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Final Project Report: The Role of Technology in Reducing Health Care Costs

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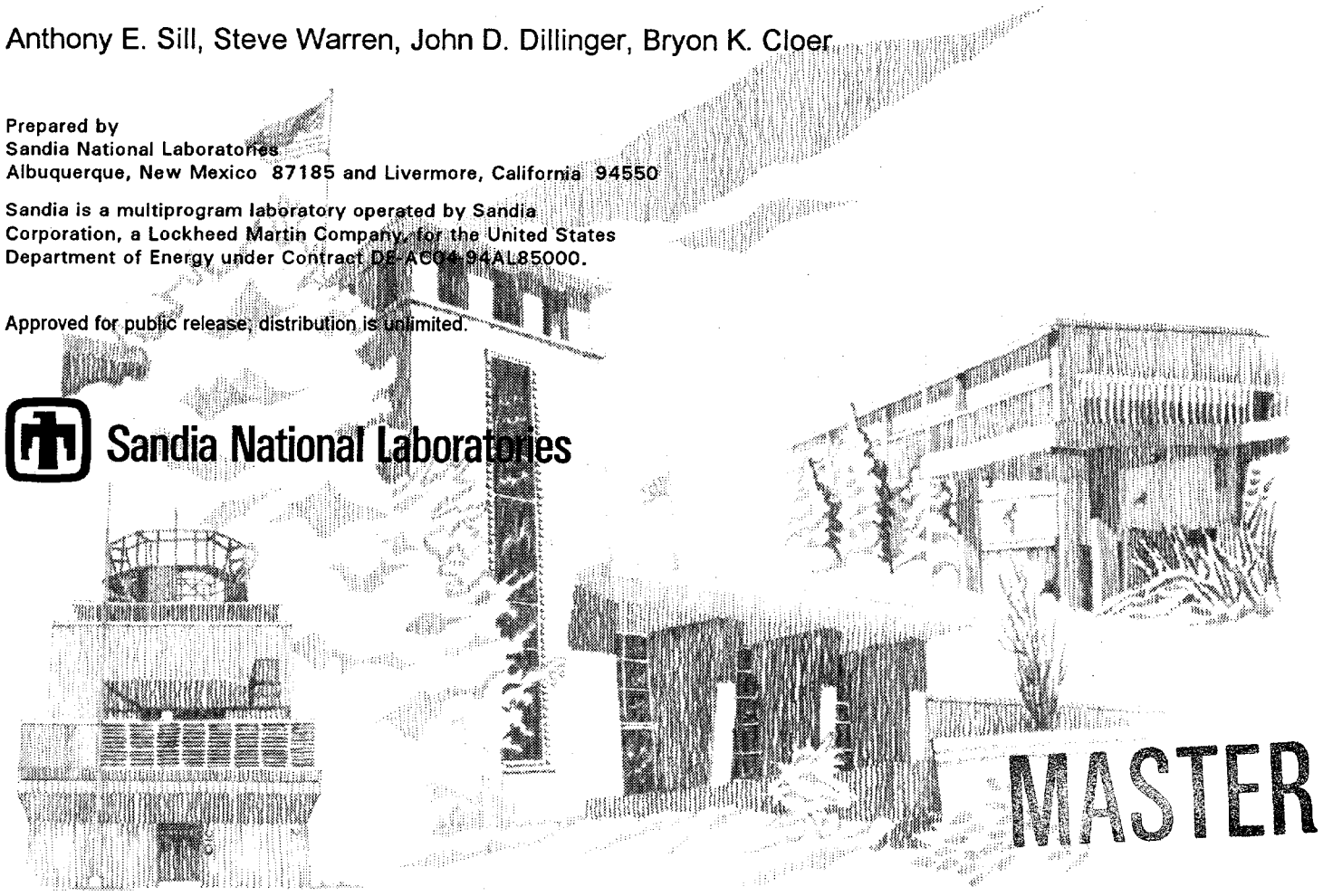

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FINAL PROJECT REPORT: THE ROLE OF TECHNOLOGY IN REDUCING HEALTH CARE COSTS

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Abstract

Sandia National Laboratories applied a systems approach to identifying innovative biomedical technologies with the potential to reduce U.S. health care delivery costs while maintaining care quality. This study was conducted by implementing both top-down and bottom-up strategies. The top-down approach used prosperity gaming methodology to identify future health care delivery needs. This effort provided roadmaps for the development and integration of technology to meet perceived care delivery requirements. The bottom-up approach identified and ranked interventional therapies employed in existing care delivery systems for a host of health-related conditions. Economic analysis formed the basis for development of care pathway interaction models for two of the most pervasive, chronic disease/disability conditions: coronary artery disease (CAD) and benign prostatic hypertrophy (BPH). Societal cost-benefit relationships based on these analyses were used to evaluate the effect of emerging technology in these treatment areas.

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Acknowledgments

This work is an aggregation of material written by many members of the project team. Most of the information originated from two sources: a series of reports written by Bryon Cloer of Sandia National Laboratories, and a comprehensive final report from an Alton Ochsner Medical Foundation contract with Sandia National Laboratories. That document was written by several people under the direction of Dr. Richard Re, M.D., the Alton Ochsner principal investigator for this effort. The report is entitled *The Role of Technology in Reducing Health Care Costs.* This work was supported by the U.S. Army Medical Research and Materiel Command, Fort Detrick, Frederick, MD.

Note

No animal or human experiments were conducted during the course of this development.

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Chapter 1 - Introduction

Study Overview

Sandia National Laboratories applied a systems approach to address the identification of innovative biomedical technologies with the potential to reduce U.S. health care delivery costs while maintaining (or improving) care quality. This study (MIPR No. MM4592KC6, SNL Proposal No. 94940719/1) was conducted by implementing top-down and bottom-up strategies.

The top-down approach addressed the identification of *future* health care delivery needs. **Biomedical technology roadmaps,** developed as part of this approach, can guide the introduction and development of technologies to meet these care delivery requirements..

The complete results of the top-down approach were published by Sandia National Laboratories in October 1996 in a separate document entitled *The Role of Technology in Reducing Health Care Cost.* This document identifies eight technologies and technology-related policies that have the potential to reduce health care costs while maintaining or improving quality. For each of these areas, strategic roadmaps were developed to provide guidance for future development and the introduction of cost-effective technologies and technology-related policies for the U.S. health care delivery system.

The roadmaps, or strategic plans, identify a common vision for timely solutions of fundamental system problems that are "needs-driven" rather than "solutions-driven." Roadmaps provide consensus in the development and introduction of innovative technologies by reducing duplication of essential research, development and application activities among stakeholders. In addition, roadmaps (1) address technology challenges that may be too expensive or too risky for a single organization to solve and (2) provide a comprehensive view for addressing solutions to broad system problems.

Because of the complexity of the issues facing the U.S. health care delivery system, a gaming approach was selected as the mechanism to build consensus and to develop roadmaps establishing technology's role in meeting care delivery needs. These ***prosperity games*** are interactive role simulations that explore complex issues in a variety of economic, political and social arenas: they are not computer simulations. The simulations are high-level exercises relying on participants' discretion, judgment, planning and negotiating skills.

The prosperity games provided participants with an understanding of some of the obstacles and opportunities associated with current and proposed technologies and technology-related policy. For example, participants explored problems and opportunities faced by doctors and other health care providers, patients, technology developers, the military, regulators, legislators, insurance agencies, lawyers, and other stakeholders in the biomedical engineering field.

The biomedical prosperity game produced a prioritized list of technology and technology-related policy areas for roadmapping, including

- advanced telemedicine,
- health and healthcare informatics,
- information and network surety,
- integrated predicative diagnostics,
- minimally invasive therapy, imaging, and energy delivery systems,
- performance measurement and outcomes research,
- preventive medicine and incentive programs, and
- rehabilitative science and assistive technologies.

Overall, the players expressed a strong interest in emphasizing general health care information areas for future technology and technology-related policy development. The players' general consensus was that the future health care information infrastructure must support systems capable of handling complex care scenarios while maintaining flexibility, responsiveness and quality. Several participants pointed out the current imbalance in health-related information: doctors are increasingly burdened with a deluge of information while patients have access to relatively little information. In particular, future health information systems were postulated that would allow individuals to proactively participate with care professionals in the improvement of their personal health status.

The list of co-sponsors for the overall roadmapping effort included the following:

- U.S. Army Medical Research & Materiel Command,
- The Koop Foundation, Inc. (KFI),
- Defense Advanced Research Projects Agency (DARPA),
- Massachusetts General Hospital,
- Pennsylvania State University Applied Research Laboratory,
- Presbyterian Hospital of Dallas, and
- Sandia National Laboratories.

It should be noted that more than 75 organizations and 150 individuals participated in the roadmap development process. Commitment from this broad spectrum of participants validates the objectives and details for each roadmap.

The complete roadmap document is available electronically on the DoD Telemedicine world wide web site at

http://www.matmo.org/news/sections/civprog/sandia.html.

The bottom-up approach **identified key technologies and outcome measures** in *existing* care delivery systems. In addition, **Care Pathway Interaction Models** were constructed for two chronic disease/disability conditions *to simulate the impact of new technology on overall costs and outcomes for these conditions.*

The goals of the bottom-up approach were

- to identify current technology usage on a national level so that likely targets for technological improvement could be identified, and
- to model the cost-effectiveness of the technology utilized in the treatment of the representative medical conditions so as to permit the identification of figures of merit for technology improvements which could lower health care costs while maintaining health care quality.

In the bottom-up approach, Sandia National Laboratories (SNL) and Alton Ochsner Medical Foundation (AOMF) sought to determine if technology could in fact lower health care costs irrespective of the ambient social climate, payment mechanism, or introduction of implicit/explicit rationing of care. To address this issue, it became important to first define the cost of technology in addition to identifying those factors which favorably or unfavorably influence that cost. Because the aim of SNL and AOMF was to identify means by which technology could reduce cost without lowering the quality of delivered care, rationing was explicitly removed from consideration as a means of reducing health care costs.

Initially, medical data bases were reviewed to determine the most frequently performed and most costly medical procedures. Two technology-intensive disease/disability states were selected for modeling to determine the effect of applying new and alternative technologies to the treatment of these disease/disability states. Aggregate and patient-specific models were then developed for each disease/disability state. As part of the model development, significant research was conducted on the economic factors related to the application of new and alternative technologies.

Development of the care pathway interaction models has provided a new methodology that can be applied to help make decisions on the introduction of technology for the treatment of other disease/disability states. These models can be used as prototypes for future models and should serve as educational tools for the investigation of the impact of a wide variety of variables on health care costs and quality.

This effort is a new paradigm for technology assessment: one which can direct similar efforts aimed at other disorders. Current approaches to technology assessment center around (1) the evaluation of technology currently employed in clinical settings or (2) pilot trials of new technology. The present effort addresses the problem in a fundamentally different manner. It attempts to predict the economic and medical impact of new technologies before they are developed. This permits the analyst to vary the figures of merit for proposed new technologies in order to identify parameters associated with reduced cost and constant or enhanced patient outcome.

The majority of the information from the bottom-up approach is available in Volume I of a May 1997 report by the Alton Ochsner Medical Foundation entitled *The Role of Technology in Reducing Health Care Costs.*

Sandia National Laboratories Project Team

The major members of the Sandia National Laboratory Project team follow:

Samuel Varnado, Ph.D. Program Manager, Co-Investigator
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Timely consultation and technology roadmap development support was also provided by these Sandia National Laboratories biomedical program thrust area leaders:

Thurman Allard, Ph.D.	Medical microelectronics
Keith Miller, Ph.D.	Assistive Technologies
Don Schroeder, Ph.D.	Minimally Invasive Therapy
Mike Sjulin	Medical Information Systems

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Chapter 2 - Economic Analysis of Selected Disease/Disability States

Formation of the Bottom-Up Approach Team

The bottom-up approach to the study was supported through a competitive contract awarded to Alton-Ochsner Medical Foundation.

Medical Research Institutions Invited to Participate

During the period from October 1994 through December 1994, Sandia developed and distributed a statement of work (SOW) to 18 medical research institutions. These institutions included

- Alton Ochsner Medical Foundation,
- Johns Hopkins University, School of Medicine,
- Stanford University Hospital,
- The Lovelace Institute (TLI),
- Massachusetts General Hospital ,
- The University of Texas, M.D. Anderson Cancer Center,
- Mayo Clinic, Department of Community Internal Medicine,
- University of California, UCSD Medical Center,
- University of California, San Francisco, Radiologic Imaging Laboratory,
- Washington University, Technology Group (St. Louis, MO),
- UCLA Medical Center, Department of Radiological Sciences,
- New York University Medical Center, Department of Neurosurgery,
- Duke University Medical Center,
- Medical College of Georgia,
- Presbyterian Hospital of Dallas,
- University of Washington (Seattle, WA),
- University of Michigan, School of Public Health, and
- University of New Mexico, School of Medicine.

This SOW identified the areas of tasking for the bottom-up approach to the study. In addition, evaluation criteria for potential partnering medical institutions were also identified.

During the period from January 1995 through March 1995, Sandia held a pre-proposal conference for the potential bidders to the request for quotation. In the conference, Sandia responded to both technical and contractual questions. A summary of the responses to these questions as well as questions formally submitted to Sandia before the conference was transcribed and sent to each of the potential medical institution bidders.

The formal RFQ was sent to the list of potential partners from 18 medical research institutions in February 1995. The RFQ established the guidelines for submitting proposals by interested institutions. It also delineated the terms, conditions, and responsibilities for participation in the study. In addition, Sandia further clarified technical and contractual questions submitted by potential bidders.

Acceptable responses were received from three leading medical research institutions:

- Alton Ochsner Medical Foundation, New Orleans, LA (with partners at the Stanford University School of Medicine and the Johns Hopkins University Division of Internal Medicine),
- The Lovelace Institute (TLI), Albuquerque, NM and
- University of Texas Southwestern Medical Center at Dallas, TX.

Evaluation of the submitted proposals was performed by a team of Sandians with broad systems experience. The evaluation was based upon the technical capabilities of each submitting organization in addition to the soundness of their proposed approach for conducting the bottom-up investigation for this study.

The proposed approach by the team headed by the Alton Ochsner Medical Foundation was very comprehensive. It identified effective methods for the collection and analysis of health care cost data which would lead to the identification, prioritization and specification of technologies with the potential to reduce health care costs. Although the quotations proposed by the other two institutions identified some strong capabilities, their proposals did not meet essential elements for conducting the study and were not considered broad enough to address all of the stated goals.

Medical Partnering Team Membership

Sandia National Laboratories' partnering team for addressing the bottom-up tasks included the following individuals:

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Summary of Bottom-Up Approach Tasks and Goals

In order to determine where technology might be best applied to reduce costs, a broad collection of health care databases was reviewed to determine a rank ordering of disease states by cost/charge and volume/frequency indices.

Outcomes measures were also collected to quantify the application of technologies for specific disease/disability states. These cost/charge, volume/frequency, and outcomes measures were used to construct **Care Pathway Interaction Models** (CPIM's) for two chronic disease/disability (D/D) states: **coronary artery disease** (CAD) of sufficient severity to warrant revascularization, and **benign prostatic hypertrophy** (BPH).

The CPIM's simulate the overall cost impact of technology on the D/D states. The models for BPH and CAD were developed such that specific costs and outcome measures for the application of a care delivery technology can be determined at an individual node or for a complete pathway within the model. Further, the CPIM's may be modified to determine care delivery characteristics as a function of future technology-based treatments.

Review of Medical Databases Task

Several national, regional, and local medical databases were reviewed to support two essential tasks of the bottom-up approach for the study:

- cost/charge and volume/frequency measures data were collected for care delivery technologies in order to compile a global rank ordering technologies, and
- cost/charge, volume/frequency, and outcome measures data were collected to develop the economic and outcomes baseline for the CPIM care delivery interaction nodes and pathways.

Because no central repository exists for administrative or outcome-related medical data in the United States, determining a rank order of technology usage required that a variety of information sources be interrogated, with the results extrapolated to the national population. These information sources included Medicare administrative records, the records of regional health maintenance organizations, and the Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample.

The characteristics considered when selecting a medical data base included the following:

1. Patient-specific, visit-specific, and population-based measures should be identified.
2. A source should address inpatient, outpatient, Medicare, and managed care delivery.
3. A database's scope should address national, regional, and/or local data.
4. Demographic information should include age, gender, ethnic origin, payer class, income level, and level of education.
5. International Classification of Diseases, 9th revision, (hereafter denoted as ICD-9) Health Care Financing Administration's Common Procedure Coding System (hereafter denoted as HCPCS) or the Current Procedural Terminology, 4th revision (hereafter denoted as CPT-4) coding structures for conditions and/or procedures should be designated.
6. Information sources (e.g. survey versus claims) should be identified.
7. The timeframe of a database's collection should be indicated (e.g. current versus past years).
8. The source data should be available within the study's time constraints, and data access cost should be minimized.

Global Rank Ordering of Cost-Effective Technologies

After an extensive review of existing databases, the following data sources were selected for the project:

1. Health Care Finance Administration,
2. Healthcare Cost Utilization Project (HCUP-3), National Inpatient Sample,
3. a southern managed care organization, and
4. a large western managed care organization.

The databases were reviewed to identify the highest aggregate "charge" and volume for given patient populations using HCPCS, ICD-9 and CPT-4 codes. Since charge data is not a direct reflection of cost, units of services (e.g. laboratory and x-ray utilization, pharmaceutical data, ICU length of stay, overall length of stay) were also obtained in order to better compare conditions associated with higher charges across providers of care. These sources not only provided information on direct, indirect, and (to some extent) opportunity cost, but they also provided information on pertinent outcomes, whether they be ultimate or surrogate measures.

A summary of the characteristics of the selected databases is as follows:

- A rank ordering of the top 200 technologies sorted by allowable charges and by frequency/volume for 1994 was obtained from the Health Care Finance Administration (HCFA) data using CPT-4 and HCPCS procedure codes. HCFA is the primary payer for the Medicare population characterized by high utilization of medical services. The data contained in the Medicare Part B files have inputs from physicians, hospitals, and outpatient facilities and include a broad listing of technologies and other services.
- A southern managed care organization provided data on approximately 63,000 enrollees in calendar year 1994. These data were used to develop a composite list of the top 200 procedures by dollar and volume.
- A large western managed care organization provided data on approximately 2.4 million enrollees in calendar year 1994. These data were used to develop a composite list of the top 200 procedures by dollar and volume.
- Data were also obtained from the National Inpatient Sample (available through the National Technology Information Service (NTIS) and the Agency for Health Care Policy and Research (AHCPR)) to address the generalization of a composite rank ordering to the U. S. population. The NIS data represent a 5% sample of all hospital discharges for the years 1988-1992.

The integration of information from these data sources was used to determine a global rank ordering of technologies in the United States. A rank ordering of combined inpatient and outpatient procedures was carried out and a listing of the top twenty procedures by dollar rank is show in Table 1. The top five medical technology charge groups in order are

1. patient visit/inpatient and outpatient,
2. chest x-ray,
3. mammography,
4. ophthalmologic services, and
5. ECG.

A rank ordering by volume was also performed, and the top twenty procedures are shown in Table 2. In this case, the top five groups were

1. patient visit,
2. chest x-ray,
3. ophthalmologic services,
4. ECG, and
5. mammography.

Note that the top five procedures by dollar order and volume order differ only in arrangement of absolute ranking of the items. Details of how the rank order data were derived are discussed in Appendix A.

Table 1. Rank Order Dollar - High Dollar Procedures Comprising the Top 20 Procedure Categories (Ranked by Total Estimated Allowed Charges*) for the Combined Inpatient and Outpatient Report

Number	Category Weight Rank	3 Digit Procedure Category (CPT and HCPCS codes**)	Abbreviated Title	Driver Procedures * for Category	Approximate Aggregate % of Dollars per Category
1	1	992	Patient Visit	Established Patient office/outpatient visit (Codes 99211-99215) Subsequent Hospital care/pro. fee (Codes 99231-99233) Initial inpatient consultative professional fee (Codes 99253-99255) Emergency Department Services (Codes 99282-99285)	41.6 % 24.3% 7.3% 7.0% Subtotal = 80.2%
2	2	710	Chest X-Ray	Radiologic examination, chest; single view (Code 71010) Radiologic examination, chest; two views (Codes 71020)	38.4% 61.6% Subtotal = 100.0%
3	3	760	Mammogram	Mammography; bilateral (code 76091) Screening Mammography; bilateral (Code 76092)	63.3% 36.1% Subtotal = 99.4%
4	4	920	Ophthalmologic Services	Ophthalmological services, medical examination and evaluation (Codes 92002-92014) Visual field examination, unilateral or bilateral (Code 92083)	88.5% 11.1% Subtotal = 99.6%
5	5	930	ECG	Electrocardiogram (ECG), routine ECG with at least 12 leads (Codes 93000-93010)	97% Subtotal = 97%
6	6	908	Psychotherapy	Individual medical psychotherapy by a physician (Codes 90843-90844) Group medical psychotherapy (Code 90853)	76.9% 7.5% Subtotal = 84.4%
7	7	933	Echocardiography	Echocardiography, real-time with image documentation (Code 93307) Doppler echocardiography, pulsed wave and/or continuous (Code 93320)	57.4% 23.1% Subtotal = 80.5%
8	8	971	Physical Medicine Treatment	Physical medicine treatment to one area (Codes 97110 and 97128††)	87.4% Subtotal = 87.4%
9	9	993	Nursing Facility Care	Subsequent nursing facility care/pro-fee (Codes 99311-99313)	99.9% Subtotal = 99.9%
10	10	768	Echography	Echography, pregnant uterus, limited (Code 76815) Echography, transvaginal (Code 76830) Echography, pelvic, not OB (Code 76856)	39.3% 16.5% 35.3% Subtotal = 91.1%
11	10†	800	Laboratory Blood Tests	Automated multichannel test (Codes 80002-80012) Lipid profile (Code 80061) Thyroid panel with thyroid stimulating hormone (Code 80092)	63.2% 14.3% 17.8% Subtotal = 95.3%

12	12	994	Evaluation and Management Service	Unlisted evaluation and management service (Code 99499)	100% Subtotal = 100%
13	13	453	Sigmoidoscopy/ Colonoscopy	Sigmoidoscopy, flexible fiberoptic, diagnostic (Code 45330) Colonoscopy, fiberoptic (Codes 45378 and 45385)	60.1% 39.9% Subtotal = 100%
14	14	735	Hip, Knee X-Ray	Radiologic examination, hip, complete (Code 73510) Radiologic examination, knee, anteroposterior and lateral view (Code 73560)	60.0% 37.9% Subtotal = 97.9%
15	14†	850	Blood Count	Blood count, hemogram and platelet count, automated (Codes 85007-85027)	95.9% Subtotal = 95.9%
16	16	883	Surgical Pathology	Surgical pathology, gross and microscopic examination (Codes 88304-88305)	100% Subtotal = 100%
17	16†	A02***	Ambulance	Ambulance service and supplies (Codes A0215, A0220, A0222)	100% Subtotal = 100%
18	18	704	CAT Scan - Head	Computerized axial tomography (CAT) scan, head or brain (Code 70450)	98.6% Subtotal = 98.6%
19	18†	774	Radiotherapy	Weekly radiotherapy management; complex (Code 77430)	99.9% Subtotal = 99.9%
20	20	767	Abdominal Echography	Echography, abdominal B scan and/or real time (Code 76700)	99.0% Subtotal 99.0%

† Some categories have similar weight ranks

* HCFA national average "allowed" charge for each relevant code was applied across each data set (Medicare Part B, WMCO, SMCO). The charge was multiplied by the frequency for each code in all datasets to generate total estimated allowed charges for each category.

†† Code has been deleted from the 1997 CPT-4 manual

** HCPCS = HCFA Common Procedural Coding System
CPT = Current procedure terminology

Table 2. Rank Order Volume - High Volume Procedures Comprising the Top 20 Ranked Procedure Categories for the Combined Inpatient and Outpatient Report

Number	Category Weight Rank	3 Digit Procedure Category (CPT and HCPCS codes***)	Abbreviated Title	Driver Procedures* for Category	Approximate Aggregate % **
1	1	992	Patient Visit	Established Patient office/outpatient visit (Codes 99211-99215) ·Subsequent hospital care/professional fee/change in status (Codes 99231-99233)	56.1 % 25.8% Subtotal = 81.9%
2	2	710	Chest X-Ray	·Radiologic examination, chest single view (Code 71010) ·Radiologic examination, chest two views (Codes 71020)	46.4% 53.5% Subtotal = 99.9%
3	3	920	Ophthalmologic Services	·Ophthalmological services, medical examination and evaluation (Codes 92002-92014)	87.1% Subtotal = 87.1%
4	4	930	ECG	·Electrocardiogram (ECG), routine ECG with at least 12 leads (Codes 93000-93010)	95.1% Subtotal = 95.1%
5	5	760	Mammogram	Mammography; bilateral (Code 76091) ·Screening Mammography; bilateral (Code 76092)	62.2% 37.1% Subtotal = 99.3%
6	6	971	Physical Medicine Treatment	·Physical medicine treatment to one area (Codes 97110 and 97128[††])	89.9% Subtotal = 89.9%
7	6[†]	993	Nursing Facility Care	·Subsequent nursing facility care/pro-fee (Codes 99311-99313)	99.9% Subtotal = 99.9%
8	8	907	Influenza Vaccine	Immunization, active; influenza virus vaccine (Code 90724)	99.8% Subtotal = 99.8%
9	9	800	Laboratory Blood Tests	·Automated multichannel test; clinical chemistry (Codes 80002, 80007, 80008, 80016, 80018, 80019) Lipid profile (Code 80061) ·Thyroid panel (Codes 80091 and 80092)	77.8% 10.9% 11.3% Subtotal = 100%
10	10	850	Blood Count	·Blood count; hemogram and platelet count, automated (Codes 85023-85027)	92.2% Subtotal = 92.2%
11	11	908	Psychotherapy	·Individual medical psychotherapy by a physician (Codes 90843-90844) ·Group medical psychotherapy (90853)	66.8% 13.4% Subtotal = 80.2%
12	12	810	Urinalysis	Urinalysis, by reagent strips (Codes 81000 and 81002)	99.9% Subtotal = 99.9%
13	13	730	Shoulder X-Ray	Radiologic examination, shoulder complete (Code 73030)	96.5% Subtotal = 96.5%

14	14	735	Hip, Knee X-Ray	Radiologic examination, hip, complete (Code 73510) Radiologic examination, knee; anteroposterior and lateral view (Code 73560)	58.7% 39.3% Subtotal = 98.0%
15	15	736	Ankle, Foot X-Ray	X-ray ankle; complete (Code 73610) X-ray foot; complete (Code 73630)	36.1% 48.8% Subtotal = 84.9%
16	15†	856	PT	Prothrombin Time (PT) (Code 85610)	99.9% Subtotal = 99.9%
17	15†	994	Evaluation and Management	Unlisted evaluation and management service (Code 99499)	100% Subtotal = 100%
18	18	844	Thyroxine, TSH	Thyroxine (Code 84436) Thyroid stimulating hormone (TSH) (Code 84443)	43.2% 56.7% Subtotal = 99.9%
19	19	768	Echography	Echography, pelvic, not OB, B-scan (Code 76856) Echography, pregnant uterus, B-scan (Code 76806) Echography, transvaginal (Code 76830)	38.3% 32.5% 18.5% Subtotal = 89.3%
20	19†	883	Surgical Pathology	Surgical pathology/gross microscopic (Codes 88304 and 88305)	100% Subtotal 100%

* Procedures in the Procedure category that collectively contribute over 80% of the total number of procedures in that category

** Aggregate percent was derived using data from each data source: Medicare, WMCO, SMCO

*** No procedures identified by HCPCS codes were listed in the top 20 procedures categories ranked by volume

† Some categories have similar weight ranks

†† Code has been deleted from 1997 CPT-4 manual

Outcomes data, both surrogate and definitive, were also collected. Surrogate measures acquired from administrative/claims databases included

- number and type of emergency room visits,
- number and type of hospitalizations,
- number of hospital readmissions,
- number and type of clinic visits, and
- number and type of procedures performed.

Definitive outcome measures collected included

- patient functional status,
- patient satisfaction,
- mortality and morbidity rates,
- complication rates, and
- fit to work status, among others.

Definitive measures were identified both pre- and post-application of specific technologic intervention.

The outcomes team used standard tools that have been developed for the collection and quantification of outcome measures. As examples, the widely-used Short Form, 36-item

(SF-36) and Dartmouth Project Cooperative (COOP) Charts for measuring patient functional status have been tested and validated [Nelson 1990, Ware 1992].

A key to the interpretation of potential outcomes variations are patient-specific characteristics that could confound the results and bias the interpretation of outcomes data. Several severity of illness indices were used by the outcomes team to assess the impact of severity on clinical outcomes.

For example, the Charlson index [Charlson 1987] was used. Other indices, including the Index of Coexistent Disease (ICED) [Greenfield 1993] and the Kaplan-Feinstein Index [Kaplan 1974] were utilized for assessing comorbidity.

Although several other severity indices have been developed to assess cost of care, the previous indices were chosen for this task since they have been developed to assess clinical outcomes. For outcomes information derived from administrative/claims data sources that prohibited access to the medical records, risk adjustment was determined using indices such as the claims-based Charlson index [Deyo 1992] or the All Patient Refined - Diagnostic Related Groups (APR-DRG) approach [Jones 1994].

Interventional Focus Areas

In order to quantify technology application in the U. S. health care system, care pathway interaction models (CPIM's) were developed for two disease/disability states. The modeling effort was two pronged. An "attention focusing model" was developed with the goal of permitting the user to easily and conveniently vary input parameters and quickly assess results so that otherwise unappreciated relationships between variables and outputs could be identified. These attention-focusing models were developed utilizing Demos, a product of Lumina Decision Systems, for MacIntosh. The models were eventually imported into Lumina Decision Systems' commercial product: Analytica. When a personal computer version of the package became available, the models were imported into the Windows 95 version of Analytica. The second modeling effort involved the development of more detailed models utilizing the ARENA Windows 95 compatible system. The ARENA models are more difficult to manipulate and interrogate but are elemental in nature, providing the user with the ability to follow specific patient cohorts over time.

Disease/Disability Conditions Assessed

Because it was the goal of the team to develop a paradigm for the development of technological figures of merit which could be applied widely in the health care system, several criteria were established for the conditions which were to be modeled for this project. These conditions were designed to ensure that the analysis format which was

developed as part of the project would be sufficiently robust to be widely utilized in future efforts by others to model health care costs. The criteria included the following:

- The technological intensity of the therapeutic modality. It was of considerable interest to Sandia to identify technologies (widely defined) which Sandia scientists and engineers could develop in order to lower costs. Therefore, the medical conditions chosen for modeling were deliberately technologically-intensive.
- The aggregate costs (dollar volume) of the condition should be large so as to provide national relevance to the issue of health care costs.
- The chosen conditions should be frequent (patient volume) to support the relevance of the analysis.
- Cost and outcome data should be available in the literature and elsewhere so as to improve the precision of the modeling.
- The chosen conditions should have a significant impact on individual patients so as to be viewed as non-trivial.

The first chosen condition was coronary artery disease of sufficient severity to consider vascular intervention. This disease can be treated by a technologically-intensive array of therapies, including coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA, or balloon angioplasty), laser angioplasty, atherectomy, stents, and soon minimally invasive coronary artery bypass grafting (mini-CAB). Treatment of this disorder is expensive, amounting to $20 billion annually. Coronary artery disease is the leading cause of death in the United States. In addition, two treatment procedures for coronary artery disease (CABG and PTCA) ranked in the top 20 procedures with the rank ordering task. Coronary artery disease is well studied both from the outcome and cost point of viewand is a major cause of morbidity, mortality, and hospitalization in the United States. **Thus, coronary artery disease met all of the study criteria.**

The second condition chosen was benign prostatic hypertrophy (BPH). Treatment of this condition is also technologically intensive and currently includes open prostatectomy, transurethral prostatectomy, laser prostatectomy, microwave therapy, transurethral needle ablation, and pharmacological therapy. The aggregate cost of BPH therapy is high, with procedures and pharmaceuticals estimated to cost over $3 billion a year. The disease is common in the over-60 age group. The primary surgical treatment for BPH (transurethral restenosis of prostate, or TURP) ranked in the top 50 procedures listed in the rank ordering task. Although there is not the abundance of outcome and cost data available for BPH that there is for coronary artery disease, adequate information exists in the literature and elsewhere for modeling purposes. Benign prostatic hypertrophy has a major impact on patients quality of life and sense of well-being. **Thus, benign prostatic hypertrophy also met the criteria for the study.**

In fact, the choice of benign prostatic hypertrophy complements the choice of coronary artery disease because, unlike coronary artery disease, BPH is in general not life threatening. Therefore, therapy is to a large extent optional. Indeed, the decision for

procedural therapy is more dependent on the patient than the physician in many cases, which contrasts with coronary artery disease, where physician decisions dominate. Finally, some have utilized information technology to impact patient choice regarding BPH therapy. Therefore, the inclusion of benign prostatic hypertrophy in this study offers the opportunity to model information technologies of this nature [Barry 1995].

The outcomes team collected data in conjunction with the Academic Medical Center Consortium (AMCC) for the Quality Measurement and Management Initiative on coronary artery disease. The data from this effort address a variety of outcomes, including

- baseline and follow-up functional status,
- satisfaction,
- adverse events and complications,
- repeat procedures, and
- death.

These data were merged with the Alton Ochsner Medical Foundation's (AOMF's) internal detailed charge file. This merged data set allowed the assessment of a large number of variables for economic analysis in developing the CPIM's.

The function of the models is essentially heuristic. The models clearly point out issues which bear on the nexus of technology and health care costs. Each of these issues is potentially worthy of future research.

First, the necessity to define health care cost is highlighted by the models. Each model recognizes that costs are both direct (payments for services rendered) and indirect (effects on society such as wages gained or lost). Therefore, it becomes clear that expenditures are not equivalent to cost. The models provide cost analysis from the point of view of the payer as well as from the perspective of the larger society. The results of simulations are dependent not only on the cost perspective assumed but also on the estimates of the costs themselves. In the case of establishing societal costs/benefits, the project team encountered the need for determining the dollar value of a life year. Appropriate economic literature was reviewed, and it was elected to estimate this value using a revealed preference methodology. The derived figure was utilized in the coronary artery disease model for calculations of societal costs/benefits.

A second major issue raised by the modeling was the growth of demand which a new procedure can produce. Based on literature review and a review of technology usage, it became clear that new technology often, if not always, stimulates increased demand for its use. Therefore, even technologies which may reduce unit costs often tend to increase aggregate direct costs. Various factors were identified as determinants of demand and were then included in the models so that they could be explored by analysts over time.

A third factor influencing the relationship of technology and health care costs is the assessment of quality-adjusted life years (QALY) and their economic impact. The

theoretical arguments related to assigning economic value to QALY's were reviewed, including those arguments dealing with the increased late medical (and non-medical) costs to which life-extending therapies expose patients. As noted above, it was elected to empirically derive the value of a quality-adjusted life year (QALY). Therefore, longevity changes, discounted for quality of life, were used in economic calculations of societal benefit in the case of coronary artery disease. In the case of benign prostatic hypertrophy, where little impact on longevity is seen and the major impact of therapy is symptomatic, it was not felt that current theory is sufficiently developed to warrant establishing an economic value for the quality component of the therapy.

Economic Analysis and Modeling

Formal economic analysis was performed in this project in order to (1) properly define the direct cost of index procedures and (2) define the economic benefit of these index procedures. These issues are both important and complex. Just as wide variations in the use of medical technology occur in the United States, wide variations occur in the charges for the provision of that technology. Moreover, outcomes and charges are often poorly correlated. Therefore, it appears reasonable to attempt to define a true cost (as opposed to charge) for the index procedures after removing the effects of the severity of patient illness and geographical price differences. These issues must be addressed in addition to those associated with the choice of an economic prospective on cost: the decision as to whether indirect or direct costs, broadly defined, are most appropriate to answer any specific question.

The economic analysis presented here demonstrates methodologies for identifying costs and cost savings associated with the conversion of patients from one procedure to another, taking into account the severity of illness in these converted patients. Also demonstrated are means for identifying ***lowest-cost*** practice patterns. This analysis utilizes 'stochastic frontier' technology and attempts to identify that pattern of inputs which produces an output of lowest cost. When corrected for quality of outcome, this kind of analysis assists the investigator in determining a benchmark cost ("lowest cost" or "best practice").

In the approach to the determination of the benefits of care, the economic analysis reviewed the multiple means by which such benefit can be calculated, including (1) wage-based, (2) time trade-off, and (3) revealed preference methodologies. A revealed preference technique for identifying the value of time in the index populations was developed and employed in the models.

The modeling effort was approached in two ways. First, an "attention focusing model" was developed with the goal of permitting the user to easily and conveniently vary input parameters and quickly assess results so that otherwise unappreciated relationships between variables and outputs could be identified. These attention focusing models were developed utilizing Demos, a product of Lumina Decision Systems, for Macintosh. The

models eventually were imported into Lumina Decision Systems' commercial product Analytica and were then imported into the Analytica Windows 95 version for IBM-compatible personal computers. The second modeling effort involved the development of more detailed models utilizing the ARENA Windows 95 compatible system. The ARENA models are more difficult to manipulate and interrogate, but are elemental in nature and so provide the user with the ability to follow specific patient cohorts over time.

The economic analyses presented here were helpful in the development of the models for health care costs found in this report. However, their value extends beyond this project in that they serve as guideposts for economic analysis of health care technology of many sorts.

Definitions

When attempting to model health care quality and costs, several variables require precise definitions. Included among these are

- health care costs,
- technology, and
- demand for care.

Health Care Costs

When analyzing health care costs one can, in theory, utilize any one of several perspectives. First, one could focus on the ***direct unit cost*** of service: the cost of providing one procedure or the cost of treating one patient. Second, one could analyze ***direct aggregate cost***: the total direct cost of all patients treated. Third, one could consider ***societal cost***, which includes all direct costs as well as societal opportunity costs/savings (also denoted as "indirect costs" in the literature) derived from such factors as days lost from work. In the SNL/AOMF project, all of these costs are modeled, but the degree of precision of the modeling falls as one moves from direct costs to aggregate costs to societal costs. That is, more uncertainty exists with regard to the impact of a technology on societal costs than on the direct unit cost. Potential cost drivers include the following:

1. number of cases,
2. number of cases per physician,
3. occurrence of adverse events (need for additional technology, death, morbidity),
4. post-procedure length of stay,
5. institutions charges per admission,
6. variable costs,
7. fixed cost,
8. patient severity cost,
9. payment incentives,

10. technology utilization,
11. willingness of physicians to provide services/technology, and
12. patient demand for services.

An additional problem associated with the definition of cost in a practical sense is related to the fact that the United States health system is administratively focused on ***charges***, not on ***costs***, because it is rooted in a traditional fee-for-service system. Yet, policy should properly be driven by cost considerations which eliminate effects of price distortions and rents (excess payments over those required to obtain a good or service). Recall that health care charges vary widely across the United States, often in ways unrelated to the outcome of care or to the volume of delivered care.

In the effort to develop direct cost data, two approaches were used:

- a "bottom-up" cost construction using time/work studies and supply costs, and
- cost-charge ratios derived empirically and from published literature.

The initial approach for the "bottom-up" cost construction effort was to utilize the recently implemented AOMF Cost Accounting System. However, inconsistencies between this system and the literature were sufficiently large that the investigators responsible for the project felt that it would be unwise to utilize this cost system as the sole arbiter of costs of health care for the indicated procedures. Not only was the system incomplete; its use as the sole determinant of a cost function would be unwise from a theoretical point of view. In effect, even if optimally functioning, the AOMF Cost Accounting System could provide information regarding the cost of medical care in only one health care system in only one geographical region of the country. Therefore, the AOMF Cost Accounting System was used to supplement the primary data sources: literature and published data (NIS, HCIA) containing cost/charge-derived information.

Three approaches were used to assess societal opportunity costs:

1. Wages were used to estimate the economic impact of a day spent out of the hospital or an extra day lived.
2. We assumed that both working and non-working individuals contribute to the economy. With that assumption, we determined an imputed economic benefit of a day (including non-wage earning activities) and multiplied that figure by the number of quality-adjusted life days gained thanks to the therapy under evaluation.
3. We utilized revealed preference techniques to identify the economic benefit of an extra year of life to a retired person.

Were revealed preferences not used, one would be required to catalog non-compensated but functionally useful activities of retired persons and then ascribe to them a market value. This procedure has considerable shortcomings when compared to the revealed preference methodology. To see the importance of properly defining economic benefit (or alternatively of understanding the implications of the chosen cost definition for the interpretation of results) one need only to consider the impact of a changing retirement age on the calculated societal cost and benefits of a treatment for coronary artery disease. Because most patients with coronary artery disease are retired or near retirement, any

societal cost/benefit calculation which is based on the increase in lifetime earnings created by virtue of technology-driven patient salvage is immediately increased if retirement age increases. This issue is relevant given the fact that by the year 2001 the retirement age in the United States for maximum social security benefit will have increased from 65 to 67 years and will increase again thereafter.

Note that the cost of health care can be influenced by physician fees, which vary from region to region. Although physician fees are a relatively modest component of total health care costs, in a fee-for-service system, physician ordering behavior (which may in part be influenced by physician fee structures) can influence the use of services and therefore costs. In addition, inefficiencies can contribute to health care costs, accounting for some of the variation in the utilization of services in different regions of the country as well as variation in health care charges. It must be noted that the "cost plus" system of reimbursement provided little incentive to hospitals or other providers to identify and reduce inefficiencies. The current SNL/AOMF proposal calculates costs with and without physician fees. The issue of efficient and inefficient providers is handled by using a distribution of costs in the model to reflect all causes of cost distribution. The investigators attempted to approach the issue of inefficiency using a novel method, ***stochastic frontier analysis***, in an effort to define "lowest cost" or "best practice" behavior and to utilize this in the generation of cost functions. Although this methodology is potentially powerful, its utilization for modeling national health care would require detailed cost data from multiple providers. Therefore, cost data for this project were obtained from nationally available sources.

Technology

Technology itself requires an operational definition for the purposes of the SNL/AOMF project. Clearly, medical hardware and the associated procedures represent "technology," but so do information (including patient education), decision support tools (e.g. prevention programs), and office visits. The modeling paradigms developed by this initiative should ideally be robust enough to include these various forms of technology.

Demand for Care

Demand for care is perhaps the hardest issue to model or define. Demand is multifactorial and varies with procedure, patient, physician, and information provided. Of particular note are alterations in demand caused by new technology (the so-called "behavioral effects") or by payor class.

Quality-Adjusted Life Years

When modeling the impact of technology on health care costs, it is important to distinguish those reductions in costs which result from increased efficiency of care from those which result from reduction in the quality of received care. Further, when we

attempt to quantify the benefits of therapy in order to compare the benefits of two competing therapies, the matter is potentially quite complex. The situation becomes more problematic when one wishes to develop a means for comparing quality of outcome, which can then be translated into societal economic value. Many attempts have been undertaken to arrive at methodologies for performing this kind of assessment, but the most prominent is based on Von Neumann-Morgenstern utility theory, which incorporates the so-called "standard gamble." This methodology permits the analyst to assess quality-of-life-related attributes in addition to simple changes in longevity. The methodology requires that test subjects compare a specific health state with a gamble, the outcomes of which are immediate death (with probability p) and perfect health (with probability [1-p]). When the value of p is varied, the point at which test subjects become indifferent to the outcome is determined. This permits an assessment of the desirability of any given health state. While a detailed description of the theory behind the standard gamble is beyond the scope of this discussion, this methodology has been used extensively in health care. When this approach is combined with estimates of longevity changes, the concept of a "quality adjusted life year" (QALY) emerges. The QALY concept enables comparisons and trade-offs to be made between interventions that have effects on outcome for both length and quality of life. The QALY concept also facilitates the calculation of cost-effectiveness ratios.

The QALY approach has been criticized for, among other things, the inability to assess the value of survival (e.g. the severity of moving from 0.3 to 0.0 on the quality of life adjustment factor scale). However, in the coronary artery disease model we have chosen to use QALY's as our measure of health outcome. This is because the revascularization strategies we are modeling produce approximately the same longevity of life. Therefore, questions relating to the character of the QALY scale over various intervals are less germane than they might be when comparing, for example, cosmetic surgery to renal dialysis. In the case of benign prostatic hypertrophy, we have not been able to ascribe QALY's to the various treatments available. Because longevity does not in general change, and the variation in symptoms does not in all cases parallel physiological parameters, it becomes difficult to quantitatively assess changes in QALY for BPH. Rather, we have chosen to examine changes in an arbitrary symptom score similar to that used by the American Urological Association.

The Value of a QALY

In analyzing the cost of health care, we considered not only the direct cost of providing care, but also such indirect costs as patients time lost from work, both during the immediate procedure and over the ensuing years. Similarly, a patient's ability to return to work could properly be counted as an offsetting opportunity which mitigates the societal costs of providing the care. The most straightforward means of estimating the value of these employment-derived opportunities and costs is to use ambient wage rate. However, these rates may be inaccurate for several reasons:

- The prevailing wage rate is likely neither gender nor race neutral and therefore the cost/opportunity estimates derived would be distorted if based on average wage.
- Wage tends to overestimate the true value of employment since the wage is, in effect, the payment required by the least willing worker to perform the job. Presumably, more willing workers would have worked for less.
- The wage methodology completely ignores non-compensated value added to the society (e.g. from a housewife). This is a comparable problem to that faced by the Senate Committee on the Consumer Price Index.

This issue leads naturally into the question of the value of a day in the life of a retired person. Such people may provide uncompensated or compensated work to the society and may benefit the economy in other ways such as through the expansion of consumer demand. How are these factors to be taken into consideration? One view holds that, once a technology is demonstrated to produce an effect on quality-adjusted life years, a conversion should in theory be possible for QALY scores for both employed and unemployed persons alike. One method which project economists have employed in making this estimate is based on ***revealed preference***. In effect, economists look at the trade-off between retiring at 65 and retiring at age 62. In the latter case, the retirement benefit is lower for several reasons, but the benefit is paid for a longer period of time, and the individual in question has additional leisure time by virtue of not working to age 65. By analyzing the current value of each of these retirement options, economists estimate a value of approximately ***$170 per day*** for the uncommitted time of the average 62-year-old person.

Cost-Benefit Analysis Applied to CAD and BPH

In its simplest form, cost-benefit analysis attempts to measure the costs and benefits of particular economic actions. While this may be conceptually simple, its details can be quite difficult. In this part, we present some important conceptual ideas in cost-benefit analysis to issues of technological change in the health care industry.

As our results indicate, there are two general consequences of technological change: (1) the quality of treatment increases along a number of dimensions and (2) as the quality of treatment increases, the number of people who demand the treatment may rise. These two effects, together with the actual dollars needed to pay for the treatment, may lead to a substantial increase in the number of dollars that pass through the health care sector to pay for treating, for example, coronary artery disease (CAD) and benign prostatic hypertrophy (BPH). One may conclude from these data that net costs to society from these illnesses have increased. However, this may be a poor interpretation of the data. Before one can tell whether net costs are rising, one must answer two important questions:

- "What is the best measure of social costs (and benefits) in health care economics?", and

- "How do we go about estimating the appropriate measure of social costs for this project?"

This part will address both of these issues.

Consistent with the well-established methodology of cost/benefit analysis in economics, we argue that when calculating the true social cost of inventing a new treatment modality, researchers must include the benefits that spring into existence due to the new technology as well as the costs associated with that technology. The "net benefit costs" are the difference between how much more we benefit as a consequence of an innovation and how much more we have to spend because of that innovation.

Appropriate Measure of Social Costs and Benefits

In order to answer the question about what is the appropriate measure for social costs, we must briefly return to first principles. In a competitive market, where outcomes are efficient, the consequence of any transaction is to raise social welfare. Hence, when we measure "social cost" what we are interested in measuring the degree to which welfare is not increased by market interaction. The welfare derived from an individual purchase is the difference between the value that a consumer places on the good purchased and the opportunity cost of actually producing the product. The relationship between the maximum value that a person, or group of people, assigns to a good and the amount of that good consumed is known as the *Marginal Benefit* (MB) or *Demand* relationship. The relationship between the opportunity cost of producing a good and the amount of the good produced is known as the *Marginal Cost* (MC) or *Supply* relationship. These relationships are plotted out in Figure 1. We can graphically illustrate the total amount of welfare that society receives from consuming a particular good in a competitive market as the shaded area on the graph.

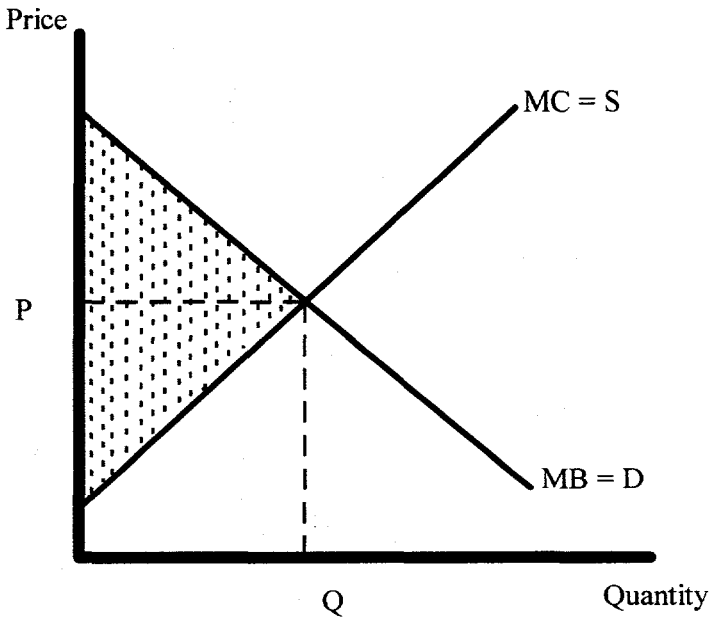

Figure 1. Fundamental supply/demand relationship in economics. (MC = Marginal Cost, S = Supply, MB = Marginal Benefit, D = Demand)

Note that in a normal, competitive market, where consumers are paying for all consumption completely out of pocket, we know that the consumer always purchases the good where the marginal benefit is exactly equal to the marginal cost. This implies that welfare is as large as it can be, and the market is efficient. Hence, if we want to know how much the last unit of the good is "worth" to society, we can simply look at how much was spent (price). However, ***in health care the consumer does not pay for all purchases completely out of pocket.*** In fact, in many circumstances the consumer may pay nothing out of pocket. This leads to the well-known "moral hazard" problem of over-consumption, which refers to a circumstance in which a consumer does not pay the full cost of the goods he purchases and therefore does not take care of himself as he otherwise would. Here, marginal benefit does not equal marginal cost, and welfare is not maximized (due to over-consumption). In addition, since third-party payers are involved, the individual cannot frequently evaluate the benefit from a medical treatment across all of its dimensions (e.g. quality). In this case, the observed willingness to pay may even be understated. Therefore, we ***cannot know the true value of a medical expenditure to society by simply observing transactions***. Consequently, we must estimate the change in welfare directly. To do this we must estimate marginal resource cost and marginal value. If marginal costs are greater than marginal value, then social welfare is reduced and we have incurred positive net social costs.

Measuring Costs

For coronary artery disease (CAD), the primary costs involved are the costs of the various medical treatments. We obtained data for the charges of CAD patients at a large

southeastern United States HMO. Our primary goal was to measure the cost savings available from switching patients from the generally more expensive CABG procedure to PTCA, assuming that the technology to make this possible becomes available. This task required two steps.

1. First, we had to account for the severity of illness in the patients who have undergone CABG. Generally, CABG patients are "sicker" than PTCA patients. Thus, this group of patients would still be more costly to treat even if they were to undergo PTCA instead of CABG. Through multivariate regression analysis, we can adjust for these factors.
2. Second, we had to translate charges into costs.

In a perfectly competitive market, firms cannot affect the price received for their products by changing their quantity of output. They therefore maximize their profits by increasing their output until the marginal cost of that output equals the market price of the output. The hospital industry, however, is not perfectly competitive. We therefore expect that firms can alter the price they receive for their products by changing the amount of their output. Therefore, we expect that the charge for a particular good or service will be above the economic cost of providing that service. Further, hospitals provide a multitude of services jointly, and those have the ability to spread costs (and make profits) across numerous different charge items. Therefore, in our cost-benefit analysisit is necessary to convert charges into costs.

Measuring Benefits

The benefits of many advanced technologies are that they permit patients to become healthier sooner and more often. Higher quality treatments thus may allow patients to return to their "normal" state earlier than with current treatments. To measure the benefits of such innovation requires us to measure the value of a person's time, or the opportunity cost of time. Opportunity cost is discussed further in a later section.

To identify opportunity costs in health care, we must define what the next best alternative to health care is for a particular patient. Let us assume that without the health care treatment the patient would have continued on with the course of their life. The standard method of evaluating this cost is in lost wages. Wages represent the result of bidding for a person's services and therefore can be expected to be close to this person's economic value. Therefore, if health care treatment would take a person making $80 per work day away from work for four days, the opportunity cost of that treatment would be $80/day * 4 days = $320.

The issue is made more complicated by the fact that patients also value their general recreational time. This problem is especially crucial for this project. In our data set of patients who had PTCA or CABG, the age of the median patient is 64 years. We can therefore expect that a large percentage of these patients are retired and therefore ***have no market wage***. Stating that these patients have no opportunity cost is a mistake. Their opportunity cost is the value they place on their own leisure time. To address this

problem, we later present a "revealed value" methodology for measuring the value of such time. The approach measures the value of a person's time by the implications of their actions (the value they place on their own time) rather than any arbitrary measurement.

Application of Cost-Benefit Analysis in This Study

A significant result of our research is a model which predicts the effect of switching technologies on the ***costs*** of providing care for two important diseases: coronary artery disease (CAD) and benign prostatic hypertrophy (BPH). Both diseases have recently undergone a revolution in treatment methods. For CAD, this revolution was the implementation of balloon angioplasty (PTCA) along with the introduction of arterial stents. For BPH, the revolution was the introduction of trans-urethral surgical techniques such as TURP, TULP, and TUNA. In both cases, the new technology involves a significant investment in medical devices and equipment.

Because of increases in the quality of treatment as well as in the number of people who demand the treatment, we are experiencing a substantial increase in the number of dollars that pass through the health care sector to pay for treatment of CAD and BPH. Before concluding that net costs to society from these conditions have increased, we must include the new benefits the technology offers as well as the costs. Again, social welfare is the difference between the benefit obtained from a productive activity and the opportunity costs of engaging in the activity. If the value of the activity is greater than the resource costs of the activity, then welfare has increased.

Health care consumers purchase services when the marginal value to them is below the true marginal cost. The prevalence of third party payers is widely viewed as a major distorting factor [Newhouse, 1992]. Such purchases represent a reduction in social welfare, and so must be counted as a true cost to society. Consequently, health economists are always suspicious that increases in raw expenditures truly represent costs.

While suspicion may be the natural tendency, Goddeeris [Goddeeris 1984a, 1984b] has demonstrated that increases in technology expenditures are not necessarily welfare-reducing, even when there is widespread distortion from health insurance. Goddeeris builds a theoretical framework which allows him to evaluate the impact of insurance-induced technological innovation on welfare. As he notes, even with models tailor-made to identify biases, it is not necessarily the case that welfare is reduced from innovation. The health care sector is characterized by various distortions, often conflicting. Therefore, whether a particular innovation has lead to a welfare reducing or increasing position for society is an empirical question. As Newhouse [Newhouse 1992] notes, real evidence on this issue is relatively scarce - despite its importance. ***Providing such evidence is a central mission of this study.***

Opportunity Costs

Providing health care is an expensive proposition for society. The most obvious costs of health care are explicit: the costs of supporting health care providers and facilities. However, there are other less obvious costs which, because they are implicit in nature, can be more difficult to measure. Economists generally label such costs as "opportunity costs." In the provision of health care, there are a number of these opportunity costs. In particular, one opportunity cost which is quite problematic to estimate is the value of the patient's time taken up by a treatment regimen.

Currently, there are three alternative approaches in the economic literature to estimating the value of a person's time

1. the human capital (wage rate) approach,
2. the market value approach, and
3. the willingness to pay approach.

Because the last method is frequently prohibitively costly to administer, the first two are often utilized. Unfortunately, we theoretically expect that the first two methods will overestimate the value of the time of individuals in the work force because of rents (i.e. wages paid in excess of the minimum amount necessary to encourage the person to work) inherent in any labor market. Further, these approaches explicitly set the value of time of retirees at zero. This in turn may bias technological innovation away from treatments that could aid the elderly.

Definition

To understand how to measure such costs requires an understanding of the meaning of the phrase "opportunity costs." Opportunity costs are defined as the value of the relevant economic resource in its "next best" economic usage. Consider, for example, a star basketball player in the National Basketball Association. His next best economic opportunity may be as a teller in a bank receiving a salary of $30,000 per year. We would therefore say that his opportunity cost of playing basketball for one year is $30,000. Often, opportunity cost is the largest part of the cost of using an economic asset.

Opportunity costs in health care work in a similar fashion. There are several specific opportunity costs involved here, though value of leisure time is the current concern. Note that opportunity costs we identify are likely to be among the *benefits* of using a new technology. We will want to identify those costs which would be incurred if the older technology is used but not incurred if the newer technology is used. These opportunity costs of old technology are costs saved when the newer technology is employed and consequently are a real social benefit from using the innovation.

Methodologies for Evaluating the Opportunity Cost of Time

As mentioned above, three competing approaches exists when assigning a value to a day lost to medical treatment:

1. the human capital approach,
2. the "market value" approach, and
3. the willingness to pay approach.

Each has significant problems, which we discuss briefly below.

The most widely used approach is the human capital model [Rice 1966 and Harrington 1991]. Fundamentally, the idea is that competitive labor markets will establish a wage rate which exactly equals the reservation wage (i.e. opportunity cost) of the marginal worker. Since this competitive wage exactly compensates the marginal worker for the value he places on giving up one hour of leisure in order to work, it represents a good proxy for the opportunity cost of time. Implicitly, this model assumes that if the patient is not in the hospital, he would be working and the income that could be generated with this time reflects the value of the time.

There are a number of serious problems with this approach. For example, it is empirically observed that women tend to earn less in the marketplace than men. Similar problems occur for any other comparisons where market wages differ systematically (e.g. a day saved for a low income person would be worth less than a day saved for a high income person). Many implied differences such as these would be objectionable to policy makers and their constituents.

Another problem is that people engage in a number of activities which are not compensated in the market, but from which they derive value. For example, cooking dinner or mowing the yard are activities which generate value for society (and which have potential markets) but are non-compensated when households undertake the activities directly rather than hiring them out in the market. The human capital/lost wages methodology does not capture these at all.

In response to this failure to incorporate non-market productive activities into measures of opportunity costs of time, the "market value" approach was utilized by Cooper and Rice [Cooper 1976]. This method involves estimating of the value of a basket of non-market productive activities. Specifically, Cooper and Rice cite a number of studies which involve time and motion analyses of the daily activities of a group of housewives. A value is assigned to their time based upon what it would cost to hire a person from the labor force to replicate the services observed. In other words, market "equivalents" are assigned to a number of household activities and these equivalents are added to the lost wages measures generated by the human capital approach.

However, this method is also flawed. For one thing, it only measures certain activities and ignores other potentially important functions completely. Surveyors only account for the activities that they actually observe the housewives undertaking. Other productive

activities (for example, mowing the lawn) which the housewives in the studies might not be observed undertaking are excluded. This generates an unpleasant degree of arbitrariness. Second, this method is incapable of reflecting the value of another class of activities for which there is no direct market compensation: pure leisure. This pleasure is perhaps highly valued, but neither of the previously mentioned methods can account for this value. However, for many populations this may be the dominant value of time. Retirees do not by definition work for wages. The value of their time is completely determined by the value they place on their productive and pure leisure activities, with the latter category perhaps constituting the large bulk of their "value of time." This problem with the retiree population is particularly significant for any study of PTCA vs. CABG where the average patient is retired or nearly so.

The final approach, first pursued rigorously by Schelling [Schelling 1965] is the "willingness to pay" methodology. It requires surveys to ask people how much they value certain gambles across possible states of the world. Unfortunately, many factors can bias the answers one gets from this approach. In particular, the values one imputes depend critically on the degree of risk aversion in the population, the homogeneity of preferences, and other issues which are difficult to address.

The "Revealed Value" Approach

The alternative that we propose is to extract information that workers reveal in their retirement decisions to estimate the revealed value of leisure time. Workers approaching retirement today currently have the option of retiring at age 62 and receiving reduced social security benefits. The retirement income they receive from their pension plans would also be lower, since less money is saved in the shortened working time. Alternatively, workers could continue to work until age 65 and receive full social security benefits, higher pension payments and the income that they earn from labor market activities.

This provides an excellent natural experiment. The cost to workers of continuing to work past age 62 is the leisure they do not get to consume. The benefit they receive from continuing to work is the present value of their increased wealth due to a longer period of savings. From first principles, we know that people should continue to work to the point that the satisfaction they receive from the increased consumption they will be able to undertake in the future equals the satisfaction they give up in consuming less leisure currently. Therefore, we can take the increase in the present value of wealth to be the dollar value of the leisure that is given up when the person decides to continue to work.

A complete discussion of this approach is beyond the scope of this document, but the results from this project analysis are displayed in Table 3. Table 3 specifies the calculated total financial benefit from not retiring at age 62 to be $112,776.03 in present value terms. To gain these additional funds, the average worker will work an additional 4.9 years. These years are discounted at a rate of 2% per year. This implies that the worker will work (in present value terms) 4.72 years to earn (in present value terms)

approximately $113,000. This in turn implies that one work year is worth $23,893.23. Assuming 250 work days in a year implies that each work day is worth $95.57. If a work day consists of nine hours (eight actually working and another hour in travel and preparation), one hour of time is worth 95.57/9 or $10.62. If a person sleeps eight hours a day, being released from the hospital a day early frees up 16 hours of leisure for retirees, worth 10.62*16= $169.90. Thus, reducing a patient's time spent in the hospital by one day creates $170 worth of leisure time.

Table 3. The value of a day of leisure.

Total Return From Not Retiring at Age 62	$112,776.03
Total Work Years (Present value) from Age 62 to Age 62.9	4.72
Return Per Work Year	$23.893.23
Return Per Work Day (Assuming 250 work days/year)	$95.57
Return Per Work Hour (Assuming 9 hours/ work day)	$10.62
Value of One Leisure Day (Assuming 16 hours of leisure in a day)	$169.90

Stochastic Frontier Methodology Applied to CAD (PTCA vs CABG)

Assessing of the impact of new technologies on health care costs is critical in today's economy. The health care sector is characterized by an extraordinary degree of innovation, perhaps more so than any other sector in the economy. Unlike many other areas, however, innovation in this sector is generally perceived as substituting newer technologies which require increased, rather than decreased, resource use: ***technological innovation appears to be cost increasing***. Clearly, we wish to understand whether this common perception is accurate. To do so, we must first understand the basic relationship between the medical care decisions required of existing and innovative technologies and how these medical "production functions" affect the cost relationships we observe.

This section addresses these issues by using stochastic frontier analysis to compare the costs of treatment for two competing interventions for coronary artery disease: coronary artery bypass grafting (CABG) and percutaneous transluminal coronary angioplasty (PTCA, or balloon angioplasty). Exploiting a unique data set, we examine costs at the ***patient level***, allowing estimation of the cost savings that would be available if technological innovations in the less expensive PTCA procedure made that treatment regimen appropriate for all patients currently undergoing CABG. Previous studies of this type employed only data at the hospital level.

Further Information in the Appendices

A detailed summary of the econometric approach to comparison of PTCA versus CABG is given in Appendix B. Appendix C contains a more complete treatment of stochastic frontier methodology and is the primary source from which the content of this section was derived. Appendix D contains an analysis of PTCA vs. CABG across several hospitals, while Appendix E contains a summary of a two-part model of the costs of treating BPH and the impact that new innovations could have on those costs.

Estimating Costs in the Hospital Via a Physicians' Workshop Model

Previous approaches to empirical examination of hospital production (either directly or through a cost function) have assumed one "global" production function for the institution, leading to models which are estimated with a high level of aggregation. In this work, we appeal to a different theoretical model of the hospital. On a conceptual level, health economists have considered hospitals to be "physicians' workshops" since Pauly's [Pauly 1980] influential monograph. This model asserts that hospitals exist to provide necessary capital equipment to physicians, each of whom creates their own team within the institution to treat patients. Each hospital is therefore not appropriately considered a "firm" in the traditional neo-classical sense. Rather, each hospital is a collection of "virtual firms," each defined by a unique provider team and production function. One can extend this analogy further by recognizing that in most circumstances the actual team utilized will be unique for each patient. That is, when a patient is admitted to the hospital he travels through a treatment process which is tailored to his particular medical needs and circumstances. A hospital is therefore a framework which supports a number of different production functions, and that the production function is best defined by using the patient as the unit of analysis.

Further, it seems reasonable to pool teams within an institution which are most closely related. For example, a team which is producing treatment for an acute myocardial-infarction (AMI) will face constraints more similar to those faced by another team treating an AMI patient than a team treating a patient for gall stones. Consequently, a strategy to minimize the possibility of inappropriately pooling "production functions" is to define the production function for a specific treatment within a single institution. Only then is one likely to be able to estimate a production function which has meaning within the framework of hospital "workshops." This approach requires detailed data on single patients from individual hospitals. We suggest that only after researchers have explored medical production functions at their natural level (the patient) can work begin on expanding the analysis to include cross-institution similarities.

Stochastic Frontier Model Formulation

When observing estimated cost differences between two groups it can be difficult to tell whether one is more efficient than the other or whether one simply had "bad luck." For many issues, such as the impact that a new technology will have on costs, we want to

explicitly control for inefficiency: we wish to estimate the cost minimization function for the two treatment groups and compare predicted costs using that relationship. Otherwise, we run the risk of making policy recommendations based not on which technology leads to the lowest cost, but rather which group happened to be behaving most efficiently when we observed them.

One technique which can accommodate differences in efficiency is ***stochastic frontier estimation***. This maximum likelihood technique has been carefully explored in the broader econometrics literature [Aigner 1977, Schmidt 1979, Kopp 1982, Kumbhakar 1987, Bauer 1990]. In general, the cost frontier relationship is of the form

$$C = C(\mathrm{P},q) + \varepsilon,$$

where ε is assumed to consist of two components, u and v, such that $\varepsilon = u + v$, where u is a one- sided positive error and v is a normally distributed (two-sided) error. The u term corresponds to the measures of inefficiency for the specific cost frontier, while v represents the usual error term in econometric regression.

This basic formulation was enhanced to meet the needs of this study. First, in order to include patient behavioral factors in the analysis, a vector of regressors, **D**, was included to represent patient characteristics that contribute to uncertainty in the mathematical relationship. Additionally, total costs for observation j are represented as the sum of costs from important sub-cost categories:

$$C \equiv C_1 + C_2 + .. + C_N,$$

where subscripts *1..N* represent cost categories 1 through N. These cost categories represent "input prices" in this model. However, after augmenting this function with the behavioral variable vector **D** and estimating the model, **D** would clearly have no explanatory power given the identity shown for C above. However, when C_i are expressed as *N-1* ratios of a normalizing cost (i.e. as C_i / C_N) then the identity above no longer holds and useful inferences can be drawn from the augmented equation.

In addition to the effect of the behavioral factors on cost, the parameters attached to C_i / C_N reveal the degree of substitution or complimentality that the two input categories have in cost. That is, if the parameter on C_i / C_N is negative, this suggests that as C_i becomes larger relative to C_N then total costs fall. This would suggest that one could lower the total cost of providing the single treatment by relying more heavily on the i^{th} input and less heavily on the N^{th}. That is, the parameters on the input ratio variables will provide important information on the most cost-effective input mix and therefore most efficient production technique. Recall that each observation represents one unit of "output," so altering the input mix as suggested by the parameter signs would allow one to lower cost without changing output at all.[1]

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[1] For example, assume the coefficient on the category representing the ratio of room cost to costs in the N^{th} category is negative and significant. That would imply that if the hospital were to change its treatment regimes to allow patients to stay in the hospital longer, the resulting changes in other treatments would, on average, reduce patient costs.

We established a mechanism to relate the charges for say, pharmacy, to the "price" of the pharmaceutical input. We decided to aggregate expenditures on pharmaceuticals and let the spending on that group of pharmaceuticals be the "price" for that "input." While there are some drawbacks to this approach, it is consistent with the relevant literature.

The final model formulation for the stochastic frontier analysis is of the form

$$C_j^k = a + \gamma_1^k P_{1,j} + \ldots + \gamma_{\sim}^k P_{\sim,j} + \Gamma^k D_j + u_j^k + v_j^k.$$

Here, the quantity is 1 for all observations, the $P_{i,j}$ represent relative input prices for the i^{th} input and the j^{th} patient (relative to the pharmacy costs), and k = PTCA or CABG. This model represents the augmented charge or cost function for both PTCA and CABG, but each intervention requires its own set of model regression parameters. The likelihood function which estimates the parameters of the above model is

$$\ln L = \frac{J}{2}\ln(\frac{2}{\pi}) - J\ln\sigma + \sum_{j=1}^{J}\ln[1-\Phi(\frac{-\varepsilon_j\lambda}{\sigma})] - \frac{1}{2\sigma^2}\sum_{j=1}^{J}\varepsilon^2,$$

where J is the number of observations, ε_j is the estimated sum of u and v, $\Phi(.)$ is the CDF of a standard normal distribution, $\sigma = \sigma_u + \sigma_v$, and $\lambda = \sigma_u / \sigma_v$. The likelihood function is maximized across σ^2_u, σ^2_v, Γ, and γ (where Γ and γ are the parameters for the equations represented in the model given above. Two important pieces of information can be obtained from this formulation:

- consistent estimates of the effect of patient covariates on the demand for the individual input shares, and
- technical inefficiency for each observation, found as

$$u_j^* = \frac{\sigma_u^*\sigma_v^*}{\sigma^*}\left[\frac{\phi\left(\frac{\varepsilon_j^*\lambda}{\sigma^*}\right)}{1-\Phi\left(\frac{\varepsilon_j^*\lambda}{\sigma^*}\right)} - \frac{\varepsilon_j^*\lambda}{\sigma^*}\right],$$

where starred terms mean estimated values and $\phi(.)$ is the PDF of the standard normal distribution [Jondrow 1982]. These relationships suggest how well a particular patient is treated relative to all other patients in the specific institution, not relative to the industry (theoretical) cost.

Patient Population

The data for this study are taken from the internal records of a large hospital located in a major southern city. These data include 532 observations representing all patients who were treated for some type of cardiac revascularization during 1994 (where a small number of observations were excluded due to missing data). The patients received either CABG or PTCA. The data are drawn from detailed charge information and medical chart abstracts. We estimate two classes of frontier: a ***charge frontier*** and a ***cost frontier***. The departmental charges are converted to costs using the cost-charge ratio for each department, as reported by the hospital to the Health Care Financing Administration in the hospital's cost reports. We therefore had access not only to the usual sorts of

information obtained from discharge abstracts but also very detailed information about specific resource usage by each patient.

Input Prices, Behavioral Factors, and Health Factors

Nine input categories exist for which charge or cost represent price. These include

1. pharmaceutical charges (the numeraire, or N^{th} input to which every other input price is relative),
2. room charge/cost (ROOM),
3. emergency room charge/cost (ER),
4. lab charge/cost (LAB),
5. rehab charge/cost (REHAB),
6. operating room charge/cost (OR),
7. catheterization lab charge/cost (CATH),
8. CV charge/cost (CV), and
9. miscellaneous charges/costs (MISC).

Again, each of these is divided by pharmaceutical charges (costs) before being entered into the regression equations above.

Behavioral variables used in the analysis include the following:

1. COM, an index which (a) represents the degree to which comorbidities exist and (b) controls for variations in patient underlying health status prior to treatment,
2. ACUMI, whether the patient was admitted with an acute myocardial infarction,
3. PRCABG, whether the patient has previously had bypass surgery,
4. PRPTCA, whether the patient has previously had angioplasty,
5. EF60, the patient's ejection fraction,
6. LEFT, if the blockage is on the left side of the heart, and
7. VES2 and VES3, whether there was blockage in two vessels, or three or more vessels, respectively.

Patient characteristics relevant to treatment of illness include

1. GENDER, a dummy variable indicating whether the patient is male, since men and women can respond differently to illness and medical treatment,
2. AGE, since responses and costs can vary significantly by patient age, and
3. SMOKER, whether the patient smokes cigarettes.

One additional important determinant of patient charges is the number of adverse events experienced by that patient. However, it is likely that the number of adverse events is a function of several of the other explanatory variables used in the charge equation. To control these dependent adverse events, we use Poission regression to predict the number of adverse events a patient should have based on his or her characteristics. The difference between actual and predicted values is then used as an explanatory variable in the charge and cost regressions.

Results

Charge Results

Several patient characteristics significantly affect the total charges for providing a PTCA. These include:

- the presence of comorbidities,
- gender,
- having had a prior CABG or PTCA procedure,
- having left main arterial disease, and
- the likelihood of unanticipated adverse events.

With the exception of prior PTCA, each increases the charge (see Table 33 in Appendix C). Having had a prior PTCA appears to significantly reduce the charge associated with the sampled PTCA procedure.

Recall that a significantly positive/negative value for one of the charge ratios indicates that using relatively more of that input will raise/lower the total charge of supplying the procedure. For PTCA procedures, three input ratios have significant positive effects:

- laboratory resources (LAB),
- operating room (OR), and
- CV inputs.

These increase total charges without any "payoff." In contrast, patients who incur relatively higher room charges (relative to pharmaceutical charges) have significantly lower total charges.

Patient characteristics also significantly affect the total charges for providing CABG services. These include

- the presence of a higher comorbidity score,
- having had a prior CABG, and
- increased unanticipated adverse events.

Each significantly increases the total charge of the CABG procedure. Unlike PTCA charges, a recent acute myocardial infarction (AMI) and the number of vessels revascularized also significantly and positively affects total charge. A recent AMI raises total charges, as does having two vessels revascularized. Oddly, having three or more vessels blocked seems to decrease total charges. Since the "standard" approach for only one or two blockages would be to use PTCA rather than CABG, it may be that those in the one or two vessel CABG group are relatively more ill than those who have blockage in three or more vessels and hence require more intensive resource use in some areas.

For CABG patients, four charge ratios are significant in the frontier estimation:

- CV diagnostics,
- catheterization lab time,
- miscellaneous charges, and
- operating room time.

Each of these raises relative charges in a non-productive manner except for the latter which, unlike PTCA, reduces total charges. That is, when the institution is using a larger proportion of its resources to actually provide the CABG procedure to a patient (which is done in the operating room), the charge to treat that patient falls.

Finally, recall that "inefficiency" means how much more charge is generated for a given patient's treatment than the lowest charge possible in the hospital given the patient's characteristics. For PTCA patients, the average estimated inefficiency is $10,248, which is 41% of the mean charge for the procedure. This suggests that the hospital is charging over $10,000 more per patient than necessary *given the lowest charge available in that institution.* For CABG patients the average excess charges are approximately the same, at about $9,990, though as a percentage of average charge the CABG inefficiency is smaller, at 22%. Both of these numbers are relatively large and suggest that there may be room for significant charge (and so potentially cost) savings in the hospital by examining which patients are treated in the more cost effective manner and emulating this procedure with other patients.

Cost Results

The qualitative results in the PTCA cost regression with respect to the non-price effects are very similar to those in the charge regression. Costs are significantly affected by

- increased numbers of comorbidities,
- patient gender,
- having had a prior CABG or PTCA,
- suffering from left main artery disease, and
- having adverse events.

Unlike the charge estimates, an acute MI just prior to the procedure does significantly affect the costs of providing the PTCA.

In terms of hospital resources, the relative use the following resources significantly affects the total cost of providing a PTCA: (1) rehabilitation and (2) CV diagnostics. The parameter estimates of these input ratios are positive, indicating that increasing the use of these inputs relative to pharmaceutical inputs will increase the total cost of the PTCA.

For CABG, the following raise the cost of providing bypass surgery:

- comorbidities,
- a recent MI,
- a prior CABG, and
- unanticipated adverse events.

In addition, having multiple vessels involved is a significant predictor, as evidenced by the positive and significant effect of having two vessels stenosed and the negative and significant effect of having 3 or more vessels stenosed. While the sign patterns may seem somewhat counter-intuitive, they are actually what one would expect in the current state

of the world. Currently, many patients who need two vessels repaired will have them done using PTCA technology. A person who is actually treated with a CABG instead is generally more sick than the average person needing two vessels reworked. However, a person who needs treatment in three vessels is not at all likely to receive PTCA.

Again, the parameter estimate on the relative use of OR resources is negative and significant. This suggests that a shift toward relatively more OR time per CABG (compared to pharmaceutical resources) may actually reduce the total cost of providing the service.

Finally, the absolute level of cost inefficiency for PTCA production is about $5,200. This represents 41% of the total average cost of supplying PTCA to patients in the institution. The absolute level of cost inefficiency for CABG patients is $7,300, or 29% of the total cost of the operation. These inefficiency estimates (at least in percentage terms) are reasonably similar to the estimates of charge inefficiency. While comparable levels of inefficiency have been found from research in other industries, this does indicate substantial room for improvement in the average cost of treatment for the two procedures.

Simulation of Changing Technology or Practice

One issue that concerns the medical community and policy-makers alike is what effect shifting treatment standards will have on charges or costs. That is, as PTCA becomes a more mature technology, and new innovations such as stents are perfected, one could imagine shifting a number of patients from the CABG treatment path to the PTCA treatment path. On the surface this would appear to be a cost-saving move, since the average charge and cost of PTCA is much less than the average charge or cost of CABG. As discussed above, however, one would not want to take such a naive approach, since the patient populations have different characteristics, the two procedures may be currently provided with different levels of inefficiency, and the average PTCA patient has blockage in fewer vessels than the average CABG patient.

Part of the motivation for the analysis above is to provide an improved methodology for estimating the cost savings from switching patients from CABG to PTCA given that appropriate PTCA technology becomes available. Using the stochastic frontier results, we can control for the observable patient characteristics and the number of vessels treated. Further, since the maximum likelihood regression results produce the "minimum cost" frontier, we can predict cost savings without the presence of confounding inefficiencies (which may or may not persist through time).

To do this we divide the CABG patients into three groups:

- those requiring treatment in one vessel,
- those requiring treatment in two vessels, and
- those requiring treatment in three or more vessels.

We then predict the charge and cost for giving each patient the CABG treatment regime. The predicted charge and cost for each group appears in the first column of Table 4. Once we have the estimated charges/costs for CABG patients under cost minimization, we then simulate what charges or costs would be required to give them PTCA. Each patient is analyzed using the PTCA frontier regression with their own personal characteristics and the charge or cost ratio values for the median PTCA patient in their group. We do this since the resource use observed for the CABG patients is clearly not the resource use we would observe if they received PTCA. The results of the predicted charge or cost of treating current CABG patients with PTCA technology appears in the third column of Table 4.

The final column in Table 4 presents the estimated savings from treating various types of CABG patients with PTCA. The savings appear to be significant. Switching one-vessel CABG patients to PTCA would save an estimated $11,966 in charges and $3,959 in costs: switching two-vessel and three-or-more-vessel CABG patients to PTCA appears to result in $25,394 and $17,156 in charge savings and $16, 387 and $8,160 in cost savings, respectively.

Table 4. Predicted Savings from Switching CABG Patients to PTCA.

Number of Vessels with Blockage	Predicted Dollars for CABG Treatment for Current CABG Patient	Predicted Dollars for PTCA Treatment for Current CABG Patient	Imputed Savings from Switching Treatment from CABG to PTCA
	CHARGES		
1 VESSEL	28,715.07	16,749.19	11,965.89
2 VESSELS	45,151.43	19,757.92	25,393.50
3 OR MORE VESSELS	39,753.08	22,596.72	17,156.36
	COSTS		
1 VESSEL	10,489.68	6,530.59	3,959.09
2 VESSELS	24,789.97	8,402.71	16,387.25
3 OR MORE VESSELS	17,830.86	9,670.52	8,160.33

Care-Pathway Interaction Models

A more complete understanding of the drivers of health care costs can be obtained by means of a complete model of the pathways by which care is delivered to patients. The

goal for development of these care pathway interaction models (CPIM's) is to identify areas where improvements in technology or the introduction of new technology could be applied to reduce costs and/or maintain or improve outcomes. All resources relevant to each step in the care delivery process were addressed so that the impact of these inputs on cost and outcome could be established.

The modeling effort was approached in two ways. First, an "attention focusing model" was developed with the goal of permitting the user to easily and conveniently vary input parameters and quickly assess results so that otherwise unappreciated relationships between variables and outputs could be identified. These attention focusing models were developed utilizing Demos, a product of Lumina Decision Systems, for Macintosh. The models eventually were imported into Lumina Decision Systems' commercial product Analytica and were then imported into the Analytica Windows 95 version for IBM-compatible personal computers. The second modeling effort involved the development of more detailed models utilizing the ARENA Windows 95 compatible system. The ARENA models are more difficult to manipulate and interrogate but are elemental in nature and so provide the user with the ability to follow specific patient cohorts over time.

Diseases and Treatments Addressed by the Models

For this study, the care pathway for two disease/disability (D/D) conditions was modeled, including diagnosis, treatment, and outcome. These conditions were

- coronary artery disease (CAD) and
- benign prostatic hypertrophy (BPH).

Coronary Artery Disease (CAD)

Coronary artery disease (CAD) was chosen for several reasons. First and foremost it is currently the leading cause of death in America. Second, invasive treatment of heart disease is technologically intensive and has seen many innovations since it was first developed in the late 1950's. It follows that heart disease is also very costly to treat, making it an excellent target for potential cost savings to healthcare providers and payers, as well as a target for monetary gain for investors in health care technologies. Simulation can be used to test the potential effects of new technologies on the cost of treatment as well as the potential benefits of treatment before actually having to bring such products to market.

Treatment Alternatives

As its name implies, CAD affects the arteries supplying the heart, restricting the flow of blood to the heart muscle. If untreated, heart disease may lead to chest pain, heart attack, and eventually mortality. The first treatment alternative is an array of medications. Medical treatment is the least invasive and the least expensive. However, many of those

treated medically for CAD will eventually need more invasive treatment due to worsening symptoms or an emergency cardiac event. The benchmark invasive procedure for cardiac revascularization is coronary artery bypass grafting (CABG). During a CABG procedure the patient's sternum is broken and his or her chest is opened to expose the heart. The heart is thermodynamically slowed and blood circulation is achieved with a bypass machine, while the blocked arteries are bypassed using either sections of vein taken from the patient's leg or an artery taken from the patient's chest. CABG is a highly specialized, very invasive surgical procedure and is therefore very costly. However, to date it remains the "gold standard" treatment for coronary artery disease.

A less invasive alternative to CABG is percutaneus transluminal coronary angioplasty (PTCA), developed in the late 1970's. PTCA is a non-surgical procedure performed by a cardiologist in which a catheter is inserted through the femoral artery in the groin region and guided into the blocked artery, where a balloon is inflated to expand the blockage. PTCA has seen increased acceptance in the treatment of less severe cases of CAD as well as in stabilization of patients whose condition is too acute to risk bypass surgery. PTCA is performed during cardiac catheterization, which is also performed preliminary to bypass surgery. PTCA is less invasive than CABG and less costly, at least in the short term. The number of PTCA procedures being performed has surpassed the number of CABG procedures being performed.

There are significant technological advancements being made in medications as well as in both invasive procedures being used to treat CAD. Major improvements have been made in the guided catheters used in PTCA, increasing the operative success of the procedure. Also, in 1995 the FDA approved the use of coronary stents. Stents are wire mesh tubes that are expanded inside the artery when the balloon is inflated during an angioplasty. The stent adds support to the diseased artery, preventing immediate collapse and discouraging restenosis. According to publications on short term outcomes, stents do appear to reduce restenosis and heart attack rates [Fichman 1994]. A minimally invasive CABG procedure has also been developed in which the arteries are bypassed using a laparoscope. By eliminating the necessity of breaking the sternum to expose the thoracic cavity, both the recovery time for CABG and the risk of post-operative infection has been greatly reduced.

Definition of the Treatment Process

The first step in modeling the treatment of coronary artery disease is to define the entire process, complete with every treatment alternative and all feasible outcome paths. The North American population forms the basis of our treatment population. Most patients enter the treatment system either because they have experienced symptoms of heart disease or because they have had a major cardiac event. A small proportion of these patients will be completely asymptomatic. First, patients will have a campaign of less invasive screening tests. If screening is positive, a cardiac catheterization is performed by a cardiologist, who makes a diagnosis and an assessment of the severity and location of

the disease. At this stage, the cardiologist makes the decision to perform a PTCA or to refer the patient to a surgeon for a CABG. This process is outlined in the flow diagram in Figure 2.

Treatment outcomes are divided into three time frames:

- short term, which covers the initial procedure and the first year post treatment,
- intermediate term, which is between one year and five years post treatment, and
- long term, which covers from five years post treatment until 25 years post treatment. Success in each time frame is defined as freedom from symptoms and freedom from major complications. Major complications include myocardial infarction, repeat revascularization (repeat CABG or PTCA) and death. If repeat revascularization becomes necessary, the patient will return to the treatment decision and the process begins again. In the CAD model, the patient will remain in the system for 25 years after initial treatment or until death.

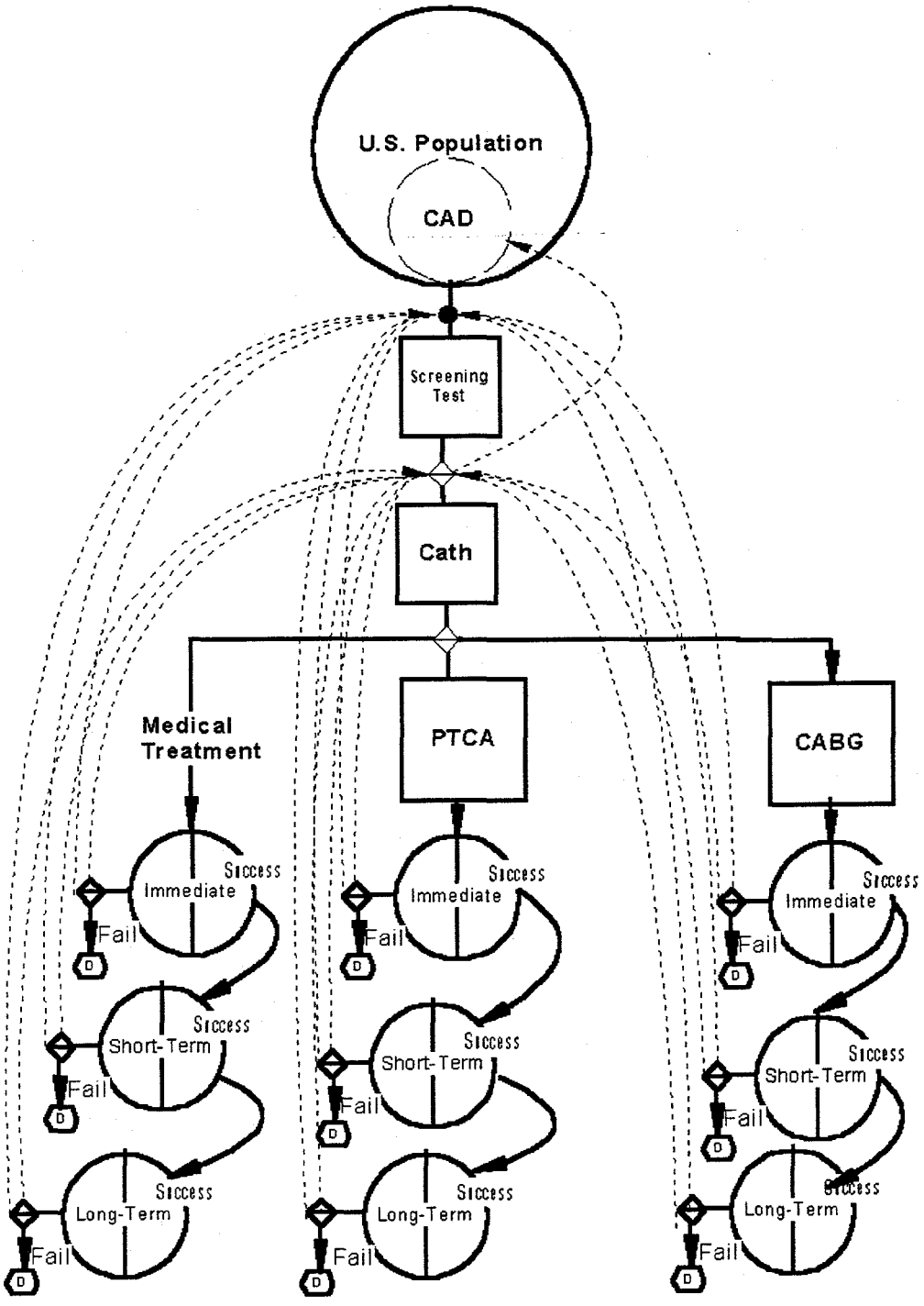

Figure 2. CAD treatment process flow diagram.

Benign Prostatic Hypertrophy (BPH)

Benign Prostatic Hypertrophy (BPH) was chosen for simulation for many of the same reasons as coronary artery disease. First, BPH affects a major proportion of the population. Studies of autopsy results have shown that BPH is present in almost all elderly men [AHCPR 1996]. Also, BPH is treated with a wide range of very different technologies. The most significant difference between the two conditions chosen is that BPH is not life threatening. In fact, considering its widespread prevalence, it would probably not be inappropriate to consider BPH a natural part of the aging process for men. If untreated, BPH could potentially lead to bothersome urinary symptoms and perhaps even kidney disease.

Types of Simulation Models

There are many different types of computer simulation. Queuing models have been used for decades in manufacturing to model static production systems and static inventory systems. In this role, a model can be used as a tool to study the effects of hypothetical changes in demand, process configurations and production capacity on throughput time, inventory levels and overall production output. Systems dynamics models have been used to study the interdependence between components of constantly changing systems, such as the relationship between predator and prey populations in the field of wildlife management or the relationship between different social groups in the field of in urban planning. Markov models have been used to explain expected changes in mortality rates due to changes in risk factor prevalence in the population by simulating probabilistic changes of state over time. More recently, simulation models have been developed to emulate human decision making behavior based on a fixed set of known rules. These models, known as expert systems, are used in mainly a diagnostic capacity. The most advanced simulation models make decisions based on feedback from model output while the model is running, much the same way that humans make decisions based on their own experience (artificial intelligence). The models that will effectively represent the relationships contained in the treatment of coronary artery disease (CAD) and benign prostatic hypertrophy (BPH) contain characteristics of each of these types of models. However, the models could not effectively be created using any one of these methods alone, so it was necessary to incorporate several of these techniques into our model.

Modeling of CAD Treatment Using Analytica

Again, the project team elected to approach the problem of modeling coronary artery disease through the creation of two distinct models. The first of these was to be an "attention fixing" model which was relatively easy to use and which had the heuristic value of pointing out to the observer interrelationships between factors which might not be immediately apparent. The attention-fixing approach is discussed in this section. Once the analyst became comfortable with the general

model for the treatment of coronary artery disease and had narrowed his areas of interest, it was envisioned he could turn to a more detailed model, capable of simulating the treatment of disease to a greater precision than that obtained through the use of the attention focusing model. The more detailed approach is discussed in the section summarizing the ARENA simulation models.

The Macintosh-compatible Analytica system was employed for the attention fixing model. This is a graphical decision/analysis system. The underlining statistical basis for this model and its methods of operation are to be found in the Analytica manual (Lumina Decision Systems Inc., Palo Alto California). The analyst has a variety of options regarding sampling techniques, sampling number, and choice of seed in the use of this model. The Analytica model is straightforward in its application and contains a variety of informational notes to aid the analyst in its use. It is important to note that the model consists of two parts: the ***Diagnosis Library*** and the ***CAD model***. Both must be loaded for the model to function. The Analytica CAD and BPH models will run on the Windows 95 version of Analytica.

The attention focusing models employed in this project were developed on a beta release of the DEMOS graphical decision system developed by Lumina Decision Systems Incorporated. In August 1996, Lumina Decision Inc. released an improved commercial version of DEMOS, termed Analytica. Although the models utilized for this project were developed on DEMOS, they were imported into Analytica and run without problem on the Analytica system. Indeed, the Analytica system offers the analyst a more convenient means of refining the models. In July 1997, Lumina Decision Systems will introduce a version of Analytica for Windows 95. The Windows 95 version of Analytica will read models generated on the Macintosh. Indeed, the project CAD and BPH models are both running without problem on an evaluation version of Analytica for Windows 95.

Note that the start-up screen for the coronary artery disease model is labeled "PTCA diagram." The initials refer to percutaneous treatment alternatives and should not be confused with PTCA or percutaneous transluminal coronary angioplasty.

The Analytica attention-focusing model must be run on a Power MacIntosh 6100/60 or higher supported by 16 + megabytes of ram. For further specifications relating to Analytica models and more detailed information about the operation of Analytica itself, contact Lumina Decision Systems, Palo Alto, CA.

Index To Important Input Variables In The Coronary Artery Disease Model

Interrelationship Diagram

Figure 3 below depicts the interrelationships between the variables used in the Analytica CAD model.

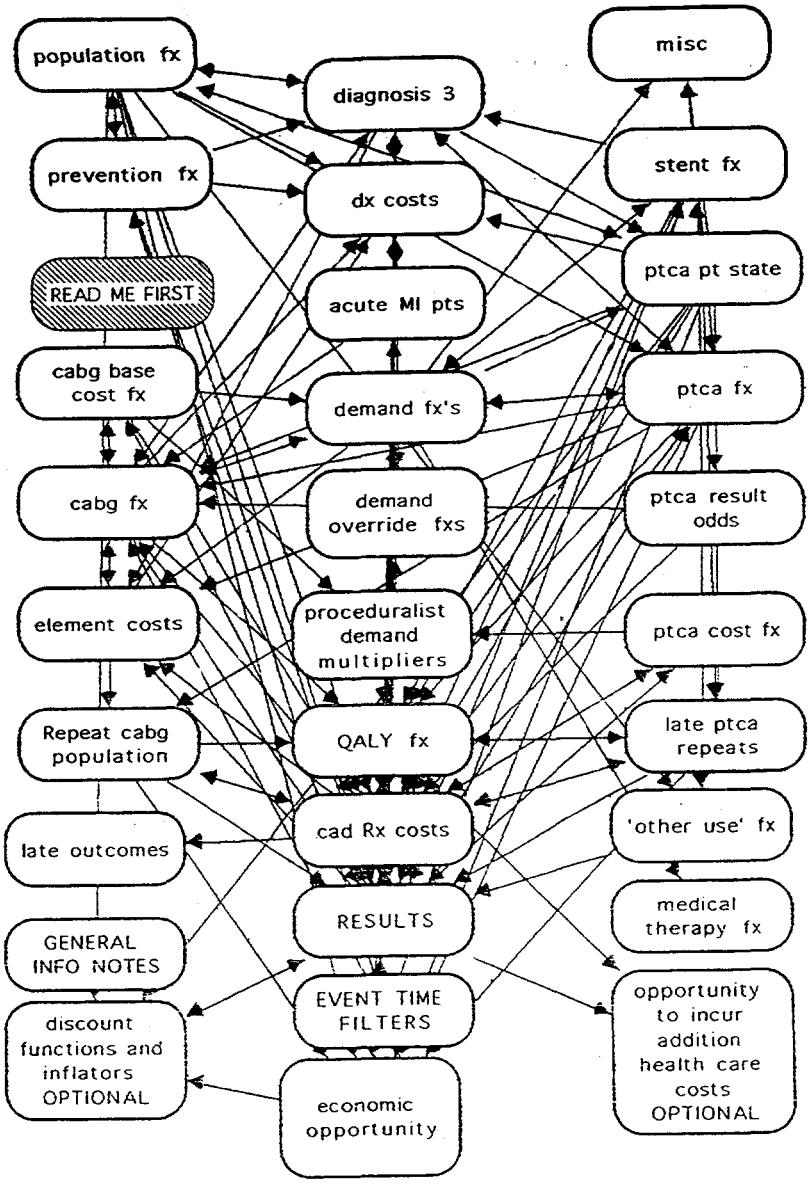

Figure 3. Depiction of the interrelationships used in the Analytica CAD model.

Stent-Related Variables

All stent-related input variables can be found in the stent function module located on the first model screen.

- Stent efficacy: The stent effect input site is clearly marked in the stent function module. After clicking down to the stent effect function, it is necessary to move down to the procedure demand/time-filter in order to enter stent efficacy rates for each specific year. Stent efficacy should be input as a value ranging from 0 to 100. Zero implies no stent effect on the restenosis rate, whereas 100 implies essentially the elimination of restenosis. Current stent technology is set at a value of 30.

- Stent access: This function is input through "stent access: fraction lesions/vessels approachable by stent." Stent access assumes values from 1.2 to 2.0, where 1.2 represents the current state of stent usage. As stents and angioplasty devices become smaller in order to approach more distal lesions, and as physicians become more aggressive in treating angioplastable multi-vessel disease with stents, this function should rise accordingly. The range of the stent access function is from 1.2 to 2.0.

- Unit stent cost: This value in the default mode is set at $3,000, a value consistent with much of the literature. However, at least one major hospital has been found which purchases stents at $1,595 per stent. Stent unit cost is likely to fall with time. It should also be recalled that stent unit cost is only one component of stent associated costs. Additional costs associated with hospitalization time and catheterization time are to be found in the "stent costs one vessel patients" function. Efforts to reduce the costs of stenting could focus either on unit stent cost or on associated hospital and catheterization laboratory cost. A similar situation pertains for multi-vessel patients and a "stent cost multi-vessel patient" input site can be found in the stent function module.

- Stent MI rate during PTCA: This variable determines the frequency with which myocardial infarction complicates angioplasty and stenting. It may fall with improved stent technology.

- Effect of stent on need for late revascularization: This function is also found in the stent function module and relates to any effect of stenting on the need for late revascularization. That is to say, stent efficacy deals with the revascularization rate in the first 24 months after procedure. Late recurrences occur. In the default mode a stent's ability to reduce late recurrences is assumed to be 1/2 that of its ability to reduce recurrences in the first two years.

PTCA Costs

- PTCA 1V cost: This function estimates the cost of a single vessel PTCA. Based on the value of the repeat number, this function includes repeated PTCA's required in the

first two years. The number of repeats in each patient who receives a repeat is assumed to be 1.34, which compares with HCIA data. Going forward this factor becomes 1.07 times the repeat number. The PTCA one vessel cost function also incorporates costs of those patients who require emergency CABG or CABG within the first two years following PTCA. It incorporates the cost of stents but does not include physician charges. This function drives the "PTCA multi-vessel cost" function and the "PTCA with lysis function," the latter applying to patients suffering from myocardial infarction.

- Repeat number: This is a derived function driven by stent efficacy and stent use. It can be found in the PTCA function module and can be changed as necessary.

- Fraction of patients with multi-vessel disease: This function can be found in the PTCA function module. It is a function of the assumed baseline probabilities of multi-vessel disease in the population, the enrichment of multi-vessel disease in the PTCA population, and the effects of changing stent access and stent efficacy. The latter two functions are assumed to influence the number of patients with multi-vessel disease who present or are referred for PTCA.

CABG Costs

- CABG patient post-op condition: This function is found in the CABG function module. Once at this function, the user can migrate down to CABG-F-T which is the input site for this variable. The CABG patient post-op condition variable ranges from 0.3 to 1 (corresponding to a CAB-F-T input value of 1 to 10). This function is designed to estimate functional status and well being of patients during the first 6 weeks after a CABG procedure. The value of 0.3 reflects considerable morbidity. If laparoscopic CABG, for example, were to be undertaken and as a result reduce morbidity, then this value could rise. The CABG patient post-op condition variable is used to drive CABG demand and to influence the choice of PTCA versus CABG.

Demand Override Functions

The demand override functions are found in the demand override functions module on the start up screen. The number of patients receiving catheterization in any given year and the number of patients presenting for a first PTCA (or first CABG) in any given year can be preset at this site. In order to preset a variable the first override function must be set at zero and the desired value of the function manually entered in the manual cath number, manual PTCA number, or manual CABG number function. The analyst may alternatively fix the number of first-time CABG patients by altering the function CABG-P2 directly, and he may alter the number of first time PTCA patients by changing the function TOTAL-PRIM.

Proceduralist Demand Multipliers

These functions assess the effect of physician reimbursement on choice of procedure and patient referral. These functions are to be found in the proceduralist demand multiplier module on the start up screen. Both the PTCA MD fee push function and the CABG MD fee push function are not likely to be operative during normal circumstances in that they do not become functional unless the reimbursement to cardiovascular surgeons for CABG falls below $1,000 and reimbursement to cardiologists for PTCA falls below $750. The analyst may change these threshold values.

Repeat Patient Populations

Both repeat CABG and repeat PTCA patients are modeled as are cross-overs between PTCA and CABG. Changes in these populations can be affected by working backwards from total CABG and total PTCA populations. In the case of total PTCA populations, one would go to total late PTCA populations and then alter any of the inputs of interest.

Population Functions

The population functions in the coronary artery disease model have been estimated from census bureau data. Risk rates have been obtained from the literature. These rates can be altered as required. The retirement age input site is also located in the population function module. In the default state, this value is set at 65 years and increases to 67.1 years after the year 2,000, as is predicted to occur under current law. This may be low in that economic data suggest that the average person retires at approximately 67.9 years (i.e. he or she works after the formal retirement period). The analyst may wish to correct for this effect.

- The ***age-adjusted employment rate*** is to be found in the population function module and can be altered as economic circumstances change.

- The ***fraction of patients with multi-vessel disease*** is set at 0.42, the estimated fraction of disease in the procedure population. However, it must be noted that this is the prevalence of multi-vessel disease in all procedure patients. The prevalence is higher in CABG patients and lower in PTCA patients. Stenting could potentially increase the rate in PTCA patients as could recent data such as that generated by the BARI investigators, which show equivalence of outcome for multi-vessel disease patients treated with PTCA or CABG.

- ***Population age related complexity***: This function is to be found in the population functions module. This function is designed to increase the severity of disease in presenting patients as the population ages.

Diagnosis 3 Library

A submodel has been constructed to provide diagnostic information to the main coronary artery disease model. This library is entitled Diagnosis 3. It must be loaded with the main model for the main model to run. Included in the Diagnosis 3 Library is the presentation module. This module contains the characteristics of coronary artery disease patients who are candidates for revascularization. Input variables based on recent data include multi-vessel versus single vessel disease, dominant right coronary artery anatomy, the presence and absence of diabetes, the fraction of the population presenting for work-up, the mandated fraction (if any) of diabetics who are assigned directly to CABG as opposed to PTCA.

The remaining modules deal with symptom presentation and test results of patients undergoing work-up. The diagnosis module and the related diagnosis cost functions are based on less than adequate data in the literature. Best estimates of costs and decision trees are utilized. However, the coronary artery disease model is not sensitive to changes in the diagnosis evaluation modules *per se* because the number of patients presenting for catheterization does agree well with historical data and is the driver of revascularization procedures and costs.

Prevention Function

The prevention function module contains a variety of input sites dealing with the cost of primary and secondary prevention and the QALY's gained by drug prevention in one patient class or another. In addition, "prevention RX" functions are included. These deal with the use of such drugs as lipid lowering agents (which are deemed to be preventive measures) *in the treatment of patients who would otherwise receive revascularization procedures*. This kind of aggressive use of "preventive therapy" in patients who would otherwise be treated with a procedure is only now being explored. Should this activity expand, the prevention function module could accommodate it. For example, the analyst may choose to enter values other than the default values of zero into the functions "percent primary CABG patients amenable to drug prevention therapy" and in the "present primary PTCA patients amenable to drug/prevention therapy."

Demand Functions

The demand functions used in the default modes of the BPH and CAD models (based on disease prevalence, the frequency of "gate way" procedures such as cardiac catheterization, focus group derived opinions, and other factors) are relatively aggressive. As technology improves, demand increases by 20% in the case of improved stent restenosis rates, 33% in the case of improved restenosis and enhanced access to lesions, and 45% in the case of the introduction of TUNA therapy for BPH. These figures are to be compared with a 26% increase in demand for cholecystectomy when laparoscopic

cholecystectomy (with some health plans seeing much lower increases). The growth rates in the use of revascularization procedures and thrombolytic agents in patients suffering from myocardial infarction, however, equal or exceed some of the default mode growth projections used here. For example, McClellan and Newhouse [McClellan 1997] have demonstrated that in the years between 1987 and 1990 certain cardiovascular technologies grew very rapidly. In relation to the treatment of myocardial infarction, the proportion of catheterized patients increased 41% (from 22.8% to 32.3% of patients) and the proportion of patients revascularized (PTCA and CABG) increased by 63% (8.1% different). Hospital costs also increased substantially, with nominal one year hospital costs increasing 34% (from $11,595 to $15,590). Therefore, the analyst is advised to evaluate a range of demand increases when assessing a potential new technology.

Results Module

The results module contains those outputs which are believed to be of most use to the analyst. Most of these outputs are self-explanatory. It is important to note, however, that when interrogating the model for a cost or the cost of any unit item (such as the cost of a QALY), the analyst must be aware of the cost function being employed. Total direct procedure costs are those associated with the procedure, excluding physician costs. The total PTCA + CABG + procedure MD cost function includes physician fees. These physician fees can be varied, but at the extremes they can affect the "physician fee demand functions."

The "total PTCA + CABG costs - economic savings" function deducts from the total PTCA + CABG + procedure MD costs, those economic savings associated with early return to work or increase longevity. This function in turn drives the "total cohort cost", but the "total cohort cost" also includes the diagnostic cost of all potential revascularization patients not simply those who actually received revascularization. That is, it reflects the increased push to diagnosis caused by improvements of technology whether or not that diagnosis leads to the use of the technology itself. In this regard it should be noted that the function "diagnosis push" increases the number of patients presenting for diagnosis of coronary artery disease and, while small in its effect, it is driven by improvements in stent technology.

"Net economic benefit" is driven by the estimates of QALY's gained from procedures multiplied by the value of a year in this patient population as assessed by the revealed preference method. This value of a life-year can be altered through the function "value of a quality life year," which can easily be entered through the "net economic benefit" function. Also important in the estimation of net economic benefit are the effects of technology on either the quality of the patient's life or the longevity of the patient's life. While most of these effects are preprogrammed (based on the available literature), the analyst is free to change these values in the net economic benefit module in order to assess the effects of anticipated technology improvements on the output. It must be

emphasized that the "net economic benefit" function is strongly affected by the dollar value assigned to QALY. This value (V-qlf) can be modified by the analyst. Also, the discount function applied to future economic benefit can be modified as needed.

"Net economic benefit is also influenced by the QALY's assigned to each treatment group, as well as the reduced QALY's gained as treatment usage increases and less-ill patients are treated. The demand function can be altered to prevent the influx of less-well patients into the system. For example, the "Dem-Multi" function can be made to prevent any dilution of the severity of multi-vessel disease in patients as stents are more widely used to treat that condition.

In assessing ratios, it is important to be mindful of the precise definition of both the numerator and the denominator. For example, the function "direct procedure costs per patient treated" reflects the direct procedure costs, including physician fees and the total number of patients treated with either PTCA or CABG (including repeat and crossover patients). The function "direct cost per primary revascular patient" is similar, but the denominator includes only first time procedure patients. As such, this ratio is a preferred estimator of costs per patient. To see this, note that all late patients derive from primary patients and therefore over time the cost per primary patient incorporates any changes in the cost per late or total patient population.

The demand override editor in the results module is designed to warn the analyst if his patient population assumptions are flagrantly incompatible. More specifically, if the sum total of patients having procedures is greater than those being cathed, then the demand override editor activates and changes the output of "total PTCA procedures", "total PTCA + CABG cost", "total PTCA + CABG + procedure MD cost," and "total patients undergoing revascularization procedure" functions all to *zero*.

Simulation Issues

The "demand influenced multi-vessel disease severity" function (DEM-MULTI) corrects for the lessening severity of multi-vessel disease which is expected to be seen in patients as stenting becomes more acceptable to patients. This is an extremely important variable insofar as it affects QALY-derived economic benefit. If the severity of multi-vessel disease falls, the QALY gained from either stenting or CABG declines, and the cost per QALY declines. If the multi-vessel disease severity is held constant (as would occur if protocols required a certain level of disease before procedures could be considered), the true economic benefit of improved stents can be more easily be seen.

Functions dealing with physician fees have been included at Medicare allowable charges in the Analytica model. These levels are substantially less than the ambient charges of physicians in the United States today. As a result, total aggregate procedures costs are lower than might otherwise be expected. However, the project team believes these

estimates reflect the true proceduralist cost and that cost estimates are validated by the fact that low priced CABGs and PTCAs can be purchased in markets heavily penetrated by health maintenance organizations. *Nonetheless, the analyst is warned that these physician fees are substantially lower, both in the coronary artery disease model and in the BPH model, than the ambient charge figures in the United States. The analyst is advised to inflate these physician fees in order to get a more realistic estimate of the spectrum of costs which might be produced by any change in stent technology or BPH therapy.*

Note that the economic models do not explicitly take into account the economic consequences of patient mortality during revascularization procedures. This is so because it is assumed that the QALY increments associated with revascularization therapy are compared with medical therapy, which in turn is compared with no therapy. Thus, the effects of mortality are included in the QALY gained estimate. Even if this were not the case, however, the economic consequences of revascularization mortality are relatively modest. This is so because the overall mortality in revascularization patients is 1.5% or less. Even assuming 10 lost years of life at an annual value of a life of $62,000, this mortality increases the value of a QALY by about $10,000.

Note that as the variable "stent access" increases (i.e. as the percentage of multi-vessel disease patients amenable to stenting increases), the simulation increases the number of stents used per person. However, the overall stent efficacy rate refers to the ability of the stents to prevent restenosis in the patient rather than the effect of the stent on any given lesion. For example, if stent efficacy is set at 0.5 and stent access is set at 1.9, this implies that a large percentage of multi-vessel patients are candidates for stenting and that the stent reduces the overall restenosis rate to 50% of the basal restenosis rate of 25%. It does not imply that each stent carries a restenosis rate of 12.5% but that the patient experiences an overall restenosis rate of 12.5%. This would appear to be a reasonable default mode assumption given that it is unlikely that patients would be subjected to repeat PTCA for restenosis in one of multiple vessels treated with stents initially. Also, it is unlikely that the stents would be used if the cumulative restenosis rate rose significantly higher than the restenosis rate now seen in single vessel disease. Nonetheless, should the analyst wish to model the circumstance in which repeat PTCA is driven by failure of each individual stent, he need only adjust the "repeat number" function and the "probability of 12 month restenosis" function upward. Both functions are to be found in the "PTCA FX" module. Note that the repeat number drives the actual cost calculation whereas the probability of 12 month restenosis drives the demand functions primarily. Therefore, while their values are approximately equal, they are not exactly so.

The "opportunity to incur additional Health Care Costs" module contains functions designed to assess the effect on later health expenditures as a result of prolonging life. The theoretical underpinnings of this approach are only now being developed. The functions in the model indicate that the consideration of late health care costs could add between approximately $500 and $2,000 to the cost of each QALY gained by

revascularization (baseline case). Meltzer [Meltzer 1997] argues that both medical and non-medical later expenditures should be considered if cost-benefit analysis is to be consistent with lifetime utility maximization. This author estimates that the consideration of these later expenditures adds between $2,000 and $3,000 to the cost of each QALY gained through revascularization. A function representing this total late cost estimate is included in the module. However, none of this late cost is incorporated into the costs generated in the results module. The analyst is free to use them when, and if, he becomes comfortable with the reliability of the estimates and the desirability of employing them.

Note that alternative functions for a given output are sometimes found in the models. These alternatives are deemed to be inferior to the preferred output function, but are included to provide the substrate for possible improvement as new data are presented in the literature. The assumptions underlying these alternatives are included in the models.

Baseline Simulations

Total procedure costs for CABG and PTCA (including conservative estimates for physician fees based on Medicare allowable charges) are estimated to be $20.9 billion in the year 2004. Were a near perfect stent (stent efficacy 0.9, stent access 1.9) to be developed, the model predicts under baseline assumptions that total costs will rise by about $10 billion to $30.11 billion. This cost increase is driven by an assumed increase in patients treated from 744,000 to 1,050,000. The cost of therapy when corrected for wages saved rises from $18.9 billion dollars in the baseline circumstance to $23.5 billion with the near-perfect stent. That is, when wages are permitted to offset some of the increased costs associated with the treatment of more patients, the increase in aggregated costs associated with improved stent technology is somewhat blunted. Nonetheless, costs rise. When societal economic benefit is estimated based on the economic value of a QALY as assessed by the revealed preference method ($62,016), net economic benefit to the society is $32.5B under baseline conditions and actually rises to $47.78B with the adoption of the improved stents, assuming that the severity of multi-vessel disease in treated patients remains constant (Note that the default mode assumes a marked fall in multi-vessel disease severity with the introduction of the ideal stent such that total QALY's gained do not increase much. Holding severity constant or only slightly decreased is more realistic). This scenario indicates the importance of determining the frame of reference to be used in determining cost when attempting to establish technology policy. Clearly, the direct and indirect cost perspectives yield different conclusions regarding the economic impact of stent technology.

Unit Costs

It is possible for improvements in technology to lower the unit cost of a procedure or service or to lower the unit cost of therapy per patient. In the case of coronary artery stents, the unit cost per procedure is actually increased by virtue of the cost of the stents

employed (typically in these models stent cost range from $750 to $3,000) as well as associated hospital and catheterization lab costs (typically in these models these costs tend to reflect historical levels, which perhaps will prove high as stents improve and competition increases). Thus, the use of stents increases the cost per PTCA procedure. However, stents have the capacity to reduce the need for repeat PTCA procedures and therefore have the capability of reducing PTCA costs per patient treated. Moreover, as stents improve so as to compete with higher cost CABG procedures (assuming total stents costs do not rise excessively) the total cost of treating a patient with a procedure (PTCA or CABG) can also be shown to fall. In the case of interventional therapy for coronary artery disease however, it is perhaps more appropriate to consider direct costs per patient undergoing primary procedural therapy. This is because direct procedure cost per patient could fall due to more inexpensive stents, while the repeat rate for patients remains high. The direct procedure cost per primary patient treated would be expected to track not only the impact of unit procedure costs but also costs associated with repeat procedures.

In the case of the baseline model (see Table 5), mean direct procedure costs per patient treated with a procedure (Mean ± SEM) is $28,260 ± $780 at a stent cost of $3,000 per stent. This falls to $26,150 ± $815 at a stent cost of $750. With an ideal stent (stent efficacy = 0.9, stent access = 1.9) the comparable figures are $28,740 ± $503 at a stent cost of $3,000 and $24,260 ± $529 at a stent cost of $750. Thus, as stent costs fall, unit costs per procedure patient can be seen to fall. This results from the conversion of higher cost CABG patients to lower cost PTCA/stent patients, and the effect increases as stent efficacy reduces the need for repeat procedures. In the case of procedure cost per primary patient treated, the baseline figure is $32,060 ± $903 with a stent cost of $3,000. This falls to $31,760 ± $555 with the ideal stent. This is a statistically insignificant reduction. However, at a stent cost of $750 the procedure cost per primary procedure patient in the baseline circumstance is $29,680 ± $931, and this falls to $23,750 ± $568 with the ideal stent. Thus, unit costs can fall even while aggregate costs rise, depending on assumptions regarding demand increase.

Thus, improvements in stent technology can reduce the unit cost per patient treated with a procedure. This cost-savings per patient is greater as stents become more effective in reducing restenosis rate following PTCA and as stents become less expensive relative to CABG costs. Moreover, if demand is assumed to be regulatable, aggregate cost-savings are achievable.

Table 5. Year 2004 results for the Analytica CAD stent simulations.

	Baseline (MEAN ± S.E.M.)	**Ideal Stent** (MEAN ± S.E.M.)
Total Procedure Cost	$20.9B ± 0.56B	$30.11B ± 0.49B
Cost-Wages Gained	$18.88B ± 1.26B	$23.5B ± 0.57B
Patients Treated	744K ± 5.75K	1.05M ± 6.79M
QALY-Based Net Economic Benefit	$32.50B ± 1.36B	$47.78B ± 2.42B (if severity of disease remains constant)
Total Procedural Cost Per Primary Revascularization Patient	$32,060 ± 903	$31,760 ± 555
Stent cost $750	$29,680 ± 931	$23,750 ± 568

These simulation results are dependant on the assumptions input to the model. For example, we have assumed relatively low physician fee costs and based these primarily on Medicare allowable charges. In reality, many physicians charge higher fees to privately insured patients. It is not atypical for surgeons to charge $10,000 for a CABG. Similarly, the BARI investigators report an estimated physician fee for multi-vessel angioplasty of $6,698, higher than the Medicare allowable charge. Similarly, hospital charges for CABG and angioplasty in many cases far exceed the cost estimates which we have input in the model. The analyst is advised to vary these and other parameters (such as stent associated costs) so as to develop a level of comfort with what actual expenditures may be under specified conditions.

For example, if one were to (1) raise the physician fee for performance of single vessel CABG from the default $1,432 to a more realistic $7,000, (2) raise the the fee for multivessel CABG from $2,033 to the more market relevant price of $10,000, (3) increase the PTCA physician fee from the default level of $1,105 to $5,152 in the case of single vessel angioplasty and $6,698 in the case of multi-vessel angioplasty, and (4) increase CABG-associated hospital charges to an average of $31,000, then a cost profile different from the default mode emerges. In particular, total procedure costs (including physician fees) rise to $27.6 billion ± $6.27 billion. Cost per primary patient revascularized increases to $43,460 ± $1,064. Net societal economic benefit, however, remains positive at $24.28B ± $1.39B, but cost per QALY increases to $33,910.

This exercise demonstrates the importance of defining costs before running a simulation. Were the analyst attempting to predict expenditures while using the default cost estimates, his predictions could vary considerably from the scenario he wished to simulate.

Perhaps the most counterintuitive finding of the coronary artery disease simulations is the result that the net social costs of interventional cardiological procedures is negative: these procedures in fact enhance social welfare and economic benefit. This conclusion is based on several inputs, including the economic value ascribed to a human life (more particularly to a quality-adjusted life year) and the costs of the various procedures. It is reasonable to explore how these values were derived.

As has been noted elsewhere, the economic benefit derived from medical care can be estimated by either the wage-based, the willingness to pay, or the revealed preference methods. Current economic thinking would argue that the revealed preference methodology is preferred. Note that this methodology is independent of employment status.

In the CAD model, the value of a quality-adjusted life year has been determined by the revealed preference method, utilizing the decision to voluntarily retire at age 62 as a natural experiment which reveals the economic value of a person's time. This approach is particularly appealing since it involves an experiment of nature dealing with the age group who participate in the therapies under consideration. As has been noted, this methodology produced a value of $170 per day. This estimate equates to an annual value of $62,016 per year. Is this figure realistic?

Cutler [Cutler, NBER WP 5750] considered a similar question. For their analysis, a value of $25,000 per year was used, with an upper bound of $50,000 per year and a lower bound of $10,000 per year. Cutler mentioned that survey evidence on the value of life for people around age 40 is $3,000,000 to $7,000,000 per 40 years of life, which equates to a considerably larger value for the value of an annual year of life. It is our belief that the figure of $62,016 per year is appropriate given that it is derived empirically (as opposed to deduced from literature), is tailored to the population age group of interest, and falls within the boundaries of prior estimates.

In their study of patients treated for acute myocardial infarction, Cutler calculates a therapy-related change in the expected value of life ranging from $2,217 to $25,994. The first of these is driven by the assumption that a net value of a life here is $10,000 per year, the latter value driven by the assumption that the net value of a life year is $50,000. According to Cutler, when the expected net value of a life-year is assumed to be $25,000 per year, the therapy-related change in the expected value of life is $11,133. When this figure is adjusted by estimate of the improved life expectancy of the general population related to therapies other than acute myocardial infarction, the therapy related change in expected value of life (for the assumption that the net value of a life year is $25,000) falls to $5,015. This estimate is likely to be conservative for the reasons outlined by Cutler.

The CAD model estimates that CABG and PTCA produce an economic benefit of $44,000 per treated patient. Because these estimates are derived from treatment-generated increases in QALY's, they have already been corrected for other beneficial changes in society which would extend life. These figures have also been discounted at the rate of 2% per annum. Projected changes in the expected value of life caused by PTCA and CABG are higher than those reported by Cutler. However, several points should be made in this regard. The patients reported by Cutler had suffered acute myocardial infarction, so the benefits of therapy in these patients were fewer, and their longevity was likely less relative to symptomatic patients who have not necessarily sustained a myocardial infarction before receiving interventional therapy. Thus, one would expect the net benefit to be greater in the case of the patients represented in the CAD model. One could argue that these estimates are conservative given the differences in projected life span of elderly patients who have sustained a heart attack (the population studied by Cutler) and all patients, young and old, who undergo PTCA and CABG (in large part prophylactically) to prevent future heart attack.

An additional point which speaks to the conservative nature of these predictions is that the CAD model makes no assumption of improvements in technology over time. This is clear when one realizes that the per-patient change in the value of expected life actually falls in the model between 1993 and 1996. (The CAD model does contain a function which will upgrade the change in quality of life years achieved by PTCA as stent and other technologies improve, but these changes in QALY's can only increase to the "gold standard" level provided by today's CABG technology. Thus, the model's predictions are conservative even when stent and CABG technology are improved since no improvement in optimal outcome is projected over current CABG capabilities.) This is of note given the fact that Cutler, et al have estimated a progressive decline in the cost of living index of about 1.1% per year and furthermore reported detectable technology driver increases in longevity after myocardial infarction. Thus, in the present model, both baseline simulations and simulations based on the changing of technology are likely to be conservative in respect to the societal cost of therapy.

At the same time it must be noted that these estimates of negative social cost are not robust when viewed against downward changes in the estimation of the value of a life year. Indeed with stent costs of $3,000 or $1,500, social costs become positive when the value of a life year approaches approximately $25,000. In any event, the conclusion of a net social good derived from cardiovascular interventional therapies is not as robust as the argument in favor of newer myocardial infarction therapy. This points out the need for continued research in the effort to more rigorously define the value of a life year.

Sensitivity Analysis

When the value of a quality-adjusted life year is reduced below $27,000, the societal benefits of interventional cardiovascular therapies turn negative (societal costs turn

positive). This is different from the case outlined by Cutler for acute myocardial infarction, where the societal benefit was approximately $5,000 under the assumption that a life-year was valued at $25,000. If unit stent cost is set at $750 per stent (recall that stent-associated costs in this circumstance may still be unrepresentatively high), societal break-even occurs at a quality-adjusted life year value of approximately $25,000.

It should be noted that all these estimates make no correction for improvements in longevity over and above those already associated with PTCA and CABG therapy in specific patient groups. Recent data suggest that longevity increases can be achieved even in a symptomatic patient with coronary artery disease when interventional therapy is utilized [Davies 1997]. Moreover, Cutler and colleagues have reported that between 1984 and 1991 the first year mortality rate of heart attack patients fell by 5%. If this figure can be extrapolated to imply an improving survival rate of patients treated with interventional cardiovascular therapies after 1991of between zero and 5%, the benefits of treatment similarly increase. Nowhere in the current models is an outcome impact on life expectancy or quality of life better than that obtained by coronary artery bypass grafting in 1990 imputed (these functions are available in the model to be adjusted per the analyst, but are set to be inactive in the default mode). This again tends to make the societal estimates of cost and benefit conservative and gives further support to our view that a net positive gain to society occurs when cardiovascular interventional technologies are employed as they currently are.

It is important to note however, that Viscusi [Viscusi 1993] reports a life year value of about $32,000, 20% above the value associated with a break-even societal benefit. Thus, this analysis (like other models of cardiovascular interventional therapy) suggests that the economics of this procedure may be poised close to the break-even benefit state, with considerable uncertainty surrounding the predicted true value of that economic benefit. Only enhanced research on outcomes and economic benefits will improve this circumstance.

If, as some have suggested, the value of a QALY is considerably greater than $25,000 a year, the societal economic benefits increase dramatically. Under baseline circumstances, if the value of a QALY is $27,000, the year 2004 net societal economic benefit is estimated to be $572 million, or essentially the break-even point. If the value of a QALY rises to $50,000, net societal economic benefit increases to $21.4 billion, or about $29,000 per patient treated. If the value of a QALY is further increased to $200,000, net societal benefit exceeds $150 billion, or more than $210,000 per case.

Similar analysis can be undertaken regarding stent technology. At a stent cost of $3,000 per stent, the baseline model predicts an economic benefit of $32.50 billion. With a near ideal stent (stent access = 1.9, stent effect = 0.9), this figure rises to $47.78B if the severity of disease in treated patients is held constant. If stent costs are set at $1,595, net economic benefit initially under basal conditions is $32.50B ± $1.36B, and this rises with the employment of the near ideal stent to $51.5B ± $2.5B if the severity of disease in treated patients is held constant. It should also be noted that the model is capable of

dissecting those changes in demand and cost associated with improved stent efficacy (that is reductions in restenosis rate), as opposed to those associated with expanded use of stents in the coronary anatomy (as is associated with the development of smaller stents and the willingness of physicians to see benefit in the stenting of multi-vascular disease patients).

It is also of interest to determine the effect of increasing CABG and PTCA costs (including physician fees) on the analysis. The default mode estimates are based on Medicare-allowed physician charges and project team estimates of the time costs of revascularization procedures. Many facilities currently charge considerably more than these amounts. Thus, to the extent the analyst wishes to simulate expenditures (rather than estimated costs) the values of these cost inputs must approach current charges (prices).

If single vessel CABG hospital costs are raised to $31,000, CABG surgeon fees are set at $7,000 for single vessel patients ($10,000 for multivessel), and PTCA physician costs are set at $5152 for single vessel disease ($6698 for multi-vessel disease), total procedure costs rise to $27.0 billion, cost per primary patient increases to $43,460 and cost/QALY rises to $36,110. Net societal economic benefit remains positive at $24.24 billion.

If the above physician costs hold but CABG cost rises to $40,000, cost/QALY is just over $36,000. Net societal benefit remains positive.

Thus, the conclusion that revascularization provides a positive societal benefit is relatively robust in the face of variations in CABG and PTCA cost estimates.

Table 6. Sensitivity analysis: net economic benefit as a function of QALY.

Value of Time	Cost/QALY	Net Economic Benefit
$100,000	$24,620	$66.18B
$71,367	$24,620	$40.37B
$62,016	$24,620	$32.50B
$60,000	$24,620	$30.12B
$50,000	$24,620	$21.11B
$30,000	$24,620	$3.08B
$20,000	$24,620	$-5.93B
$10,000	$24,620	$-14.95B

Table 7. Sensitivity analysis: net economic benefit as a function of CABG cost.

Single Vessel Procedure Fees			**Cost (Benefit) $ 14.07B**		
Surgical Fee	CABG Hospital Cost	Cardiologist Fee	Procedure Costs	Cost/ QALY	Net Economic Benefit
$1,432	$23,500	$1,105	$20.08B	$24,620	$32.50B
$7,042	$31,000	$5,152	$27.6B	$33,910	$24.28B
$7.042	$45,000	$5,152	$31.44B	$38,000	$18.49B
$7,042	$55,000	$5,152	$33.65B	$42,390	$14.24B
$7,042	$65,000	$5,152	$35.94B	$46,380	$10.67B

Cost-Effectiveness Analysis

Cost-effectiveness analysis is a commonly-used methodology for comparing the ability of different technologies to reduce health care costs. In cost-effectiveness analysis, the researcher compares the cost per unit of benefit generated by two competing procedures. Cost-effectiveness analysis differs from cost-utility and cost-benefit techniques primarily in the measurement of benefits. Although this technique uses clinical outcomes (e.g. functional status and quality of life), it does not attempt to assign monetary measures to all outcomes generated by different medical technologies.

Methodology

Sloan [Sloan 1995] described a methodology for cost-effectiveness analysis as identified by the Department of Health and Human Services in 1992. The methodology is as follows:

1. ***Define the intervention.*** This includes specifying the nature of the intervention, the type of patient to be treated, and the alternative to the intervention. In some cases, a medical intervention is compared to the natural history of the disease without treatment.
2. ***Identify relevant costs.*** Costs include direct (medical) costs as well as indirect costs such as patient time, lost earnings, and social intervention costs.
3. ***Identify relevant benefits.*** Benefits include net health benefits to the patient (after removal of adverse side effects) as well as indirect benefits such as greater productivity.
4. ***Measure costs.*** This requires attaching a monetary value to all cost components, including medical inputs and an individual's time.
5. ***Measure benefits.*** This entails converting all benefits into a single metric (e.g. quality-adjusted life years, or QALY).
6. ***Account for uncertainties.*** This involves using Monte Carlo simulations or other methods to test the sensitivity of the conclusions to variations in perceived costs and benefits.

Again, the cost analysis team identified two commonly used coronary artery disease interventions as initial targets for this methodology. These are PTCA (percutaneous transluminal coronary angioplasty) and CABG (coronary artery bypass grafts). Both of these interventions, being technologically intensive, provided a rich set of issues to guide the development of a model for technology assessment.

Cost Effectiveness Ratio

The six steps of cost-effectiveness analysis can be summarized in the construction of a "cost-effectiveness ratio." This ratio is a calculation of the cost differences of alternative treatments weighted by outcomes measures. Determining a cost-effectiveness ratio

includes generating an economically sound measure of the cost of the procedures or condition being analyzed. A well-specified model of the cost of treating a condition could include measures of inputs used in the treatment, patient characteristics, input prices, and treatment mode (if different modes are being compared). A description of the cost measurement process is as follows:

Let Z_{ir} = the amount of input r used by patient i,
X_i = patient characteristics,
M_i = mode of treatment for patient i,
P_r = price of input r,
R = total number of types of inputs, and
N = number of patients.

In this case, the cost of treating patient i is

$$C_i = \sum_{r=1}^{R} P_r Z_{ir}$$

The overall cost of treating the condition is then

$$C = \sum_{i=1}^{N} C_i$$

Important statistical issues exist regarding variation in the cost of treatment and how that variation is related to the type of treatment applied. In order to do this, a model is posed which relates input usage to patient characteristics and mode of treatment. Let Z_i be the vector of inputs used to treat patient i. The vector of inputs chosen is affected by patient characteristics and mode of treatment, so $Z_i = F(X_i, M_i)$. Because of random variation or unobserved patient characteristics, these relationships include error: $Z_i = F(X_i, M_i) + e_i$. This forms the basis of the statistical model used to estimate costs. From this theoretical relationship, an estimated vector of input usage conditional on patient characteristics can be identified. From this estimated input vector, an estimated cost conditional on patient characteristics can be obtained.

Cost-Effectiveness Analysis: Stent Technology

A cost-effectiveness analysis would require that we determine the cost per QALY or similar measure of outcome. In the baseline state, the model predicts a cost of $25,150 ± $680 per QALY in the year 2004. With the introduction of a near-ideal stent (stent efficacy = 0.9, stent access = 1.9) this cost per QALY rises. This paradoxical increase in the cost of a QALY with improvement in stent technology can be shown to result directly from the assumption that as the stents improve, more patients with marginal indications for therapy (and therefore, patients who will derive less benefit per procedure) will be recruited into the population undergoing procedural therapy. In fact, if the severity of multi-vessel disease is held constant in the stented patient population, the cost per QALY actually falls slightly to $24,700 ± $370.

Moreover, if stent cost is reduced to $750, the baseline cost per QALY falls to $23,790 ± $700. With the introduction of the near ideal stent and with the severity of multi-vessel disease held constant, cost per QALY falls dramatically to $19,630 ± $350. This result indicates that improved stent technology can be demonstrated to improve the cost-effectiveness of interventional therapy. Moreover, these simulations suggest that the cost of interventional therapy per quality of life year gained ranges from about $19,000 to $25,000.

McClellan and Newhouse [McClellan 1997] estimate that the average cost of each additional year of survival provided to acute MI patients by more intensive medical treatment is at least $40,000 in 1987 dollars; more plausible estimates are $70,000 or more. This estimate is based on rather elaborate corrections for severity of illness and treatment patterns. Absent these corrections, the cost per year of life gained falls to approximately $30,000. Interestingly, these authors contend that what benefit enhanced technology has provided to the treatment of myocardial infarction patients is not necessarily associated with revascularization itself, but perhaps with better overall cardiological care. This conclusion is based on their observation that the majority of benefit obtained in interventional cardiology centers is obtained in the first day survival rate, a time during which few patients had yet received therapy. This conclusion appears counterintuitive and does not appear consistent with data indicating that time to revascularization is an important predictor of result. Thus, the conclusion is suspect as it relates to the benefit of current revascularization technology.

However, comparing this paper with National Bureau of Economic Research Working Paper 5750 by the same authors, it would appear that (1) the treatment cost of acute myocardial infarction from a societal point of view appears to have fallen between 1988 and 1993, (2) the treatment cost of an acute myocardial infarction appears to be about $70,000 per life-year gained in 1990 (figures based on 1987 dollars), and (3) the benefit of aggressive treatment appears to be unrelated to revascularization procedure. This study predates modern revascularization strategies, and its conclusions may not be applicable today.

As has been demonstrated (see thesection on cost-effectiveness), the CAD model predicts that the cost per QALY under baseline assumptions ranges from about $19,000 to $25,000. As noted above, McClellan and Newhouse have estimated the treatment of acute myocardial infarction cost at $40,000 to $70,000 or more per QALY achieved. This estimate gives some support to the CAD model predictions. Medical experience teaches that patients who have sustained myocardial infarctions are significantly more ill than those who simply suffer with angina and coronary artery disease, and their prognosis both in terms of longevity and function after therapy is diminished compared to those who have not sustained a myocardial infarction. The loss of ventricular muscle mass following a myocardial infarction is associated with a wide variety of complications, not the least of which is ventricular dilatation and enhanced susceptibility to congestive heart failure and arrhythmia. Thus, it would appear reasonable to assume that the cost of a quality life-year gained by the treatment of acute myocardial infarction would be higher

than that for the treatment of a patient with coronary artery disease who has not sustained an infarction. One could argue that this would not be the case, were the treatment of myocardial infarction to restore the patient to near perfect health, but sadly this is not the circumstance. Thus we can assume that the 40,000 to 70,000 + figure per QALY should represent an upper bound for the cost per QALY associated with the procedural treatment of coronary artery disease. Indeed, the relative magnitudes of our $19,000 to $25,000 figure and McClellan and Newhouse's $40,000 to more than $70,000 figure seems reasonable.

Coronary Artery Disease Laparascopic CABG Simulation

Coronary Artery Bypass (CABG) grafting is an effective means of restoring blood flow to ischemic myocardium and thereby improving the symptomology of patients (in many instances extending their life spans). Recent data (Davies RF et al Circulation 95: 2037-2043, 1997) suggest that re-vascularization may be effective in preventing morbidity and mortality even in asymptomatic patients: patients who are not now considered candidates for re-vascularization therapy. Thus, the demand for coronary bypass and angioplasty therapy will likely increase with time.

A major impediment facing patients who wish to under go a coronary artery bypass graft procedure is the significant morbidity and mortality associated with the procedure. CABG can only be described as a major procedure with a prolonged time to full recovery. Because sternotomy is required, patients cannot exert themselves or return to work for six weeks. Because of the morbidity associated with coronary artery bypass grafting surgeons have sought alternative means of approaching the coronary arteries so as to provide the same benefits as current-day CABG procedures with less morbidity. To this end, minimally invasive CABG procedures are coming under development. These procedures are known also as PORT-ACCESS heart surgery or even laparoscopic CABG. In general, two approaches have been developed thus far. One involves placing the patient on heart lung bypass as is customary in the present CABG, while the other involves operating on the beating heart. Currently both procedures appear to be promising, although given constraints of access, it appears that at the present time only about 20 to 25% of patients could be candidates for this procedure. This is because the posterior aspect of the heart is difficult to access. However, we anticipate that with continued development the procedure will become more widely applicable.

The coronary artery disease model has been developed to simulate potential laparoscopic CABG procedures. To this end one can enter the CABG function module, scroll down to "CABG-PATIE" (a function which reflects the post-operative state of well-being of a CABG patient), and then scroll down further to the function CABG-F-T. This function in the default position is set at one. Should it reach 3.33 the implication would be that the patient experiences very little (if any) morbidity following the procedure. In order to simulate the port access minimally invasive heart surgery of the future, this function was

set at 2.5 after the year 1998. Next, the inpatient CABG cost were reduced to reflect the shorter time thatminimally invasive CABG patients will spend in the hospital. "Inpatient -2" can be entered through the CABG function module. From there one can drill down to "inpatient -". In order to simulate the effects of a laparoscopic CABG procedure, room costs, ICU room costs, and supply costs were all multiplied by 0.5; other costs were left unchanged. This had the effect of reducing "inpatient 2" the in-hospital CABG cost to about $20,800.00.

Next, the function "value-of-w3" which can be reached in the economic opportunities module, was adjusted so that the function "CABG days lost" (the number of days a CABG patient loses from work) was multiplied by 0.33, reflecting the fact that, in the case of minimally invasive CABG, work days lost fall from 42 to 14. Finally, it should be noted that because no reduction was made in "CABG post-operative patient condition," "the cost", or in the value of work days lost, this formulation assumes that virtually all CABG patients are candidates for the minimally invasive feature.

When this simulation is run, the total number of CABG patients increases to 601,000, with the total PTCA patients remaining at about 400,000. The total number of revascularization procedures climbs to 1.2 million. This increase in procedure number reflects the increased demand for CABG which would be associated with a marked decrease in CABG morbidity. "Total procedure and physician cost" increases from $20.9 ± 0.56 billion in the baseline state to $25.7± .71 billion after the introduction of minimally invasive CABG. That this increase in aggregate cost is almost totally accounted for by the increased demand for procedures can be seen from the fact that while total revascularization cost per primary revascularization patient was approximately $32,000 ± 903 in the baseline state, this falls to $29,000 ± 905 dollars following the introduction of minimally invasive coronary artery bypass grafting. That is, the introduction of the new procedure actually lowers unit cost per patient treated but stimulates a sufficient increase in demand (744,000 patients in the baseline circumstance, one million after the introduction of the new technology) to increase aggregate costs.

Total direct costs minus wages gained ("total cohort cost") are projected to rise (from $18.66 ± 1.26 billion to $22.32 ± 2.10 billion) following the introduction of the new technology. However, when these figures are expressed on a per-patient-undergoing-revascularization basis, the direct cost minus wages gained per revascularization patient fall from $25,080.00 in the baseline case to $22,250.00 following the introduction of the new technology.

Net societal economic benefit after the introduction of the new technology is also projected to rise. However, this result and the QALY-derived estimates below result in large measure from the fact that no diminution in the severity of multi-vessel coronary artery disease is assumed following the introduction of minimally invasive CABG. It is left as an exercise to the reader to set the "dem-multi" function to a lower level than its default value of .9542 and apply it to CABG derived QALY's in order to reflect any diminution of disease severity. However, assuming no such diminution occurs, the cost

per QALY falls to $20,840 ± 595.00 following the introduction of the technology. However, it must be repeated that net societal economic benefit, net societal economic benefit per procedure patient and cost per QALY all are critically dependent on the value selected for the diminution for the severity of multi-vessel disease.

In summary, this exercise demonstrates that the introduction of a minimally invasive CABG technology can be expected to increase the number of revascularization procedures performed and the total cost of carrying out those procedures. However, if the minimally invasive CABG procedure is as effective as the current procedure, the total cost of revascularization per primary patient is likely to fall, indicating that the new technology has provided a means to more efficiently treat the individual patient. Net societal economic benefit also seems to increase under these circumstances, but this conclusion is dependent on assumptions regarding the severity of multi-vessel disease in the expanded CABG population. The study of the sensitivity of these results to the severity of multi-vessel disease in the CABG population is left as an exercise.

Modeling of BPH Treatment Using Analytica

Summary of the Benign Prostatic Hypertrophy Analytica Model

The benign prostatic hypertrophy (BPH) model is designed to permit the simulation of the costs and outcomes associated with the introduction of a variety of therapies for prostatic hypertrophy. Currently in the United States, the predominant mode of therapy for symptomatic benign prostatic hypertrophy is the transurethral prostatectomy (TURP). This procedure has generally superseded the open prostatectomy for benign prostatic hypertrophy. However, over recent years a variety of procedures, including laser technologies, microwave prostatic ablation, and transurethral needle ablation of the prostate have been developed. These procedures vary considerably in their costs. While the outcomes of these procedures are largely unknown at this time, it can be reasonably anticipated that these outcomes will vary both in the quality of symptomatic relief and the durability of that relief. Moreover, during recent years a variety of medical therapies (including five alpha reductase inhibitors and alpha adrenergic blocking agents) have come on the market to provide symptomatic relief for prostate patients. At the same time new educational efforts have been developed which inform the prostate hypertrophy population of the true risks and benefits of interventional therapy. Because the interventional therapy of prostatic hypertrophy is in large measure directed at providing symptomatic relief to patients, as opposed to improving longevity or general health (since it is now relatively rare for patients to be permitted to develop significant renal insufficiency without a procedure), the treatment of benign prostatic hypertrophy is directed increasingly by the patient as opposed to the physician, and the success of that therapy is increasingly determined by the subjective improvements which patients perceive. Thus, the treatment of benign prostatic hypertrophy is a complex process in which procedural technology, economic forces, and patients' desires interact in a complex fashion.

The BPH model consists of two portions. The first is a library entitled "Base Population." Here, data deal with the United States population at risk for BPH. This library drives the remainder of the model and the main BPH model cannot be operated without it.

The presentation screen of the BPH model consists of several clearly identified modules. Important among these is the presentation module in which is entered the prevalence of various forms of prostate-related symptoms and signs (clinical findings). The "therapy outcomes" probability module houses the literature-derived best estimates of complications and outcomes of interventional therapy for prostate disease. In most instances, these outcomes probabilities are driven by the module "UCNA surgical Rx outcomes". The latter module incorporates the surgical outcomes results published in the Urological Clinics of North America (UCNA). Other therapy outcome probabilities are derived from the "UCNA medical Rx outcomes" function which similarly reports Urological Clinics of North America estimates for medical therapeutic outcomes.

The diagnostic module outlines a variety of diagnostic tests which can be used in patients with benign prostatic hypertrophy. However, this module (with the exception of cystoscopy in patients about to undergo procedure) does not drive the main model to any significant extent because in recent years diagnostic testing has been scaled back for patients with benign prostatic hypertrophy. However, should one wish to estimate the impact of the reintroduction of these tests, this module could prove helpful.

A "QALY" module appears on the first screen, and this is something of a misnomer. Because benign prostatic hypertrophy therapy has little impact on longevity, any estimate of QALY changes will be largely driven by changes in symptomatology. While a variety of symptom scores are available, it is not possible at this time to convert these changes in symptoms to a true change in QALY. Therefore, the labeling of this module as "QALY" is more a hope or plan for the future based on future research than a reality for today. As noted in the QALY module, symptom score estimates are derived from a variety of sources including the work of Dr. Clause Roehrborn of the University of Texas. It is important to note however that no economic benefit is associated with change in symptom score or QALY in this model.

The "procedure functions" module contains the cost data associated with a variety of procedures as well as the number of procedures which are likely to be preformed. The procedural MD demand multiplier is a module which attempts to estimate how physicians will respond to changing reimbursement for procedures. That is, as one procedure is favored over another in terms of reimbursement, physicians may be tempted to perform it more often.

The "patient education" module permits the analyst to introduce estimates regarding the impact of patient education on the use of procedural therapies. In the baseline mode it is assumed that were education to be widely available, the rate of TURP would fall by 28%. Therefore, the effect of education on TURP function is driven by the availability of education, and the analyst can set this function as he wishes. In the default mode, this function is scaled up from 10% in 1992 to 60% in 1994. Similar educational availability and effect functions are found for other technologies, and the analyst is advised to be aware of this because in many cases the educational impact and availability functions mirror those assumed to be present for TURP.

The remainder of the modules on the start-up page are self explanatory. The analyst is advised to read the "info notes" carefully. In particular, it is important to note that baseline BPH population data prior to 1995 were derived from HCIA, and these data were used to extrapolate the 1996 baseline TURP population and cost.

In the case of benign hypertrophy, the project team again created two models. The first "attention focusing model" is designed to provide the analyst an easy-to-use tool having the heuristic value of pointing out to the observer interrelationships between factors which might not be immediately apparent. The second, more detailed model is

constructed utilizing ARENA. Again the ARENA model is elemental in that individual patients or small cohorts of patients can be tracked over time. Just as a library model (Diagnosis 3) is required for operation of the coronary artery disease model, so too is the library "base population" required for the operation of the BPH model. The "base population" model must be loaded for the BPH model to run.

Index To Important Input Variables In The Benign Prostatic Hypertrophy Model

Interrelationship Diagram

Figure 4 below depicts the interrelationships between the variables used in the Analytica BPH model.

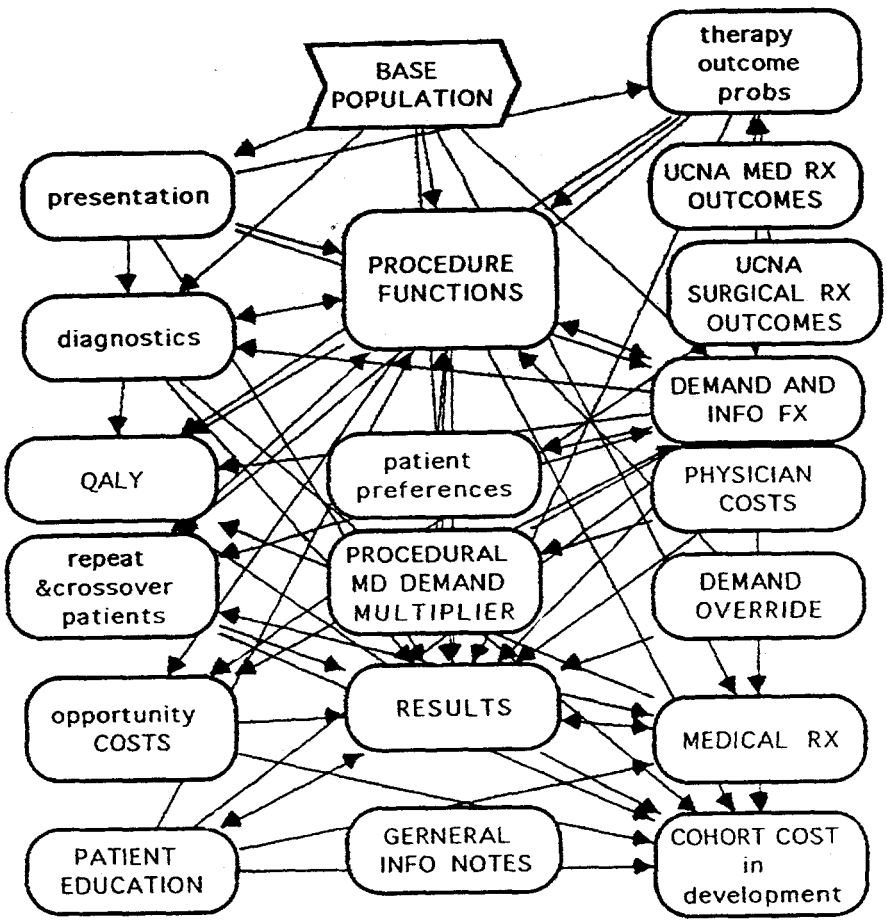

Figure 4. Depiction of the interrelationships used in the Analytica BPH model.

Population Related Variables

All population-related input variables are to be found in the "based population 7/8" library.

Male population at risk. The male population at risk is derived from census figures and an age-adjusted risk for BPH. Both these variables can be modified by scrolling down through the function module in base population 7/8.

Variables Related to Repeat Procedures and Patients Crossing Over From One Procedure to Another

The "repeat and crossover patients" module contains important variables which influence the rate of repeat procedures as well as the rate at which patients having repeat procedures switch from one type of procedure to another. In general, both first-year repeat rates and five-year repeat rates can be individually entered. In the case of transurethral prostatectomy, data from Urology 44:692-699, 1994 is employed to indicate an average first-year repeat rate for TURP of 1.3%. Repeat functions for years four through five (and later if desired) can be entered directly through the "therapy outcome probabilities" module. In the case of transurethral prostatectomy five year repeat rates ranging from about 12 to 6% for BPH are reported. This repeat rate appears to be changing with time and its value can influence results of the simulation significantly. The analyst is to pay careful attention to the literature in regard to the true value of this parameter at any given time, and the analyst is further advised to perform sensitivity analysis around any chosen repeat rate. The one-year and five-or-more-year repeat rate for newer technology (e.g. TUNA and microwave) are as yet unknown and can only be estimated. In the BPH model default mode, estimates derived from focus groups have been used, but again the analyst is advised to update these in an ongoing fashion.

Relief Of Symptoms

The "therapy outcome probabilities" module contains the various outcomes of procedural therapy for BPH. This module includes functions which bear on the relief of "irritative symptoms" by various procedures. Because the irritative symptoms of prostatism (for example nocturia) are particularly bothersome to patients and appear to be differentially affected by therapies, these input values must be carefully considered.

Transurethral Prostatectomy for Indications Other Than Benign Prostatic Hypertrophy

A complication in modeling the procedure therapy of benign prostatic hypertrophy results from the fact that some transurethral prostatectomies are performed for reasons other than benign prostatic hypertrophy. For example, some patients with prostate cancer undergo TURP in order to relieve symptoms. These transurethral prostatectomies should not properly be modeled as an element of the therapy of benign prostatic hypertrophy. Similarly, some patients who undergo transurethral prostatectomy for benign prostatic hypertrophy are subsequently found to have prostate cancer. These patients are considered in the simulation to be BPH patients. In other words, the model assumes an "intention to treat" perspective. In general, approximately 87% of TURPs are done for benign prostatic hypertrophy. This variable must be followed over time and the analyst must be aware of its potential significance, particularly when he attempts to compare results of the simulation with actual TURP rates. The cost of therapy for patients who are incidentally determined to have prostate cancer at the time of TURP is given in the "cost of malignant disease" function, which is found in the "results" module. Based on literature support, (cited in the "cost of malignant disease" function) an incidental rate of prostate cancer of 10% is assumed. Further, the cost of therapy for a patient so detected is assumed to be $10,000. Should the analyst wish to change either of these variables, he can do so directly by accessing the "cost of malignant disease" function. No economic benefit is ascribed to the treatment of incidentally detected prostate cancer, but the analyst may choose to make such an addition if subsequent data makes that a reasonable assumption. Finally, the "cost of malignant disease" function does not consider those patients whose prostate cancer is detected by PSA screening. These patients are in general sent directly for open prostatectomy. Screening is rapidly becoming common place. Therefore, it was not elected to consider PSA-detected cancers as part of the BPH simulation. However, should the analyst wish to assume that the work-up for BPH drives a percentage of PSA detected cancers, he is free to enter this assumption in the "cost of malignant disease" function.

The analyst is again advised to review the definition of cost functions and functions in which cost is to be found as an element in a ratio. This is so because, depending on what one wishes to include in the definition of "cost," results can vary. The BPH model presents many variants for calculating cost-benefit and other cost-related functions, and the analyst is advised to pay particular attention to the definition of any function he or she interrogates.

Simulation Results

Results from these simulations are summarized in Table 8. In the default mode, the model describes a fall in the total number of procedures for benign prostatic hypertrophy from approximately 330,000 in 1992 to approximately 270,000 in 1995, with a slight

increase to 298,000 by 1997. Thereafter, demographic pressures continue to increase the number to about 320,000 in the year 2005. This is still below the 1992 figure. This relative fall off in procedures is ascribed to improved patient education and the availability of pharmacological therapy. It can also be assumed that, as more patients present for radical prostatectomy (because of PSA screening induced demand), urologists may choose to perform that procedure in preference to TURP. The approximately 320,000 procedures which are expected to occur in the year 2005 will carry a cost of about $3.3 billion. At the same time it should be noted that, in the year 2005, the model in the default mode estimates that approximately 660,000 patients will be under treatment (either medically or surgically) for benign prostatic hypertrophy.

The availability of transurethral needle ablation (TUNA) technology can be simulated by scaling up availability from zero in 1996 to 0.9 in 2001 in the "TUNA availability" function and also increasing the "info TUNA" function to .91. Both these functions are found in the "demand and info FX" modules. The TUNA information function is designed to simulate the degree to which knowledge about the TUNA procedure and its outcomes is available to physicians and patients, while the TUNA availability function is designed to permit the simulation of the availability of the technology itself. If the 5-year repeat rate for TUNA is assumed to be 20%, then the total number of procedures for BPH predicted to occur in the year 2005 rises to approximately 444,000. Of these, 296,000 are projected to be TUNA procedures. Thus TUNA is anticipated to not only increase the total demand for procedures, but to displace to some extent transurethral prostatectomy. It should also be noted that in the case of TURP, repeat procedures over 5 years are less frequent than in the case of coronary artery disease. The model also suggests that the total number of patients under medical and surgical therapy will increase to 769,000 by the year 2005. This obviously assumes that TUNA is not only capturing some patients who previously would have received TURP but also has induced additional patients into the treatment paradigm including medical treatment. In effect, the model predicts a 16% increase in the total symptomatic BPH population presenting for procedure therapy. This data is not inconsistent with data from Israel and elsewhere suggesting there is a large untapped population with symptomatic BPH.

The total cost of procedure patients in the baseline simulation is $3.30 ± .306 billion (Mean ± S.E.M.) in the year 2005. With the introduction of the TUNA procedure, this cost is expected to fall insignificantly to $3.28 ± .256 billion. However, this is an aggregate cost of therapy. The total cost per procedure in the baseline state is $10,213, and this falls to $7,382 after the introduction of the TUNA. When per-patient costs are calculated, the per-patient procedure cost is $10,928 in the baseline case and $8,180 after the introduction of TUNA. Therefore, TUNA clearly produces a unit cost-saving, whether that unit cost is calculated per procedure or per patient. Because BPH therapy is in large degree "optional", the control of patient volumes is perhaps more easily achieved in the therapy of BPH than in the therapy of a life-threatening disease such as coronary artery disease. Therefore, any tendency to constrain demand increase following the introduction of TUNA could be expected to decrease aggregate procedure costs.

Estimates of costs in the BPH model are sensitive to the assumed cost of a TUNA as well as to its repeat rate. Of particular importance is the value assigned to the cost of physician time. This is an extremely difficult value to obtain, and physician charges vary widely. Nonetheless, the model uses a reasonable estimate based on Medicare-allowable charges and ambient charges in the community.

If one calculates the aggregate symptom score improvement following procedure therapy, one sees that this score increases from 3.48 ± 0.38 million units to 4.60 ± 0.17 million units. That is, the introduction of TUNA is associated with a net improvement in symptomatology score of about 30%. If one calculates the symptom score improvement per total dollars spent on procedures, this value rises from 1.04 ± .11 mil units per dollar to 1.40 ± .51 mil units per dollar. That is to say, the value obtained in terms of symptomatic relief per procedure dollar spent increases after the introduction of TUNA.

In summary, this simulation, albeit sensitive to estimates regarding TUNA repeat rates, physician- associated fees, and demand, predicts that the introduction of TUNA will hold aggregate costs constant while reducing unit costs. In addition, it will increase aggregate symptomatic improvement.

Table 8. Benign prostatic hypertrophy baseline simulation year 2000 results.

Total Costs of Patients Treatedwith a Procedure	$3.23 B ± .0269B
Aggregate Number of Procedure Patients	298,400 ± 2,756
Aggregate Number of Procedures	315,900 ± 2,901
Aggregate Number of Patients Treated Pharmacologically or with a Procedure	656,900 ± 2,719
Aggregate Improvement in Symptom Score Produced by Procedures	3.401 ± .369 million units
Improvement in Symptom Score Produced by Procedures Divided by Total Cost of Procedures	1.043 ± 10.112 milli units/dollar
Improvement in Symptom Score by Medical Therapy per Dollar Spent on Medical Therapy:	1.598 ± .0264 milli units/dollar

Sensitivity Analysis of TURP Repeat Rate

Evidence indicates that the rate of repeat transurethral prostatectomy for benign prostatic hypertrophy is falling. The analyst might properly wish to perform sensitivity analysis on the value of this rate. Historically, the eight-year repeat rate for TURP following an initial TURP for benign prostatic hypertrophy has ranged from about 20% in 1987

[Wennberg 1987] to a 1994 value of about 5.5% [Lu-yao 1994]. Lu-yao et al report a first year TURP repeat rate for BPH of about 1.3% and a five year rate of 5.3%.

In performing sensitivity analysis one must note that the default position of the BPH model is set at a first-year repeat rate of 1.26% and a five-year repeat rate of 12.6%. In the default mode the simulation predicts year 2004 total procedure costs of 3.23 ± .03 billion dollars. This cost is driven by 316,000 ± 3,219 procedures. If the Lu-yao figures are used (first-year repeat rate of 1.26%, five-year repeat rate of 5.5%) the total cost of procedures falls to $3.03 ± .025 billion. This figure is driven by a total of 295,000 ± 2,730 procedures. See Table 9 for a summary of these results.

Thus, the estimate of procedure cost and number of procedures is sensitive to the TURP repeat rate. Two conclusions can be drawn from this observation. First, the falling TURP rate (likely caused by increased education of the population regarding the cost and benefits of the procedure), coupled with the availability of pharmacological therapy has also been associated with a decrease in TURP repeat procedures (with additional savings). Second, this analysis confirmed that those technologies or interventions which reduce the need for repeat procedures (i.e. those that produce a durable result) have the potential to reduce costs.

Table 9. Sensitivity analysis of transurethral prostatectomy repeat rate: year 2005 results.

Total Cost of Patients Treated with a Procedure	**Aggregate Number of Procedures Performed**
(Assuming a TURP first year repeat rate of .0126 and a repeat rate years 4-5 of 0.113)	
$3.234B ± .031B	316,300 ± 3,219
(Assume a Year-One TURP Repeat Rate of .0126 and Year 4-5 Repeat Rate of 0.042)	
$3.028B ± .025B	295,200 ± 2,037

Note that when changing the five-year TURP repeat rate, one should also consider altering the "TURP redos" function in the "procedure functions" module. This is because the "TURP redos" contains preset repeat TURP numbers for the first six years of the simulation. Should the analyst wish to systematically change past and future estimates of TURP redo rates, he should consider changing the historical repeat rates included in this function. Also note that this function corrects the TURP five-year repeat rate to a six-year value.

The default mode of the benign prostatic hypertrophy model includes a gradual but modest phase-in of both TUNA and microwave procedures. This phase-in is accompanied by default mode repeat rates for each procedure. The analyst may prefer to zero out the introduction of these new technologies and use that state as baseline.

The distinction between aggregate number of procedures and aggregate numbers of procedure patients primarily reflects the number of patients who have more than one procedure in a year. If a patient returns for a repeat procedure in a subsequent year, he is counted as a procedure patient. If he has two procedures in a year, he is counted as one patient in the function "number of procedure patients" and as two procedures in the "number of procedure" function.

The symptom score calculations ascribe benefit to each patient who receives a procedure irrespective of whether it is a repeat procedure or a primary procedure. In other words, the duration of the symptom relief is not included in the symptom score calculation. This correction could be made by simply multiplying the improvement in symptom score for each treatment modality by a number equal to one minus the fraction of patients who will have repeat procedures in the time span under consideration. This has not been done in this function for two reasons. First, the correction is small. Second, the improvement in symptom score is derived from subjective judgments in the literature which vary considerably from study to study and indeed from patient to patient. Also, whether the negative value arbitrarily ascribed to those few patients who undergo procedural death is appropriate or not is debatable. For all these reasons the project team believes that future research will be required to further refine the changes in symptomatology associated with the treatment of benign prostatic hypertrophy, and it was elected not to elaborate on this point any further in the model. However, if an analyst wishes to model duration of symptom relief or a variety of utilities associated with the relief of particular symptoms, the model offers the opportunity to do this.

A Representative Simulation of the Introduction of Microwave Therapy

It is assumed that microwave therapy becomes available in the year 1996 and that its availability increases to a maximum of 90% in the year 1999 and thereafter. The first year repeat rate for microwave therapy is assumed to be 0.1, and the rate over years 2 through 5 is assumed to be 0.2285. With these assumptions, the year 2005 results of the simulation are as shown in Table 10.

Table 10. BPH simulation results from the introduction of microwave therapy.

Total Cost of Patients Treated with Procedure	$3.689B ± .0254B
Aggregate Number of Procedures	507,600 ± 3,738
Aggregate Number of Patients Treated with Procedure	467,100 ± 3,234
Total of Patients Treated with Either a Procedure or Pharmacological Therapy	822,100 ± 3,508
Aggregate Improvement in Symptom Score Produced by Procedures	5.961 ± .163 million units
Improvement in Symptom Score Divided by Total Procedure Cost	1.641 ± .0420 milli units per dollar
Total Improvement in Symptom Score in Pharmacologically Treated Patients per Dollar Spent	593 ± .0263 milli units per dollar

Simulation of the Introduction of Transurethral Needle Ablation (TUNA) as Therapy for Benign Prostatic Hypertrophy

In this simulation it is assumed that information regarding TUNA is available to 91% of patients and physicians. It is further assumed that the TUNA technology itself is available to no one in 1995, to 1% of the population in 1996, to 20% in 1997, to 70% in 1998, and to 90% of the population thereafter. The one-year TUNA repeat rate is assumed to be 0.068 and the repeat rate in years 2 to 5 is assumed to be 0.20. Year 2005 results are shown in Table 11 below.

Table 11. Simulation results from the introduction of transurethral needle ablation (TUNA) as a therapy for benign prostatic hypertrophy.

Total Costs of Patients Undergoing a Procedure	$3.326 ± .0249B
Aggregate Number of Procedure Patients	408,200 ± 3,050
Aggregate Number of Procedures	451,200 ± 3,620
Aggregate Improvement in Symptom Score Produced by Procedures	4.671 ± .166 million units
Improvement in Symptom Score by Procedures per Dollar of Total Procedure Cost	1.401 ± .0477 milli units/dollar
Improvement in Symptom Score by Medical Therapy per Dollar Expended on Medical Therapy	1.595 ± .0263 milli units/dollar

These data indicate that the introduction of TUNA is associated with an increase in total procedure costs driven in large measure by an increase in total procedure patients. Both cost per patient and cost per procedure fall significantly. Cost per patient falls from $10,839 to $8,137, for example. Thus the introduction of the TUNA technology clearly reduces unit cost while producing a modest increase in aggregate cost based on a large increase in the number of procedural patients. Symptom improvement per dollar expended on procedural care similarly rises, although it does not equal the benefit per dollar spent on those patients who are amenable to pharmacological therapy.

If the TUNA repeat rate is set to approximate the TURP repeat rate in the default mode, a slightly different pattern emerges. Specifically, when the first year TUNA repeat rate is set at 0.0131 and the repeat rate during years 2 to 5 is set at 0.113, the total cost of procedures falls to 3.099 ± 0.0221 billion dollars. The number of procedure patients falls slightly to 390,400 ± 2,990. This is because procedure patients in any one year includes some repeat patients from prior years, and as the repeat rate falls, the number of patients presenting for therapy in any year's cohort of patients declines. The number of procedures performed similarly declines to 416,700 ± 3,225.

This sensitivity analysis of the effective TUNA repeat rate clearly indicates that if ***TUNA repeat rate approaches that of TURP in prior years*** (recall TURP repeat rate appears to be falling), ***aggregate costs as well as unit costs will fall***.

This analysis states that the durability of a procedurally-derived result (i.e. the lack of the need for repeat procedures) can save money even in the aggregate. This occurs principally because patients are removed from the system and do not require follow-up therapy for the diagnosis in question.

Modeling of CAD Treatment Using ARENA

The platform chosen for the more detailed model was the Windows 95 compatible ARENA system. This is an elemental modeling system, meaning that one or a small cohort of patients of various composition are repetitively introduced to the model and outcomes determined on the basis of probabilistic methods. While relatively cumbersome to operate, the model has the advantage of providing fine detail. The fates of individual patients or patient cohorts can be interrogated and the status of patient cohorts at any given time can be learned. This is different from the Analytica system, which will only produce aggregate probabilistic outcomes for the entire population or define subsets of the population.

The goal of the ARENA modeling portion of this project was to define the system of relationships between the critical factors involved in the treatment of coronary artery disease (CAD) and to develop a simulation model to provide information to decision makers concerning the potential impact of changes to the system such as the introduction of new treatment technologies. A simulation model is a mathematical representation of a real world system that should imitate the behavior of the real system as long as all of the assumptions on which the model has been developed hold. Simulation is best suited for systems that are too complex for basic analytical tools, or for systems in which the interactions within the system are the focus of study. The study of the treatment of coronary artery disease fits both of these criteria. Although data analysis forms the foundation of any model, there are simply too many relationships involved to grasp overall behaviors and the impact of changes using analytical methods alone. Furthermore, many of the intricate relationships within the system are not exactly known but may be uncovered by the model itself while under development.

The product chosen for this modeling task was ARENA. It is a discrete event modeling package that has been actively developed by Systems Modeling Corp since the mid eighties. It runs under either Windows 95 or Windows NT on a 486+ computer with 16+ MB of RAM. ARENA was developed mainly for modeling manufacturing systems. However. it is very flexible and can be used for any modeling application. ARENA is basically a C shell that allows the programmer to write large complex routines by simply clicking on one of an extensive library of icons and then filling in the required blanks. ARENA also accepts user-written routines in C and in FORTRAN and has the ability to communicate directly with Microsoft database and spreadsheet applications. ARENA contains an extensive animation facility that allows the modeler to view displays of output while the model is running. This allows for constant monitoring of all model components, an effective aid during model development. It also contains facilities to generate most known mathematical functions and probability distributions and has an input analyzer that can develop distributions to be used in the model directly from raw data.

Project models are designed to forecast demand for treatment, make treatment decisions and then forecast treatment outcomes and future demand based on these outcomes.

ARENA allows the user to represent each individual patient by creating a database file to store unique demographic and clinical characteristics as well as complete treatment history. This allows us to simulate treatment decisions as well as forecast outcomes based on the complete set of significant factors as they simultaneously change over time. It also allows us to make technological changes that affect a very specific patient group. The model calculates the costs and the benefits of treatment and performs economic analysis of the treatment alternatives and the impacts of technology.

Modeling Methods

Population Demographics

The next step in modeling the treatment of CAD is to generate the population at risk. Analysis of nation-wide projections for invasive treatment of heart disease (not all of which is ischemic heart disease) revealed that over 90% of those currently being treated in the United States were above the age of 40. Therefore, we restricted our study to this portion of the population [HCIA NIP 1996]. Demographic tables were extracted from U.S. Census data to get the historical distribution of age of the American population [U.S. Bureau of Census 1994]. Aging chain theory was then used to forecast the population demographics until the year 2005. Calculations were verified against 5 year interval forecasts from the Census Bureau with minimal error (<0.05 for any given five-year interval). This analysis revealed that the surge in the birthrate between the years 1946 and 1965 was clearly visible in the data. This finding not only verified that we are faced with a changing distribution of age in the U.S., but it also gave us very accurate estimates regarding its magnitude. The surface plot in Figure 5 illustrates these findings.

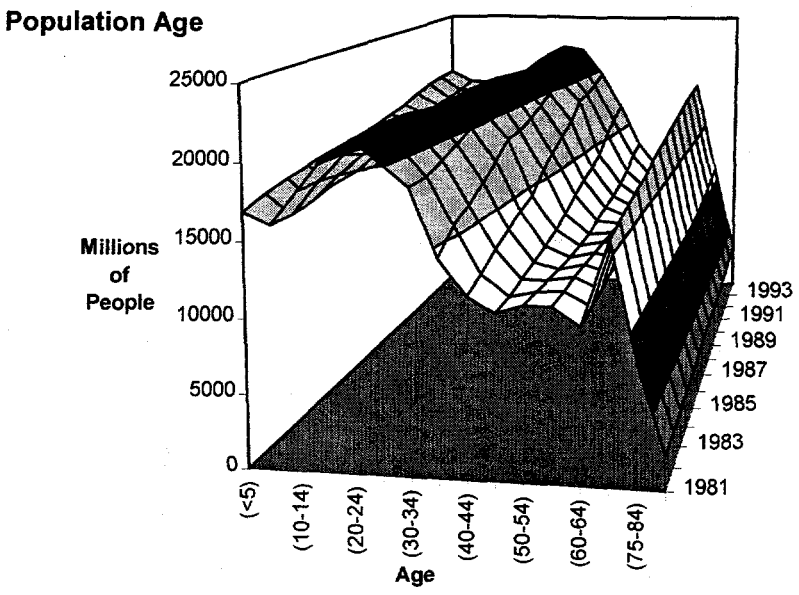

Figure 5. Distribution of age between 1980 and 1994.

The darker area represents the aging of the "Baby Boomers." From the historical trend, it is not difficult to see impact that this group has on the population. Furthermore, the eldest members of this group are just beginning to enter the high risk age groups for heart disease. During the next twenty years the number of people at risk for heart disease will grow by 50% (by conservative estimates). Although changing social attitudes toward low fat diets, regular exercise, and cigarette smoking will at least offset the progression of heart disease, the surge in the at-risk population will still have a significant impact on demand for treatment.

The age characteristics of the population have been incorporated into the model in the form of an 8X15 variable array named PopulationDemographics. The at-risk population (40+) has been divided into eight age groups: 40-44, 45-49, 50-59, 60-64, 65-74, 75-84 and 85+. The array contains the number of people in each age group, reported in thousands, from the years 1992 until 2006. The number of patients requiring treatment for heart disease that the population will generate is calculated based on this array.

Demand for Current Treatment Methodologies

Historical Analysis

Currently, experts speculate that 13 million people in the U.S. have coronary artery disease and that between 600,000 and 700,000 are being revascularized annually with CABG or PTCA. In order to determine the historical behavior of demand, a time series for the number of procedures performed was fashioned using three data sets (see Figure 6):

- RAND (1982-1987),
- National In-Patient Sample(1988-1991), and
- H.C.I.A. National Inpatient Profile (1992-1994).

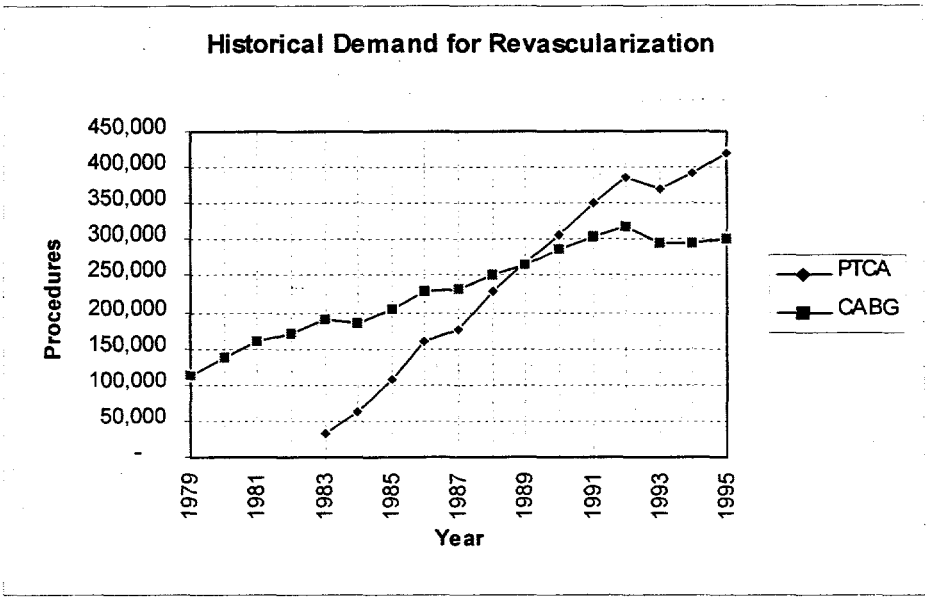

Figure 6. Historical demand for revascularization.

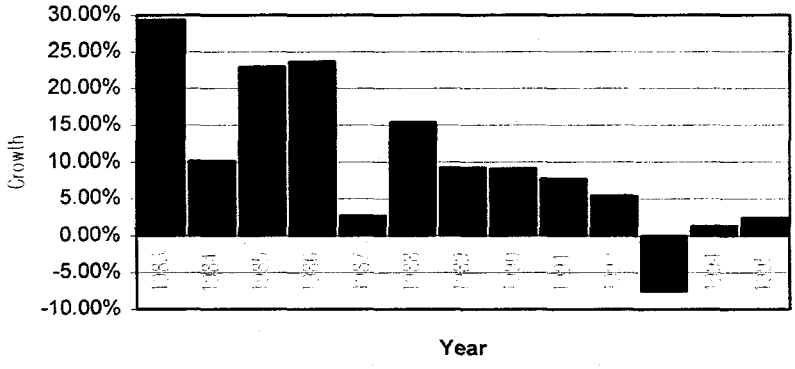

Figure 7. Growth of the PTCA market share.

Next, we controlled for population growth and compared the annual change in the growth rate of demand. This technique is more typically called a market share analysis. Some interesting patterns began to emerge for both procedures. First, as shown in Figure 7, the rates of change for demand for PTCA plotted from 1983-1995 follow a growth pattern which is extremely similar to the growth section of a standard product or technology cycle as it reaches maturity. Also, we know that the first PTCA was performed in 1976, so we can see that it has taken roughly 20 years to reach a point near market saturation.

This analysis gave us feasibility ranges for both the market growth pattern and the time until market saturation for a newly introduced, invasive, and technologically-intense health care product.

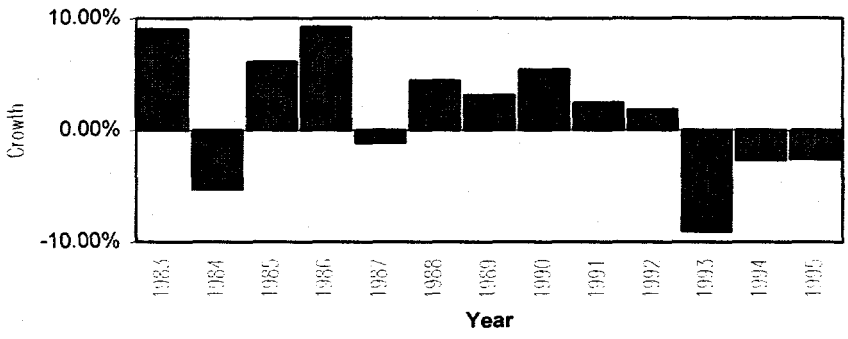

Figure 8. Growth of the CABG market share.

The same analysis was performed on the number of CABG procedures, and the rate of growth remained between +10% and -10% over the entire interval (see Figure 8). This is very similar to the range of growth at the end of the interval for PTCA shown above. Therefore, it appears reasonable to assume that this random pattern represents random market variation around a baseline level of saturation for these types of procedures. Also, during this period, PTCA and CABG (with very little variation) comprised all cardiac revascularization procedures, making them mutually exclusive and collectively exhaustive choices for treatment at any one time (rare patients will require an emergency CABG immediately following a failed PTCA). Furthermore, if we assume no inappropriate use of these procedures due to supply induced demand, we can then say that their combined usage represents the rate of baseline necessity for invasive cardiac revascularization. This is used as a baseline for modeling future demand.

Modeling

Modeling demand is a two step process. In the model, demand is ultimately determined by the decision module and by functions of the individual technologies. However, it is also necessary to first be able to control the number of patients entering the system within a reasonable range. The baseline necessity is calculated and then adjusted with linear combinations of a series of growth functions that mimic the historical patterns of PTCA and CABG. Baseline rates are adjusted for first year failure rates for both procedures to avoid double counting. Three functions were written to represent changes in demand using uniform probability distributions with parameters within a certain feasibility range:

- StableMarketGrowth increases demand randomly between 10% and 20%,
- MarketSaturation exactly imitates the behavior of CABG growth shown above, and
- StableMarketDecline decreases demand randomly between 0%-10%.

The parameters of each of these three functions can be redefined by the user and they can be combined with logical expressions to represent an infinite number of demand scenarios.

We thought that, in order to more accurately predict potential changes in future demand it was necessary to determine what makes these changes occur. At this stage, the model will give us accurate estimates of future demand. However, the model lacks the level of detail necessary to predict changes in demand from factors other than changes in population number and the effectiveness of the procedures themselves. Although these two factors are a major proportion of demand increase, we must decompose the components of demand further. There are several underlying factors driving the nation-wide demand for invasive healthcare procedures. First, there are ***regulations*** that constrain the demand for procedures prior to each state approving the technology. Next, there are the ***organizational factors*** within the hospital that determine whether each facility will acquire the new technology once it has been approved. Organizational factors include the number of specialists working within the hospital that desire the new technology and the capital budgeting policy of the owners concerning the requisition of new equipment. ***Competition*** from other area hospitals that possess the new technology as well as ***fear of malpractice suits*** for not using technologies (that may now be considered the most appropriate) will influence these capital budgeting decisions. Another factor that has a serious impact on demand is the ***method of payment*** for the new technology, which in most cases is based on the generosity of insurance coverage. When reimbursement for a technology is generous and prompt, the procedure will be used much more readily than a technology whose reimbursement is regulated by insurance companies or where reimbursement may be unsure due to lack of insurance coverage [Cutler 1996].

The current economic situation in the treatment of heart disease is quite complex. First, the growth in the number of hospitals acquiring PTCA as a new technology seems to have slowed with very similar behavior to the growth of total utilization of PTCA. Governmental regulation is no longer an issue, as PTCA has been available in the marketplace for long enough to be approved in all states where its use in desired. It is possible that PTCA has simply reached a level of total saturation; but it is also likely that the growth of PTCA is being slowed by economic pressures. Managed care organizations are applying extensive pressure to the level of reimbursement by scrutinizing hospital costs and by competitively shopping heath care products. At first, one might assume that these factors when combined will cause a definite decline in the number of PTCA procedures. However, there are more confounding factors involved. The number of cardiovascular specialist practicing in the United States has grown at twice the rate of other specialties and, according to our consultants, has quite probably grown to a level beyond necessity [U.S. Bureau of Census 1995]. Although the over-saturation of cardiologists may be accepted as fact, the impact that this phenomenon will have on future demand is still unclear. Many of these specialists will simply retire early, and many will be retrained. However, the clear issue is that the number of practicing cardiologists is going to decrease ***gradually*** over time until a more appropriate

equilibrium is reached. Therefore, it has been realized that it may be more appropriate to test the model under linear combinations of the various market condition functions written from the historical demand analysis rather than to attempt to mathematically predict this complex and definitely ambiguous set of relationships.

Treatment Decision Module

When cardiac revascularization becomes necessary, the decision of which treatment will be used is much more complex than it may appear on the surface. It depends a great deal on the demographic and clinical characteristics of the individual patient as well as their complete treatment history. The treatment decision must also be dynamic, having the ability to represent changing attitudes toward alternative treatments from the patient point of view and the physician's point of view. It must also be able to reflect the knowledge that will be gained from long-term clinical outcomes research. The decision whether to treat with CABG or PTCA is made using an adaptation of proportional hazards theory [Marshall 1994]. Many of the beta coefficients are calculated as a functions of time, and several coefficients are calculated based on the outcomes of the model itself. The probability of the individual patient having CABG vs. PTCA once revascularization becomes necessary is calculated using the following equation:

$$\mathbf{P(CABG|X)} = \frac{\exp(\alpha + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \ldots \beta_n x_n)}{1 + \exp(\alpha + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \ldots \beta_n x_n)}$$

Where $\mathbf{X} = \{x_1, x_2, x_3 \ldots x_n\}$

X is assumed to be the complete set of factors affecting this decision

$$\exp(\beta_i) = \frac{a_i * d_i}{b_i * c_i}$$

	Patient Charateristic	
Outcome	**Present**	**Absent**
CABG	a_i	b_i
PTCA	c_i	d_i

Static and Dynamic Treatment Decision Factors

Table 12. Static and dynamic treatment decision factors.

STATIC TREATMENT DECISION FACTORS		
Patient Demographics	**Odds Ratio**	β_i
Age (40-59)	0.65	-0.43
Age (60-64)	1.01	0.01
Age (65-69)	1.20	0.18
Age (70-74)	1.35	0.30
Age (75+)	1.25	0.22
Patient Clinical Characteristics	**Odds Ratio**	β_i
Male Gender	1.20	0.19
Single Vessel Disease	0.02	-3.78
Double Vessel Disease	5.98	1.79
Triple Vessel Disease	11.52	2.44
Four or More Vessels	16.44	2.80
Left Main Disease	9.79	2.28
NY Angina Class I & II	0.87	-0.14
NY Angina Class III & IV	0.69	-0.37
Ejection Fraction > 50%	3.06	1.12
Comorbid Conditions	**Odds Ratio**	β_i
Diabetes	1.24	0.21
PVD	1.06	0.06
COPD	1.00	0.00
TIA	1.32	0.28
Hypertension	1.18	0.16
Hypercholesterolimia	0.85	-0.17
DYNAMIC TREATMENT DECISION FACTORS		
Treatment History	**Odds Ratio**	β_i
Previous MI	4.89	1.59
Recent MI (30days)	1.00	
Acute MI (Currently)	1.00	
Prior PTCA	0.54	-0.61
Prior CABG <= 1	0.26	-1.34
Prior CABG = 2		
Prior CABG = 3		

Abstract Treatment Decision Factor Routines

Level of Invasiveness of Treatment

This variable was developed to emulate the patient's aversion to invasive treatment. Using a focus group of two cardiologists and a thoracic surgeon, a simple scoring system was developed so that treatment alternatives could be compared from the patient's point of view. CABG was given a score of 10, which was decided would be the maximum. PTCA was given a score of 4, and Mini-CAB, a minimally invasive bypass procedure currently being initiated, was given a score of 7. These scores are manipulated into the logistic regression format (by comparing their magnitudes), and a coefficient is calculated to influence the treatment decision toward the less invasive procedure. It should also be noted that the patients probably gauge the level of invasiveness for a procedure by the average length of the hospital stay. If all other factors are equal, every patient will desire the least invasive procedure. Therefore, there must be a factor to be used as a counter-weight to effectively represent reality. (Every patient does not choose the recommendation to have a PTCA). The other half of the treatment trade-off is the knowledge of the long term effectiveness of the procedure in the individual patient. In most basic terms: "How much is it going to hurt?" vs. "How well is it going to work?"

Knowledge of Long-Term Treatment Outcomes

It was necessary to incorporate components into the model so that the treatment chosen would be influenced by the results of the long term success rates of the procedures. This is done by incorporating a variable into the treatment decision that is based on the results of the model itself. Ten-year event-free survival rates of PTCA and CABG are logistically regressed, and the coefficient is used in the initial treatment decision as well as in the treatment decisions contained in the outcomes modules. The magnitude of this coefficient has been constrained to reflect the presence of the learning curve. (The results of a ten year cohort study would not be available for 10 years. However, there would be preliminary reporting that would give some indication of the final results.) Because the treatment decision is in many different places in the model which represent different points in history, it has been written as a function of time so that each decision module will make the appropriate decision for its particular point in the future.

Potential Changing Practices in the Treatment Alternatives

Until recently, the use of PTCA was considered appropriate only in cases of a single blockage and in cases in which the patient was not suitable for surgery because of acute myocardial infarction or comorbid conditions. An analysis of the 1994 HCIA National Inpatient Profile showed that 85% of PTCA procedures coded were performed on a single

artery. Furthermore, partially due to the fact that CABG is not considered appropriate to treat a single blockage except in the case of the left main coronary artery, we found that 90% of procedures performed on single vessel disease were PTCA. More recently, PTCA has gained acceptance for use in multiple vessel disease. This potential change in practice may be evolving for several reasons. First, the catheters used in PTCA have seen technological advancements, giving cardiologists the ability to reach more arteries. Second, because PTCA is much less invasive than CABG, it is a very attractive alternative to the patients when presented with the options. It may be due to the growth in the number of cardiologists in America. No matter what the reason, the current literature on the treatment of coronary artery disease is replete with randomized clinical trials comparing the outcomes of PTCA and CABG in multiple vessel disease.

The coefficients for the number of diseased arteries have been made variable and are re-calculated annually. Routines have been written that will bring PTCA and CABG usage to a user-defined equilibrium over a user-defined period of time. Each year, the regression coefficients are driven asymptotically closer to 0, making the treatment decision indifferent to the number of vessels diseased. This gives us very accurate emulation of the phenomenon that will take place if PTCA becomes more accepted in the treatment of multiple vessel heart disease. We performed logistic regression of the HCIA Patient Level Data from All-Payer States [HCIA PLD 1996]. The results revealed the number of vessels diseased to be the most statistically significant of all of the independent factors as well as the coefficients with the largest values. This analysis verified that the number of arteries diseased is the most important factor in the decision whether PTCA or CABG is chosen as a treatment.

Treatment Outcomes Module

Basic Structure

There were many issues involved with modeling medical treatment outcomes. The first issue concerned the length of the time frame that would be used. When modeling population dynamics, it is necessary to be able to represent the entire lifetime of each individual, and therefore their complete lifetime of treatment. The amount of time between the age of the average heart disease patient and average "all cause" mortality in America is about 25 years. There was no shortage of detailed information on long-term outcomes for both PTCA and CABG in the medical literature. However, the longest study for CABG was 15 years [Weintraub 1994] and the longest for PTCA was 12 years [Mick 1994]. Fortunately, event rates for both procedures were extremely regular and fell well within the limits of what could be considered mathematically predictable. Also, plots of outcome curves for both PTCA and CABG were uniform across many studies.

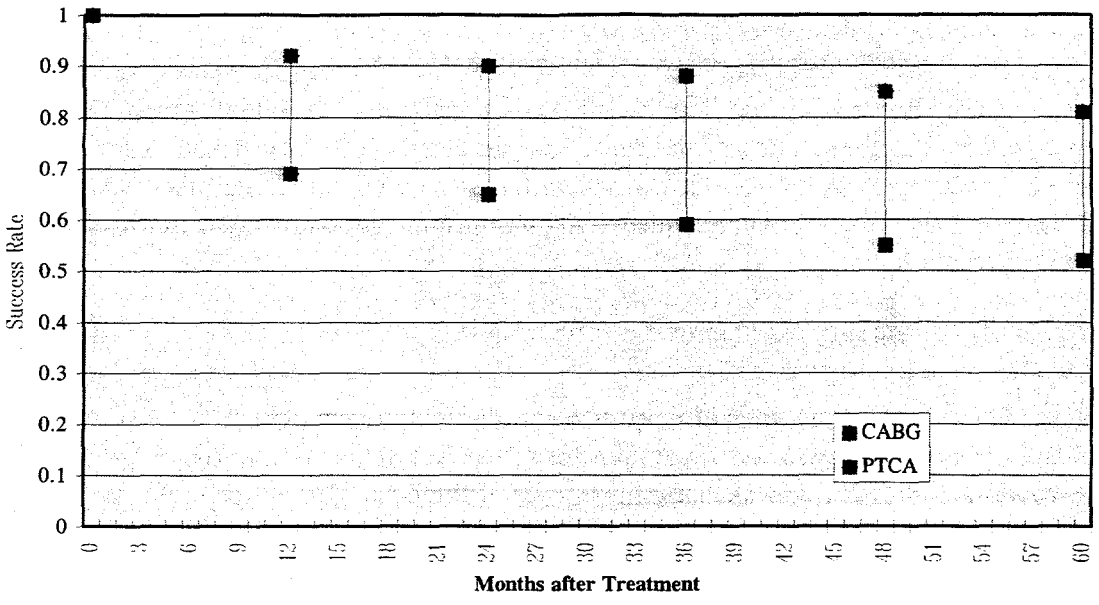

Figure 9. Event-free survival after treatment.

At this point several differences in the outcomes for these two procedures became apparent. First, the rate of myocardial infarction after both procedures is very similar. Second, the rate for repeat procedures after PTCA and the rate for repeat procedures after CABG are very different. The first year failure rate for PTCA is consistently reported between 20% and 30%, and for CABG it is between 5% and 10% (see Figure 9). By 5 years, the probability of failure for PTCA has risen to over 50% in most studies, and the probability for failed CABG has remained below 20%. The standard reporting method for procedure outcomes monitors the proportion of the treatment population of the population free from major post treatment events, which exactly defines the inverse of the "first failure" event rate. For PTCA and CABG, post treatment events are defined as myocardial infarction, repeat PTCA, repeat CABG and death. The difference in the points plotted above represents the difference in effectiveness between CABG and PTCA, or from a purely mathematical viewpoint, the proportion of post treatment cardiac events that could be avoided if CABG were used exclusively.

Many of the studies provided data (for each of the four post procedural events) for the population broken down by many of the patient characteristics of interest. This allowed us to again use proportional hazards theory to more accurately predict outcomes given the characteristics of the individual patient. The modeling theory used for the outcomes module was designed to be identical to the cohort studies used in its development. At certain time intervals, each patient is checked for status and, based on historical cohort studies and their given set of characteristics, they will either remain free from cardiac events or they will not (dichotomy). A standard decision tree process is used to represent this concept. The one drawback of proportional hazards theory is that it is based on a

terminating event. The theory does not necessarily hold for multiple events, probably because with multiple events there is some level of dependence that must be defined [Blackstone 1996]. There has been excellent work in this area. However, no exact solutions are known. We handled this situation by running the model (assuming independence) and constraining the risk of future events until a verifiable distribution of lifetime events prior to mortality was reached. It should be noted that this could be a way to determine the level of dependence between multiple cardiac events and may warrant further investigation.

Effects of Technology on Treatment Effectiveness

Since the long term outcomes of various technological improvements for PTCA and CABG are still unknown, it is most appropriate to let the user define the desired level of improvement in effectiveness using the curves of the basic known technology as a baseline. There are several dimensions that must be considered when analyzing the impact that a new technology will have on treatment outcomes. First, there is the maximum potential reduction in the cardiac event rate that new technology will have. Second, this potential must be constrained to effectively represent infusion of the technology into the marketplace. Third, it must also be constrained by the learning curve to represent the fact that more experienced specialists produce better outcomes results. Logistic growth equations using the maximum potential effect as a threshold were used. Examples are given below for the impact of cardiac stents.

Calculation of Treatment Cost

Treatment cost for both PTCA and CABG are estimated using the HCIA data set which provided discrete distributions of charge (quartiles) for each ICD-9 procedure code [HCIA PLD 1996]. These discrete distributions were then converted to continuous charge functions in an attempt to create a more accurate representation of the original data. Cost must be calculated from charge using global cost-to-charge ratios. It was necessary to use a bottom-up order in our analysis because health care research report findings in terms of charge, not cost. Charge is simply much easier to verify than cost. The model is set to use the global cost-to-charge ratio of 0.67. However, this variable can be changed at the user's discretion to reflect potential cost savings.

Analysis of CAD Model Output

Generating Output with the ARENA Model

The CAD model automatically generates output reports in Microsoft Excel file format so that they be easily analyzed using a spreadsheet tool. A report template has also been included so that data can be cut and pasted from a raw data file into an easily readable report. The report contains annual figures on demand, hospital charges and costs, professional fees, QALYs and net benefit. The report is divided into 8 sections: Primary

CABG, Repeat CABG, Total CABG, Primary PTCA, Repeat PTCA, Total PTCA, Total Procedures and Dissection of Demand. A report template has also been included that will automatically generate the means and 95% confidence intervals for the entire output report.

Baseline Results and Confidence Intervals

The ARENA model was developed using studies from a certain technological era. Therefore, in its baseline state, it reflects the outcomes from that era. All of the routines that affect the treatment decision and the outcomes are deactivated. This scenario addresses the question, "Given zero change in technology, where will the system be in 2005?" Twenty replications of this "baseline scenario" were run and 95% confidence intervals were calculated on the output. The results are represented in the following figures.

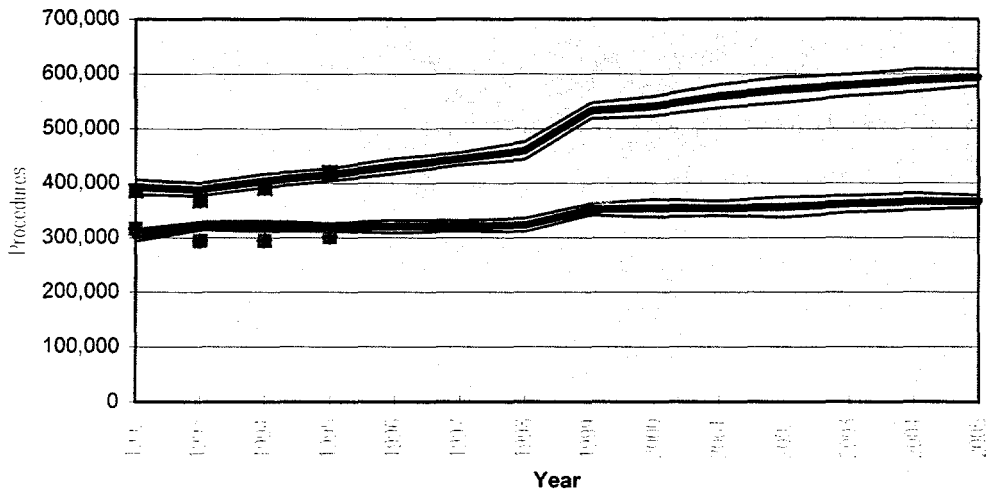

Figure 10. Demand for revascularization.

As shown in Figure 10, the model indicates that by year 2005 demand for revascularization procedures will grow to 960,153 ± 8634 procedures, comprised of 593,733 ±15,256 PTCA (upper) procedures and 366,642 ± 10,910 CABG (lower) procedures. The plotted points represent the number of procedures taken from the historical demand analysis for the years data were available. These data verify that, at least during the period of known history, the model is working well. The thin lines, which represent the 95% confidence interval around each mean (thick line) show how little variation the model generates between replications. It should be noted that, at the baseline, demand is assumed to be fully saturated at 1992 rates and that increases in demand are due exclusively to population growth.

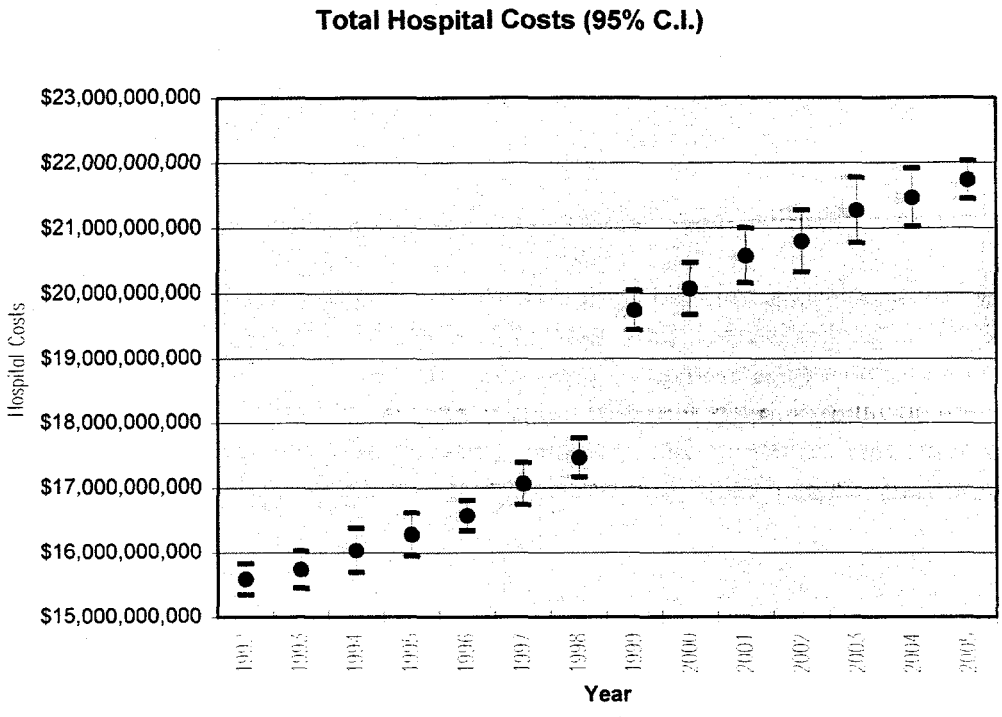

Figure 11. Hospital costs as a function of time.

The diagram in Figure 11 illustrates the mean and 95% confidence interval on total hospital costs at the baseline. According to the model, hospital costs will rise from a current level of \$17.1 $\pm$ 0.161 billion to 21.7 $\pm$ 0.144 billion by the year 2005 if technology and demand rates remain at current levels.

We have learned from history that a new technology will increase demand for treatment and therefore increase total costs. However, if this technology has the ability to decrease treatment failure rates by a magnitude greater than the increase in demand, and re-treatment is a major portion of demand, then such a technology has the potential to actually decrease demand and have a negative impact on total treatment costs. This may be the case with PTCA. Approximately 25% of all PTCA procedures performed will fail in the first year, generating demand for another procedure in the same year.

Sensitivity Analysis

Potential Effects of Coronary Stent

The literature shows that coronary stents have the potential to decrease PTCA failure rates and therefore constrain demand [Fichman 1994]. To test the impact of the introduction of the coronary stent, the following scenario was produced. We assumed that the near-perfect coronary stent would have the potential of reducing the failure rate

of PTCA by 30%. Demand was fixed at baseline rates and the model was run, decrementing the failure rate of PTCA in 2% intervals until the near perfect 30% reduction was reached. Saturation level was set at 85%, to be reached within 10 years. The learning curve was also set to 10 years and the price for the stent to $3,000. The surface plot in Figure 12 below illustrates the impact that this scenario would have on total demand for revascularization.

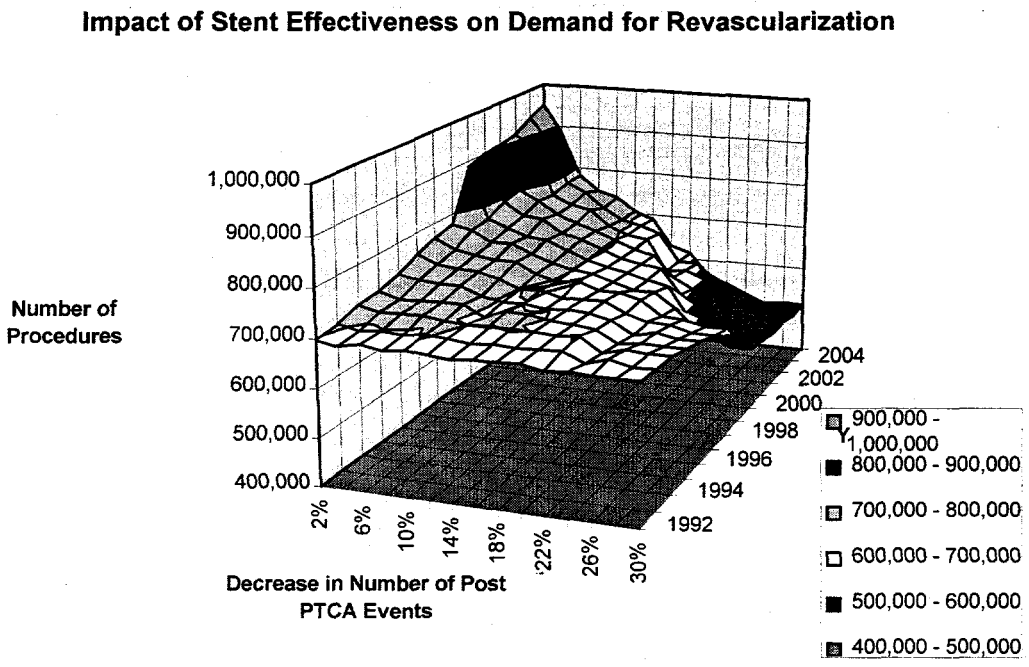

Figure 12. Impact of stent effectiveness on demand for revascularization.

The model indicates that, by the year 2005, demand for revascularization could be reduced to 513,000 procedures at a total cost of around $13.15 billion. This is quite a significant decrease in demand, and cost is actually reduced from present values. In reality, demand cannot be constrained at current levels, and market factors will tend to obstruct the level of cost savings. Therefore, these numbers should only be viewed as indicating the potential for cost reduction along with the general magnitude of that reduction.

Sensitivity analysis was also done to test the impact of the price of the coronary stent on total cost. The stent price was reduced from $3000 to $1500 in increments of $200, holding demand and current levels of effectiveness fixed. The price of the stent will have very little impact on overall cost when compared to the other factors. In fact, the average PTCA has a mean price of $17,000 and professional fees of $6700, so a total unit change of $1500 yields little savings, and incremental changes of $200 have little effect. The situation is different if multiple stents per patient are used.

Potential Effects of Laparoscopic CABG

According to expert panel members, the Laparoscopic CABG will be very similar to a normal CABG. It will cost virtually the same, and the average hospital stay will be decreased by only a few days (not accounting for outliers from increased hospital stays due to complications). The major difference is in the time it takes to return to normal activity and to work. The sternum is divided during a CABG procedure, and it takes 6 weeks for bone to completely heal. Because the laparoscope eliminates the necessity to divide the sternum, full recovery will be achieved much sooner for most patients. Although the Mini-CAB is still more invasive than PTCA, it offers the superior outcome results of CABG. A sensitivity analysis was run, introducing the Mini-CAB, with a 10-year infusion period to reach an 85% market saturation point. Like the cardiac stent, we assumed a maximum potential to reduce post procedural events by 30% and a learning period for the new technology of 10 years. The model shows that the Mini-CAB has the potential to reduce demand to 726, 900 procedures at a total cost of $17.9 billion. (This assumes that all patients are candidates for Mini-CAB, which is currently not the case.) The impact on both demand and total cost was much less than that of cardiac stents. This was true for a number of reasons. First, because CABG has significantly lower failure rates than PTCA, the impact made by the same rate of reduction is significantly less. Demand is 200,000 procedures lower than baseline by 2005 because a more effective substitute has been offered for PTCA, not because CABG has become more effective. Mini-CAB requires fewer repeat procedures than PTCA, but it is more expensive.

Modeling of BPH Treatment Using ARENA

Modeling Methods

Population Demographics

The population at risk of BPH falls within the same age demography as those for heart disease. However, BPH only affects males. The proportion of males in the population was determined, and the base population through the year 2006 was calculated from the base population calculated for the CAD model. It should be noted that an update of the Statistical Abstract contained new tables with the level of detail necessary for our model. However, because our calculations were well within the accepted error of the forecasts produced by the Census Bureau, we left the tables unchanged.

The patient characteristics of interest in the model are the symptoms which are commonly accepted by the American Urological Association (AUA) when evaluating prostate function. These symptoms include

- nocturia (frequent urination during the night),
- dribbling,
- hesitancy,
- straining, urgency,

- stopping and starting,
- incomplete emptying, and
- weak urine stream.

Using these characteristics, the model calculates the AUA symptom score and the AUA obstructive score [Garraway 1994].

Patient characteristics that directly affect patient quality of life are also accounted for in the model. These include

- sleeplessness,
- the necessity of limiting fluids before bedtime and travel,
- limiting travel to 2 hours, and
- avoidance of certain activities.

These characteristics are used to generate the AUA bothersome score, which is a widely used gauge for quality of life of patients with urinary conditions. Clinical variables of interest include the size of the prostate, the peak urinary flow rate, and the maximum urinary volume that can be retained. Estimates of the prevalence of these characteristics in the population were extracted from published population-based studies [Chute 1993].

Patient generation routines used in the BPH model are more advanced than those used the CAD model. The BPH model generates the entire male population of North America (1=1000 scale), urinary symptoms are assigned, and logistic regression is used to determine if each individual has BPH. Because we are modeling the entire diseased population, prevention can now be represented, at least in terms of potential changes in urinary symptomology.

Demand for Current Treatment Methodologies

Analysis of current utilization for treatment of BPH was much more complex than for CAD. Open prostatectomy and transurethral resection of the prostate are used to treat prostate cancer as well as BPH. Therefore, it was necessary to determine exactly what proportion of these procedures were being performed exclusively for BPH. An analysis of patient level data from HCIA [HCIA PLD 1996] revealed that 87% of TURP's are performed on patients for BPH only, but only 5% of Open Prostatectomies are performed on patients with BPH only (see Figure 13). A similar situation was discovered when investigating the drug treatment, because the alph-adrenergic blocking drugs (e.g. Hytrin) are also used as a treatment for hypertension. Utilization for both Hytrin and Proscar were determined from analysis of a report of pharmaceutical utilization ordered from IMS America, Inc. This analysis revealed several things. There has been a major decrease in utilization of the more invasive treatments for BPH. This is due in part to increased levels of education concerning the adverse outcomes associated with invasive treatment and the likely outcomes of non-procedural therapy. Medical treatments have become a welcome alternative, seeing growth in utilization over the same study period. In fact, the growth in drug use more than compensates for the decline in surgical procedures.

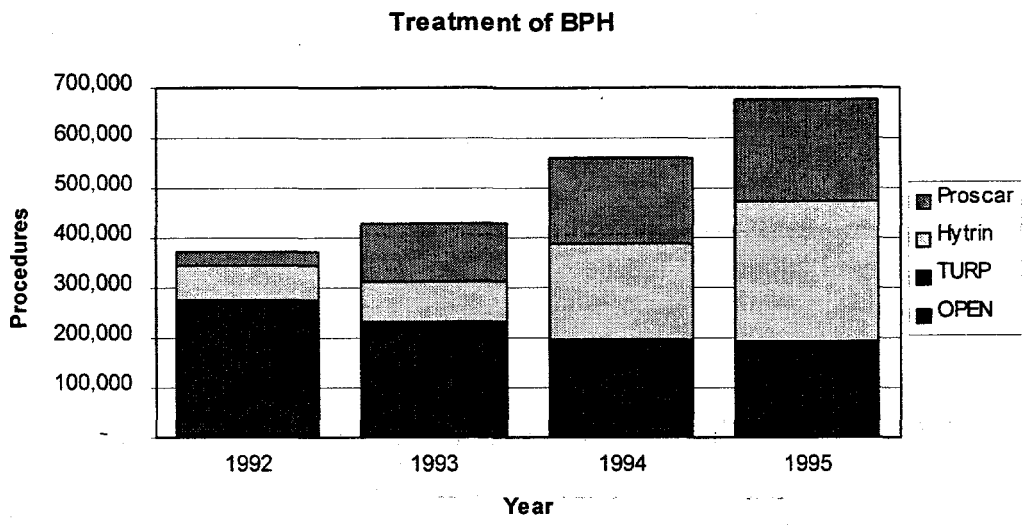

Figure 13. Procedure distribution for the treatment of BPH.

Treatment Decision Module

Treatment selection for the BPH model differs from the CAD model in several ways. First, because BPH is not life threatening, the decision to treat becomes an issue of quality of life rather than necessity. Because of this fact, the choice of treatment (or whether to treat at all) is to a large extent determined by the individual priorities of the patient as opposed to being solely determined by the physician (critical pathways). Also, the BPH model has eight alternatives. These include five invasive treatment options: open prostatectomy, transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), transurethral needle ablasion (TUNA), and transurethral microwave therapy (TUMT) as well as two drug treatment options: an alpha adrenergic blocking agent (e.g. Hytrin) and an α–reductace inhibitor, Proscar. The final alternative is to monitor the patient for worsening symptoms, but not to treat at the current time (watchful waiting). Because the treatment decision for BPH is not a dichotomous decision like the choice between PTCA and CABG, logistic regression theory does not apply. The method used is an adaptation of benefit/ regret analysis taken from widely-accepted decision theory.

First, the expected benefit for each treatment alternative is calculated using the potential for beneficial outcome and the magnitude of the potential benefit. The unit measure for benefit of treatment in the BPH model is a reduction in the AUA symptom score. Next, expected regrets are calculated using the probabilities of adverse events and post treatment urinary complications for each treatment alternative. Because each individual patient has a different set of priorities, benefits and regrets are then weighted using a system developed from a ranked list of patient preferences. These scores are then constrained to reflect the level of actual knowledge (Education of Fact) available for each treatment. Benefit scores and regret scores are then combined to create a composite

expected outcome score for each treatment. The treatments are then ranked according to score and checked for availability for each individual patient. The treatment with the highest score that is currently available is chosen.

Treatment Outcomes Module

The treatment outcomes module in the BPH model is very similar to the treatment outcomes module in the CAD model, with a few exceptions. Because there are not definite events associated with BPH, we have defined treatment failure as no change or an increase in the AUA symptom score. The time frame has also been shortened to 15 years because the ***average patient treated for BPH is 10 years older than the average patient treated for CAD***. The analyst using the BPH model should be aware of the fact that long term clinical results for many of the treatments studied were unavailable. Therefore, the long-term risk of failure was mathematically extrapolated from short term studies. As long-term clinical data becomes available, the model should be updated to increase the accuracy of the results.

Analysis of BPH Model Output

Figure 14 below illustrates the number of procedures that the BPH model predicts along with the historical data (single points of the same shape) taken from our demand analysis.

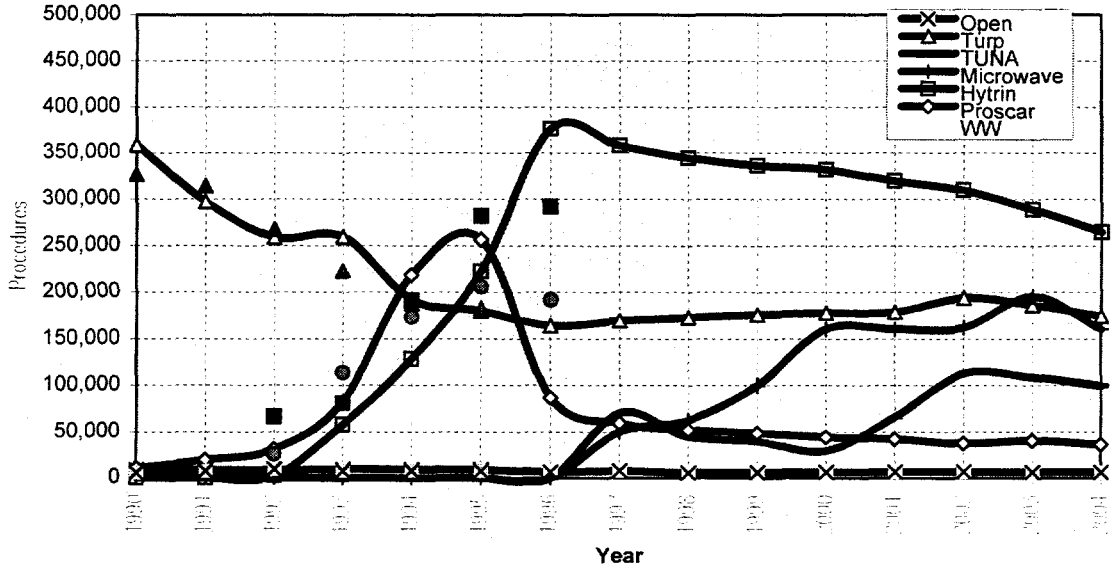

Figure 14. Validation of BPH model data.

The model predicts demand for the invasive treatments (TURP, TUIP and open prostatectomy) with excellent accuracy. The demand for the drug treatments is not quite

as accurate, but acceptable for modeling purposes. The objective was to create the current market framework so that the introduction of TUNA and TUMT can be studied in this multiple alternative environment.

The model predicts that, by 2004, total demand for treatment of BPH will reach 582,300 procedures at a total cost of $1.56 billion. Although demand for treatment has increased from a predicted 324,800 in 1990, total cost has decreased from the predicted $1.95 billion in 1990. This is due in part to the introduction of cost saving TUNA and Microwave treatments. However, the majority of the savings are due to the introduction of drug treatments as an alternative to invasive procedures. With the introduction of Proscar and Hytrin, the number of TURP is reduced. This is predicted by the model and verified by the historical data. The model does not directly indicate that the potential benefits of TUNA and TUMT will decrease the number of TURP procedures further. Instead, they will become a more attractive alternative for those already being treated with drugs. It should be noted, however, that without the introduction of medical therapy for BPH, the number of TURP procedures would have continued to rise. Also, medical treatment for many patients is only temporarily effective in reducing symptoms. Therefore, the patients being drawn from drug treatment in the latter part of the time frame to have a TUNA or TUMT are patients that would be having a TURP if the TUNA and TUMT were not available. Furthermore, they would have had a TURP originally if the drug treatments were not available.

Chapter 3 - Technology Road Mapping

Description of the Top-Down Approach

*This study's Top-Down Approach developed **Biomedical Technology Roadmaps** for eight innovative biomedical technology areas with the potential to reduce U.S. health care delivery costs while maintaining (or improving) care quality.*

The Top-Down Approach to the study used Prosperity Games to identify eight areas where Technology Roadmaps could be developed. Prosperity Games are executive-level interactive simulations that explore complex issues in a variety of economic, political and social arenas. The simulation provided participants (about 70-80 total) with an understanding of some of the obstacles and opportunities associated with current and proposed technologies. For example, problems and opportunities faced by doctors and other health care providers, patients, technology developers, the military, regulators, legislators, insurance agencies, lawyers, and other stakeholders in the biomedical engineering field were explored.

The Biomedical Prosperity Game was co-sponsored by the US Army Research and Materiel Command, the Department of Defense Advanced Research Projects Agency (ARPA) and the Koop Foundation, Inc.. These co-sponsors are leaders in advancing the development and introduction of biomedical technologies. Their co-sponsorship was an important means for pooling resources to achieve each organization's similar goals for lowering the cost of and improving the quality of future biomedical technologies.

The product resulting from the Prosperity Game was a Biomedical Technology Outline along with development objectives for eight innovative biomedical technology areas with the potential to reduce care delivery costs while maintaining (or improving) care quality. The Game's atmosphere reinforced a consensus about the important technologies and their development objectives. It also helped develop relationships, partnerships, and a cooperative spirit among the stakeholders of the major biomedical technology and techno-policy related areas.

The Prosperity Game was followed by a Technology Roadmap workshop. The workshop was held March 1996 and was attended by about 150 persons with particular expertise in the identified biomedical technology areas. Participants in the Workshop developed the Biomedical Technology Roadmaps, which are considered to be the important deliverable from this study's Top-Down Approach.

The Biomedical Technology Roadmaps identified those technology advances that are needed to "leapfrog" present concepts, reduce health care costs and maintain or increase present levels of quality. The essential components of Technology Roadmaps address

- Requisite resources,
- Cost goals,
- Quality goals,
- Time goals, and
- Critical infrastructure and core competency needs

(among other important parameters) for the introduction and application technologies in the US health care system.

The Sandia team that developed the Biomedical Technology Roadmaps has a broad, technical systems background. To date, the members of the team have addressed roadmaps for other complex issues in U.S. Infrastructure, electronics manufacturing, environmental technology, global economic competitiveness, university business school education, the restructuring of the Department of Energy and its National Laboratories, petroleum drilling technologies, and Department of Defense sensor systems.

The broad acceptance and buy-in gained in the development of the Roadmaps by the participating stakeholders will be important for launching the partnerships and alliances necessary for carrying out the Roadmaps. Ownership by the broader biomedical industry is key to deriving the full benefits of the Roadmaps. Each participant in this development process has been encouraged to support consortiums and work groups that can provide the execution and follow-up of the Roadmaps. In addition, the Roadmaps could provide a framework for organizing a national initiative in biomedical engineering technology.

The following sections provide additional detail on these concepts related to the development of the Biomedical Technology Roadmaps.

Introduction to the Biomedical Prosperity Game Concept

Prosperity Games simulate and explore complex issues.

A Prosperity Game is a new type of forum for simulating and exploring complex issues in a variety of areas including economics, politics, sociology, environment, education, research, health care, etc. The issues can be examined from a variety of perspectives ranging from a global, macroeconomic and geopolitical viewpoint down to the details of customer/supplier/market interactions in specific industries. The concept originated in meetings with the staff of New Mexico Senator Jeff Bingaman, with Lee Buchanan of the Advanced Research Projects Agency (ARPA), and with other government and industry leaders. The conceptual implementation has been further developed by former Sandia National Laboratories employees, J. Pace Vandevender and Marshall Berman, to address a wide variety of applications.

Prosperity Games are an outgrowth of move/countermove and seminar war games. They are executive-level interactive simulations that encourage creative problem solving and decision-making, and explore the possible consequences of those decisions in a variety of economic, political and social arenas. The simulations are high-level exercises of discretion, judgment, planning and negotiating skills; they are not computer games. They explore the challenges and opportunities faced by businesses, government, laboratories, universities and the public.

Ten previous Prosperity Games have explored environmental issues, economic competitiveness in electronics manufacturing and information technology, university business education, the business case for diversity, and the relationships of the Department of Energy National Laboratories. This was the first Game designed to address biomedical technologies. A recent Prosperity Game also explored national security issues affecting U.S. Infrastructure

Gaming Theory

In mathematics, game theory is the study of strategic aspects of situations of conflict and cooperation. Game theory approaches conflicts by asking a question as old as games themselves: "How do people make 'optimal' choices when these are contingent on what other people do?" (see Brams 1993). Game theory originated with the mathematician John von Neumann as early as 1928. The collaboration of von Neumann on theory and Oskar Morgenstern on applications to economic questions led to the seminal book *The Theory of Games and Economic Behavior* (see von Neumann) that first appeared in 1944, and was later revised in 1947 and 1953. Game theory is an approach to developing the best strategies to beat a competitor or enemy.

The Biomedical Prosperity Game involved look-ahead strategies

A game is defined by a set of rules that specify the players, their desired goals, allowed interactions, and a method of assessing outcomes. There can be one or more goals with different levels of importance. The players adopt strategies, and the interactions of the "moves" based on those strategies lead to outcomes which may or may not be consistent with the players' goals. Complex games involve look-ahead strategies that address the different possible moves that an opponent could make. It is important to try to understand an opponent's goals in order to maximize the probability of a favorable outcome. Games can be sequential, with player interaction allowed between moves.

Objectives of the Biomedical Prosperity Game

The Biomedical Prosperity Game© produced the following specific and general accomplishments:

Identify critical technology issues that affect the cost and quality of health care.

SPECIFIC ACCOMPLISHMENTS:

- Identified advanced/critical technology issues that affect the cost and quality of health care.
- Explored the development, patenting, manufacturing and licensing of needed technologies that would decrease costs while maintaining or improving quality.
- Identified policy and regulatory changes that would reduce costs and improve quality and timeliness of health care delivery.
- Identified and applied existing resources and facilities to develop and implement improved technologies and policies.
- Developed a Biomedical Technology Roadmap for industry and government cooperation.

GENERAL ACCOMPLISHMENTS:

- Developed partnerships, teamwork, and a spirit of cooperation among health care consumers and providers, researchers, regulatory agencies, industry, government, and other stakeholders in the health care system.
- Increased awareness of the needs, desires and motivations of the different stakeholders.
- Brought conflict into the open and managed it productively.
- Explored long-term strategies and policies.
- Provided input for possible future legislation.
- Stimulated thinking.
- Provided a potentially life-altering learning experience.

The Game explored biomedical technology simultaneously from three points of view, that of consumers, providers and the nation. The **consumers** represented patients and their problems (including diseases and disabilities), costs for services as well as insurance, treatment options, and overall quality of care and quality of life. All **providers** and related organizations involved in health care were represented including doctors, hospitals, research organizations, manufacturers, and the problems they encountered such as costs, delivery systems, regulations, research and development, etc. Since health care costs consume 14.1% of US gross domestic product and 18.5% of total public spending, this area is of utmost importance to the **nation**. Health care costs are also reflected in the costs of all products and services, and affect our ability to compete internationally. Hence, private and public representatives of national stakeholders (including legislators, insurers, government customers and payers, lawyers, etc.) where included in the Game.

Over the course of the Game, patients developed diseases, disabilities, and aging problems that where treated by doctors and nurses using available technologies, and new technologies developed during the Game. Suppliers, manufacturers, congressional

representatives, researchers, national laboratories, regulators, lawyers, insurance companies, finance, and news media played their real-life roles.

Results of the Game were combined with the expertise of a large group of health care professionals and stakeholders to create Technology Roadmaps for the future of the health care system in biomedical engineering.

Biomedical Prosperity Game Description

Biomedical Prosperity Game Teaming Groups

The Game incorporated eleven basic teams:

- **Consumers** representing patients from all demographic groups in the US.
- **Two Provider** teams. One representing independent physicians and hospitals and IPAs (Independent Practice Associations) who bill on a fee-for-service basis, and the other representing Health Maintenance Organizations (HMOs).
- **Insurance Payers** representing private and public (Medicare, Medicaid) insurance organizations. Large companies were also represented in their role of insurance providers.
- **Legislators** representing the US Congress and State legislatures.
- **Suppliers/Manufacturers** representing companies that make and sell biomedical devices and equipment.
- **US Food and Drug Administration and State Regulators**
- **Planning/Funding Organizations** representing the private and public (including the Department of Defense, National Science Foundation, private foundations, etc.) organizations that provide resources to fund research and development of new biomedical technologies and that perform strategic planning.
- **Universities/Laboratories** that perform the research and development of new technologies.
- **Lawyers** that provide consulting and legal assistance to all parties.
- **A Control Team** that directed the conduct of the Game, resolved all disputes, and played all other roles required in the Game including that of financial institutions, news media, scientific publications, foreign countries, polling, computing, etc.

It should be noted that every Prosperity Game is unique because the outcomes depend on the players. Players were selected to represent their real-life roles as faithfully as possible. Their creativity and commitment to the simulation determine the success of the Game.

Technology Areas Addressed by the Biomedical Prosperity Game

The players were encouraged to develop innovative technologies across a broad set of biomedical technology areas. These areas were grouped into the following preliminary categories as a starting point for the players' consideration:

1. Advanced diagnostics
2. Assistive technologies for the elderly and disabled
3. Energy delivery devices (lasers, ultrasound, etc.)
4. Health Informatics
5. Microelectronics and sensors
6. Minimally invasive therapies
7. Outcomes research tools
8. Telemedicine

Technology includes the results of engineering analysis, design, and materials; and product development entailing hardware (electronic, mechanical, electro-mechanical), software, and systems approaches. *Drugs were not specifically investigated in the Game.* However, if a team decided that drugs were the only viable approach, it was noted in the Game records.

Policy Areas Addressed by the Biomedical Prosperity Game

Our goal was not to reform the entire medical system. Rather, these policies address ways to improve the processes involved in funding, developing, testing, approving, and marketing new technologies with special emphasis on reducing costs while increasing the quality of care. A list of Biomedical Technology-Related Policy areas includes:

1. Legislative changes, regulatory improvements and reforms
2. Government incentive programs
3. Information surety and security
4. Tort liability reform
5. Metrics and systems for evaluating the costs and increases in health care quality resulting from the introduction of new technologies
6. Funding allocation systems

Biomedical Prosperity Game Execution

The primary Game objective was to explore existing and future biomedical technologies, with emphasis on lowering costs and maintaining quality. This exploration required highly skilled players with a strong knowledge of the biomedical field, the ability to read and digest a significant amount of information, and the confidence to make decisions, observe their consequences, and alter their decisions accordingly.

The design of the Game guided the assembled stakeholders from the broader US Health Care System to improve care delivery through improved technology, as demonstrated by:

- Cost reduction through the introduction of cost-effective technology,
- Unacceptable physical consequences of inadequate technology,
- Political pressure on the Legislative Team to reduce the cost of health care and increase care delivery productivity, and
- Rewarding cooperation for the development of innovative biomedical technologies.

The Game's play ran in four sessions on the first day of the Game event. The four sessions addressed the future time epochs from January, 1996 to the end of 2003, a compression of eight years into one and a half days. This time compression of 2000:1 (1 Game minute ~ 1.5 days) means that many aspects and issues were treated very approximately. The Game's design was intended to qualitatively capture these concepts to assist decision makers in understanding today's environment and the possibilities of significant future improvements. *This learning process was used to build a Biomedical Technology Roadmap which incorporates technical and policy changes that will ultimately benefit the nation with lower costs and high quality health care.*

The central theme of the Game, as in real life, was the relationship between the patients (Consumer Group) and health care delivery professionals (Providers Group) in the event of accident, illness, disability or aging. The patients were provided with Disease/Disability (hereafter denoted as D/D) cards that described their assigned age and symptoms. The D/D cards listed:

- Treatment options that are available in the year(s) designated by particular Game session,
- Placeholders for new technology-based treatments that may be developed during the play,
- Various possible outcomes and associated probabilities, and
- Estimates of direct treatment costs and long-term costs to society by either dying, remaining ill, or completely recovering and returning to the workforce.

As the Game progressed in time, additional technology treatment options were created to update the technology treatment placeholders on the cards.

Several diseases and/or disabilities (due to illness, accidents, battlefield casualties, or aging) were defined for each of the technology areas, and these provided the basis for the D/D cards. The cards addressed at most four possible generic outcomes with associated probabilities and returns on investment for working life up to age 65 (these outcomes being modified according to the particular D/D). Life expectancy was assumed to be 75 for all patients. D/D cards were given to individual consumers describing their condition and treatment options. In addition, the Provider teams were given "team" D/D cards representing global health care problems that needed to be solved by their team (e.g., breast cancer screening or disaster evaluation and triaging).

For the initial Game sessions, only current technologies were available as treatment options. All new technologies had to be developed either through Technology and Policy Toolkit Options or through the natural processes of the Game (i.e., research,

development, patenting, licensing, clinical testing, regulatory approval, manufacturing, marketing, gaining insurance coverage, etc.). During play, the care providers delivered care to their patients, choosing among the available treatment options, taking into consideration the patient's insurance and income, overall health, and any other considerations deemed important.

For the latter Game sessions, the Control team kept the providers abreast of the newly developed and licensed technologies, including costs, and possible outcomes and their probabilities. All new technologies included costs associated with research and development.

The Game simultaneously explored two dynamic systems: the health care delivery system and the technology development and marketing system. The delivery system encompassed three tightly knit teams: consumers, providers and insurers. The consumers had discretionary income that could be used to purchase health insurance and save for personal expenses such as premiums or copayments. The private insurers spread the risk among the mix of healthy and sick people and sought to make a profit. Government insurers covered a segment of the population including the elderly and the poor. Providers delivered health care directly to their patients and also sought to profit from their labors.

The technology system encompassed the researchers and those who funded research, the suppliers and manufacturers, and the regulatory agencies. Their objectives were to create new technologies and products that are safe and effective, and deliver them to the health care providers.

The legislators strongly influenced both systems. They provided a large fraction of the money needed in health care delivery/consumption. They also supported research and development of new and improved technologies. They could also set national objectives and policies for a large fraction of the health care expenditures.

Lawyers also played roles in both systems. They could be involved in litigation between any of the stakeholders (e.g., malpractice suits, product liability litigation, etc.). They could also assist in securing and defending intellectual property rights, lobbying, and mediating disputes.

The primary "move" in the Game was represented by an agreement or contract. These agreements were negotiated among two or more teams and had to represent an exchange of value for value. If the agreements involved uncertain future outcomes, these were determined probabilistically by the Control team. The agreements had to be accompanied with money that was transferred between partners. Two secondary "moves" included investments in Toolkit options, and D/D cards with their associated outcomes, costs, and quality evaluations.

All teams were provided with a list of near-term and long-term challenges. This information, coupled with the experience and expertise of the players, launched them into the real-world simulation of the Game. The Game was "won" by successfully meeting the prescribed challenges and accomplishing the long-term objectives of the teams and individual players. Players sought to accomplish their goals following the most realistic alternatives available.

Figure 15 illustrates some (but certainly not all) of the possible interactions that could occur during the Game execution. This experiential process developed the relationships and provided the inputs and innovative thinking that were used in the development of the Biomedical Technology Roadmap.

Figure 3.1. Schematic of Some Possible Team Interactions

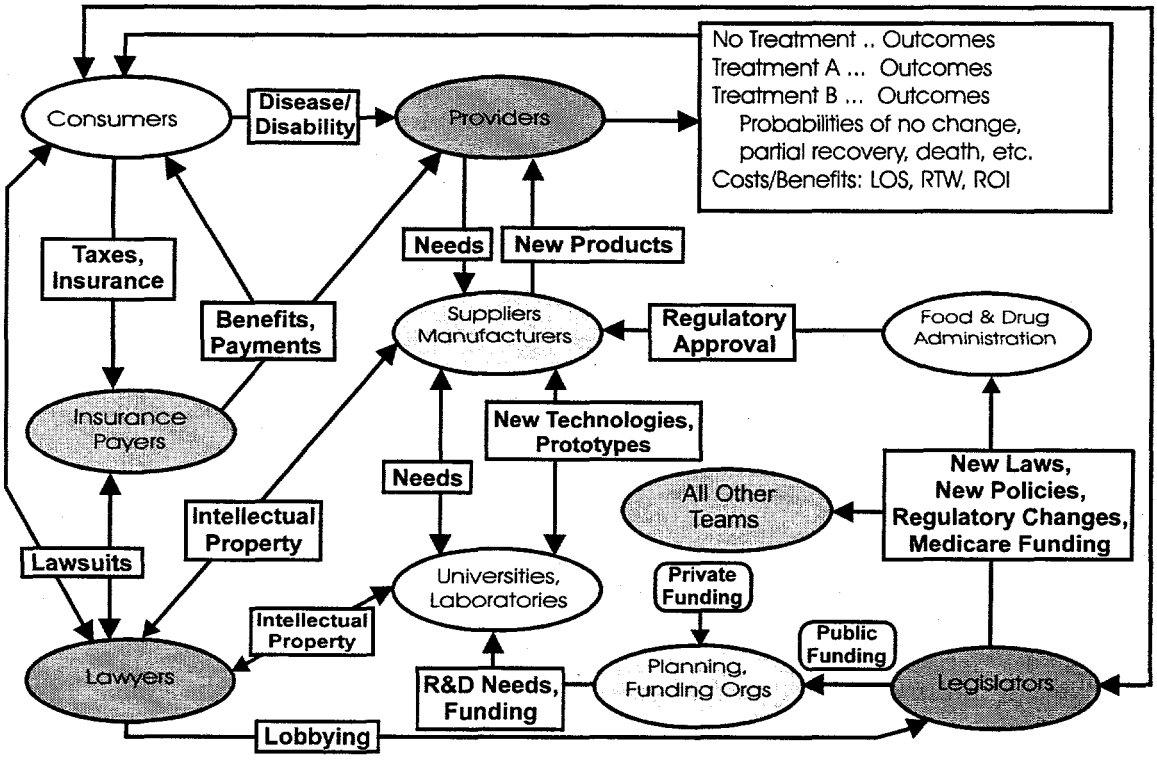

Figure 15. Schematic of some possible team interactions.

Technology Development Process

Table 13 illustrates the full process for technology development, licensing and marketing as it currently exists. Changes and improvements in this process were accomplished in the Game by negotiating agreements among all affected stakeholder teams. All determinations of future results (e.g., successful research, successful clinical testing, etc.) were decided probabilistically after assigning a mean investment and mean time. In the

context of the Game, all specified long-duration events (such as conducting clinical trials) were assumed to have already been accomplished in the event of a successful outcome. Representatives from all negotiating parties had to bring the agreements and money to Control for acceptance, probabilistic determinations, and confirmation.

Table 13. Standard Process for Technology Development

Action	Affected Teams	Move
Funding agencies get money for desired R&D	Legislators, Funding Orgs, Universities/Labs, et al.	Agreements - money transfer
Disburse funds	Funding Orgs, Universities/Labs, et al.	Agreements - money transfer
Perform R&D	Universities/Labs, Suppliers/Manufacturers	Agreements - probability assignment and dice roll; possibly money transfer
Secure intellectual property rights	Lawyers, Universities/Labs, Suppliers/Manufacturers, Control team = patent office	Agreements - money transfer
Negotiate terms (time, cost, etc.) of clinical testing and conduct trials	FDA, Universities/Labs, Suppliers/Manufacturers	Agreements - probability assignment and dice roll; possibly money transfer
Get FDA approval	FDA, Universities/Labs, Suppliers/Manufacturers	Agreements - possible money transfer
Manufacture technology and products	Suppliers/Manufacturers, Control team	Agreements - money transfer
Sell technology to providers	Suppliers/Manufacturers, Providers	Agreements - money transfer
Convince insurers to cover treatment costs	Suppliers/Manufacturers, Providers, Insurers	Agreements - money transfer
Technology becomes available for treating patients.		

Measure of Game's Care Quality

In the Game, the quality of care was measured by a short questionnaire supplied to the patients and their care delivery professionals. The questionnaire was incorporated on the back side of each D/D card and addressed the following topic areas:

- the reasonability of cost,
- the efficiency of treatment,
- the appropriateness of treatment,
- the minimization of risk,

- the adequacy of technology utilized,
- overall patient satisfaction, and
- whether the treatment improved the quality of life.

Each player answered the questions independently, and the results were tabulated and identified for each D/D state and treatment option.

Measure of Game's Care Cost

A simple algorithm was developed that incorporated information from the D/D cards into estimates of costs as a function of time in the Game. Costs included initial treatment, hospital stay, other costs and return on investment. The costs to develop and introduce "new" technologies were also included. The algorithm was intended only to provide a rough qualitative estimate, and perhaps guide further, much more comprehensive econometric research

Disease/Disability Card Description

The D/D cards were developed by Dr. Fidel Davila of the Scott & White Clinic, Texas A&M College of Medicine, Temple, TX. In addition, Drs. David Rattner, Steven Dawson, and Elizabeth Mort from the Massachusetts General Hospital (MGH) provided card design suggestions concerning coverage of pervasive disease states, potential treatment options and probabilities, and outcomes considerations. Sandia National Laboratories constructed a basic set of Technology and Policy Toolkit Options, which, when chosen for development during Game execution by a single or collection of Game Team(s), were added to the D/D cards' available treatment options. A later section provides further details on the initial set of Technology and Policy Toolkit Options. These Toolkit Options were reviewed and augmented by Drs. Davila and Rattner.

The D/D cards served the following functions in the game:

- Introduced the players to the pervasive diseases and disabilities addressed by the health care delivery system,
- Listed the costs of conventional and advanced treatment options,
- Estimated the costs to develop new technologies,
- Illustrated probabilities of positive and negative patient outcomes and how these outcomes might improve with advanced technologies, and
- Estimated the potential return on investment which is dominated by the ability of the consumer to return the productive working population or to reduce the fiscal drain on the health care system.

There were 32 D/D cards available in the game, as shown in Table 14. Twenty four of these applied to individual consumers (patients) and eight to the provider teams. D/D cards 6, 7, 8, 21, 22, 25, 27, and 30 applied to the Provider teams. These cards focused on the potential benefits of diagnostics and prevention in the early detection of diseases

(e.g., cancer screening). They also explored the process for adopting new procedures in a conservative HMO system, and the approach to dealing with major disasters.

Table 14. D/D Cards, Insurance Type, and Patient Descriptions

DD01	Private	Adverse Drug Reaction
DD02	Private	Diffuse Atherosclerosis
DD03	Gov.	Massive Battlefield Injuries
DD04	Private	Knee Osteoarthritis
DD05	Gov.	Blindness
DD06	Provider	Breast Cancer Screening
DD07	Provider	Cancer Screening Interpretation
DD08	Provider	Colon Cancer Screening
DD09	Private	Heart Replacement
DD10	Private	Insulin Dependent Diabetes Mellitus
DD11	Gov.	Hearing Loss
DD12	Gov.	Hip Fracture
DD13	Gov.	Home Bound Patient
DD14	Private	Ischemic Heart Disease Diagnosis
DD15	Private	Ischemic Heart Disease Treatment
DD16	Gov.	Kidney Failure
DD17	Gov.	Liver Replacement
DD18	Private	Lung Cancer
DD19	Private	Lung Replacement
DD20	Gov.	Medication Compliance/Monitoring
DD21	Provider	New Information Dissemination
DD22	Provider	New Procedure Adoption
DD23	Private	Paraplegic
DD24	Private	Premature Birth
DD25	Provider	Prostate Cancer Screening
DD26	Gov.	Quadriplegia
DD27	Provider	Skin Cancer Screening
DD28	Gov.	Tissue Diagnosis
DD29	Private	Unknown Critical Information
DD30	Provider	Disaster Evaluation and Triaging
DD31	Gov.	Burn debridement
DD32	Gov.	Threatened early delivery

For individual patients, the following represented a typical set of outcomes:

Outcome	Return on Investment
None (death or no change)	$0
Poor (invalid; unable to work)	-$20,000 per year for expected remaining lifetime
Partial (able to work part time)	+$10,000 per year until age 65
Complete (full recovery)	+$30,000 per year until age 65

These outcomes and returns were used for post-game analysis of the impact of technology on medical costs. They illustrate the potential benefits to society of returning patients to the work force or reducing costs for long-term care. An example of a D/D card for "Diffuse Atherosclerosis" is shown in Figure 16.

An examination of the "Diffuse Atherosclerosis" card reveals the return-on-investment and treatment option potentials by advancing biomedical technologies. The estimated frequency of the atherosclerosis condition is about 100,000 cases per year in the US. Currently available treatments include balloon angioplasty and bypass surgery. There is a significant probability of no change or death for both of these procedures. Furthermore, patients may be required to return for additional treatment or surgery in a few years, even if the surgery is successful. Option T33 is a laser device that completely removes atherosclerotic lesions (see Toolkit Option T33). The development of this technology posed the potential for reducing total treatment costs by a factor of five, and tripled the probability of complete recovery for about eight years. The expected return on investment (sum of the products of probability times total return on investment per outcome) for bypass surgery was -$78,000 per patient. With the laser technology, the return was +$64,000. Hence, over the time span of interest (1 to 8 years), the net return to society for the laser treatment (assuming 100,000 patients) would be $6.4 billion dollars (compared to a loss of $7.8 billion). Thus, it can be seen that the return-on-investment far exceeds the assumed initial technology development cost of $80 million.

CARD 2	DIFFUSE ATHEROSCLEROSIS	FREQUENCY ~ 100,000/yr.
45 year old, private insurance		
Patient:	A judge has familial hypercholesterolemia with symptomatic multi-vessel coronary artery disease, carotid,	
Doctor:	kidney and leg arterial lesions. Therapeutic interventions are needed.	
Recorder:		
Date/Time:		

Treatment options	Total treatment costs	Technology development cost	Outcome	Probability #	Probability Range	Length of recovery to 65	Length of recovery total	Productivity/ yr/patient	Total return on investment
Balloon angioplasties	$15,000	NA	None (death)	0.30	0.00-0.30	0		0	($15,000)
			Poor	0.35	0.31-0.65	1		($20,000)	($35,000)
			Partial	0.30	0.66-0.95	2		$10,000	$5,000
			Complete	0.05	0.96-1.00	3		$30,000	$75,000
Coronary arteries bypass surgery; carotid and abdominal surgery	$100,000	NA	None (death)	0.20	0.00-0.20	0		0	($100,000)
			Poor	0.30	0.21-0.50	2		($20,000)	($140,000)
			Partial	0.40	0.51-0.90	4		$10,000	($60,000)
			Complete	0.10	0.91-1.00	6		$30,000	$80,000
Not currently available See option T33	$20,000	$80M	None (death)	0.10	0.00-0.10	0		0	($20,000)
			Poor	0.20	0.11-0.30	3		($20,000)	($80,000)
			Partial	0.40	0.31-0.70	6		$10,000	$40,000
			Complete	0.30	0.71-1.00	8		$30,000	$220,000
Not currently available See option T34	$25,000	$120M	None (death)	0.05	0.00-0.05	0		0	($25,000)
			Poor	0.20	0.06-0.25	4		($20,000)	($105,000)
			Partial	0.35	0.26-0.60	8		$10,000	$55,000
			Complete	0.40	0.61-1.00	10		$30,000	$275,000
Not currently available See option T9	$25,000	$320M	None (death)	NA		0		0	NA
			Poor	0.10	0.00-0.10	5		($20,000)	($125,000)
			Partial	0.30	0.11-0.40	10		$10,000	$75,000
			Complete	0.60	0.41-1.00	15		$30,000	$425,000

Figure 16. Patient Disease/Disability Card

Technology and Policy Toolkit Options

The Game Players had two ways in which they could advance the available biomedical technologies as treatment options. One means was a conventional approach that involved realistic processes of negotiations and contracts among stakeholders. Another means presented in the context of this Game was through direct investment of options through the Toolkit Options.

The Toolkit Options were composed of a list of technology and policy options that teams and players could invest in. The control team created an initial list of potential options and assigned a total resource investment required to yield a 50% probability of success to develop and introduce the option. Teams were encouraged to determine which of these or other technology and policy options were important to address their future priorities. Investments were made by individual Teams, however, the Teams were encouraged to partner with other Teams according to mutual priorities. For newly identified options not on the initial list, "experts" from the Game Control team assigned the amount of mean investment required to yield a 50% probability of a successful outcome. The total investments from all teams were processed and the success or failure was determined by

random number generation. It should be noted that investments made in unsuccessful options were permanently lost.

The outcomes of the Toolkit investments were determined probabilistically as shown by the example in Figure 17. The baseline probability increased with increasing investment following a normal distribution with mean x and standard deviation ♦ = x. Hence, from the example, an investment of twice the mean, $200M, would yield a success probability of 0.84. To take into account factors other than total investment, a uniform distribution is superimposed on the normal distribution to reflect uncertainties and risks in the real world for accomplishing major technology or policy breakthroughs. This uniform distribution can increase or decrease the baseline probability by as much as 16%.

Toolkit Options provided an indication of some possible advances in technology, or policy changes that might significantly improve health care quality and lower costs. These Options were meant to encourage collaboration among the many stakeholders and to indicate the highest priority technology and policy objectives of the players.

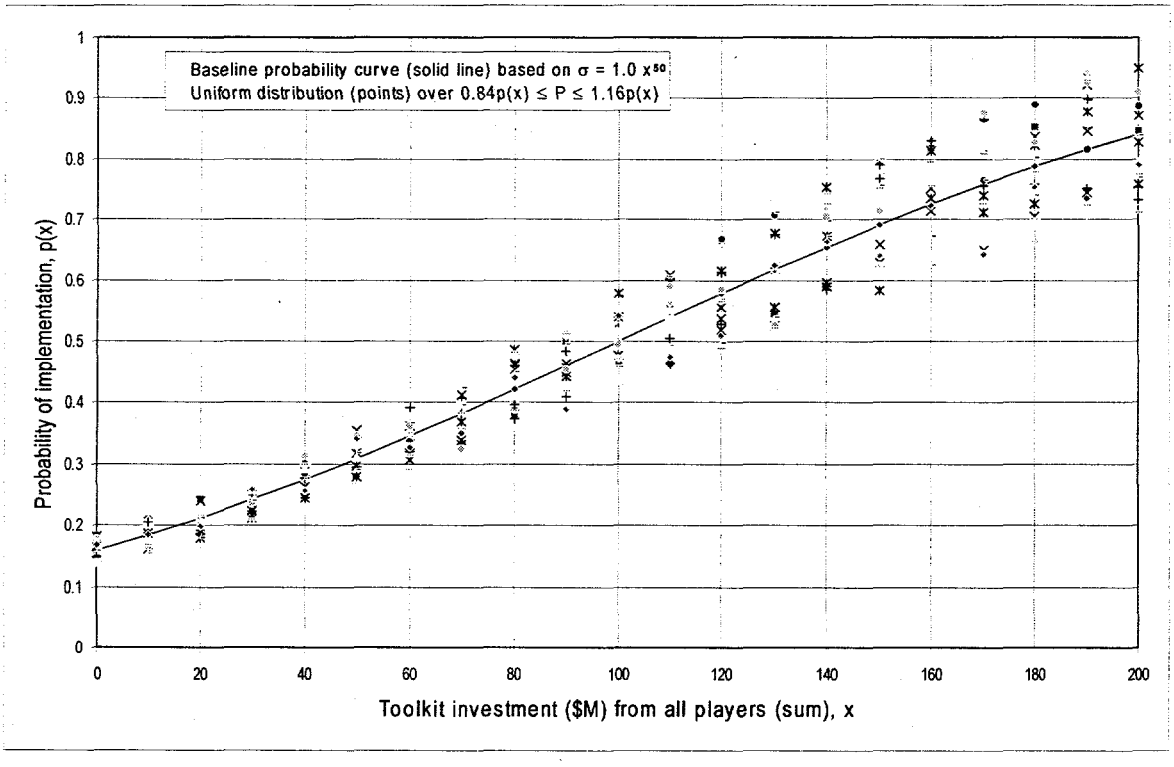

Figure 17. Probabilistic Determination of Toolkit Investments Outcomes

Gaming Dollars

The function of money in the Game is to introduce the concept of finite resources. This forced the players to create options and assign priorities that simulated real life. However, this Game was complicated by the fact that it dealt with individual patients and their treatments together with national issues related to government appropriations, research funding and performance, and overall industry income and outflow. A single currency definition could not apply to all these situations and simultaneously provide the players with value measures that simulated reality. Hence, the Sandia Game design team designed the following system to accommodate these diverse objectives.

All the bills circulating in the game were denominated in game dollars - $G. Game dollars came in two colors: green and yellow. Green dollars circulated primarily among the health delivery triad - consumers, providers, and insurers. Yellow dollars circulated *exclusively* within the national technology development system. Conversion factors, as shown in Table 15, were assigned for crossovers.

Table 15. Conversion Descriptors for Game Dollars

Team	Dollar Type	Conversion for agreements, contracts
Consumers:	Green	$1 = $200
Provider 1: IPAs, individuals	Green	$1 = $200
Provider 2: HMOs	Green	$1 = $200
Insurance Payers:	Green	$1 = $200
Legislature	Green and Yellow	$1 = $1 for appropriations to health insurance $1 = $0.5 million for all other appropriations
Suppliers/Manufacturers	Yellow	$1 = $0.5 million
US FDA, Other Regulators	Yellow	$1 = $0.5 million
Planning/Funding Organizations	Yellow	$1 = $0.5 million
Universities/Laboratories	Yellow	$1 = $0.5 million
Lawyers	Green and Yellow	Depends on customer

Green dollars were used by consumers and insurers to pay for treatments and insurance policies (and any legal expenses related to an individual). If green dollars were used for any expense other than treatments (e.g., providers wishing to purchase products from suppliers or invest in research), each green dollar was worth $200.

Yellow dollars represented national expenses (research, manufacturing, etc.). In that environment, one game dollar represented $0.5 million. The two types of dollars allowed

the game to accurately estimate both the real costs to the patients for treatments and the real costs of research, developing, testing and manufacturing new technologies and products.

Table 16 indicates the funding (i.e., income) that was provided to each Team for each Game session.

Table 16. Team and Player External Income Per Session

Team	1996-1997	1998-1999	2000-2001	2002-2003
Consumers: *Each player receives this amount.*		$45,000	$48,000	$52,000
Provider 1: IPAs, individuals				
Provider 2: HMOs				
Insurance Payers: Private				
States	33.8%	TBA	TBA	TBA
Medicare, Other Federal	64.7%	TBA	TBA	TBA
Legislature: Federal (66.2%)		$180,000	$192,000	$208,000
States (33.8%)				
Suppliers/Manufacturers		$800	$900	$1000
US FDA	0.1%	TBA	TBA	TBA
Other Regulators				
Planning/Funding Organizations:				
Government (DoD, NSF, Koop, etc.)	1.4%	TBA	TBA	TBA
Private Foundations		$200	$200	$200
Universities/Laboratories				
Lawyers				

TBA: To be appropriated by the legislators

Biomedical Technology Issues and Potential Solutions

The second day of the Game was devoted to initiating the development of Biomedical Technology Roadmaps for the technologies (and policies) promoted by execution of the Game. During the opening session on the second Game day, each Game Team identified the most important issues and potential solutions for employing technologies and related policies in reducing costs and increasing quality. The areas identified were based on real-life and Game experiences from the first Game day. Issues were prioritized and the top one or two issues and solutions were presented to the entire group of Game participants in a plenary session. Issues not addressed by an identified technology or policy area promoted a new technology or policy area for roadmapping.

Biomedical Technology and Policy Roadmapping

Following the initial issues session on day two, the Game players reassembled according to gaming tables arranged by Biomedical Technology and Policy areas of primary interest. The reassembled players created a vision statement for the future of the specific technology or policy area, and then outlined the key elements for Biomedical Roadmaps. The resulting collection of Biomedical Technology Outlines (along with key development objectives) for each important biomedical technology area became important products for further development in the Technology Roadmap Workshops.

Table 17 shows a sample template for a Biomedical Technology Outline. Following this are definitions of key terms for developing a Roadmap outline:

Roadmap Development Definitions

Vision	A high-level view of the purpose of the particular technology area in health care.
Champions	People who lead, provide guidance for and participate in roadmapping exercises.
Objectives	Goals identifying the future advances in the particular technology area.
Drivers	Specific characteristics of technologies that must be available to achieve the desired objective.
Sub-technologies	Classes of technologies that hold promise in enabling the objective.
Sponsoring organizations	Potential funders, researchers, etc., related to the sub-technology classes or technology drivers.
Attributes	Specifics related to the objective, such as cost, size, speed, policy, technical requirements, etc.

Table 17. General Technology Area

Table 3.5. General Technology Area:	TA8 - TELEMEDICINE		
Vision of the future for the technology area: *Exploit information technologies to deliver medical services between locations*			**Champions:**
	Current (0-3 years)	**Near-term (3-6 years)**	**Far-term (6-15 years)**
Objective:	• *Intra-organization applications*	• *Inter-organization applications*	• *Global applications*
Drivers:	• *Local area networks* • *Limited knowledge sharing* • *Intra-org. security*	• *Wide area networks* • *Partial knowledge sharing* • *Inter-org. security*	• *Global networks* • *Full, global knowledge sharing* • *Global security*
Sub-Technologies:	• *Communications* • *Computing*	• *Communications (mod. bandwidth, rate)* • *Computing (mod. res. video)*	• *Communications (high bandwidth, rate)* • *Computing (high res, storage, access)* • *Robotics devices*
Sponsoring Organizations:	• • •	• • •	• • •
Attributes:	• *Data rates ...* • *Line cost ...* • *Video resolution ...*	• • •	• • •

Biomedical Technology Roadmap Description

Summary Goal

This study's Top-Down Approach developed Biomedical Technology Roadmaps for each innovative biomedical technology area with the potential to reduce U.S. health care delivery costs while maintaining (or improving) care quality.

Rationale for Technology Roadmap Development

These Roadmaps provide important planning and forecasting guidelines for the development and introduction of biomedical technologies with the stated cost and quality characteristics. It is intended that these Roadmaps be used to provide consensus in the research and development of the identified technologies by:

- Providing a unique tool for coordinating necessary development and application activities,
- Reducing duplication of effort in research and development efforts,
- Addressing biomedical technology challenges that may be too expensive or risky for a single organization to solve, and
- Ensuring that the broader US biomedical industry addresses the basic technology options to ensure that future care delivery needs are met.

It is also intended that these Roadmaps provide a long range view of the future product and technology needs of the broader US Health Care delivery system. Each Roadmap is designed as a working document and may be updated as required.

Sandia National Laboratories' several roles in this Roadmapping effort were as follows:

Motivator	Sandia was very committed to this effort in the national interest,
Catalyst	Builder of consensus as a quasi-government, quasi-business entity,
Consultant	Sandia's technology core competencies are compatible with the broader biomedical area,
Facilitator	Sandia managed the development process, the participants owned the content, and as
Participant	Sandia maintains unique facilities and capabilities on a "neutral" ground.

Roadmapping Methodology

The Roadmaps developed in this study addressed the broad range of innovative technologies required to meet the health care delivery products and services of the future with the stated goals for cost and quality. Specific Roadmaps were developed for:

- advanced telemedicine,
- health and healthcare informatics,
- information and network surety,
- integrated predicative diagnostics,
- minimally invasive therapy, imaging, and energy delivery systems,
- performance measurement and outcomes research,
- preventive medicine and incentive programs, and
- rehabilitative science and assistive technologies

The following methodology presents a broad outline that was, in some part, addressed by the roadmap development activities of this study:

1. Identify care delivery products, services, and needs,
2. Identify requirements for these needs,
3. Identify technology drivers that address these requirements,
4. Quantify these drivers' attributes (e.g., performance, cost, characteristics, etc.)
5. Establish a timeline required for achieving the attributes,
6. Determine critical infrastructure (e.g., resources, core competencies, etc.) required
7. Identify potential show-stoppers (i.e., obstacles) as well as opportunities
8. Determine priorities for each preceding area
9. Implement within a working group, consortium, or other alliance process.

Technology development and application requirements are derived by addressing the ***technology user pull*** and the ***technology developer push***. Eventual cost-effective products that promote quality outcomes depend on forecasting future product capabilities and the technologies required to realize those capabilities. The user is essential to forecasting the future required capabilities. Likewise, the developer is essential to identifying a comprehensive evaluation of technologies required in meeting the users' desired products.

Roadmapping Events

The events for the development and implementation of the Roadmaps took place from November 1995 through September 1996. These primary events included:

• Biomedical Prosperity Game (*BPG*)	November 1-3, 1995
• Technology Roadmap Workshop 1 (*TR1*)	April 22-24, 1996
• Completion of Individual Technology Roadmaps	August 1, 1996
• Completion of edit and format of Final Biomedical Technology Roadmap Document	October15, 1996

- Completion of print of Final Document; Dissemination of Final BTR Document to Individuals, Organizations and Consortiums — November 11, 1996

The Biomedical Prosperity Game initiated this process on November 1-3, 1995 at Albuquerque, NM. Its unique format addressed the following steps of the roadmap development process:

WHO Identified leaders, sponsors, and participants, and

WHAT Established high level needs of the care delivery system and potential technology solutions area.

The principal output of the Game, Biomedical Technology Outlines encapsulated this information.

A Technology Workshop event was held April 22-24 1996 to advance the first drafts of each Roadmap. This first Technology Workshop event (and working groups) addressed the following steps of the process:

WHAT Provided details of high level needs and solutions

HOW Determined infrastructure, resources, etc. required to accomplish

WHEN Established the timelines

Each of the Roadmap Champions and Work Groups submitted the final versions of the Biomedical Technology Roadmaps by August 1, 1996. The Roadmaps were edited and formatted for final document presentation consistency. Printing of the final Biomedical Technology Roadmap document was completed by the end of November. Copiers of the final document have been disseminated to health care technology and policy stakeholders. It is also available electronically on the DoD Telemedicine World Wide Web site at:

http://www.matmo.org/news/sections/civprog/sandia.html.

Chapter 4 - Conclusions

Modern medicine is characterized by the use and refinement of an ever-expanding array of technologies. The interrelationship of technology and medical costs depends upon the definition of cost on the one hand and the characteristics (figures of merit) of the technologies on the other. In addition, a variety of societal factors, most particularly the demand for innovative therapy, can powerfully impact aggregate expenditures for health care. The health care planner must be aware of these often complex interrelationships.

As a first step to understanding these relationships, Sandia National Laboratories applied a systems approach to identifying innovative biomedical technologies with the potential to reduce U.S. health care delivery costs while maintaining care quality. This study was conducted by implementing both top-down and bottom-up strategies. The top-down approach used prosperity gaming methodology to identify future health care delivery needs. This effort provided roadmaps for the development and integration of technology to meet perceived care delivery requirements. The bottom-up approach identified and ranked interventional therapies employed in existing care delivery systems for a host of health-related conditions. Economic analysis formed the basis for development of care pathway interaction models for two of the most pervasive, chronic disease/disability conditions: coronary artery disease (CAD) and benign prostatic hypertrophy (BPH). Societal cost-benefit relationships based on these analyses were used to evaluate the effect of emerging technology in these treatment areas.

The following general conclusion was reached based upon these top-down and bottom-up analyses. In general, technologies which

- produce durable results and therefore lessen the need for repeat procedures,
- limit unnecessary or less-than-optimal use of procedures (as in the case of information given to patients or physicians),
- produce quality results at markedly reduced costs, or
- render positive both patient lifetime utility and its related economic societal benefit

can reduce health care costs variably defined. The definition of "health care cost" and the perspective from which it is defined are important in this scenario. Health care "expenditures" need not be equal to heath care "costs." When technologies currently in use are rank-ordered by dollar using Medicare-allowable charges for services, it is apparent that office visits, chest x-rays, ophthalmologic services, mammography, EKG, and a variety of other medical technologies are used at high cost and therefore present targets for cost reduction by the innovative use of technology.

This work indicates that additional research is required in critical study areas if the relationship between technology, health care expenditures, and health care costs is to be understood. Prominent among these are the nature of the increase in demand (which occurs following the introduction of a new technology), the economic value of time (both of an employed and unemployed person), the refinement of the definition of a quality-

adjusted life year (QALY) with sufficient theoretical underpinnings to permit an economic value to be placed on a QALY, methods to accurately assess the effect of medical therapies on patient QALY's, and the exploration of the potential of managed care to direct technology usage and control demand. The following sections present concluding thoughts specific to the bottom-up and top-down economic approaches.

Bottom-Up Approach: Cost-Effectiveness Analysis for Selected Disease/Disability States

Econometric Analyses

The functionality of the models used in this study was essentially ***heuristic***. The models clearly point out three issues which bear on the nexus of technology and health care costs. Each of these issues is worthy of future research.

First, the ***necessity to define health care cost*** is highlighted by the models. Each model recognizes that costs are both direct (payments for services rendered) and indirect (effects on society such as wages gained or lost). Therefore, it becomes clear that ***expenditures are not equivalent to cost***. The models provide cost analysis from the point of view of the payer as well as from the perspective of the larger society. The results of simulations are dependent not only on the cost perspective assumed but also on the estimates of the costs themselves. In the case of establishing societal costs/benefits, the project team encountered the need for determining the dollar value of a life year. Appropriate economic literature was reviewed, and team members elected to estimate this value using a ***revealed preference methodology***. The derived figure was utilized in the coronary artery disease model for calculations of societal costs/benefits.

A second major issue raised by the modeling was the ***growth of demand*** which a new procedure can produce. Based on literature review and a review of technology usage, it became clear that new technology often, if not always, stimulates increased demand for its use. Therefore, even technologies which reduce unit costs often tend to increase aggregate direct costs. Various factors were identified as determinants of demand and were then included in the models so that they could be explored by analysts over time.

A third factor influencing the relationship of technology and health care costs is the ***assessment of quality-adjusted life years*** (QALY) and their economic impact. The theoretical arguments related to assigning economic value to QALY's were reviewed, including those arguments dealing with the increased late medical (and non-medical) costs to which life-extending therapies expose patients. As noted above, it was elected to empirically derive the value of a QALY. Therefore, longevity changes, discounted for quality of life, were used in economic calculations of societal benefit in the case of coronary artery disease. In the case of benign prostatic hypertrophy, where little impact on longevity is seen and the major impact of therapy is symptomatic, it was not felt that

current theory is sufficiently developed to warrant establishing an economic value for the quality component of the therapy.

Using cost models in a heuristic fashion, the following summary conclusions were reached:

- Technologies now under development can ***lower the unit cost of therapy***, whether that unit cost is calculated per procedure or per patient treated. If demand growth is vigorous, aggregate costs are likely to increase.
- Even if aggregate costs increase with the introduction of new technology, ***societal costs remain negative in many instances*** (i.e. ***societal benefit is positive***). A more strict economic evaluation of a technology would require that the positive societal benefit outweigh any additional health care costs experienced by the patient prior to a terminal illness. Note that this prediction of a positive societal benefit is dependent in some instances on pricing distortions in the health care market.
- Technologies which produce more ***durable results*** and thereby lessen the need for repeat procedures have the potential to further reduce cost by effectively removing patients from further interaction with the health care system. This can be seen in the use of stents (by reducing restenosis rate) and in the use of transurethral needle ablation for BPH. Similarly, prevention of disease lowers costs.
- Information technology that ***reduces unnecessary procedures*** (e.g. patient education for treatment of benign prostatic hypertrophy) can lower health care costs because it reduces demand (albeit inappropriate demand).
- Technologies which produce the same result as an alternative technology, but at ***lower cost per unit***, can reduce aggregate cost because they tend not to increase demand.
- Estimates of societal cost/benefit derived from technology usage are ***sensitive*** to the ***economic value ascribed to a quality life year gained***. Further research in this area is recommended.
- Mathematical modeling techniques such as **stochastic frontier analysis** offer novel ways to identify "lowest cost" practices and thereby ***identify a true cost baseline*** for the provision of medical care.
- The rank ordering task revealed that the ***office visit***, when defined as a technology, ranks high in cost when compared to other technologies. This suggests that more research is warranted for determining ways to reduce the number and/or expense of office visits while maintaining quality of care.

In many cases, technology can be shown to lower health care costs if the societal response to technology is understood and the societal costs/benefits associated with technology are fully considered and understood.

Care Pathway Integration Modeling

The following summary conclusions were reached based on multiple simulations using the CAD and BPH models:

- In the treatment of CAD or BPH, technological improvements can be expected to raise aggregate expenditures for care.
- Unit costs can be lowered by technological innovations.
- In general, technologies which produce satisfactorily durable results (thereby lessening rework) have the opportunity to reduce aggregate and societal costs.
- Improvements generated as a result of technology use can increase demand for use of the technology.
- Societal costs/benefits of innovative technology were calculated by one of two methods. The first centered on the use of wage rates to estimate aggregate economic benefit provided by therapy (wage-based method). The second method determined the value of a day of average life to patients in the near retirement age by studying retirement tradeoffs and decisions of the American population (the *revealed preference* method). When the wage-based method was employed, the cost of treating a disorder such as CAD could be seen to vary with societal policy, such as an increase in the retirement age. An increase in the retirement age tended to decrease the total cost for interventional therapy of CAD by virtue of extending the work life of patients benefiting from this therapy. Nonetheless, the analysis predicted a net cost to society for these therapies. However, when the revealed preference method was used, projections indicate that the cost of therapy is negative and will remain negative through the year 2004.
- Information technology which limits unnecessary technology use through patient and physician education can lower costs because it directly lowers demand. Although this kind of information technology lowers costs, it also appears in the simulations to lower aggregate relief of symptom score. This conclusion must be further explored since some BPH patients have chosen less invasive therapies such as pharmacological therapy over procedural therapy, which might in theory provide a more durable relief of symptoms, albeit with increased short-term risk.
- The models showed that if sufficiently severe cost controls are imposed on technology, aggregate costs can fall. Unfortunately, the impact of such cost controls on the development of new technologies can be anticipated to be negative. From the revealed preference economic view, this effect can be detrimental to social well-being. Strategies designed to mitigate any influx of less-ill patients as a result of technological improvement can mitigate cost increases (or produce cost reductions) with variable effects on societal benefit.
- The models also show that utilization controls will lower aggregate costs, but quality or symptom relief will likely be lowered in the process. An exception would be those cases in which therapy is inappropriate and where, in effect, utilization control reduces waste.
- The simulations pointed out the effect of patient demand on aggregate costs. The advent of a new technology can increase patient demand for that technology in multiple ways. Indeed, a new technology may also find application to totally unexpected areas of care, thereby increasing demand further. Also, indirect increases in demand can occur in that a new technology can prompt more patients to seek

diagnostic testing, thereby enhancing the detection of a second disease. Finally, by permitting patients to live longer, technological advances permit patients to be exposed to the risk of developing subsequent disorders accompanied by additional treatment costs.

Methods By Which Technology Can Reduce Societal Health Care Costs

Although it is relatively easy to envision technologies which reduce the unit cost of delivered service, it is more difficult to envision ways in which technology can reduce aggregate costs given the push to demand which a new technology causes. However, based on project simulations, there are several ways in which cost reductions can occur.

The first is the deliberate limitation of the expansion and use of the technology. In effect, this methodology equates to a form of rationing in that not all patients who are desirous of using the technology will have access to it. However, this strategy can maintain or enhance the quality of care while lowering costs. This strategy is increasingly being considered by prepaid health care delivery systems, state governments, and others. The present modeling effort can accommodate this strategy and simulate the effects of various strategies to limit access to care.

The cost lowering impact of proposed technology could be so great that even in the face of increased demand and of increased utilization of the technology for unanticipated purposes, the aggregate cost falls. In general, this would require a major reduction in costs and possibly a quantum leap in technological development.

New technology could increase societal productivity by enhancing the aggregate productivity of the citizens. For example, the prevention of premature mortality in a working population would enhance the Gross Domestic Product. As mentioned in the economic analysis section of this report, the prevention of morbidity and mortality even in unemployed patients can have a salutary economic effect. It is important to note however, that this opportunity cost of societal activities appears only when the cost benefit analysis is done from the societal point of view and not from that of the health care payor.

Top-Down Approach: Technology Roadmapping Efforts

Biomedical technology roadmaps were a major result of this effort. The primary goal of development of these roadmaps was to focus on areas where technology can have a major impact on cost reduction in the health care industry. The roadmaps, or strategic plans, identify a common vision for timely solution of fundamental system problems that are "needs-driven" rather than "solutions-driven." These roadmaps provide consensus in the development and introduction of innovative technologies by reducing duplication of essential research, development and application activities among stakeholders. The major benefits of these strategic plans are (1) they address technology challenges that may be

too expensive or too risky for a single organization to solve and (2) they provide a comprehensive viewpoint for addressing solutions to broad health care system problems.

The roadmap areas are

- advanced telemedicine,
- health and healthcare informatics,
- information and network surety,
- integrated predicative diagnostics,
- minimally invasive therapy, imaging, and energy delivery systems,
- performance measurement and outcomes research,
- preventive medicine and incentive programs, and
- rehabilitative science and assistive technologies.

These areas include U.S. health care system resources, costs, quality and time goals, critical infrastructure requirements, and core competency needs. In order to ensure the credibility of each roadmap, the working group champions for the technology areas obtained critiques from a wide variety of organizations and individuals with recognized expertise in each particular field. More than *75 organizations and 150 individuals* have participated in the biomedical technology roadmap development process. Concurrence from this broad spectrum of participants validates the usefulness of the roadmaps. To begin the address future health care technology and technology-related policy, the prosperity game brought together stakeholders representing *44 organizations* having expertise in the broad spectrum of health care technologies. The roadmaps should serve as tools to help make decisions on future health care activities. They have been widely distributed, and we are continuously receiving requests for additional copies. The complete roadmap document is available electronically on the DoD Telemedicine world wide web site at

http://www.matmo.org/news/sections/civprog/sandia.html

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Appendix A - Derivation of Rank Order Data

Data Sources

A systematic approach to addressing the data sources used for the rank ordering task was adopted. The project team specified inclusion criteria for the data sources, formulated a plan for searching the data sources, collected and analyzed the data.

The inclusion criteria were as follows: data was to be recent (1992 to present); data was to be reflective of the U.S. population (neonate to elderly); data was to be reflective of different payer groups (e.g. Medicare, managed care, fee for service); data was to be procedure code-oriented; data was to reflect utilization and dollar amount of services. The most recent uniformly available data at the onset of this project was from calendar year 1994. Therefore, we reviewed the 1990 U.S. Bureau of Census Data projected to 1994 to assess the demographic breakdown of the U.S. population. (Of note, review of the trend data (1992 - 1995) did not reveal any major changes in demographic breakdown of the U.S. population over this 4 year time period). This information together with variation in healthcare delivery indicated the need for data from multiple sources. Thus, several data sources were included in this project: Medicare data (inpatient and outpatient), data from a Western Managed Care Organization (MCO), data from a Southern MCO, and National Inpatient Sample (NIS) data.

The Medicare population consists of potentially high utilizers of healthcare services. To review health care utilization in inpatient and outpatient settings, the project team obtained the top 200 procedures (predominantly captured by CPT-4 codes) by allowed services from HCFA (Health Care Financing Administration) Part B Medicare files (1). The Part B files include non-institutional services: physician; clinical laboratory; durable medical equipment/supplies; prosthetics and orthotics; facility charge for freestanding ambulatory surgical centers; blood; outpatient speech, occupational and physical therapy; monthly ESRD (end stage renal disease) capitation; parenteral and enteral supplies; ambulance; immunosuppressive drugs, pneumococcal vaccines. The Part B files reflect procedures occurring in both inpatient and outpatient settings. The Medicare Part B data is based on the Health Care Financing Administration's Common Procedure Coding System (HCPCS). The HCPCS codes are required when providers report services and procedures provided to Medicare beneficiaries. HCPCS is a three-level coding system. The first level is based on the CPT codes that are published and updated annually by the American Medical Association (2). It is five digit system that describes procedures, and services physicians provide to patients but does not include non-physician procedures, services and specific supplies. The second level of this coding system is referred to as National Codes, or sometimes by the acronym, "HCPCS" (3). These codes are published and updated yearly by the Health Care Financing Administration, and these codes supplement CPT. Codes are included for non-physician services and procedures such as

ambulance services and durable medical equipment. The codes are 5 digit alphanumeric codes. The third level of the HCPCS system is based on local codes that are used to note new procedures or specific supplies for which there is no national code. These codes, like the level two codes are five-digit alphanumeric codes (an alphabetic character followed by four digits). For the healthcare occurring in short-stay hospital facilities only, characteristics of inpatient billing practices resulted in our use of rank ordering by DRG (Diagnostic Related Group) to assess technology utilization in short-stay hospitals. We obtained data that was generated from the 100% MedPAR file (Medicare Provider Analysis and Review file) from HCFA. HCFA provided aggregated data regarding procedures and conditions by DRG code that resulted from inpatient discharges from short-stay hospitals. The following information was provided: DRG, charges/DRG (total, covered and Medicare reimbursed), number of discharges, and average length of stay. Descriptions for DRG's can be found in St. Anthony's DRG Guidebook (4).

The western MCO provided information regarding its 1994 enrollees (over 2.4 million). For hospitalizations in 1994, data was provided on the top 200 principal procedures (ICD-9 procedure code) by volume (high to low) for all inpatient and outpatient (i.e. same day surgery) procedures. The top 200 office visit procedures (CPT-4 codes) ranked by volume (high to low) for one representative month in 1994 was provided. These codes were translations of an appointment reason code; the coding process was not designed to capture all procedures performed in the office. In addition, the top 200 radiology procedures (predominantly CPT-4 coding) were provided rank-ordered by volume for one representative month in 1994. Prior to analysis, the ICD-9 codes were translated into CPT-4 coding; the one month data was used to estimate 1 year data; and the individual data files were integrated with the other data files from the MCO.

The southern MCO provided data on approximately 63,000 enrollees in calendar year 1994; Medicare patients were not included in the MCO in 1994. A composite list of the top 200 procedures (CPT-4 and HCPCS codes) for 1994, rank-ordered by volume, was obtained. The report included inpatient and outpatient hospitalizations, office visits, radiology and laboratory utilization. A separate list of the top 200 procedures rank ordered by "amount paid" by the SMCO was also obtained. This was done in an effort to determine correlation of rank order by volume versus rank order by dollar.

Data regarding inpatient utilization was obtained from the Agency for Healthcare Policy and Research (AHCPR) Healthcare Cost and Utilization Project (HCUP-3) (5). The HCUP-3 Nationwide Inpatient Sample (NIS) contains data from approximately 900 U.S. Hospitals (approximately 20 percent sample of U.S. community hospitals). It contains data from records for all stays in the sample hospitals. The NIS Release 1 for 1992 was drawn from a sample of hospitals in 11 states: Arizona, California, Colorado, Florida, Illinois, Iowa, Massachusetts, New Jersey, Pennsylvania, Washington and Wisconsin. The sample is a stratified probability sample designed to be representative of the universe of U.S. community hospitals. (The American Hospital Association (AHA) designates community hospitals as all non-Federal, short-term general hospitals (open to the public) and specialty hospitals.) The HCUP-3 sample available at the onset of this project (1995)

spanned the period from 1988 to 1992. From these patient-level records, we derived the top 200 inpatient procedures (ICD-9 coding) by volume for 1992. When the 1993 data became available in 1996, we generated a top 200 list for 1993. Correlation analysis of the rank ordered lists from 1992 versus 1993 revealed that the lists were highly correlated (Spearman rank correlation r=0.90 for the ranks; Pearson correlation r=0.87 for the frequency counts). This paper reports on the 1992 data because it was the initial data set available for this analysis. In the spring of 1997, the 1994 NIS data was released. From these inpatient records, we derived the top 200 DRG codes for hospitalizations. This was done in an effort to obtain a comparable dataset to the Medicare short-stay hospital data; the two data sets were used to generate a weighted rank-order list of the top DRG's in the U.S. short-stay hospitals.

Demographics

From the 1994 projections of the 1990 U.S. Bureau of Census Data, the demographic breakdown of the U.S. Population was as follows: of the approximate 260 million people in the U.S. in 1994, 51% were women, 58% were between 20 - 64 years of age (13% are greater than 64 years old), 74% white non-Hispanic, and 85% were insured (13% with Medicare). Of note, the proportion of the U.S. population that is insured by managed care organizations is increasing.

The demographic breakdown for the unique populations from the different data sources used for this project is provided below. The Medicare population in 1994 consisted of approximately 37 million beneficiaries (over 13% of the U.S. Population): 57% women, 89% aged (vs 11% disabled), and 84% white. The Western MCO 1994 enrollees included over 2.4 million patients: 51% women, 62% between the ages of 21 - 65 years of age (11% greater than 65 years old), 70% white, (data on race available for enrollees 20 years of age and older). The Southern MCO provided data on over 63,000 enrollees for 1994. The population consisted of 48% women, 66% persons aged 20 - 64 years (17% were greater than 65). No data was available regarding race/ethnic origin. The HCUP-3 NIS 1992 data set included approximately 6,195,744 patient hospitalizations. The following reveals the demographic breakdown: 42% women, 58% white, 34% Medicare, 46% persons aged 21 - 65 years (32% persons greater than 65 years old).

In attempting to identify leading procedures that should be assessed for potential technological innovation, some investigators may only seek to identify leading high-volume or leading high-dollar procedures. In order to assess the impact of using one rank ordered list over another (dollar vs volume), we used rank ordered reports generated from the 1994 Medicare Part B (over 36 million enrollees) and the 1994 SMCO data (over 64 thousand enrollees) to determine correlations between rank order by volume of procedures vs. rank order by dollar amount (8). For the Medicare Part B, the correlation between the rank order by volume vs by "allowed charge" for the top 200 procedures was as follows: $r = 0.27$, $p =$ less than .00005. For the SMCO, the correlation between the rank order by volume vs the "amount paid" for the top 200 procedures was as follows: r

= 0.48, p = less than .00005. Although significant, the relatively poor correlations identified in this analysis between rank order by volume of procedure vs dollar amount indicated the need to assess these two aspects of the procedures (volume and dollar) independently when selecting procedures for study. Based on this analysis, it was decided that we would pursue separate lists ranked by volume and dollar for both the combined report and the inpatient report.

Dollar Data

The data obtained from the various data sources reflected utilization of procedures or the number of procedures performed by code category in a given period of time. Obtaining meaningful and comparable data regarding cost, charge, and/or expenditures for various procedures was a complex task. First, there is noted geographic and payer variation in charges per procedure (6,7). Second, there is no universal cost accounting system in place that can provide accurate cost estimates for procedures that are representative of all U.S. practices. In addition, charges for individual procedures performed in the hospital are difficult to isolate from the confounding effects of other procedures performed during the same admission and length of stay. Consequently, identification of a source for dollar estimates that would allow uniform reranking of the high volume procedures by dollar amount required different approaches. For those procedures identified by CPT-4 and HCPCS procedure codes, we utilized HCFA Part B allowed charges averaged across the U.S. for each code. The data was obtained from the HCFA Public Use File (i.e. Part B Procedure File (1)) for calendar year 1994. This file provided an array of every Part B procedure. In addition, it showed the related frequency and submitted and allowed charges for services processed by carrier. The dollar figure generated with this approach for each code was applied to each data set used for the combined report. For the inpatient report only, we used the average covered charge for each DRG generated from the 1994 MedPAR file for those procedures occurring in the hospital. This average charge obtained from the MedPAR file was applied to the DRG's identified in the 1994 NIS database.

Data Preparation And Assessment

The data sets obtained for this project were used to generate two types of rank-ordered lists: rank-ordered by volume (ROV) and rank-ordered by dollar (ROD). Although the initial goal was to generate two (2) lists (ROV and ROD) that would combine both inpatient and outpatient procedures, additional lists (ROV and ROD) containing only inpatient procedures were also generated. This was considered important in light of the fact that there are different drivers of technology utilization in the inpatient vs the outpatient setting; such a report could provide useful information for targeting technology innovation in hospitalized settings. Therefore, the data was assessed and presented as follows: ROV list for combined inpatient and outpatient procedures as well as inpatient

procedures only; ROD list for combined inpatient and outpatient procedures as well as inpatient procedures only.

Rank Order By Volume (ROV)

For the combined inpatient and outpatient report (Combined Report), the following data sources were used: Medicare Part B, WMCO, SMCO. The majority of the procedures identified were captured primarily by ICD-9 or CPT-4 procedure codes. These 2 coding systems were developed independently; thus, there was no direct "map" between the 2 coding systems. For the Combined Report, it was necessary to translate the ICD-9 procedure codes to CPT-4 codes. This was a tedious task involving effort from personnel in the medical records department. They translated the codes and provided a "map" between the 2 coding systems for the procedure codes identified in the rank-ordered lists for this project. Two primary issues were identified in this process: one, for some ICD-9 codes, there were multiple CPT-4 codes that were related; two, there was overlap in the code descriptions. In an effort to minimize the potential effect of these two issues overestimating the rank-ordered status of some procedures, we grouped the data using CPT-4 codes collapsed to the first 3 digits. For the few procedures captured by HCPCS codes, we grouped the data using the alphanumeric codes collapsed to the first 3 digits. (The complete procedure codes in the category that collectively constituted over 80% of the procedures for the top 20 categories were reported). For each data source used for the ROV Combined Report, a rank-ordered list by collapsed code (CPT and HCPCS) was generated. In an effort to provide a single rank-ordered report (ROV) for the combined inpatient and outpatient procedures, the procedures were reranked based on the weighted rank calculated with the inverse of the mean rank of each procedure grouping from each data source. The steps are summarized as follows: data on the top 200 procedures identified by the 5-digit procedure codes were entered into a d-Base III plus file. After a new field was created for the procedure category based on the first three digits of the procedure code, a new file was created for each data source that aggregated the volume over the category code. Procedures were ranked in descending order based on the aggregated volume of the categories. A weight for each category rank was calculated based on the inverse average of the three original ranks. For those categories with a missing rank (the procedure did not fall into the top 200 ranked procedures) they were given the highest rank for the data set (i.e. 200). Based on the calculated rank weights, the procedure categories were re-ranked in descending order. Once the highest volume procedure categories were identified using the process described above, we itemized the individual procedure codes making up each of the top 20 procedure categories. The individual procedure codes making up at least 80% of the procedure code category are provided in Table 18.

The ROV Inpatient Report was generated using 2 sources: 1994 HCUP-3 NIS and the 1994 MedPAR file. Because inpatient discharge files (the source of this data) contain conditions and procedures by DRG code, we generated the list based on DRG codes. For the two data sets used for this Inpatient Report, a rank-ordered list by DRG code was

generated. In an effort to provide a single rank-ordered report (ROV) for inpatient procedures, the procedures were reranked based on the weighted rank calculated with the inverse of the mean rank of each procedure code from each data source. The following steps summarized the methodology used. A weighted national estimate for the total number of discharges for each DRG was estimated using the 1994 NIS data. (The estimated total discharges for all DRGs was 34,622,203). The top 200 DRG's were extracted and placed in a separate file together with the estimated total number of discharges for each DRG and the ranks that were assigned based on the number of discharges in descending order. Data obtained from HCFA (that was based on the MedPAR file) was provided in a format that aggregated the DRGs from short-stay hospitals in the MedPAR file and ranked them in descending order by number of discharges per DRG. The two data sets (NIS and MedPAR) were merged together by the DRG code while retaining the original rank in each unique data set. A weight for each DRG rank was calculated based on the inverse average of the original ranks. Any DRG code that had a missing rank (i.e. a specific DRG code was ranked in the top 200 codes for 1 data set but not for the other data set) was given the highest rank for the data set (i.e. 200). Therefore, if a DRG ranked top in both data sets, it would be given a higher weight. Based on the rank weights, the merged data were reranked in descending order.

Rank Order By Dollar (ROD)

For the Combined Report containing CPT-4 and HCPCS codes, the average national HCFA Medicare Part B allowed charge itemized per code was used. For the Inpatient Report using DRG codes, the average national covered charge itemized per DRG-code was used. This data was obtained from a HCFA download of the MedPAR file from calendar year 1994.

In rank ordering the procedures by dollar for the Combined Report, similar steps were followed as with the rank ordering by procedure volume described above. However, the average HCFA allowed charges multiplied by volume replaced the volume for each procedure in calculating the ranks and the weight ranks for the different categories. The average allowed charge for each category had to be weighted by the volume (combined for the three data sets) of the procedures making up the category. This was necessary because using only the simple averages of the charges making up the three digit procedure category would have over-estimated the average since many of the more expensive procedures had low volumes. In addition, it was necessary to use the weighted average so that the total estimate of charges for each category would match the sum of total estimates of the procedure charges making up that category. In rank ordering the procedures by dollar for the inpatient report, similar steps were followed as with the rank ordering by DRG volume described above. However, the average HCFA covered charge was multiplied by the number of discharges which resulted in a number that replaced the number of discharges for each DRG in the steps outlined above.

ROV and ROD Results

Using the data sources described in the methods section; we generated rank ordered lists: Combined Report: ROV and ROD; Inpatient Report: ROV and ROD. We report the procedures comprising the top 20 procedure categories generated for each list. (Table 18 through Table 23).

Discussion

The goal of this project was to obtain information regarding utilization of current health care technologies; the high volume and/or high cost technologies identified could guide future efforts for technology development and for assessing the potential of existing and future technologies potential to reduce health care cost while maintaining or improving quality of healthcare. From the three data sets (Medicare, WMCO, SMCO), used for the Combined Reports, we reported the leading procedures ranked by volume and by dollar for combined inpatient and outpatient encounters. In addition, the leading DRGs (diagnostic related groups) in hospital short-stay facilities have been identified and ranked by dollar and volume using two data sources: HCUP 3-NIS and MedPAR.

Rank Ordering Of Combined Inpatient And Outpatient Procedures

The top five procedure categories ranked by dollar and volume are the following: patient visits (inpatient and outpatient), chest x-rays, mammograms, ophthalmological services, and electrocardiograms (9). Patient visit (inpatient and outpatient) was the leading procedure category for both dollar and volume rankings. Although this was not unexpected, it provides quantitative information that may support the need and/or use of telemedicine or similar technology in the evaluation and management of patients.

Although the rank ordering of procedures by volume and dollar for the combined inpatient and outpatient report (Table 18 and Table 19) are similar (Spearman Rank Order correlation coefficient = 0.67 $p < .001$), there are notable differences. Procedure categories that were listed in the high-volume ranking, but not in the high-dollar ranking included: influenza vaccine, urinalysis, shoulder x-rays, ankle and foot x-rays, prothrombin time, and thyroxin and thyroid stimulating hormone tests. Procedure categories that were ranked in the high-dollar list but were not included in the high-volume rank ordered list are as follows: sigmoidoscopy/colonoscopy, ambulance services, CAT-scan of the head, radiotherapy, and abdominal echography. Identifying procedure categories that are defined by high-volume and high-dollar rankings provides a basis for evaluation of technologies that may potentially reduce healthcare cost while maintaining or improving quality of care. However, it is important to assess high-volume and high-dollar procedures separately. For those procedures that are identified as high-volume, hypotheses could be generated regarding appropriate utilization of these procedure services. Implementation of information transfer systems among healthcare

providers and between healthcare providers and their patients may facilitate appropriate utilization of some procedures (e.g. sigmoidoscopy/colonoscopy, thyroid testing, breast cancer screening (mammography)). For high-dollar procedures (that are deemed to be appropriately utilized), efforts could be targeted at technological innovation that could result in less invasive and/or less expensive ways of delivering these services/procedures. For example, new technologies that would allow the assessment of blood count and/or blood chemistry evaluation without having to collect the blood sample intravenously may ultimately result in a less expensive approach to performing these blood tests. Conversely, procedures currently ranked as high-dollar may "lose their ranking" if the operative payment mechanism is implemented. For this project, Medicare "allowed" and "covered" charges were used to rank the procedures across data sources in descending order. Application of another payment scheme might result in a change in rank of some or all procedures.

Rank Ordering Of Inpatient Procedures

Because of inpatient billing practices that result in grouping procedure charges in an effort to generate a single bill for the hospitalization, it was not feasible to determine specific charges for individual procedures that occur in the hospital. This was particularly an issue with the smaller, "low cost" procedures such as venipuncture, X-rays, spinal taps. Therefore, inpatient utilization was assessed using DRG's, a system for billing for hospitalizations put forth by HCFA. Although the correlations between the rated ranks by the number of discharges and the weighted ranks by total covered charges for the DRGs assessed was considered good (Spearman rank correlation coefficient = 0.8226; $P < 0.001$) there are differences in the DRGs listed in Table 21 and Table 22 which provide information on the top 20 DRGs that are ranked by dollar and by volume respectively. DRGs that were present in the rank order by volume top 20 list but not present in the rank order by dollar top 20 list are as follows: major joint and limb reattachment procedures of the lower extremities (DRG 209), angina pectoris (DRG 140), esophagitis, gastroenteritis and miscellaneous digestive disorders (DRG 182), nutritional and miscellaneous metabolic disorders (DRG 296), cardiac arrhythmia and conduction disorders with complications (DRG 138), chest pain (DRG 143), kidney and urinary tract infections (DRG 320), chemotherapy without acute leukemia as a secondary diagnosis (DRG 410). DRG's appearing in the top 20 rank order by dollar but not in the top 20 rank order by volume are as follows: tracheostomy except for face, mouth and neck diagnosis (DRG 483), coronary bypass with cardiac catheterization (DRG 106), respiratory system diagnosis with ventilator support (DRG 475), coronary bypass without cardiac catheterization (DRG 106), other vascular procedures with complications (DRG 478), extensive operating room procedures unrelated to the principal diagnosis (DRG 468), and major cardiovascular procedures with complications (DRG 110). In reviewing the data that combined both the National Inpatient Sample Data and the Medicare data, it is interesting to note that the top 5 DRG's that are ranked by number of discharges are predominantly medical diagnosis: heart failure and shock (DRG 127), simple pneumonia and pleurisy (DRG 89) cerebral vascular disorders (DRG 14), chronic obstructive

pulmonary disease (DRG 88) and psychoses (DRG 430). Of note, the top 5 DRG's ranked by total covered charges are predominantly surgical in nature: major joint and limb reattachment procedures of the lower extremity (DRG 209) tracheostomy (DRG 483), coronary bypass with cardiac catheterization (DRG 106), and major small and large bowel procedures with complications (DRG 148) with the exception of heart failure and shock (DRG 127). In selecting conditions/procedures for further evaluation and potential technological innovation, assessing both high volume and high dollar conditions/procedures would be appropriate.

The authors noted that in combining the Medicare and National Inpatient Sample data, this may have biased the data to reflect more of the hospitalizations for Medicare patients than for the U.S. population as a whole. Of note, the National Inpatient Sample reflects all payers and therefore includes Medicare as well as non-Medicare patients. Therefore, we also assessed the top 20 DRG's that were ranked for the National Inpatient Sample both by volume and by dollar of note, the Spearman correlation between volume and charges for the 1994 NIS data was 0.78, $p < 0.001$ (the 4 DRGs with missing charges were excluded from this analysis). The most noted difference between these rank ordered lists (Table 22 and Table 23) and Table 20 and Table 21 are the inclusion of procedures/conditions related to birth: vaginal delivery without complicating diagnosis (DRG 373), normal new born (DRG 391), neonate with other significant problems (DRG 390), cesarean section without complication (DRG 371), vaginal delivery with complicating diagnoses (DRG 372), full-term neonate with major problems (DRG 389). Therefore, based on a sample representative of the U.S. population, there is sufficient data regarding volume and dollars expended on hospitalizations related to birth; this information could provide a foundation for program planning as well as technological innovation.

A potential limitation of this study's conclusions is that administrative data was used as the primary source of information. The results of any study using administrative data are dependent on accurate and reliable coding of the procedures and/or conditions that are under study (10). Procedures or conditions can be miscoded and/or can not be coded (missing data). The experience of several authors (MK-W, RNR, AA) revealed that coding for procedures was reliable (11). In addition, the accuracy of procedures coded was better than that of some diagnoses coded (unpublished data). Nevertheless, administrative data-bases were designed to predominantly track utilization of services for billing purposes; therefore, the use of administrative databases to address the goal of rank ordering technologies utilized in the U.S. was appropriate. With the use of administrative databases, issues regarding patient confidentiality are important. Sometimes, administrative databases do not allow for the assessment of procedures by patient. The unit of analysis for this project was the number of procedures/services utilized and not the number of patients undergoing procedures.

Administrative databases use coding systems that are updated annually. In using the results reported in this paper to compare with subsequent data that becomes available from similar sources, one should be to be aware of the potential impact of coding changes and technology changes on documentation of procedure frequency (12). For example, in trending the HCUP-3 NIS data (1990 - 1993) there was a noted change in rank (15 to 2708) and frequency (512,178 to 30) over the 4 years for mechanical ventilation

procedures captured by ICD-9 code 93.92. Although one might conclude that utilization of mechanical ventilation is decreasing over time in U.S. short-stay hospitals, this conclusion would be erroneous based on the data provided. The change in rank and frequency for mechanical ventilation resulted from the ICD-9 code 93.92 becoming obsolete in 1991. Follow-up regarding the changes in coding would be necessary to fully assess trend changes in mechanical ventilation use or any other procedure. Misunderstanding of coding and technology/practice changes may lead to erroneous conclusions regarding technology utilization in the U.S. hospitals.

Table 18. Rank Order Volume - High Volume Procedures Comprising the Top 20 Ranked Procedure Categories for the Combined Inpatient and Outpatient Report

Number	Category Weight Rank	3 Digit Procedure Category (CPT and HCPCS codes***)	Abbreviated Title	Driver Procedures* for Category	Approximate Aggregate % **
1	1	992	Patient Visit	Established Patient office/outpatient visit (Codes 99211-99215) ·Subsequent hospital care/professional fee/change in status (Codes 99231-99233)	56.1 % 25.8% Subtotal = 81.9%
2	2	710	Chest X-Ray	·Radiologic examination, chest single view (Code 71010) ·Radiologic examination, chest two views (Codes 71020)	46.4% 53.5% Subtotal = 99.9%
3	3	920	Ophthalmologic Services	·Ophthalmological services, medical examination and evaluation (Codes 92002-92014)	87.1% Subtotal = 87.1%
4	4	930	ECG	·Electrocardiogram (ECG), routine ECG with at least 12 leads (Codes 93000-93010)	95.1% Subtotal = 95.1%
5	5	760	Mammogram	Mammography; bilateral (Code 76091) ·Screening Mammography; bilateral (Code 76092)	62.2% 37.1% Subtotal = 99.3%
6	6	971	Physical Medicine Treatment	·Physical medicine treatment to one area (Codes 97110 and 97128††)	89.9% Subtotal = 89.9%
7	6†	993	Nursing Facility Care	·Subsequent nursing facility care/pro-fee (Codes 99311-99313)	99.9% Subtotal = 99.9%
8	8	907	Influenza Vaccine	Immunization, active; influenza virus vaccine (Code 90724)	99.8% Subtotal = 99.8%
9	9	800	Laboratory Blood Tests	·Automated multichannel test; clinical chemistry (Codes 80002, 80007, 80008, 80016, 80018, 80019) Lipid profile (Code 80061) ·Thyroid panel (Codes 80091 and 80092)	77.8% 10.9% 11.3% Subtotal = 100%
10	10	850	Blood Count	·Blood count; hemogram and platelet count, automated (Codes 85023-85027)	92.2% Subtotal = 92.2%

11	11	908	Psychotherapy	·Individual medical psychotherapy by a physician (Codes 90843-90844) ·Group medical psychotherapy (90853)	66.8% 13.4% Subtotal = 80.2%
12	12	810	Urinalysis	Urinalysis, by reagent strips (Codes 81000 and 81002)	99.9% Subtotal = 99.9%
13	13	730	Shoulder X-Ray	Radiologic examination, shoulder complete (Code 73030)	96.5% Subtotal = 96.5%
14	14	735	Hip, Knee X-Ray	Radiologic examination, hip, complete (Code 73510) Radiologic examination, knee; anteroposterior and lateral view (Code 73560)	58.7% 39.3% Subtotal = 98.0%
15	15	736	Ankle, Foot X-Ray	X-ray ankle; complete (Code 73610) X-ray foot; complete (Code 73630)	36.1% 48.8% Subtotal = 84.9%
16	15†	856	PT	Prothrombin Time (PT) (Code 85610)	99.9% Subtotal = 99.9%
17	15†	994	Evaluation and Management	Unlisted evaluation and management service (Code 99499)	100% Subtotal = 100%
18	18	844	Thyroxine, TSH	Thyroxine (Code 84436) Thyroid stimulating hormone (TSH) (Code 84443)	43.2% 56.7% Subtotal = 99.9%
19	19	768	Echography	Echography, pelvic, not OB, B-scan (Code 76856) Echography, pregnant uterus, B-scan (Code 76806) Echography, transvaginal (Code 76830)	38.3% 32.5% 18.5% Subtotal = 89.3%
20	19†	883	Surgical Pathology	Surgical pathology/gross microscopic (Codes 88304 and 88305)	100% Subtotal 100%

* Procedures in the Procedure category that collectively contribute over 80% of the total number of procedures in that category

** Aggregate percent was derived using data from each data source: Medicare, WMCO, SMCO

*** No procedures identified by HCPCS codes were listed in the top 20 procedures categories ranked by volume

† Some categories have similar weight ranks

†† Code has been deleted from 1997 CPT-4 manual

Table 19. Rank Order Dollar - High Dollar Procedures Comprising the Top 20 Procedure Categories (Ranked by Total Estimated Allowed Charges*) for the Combined Inpatient and Outpatient Report

Number	Category Weight Rank	3 Digit Procedure Category (CPT and HCPCS codes**)	Abbreviated Title	Driver Procedures * for Category	Approximate Aggregate % of Dollars per Category
1	1	992	Patient Visit	Established Patient office/outpatient visit (Codes 99211-99215) Subsequent Hospital care/pro. fee (Codes 99231-99233) Initial inpatient consultative professional fee (Codes 99253-99255) Emergency Department Services (Codes 99282-99285)	41.6 % 24.3% 7.3% 7.0% Subtotal = 80.2%
2	2	710	Chest X-Ray	Radiologic examination, chest; single view (Code 71010) Radiologic examination, chest; two views (Codes 71020)	38.4% 61.6% Subtotal = 100.0%
3	3	760	Mammogram	Mammography; bilateral (code 76091) Screening Mammography; bilateral (Code 76092)	63.3% 36.1% Subtotal = 99.4%
4	4	920	Ophthalmologic Services	Ophthalmological services, medical examination and evaluation (Codes 92002-92014) Visual field examination, unilateral or bilateral (Code 92083)	88.5% 11.1% Subtotal = 99.6%
5	5	930	ECG	Electrocardiogram (ECG), routine ECG with at least 12 leads (Codes 93000-93010)	97% Subtotal = 97%
6	6	908	Psychotherapy	Individual medical psychotherapy by a physician (Codes 90843-90844) Group medical psychotherapy (Code 90853)	76.9% 7.5% Subtotal = 84.4%
7	7	933	Echocardiography	Echocardiography, real-time with image documentation (Code 93307) Doppler echocardiography, pulsed wave and/or continuous (Code 93320)	57.4% 23.1% Subtotal = 80.5%
8	8	971	Physical Medicine Treatment	Physical medicine treatment to one area (Codes 97110 and 97128††)	87.4% Subtotal = 87.4%
9	9	993	Nursing Facility Care	Subsequent nursing facility care/pro-fee (Codes 99311-99313)	99.9% Subtotal = 99.9%
10	10	768	Echography	Echography, pregnant uterus, limited (Code 76815) Echography, transvaginal (Code 76830) Echography, pelvic, not OB (Code 76856)	39.3% 16.5% 35.3% Subtotal = 91.1%
11	10†	800	Laboratory Blood Tests	Automated multichannel test (Codes 80002-80012) Lipid profile (Code 80061) Thyroid panel with thyroid stimulating hormone (Code	63.2% 14.3% 17.8%

				80092)	Subtotal = 95.3%
12	12	994	Evaluation and Management Service	Unlisted evaluation and management service (Code 99499)	100% Subtotal = 100%
13	13	453	Sigmoidoscopy/ Colonoscopy	Sigmoidoscopy, flexible fiberoptic, diagnostic (Code 45330) Colonoscopy, fiberoptic (Codes 45378 and 45385)	60.1% 39.9% Subtotal = 100%
14	14	735	Hip, Knee X-Ray	Radiologic examination, hip, complete (Code 73510) Radiologic examination, knee, anteroposterior and lateral view (Code 73560)	60.0% 37.9% Subtotal = 97.9%
15	14†	850	Blood Count	Blood count, hemogram and platelet count, automated (Codes 85007-85027)	95.9% Subtotal = 95.9%
16	16	883	Surgical Pathology	Surgical pathology, gross and microscopic examination (Codes 88304-88305)	100% Subtotal = 100%
17	16†	A02***	Ambulance	Ambulance service and supplies (Codes A0215, A0220, A0222)	100% Subtotal = 100%
18	18	704	CAT Scan - Head	Computerized axial tomography (CAT) scan, head or brain (Code 70450)	98.6% Subtotal = 98.6%
19	18†	774	Radiotherapy	Weekly radiotherapy management; complex (Code 77430)	99.9% Subtotal = 99.9%
20	20	767	Abdominal Echography	Echography, abdominal B scan and/or real time (Code 76700)	99.0% Subtotal 99.0%

† Some categories have similar weight ranks

* HCFA national average "allowed" charge for each relevant code was applied across each data set (Medicare Part B, WMCO, SMCO). The charge was multiplied by the frequency for each code in all datasets to generate total estimated allowed charges for each category.

†† Code has been deleted from the 1997 CPT-4 manual

** HCPCS = HCFA Common Procedural Coding System
CPT = Current procedure terminology

*** HCPCS alphanumeric code

Table 20. Rank order volume: weighted ranks for the top 20 DRG's ranked by number of discharges for inpatient data* only

NUMBER	WT RANK	DRG	DESCRIPTION
1	1	127	HEART FAILURE AND SHOCK
2	2	89	SIMPLE PNEUMONIA AND PLEURISY AGE GREATER THAN 17 WITH COMPLICATIONS
3	3	14	SPECIFIC CEREBROVASCULAR DISORDERS EXCEPT TRANSIENT ISCHEMIC ATTACK
4	3	88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
5	3	430	PSYCHOSES
6	6	209	MAJOR JOINT AND LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY
7	7	140	ANGINA PECTORIS
8	7	182	ESOPHAGITIS, GASTROENTERITIS AND MISCELLANEOUS DIGEST DISORDERS AGE GREATER THAN 17 WITH COMP
9	9	112	PERCUTANEOUS CARDIOVASCULAR PROCEDURES
10	9	174	GASTROINTESTINAL HEMORRHAGE WITH COMPLICATIONS
11	11	296	NUTRITIONAL AND MISCELLANEOUS METABOLIC DISORDERS AGE GREATER THAN 17 WITH COMPLICATIONS
12	12	138	CARDIAC ARRHYTHMIA AND CONDUCTION DISORDERS WITH COMPLICATIONS
13	13	143	CHEST PAIN
14	14	79	RESPIRATORY INFECTIONS AND INFLAMMATIONS AGE GREATER THAN 17 WITH COMPLICATIONS
15	14	416	SEPTICEMIA AGE GREATER THAN 17
16	16	462	REHABILITATION
17	17	148	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITH COMPLICATIONS
18	18	121	CIRC. DISORDERS WITH ACUTE MYOCARDIAL INFARCTION AND CARDIOVASCULAR COMPLICATIONS DISCHARGED ALIVE
19	18	320	KIDNEY AND URINARY TRACT INFECTIONS AGE GREATER THAN 17 WITH COMPLICATIONS
20	18	410	CHEMOTHERAPY WITHOUT ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS

* Data = 1994 Medicare (MedPAR) and 1994 National Inpatient Sample (NIS) data

Table 21. Rank order dollar: weighted ranks for the top 20 DRG's ranked by total covered charges† for inpatient data* only

NUMBER	WT RANK	DRG	DESCRIPTION
1	1	209	MAJOR JOINT AND LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY
2	1	483	TRACHEOSTOMY EXCEPT FOR FACE, MOUTH AND NECK DIAGNOSES
3	3	106	CORONARY BYPASS WITH CARDIAC CATHETERIZATION
4	4	127	HEART FAILURE AND SHOCK
5	5	148	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITH COMPLICATIONS
6	6	89	SIMPLE PNEUMONIA AND PLEURISY AGE GREATER THAN 17 WITH COMPLICATIONS
7	6	430	PSYCHOSES
8	6	112	PERCUTANEOUS CARDIOVASCULAR PROCEDURES
9	9	14	SPECIFIC CEREBROVASCULAR DISORDERS EXCEPT TRANSIENT ISCHEMIC ATTACK
10	10	462	REHABILITATION
11	11	475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT
12	12	88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
13	12	79	RESPIRATORY INFECTIONS AND INFLAMMATIONS AGE GREATER THAN 17 WITH COMPLICATIONS
14	12	107	CORONARY BYPASS WITHOUT CARDIAC CATHETERIZATION
15	15	478	OTHER VASCULAR PROCEDURES WITH COMPLICATIONS
16	16	416	SEPTICEMIA AGE GREATER THAN 17
17	16	468	EXTENSIVE OPERATING ROOM PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS
18	16	110	MAJOR CARDIOVASCULAR PROCEDURES WITH COMPLICATIONS
19	19	121	CIRCULATORY DISORDERS WITH ACUTE MYOCARDIAL INFARCTION AND CARDIOVASCULAR COMPLICATION, DISCHARGED ALIVE
20	20	174	GASTROINTESTINAL HEMORRHAGE WITH COMPLICATIONS

* Inpatient data = 1994 Medicare (MedPAR) and 1994 National Inpatient Sample

† Total covered charge was generated using the national average Medicare "covered" charge per DRG time the frequency of the relevant DRG

Table 22. Rank Order Volume: top 20 DRGs ranked by the weighted national estimates of the total number of discharges for 1994 National Inpatient Sample Data

RANK	DRG	DESCRIPTION	WEIGHTED ESTIMATE OF TOTAL # OF DISCHARGES
1	373	VAGINAL DELIVERY WITHOUT COMPLICATING DIAGNOSES	2,488,530
2	391	NORMAL NEWBORN	2,464,317
3	127	HEART FAILURE AND SHOCK	951,821
4	390	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	819,659
5	430	PSYCHOSES	796,316
6	89	SIMPLE PNEUMONIA AND PLEURISY AGE GREATER THAN 17 WITH COMPLICATIONS	615,274
7	371	CESAREAN SECTION WITHOUT COMPLICATION	563,507
8	14	SPECIFIC CEREBROVASCULAR DISORDERS EXCEPT TRANSIENT ISCHEMIC ATTACK	534,237
9	88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	511,064
10	209	MAJOR JOINT AND LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY	500,476
11	112	PERCUTANEOUS CARDIOVASCULAR PROCEDURES	454,142
12	182	ESOPHAGITIS, GASTROENTERITIS AND MISCELLANEOUS DIGESTIVE DISORDERS AGE GREATER THAN 17 WITH COMPLICATIONS	450,676
13	140	ANGINA PECTORIS	445,797
14	143	CHEST PAIN	430,976
15	174	GASTROINTESTINAL HEMORRHAGE WITH COMPLICATIONS	400,543
16	359	UTERINE AND ADNEXA PROCEDURES FOR NON-MALIGNANCY WITHOUT COMPLICATIONS	381,961
17	372	VAGINAL DELIVERY WITH COMPLICATING DIAGNOSES	328,331
18	389	FULL TERM NEONATE WITH MAJOR PROBLEMS	323,689
19	296	NUTRITIONAL AND MISCELLANEOUS METABOLIC DISORDERS AGE GREATER THAN 17 WITH COMPLICATIONS	320,202
20	138	CARDIAC ARRHYTHMIA AND CONDUCTION DISORDERS WITH COMPLICATIONS	314,685

Table 23. Rank Order Dollar: top 20 DRG's ranked by the total covered charges† For the 1994 National Impatient Sample (NIS) Data

RANK	DRG	DESCRIPTION	AVERAGE COV HCFA CHARGES	WEIGHTED EST # OF DISCH	TOTAL COVERED CHARGES
1	483	TRACHEOSTOMY EXCEPT FOR FACE, MOUTH AND NECK DIAGNOSES	$152,190.60	71,385	$10,864,126,001
2	209	MAJOR JOINT AND LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY	$ 19,769.88	500,476	$ 9,894,352,667
3	106	CORONARY BYPASS WITH CARDIAC CATHETERIZATION	$ 51,476.68	176,187	$ 9,069,522,569
4	389	FULL TERM NEONATE WITH MAJOR PROBLEMS	$ 27,982.57	323,689	$ 9,057,649,022
5	430	PSYCHOSES	$ 11,299.08	796,316	$ 8,997,634,247
6	127	HEART FAILURE AND SHOCK	$ 9,026.47	951,821	$ 8,591,583,405
7	112	PERCUTANEOUS CARDIOVASCULAR PROCEDURES	$ 18,516.73	454,142	$ 8,409,223,461
8	373	VAGINAL DELIVERY WITHOUT COMPLICATING DIAGNOSES	$ 3,324.56	2,488,530	$ 8,273,268,255
9	148	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITH COMPLICATIONS	$ 29,145.64	274,396	$ 7,997,447,481
10	89	SIMPLE PNEUMONIA AND PLEURISY AGE GREATER THAN 17 WITH COMPLICATIONS	$ 9,484.51	615,274	$ 5,835,573,688
11	14	SPECIFIC CEREBROVASCULAR DISORDERS EXCEPT TRANSIENT ISCHEMIC ATTACK	$ 10,695.51	534,237	$ 5,713,936,653
12	390	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	$ 6,707.81	819,659	$ 5,498,116,446
13	475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	$ 33,367.58	160,178	$ 5,344,752,387
14	107	CORONARY BYPASS WITHOUT CARDIAC CATHETERIZATION	$ 39,645.84	124,828	$ 4,948,911,258
15	462	REHABILITATION	$ 16,982.44	268,745	$ 4,563,945,311
16	88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	$ 8,489.62	511,064	$ 4,338,737,177
17	468	EXTENSIVE OPERATING ROOM PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	$ 31,430.08	130,529	$ 4,102,536,396
18	79	RESPIRATORY INFECTIONS AND INFLAMMATIONS AGE GREATER THAN 17 WITH COMPLICATIONS	$ 14,303.48	273,835	$ 3,916,794,048
19	110	MAJOR CARDIOVASCULAR PROCEDURES WITH COMPLICATIONS	$ 37,637.83	103,557	$ 3,897,661,010
20	478	OTHER VASCULAR PROCEDURES WITH COMPLICATIONS	$ 21,094.77	180,894	$ 3,815,917,656

† Total covered charges was generated using the national average Medicare "covered" charge per DRG times the frequency of the relevant DRG identified in the NIS data

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Appendix B - Econometric Analysis of Savings Available from PTCA Innovation: The Nine Category Approach

Introduction

There are two competing technologies for the treatment of Coronary Artery Diseases (CAD), PTCA and CABG. It is generally recognized that for those patients for which it is appropriate, PTCA is the less expensive treatment, at least for the initial intervention. For many patients, however, PTCA is not an appropriate treatment. The goal of this part, as well as the next, is to determine the amount of savings available if new technologies could make PTCA viable for the patients who currently undergo CABG treatment.

This amount cannot be calculated by simply taking the average CABG treatment costs and subtracting it from the average PTCA treatment cost. The reason is that CABG patients have systematically different characteristics than PTCA patients. In particular, CABG patients may be "sicker" and thus require more intensive treatment. This requirement would continue to be true even if it were possible to treat those patients with PTCA.

Thus, we attempt to conduct a hypothetical "thought exercise": How much would be saved if we could treat CABG patients with PTCA technology? A special feature of this test is that we are able to break down costs by nine separate areas in the hospital. Thus, not only are we able to predict the relevant cost savings, but also to predict where in a hospital those cost savings would occur.

Data Sources

Our data comes from a large hospital in a major city in the Southern part of the United States. We have in our data every patient who underwent either CABG or PTCA at that hospital during 1994. We also have data on detailed charges for each patient. Thus, for one patient we could conceivably have thousands of individual charges items in our data set. We will conduct our analysis on both charges and costs. We will generate costs by employing detailed cost to charge ratios reported by that hospital for Medicare cost reports.

We have taken the numerous charges per patient and aggregated them into nine categories. The nine categories are

1. room charges,

2. intensive care,
3. laboratory and radiology,
4. pharmacy,
5. rehabilitation,
6. operating room,
7. catheterization laboratory,
8. cardiovascular diagnostic, and
9. miscellaneous.

Due to the differences in procedures, CABG and PTCA patients are likely to have different intensities of uses across several of the categories. For instance, PTCA treatments make intensive use of the catheterization laboratory and little use of the Operating Room. For CABG, the reverse is true. This presents estimation issues that we will deal with below in Section III.

We also have detailed data on patients' health conditions, and use it as explanatory variables in our regressions. The patient characteristics are:

1. Treatment type. (Abbreviated below as TREAT) The treatment the patient underwent, CABG=1, PTCA=0;
2. Comorbidity (COM). The comorbidity score of the patient, which indicates the severity of illnesses other than CAD that the patient might have;
3. Gender. Whether or not the patient was a man (Gender=1) or a woman (Gender=0);
4. Smoker. Equals 1 if patients smokes, 0 otherwise;
5. Age. Age of the patient in years;
6. Acute myocardial-infarction within 24 hours of admission (AMI=1 if occurred, 0 otherwise);
7. If the patient had prior CABG treatment (PR_CABG=1 if treated with CABG previously, 0 otherwise);
8. If the patient had a prior PTCA treatment (PR_PTCA=1 if previously treated, 0 otherwise);
9. The ejection fraction of the patient's heart (EF60). We note that many patients had missing data for this entry. Consultations with clinicians indicated that this is likely to occur when the patients has a normal ejection fraction of 60. We therefore set the EF60 of patients with unknown values to 60;
10. Whether the patient's heart had stenosis of two or more vessels (VES2);
11. Whether the patient's heart had stenosis of three or more vessels (VES3);
12. Whether the patient's heart had stenosis of the left main artery (LEFT);
13. The number of unpredicted adverse events that occurred to the patient while in the hospital (UNADV). We describe how this variable is derived below in Subappendix B1. Table 24 presents the variable means, broken down by CABG and PTCA patients.

Table 24. Variable Means (Standard Deviations in Parentheses)

Variable	CABG Patients	PTCA Patients	All Patients
Comorbidity	1.78 (1.86)	1.43 (1.56)	1.53 (1.65)
Gender	0.20 (0.40)	0.32 (0.47)	0.28 (0.45)
Smoker	0.55 (0.50)	0.35 (0.48)	0.41 (0.49)
Age	62.56 (9.95)	64.50 (11.60)	63.96 (11.2)
AMI	0.09 (0.26)	0.10 (0.30)	0.10 (0.29)
Prior CABG	0.12 (0.33)	0.28 (0.45)	0.24 (0.43)
Prior PTCA	0.18 (0.39)	0.38 (0.49)	0.33 (0.47)
EF	52.18 (15.00)	55.70 (13.50)	54.73 (14.0)
VES2	0.94 (0.25)	0.67 (0.47)	0.74 (0.44)
VES3	0.83 (0.38)	0.37 (0.48)	0.50 (0.50)
LEFT	0.29 (0.46)	0.06 (0.25)	0.13 (0.33)
UNADV	-0.16 (2.79)	-0.14 (2.04)	-0.15 (2.27)
Room Charges ($)	5720 (4717)	2019 (1826)	3038 (3354)
Intensive Care Charges ($)	8349 (17623)	2831 (5077)	4351 (10,48)
Laboratory/ Radiology Charges ($)	4285(10,146)	1579(2508)	2365 (4162)
Pharmacy Charges ($)	4284(10,147)	1018(2586)	1917 (5931)
Rehabilitation Charges ($)	628(680)	105(227)	249 (459)
Operating Room Charges ($)	21,340(6427)	527(1945)	6259 (10,03)
Catheterization Laboratory Charges ($)	2427(3174)	15,822(6419)	12,133 (827)
Cardiovascular Diagnostic Charges ($)	647(2100)	571(3795)	592 (3412)
Miscellaneous Charges ($)	12,050(20344)	1984(5641)	4756 (12,51)
Total Charges ($)	59,917(63,154)	26,457(20,898)	35,672 (40,408)
Number of Observations	141	371	512

Econometric Issues

One of the things we wish to accomplish is to predict the savings associated with switching a CABG patient to PTCA. To do so requires that we apply the proper econometric modeling. In this context, we face two important econometric issues: sample selection bias and censoring.

Sample Selection Bias

Sample selection bias may result because treatment type is a function of many of the same variables that determine charge (or cost). If selection bias does occur to a high degree, Ordinary Least Squares (OLS) regression is not the appropriate estimation procedure. For example, consider whether or not a particular patient is a smoker. This variable will influence both charge and treatment type. The question arises as to how smoking effects charge. Does smoking increase charge because it increases the resources necessary for care, or does it increase charge because it increases the probability of the patient receiving a CABG, which is a more expensive procedure? Because treatment is not necessarily determined in a linear way, the question of selection bias is both important and complex.

In an attempt to determine if selection bias is important to the charge equations, we first performed the estimation of a model where each regression is allowed to have a different set of coefficients and then a regression where both sets of coefficients were restricted to be the same. First we will explain the structure of the model, and then we will explain the econometric results

We start by assuming a model of the choice made between PTCA and CABG.[2] We assume that the probability of a CABG treatment for patient (i) is $\Phi(\gamma Z_i)$, where $\Phi(\cdot)$ is the cumulative normal density function, γ is a set of estimated coefficients, and Z_i is the set of explanatory variables. In Subappendix B2 we report the results of this "Probit" estimation for our data set.

Given this choice, we have two potential econometric models. For CABG patients, we have

$$\text{Charge} = b_c'X_1 + u_{c1} \text{ if } \gamma Z_1 < \varepsilon_1 \text{ i.e., if CABG treatment (see Subappendix B1)} \quad (1)$$

and for PTCA patients;

$$\text{Charge} = b_p'X_i + u_{pi} \text{ if } \gamma Z_i < \varepsilon_i \quad \text{i.e. if PTCA treatment.} \quad (2)$$

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[2] For the most part this model comes from: G.S. Maddala, *Limited Dependent and Qualitative Variables in Econometrics*, Econometric Society Monographs, Cambridge University Press, 1983, pp 223-228.

In these equations, b_c and b_p represent the estimated coefficients on the CABG and PTCA costs functions, X_i represents the set of explanatory variables described above, and u_{ci} and u_{pi} represent the normally distributed error terms on each charge equation.

In order to estimate the model in a way which allows us to test the validity of the assumption of different coefficients, we must reformulate the model. If we take the expected value of Charge we get:

$$E(Charge) = [E(Charge|TREAT=CABG)] \times [Prob(TREAT=CABG)] + [E(Charge|TREAT=PTCA)] \times [Prob(TREAT=PTCA)]. \quad (3)$$

Here E is the expected value operator and "|" is read as "given that". The expected value of Charge is equal to the expected value of Charge given that Treatment is CABG times the probability that Treatment is CABG plus the expected value of Charge given that Treatment is PTCA times the probability that Treatment is PTCA.

If we put the equation for γZi into probit form, we can recover the results of the probit estimation of PTCA vs. CABG. The probability of individual i receiving a CABG is given by $F(\gamma Z_i)$ which is the CDF of a normal zero-one random variable. Because patients only arrive in our sample if they undergo either CABG or PTCA, if the probability of CABG is F_i, it implies the probability of PTCA is $1-F_i$.

Each of the charge equations (1) and (2) is a truncated regression. A truncated regression is a regression which has some of the useable observations removed based on some criteria, here treatment type. This type of truncation results in an expectation of the form. $E(Charge) = b'X_i - s(f_i/F_i)$ (Maddala equation 8.12) for truncation "from below " (CABG equation) and $E(Charge) = b'X_i + s(f_i/1-F_i)$ (Maddala equation 8.13) for truncation "from above " (PTCA equation), where f_i is the PDF of a normal zero-one variable.

The term on the end of the equations, $s(f_i/F_i)$ or $s(f_i/1-F_i)$ accounts for the truncation. The s variable is the standard deviation of the equation, implying there is a different s associated with each equation. The variable s_{cu} is the standard error of the CABG only (equation (1)) and s_{pu} is the standard error from the PTCA only (equation (2)). Though s is a defined parameter it can be treated as a coefficient to be estimated, because asymptotically (as our data set becomes systematically larger) the estimated value will equal the true value.

Filling in the values for each of the pieces of equation (3) yields:

$$E(Charge) = [b_c'X_i - s_{cu}(f_i/F_i)] \times [F_i] + [b_p'X_i + s_{pu}(f_i(1-F_i))] \times [1-F_i]. \quad (4)$$

Multiplying this out gives us

$$E(\text{Charge}) = \beta_c'X_i\Phi_i - \sigma_{cu}f_i + \beta_p'X_i(1-\Phi_i) + \sigma_{pu}f_i. \quad (5)$$

Rearranging equation (5) eventually yields

$$E(\text{Charge}) = \beta_p'X_i + (\beta_c' - \beta_p')X_iF_i + f_i(\sigma_{pu} - \sigma_{cu}), \quad (6)$$

where F_i and f_i are from the probit of PTCA vs. CABG.

This form has several advantages. X_i is known and both F_i and f_i are estimable via the Probit procedure discussed in Subappendix B2. Therefore the model can be expressed as a simple linear regression with β_p', $(\beta_c' - \beta_p')$, and $(\sigma_{pu} - \sigma_{cu})$ as coefficients to be estimated. It is straightforward to test whether the individual coefficients are significantly different between the CABG and PTCA equations. It is accomplished for one coefficient by a simple t-test on the appropriate coefficient of $(\beta_c' - \beta_p')$; if the coefficient is significantly different than zero then the coefficients in each model are significantly different. The whole model specification can be tested by a likelihood ratio test on the coefficients of $(\beta_c' - \beta_p')$ and $(\sigma_{pu} - \sigma_{cu})$.

Using the estimated, rather than the actual, values of F_i and f_i introduces heteroskedasticity into the equation. This causes the estimated t-statistics to be biased away from zero. Therefore we use a likelihood ratio test to test the validity of the model.

The likelihood function is a measure of how likely the it is for us to get the actual observed results, based on the estimated model. The likelihood function measures how closely the pattern of dependent variables based on the estimated coefficients match the actual observed pattern of dependent variables. One of the things OLS does is to maximize the value of the likelihood function. The likelihood function is a well known function which gives us a number that we may use to test different model specifications.

The likelihood ratio test requires the estimation of two models; the restricted and the unrestricted models. We then generate a statistic that allows us to test whether the two models are significantly different in a statistical sense. Specifically, $2 \times [\ln(L_{\text{unrestricted}}) - \ln(L_{\text{restricted}})] \sim \chi^2(\#\text{ restrictions})$. The symbol "~" is read "*is distributed as*", "*ln*" is the natural logarithm operator, "*L*" is the value of the likelihood function from the appropriate model, and "*#restrictions*" is the number of restrictions on the restricted model which are the degrees of freedom for the χ_2 statistic. For this specific instance the two models are:

$$\text{Charge}_{\text{unrestricted}} = \beta_p'X_i + (\beta_c' - \beta_p')X_iF_i + f_i(\sigma_{pu} - \sigma_{cu}) + \text{error} \quad (7)$$

and

$$\text{Charge}_{\text{restricted}} = \beta_p'X_i + \text{error} \quad (8)$$

Equation (8) is the restricted model with the restrictions that (s_{pu} - s_{cu}) and (b_c'-b_p') are zero. Note that (8) is a straightforward linear regression model, while (7) is the more complex switching model defined originally by equations (1) and (2).

First we estimated equations (7) and (8) by OLS to compare the likelihood ratios. There are 13 coefficients restricted to be zero; twelve for (b_c'-b_p') and one (s_{pu}-s_{cu}). That is that the twelve coefficients on the explanatory variables are the same for both PTCA and CABG [b_c'=b_p' or (b_c'-b_p') = 0], and the standard error of both models is the same [(s_{up}-s_{cu}) = 0]. The 95% critical value from a $c^2(13)$ is approximately 22.36, thus any result above 22.36 would indicate that the appropriate model is the switching model postulated in (1) and (2) while lower results would indicate that the correct model should be a simple linear model with all coefficients the same for both PTCA and CABG. The results are summarized below in Table 25.

Table 25. Test of Different Coefficients for CABG and PTCA. 95% Cutoff Threshold: 22.3620.

Category	Log-Likelihood of Unrestricted Model (Equation (7))	Log-Likelihood of restricted Model (Equation (8))	Likelihood Ratio Test Statistic $2 \times [\ln(L_{unrestricted}) - \ln(L_{restricted})]$
Room	-1060.99	-1067.90	13.82
Intensive Care	-1258.73	-1264.13	10.80
Laboratory/ Radiology	-1050.51	1055.28	9.54
Pharmacy	-654.78	-667.93	26.30
Rehab	-1080.37	-1092.37	24.00
Operating Room	-1077.26	-1092.30	30.08
Catheterization Lab.	-1122.25	-1135.28	26.06
Cardiovascular Diag.	-778.64	-785.42	13.56
Miscellaneous	-643.98	-655.58	23.21

The likelihood ratio statistic is chi square variable with 13 degrees of freedom. At the 95% level this value is 22.3620. Therefore, if the likelihood ratio test statistic is greater than 22.3620 we reject the hypothesis that model (1) is the correct model.

The relevant statistics for Room, Intensive Care, Laboratory/Radiology, and Cardiovascular Diagnostic are all below this critical level. This implies that it is appropriate to run one regression with CABG and PTCA patients together for those four categories., using the treatment variable alone to account for the difference between CABG and PTCA patients. The relevant statistics for Pharmacy, Rehabilitation, Operating Room, Catheterization Laboratory, and Miscellaneous, however, are all above the cutoff level of 22.36. This implies that we should run two separate regressions for each category, one for the CABG patients and one for the PTCA patients.

Censoring

For many of the patients, charges in particular categories were zero. For example Operating Room Charge is zero for many patients because PTCA does not, in general, require an time in the operating room. Because of this, the question of censoring arises. A censored regression is one in which the dependent variable must be greater than some level in order to be observed. If it is not greater than this critical value, then a zero is observed. Take, for example, Intensive Care Charge. This variable is dependent on how "sick" a patient is, the "sicker" the patient, the higher the intensive care charge. However, the patient must have some minimum level of "sickness" before he is remitted to intensive care. If we try to estimate a linear model when a censored model is appropriate, then our estimates may be biased. In other words, using a linear model, implies everyone with an Intensive Care charge of zero would be required to be equally "sick", which may not be true.

Expressed mathematically, let the "sickness" of a patient be $\mathbf{a}'X_i$. So we have a model of the form:

$$\text{Charge} = \mathbf{a}'X_i + u_i \text{ if } \mathbf{a}'X_i + u_i > 0 \quad (9)$$

$$\text{Charge} = 0 \text{ if } \mathbf{a}'X_i + u_i < 0 \quad (10)$$

Note that in this model the minimum "sickness" level is set to 0. If we were to change it, the only effect would be to change the constant term by whatever we set the minimum level to be. Thus we use zero for simplicity.

A well- known procedure, called Tobit, exists for estimating this type of model. Estimation of a Tobit model is very similar to the switching model defined by (1) and (2). All that is necessary is to define separate functions for each of the cases (9) and (10). First take the expected value as defined by:

$$E(\text{Charge}) = [E(\text{Charge}|\text{Charge} > 0)] \times [\text{Prob}(\text{Charge} > 0)] + [E(\text{Charge}|\text{Charge} = 0)] \times [\text{Prob}(\text{Charge} = 0)]. \quad (11)$$

If we define a dummy variable that is zero when Charge = 0, and 1 when Charge > 0, then perform a Probit analysis with that dummy as the dependent variable and X as the independent variables we can estimate Prob(Charge = 1) and Prob(Charge = 0). Specifically, the estimated probability is $\mathbf{d}'X_i = F_i$ = Prob(Charge = 1) and $(1 - F_i)$ = Prob(Charge = 0), where $\mathbf{d}$ are the estimated probit coefficients. It can be shown that E(Charge|Charge > 0) can be estimated by $\mathbf{a}'X_i+\mathbf{s}(f_i/F_i)$, where f_i and F_i are estimated from the probit analysis, and $\mathbf{s}$ can be treated as a coefficient to be estimated. Of course, E(Charge|Charge = 0) is 0. Filling in the values for equation (11) gives us:

$$E(\text{Charge}) = [\mathbf{a}'X_i+\mathbf{s}(\phi_i/F_i)] \times [F_i] + [0] \times [1 - F_i]. \quad (12)$$

This can be rearranged into:

$$E(\text{Charge}) = \mathbf{a}'X_iF_i + \mathbf{s}f_i, \quad (13)$$

which can be estimated either by maximum likelihood methods or by a two step process.

We performed the Tobit analysis on all of the Charge categories where it was appropriate (where there were sufficient zeros). Pharmacy Charge and Miscellaneous Charge did not contain zeros and thus were not estimated via Tobit, but all others were. (If all observations are positive, then the two procedures would be identical.)

Equation (13) varies from a straight OLS estimate in F_i and $\mathbf{s}f_i$. A sufficient restriction to make the Tobit equation equal to the OLS equation is $F = 1$, which means that all observations are positive. This would imply $f = 0$. The 95% value for one restriction is $\chi^2(1) = 3.84146$. This statistic is calculated by taking twice the differences of the relevant log-likelihood functions. Below Table 26 shows the likelihood ratio tests statistics for Tobit vs. OLS.

Table 26 shows that for five of the seven categories tested, Emergency, Laboratory and Radiology, Rehabilitation, Operating Room and Catheterization Laboratory, the relevant test statistic is above the 95% cutoff level of 3.84146. That implies that for these five categories Tobit, rather than OLS, is the appropriate estimation technique. For Room and Miscellaneous charges, however, the relevant test statistic was under the 95% cutoff level. For these charge categories, OLS is the appropriate estimation technique.

Table 26. Test of Tobit vs. OLS. 95% Cutoff Threshold: 3.84146

Category	Tobit Log-Likelihood	OLS Log-likelihood	Likelihood Ratio Test Statistic
Room	-4445.25	-4446.56	2.6
Intensive Care	-4386.25	-4401.00	29.5

Laboratory/ Radiology	-4456.73	-4458.82	4.2
Pharmacy	N/A	N/A	N/A
Rehabilitation	-2617.44	-2668.28	101.7
Operating Room	-1939.09	-2163.93	449.7
Cath Lab	-4477.51	-4491.47	27.9
Cardiovascular Diag.	-4818.01	-4818.13	0.2
Miscellaneous	N/A	N/A	N/A

Table 27 summarizes the results of our econometric tests. These tests indicate we should run the charge regressions for Room and Cardiovascular Diagnostics with CABG and PTCA patients pooled together using OLS; for Intensive Care and Laboratory/Radiology we should run separate CABG and PTCA regressions using Tobit, for Pharmacy and Miscellaneous we should run separate regressions using OLS, and for Rehabilitation, Operating Room and Catheterization Laboratory we should run separate regressions using Tobit.

Table 27. Summary of Econometric Tests

Category	Regressions Run Together or Separately?	OLS or Tobit?
Room	Together	OLS
Intensive Care	Together	Tobit
Laboratory/ Radiology	Together	Tobit
Pharmacy	Separately	OLS
Rehabilitation	Separately	Tobit
Operating Room	Separately	Tobit
Cath Lab	Separately	Tobit
Cardiovascular Diag.	Together	OLS
Miscellaneous	Separately	OLS

Estimating Cost Differences

Given our econometric modeling results of Section III, we are now in a position to estimate the available charge and savings from making PTCA technology available to all CABG patients. We make such estimations as follows: First, we run the appropriate regressions as indicated in Table 27 on each charge category. We then estimate for each CABG patient what their expected (as opposed to their actual) charges would be. We then, using the appropriate equations, estimate what the expected charges for that patient would be were PTCA technology to be available to them. Once that is completed, we calculated a mean savings for each category by summing up all the individual savings and dividing by the number of patients in the sample.

The estimated savings are listed below in Table 28. Table 28 indicates the mean charge of the CABG patients, the mean expected charge were they to undergo PTCA treatment, and the mean expected savings. The last line of the table presents totals charge savings across the nine charge categories. Parenthesis indicate negative numbers.

Table 28. Charge Savings Available From PTCA Technology Category By Category

Category	Mean PTCA Charge	Mean CABG Charge	Net Charge Savings
Room	$2239	$5720	$3481
Intensive Care	2316	5661	3345
Laboratory / Radiology	1342	3394	2052
Pharmacy	338	2773	2435
Rehabilitation	124	525	401
Operating Room	308	20,626	20,319
Cath Lab	16,101	2284	(13,817)
Cardiovascular Diag.	624	647	23
Miscellaneous	394	8558	8144
Total	**23,786**	**50,088**	**26,302**

Note that the savings are largest with respect to the operating room, with an average savings of over $20,000. Important savings for PTCA patients also arise in Room Charges, Intensive Care, Laboratory, Pharmacy, and under Miscellaneous charges. Since, however, PTCA patients make intensive use of the Cath Lab, additional charges in that area for PTCA amount to almost $14,000. The total charge savings available from enhanced PTCA technology amount to over $26,000 per patient.

We are also able to use this data to capture the cost savings to society available from such innovations. In a perfectly competitive market, a firm's charge is equal to its (economic) costs. Hospitals, however, may not compete in fully competitive markets and therefore may have charges greater than their economic costs. It is therefore necessary, when converting from charge savings to cost savings, to have in hand appropriate cost/charge ratios. We have such information, category by category, supplied to us by the accounting staff at the surveyed hospital.

We have applied these data to our charge savings and present it below in Table 29. It turns out that our estimated cost savings of $14,000 are well below the estimated charge savings of $26,300. Since the cost/charge ratios are less than one in every category (the hospital is not selling anything at a loss), we would expect costs to be less than charges. But in this case, the cost savings is only about 53 percent of the charge savings.

The major factor in this difference occurs in the operating room category. CABG patients incur on average a charge of $20,600 in the operating room, which would be reduced to $300 were they to undergo PTCA, for a charge savings of over $20,000. However, the cost/charge ratio for the operating room at this hospital is only 0.403, implying that only slightly more than 40 percent of the charge savings are actual cost savings. Thus, a charge savings of over $20,000 turns into a cost savings of a little less than $8200.

Table 29. Cost Savings Available From PTCA Technology

Category	PTCA Charge Savings	Cost/Charge Ratio	PTCA Cost Savings
Room	$3481	0.866	$3014
Intensive Care	3345	0.704	2284
Laboratory/ Radiology	2052	0.648	1330
Pharmacy	2435	0.375	913
Rehabilitation	401	0.684	274
Operating Room	20,319	0.403	8,188
Cath Lab	(13,817)	0.408	(5637)
Cardiovascular Diag.	23	0.420	10
Miscellaneous	8144	0.444	3592
Total	26,302	-	14,001

Conclusion

This approach finds that significant per-procedure cost savings would be available if PTCA technology could be adopted for use in all patients currently undergoing CABG, assuming comparable outcomes and repeat procedure rates. Our analysis indicates that the savings would amount to over $26,000 in charges or over $14,000 in costs per patient, with significant savings in several parts of a hospital. Total expenditures for revascularization would vary, depending on the relevant rate of procedure. Thus, technology that could further extend PTCA technology to more patients could generate substantial savings for the economy.

Subappendix B1: Calculating Unexpected Adverse Events

One of the important determinants of patient charges is the number of adverse events experienced by that patient. However, it is likely that the number of adverse events is a function of several of the other explanatory variables used in the charge equation. For example, the less healthy an individual is, the greater the expected charge is likely to be, but the number of adverse events for that patient are likely to be higher also.

We are thus interested in controlling for the adverse events which are the result of the other explanatory variables. To do this we model the number of adverse events based on other variables. We then use this model to predict the number of adverse events a patient should have based on his characteristics. The difference between that actual and predicted values is then used as an explanatory variable in the charge regression.

To illustrate this, consider a model with three variables in the form:

$$\text{Charge} = b0 + b1*\text{comorbidity} + b2*\text{adverse events} + \text{error}_1. \qquad (1)$$

In our model, however, adverse events is a function of comorbidity. A person with a comorbidity score of X is expected to have Y=F(X) adverse events. Because of this comorbidity has two effects on charge. One effect is the direct effect, and the other is an indirect effect based on comorbidity's effect on adverse events. This violates one of the assumptions of standard statistics and makes the OLS estimates of b_1 and b_2 unreliable.

What is done then to avoid this problem is to formulate a model of the form:

$$\text{Adverse events} = a_0 + a_1*\text{comorbidity} + \text{error}_2. \qquad (2)$$

Combining (1) and (2) yield a model of the form:

$$\text{Charge} = c_0 + c_1*\text{comorbidity} + c_2*\text{unexpected adverse} + \text{error}_1, \qquad (3)$$

where $c0 = b0 + a0$, $c1 = a1 + b1$, $c2 = b2$, and unexpected adverse = error_2. In this model the right hand side variables are independent, and thus the model may be estimated by standard techniques (assuming that the other usual econometric assumptions hold).

The challenge then is to estimate a model for adverse events. However, adverse events are not a continuous variable, so standard techniques are not applicable. Instead of standard regression we use Poisson regression.

A Poisson random variable is a count variable. It measures the number of discrete occurrences of an event in some time period, in the case the number of adverse events in the patient's recovery period. The variable in the adverse events model has the probability distribution function defined by:

$$\text{Prob}[\text{adverse} = y] = (\exp\{-q\} * q^y)/(y!). \qquad (4)$$

To complete the model we must specify q as a function of other variables. The general form is $q = \exp\{Xb\}$. Where b is a vector of parameters to be estimated and X is a vector of patient characteristics. For this model the patient characteristics in the X vector are: AMI (acute MI within 24 hours of procedure), PCABG (prior CABG), PPTCA (prior PTCA), PMI (prior MI), COM (comorbidity), SMOKER, PRIORITY (patient priority level), AGE, VESSEL2 (stenosis in two or more vessels), CASETYPE (PTCA = 0, CABG = 1), GENDER. Setting y = actual number of adverse events, one can then estimate the b vector via maximum likelihood methods.

The expected value of a Poisson variable is q, which in this case is $\exp\{Xb\}$. With the maximum likelihood estimates of b one can predict the number of adverse events for each patient, then define:

$$\text{Unexpected Adverse} = \text{True Adverse} - \exp\{Xb\}. \quad (5)$$

Now the values for the unexpected adverse events can be used as an explanatory variable in the charge regression.

The results of the maximum likelihood estimation of the Poisson process are detailed below:

Table 30. Poisson Regression Estimates (Significant Coefficients in bold)

Variable	Coefficient	T-statistic
PCABG	**0.495**	5.47
PPTCA	-0.111	-1.31
AMI	**0.659**	7.26
PMI	-0.645	-1.51
COM	**-.186**	9.97
SMOKER	0.105	1.39
PRIORITY	**-0.130**	-5.41
AGE	0.00152	0.83
VESSEL2	-0.0698	-0.61
CASETYPE	**0.424**	5.06
GENDER	**0.255**	2.92

Subappendix B2: The Choice of PTCA Vs. CABG

The probit model is used to examine binary choice variables. In this case, we are interested in examining whether a given patient will receive PTCA or CABG as a treatment. Thus, the dependent variable, Y_i, is assigned a value of 0 when we observe PTCA and a value of 1 when we observe CABG. The expected value of Y, which is equal to P_i, the probability of receiving CABG, is then regressed on a set of explanatory variables.

This analysis becomes crucial in our statistical tests in Part 4. The test for sample selection bias requires us to have estimated probabilities of PTCA and CABG. Given this, probit analysis was performed on our data set, allowing us to generate PTCA and CABG probabilities for each patient. The variables used analysis were:

1. Comorbidity score (COM)
2. Patient gender (GENDER)
3. History of smoking (SMOKER)
4. Patient age (AGE)
5. Whether the patient received a PTCA or CABG within 24 hours of an MI (AMI)
6. Whether the patient had a prior CABG (PRCABG)
7. Whether the patient had a prior PTCA (PRPTCA)
8. Ejection fraction (EF)
9. A dummy variable which is equal to one if two vessels show stenosis (VES2)
10. A dummy variable which is equal to one if three or more vessels show stenosis (VES3)
11. A dummy variable which ii equal to one if the left main coronary artery shows stenosis (LEFT).

The probit regression has the form:

$$E(Y_i) = P_i = F(\beta_0 + \beta_1*COM_i + \beta_2*GEN_i + \beta_3*SMK_i + \beta_4*AGE_i + \beta_5*AMI_i + \beta_6*PRCABG_i + \beta_7*PRPTCA_i + \beta_8*EF_i + \beta_9*VES2_i + \beta_{10}*VES3_i + \beta_{11}*LEFT_i + e_i)$$

Where the subscript i denotes the value for patient i. Thus, P_i is the probability of patient i receiving a CABG. Also the function F is the cumulative distribution function (CDF) for a standard normal variable, which insures the resulting probability is between 0 and 1. The results of the probit regressions are reported below.

Table 31. Probit Results (Significant coefficients in bold)

Variable	Coefficient	T-statistic
Constant	-0.318	-0.65
Comorbidity	0.0692	1.86
Gender	**-0.372**	-2.49
Smoker	0.238	1.83
Age	**-0.020**	-3.32
AMI	-0.217	-1.13
PRCABG	**-1.087**	-6.63
PRPTCA	**-0.363**	-2.60
EF60	0.0012	0.25
VES2	**-0.537**	2.58
VES3	**1.019**	6.35
LEFT	**1.033**	5.51
Number of Observations: 663% CABG in Sample: 26.2% % Correct Predictions: 82.4 Log-Likelihood: -266.94		

Significant variables are Gender, Age, PRCABG, PRPTCA, VES2, VES3, and LEFT. These regression coefficients are used to generate the probabilities used in the sample selection test regressions in Part 4.

Appendix C - Stochastic Frontier Estimation of Cost Models Within the Hospital: The Case of CABG and PTCA

Introduction

Assessing of the impact of new technologies on health care costs is a critical pursuit in today's economy. The health care sector is characterized by an extraordinary degree of innovation, perhaps more so than any other sector in the economy. Unlike many other areas, however, innovation in this sector is generally perceived as substituting newer technologies which require increased, rather than decreased, resource use. That is, technological innovation appears to be cost increasing. Clearly, we wish to begin the process of determining whether this common perception is accurate. To do so, we must first understand the basic relationship between the medical care decisions required of existing and innovative technologies and how these medical "production functions" affect the cost relationships we observe.

In this part we address these issues by comparing the costs of treatment for two competing technologies for the treatment of coronary artery disease, coronary bypass surgery (CABG) or balloon angioplasty (PTCA). Exploiting a unique data set, we examine costs at the patient level, which allows us to estimate the cost savings that would be available if technological innovations in the less expensive PTCA procedure made that treatment regimen available to all the patients currently undergoing CABG. This approach is in contrast to previous cost studies, which only employed data at the hospital level.

Section II of our paper addressing several conceptual issues in the estimation of cost functions for hospital services. In Section III we present our estimation technique, data, and specification. Section IV reports the results of our cost estimation. Section V presents the estimated costs savings that would be available as the result in innovation in PTCA technology, and Section VI contains our conclusions.

Estimating Costs in the Hospital: A Return to the Physicians' Workshop Model

The Appropriate Level of Aggregation

Many researchers who have empirically examined hospital production (either directly or via a cost function) have assumed one "global" production function for the institution. That is, they posit a relationship between broad classes of inputs (e.g. numbers of nurses,

numbers of employees, numbers of beds, etc.) and a small set of outputs, typically discharges or bed-days, and employ data aggregated at the per hospital level. Recent examples of such studies include Conrad and Strauss (1983), Menke (1990), Carey and Stefos (1992) and Zuckerman, et al. (1994). Alternatively, there is a second widely used approach based upon Newhouse (1970), which assumes that there is a "global" utility function for the hospital. This utility function leads to behavioral relationships between available inputs and some output measures. Examples of this (larger) branch of the literature include Granneman, et al. (1986), Thorpe (1988), Wagstaff (1989), Thorpe and Phelps (1990) and Bradford and Craycraft (1996).

The approaches highlighted above have lead to models which are estimated with a high level of aggregation. For example, in the Zuckerman, et al. model, total costs for the hospital (across all departments for three separate treatment settings) are estimated as functions of variables such as percentage of beds classified as intensive care, average Medicare casemix, share of admissions from out of state and the like. This introduces a potentially serious problem with aggregation bias. Ahern (1993) explores this problem by explicitly accounting for the "softness" in production functions in medicine. She points out that there may be a number of approaches to treating a particular illness, none of which are clearly superior to the others. Consequently, it is not surprising that one observes significant variations in treatment even across small areas. Therefore, estimating production functions can be problematic when using hospitals as the level of aggregation.

In this work, we will appeal to a different theoretical model of the hospital. On a conceptual level, health economists have considered hospitals to be "physicians' workshops" since Pauly's (1980) influential monograph. This model asserts that hospitals exist to provide necessary capital equipment for physicians who each create their own team within the institution to treat patients. Each hospital is therefore not appropriately considered a "firm" in the traditional neo-classical sense. Rather, each hospital is a collection of "virtual firms," each defined by a unique provider team and production function. One can extend this analogy further by recognizing that in most circumstances the actual team utilized will be unique for each patient. That is, when a patient is admitted to the hospital he travels through a treatment process which is tailored to his particular medical needs and circumstances.

A hospital is therefore a framework which supports a number of different production functions, and that the production function is best defined by using the patient as the unit of analysis. Note that this framework is fairly far removed from the notion of one production function for "hospitals" which can be estimated by examining behavior across a large number of institutions. Instead, this model requires that we examine production at the level of the patient.

Further, it seems most reasonable to pool teams within an institution which are most closely related. For example, a team which is producing treatment for an acute myocardial-infarction (AMI) will face constraints most similar to those faced by another

team treating an AMI patient than a team treating a patient for gallstones. Consequently, a strategy to minimize the possibility of inappropriately pooling "production functions" is to define the production function for a specific treatment within a single institution. Only then is one likely to be able to estimate a production function which has meaning within the framework of hospital "workshops." This approach requires detailed data on single patients from individual hospitals. We suggest that only after researchers have explored medical production functions at their natural level (the patient) can work begin on expanding the analysis to include cross-institution similarities.

Introducing Non-Cost Minimizing Behavior

Economists have long recognized that there may be perverse incentives within hospitals (for example, the former Medicare reimbursement cost-plus method which paid hospitals more when they spent more on treating a patient). These incentives lead providers (teams) to follow objectives which are not aimed primarily (or even at all) at minimizing costs. Therefore, when we observe estimated cost differences between two groups it will be impossible to tell whether is it because one is more efficient than the other or whether one simply had "bad luck." For many questions, such as what impact using a new technology will have on costs, we want to explicitly control for inefficiency. That is, we wish to estimate the cost minimization function for the two treatment groups and compare predicted costs using that relationship. Otherwise, we run the risk of making policy prescriptions based not on which technology leads to the lowest cost, but rather based on which group happened to be behaving most efficiently when we observed them. It is possible that one group is behaving inefficiently which, using ordinary least square (OLS) would lead to higher predicted costs even though the group's cost minimization function lies below the cost minimization function of the other group. Policy based on OLS in this circumstance would be in error.

One technique which can accommodate differences in efficiency is stochastic frontier estimation. This maximum likelihood technique has been carefully explored in the broader econometrics literature (see, for example, Aigner et al., 1977; Schmidt and Lovell, 1979; Kopp and Diewert, 1982; Kumbhakar, 1987 and Bauer, 1990). However, in health economics it has enjoyed a somewhat mixed reception.3 The most important complaint related to the unreasonable level of aggregation in existing applications (as discussed above). Such concerns should be assuaged in models which explore production at the level of the patient within a specific disease category within a specific hospital. We believe the analysis pursued below responds to the critics of frontier analysis.

In general, cost frontiers are specified as follows. The general cost frontier is of the form

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3 For example, the *Journal of Health Economics* devoted a recent issue (Volume 13, 1994) to the discussion of stochastic frontiers. The *Journal* published a series of responses to papers using the technique where the commentators expressed skepticism regarding the use of frontier analysis (see Dor, 1994; Newhouse, 1994; and Skinner, 1994).

$$C = C(P,q) + \varepsilon,$$

where ε is assumed to consist of two components, such that $\varepsilon = u + v$, where u is a one-sided positive error and v is a normally distributed (two-sided) error. The u term corresponds to the measures of inefficiency for the specific cost frontier, while v represents the usual error term in econometric regression.

Note that this cost frontier is derived from the production frontier and is theoretically a function of the output level within the team and of input prices, C(q, **p**), where **p** is a vector of input prices and q is the level of output. However, in this particular application, q = 1 for all observations because each team produces one "treatment," since a team is defined for each patient. In addition, relative prices are the primary theoretical issue for cost minimization (or deviations from that). Therefore, consistent with Schmidt and Lovell (1979, 349), we select one input price per department to serve as a normalizing factor, and represent the remaining N-1 input prices as ratios of the numeraire price, $\mathbf{P_N}$.

Modifying the Basic Stochastic Cost Frontier:

Before specifying the exact form of the estimator for this model, we must consider augmenting the usual technical relationships presented above. Gaynor and Pauly (1990) point out that for firms which maximize utility, rather than profits, the technical production and cost functions are never observable. This is because behavioral factors which are associated with tastes and preferences enter each decision. Models which omit these behavioral factors will be mis-specified. Extending their arguments in a straight forward fashion also suggests that any factors which contribute to the uncertainty with which the agents approach the decision processes they face will "corrupt" the technical functions in the sense that we may observe different behaviors arising from agents facing the same (q, **p**) set when these taste or uncertainty factors differ. Therefore, we will include a set of regressors in each of the estimated equations which correspond to these augmenting factors, **D**. This vector **D** will include patient characteristics.

A second point about specification and inference for this particular model is in order before we present the final model. In our model, we will set total costs for observation j as the sum of costs from important sub-cost categories:

$$C \equiv C_1 + C_2 + .. + C_N,$$

where subscripts *1....N* represent cost categories 1 through *N*. As will be discussed below, these cost categories will represent "input prices" in this model. However, if one augments this function with the behavioral variable vector, **D**, and estimates the model, **D** would clearly have no explanatory power given the identity in (2). However, when C_i is expressed as *N-1* ratios of the normalizing cost (i.e., as C_i / C_N) then the identity in (2) no longer holds and useful inferences can be drawn from the augmented equation.

In addition to the effect of the behavioral factors on cost, the parameters attached to C_i / C_N will reveal the degree of substitution or complimentarily that the two input categories have in cost. That is, if the parameter on C_i / C_N is negative, this suggests that as C_i becomes larger relative to C_N then total costs fall. This would suggest that one could lower the total cost of providing the single treatment by relying more heavily on the i^{th} input and less heavily on the N^{th}. That is, the parameters on the input ratio variables

will provide important information on the most cost-effective input mix, and so most efficient production technique. Recall that each observation represents one unit of "output", so altering the input mix as suggested by the parameter signs would allow one to lower cost without changing output at all.[4]

Finally, we must establish a mechanism to relate the charges for, say, pharmacy to the "price" of the pharmaceutical input. One approach would be to use the unique price reported in our data for every compound that is administered as arguments in the cost function. Similar dis-aggregation could be applied for all inputs. There are three major problems with this method. First, there will be many patients who do not use a particular compound (or stent, EKG lead, etc.) so there will be a significant problem with many zero prices. Second, this approach is extraordinarily tedious and pedestrian, to the point of impracticality. Third, since we restrict ourselves to patients at the same institution (for the theoretical reasons discussed above), each patient should show the same unit price for, say, aspirin. A regression model would not be estimable then, since the Hessian will be singular.

What is required is some level of aggregation. That is, we must aggregate the expenditures on, say, certain classes of pharmaceuticals and let the spending on that group of pharmaceuticals be the "price" for that "input." While there are some drawbacks to this approach, it is consistent with the relevant literature. For example, Hadley, et al. (1994) estimate stochastic cost frontiers for nursing homes and use actual depreciation and interest expenses per bed and wages paid per full time equivalent employee as proxies for the "price" of capital and labor.

Data and Specification

Data Description

The data for this study are taken from the internal records of a large hospital located in a major Southern city. There are 532 observations representing all patients who were treated for some type of cardiac revascularization during 1994 (where a small number of observations were excluded due to missing data). The patients received either CABG or PTCA. The data are drawn from the detailed charge information and medical chart abstracts. We estimat two classes of frontier: a charge frontier and a cost frontier. The departmental charges are converted to costs using the cost-charge ratio for each department, as reported by the hospital to the Health Care Financing Administration in

[4] For example, assume the coefficient on the category representing the ratio of room cost to costs in the Nth category is negative and significant. That would imply that if the hospital were to change its treatment regimes to allow patients to stay in the hospital longer, the resulting changes in other treatments would, on net, reduce patient costs.

the hospital's cost reports. We therefore had access not only to the usual sorts of information obtained from discharge abstracts but also very detailed information about specific resource usage by each patient.

Dependent Variable

The dependent variable is the total charge for treatment recorded in the hospital's accounting database and the total cost (converted from the charge using the departmental cost-to-charge ratio for the institution and then aggregated across departments). The charge is not the amount collected, nor does it represent the allowable DRG payment for those patients covered by Medicare. Rather, it represents what the institution would charge for a customer without reference to any exogenously imposed payment constraints. That is, it is a number which is used internally by the institution to track resource use. (The amounts actually billed are a separate entry in the accounting process for this institution.) Charge data should be highly correlated with the actual use of resources in each case. Consequently, the cost measure we calculate from charges should also reflect (hopefully, more directly) real input use.

Explanatory Variables: Input Prices

There are eight input categories for which charges or costs in each represent price. Pharmaceutical charges (costs) are used as the numeraire (i.e., the Nth input to which every other input price in (3) and (4) below are relative). The remaining input prices are Room Charge/Cost (ROOM), Emergency Room Charge/Cost (ER), Lab Charge/Cost (LAB), Rehab Charge/Cost (REHAB), Operating Room Charge/Cost (OR), Catheterization Lab Charge/Cost (CATH), CV Charge/Cost (CV) and Miscellaneous Charges/Costs (MISC). Each of these is divided by pharmaceutical charges (costs) before being entered into the regression equations in (3) and (4) below.

Explanatory Variables: Behavioral and Health Factors

A number of additional variables enter (3) below in order to control for behavioral factors which should be important. An index which represents the degree to which comorbidities exist, COM, controls for variations in patient underlying health status prior to the treatment. Several other comorbidity factors are also included. These are whether the patient was admitted with an acute myocardial infarction, ACUMI, whether the patient has previously had bypass surgery, PRCABG, or previously had angioplasty, PRPTCA, the patient's ejection fraction, EF60,[5] if the blockage is on the left side of the heart,

[5] Some of the patients in our data set did not have an ejection fraction recorded. Clinicians informed us this generally occurs when the ejection fraction equals 60, the normal level. Therefore, for the patients with missing data, we set the ejection fraction to 60.

LEFT, or whether there was blockage in two vessels, VES2, or three or more vessels, VES3.

A few patient characteristics relevant to treatment or illness are also included. Since men and women may respond differently to illness and medical treatment, a dummy variable indicating whether the patient is male, GENDER, is also included. Likewise, responses and costs may vary significantly by age, so the patient age, AGE, appears. Finally, one patient behavioral factor, whether the patient smokes cigarettes, SMOKER, is included. Table 32 presents the means of the dependent and independent variables by patient type (PTCA or CABG).

An additional important determinant of patient charges is the number of adverse events experienced by that patient. However, it is likely that the number of adverse events is a function of several of the other explanatory variables used in the charge equation. For example, the less healthy an individual is, the greater the expected charge is likely to be, but the number of adverse events for that patient are likely to be higher also.

We are thus interested in controlling for the adverse events which are the result of the other explanatory variables. To do this we model the number of adverse events, based on other variables, using Poisson regression. We then use this model to predict the number of adverse events a patient should have based on his characteristics. The difference between that actual and predicted values is then used as an explanatory variable in the charge and cost regressions.

Estimation Issues

There are a number of potential functional form specifications which can be adopted. Theory provides no guidance in this respect. Additionally, given that CABG and PTCA, while ostensibly treating the same condition, are relatively disparate technologies, there is no theoretical reason to suspect that the same cost function necessarily underlie each. We undertook a series of pre-tests to determine how best to proceed.

Our first concern was whether PTCA and CABG patients should be pooled together into one regression. Our ex ante expectations are that this is not likely to be reasonable. The medical procedures are quite different. Additionally, the mean total charge and cost for each are quite disparate: the mean total charge for PTCA in the sample is $26,458, while the mean total charge in the sample for CABG is $47,509. We ran a likelihood ratio test on the hypothesis that PTCA and CABG patients can be pooled into a single cost function. The test statistic for this test with 23 degrees of freedom (which was performed using the double log specification) was 46.53, which rejects the null hypothesis at the 5 percent level of significance. (The relevant test cutoff is 35.2) Given this result, and our

ex ante expectations, we will estimate all of the models hereafter separately for PTCA and CABG patients.

A second concern was which functional form to use. To this end, we estimated the model three times for each group and dependent variable, using linear, right semi-log and left-semi log specifications. We recovered the value of the log likelihood function for each, and the difference between the average total charge or cost and average predicted total charge or cost for each regression. For PTCA patients, the linear model was clearly superior in terms of yielding the highest value to the log likelihood function and generating estimated total charges/costs which most closely approximated actual total charge. On the other hand, the linear and right semi-log functional forms both preformed fairly well in terms of maximizing the log likelihood function and minimizing the difference between predicted and actual charges for the CABG patients. For consistency we chose to use the linear functional form for the CABG patients as well.

This models will follow the basic model discussed in Bauer (1990, 42). Assume that the augmented charge or cost function for PTCA and CABG patients are

$$C_j^k = a + \gamma_1^k P_{1,j} + \ldots + \gamma_{\cdot}^k P_{\cdot,j} + \Gamma^k D_j + u_j^k + v_j^k.$$

where the quantity is 1 for all observations and the $P_{i,j}$ represent relative input prices for the i^{th} input and the j^{th} patient (relative to the pharmacy costs) and k = PTCA, CABG.

Given this, the likelihood function which estimates the parameters of (3) are

$$\ln L = \frac{J}{2}\ln(\frac{2}{\pi}) - J\ln\sigma + \sum_{j=1}^{J}\ln[1-\Phi(\frac{-\varepsilon_j\lambda}{\sigma})] - \frac{1}{2\sigma^2}\sum_{j=1}^{J}\varepsilon^2,$$

where J is the number of observations, ε_j is the estimated sum of u and v, $\Phi(.)$ is the CDF of a standard normal distribution, $\sigma = \sigma_u + \sigma_v$ and $\lambda = \sigma_u / \sigma_v$. The likelihood function is maximized across σ^2_u, σ^2_v, Γ and γ (where Γ and γ are the parameters for the equations represented in (3)).

From the estimated models we obtained a number of important pieces of information. The first are consistent estimates of the effect of the patient covariates on the demand for the individual input shares. Second, the technical inefficiency for each observation is found as

$$u_j^* = \frac{\sigma_u^*\sigma_v^*}{\sigma^*}\left[\frac{\phi\left(\frac{\varepsilon_j^*\lambda}{\sigma^*}\right)}{1-\Phi\left(\frac{\varepsilon_j^*\lambda}{\sigma^*}\right)} - \frac{\varepsilon_j^*\lambda}{\sigma^*}\right],$$

where starred terms mean estimated values and $\phi(.)$ is the PDF of the standard normal distribution (See Jondrow, et al. 1982).

Finally, it is important to note what the inefficiency estimates do and do not suggest. First, the estimated u_i^* do not reflect how cost-effectively a particular patient is treated relative to the industry (theoretical) cost minimization. That frontier is not estimated.

What the inefficiencies do reflect is how well a patient is treated relative to all other patients in the specific institution.[6] That is, a set of patients within the sample are "defined" as charge or cost minimizing and all other patients in the sample score relative to these. Finally, in this case "cost minimizing" means strictly "best at minimizing resource costs." We are sensitive the probability that this notion of cost minimization may differ significantly from the physician's or patient's ideas of best practice.

Results

Table 33 presents the results of the stochastic frontier charge estimates for PTCA and CABG patients in regression equation (3). A number of results are of interest in the PTCA equation. First, note that several of the personal characteristics - the presence of comorbidities, gender, having had a prior CABG or PTCA procedure, having left main arterial disease and the likelihood of unanticipated adverse events - significantly affect the total charges for providing a PTCA. With the exception of prior PTCA, each increases the charge. Having had a prior PTCA appears to significantly reduce the charge associated with the sampled PTCA procedure. The lack of significance for a few variables is also interesting. Having blockage in more than one vessel, VES2 and VES3, does not change charges in a statistically significant manner. Further, having suffered an AMI very recently seems to have no statistical effect on total charges.

Recall that the effect of the charge ratios on the total charge of the PTCA procedure can inform us with respect to the most efficient mix of inputs. That is, a significantly positive effect of one of the charge ratios indicated that using relatively more of that input will raise total charge of supplying the procedure. A significantly negative effect indicates that one could increase the relative use of that input and decrease the total charge of the procedure. For PTCA procedures, three input ratios have significantly positive effects. The results indicate that using relatively more laboratory resources (LAB), operating room (OR) and CV inputs significantly increases total charges, without any "payoff" (i.e., more is spent, though the quantity stays the same). In contrast, patients who incur relatively higher room charges (relative to pharmaceutical charges) have significantly lower total charges.

Perhaps a more useful way to think about the parameters on ROOM, LAB, OR and CV are in terms of *elasticities*. An elasticity is a measure of what percentage change one observes in one thing given a one percent increase in something else. In this case, the elasticity would be the percentage increase in total charge of the PTCA one would observe from a one percent increase in the relative use of an input. For the room charges, the elasticity is -0.10, suggesting that total charges fall by a tenth of a percent if the institution were to increase the relative use of room resources by one percent. The

[6] We note that the cost estimation can only estimate the cost minimization frontier in the data set. We therefore cannot estimate the industry cost frontier with the data available to us.

calculated elasticity of the laboratory resources is 0.10, the estimated elasticity of the operating room is 0.01, and the estimated elasticity for the CV unit is 0.03. In each of these cases, the response of total charge is somewhat muted (i.e. *inelastic*); however, even a three or four percent decrease in total charge would be very significant from a managerial perspective. These elasticities do suggest that charge reductions in this range are at least potentially feasible.

Table 33 also contains the results of the stochastic frontier charge estimation for the CABG patients. As with the PTCA cases, patient characteristics are important for those undergoing CABG treatments. The presence of a higher comorbidiy score, having had a prior CABG, and increased unanticipated adverse events significantly increases the total charge of the CABG procedure. Unlike the PTCA, we find that a recent acute myocardial infarction and the number of vessels revascularized also significantly and positively affects total charge. A recent AMI raises total charges, as does having two vessels revascularized. Oddly, having three or more vessels blocked seems to decrease total charges. Since the "standard" approach for only one or two blockages would be to use PTCA rather than CABG, it may be that those in the one or two vessel CABG group are relatively more ill than those who have blockage in three or more vessels, and hence require more intensive resource use in some areas.

For CABG patients, four of the charge ratios are significant in the frontier estimation. Using relatively more CV diagnostics, relatively more catheterization lab time and relatively more miscellaneous charges raises relative charge in a non-productive manner (charges go up and output is constant). However, unlike the PTCA case, using relatively more operating room time reduces total charges. That is, when the institution is using a larger proportion of its resources in actually providing the CABG procedure to a patient (which is done in the operating room), the charge from treating that patient falls.

Again, the most straight forward means of interpreting the magnitude of these significant effects is to use elasticities. The operating room elasticity is largest, at -0.36; increasing the relative use of the OR by one percent would lead to over a one-third percent decrease in total charges. This is much larger than the other effects for CABG (and PTCA). The elasticity for miscellaneous charges is next in magnitude, at 0.22, followed by the elasticity for the cath lab at 0.06 and, finally, the elasticity for the CV diagnostics at 0.02. It would take slightly more than a one percent decrease in the relative use of each of these three to equal the charge savings associated with a one percent increase in the relative use of the operating room. Still, the magnitude of these effects are large enough to bring a three or four percent decrease in total charges into the feasible range with no decrease in the provision of service. The possibility that such charge reductions can be achieved by adjusting the production technology is intriguing, and deserving of more attention.

Finally, Table 33 presents estimates of the average charge "inefficiency" of the PTCA and CABG procedures being undertaken within the institution. Recall that in this case "inefficiency" means how much more charge is generated for a given patient's treatment than the lowest charge possible in the hospital given the patient's characteristics. That is,

charge inefficiency reflects the variation within the institution in charges, and can not speak to how well the cost minimization in this institution compares to cost minimization in another. For PTCA patients, the average estimated inefficiency is about $10,248, which is about 41 percent of the mean charge for the procedure. This suggests that the hospital is charging over $10,000 per patient more than necessary *given the lowest cost available in that institution.* For CABG patients the average excess charges are approximately the same, at about $9,990; though, as a percentage of average charge, the CABG inefficiency is smaller, at 22 percent. Both of these numbers are relatively large, and suggest that there may be room for significant charge (and so potentially cost) savings in the hospital by more careful examination of which patients are treated in the more cost effective manner and working to emulate the procedures used on them with other patients.

Table 34 presents the estimates of the stochastic *cost* frontier for both PTCA and CABG patients. The qualitative results in the PTCA cost regression with respect to the non-price effects are very similar to those in the charge regression. Increased numbers of comorbidities, patient gender, having had a prior CABG or PTCA, suffering from left main artery disease and having adverse events all significantly affect costs. Unlike the charge estimates, an acute MI just prior to the procedure does significantly affect the costs of providing the PTCA.

In terms of hospital resources, the relative use of lab resources, the relative use of rehabilitation services and the relative use of CV diagnostic resources significantly affect the total cost of providing a PTCA. The parameter estimates on both of these input ratios are positive, indicating that increasing the use of these inputs relative to pharmaceutical inputs will increase the total cost of the PTCA. This suggests that the average patient in the PTCA sample uses relatively too much of these inputs to achieve strict cost minimization. While statistically significant, the magnitude of these effects is not large. The lab input has the largest elasticity, at 0.12, which suggests that a 1 percent increase in the relative use of lab services will raise total cost by a bit more than one-tenth of 1 percent. The elasticities of rehabilitation and CV diagnostic services are even smaller, at 0.02 and 0.03 respectively.

For CABG, comorbidities, a recent MI, a prior CABG and unanticipated adverse events raise the cost of providing bypass surgery. In addition, having multiple vessels involved is a significant predictor, as evidenced by the positive and significant effect of having two vessels stenosed and the negative and significant effect of having 3 or more vessels stenosed on total costs. While the sign patterns may seem somewhat counterintuitive, they are actually what one would expect in the current state of the world. Currently, many patients who need two vessels repaired will have them done using PTCA technology. Such a person that is actually observed with a CABG instead suggests that this person is relatively more sick than the average person who needs two vessels reworked. However, a person who needs treatment in three vessels is not at all likely to receive PTCA.

Again, the parameter estimate on the relative use of the OR resources is negative and significant. This suggests that a shift toward relatively more OR time per CABG (compared to pharmaceutical resources) may actually reduce the total cost of providing the service. The magnitude of this effect is also relatively large when compared to the other elasticities. The estimated elasticity of cost with respect to relative OR use is 0.31. This means that a one percent increase in relative use of the OR will reduce the total CABG cost by one-third of 1 percent. The other statistically significant medical inputs have positive effects on total costs, indicating over-use on average. These are the emergency room and the cath lab. The elasticities of these input ratios are smaller than for the OR, at 0.14 and 0.06 respectively.

Finally, the cost inefficiencies estimated for PTCA and CABG are presented at the bottom of Table 34. The absolute level of cost inefficiency for PTCA production is about $5,200. The represents 41 percent of the total average cost of supplying the PTCA to patients in the institution. The absolute level of cost inefficiency for CABG patients is $7,300, or 29 percent of the total cost of the operation. These inefficiency estimates (at least in percentage terms) are reasonably similar to the estimates of cost inefficiency. While comparable levels of inefficiency have been found in other research of other industries, this does indicate a substantial room for improvement in the average cost of treatment for the two procedures.

However, a strong word of caution is in order. These results are only suggestive, and much more research is necessary to determine how the inefficiency is related to adverse events or quality. While our patient-specific comorbidity and health indicators should have captured most of the variation in relative "complexity", it may be that the measured "inefficiency" captures some measure of quality. A more complete model would be required to determine what this inefficiency actually means. However, the implications are quite intriguing and significant enough to warrant more attention.

Simulating Changing Technology or Practice

One issue that concerns the medical community and policy-makers alike is what effect shifting treatment standards will have on charges or costs. That is, as PTCA becomes a more mature technology, and new innovations such as stents are perfected, one could image shifting a number of patients from the CABG treatment path to the PTCA treatment path. On the surface this would appear to be a cost-saving move, since the average charge and cost of PTCA is much below the average charge or cost of CABG (as can be seen from Table 32 for this sample). As discussed above, however, one would not want to take such a naive approach, since a number of factors might intervene. The patient populations have different characteristics. The two procedures may be currently provided with different levels of "waste" (or inefficiency). The average PTCA patient has blockage in fewer vessels than the average CABG patient.

Part of the motivation for the analysis above is to provide an improved methodology for estimating the cost-savings from switching patients from CABG to PTCA, given that appropriate PTCA technology becomes available. Using the stochastic frontier results, we can control for the observable patient characteristics and the number of vessels treated. Further, since the maximum likelihood regression results produce the "minimum cost" frontier, we can predict cost savings without the presence of confounding inefficiencies (which may or may not persist through time).

To do this we divide the CABG patients into three groups: those requiring treatment in one vessel, those requiring treatment in two vessels, and those requiring treatment in three or more vessels. We then predict the charge and cost for giving each the CABG treatment regime. The predicted charge and cost for each group appears in the first column of Table 35. Once we have the estimated charges/costs for giving these patients CABG under cost minimization, we then simulate what charges or costs would be to give them PTCA. To do this, each patient is put through the PTCA frontier regression with their own personal characteristics, and with the charge or cost ratio values for the median PTCA patient in their group (e.g., the charge ratios entered for a two-vessel CABG patient going through the PTCA equation are the charge ratios for the median two-vessel PTCA patient). We do this since the resource use observed for the CABG patients is clearly not the resource use we would observe if they received PTCA. (Recall, that the hypothesis of identical charge functions was rejected above.) The results of the predicted charge or cost of treating current CABG patients with PTCA technology appears in the second column of Table 35.

The final column in Table 35 presents the estimated savings from treating various types of CABG patients with PTCA. The savings appear to be significant. Switching one-vessel CABG patients to PTCA would save an estimated $11,966 in charges and $3,959 in costs; switching two-vessel and three or more vessel CABG patients to PTCA appears to result in $25,394 and $17,156 in charge savings and $16, 387 and $8,160 in costs, respectively.

Conclusions

Assessing the impact of new technologies on health care costs is an important area for research. Given the high level of innovation in the health care sector, care must be taken to understand the likely cost consequences of innovations before increasingly scarce resources are devoted to them. Often, innovation seems to substitute newer technologies which require increased cost for older, less expensive technologies. This paper evaluates this common perception for technologies used to treat coronary artery disease: PTCA and CABG . In undertaking this evaluation, we estimated two separate stochastic frontier models, one for PTCA patients and one for CABG patients, using data taken from detailed clinical and chart files from a large Southern hospital. The analysis indicates several things.

First, there is substantial variation in the medical treatment practice even within this one institution. This is revealed as significant levels of inefficiency in the treatment of the average patient for both PTCA and CABG, where nearly $5,200 dollars in costs (41 percent of total spending) are incurred "unnecessarily" on the average PTCA patient and nearly $7,230 (29 percent of total spending) are spent "unnecessarily" on the average CABG patient. Second, the particular hospital in question could reduce its costs for care, without reducing the quantity of care, by reallocating its resources to emphasize spending relatively less on some categories of cost and spending relatively more on other categories of cost. Finally, the analysis indicates that if PTCA and CABG were perfect medical substitutes, then significant savings per patient could in fact be had by switching patients from CABG to PTCA. Clearly, this is a counter- factual situation, but it does suggest that research which is focused on making the two treatment regimes more substitutable may be able to lead to lower costs for treating a patient suffering from coronary artery disease.

Table 32. Means of Variables for PTCA and CABG Patients

Explanatory Variable	PTCA Patients		CABG Patients
Comorbidity Factors			
COM	1.4375		1.5909
GENDER	0.3125		0.1970
SMOKER	0.3560		0.5455
AGE	64.4022		62.2359
ACUMI	0.0978		0.0682
PRCABG	0.2826		0.0985
PRPTCA	0.3859		0.1742
EF60	55.7853		52.8485
VES2	0.6630		0.9318
VES3	0.3723		0.8333
LEFT	0.0625		0.2879
UNADV	-0.2539		-0.6491
Charge Ratios	**PTCA Patients**		**CABG Patients**
ROOM/PHAR	5.6106		2.3661
ER/PHAR	4.3453		1.9380
LAB/PHAR	2.5332		1.3780
REHAB/PHAR	0.2013		0.2519
OR/PHAR	0.4434		10.5813
CATH/PHAR	68.7284		1.0400
CV/PHAR	0.7687		0.1890
MISC/PHAR	2.9053		3.5588
TOTAL CHARGE	25118.59		46146.09
Cost Variables	**PTCA Patients**		**CABG Patients**
ROOM/PHAR	5.6106		5.367
ER/PHAR	8.132		3.665
LAB/PHAR	4.367		2.362
REHAB/PHAR	0.3652		0.4522
OR/PHAR	0.4800		11.09
CATH/PHAR	74.39		1.104
CV/PHAR	0.8567		0.2089
MISC/PHAR	3.436		4.178
TOTAL COST	12607.41		25079.33
Number of Observations	368		132

Table 33. Stochastic Frontier Estimations of TOTAL CHARGE for PTCA and CABG Patients (Linear). T-Statistics in Parentheses

Explanatory Variable	PTCA Patients		CABG Patients
CONSTANT	10693 (2.279)**		22328 (2.216)**
COM	1529.7 (4.301)***		2302.5 (3.274)***
GENDER	2224.2 (1.690)*		3971.8 (1.589)
SMOKER	914.93 (0.750)		739.15 (0.311)
AGE	31.407 (0.542)		29.119 (0.227)
ACUMI	2185.5 (0.884)		12124 (3.746)***
PRCABG	5806.8 (4.053)***		7113.3 (1.966)**
PRPTCA	-2497.2 (-2.104)**		1003.1 (0.431)
EF60	-4.1937 (-0.096)		24.899 (0.376)
VES2	-1941.6 (-1.167)		14411 (2.733)***
VES3	1311.7 (0.749)		-6126.8 (-1.891)*
LEFT	5655.4 (2.919)***		2085.8 (0.831)
UNADV	3988.4(12.539)***		3680.8 (4.814)***
(ROOM / PHAR)	-427.31 (-2.147)**		-1225.5 (-0.736)
(EMERG / PHAR)	-75.336 (-0.432)		1853.8 (1.463)
(LAB / PHAR)	943.04 (2.832)***		800.42 (0.211)
(REHAB / PHAR)	2835.3 (1.607)		-4402.5 (-0.645)
(OP / PHAR)	605.60 (2.770)***		-1549.5(-4.661)***
(CATH / PHAR)	-2.4902 (-0.202)		2555.7 (2.910)***
(CV / PHAR)	1128.4 (7.102)***		3837.4 (1.912)*
(MISC / PHAR)	-489.97 (-1.159)		2793.8 (2.421)**
Log-Likelihood	-3875.740		-1375.673
Inefficiency in Absolute Dollars	$10247.71		$9990.47
Inefficiency as a Percent of Charges	40.8 %		21.6 %

Table 34. Stochastic Frontier Estimations of TOTAL COST for PTCA and CABG Patients (Linear). T-Statistics in Parentheses

Explanatory Variable	PTCA Patients		CABG Patients
CONSTANT	3676.3 ** (1.58)		11615 ** (1.77)
COM	699.43 *** (3.96)		2429.8 *** (4.00)
GENDER	1124.6 * (1.72)		1031 (0.52)
SMOKER	415.12 (0.67)		-795.53 (0.61)
AGE	30.85 (1.06)		-46.56 (0.58)
ACUMI	1869.5* (1.78)		11430 *** (5.01)
PRCABG	2761.6 *** (4.00)		9606.4 ** (4.25)
PRPTCA	-1434.3 ** (2.411)		832.09 (0.53)
EF60	1.91 (0.09)		22.39 (0.43)
VES2	-598.68 (0.76)		10149 ** (2.36)
VES3	425.35 (0.54)		-7002.2 *** (3.17)
LEFT	4619.1 *** (5.54)		695.37 (0.33)
UNADV	2053 *** (18.59)		3874.5 *** (9.10)
(ROOM / PHAR)	-66.96 (1.55)		90.82 (0.17)
(EMERG / PHAR)	-22.79 (0.53)		958.58* (1.86)
(LAB / PHAR)	342.21 *** (3.80)		-367.06 (0.21)
(REHAB / PHAR)	743.69* (1.66)		1228.4 (0.44)
(OP / PHAR)	101.99 (0.87)		-710.89 *** (3.33)
(CATH / PHAR)	-7.48 (1.31)		1281.2 ** (1.94)
(CV / PHAR)	457.29 *** (6.22)		-153.67 (0.09)
(MISC / PHAR)	-175.96 (1.05)		734.92 (0.99)
Log-Likelihood	-3666.53		-1387.34
Inefficiency in Absolute Dollars	$5213.48		$7323.07
Inefficiency as a Percent of Costs	41.4 %		29.2 %

Table 35. Predicted Savings from Switching CABG Patients to PTCA

Number of Vessels with Blockage	Predicted Dollars for CABG Treatment for Current CABG Patient	Predicted Dollars for PTCA Treatment for Current CABG Patient	Imputed Savings from Switching Treatment from CABG to PTCA
CHARGES			
1 VESSEL	28,715.07	16,749.19	11,965.89
2 VESSELS	45,151.43	19,757.92	25,393.50
3 OR MORE VESSELS	39,753.08	22,596.72	17,156.36
COSTS			
1 VESSEL	10,489.68	6,530.59	3,959.09
2 VESSELS	24,789.97	8,402.71	16,387.25
3 OR MORE VESSELS	17,830.86	9,670.52	8,160.33

Appendix D - PTCA vs. CABG Across Several Hospitals

Introduction

In order to develop the Care Pathway Interaction Model for Coronary Artery Disease (CAD) it was necessary to model the demand for CAD treatment, and the types of treatment, across the American economy. To accomplish this, it was necessary to model in econometric terms the choice of PTCA vs CABG. Ideally, it would have been desirable to obtain data with detailed patient by patient characteristics from all hospitals in the country$_s$, but such data was not available. However, data from selected hospitals across the country was available, and this data was used to econometrically model the factors that affect the decision by patients and doctors to use either PTCA or CABG to treat CAD. The following section describes the data, and the section after that present the econometric results.

Data and Estimation Technique

We received hospital-based, patient-level data from 12 institutions in the academic medical center consortium. However, the data from several hospitals was incomplete, and data from only six hospitals could be used for analysis. The variables used in the analysis and the predicted effects of these variables on the outcome of CABG treatment as predicted by consultations with clinicians were:

1. Comorbidity score (COM). Predicted effect: Uncertain.
2. Patient gender (GENDER). Predicted effect: Uncertain.
3. History of smoking (SMOKER). Predicted effect: Uncertain.
4. Patient age (AGE). Predicted effect: Uncertain.
5. Whether the patient received a PTCA or CABG within 24 hours of an MI (ACUMI) Predicted effect: Negative. CABG is a difficult regimen for someone who has just had an MI.
6. Whether the patient had a prior CABG (PRCABG). Predicted Effect: Negative.
7. Whether the patient had a prior PTCA (PRPTCA). Predicted effect: Uncertain.
8. Ejection fraction (EF). Predicted Effect: Negative. Low EF implies patient may not do well in surgery.
9. A dummy variable which is equal to one if two vessels show stenosis (VES2). Predicted effect: Positive. CABG does better with multiple vessels operations.
10. A dummy variable which is equal to one if three or more vessels show stenosis (VES3). Predicted effect: Positive. CABG does better with multiple vessels operations.

11. A dummy variable which is equal to one if the left main coronary artery shows stenosis (LEFT). Predicted effect: Positive. Due to the geometry of the heart, CABG does better with left main disease.

The probit model is used to examine binary choice variables. In this case, we are interested in examining whether a given patient will receive PTCA or CABG as a treatment. Thus, the dependent variable, Y_i, is assigned a value of 0 when we observe PTCA and a value of 1 when we observe CABG. The expected value of Y, which is equal to P_i, the probability of receiving CABG, is then regressed on a set of explanatory variables. Given these explanatory variables, the probit regression has the form:

$$(1) \qquad E(Y_i) = P_i = F(\beta_0 + \beta_1*COM_i + \beta_2*GEN_i + \beta_3*SMK_i + \beta_4*AGE_i + \beta_5*ACUMI_i +$$

$$\beta_6*PRCABG_i + \beta_7*PRPTCA_i + \beta_8*EF_i + \beta_9*VES2_i + \beta_{10}*VES3_i + \beta_{11}*LEFT_i + e_i)$$

Where the subscript i denotes the value for patient i. Thus, P_i is the probability of patient i receiving a CABG. Also the function F is the cumulative distribution function (CDF) for a standard normal variable, which insures the resulting probability is between 0 and 1. Probit analysis was performed on each hospital individually, and on all hospitals as an aggregate group. The aggregate analysis includes a dummy variable for each hospital.

Results

Regressions Across the Six Hospitals

Table 36, Table 37 and Table 38 give the regression results across the six hospitals in our sample, as well as the regression results for the data aggregated.

Table 36. Hospitals 002, 003, 004, and 005 (T-statistics in Parentheses, significant coefficients in bold)

Variable	Hospital 002	Hospital 003	Hospital 004	Hospital 005
Constant	**-1.076** (-3.33)	**1.448** (2.97)	**-1.098** (-2.36)	-0.109 (-0.32)
Comorbidity	0.030 (1.47)	0.044 (0.92)	**0.127** (2.25)	**0.123** (3.42)
Gender	**-0.185** (-2.21)	-0.116 (-0.91)	-0.077 (-0.58)	0.106 (1.12)
Smoker	0.101 (1.02)	-0.153 (-1.18)	0.142 (1.05)	0.116 (1.19)
Age	-0.00259 (-0.69)	**0.0149** (2.66)	0.0052 (0.93)	0.0133 (3.25)
ACUMI	**-1.146** (-6.54)	0.318 (0.98)	**-1.590** (-5.61)	**-2.08** (-5.97)
PRCABG	**-1.132** (-11.60)	**-0.878** (-4.13)	**-1.192** (-6.02)	**-0.656** (-5.42)
PRPTCA	**-0.237** (-3.00)	-0.030 (-0.180)	-0.187 (-1.42)	-0.151 (-1.54)
EF	-0.00384 (-1.45)	**-0.41** (-6.84)	-0.0073 (-1.70)	**-0.028** (-7.83)
VES2	**0.753** (5.40)	**-0.352** (-2.39)	**1.101** (6.64)	**0.677** (5.71)
VES3	**1.102** (12.07)	**0.789** (4.59)	**0.803** (5.96)	**0.842** (8.41)
LEFT	**0.958** (8.28)	**1.535** (4.62)	**1.232** (5.71)	**1.027** (5.38)
Number of Observations	1767	578	751	1280
% CABG in Sample	37.0	60.1	53.0	52.3
% Correct Predictions	78.38	72.8	80.0	78.83
Log-Likelihood	-809.65	-312.65	-324.96	-602.21

Table 37. Hospitals 007, 012, and Six Hospitals Aggregated (T-statistics in Parentheses, significant coefficients in bold)

Variable	Hospital 007	Hospital 012	Six Hospitals Aggregated
Constant	0.298 (0.70)	-0.525 (0.90)	**-0.634** (-3.85).
Comorbidity	-0.0147 (-0.38)	-0.0178 (-0.29)	**0.0359** (2.59)
Gender	**-0.405** (-3.15)	-0.00061 (-0.00)	**-0.129** (-2.88)
Smoker	0.0231 (0.16)	-0.109 -(0.63)	0.0682 (1.43)
Age	-0.0041 (1.01)	-0.0031 (-0.49)	**0.0059** (3.28)
ACUMI	**-0.782** (-4.22)	**-1.276** (2.25)	**-1.056** (-11.37)
PRCABG	-0.233 (-1.73)	**-0.677** (-3.06)	**-0.738** (-13.28)
PRPTCA	**-0.373** (-3.25)	**-0.517** (-2.53)	**-0.252** (-5.56)
EF	**-0.0181** (-3.22)	**-0.0183** (-2.66)	**-0.0145** (-9.09)
VES2	**0.377** (2.12)	**0.637** (2.84)	**0.466** (7.98)
VES3	0.272 (1.93)	**0.780** (3.86)	**0.818** (16.66)
LEFT	**0.547** (3.50)	0.229 (0.85)	**0.870** (12.76)
Number of Observations	621	304	5301
% CABG in Sample	42.8	44.4	46.6
% Correct Predictions	67.5	74.3	74.6
Log-Likelihood	-377.50	-162.58	-2761.40

Table 38. Dummy Variable Values in Aggregate Equation (Hospital 002 Null Hospital, Significant Values in bold)

	Hospital 003	Hospital 004	Hospital 005	Hospital 007	Hospital 0012
Coeff.	**0.804**	**0.495**	**0.519**	0.119	**0.281**
T-statistic	11.29	7.72	9.70	1.80	3.17

We interpret Table 38 first. We use hospital 002 as the "null hospital" in our aggregate equation, which implies that we ran dummy variables for the five other hospitals. All of these coefficients were positive and statistically significant. (The coefficient for hospital 007 was only marginally significant.) This implies that at each of these five hospitals there is a higher proclivity to use CABG instead of PTCA, when compared to hospital 002.

Not only do hospitals differ with respect to their "initial CABG proclivity," but they also respond differently to differences in patients' conditions. Table 39 summarizes the estimated effects of different factors across the six hospitals. On many of the variables, there is a striking lack of uniformity. The patient's comorbidity score was only statistically significant in two hospitals. Gender was significant in three hospitals, smoking in one hospital and age was significant in two hospitals. The effects were more consistent for prior MI, prior CABG, and left main disease (significant in five hospitals), and prior PTCA and ejection fraction (significant in four hospitals). Only the dummy variable for two blocked vessels was significant with the same sign across all six hospitals. (All six coefficient on the variable for three blockages are significant, but one has the opposite sign of the other five.)

Table 39. Coefficient Significance Across Six Hospitals

Variable	Number Significant	Sign
COM	2	+
Gender	3	-
Smoker	1	+
Age	2	+
ACUMI	5	-
PRCABG	5	-
PRPTCA	4	-
EF	4	-
VESS2	6	+(5), -(1)
VES3	6	+
LEFT	5	+

A procedure was performed where the treatment for every patient in the data set was predicted based on each hospital's estimated equation. What was done was to take every patient's characteristics, and then to predict what kind of procedure they would undergo if they went to each of the six hospitals. The results of this procedure are presented in Table 40. Again, we found important differences across the six hospitals. For example, according to our estimates, only 32 percent of the patients would have undergo CABG treatment had they been at hospital 007, while almost 54 would have been treated with CABG had they gone to hospital 005.

Table 40. Predicted CABG at Each Hospital (5301 Total Observations)

Hospital Number	Number CABG Predicted	% CABG Prediction
002	2215	41.8
003	2821	53.0
004	2704	51.0
005	2852	53.8
007	1691	31.9
012	2377	44.8
All Six Hospitals	2408	45.4

Testing For Different Coefficients Across Hospitals

We have observed that these six hospitals weigh different factors when deciding whether a patient should undergo PTCA or CABG treatment. This section explored whether the differences between hospitals are statistically significant. If the differences are significant, it is statistically inappropriate to pool data from these hospitals together in an aggregate equation.

To undertake this task, we first constructed an "unrestricted model"from the six individual regression results reported in Table 36 and Table 37. We then constructed a "likelihood ratio" for these six regressions. This is simply the sum of the likelihood functions for the six regressions. We then took our "restricted model," which is the model where the data is pooled across the six hospitals using dummy variables for the other five hospitals. The likelihood ratio for this model is the likelihood ratio reported at the bottom of the fourth column of Table 37.

The likelihood ratio from the unrestricted model is subtracted from the likelihood ratio from the restricted model and then multiplied by -2. Under the null hypothesis that the coefficients across the six hospitals are similar, this statistic is distributed according to a $\chi 2$ distribution with degrees of freedom equal to the number of restrictions. In this case the number of restrictions are 55 (11 coefficients from five models restricted to be the same as the coefficients from the eight model). The 5% critical value from a $\chi 2(55)$ is approximately 74.

The sum of the log-likelihoods from the six hospital models is 2589.36. The log-likelihood of the restricted (aggregated) model is 2761.40. Twice the difference is 2*172.04=344.08, greater than the value of $\chi 2(55)$. Thus, we cannot statistically aggregate the hospitals.

Meta-Analysis

Even though we cannot statistically aggregate the data from the six hospitals, we can perform a "meta-analysis" (see Wolf, 1986), comparing the results across the six hospitals. To calculate the meta-coefficients, we simply take the average coefficient for each independent variable across the six regressions.

The significance levels of the coefficients is more complicated to calculate. Let p_{ij} equal the p-values for the coefficient on independent variable i in the regression relating to hospital j, calculated from the relevant t-statistic. Define S_i as

(2) $S_i = -2\Sigma \ln p_{ij}$ over all hospitals j.

If the meta-coefficient on variable i is insignificant, S_i is distributed $\chi 2(12)$, with a 5 percent cut-off level of 21.0. From this, we can calculate the p-values on our meta-coefficients. Table 41 gives the results of our meta-analysis.

Table 41. Meta-Analysis

Variable	Meta-Coeff. Estimate	$\chi 2$ Statistic	p-Value
Constant	-0.002	37.48	0.000
Comorbidity	0.0487	28.44	0.005
Gender	-0.113	25.50	0.013
Smoker	-0.020	12.06	0.441
Age	0.0053	30.26	0.003
ACUMI	-1.093	138.57	0.000
PRCABG	-0.793	146.35	0.000
PRPTCA	-0.249	42.63	0.000
EF	-0.0196	96.60	0.000
VES2	0.532	0.532	0.000
VES3	0.754	0.754	0.000
LEFT	0.921	0.921	0.000

We observe that all coefficients but the one on smoking are statistically significant. We also note that the signs on these coefficients are consistent with what was predicted to us by clinicians.

Table 42 presents the marginal effects in our meta-model. We first estimated the probability of CABG treatment for our "standard" patient. Since all of our variables are either categorical (dummy) variables, or reported only in integers, we either used median values or the integer values closest to the mean values. The CABG percentage for our standard patient was 71.2 percent.[7] We then calculated the changes in the probability of CABG treatment given a change in one of the explanatory variables, holding all the other variables at their mean (median) levels.

[7] The total CABG percentage in our data set was 45.4 The median value, however, for VES3 (three vessel blockages) is 0.52, which increases greatly the CABG probability of our mean (median) patient.

Table 42. Marginal Effects in Meta-Model (CABG Probability of "Standard" Patient: 71.2%)

Explanatory Variable	Mean (Median) Value of Standard Patient	Marginal Change Made in Explanatory Variable	CABG Probability	Change in CABG Probability
Comorbidity	1.03 (1)	Increase to 2	72.8%	1.6%
		Increase to 4	75.9	4.8
		Increase to 7	80.2	9.1
Gender	0.28 (0)	Increase to 1	67.2	-4.0
Smoker	0.25(0)	Increase to 1	71.8	0.7
Age	64.16(64)	Increase to 65	71.3	0.2
		Increase to 70	72.2	1.1
		Reduce to 58	70.1	-1.1
ACUMI	0.07(0)	Increase to 1	29.6	-41.5
PRCABG	0.15(0)	Increase to 1	40.7	-30.4
PRPTCA	0.25(0)	Increase to 1	62.1	-9.0
EF	56.98(57)	Increase to 58	70.5	-0.7
		Reduce to 27	87.4	16.2
VES2	0.75(1)	Reduce to 0 (implying VES3 reduced to 0)	23.3	-47.8
VES3	0.53(1)	Reduce to 0	42.2	-28.9
LEFT	0.12(0)	Increase to 1	93.0	21.9

The comorbidity score appears to have only a small impact on the CABG percentage, increasing it to 1.6 percent with a comorbidity change of 1, and 9.1 percent with a comorbidity change of 7. Moving from a male to a female patient reduces the CABG probability 4.0 percent. Age has very small effects, with a reduction in age of 7 reducing the CABG probability 1.1 percent.

Somewhat larger effects show up on the variables representing a patient's medical history. A heart attack in the last 24 hours reduces the CABG probability 41.5 percent.

Prior CABG treatment reduces the probability 30.4 percent, while a prior PTCA treatment reduces that probability 9.0 percent. Small changes in the ejection fraction induce small changes in the CABG percentage, but a reduction in the EF by 30 increases the CABG percentage by 16.2.

Changes in the nature of the blockages has large effects on probability of CABG. Setting VES2=0 (which implies setting VES3=0, and is equivalent to reducing the number of blockages from 3 or more to 1) reduces the CABG probability 47.8 percent. Setting only VES3=0, which implies reducing the number of blockages to 2, reduces the CABG probability by 28.9 percent. On the other hand, giving the patient left main disease increases the CABG probability by 21.9 percent, so 93.0 percent.

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Appendix E - A Two-Part Model of the Costs of Treating Benign Prostatic Hyperplasia and the Impact of Innovation

Introduction

One of the most common chronic conditions affecting men in the U.S. is benign enlargement of the prostate, known as benign prostatic hyperplasia or BPH. This condition affects as many as three quarters of all men aged 80 and older, and more than half of men who are at least 60 years old (AHCPR, 1997). There are a wide variety of treatments for BPH, ranging from a surgical procedure involving a large incision in the abdomen (open prostatectomy) to pharmaceutical therapy - or even simple "watchful waiting." Currently, however, the transurethral resection of the prostate (TURP) has achieved a position of dominance for medical interventions. Recent development of more non-invasive treatment modalities - such as transurethral microwave thermotherapy, alpha blocker drug therapies or alpha-reductase inhibitor drug therapies - have stimulated debate regarding what is the most cost-effective method for treating BPH in the general population. In this paper we will estimate the average costs of providing a TURP. This measure of average costs can inform cost effectiveness studies of TURP, or inform cost-benefit studies of alternative treatment methods.

The treatment decision process for BPH is atypical for many medical conditions which assail the elderly population. In part this is due to the nature of the disease. The primary concern is associated with discomfort of the patient; in nearly all circumstances BPH will not threaten the life of the patient or have consequences for other aspects of the patient's health. Whether a patient will receive treatment or not depends on both the patient's own perception of his discomfort and inconvenience and on the discussions he has with his physician. The process has been referred to as "shared decision making." (See, for example, Roerhborn (1995, 32).) This has implications for estimating costs. Specifically, we must capture two levels of decision making: first we must model the decision to seek treatment or not; second, we must model the cost of treatment, conditional on the patient having decided to seek it.

This section proceeds by first exploring the alternative econometric models that could be utilized to capture the multi-step cost model associated with TURP. We present the advantages and disadvantages of several models, and the reasons for selecting the model we chose. Second, we discuss the two primary data sources, and how they will be combined in our model. Next, we estimate a model which describes the decision to seek treatment. Following that, we estimate the model of conditional treatment costs. Finally, we put the two models together to create a single model of the costs associated with TURP, which can be used for policy analysis, in that this model will predict the cost

associated with supplying TURP to the average man with BPH, rather than supplying TURP to the men who actually selected it. The combined model will be appropriate for asking questions about several issues, including the cost consequences of expanding access to TURP.

Models of Self-Selection

There is a long literature in economics dealing with consistent estimation in the face of data which are characterized by a large number of zeros. Such models usually take the form:

$$\begin{aligned} y_i^* &= \beta x_i + u_i \\ u_i &\_ N(0,\sigma^2), \end{aligned} \quad \textbf{(1)}$$

where the dependant variable is not always observed, such that the observed data is generated according to the rule:

$$y_i = \begin{cases} y_i^* & \text{if } y_i^* \geq 0 \\ 0 & \text{otherwise.} \end{cases} \quad \textbf{(2)}$$

In this model, y_i represents the costs of providing a TURP to a man suffering from BPH.

One of the earlier methodologies developed for consistent estimation is from Tobin (1958). This model, known as the Tobit, assumes that the unobserved data (i.e. censored data) arise because y_i^* takes on negative values which, for technological or rationality reasons, cannot be observed. The Tobit is less appropriate, however, to situations where the unobservability of the dependant variable is due to some explicit choice.

Heckman (1978) proposed an alternative estimator when the censoring is due to actual choices made by the agents which are being examined. This two-stage model is relatively straight forward. It involves creating an additional variable, I_i which equals one when the data are observed and zero otherwise. For this research, I_i takes a value of 1 when a man receives a TURP, and 0 otherwise. The structural equation for this model is generally found by first estimating a probit to the form:

$$I_i = \gamma x_{1i} + \eta_i, \quad \textbf{(3)}$$

and then recovering the inverse Mill's ratio $\lambda = \phi(\gamma x_1) / \Phi(\gamma x_1)$, where $\phi(\,.\,)$ and $\Phi(\,.\,)$ represent the probability density function and the cumulative density function of the standard normal distribution, respectively. Given the inverse Mill's ratio from the first stage, the unconditional estimate of the dependant variable of interest is found by running two-stage least squares estimate on

$$y_i = \beta x_{2i} + \rho\sigma \lambda_i + u_i. \quad (4)$$

Note that x_1 and x_2 must share many variables in common, though x_1 will, in general, contain identifying variables which are excluded from x_2. Also x_1 and x_2 are generally taken from the same sample. A second variant of this model is available which estimates both stages simultaneously via maximum likelihood.

This model is based upon a number of assumptions, and generally is appropriate when the decision process whether to choose a positive level of y_i is closely related to the decision process which describes the amount of y_i chosen, given the choice to consume some positive amount. There are situations, however, in which this assumption does not necessarily hold. Further, in most circumstances identifying restrictions are needed to eliminate variables from the second stage of the process. That is, researchers must find variables which influence the choice to pick a positive level of y_i but do not affect the decision regarding the level of y_i. Such restrictions may be difficult or impossible to defend in many circumstances.[8] Also, this Heckman model require that x_1 and x_2 be drawn from the same sample, so that an inverse Mill's ratio can be created for each observation.

A third model has been developed to deal with censored data, and has found wide-spread adoption in health economics. This model was initially explored by Cragg (1971), and later received much more attention due to work by researchers on data generated by the RAND Health Insurance Experiment. Labeled the Two-Part model, it involves estimating a first stage probit or logit, as in **(3)** above, and then estimating on the sub-sample which contains only positive levels of y_i. The unconditional expected value of y_i can then be recovered using

$$\ln(y_i) = \beta x_i + u_i \quad (5)$$

$$E[y_i] = P_i \exp(b x_i)\theta, \quad (6)$$

where P is the predicted probability of a positive level of y_i and is the average of the exponential of errors from **(5)**. For an example of this model in use, see Manning, et al. (1995).

A substantial debate has been underway for a number of years regarding the relative superiority of the Heckman Self-Selection model versus the Two-Part model. Evidence

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[8] Note that it may be possible to identify the first stage of the process off of the non-linearities in the probit estimator. The problem with this is that it may introduce serious multicollinearity between the inverse Mill's ratio and the variables in x_2. In this case, the research is with no recourse.

presented to date have centered primarily around theoretical claims in favor of the selection model, and Monte Carlo simulation results which have not resolved the matter. On the theoretical front, questions have been raised as to whether there is any joint distribution of (η, u) which is consistent with the Two-Part model (i.e., whether the two equations can ever be stochastically independent). On the Monte Carlo front, a series of simulations have been published which indicate that the Two-Part model dominates the sample selection model (Duan, et al., 1984; Hay et al., 1987). Other authors find that the Two-Part model and sample selection models are either roughly equivalent, or each slightly superior in certain circumstances (Leung and Yu, 1996; Duan and Rogers, 1987).

Here we will utilize the Two-Part model for several reasons. First, given that we are ultimately interested in modeling the cost of TURP, it is reasonable to assume that the decision whether to receive a treatment is independent of the decision to spend a marginal dollar. The first decision involves heavy patient participation. However, the decision to spend a marginal dollar is likely made exclusively by the physician performing the procedure. In this case, a model which assumes intrinsically separate decisions is a better conceptual fit.

A second reason to utilize the Two-Part model follows from the nature of our data. The data we use for the costs of TURP are taken from the 1994 discharge abstracts reported to HCIA from the five "all payer" states (California, Colorado, Florida, Maryland and New Jersey). This data, based as it is on discharges, contains only information on those men who actually underwent the procedure. To model the likelihood of the procedure, we utilize a different data set, the *National Health Interview Survey* (NHIS, years 1986-1994). This is a survey of the general population, which includes men with BPH, some of whom opt for a TURP and some of whom do not. Using this data, we can estimate the first stage logit equation to predict the likelihood of a TURP, and use the predicted probability of a TURP for the average man with BPH as the unbiased estimate of the likelihood for each person in the all-payer sample, in order to implement equation **(6)**.

The First Part Treatment Decision

The first stage of the Two-Part model involves estimating **(3)** - whether a TURP is obtained or not - via a logit procedure (which simply insures that the prediction for the likelihood of a TURP does not fall outside the [0,1] interval). The logit is estimated across a sample of men from the NHIS who suffer from BPH. Of the 502 men in the sample, 12.2 percent (or 61) opted to undergo a TURP. We regress the [0,1] indicator across a number of explanatory variables. These are:

AGE	The age of the patient
BLACK	A dummy variable equaling 1 when the man is black
HISP	A dummy variable equaling 1 when the man is Hispanic
MARRIE	A dummy variable equaling 1 when the man is married

EDUC	Years of education completed
INCOME	Annual income
$INCOME^2$	Annual income, squared
WORK	Whether the BPH restricts the man's ability to work
HEALTH	Self-reported health status
ACTLIMIT	Whether the BPH restricts the man's normal daily activities
ONSET	How long since the BPH was diagnosed
NE	A dummy variable equaling 1 when the man lives in the Northeast
MW	A dummy variable equaling 1 when the man lives in the Midwest
SO	A dummy variable equaling 1 when the man lives in the South
RURAL	A dummy variable equaling 1 when the man lives in a rural setting
NONPROF	A dummy variable equaling 1 when the man was admitted to a non-profit hospital
OTHERHOS	A dummy variable equaling 1 when the man was admitted to a hospital that was neither for-profit nor not for profit
YEAR>89	A dummy variable indicating the TURP occurred after 1989
YEAR>91	A dummy variable indicating the TURP occurred after 1991
UROL	A dummy variable indicating the man visited a urologist
YR91*UR	An interaction term between YEAR>91 and UROL

Several variables require explanation. Economists have long argued about whether hospital ownership affects decisions within the institution. For this reason, we include the dummy variables for hospital types to see if for-profit hospitals are more likely to perform TURPs than other kinds of hospitals. A significant parameter on either hospital dummy would indicate that for-profits behave differently.

In addition, several important changes have taken place in medical technology related to the diagnosis or treatment of BPH during the years. In 1989, a new test for prostate cancer - the PSA test - became widely available. While this test does not detect BPH, a common perception among urologists is that it did bring more men into contact with providers, who were then in a position to diagnose BPH independently of the possibility of cancer. This motivates the YEAR>89 dummy variable. In 1991, alpha blockers were recognized as a potentially effective treatment alternative to more invasive methods for BPH. Consequently, one would expect substitution away from TURP after this time, which explains the inclusion of YEAR>91. Finally, given that a medical alternative became both available and widely publicized after 1991, it is possible that urologists might respond to this "threat" to their livelihood by increasing the strength of their recommendations for TURP. To control for this, an interaction term between YEAR>91 and UROL is included.

The regression results for the logit model are presented in Table 43.

Table 43. Regression Results for First-Stage Logit on Probability of TURP (T-statistics in parentheses, significant coefficients in bold)

Variable	Coefficient	Variable	Coefficient
Constant	**-4.37** **(2.15)**	NE	**-1.5102** **(3.11)**
AGE	**0.4218** **(2.18)**	MW	-0.4614 (1.09)
BLACK	0.7097 (1.28)	SO	-0.2823 (0.72)
HISP	0.9128 (1.48)	RURAL	0.0804 (1.02)
MARRIED	-0.1775 (0.44)	NONPROF	**1.3319** **(3.30)**
EDUC	0.4250 (0.82)	OTHERHOS	0.8245 (1.56)
INCOME	0.0118 (0.17)	YEAR>89	-0.6244 (1.04)
INCOME2	-0.1938 (0.67)	YEAR>91	-0.3272 (0.50)
WORK	0.6157 (1.54)	UROL	-0.0183 (0.04)
HEALTH	-0.0432 (0.32)	YR91*UR	**1.5735** **(2.08)**
ACTLIMIT	0.1440 (0.61)		
ONSET	**-0.3683** **(2.44)**		

While the primary reason for estimating the logit treatment choice equation is to condition the cost estimates, several results from Table 44 are of interest. Men living in the Northeast are significantly less likely to receive a TURP for their BPH than men living in the other regions of the U.S. This suggests interesting practice variation, though the source of this variation cannot be determined with this analysis. Of somewhat more interest is the parameter estimate on the interaction term between YEAR>91 and UROL. This parameter is positive and significant, which indicates that after 1991, seeing a urologist increased a man's chance of having a TURP - which was not true prior to 1991 (as evidenced by the very insignificant parameter estimate on UROL). This result is

consistent with the hypothesis that the introduction of pharmaceutical therapies for BPH lead urologists to increase the pressure they brought to bear on their patients to accept a TURP. However, it is also consistent with the presence of selection effects after 1991, such that only the most likely candidates for TURP actually made it to a urologist, with the less severe BPH patients receiving medical therapy from their general practitioner.

Once the logit model of equation **(3)** is estimated, we can recover the predicted likelihood of a TURP, P , for the average man in the NHIS sample. This predicted probability of a TURP will be taken as an unbiased estimate of the likelihood of a TURP for each man in the cost regressions below. Hence, P will replace P_i when we finally construct the unconditional cost model from equation **(6)**. The conditional cost estimation is performed in the next section.

The Cost of Undergoing a TURP

As discussed above, a TURP is an elective procedure. Undergoing a term involves significant economic costs. Thus, any technology that reduces the number of decisions to undergo TURP may well save resources for society. In this section, we attempt to model the hospital costs of undergoing TURP.

Data and Estimation Issues

The data for this section comes from the "All-Payer" data set, data from 1994 on all payers in all hospitals in five different states: California, Colorado, Florida, Maryland, and New Jersey. Within each state are a different number of hospitals, and within each hospital are a different number of patient observations, as summarized in Table 44.

Table 44. Data Summery by State

State	Hospitals	Observations	Usable Observations
California	347	13761	10866
Colorado	41	1505	1311
Florida	175	9081	8122
Maryland	82	2513	2182
New Jersey	84	5357	4159
Total	729	32,127	26,640

Our goal is to econometrically model the determinates of total hospital charge for a patient undergoing TURP. The explanatory variables available to us in the All-Payer data set are

lnTOTAL	The natural logarithm of Total Charge.
AGE	The age of the patient.
COMP	A dummy variable equal to 1 if the patient suffered complications, 0 otherwise.
EMERG	A dummy variable equal to 1 if the patient was admitted to the emergency room, 0 otherwise.
RISK	The patient's risk adjusted mortality index developed at HCIA.
RACE	A dummy variable equal to 1 if the patient is known to be white, 0 otherwise.
DRG306	A dummy variable equal to 1 if the patient was billed for prostatectomy with complications, 0 otherwise.
DRG307	A dummy variable equal to 1 if the patient was billed for prostatectomy without complications, 0 otherwise.
DRG336	A dummy variable equal to 1 if the patient was billed for transurethral prostatectomy with complications, 0 otherwise.
MEDICARE	A dummy variable equal to 1 if the primary payer was Medicare, 0 otherwise.
MEDICAID	A dummy variable equal to 1 if the primary payer as Medicaid, 0 otherwise.

BLUE CROSS	A dummy variable equal to 1 if the primary payer was Blue Cross, 0 otherwise.
OTHER INSURANCE	A dummy variable equal to 1 if the primary payer was another form of insurance, 0 otherwise.

As stated above, there are 729 different hospitals in the sample. We expect that each hospital will have its own specific impact on costs. In other words, one hospital may be naturally more or less costly than another, all patient characteristics held constant.

Conceptually, we could adjust for such characteristics by running a dummy variable for each hospital. With 729 hospitals, however, that could be computationally difficult. Instead, we run a "fixed effects estimated. The fixed effects estimator is calculated as follows: Let $\{X_{ij}, \mathbf{Y_{ij}}\}$ be the vector of the dependent variable X (total cost) and explanatory variables **Y**, where the subscript (i) refers to patient (i) and the subscript (j) refers to patient (j). Let X_m equal the mean value for X for all the patients in hospital (j) and $\mathbf{Y_m}$ equal a vector of mean values for the variables in those same patients in hospital (j). Let $X^f_i = X_{ij} - X_m$, and $\mathbf{Y^f_i} = \mathbf{Y_{ij}} - \mathbf{Y_m}$. Fixed effects regressions involves running a regression of $\mathbf{Y^f_i}$ on X^f_i. (See Judge, et. al (1985, 530-533).) We therefore will suppress the constant term in the regression, as well as the dummy variables for each of the hospitals (though none of these are of interest to the present investigation.)

Estimation Results

Table 45 presents the results of the estimation of the fixed effects model by states, and for an aggregate model across all five states. Patient age is positive and significant in all six regressions, indicating that the older a patient is, the higher the relevant medical costs. Patients with complications also generated higher charges, with the charge increase ranging from 30 to 42 percent. Patients admitted to the emergency room increase costs from 44 to 61 percent.

On the other hand, the patients risk adjusted mortality index had weaker effects. It was only significant in three of the five state equations, and at a relatively low level. The variable for race is insignificant in all five of the state equations.

As for the DRG variables, patients with complications relating to prostatectomy were estimated to have significantly higher costs, with charge increases of 31 to 55 percent. Prostatectomy without complications was not significantly more expensive than the prostatectomy with complications in four of the five state equations. If the patient underwent transurethral prostatectomy with complications, that acted to raise charges significantly, in the range of 12 to 20 percent.

With respect to the payer classes, none of the four variables for payer class was significant in the regressions for California, Colorado, Florida, and Maryland. Three of the four, however, where significant in New Jersey. We take this as an indication that

medical insurance plans are different in New Jersey, that is, that managed care has a smaller share of practices there and has not come to change treatment regimen.

Table 45. Estimation Results - All Payer Data (T-statistics in Parenthesis, significant coefficients in bold)

Variable	California	Colorado	Florida	Maryland	New Jersey	Aggregate Equation
AGE	**0.00157** (3.98)	**0.00257** (2.291)	**0.00280** (5.410)	**0.00451** (3.918)	**0.00533** (5.537)	**0.00275** (9.603)
COMP	**0.297** (25.554)	**0.309** (8.746)	**0.281** (22.630)	**0.230** (9.796)	**0.421** (17.067)	**0.304** (39.996)
EMERG	**0.461** (26.481)	**0.445** (6.453)	**0.425** (27.350)	**0.621** (20.185)	**0.584** (29.436)	**0.514** (55.747)
RISK	0.000021 (1.657)	**0.000080** (3.029)	0.000041 (1.235)	**0.000436** (2.105)	**0.000047** (2.052)	**0.000043** (4.368)
RACEO1	-0.0142 (1.717)	0.0376 (1.405)	-0.0257 (1.938)	-0.0350 (1.591)	-0.0345 (1.600)	**-0.0183** (2.870)
DRG306	**0.313** (18.998)	**0.425** (9.275)	**0.324** (19.574)	**0.342** (9.200)	**0.555** (17.466)	**0.364** (35.346)
DRG307	0.0454 (1.670)	0.0202 (0.240)	**0.0773** (2.204)	0.0612 (1.008)	-0.0172 (0.298)	**0.0499** (2.570)
DRG336	**0.134** (19.303)	**0.142** (6.942)	**0.118** (13.544)	**0.124** (6.469)	**0.200** (13.691)	**0.140** (28.997)
MEDICARE	0.00283 (0.121)	-0.00444 (0.087)	-0.00943 (0.366)	0.00829 (0.130)	**-0.108** (2.453)	-0.0217 (-1.430)
MEDICAID	0.00422 (0.165)	0.0868 (1.105)	-0.0559 (1.320)	-0.0201 (0.224)	-0.109 (1.489)	-0.0226 (1.192)
BLUE CROSS	0.0245 (0.831)	-0.0454 (0.665)	0.0225 (0.790)	-0.0174 (0.261)	**-0.1128** (2.375)	-0.0212 (1.165)
Other Insurance	-0.0228 (0.964)	-0.0353 (-0.683)	-0.0244 (0.897)	-0.0272 (0.418)	**-0.1500** (3.339)	**-0.0515** (3.317)
RSS	1066.66	126.78	209.97	257.94	687.17	3028.85
R^2	0.214	0.241	0.237	0.355	0.385	0.270

Testing for Fixed Effects and For An Aggregate Model

Econometrically, our first test is to see whether the fixed effects model (in effect, a dummy variable for each hospital) is appropriate. To test this, we set up two models. In the first model all hospitals were assumed to be identical, all of the observations for one state were pooled and a standard regression estimated via ordinary least squares. In the second, fixed effects, model the marginal effects of each characteristic was assumed to be the same for all hospitals, but the hospitals differed in the intercept term. A model was created with a dummy variable for each hospital in addition to the characteristic variables. The two models were then compared based upon the sum of squared errors. As discussed above, it can be shown that the patient characteristic coefficients of the second model, the one with multiple intercept terms, can be estimated without the intercept terms.

Let the number of restrictions, # REST = the number of hospitals in the state. Let the degrees of freedom df = the number of observations minus #REST minus the number of variable coefficients minus 1, SSE_r = sum of squared errors from the restricted, one intercept, model; and SSE_u = sum of squared errors from the unrestricted, multiple intercept, model. It is known that if the hospitals are all identical the test statistic:

$$F = [(SSE_r - SSE_u)/(\#\ REST)] / [SSE_u/df]$$

follows an F-distribution with df the numerator and # REST the denominator degrees of freedom. Table 46 presents the results of these tests for all of the hospitals in all states. As the table demonstrates the hypothesis of identical intercepts for each hospital is strongly rejected in favor of the alternative that each hospital has a separate intercept term.

Table 46. Test For Fixed Effects

State	SSE_r	SSE_u	#REST	df	Test Statistic	F(1%) critical
California	1878	1067	346	10,507	23.09	1.19
Colorado	198	127	40	1258	17.57	1.61
Florida	1243	846	174	7935	21.39	1.27
Maryland	324	258	81	2088	6.56	1.41
New Jersey	899	687	83	4063	15.11	1.40

The next question we are interested in whether the coefficients are the same across states. To do this we estimate a separate regression for each state, and then an aggregate equation across all five states, using the fixed effects model. We then compare the sum of squared errors of the five state models to an aggregate model with all of the data from all five states.

In this case it is known that:

$$(SSE_r - SSE_u)*(T-K)/J*SSE_u \sim F(J,T-2K),$$

where J = number of restrictions, T = # obs, and K = # parameters in unrestricted model. In this case J = 48, and T-K = 26628. The 1% critical value for F(40,¥) is 1.59. As Table 46 indicates, the sum of the squared errors across the five state models is 2984, while the sum of squared errors in the aggregate model is 3028. This implies the relevant F statistic $F = (SSE_r - SSE_u)*(T-K)/J*SSE_u = 8.23 > 1.59$. Thus, the hypothesis that all states are the same is rejected at the 1% level.

Testing For Differential Effects Across States

While the statistical models for each state are significantly different in a statistical test, a brief review of the relevant parameters indicates they may not be greatly different in an economic sense. The consideration that arises here is the difference between statistical significance and practical importance. Each of these models has several thousand

observations. This means that it may be possible to very accurately measure the coefficients in question. Something that is measured very accurately may be statistically significantly different than another thing that is also measured very accurately.

For example, if we can measure a person's weight in grams we can say that the difference in their weight from one hour to the next is significantly different, while for any practical application the difference of a few grams does not make any difference. Put another way, in this situation it could be the case that using one set of coefficients we could predict a patient's total charge to be $1,000.00 while using the coefficients from a different state we would predict the total charge to be $1,001.00, but because a standard error is only a few cents we find these coefficients to be significantly different in the statistical sense.

To address this issue we used the coefficients from each state to estimate the total charge of a "typical" patient and to estimate the changes in those charges when one of the typical patient's characteristics change. The typical patient is the median patient from California (the largest data set) and his characteristic are as follows: AGE=70; COMP=0; EMERG=0; RISK=20; RACE01=1; DRG306=0; DRG307=0; DRG336=0; MEDICARE=1; MEDICAID=0; BLUE CROSS=0; Other Insurance=0.

We calculate the changes by changing one of the relevant variables, and setting the others equal to our typical patient. For example, we change COMP from 0 to 1, and leave all the other variables equal to that of the typical patient. This raises charges by approximately $3000 in California, $2400 in Colorado, $2800 in Florida, $1200 in Maryland, and $4500 in New Jersey. The results of the predictions are listed in Table 47:

Table 47. Different Effects Across States

	California	Colorado	Florida	Maryland	New Jersey
Charge for "Typical" Patient	$8718	$6023	$8837	$4489	$8598
	Predicted Changes in Charges				
Explanatory Variable's New Setting	California	Colorado	Florida	Maryland	New Jersey
AGE=60	-$136	-$168	-$244	-$198	-447
COMP=1	3013	2402	2872	1162	4507
EMERG=1	5107	3711	4679	3867	6823
RISK=100	15	43	29	159	32
RACE01=1	124	-244	230	160	302
DRG306=1	3215	3510	3385	1831	6384
DRG307=1	405	135	710	283	-147
DRG336=1	1249	1009	1102	590	1899
MEDICARE=0	-25	30	84	-37	977
MEDICAID=19	12	633	-402	-126	-18
BLUE CROSS=1	191	-266	287	-114	-45
Other Insurance=1	-221	-201	-131	-156	-357

It would appear that there are practical differences among states. Reducing the ages of the patient from 70 to 60 decreases costs by $136 in California and $447 in New Jersey. Complication increase the cost of a TURP by $1200 in Florida, and $4500 in New Jersey.

Note that having MEDICAID = 1 necessitates that MEDICARE = 0. The same is true for all other payer variables.

On the other hand, most of the predicted changes are of the same direction and magnitude.

Unconditional Cost of TURP

With the treatment choice logit and the conditional cost estimates by state from earlier, we can construct an average unconditional prediction for the costs of TURP using equation 7. Modifying this expression slightly to reflect the use of the average probability of a TURP as a unbiased proxy for the estimated probability for each person in the cost data, the expected unconditional cost of a TURP is:

$$E[Cost_i] = \bar{P}\exp(b\,x_i)\frac{\Sigma[\exp(\ln(Cost_i) - b\,x_i)]}{n} \quad (7)$$

Note that this expression gives the expected cost of a TURP for the average man with BPH, rather than the average man who received a TURP. From a policy perspective the expression in (7) is the relevant expectation. If we are considering policies which expand the availability of TURP, we will want to know how much it will cost to treat the average man, not the average man already receiving treatment.

Since our F-Tests in the previous section indicate that each state has a different model, the average expected cost of a TURP will be calculated for each state. Also, the multiplicative factors attached to $exp(bx_i)$ in (7) are constants, so the average cost can be obtained by simply transforming the average predicted cost from the regressions inTable 45. The predicted unconditional cost of TURP are found in Table 48 below.

Table 48. Average Predicted Unconditional Cost of TURP by State

State	Multiplicative Factor:P *	Predicted Conditional Cost of a TURP	Predicted Unconditional Cost of a TURP
California	0.1268	$8,908	$1,130
Colorado	0.1278	$6,218	$750
Florida	0.1276	$8,413	$1,074
Maryland	0.1285	$3,832	$492
New Jersey	0.1358	$8,565	$1,163

The second column in Table 48 is the predicted cost of supplying a TURP to those men who actually received the procedure. The third column is the predicted cost of supplying a TURP to the average man with BPH, independently of whether he actually receives a

TURP or not. Note that the dollar amounts in column three are quite low relative to the dollar amounts in column two. Recall that the average man with BPH does not opt to receive a TURP. That the average man does not receive treatment suggests that the condition is not sufficiently severe to warrant the costs of the treatment. If the resource costs necessary to supply a TURP is related to the severity of the enlargement, then it is not at all surprising to find these costs are low in the general BPH population. However, the disparity is quite large, which suggests that this approximation should be taken with some caution.

Conclusion

BPH is one of the most common chronic conditions for men in the U.S., affecting the majority of men over the age of 60. The current "gold standard" treatment for BPH symptoms which are serious enough to warrant intervention is the transurethral resection of the prostate, TURP. Given the widespread use of this procedure, and the millions of dollars that are paid each year by insurers and patients to secure this treatment, the dearth of careful empirical estimates of the true cost of the procedure is remarkable. This study has sought to close this gap by estimating a consistent model of the cost of TURP, controlling for both the decision to seek treatment, and the resource costs incurred when treatment is pursued. The Two-Part model common in health economic research is utilized. The results suggest that the cost associated with providing a TURP for the average man with BPH would be $492 to $1,163 (depending on the state of residence). Hopefully, these calculation will be useful to researchers, payers and providers who wish to undertake cost-benefit or cost-effectiveness analysis of this common procedure.

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