	0.059	0.8638
BED MEDIUM	2.765	0.177	0.4674
#DBS PER HOSP	0.970	0.946	0.0181*
TOTAL DISCHARGES/HOSP	1.000	1.000	0.0197
MEDREIMB	0.557	0.138	0.4105

*** denotes statistically significant findings (P < 0.05)**

Appendix L

Non Death Disposition – Short Run Full Sample

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.035	1.002—1.070	0.0362*
FEMALE	0.827	0.485—1.413	0.4871
INCOME ≤ $44,999	0.632	0.361—1.105	0.1071
MEDICAID	21.751	5.118—92.444	<0.0001*
MEDICARE	3.634	1.570—8.411	0.0026*
ERSOURCE	>999.999	.	0.9997
ERTYPE	<0.001	.	0.9997
CHARLSON	1.587	1.057—2.383	0.0259*
MIDWEST	0.409	0.129—1.299	0.1292
SOUTH	0.331	0.090—1.211	0.0946
WEST	0.177	0.049—0.642	0.0084*
ANYCOMP	3.703	1.734—7.908	0.0007*
HTEACH	1.473	0.516—4.209	0.4691
BEDSIZE MEDIUM	0.851	0.180—4.019	0.8382
# DBS PER HOSP	1.001	0.994—1.007	0.8693
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.2618
MEDREIMB	1.287	0.746—2.219	0.3638

*** denotes statistically significant findings (P < 0.05)**

Appendix M

Non Death Disposition – Short Run Subsample

Hierarchical Logistic Multivariate Model

Variable	Odds Ratio	95% Confidence Interval	P-Value
AGE	1.022	0.969—1.078	.4187
FEMALE	1.356	0.603—3.049	.4612
INCOME ≤ $44,999	0.925	0.400—2.139	.8545
MEDICAID	83.872	12.123—580.268	<0.001*
MEDICARE	4.496	1.163—17.378	0.0294*
ERSOURCE	>999.999	.	0.9998
ERTYPE	<0.001	.	0.9998
CHARLSON	0.801	0.342—1.879	0.6096
MIDWEST	0.942	0.247—3.591	0.9296
SOUTH	0.058	0.009—0.359	0.0023*
WEST	0.091	0.006—1.380	0.0838
ANYCOMP	1.064	0.166—6.818	0.9479
TEACHING HOSP	0.385	0.083—1.784	0.2220
BEDSIZE MEDIUM	1.959	0.309—12.418	0.4744
# DBS PER HOSP	0.987	0.968—1.006	0.1773
TOTAL DISCH / HOSP	1.000	1.000—1.000	0.0672
NUMDOC	1.058	1.020—1.097	0.0029*
MEDREIMB	4.474	1.385—14.454	0.0124*

*** denotes statistically significant findings (P < 0.05)**

Appendix N

Length of Stay – Short Run Full Sample

Hierarchical Negative Binomial Multivariate Model

Variable	**Estimate**	**t Value**	**P-Value**
INTERCEPT	0.1561	0.32	0.7538
AGE	0.006669	1.75	0.0797
FEMALE	-0.01455	-0.22	0.8232
INCOME ≤ $44,999	-0.1128	-1.68	0.0930
MEDICAID	0.09794	0.43	0.6652
MEDICARE	0.2136	2.68	0.0075*
ERSOURCE	0.8763	0.97	0.3343
ERTYPE	-1.1523	-1.54	0.1234
CHARLSON	0.1452	2.50	0.0125*
MIDWEST	-0.1605	-0.47	0.6402
SOUTH	0.01047	0.29	0.7754
WEST	-0.06547	-0.19	0.8487
ANYCOMP	0.8537	7.65	<0.0001*
HTEACH	0.1836	0.60	0.5490
BEDSIZE MEDIUM	-0.3542	-0.99	0.3206
#DBS PER HOSP	0.000181	0.08	0.9346
TOTAL DISCHARGES	-0.00000257	-0.31	0.7574
MEDREIMB	0.03760	0.54	0.5914

*** denotes statistically significant findings (P < 0.05)**

Appendix O

Length of Stay – Short Run Subsample

Hierarchical Negative Binomial Multivariate Model

Variable	Estimate	t Value	P-Value
INTERCEPT	1.0567	1.96	0.0643
AGE	-0.00092	-0.17	0.8665
FEMALE	0.1171	1.33	0.1838
INCOME $\leq$ \$44,999	-0.00418	-0.05	0.9626
MEDICAID	0.3607	1.53	0.1272
MEDICARE	0.3545	3.17	0.0016*
ERSOURCE	1.5013	1.42	0.1570
ERTYPE	-0.9402	-1.03	0.3015
CHARLSON	0.06180	0.71	0.4780
MIDWEST	-0.272	-0.97	0.3302
SOUTH	-0.5490	-1.73	0.0838
WEST	-0.7720	-1.81	0.0716
ANYCOMP	0.2320	1.07	0.2869
TEACHING HOSPITAL	-0.1555	-0.54	0.5910
BEDSIZE MEDIUM	0.06088	0.19	0.8489
# DBS PER HOSP	-0.00031	-0.09	0.9301
TOTAL HOSP DISCH	-0.00001	-1.35	0.1787
NUMDOC	0.008131	1.86	0.0639
MEDREIMB	0.2343	2.10	0.0359*

*** denotes statistically significant findings (P < 0.05)**

Appendix P

Log Total Charges – Short Run Full Sample

Hierarchical Ordinary Least Squares Multivariate Model

Variable	PARAMETER ESTIMATE	t-Statistic	P-Value
INTERCEPT	9.8759	22.86	<0.0001
AGE	-0.00362	-1.70	030894
FEMALE	-0.00517	-0.14	0.8899
INCOME ≤ $44,999	-0.01857	-0.50	0.6194
MEDICAID	0.3277	2.63	0.0086*
MEDICARE	0.07215	1.66	0.0981
ER SOURCE	1.0463	2.20	0.0284*
ER TYPE	-0.8440	-2.26	0.0185*
CHARLSON	0.1055	2.85	0.0045*
MIDWEST	0.2970	0.89	0.3748
SOUTH	0.1734	0.48	0.6328
WEST	0.7271	2.14	0.0329*
ANYCOMP	0.08349	1.13	0.2568
TEACHING HOSPITAL	0.7211	2.47	0.0137*
BEDSIZE MEDIUM	-0.2662	-0.84	0.3998
# DBS PER HOSP	0.000306	0.13	0.8953
TOTAL DISCH / HOSP	-0.00000495	-0.63	0.5274
MEDREIMB	0.02395	0.60	0.5499

*** denotes statistically significant findings (P < 0.05)**

Appendix Q

Log Total Charges – Short Run Subsample

Hierarchical Ordinary Least Squares Multivariate Model

Variable	Parameter Estimate	t-Statistic	P-Value
INTERCEPT	9.6287	14.28	<0.0001
AGE	-0.00556	-1.60	0.1097
FEMALE	0.008671	0.15	0.8800
INCOME ≤ $44,999	0.05510	0.98	0.3295
MEDICAID	0.3711	2.37	0.0182*
MEDICARE	0.05250	0.76	0.4486
ER SOURCE	2.7438	3.56	0.0004*
ER TYPE	-2.0954	-3.56	0.0004*
CHARLSON	0.1030	1.80	0.0719
MIDWEST	0.3865	0.78	0.4349
SOUTH	0.3000	0.59	0.5571
WEST	0.8569	1.41	0.1595
ANYCOMP	1.0596	0.53	0.5951
TEACHING HOSPITAL	0.08173	2.35	0.0192*
BEDSIZE MEDIUM	1.0596	-0.54	0.5867
# DBS PER HOSP	0.001785	0.33	0.7451
TOTAL DISCH / HOSP	-0.00001	-1.08	0.2795
# DBS PER PHYSICIAN	0.004301	1.38	0.1691
MEDREIMB	0.05297	0.73	0.4666

*** denotes statistically significant findings (P < 0.05)**

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VITA

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Prior to joining Teva Pharmaceuticals, Jane was Assistant Director of Research in the Center on Aging at the University of Kansas Medical Center where she managed NIH stroke studies. At Eli Lilly and Company, Jane was an Associate Health Economist in Global Health Economics Research where she worked on compounds used in the treatment of schizophrenia, bipolar disorder, and depression.

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