The Effect of Medicare's New Technology Add-on Payment

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Dedication

For Tim.

Abstract

The new technology add-on payment (NTAP) is the first payment incentive under Medicare's inpatient prospective payment system (IPPS) related to technology. Implemented in 2001, the NTAP reimburses hospitals up to fifty percent of the cost related to the use of eligible new technologies in addition to the prospective Medicare Severity Diagnostic Related Group (MS-DRG) payment. The NTAP was implemented to ensure access of new clinically beneficial technologies to Medicare beneficiaries while the prospective payment system recalibrated to reflect the cost of new technology. For a technology to be eligible for NTAP, it must meet three criteria: (1) the technology must be considered new, as defined by the Centers for Medicare and Medicaid Services (CMS) as within two to three years following FDA approval; (2) the technology must be considered costly and inadequately reimbursed under the current MS-DRG assignment; (3) the technology must provide a substantial clinical improvement to Medicare beneficiaries. Once a technology is granted new technology add-on payment status, a hospital is eligible to receive NTAPs for up to three years. Upon the sunset of the NTAP, the prospective DRG rates are recalibrated to reflect the utilization of the new technology and a hospital will receive only the associated DRG payment when the technology is used. As of September 30, 2007, seven technologies have been granted NTAP status. With the exception of one pharmaceutical technology, all of the technologies have been implantable medical devices.

This research evaluates the effect of Medicare's NTAP program. The NTAP policy offers the unique opportunity to evaluate hospitals' response to payment incentives

under a mature prospective system. This research is the first to evaluate the value of the NTAP policy and empirically estimate the effect of the NTAP policy on the utilization of new technology. The thesis is organized around three research questions: 1) does the presence of the NTAP policy affect the probability new technology is used? 2)does the amount of the NTAP affect the probability a new technology is used? 3) what is the value of the NTAP policy?

The results increase the understanding of how hospitals respond to payment incentives, which is becoming increasingly important as health care reform seeks to develop incentives to improve the efficiency, quality and safety of health care delivered.

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Disclosure Statement

In full disclosure, Lindsay Bockstedt was an employee of Medtronic during the dissertation research. Some of the technologies included in this research are technologies manufactured by Medtronic. This research was done independent of her employment. The research does not represent to views or opinions of Medtronic.

Chapter 1

Introduction

[1]

Prior to the implementation of Medicare prospective reimbursement systems, technological advances were driven by a generous reimbursement system that paid health care providers for the cost of care provided. Retrospective determination of payment compensated hospitals for endogenous decisions regarding length of stay, intensity of resources, and technologies used[1]. Not only did the retrospective cost-based reimbursement compensate both the developers and adopters of new technology, it encouraged rapid hospital adoption of new high cost technology[2]. In 1983, Medicare implemented an inpatient prospective payment system (IPPS). Under the IPPS, Medicare pays hospitals a fixed, prospectively determined amount for each inpatient hospitalization based on Medicare Severity Diagnosis-Related Groups (MS-DRGs). Each MS-DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that MS-DRG. These fixed, prospective payments encourage hospitals to operate efficiently but also put hospitals at risk for higher costs associated with changes in technology since new technologies are typically introduced without adjustments to the payment levels[3, 4, 5].Without appropriate payment to the hospital at the point of use, technologies that provide value to patients and the health care system over time could face significant barriers to access[6].

[1] Portions of this chapter is ©of Health Affairs 2008. Clyde A., Bockstedt, L., Farkas, J., and Jackson, C. Experience with Medicare's New Technology Add-On Payment. *Health Affairs*, 27(6):1632-1641, 2008.

While CMS annually revises the MS-DRGs using data from inpatient claims submitted for inpatient services rendered to Medicare beneficiaries, the MS-DRG classifications and weights are generally based on data from claims for inpatient services provided two fiscal years prior to the fiscal year in which they will be used. This can create a two to three-year delay between the market introduction of a new technology and the recalibration of MS-DRG weights to reflect the added cost of the new technology. During this period, hospitals that adopt the new technology may experience financial losses.

1.1 Description of the Medicare New Technology Add-on Payment Program

In 2000, Congress took steps to ensure that Medicare beneficiaries would have timely access to new, breakthrough technologies that, absent any additional payments, would be inadequately paid under the existing DRG amount. Section 533 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) mandated an additional payment that "recognize[s] the costs of new medical services and technologies under the [inpatient] payment system"[7]. The intent of the additional payments was to bridge the recalibration delay by providing a temporary payment mechanism for the use of new technologies in addition to the DRG payment amount the hospital would otherwise receive. The additional payments were to be provided until CMS had inpatient claims data for MS-DRG rate setting which reflected the added costs of the new technology.

In 2001, CMS used its discretionary authority provided under the statute to issue regulations specifying a process and criteria for granting new technology add-on payments (NTAP). The program definitions established by CMS provide that only new technologies meeting specific cost thresholds and demonstrating substantial clinical improvement over existing services would qualify for an NTAP. CMS also established specific limits to the additional payments made under the NTAP program to ensure that the Medicare program and hospitals would share in the financial risk of providing costly new technologies.

Additional modifications to the underlying statute enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS

to update the criteria in 2004. As the NTAP program has evolved, Congress has provided pressure to expand access to new technology while CMS has used its authority granted in the statute to establish regulatory criteria requiring that new technologies meet certain criteria in order to qualify for NTAPs.

Today, in order for a technology to be eligible for an NTAP, it must meet the following conditions[8]:

- The technology must be new, which CMS generally defines as within 2-3 years following FDA approval and/or market introduction.
- The existing MS-DRG payment must be inadequate, where the expected average charges for services involving the new technology exceed a threshold set for each MS-DRG. The MS-DRG thresholds are determined annually by CMS and are equal to the geometric mean standardized charge of all cases in a particular MS-DRG plus the lesser of 75 percent of the national adjusted operating standardized payment amount (increased to reflect charges instead of costs) or 75 percent of one standard deviation of mean charges by MS-DRG.
- The technology must be a substantial clinical improvement over existing services, as determined by CMS following a set of general criteria published in regulation (as described below).

To determine if the new technology meets the substantial clinical improvement requirement, CMS evaluates a request for an NTAP against the following criteria[9]:

- The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

- Reduced mortality rate with use of the device.
- Reduced rate of device-related complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment because of the use of the device.
- Decreased pain, bleeding, or other quantifiable symptoms.
- Reduced recovery time.

Also, because the NTAP program is for operating costs, the new technology must not be a capital-related expense.

For technologies that meet the eligibility criteria and receive approval by CMS, the determination of the NTAP payment amount is based on the cost to hospitals for the new technology. The NTAP amount is calculated distinctly for each eligible discharge which includes the technology, and NTAPs are only made when the estimated cost of the case exceed the payment that would otherwise be made to the hospital (excluding outlier payments but including higher payments due to medical education, serving a high proportion of low-income patients, and adjustments for area wage differences).

The NTAP amount is equal to the lesser of (1) fifty percent of the amount by which the total covered costs of the case exceed the MS-DRG payment, or (2) 50 percent of the costs of the new technology[10] (1.1). The NTAP formula established by CMS requires the Medicare program and hospitals to share in the financial risk of providing costly new technologies. The NTAP limit - which is linked to the price of the technology as reported by manufacturers to CMS - is established by CMS when it publishes findings on new technology applications in the IPPS annual final rule.

The NTAP formula may be written as:

$$NTAP = \begin{cases} .5 * (CH_{u,i,j} * CCR_j - DRG_j) & \text{if } .5 * (CH_{u,i,j} * CCR_j - DRG_j) < MAX \\ MAX & \text{otherwise .} \end{cases} \tag{1.1}$$

, where u indicates the use of a NTAP eligible new technology; i is indexes an individual patient; j indicates a hospital; $CH_{u,i,j}$ represents the total hospital charges for a given admission; CCR_j represents the hospital specific operating cost-to-charge ratio; DRG_j represents the total DRG payment for a given admission including adjustments for wage index, indirect medical education, and disproportionate share; MAX represents the maximum eligible NTAP amount for the associated technology used.

1.1.1 Examples of the NTAP Policy at Work

Below are three examples of the NTAP policy for cases involving a technology with an estimated cost of $5,000 in a MS-DRG that reimburses $30,000.

Example 1: Case Where No NTAP is Paid

Assume the charges for a particular case are $20,000. After applying the hospital's cost-to-charge ratio, the cost of the case is estimated at $10,000. Since the cost ($10,000) is less than the MS-DRG payment ($30,000) no NTAP is provided.

Example 2: Case Where the Maximum NTAP Amount is Paid

Assume the cost of the case is estimated to be $50,000. Since the cost of the case is greater than the MS-DRG payment, an NTAP is made. To determine the amount of the NTAP, compare 50 percent of the excess costs not covered by the MS-DRG payment ($10,000) to 50 percent of the cost of the new technology ($2,500). Since 50 percent of the cost of the new technology is less than 50 percent of the excess costs, the NTAP amount would equal $2,500. Therefore, the total payment to the hospital would equal $32,500.

Example 3: Case Where the NTAP Equals 50 Percent of Excess Cost Not Covered by the MS-DRG

Assume the total cost of the case is estimated to be $31,000. The NTAP amount would be equal to 50% of the excess cost not covered by the MS-DRG payment ($500) since it is less than 50 percent of the new technology cost ($2,500). Therefore, the total payment to the hospital would equal $30,500.

When first enacted in BIPA, the NTAP program was required by law to be budget neutral. Amounts projected to be spent on NTAPs were to be offset by a corresponding decrease in the standardized amounts used to determine payments for discharges across

all MS-DRGs, thus holding overall spending under IPPS constant. The budget neutrality requirement was a cause of concern among hospitals since additional payments for new technology would be financed by reductions in all other MS-DRG payments to hospitals [11]. Congress amended the NTAP provision in the MMA both to remove the requirement that the NTAP be budget neutral and to lower the cost threshold for new technologies to qualify for add-on payments. The Congressional Budget Office (CBO) estimated that the program modifications established in the MMA would increase Medicare inpatient payments by $0.5 billion over ten years beginning with technologies eligible for FY 2005. Since Congress eliminated the budget neutrality requirement, hospitals have advocated for more expansive application of the NTAP program[11].

1.2 Experience with the Medicare New Technology Add-on Payment Program

Applicants for NTAPs submit a formal request, including a full description of the clinical applications of the new technology and the results of clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, along with cost data to demonstrate the technology meets the cost threshold establishing that the current MS-DRG payment is inadequate. CMS then provides opportunities for public comment, including a town hall meeting (required by the MMA) to discuss whether the new technology represents a substantial clinical improvement or advancement, and publication of discussion in the annual IPPS proposed rule, which is subject to public notice and comment.

1.2.1 The Applications

As of September 30, 2007, CMS has received twenty-eight unique applications for consideration of NTAPs. Of the submitted applications, eight were found not to be "new" under the program requirements, one had not received FDA approval, and one did not meet the cost criterion. Of the eighteen remaining applications, seven were found not to provide a substantial clinical improvement and seven were approved for NTAPs[12, 8, 13, 14, 15, 16, 17, 18].

The seven approved technologies are: (1) drotrecogin alpha (activated) protein for the treatment of severe sepsis associated with acute organ dysfunction, (2) bone morphogenetic proteins for spinal fusion, (3) bilateral deep brain stimulation for the treatment of Parkinson's disease, (4) cardiac resynchronization therapy with defibrillation (CRT-D), (5) rechargeable implantable spinal cord stimulation for chronic pain, (6) endovascular graft repair of the thoracic aorta, and (7) interspinous process decompression system for lumbar spinal stenosis. With the exception of the drotrecogin alpha (activated) proteins, all NTAP technologies are implantable medical devices.

- **Drotrecogin alpha (activated) protein for the treatment of severe sepsis associated with acute organ dysfunction**

  Drotrecogin alpha (activated) proteins was FDA approved on November 21, 2001. Drotrecogin alpha (activated) protein is an intravenously infused pharmaceutical indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death as determined by APCHE II score $\gneq 25$. Drotrecogin alpha (activated) protein is a recombinant version of the naturally occurring Activated Protein C, which is needed to ensure the inflammation and clotting in the blood vessels. Patients with severe sepsis cannot convert sufficient quantities of Protein C to the activated form. Drotrecogin alpha (activated) protein has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs [12].

- **Bone morphogenic proteins for spinal fusions**

  Bone morphogenic proteins (BMP) for spinal fusions was FDA approved on July 2, 2002. The technology is used to treat degenerative disc disease of the lumbar spine. Bone morphogenic proteins consists of a solution of recombinant human bone morphogenetic protein that is applied through use of an absorbable collagen sponge and an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This technology is done in place of the traditional iliac crest bone graft, where bone is harvested from the patients' iliac crest and placed in the spine to fuse the vertebrae together and stabilize the spine. The use of the

new technology reduces the operating time, hospitalizations, blood loss, and may result in greater fusion success[19].

- **Bilateral deep brain stimulator for the treatment of Parkinson's disease**

  Bilateral deep brain stimulation (b-DBS) was FDA approved on December 13, 2003. The technology is an implantable neurostimulator device designed to deliver electrical stimulation to the subthalamic nucleus or internal globus pallidus to reduce the symptoms caused by abnormal neurotransmitter levels that lead to abnormal cell-to-cell electrical impulses in Parkinson's Disease and essential tremor. The bilateral deep brain stimulation technology is intended to treat Parkinson's disease and essential tremor patients who have bilateral symptoms. Prior to the bilateral deep brain stimulation technology, patients with bilateral symptoms were implanted with two unilateral deep brain stimulation devices - one to treat either sides of the symptoms - thus requiring additional surgery in the chest cavity to place the second generator, and alongside the neck to tunnel the additional lead to connect to the second generator. The bilateral deep brains stimulation reduces operating time, the number of surgical sites, and the potential for post-surgical infection.

- **Cardiac resynchronization therapy (bi-ventricular pacing)**

  Cardiac resynchronization therapy (CRT-D) was FDA approved on June 26, 2002. Cardiac resynchronization therapy is a therapy for chronic heart failure and provides electrical stimulation to the right atrium, right ventricle, and left ventricle to resynchronize ventricular contractions and improve the oxygenated blood flow to the body. This technology combines cardiac resynchronization therapy with defibrillation for patients with moderate to severe heart failure who meet the criteria for an implantable cardiac defibrillator. Unlike traditional implantable cardiac defibrillators (ICD), CRT-D treats 1) the symptom of heart failure and 2) the high risk of ventricular arrhythmias, which would cause sudden cardiac arrest. Prior to CRT-D, patients would have only been able to receive therapy to treat one of the two risks mentioned above.

- **Rechargeable implantable spinal cord stimulator for chronic pain**

Rechargeable implantable spinal cord stimulators (r-SCS) were FDA approved on April 27, 2004. Rechargeable neurostimulation therapy is an implanted medical device for the treatment of chronic pain. Leads providing electrical stimulation are implanted into the epidural space of the spinal cord and the rechargeable generator is implanted in a pocket in the abdomen. Patients who receive spinal cord stimulation have various energy needs and stimulation requirements depending on the location and chronicity of the pain. Patients with high energy needs benefit from the rechargeable technology as it will significantly reduce the number of replacement surgeries and generators required. Prior to the use of rechargeable neurostimulators, patients with high energy needs to control their pain would have their primary cell generators replaced when the battery was depleted. A rechargeable generator enables to patient to recharge the battery and avoid replacement surgeries.

- **Endovascular graft repair of the thoracic aorta**

  Endovascular graft repair (EVG) was FDA approved on March 23, 2004. Endovascular graft repair is a less invasive treatment option to the traditional open surgical approach for descending thoracic aortic aneurysms. The traditional open surgical repair of the thoracic aorta is associated with high morbidity and mortality as the surgery is frequently performed under emergency conditions. The new technology is a tubular stent graft mounted on a catheter delivery system that is inserted via a small incision in the patient's groin and replaces the synthetic graft normally sutured in place during the open surgical repair.

- **Interspinous process decompression system for lumbar spinal stenosis**

  Interspinous process decompression (ISPD) was FDA approved on November 11, 2005. The technology is used to treat lumbar spinal stenosis, a condition that occurs when the spaces between bones in the spine become narrowed due to arthritis or other age related conditions. The narrowing of the space, or stenosis, causes the compression of nerves within the spinal cord resulting in pain, numbness, and weakness. The intraspinous decompression technology is a minimally invasive treatment alterative to conservative treatment such as physical therapy and exercise, and spinal fusion surgery. The new technology is made of titanium allow

and consists of a spacer and a wing assembly. The device is implanted between the spinous processes of the lumbar spine, and it limits the extension of the spine in the affected area thus resulting in less compressed nerves. The technology may improve a patient's ability to function and reduce some of the pain associated with lumbar spinal stenosis.

1.2.2 The Claims and Their Financial Impact

Using the Medicare Provider and Analysis Review (MedPAR) limited dataset from Federal fiscal years when technologies were eligible to receive NTAPs, we identified claims where the new technologies were used.[2] Claims where the new technologies were used were identified with the combinations of ICD-9 CM diagnosis and procedure codes specified for each eligible technology as outlined in the Federal Register. For each identified claim we calculated the NTAP amount. The sum, mean, standard deviation, and median NTAP amounts were calculated for each technology (Table 1.2).

CMS estimates the maximum financial impact for each NTAP-eligible technology and publishes the estimates in the proposed and final IPPS rules. CMS projects maximum financial impact based on the maximum NTAP amount and the expected volume utilization of the new technology (Table1.1). We compared the actual expenditures under the NTAP program (as estimated by the sum of the NTAP amounts of identified claims) to the annual CMS projections.

With the exception of bone morphogenetic proteins for spinal fusion, CMS did not expend the maximum expected amount on each technology approved for NTAP. There are two possible sources of lower than expected expenditures: the projected utilization of the new technologies and NTAP amounts paid. In calculating the maximum financial impact, CMS assumed that the majority of hospitals using the new technologies approved for NTAPs would receive the maximum NTAP available. However, analysis of the NTAP amounts paid demonstrates that the NTAP amounts are highly variable.

Only two out of the seven technologies' median NTAP equals the maximum NTAP available (Table1.2).

There is also high within-technology variation in the NTAP amounts (Table1.1).

[2] Coding specifics on the identification of technologies in the Medicare claims data is described in detail in Chapter 3

Table 1.1: Projected versus Actual New Technology Add-On Payments

Technology	Year(s) Eligible for NTAP	Projected Total Expenditures (*in millions*)	Actual Total Expenditures *(in millions)*	Difference
Drotrecogin alpha (activated) - Xigris™	FY 03	$74.8	$12.2	($62.6)
	FY 04	$10.0	$14.8	$4.8
	Total	**$84.8**	**$27.0**	**($57.8)**
INFUSE® (Bone Morphogenetic Proteins for Spinal Fusions)	FY 04	$4.4	$12.2	$7.8
	FY 05	$7.8	$8.2	$0.4
	Total	**$12.2**	**$20.4**	**$8.2**
InSync® Defibrillator System (Cardiac	FY 05	$341.0	$151.9	($189.1)
	Total	**$341.0**	**$151.9**	**($189.1)**
Kinetra® Implantable Neurostimulator for Deep Brain Stimulation	FY 05	$11.9	$1.4	($10.5)
	FY 06	$12.8	$1.2	($11.6)
	Total	**$24.7**	**$2.6**	**($22.1)**
Restore® Rechargeable Implantable Neurostimulator	FY 06	$6.0	$1.0	($5.0)
	FY 07	$6.0	$1.4	($4.6)
	Total	**$12.0**	**$2.4**	**($9.6)**
Endovascular graft repair of the thoracic aorta	FY 06	$16.6	$12.8	($3.8)
	FY 07	$16.6	$14.0	($2.6)
	Total	**$33.2**	**$26.8**	**($6.4)**
X STOP Interspinous process decompression system	FY 07	$9.4	$9.6	$0.2
	FY 08	NA	NA	NA
	Total	**$9.4**	**$9.6**	**$0.2**

SOURCE: Centers for Medicare and Medicaid Services:
Changes to Hospital Inpatient Prospective Payment System, Final Rules FYs 2003 - 2008

Table 1.2: New Technology Add-On Payments

Technology	Year(s) Eligible for NTAP	N	Maximum Add-On Payment	Mean ± Std	Median
Drotrecogin alpha (activated) - XigrisTM	FY 03 - FY 04	9,803	$3,400	$2,757 ± $1,292	$3,400
INFUSE® (Bone Morphogenetic Proteins for Spinal Fusions)†	FY 04 - FY 05	7,724	-	$2,648 ± $2,737	$1,955
	FY 05	2,548	$8,900	$4,804 ± $3,833	$3,713
	FY 04	5,176	$1,955	$1,588 ± $735	$1,955
InSync® Defibrillator System (Cardiac Resynchronization Therapy)	FY 05	33,700	$16,263	$4,506 ± $6,125	$1,163
Kinetra® Implantable Neurostimulator for Deep Brain Stimulation	FY 05 - FY 06	483	$8,285	$5,413 ± $3,587	$8,285
Restore® Rechargeable Implantable Neurostimulator	FY 06 - FY 07	381	$9,320	$6,186 ± $3,452	$7,592
Endovascular graft repair of the thoracic aorta	FY 06 - FY 07	3,613	$10,599	$7,438 ± $3,807	$9,856
X STOP Interspinous process decompression system ‡	FY 07 - FY 08	4,093	$4,400	$2,346 ± $1,555	$2,270

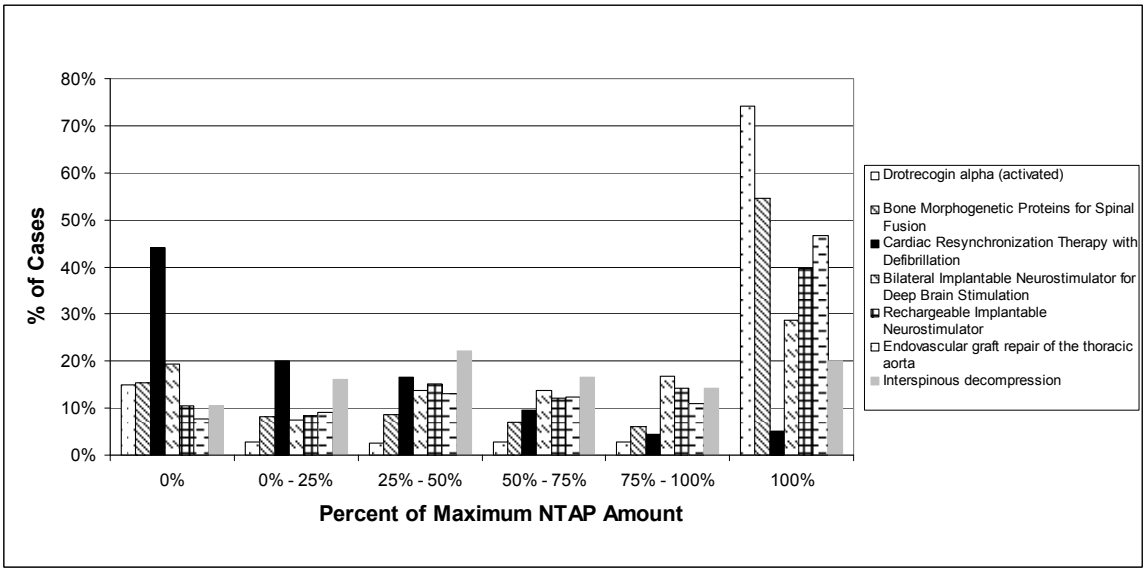
SOURCE: Authors' calculations, MedPAR LDS 10/1/2002 - 9/30/2007

† The maximum add-on payment and criteria for receiving the payment differs between FY 2004 and FY 2005

‡ Results only based on FY 2007 claims data; FY 2008 claims data was not available at time of analysis.

The variation demonstrates not only the underlying variation in hospital costs and DRG payments, but also the variation in hospital coding and charging practices.

Figure 1.1: Distribution of NTAP Amounts by Technology



1.2.3 Discussion of Results

The NTAP program has improved payment for breakthrough medical technologies. The median and mean NTAP amounts show that the actual costs per case exceed the MS-DRG payments. Without the additional payment amounts, many hospitals would have incurred financial losses as a result of using the new technology.

The NTAP program has also resulted in both lower overall spending than projected by CMS and high within-technology variation in the NTAP amounts. One potential explanation for this finding is that the NTAP amounts are dependent upon hospital charges adjusted to costs. To determine whether the costs of a case with an approved new technology should receive an add-on payment (and if so, how much), CMS uses billed charges for the case and estimates costs from those charges by applying the hospital operating cost-to-charge ratio. If the estimated costs of the case exceed the actual DRG payment for the case (excluding outlier payments), the hospital will receive

an NTAP.

Previous research has demonstrated that hospitals' charging practices and mark-ups on supplies (including implanted medical devices) can vary for a number of reasons, such as payer mix, utilization, market forces, and the cost of supplies [20]. Distortions in payment for the types of high-cost technologies that meet the CMS cost threshold to merit additional payment to qualify for an NTAP could be due to the problem known as "charge compression." Charge compression occurs when hospitals mark-up low cost items proportionately more than high-cost items, but CMS's payment methodology assumes a uniform mark-up rate when estimating costs from billed charges [21].

The use of a single, uniform "cost-to-charge ratio" to derive costs from charges results in underestimating the cost of the high cost items and overestimating the cost of lower cost items. Variations across hospitals in charge mark-ups and cost estimates for cases that include qualifying new technologies may contribute to the skewed NTAP distribution across hospitals. In particular, it may be a contributing factor why the two NTAPs with the lowest maximum payment amounts were the only products where the median actual NTAP payment levels equaled the maximum allowable amount. Costs for cases involving other higher-cost NTAPs may have been underestimated as a result of charge compression, possibly leading to artificially reduced NTAP payment levels.

1.2.4 Policy Implications

NTAP Criteria Limit Qualifying Technologies

Through regulatory provisions, CMS has structured the program criteria to ensure that only a subset of new technologies qualifies for an NTAP. Most notably, application of the substantial clinical improvement criterion enables CMS to find that only medical technologies proven to be an advance over existing technologies can qualify for an NTAP. The substantial clinical improvement criterion has been criticized for lacking clarity. In recent inpatient payment regulations, CMS has sought public comments to make the process more predictable and transparent [16]. While comments have been submitted, CMS has chosen to retain its flexibility.

Despite criticism, we have found that the existing criteria used by CMS to determine if a technology represents a substantial clinical improvement offer appropriate discretion and flexibility on the parts of both applicants and CMS to, respectively, demonstrate and

decide whether a new technology truly represents an advance in care. While "flexibility" can be viewed as "lacking clarity", it may be important for CMS to retain discretion given the range of technologies and disease states involved. For example, CMS may appropriately require less extensive clinical data when considering whether to approve a new treatment option for patients with a potentially fatal and previously untreatable condition.

Technologies That Have Qualified Have Continued to Be Proven of High Value

Although new technologies must exceed cost thresholds set for each MS-DRG to qualify for an NTAP, a cost-effectiveness analyses related to the technology are not a requirement for an NTAP. However, independent of NTAP, cost analyses have been published on all technologies receiving NTAPs [22, 23, 24, 25, 26, 27, 28]. As is typical with cost analyses, much of the research is completed and published after the technologies were introduced and the NTAPs were granted [29]. The application of the clinical evaluation criteria that require the technology to be a substantial clinical improvement over existing services could be serving as a reasonable proxy for value while also allowing timely reimbursement to breakthrough technology.

Addressing Charge Compression Will Help Ensure Accurate Payment

While the problem of charge compression may be skewing payments, CMS has implemented steps to address this issue over the long run[17]. Specifically, CMS has added a cost center to the hospital cost report to ensure that the costs and charges for relatively inexpensive medical supplies are reported CMS09. Specifically, CMS has added a cost center to the hospital cost report to ensure that the costs and charges for relatively inexpensive medical supplies are reported separately from the costs and charges of more expensive implantable devices. The addition of a new cost center for implantable devices has been separately from the costs and charges of more expensive implantable devices. The addition of a new cost center for implantable devices has been supported by the major hospital associations, CMS consultant reports, MedPAC and the medical technology industry. These steps will help to ensure appropriate MS-DRG assignment and payment when the NTAP expires.

Increasing the Adequacy of NTAP Amounts

While the NTAP program is structured to have shared risks for the costs of new technology, hospitals and others have argued that the maximum payment amounts provide an inadequate level of support to hospitals to cover the costs of the new technology. Raising the payment standard from 50 to 80 percent would be consistent with other mechanisms (such as outlier payments) in which there are shared risk for factors or costs extending beyond hospitals' direct control. This increase in payment would improve payments for all hospitals receiving NTAPs greater than zero. However, without evidence that inadequate NTAP amounts are posing a barrier to the adoption of qualifying medical technologies (which is outside the scope of this paper), CMS nor Congress have acted to increase the maximum payment amount.

1.2.5 Thesis Research

This research evaluates the effect of Medicare's NTAP program. The NTAP is the first payment incentive under Medicare's Inpatient Prospective Payment System (IPPS) since its 1983 implementation. It offers the unique opportunity to evaluate hospital's response to payment incentives under a mature prospective system. Hospital response to payment incentives and mechanisms will become increasingly important with the recent passage of health care reform as it lays the groundwork for additional hospital payment incentives to achieve efficiency, quality and patient safety objectives. This research is the first to evaluate the value of the NTAP policy and empirically estimate the effect of the NTAP policy on the utilization of new technology. The thesis is organized around three research questions: 1) does the presence of the NTAP policy effect the probability new technology is used? 2)does the amount of the NTAP effect the probability a new technology is used? 3) what is the value of the NTAP policy?

The remainder of the dissertation is outlined as follows:

- Chapter 2 is a literature review focusing on the economic theory of hospital behavior and previous research on the effect of prospective payment systems on the adoption and utilization of technology.
- Chapter 3 describes the research methods. The data, technologies, econometric methods and analyses are presented in this chapter. The methods section is organized into three sections based on the three research questions above 1) Post

NTAP analysis, which addresses the research question related to the presence of the NTAP policy and its effect on the probability new technology is used; 2) Expected NTAP analysis, which addresses the research question related to the amount of the NTAP and its effect on the probability a new technology is used; and 3) Value Analysis, which addresses the economic value of the NTAP policy.

- Chapter 4 presents the results of the the Post NTAP analysis,which addresses the research question related to the presence of the NTAP policy and its effect on the probability new technology is used.
- Chapter 5 presents the results of the Expected NTAP analysis, which addresses the research question related to the amount of the NTAP and its effect on the probability a new technology is used.
- Chapter 6 presents the results of the Value Analysis, which addresses the economic value of the NTAP policy.
- Chapter 7 presents the conclusions and implications of the research.

Chapter 2

Literature Review

2.1 Economic Theory of Hospital Behavior

United States hospitals are not subject to the same market forces as other firms [30, 31, 32]. In addition to a strong regulatory environment controlling firm entry and exit, hospitals can carry substantial bad debt, are subject to exogenous pricing structures, and enjoy philanthropic donations. Historically, there has been little incentive for hospitals to operate efficiently as the market forces do not weed out inefficient firms.

The majority of hospitals are non-profit organizations. There are multiple theories of what hospitals consider to be their operating objectives. Pauly and Redisch (1973) constructed a hospital utility function that maximizes physician preferences as the hospital's primary objective. The model considers hospitals to be the doctor's workshop. Whereas, others assumed the residual claimant of the non-profit hospital's profit is the hospital administration, which implies the hospital maximizes some combination of quality and quantity of services to indirectly maximize the hospital's prestige[32, 33].

IPPS created the direct incentive for hospitals to minimize cost and encouraged hospitals to focus on profit. Post IPPS, theoretical models about hospital behavior incorporated profit as an objective in its utility function[34, 35]. Given a fixed pre-determined price per admission, hospitals should respond by reducing operational cost per admission. A hospital can reduce operational cost by reducing resource intensity and increasing selection behavior. Studies evaluating the effect of prospective payment on hospital behavior demonstrated substantial reductions in length of stay

per admission, decreased quality (e.g. increased mortality), and increased selection behavior[35, 4, 3, 36, 5]. While hospitals responded to the new incentives introduced by IPPS, "others have argued that hospitals are concerned with patient benefits and quality"[30]. The Hodgkin and McGuire (1994) model of hospital behavior incorporates both of these objectives. The model assumes a hospital's utility is a function of profit and intensity, where intensity captures the resources inputted during a patient's admission, technological sophistication and prestige. The Hodgkin and McGuire (1994) model predicts that increasing the case payment will increase hospital's utility of both profit and intensity.

By extending the results of this model, one can hypothesize that the presence or amount of the NTAP will influence a hospital's behavior regarding the decision to use a new technology. The NTAP may increase the expected profit of a particular admission by increasing the revenue and/or reducing costs of an admission. Further, a hospital may have gains in utility due to a change in intensity, suggesting that some hospitals may adopt a technology regardless of its effect on profit due to an underlying objective such as prestige.

2.2 The Effect of Prospective Payment on Hospital Technology Adoption

There is a large body of literature examining the determinants of technology adoption and technological diffusion patterns[37, 38]. A subset of the literature examines how expected profitability of a new technology influences the adoption and diffusion of new technologies[39, 40]. Generally speaking, new technologies with higher expected profitability will lead to faster adoption[2, 39, 40]. Therefore, the NTAP, which may increase the potential profit, should increase adoption.

Despite the large body of technology adoption literature, there is a limited body of empirical literature evaluating the effect of prospective payment on technology adoption. The literature searches performed resulted in three articles that directly estimated the effect of prospective payment on technology adoption, whereas the other articles either evaluated a different payment mechanism's effect on technology adoption and extended its results to Medicare's IPPS, or speculated the effect of PPS on technology adoption.

None of the identified articles focus on medical devices, rather all of the literature concentrates on capital expense technologies.

Romeo and Wagner examine the effect of state prospective payment systems on hospital decisions to adopt "little ticket" technologies. "Little ticket" technologies refer to technologies with capital acquisition costs of less than $100,000. Five technologies' (electronic fetal monitoring, volumetric infusion pumps, upper gastrointestinal fiberoptic endoscopes, automated bacterial susceptibility testing, and centralized energy management systems) adoption was evaluated in three states with prospective payment systems (New York, Indiana, and Pennsylvania). Centralized energy management systems and automated bacterial susceptibility testing were considered to be cost-saving technologies as opposed to the other cost-increasing technologies[41].

The investigators' input demand function treated input prices of technologies as endogenous due to the price negotiations between manufacturers and hospitals, and assumed hospitals' behavior was represented by a profit maximizing firm. Given the variability in the state prospective payment systems, there was variation in the availability, extent, and speed of hospital technology adoption. New York, which had the most stringent prospective payment system, led to decreased technology adoption for all three of the cost increasing technologies, and increased adoption of the two technologies with potential cost-savings. Maryland's prospective payment system is convoluted compared to New York and Indiana. Maryland's prospective payment system encourages the adoption of cost-saving technologies, yet the researchers found no significant effect of cost saving technologies on adoption behavior. Further, the quality of the Maryland data was poor and the researchers concluded Maryland's results were inconclusive. Indiana's prospective payment system was the most loosely designed system compared to the other two states. Perhaps due to administrative oversight, the payment system encouraged hospitals to add new billable procedures to charges. This design flaw is consistent with the investigators' findings that all technologies regardless of cost-saving or cost-increasing status experienced increased adoption[41].

Despite the variability in payment systems, the data demonstrates that prospective reimbursement affects the adoption of new technologies. More specifically Romeo and Wagner's article emphasizes the importance of prospective payment system design. A prospective payment system should be carefully evaluated for incorporation of adverse

or unintended incentives.

Building on Romeo and Wagner, Lee and Waldman evaluated the effect of the same state prospective payment systems on the adoption and diffusion of the same five technologies. Lee and Waldman developed a more theoretically sound estimator that accounts for the timing and censoring of observations inherent in technology adoption data. Lee and Waldman critique Robert et al.'s use of probit models as they "suppress information on the timing of adoption characterizing firms simply as adopters or non-adopters"[42]. Not only is right censoring an inherent feature in adoption and diffusion studies, left-censoring can occur mainly as a data artifact since early adopters often are indistinguishable[42]. Ignoring such censoring issues will result in inefficient estimates. Lee and Waldman find that prospective reimbursement affects the adoption of some technologies, though not dramatically. However, cost-saving technologies are the exception. Lee and Waldman find more consistent and convincing relationship between prospective payment systems and the adoption and diffusion of cost-saving technologies[42].

Weiner, et al. evaluated whether Medicare's prospective payment system lowered the utilization of high cost technology by examining changes in the cost of care provided in intensive care units (ICU). The authors hypothesize that DRGs will lower the cost of care provided in the technology dependent ICUs. Weiner, et al. did not find any significant changes in the cost of care provided in ICUs, suggesting that hospitals will protect their technical core regardless of rate regulation[43].

Of the three empirical articles examining the relationship between prospective payment systems and technology adoption, there are inconclusive results. Romeo, et al. and Lee, et al. evaluated the same technologies and payment systems. While using different methodology, the authors both find that prospective reimbursement systems affect technology adoption. Lee et al. finds stronger and more consistent results that prospective reimbursement positively affects adoption and diffusion of cost-saving technologies compared with Romeo et al. Whereas, Weiner evaluates Medicare's prospective reimbursement system and finds no change in the cost of care in an ICU, suggesting that prospective reimbursement does not affect technology utilization. Weiner does not evaluate a diverse group of hospital-based technologies, and does not have sufficient data or methods to generalize the study's findings. Further, Weiner examines the use

of technologies already existing within a hospital and does not examine the adoption of new technology. It may be argued that the prospective DRG payments reflect the current utilization of technology within and ICU, thus causing no change in technology utilization. In sum, the empirical articles identified are inconclusive on the effect of prospective reimbursement on technology adoption.

Wedig, et al. examined hospital capital investment decisions in various payment systems. The payment systems evaluated were cost reimbursement, 100% of charges reimbursement, and percent of charges, none of which are prospective payment systems. The authors make distinctions between for-profit and non-profit status of hospitals. The theoretical model determines that cost-based reimbursement is ambiguous on capital investment. Further, the authors extend the results to prospective payment. The authors' theoretical model suggests that prospective payment will negatively affect capital investment. There is potential that prospective payment will disproportionately affect non-profit hospitals as it is assumed that "proprietaries are better able to adapt to such changes and are more financially viable institutions to start with"[44].

Other articles identified speculate the effect of prospective payment on technology adoption[45, 46, 47, 48, 49]. One article attributes the slower adoption of magnetic resonance imaging (MRI) compared with computerized tomography (CT) to Medicare's prospective payment system because CTs were introduced and adopted by hospitals prior to the implementation of IPPS[45]. Every fiscal year Medicare publishes the new DRG prospective payment rates. Due to the rate making process and data collection lag, it takes approximately two years for the reimbursement rates to reflect a new technology. Newhouse suggests that the uncertain future reimbursement for new technologies will decrease hospital investment in new technologies[46]. Lave speculates that prospective DRG payments will stimulate the development of cost-reducing technologies as hospitals will be seeking innovative ways to improve its efficiency and lower costs[47].

Prospective payment results in lower inpatient revenue compared with retrospective cost-based reimbursement. Warner speculates six first-order effects of reducing inpatient revenues. First, hospitals will decrease utilization of already existing technology. This decrease in utilization will take place by reducing the intensity and frequency of resources, e.g. fewer laboratory tests per admission. Second, increased utilization of already existing lower cost alternatives will occur. If two technologies are available to

treat an admitted patient, the hospital will use cost as the deciding factor when previously choice was based on physician and hospital preference. Warner's third and fourth effect of prospective payment can be summarized as prospective payment will lead to a reduction in the flow of new cost-increasing technologies and increase the adoption of new cost-saving technologies. Similar to some of the articles discussed above, hospitals will adopt cost-saving technologies more rapidly and limit the adoption and utilization of cost-increasing technologies with uncertain future reimbursement. Fifth, prospective payment will lead to decreased diffusion of already existing technologies. For example, hospitals that have already adopted a technology will limit its diffusion into practices of other physicians or hospital units. Lastly, Warner anticipates that increased cooperation and coordination among hospitals will occur. Hospital administrators will work with area hospitals to minimize the duplication of efforts and excess capacity. Such coordination may result in specialization, especially in urban areas capable of sustaining specialized health care facilities[48].

The speculative articles rely on the assumption that hospital level cost-containment shifts administrative decision-making power toward the hospital. Physicians determine the appropriate use of technology for treating a particular patient based upon assessed need. Further, physicians will adopt certain technologies without the consideration of costs[50]. "DRGs offer administrators not only the reason, but also the management tools needed to gain control over [physician] resource use within hospitals, [however the flaw in this logic] is that a reimbursement policy will force a change in the distribution of decision-making within hospitals"[43]. Physicians and hospital administrators are competing forces related to technology adoption under prospective payment. Physicians are motivated to provide the highest quality of care possible regardless of cost whereas hospitals are stressed to deliver high quality care in a cost-effective way[51]. Not only do physician and hospital motivations differ, the incentive structures incorporated into the Medicare payment systems are opposing. Physicians operate under a fee-for-service payment system as opposed to the prospective DRG payment system[52]. While both payment systems are prospective, physicians will receive a payment for every procedure performed during a hospital admission, whereas a hospital will receive one payment (regardless of the number of procedures performed by the physician). The opposing incentive structures will affect how a hospital adopts new technology, as it will relate to

which party has the most decision-making authority[53].

In addition to the physician-hospital relationship moderating how prospective payment will affect hospital-based technology adoption, competition among area hospitals and hospital administrators' lack of information pertaining to new technologies' benefits may be affecting the relationship between prospective payment and technology adoption[54, 55]. In summary, there are potential moderating variables affecting the relationship between prospective payment and hospital-based technology adoption, such as physician preferences, decision-making authority within a hospital, information, and competition. Further, the majority of the articles, especially those predicting a negative effect between prospective reimbursement and technology adoption, do not incorporate these moderating variables into their analyses. Lastly, there may be different effects related to prospective payment and technology adoption. Manufacturers may concentrate research and development efforts on cost-saving technologies or technologies unrelated to common health conditions prevalent in the Medicare population[1].

2.3 Discussion

There are few empirical studies evaluating the effect of prospective payment on hospital-based technology adoption. The most empirical articles evaluated five technologies' adoption within three states' prospective payment systems[41, 42]. One article evaluated Medicare's inpatient prospective payment system on technology utilization within an ICU[43]. These three articles vary in methods and technologies of interest and when synthesized yields inconsistent results. The two similar articles conclude that prospective payment affects technology adoption, especially related to cost-saving technologies.

The remainder of the articles discussed is speculative on how prospective payment affects technology adoption. The majority of the speculative articles suggest that prospective payment will reduce the adoption of new technologies because it motivates a hospital to contain costs. However, a hospital may preserve its technological core, and the effect may differ by hospital ownership status[44]. Further, the articles that suggest the relationship between prospective payment and technology adoption may be moderated by physician preferences, competition, and information.

The majority of the articles discussed were written during either during the Carter

administration or at the time Medicare's inpatient prospective payment system was implemented. There is limited research that carefully evaluates the effect of prospective payment on technology adoption. The Carter Administration Cost Containment Act proposed a limit on inpatient revenues, which generated a body of literature on how reducing inpatient revenues would affect medical technology[48]. Medicare's inpatient prospective payment system was implemented in 1983, which led to a body of policy literature related to how prospective payment systems would affect technology adoption. However, little research has been done since its policy relevance became less significant.

While the effect of prospective payment on technology adoption is empirically inconclusive, the implementation of the new technology add-on payment provides a new opportunity to evaluate this relationship. The Medicare new technology add-on payment was implemented to ensure timely and appropriate adoption of new technologies. Therefore, its implementation is based on the assumption that prospective DRG payment negatively affected the adoption and utilization of new breakthrough technology. From the literature review, it is uncertain whether the decision to implement a new technology add-on payment is empirically warranted as there is limited and inconclusive evidence demonstrating a significant negative effect between prospective payment and technology adoption.

Another important distinction is that all of the literature reviewed either referred to capital technologies or did not make the distinction between capital and operational expense technologies. The new technology add-on payment is intended for medical technologies that are related to hospitals' operational expenses. For example, medical devices implanted in patients are related to operational expenses, e.g. pacemakers and artificial spinal discs. Further, when applying for a new technology add-on payment the Center for Medicare and Medicaid Services (CMS) will deduct the capital expenses related to a new technology when determining whether it meets the cost criteria.

The literature focuses on capital technologies such as ICU equipment and large diagnostic machines. While, the relationship between prospective payment and the adoption of capital technologies is an important question, it is not beneficial in extending the argument to hypothesize how new technology add-on payments will affect hospital technology adoption.

2.4 Conclusion

This literature review sought to answer the research question: how have Medicare's prospective DRG payments affected hospital-based technology adoption? The results of the literature review were to justify hypotheses related to how Medicare's new technology add-on payments have affected hospital-based technology adoption because the implementation of add-on payments is based on the assumption that prospective DRG payments negatively affect adoption.

Few articles empirically assessed the impact of prospective payment on technology adoption, yielding inconclusive results. One common theme in the articles that speculated the effect of prospective payment on technology adoption and validated in two empirical articles was hospitals will adopt cost-saving technologies in effort to improve efficiency and lower costs. The majority of the articles discussed speculated the effect of prospective payment on technology adoption, all of which concluded that there will be a negative effect on cost-increasing technologies and potentially a positive effect on adoption of cost-saving technologies. The speculative articles were written during a time of extreme policy relevance, either during the Carter Administration's Cost Containment Act or the implementation of Medicare's inpatient prospective payment system.

Lastly, the articles reviewed were mainly related to capital technologies or failed to make the distinction between capital and operational expenses for technologies. The lack of distinction limits the extension of the results to hypothesize the relationship between new technology add-on payments and hospital-based technology adoption because add-on payments are intended for technologies consuming operational expenses and is implemented as an amalgamation of incentive structures in both prospective payment and retrospective cost-based payment systems.

Chapter 3

Methods

3.1 Data

The primary data set used in analysis is the Medical Provider Analysis and Review (MedPAR) limited data set, which is a CMS administrative data set containing 100% of inpatient hospital admissions for Medicare fee-for-service beneficiaries. The fiscal year (FY) 2003-2007 MedPAR data were linked to the CMS Provider of Service (POS), cost report, provider impact, and Hospital Compare data files via hospital provider numbers to obtain detailed hospital characteristics.

3.1.1 Computer Software

All data sets were extracted using SAS v. 9.2 and analyzed using STATA v. 10. Data were converted to the appropriate file structures using StatTransfer. All graphics and charts were developed using Microsoft Excel, R, or STATA.

3.1.2 MedPAR Data

MedPAR data were obtained under the CMS Data Use Agreement #17327. MedPAR is a database of inpatient hospital admissions for Medicare fee-for-service beneficiaries. Each record in the MedPAR data set represents a hospital admission. The MedPAR data obtained is a limited data set, which further de-identifies specific patient level information. Therefore, residential zip code is aggregated into residential county and

date of admission is aggregated to quarter of admission. Patient age, sex, race are included in the data. In addition to the patient level information, each record contains up to nine International Classification of Disease, Ninth Revision (ICD-9) codes, up to 6 ICD-9 Clinical Modification procedure codes, hospital identification, hospital and revenue center level charges, discharge status and location, time to mortality, DRG coding, and payment.

The NTAP policy is specific to inpatient hospital admissions and is only applicable to Medicare fee-for-service beneficiaries. MedPAR data captures all instances of new technology use and represents all cases where NTAP incentive applies. The first technology eligible to receive NTAPs began on October 1, 2002. Given the complexity of the data collection system, there is a two year lag period for obtaining the MedPAR claims data. The analysis uses MedPAR data from October 1, 2002 – September 30, 2007.

3.1.3 Hospital Characteristics

CMS produces the Provider of Service (POS) file which provides hospital specific characteristics for every Medicare participating hospital in the United States. Examples of the variables included in the POS file are size (e.g. number of beds), ownership type, specialty wards, graduate medical education programs, and urban or rural location. The cost report file provided information on the percentage of Medicare business within a hospital and the operating cost-to-charge ratios. The Hospital Compare file provided hospital-specific quality metrics on heart failure re-admission rates used in the Value Analysis. The hospital impact file was used to obtain payment adjustment factors such as wage index, disproportionate share, and indirect medical education. Hospitals are identified across all files using the federally assigned six digit Medicare Provider Number. The MedPAR claims were linked to the POS, cost report, impact, and Hospital Compare data files using the Medicare Provider Number.

3.2 The Technologies

Descriptions of the technologies approved to receive NTAPs are described in detail below. All technologies can be identified in the MedPAR claims using specific combinations of ICD-9 diagnosis and procedure codes. In addition to identifying the use of the new technologies in the claims, it is necessary for analytical purposes to identify the predecessor or substitute technology in the data. The use of the predecessor or substitute technology represents where the decision not to use the new technology was made; details regarding how these cases were identified is also described below.

- **Drotrecogin alpha (activated) protein for the treatment of severe sepsis associated with acute organ dysfunction**

  Drotrecogin alpha (activated) proteins was FDA approved on November 21, 2001. Drotrecogin alpha (activated) protein is an intravenously infused pharmaceutical indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death as determined by APCHE II score $\gtrsim 25$. Drotrecogin alpha (activated) protein is a recombinant version of the naturally occurring Activated Protein C, which is needed to ensure the inflammation and clotting in the blood vessels. Patients with severe sepsis cannot convert sufficient quantities of Protein C to the activated form. Drotrecogin alpha (activated) protein has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs [12].

  Drotrecogin alpha (activated) protein cases were eligible for a maximum NTAP of $3,400 from October 1, 2002 – September 30, 2004. Cases where the new technology was used were identified using ICD-9 procedure code 00.11 (infusion of drotrecogin alpha (activated). Cases where the decision not to use the new technology was made were classified as patients with severe sepsis with acute organ dysfunction without the use of drotrecogin alpha (activated) proteins. These cases were identified using ICD-9 diagnosis codes 995.92 (Severe sepsis with acute organ dysfunction, or multiple organ dysfunction) and 038.X (septicemia), without the procedure code 00.11.

  There was difficulty identifying an appropriate substitute technology group for

alpha-proteins. The same date that the NTAP policy became effective, the ICD-9 diagnosis code 995.92 (severe sepsis with acute organ dysfunction, or multiple organ dysfunction) was implemented. It was evident that there was a learning curve related to the use of the new ICD-9 diagnosis codes as a there was a large degree of under-reporting of sepsis. Given the difficulty in identifying an adequate substitute technology group α-proteins have been excluded from additional analysis.

- **Bone morphogenic proteins for spinal fusions**

  Bone morphogenic proteins (BMP) for spinal fusions was FDA approved on July 2, 2002. The technology is used to treat degenerative disc disease of the lumbar spine. Bone morphogenic proteins consists of a solution of recombinant human bone morphogenetic protein that is applied through use of an absorbable collagen sponge and an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This technology is done in place of the traditional iliac crest bone graft, where bone is harvested from the patients' iliac crest and placed in the spine to fuse the vertebrae together to stabilize the spine. The use of the new technology reduces the operating time, hospitalizations, blood loss, and may result in greater fusion success[19].

  Bone morphogenic proteins for spinal fusions were eligible for a maximum NTAP of $8,900 from October 1, 2003 – September 30, 2004, and $1,955 for October 1, 2004 – September 30, 2005. Bone morphogenic proteins for spinal fusion cases were identified using the combination of ICD-9 procedure codes 84.51 (insertion of interbody spinal fusion device) and 84.52 (insertion of recombinant bone morphogenic protein rhBMP) that map to DRGs 497 or 498. Due to coding changes that occurred on 10/1/2004 cases after that 10/1/2004 were identified with 84.51 and 84.52 and 81.05 (dorsal and dorsolumbar fusion, posterior technique), 81.08 (lumbar and lumbosacral fusion, posterior technique), 81.35 (refusion of dorsal and dorsolumbar spine, posterior technique), or 81.38, (refusion of lumbar and lumboscardal spine, posterior technique) and are assigned to DRGs 497 or 498.

Cases where the decision not to use the new technology was made will be identified during October 1, 2003 – September 30, 2004 using 84.51 without 84.52, and are assigned to DRGs 497 or 498; during October 1, 2004 – September 30, 2005 using 84.51 with 81.05, 81.08, 81.35, or 81.38 and without 84.52 and are assigned to DRGs 497 or 498.

- **Bilateral deep brain stimulator for the treatment of Parkinson's disease**

  Bilateral deep brain stimulation (b-DBS) was FDA approved on December 13, 2003. The technology is an implantable neurostimulator device designed to deliver electrical stimulation to the subthalamic nucleus or internal globus pallidus to reduce the symptoms caused by abnormal neurotransmitter levels that lead to abnormal cell-to-cell electrical impulses in Parkinson's Disease and essential tremor. The bilateral deep brain stimulation technology is intended to treat Parkinson's disease and essential tremor patients who have bilateral symptoms. Prior to the bilateral deep brain stimulation technology, patients with bilateral symptoms were implanted with two unilateral deep brain stimulation devices - one to treat either sides of the symptoms - thus requiring additional surgery in the chest cavity to place the second generator, and alongside the neck to tunnel the additional lead to connect to the second generator. The bilateral deep brains stimulation reduces operating time, the number of surgical sites, and therefore the potential for post-surgical infection.

  Bilateral deep brain stimulation cases were eligible for a maximum NTAP of $8,285 from October 1, 2004 – September 30, 2006. Bilateral deep brain stimulation cases were identified using the combination of ICD-9 codes 02.93 (implantation or replacement of intracranial neurostimulator leads) and 86.95 (insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable). Cases where the decision not to use the new technology was made were patients that received unilateral deep brain stimulation for the treatment of Parkinson's disease. Unilateral deep brain stimulation cases were identified using 02.93 and 86.94 (insertion or replacement of single array neurostimulator pulse generator, specified as non-rechargeable).

- **Cardiac resynchronization therapy (bi-ventricular pacing)**

Cardiac resynchronization therapy (CRT-D) was FDA approved on June 26, 2002. Cardiac resynchronization therapy is a therapy for chronic heart failure and provides electrical stimulation to the right atrium, right ventricle, and left ventricle to resynchronize ventricular contractions and improve the oxygenated blood flow to the body. This technology combines cardiac resynchronization therapy with defibrillation for patients with moderate to severe heart failure who meet the criteria for an implantable cardiac defibrillator. Unlike traditional implantable cardiac defibrillators (ICD), CRT-D treats 1) the symptom of heart failure and 2) the high risk of ventricular arrhythmias, which would cause sudden cardiac arrest. Prior to CRT-D, patients would have only been able to receive therapy to treat one of the two risks mentioned above.

Cardiac resynchronization therapy cases were eligible for a maximum NTAP of $16,262.50 from October 1, 2004 – September 30, 2005. Cardiac resynchronization therapy were identified using ICD-9 codes 00.51 (implantation of cardiac resynchronization defibrillator, total system [CRT-D]) or 00.54 (implantation or replacement of cardiac resynchronization defibrillator, device only [CRT-D]). Cases where the decision not to use the new technology was made were identified as patients with congestive heart failure unspecified (ICD 9 code 428.0), systolic heart failure (ICD 9 code 428.2), diastolic heart failure (ICD 9 code 428.3), or combined systolic and diastolic heart failure (ICD 9 code 428.4) as a primary diagnosis, and received an implantable cardiac defibrillator as identified through DRGs 515, 535, or 536.

- **Rechargeable implantable spinal cord stimulator for chronic pain**

  Rechargeable implantable spinal cord stimulators were FDA approved on April 27, 2004. Rechargeable neurostimulation therapy is an implanted medical device for the treatment of chronic pain. Leads providing electrical stimulation are implanted into the epidural space of the spinal cord and the rechargeable generator is implanted in a pocket in the abdomen. Patients who receive spinal cord stimulation have various energy needs and stimulation requirements depending on the location and chronicity of the pain. Patients with high energy needs benefit from the rechargeable technology as it will significantly reduce the number of

replacement surgeries and generators required. Prior to the use of rechargeable neurostimulators, patients with high energy needs to control their pain would have their primary cell generators replaced when the battery was depleted. A rechargeable generator enables to patient to recharge the battery and avoid replacement surgeries.

Rechargeable implantable spinal cord stimulator cases were eligible for a maximum add-on payment of $9,320 from October 1, 2005 – September 30, 2007. Rechargeable neurostimulator cases were identified using 86.98. Cases where the decision not to use the new technology was made were identified as patients implanted with non-rechargeable spinal cord stimulator cases. Non-rechargeable spinal cord stimulator cases were identified using 86.94 (implantation of single array implantable pulse generator) or 86.95 (implantation of dual array implantable pulse generator) that fall into a any of the following DRGs: 007 (peripheral & cranial nerve & other nervous system procedure with cc), 008 (peripheral & cranial nerve & other nervous system procedure without cc), 499 (back & neck procedures except spinal fusion with cc), 500 (back & neck procedures except spinal fusion without cc), 531 (spinal procedures with cc), or 532 (spinal procedures without cc).

- **Endovascular graft repair of the thoracic aorta**

  Endovascular graft repair (EVG) was FDA approved on March 23, 2004. Endovascular graft repair is a less invasive treatment option to the traditional open surgical approach for descending thoracic aortic aneurysms. The traditional open surgical repair of the thoracic aorta is associated with high morbidity and mortality as the surgery is frequently performed under emergency conditions. The new technology is a tubular stent graft mounted on a catheter delivery system that is inserted via a small incision in the patient's groin and replaces the synthetic graft normally sutured in place during the open surgical repair.

  Endovascular graft repair of the thoracic aorta cases were eligible for a maximum add-on payment of $10,599 from October 1, 2005 – September 30, 2007. Endovascular graft repair cases were identified using ICD-9 code 39.73 (endovascular implantation of graft in thoracic aorta). Cases where the decision not to use the new technology were identified as patients who received a synthetic graft during

open heart surgery. Synthetic graft patients were identified using ICD-9 procedure code 39.79 (other endovascular repair (of aneurysm) of other vessels) with diagnoses of 441.2, 441.1, or 441.01.

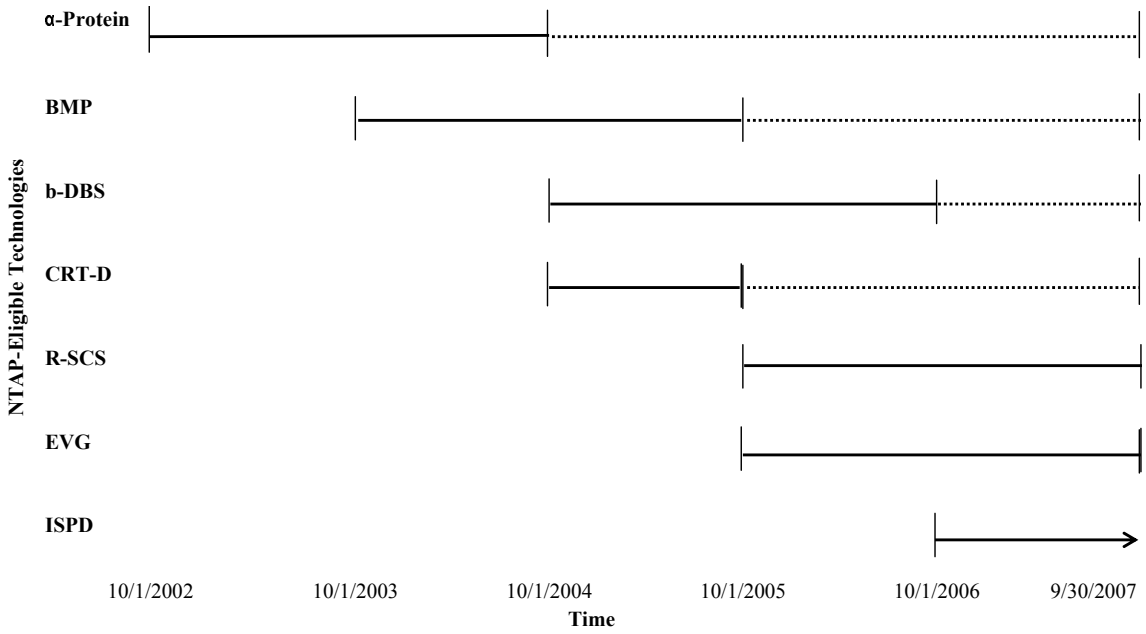
- **Interspinous process decompression system for lumbar spinal stenosis**

  Interspinous process decompression (ISPD) was FDA approved on November 11, 2005. The technology is used to treat lumbar spinal stenosis, a condition that occurs when the spaces between bones in the spine become narrowed due to arthritis or other age related conditions. The narrowing of the space, or stenosis, causes the compression of nerves within the spinal cord resulting in pain, numbness, and weakness. The intraspinous decompression technology is a minimally invasive treatment alterative to conservative treatment such as physical therapy and exercise, and spinal fusion surgery. The new technology is made of titanium allow and consists of a spacer and a wing assembly. The device is implanted between the spinous processes of the lumbar spine, and it limits the extension of the spine in the affected area thus resulting in less compressed nerves. The technology may improve a patient's ability to function and reduce some of the pain associated with lumbar spinal stenosis.

  Interspinous process decompression cases have been eligible to receive a maximum add-on payment of $4,400 from October 1, 2006 – September 30, 2008. Interspinous process decompression system cases were identified using ICD-9 procedure code 84.58 (implantation of interspinous process decompression device). Cases where the decision not to use the new technology was made were identified with ICD-9 diagnosis code 724.02 (spinal stenosis of the lumbar region) and are assigned to DRGs 499 (back and neck procedures except spinal fusion with complications or comorbidities) or 500 (back and neck procedures except spinal fusion without complications or comorbidities).

The timing of the NTAPs for particular technologies is summarized in the following figure.

Figure 3.1: NTAP Technology Timeline



The combinations of ICD-9 procedure and diagnosis codes, and DRGs are summarized in the Table 3.1.

Table 3.1: Coding Specifications for Analysis

Technology		ICD-9 Procedure Codes	ICD-9 Diagnsosis Codes	DRGs
BMP	Use	84.51 (insertion of interbody spinal fusion device) & 84.52 (insertion of recombinant bone morphogenic protein rhBMP)	81.05 (dorsal and dorsolumbar fusion, posterior technique), 81.08 (lumbar and lumbosacral fusion, posterior technique), 81.35 (refusion of dorsal and dorsolumbar spine, posterior technique), or 81.38, (refusion of lumbar and lumboscardal spine, posterior technique*	497 (spinal fusion except cervical w/ cc) or 498 (spinal fusion except cervical w/o cc)
	Not Use	84.51 (insertion of interbody spinal fusion device) without 84.52 (insertion of recombinant bone morphogenic protein rhBMP)	81.05 (dorsal and dorsolumbar fusion, posterior technique), 81.08 (lumbar and lumbosacral fusion, posterior technique), 81.35 (refusion of dorsal and dorsolumbar spine, posterior technique), or 81.38, (refusion of lumbar and lumboscardal spine, posterior technique*	497 (spinal fusion except cervical w/ cc) or 498 (spinal fusion except cervical w/o cc)
b-DBS	Use	02.93 (implantation or replacement of intracranial neurostimulator leads) & 86.95 (insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable)		
	Not Use	02.93 (implantation or replacement of intracranial neurostimulator leads) & 86.94 (insertion or replacement of single array neurostimulator pulse generator, specified as non-rechargeable)		
CRT-D	Use	00.51 (implantation of cardiac resynchronization defibrillator, total system [CRT-D]) or 00.54 (implantation or replacement of cardiac resynchronization defibrillator, device only [CRT-D]).		
	Not Use		428.0 (congestive heart failure unspecified), 428.2 (systolic heart failure), 428.3 (diastolic heart failure), or 428.4 (combined systolic and diastolic heart failure)	515 (cardiac defibrillator implant w/o cardiac cath) 535 (cardiac defibrillator implant w/ cardiac cath w/ ami/hf/shock) 536 (cardiac defibrillator implant w/o cardiac cath w/ ami/hf/shock)
R-SCS	Use	86.98 (insertion or replacement of dual array neurostimulator pulse generator, rechargeable)		
	Not Use	86.94 (implantation of single array implantable pulse generator) or 86.95 (implantation of dual array implantable pulse generator)		007 (peripheral & cranial nerve & other nervous system procedure with cc), 008 (peripheral & cranial nerve & other nervous system procedure without cc), 499 (back & neck procedures except spinal fusion with cc), 500 (back & neck procedures except spinal fusion without cc), 531 (spinal procedures with cc), or 532 (spinal procedures without cc)
EVG	Use	39.73 (endovascular implantation of graft in thoracic aorta)		
	Not Use	39.79 (other endovascular repair (of aneurysm) of other vessels)	441.2 (Thoracic aneurysm without mention of rupture), 441.1(Thoracic aneurysm, ruptured), or 441.01 (Thoracic)	
ISPD	Use	84.58 (implantation of interspinous process decompression device)		
	Not Use		724.02 (spinal stenosis of the lumbar region)	499 (back and neck procedures except spinal fusion with complications or comorbidities) or 500 (back and neck procedures except spinal fusion without complications or comorbidities)

* only effective FY 2005

3.3 Post NTAP Analysis

The objective of this analysis is to determine whether the presence of the NTAP policy has an effect on the use of the new technology. In effort to isolate the incentive effect from the natural adoption effect the analysis was limited to hospitals where the choice set of using the new technology and using the substitute technology was present. Specifically, the analysis was limited to hospitals where the new technology was being used within the first year of FDA approval were included in the analysis.

Of the technologies that have been eligible for NTAPs, four have an observable post NTAP time period within the data available at the time of analysis: (1) bone morphogenetic proteins for spinal fusions (BMP), (2) bilateral deep brain stimulator for the treatment of Parkinson's disease (b-DBS), and (3) cardiac re-synchronization therapy (CRT-D).

3.3.1 Dependent Variable

The dependent variable is the use of new technology. The variable is a dichotomous variable where $Y_{i,j}$ =1 when the new technology was used and $Y_{i,j}$ =0 when the new technology was not used, where i indicates the individual patient and j indicates the hospital.

3.3.2 New Technology Add-on Payment Policy

The analysis uses a pre-post design and focuses estimates the effect of the NTAP policy on the probability of use. The variable, N, is a dichotomous variable where N =1 during the time period when the technology was eligible for the additional payment and N =0 during the time period after the new technology payment policy.

3.3.3 Other Explanatory Variables

Other explanatory variables used in this analysis can be classified as either hospital or patient characteristics. Demographic patient characteristics included are age, sex, and race. To estimate severity of illness, the Charlson Co-morbidity Index was estimated using the complications and co-morbidities the patient had upon admission to the hospital [56].

Hospital characteristics included are the number of graduate medical residents, number of physicians in the hospital, ownership type (non-profit, for-profit, government), presence of a specialty ward related to the new technology, number of beds, and the percent of hospital business attributable to Medicare beneficiaries.

An ordinal time variable representing the quarter when the hospital admission occurred is included to control for the natural technology diffusion pattern. In addition interaction terms between the NTAP and various hospital and patient characteristics were included to determine whether certain characteristics have a differential impact on the probability of use during and post incentive periods.

3.3.4 Estimation

For each technology, a logistic model estimated the probability the new technology was used. The empirical model estimates the effect of the NTAP on the decision to use a new technology on a given patient. The basic model can be written as follows:

$$Y_{i,j} = \alpha + \beta N + \gamma H_j + \phi I_{i,j} + \theta N H_j + \eta N I_{i,j} + \tau T + \epsilon_{i,j} \tag{3.1}$$

, where j: hospital subscript; i: individual patient subscript; α: intercept; N is the NTAP indicator variable; H_j: a vector of hospital characteristics; $I_{i,j}$: a vector of individual characteristics; NH_j: is a vector of interaction terms between N and select hospital characteristics; $NI_{i,j}$: is a vector of interaction terms between N and select individual characteristics (age, co-morbidities); T: is the ordinal time variable indicating the quarter of hospital admission; $\epsilon_{i,j}$: error term.

The standard errors were clustered by hospital to allow for for within-hospital correlation thus resulting in more conservative standard error estimates.

The marginal effect of the NTAP policy on the probability of use is calculated for each technology. The marginal effect measures the effect of NTAP expiration on the predicted probability of use while holding all other explanatory variables constant, except the NTAP policy indicator. The marginal effect provides the overall impact of the NTAP and the logistic regression coefficients are nonlinear estimates of explanatory variables on new technology use.

3.4 Expected NTAP Analysis

A hospital faces two payment rates conditional on its decision on whether to use the NTAP-eligible technology or the previous standard of care. If the hospital chooses to use the new technology, the total Medicare reimbursement rate will include the prospective DRG rate and the NTAP. If the hospital chooses not to use the new technology, the total reimbursement will be the prospective DRG rate. Therefore, the NTAP represents a potential marginal increase in revenue to a hospital. Similar to the post-NTAP analysis, this analysis is limited to hospitals who have adopted the technology and therefore is within its choice set to use or not use in a given patient. This analysis focuses on the expected NTAP amount and is therefore limited to the time period for each technology when the NTAP is effective. The technologies evaluated in this analysis are: (1) bone morphogenetic proteins for spinal fusions (BMP), (2) bilateral deep brain stimulator for the treatment of Parkinson's disease (b-DBS), (3) cardiac resynchronization therapy (CRT-D), and (4) rechargeable spinal cord stimulation. Despite having the complete data for the NTAP incentive time period, endovascular graft repair was not evaluated. Upon introduction, 96% of cases used the new technology, whereas only 4% used the substitute technology. The technologies evaluated in this analysis are limited to those where full data on their NTAP experience was available. Therefore, interspinous decompression was not evaluated as data on its final year of NTAP eligibility was not available at the time of analysis.

3.4.1 Calculation of the Expected NTAP Amount

Exogenous hospital and patient characteristics, and the hospital decision whether to use the new technology are observed. The NTAP calculation is dependent upon the charges for a particular hospital admission (1.1). However, we only observe charges related to the new technology if the hospital uses the new technology. Further, hospital charges are endogenous, as the hospital determines the charge related to the new technology. Therefore, it is necessary to choose an estimation procedure that accounts for the selection bias of hospital charges. A predicted NTAP value ($\widehat{NTAP}$) is estimated using a two-part model. The predicted NTAP amount is then used in the equation estimating the impact the NTAP amount has on the probability of new technology use.

If a hospital uses an NTAP-eligible technology, it does not necessarily receive an additional payment. An NTAP is only received if a new technology has been used during an inpatient hospital visit, and the hospital billing practices reflects the actual cost related to the new technology. The hospital must adjust charges appropriately in order for the estimated cost be greater than the DRG payment. As seen in Figure 1.1, the NTAP distribution has a mass of zero amounts.

A two-part model was used to predict the NTAP payment as the NTAP amounts includes many zero dollar observations[57, 58].

The first part of the two part model predicts the probability a hospital received an NTAP payment, or $Pr(NTAP_{i,j} > 0 = \theta x'\beta)$, where θ represents the logit function.

$$p_{i,j} = \alpha + \phi I_{i,j} + \beta K_{i,j} + \eta D_j + u_{i,j} \tag{3.2}$$

Where $p_{i,j}$ is a binary variable indicating whether a particular observation received an NTAP payment; $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); $K_{i,j}$ is the diagonal matrix of $I_{i,j}I_{i,j}$ for patient level interactions (age*Charlson score, sex*Charlson score); D_j is a vector of dummy variables equal to 1 if patient i is seen by the j^{th} hospital, representing the hospital fixed effect; and $u_{i,j}$ is the error term.

The second part of the model predicts NTAP conditional on non-zero payments. To obtain unconditional predicted NTAPs, the probabilities of receiving an NTAP are multiplied by expected levels from the second part of the model:

$$E(NTAP_{i,j}|x_{i,j}) = Pr(NTAP_{i,j} > 0|x_{i,j})E(NTAP_{i,j}|x_{i,j}, NTAP_{i,j} > 0). \tag{3.3}$$

A lognormal model with hospital fixed effects was used to estimate the NTAP dollar amounts:

$$ln(NTAP_{i,j}) = \alpha + \phi I_{i,j} + \beta K_{i,j} + \eta D_j + u_{i,j} \tag{3.4}$$

Where $ln(NTAP_{i,j})$ is the natural log of the new technology add-on payment, which adjusts for the upper tail of the distribution; $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); $K_{i,j}$ is the diagonal matrix of

$I_{i,j}I_{i,j}$ for patient level interactions (age $*$ Charlson score, sex $*$ Charlson score); D_j is a vector of dummy variables equal to 1 if patient i is seen by the j^{th} hospital, representing the hospital fixed effect; and $u_{i,j}$ is the error term.

The expected value of the conditional lognormal NTAP is:

$$Pr(NTAP_{i,j} > 0|x_{i,j}) = exp\left(ln(\widehat{NTAP}_{i,j}) + \frac{1}{2}\sigma^2\right) \tag{3.5}$$

The error terms from (3.4) were normally distributed for all technologies, therefore no smearing estimate was used when re-transforming the natural log of NTAP to actual dollar amounts [57].

3.4.2 Modeling Use of New Technology

A discrete choice model using a logistic functional form is used to estimate the probability a hospital uses a new technology. The variable of interest is the NTAP amount, predicted from (3.5). The model incorporates patient and hospital characteristics, and tested for various interaction effects.

$$y_{i,j} = \alpha + \zeta\widehat{NTAP}_{i,j} + \phi I_{i,j} + \gamma H_j + \beta K_{i,j} + \theta H_j I_{i,j} + \tau_t + \epsilon_{i,j} \tag{3.6}$$

,where $y_{i,j}$ represents the use of the new technology where it is equal to 1 if the technology is used in patient i and zero otherwise; $\widehat{NTAP}_{i,j}$ represents the predicted NTAP amount; $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); H_j is a vector of the j^{th} hospital characteristics (ownership type, urban location, Medicare percentage, number of beds, number of residents, number of physicians, operating cost to charge ratio, and the prior use of the substitute technology before the NTAP became effective); $K_{i,j}$ is the diagonal matrix of $I_{i,j}I_{i,j}$ for patient level interactions (age*Charlson score, sex*Charlson score); $H_jI_{i,j}$ interactions between the j^{th} hospital and i^{th} patient characteristics (Charlson*Medicare percentage, length of stay*ownership type, Charlson score*ownership type); τ_t represents quarter time dummy variables; and $\epsilon_{i,j}$ is the error term.

Further, to reduce the biases and potential instability of the parameter estimates

when modeling the use of new technology (3.6), the jackknife method was used to estimate the standard errors. Jackknifing is a non-parametric technique similar to bootstrapping where the model (3.6) is repeatedly estimated using a sub-sample of $n-1$ observations. Specifically for this model, the subsamples included $j-1$ observations where all observations from a randomly selected hospital were removed and (3.6) was repeatedly re-estimated. The standard error is then calculated from the truncated subsamples, which is equal to the standard deviation of the sample mean of the parameter estimates.

In addition to (3.6), a use equation including hospital fixed effects was also estimated. This was estimated to determine whether hospitals were selecting patients for the new technology who would yield a higher NTAP amount.

$$y_{i,j} = \alpha + \zeta \widehat{NTAP}_{i,j} + \phi I_{i,j} + \beta K_{i,j} + \eta D_j + \tau_t + \epsilon_{i,j} \tag{3.7}$$

,where everything is identical to (3.7) except ηD_j which is a vector of dummy variables equal to 1 if patient i is seen by the j^{th} hospital, representing the hospital fixed effect.

3.5 Value Analysis

Heart disease is the leading cause of death in the United States killing approximately 700,000 people each year [59]. People that die from heart disease typically die from either sudden cardiac death or progressive chronic heart failure (CHF)[60]. Cardiac-resynchronization therapy combined with cardiac defibrillation (CRT-D) is an implantable device therapy that improves oxygenated blood flow to patients with patients with chronic heart failure by resynchronizing ventricular contractions. In a randomized control trial, the utilization of this technology has been shown to significantly reduce mortality and improve other health-related outcomes [61].

On October 1, the Centers for Medicare and Medicaid (CMS) granted CRT-D new technology add-on payment (NTAP) status. The NTAP status enabled hospitals to receive an additional payment up to $16,262.50 for one year in effort to encourage CRT-D utilization in clinically appropriate patients. The NTAP amount represents 50% of the expected cost of the new technology. Therefore, in addition to the prospective DRG

payment, implanting hospitals could increase their inpatient hospital revenue for cases where CRT-D was used.

This analysis first estimates the impact of CRT-D on patient mortality. The second portion of the analysis uses the findings from the Post NTAP Analysis and the Expected NTAP Analysis to determine the value of the NTAP in terms of the cost per life saved.

3.5.1 Dependent Variable

The dependent variable of interest is death. The data are right censored, as the days from admission to death up to one year post-discharge are observed. A dichotomous variable created from the admission to death interval was created where $Y_{i,j}$ =1 if we observed the patient death and $Y_{i,j}$ =0 if death was not observed.

3.5.2 Hospital Quality Measures

A hospital quality measure was included as an explanatory variable. The hospital thirty day heart failure readmission rates were included as an explanatory variable to measure the effect of hospital heart failure treatment quality on probability of death.

3.5.3 Use of CRT-D

The use of CRT-D is a dichotomous endogenous regressor. Use is an endogenous variable as the hospital chooses whether to implant a given patient with CRT-D. Due to the endogeneity of use, a estimation procedure that can account for the correlation between errors is employed.

3.5.4 Other Explanatory Variables

Other explanatory variables used in this analysis can be classified as either hospital or patient characteristics. Demographic patient characteristics included are age, sex, and race. To estimate severity of illness, the Charlson Co-morbidity Index was estimated using the complications and co-morbidities the patient had upon admission to the hospital.

Hospital characteristics included are the number of graduate medical residents, number of physicians, ownership type (non-profit, for-profit, government), presence of a specialty ward related to the new technology, number of beds, and the percent of hospital business attributable to Medicare beneficiaries.

An ordinal time variable representing the quarter when the hospital admission occurred is included to control for the natural technology diffusion pattern. In addition interaction terms between the NTAP and various hospital and patient characteristics were included to determine whether certain characteristics have a differential impact on the probability of use during and post incentive periods.

3.5.5 Instrumental Variable Probit

An instrumental variable probit model with a dichotomous outcome (death), an endogenous dichotomous regressor (use), is used to estimate the effect of use on the probability of death.

Equation (3.8) is the reduced-form equation that estimates the endogenous use variable in terms of exogenous variables. The instruments used to identify the reduced-form equation is the predicted NTAP amount, or $\widehat{NTAP}$, and the binary NTAP policy indicator N. Both variables are correlated with use of new technology, but would not the probability a patient dies, therefore making it a potentially strong instrument.

A logistic model was used to estimate the effect of the use of the new technology, the expected NTAP, patient characteristics and hospital characteristics had on the probability of death.

$$y2_{i,j} = \alpha + \zeta\widehat{NTAP}_{i,j} + \beta N_{i,j} + \phi I_{i,j} + \gamma H_j + \eta NI_{i,j} + \tau T + \tau_1 T^2 + v_{i,j} \tag{3.8}$$

Where $y_{i,j}$ represents the use of the technology equal to 1 if CRT-D is used in patient i and zero otherwise; $\widehat{NTAP}$ represents the expected NTAP amount calculated from (3.4); $N_{i,j}$ is the binary NTAP policy indicator that equals one during the incentive time period and zero otherwise; $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); $NI_{i,j}$ is the interaction effect between Charlson score and the incentive time period, which was shown to be significant in the post-NTAP analysis; H_j is a vector of the j^{th} hospital characteristics (ownership

type, Medicare percentage, number of beds, number of residents, number of physicians, operating cost-to-charge ratio, prior use of the substitute technology the year before the NTAP became effective); T is an ordinal time variable indicating the quarter of hospital admission; T^2 is the ordinal time variable squared to address some non-linearity of the model; and $v_{i,j}$ is the error term.

The second stage of the instrumental variable probit estimates the outcome of interest, death, while adjusting for the endogeneity of use with the first stage.

$$y1*_{i,j} = \alpha + \chi y2_{i,j} + \phi I_{i,j} + \gamma H_j + \tau T + \tau_1 T^2 + u_{i,j} \tag{3.9}$$

Where $y1*_{i,j}$ is a dichotomous variable indicating death that equals 1 when death in patient i is observed and zero otherwise; $\chi y2_{i,j}$ is the exogenous use variable predicted from (3.8); $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); H_j is a vector of the j^{th} hospital characteristics (30 day heart failure readmission rate, ownership type, Medicare percentage, number of beds, number of residents, number of physicians, prior use of the substitute technology the year before the NTAP became effective); T is an ordinal time variable indicating the quarter of hospital admission; T^2 is the ordinal time variable squared to address some non-linearity of the model; and $u_{i,j}$ is the error term.

It is assumed that the error terms $(u_{i,j})$ and $(v_{i,j})$ are correlated by ρ and are jointly normally distributed, $(u_{i,j}, v_{i,j}) \sim N(0, \Sigma)$ [62]. Instrumental variable analysis allows the prediction of use and then runs a probit regression on the probability of death on regressors and the residuals from the reduced form model. This two-step approach will also report the correlation of the errors between the two models and test its significance using a Wald test for exogeneity, which tests the null hypothesis that ρ is equal to zero.

In addition to the instrumental variable probit, bivariate probit and linear instrumental variable models were estimated to validate the robustness of the results. The methods and results of these models are included in the Appendix.

Chapter 4

Post NTAP Analysis Results

The objective of this analysis is to determine whether the presence of the NTAP policy has an effect on the use of the new technology. Three technologies with observable post-incentive time periods were included in the analysis: cardiac resynchronization therapy (CRT-D), bone morphogenetic proteins (BMP), and bilateral deep brain stimulators (b-DBS). A logistic model with utilization as a dependent variable is estimated using exogenous hospital and patient characteristics and a NTAP policy indicator variable.

4.1 Post NTAP Analysis

The percent of NTAP technology use over time is presented in Figure 4.1, Figure 4.2, and Figure 4.3. With the exception of bilateral deep brain stimulation, it is not certain upon visual inspection whether the percentage use of the new technologies declined upon the expiration of the NTAP. It appears that upon the expiration of the NTAP, the percentage use of bilateral deep brain stimulation declined, whereas the magnitude and direction the NTAP policy is uncertain with respect to cardiac re-synchronization therapy and bone morphogenetic protein.

4.1.1 Baseline Characteristics

Baseline patient characteristics are summarized in Table 4.1. Bone morphogenetic proteins were used in 41% of all eligible patients; cardiac re-synchronization therapy was used in 44% of all eligible patients; and bilateral deep brain stimulation was used in 56%

Figure 4.1: Percent Use of Cardiac Resynchronization Therapy

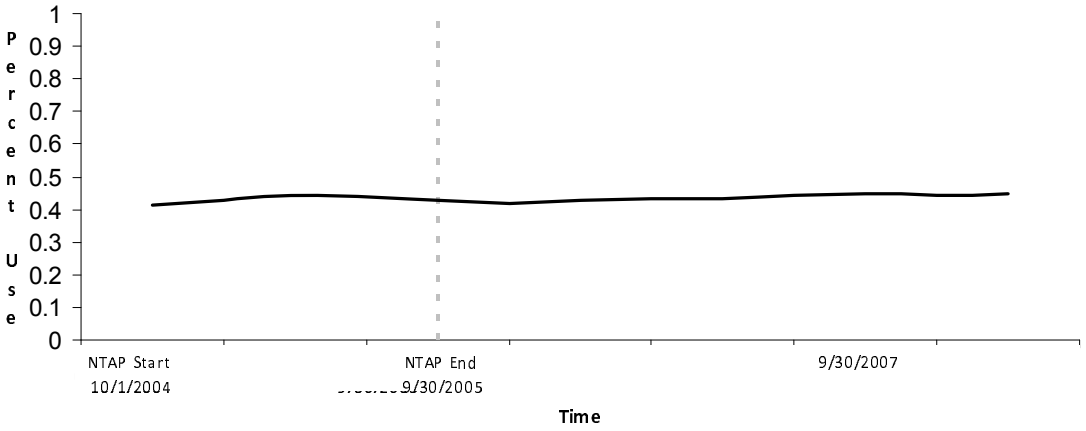


Figure 4.2: Percent Use of Bone Morphogenetic Proteins

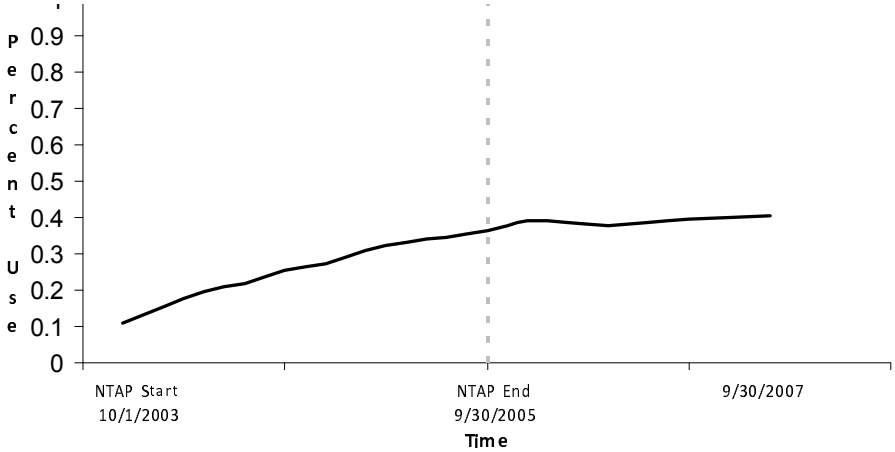
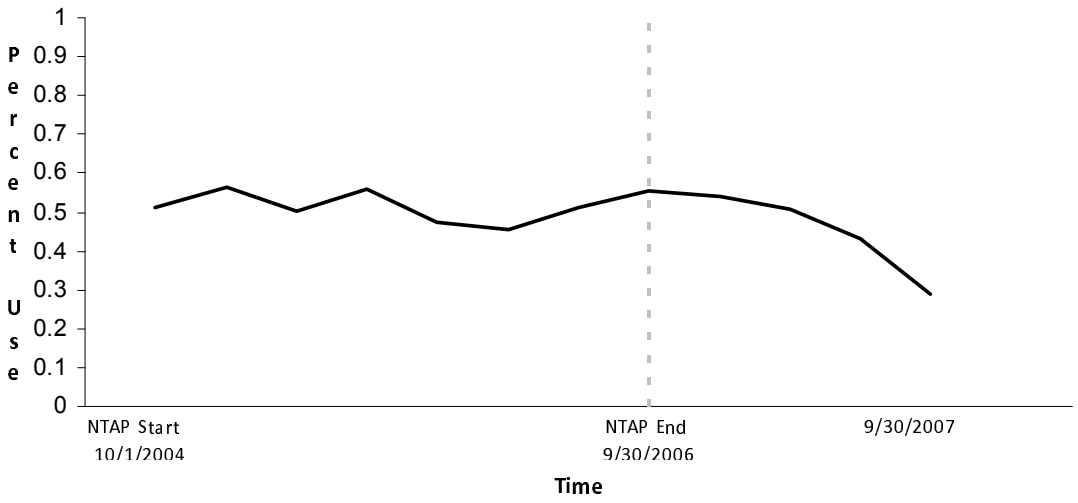


Figure 4.3: Percent Use of Bilateral Deep Brain Stimulation



of eligible patients included in the analysis. All patients receiving the new technologies had significantly lower Charlson scores compared to patients who received the substitute technology ($p< 0.05$); therefore patients who received the new technologies had fewer complications and co-morbidities at implant compared to patients who received the substitute technologies. The majority of all patients included in the analysis were between 65 and 75 years of age and did not significantly differ between groups. The age distribution is expected as the data represents the United States Medicare population.

Characteristics of the hospitals included in the analysis are summarized in Table 4.2. Hospitals included in this analysis were limited to those using the new technology of interest within the first year of FDA approval. All hospitals have similar characteristics across the technologies. Between 16–18 percent have dedicated specialty wards related to the new technology and 71-78 percent of hospitals are non-profit organizations. In addition, Medicare beneficiaries account for 55–65 percent of the overall hospital days. Bilateral deep brain stimulation is a highly specialized technology and is more concentrated than BMP or CRT-D.

For profit hospitals are significantly more likely than non-profit hospitals to use BMP during the incentive time period than after($p < 0.05$). Adoption of CRT-D and

Table 4.1: Patient Characteristics

	BMP			CRT-D			b-DBS		
Patient Characteristics	**Use**	**No Use**	**p-value**	**Use**	**No Use**	**p-value**	**Use**	**No Use**	**p-value**
Number of Patients	22,049	31,212		94,163	118,029		659	501	
Charlson Score - mean (sd)	0.54 (0.81)	0.57 (0.89)	0.0007	1.10 (1.11)	1.15 (1.10)	<.0001	0.28 (.60)	0.41 (0.78)	0.0009
Sex			0.2243			<.0001			0.8904
Female - %	64%	63%		26%	25%		37%	38%	
Race			0.4236			<.0001			0.737
Non-white - %	9%	9%		16%	13%		43%	45%	
Age			0.0481			<.0001			0.0275
25-64 yr. - %	26%	26%		17%	13%		30%	22%	
65-79 yr.- %	66%	65%		62%	62%		65%	47%	
80+ yr. - %	8%	9%		21%	26%		5%	7%	

Table 4.2: Hospital Characteristics

	Technology		
Hospital Characteristics	**BMP**	**CRT-D**	**b-DBS**
Number of Hospitals	861	1183	102
Number of Beds - mean (sd)	389 (269)	405 (256)	654 (368)
Number of Residents - mean (sd)	38 (120)	48 (132)	170 (250)
Number of Physicans - mean (sd)	21 (66)	43 (587)	52 (121)
Ownership			
Non-profit - percent	71%	71%	78%
For-profit - percent	18%	18%	7%
Government - percent	11%	12%	15%
Specialty Ward - percent	16%	16%	18%
Medicare Percent - mean (sd)	0.55 (0.48)	0.65 (0.74)	0.60 (0.81)

Table 4.3: Post-NTAP Results

	Technology		
	CRT-D	**BMP**	**b-DBS**
Incentive	1.261 (0.130)*	.842 (0.216)	.222 (0.259)
Patient variables			
Age Group			
65 -79 yrs	1.276 (0.025)*	1.056 (0.043)	1.298 (0.433)
80+ yrs	1.558 (0.037)*	.947 (0.058)	.363 (0.176)*
Race - white	1.230 (0.027)*	1.086 (0.066)	.626 (0.331)
Sex - female	0.980 (0.147)	1.014 (0.254)	.547 (0.175)
Charlson Score	.983 (0.006)*	0.998 (0.144)	.856 (0.177)
Hospital Variables			
Number of Residents	1.000 (0.000)	1.000 (0.000)	1.000 (0.001)
Number of Physicians	1.000 (0.000)	.999 (0.001)	.994 (0.002)*
Number of Beds	1.000 (0.000)	1.000 (0.002)*	1.000(0.001)
Medicare Percent	1.106 (0.192)	.540 (0.235)	0.188 (0.042)
Specialty Ward	.964 (0.045)	1.086 (0.115)	.867 (.319)
Hospital Ownership			
For Profit	1.099 (0.063)	0.843 (0.128)	10.992 (5.89)*
Government	.940 (0.074)	1.13 (0.149)	.581 (0.374)
Time			
Quarter	1.019 (0.003)*	1.069 (0.007)*	.960 (0.799)
Patient Variable Interactions			
Incentive*Age 65-79 yrs	.983 (0.287)	.886 (0.043)*	.618 (0.188)
Incentive*Age 80+ yrs	.932 (0.032)*	0.848(0.065)*	.930 (0.516)
Incentive*Race	.990(0.032)	.968 (0.066)	1.759 (1.102)
Incentive*Charlson Score	.945 (0.009)*	0.921 (0.020)*	.684 (0.193)
Hospital Variable Interactions			
Incentive*Number of Residents	1.000 (0.000)	1.000 (0.000)	1.000 (0.001)
Incentive*Number of Physicians	1.000 (0.000)	1.000 (0.000)	1.003 (0.002)
Incentive*Number of Beds	1.000 (0.000)	1.000 (0.000)	.999 (0.001)
Incentive*For Profit Ownership	.946 (0.049)	1.404(0.171)*	1.146 (0.592)
Incentive* Government Ownership	.961 (0.078)	1.126(0.149)	2.88 (1.68)
Incentive*Medicare Percent	.906 (0.158)	1.749 (0.745)	63.769 (144.8)
Incentive*Specialty Ward	.944(0.321)	1.086 (0.115)	.868 (0.319)

^Values reported are odds ratios with standard errors in parenthesis.

* indicates p-value <0.05

Table 4.4: Marginal Effect of NTAP Policy

	Technology		
	CRT-D	**BMP**	**b-DBS**
Marginal Effect of NTAP Policy	0.021 (0.014)*	0.001 (0.0004)*	0.056 (0.009)*

^Values reported are probabilities with standard errors in parenthesis.
* indicates p-value <0.05

BMP significantly increased over time. CRT-D and BMP were implanted in less severe patients during the incentive period compared to after the NTAP expired ($p < 0.05$).

The results from the post-NTAP analysis estimates the NTAP policy led to a 0.1% to 5.6% increase in the utilization of the NTAP-eligible technologies($p < 0.05$). The magnitude of the effect is different for each technology analyzed. The NTAP had the largest effect on CRT-D and b-DBS, 2.1% and 5.6%, respectively.

4.1.2 NTAP Policy Increased Utilization

The NTAP policy marginally increased the utilization of new technologies granted NTAP status. The NTAP was implemented in 2001 to ensure that Medicare beneficiaries would have timely access to costly, new technologies that, absent any additional payments, would be inadequately paid under the existing inpatient prospective payment system [63].

The post-NTAP analysis found the NTAP policy led to a 0.1% to 5.6% increase in the utilization of the NTAP-eligible technologies ($p < 0.05$). The magnitude of the effect is different for each technology analyzed. The NTAP had the largest effect on CRT-D and b-DBS, 2.1% and 5.6%, respectively. A probable explanation for the small effect on BMP is the physician payment component, which is unobserved in this analysis. The use of BMP reduces the physician procedure volume, which is the primary driver of physician reimbursement. Bone morphogenetic proteins replace the need to harvest bone from the iliac crest, which is then used in the spinal fusion. Bone morphogenetic proteins eliminates the additional surgical procedure, and by definition the additional physician payment, typically performed during a spinal fusion. This unobserved physician bias may not be as large in b-DBS or CRT-D, as the surgical procedures are nearly identical

to the substitute procedures.

For profit hospitals are significantly more likely to use BMP during the incentive time period than after ($p < 0.05$). One possible explanation why for-profit hospitals did not respond the same way when approaching CRT-D as with BMP is the medical condition it treats. CRT-D is a life-saving technology implanted in patients with heart failure and hospitals may not have as much discretion when making decisions regarding its use. In addition, CRT-D has the highest NTAP threshold ($16,262.50) and by definition is the highest cost technology that received NTAP status. It is possible that the high cost of the device hindered utilization or that a positive change in profit was not expected. Both BMP and b-DBS are elective and discretionary procedures. Deep brain stimulation is a highly concentrated technology with only seven percent of implanting hospitals being for-profit institutions, which may explain the positive but insignificant effect of for-profit hospitals during the incentive time period.

These results suggest that the NTAP policy had a small but significant impact on the probability a technology is used. While on average there is an increase in the overall probability of technology use, the magnitude is not consistent across technologies or hospitals. In addition, physician reimbursement is unobserved, which may bias the overall NTAP effect. Research that evaluates the additional NTAP-eligible technologies and incorporates physician information will provide insight on the consistency of the NTAP policy effect.

Chapter 5

Expected NTAP Analysis Results

5.1 Expected NTAP Analysis

This analysis evaluates how the new technology add-on payment (NTAP) amount impacts the utilization of new technologies. The analysis evaluates four technologies during the time period when the NTAP was effective: (1) bone morphogenetic proteins for spinal fusions (BMP), (2) bilateral deep brain stimulator for the treatment of Parkinson's disease (b-DBS), (3) cardiac resynchronization therapy (CRT-D), and (4) rechargeable spinal cord stimulation. Due to the endogeneity of the NTAP, a two-part model is used to estimate the expected NTAP amount for a given hospital admission. The expected NTAP amount is then included in the logistic regression equation estimating how the NTAP amount affects new technology utilization.

5.1.1 Estimation of the NTAP Amount

Due to the endogeneity and selection bias of hospital charges the expected NTAP amount ($\widehat{NTAP}$) was estimated from (3.3), (3.4), (3.5). Table 5.1 summarizes the results of $\widehat{NTAP}$ amount compared to the actual NTAP amount. Table 5.1 also summarizes the predicted probability a NTAP was received given use of the new technology resulting from (3.4) compared to the actual probability a NTAP payment was received given use, or $Pr(NTAP > 0|Y_{i,j} = 1)$. The predicted NTAP amounts and predicted probabilities are fairly good representations of the actual amounts received.

Table 5.1: Actual vs. Predicted NTAP Amounts

	CRT-D	BMP	b-DBS	r-SCS
Predicted NTAP Amount - mean (SD)	$4,182 ($5,118)	$2,482 ($2,397)	$4,950 ($3,242)	$6,230 ($3,439)
Actual NTAP Amount - mean (SD)	$2,330 ($2,479)	$944 ($1,657)	$3,359 ($2,708)	$3,403 ($2,816)

The unique distribution of the actual NTAPs was discussed in Chapter 1 and summarized in Table 1.2. The cases used in this analysis differ slightly from Table 1.2 as it was limited to hospitals that were known to have a choice of technology and includes a substitute technology group. The following figures are histograms of the actual NTAP amounts in this analysis compared to the predicted NTAPs. The histograms provide a more granular view of the summarized information in Table 5.1. The histograms of the predicted NTAP amounts generally follow the same distribution of the actual NTAP amounts, further validating the prediction model.

Figure 5.1: Distribution of Actual NTAP Amounts for CRT-D

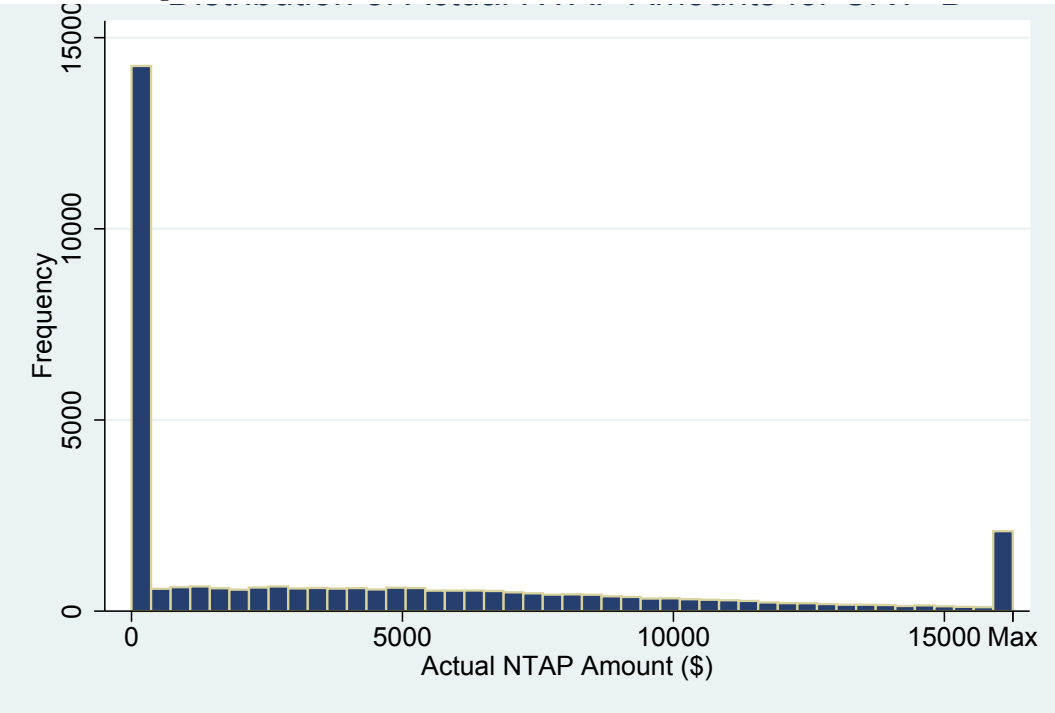
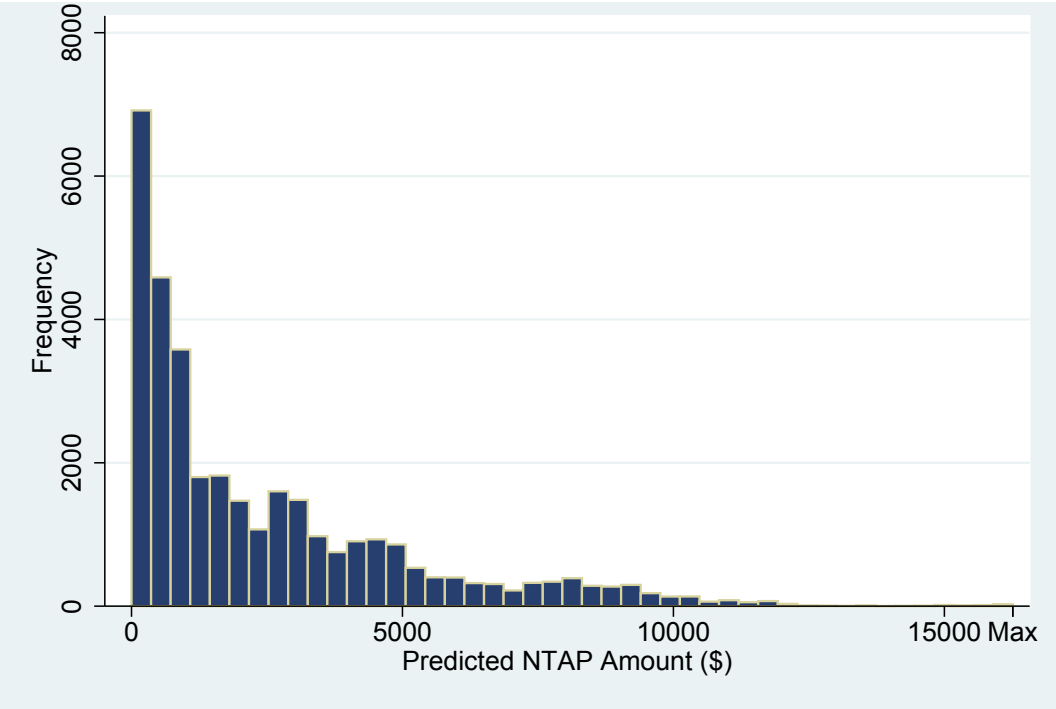


Figure 5.2: Distribution of Predicted NTAP Amounts for CRT-D



5.1.2 Estimating the Effect of the NTAP Amount on Use

$\widehat{NTAP}$ has a small positive and significant effect on the probability of use for all technologies. The odds ratio of the $\widehat{NTAP}$ on the probability of use was 1.00007 for CRT-D, 1.00106 for BMP, 1.00056 for b-DBS, and 1.00024 for r-SCS. The largest effect of $\widehat{NTAP}$ was seen in BMP. The NTAP policy for BMP changed for the second and final year BMP was eligible for NTAPs. The initial NTAP maximum was $8,900 for fiscal year 2004, but was reduced to $1,900 for fiscal year 2005. The BMP model was re-estimated to determine whether there was a differential affect between fiscal years 2004 and 2005 as a result of the NTAP policy change. As seen in Table 5.4 the odds ratio of the $\widehat{NTAP}$ on use is 1.00119 ($p < 0.05$) for fiscal year 2004, which is higher than when the fiscal years are combined. In 2005, the expected NTAP amount has a positive but insignificant effect on the probability of BMP use (Table 5.5). When the maximum NTAP payment was reduced from $8,900 to $1,900 the effect of the payment became insignificant, thus demonstrating provider responsiveness to the actual NTAP amount.

Figure 5.3: Distribution of Actual NTAP Amounts for BMP

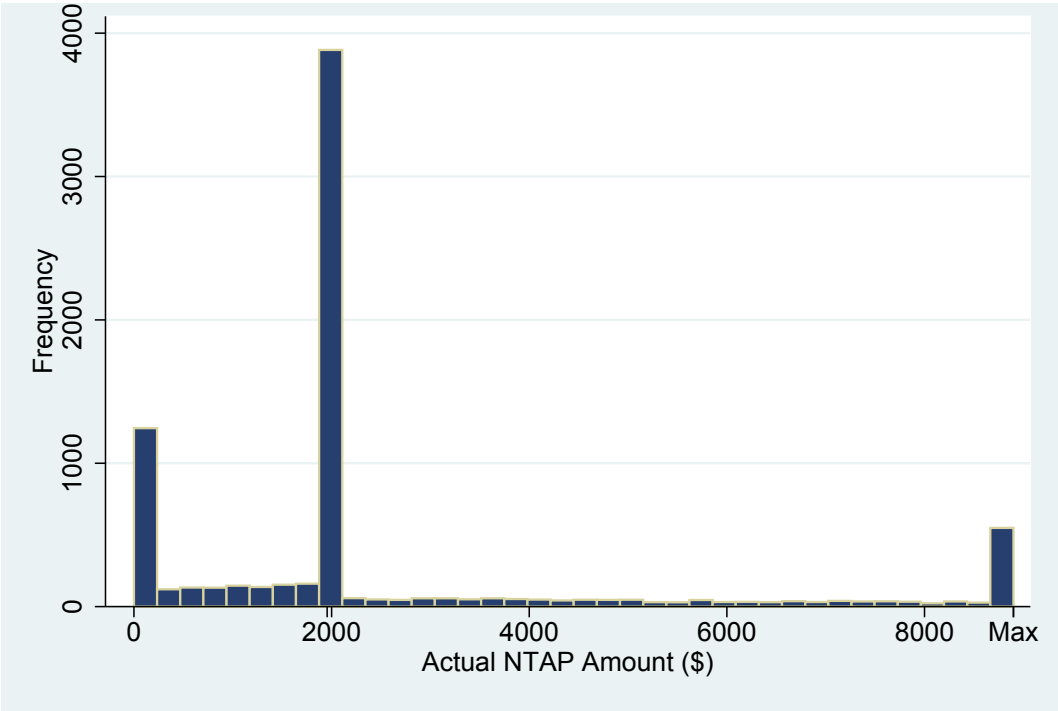


Figure 5.4: Distribution of Predicted NTAP Amounts for BMP

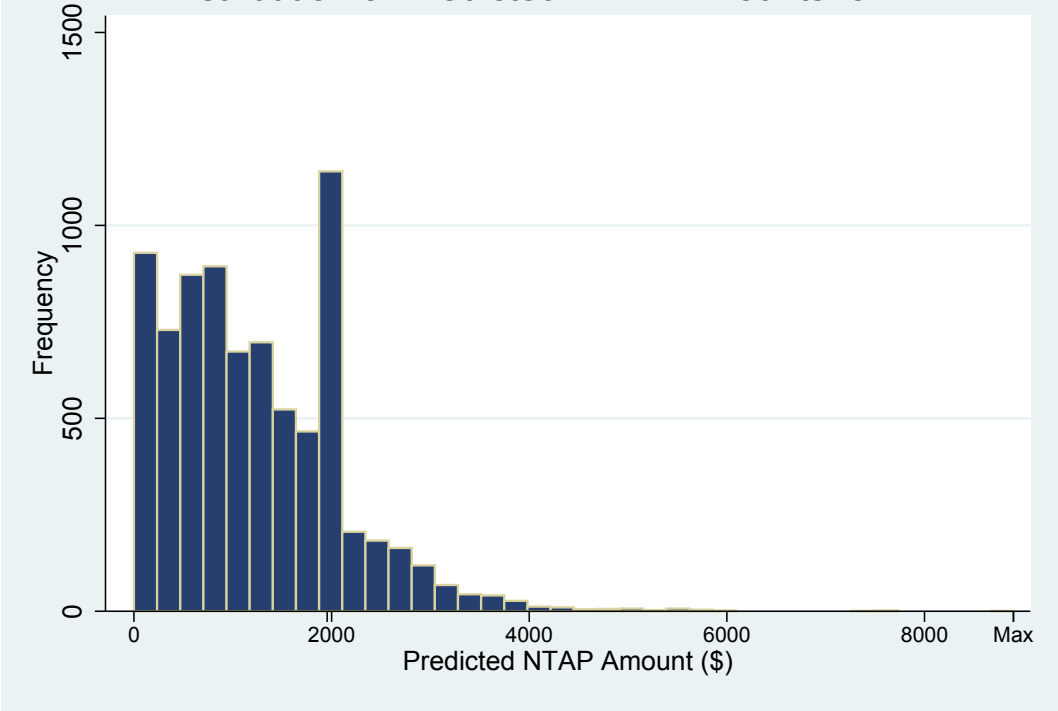


Figure 5.5: Distribution of Actual NTAP Amounts for b-DBS

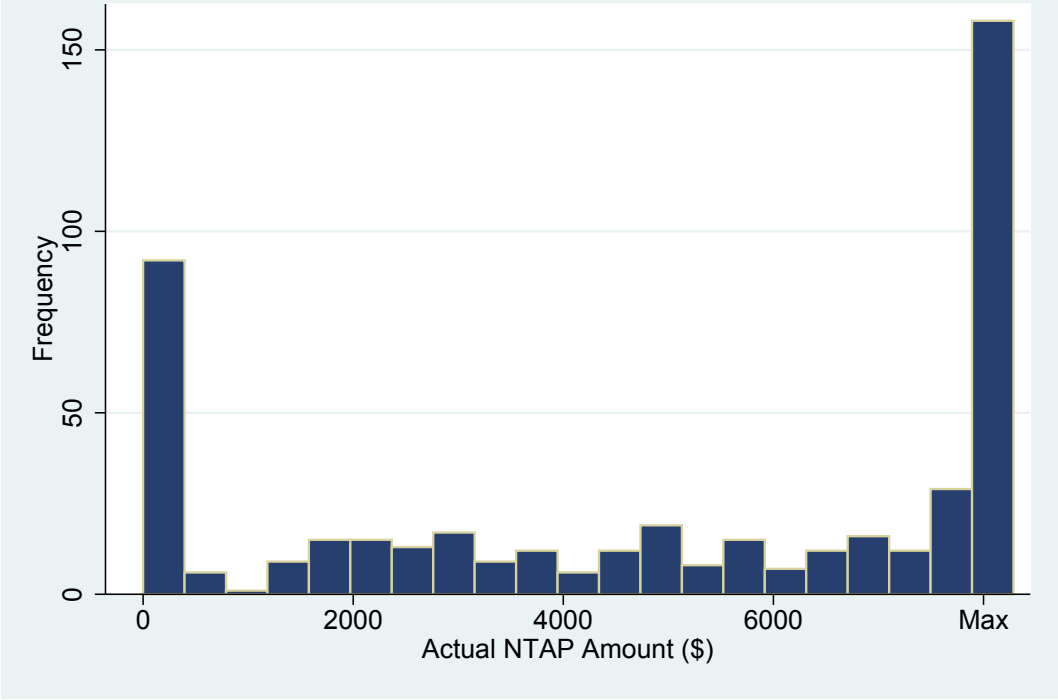


Figure 5.6: Distribution of Predicted NTAP Amounts for b-DBS

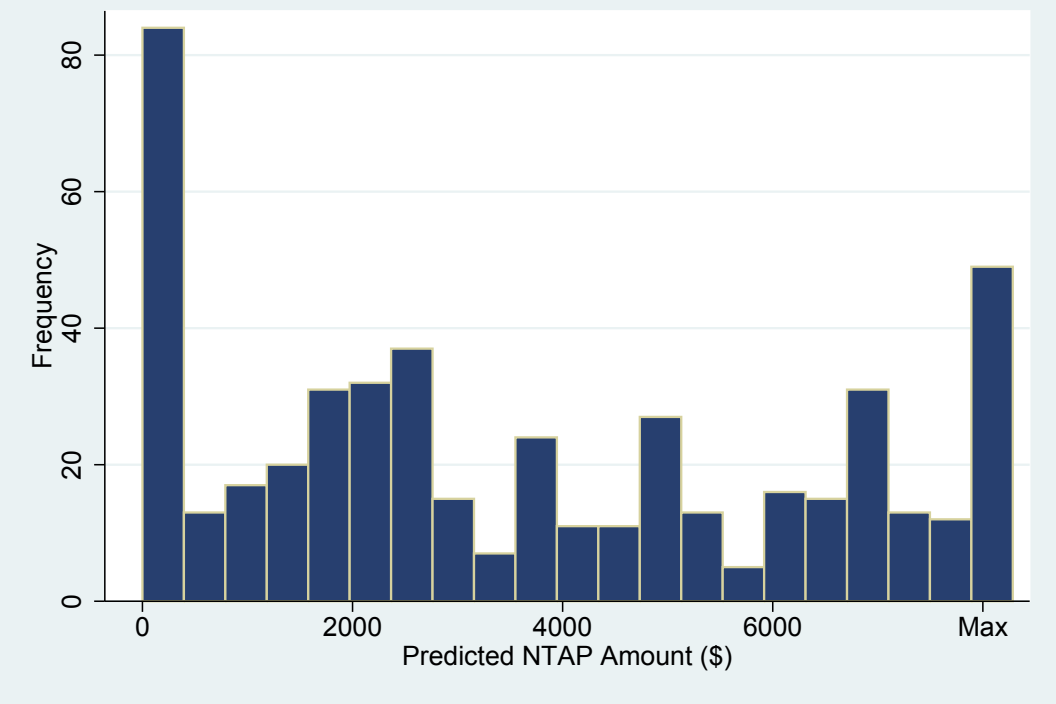


Figure 5.7: Distribution of Actual NTAP Amounts for r-SCS

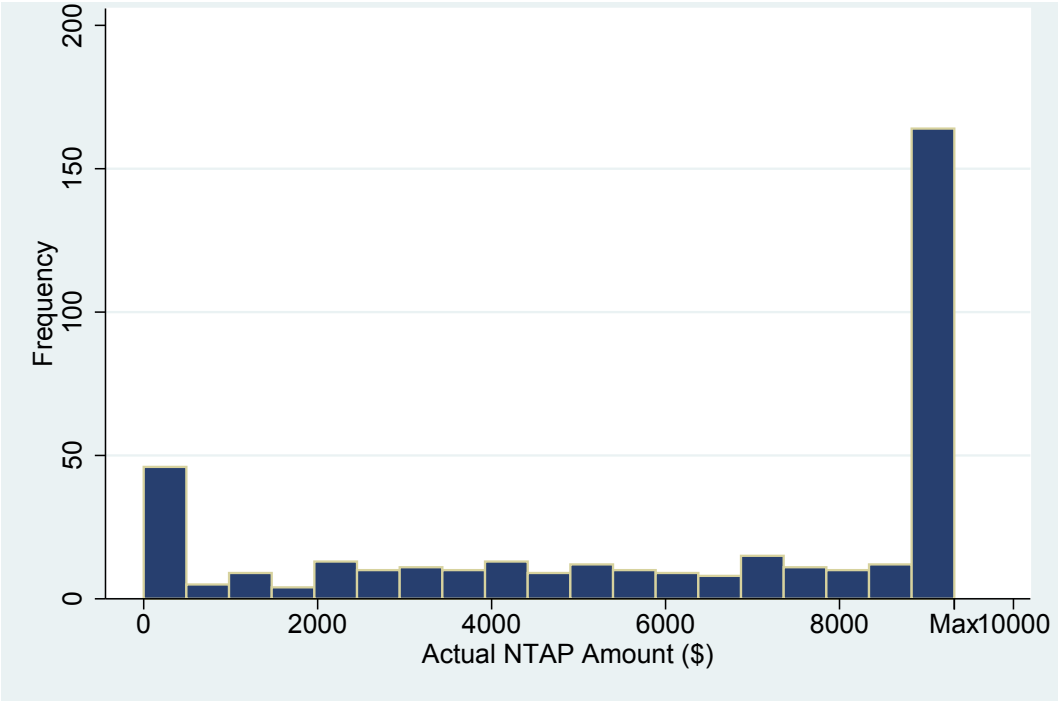
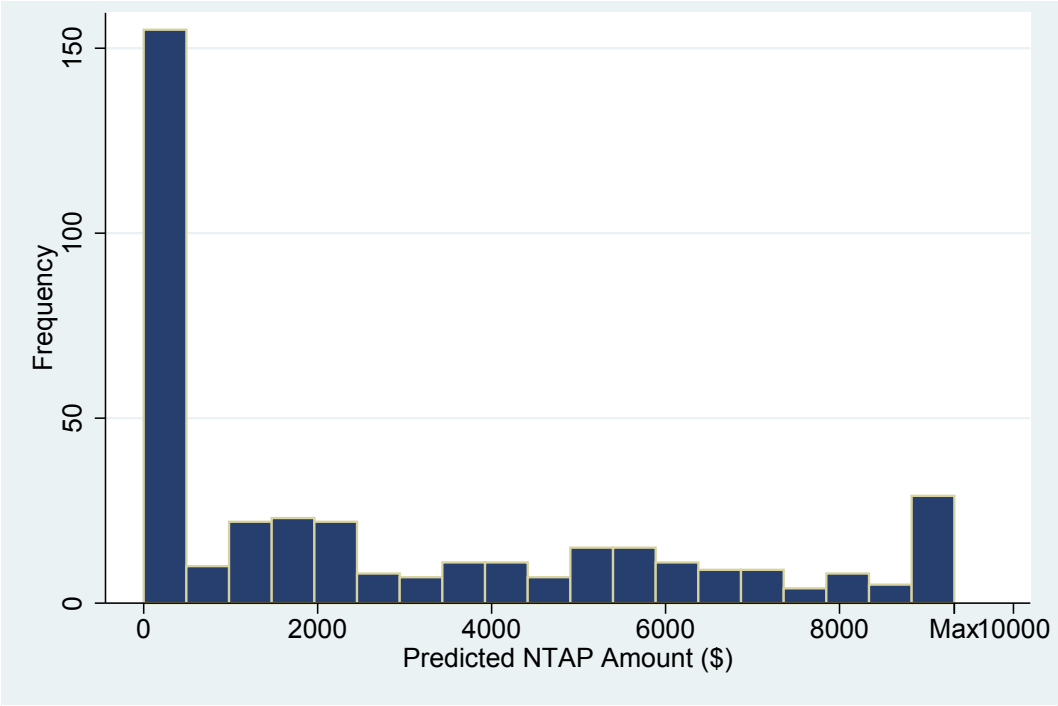


Figure 5.8: Distribution of Predicted NTAP Amounts for r-SCS



Interactions between Charlson score and hospital ownership, age, sex, hospital Medicare percentage, and length of stay were tested and were not significant in any of the technology models.

Table 5.2: Cardiac Resynchronization Therapy (CRT-D)

	Odds Ratio	Jackknife Standard Error	Jackknife t statistic	p-value
Predicted NTAP	1.00007	0.00002	4.47	<0.000
Patient Variables				
Charlson Score	0.92182	0.00930	-8.07	<0.000
Age Group				
65-79 yrs	1.17851	0.03525	5.49	<0.000
80+ yrs	1.28928	0.05212	6.28	<0.000
Female	1.04529	0.02176	2.13	0.034
Hospital Variables				
Hospital Ownership				
Non-Profit	0.69813	0.11963	-2.10	0.036
Government	1.01572	0.11306	0.14	0.889
Urban Location	1.47599	0.17119	3.36	0.001
Number of Beds	0.99561	0.00054	-8.05	<0.000
Medicare Percentage	1.10547	0.04271	2.60	0.010
Number of Residents	1.00257	0.00041	6.33	<0.000
Number of Physicians	0.99997	0.00017	-0.18	0.855
Operating Cost to Charge Ratio	0.44838	0.16532	-2.18	0.030
Prior Use	1.00596	0.00147	4.07	<0.000
Time Variables				
Quarter 2	1.08312	0.02900	2.98	0.003
Quarter 3	1.07765	0.03060	2.63	0.009
Quarter 4	1.02580	0.03264	0.80	0.424

5.1.3 Marginal Effects

The marginal effects of $\widehat{NTAP}$ on the probability of use are summarized in Table 5.8. The marginal effects of $\widehat{NTAP}$ on use were calculated at the median, maximum, and maximum plus ten percent. Given the bimodal distribution of the NTAP, the marginal effects were calculated at the median rather than the mean. The marginal effect of $\widehat{NTAP}$ taken at the median were positive and significant across all technologies evaluated.

Table 5.3: Bone Morphogenetic Protein (BMP)

	Odds Ratio	Jackknife Standard Error	Jackknife t-statistic	p-value
Predicted NTAP	1.00101	0.00042	2.43	0.020
Patient Variables				
Charlson Score	0.95576	0.08684	-0.50	0.621
Age Group				
65-79 yrs	0.77035	0.23750	-0.85	0.402
80+ yrs	0.91215	0.54234	-0.15	0.878
Female	1.25488	0.18826	1.51	0.138
Hospital Variables				
Hospital Ownership				
Non-Profit	0.21276	0.26790	-1.23	0.226
Government	0.28884	0.33565	-1.07	0.291
Number of Beds	0.99613	0.00308	-1.26	0.216
Medicare Percentage	1.21315	1.60238	0.15	0.884
Number of Residents	0.94132	0.04588	-1.24	0.222
Number of Physicians	1.03204	0.01997	1.63	0.111
Operating Cost to Charge Ratio	0.08529	0.35815	-0.59	0.561
Prior Use	0.97186	0.03398	-0.82	0.419
Time Variables				
Quarter 2	0.19696	0.37685	-0.85	0.401
Quarter 3	0.36608	0.71717	-0.51	0.611
Quarter 4	0.17241	0.31893	-0.95	0.347
Quarter 5	0.57313	1.03983	-0.31	0.761
Quarter 6	0.58666	1.04932	-0.30	0.767
Quarter 7	0.63616	1.15041	-0.25	0.804
Quarter 8	1.03977	1.89896	0.02	0.983
Quarter 9	1.12947	2.04897	0.07	0.947

Table 5.4: Bone Morphogenetic Protein (BMP)FY 2004

	Odds Ratio	Jackknife Standard Error	Jackknife t-statistic	p-value
Predicted NTAP	1.00117	0.00038	3.10	0.003
Patient Variables				
Charlson Score	0.76276	0.14537	-1.42	0.163
Age Group				
65-79 yrs	0.83618	0.26805	-0.56	0.580
80+ yrs	1.62428	1.27214	0.62	0.539
Female	1.11970	0.28395	0.45	0.658
Hospital Variables				
Hospital Ownership				
Non-Profit	0.14438	0.20518	-1.36	0.181
Government	0.49734	0.74077	-0.47	0.642
Number of Beds	0.99922	0.00386	-0.20	0.841
Medicare Percentage	0.24018	0.71955	-0.48	0.637
Number of Residents	0.97829	0.09841	-0.22	0.828
Number of Physicians	1.04287	0.03203	1.37	0.179
Operating Cost to Charge Ratio	0.42811	1.57055	-0.23	0.818
Prior Use	0.96830	0.03093	-1.01	0.319
Time Variables				
Quarter 2	0.27743	0.49160	-0.72	0.473
Quarter 3	0.59997	1.13011	-0.27	0.788
Quarter 4	0.24336	0.40785	-0.84	0.404
Quarter 5	0.79384	1.32898	-0.14	0.891

Table 5.5: Bone Morphogenetic Protein (BMP)FY 2005

	Odds Ratio	Jackknife Standard Error	Jackknife t-statistic	p-value
Predicted NTAP	1.00098	0.00076	1.29	0.218
Patient Variables				
Charlson Score	1.11671	0.15270	0.81	0.434
Age Group				
65-79 yrs	0.81266	0.40673	-0.41	0.685
80+ yrs	0.83334	0.77383	-0.20	0.847
Female	1.30625	0.21505	1.62	0.129
Hospital Variables				
Hospital Ownership				
Non-Profit	0.22602	0.63009	-0.53	0.603
Government	0.14650	0.37471	-0.75	0.466
Number of Beds	0.99403	0.00910	-0.65	0.525
Medicare Percentage	1.17769	0.28052	0.69	0.504
Number of Residents	0.83255	0.28512	-0.54	0.602
Number of Physicians	1.05383	0.09503	0.58	0.571
Operating Cost to Charge Ratio	0.00412	0.06242	-0.36	0.723
Prior Use	0.96928	0.04731	-0.64	0.534
Time Variables				
Quarter 6	0.63917	0.47169	-0.61	0.555
Quarter 7	0.74111	0.51484	-0.43	0.673
Quarter 8	1.06271	0.68569	0.09	0.926
Quarter 9	1.24511	0.72860	0.37	0.714

Table 5.6: Bilateral Deep Brain Stimulation (b-DBS)

	Odds Ratio	Jackknife Standard Error	Jackknife t-statistic	p-value
Predicted NTAP	1.00059	0.00018	3.32	0.002
Patient Variables				
Charlson Score	0.79458	0.13043	-1.40	0.171
Age Group				
65-79 yrs	2.28290	0.91718	2.05	0.048
80+ yrs	0.56802	0.36142	-0.89	0.381
Female	1.13190	0.33207	0.42	0.676
Hospital Variables				
Hospital Ownership				
Non-Profit	0.30248	0.53754	-0.67	0.435
Government	0.25754	0.49294	-0.71	0.403
Number of Beds	0.99921	0.00115	-0.68	0.487
Medicare Percentage	1.01299	0.11844	0.11	0.794
Number of Residents	1.00077	0.00132	0.58	0.564
Number of Physicians	0.99762	0.00353	-0.67	0.471
Operating Cost to Charge Ratio	0.03426	0.08446	-1.37	0.246
Prior Use	0.86686	0.10933	-1.13	0.292
Time Variables				
Quarter 2	1.74926	1.57225	0.62	0.518
Quarter 3	1.61698	1.46659	0.53	0.605
Quarter 4	1.01759	0.81205	0.02	0.917
Quarter 5	1.20909	0.86613	0.27	0.745
Quarter 6	0.48344	0.51006	-0.69	0.596
Quarter 7	1.19444	1.44255	0.15	0.819
Quarter 8	1.23141	1.18660	0.22	0.780

Table 5.7: Rechargeable Implantable Neurostimulators

	Odds Ratio	Jackknife Standard Error	Jackknife t statistic	p-value
Predicted NTAP	1.00023	0.00002	10.18	<0.000
Patient Variables				
Charlson Score	1.35619	0.12557	3.29	0.004
Age Group				
65-79 yrs	0.91872	0.12286	-0.63	0.535
80+ yrs	2.78922	0.84037	3.40	0.003
Female	0.74220	0.08053	-2.75	0.014
Hospital Variables				
Hospital Ownership				
Non-Profit	0.96107	0.14072	-0.27	0.790
Government	0.55121	0.19326	-1.70	0.108
Number of Beds	1.00051	0.00030	1.69	0.109
Medicare Percentage	0.43766	0.23867	-1.52	0.148
Number of Residents	0.99925	0.00024	-3.15	0.006
Number of Physicians	0.99989	0.00014	-0.80	0.433
Operating Cost to Charge Ratio	0.11747	0.05874	-4.28	0.001
Prior Use	0.92984	0.01894	-3.57	0.002
Time Variables				
Quarter 2	0.64274	0.24056	-1.18	0.254
Quarter 3	1.11698	0.39459	0.31	0.758
Quarter 4	0.89499	0.39163	-0.25	0.803
Quarter 5	0.78364	0.28008	-0.68	0.504
Quarter 6	1.45528	0.40781	1.34	0.198
Quarter 7	0.68937	0.22894	-1.12	0.278
Quarter 8	0.27663	0.07165	-4.96	<0.000

The probability of use at the median NTAP payment expectation ranged between 0.17 – 0.57. The probability of use at the maximum NTAP payment expectation ranged between 0.66 – 0.99. The marginal effect of increasing the median payment by one dollar are all small, positive and significant.

It is conceptually difficult to understand the impact of increasing the NTAP by one dollar since the marginal effect of use is so small. Therefore, increasing the maximum NTAP by 10% was evaluated. Increasing the NTAP threshold by ten percent would result in a 0.03% to 4.6% increase in the use of new technology. Specifically, a ten percent increase in the maximum NTAP amount would result in a 0.03% increase in the use of b-DBS, 0.05% increase in the use of BMP, 2.5% increase in the use of CRT-D, and a 4.7% increase in the use of r-SCS. The marginal effect of increasing the maximum payment for BMP and b-DBS are smaller relative to CRT-D and r-SCS as the probability of use at the maximum NTAP amount is close to one, 0.9992 and 0.9822 respectively, so any incremental increase in the maximum amount will yield minimal increasing returns.

Table 5.8: Marginal Effect of NTAP

	Mean NTAP	Max NTAP	Max NTAP +10%	Difference between Max and Max + 10% NTAP
CRT-D	$4,182	$16,263	$17,889	$1,626
Marginal Effect	0.0000181*	0.0000163 *	0.0000156 *	0.038747
Pr(Use)	0.45121337	0.665148	0.6910652	0.000000
BMP	$2,482	$8,900	$9,790	$890
Marginal Effect	0.000225*	0.0000015*	0.00000047*	0.000000
Pr(Use)	0.5747	0.998864	0.9995369	0.000000
b-DBS	$4,950	$8,285	$9,114	$829
Marginal Effect	0.0000771*	0.0000146 *	0.00000919 *	0.000000
Pr(Use)	0.8437	0.97432565	0.98403007	0.000000
r-SCS	$6,230	$9,320	$10,252	$932
Marginal Effect	0.000056*	0.0000438 *	0.000039 *	-9,790.000000
Pr(Use)	0.59028126	0.74658268	0.7851995	0.000000

5.1.4 Across Hospital Response to NTAP Amount

A hospital fixed effect model estimating the effect of $\widehat{NTAP}$ on use was also estimated to determine whether the effect on use was within or across hospitals. Table 5.9 reports the effect of $\widehat{NTAP}$ on use in the hospital fixed effects model. $\widehat{NTAP}$ has an insignificant

effect on the use across all technologies, suggesting the NTAP does not have an effect on within hospital utilization. These results show hospitals are not choosing whether to use the new technology based upon patients who would yield a higher NTAP amounts.

Table 5.9: Effect of Predicted NTAP on Use: Hospital Fixed Effects

Technology	Predicted NTAP	Standard Error	p-value
Cardiac Resynchronization Therapy (CRT-D)	-0.00005	0.00005	0.32900
Bone Morphogenetic Protein (BMP)	0.00003	0.00004	0.35400
Bilateral Deep Brain Stimulation (b-DBS)	0.00043	0.00041	0.29900
Rechargable Implantable Neurostimulation (r-INS)	-0.00018	0.00023	0.43400

5.1.5 Expected NTAP Amount Increased Utilization

The amount of the expected NTAP amount increased utilization slightly. Hospitals have argued that the current maximum payment amounts provide an inadequate level of support to hospitals to cover the costs of the new technology [63]. Increasing the payment threshold would improve NTAP payments to all hospitals receiving NTAPs greater than zero. Specifically, increasing the payment threshold by 10% would have increase utilization of the new technology by 0.03% – 4.7%. The largest effect would be seen in CRT-D and r-SCS. The marginal effect of increasing the maximum payment for BMP and b-DBS are smaller relative to CRT-D and r-SCS. The probability of BMP and b-DBS use at the maximum NTAP amount is close to one, 0.9992 and 0.9822 respectively, so any incremental increase in the maximum amount will yield minimal increasing returns. Whereas, the probability of CRT-D and r-SCS use at the maximum NTAP amount is 0.69 and .796, respectively. Therefore marginally increasing the threshold would increase the probability the technology is used relative to its substitute greater than BMP or b-DBS.

The probability of use at the median NTAP expectation ranged from 0.17 - 0.57. The highest probability at the median expectation of use being with b-DBS, suggesting

it is the most sensitive technology to the actual NTAP amount. Increasing the expected NTAP amount by one dollar yielded greatly affects the probability b-DBS is used.

A hospital could base its decision to use a new technology in a given patient based upon the characteristics of the patient. For example, a hospital may decide to implant the new technology in a particular patient because it believes the patient would yield a higher expected NTAP amount. Patients with more severe conditions or an anticipated higher length of stay by definition would yield higher NTAP amounts as the charges would be greater. However, the hospital fixed effect model found that hospitals do not base their decision to use a new technology on patients that are anticipated to yield higher NTAPs. Rather, the sensitivity to the NTAP amount is hospital specific, not patient specific.

The magnitude of the NTAP amount on the decision to use the new technology is highly dependent on the technology, and possibly the disease area. The technologies evaluated are diverse and not concentrated in a particular therapy area. Therefore, consistency of the effect within medical specialties is not possible to evaluate. The financial situation within disease or therapy areas may be driving the sensitivity to the NTAP amounts. From a policy perspective, it is difficult to make a general policy recommendation related to where the NTAP amount should be set as the variability is too great.

Chapter 6

Value Analysis Results

Cardiac resynchronization therapy (CRT-D) is used in patients with heart failure. Mortality is a highly relevant outcome for the patient population in which CRT-D and its substitute technology, implantable cardiac defibrillators, are used. The objective of this analysis is to assess the value of the NTAP policy by comparing the incremental cost of the policy to the incremental benefits. The first part of the analysis estimates the effect of CRT-D utilization on patient mortality using an instrumental variable analysis to address the endogeneity of CRT-D utilization. The second part of this analysis, pulls from the Chapters 1, 4, and 5 and the findings from the instrumental variable analysis to estimate value of the NTAP policy in terms of cost per life year saved.

6.1 Value Analysis

Initially, a non-instrumented probit analysis was conducted. Table 6.1 summarizes the results and Table 6.2 summarizes the marginal effects. In the non-instrumented analysis CRT-D utilization positively influences death ($p< 0.05$), suggesting that CRT-D has a significantly higher probability of death compared to implantable cardiac defibrillators (ICD). Specifically, CRT-D utilization increases the probability of death 2.98% relative to ICDs. This result contradicts all randomized clinical trial evidence comparing CRT-D to ICDs [64, 61]. Further, such a result would imply Medicare made an inaccurate conclusion regarding CRT-D with respect to its "substantial clinical improvement" criterion required for a technology to be granted NTAP status.

The analysis in Chapter 4 found that as the Charlson score increased the probability of CRT-D use decreased (Table 4.3). The increasing number of co-morbidities resulted in a reduction in the probability the new technology was used. Additionally, there was a significant interaction between Charlson score and the NTAP policy, suggesting that patients with fewer co-morbidities were implanted with CRT-D during the incentive time period.

Interpreting the non-instrumented probit results in conjunction with the results from Chapter 4 suggest that compared to ICDs, CRT-D is used in healthier patients who are more likely to die. Such a result contradicts clinical research and Medicare's decision that CRT-D significantly improved health outcomes for heart failure patients. A more likely explanation is CRT-D is being implanted in sicker patients and an unobserved component of patient severity is negatively correlated with the Charlson score, but positively correlated with CRT-D utilization.

Including the decision to use or not use CRT-D in the regression analysis implies use is exogenous. However, CRT-D utilization is an endogenous variable. The previous Chapters have estimated how much of the decision to use the new technology is influenced by the NTAP incentive. Addressing the endogeneity of CRT-D use is necessary to obtain unbiased estimates of how CRT-D affects the probability of patient death. The following section reports the results of the instrumental variable probit analysis, which addresses the endogeneity of CRT-D utilization and reduces the bias that sicker patients are more likely to receive CRT-D.

6.1.1 Instrumental Variable Probit

[1]

The endogeneity of CRT-D use is addressed with an instrumental variable probit model. Table 6.3 and Table 6.4 summarize the results of the instrumental variable probit analysis. The first stage of the IV-probit estimates CRT-D utilization with exogenous predictors. Both N and $\widehat{NTAP}$ are used as instruments for use. As shown in Chapter 4 and Chapter 5, N and $\widehat{NTAP}$ are significant predictors of utilization. An instrument must be correlated with the endogenous regressor but not the outcome of interest. In

[1] A bivariate probit and a linear instrumental variable model were also estimated to validate the robustness of the findings. The methods and output for both models are included in the Appendix.

Table 6.1: Non-IV Probit Results

	Coefficient	Robust Standard Error	z	P-value
Use				
Patient Variables	0.15844	0.01050	15.09	<0.000
Length of Stay	0.04632	0.00097	47.76	<0.000
Charlson Score	0.16055	0.00345	46.48	<0.000
Age Group				
65-79 yrs	0.08514	0.01269	6.71	<0.000
80+ yrs	0.34889	0.01428	24.43	<0.000
Female	-0.05112	0.00975	-5.24	<0.000
Hospital Variables				
Heart Failure Readmission Rate	0.01067	0.00278	3.83	<0.000
Hospital Ownership				
Non-Profit	-0.05997	0.01811	-3.31	0.001
Government	-0.01490	0.02428	-0.61	0.539
Number of Beds	0.000004	0.00003	0.16	0.875
Number of Residents	-0.00010	0.00003	-2.91	0.004
Number of Physicians	-0.00001	0.00000	-3.67	<0.000
Prior Use	-0.00047	0.00017	-2.85	0.004
Time Variables				
Quarter	-0.01119	0.00627	-1.79	0.074
Quarter-squared	-0.00180	0.00043	-4.22	<0.000
Constant	-1.82621	0.07089	-25.76	<0.000

Table 6.2: Non-IV Marginal Effects

Variable	dy/dx	Standard Error	z	P-value	X
Use*	0.028935	0.001960	14.76	<0.000	0.345743
Patient Variables					
Length of Stay	0.008198	0.000180	46.16	<0.000	4.85598
Charlson Score	0.028414	0.000620	45.79	<0.000	1.12773
Age Group*					
65-79 yrs	0.014875	0.002200	6.76	<0.000	0.619381
80+ yrs	0.069514	0.003210	21.63	<0.000	0.227845
Female*	-0.008902	0.001670	-5.32	<0.000	0.253024
Hospital Variables					
Heart Failure Readmission Rate	0.001889	0.000490	3.83	<0.000	23.8586
Hospital Ownership					
Non-Profit	-0.010838	0.003340	-3.24	0.001	0.774039
Government	-0.002618	0.004230	-0.62	0.536	0.096276
Number of Beds	0.000001	0.000000	0.16	0.875	490.911
Number of Residents	-0.000017	0.000010	-2.9	0.004	74.0258
Number of Physicians	-0.000001	0.000000	-3.66	<0.000	56.0165
Prior Use	-0.000084	0.000030	-2.87	0.004	73.2315
Time Variables					
Quarter	-0.001980	0.001110	-1.78	0.074	7.1489
Quarter-squared	-0.000318	0.000080	-4.23	<0.000	64.2637

* dy/dx is for discrete change from 0 to 1

this analysis it is assumed that N and $\widehat{NTAP}$ are correlated with utilization, but not death. Consistent with the analyses in Chapter 4 and Chapter 5, the first stage of the instrumental variable probit analysis shows N and $\widehat{NTAP}$ positively affect CRT-D utilization ($p < 0.05$). N has a larger effect than $\widehat{NTAP}$, which makes it a stronger instrument.

The second stage of the IV-probit models the probability a given patient dies while adjusting for the endogeneity of use. The negative coefficient of use in the second stage suggests that CRT-D resulted in a significant reduction in all-cause mortality ($p < 0.05$) relative to ICDs. All patient characteristics (age, sex, Charlson index, and length of stay) significantly impact death ($p < 0.05$). Hospital size and the number of physicians within a hospital have small, but negative effects on death ($p < 0.05$). The quarter of the admission is negatively related to death, suggesting improved implant technique or better patient selection occurred over time. Finally, the hospital 30 day heart failure readmission rate is positively related to death ($p < 0.05$), implying a general hospital quality metric is significantly related to a given patient's outcome.

The correlation of the errors between the two stages, ρ, is 0.37. The positive coefficient of ρ indicates positive correlation between the errors of the two stages. The unobserved factors that make it more likely for a patient to die also make it more likely that a patient is implanted with the new technology. The hypothesis test of exogeneity ($\rho = 0$) is rejected with a p-value < 0.000, suggesting endogeneity is a significant issue that can be addressed through instrumentation. Endogeneity is a significant issue with respect to this model, which suggests that the results from the non-instrumented probit and probit models should differ. This is indeed the case as the coefficient of use switches signs between the models (from 0.158 to -0.666), so the utilization of CRT-D decreases the probability of death. The non-instrumented analysis ignores the endogeneity of use and leads to an overestimation of the effect of CRT-D utilization on the probability of death.

The marginal effects from the instrumental variable probit are presented in Table 6.5. The main marginal effect of interest is CRT-D use. CRT-D reduced all-cause mortality by 11.7% relative to ICDs ($p < 0.05$). In a large randomized control trial, CRT-D was shown to reduce all-cause mortality by 36% compared to implantable cardiac defibrillators [64]. While the marginal effect is lower (11.7% vs. 36%), it is a conservative

Table 6.3: IV First Stage Results

	Coefficient	Robust Standard Error	z	P-value
Instrumental Variables				
Incentive	0.457994	0.010199	44.91	<0.000
Predicted NTAP	0.000017	0.000002	7.25	<0.000
Patient Variables				
Length of Stay	0.001476	0.000330	4.47	<0.000
Charlson Score	-0.000186	0.001350	-0.14	0.891
Age Group				
65-79 yrs	0.036114	0.003508	10.3	<0.000
80+ yrs	0.065420	0.004779	13.69	<0.000
Female	0.011451	0.002709	4.23	<0.000
Hospital Variables				
Medicare percent	0.005654	0.004912	1.15	0.25
Operating Cost-to-Charge Ratio	-0.048942	0.055378	-0.88	0.377
Hospital Ownership				
Non-Profit	0.040112	0.019122	2.1	0.036
Government	0.037830	0.023139	1.63	0.102
Heart Failure Readmission Rate	0.000216	0.002386	0.09	0.928
Number of Beds	-0.000480	0.000048	-9.95	<0.000
Number of Residents	0.000294	0.000049	5.99	<0.000
Number of Physicians	-0.000005	0.000001	-3.47	0.001
Prior Use	0.000971	0.000217	4.48	<0.000
Time Variables				
Quarter	-0.012017	0.002830	-4.25	<0.000
Quarter-squared	0.004707	0.000162	29.09	<0.000
Interaction Effect				
Incentive*Charlson Score	-0.0161908	0.0021497	-7.53	<0.000
Constant	-0.0035147	0.0717704	-0.05	0.961
Athrho	0.3904499	0.0182289	21.42	<0.000
Lnsigma	-0.8513946	0.0052171	-163.19	<0.000
Rho	0.371748	0.0157097		
Sigma	0.4268193	0.0022267		

Table 6.4: IV Second Stage Results

	Coefficient	Robust Standard Error	z	P-value
Use	-0.665652	0.039307	-16.93	<0.000
Patient Variables				
Length of Stay	0.043660	0.000957	45.62	<0.000
Charlson Score	0.141602	0.003703	38.24	<0.000
Age Group				
65-79 yrs	0.115172	0.012293	9.37	<0.000
80+ yrs	0.389041	0.013918	27.95	<0.000
Female	-0.037552	0.009358	-4.01	<0.000
Hospital Variables				
Heart Failure Readmission Rate	0.009051	0.003274	2.76	0.006
Hospital Ownership				
Non-Profit	-0.023470	0.024907	-0.94	0.346
Government	0.014587	0.030444	0.48	0.632
Number of Beds	-0.000416	0.000065	-6.44	<0.000
Number of Residents	0.000161	0.000048	3.36	0.001
Number of Physicians	-0.000010	0.000003	-3.85	<0.000
Prior Use	0.000414	0.000311	1.33	0.183
Time Variables				
Quarter	-0.131626	0.007788	-16.9	<0.000
Quarter-squared	0.006679	0.000545	12.27	<0.000
Constant	-1.0031	0.0897738	-11.17	<0.000

estimate of the impact of CRT-D on death. A smaller effect of use on death is expected as the real world utilization of CRT-D may be broader than the clinical trial population, and the ability to control for clinical measures such as the heart failure severity classification is unavailable with the use of administrative claims data. The follow-up time period related to death is only one year in the claims data, but slightly over two years in the clinical trials. Additionally, the all-cause mortality outcome from the clinical trial is a secondary endpoint, so the clinical trials were not powered to find statistical differences of all-cause mortality between CRT-D and ICDs.

Table 6.5: Marginal Effects

Variable	dy/dx	Standard Error	z	P-value	X
Use*	-0.116897	0.007530	-15.53	<0.000	0.346325
Patient Variables					
Length of Stay	0.008602	0.000220	39.94	<0.000	4.87885
Charlson Score	0.027897	0.000690	40.62	<0.000	1.12941
Age Group*					
65-79 yrs	0.022327	0.002380	9.37	<0.000	0.619082
80+ yrs	0.086511	0.003620	23.92	<0.000	0.228136
Female*	-0.007317	0.001810	-4.05	<0.000	0.253195
Hospital Variables					
Heart Failure Readmission Rate	0.001783	0.000650	2.75	0.006	23.8818
Hospital Ownership*					
Non-Profit	-0.004660	0.004970	-0.94	0.348	0.783006
Government	0.002894	0.006090	0.48	0.635	0.096194
Number of Beds	-0.000082	0.000010	-6.14	<0.000	495.939
Number of Residents	0.000032	0.000010	3.35	0.001	74.9749
Number of Physicians	-0.000002	0.000000	-3.82	<0.000	56.746
Prior Use	0.000082	0.000060	1.32	0.188	73.2667
Time Variables					
Quarter	-0.025932	0.001740	-14.86	<0.000	7.17766
Quarter-squared	0.001316	0.000120	11.11	<0.000	64.6981

6.1.2 CRT-D Use Decreases Mortality

The analysis shows the efficacy results from randomized controlled trials are sustained in real-world clinical practice. After addressing the endogeneity of CRT-D utilization, CRT-D is shown to decrease all-cause mortality relative to ICDs. While the effect is

smaller than highly controlled clinical trials, CRT-D is shown to provide significant clinical benefit to the Medicare beneficiaries with heart failure.

CRT-D resulted in a substantial clinical improvement compared to the standard of care. The third requirement for a new technology to be granted NTAP status is it must provide a substantial clinical improvement to Medicare beneficiaries. Medicare bases its decision regarding "substantial clinical improvement" largely on clinical trial evidence available at the time of consideration. Medicare typically reviews the same evidence the FDA reviews when determining whether a technology is safe and effective. However, Medicare is examining the evidence with the objective of determining whether a technology improves patient outcomes relevant the Medicare beneficiary population. By design, clinical trials enroll a homogenous population in order to estimate the true treatment effect. It is difficult to determine whether a technology proven to be efficacious in a randomized clinical trial will be effective when applied in a highly heterogenous population. In the case of CRT-D a similar treatment effect was seen in the Medicare population. CRT-D resulted in a substantial clinical improvement, and the body of evidence Medicare considered in the NTAP determination process is consistent with the outcomes achieved in its population.

6.1.3 Is the NTAP Adding Value to the Medicare Program?

The NTAP policy increased the utilization of a life-saving technology. During the incentive time period, 33,729 people received CRT-D and 42,933 people received the substitute technology. As discussed in Chapter 4, the NTAP policy led to a 2.1% increase in CRT-D utilization. Therefore, 694 people were implanted with CRT-D due to the incentive. The mortality change from users to non-users decreases by 11.7%. 10.8% of users died, so an 11.7% reduction in mortality results in a 9.5% mortality rate for CRT-D. Therefore, the policy resulted in 694 people who received CRT-D who would not have otherwise, 9 of whom survived that would not have otherwise.

To determine the value of the NTAP policy, it is necessary to compare the incremental cost of the policy to the incremental benefit of the new technology. We know that the NTAP policy resulted in 9 incremental survivors. If the NTAP did not exist, CRT-D would have been reimbursed the same as ICDs, it's substitute technology. The average hospital reimbursement amount for ICDs during fiscal year 2005 was $34,868.

As seen in Table 1.2, the average NTAP amount for CRT-D was $4,506. The cost to Medicare if no NTAP policy was granted to CRT-D would have been approximately $1.18 billion dollars (33,729*$34,868) whereas the cost to Medicare with the NTAP policy for CRT-D was approximately $1.3 billion dollars (33,729*($34,868+$4,506)). The incremental cost of the NTAP policy is $152 million. The average cost per life saved is $17.2 million dollars, which exceeds many commonly cited estimates of the value of life [65]. Further, if all claims using CRT-D received the maximum NTAP amount, the cost per life saved drastically escalates to over $62 million. When CMS projects the expenditures for the NTAP policy, it assumes all claims using the eligible technology will receive the maximum amount. As shown in Chapter 1, the CMS projected expenditures exceed the actual expenditures for the NTAP program. Therefore, the implicit value of the NTAP policy, as measured by cost per life saved, is $62 million.

Viscussi (1993) conducts a systematic literature review in attempt to estimate the value of life [65]. The article estimates the value of life to range from three million to seven million dollars. A more recent article by Lutter, Morrall and Viscussi (1999) estimates the value of life to be fifteen million dollars [66]. While these estimates are not adjusted for inflation to represent current dollars, the value estimates are lower than the cost per life saved under the NTAP program. Additionally, the beneficiaries with chronic heart failure in the Medicare program are elderly and have a lower expected life expectancy. So while the estimates represent the value of an entire life, the patient population the NTAP policy for CRT-D affects have a short life expectancy. Therefore, from this perspective the value of the policy is very low. Medicare should allocate resources toward incentive programs that result in greater value to the Medicare program and its beneficiary population.

While the value of the NTAP is low, comparing the cost-effectiveness ratio of the NTAP policy to other health interventions would provide some context of the willingness to pay within the health care system for improvements in health and mortality. There are very few articles estimating the value of other health interventions in terms of cost per life saved. The majority of cost-effectiveness articles evaluate the cost per life-year saved or the cost per quality-adjusted life year, which accounts for the variation in life expectancy in estimating the value of life. One article estimates the value of the Medicaid program in terms of the cost per infant life saved [67]. The research finds

the cost of Medicaid eligibility is $1.7 million dollars per infant life saved, which is significantly lower than the NTAP program and well below estimates of the value of life. Additionally, the life expectancy of the beneficiaries of the Medicaid program is significantly higher (nearly an entire life) compared to those benefitting from the NTAP program. One article estimates the mortality benefit associated with Medicare eligibility [68]. However, no dollar amounts are associated with the lifetime costs of providing benefits. The article finds Medicare eligibility reduces mortality by one percent and up to twenty percent for the severely ill. It would be interesting to incorporate the average lifetime expenditures to determine what the cost per life saved is within the Medicare program, which would be a relevant program to compare the value of the NTAP policy to. Literature on the cost per life saved of health interventions is minimal, however, one example demonstrates a cost per life year saved to be significantly lower than the NTAP policy.

As hospitals become more adept with the NTAP payment mechanism and charges begin to reflect the true cost of resources used, the value of the NTAP program will decrease substantially. As demonstrated with an average NTAP payment of $3,802 for a technology eligible for a maximum NTAP of $16,262.50, not every use of the new technology results in a maximum NTAP amount. The formula for NTAP is dependent upon the hospital charges. If 50% of the excess cost (as calculated by deflating charges to costs) exceeds the DRG payment amount, an NTAP equaling 50% of the excess costs, limited at the NTAP threshold, is paid to the hospital. For a hospital to increase its NTAP amount it must increase the charges for the admission to reflect the true cost of the new technology. Additionally, with the implementation of a single cost center for implantable medical devices, the issue of charge compression should diminish over time making it easier for CMS and hospitals to capture and report the actual cost of medical devices and supplies. Increased accuracy of charges and costs will occur with the new cost center without hospitals drastically changing their internal charge setting practices. Increased awareness and education about the NTAP program combined with the implementation of a new cost center, it is reasonable to expect that hospitals will be more likely to receive the maximum NTAP amount, thus increasing the cost of the NTAP program and making it increasingly important to understand and evaluate its value.

6.1.4 Limitations

The only technology evaluated in this analysis was CRT-D. CRT-D was chosen for this analysis because it has a concrete mortality end point, which is observable in claims data. All technologies granted NTAP status must demonstrate substantial clinical improvement. While the substantial clinical improvement criterion is vague by definition, it is flexible in the interpretation of what constitutes a clinically valuable technology. As described in detail in Chapter 1, reducing mortality is only one example of an outcome that is frequently used to evaluate substantial clinical improvement. Increasing the quality of life, reducing complications, decreasing pain and other quantifiable symptoms are other examples of what CMS considers a substantial clinical improvement. The estimated cost per life saved is greater than most estimates of the value of life, however it does not take into consideration other clinically meaningful differences between CRT-D and its substitute technology. Incorporating other clinically meaningful endpoints and its impact on quality of life may yield a more acceptable cost benefit ratio for the NTAP policy. Additionally, incorporating other endpoints into the analysis would enable the evaluation of all technologies receiving NTAPs. A mortality endpoint is not relevant to the other technologies analyzed in this research. BMP, b-DBS, and r-SCS are technologies that improve functionality and quality of life, not the duration of life.

One such an endpoint is the quality-adjusted life year (QALY). The QALY is a metric that combines the mortality and morbidity of a condition into a single outcome. The QALY is used in cost-utility analysis which provide a cost per quality-adjusted life year as its cost benefit ratio. The main advantage of the QALY is its cross-health condition applicability. The QALY is a metric that can be applied to all disease states and enables the value comparison across diseases and treatments. However, section 1182 of the Health Reform legislation prohibits the use of the quality-adjusted life year and cost per quality-adjusted life year as "a threshold to determine coverage, reimbursement or incentive programs" under the Medicare program [69]. Lacking the ability to evaluate the NTAP program using commonly accepted cost per QALY metrics, Medicare should quantify the benefits of increasing access to new technologies in terms of additional clinical endpoints such as patient satisfaction, reduced complications, and other clinical measures that are commonly used across therapies and diseases.

The NTAP program increased utilization of a life-saving technology. Additional evaluation is needed to further assess the value of the NTAP policy. The analysis shows that hospitals will utilize new technology regardless of incentive payments. However, the incentive increases access to Medicare beneficiaries. The question is whether the incremental increase in utilization due to the incentive is worth the additional expense. To fully answer the question, consideration of a more generalizable patient outcome will yield a more comprehensive conclusion.

Chapter 7

Conclusion

It is commonly agreed that technology is a significant driver of health care costs [36]. The NTAP policy encourages the utilization of costly new technologies within the United States health system which has an unsustainable growth rate of expenditures. While technology is a driver of health care costs, not all technological change is necessarily bad. To evaluate whether new technology brings value to the health system it is necessary to compare the incremental cost of the technology relative to its incremental benefits. If the cost outweighs the benefits then the technological change is a welfare loss to society, but if the opposite is true then the technological change benefits society. Additionally, with the passage of U.S. health reform, there is a concerted effort to slow the growth of health care expenditures. Initiatives designed to align the incentives of health care providers to simultaneously improve the quality of care and reduce costs are being tested and implemented. It is within this context that the NTAP policy an interesting case study as it is both a provider incentive, but at the same time encourages the use of costly new technologies.

The new technology add-on payment (NTAP) is the first payment incentive under Medicare's inpatient prospective payment system (IPPS) related to technology. Implemented in 2001, the NTAP reimburses hospitals up to fifty percent of the cost related to the use of eligible new technologies in addition to the prospective MS-DRG payment. The NTAP was implemented to ensure access of new clinically beneficial technologies to Medicare beneficiaries while the prospective payment system recalibrated to reflect the cost of new technology. For a technology to be eligible for NTAP, it must meet

three criteria: (1) the technology must be considered new, as defined by the Centers for Medicare and Medicaid Services (CMS) as within two to three years following FDA approval; (2) the technology must be considered costly and inadequately reimbursed under the current MS-DRG assignment; (3) the technology must provide a substantial clinical improvement to Medicare beneficiaries. As of September 30, 2007, seven technologies have been granted NTAP status. With the exception of one pharmaceutical technology, all of the technologies have been implantable medical devices.

This research evaluated the effect of Medicare's NTAP program on the utilization of new technology. The NTAP provides the unique opportunity to evaluate hospital response to payment incentives under a mature prospective system. Hospital response to payment incentives and mechanisms will become increasingly important with the recent passage of health care reform as it contains provisions for additional hospital payment incentives to improve efficiency, quality and patient outcomes.

This research is the first to evaluate the value of the NTAP policy and empirically estimate the effect of the NTAP policy on new technology utilization. The thesis is organized around three research questions: 1) does the presence of the NTAP policy affect the probability new technology is used? 2)does the amount of the NTAP affect the probability a new technology is used? 3) what is the value of the NTAP policy?

The hypotheses of this research – that the new technology add-on payment (NTAP) policy and incentive amount increases utilization of new technology – are supported by the results. The NTAP policy marginally increased utilization of new technologies. The post-NTAP analysis examined three technologies with observable post-incentive time periods: cardiac resynchronization therapy (CRT-D), bone morphogenetic proteins (BMP), and bilateral deep brain stimulation (b-DBS). The results from the post-NTAP analysis finds the NTAP policy increases the utilization of the NTAP-eligible technologies between 0.1% and 5.6 percent. There is variability in the magnitude of the effect across the technologies evaluated. The NTAP had the largest effect on CRT-D and b-DBS, 2.1% and 5.6%, respectively.

The NTAP policy is based on the assumption that prospective payment system negatively affects the utilization of new costly technologies. One study suggested that under prospective payment systems hospitals will limit the utilization of technologies with uncertain future reimbursement [48]. The NTAP reduces financial uncertainty

by establishing a temporary cost-sharing program between Medicare and the hospitals while future reimbursement rates recalibrate. Hospitals receive an increase in revenue when the new technology is used, thus minimizing the financial burden of technology adoption. Additionally, the NTAP reduces uncertainty related to the clinical value of new technology. Technologies that are granted NTAP status have been vetted by CMS and determined to provide improved clinical outcomes compared to the current standard of care.

The expected NTAP amount marginally increases the probability the new technology is used. However, the response to the payment amount varies by technology. Literature evaluating the effect of prospective payment systems on technology adoption suggests hospitals will increase the utilization of cost-saving technologies and reduce utilization of cost increasing technologies. In a mature prospective payment system such as IPPS, hospitals have become acclimated to the financial environment. The NTAP provides a unique opportunity for a hospital to increase its revenue under a financially constrained prospective payment system. However, an increase in revenue does not necessarily translate into an increase in profit. The variability of the effect across technologies may be related to the expected change in profit for given technology and the financial environment within a particular therapy area. The largest response to the expected NTAP amount was seen in rechargeable spinal cord stimulation and cardiac resynchronization therapy. The technologies may have reduced operational costs within the hospital enough to offset the increased cost of the technology, thus yielding a higher expected profit than the current standard of care. Evaluation of the expected change in profit may provide more explanation on the variability of response with respect to the expected NTAP amount.

Policymakers implemented the NTAP policy to ensure timely access to new technologies that have been proven to be a substantial clinical improvement in the treatment of a disease. The NTAP policy has been shown to increase utilization of new technologies that would not have occurred otherwise. The NTAP policy has proven to be a successful policy achieving the policymakers intentions. While it marginally increased utilization of new technologies, it has done so with lesser than expected cost. The lower than expected costs is largely do to the variability in the actual NTAP amounts paid to hospitals.

Hospitals have argued that the current maximum NTAP payment amounts provide an inadequate level of support to hospitals to cover the costs of the new technology [63]. The NTAP was implemented to be a cost sharing program between Medicare and hospitals with respect to new technology. The results of this research finds increasing the cost sharing of CMS (e.g. increasing the maximum NTAP amount) would result in slightly more utilization. However, the largest effect of the policy is seen in granting of NTAP status to a technology rather than the maximum payment amount. In addition, hospitals are not maximizing the increased revenue available. Hospitals are using the new technology, but on average are not receiving a NTAP payment close to the maximum allowable amount. From a policy perspective, the current cost-sharing arrangement between hospitals and Medicare is sufficient as hospitals would only marginally respond to increasing the payment threshold and hospitals are currently receiving less than the available add-on payment.

If policy makers simply want to increase the utilization of new clinically beneficial technologies, providing a payment incentive such as the NTAP to a broader range of technologies will have the largest impact on utilization compared to changing the payment mechanism.

The NTAP policy has increased access to clinically meaningful technologies. These technologies have continued to prove their clinical and economic value even after the NTAP expiration [63]. CMS is restricted from explicitly considering cost when determining whether to cover a particular therapy, technology, or procedure. However, given the budget constraints of the Medicare program, CMS needs to be concerned about the value of its policies used to increase the utilization of costly technologies. In examining one technology, the cost of the NTAP policy outweighed the benefits the technology brought to Medicare beneficiaries. The NTAP policy increased the utilization of a life-saving technology. In the Medicare population, cardiac resynchronization therapy decreased mortality by more than eleven percent relative to its substitute technology. However, the incremental cost of the NTAP compared to the incremental benefit results in a cost per life saved significantly higher than commonly used estimates of the value of life. Additionally, the cost per life saved of the NTAP policy was is significantly higher than other health interventions such as Medicaid eligibility. Further, the value calculation is based upon the average NTAP payment for the use of the new technology,

which is significantly lower than the maximum threshold set by CMS. As hospitals begin to be more successful in obtaining NTAP amounts closer to the maximum threshold (through adjusting hospital charges), the value of the policy becomes even lower. While this analysis only examines one technology and one outcome, it demonstrates that there was a substantial amount of money spent on the utilization of the new technology with a minimal improvement in relevant health outcomes. Such a result suggests the NTAP policy is an inefficient use of Medicare resources.

The NTAP policy had a small effect on hospital utilization. Regardless of the incentive, hospitals would have used the new technologies granted NTAP status. One explanation for such a minimal increase is hospitals adopt technologies with proven clinical outcomes regardless of cost. The technologies that receive NTAPs are shown to improve clinical outcomes. Hospitals trying to maximize the quality of care provided within its institution may adopt technologies to improve the health outcomes of its patients regardless of payment incentives.

Another explanation for such a minimal increase in utilization due to the NTAP policy is physicians are the more powerful decision makers. Physician behavior and characteristics are unobserved variables in all analyses. With physicians being unobserved, it is not possible to understand the physician-hospital dynamic and delineate the decision making process with respect to technology use. While hospitals carry the financial burden related to the cost of the new technology, physicians determine the appropriate use of technology for treating a given patient. Hospitals and physicians are competing forces with misaligned financial incentives. Physicians operate under a fee-for-service reimbursement structure in the Medicare program, whereas hospitals operate under a fixed prospective payment system. Physicians are financially rewarded for the quantity of services provided whereas hospitals are negatively impacted by the quantity of services provided by physicians. Physicians may use a new medical technology without consideration of its cost or financial implications within the hospital that he or she practices because they bear no financial risk. In the current environment, hospitals compete by maximizing profit in addition to quality. Hospitals rely heavily on physicians for the quality objective and want to be perceived by the community as a high quality institution with the newest technology available. The NTAP policy may

have had a larger effect if there was greater alignment between the hospital and physicians. For example, if hospitals were the more dominant decision maker with respect to technology, there may have been greater restriction on new technology prior to the implementation of the NTAP. Under such a scenario, the NTAP may have resulted in a greater effect as hospitals would shift technology purchasing decisions to those that yielded the greatest impact on its profit.

Hospital and physician alignment is increasing. With the passage of health reform, greater alignment of financial incentives between physicians and hospitals will develop through provisions such as accountable care organizations and bundled payments. An accountable care organization (ACO) is an entity to consist of various health care providers, such as physicians, largely centered around the hospital. An ACO will be responsible for a patient population and will be able to distribute savings among its providers if certain quality and cost metrics are achieved. Bundled payments will be a new payment mechanism that provides a single payment to a hospital covering the cost of the services for an individual episode of care. The payment includes the pre-hospital care in addition to post-acute care following a hospital admission and may encompass physician payments. These two provisions, ACOs and bundled payments, are clear signals that Medicare will be focused on achieving aligned financial incentives between hospitals and physicians and holding them accountable for the cost and quality of care provided to its beneficiaries.

To the extent reimbursement becomes dependent upon improving quality, either through reduced complications, increased patient satisfaction, and reduced cost and utilization for a given episode of care, hospitals will seek out technologies proven to improve patient outcomes while reducing long-term costs. The increased focus on improved patient outcomes increases the evidence development requirement for technology manufacturers. It will be increasingly important to not only demonstrate a particular technology is safe and efficacious, but also effective in achieving patient outcomes relevant to hospitals. The NTAP policy reimburses for the use of a technology shown in randomized controlled trials to achieve improved patient outcomes, however the payment system is reforming to reimburse for realized patient outcomes rather than use of a particular technology, procedure or therapy.

The research evaluates how the Medicare New Technology Add-on Payment policy

affects a hospitals' decision to use a new technology. The data used for analysis are inpatient hospital claims, and did not include physician level information. Therefore, physician influence on hospital's technological decisions is not directly observed. As discussed earlier, physician influence is necessary to fully understand the effect the NTAP policy has on new technology utilization.

The NTAP program is specific to the inpatient hospital setting. This research does not analyze the utilization of technologies in other care settings, and therefore assumes no differential behavior exists between inpatient and outpatient utilization. Rechargeable spinal cord stimulators and bilateral deep brain stimulators received similar payment incentives in the outpatient hospital setting, which reduces any potential bias. Additionally, BMP is only performed in the inpatient setting, so no bias is expected. Lastly, CRT-D is usually implanted post a heart failure event, which typically result in an inpatient hospitalization.

This research comprehensively evaluated four technologies, but only focused on one technology when evaluating the value of the NTAP policy. Additional research that incorporates clinical outcomes, not exclusive to mortality, should be evaluated to fully understand the value of the NTAP policy.

In summary, this research examined the influence of a payment incentive in a mature prospective payment system. The results demonstrate that the NTAP achieved policymakers' objectives by assuring patient access to new clinically meaningful technologies. The NTAP marginally increased the utilization of new technologies, and did so at a lower than projected cost. The lower costs can be attributed to hospitals variability in NTAP amounts. Despite responding to the payment incentive, hospitals were fairly ineffective in maximizing the increased potential revenue. In one analysis of value, the cost of the NTAP policy outweighed the benefits of the technology. In an era of using incentives to achieve a higher value of the health care dollar, understanding the dynamics between providers and how they respond to such incentives is imperative. This research shows that providers are indeed responsive to financial incentives despite their understanding of the actual mechanism. Incentive programs such as the NTAP will only become more effective as increased alignment between hospitals and physicians occur. As incentive programs develop within the health care system, simplicity in the mechanism and the overall value added to the health care system is necessary to improve efficiency.

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Appendix

A.1 Bivariate Probit

A.1.1 Methods

The bivariate probit model may be more appropriate model to evaluate the effect of CRT-D use on death as it simultaneously models two binary outcomes (use and death) that are potentially related. Unlike the instrumental variable probit, the bivariate probit model does not require the identification of specific instrumental variables. Rather, the bivariate probit jointly models use and death as a function of explanatory variables. The model assumes that the errors from the two equations have a joint normal distribution, with means equal to one and correlation ρ.

The following equations are nearly identical to those in the instrumental variable probit, however the death, in addition to use, is considered an unobserved latent variable (A.1) (A.2).

$$y^*1_{i,j} = \alpha + \chi y2_{i,j} + \phi I_{i,j} + \gamma H_j + \tau T + \tau_1 T^2 + \epsilon_{1_{i,j}} \tag{A.1}$$

$$y^*2_{i,j} = \alpha + \zeta \widehat{NTAP}_{i,j} + \beta N_{i,j} + \phi I_{i,j} + \gamma H_j + \tau T + \tau_1 T^2 + \epsilon_{2_{i,j}} \tag{A.2}$$

where the $\varepsilon_{1i,j}$ $\varepsilon_{2i,j}$ are jointly normally distributed with correlations of ρ.

$$y1 = \begin{cases} 1 & \text{if } y^*1_{i,j} > 0 \\ 0 & \text{if } y^*1_{i,j*} \leq 0 \end{cases} \tag{A.3}$$

and

$$y2 = \begin{cases} 1 & \text{if } y^*2_{i,j} > 0 \\ 0 & \text{if } y^*2_{i,j} \leq 0 \end{cases} \tag{A.4}$$

After estimation of the bivariate probit model, the predicted probabilities for all combinations of the dependent variables can be calculated.

A.1.1 Results

Table A.1: Bivariate Probit Results

	Coefficient	Robust Standard Error	Z	P-value
Death				
Patient Variables				
Length of Stay	0.04616	0.04616	0.00097	<0.000
Charlson Score	0.15860	0.15860	0.00345	<0.000
Age Group				
65-79 yrs	0.09452	0.09452	0.01278	<0.000
80+ yrs	0.36469	0.36469	0.01430	<0.000
Female	-0.04866	-0.04866	0.00978	<0.000
Hospital Variables				
Hospital Ownership				
Non-Profit	-0.05598	-0.05598	0.01893	0.003
Government	-0.00889	-0.00889	0.02488	0.721
Heart Failure Readmission Rate	0.01010	0.01010	0.00278	<0.000
Number of Beds	-0.00008	-0.00008	0.00003	0.004
Number of Residents	-0.00004	-0.00004	0.00003	0.159
Number of Physicians	-0.00001	-0.00001	0.00000	<0.000
Prior Use	-0.00030	-0.00030	0.00018	0.098
Time Variables				
Quarter	-0.03359	-0.03359	0.00601	<0.000
Quarter-squared	-0.00027	-0.00027	0.00041	0.509
Constant	-1.67554	-1.67554	0.07016	<0.000
Use				
Incentive	1.84503	1.84503	0.03044	<0.000
Predicted NTAP	0.00005	0.00005	0.00001	<0.000
Patient Variables				
Length of Stay	0.00578	0.00578	0.00116	<0.000
Charlson Score	-0.01755	-0.01755	0.00406	<0.000
Age Group				
65-79 yrs	0.12449	0.12449	0.01202	<0.000
80+ yrs	0.21325	0.21325	0.01625	<0.000
Female	0.03675	0.03675	0.00884	<0.000
Hospital Variables				
Hospital Ownership				
Non-Profit	0.16800	0.16800	0.06756	0.013
Government	0.16669	0.16669	0.08316	0.045
Number of Beds	-0.00190	-0.00190	0.00021	<0.000
Medicare Percent	0.02788	0.02788	0.01645	0.09
Number of Residents	0.00113	0.00113	0.00017	<0.000
Number of Physicians	-0.00001	-0.00001	0.00000	<0.000
Operating Cost to Charge Ratio	-0.24299	-0.24299	0.18917	0.199
Prior Use	0.00322	0.00322	0.00076	<0.000
Time Variables				
Quarter	-0.00782	-0.00782	0.00856	0.36
Quarter-squared	0.01641	0.01641	0.00047	<0.000
Constant	-1.98119	-1.98119	0.09616	<0.000
/athrho	0.14074	0.00677	20.8	<0.000
rho	0.13982	0.00663		

Wald test of rho =0: chi2(i) = 432.689, p-value = <0.000

Table A.2: Predicted Probabilities

Predicted Probability	Mean	Standard Error
Death = 1, Use = 1	0.04874	0.00012
Death = 1, Use = 0	0.06817	0.00015
Death = 0, Use = 1	0.29622	0.00047
Death = 0, Use = 0	0.58687	0.00049

A.2 Linear Instrumental Variable Analysis

A.2.1 Methods

A two-stage least square estimation of was used to address the endogeneity of use on the outcome of interest, death.

Equation (A.5) is modeling the endogenous regressor, use. Equation (A.5) is identified by *N* and *NTAP-hat* and other exogenous variables.

$$y2_{i,j} = \alpha + \zeta \widehat{NTAP}_{i,j} + \beta N_{i,j} + \phi I_{i,j} + \gamma H_j + \tau T + \tau_1 T^2 + v_{i,j} \qquad \text{(A.5)}$$

Where $y_{i,j}$ represents the use of the technology equal to 1 if CRT-D is used in patient i and zero otherwise; *NTAP-hat* represents the expected NTAP amount calculated from (3.4); $N_{i,j}$ is the binary NTAP policy indicator that equals one during the incentive time period and zero otherwise; $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); H_j is a vector of the j^{th} hospital characteristics (ownership type, Medicare percentage, number of beds, number of residents, number of physicians, operating cost-to-charge ratio, prior use of the substitute technology the year before the NTAP became effective); T is an ordinal time variable indicating the quarter of hospital admission; T^2 is the ordinal time variable squared to address some non-linearity of the model; and $v_{i,j}$ is the error term.

The second stage of the instrumental variable model estimates the outcome of interest, death, while adjusting for the endogeneity of use with the first stage.

$$y1_{i,j} = \alpha + \chi y2_{i,j} + \phi I_{i,j} + \gamma H_j + \tau T + \tau_1 T^2 + u_{i,j} \qquad \text{(A.6)}$$

Where $y_{i,j}$ is a dichotomous variable indicating death that equals 1 when death in patient i is observed and zero otherwise; $\chi y_{2i,j}$ is the exogenous use variable predicted from (3.8); $I_{i,j}$ is a vector of the i^{th} patient characteristics (age, sex, Charlson score, length of hospital stay); H_j is a vector of the j^{th} hospital characteristics (30 day heart failure readmission rate, ownership type, Medicare percentage, number of beds, number of

residents, number of physicians, prior use of the substitute technology the year before the NTAP became effective);); T is an ordinal time variable indicating the quarter of hospital admission; T^2 is the ordinal time variable squared to address some non-linearity of the model; and $u_{i,j}$ is the error term.

A.2.1 Results

Table A.3: Linear IV Results: First Stage

	Coefficient	Robust Standard Error	t	P-value
Instrumented Variables				
Incentive	0.437377	0.010279	42.55	<0.000
Predicted NTAP	0.000018	0.000003	7.23	<0.000
Patient Variables				
Length of Stay	0.001502	0.000329	4.56	<0.000
Charlson Score	-0.005703	0.001182	-4.83	<0.000
Age Group				
65-79 yrs	0.036164	0.003507	10.31	<0.000
80+ yrs	0.065656	0.004778	13.74	<0.000
Female	0.011338	0.002702	4.2	<0.000
Hospital Variables				
Medicare percent	0.006040	0.005105	1.18	0.237
Operating Cost-to-Charge Ratio	-0.058103	0.058105	-1	0.317
Heart Failure Readmission Rate	0.000184	0.002393	0.08	0.939
Hospital Ownership				
Non-Profit	0.040747	0.019195	2.12	0.034
Government	0.038716	0.023194	1.67	0.095
Number of Beds	-0.000480	0.000048	-9.97	<0.000
Number of Residents	0.000295	0.000049	6.01	<0.000
Number of Physicians	-0.000005	0.000001	-3.41	0.001
Prior Use	0.000969	0.000216	4.48	<0.000
Time Variables				
Quarter	-0.012591	0.002852	-4.42	<0.000
Quarter-squared	0.004736	0.000163	29.13	<0.000
Constant	0.009087	0.072762	0.12	0.901

Table A.4: Linear IV Results: Second Stage

	Coefficient	Robust Standard Error	t	P-value
Use	-0.1366	0.0085	-16.03	<0.000
Patient Variables				
Length of Stay	0.0117	0.0003	38.78	<0.000
Charlson Score	0.0299	0.0008	36.79	<0.000
Age Group				
65-79 yrs	0.0218	0.0022	10.11	<0.000
80+ yrs	0.0768	0.0029	26.64	<0.000
Female	-0.0081	0.0018	-4.53	<0.000
Hospital Variables				
Heart Failure Readmission Rate	0.0018	0.0006	2.81	0.005
Hospital Ownership				
Non-Profit	-0.0048	0.0050	-0.96	0.338
Government	0.0017	0.0061	0.27	0.784
Number of Beds	-0.0001	0.0000	-6.54	<0.000
Number of Residents	0.0000	0.0000	3.38	0.001
Number of Physicians	0.0000	0.0000	-3.72	<0.000
Prior Use	0.0001	0.0001	1.4	0.163
Time Variables				
Quarter	-0.0299	0.0018	-16.92	<0.000
Quarter-squared	0.0016	0.0001	13.79	<0.000
Constant	0.1512	0.0173	8.72	0

Table A.5: Linear IV Results: Endogeneity Test

Variable	R-sq.	Adjusted R-sq.	Partial R-sq.	Robust F(4,1105)	Prob > F
Use	0.1949	0.1948	0.0609	853.242	<0.000

(F statistic adjusted for 1106 clusters in hospid)