

ESSAYS ON HEALTH ECONOMICS
IN COSTA RICA

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Andrea Navarro Monge

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ESSAYS ON HEALTH ECONOMICS IN COSTA RICA

Andrea Navarro Monge, Ph.D.

Cornell University 2020

Public insurers have limited resources and are faced with a trade-off between individual and collective welfare. This results in rationing, which means some services are available while others are not; and translates into limitations in access to health care. Health care is a need everyone will face at some point, therefore understanding resource allocation to optimize access is vital. This dissertation focuses on contributing evidence in support of policies to achieve this.

Costa Rica is a developing country with a public insurer providing universal health care coverage. The country's health outcomes are closer to developed nations than to its socioeconomic peers; all of which make it a valuable research setting. These insights contribute to the ongoing discussion of how to organize health care systems with limited resources while having the goal of maximizing coverage and access to health care.

The first chapter provides the first empirical evidence on litigation (where an individual sues an insurer to obtain coverage) as a safety valve to avoid rationing. I construct a novel dataset from all Costa Rican litigation requesting access to drugs, and for all cases involving cancer I use clinical guidelines to determine expected benefits. Using a probit model to predict successful litigation I find that higher benefit drugs have a higher likelihood of approval, but the benefit-cost ratio has no effect. An event study shows no evidence that drugs gaining coverage affects trends in drug requests. The second chapter further explores litigation using prevalence and mortality to characterize cancer cases. No pattern is evidenced for either measure which supports litigation as a complimentary mechanism for access that is sensitive to individual heterogeneity.

The third chapter examines how preventive and primary care services affect elderly health by exploiting a natural experiment where the treatment was to increase access by adding providers.

I measure the treatment's effect on health care utilization, nutritional outcomes, mental health, chronic diseases, and disability status using a difference-in-differences model. With treatment, all measures of healthcare utilization increased significantly. Findings on health outcomes are small and mixed, showing health possibly improving in some measurements and worsening in others.

BIOGRAPHICAL SKETCH

Andrea Monge completed medical school and pursued a Residency in Head and Neck Surgery from the University of Costa Rica, graduating both *magna cum laude*. Following an interest in public policy and global health she continued her studies with a Master's in Public Health with an emphasis in Health Management from the University of Costa Rica, graduating *suma cum laude*.

After working several years as a Head and Neck Surgeon in large teaching specialty hospitals, she came to Cornell University joining the Policy Analysis and Management doctoral program with a concentration in health economics. Her research interests are health economics, global health, policy analysis, economic evaluations, and health services.

I dedicate my dissertation to my family for being the cornerstone of everything I am today. Words fail to express how much their unwavering and unconditional support has meant and continues to mean to me. I dedicate my dissertation to my mom, who tirelessly makes the impossible possible, and has never stopped cheering me on; to my dad who, since that first book he gave me, has dedicated himself to diligently challenging me to strive for nothing less than excellence; to my siblings who remind me everyday of the importance of living life to the fullest and fighting for one's dreams; to my grandparents whose sage advice and words of encouragement have been ever present.

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TABLE OF CONTENTS

List of figures	ix
List of tables	x
List of abbreviations	xi
Chapter 1. Litigation and access to health care: evidence from 3,124 cases	1
1.1 Introduction	1
1.2 Background	3
1.2.1 Costa Rican health care system	3
1.2.2 Costa Rican litigation setting	4
1.2.3 Existing evidence	6
1.3 Conceptual model	9
1.4 Data	10
1.4.1 Court ruling selection and initial data extraction process	10
1.4.2 Covered drug lists	10
1.4.3 Benefits construction	11
1.4.4 Drug costs	12
1.4.5 Descriptive statistics	12
1.5 Methods	15
1.5.1 Model for Court approval probability	15
1.5.2 Model for drugs gaining coverage and litigation	16
1.6 Results	17
1.6.1 Stylized facts on litigation	17
1.6.2 Court decision determinants	20
1.6.3 Predicting Court approval probability	23
1.6.4 Court requests and PI coverage	27
1.6.5 Approximation of court cost-effectiveness	29
1.7 Conclusion	30
References	32
Appendix	37
Chapter 2. Analyzing prevalence and mortality in litigation requesting access to drugs	43
2.1 Introduction	43
2.2 Institutional setting	46
2.3 Conceptual role of prevalence and mortality	48
2.4 Data	51
2.4.1 Descriptive statistics	52
2.5 Methods	57
2.6 Results	59
2.6.1 Likelihood of Court approval	61
2.7 Conclusion	64
References	66
Appendix	68

Chapter 3. The effect of primary care on elderly health outcomes: evidence from a natural experiment **70**

- 3.1 Introduction 70
- 3.2 Background 74
 - 3.2.1 Health areas 74
 - 3.2.2 Natural experiment 75
- 3.3 Methods 78
- 3.4 Data 80
 - 3.4.1 Sociodemographic characteristics 80
 - 3.4.2 Health care utilization 80
 - 3.4.3 Survey of health aging and longevity 81
- 3.5 Results 83
 - 3.5.1 Areas before treatment 83
 - 3.5.2 Areas after treatment 91
 - 3.5.3 Individual level health outcomes 92
- 3.6 Discussion 95
- References 98
- Appendix 103

LIST OF FIGURES

1.1	Drug requests to the Costa Rican Constitutional Court per 100,000 persons	5
1.2	Conceptual model for litigation’s role in drug access	8
1.3	Approval probabilities by drug for 1,741 cases	18
1.4	Approval probability of selected requested drugs over time	19
1.5	Autocorrelation coefficients for drug approval probability time series with a one-year lag (drugs = 269)	20
1.6	Approval probability and benefit-cost ratios for requested drugs (n = 85)	22
1.7	Event study for drug requests controlling for never covered drugs	28
A1.1	Approval probability by diagnosis for 2,722 cases	41
A1.2	Approval probability of requested drugs classified into cancer or not cancer drugs over time	41
A1.3	Approval probability and different variable measurements: requested drug’s benefits and costs, incremental benefits and incremental costs	42
2.1	Hypothetical factors related to prevalence and mortality affecting judge’s decisions and the resulting cost benefit ratios (ICBRs) from treatments	49
2.2	Diagnoses classified according to prevalence and mortality terciles with the rate of Court cases per 1,000 people with the diagnosis	59
2.3	Diagnoses classified according to prevalence and mortality terciles with the diagnosis’ Court approval probability	60
2.4	Diagnoses classified according to prevalence and mortality with the requested treatment’s cost benefit ratios	61
A2.1	Diagnoses classified according to prevalence and mortality terciles with the diagnosis’ Court approval probability	69
3.1	Map of treated and control health areas	78
3.2	Health care utilization over time for treated relative to control health areas	87
3.3	Policy’s effect on the ratio of valid over all Emergency Room (ER) visits	89
A3.1	Additional health care utilization measures over time for treated relative to control health areas	107

LIST OF TABLES

1.1	Descriptive statistics for drug requests	13
1.2	Descriptive statistics for cancer drug requests	14
1.3	Marginal effects on Court approval probability using incremental benefits and costs .	24
1.4	Marginal effects on Court approval probability using benefit-cost ratios	25
1.5	Marginal effects on Court approval probability from additional specifications: using requested drug measures and only early stage cases	26
1.6	Court’s incremental cost-effectiveness ratios	29
A1.1	Approval probability for the most frequently observed drugs, diagnoses and medical specialties	37
A1.2	Probit regressions predicting Court approval probability using incremental benefits and costs	38
A1.3	Probit regressions predicting Court approval probability using benefit-cost ratios . .	39
A1.4	Additional probit regressions predicting Court approval probability: using requested drug measures and only early stage cases	40
2.1	Descriptive statistics for cancer drug requests (2009-2015)	53
2.2	Characteristics of cancer diagnoses observed in Court cases	54
2.3	Diagnoses in Court cases according to prevalence and mortality levels (defined using terciles)	58
2.4	Marginal effects from probit models predicting Court approval of drug requests . . .	63
A2.1	Predicting the proportion of cases for a diagnosis over all diagnosis using prevalence and mortality	68
3.1	Summary statistics for health area sociodemographic characteristics prior to treatment	84
3.2	Summary statistics for health area health care utilization measures <i>per capita</i> prior to treatment	85
3.3	Summary statistics for surveyed elders prior to treatment	90
3.4	Effects on health outcomes estimated from differences-in-differences model	93
A3.1	Costa Rican health areas, their treatment status and timing	103
A3.2	Results from predicting treatment status using health area sociodemographic char- acteristics	105
A3.3	Summary statistics for health area sociodemographic characteristics during treatment	105
A3.4	Summary statistics for health area measures of health care utilization <i>per capita</i> during treatment	106

LIST OF ABBREVIATIONS

Adj	Adjusted
BMI	Body Mass Index
CCSS	Costa Rican Social Security System, from the Spanish “ <i>Caja Costarricense de Seguro Social</i> ”
CRELES	Costa Rican Longevity and Healthy Aging Study
EBAIS	Basic Integrated Health Care Team, from the Spanish “ <i>Equipo Básico de Atención Integrada de Salud</i> ”
ER	Emergency Room
g	Gram
GAM	Great Metropolitan Area, from the Spanish “ <i>Gran Área Metropolitana</i> ”
HDI	Human Development Index
HDL	High Density Lipids
ICBR	Incremental Cost-Benefit Ratio
ICER	Incremental Cost-Effectiveness Ratio
INEC	National Institute for Statistics and Census, from the Spanish “ <i>Instituto Nacional de Estadística y Censos</i> ”
kcal	Kilocalorie
mcg	Microgram
mg	Miligram
mmHg	Milimeters of mercury
NCCN	National Comprehensive Cancer Network
OECD	Organization for Economic Co-operation and Development
PI	Public Insurer
SD	Standard deviation
Std	Standard
UNDP	United Nations Development Programme
WHO	World Health Organization

CHAPTER 1

LITIGATION AND ACCESS TO HEALTH CARE: EVIDENCE FROM 3,124 CASES

1.1 Introduction

Public insurers have limited resources and are faced with a trade-off between individual and collective welfare (Hauck et al. 2019; Kim et al. 2015; Schut and Van de Ven 2005; Verguet et al. 2016). Individual preferences reveal a set of services with any benefit, whereas collective preferences include only services with the highest value. In order to function the insurer must have a set of rationing rules which means that some services will not be covered (Bryan et al. 2007).

Individuals find ways to get around rationing –a safety valve. For instance, in the United Kingdom there are reports of people traveling to another country to obtain a service (Stepahno 2019). The most common safety valve is litigation, where an individual sues an insurer to obtain coverage for a service (Flood and Gross 2014). Litigation is not limited to public systems, but in these, the collective side of the trade-off is society at large, making it particularly relevant for social planning (Jung et al. 2014).

There is no empirical evidence on litigation as a safety valve for accessing health care services. This paper provides the first evidence by using novel hand-collected data on litigation decisions about access to drugs. The goal is to determine what factors predict litigation success and to explore the possible relationship between a drug gaining coverage and the frequency of litigation.

Even though litigation’s origin is individual –a person sues the insurer-, as a mechanism to access drugs from a public insurer it acquires a collective effect. This effect comes from changing the use of public funds –successful litigation forces the insurer to reallocate resources to meet the litigating individual’s request.

This extended effect places litigation for access to health care services in an intersection of economics and law embodied by using economic theory to understand legal decisions. Using an economic framework for this purpose is often appropriate theoretically, but there is little evidence that legal decisions actually consider economic concepts (Clarke and Kozinski 2019).

When making decisions about access to drugs, public insurers use economic evaluations (Neu-

mann et al. 2015), individuals use their preferences, however what judges use is unknown. I postulate that if legal decisions are determined by expected benefits or the benefit-cost ratio from a requested drug then a link can be suggested to either the individual (individual welfare) or the public insurer (collective welfare).

I construct a database using the universe of Costa Rican litigation requesting access to drugs (n = 3,124). Hand-collected data on litigation decisions was linked to drug coverage status¹ by the public insurer and drug costs. I then selected all cases where the litigant has a cancer diagnosis (n = 1,236) and hand-collected data from clinical practice guidelines² to determine at an individual level the expected benefits from the drug they are currently taking and the drug they are requesting.

Costa Rica is a small five million people developing country with a publicly funded health care system with health outcomes *on par* with developed nations. Their public insurer provides extensive coverage and is affected by litigation at increasing rates. By design, litigation on drug access only directly affects the individual or individuals litigating, has low barriers to access and is the exclusive purview of one Court –the the Constitutional Court (Programa Estado de la Nacion 2017).

Using a probit model, I predict the probability of successful litigation (Court approval of a drug request that forces the insurer to provide the drug) using expected benefits and costs with a host of case specific controls. A second model predicts approval using the requested drug’s benefit-cost ratio. Using an event study model I predict litigation trends relative to a drug gaining coverage from the insurer.

From the descriptive analysis I find that individual case characteristics matter for Court decisions, legal precedent –previous Court decisions determining future decisions- does not play a role, there is a weak correlation between benefits and Court approval, and no correlation for the benefit-cost ratio.

The probit model reveals that higher benefit drugs have a higher likelihood of approval, but the benefit-cost ratio has no effect. Interestingly costs have a large positive effect on the likelihood of approval. Drugs gaining coverage do not appear to have an effect on drug request trends. From back-of-the-envelope calculations I find that the Court has an incremental cost-effectiveness ratio

¹Whether a drug is covered by the insurer or not. If it is covered, for what diagnosis and at which dosing.

²International medical standard for cancer diagnosis and treatment based on peer-reviewed literature and expert criteria.

above the World Health Organization’s recommended threshold and thus the drugs would not be provided.

The remainder of this paper is structured as follows: section 2 explains the institutional setting and background existing evidence; section 3 presents the conceptual model for access to drugs litigation; section 4 details the data construction process; section 5 explains the methods used; section 6 presents and discusses the results; and section 7 contains the conclusions.

1.2 Background

1.2.1 Costa Rican health care system

Costa Rica is a developing country in Central America of about 5 million³ with a far-reaching and well-established health care and litigation systems. Established in 1941, the country has a tax-funded single-payer health care system that is well known by every Costa Rican. A comprehensive package of services are provided free at point-of-use over a wide network of providers located throughout the country. The providers are all part of a centralized autonomous institution⁴ known as the Costa Rican Social Security Institution⁵. This institution functions as a public insurer and henceforth will be referred to as such.

The centralized authorities determine system-wide regulations including drug coverage. For this, the Centralized Pharmacotherapy Council publishes Official Drug Coverage Lists⁶ that are valid for every provider in the network. The Lists specify the drug, how it is to be used and by whom. This means that for every drug, covered dosing and diagnosis combinations are specified.

Although the public insurer indicates that the Lists are based on cost-effectiveness (Comite Central Farmacoterapia 2014), the decision process and data used are not publicly available. Since clinical trials are not usually conducted in Costa Rica the data must come from international sources. These Lists are the rationing rules for drug coverage. A drug included in the List is provided at no cost to individuals once their doctor prescribes it. If a drug is not included then it is not available to the individual even if their doctor prescribes it.

³Costa Rican National Statistics Institute, June 2019.

⁴Administratively independent from the government.

⁵Translation from the Spanish “*Caja Costarricense de Seguro Social*”.

⁶Translated from the Spanish “*Lista Oficial de Medicamentos*”.

1.2.2 Costa Rican litigation setting

The judicial system had no relationship with the health care system until 1989 when the Constitutional Chamber of the Supreme Court was created. This Chamber serves as the country's highest judicial authority regarding interpretation of the Constitution. It was designed to be accessible by everyone and serve as a tool for accountability. To achieve this, its rulings are strictly enforced with six month follow-up periods, legal formalism is not required to file a case, there is no monetary cost to use the Chamber, and it is open year-round (Programa Estado de la Nacion 2017).

The Costa Rican Constitution endorses the human right to life, and which since 1991 the judicial system interprets this as the right to health (Programa Estado de la Nacion 2017). The right to health is derived from the United Nation's declaration of human rights and is interpreted by the Costa Rican government as having to guarantee a minimum standard of health to its population (Rodriguez Loaiza et al. 2018). In order to achieve this Costa Rica uses its public insurer (as described in Section 1.2.1).

Litigation requesting drug access is a constitutional right due to its legal rationale being the right to health, and is therefore handled exclusively by the Constitutional Chamber (henceforth referred to as the Court)⁷. A typical case involves an individual who considers that their right to health is violated by the public insurer not providing a drug for their diagnosis. The individual or someone representing them (who does not have to be a lawyer) files a claim to the Court. The claim identifies the individual whose right was potentially violated, and what drug they believe the insurer should provide to correct the violation. Evidence to support the claim is allowed but not required.

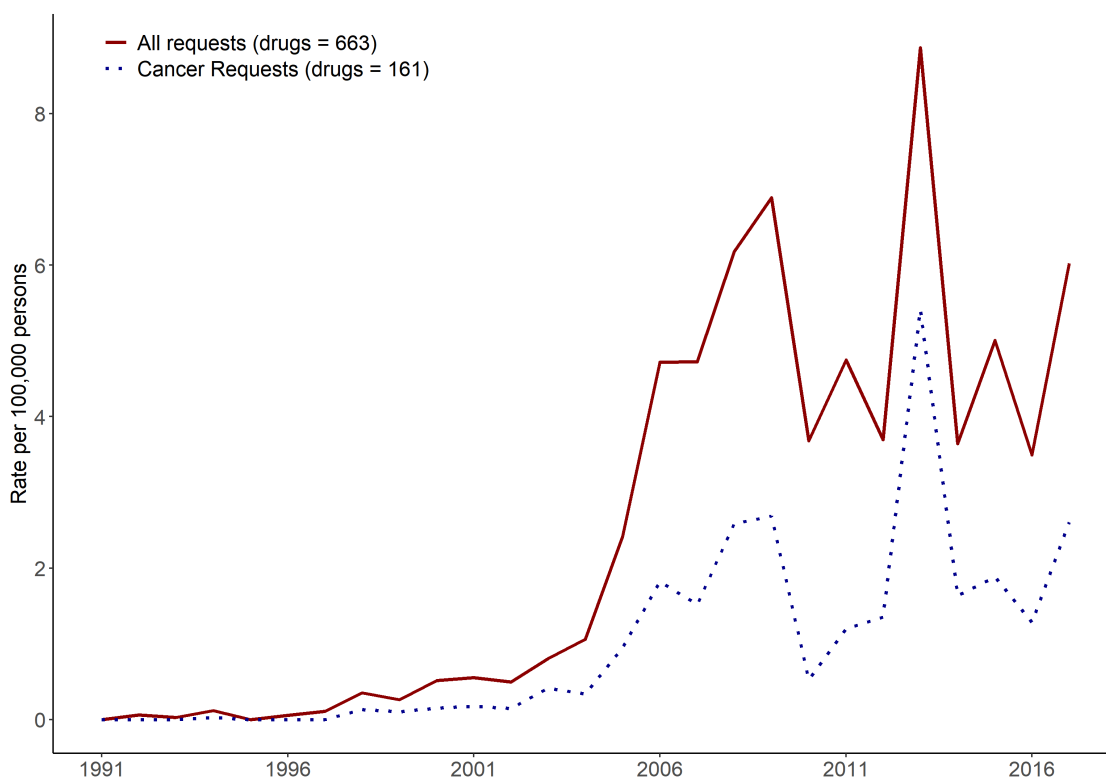
The Court's magistrates (judges) initiate the litigation process by informing the insurer and allowing them a brief period of time to submit evidence in their defense. The magistrates then deliberate and make their decision to approve or reject the drug request. If approved, the Court determines how long the insurer has to comply. Finally, the decision is notified to both involved parties.

Drug requests have increased dramatically since 2004. There were 175 requests from 1991 to

⁷Known as the "Fourth Chamber" from the Spanish "Sala Cuarta".

2004, and nearly 3,000 in a similar period after that (2005-2017). In Figure 1.1 the rate of drug requests per 100,000 persons depicts this increase. About 40 percent of drug requests have a cancer diagnosis associated and have experienced a similar increasing trend (dotted line). What has drawn public controversy is the perceived excessive spending of public funds on one person (Norheim and Wilson 2014). An example of this is a 2001 case where in one hour the Court approved a request for a drug costing a quarter million dollars annually for a teenager (Rodriguez Loaiza et al. 2018).

Figure 1.1: Drug requests to the Costa Rican Constitutional Court per 100,000 persons



Source: data on requests from the Costa Rican Judicial Information System and population data from the Costa Rican Institute of Statistics. *Notes:* rates estimated for 100,000 persons. Number of different drugs for all requests, 663; for cancer requests, 161. Cancer requests correspond on average to 38.9 percent of requests. Rapid increase after 2004 related to a series of cases highly publicized by the media.

Even though such dramatic cases are rare, there is no empirical evidence evaluating these cases. A 2014 paper in *Health and Human Rights Journal* concluded that litigation for drug access in Costa Rica doesn't generate fairness from 37 randomly selected approved cases. Fairness was defined as high priority, and priority was based on effectiveness, severity of diagnosis, and cost-effectiveness for an average patient with their diagnosis at average severity (Norheim and Wilson 2014). A

follow-up by the same authors in 2018 repeated the process with 98 cases from 2016 and found a slight gain in fairness (Norheim and Wilson 2019). The results are suggestive, but not based on comprehensive or systematic analysis.

1.2.3 Existing evidence

This section provides a brief overview of relevant existing evidence. First regarding rationing and economic evaluations in healthcare, then about the intersection of law and economics. Rationing originates from government imposed rules based on a social planner's perspective (Araújo et al. 2011; L. Levaggi and R. Levaggi 2017; Salvucci 2014; Zweifel 2015). In the case of a public insurer, policymakers and health care professionals use rules based on economic evaluations (Baji et al. 2016; Bommier and Stecklov 2002; Fleck 2011) and have a preference for equality in the allocation of health (Bleichrodt et al. 2005).

Studies looking into how the general population thinks governments should make rationing decisions for health care conclude that benefit distribution should be at the forefront (Anderson et al. 2011; Green and Gerard 2009). This means that both perspectives are in agreement that health care benefits should be a primary decision factor. Therefore it is not surprising that cost-effectiveness and cost-utility analyses have become commonplace and have some role in practically all health care systems (Bryan et al. 2007; Cylus et al. 2016; Eichler et al. 2004). Cost-effectiveness includes non-health benefits, distributional consequences and equity making it ideal for social planning (Aaron 2008; Verguet et al. 2016).

However, defining rationing rules from cost-effectiveness analysis is complex, and most research suggests that rules should have some flexibility in response to population heterogeneity (Bridges et al. 2010; Linley and Hughes 2013; Ottersen et al. 2016), however there is no consensus about the extent and mechanism of flexibility. One consequence of no flexibility are safety valve mechanisms like litigation (Boumil and Curfman 2013; Flood and Gross 2014; Mota 2013; Mpinga and Hasselgård-Rowe 2014).

Literature specifically about litigation lacks empirical evidence (Chapman 2016; Davis 2015). In agreement with the trade-off that economic literature describes, the public policy literature has plenty of case studies that theorize that from an individual perspective litigation improves well-being by serving as a tool for government accountability and allowing for self-selection that

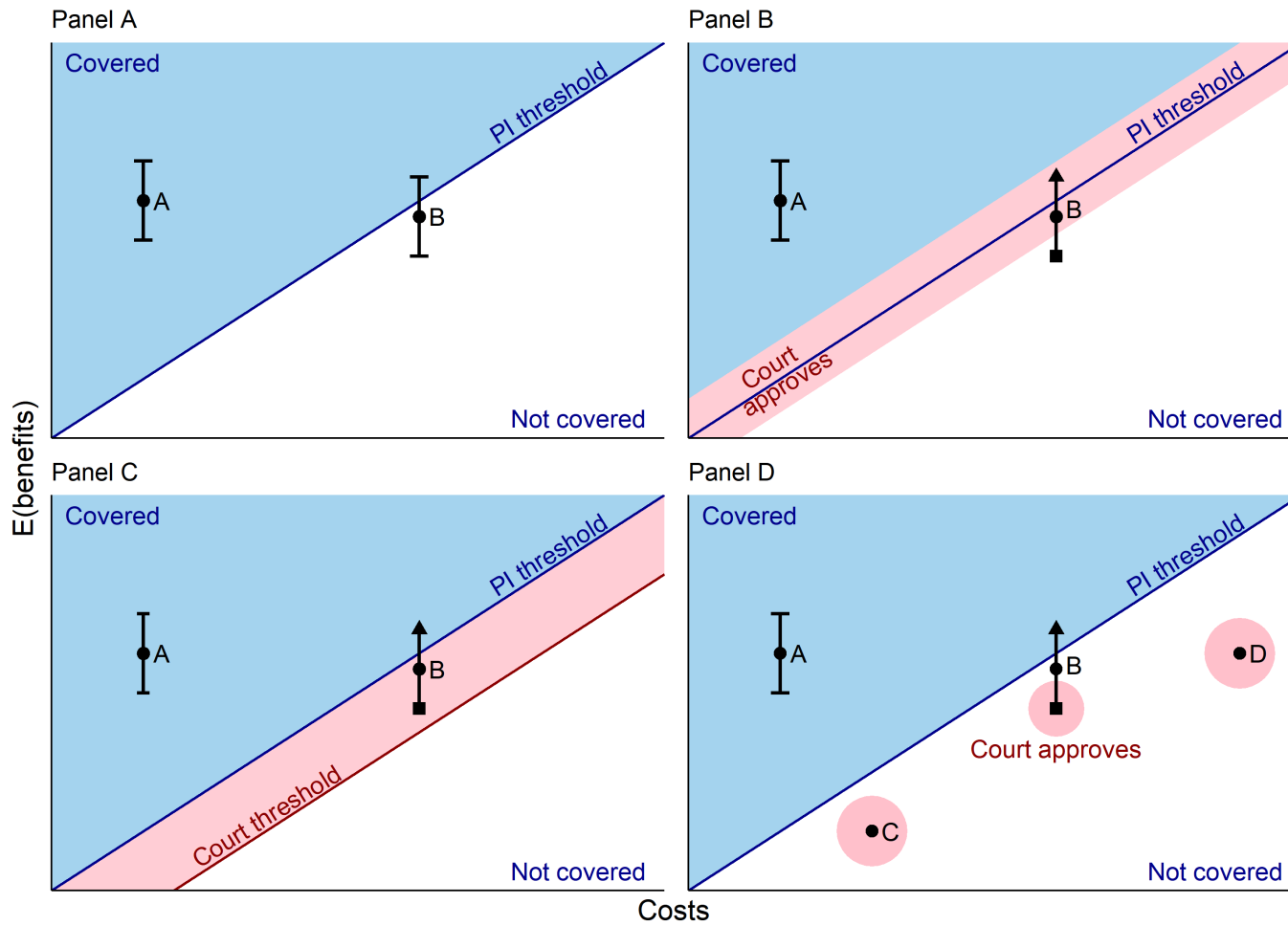
accounts for individual heterogeneity in benefits (Biehl, Amon, et al. 2012; Biehl, Socal, et al. 2016; Da Silva and Terrazas 2011; Mota 2013; Rosenbaum 2000). From the perspective of the social planner litigation worsens well-being by reallocating resources from the optimal social plan (Brinks and Gauri 2014; Gianella-Malca et al. 2013; Hogerzeil, Liberman, et al. 2013; Hogerzeil, Samson, et al. 2006; Mahajan 2012; Vargas-Peláez et al. 2014). Echoing these concerns, legal philosophy discusses the topic in terms of whether social planning or individual concerns should be motivation for legal decisions (Roa and Klugman 2014; Yamin and Lander 2015).

This type of litigation has increased in recent years, in particular in health care systems based on public insurance such as Brazil, Argentina, South Africa, Indonesia and others (Abramovich et al. 2008; Avila Machado et al. 2011; Brinks and Gauri 2014; Da Silva and Terrazas 2011; Gable and Meier 2013). A major reason for the increase is requesting access to drugs due to the expensive prices that result from pharmaceutical innovation (Biehl, Amon, et al. 2012; Nunes 2010). Returning to the motivation behind rules for access to drugs, one hypothesis is that the market for drugs can be made more efficient by considering the value of a drug (cost-benefit evaluation) not just its benefits (Dillender 2018; Kleinke 2004).

The intersection of law and economics is complex, but provides a solid starting point for exploring the effects of litigation requesting drugs. From a methods standpoint, judge identity can be used as an instrumental variable, and its use estimating causal effects has been clearly documented (Aizer and Doyle 2015; Bourreau-Dubois et al. 2014; Nakosteen and Zimmer 2014; Okudaira 2018). If the goal is to study the determinants of legal decisions however, then logistic and probit regressions have been used to explain the likelihood of outcomes (Berger and Neugart 2012; Blanes I Vidal and Leaver 2011; Melfi and Bethel 1989).

These methods do not necessarily provide insight into the use of economics in legal practice. In other words, while economic theory can serve as a framework for legal issues, it is rarely used in implementing solutions. Clarke and Kozinski 2019 summarize these concerns as there being little evidence of legal decisions being based on economics concepts (such as “efficiency”) and the underlying cause of this being institutional constraints.

Figure 1.2: Conceptual model for litigation's role in drug access



8

Notes: E(benefits), expected benefits; PI, public insurer. Covered drugs (dark shading), cost-effectiveness is sufficient so the PI provides them at no cost; Not covered (no shading), cost-effectiveness is insufficient so the PI doesn't provide the drug; Court approves (light shading), possible cost-effectiveness values for which the Court approves requests. Panel A, access to drugs regulated by the PI's rationing rule using cost-effectiveness to set a threshold. Panel B, access to drugs possible via litigation and the Court focuses on drug benefit heterogeneity around the PI threshold. Panel C, the Court decides using a cost-effectiveness threshold of their own. Panel D, the Court decides based on individual cases.

1.3 Conceptual model

The process of implementing rationing rules to determine drug coverage by a public insurer (PI) is institution-specific, but at its core there is a measure of expected benefits and costs. In Figure 1.2, the y-axis shows expected benefits and the x-axis the costs of covering a drug for the PI. The PI sets a cost-effectiveness threshold (PI threshold) to decide which drugs are covered (shaded area above the threshold) and which are not (non-shaded area below the threshold).

In Panel A, the health care system only has PI rationing rules to determine drug access. Drug A is covered –provided at no cost to an individual- whereas drug B is not. The costs of the drug do not vary across individuals but the expected benefits do (distribution of benefits indicated by the bars). With individual heterogeneity, some individuals expect to receive more benefits than the average user, and some less.

For patients whose actual expected benefits from B place them above average (upper bound of error measurement –triangle), they pass the PI’s rule for covering drugs, but since the decision for B was made based on average measurements, they are denied coverage. If litigation to gain access to drugs works by allowing these individuals to obtain the drugs, then it could be expected to ameliorate inefficiencies due to individual heterogeneity.

This scenario can be seen in Panel B, where the court deciding on litigation requests approves cases for which benefits and costs place the drug in the area just above and below the PI’s threshold (light shading). The cases litigating for drug B with benefits at the upper-bound (triangle) are approved and the PI must cover the drug for that person (who will have no added out-of-pocket expense), while the cases with benefits at the lower-bound (square) are not approved so the PI doesn’t have to cover the drug.

However, there is no evidence that this is how courts decide on access to drugs. An alternative is the court having a lower threshold than the PI (Panel C). Another one is the court not having a cost-effectiveness, benefits or cost threshold, just considering individual cases and deciding to approve them or not (Panel D). Here drug requests for B at its lower bound (square), C and D were approved, but a case involving B at its average would be rejected. In both of these alternatives (Panels C and D) lower-benefit cases for drug B are approved by the court, and these decisions do not match the PI’s rules.

1.4 Data

1.4.1 Court ruling selection and initial data extraction process

In order to address the questions posed above, I construct a novel data set using Court decisions on cases requesting drugs, drug coverage status by the PI, drug costs and individual level expected benefits. Court rulings (decisions) are recorded in the Costa Rican Judicial Information System for the whole country. The rulings are stored as documents in Spanish consisting of three parts: the request filed by the injured party, a summary of the defense's evidence, and the court's decision. On average these documents were 8.9 pages long.

A search was conducted for all cases filed at the Court with the keyword *drug*⁸ yielding 5,659 cases from 1991 to 2017. After reviewing each of these cases, 3,124 were found to be regarding a drug request. I read each of these cases carefully and hand-collected specific data points.

First, I identify the requested drug, and determine whether it is a generic or not. Next, I determine the diagnosis and medical specialty associated to the case. Then, I focused on Court process variables, which are characteristics of the legal process. These include the date of filing and of the decision, from which Court deliberation time was calculated as the number of days from filing to decision, defense strength (number of evidence documents submitted by the PI), appeal status (whether the case is an appeal of a previous Court decision or not), and the decision (approval or not of the drug request).

1.4.2 Covered drug lists

The next step was determining drug coverage status for the 663 different drugs and integrating this information into the data collected from the rulings. The PI has drug-diagnosis lists created based on cost-effectiveness analysis that serve as rationing rules for the entire health care system via the PI administering services. The lists were published in official documents biannually from 1992 to 2014. After this they were published on a quarterly basis (the last one included in this paper was published on February 2019).

Each of the 663 drugs were searched for among the lists to determine on which date they gained coverage or if they never had it up to February 2019. These dates were then compared to the date

⁸The word used was "*medicamento*" which in Spanish is used for *drug* and *medication*.

when the case was filed to determine if at the time of the request the drug was covered or not by the PI.

It could be expected that once a drug gains coverage it is no longer brought up in litigation, however this is not what I observed. The reasons for requesting a covered drug are if the use (diagnosis or dosing) is different from the combination stated in the aforementioned list; or if a specific brand is requested.

A different use is for instance a drug listed as covered for breast cancer but not for colon cancer. Therefore a patient with colon cancer would have to litigate to obtain the drug. As for the second reason, the PI provides a generic drug when available and typically has one brand for each drug. If an individual prefers a different brand they would have to litigate to obtain it.

1.4.3 Benefits construction

From the 3,124 requests, 39.6 percent of them (1,236 cases) have a cancer diagnosis (medical specialty is oncology). The clinical standard for diagnosis and treatment of cancer is defined in unambiguous terms by internationally accepted guidelines. Due to this standard, cancer cases allow a determination to be made on benefits and costs at a individual level.

The first step in determining the benefits was going through each of the 1,236 cases and collecting data on the individual filing the case (age, gender) and all information related to their diagnosis. Additionally, I determined what drug was currently prescribed to the individual (before litigation).

Also from the Court documents, I determined whether the requested drug was replacing the prescribed drug, if it is symptomatic treatment (the requested drug manages symptoms not treats the cancer), and if the requested drug is the same molecule as the prescribed one⁹.

Using individual variables and diagnosis information, each individual's cancer stage was determined according to the Tumor-Node-Metastasis System of the International Union Against Cancer¹⁰. Stage is a discrete numerical value with increasing severity from 1 to 4. Stage 1 and 2 are generally considered an early diagnosis, and 3 or more advanced.

Having the stage for each case, I proceeded to use the National Comprehensive Cancer Network's (NCCN) clinical practice guidelines¹⁰ to evaluate the prescribed and requested drugs. These

⁹Bio-equivalent drugs are drugs that have been tested and proven to produce the same effect *in vivo*.

¹⁰The standard method accepted by the worldwide medical community.

guidelines provide recommendations specific to individual-diagnosis-stage combinations and explain the peer-reviewed medical literature on which they are based.

For each case, I found what the guidelines recommend about the requested and prescribed drugs for each case. The recommendation includes dosing and duration of a single or combination of drugs. From the evidence that informed the recommendation I determine clinical endpoints¹¹ to measure expected benefits from using the requested and prescribed drugs.

I use months of progression-free survival as clinical endpoint. It is defined as the time it takes for the disease to progress after begging treatment. This measure is widely used in cancer research, and is supported by the United States Food and Drug Administration¹² (Food and Drug Administration 2018, December).

1.4.4 Drug costs

Costs for requested and prescribed drugs¹³ were determined using public tenders in the Costa Rican National Comptroller Office. The documents have details on the price and number of doses bought by the PI in the year when the case was decided. The prices were adjusted to 2017 United Stated dollars and included in the database. The expected treatment cost was estimated based on the dosing and length of treatment recommended by the NCCN guidelines.

1.4.5 Descriptive statistics

For all the requests I show descriptive statistics in Table 1.1. As I have mentioned before, there are 3,124 requests, 663 different drugs, 290 of those drugs were requested only once, 307 different diagnoses and 26 different medical specialties.

The mean Court approval is 0.55. Requests that are appeals made up 6 percent of cases. The mean deliberation time is 35 days, and by three and six months, 94.8 and 98.4 percent of cases were resolved. A quarter of the requests were for drugs that were already covered (25 percent), and 37 percent of requests involve drugs that never gain coverage until February 2019. Over half of the requests (53 percent) were for generic drugs (no brand was specified).

¹¹Outcome that represents direct clinical benefit(Food and Drug Administration 2018, December)

¹²United States Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

¹³Requested drugs, n = 161; prescribed drugs, n = 61.

Table 1.1: Descriptive statistics for drug requests

No. of requests	3,124			
No. of drugs	663			
No. of drugs requested once	290			
No. of diagnoses	307			
No. of medical specialties	26			
<i>Court decision process</i>	<i>Mean</i>	<i>SD</i>	<i>Min</i>	<i>Max</i>
Approval	0.55	0.50	0	1
Appeals	0.06	0.23	0	1
Deliberation time (days)	35	36	0	350
<i>Requested drug</i>				
Covered ¹	0.25	0.44	0	1
Never becomes covered	0.37	0.48	0	1
Generic	0.53	0.50	0	1

¹ Drug covered by the Public Insurer’s benefits package at the time the request was filed.

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017.

Among the ten most frequently requested drugs, 7 are for treating cancer and their approval probabilities range from 0.48 to 0.90. As for the diagnoses, they were all chronic diseases or cancers with approval probabilities of 0.30 to 0.82 (see Appendix Table A1.1).

Descriptive statistics for cancer requests are in Table 1.2. There are 1,236 requests, 161 distinct drugs, 65 of which were only requested once, and 50 different diagnoses.

The mean Court approval for cancer requests is 0.70. The percentage of appeals and average deliberation time are the same as for all the requests. The mean age of the individuals litigating was 53 years old and 65 percent were female. On average the individuals had a cancer stage 3.22 (median stage 3) which makes their diagnoses advanced.

In contrast to the full data set, only 18 percent of cancer requests were drugs that were already covered. A higher percentage were drugs that never gain coverage (42 percent). Requests for generic drugs were a much higher 60 percent. Requests for the same molecule were 17 percent; and for symptomatic treatment only 6 percent. Last, 44 percent of requests were to replace their currently prescribed drugs.

Regarding costs, the average for a recommended treatment (duration and dosing) of requested drugs is 20,566 dollars, and for prescribed drugs is 5,390. Incremental costs were calculated as requested minus prescribed drugs, and the average was 17,777 dollars with a minimum of -24,927

Table 1.2: Descriptive statistics for cancer drug requests

No. of requests	1,236			
No. of drugs	161			
No. of drugs requested once	65			
No. of diagnoses	50			
<i>Court decision process</i>	<i>Mean</i>	<i>SD</i>	<i>Min</i>	<i>Max</i>
Approval	0.70	0.46	0	1
Appeals	0.06	0.24	0	1
Deliberation time (days)	35	33	0	329
<i>Individual</i>				
Age	52.87	15.57	2	98
Gender (male=1)	0.35	33.47	0	1
Cancer stage (1 to 4)	3.22	0.24	1	4
<i>Requested drug</i>				
Covered ¹	0.18	0.39	0	1
Never becomes covered	0.42	0.49	0	1
Generic	0.60	0.49	0	1
Same molecule ²	0.17	0.38	0	1
Symptomatic ³	0.06	0.24	0	1
Replace current ⁴	0.44	0.50	0	1
<i>Costs (USD) and benefits (progression-free survival in months)⁵</i>				
Cost of requested drug	20,566	19,731	3	94,785
Cost of prescribed drug	5,390	11,400	0	70,567
Incremental costs ⁶	17,777	18,986	-24,927	94,835
Benefits of requested drug	16	13	0	126
Benefits of prescribed drug	11	8	0	60
Incremental benefits ⁶	5	11	-50	90
Ratio (months per \$1,000) ⁷	5	25	-17	626

¹ Drug covered by the Public Insurer's benefits package at the time the request was filed.

² The requested drug and currently prescribed drug are bio-equivalent.

³ Requested drug treats symptoms not the cancer itself.

⁴ Requested treatment replaces prescribed treatment.

⁵ Costs are adjusted for inflation to 2017 USD.

⁶ Incremental refers to the difference between requested and prescribed drugs.

⁷ Ratio of incremental benefits to incremental costs.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017.

and maximum 94,835. There are 66 cases (5.3 percent) with zero or negative incremental costs, so the requested drug was cheaper than what they were already receiving.

The average progression-free survival or benefits¹⁴ from requested drugs is 16 months, and from prescribed drugs 11 months. The average incremental benefits is 5 months, the minimum -50 and maximum 90. Similar to incremental costs, incremental benefits were calculated by subtracting

¹⁴For ease of interpretation I will from this point on refer to progression-free survival as benefits measured in months.

benefits from using requested and prescribed drugs. For 58 cases (4.7 percent) benefits were not determined. As for benefits, in 68 cases they are negative and in 203 cases they are zero. Negative incremental benefits means that the requested drug provided less expected months free of progression than their current drug. Zero incremental benefits correspond to when same molecule drugs were requested, so there was no difference in the months each drug provided.

The ratio of months per 1,000 dollars was calculated by dividing incremental benefits by incremental costs. The average ratio was 5 months per 1,000 dollars, the minimum was -17 and maximum 626.

1.5 Methods

The first step to understanding litigation for access to drugs was to conduct descriptive analysis to understand how the phenomenon is manifesting. From this I was able to determine several stylized facts that provide a picture of the data.

The two models used to explore the data were predicting Court approval probability using a binary probit model, and an event study where drugs gaining coverage is the event and I predict Court requests.

1.5.1 Model for Court approval probability

To examine the factors that determine Court approval I use as the dependent variable the Court's decision to approve or not each request for a drug. It is assigned a value of 1 if the request was approved for case i and 0 if rejected. This binary variable suggests a probit model that can be summarized as:

$$decision_i = \beta_0 + \sum_{j=1}^k \beta_j X_{ij} + \epsilon_i, \quad i = 1, \dots, 1236$$

where $decision$ is the binary dependent variable, the X 's are the independent variables hypothesized to affect approval probability for a drug request, ϵ_i is a normally distributed error term, and the β 's are coefficients estimated by maximum likelihood. The specific form of the equation estimated is:

$$decision_i = \beta_0 + \beta_1 pred_i + \beta_2 X_i + \tau_t + \delta_g + \epsilon_{id}, \quad i = 1, \dots, 1236 \quad (1)$$

where the subscript i represents the case number, τ are year fixed effects, δ are diagnosis fixed effects, and ϵ_{id} are robust standard errors clustered at the drug level.

The main explanatory variables are represented by $pred_i$ and there are two different cases. In one specification I use incremental benefits and costs, and in the other I use the benefits to costs ratio. All three variables were standardized so that the resulting coefficients could be interpreted as a change of 1 standard deviation (SD).

For every specification I include the following control variables in X_i : individual (age, gender, stage), drug (generic, same molecule, symptomatic, substitute), coverage status and court process (deliberation time, defense, appeal) control variables are included.

Marginal effects were estimated for each of the specifications in order to predict effects on Court approval probabilities. Additional specifications were run using as main explanatory variables requested drug benefits and costs, and sub-setting requests to only cases with early stage diagnoses.

1.5.2 Model for drugs gaining coverage and litigation

In order to examine how Court request's trends change relative to a drug gaining coverage I use an event study model. The hypothesis is that drug requests increase until the PI grants coverage, and afterwards requests decrease if litigation is responding to drugs gaining coverage.

The event is defined as the month when a drug gains coverage, and I aggregate all 63 drugs that I observe gaining coverage. As control drugs I use requests for those that never gain coverage. This allows me to analyze the coefficients on various indicator variables for time relative to the event. The non-parametric event study specification is

$$y_{dt} = coverage_d + \left[\sum_{-143}^{-2} \beta_y I(t - t_d^* = y) + \sum_0^{145} \beta_y I(t - t_d^* = y) \right] + \epsilon_{dt} \quad (2)$$

where d is drug; t is month; y_{dt} is the outcome of drug-month requests; and I is an indicator measuring time relative to the implementation period t_d^* . The variable $coverage_d$ is 1 if drug d is covered in time t and 0 if it is not covered. Last, ϵ_{dt} are drug-month standard errors.

The omitted category (β_{-1}) is the month prior to a drug gaining coverage. The key coefficients of interest are the pattern on the β_y which estimate the outcome at a given t relative to the omitted category β_{-1} . The advantage of this model is that it allows assessing visually the pattern of requests

relative to the date of drugs gaining coverage (Dobkin et al. 2018; Freyaldenhoven et al. 2019).

1.6 Results

1.6.1 Stylized facts on litigation

The first fact from the data that I want to highlight is the fact that no one medical specialty, diagnosis or drug guarantees Court approval or rejection. From the 26 different medical specialties involved, excluding oral surgery¹⁵, all have more than 5 cases and none have an approval probability of 0 or 1.

Preventive care has the highest approval probability at 0.71; and the lowest is Nephrology at 0.20. The probabilities vary across the different specialties without any automatically guaranteeing a Court outcome.

Out of 307 diagnoses, 84 have more than 5 cases and among these only one diagnosis, epidural fibrosis is associated with a 0 probability and none have a 1 probability (see Appendix, Figure 1.3). Out of 663 drugs, 130 have more than 5 cases and among these, diazepam and lorazepam are associated with 0 probability. Both are highly addictive benzodiazepines used in the treatment of severe psychiatric diagnoses¹⁶.

Asparaginase, crizotinib, natalizumab, and vemurafenib have a approval probability of 1. The first is a enzymatic supplement used in the treatment of leukemia and lymphoma, the next two are monoclonal antibodies used in the treatment of autoimmune diseases and the last is used to treat skin cancer. In Figure 1.3 all drugs with more than 9 cases are shown, with each bar representing a drug and their approval probabilities on the y-axis; this shows visually that none of the 77 drugs had a probability of 0 or 1.

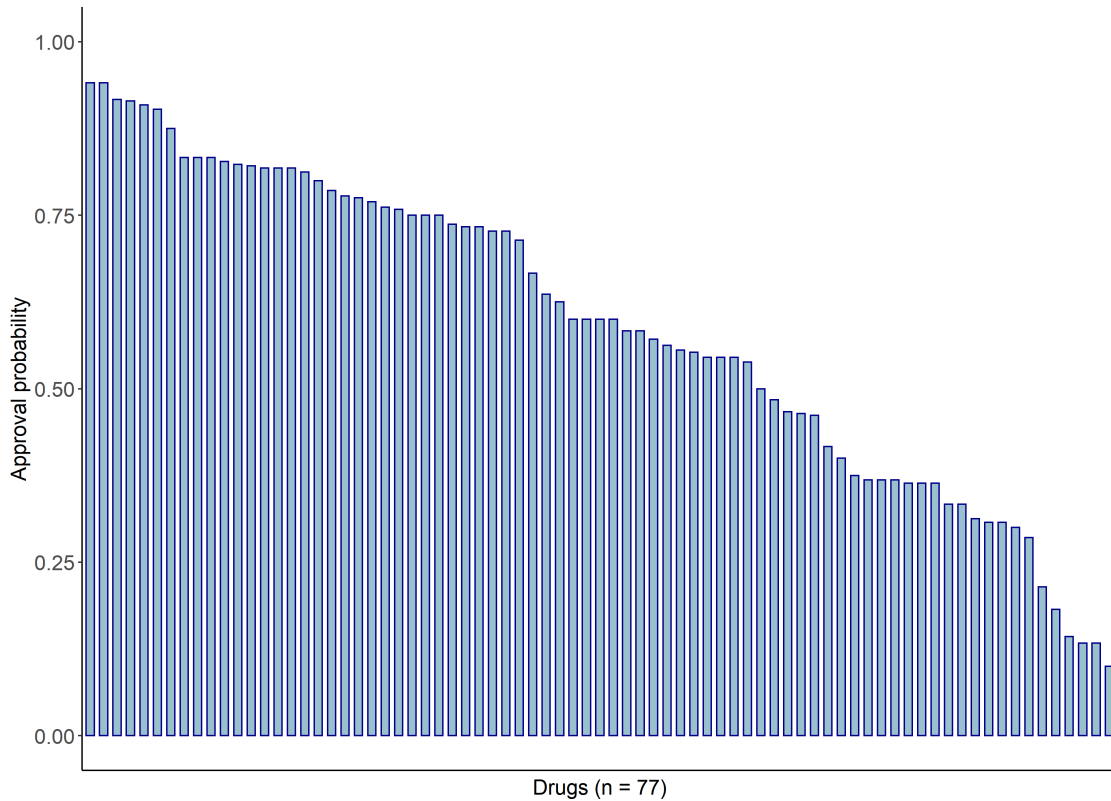
These observations suggest that there are other considerations for the Court beyond specialty, diagnosis and drug. The next fact is about the possibility of legal precedent. Legal precedent refers to a Court's decision influencing a subsequent decision for the same drug. For every drug with more than 5 cases, I analyzed the approval probability over time since the first request happened.

In Figure 1.4 approval probabilities for drugs (sample set of 9 drugs) are plotted as a solid line with the y-axis being approval probability and the x-axis years since first request. Each panel

¹⁵There was only 1 case involving oral surgery.

¹⁶The other use is anesthesia but that is not an option for patient use.

Figure 1.3: Approval probabilities by drug for 1,741 cases



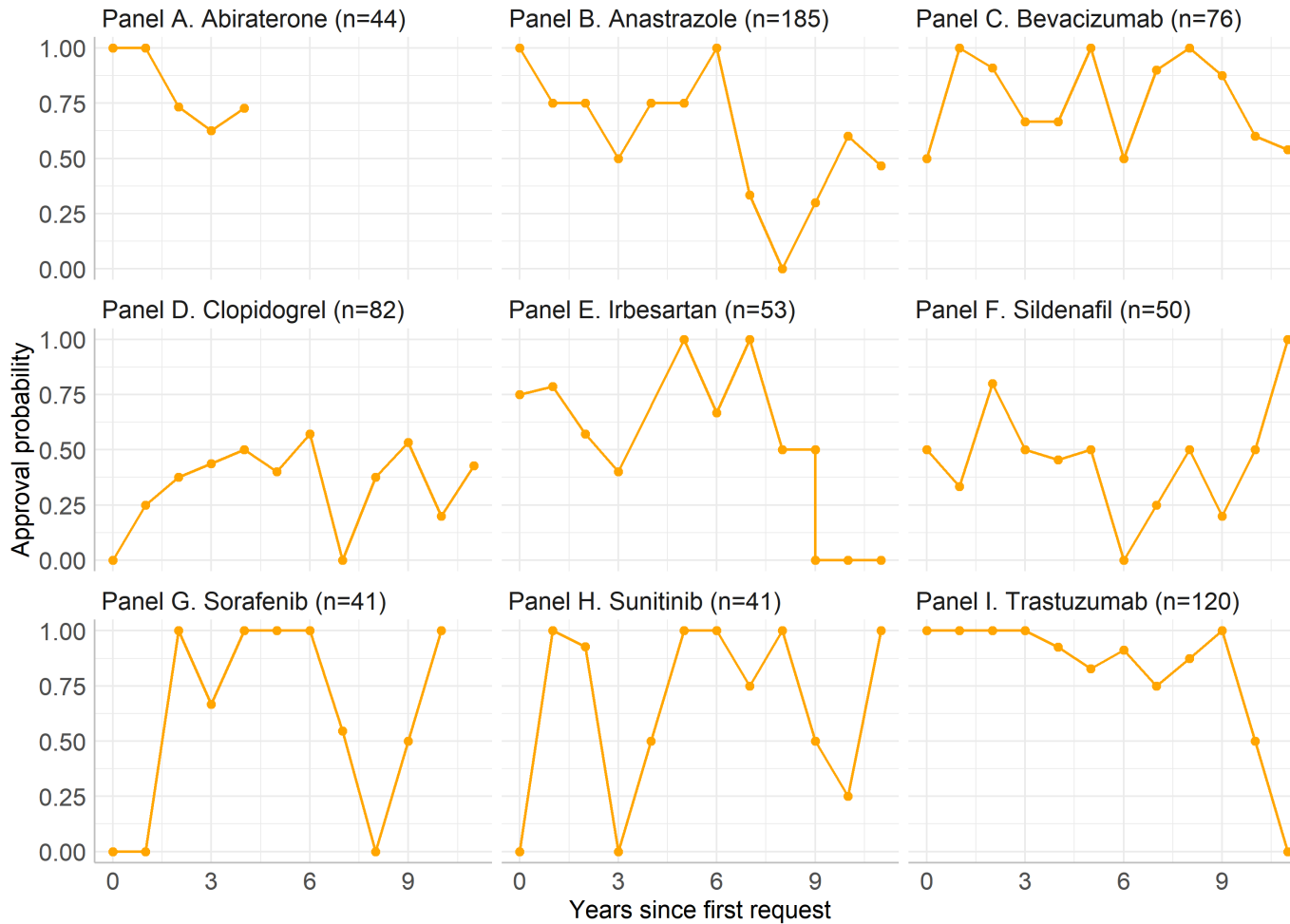
Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* Sample limited to drugs with more than 9 requests (77 different drugs with 1,741 cases among them). Every bar represents all cases for a drug, and no drugs have a probability of 0 or 1.

presents a different drug and if legal precedent were a consideration for the Court, we would expect a flattening of the line, but this is not observed. When grouping drugs by those for cancer treatment and those not for cancer treatment likewise there is no flattening of the plotted lines (see Appendix, Figure A1.2).

To further examine legal precedent, each drug was set up as a time series and aggregated using the first year a drug is requested as 0. Using an autocorrelation function I estimate coefficients of correlation between the observed time series and itself with a lag.

The results for a lag of 1 year can be seen in Figure 1.5. The coefficients are on the y-axis and years after the first request are on the x-axis. At lag 0, the correlation is as expected by definition 1 (the data is correlated with itself perfectly), and in all subsequent years the results are within the bounds of the 95 percent confidence interval (shown as dotted horizontal lines). The results held when lags of 5 and 10 years were introduced.

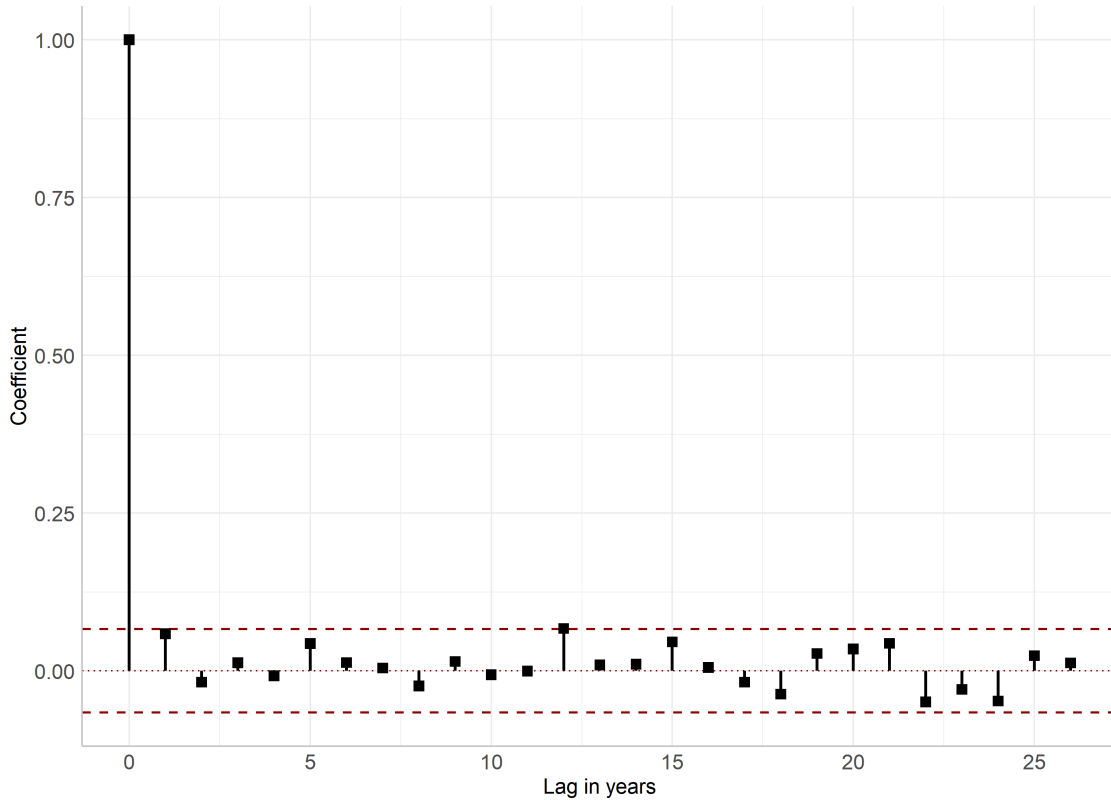
Figure 1.4: Approval probability of selected requested drugs over time



Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. Notes: All cases for a drug are defined as a time series and plotted independently. The 9 selected drugs are among those with the highest number of cases and are meant as examples. If Court decisions on one year affect subsequent decisions the trend over time would be horizontal.

The fact from this portion of data analysis was that legal precedent doesn't appear to play a role in Court decisions. In addition to the previous fact this suggests that the Court takes into consideration individual case characteristics when making decisions.

Figure 1.5: Autocorrelation coefficients for drug approval probability time series with a one-year lag (drugs = 269)



Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* 95% confidence interval shown by horizontal dashed lines. Year 0 shows a correlation of 1 by design (data correlates with itself). All drugs with more than 5 requests ($n=269$) were organized as time series and aggregated based on the year of the first request being defined as 0.

1.6.2 Court decision determinants

If Court decisions are based on the requested drug's incremental benefits for the individual, then I would expect a positive correlation to approval probability. Regarding incremental costs since they would impact the PI and not the individual, there should be no correlation with probability. If the Court's decisions are more in line with the PI's perspective, then I would expect a negative correlation between costs and approval.

However, from the perspective of the PI, it is a drug's benefit-cost ratio that should be the

determinant factor for a drug being made accessible. As such, I would expect a positive correlation between the ratio and Court approval probability that exceeds that of incremental costs.

The correlation coefficient for requested drug benefits and approval probability is 0.08, and for incremental benefits 0.18. For requested drug costs it is 0.27 and for incremental costs 0.29. A series of scatterplots showing this relationship with approval probability in the y-axis and the corresponding measure of benefits and costs in the x-axis is presented in Figure A1.3. In Panel A and B requested drug's benefits and costs are shown, and in C and D the incremental benefits and costs. The solid lines show generalized linear models approximating the relationship between the variables.

For benefits the correlation is too small to be considered a linear relationship, and visually in Panel A we can see the model suggests a very slight negative relationship. Even though incremental benefits have a correlation it is too low to be considered clear, but it is just barely more than double that of benefits. In Panel C, the model shows a clearer positive relationship.

These findings suggest that it is the difference between the benefits from the requested and prescribed drugs that matter not just the benefits from the requested drug. Having incremental benefits be more relevant to decisions would be justified based on medical criteria for deciding between interventions.

When examining costs, the coefficient shows a weak positive correlation, and in Panel B the model shows the same relationship. As for incremental costs the correlation is not significantly different from costs, and Panel D shows a positive relationship.

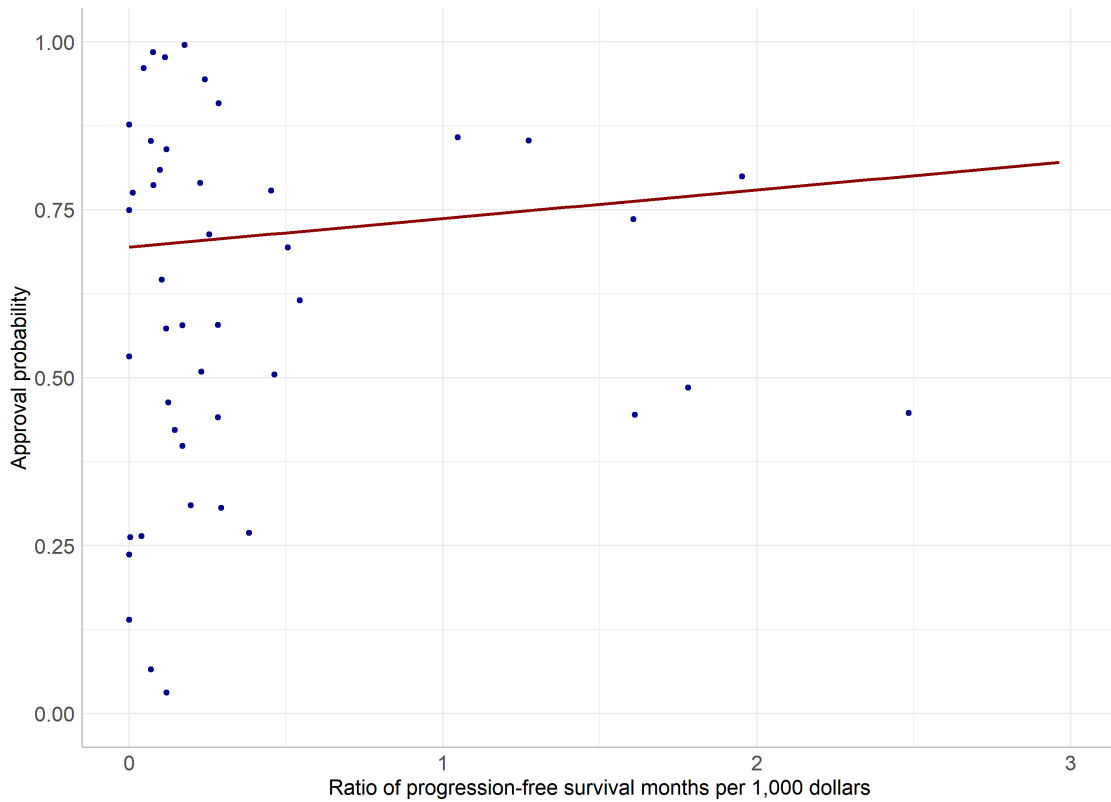
Since both costs and incremental costs have not significantly different results it could be inferred that the cost of requested drugs is behind the correlation (prescribed drug costs are not playing a role in the findings).

It is unexpected that costs have a stronger correlation to approval probability than benefits. One possible explanation for this has to do with the nature of a cancer diagnosis, where complete cures or remission are not the norm in particular for advanced stage diagnoses (as we see in this data where the mean stage is 3.2 out of 4). This relationship will be further explored in the following sections.

The correlation coefficient between the benefit-cost ratio and Court approval probability is 0.03, which like benefits suggests that there is no relationship. In Figure 1.6 a scatterplot for drugs with

more than 6 cases is presented with the y-axis as approval probability and x-axis has the ratio of progression-free survival months per 1,000 dollars. Like in the previous figures, the solid line shows the result from estimating a generalized linear model, and shows a positive relationship.

Figure 1.6: Approval probability and benefit-cost ratios for requested drugs (n = 85)



Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* scatter points each represent average measures over all cases of specific drug. Sample limited to drugs with more than 5 cases. A generalized linear model is shown as a solid line.

The scatterplot shows most drugs concentrated below 1 month gained per 1,000 dollars, and a sparse few cases with more than 1 month. This suggests that even though the model shows a positive relationship, the correlation coefficient as 0 seems to match the scatter of the data.

To formalize the analysis of determinants of Court decisions in the next section I show the results from the binary probit model predicting approval probability for Court cases. Based on the findings from this section I would expect incremental benefits to show small positive effects, incremental costs to show larger effects, and their ratio to show no effect. Controlling with individual, requested drug and court process characteristics I examine if these results support the findings.

1.6.3 Predicting Court approval probability

The two main predictors of interest for Court decisions are incremental benefits and costs, and their ratio. They are run separately for two main reasons, first variation in incremental benefits and costs would be captured by their ratio, and second theoretically they represent different perspectives for making approval decisions. Approval based on benefits supports an individual perspective, one based on the ratio supports the PI's perspective. Every estimation of the model includes year fixed effects and a set of controls as described in the section 1.4.

These results can be seen in Tables 1.3 and 1.4. Column 1 shows results using only the main predictors (incremental measures or their ratio), column 2 adds individual variables, column 3 adds requested drug variables and diagnosis fixed effects, column 4 adds court process variables and column 5 adds diagnosis fixed effects.

Every specification was evaluated using loglikelihood tests, pseudo R^2 and Akaike information criterion, with all showing similar results but the first three specifications (columns 1 to 3) having slightly better explanatory power. Even though results are consistent throughout all specifications, Court process variables could suffer from endogeneity concerns due to unobserved Court process characteristics (I only observe a few of the Court's characteristics).

Therefore, column 3 is the preferred specification. Marginal effects for specifications from columns 1 to 3 are shown in Tables 1.3 and 1.4, and I will focus on the results from column 3 due to the reasons previously explained.

A 1 SD increase in incremental benefits (11 months of progression-free survival) increases approval probability by a not significant 1.9 percentage points (just above 0). The same increase in incremental costs (18,986 dollars) increases approval probability significantly by 3.5 percentage points (Table 1.3). As for a 1 SD increase in the benefit-cost ratio (28.7 months per 1,000 dollars) leads to no significant change in approval probability (Table 1.4).

An increase of 11 months free of disease progression having such a small effect is unexpected if benefits are supposed to explain Court's decisions. The effects of costs almost double those of benefits. From an individual perspective costs shouldn't have an effect on Court decisions. The results suggest that benefits matter but so do costs. This means that the explanation that individual benefits drive Court decisions is insufficient.

Table 1.3: Marginal effects on Court approval probability using incremental benefits and costs

	(1)	(2)	(3)
Incremental benefits ¹	0.027* (0.015)	0.025* (0.014)	0.019 (0.013)
Incremental costs ²	0.039*** (0.012)	0.044*** (0.012)	0.035*** (0.013)
Age		-0.008** (0.004)	-0.004 (0.004)
Gender (male=1)		0.029 (0.029)	-0.028 (0.030)
Stage		0.057*** (0.017)	0.024 (0.018)
Generic			0.138*** (0.032)
Same molecule ³			-0.223** (0.052)
Symptomatic treatment ⁴			-0.475*** (0.100)
Substitute treatment ⁵			-0.092 (0.034)
Covered			-0.040 (0.045)
Never covered			0.065* (0.036)
Year fixed effects	X	X	X
Diagnoses fixed effects			X

¹ Standardized incremental benefits in months of progression-free survival.

² Standardized incremental costs (2017 USD).

³ Prescribed and requested drugs are bio-equivalent.

⁴ Requested drug treats symptoms not the cancer itself.

⁵ Requested drug substitutes the prescribed one.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). A 1 standard deviation (SD) increase in incremental benefits equals a 11 month increase. A 1 SD increase in incremental costs equals a \$18,986 increase in costs. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

The ratio being not significant and zero suggests that the explanation from the PI’s perspective is also not sufficient. A possible explanation for costs being as important as they appear in the results is that more expensive drugs have greater benefits, but these benefits are small in magnitude due to the nature of the diagnoses.

An additional mechanism could be that costs serve as a signal to the Court about a drug’s benefits. The caveat to this is that cost data is not part of Court documents. Also most of these drugs were not covered at time of request (82 percent), so the PI’s costs are unknown because they will only initiate a public tender to buy the drug after it is mandated by the Court. Therefore the

Table 1.4: Marginal effects on Court approval probability using benefit-cost ratios

	(1)	(2)	(3)
Benefit-cost ratio ¹	-0.015 (0.021)	-0.019 (0.021)	-0.029 (0.022)
Age		-0.009** (0.004)	-0.005 (0.004)
Gender (male=1)		0.034 (0.029)	-0.026 (0.030)
Stage		0.048*** (0.017)	0.018 (0.017)
Generic			0.139*** (0.032)
Same molecule ²			-0.098* (0.053)
Symptomatic treatment ³			-0.289*** (0.099)
Substitute treatment ⁴			-0.060* (0.031)
Covered			0.060 (0.045)
Never Covered			0.067* (0.037)
Year fixed effects	X	X	X
Diagnoses fixed effects			X

¹ Standardized cost-benefit ratio in months of progression-free survival per \$1,000.

² Prescribed and requested drugs are bio-equivalent.

³ Requested drug treats symptoms not the cancer itself.

⁴ Requested drug substitutes the prescribed one.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). A 1 standard deviation increase in cost-benefit ratio equals an increase of 28.7 months of progression-free survival per \$1,000. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

real costs wouldn't be available for the Court as they decide.

Associated with this, an additional specification using requested drug's benefits and costs instead of incremental benefits and costs was run and the marginal effects are presented in column 1, Table 1.5¹⁷. A 1 SD increase in requested benefits (12.8 months) is associated with a 1.7 percentage points increase in approval probability significant at a 10 percent level. The same increase in requested costs (19,731 dollars) has a 5.1 percentage points increase in probability significant at a 1 percent.

Regarding individual variables, age has a small not significant negative effect on approval with the lower bound confidence interval including 0. Gender had a likewise small not significant negative

¹⁷Probit coefficient results can be found in column 1, Table A1.4.

Table 1.5: Marginal effects on Court approval probability from additional specifications: using requested drug measures and only early stage cases

	(1)	(2)
Requested benefits ¹	0.017* (0.014)	
Requested costs ²	0.051*** (0.015)	
Incremental benefits ³		0.004 (0.017)
Incremental costs ⁴		0.059 (0.048)
Age	-0.010** (0.004)	-0.011 (0.011)
Gender (male=1)	0.017 (0.029)	0.215** (0.094)
Stage	0.047*** (0.018)	-0.094 (0.083)
Year fixed effects	X	X
Stage <3		X

¹ Standardized requested drug's progression-free survival months.

² Standardized requested drug's costs in 2017 adjusted \$1,000.

³ Standardized incremental benefits in months of progression-free survival.

⁴ Standardized incremental costs (2017 USD).

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). A 1 standard deviation (SD) increase in incremental benefits equals a 12.8 month increase. A 1 SD increase in incremental costs equals a \$19,731 increase in costs. A 1 SD increase in incremental benefits equals a 11 month increase. A 1 SD increase in incremental costs equals a \$18,986 increase in costs. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$. For column (2) the sample was subset to cases with an early diagnosis (stage <3).

effect. These results are in line with stage capturing any effects from age and gender.

Cancer diagnosis stage had a small positive not significant effect on approval probability. It is surprising that the effects of stage are not significant, though the magnitude and sign are in line with more advanced disease increasing the likelihood that the Court approves a case.

Advanced stage diagnosis could suggest a higher degree of cases where the requests are a “*last resort*” and benefits will be smaller. To test this I ran the same specification on a subset of only cases with a stage equal or less than 2. This corresponds only to cases with an early stage diagnosis and the marginal effects of this are shown in column 2, Table 1.5¹⁸.

A 1 SD increase in incremental benefits has no effect on approval probability; and the same

¹⁸Probit coefficient results in column 2, Table A1.4.

increase in incremental costs has a small positive effect, though much smaller and no longer significant when compared to the full sample. Incremental benefits becoming 0 is surprising, as reducing diagnosis severity would have been expected to increase benefits. It is interesting that the effect of incremental costs decreased substantially which could be related to these drugs not being as cutting-edge or rare.

Requested drug variables show that requesting a generic drug has a large positive significant effect on approval probability. Requesting the same molecule¹⁹ and symptomatic treatment had a large negative significant effect on the probability. The requested drug replacing prescribed drugs has a large not significant effect.

By definition requesting the same molecule and symptomatic treatment provide no incremental benefits for a cancer diagnosis, and as such their effects being negative, significant and large fits with the results that benefits matter for Court decisions.

Requesting a covered drug had a negative not significant effect on approval probability; and requesting a never covered drug had a positive barely significant effect. As mentioned before, a drug already covered by the PI is requested via litigation when the use is not covered or when a specific brand is being requested.

Given the hypothesized direct link between coverage and litigation, it is surprising that the effect is not significant. The direction of the effect, negative, suggests that alternate uses and specific brands do not help make the case for access to a drug from the Court's perspective.

As for a drug never gaining coverage (up until February 2019), it is interesting that the effect is positive. This could suggest that a drug being covered gives a specific context for the drug and the Court does consider this, but a never covered drug has no background decision about how to use it. However, further evidence is needed to be able to fully understand this relationship.

1.6.4 Court requests and PI coverage

The relationship between the amount of litigation for a drug and said drug gaining coverage is unknown. If it does exist, it would be plausible to expect a dose response behavior, where drug requests are increasing up to coverage being gained. In other words, before coverage, there is an increasing trend in the amount of litigation observed with the underlying mechanism being that

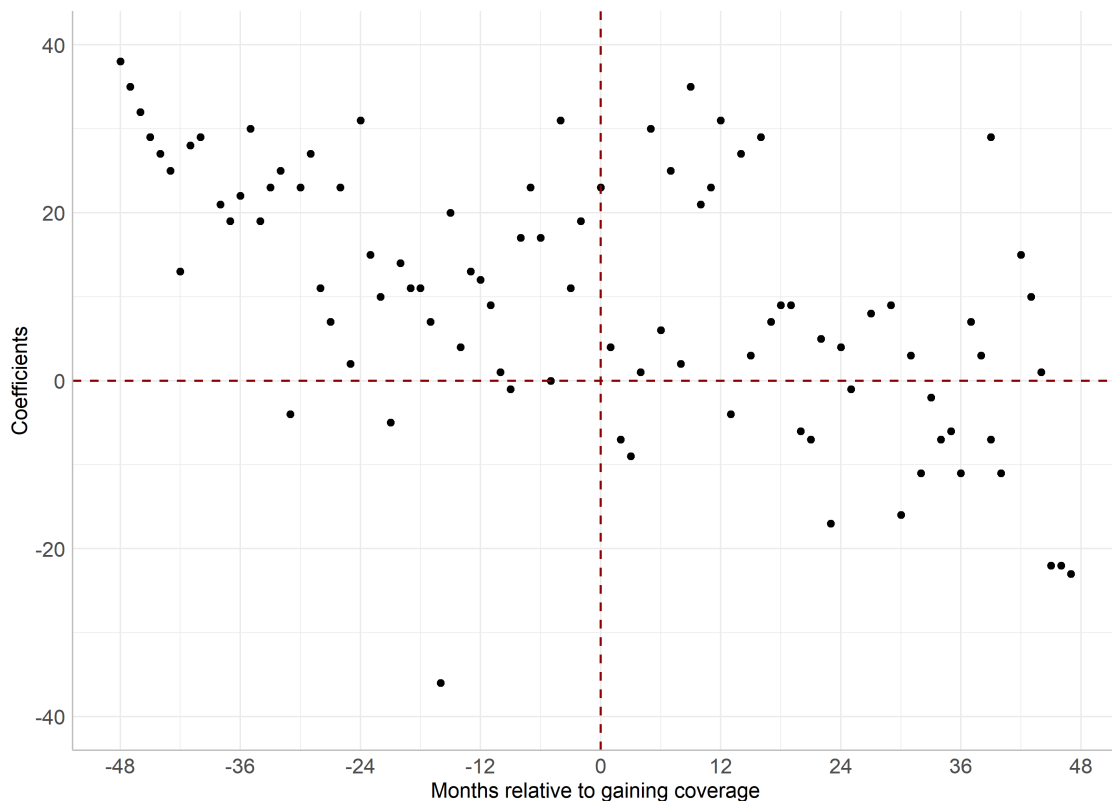
¹⁹Requested and prescribed drugs for each case are bio-equivalent.

requests trigger the PI to review evidence for the drug and change its coverage status.

After coverage is gained, it would be expected that requests decrease due to the drug now being available without requiring litigation. Unless, the drug is now being requested for alternate uses (not the one for which coverage was granted), leading to an increase in requests post coverage. Additionally, increased drug salience due to coverage could compound the effect of requests for alternate uses.

The results of the event study examining Court requests relative to the when drugs gain coverage are presented in Figure 1.7. The y-axis shows the coefficients aggregated across all drugs that gain coverage, and in the x-axis their corresponding month relative to gaining coverage up to 4 years before and after. The dashed vertical line shows the month when coverage was gained, and the immediately prior month is omitted.

Figure 1.7: Event study for drug requests controlling for never covered drugs



Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* event defined as the month when coverage is gained (dashed vertical line) with the immediately previous month omitted (-1); a coefficient of 0 would mean that covered and not covered drug requests are equal (dashed horizontal line). The hypothesized pattern was an increasing pre-trend due to increased requests leading to the Public Insurer deciding to grant a drug coverage; a decreasing post-trend due to the gained coverage meaning that requests are no longer required to obtain the drug. No clear pre-trend nor post-trend was observed.

A visual inspection of the coefficients shows no clear pattern on either side of the event. This suggests that even though drug coverage is the PI’s most direct way to impact drug requests, the evidence does not suggest a relationship.

1.6.5 Approximation of court cost-effectiveness

A standard for economic evaluations of health care is using incremental cost-effectiveness ratios (ICERs) to determine whether an intervention should be covered by a PI. Using back-of-the-envelope calculations with data from the Court’s decisions I find that for approved cases the ratio was 3,603 dollars per month; and for rejected cases 3,414 dollars per month (Table 1.6). Approved cases have as expected a higher ICER than rejected cases.

Table 1.6: Court’s incremental cost-effectiveness ratios

Parameter	Estimate
<i>Approved cases</i>	
Sum of incremental benefits ¹	4,718
Sum of incremental costs ²	17,000,210
Ratio of Δ costs/ Δ benefits	3,603
<i>Rejected cases</i>	
Sum of incremental benefits ¹	1,456
Sum of incremental costs ²	4,971,637
Ratio of Δ costs/ Δ benefits	3,414

¹ Benefits are months of progression-free survival.

² Costs adjusted to 2017 USD.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* back-of-the envelope calculations for incremental cost-effectiveness ratios. Incremental refers to the difference between requested and prescribed measures. The ratio is the incremental expenses to gain 1 month of progression-free survival.

The World Health Organization (WHO) recommends that health care systems cover interventions with an ICER under 2,433 dollars²⁰ (Marseille et al. 2015). The Court’s ICERs unambiguously do not pass the WHO’s rule and would not be recommended for coverage by the WHO.

For the United Kingdom, the National Institute for Health and Care Excellence continues to use a standard threshold of 25,666 to 38,499 dollars²¹ (Paulden 2017), which corresponds to 2,139 to 3,208 monthly. Again, both the approved and rejected cases exceed the threshold and would not

²⁰The recommendation is less than 3 times the country’s gross domestic product, which for Cost Rica in 2017 corresponds to 29,196 annually and 2,433 monthly.

²¹Converted from 20,000 to 30,000 sterling pounds.

be covered by the health care system.

In the United States, over 3 quarters of cost-utility analyses use values between 50,000 and 100,000 dollars per quality adjusted life year as threshold (Cameron et al. 2018). This corresponds to 4,167 and 8,333 monthly. Using these thresholds, the Court's cases pass and should be covered.

Considering the WHO rule is aimed at nascent public health care systems it is not surprising that Costa Rica is making decisions above this standard. Likewise it is unsurprising that the threshold of a privately driven system like the US suggests that all of the Court's cases should be approved. In contrast it is unexpected that a wealthy developed country with a well-established health care system has thresholds below what the Court is deciding on.

1.7 Conclusion

Resource scarcity is common to all health care systems as is rationing. Inevitably this causes a trade-off between individual and collective preferences, where the collective could be a private insurer or all tax-payers. Regardless, individuals will seek an out from rationing. Considering increasing medical costs and greater wealth inequality it is not surprising that a mechanism such as litigation is increasing (Cubillos et al. 2012).

Litigation as a means of accessing drugs is directly linked to an economic framework since it is challenging the rationing decisions made by public insurers where the standard is deciding based on economic evaluations (Neumann et al. 2015). Using a novel hand-collected dataset for the universe of Costa Rican litigation requesting drugs, I find that individual case characteristics matter when judges rule on whether a drug request is approved or not.

From the cases with a cancer diagnosis where I constructed an individual-level measure of benefits was constructed based on best clinical practice guidelines²² and used to predict Court decisions based on benefits or benefit-cost ratios.

Findings show that higher benefit drugs have higher approval probabilities; higher costs also result in an increase in approval probability; and benefit-cost ratios have no effect. This suggests that benefits alone are not sufficient to explain Court decisions and benefit-cost ratios don't explain them. These results support economics and law literature that find that even if legal decisions are

²²Peer-reviewed expert consensus guidelines that are accepted by the medical community as the standard for diagnosis and treatment of cancer.

framed from an economic perspective rarely do judges use those concepts to decide (Clarke and Kozinski 2019).

Currently in Costa Rica, the PI's only policy associated to –even though it was not created nor expected to address– litigation for drug access is updating drug coverage lists. In practically every case when a not covered drug was requested (82 percent of cases), the Public Insurer's defense stated that the drug was evaluated, found lacking in value and therefore not covered. However, predicting drug request trends relative to when a drug gains coverage showed no evidence that there was a relationship. This finding suggests that either the PI allows the Court to continue to serve as safety valve or it needs to reform its policies to find an alternate outlet because their current setup does not appear to be doing anything to affect litigation for drug access.

Access to health care is easily recognized as one of the most complex public policy issues around the world, and rationing a ubiquitous concern. Even when discussed outside of the discipline of economics, the concepts used are from an economics framework (Liscow 2014). Even so, the results do not show that economics is the main determinant for litigation decisions, which are essentially focused on access to health care. Even if individually a person's preferences would not agree with rationing, their preference regarding government rationing is that it is done using economic evaluations (Cameron et al. 2018). In this specific scenario, Court decisions not being based on economics fails to improve social well-being.

The analysis throughout this paper has been primarily descriptive, and additional assumptions would be needed to make inferences about an optimal rationing mechanism. The descriptive facts in this paper are an important first step in understanding litigation as a safety valve for health care rationing and are useful for setting up future economic models that can more precisely quantify its impact on individuals and society.

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Appendix

Table A1.1: Approval probability for the most frequently observed drugs, diagnoses and medical specialties

	(1) Frequency	(2) Approval probability	(3) SD
<i>Requested drug</i>			
Anastrozole	185	0.48	0.50
Trastuzumab	120	0.89	0.31
Clopidogrel	82	0.35	0.48
Bevacizumab	76	0.74	0.44
Irbesartan	53	0.53	0.50
Sildenafil	50	0.44	0.50
Mercaptopurine	48	0.90	0.31
Abiraterone	44	0.77	0.42
Sorafenib	41	0.71	0.46
Sunitinib	41	0.78	0.42
<i>Diagnosis</i>			
Breast cancer	481	0.66	0.47
Epilepsy	131	0.50	0.50
Prostate cancer	115	0.67	0.47
Leukemia	108	0.82	0.38
Diabetes mellitus type 2	85	0.35	0.48
Hypertension	81	0.47	0.50
Colon cancer	74	0.72	0.45
Depression	60	0.30	0.46
Ischemic cardiopathy	60	0.38	0.49
Kidney cancer	57	0.75	0.43
<i>Medical Specialty</i>			
Oncology	1,236	0.70	0.46
Neurology	326	0.50	0.50
Cardiology	291	0.51	0.50
Psychiatry	232	0.32	0.47
Gastroenterology	210	0.60	0.49
Endocrinology	120	0.46	0.50
Rheumatology	114	0.51	0.50
Pulmonology	72	0.58	0.50
Urology	67	0.34	0.48
Infectology	52	0.44	0.50

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* the 10 most frequently requested drugs, diagnosis and medical specialties are shown. Approval probability was calculated using all the requests for each of the presented categories. None of the categories show a 0 or 1 approval probability.

Table A1.2: Probit regressions predicting Court approval probability using incremental benefits and costs

	(1)	(2)	(3)	(4)	(5)
Incremental benefits ¹	0.084 (0.052)	0.078* (0.046)	0.002 (0.042)	0.021 (0.042)	0.001 (0.044)
Incremental costs ²	0.120*** (0.040)	0.136*** (0.041)	0.114*** (0.043)	0.116*** (0.044)	0.099* (0.053)
Age		-0.026* (0.014)	-0.014 (0.014)	-0.016 (0.015)	-0.036** (0.017)
Age ²		0.000 (0.000)	0.000 (0.000)	0.000 (0.000)	0.000** (0.000)
Gender (male=1)		0.089 (0.092)	-0.093 (0.099)	-0.113 (0.101)	0.081 (0.153)
Stage		0.177*** (0.051)	0.078 (0.058)	0.076 (0.060)	0.133* (0.070)
Generic			0.452*** (0.109)	0.434*** (0.111)	0.363*** (0.128)
Same molecule ³			-0.399** (0.180)	-0.505*** (0.183)	-0.596** (0.234)
Symptomatic treatment ⁴			-0.817*** (0.266)	-0.913*** (0.263)	-1.061*** (0.311)
Substitute treatment ⁵			-0.086 (0.115)	-0.095 (0.117)	-0.097 (0.145)
Covered			0.160 (0.156)	0.151 (0.159)	0.231 (0.182)
Never covered			0.214* (0.125)	0.210 (0.128)	0.139 (0.154)
Deliberation time (days)				-0.003* (0.001)	-0.003* (0.002)
Defense intensity ⁶				0.040*** (0.014)	0.042*** (0.014)
Appeal				-0.889*** (0.165)	-0.924*** (0.171)
(Intercept)	4.264*** (0.445)	4.470*** (0.593)	5.178*** (0.562)	5.162*** (0.581)	-0.308 (0.918)
Year fixed effects	X	X	X	X	X
Diagnoses fixed effects			X		X
Loglikelihood test	0.000***	0.000***	0.000***	0.000***	0.000***
Pseudo R ²	0.100	0.114	0.156	0.189	0.244
AIC	1407	1394	1342	1299	1299

¹ Standardized incremental benefits in months of progression-free survival.

² Standardized incremental costs (2017 USD).

³ Prescribed and requested drugs are bio-equivalent.

⁴ Requested drug treats symptoms not the cancer diagnosis.

⁵ Requested drug substitutes the prescribed one.

⁶ Number of pieces of evidence submitted by the defense.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017.
Notes: all columns report coefficients from probit regression estimates of equation (1). A 1 standard deviation (SD) increase in incremental benefits equals a 11 month increase. A 1 SD increase in incremental costs equals a \$18,986 increase in costs. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

Table A1.3: Probit regressions predicting Court approval probability using benefit-cost ratios

	(1)	(2)	(3)	(4)	(5)
Benefit-cost ratio ¹	-0.044 (0.070)	-0.059 (0.060)	-0.094 (0.058)	-0.070 (0.057)	-0.061 (0.064)
Age		-0.028** (0.014)	-0.015 (0.014)	-0.016 (0.015)	-0.034** (0.017)
Age ²		0.000* (0.000)	0.000 (0.000)	0.000 (0.000)	0.000** (0.000)
Gender (male=1)		0.104 (0.092)	-0.083 (0.099)	-0.104 (0.101)	0.074 (0.153)
Stage		0.148*** (0.051)	0.060 (0.058)	0.055 (0.060)	0.121* (0.070)
Generic			0.454*** (0.109)	0.435*** (0.111)	0.348*** (0.126)
Same molecule ²			-0.322* (0.181)	-0.447** (0.184)	-0.511** (0.233)
Symptomatic treatment ³			-0.843*** (0.267)	-0.942*** (0.262)	-1.094*** (0.310)
Substitute treatment ⁴			-0.197* (0.107)	-0.210* (0.109)	-0.197 (0.134)
Covered			0.195 (0.155)	0.180 (0.158)	0.283 (0.179)
Never covered			0.220* (0.128)	0.210 (0.132)	0.174 (0.155)
Deliberation time (days)				-0.002 (0.001)	-0.003* (0.002)
Defense intensity ⁵				0.039*** (0.014)	0.041*** (0.014)
Appeal				-0.888*** (0.164)	-0.930*** (0.170)
(Intercept)	5.975*** (1.533)	6.574*** (1.438)	7.212*** (1.386)	6.810*** (1.377)	0.911 (1.402)
Year fixed effects	X	X	X	X	X
Diagnoses fixed effects			X		X
Loglikelihood test	0.000***	0.000***	0.000***	0.000***	0.000***
Pseudo R2	0.091	0.104	0.153	0.185	0.242
AIC	1418	1407	1345	1303	1300

¹ Standardized cost-benefit ratio in months of progression-free survival per \$1,000.

² Prescribed and requested drugs are bio-equivalent.

³ Requested drug treats symptoms not the cancer itself.

⁴ Requested drug substitutes the prescribed one.

⁵ Number of pieces of evidence submitted by the defense.

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). A 1 standard deviation increase in cost-benefit ratio equals an increase of 28.7 months of progression-free survival per \$1,000. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

Table A1.4: Additional probit regressions predicting Court approval probability: using requested drug measures and only early stage cases

	(1)	(2)
Requested benefits ¹	0.053 (0.044)	
Requested costs ²	0.158*** (0.049)	
Incremental benefits ³		0.014 (0.055)
Incremental costs ⁴		0.200 (0.170)
Age	-0.032** (0.014)	-0.038 (0.033)
Age ²	0.000** (0.000)	0.000 (0.000)
Gender (male=1)	0.053 (0.093)	0.724** (0.344)
Stage	0.146*** (0.054)	-0.318 (0.294)
(Intercept)	5.326*** (0.691)	1.586 (1.722)
Year fixed effects	X	X
Stage < 3		X
Loglikelihood test	0.000***	0.000***
Pseudo R2	0.112	0.250
AIC	1397	287

¹ Standardized requested drug's progression-free survival months.

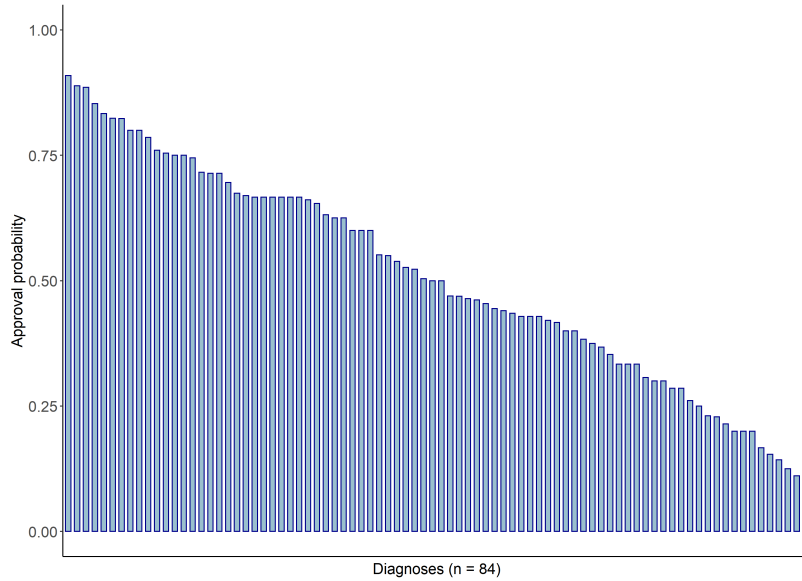
² Standardized requested drug's costs (2017 USD).

³ Standardized incremental benefits in months of progression-free survival.

⁴ Standardized incremental costs (2017 USD).

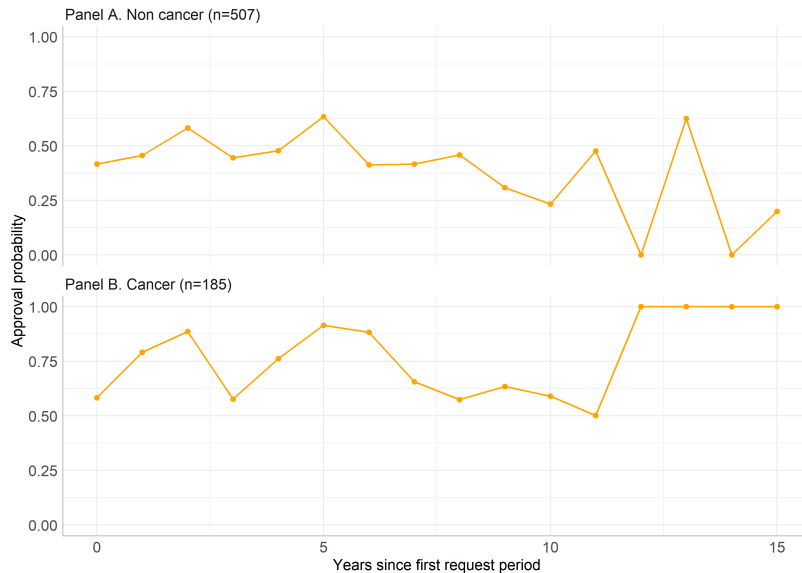
Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). A 1 standard deviation (SD) increase in incremental benefits equals a 12.8 month increase. A 1 SD increase in incremental costs equals a \$19,731 increase in costs. A 1 SD increase in incremental benefits equals a 11 month increase. A 1 SD increase in incremental costs equals a \$18,986 increase in costs. Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$. For column (2) the sample was subset to cases with an early diagnosis (stage <3).

Figure A1.1: Approval probability by diagnosis for 2,722 cases



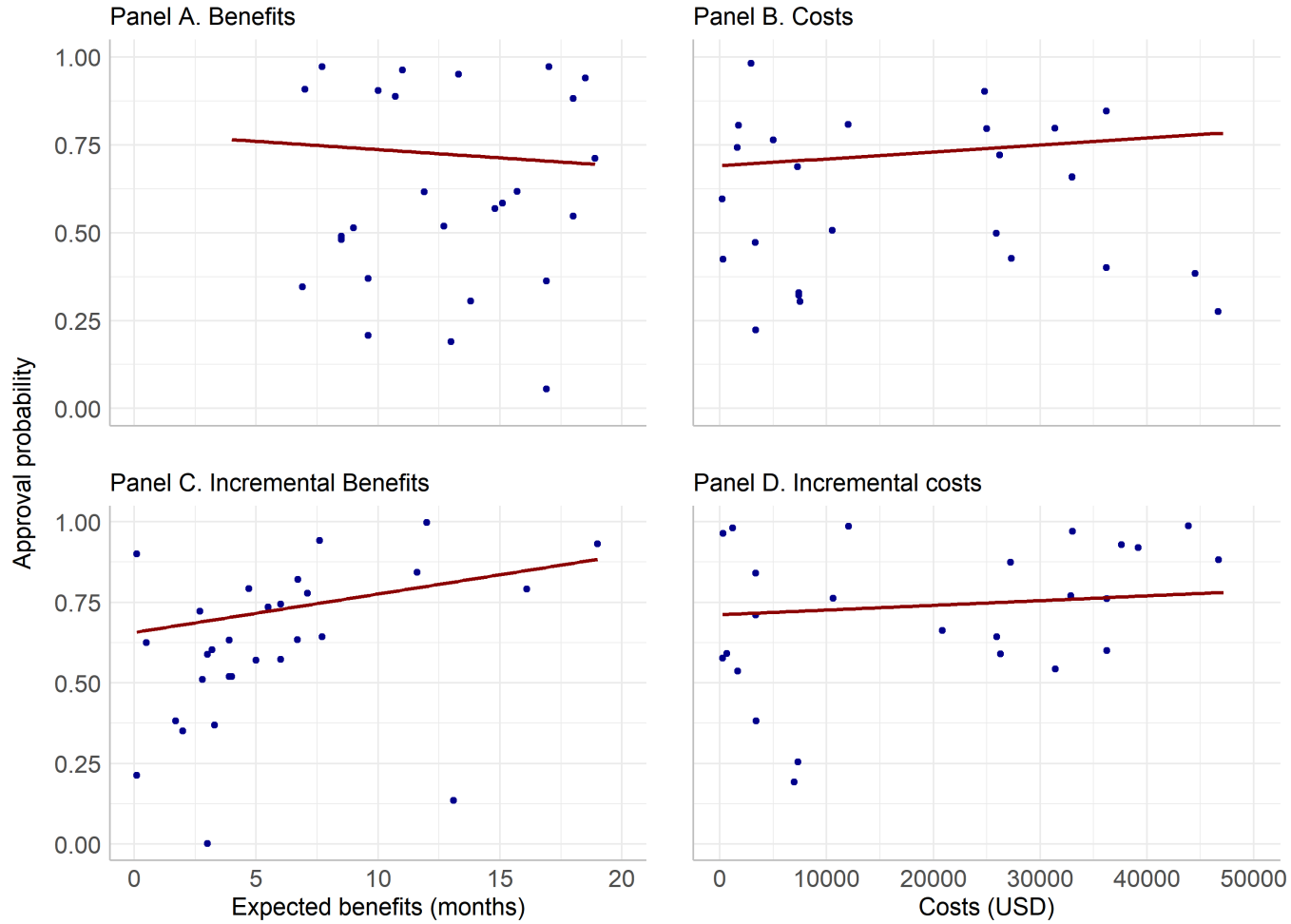
Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* Sample limited to diagnoses with more than 6 requests (84 different diagnoses with 2,722 cases among them). Every bar represents all cases for a diagnoses, and no diagnosis has a probability of 1. Only one diagnosis has a probability of 0, epidural fibrosis. Epidural fibrosis is a degenerative idiopathic (unknown causes) disease.

Figure A1.2: Approval probability of requested drugs classified into cancer or not cancer drugs over time



Source: primary hand-collected data for all requests in Costa Rica from 1991 to 2017. *Notes:* All cases for a drug are defined as a time series and aggregated according to if they are or not cancer treatment drugs. Each category was plotted independently. If Court decisions on one year affect subsequent decisions the trend over time would be horizontal.

Figure A1.3: Approval probability and different variable measurements: requested drug's benefits and costs, incremental benefits and incremental costs



Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* scatter points each represent average measures over all cases for each drug with more than 6 cases ($n = 85$). Sample limited to drugs with more than 5 cases. A generalized linear model is shown as a solid line. Benefits measured as progression-free survival months (time from taking the drug before disease progressed); costs adjusted to 2017 dollars; incremental benefits and costs calculated by subtracting the measure for requested minus prescribed drugs.

CHAPTER 2

ANALYZING PREVALENCE AND MORTALITY IN LITIGATION REQUESTING ACCESS TO DRUGS

2.1 Introduction

Rationing is inevitable in health care systems, and regardless of the system type, this creates trade-offs between individual and collective preferences (Bryan et al. 2007; Hauck et al. 2019; Verguet et al. 2016). When possible, litigation is becoming increasingly the mechanism of choice to get around rationing (Flood and Gross 2014). The basic premise being that an individual sues a health care provider to obtain a rationed good or service (Vargas-Peláez et al. 2014).

We know that public insurers, as a standard, decide rationing based on economic evaluations (Neumann et al. 2015). However, how litigation as a safety valve to escape rationing makes its decisions is not fully understood.

In previous work I studied possible factors determining how litigation decisions are taken which served as a first step in understanding how this mechanism works as part of public resource distribution (Monge 2020). In this paper I look at the types of diseases involved in litigation requesting access to drugs for cancer treatment. There are many ways to characterize a disease, but few are so widely understood and used as prevalence and mortality.

They are relevant for health care providers, their patients, and the patients' families in understanding the diagnosis and choosing treatment avenues. They are factors in biomedical research and innovation, being almost ubiquitously used as justification for any initiative. Furthermore, they permeate the general consciousness as measures of disease burden and severity.

Therefore, using prevalence and mortality data to characterize diagnoses, I explore the types of cancers that are involved in litigation to access drugs from the public insurer in Costa Rica. I focus on two aspects of the litigation process. First I look at whether patterns in what diseases use litigation can be explained by health care coverage. Second, I test if diagnosis prevalence and mortality are factors determining litigation decisions.

Costa Rica has a publicly funded health care system run by a national public insurer, and health outcomes comparable to developed nations (Norheim and Wilson 2019). When the public insurer

is sued requesting a drug, the lawsuit's resolution will by design only impact the involved parties, so for another individual to obtain the same drug from the public insurer they would have to sue.

Over time, litigation cases have increased (Programa Estado de la Nacion 2017) garnering more attention from both the general public, health authorities¹ and government (Norheim and Wilson 2014).

If the Costa Rican health care system were achieving its goal of universal and comprehensive coverage, then there should be no litigation to access drugs. Since litigation does happen, I investigate the types of cancers using it to determine if there is an identifiable pattern to explain it. These patterns would consist of mostly high or low prevalence cancers being the main contributors to litigation cases. Such a pattern would mean that either rare or common cancers are not being sufficiently covered by the public insurer. Likewise, for mortality the patterns would be high or low mortality cancers being over-represented among litigation cases, suggesting that either non-lethal or lethal cancers are not being suitably covered. Such patterns would have strong policy implications in terms of trade-offs between individual and collective well-being.

For example, if rare cancers are the main contributors to litigation, then one could conclude that there is a specific coverage gap. These diseases typically have more limited treatment options, are more expensive to treat, and have less evidence of their treatment's benefits. All of this could have led to treatments being excluded from coverage due to failing to pass cost-effectiveness thresholds, and so patients would use litigation to obtain the treatment.

Moving on to litigation decisions, these are taken by a panel of judges in the Constitutional Court (henceforth referred to as the *Court*) –the official judicial institution in charge of all cases involving access to health care². Prevalence and mortality are commonly understood measurements and can change how a diagnosis is perceived outside of the health care field. As such, it is reasonable to expect them to affect decisions being made by judges.

The effects of prevalence and mortality on the probability that a request for a drug is approved by judges are unknown. Increased mortality in a diagnosis is likely to induce sympathy and increase approval probability, while increased prevalence (a diagnosis being more common) is likely to make a judge cautious about any decision due to a larger possible pool of similar patients existing.

¹The health care system is administratively autonomous from the executive, judicial and legislative branches of government.

²Further explanation of this can be found in section 2.2.

Previous work showed that judges were more likely to rule in favor of requests for high-benefit drugs, and treatments that improved the probability of survival (Monge 2020). This suggests that judges might give a premium to survival and work against sympathy; in this paper I use mortality measures to attempt and understand if survival is indeed a determining factor.

Since prevalence and mortality are tied to treatment benefits and costs, if they are being used to make decisions, they are also directly impacting the distribution of public resources and the population's health outcomes. I further look into benefits and costs using incremental cost benefit ratios. I expect the highest ratios to be found for treating cancers that are rare (increased costs) and lethal (reduced benefits), while the lowest for treating common and non-lethal cancers (increased benefits).

Using prevalence and mortality data for cancer from the Costa Rican Ministry of Health and National Institute for Statistics and Census and litigation case level data from the Costa Rican Health Care Litigation dataset³ I perform a descriptive analysis to look for patterns in the types of diseases using litigation. Then I use a probit model to predict the likelihood of successful litigation with prevalence and mortality as predictors of interest.

The results of the analysis show that prevalence and mortality of the diagnoses involved in Court cases do not show that a diagnosis type is mainly responsible for litigation. This supports that the Costa Rican health care system is fulfilling its goal of expansive coverage. As for the Court as a mechanism to access treatments, this supports that Court use is responding to individual heterogeneity creating demand that remains unmet due to system wide cost-effectiveness rules.

From the probit model, I find that prevalence does not appear to be a factor determining Court decisions. Its relationship to incremental costs and benefits is unclear, but rare diseases are not the main force behind high incremental cost benefit ratios.

Regarding mortality, it corroborates previous findings, that survival is valued by the Court. Increasing mortality, decreases the likelihood of a request being approved. High mortality diagnoses have higher incremental cost benefit ratios supporting that the Court is focusing on any chance of survival (treatments for more lethal cancers typically have less benefits) without being concerned about costs.

The remainder of this paper is structured as follows: section 2.2 explains the institutional

³Dataset I constructed for previous work (Monge 2020). Further details can be found in section 2.4.

setting; section 2.3 details the conceptual role prevalence and mortality; section 2.4 presents the data used; section 2.5 explains the methods applied; section 2.6 details and discusses the results; and section 2.7 contains the conclusions.

2.2 Institutional setting

Costa Rica is a small Central American country with long-standing⁴ and far-reaching health care and litigation systems. The tax-funded single-payer health care system provides a comprehensive package of services free at point-of-use over an extensive network of providers. All providers are part of a centralized institution that functions as a public insurer and will henceforth be referred to as such⁵.

The public insurer has a Centralized Pharmacotherapy Committee which determines system-wide regulations for pharmaceutical products. Drug coverage is managed through an official formulary⁶ which lists combinations of prescriber-drug-diagnosis that have been approved as cost effective.

The prescriber refers to the personnel considered adequate to prescribe the drug. This could be a specialized or general physician or nurse, a primary care attendant, a medical technician, among others. The drug is listed by its active principle (the molecule)⁷, with all possible approved presentations and dosage ranges. The diagnosis is specified according to the World Health Organization's International Classification of Diseases.

All drugs in the formulary are covered, which means they will be provided at no cost across the entire provider network. If a drug is not covered, it cannot be obtained via the public insurer.

In practice, a patient meets the health care provider and receives a prescription deemed appropriate by the provider for their diagnosis. The patient then goes to the pharmacy, and the treatment is dispatched. If the provider considers a treatment outside of the formulary as appropriate, they can make an internal request to the aforementioned Pharmacology Committee. The patient has no agency in this process, it is entirely within the public insurers administrative purview⁸.

⁴Established in 1941.

⁵Officially known as the Costa Rican Social Security Institution, as translated from the Spanish "*Caja Costarricense de Seguro Social*".

⁶Known as the Official Pharmaceuticals List, as translated from the Spanish *Lista Oficial de Medicamentos*.

⁷By law –as a cost control mechanism– if a generic version of the drug is available it must be the prescriber and pharmacist's first choice.

⁸The public insurer does not disclose any data on these requests.

The judicial system's relationship with the health care system began when the Constitutional Chamber of the Supreme Court was established in 1989. The Chamber was designed to be easily accessible and serve to allow accountability when interpretation of the Constitution is in question. It is the highest legal authority in the Country, and is characterized by having its decisions strictly enforced within six months of being determined, legal formalism is not required, there are no fees to use it, and is open year-round (Programa Estado de la Nacion 2017).

The Costa Rican Constitution endorses the human right to life and the judicial system interprets this as the right to health (Programa Estado de la Nacion 2017). Litigation about deficiencies in health care access is considered a violation of constitutional rights and is purview of the Constitutional Chamber (henceforth referred to as the Court).

An typical example is a person who considers their right to health is being injured by the public insurer not providing a drug. This person⁹ files a claim explaining how their right was violated (the drug not being provided) and how it can be rectified (their specific request). Though evidence supporting the claim can help it is not required.

The Court then begins deliberation of the claim. The public insurer (as defendant) is notified and allowed to provide evidence in their favor. A five judge panel¹⁰ reviews the case and determines if they approve or reject the request by simple majority. If approved the sentencing includes a time period for fulfillment by the public insurer.

As has been explained, if a patient is not satisfied with the drug coverage provided by the public insurer, their only recourse is to use the Court or obtain the product by their own means. Besides costs being a consideration, many pharmaceuticals are not sold by private pharmacies¹¹ Additionally, privately acquired drugs cannot be administered by the public insurer's personnel, so drugs that require any form of monitoring or hospitalization for their use would have the added cost of paying for private services.

In this context, the Court has emerged as a mechanism to access drugs bypassing rationing rules determined by the public insurer. Judging the drug requests as reasonable or unreasonable is

⁹Or someone representing them (who does not have to be a lawyer).

¹⁰There are five main judges (also referred to as magistrates) at all times. There are two alternates in case main judge is unable to participate in a case.

¹¹Since over 90% of the population is covered by the public insurer, the private market (including out-of-pocket and private insurance) is small. Therefore private providers do not typically carry expensive and/or rarely used drugs since it would not be profitable.

complex. From a clinical perspective, if the request increases expected benefits while outweighing the risks, it is reasonable for a patient to demand the treatment. From a policy perspective, a request that improves efficacy could be considered reasonable.

These perspectives are not necessarily in opposition, they most likely overlap in most cases. However, this depends greatly on how benefits, risks, and efficacy are being measured. The available evidence in support of these measurements varies widely, from reliable to unreliable, peer-reviewed to single case reports, or something in between.

The measurements evaluating treatments are determined based on what disease is being treated, so characterizing the types of diseases using the Court to gain access to treatments is vital in understanding how the mechanism is functioning.

Among the most standard indicators characterizing a disease are prevalence and mortality. These epidemiological measures are extensively used in medicine (Wunsch and Gourbin 2018). In a clinical setting they are necessary inputs to understand a disease's behavior and give context to treatment options for both the clinician and the patient; while in a policy setting, they are vital indicators used in planning resource allocation for health care.

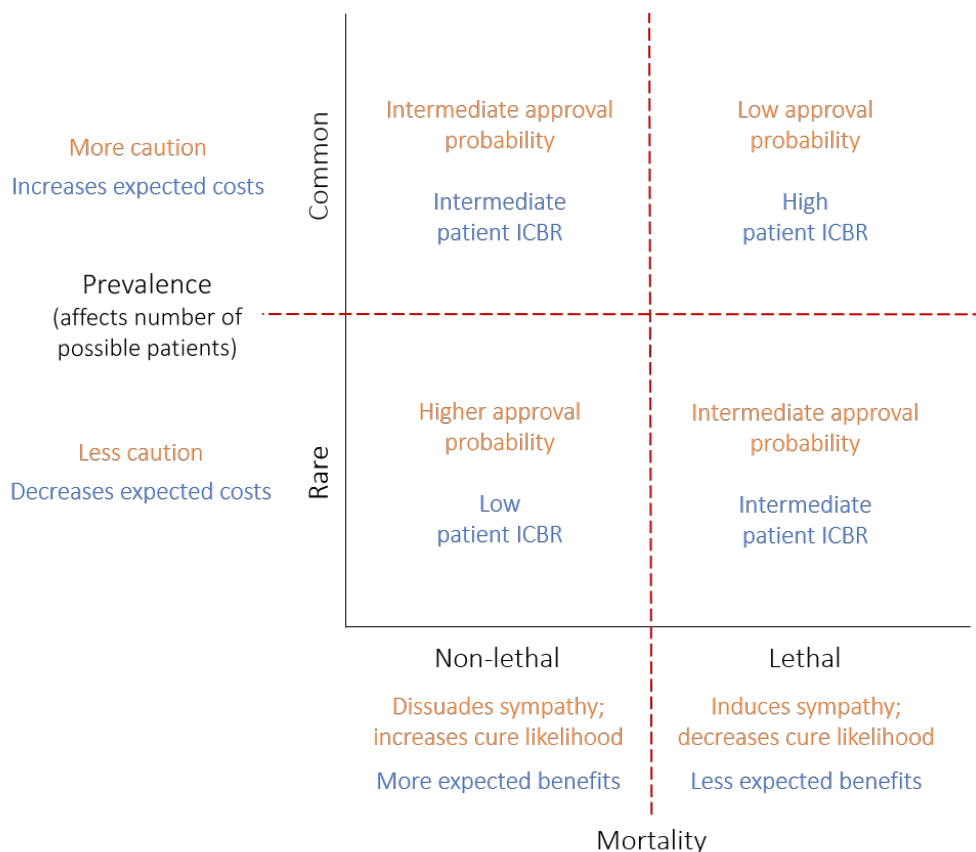
2.3 Conceptual role of prevalence and mortality

A guiding principle for the Costa Rican health care system is universality, which is interpreted not only as giving access to all, but giving sufficient access to all. In practice this means that no disease is considered too rare or too expensive to be managed covered by the public insurer.

If this goal has been achieved, then one would expect that cases using the Court to access drugs show no pattern in terms of prevalence rates for the diagnoses involved. If rare diagnoses are found to be the main source of Court cases, this means that patients with these diseases are not receiving adequate treatment. Since by law no diagnosis can be excluded from coverage, this would mean that the treatment options covered are not meeting patient's demands.

One possibility that could contribute to such a scenario, is if requests are mostly for orphan, experimental or recently innovated drugs. These drugs typically have high costs, and low or still unsubstantiated by peer-reviewed evidence benefits. In these conditions, the public insurer would not include the drugs in the official formulary, forcing patients who want access to them to go to Court.

Figure 2.1: Hypothetical factors related to prevalence and mortality affecting judge’s decisions and the resulting cost benefit ratios (ICBRs) from treatments



Notes: Incremental cost benefit ratios (ICBR) serve as a proxy measure of effectiveness. The numerator is incremental costs and the denominator incremental benefits. Prevalence is divided into rare (low prevalence) and common (high prevalence) cancers. Mortality is divided into non-lethal (low mortality) and lethal (high mortality) cancers. Notions of sympathy, perception of the likelihood of being cured, and caution due to the possible number of patients are hypotheses of how judges might feel regarding the probability of dying from a diagnosis and would impact the probability that a judge approves a request. Expected costs and benefits are interpreted from the judge’s perspective, so what they would expect in each scenario. Relationships between approval probability and benefits and cure likelihood are supported by the findings of Monge 2020.

Like with prevalence, I would not expect a specific mortality pattern to be observed among the Court requests. From the public insurer’s perspective there is no reason for mortality to determine coverage. However, more lethal diseases could lead to patients demanding orphan, experimental or recent innovation drugs, which as stated previously could be justified in not being covered from an effectiveness perspective (based on cost-effectiveness or cost-benefit analyses).

I would not expect a pattern of common diseases or non-lethal diseases being the main contributors to Court cases, given that Costa Rica has good health outcomes overall (Norheim and Wilson 2019). If this were observed, I would hypothesize that the group self-selecting to go Court

would be significantly different from the overall population.

Continuing with how prevalence and mortality could influence Court decisions, I begin with prevalence. Rare diagnoses mean that there are fewer potential patients, whereas common diagnoses mean that there are more potential patients. Judges might be more reluctant to approve a request for a common disease –especially high-cost requests-, since there are more potential other patients (possible future cases), whereas they might be less cautious if the disease is rare.

Additionally, judges are less likely to have any knowledge of rare diseases, so their ability to determine a treatment’s effectiveness may be more limited. The opposite is true for common diseases.

Lethal diseases are likely to induce sympathy in judges which would increase the likelihood that their requests are approved regardless of benefits or costs. For non-lethal diseases, sympathy would not play a factor and the approval probability is likely to be lower, especially for high-cost or low-benefit drugs.

Additionally, independent of judges’ perceptions, mortality and prevalence changes the benefits and costs expected from drug requests. Due to low survival probabilities for more lethal cancers, expected benefits from treatment will be lower than for less lethal cancers.

Rare diseases are more likely to have less treatment options, and these are more likely to be high-cost and have less expected benefits -or for these benefits to not have yet been proven (Pavlidis et al. 2015). This suggests that there will be increased expected costs from rare disease treatment requests than for common diseases.

These possible effects are shown in Figure 2.1. The x-axis is mortality; the y-axis is prevalence. Each quadrant shows an intersection between mortality and prevalence, with the corresponding prediction regarding approval of a request, and the resulting incremental cost-benefits ratio (ICBR) of the requested treatment.

Rare cancers are expected to have high approval probabilities and ICBRs when compared to common cancers, due to judges being less cautious and costs probably being higher. Within the rare cancers, more lethal ones (lower right quadrant) are expected to have higher approval probabilities and ICBRs than non-lethal ones (lower left quadrant), due to inducing sympathy in judges and having less chances of survival regardless of treatment.

Among common cancers, non-lethal ones (upper left quadrant) are expected to have lower

approval probability and ICBRs due to less sympathy and less expected benefits when compared to more lethal cancers (upper right quadrant).

2.4 Data

Prevalence and mortality data for cancer diagnoses was obtained from the Costa Rican Health Ministry's Epidemiological Observatory. The data is recorded according to anatomical location which allowed for a precise match between the Ministry's diagnoses and those from the Court cases.

The data consists of measures of prevalence and mortality specific to age group¹², sex and cause from 2009 to 2015 for Costa Rica. In order to calculate rates, population data (with age and sex specific entries) was taken from the National Institute of Statistics.

Mortality rates were corroborated with the public insurer's National Tumor Registry which allows access to aggregated data on cancer mortality. Though the rates are informative, the measure I use for analysis shows the risk of dying from the diagnosis. Thus, cause specific mortality values were converted into the probability of dying within a five year period conditional on having the specific cancer being evaluated.

Data about access to health care litigation was taken from the Costa Rican Health Litigation Database I constructed for a previous project (Monge 2020). Though the database spans a longer time period, I selected data spanning from 2009 to 2015 to match prevalence and mortality data. This includes all Court decisions in Costa Rica where a drug was requested to treat cancer, drug costs and individual level expected benefits.

Variables directly from the court case include those about the court process, individual and drug characteristics. Court process variables are time of filing and of the decision, deliberation time, appeal status¹³, and the decision about the request).

Individual characteristics refer to the defendant and include their age, sex, diagnosis and cancer stage. I determined stage according to the Tumor-Node-Metastasis System of the International Union Against Cancer¹⁴. Stage is a discrete numerical value with increasing severity from 1 to 4. Stage 1 and 2 are generally considered an early diagnosis, and 3 or more advanced.

¹²Groups are for every 10 years, starting at 0 to 10, and ending in above 100.

¹³Indicator variable on whether the case is an appeal of a previous Court case.

¹⁴The standard method accepted by the worldwide medical community.

Diagnosis were specified within the text of the Court case providing rich details which allowed for a exact match to the corresponding anatomical location cancer measure in the prevalence and mortality data. As such measures for age group, sex and cause specific prevalence rates and probabilities of dying in five years were included at the individual level.

Drug characteristics include what drug was requested, whether it is generic or not, whether the request is for the same molecule as the prescribed one¹⁵, whether the requested treatment is symptomatic or curative, and whether it replaces the current prescription or not.

Drug costs were determined using the drug price and number of doses¹⁶ needed for each individual case. Prices were adjusted to 2017 United States dollars. The expected treatment cost was estimated based on the dosing and length of treatment recommended by the National Comprehensive Cancer Network’s (NCCN) clinical practice guidelines¹⁴.

Benefits from drug treatments were determined by matching the case specific individual-diagnosis-stage combination to the guideline’s recommendations for that same combination. The recommendations include treatment options (including drug, dosage, and duration), and the expected benefits from it measured by different clinical end-points¹⁷.

I use months of progression-free survival as clinical endpoint. It is defined as the time it takes for the disease to progress after beginning treatment. This measure is widely used in cancer research, and is supported by the United States Food and Drug Administration¹⁸ (Food and Drug Administration 2018, December).

2.4.1 Descriptive statistics

Descriptive statistics for Court cases with a cancer diagnosis can be seen in Table 2.1. Over the six-year period studied, there were 686 drug requests to treat cancer. Within these requests, 105 distinct drugs and 41 diagnoses were involved. The mean observed approval probability was 0.69, so almost 70% of cases were successful, meaning the judges ordered the public insurer to provide the drug treatment to the patient.

¹⁵Bio-equivalent drugs are those that have been tested and proven to produce the same effect *in vivo*.

¹⁶Taken from public tenders recorded by the Costa Rican National Comptroller Office about purchases made by the public insurer.

¹⁷Outcome that represents direct clinical benefit (Food and Drug Administration 2018, December)

¹⁸United States Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

Table 2.1: Descriptive statistics for cancer drug requests (2009-2015)

Number of requests	686			
Number of drugs	105			
Number of diagnoses	41			
<i>Court decision process</i>				
	<i>Mean</i>	<i>SD</i>	<i>Min</i>	<i>Max</i>
Approval	0.69	0.46	0	1
Appeals ¹	0.06	0.23	0	1
Deliberation time (days)	33	29	0	278
<i>Individual</i>				
Age	53.00	16.59	2	98
Gender (<i>male=1</i>)	0.34	0.47	0	1
Cancer stage (1 to 4)	3.06	0.83	1	4
<i>Requested drug</i>				
Generic	0.54	0.50	0	1
Same molecule ²	0.28	0.45	0	1
Symptomatic ³	0.06	0.24	0	1
Replace current ⁴	0.48	0.48	0	1
<i>Costs (USD) and benefits (progression-free survival in months)</i>				
Incremental costs ⁵	13,913	17,584	-24,927	67,980
Incremental benefits ⁶	5.02	13.21	-50	90
<i>Prevalence and mortality</i>				
Prevalence rate ⁷	115	108	0.200	279
5-year mortality probability ⁸	0.273	0.110	0.005	0.824

¹ Appeals are against previous Court decisions.

² Requested and current drugs have the same active principle and effect.

³ Requested drug is not intended to cure, but to help with symptoms.

⁴ Requested drug replaces the currently used treatment.

⁵ Difference between requested and currently used treatment costs in USD adjusted to 2017.

⁶ Difference between requested and currently used treatment benefits in months of survival without disease progression.

⁷ Average diagnosis prevalence rate per 100,000 people in Costa Rica, according to sex, 10-year age and calendar year bins.

⁸ Average probability of dying during a 5-year survival period conditional on having the disease, sex, 10-year age group, and calendar year bins.

Source: primary hand-collected data for all requests for cancer drug treatments in Costa Rica from 2009 to 2015.

Litigation regarding health care is filed directly with the Court, so appeals are on cases the Court has previously ruled not in favor of. There were forty appeals cases (6%), and this group has an approval probability of only 35%.

The mean deliberation time (period spanning from when the case was filed to when the final decision was notified to the defendant and accused) is 33 days. The Court has expressed a concerted effort in resolving health care cases in a timely manner and this is evidenced, not only by a median deliberation time of 27 days, but also 75% of cases were resolved by 35 days and 90% by 58 days.

Table 2.2: Characteristics of cancer diagnoses observed in Court cases

<i>Diagnoses grouped according to the anatomical system affected</i>	(1) <i>Number of cases</i>	(2) <i>Court cases per 1,000 people¹</i>	(3) <i>Court approval probability</i>	(4) <i>Court case mean age</i>	(5) <i>Mean diagnosis stage</i>	(6) <i>5-year mortality probability²</i>	(7) <i>Prevalence rate³</i>
Endocrine System	21	1.15	0.921	48.29	3.66	0.259	27.93
Gastrointestinal System	86	1.51	0.708	57.62	3.62	0.372	22.07
Hematolymphatic System	124	5.59	0.599	54.62	2.61	0.125	13.58
Integumentary System	7	3.03	0.500	44.58	4.00	0.210	3.53
Musculoskeletal System	8	4.94	0.688	30.88	3.88	0.325	1.24
Nervous System	20	2.44	0.570	31.01	3.91	0.299	8.19
Reproductive System -Female	301	10.87	0.420	55.85	3.09	0.248	41.23
Reproductive System -Male	67	1.94	0.879	45.61	3.65	0.225	52.84
Respiratory System	31	1.53	0.808	61.45	3.38	0.321	12.38
Urinary System	21	2.19	0.900	70.50	4.00	0.288	14.67

¹ Number of Court cases per 1,000 people with the diagnosis.

² Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.

³ Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.

Source: primary hand-collected data for all drug requests in Costa Rica from 2009 to 2015, population data from the National Institute for Statistics and Census, and prevalence and mortality data from the Costa Rican Health Ministry's Epidemiological Observatory.

Notes: Cancers included in the endocrine system are neuroendocrine and thyroid; in the gastrointestinal system are appendiceal, colon, gall bladder, gastric, liver, pancreatic, peritoneal, and rectal; in the hematolymphatic system are leukemia, lymphoma, lymphoproliferative disorder, multiple myeloma, and myelodysplastic syndrome; in the integumentary system are melanoma and ocular; in the musculoskeletal system are Ewing sarcoma, Kaposi sarcoma, osteosarcoma, and sarcoma; in the nervous system are astrocytoma, oligoastrocytoma, spinal, tympanic glomus, and other undetermined histopathologies; in the reproductive system -female are breast, endometrial, ovarian, uterine, and vaginal; in the reproductive system -male are prostate and testicular; in the respiratory system are laryngeal, lung, occult primary, oral, and tongue; in the urinary system are kidney and vesical.

The defendants in these cases are cancer patients with a mean age of 53, 34% female and had an average cancer stage of 3.06. The stage is particularly relevant, as in general stages 3 and 4 are considered advanced disease stages which increases treatment complexity and decreases expected survival.

The variables describing the requested drug characterize what type of request defendants are making. Generic refers to requests that do not specify a drug brand. This is observed in 54% of cases, and these could be interpreted as reasonable requests since branded drugs are bio-equivalent and do not produce different effects. However, requesting a brand would be reasonable if the reason for the specific brand is due to adverse effects from consuming the generic, or there is not generic version available.

Requests for the same molecule indicate that the patient's request is for a drug that is bio-equivalent to the current treatment being provided by the public insurer. This happens in 28% of cases and would be unreasonable requests due to both drugs producing the same effects unless adverse effects are proven to occur with the current treatment.

Cases where the drugs requested are symptomatic occur in only 6% of cases. Symptomatic treatments, as defined in a clinical setting, refers to treatments whose goal is to address symptoms not the disease itself. Examples of symptomatic drugs include anti-emetic (to counter nausea and vomiting) medication and pain killers which do not treat the disease but are necessary for cancer patients.

In almost half of the cases (48%), the requested treatment would replace the treatment currently being provided by the public insurer. This measure suggests that patients are receiving treatment, just not one that completely satisfies their demand.

Case specific incremental costs are the difference in costs between the requested treatment and the treatment being received from the public insurer. The mean change in costs requested is 13,913 USD, and the median is 3,291 USD. This corresponds with the wide range of values observed. Thirty-one cases have a negative change, so the requested treatment is cheaper than the current treatment, while 237 cases have a positive change above 20,000 USD.

Case specific incremental benefits are measured in months of survival free of disease progression gained from using the requested treatment versus the treatment received from the public insurer. The mean is 5.02 and median 2.70 months, with again a wide range. Forty-seven cases have negative

values which means that the requested treatment reduced the expected months of survival (these would be considered unreasonable requests); seventy-three cases have expected survival gains of more than one year.

The 41 diagnoses observed were grouped according to what anatomical system they involve and are presented in Table 2.2 along with several descriptive characteristics. The most observed diagnosis was breast cancer, which is reflected in the Female Reproductive System having the most cases.

For each diagnosis, conditional on having the disease, the rate per 1,000 people of Court cases was calculated. In column 2, the average rate for the diagnoses corresponding to the listed anatomical system is shown. For instance, for every 1,000 persons with a hematolymphatic system cancer (including lymphoma, myeloma, leukemia, among others) over the six-year period, 6 persons filed a Court case requesting a drug.

The highest rates can be found among cancers of the female reproductive system (11 cases filed for every 1,000 cancer patients) and the above mentioned hematolymphatic system. The lowest rates of around 2 Court cases for every 1,000 patients correspond to the endocrine, gastrointestinal, male reproductive and respiratory systems.

The probability of the Court approving the request for each category is shown in column 3. These range from 0.420 for cancers of the female reproductive system, to 0.921 for cancers of the endocrine system. In column 4 the mean age is presented. None of these values are unexpected, with most being in the middle age range.

In column 5, the mean diagnosis stage is shown. The lowest is 2.61 for hematolymphatic cancers, however this approaches three which is considered advanced. Four categories have stages above 3.75 (integumentary, musculoskeletal, nervous, and urinary systems) which indicates cases with high treatment complexity and low cure expectations.

Columns 6 and 7 refer to Costa Rican prevalence and mortality over the studied period. Mortality was determined as the probability of dying during a five-year survival period conditional on having the disease. Prevalence was determined as a rate over 100,000 persons.

The probability of dying within five-years is between 0.210 and 0.372 for every category except hematolymphatic cancers which have a lower 0.125 probability. These values being similar among each other is supported by good overall country level health outcomes (such as high longevity, and

morbidity and mortality profiles) and readily available health care.

Prevalence rates show a completely different picture. Reproductive system cancers for both sexes are very prevalent, with rates of above 40 cases per 100,000 people (led by breast cancer for females and prostate cancer for males). Gastrointestinal and endocrine systems have rates of 22 and 28 cases respectively. These values are expected given Costa Rica’s morbidity profile which is characterized as a hot-spot for gastric and thyroid cancer (Monica S. Sierra et al. 2016; Mónica S. Sierra et al. 2016).

Cancers affecting the hematolymphatic, respiratory and urinary systems have prevalence rates, as expected, in the teens. Cancers affecting the integumentary, musculoskeletal, and nervous systems, which are rare, have rates of 3.53, 1.24 and 8.19 cases per 100,000 persons respectively.

2.5 Methods

To begin, I conducted a descriptive analysis to observe prevalence and the probability of dying in relation to the diagnoses involved in litigation cases requesting drugs for cancer treatment. Prevalence rates and the probability of dying for each diagnosis were classified using terciles to create a high, mid, and low category of prevalence and mortality.

To determine the possible role of prevalence and mortality in Court decisions, I use an econometric model to predict approval (indicated by the binary variable *decision*, where approval is 1, and rejection is 0). The main predictors (*pred*) of interest are prevalence, included as a rate, and mortality, included as the probability of dying.

Both variables are adjusted by sex, age, and are cause specific as described in section 2.4. As an example, for case *i* which involves a 54 year old woman with rectal cancer in year *t*, the associated prevalence rate and probability of dying will be adjusted to a woman in the 50 to 60 age group and be specific to rectal cancer for year *t*.

Each predictor is included in the model separately, thus the probit model I estimate is as follows:

$$decision_i = \beta_0 + \beta_1 pred_i + \beta_2 ben_i + \beta_3 costs_i + \beta_4 X_i + \tau_t + \epsilon_i, \quad i = 1, \dots, 686 \quad (1)$$

where the *X*’s are control variables, the subscript *i* represents a case, τ_t are year fixed effects, and ϵ_i is an error term.

Table 2.3: Diagnoses in Court cases according to prevalence and mortality levels (defined using terciles)

<i>Prevalence level</i> ¹	<i>Diagnosis</i>	(1) <i>Number of Court cases</i>	(2) <i>Court cases per 1,000 people</i> ²	(3) <i>Court approval probability</i>	(4) <i>5-year mortality probability</i> ³	(5) <i>Prevalence rate</i> ⁴	
<i>Panel A. High mortality level</i> ¹							
High	Gastric Cancer Lung Cancer	Occult Primary	32	0.81	0.782	0.367	40.394
Mid	Astrocytoma Brain Cancer ⁵ Glioblastoma	Liver Cancer Oligoastrocytoma Pancreatic Cancer	52	2.06	0.593	0.394	12.876
Low	Ewing Sarcoma Osteosarcoma	Peritoneal Cancer Sarcoma	8	4.38	0.617	0.407	1.398
<i>Panel B. Mid mortality level</i> ¹							
High	Colon Cancer	Rectal Cancer	43	1.89	0.733	0.301	34.845
Mid	Kidney Cancer Ovarian Cancer	Vesical Cancer	45	3.43	0.880	0.294	13.378
Low	Gall Bladder Cancer Laryngeal Cancer Neuroendocrine Tumor	Oral Cancer Tongue Cancer	8	1.60	0.844	0.290	3.070
<i>Panel C. Low mortality level</i> ¹							
High	Breast Cancer Leukemia Lymphoma	Prostate Cancer Thyroid Cancer Uterine Cancer	465	3.80	0.690	0.209	62.392
Mid	Endometrial Cancer Multiple Myeloma	Myelodysplastic Syndrome Testicular Cancer	20	1.35	0.565	0.161	11.326
Low	Appendiceal Cancer Kaposi Sarcoma Lymphoproliferative Disorder Melanoma	Ocular Tumor Spinal Cancer Tympanic Glomus Vaginal Cancer	13	2.54	0.322	0.198	1.956

¹ Levels determined using terciles to classify the diagnoses' prevalence and probability of dying over all diagnoses observed in Court cases.

² Number of Court cases per 1,000 people with the diagnosis.

³ Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.

⁴ Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.

⁵ Cancers of the nervous system with undetermined histopathologies.

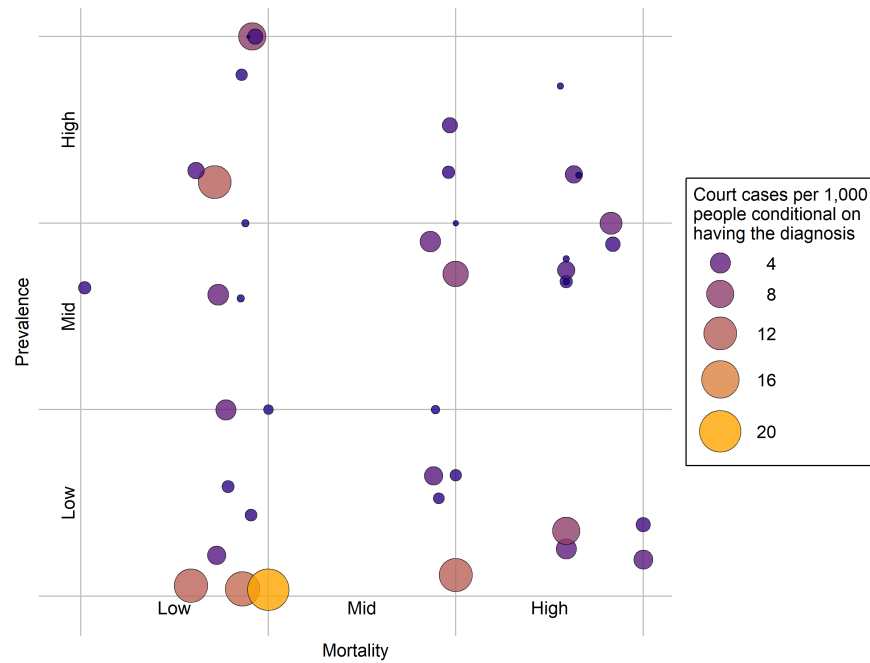
Source: primary hand-collected data for all drug requests in Costa Rica from 2009 to 2015, population data from the National Institute for Statistics and Census, and prevalence and mortality data from the Costa Rican Health Ministry's Epidemiological Observatory.

Incremental benefits (*ben*) and costs (*costs*) are standardized so that the resulting coefficients can be interpreted as a change of a standard deviation. For benefits this is 13 months of survival without cancer progression, and for costs this means 17,600 USD.

For every specification I include the following control variables in X_i : individual, drug, diagnosis, and court process variables as described in section 2.4. Marginal effects were estimated for each specification in order to predict effects on the likelihood that the Court approves a drug request.

2.6 Results

Figure 2.2: Diagnoses classified according to prevalence and mortality terciles with the rate of Court cases per 1,000 people with the diagnosis

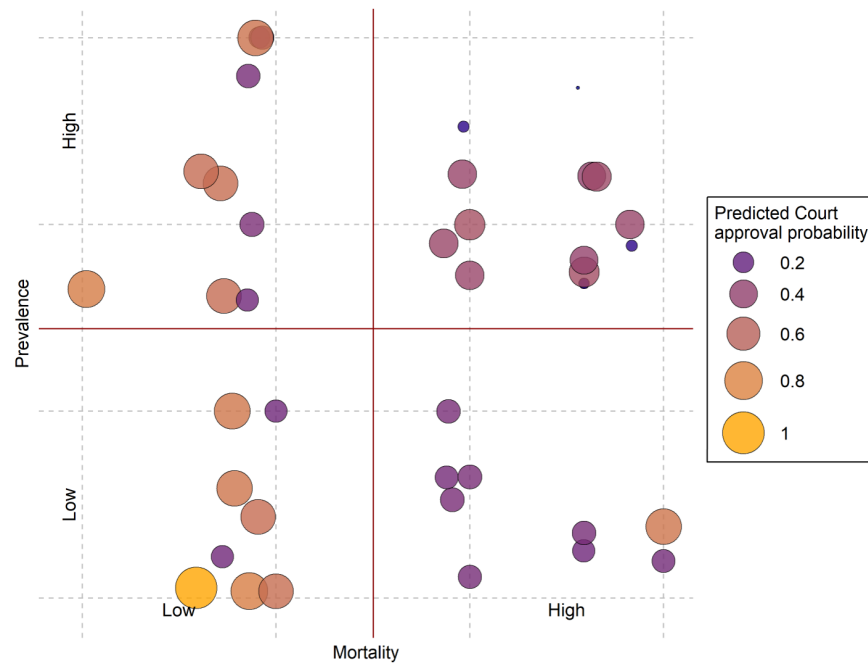


Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases ($n = 686$) collapsed by diagnosis ($n = 41$). Each diagnosis is plotted onto the grid with its size corresponding to the number of Court cases per 1,000 people with the diagnosis.

The result of using terciles to classify diagnoses into groups according to prevalence and mortality is shown in Table 2.3. Each panel shows a different mortality level, and the mean value for this can be seen in column 4 (it decreases between panels). Within each panel, every row represents a decreasing level of prevalence, and the mean values for this can be seen in column 5 (decreasing within the panel).

The diagnoses groups in each panel and row are as would be expected from standard medical

Figure 2.3: Diagnoses classified according to prevalence and mortality terciles with the diagnosis' Court approval probability



Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases ($n = 686$) collapsed by diagnosis ($n = 41$). Each diagnosis is plotted onto the grid with its size corresponding to the diagnosis' likelihood of approval by the Court.

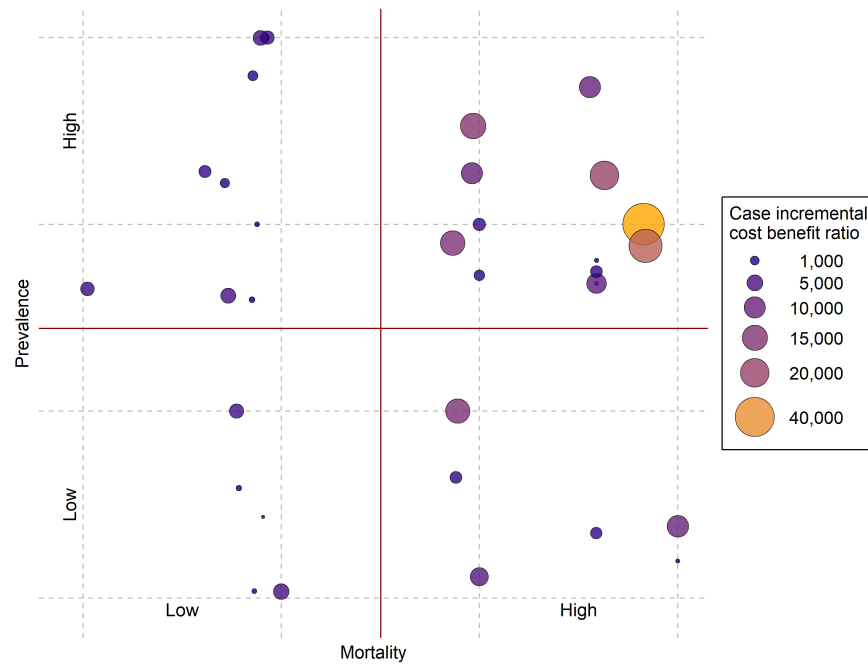
practice (Bray et al. 2018) and Costa Rican cancer profiles (Global Health Observatory 2015). In column 2, the number of Court cases per 1,000 people with the diagnosis shows similar values across panels. The mean rates being 2.42, 2.31, and 2.57 for Panels A, B, and C respectively.

In column 3, the probability of drug requests being approved by the Court for each group is reported. Panels A and B show similar high probabilities, while the last panel for low mortality has lower probabilities. Within panels, there is no consistent pattern for the rate of Cases (column 2) or approval probabilities (column 3), so there does not appear to be different behaviors between rare and common cancers.

In Figure 2.2 each diagnosis is plotted according to their prevalence and mortality, with the gray grid lines representing the terciles. The size of each diagnosis shows the rate of Court cases per 1,000 people with the diagnosis according to the scale shown in the legend.

As was expected, and in support of the findings described for Table 2.3, the diagnoses are scattered across mortality and prevalence without a salient pattern. Regarding usage of the Court to obtain drugs, there seem to be slightly lower rates in the upper right area. These would be

Figure 2.4: Diagnoses classified according to prevalence and mortality with the requested treatment’s cost benefit ratios



Notes: Prevalence and mortality classified using terciles (divided by dotted grid lines). Cases ($n = 686$) collapsed by diagnosis ($n = 41$). Each diagnosis is plotted onto the grid with its size corresponding to the case specific incremental cost benefit ratio (ICBR). The incremental cost benefit ratio is calculated by dividing the incremental costs (difference between the requested drug’s costs and current drug’s costs) in 2017-adjusted USD and incremental benefits (difference between the requested drug’s expected benefits and current drug’s expected benefits in months of survival free of cancer progression). So the ICBR is in terms of dollars spent to gain 1 month of survival without the cancer getting worse. Relating these results to the hypothesized ICBRs (see Figure 2.1) is done dividing the plot in quadrants (solid lines).

diagnoses with higher than average prevalence and mortality.

The same diagnoses scatter, but with the size of the shape showing diagnosis specific Court approval probability can be observed in Figure A2.1. The upper right area (high prevalence and mortality) diagnoses are in the high end of the approval probability scale, but these high probabilities are not exclusive to the area.

While there are low approval probability diagnoses in the rest of the areas, most can be found in the lower left area where low prevalence and low mortality meet. This relationship will be further examined with the analysis of Court decisions.

2.6.1 Likelihood of Court approval

Table 2.4 contains marginal effects from probit models predicting Court approval of cancer drug requests. Columns 1 through 4 are different specifications for the model testing whether prevalence

impacts decisions; columns 5 through 8 are the same specifications but for the model with mortality.

Increasing cancer diagnosis prevalence (more common) decreases the likelihood of approval for a case by 0.01 percentage points. While the change matches the prediction that the more common a diagnosis, the lower the approval probability, the magnitude -though distinguishable from zero- is too small for it to be reasonable to conclude that prevalence is a relevant factor in judges' decision process.

Additionally, these specifications do not demonstrate significant effects for incremental benefits and costs. This suggests that the predicted effects of prevalence on drug benefits and costs are not being observed.

Increasing cancer diagnosis mortality (more lethal) decreases the likelihood that a request is approved by 29 percentage points. This change does not match the prediction that lethality induces sympathy in judges resulting in high approval probabilities. It does support the previous finding that the likelihood of approval increases when a request has a higher survival possibility (Monge 2020).

This finding was observed in terms of higher benefit drugs and requests for additional curative treatments being more likely to be approved. Additionally, requests that did not have a clear path to cure the cancer were less likely to be approved.

From the result that increased mortality decreases approval probability, I observe that sympathy does not play a role, or is overpowered by the possibility of survival. Higher mortality means less chances of survival, and results in less likelihood that a request is approved.

Regarding incremental benefits, the effects are imprecise and small. Incremental costs show that, like in previous work, increasing costs increases the likelihood of approval. This relationship could be rooted in the fact that more lethal diagnoses can induce last-resort type requests.

Further insight into benefits and costs relationship with prevalence and mortality can be found in Figure 2.4, where diagnoses are plotted with their average requested treatment ICBR as a size scale. As was predicted in theory and expected from the previous results, higher mortality (area to the right of the vertical dashed line) results in higher ICBRs (larger size diagnoses).

Table 2.4: Marginal effects from probit models predicting Court approval of drug requests

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Disease prevalence ¹	-0.0011*** (0.0002)	-0.0010*** (0.0002)	-0.0006** (0.0002)	-0.0001* (0.0000)				
Probability of dying ²					-0.0470 (0.1639)	-0.1041 (0.1632)	-0.2255 (0.1701)	-0.2866* (0.1601)
Incremental Benefits ³		0.0159 (0.0186)	0.0153 (0.0177)	-0.0034 (0.0171)		0.3320* (0.0200)	0.0191 (0.0178)	0.0057 (0.0170)
Incremental Costs ⁴		0.0270 (0.0196)	0.0310 (0.0199)	0.0158 (0.0203)		0.0602** (0.0189)	0.0475** (0.0186)	0.0139* (0.0090)
Year FE	X	X	X	X	X	X	X	X
Individual Controls			X	X			X	X
Drug Controls				X				X
Observations	686	656	656	656	683	653	653	653
Pseudo R ²	0.454	0.523	0.548	0.580	0.421	0.500	0.649	0.590
AIC	820	766	752	733	848	785	751	724

¹ National rate per 100,000 people in Costa Rica.

² Probability of dying during a five year survival period conditional on having the disease.

³ Standardized measure of months free of disease progression. A 1 SD change is 13.22 months.

⁴ Standardized measure of costs in 2017 USD. A 1 SD change is 17,597 USD.

Notes: Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$. Every specification includes year fixed effects, controls as indicated in the table. Individual controls include: age, age squared, sex, cancer stage, deliberation time, and indicator variables for defense and appeal status. Drug controls include: indicators for whether the requested drug is generic or not, whether it is bio-equivalent (same active principle and pharmacological effect) to the current drug being taken, whether it is a drug to treat symptoms (as opposed to attempting to cure the disease), and whether it substitutes the current drug being taken. *AIC* stands for the Aikake Information Criterion.

The relationship with prevalence is not as predicted. Higher ICBRs are found for more common cancers (area above the dashed horizontal line), not for rare ones. One possible explanation behind this has to do with requests being more unreasonable, or related to requesting different treatment options (more available for common than rare diseases) that do not necessarily yield more benefits (same or smaller denominator) while increasing costs.

For instance, requests for a specific brand instead of the generic. This type of request would have little to no benefits, while having large changes in costs. Such options do not even exist for rarer diseases where treatment options are limited.

Every specification was reviewed using loglikelihood tests, pseudo R^2 and the Akaike information criterion. The specifications including all controls (columns 4 and 8) resulted in the best explanatory power (Table 2.4).

2.7 Conclusion

The types of cancers involved in access to drugs litigation gives merit to the Costa Rican system's claim to be providing comprehensive and universal coverage. No pattern is evidenced for both prevalence and mortality. This supports the possible contribution of the Court as a complimentary mechanism for access to drugs being its availability to address individual heterogeneity in the population. An ability that institutions making population level rationing rules lacks (Cameron et al. 2018).

Furthermore, judges highly value survival when making judgments about the merit of a request is seen in the fact that decreasing mortality –increasing survival–, increases the likelihood of Court approval. From previous work (Monge 2020) and current economics and law literature (Clarke and Kozinski 2019), there is no evidence that economic concepts such as effectiveness are used in judicial rulings, however the finding regarding mortality suggests that there could be a role for such concepts.

Such an inclusion could pacify concerns that a mechanism –like litigation– without clear rules will squander resources or be abused. Indeed finding that high mortality diagnoses have higher cost benefit ratios (more costs per benefit gained than other treatment options) supports that the Court is focusing on any benefits with being concerned about costs, suggests that those concerns –even if they could be exaggerated– cannot be dismissed without further evidence.

As a mechanism to circumvent rationing, litigation embodies the conflicting nature in a trade-off between individual and collective preferences. On one hand, it allows access that would otherwise not exist to health care services, but on the other, it reallocates resources from a plan that a collective had already agreed upon.

Considering the strain health care systems often find themselves in, the question of how to ration is both increasingly complex and urgent (Chandra and Staiger 2017; Liscow 2014). A mechanism such as litigation sheds light on the need for both flexibility and structure. Flexibility to account for individual heterogeneity in demand, and structure to ensure effectiveness in resource utilization.

The analysis in this paper is descriptive, and focuses on local disease patterns, however it provides insight into the complexity of an optimal rationing mechanism. These facts contribute to understanding how litigation serves as a safety valve for health care rationing, and the many factors that future economic models must consider when evaluating the impact this phenomenon has on individuals and society.

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Appendix

Table A2.1: Predicting the proportion of cases for a diagnosis over all diagnosis using prevalence and mortality

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Disease prevalence ¹	0.0023*** (0.0001)	-0.0022*** (0.0001)	-0.0021*** (0.0001)	-0.0018*** (0.0001)				
Probability of dying ²					-0.6297*** (0.0899)	-0.5600*** (0.0760)	-0.5114*** (0.0662)	-0.4384*** (0.0716)
Incremental Benefits ³		0.0080 (0.0061)	0.0042 (0.0057)	0.0119** (0.0053)		-0.0329** (0.0127)	0.0184** (0.0086)	0.0072 (0.0080)
Incremental Costs ⁴		-0.0242*** (0.0059)	-0.0192*** (0.0059)	-0.0044 (0.0062)		-0.0843*** (0.0087)	0.0766*** (0.0085)	-0.0252*** (0.0082)
Year FE	X	X	X	X	X	X	X	X
Individual Controls			X	X			X	X
Drug Controls				X				X
Observations	686	656	656	656	683	653	653	653
F statistic p-value	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Adjusted R ²	0.804	0.812	0.825	0.846	0.271	0.368	0.536	0.680

¹ National prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.

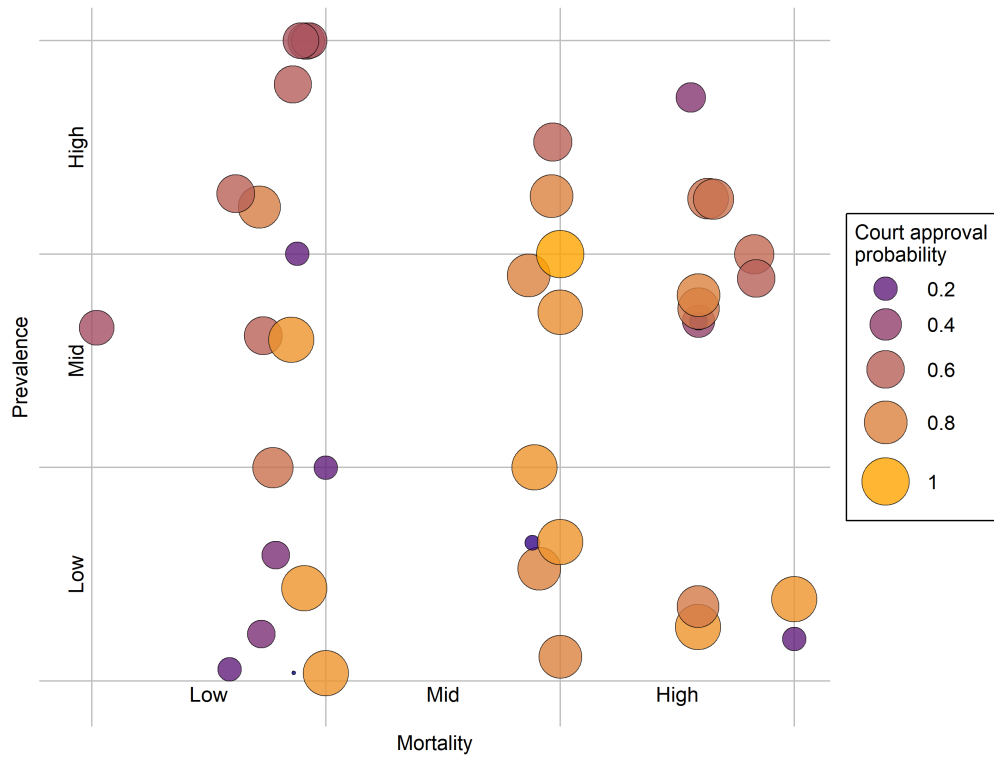
² Probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.

³ Standardized measure of months free of disease progression. A 1 SD change is 13.22 months.

⁴ Standardized measure of costs in 2017 USD. A 1 SD change is 17,597 USD.

Notes: Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$. The proportion of cases was calculated dividing the number of cases of a diagnosis by all the observed cases ($n = 686$). The numerator was determined according to diagnosis-10-year age group-sex-calendar year bins. The proportion is the outcome variable, so the coefficients show the effect on the number of cases from the main explanatory variables listed above and controls. Every specification includes year fixed effects; controls were added as indicated in the table. Individual controls include: age, age squared, sex, cancer stage, deliberation time, and indicator variables for defense and appeal status. Drug controls include: indicators for whether the requested drug is generic or not, whether it is bio-equivalent (same active principle and pharmacological effect) to the current drug being taken, whether it is a drug to treat symptoms (as opposed to attempting to cure the disease), and whether it substitutes the current drug being taken.

Figure A2.1: Diagnoses classified according to prevalence and mortality terciles with the diagnosis' Court approval probability



Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases ($n = 686$) collapsed by diagnosis ($n = 41$). Each diagnosis is plotted onto the grid with its size corresponding to the diagnosis' likelihood of approval by the Court.

CHAPTER 3

THE EFFECT OF PRIMARY CARE ON ELDERLY HEALTH OUTCOMES: EVIDENCE FROM A NATURAL EXPERIMENT

3.1 Introduction

With the worldwide population aging as it undergoes another demographic transition, it is estimated that by the year 2050 2.1 billion people will be over 60 years old, which will be about a fifth of the world population (Harper 2014). Aging implies changing patterns in health care utilization, for instance in the Netherlands a 37 percent increase in the use of elderly care between 2008 and 2030 is expected (Eggink et al. 2016). Such a change will bring about a host of challenges that public policy will have to face, and one of these will be the role of health care in achieving optimal well-being for the elderly.

Understanding the complex relationship between healthcare and health status for elders is indispensable to have the possibility of developing policies that invest resources efficiently (Hrevtsova 2012). This paper seeks to contribute in understanding how preventive and primary care services affect elderly health by using a natural experiment that occurred in the context of a single-payer healthcare system with universal coverage.

A basic premise in health economics is that investing in health will increase an individual's health stock, therefore it is intuitive to consider that increasing access to health care would increase health outcomes. However, we know that this oversimplification fails to account for the complexities of how health is perceived and consumed, and in particular for this population group whose health is characterized by increased morbidities and frailty which contribute to their increasing costs (Eckardt et al. 2017; Sirven and Rapp 2017), and it is precisely this what I explore with this paper using a natural experiment and a difference-in-differences model.

In 2004 Costa Rica's healthcare network announced that the following year a new policy would take effect to increase access to healthcare for their population. Costa Rica is a small developing country that boasts health measures that compete with OECD countries and has a universal cov-

erage single-payer healthcare system run by the Costa Rican Social Security System (CCSS¹). Said policy involved changing a host of administrative procedures not related to healthcare provision and a pledge by the CCSS to increase the number of primary care providers (who oversee preventive services as well) to improve geographical access to the network.

The new providers –established between 2005 and 2008- were supposed to be distributed according to the results from internal needs reports. However, the sites began construction as soon as the central administrative authorities processed the reform paperwork resulting in a distribution –that disregarded the reports- with winning and losing areas that upon analysis have no statistical differences in their sociodemographic and health utilization characteristics before the treatment.

Employing this situation and combining it with results from a longitudinal survey conducted on a representative sample of Costa Rican elderly, I estimate the effect of having increased access to preventive and primary care on healthcare utilization, nutritional outcomes, mental health, chronic disease indicators and disability status, using a difference-in-differences model while controlling for sociodemographic characteristics. The outcomes mentioned include objective measures for systolic blood pressure, glycated hemoglobin, iron blood levels, cholesterol, and body mass index, which correspond to blood tests and anthropomorphic measures taken with the survey.

Since the focus is primary and preventive health care, the first part of the existing literature that must be considered, is that these types of care have ample evidence of improving health outcomes for children (Attanasio et al. 2015; Brockerhoff and Derose 1996; Chin Chen et al. 2007; Gruber et al. 2014) and promoting healthier lifestyles and preventing future suffering (Barbaresco et al. 2015; Pauly et al. 2014; Tian et al. 2010). However, the issue becomes less clear when considering the effect solely on the elderly.

There are case studies showing how cost-saving preventive care interventions are by avoiding possible future complications (Irons et al. 2008; Irvine et al. 2010; Müller et al. 2015; Pihl et al. 2011; Powell-Griner et al. 1999), but none are able to prove changes in life expectancy (Cheng et al. 2015; Eric De Jonge et al. 2014; Shigeoka 2014). Even if life expectancy were increased, this means that there is more time for costly diseases to strike, and so these costs outpace the cheaper last year of life –where cost decreases the later in life it happens (Gandjour 2009).

Beyond the financial component, since mortality is not changing, an argument exists that pre-

¹CCSS comes from the Spanish, “*Caja Costarricense de Seguro Social*”.

ventive care is simply selecting cause of death, which may not be in the patient's interest (Mangin et al. 2007; McConnell 2013).

Another consideration relating to the previous discussion is that there is evidence that access to healthcare services over the life course does impact life expectancy (Gu et al. 2009), so the evidence of no benefit from cases or from increasing access to one age group might be too small in scope or quick in judging the effects. In addition, the feeling of safety that comes from having access to preventive and primary care services should not be ignored given its contribution to self-assessed health measurements (Alós Almiñana and Bonet Deán 2008).

Regardless of mortality, after analyzing the cost of adopting proven preventive services in the United States (as defined by the United States Preventive Services Task Force) and the possible savings, Maciosek et al. 2010 found that while health benefits were important, the interventions were cost-neutral. However, the authors did estimate that increasing the use of these services to 90 percent would have resulted in savings of up to 3.7 billion (Maciosek et al. 2010). This leads us to the next part of the literature to examine, which is regarding barriers in access to healthcare. Removing barriers are part of mechanisms to reduce preventable emergency room visits (Kolstad and Kowalski 2012) and hospital admissions (Chin Chen et al. 2007; Dolton and Pathania 2016; Edes et al. 2014; Nakanishi et al. 1996).

One of the most important –and the barrier alluded to above– is health information, which weighs heavily in determining demand for medical care (Arrow 1963). Empirical evidence shows that awareness of preventive care services is a major factor in the probability of utilization (Chun Chen et al. 2013; Cheng et al. 2015; Hsieh and Shing-Jong 1997; Hsiou and Pylypchuk 2012; Parente et al. 2005).

Socioeconomic status is another factor that determines the use of preventive care, even after adjusting for insurance coverage, education, and socio-demographic characteristics, the working poor use these services less (Ross et al. 2007).

When focusing on the elderly, cost and geographical proximity some of the most common barriers (Buchmueller et al. 2006; Fitzpatrick et al. 2004; Horton and Johnson 2010). Indeed, reducing costs has very strong evidence in improving utilization of primary care services (Barbaresco et al. 2015; Chung et al. 2015; Ghislandi et al. 2015; John et al. 2013; Maxwell et al. 2011; Raissian and Lopoo 2015; Sabik and Bradley 2016; Scheil-Adlung and Bonan 2013; Shigeoka 2014; Wehby 2013).

Likewise less geographic distance to location is associated with greater conditional probability of using services (Billi et al. 2007; Carey et al. 2016; Lu and Slusky 2016; Nemet and Bailey 2000; Wong et al. 2016), but when it comes to relating this to improved health outcomes the results are not so simple.

Regarding hospitals, there is ample literature about mergers or closures improving efficiency of remaining providers (Capps et al. 2010; Lindrooth et al. 2003), even if health outcomes in relation to hospital proximity suggest longer distances increase fatalities (Bertoli and Grembi 2017), or are related to lower quality of care for segregated groups (Dimick et al. 2013).

As for primary care, Li et al. measured the effects of doctors on mortality rates finding that in-state physicians contribute more in lowering mortality than out-of-state physicians (Li 2014), though this focused on specific diseases. Another important study used a specific health outcome –glycemic control– to measure the effect of distance to primary care provider, finding that increased distance was related to poorer control (Strauss et al. 2006).

Considering then that preventive and primary are investments in health, the result of increasing their use would be a larger output of healthy time. It is this concept from Grossman’s model of health capital (Grossman 1999) that I will explore using Costa Rica’s health care system.

Current literature about this has limitations with regards to measuring this phenomenon, but by exploring it in the Costa Rican elderly population, we can make sure that there is a very high degree of patient information, a lifetime of access to care, very low-to-no costs faced by patients, and a relatively homogeneous population. This leaves as the main barrier for access geographical distance, thus creating an ideal situation to test the hypothesis that increasing access improves health outcomes.

Using the variation within a specific geographic area over time at an individual level, the controls capture changes in local prevalence and access to care. An assumption that could be problematic is regarding the degree of awareness needed for preventive care services to be used. In Costa Rica’s context of 86 percent of the population having insurance coverage; and the prolific message that since the 1950’s has ingrained as part of the national identity that health is a right guaranteed by the CCSS (Programa Estado de la Nacion 2017) makes assuming that people are aware that they have access to health care and who will provide it valid. As for those uninsured it is common knowledge that pregnant women, children and the elderly receive care regardless of insurance status

and that everyone belongs to a primary care health center (Consejo Nacional de la Persona Adulta Mayor and Universidad de Costa Rica 2007; Garcia 2004).

To differentiate the effect of preventive services from those of primary care, changes in risky behaviors (alcohol consumption), food consumption patterns and body mass index (measurements) are explored since the institution does not provide nutritional services, therefore primary care would not have an impact. Outcomes from blood and urine tests would represent a combination of primary and preventive services. Considering aging is inevitable, and the increased costs of medical care as we age (Harper 2014), it is particularly important to understand how increased availability of preventive and primary care are affecting elders' health.

The next section describes the background of the natural experiment, and the third and fourth sections discuss the data and empirical approach, respectively. The fifth section discusses the findings, and the final section concludes.

3.2 Background

3.2.1 Health areas

In the 1980's the CCSS, in an effort to achieve more efficient goal-oriented care, decided to establish a geographical division of the country tailored to healthcare needs. The objective was to change the entry point into the health system when it was not emergent care, and establish a basic level of healthcare that guaranteed equal access to high-quality primary care regardless of where within the country the individual lived.

This division roughly followed the administrative separation into counties, with differences stemming from the fact that health areas could not have more than 15,000 residents. The Areas would serve as a planning and evaluation unit that would ensure equal opportunities and were expected to provide equal results. For this to happen, the government gave resources and infrastructure so that equivalent primary care services were available within each Area.

Residents of an Area are restricted to using the primary care network within the Area where they live. Other healthcare services, such as clinics and hospitals, are accessed through referrals, and are not bound by geographical borders. To get a referral, the patient must go to her Area's primary care network. Emergency care is exempt from these referral rules. Despite criticism that

the system was not designed to cope with rapidly changing population composition, the basic rules of geographical empanelment hold today. Even so, borders have changed and some new Areas have been added and others have merged.

In order to cope with the changing population and landscape, the government introduced the concept of basic integrated health care teams (EBAIS) in 1994 (Pescet et al. 2017) in order to ensure that health needs were being met. The Teams were in charge of providing comprehensive primary health care to a target of 5,000 people (again where a person lives determines which Team they go to). The idea was, and continues to be, that the Teams are health centers embedded in the community that must meet their target population's primary healthcare needs, while continuously performing preventive care and promoting healthy lifestyles.

Each Team is composed of the same 5 providers: a doctor, a nurse, a medical clerk, a community health worker and a pharmacist. The health center's infrastructure and equipment, where each Team works, are almost identical: two examination rooms, procedures room, waiting area, administrative area, break room, pharmacy, meeting room/class room for about 20 people, and safe storage area. In order for a Team to be deployed, all the members must be available.

The Teams make up the network of primary care within an Area, and the number of them that are active has changed over time to cope with changes in demand. This means that even though initially a similar number of Teams existed in each Area, this has evolved over time. The system has been successful in guaranteeing basic healthcare to the point that virtually any person you ask knows they have a Team assigned to them, even if they have never actually sought medical care (Consejo Nacional de la Persona Adulta Mayor and Universidad de Costa Rica 2007; Rodriguez 2006).

3.2.2 Natural experiment

The change to this system that I use for this paper occurs in 2004. The CCSS decided that in order to further improve access to healthcare, and in particular due to the expansion and merging of metropolitan areas, the number of Teams would be increased (Rodriguez 2006).

The central administrative authorities decide to whether establish new Teams. They oversee delivering the necessary funding both for setting up and/or building the facilities and the selection/hiring process of the Team's members. The usual procedure consists of Areas requesting a

new Team and providing evidence to back up the request in the end-of-year report. This is then considered by the Medical Management Division (one of five divisions that constitutes the CCSS's central authorities), which decides whether to approve the request.

Regarding personnel, the last two decades have seen no shortage of primary care physicians, pharmacists or nurses, since twice a year the new graduates have access to the new postings the CCSS must fill. For doctors and nurses, the ratio of graduates-to-postings is two to one, and pharmacists four to one, so essential positions are filled (Garcia 2004). This happens due to a combination of compulsory laws that dictate that to become a licensed practitioner one must participate in the postings process, and the fact that these positions are highly coveted by new graduates, as they guarantee work for at least a year with benefits and a salary that exceed starting level jobs in the private market. Additionally, the start date for work is within a month and therefore requires no job searching.

The Team members are paid a fixed salary. There are no financial incentives for either the quantity or quality of care provided. Benefits refer to housing or a fixed salary increase based on relocation requirements or willingness to work in rural areas². This means that the usual delays for a Team being set up are the infrastructure construction to some degree, and the decision time by the central authorities to a greater degree. In 2004 a restructuring plan was unveiled with the goal to reduce the bureaucratic lag and increase efficiency in the healthcare system. The former was to be achieved by a freeze on hiring of non-medical personnel and updating information technologies, and the latter was to be achieved by increasing the number of Teams by 70³ over the following 3 years (starting in 2005).

The Team increase, which means an increased number of providers within an Area network, is the natural experiment that I examine. The restructuring plan does not include the procedure for selecting where the Teams were placed, it only specifies that a Special Report on Needs was requested by the CCSS's Medical Division from each Area. Based on previous site selection procedures, said report would be used to determine priorities and roll out funding accordingly.

²There have been proposals to develop a incentive system to reward good quality of care on an Team basis, so that the incentive goes to the Team however it has yet to be established. The result of this proposal was yearly goals that must be met, but not for an incentive but to avoid a reprimand for the Team leader (3 reprimands –which can also be caused by other misconducts- lead to an independent committee being summoned to evaluate termination of contract).

³There was no further indication or explanation about the number stated by the CCSS (Rodriguez 2006).

After checking the official CCSS yearly outcomes reports, only 31 new Teams began operating between 2005 and 2008 (see Table A3.1). There is no official statement explaining how the sites were chosen. This situation generated Areas that had increased Teams in their network, so their residents had increased access to preventive services and primary care. For some Areas, their networks didn't change, so their residents experienced no increased access. Since the Teams are the entry point to the system and provide the same care, all other providers (secondary and further levels) remained the same.

To corroborate if site selection was based on requests (justified by health needs or healthcare services utilization), I contacted the Areas to determine when they submitted the Special Needs Reports⁴. The provided dates then compared to the date of inauguration for the Team⁵ revealing that only nine sites had their Areas submit the report before the Team began functioning. However, four of these were within three months of the Team beginning to work, which makes it implausible that the report was received, considered, funding dispatched, and the local setup completed in that time frame. It is much more reasonable that the Team was deployed without the report having been considered.

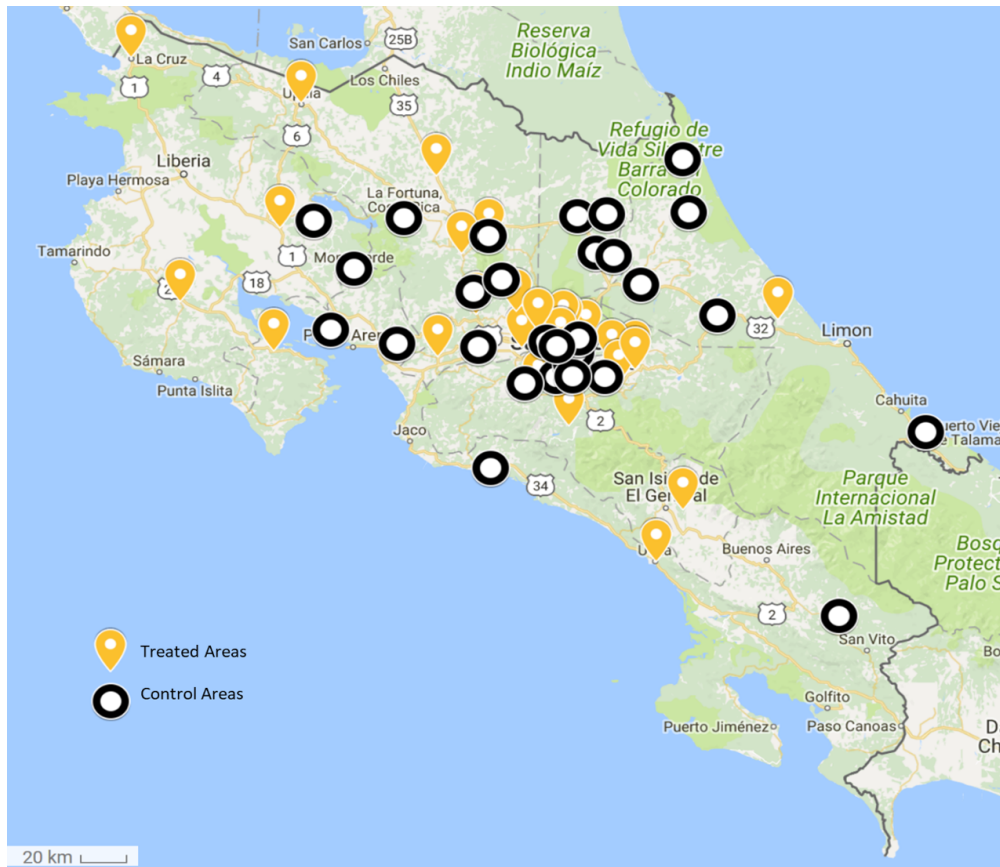
Since Teams increase the number of providers within an Area's network, the area will be the geographical unit where variation will be observed. The treated Areas are those where a new Team was established between 2005 and 2008, and the control ones are those who in that time did not receive a new Team. For both groups, Areas in which new clinics were established were excluded as these they distort preventive care and primary care services since they work as hubs where Teams are merged and additional services (beyond the basic ones a Team has) are provided. Usually besides the Teams, these clinics have specialists or adjunct services like dentists and optometrists, a small number of beds, imaging and laboratory services. This makes comparing them directly to a new Team not valid for this paper. The number of new clinics is very small; throughout the observed period only four started up.

This geographical distribution can be observed in Figure 3.1, which shows a map with the

⁴Out of 95 areas, I was able to contact 61 (via email or phone) and 42 responded with the dates of report submission. The 34 not reached was due to a lack of functioning contact information. Of those contacted, 10 didn't respond and 9 were unable to find the information requested.

⁵The dates for inauguration are a matter covered by Costa Rican media. The year when the Team starts to function comes from the CCSS yearly outcomes reports and then a search in the 3 largest newspapers (La Nacion, Diario Extra, La Republica) revealed the exact date when the site began to work.

Figure 3.1: Map of treated and control health areas



Notes: The treatment sites marked correspond to the new Team location. The control sites show the approximate center of the Area. Upon further data collection regarding geographical borders, a more precise location map is possible.

treatment and control areas marked. The treatment sites marked correspond to the new Team location. The control sites show the approximate center of an Area that did not receive a new Team. There is a higher concentration of sites in greater metropolitan areas⁶, which corresponds to the higher number of Areas located there as well as 50 percent of the country's population residing there.

3.3 Methods

My first step is to analyze whether the treatment and control Areas differed prior to the treatment. For this, I used data on sociodemographic characteristics from 2000 to 2004 from the Institute for Statistics and Census (INEC), as it covers the entire country and can be aggregated

⁶Known as the Great Metropolitan Area (GAM), it consists of 4 cities whose borders are now joint.

at an Area level. Using a t-test for the means of two unpaired samples with unequal variances, I compare the two groups of Areas to determine if there were differences prior to the treatment. A regression of sociodemographic characteristics on a treatment indicator variable was used as a complementary test of whether there were patterns in the sociodemographic characteristics of the Areas that could predict if they were treated or not.

I then examine whether healthcare utilization trended differently between the Areas over time. The data for this analysis comes from the CCSS's Statistical Yearbooks from 2002 to 2012. I conducted the same procedure using t-tests to compare pre-treatment values. Then, I ran time-series regressions for these variables while using an interaction term between year dummies and a treatment indicator. This will show any possible patterns in relation to the treatment moment which will be normalized to year 0 according to each Area.

To examine healthcare use and health outcomes at the individual level, I use the Costa Rican Longevity and Health Aging Study (CRELES), which followed elderly individuals over a 9-year period collecting data in three waves. This data set will be further discussed later, but weights are taken from their results and used to compensate for the age distribution and oversampling of the oldest participants.

My identifying assumption is that in the absence of treatment, the average change in the health outcomes would have been the same for both types of health areas, and so the difference-in-differences model is identified through time-series linear regressions in which the unit of observation is an individual (i) and in a specific health area (h). The difference-in-differences term would be $treat_{ih} * post_{ih}$, and defined by the interaction between a post policy indicator ($post$) that is 0 for the pre-policy period (before December 31st, 2004) and 1 for the post-policy period (from 2006 to 2012), and a treatment-control difference ($treat$) where being in a control area is 0 and in a treated area is 1.

Each of the regression models includes a different health outcome of interest (y_{ih}), individual fixed effects (δ_i), Area fixed effects (δ_h), and a residual error term ϵ_{ih} . Given the inclusion of fixed effects into the models, the $post$ indicator is dropped. This can be seen in the following equation,

$$y_{ih} = \beta_0 + \beta_1 treat_{ih} + \delta_h + \delta_i + \epsilon_{ih} \quad (1)$$

The β_1 coefficient is intended to estimate the effect of the treatment on the health outcome. I cluster standard errors at the area level (59 areas) to prevent complications with serial correlation, which is in line with the level of data being used throughout.

3.4 Data

3.4.1 Sociodemographic characteristics

As I briefly mentioned earlier, data on the sociodemographic situation of the Areas before and after the policy change comes from the Costa Rican Statistical Institute's (INEC) databases. The INEC is responsible for the national census data and collects cross-sectional data for the entire country over a large number of variables. Using aggregated data at the Area level, I determined variables for the population's age distribution, income levels, educational attainment, and human development scores⁷ from 2002 to 2011. These data allow me to explore whether treated and control areas were comparable prior to the policy.

3.4.2 Health care utilization

Using data from the CCSS's Statistical Yearbook from 2002 to 2012, I have data for how much healthcare was provided in each Area per capita. The measures focus on primary care utilization and on primary care provider's actions.

I observe the number of general consults, which refers to the number of visits to general physicians that took place per year in a specific Area. The number of first-time consults refers to the number of visits to general physicians where it was the patient's first visit to a primary care provider in the Area's network⁸.

I also observe the number of emergency room (ER) visits and valid (from a medical perspective) emergencies. The first is simply the number of visits to emergency rooms (of any health center in the country) according to the patient's home address (this determines which Area gets the visit counted as theirs). After every ER visit is resolved, it is classified by the discharge physician as a valid emergency or not. A "valid" qualifier indicates that care should have been provided in the ER

⁷As defined by the United Nations Development Program (UNDP).

⁸This means that they could be transfers (migration) or truly new to the Costa Rican Health System. This distinction however would not affect the results observed, since they are new to accessing the Area's network which is what the treatment is expected to affect.

as opposed to a different level of care. This different level does not mean primary care necessarily, it can also mean outpatient specialist services or tertiary care (e.g., clinics, regional or national hospitals). Using both these measures a third is derived: a ratio of “valid” ER visits to all visits.

Another recorded variable is the number of prescriptions filled per Area (limiting this to those prescribed by general physicians). Finally, the quantity of laboratory tests and X-rays performed were measured according to which Area’s network the prescriber belongs to. Since these tests are performed at a health center located in a different place from where the prescriber is located, they are measured based on which network the provider belongs to.

It is important to note that some of these tests are not interpreted by the general physician and a report must be complete by a corresponding specialist or other person, whose labor might not have changed regardless of an increase in possible prescribers. Since the count is of tests performed, if there is a lag due to this bottleneck, it would not be noticed with these measures. This means the number of tests observed could be less than that being demanded in an Area.

3.4.3 Survey of health aging and longevity

The CRELES is a longitudinal study and the source for the individual survey data (Rosero-Bixby et al. 2010, July 21). The data were collected using a comprehensive survey including blood and urine samples, body measurements and functional testing in three waves⁹ based on a national sample representing older adults (had to be at least 60 years of age at the time of the first interview) in Costa Rica, with an oversampling of older seniors¹⁰. Initially 9,600 elders were selected randomly from the database of the year 2000 Population Census. The sub-sampling included about 5,000 individuals from which 2,827 were located, agreed to participate and it was possible to follow them through all 3 waves. Although no-answer rate was high (43 percent)¹¹, one third of that was due to death of the participants (19 percent).

Geographically, the sample encompassed 60 health areas (from a total of 102 in the whole country), which cover 59 percent of the country. The survey provides weights that allow one to replicate the structure for sex, age, residence and education of the whole 2005 population of Costa

⁹The first wave began in November 2004, the second in 2006, and the last in 2009.

¹⁰The sampling fraction in varied between one percent for individuals born between 1941 and 1945, and 100 percent for the individuals born before 1905.

¹¹The participants lost were due to death (19 percent), inability to locate the participant (18 percent), change of residence (two percent), and declining to participate (four percent).

Rica born in 1945 or before.

The CRELES data provide a rich set of demographic and economic variables at an individual level that will serve as controls, including education level and living in an urban setting, income level, and spouse's characteristics. Importantly it identifies which Area the participant resides in which therefore identifies the network of providers that the individual uses to get healthcare.

Regarding health results, I observe measures for nutritional behaviors, mental health and functional outcomes, and indicators for chronic diseases. Body mass index (BMI), caloric intake (daily number of kilocalories consumed), protein intake (grams of protein consumed per day), alcohol intake (grams of alcohol consumed per day), and blood iron (micromoles per liter)¹². BMI and iron are observed directly, the first via measurements taken by the interviewer, and the second using a blood test. The rest of the measures are self-reported.

For mental health, a measure of the Mini-Mental State Examination¹³ for each individual (standardized for the score to be from 0 to 100) referred to as Cognitive State scale was observed. Also, a measure of depression (Depression Index) is used which corresponds to a standardized result of the Geriatric Depression Scale¹⁴ for each person.

Functional outcomes were measured with functional and general disability scores¹⁵ and a measure of the daily activities index¹⁶. Functional disability refers specifically to physical limitations, while general refers to a broad evaluation of any disability.

Health outcomes related to chronic diseases were measured using observations of systolic blood pressure levels (in millimeters of mercury, mmHg), glycated hemoglobin¹⁷ (measured as the percent of hemoglobin that is glycated) and cholesterol levels (milligrams per deciliter). If untreated, a high systolic blood pressure level can lead to heart attacks, strokes, and considerable cardiovascular risks (Basile and Bloch 2017). Glycated hemoglobin is fundamental for the control of diabetes mellitus,

¹²Iron is also needed for energy, good muscle and organ function. The source of all the body's iron is food.

¹³Used since 1975 and accepted as a standard measure of cognition is assess cognition function (Sheehan 2012). A score above 24 out of 30 is normal.

¹⁴Used since 1986 it specifically targets the elderly population and is the most reliable tool to evaluate depression for this age group. Scores from 0-4 are normal, and the maximum score is 15 (Conradsson et al. 2013).

¹⁵Refers to functional and general disability scores standardized to scores from 0 to 100.

¹⁶This refers to a list of Activities of Daily Living in use since the 1950's which revolve around everyday necessities from grooming to preparing meals to using phones or going to the bank.

¹⁷This is one of the most important markers for Diabetes Mellitus as it reflects how adequate glucose control has been in the last three months from when the measure is taken. The American Diabetes Association recommends levels below seven percent for most patients, as levels higher suggest increased mortality rates (McCulloch et al. 2017).

and is predictive of further morbidity. This measurement indicates whether a patient has controlled their blood glucose over the last three months, and is used as a target for treatment (McCulloch et al. 2017). Reducing either of these two measures is considered an improvement in health and a reduction of future risks.

Since unfortunately no further waves were conducted, for this outcome data there are only one or two measures before and after the treatment. Nonetheless, given the objective nature of the nutritional and chronic illness indicators, and considering the individual level of follow-up, the results provide insight into what is happening with their health. Even if more waves would have followed, considering the age of the participants it is entirely possible that new cohorts would have had to be the ones followed due to mortality given the life expectancy already reached.

3.5 Results

3.5.1 Areas before treatment

Sociodemographic characteristics Table 3.1 reports the Summary Statistics for sociodemographic variables. The geographic characteristics for the Areas reflect the fact that their design was based not on geographical distance but on population quantity, so their variability is large. The mean area covered by the Control and Treatment Areas is significantly different (based on the results of the t-test performed). However, when considering them according to the population they cover, the mean square kilometers *per capita* covered by control and treated Areas are not significantly different.

The mean percent of urban areas is also different for the groups, 54 percent for the Treated and 69 percent for the Control. When considering this in terms of the population living in each Area, the mean square kilometers of urban environment *per capita* for the control Areas is 0.007, and for treated Areas it is 0.009. These results fit with the fact that Areas with more rural zones would need to cover more area to have an equivalent number of people living in them than Areas with a more urban setting. This difference, treated Areas having more urbanization, is problematic as results could be confounded by the type of Area being observed (rural vs. urban) and not from the treatment.

The means for population in the Areas are 21,160 for Control and 21,440 for Treated, with no

Table 3.1: Summary statistics for health area sociodemographic characteristics prior to treatment

	<i>Control Areas</i>		<i>Treated Areas</i>		<i>t-test</i> ¹
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	
Population Density	180	605	301	915	-1.54
Population (1,000s)	21.26	7.10	21.44	9.94	-0.32
HDI ²	0.73	0.07	0.73	0.09	0.23
Monthly Income (log USD)	2.52	0.97	2.50	1.02	1.30
Population Over 65 (<i>per capita</i>)	0.06	0.03	0.06	0.02	1.10
Area (km ² <i>per capita</i>)	0.02	0.01	0.01	0.01	1.12
Urban (area <i>per capita</i>)	0.01	0.01	0.01	0.01	-2.02*
Observations	196		189		

* Significant at 5 percent level.

¹ Two sample t-test for means of control and treatment areas.

² HDI, Human Development Index.

Sources: Sociodemographic characteristics come from the National Institute of Statistics (INEC) from 2000 to 2004.

significant difference being reported. This matches with the notion that the Areas are to cover equivalent population. As for the population over age 65, the average for Control Areas is 6.4 percent and for Treated 6.1 percent without there being a significant difference.

The pattern shown from the geographical characteristics suggests that Control Areas are slanted towards rural areas and Treated Areas towards urban areas. The higher number of people in the Treated versus the Control would again fit with this assessment.

The average HDI is 0.73 for both groups of Areas. This index is important because it measures poverty, vulnerability, and infrastructure. Additionally, this measure has been widely used in developing countries to demonstrate trends of improvements and progress for the population's well-being, which is why it being not significantly different is relevant for determining whether the groups are comparable before the treatment.

Finally, the mean monthly income for both groups is not significantly different. These results support the possibility to compare the Treated and Control Areas, even if they are not perfectly equal, they do demonstrate levels of development, income and population over age 65 that are statistically equal. The regression using sociodemographic characteristics to predict treatment status (see Table A3.2) resulted in a model with a low capacity to explain this ($R = .05$), once again supportive of the notion that these characteristics are not related to the policy change. Yet, population over age 65, HDI and area covered, are significant in this model. So, the probability of an Area being classified as Treated decreases by 0.0077 if there is a one-point increase in the

percentage of the population over 65., decreases by 0.1343 if there is a one-point increase in the HDI, and decreases by 0.0002 if there is a one square kilometer increase in the area covered.

This suggests that increasing the population of interest (elders) decreases the chances that the Area is treated, but by ensuring area and individual effects are controlled this shouldn't cause further problems. The increase in HDI and the greater geographical area decreasing the chances of the Area being treated are in line with the previous observation that Treated areas have higher urbanization.

Health care utilization Summary statistics for the measures of healthcare utilization are in Table 3.2; and show that all the variables are not statistically different based on the results from the t-tests, except for the ratio of “valid” to all ER visits. The results are expressed in terms of the population in each Area.

Table 3.2: Summary statistics for health area health care utilization measures *per capita* prior to treatment

	<i>Control Areas</i>		<i>Treated Areas</i>		<i>t-test</i> ¹
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	
General Physician Consults	2.88	1.89	3.05	2.18	-1.95
First Time Patient Consults	1.07	0.79	1.16	0.87	-1.90
Emergency Room (ER) Visits	0.45	0.58	0.44	0.44	0.25
Valid ER Visits	0.25	0.32	0.28	0.29	-0.85
Ratio Valid to All ER Visits	0.59	0.20	0.66	0.13	-3.66*
General Physician Visits	2.95	9.00	4.57	8.64	-1.81
Laboratory Tests	6.46	19.39	9.76	20.53	-1.62
X-rays	4.64	14.10	7.15	13.84	-1.76
Observations	118		114		

Significance levels are shown as * for a $p < 0.05$.

¹ Two sample t-test for means of control and treatment areas.

Notes: Variables are *per capita* according to each Area. *Sources:* Health care utilization data comes from the CCSS's statistical yearbooks from 2002 to 2004.

The means for general physician consults show that in Control Areas 60,810 visits per year happened, and for Treated Areas 65,395 visits took place in the years before the treatment. Considering this paper's focus is on primary care, it is vital that the healthcare use of general practitioners be comparable. The number of first-time patients represent access to healthcare and on average was again similar for both groups, and roughly 38 percent of the number of general visits.

The number of emergency room visits was 9,485 for Control, and 9,325 for Treated Areas on

average; and the number for valid visits are 5,352 and 5,971 respectively. Emergency room visits are not affected by increasing providers from the supply side, but can be affected since improving preventive and primary care would be expected to reduce unnecessary trips to the ER.

The mean ratio of valid ER visits to all ER visits was 0.59 for Control Areas and 0.66 for Treated Areas. This means that slightly more than half the visits were classified as valid emergencies in Control Areas, and even more than that were valid for the Treated Areas. The means of the ratios were significantly different between the groups at a 95 percent confidence level, even though the numbers were not different. This difference is problematic for any further results given that it implies that Treated Areas have a higher number of “valid” visits relative to all visits prior to treatment. Since the expected result of increasing primary and preventive care would be to reduce unnecessary visits to the ER, this difference would suggest that there could be another factor influencing what is seen post-treatment.

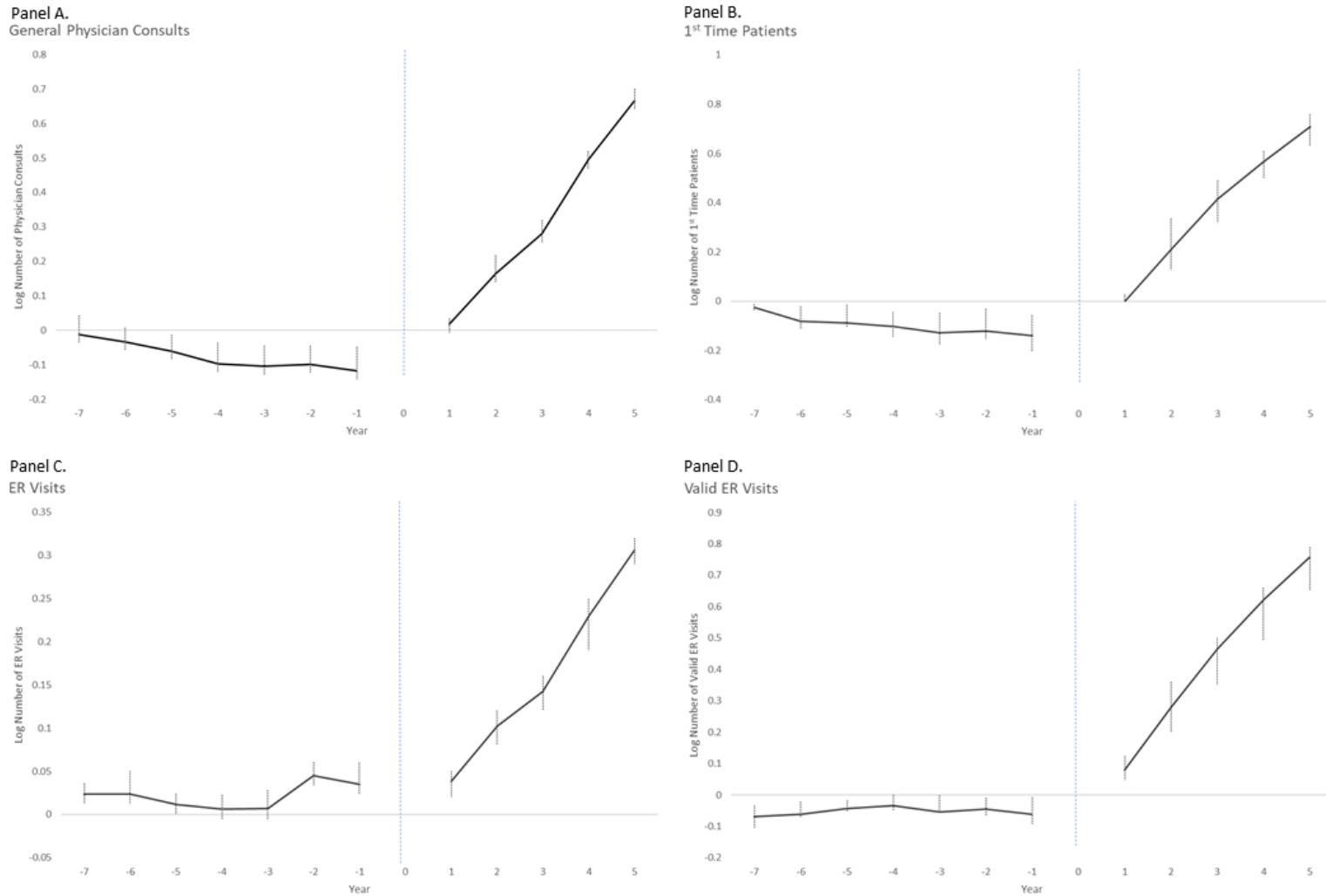
X-rays and laboratory tests are indicated almost twice as much as the number of prescriptions filled for both groups. For Treated Areas, the average number of X-rays is 153,278; of laboratory tests is 209,178; and of prescriptions is 98,041; for Control Areas, the averages are 98,163; 136,668; 62,312 respectively. Based on these results there is support that the baseline pre-treatment tests and prescriptions are comparable between Treatment and Control Areas.

A limitation for prescriptions that may cause this number to be underestimated is that for simpler prescriptions patients may choose not to wait and fill the prescription and just purchase the medication from the private market. This choice would have to do with the opportunity cost of waiting and unfortunately there is no way to measure this from the available data.

As was mentioned earlier, tests and imaging could also be under-counted because they represent when these procedures were completed, not ordered. Due to a possible discrepancy given an increased demand (from the increased Teams) but no increase in the supply of laboratories and imaging services, these numbers may not reflect the real increased demand.

The fact that the observed results are not significantly different supports the idea that the groups before treatment can be compared. Nonetheless, except for the number of ER visits, all the variables measured have higher means for the treated Areas. This is problematic for the identification strategy given that it could suggest a pattern where treated Areas had prior to treatment already a higher utilization of healthcare. It could be argued that the treatment was de-

Figure 3.2: Health care utilization over time for treated relative to control health areas



Notes: Regressions for healthcare utilization variables overtime including year dummies. General consults refer to number of patients who visited a general practitioner. First time patients are new patients coming to visit those physicians. Valid ER visits refer to ER visits that were classified as needing emergent care. Year represents when the treatment occurs for each health area (normalized at 0, represented by the dashed vertical line). The standard errors are shown by the vertical dotted lines perpendicular to the main line.

ployed to Areas that had higher demand (represented by the higher utilization), but the timing of the new provider doesn't match the report submitted by the Area that would have requested the treatment.

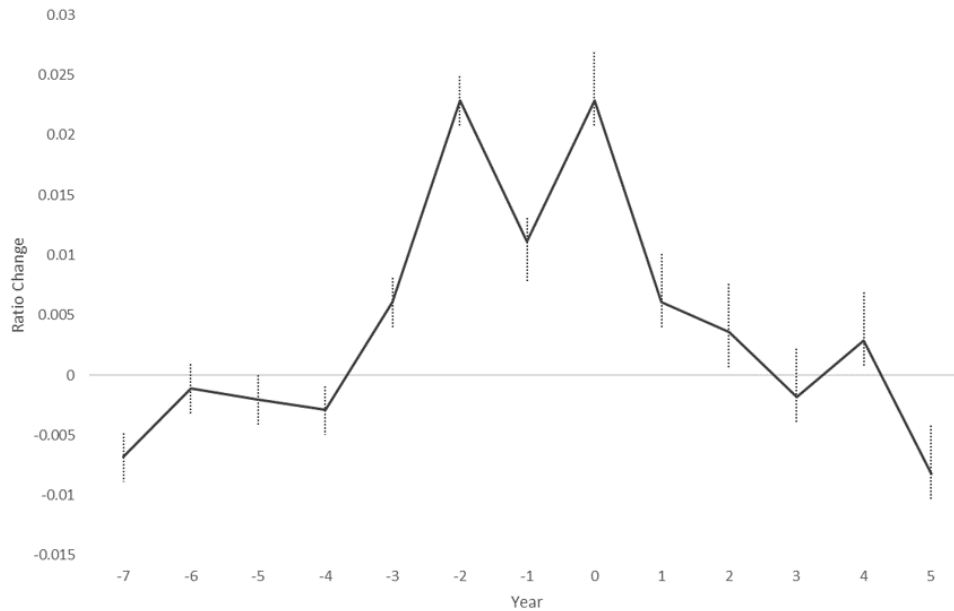
In Figure 3.2 I present results from regressions with the y-axis measuring the log number of the type of visit and the x-axis identifies time with the year of treatment normalized to 0. Here, I focus on the trends prior to the policy; later I discuss the impact of the policy in the post period. For general physicians we can see that one year before the treatment there was a decrease in the difference between the number of physicians in Treated and Control Areas of 0.1175. This means the difference between Treated and Control Areas decreased from the previous year by 889 visits in year -1. In the figures we can see that before the treatment, there was little change in the difference between groups of Areas' numbers of general physicians, first time patients, emergency room and valid emergency room visits.

ER visits show that prior to treatment Treated Areas had a higher number than Control Areas, and are distinct from general consults, first time patients and "valid" ER visits which all have a downward slope. This means that in the years before the event, the difference between Treated and Control Areas reduced each year from the previous one. Therefore, we know that Treated Areas have less visits than the Control Areas prior to treatment, and the difference does not include zero. This could suggest that Treatment Areas have too little healthcare utilization, and so them receiving Treatment could be deliberate. However, as was mentioned earlier, healthcare use means suggest the opposite that there is a pattern of higher use in Treated Areas.

Following this same concept, I analyzed prescriptions, laboratory tests and x-rays (Figure A3.1 in the Appendix). Again, the plotted line represents the difference between the change in number of the independent variable between Treated and Control Areas each year (with the year of treatment being 0). Visually it is demonstrated that before treatment the differences are close to 0, and don't show a noticeable trend or pattern. Prescriptions and laboratory tests actually include 0 in their pre-treatment period supporting the notion that the Areas are not different.

Figure 3.3 displays the results of regressing the ratio of "valid" ER visits to all ER visits overtime (using year dummies) without separating the Treatment and Control groups (since these groups' differences were significant before the treatment). The Treatment happens at year 0. From what is observed, 3 years prior to treatment the ratio's change rate increases and continues this pattern

Figure 3.3: Policy's effect on the ratio of valid over all Emergency Room (ER) visits



Notes: Valid ER visits refer to ER visits that were classified as needing emergent care. The ratio of Valid to all visits refers to how many of the Area's visits were classified as requiring treatment in the ER by the discharging physician. Year represents when the treatment occurs for each health area (normalized at 0, represented by the dashed vertical line). The standard errors are shown by the vertical dotted lines perpendicular to the main line.

until the treatment happens, separating itself from 0. However, observing the standard errors shows that even if between year -2 and 0 the coefficients are different from 0, the previous years have large standard errors.

Individual health parameters Table 3.3 reports the summary statistics for the surveyed individuals over the pre-treatment period for Control and Treatment Areas, with the last column showing the results of t-tests for the means of each group of Areas.

Panel A shows sociodemographic characteristics for the individuals with age, sex, educational attainment and income not showing significant differences. The average age among the surveyed elders is 76, and there is a higher percentage of female participants in both groups of Areas.

Living in an urban area does show a significant difference with the mean for Control Areas is that 74 percent live in an urban setting and in Treated Areas only 56 percent. This seems to contradict the earlier finding that Control Areas are more rural and larger (Table 3.1), however since this represents where individuals live it would be more specific to the real conditions that I

Table 3.3: Summary statistics for surveyed elders prior to treatment

	<i>Control Areas</i>			<i>Treated Areas</i>			<i>t-test</i> ¹
	<i>No.</i>	<i>Mean</i>	<i>SD</i>	<i>No.</i>	<i>Mean</i>	<i>SD</i>	
<i>Panel A. Sociodemographic Characteristics</i>							
Age	646	72.26	10.16	2108	76.43	10.26	-0.37
Sex	646	1.54	0.50	2108	1.54	0.50	-0.22
Years of education	646	4.68	4.34	2108	4.80	3.58	1.22
Urban	646	0.74	0.44	2108	0.56	0.50	8.35*
Total Monthly Income	644	4.11	2.72	2103	3.88	3.60	0.15
<i>Panel B. Nutritional Outcomes</i>							
BMI	614	25.93	5.31	2017	25.99	5.38	-0.25
Calorie Intake (kcal)	643	2,124	718	2103	2,085	720	1.20
Protein Intake (g)	643	69.22	24.09	2103	68.28	24.65	0.86
Alcohol Intake (g)	643	246	156	2103	246	140	-0.02
Blood Iron (mcg)	643	16.06	4.99	2103	16.00	5.19	0.27
<i>Panel C. Mental Health Outcomes</i>							
Cognitive State Scale	646	85.09	12.72	2105	84.01	12.69	1.88
Depression Index	505	0.08	0.27	1557	0.10	0.30	-1.49
<i>Panel D. Functional Outcomes</i>							
Functional Abilities Score	645	37.12	33.59	2104	40.86	34.35	-2.61*
General Disability Score	645	22.09	26.58	2104	24.59	27.10	-2.06*
Daily Life Activities Index	636	0.29	0.45	2035	0.34	0.47	-2.25*
<i>Panel E. Outcomes Related to Chronic Diseases</i>							
Systolic Blood Pressure (mmHg)	642	131	4.20	2086	135	7.81	-1.36
Glycated Hemoglobin (%)	601	7.32	0.70	1952	7.37	0.75	-1.33
Cholesterol Measure (mg)	643	195	7.64	2103	178	5.20	2.94*

Significance levels are shown as * for a $p < 0.05$.

¹ Two sample t-test for means of control and treatment areas.

Notes: Data from the first and/or second waves of CRELES (according to if they were previous to treatment in their Area of residence).

am observing. Regardless this applies to where the individuals surveyed live not the aggregate conditions of the Area.

In Panel B, nutritional outcomes show that BMI's average is 25.93 and 25.99 for Control and Treated Areas respectively, which puts both at a classification of overweight. Calorie intake, protein intake, alcohol intake –all self-reported-, don't show differences before the treatment between the groups. As for blood iron –measured via a blood test-, the average is 16 mcg for both groups of areas.

Panel C shows the results for individuals' mental health outcomes. The Cognitive State Scale and Depression Index both show no significant differences between the Treated and Control. The

first one shows a slight worsening in mental state, and the latter an improvement close to 0. In Panel D, functional outcomes are shown, and all are significantly different between the groups. When looked at in points, the mean Functional Abilities Scores only differ by 3.74 and the General Disability Score by 2.50 points from 100, and considering the number of parameters that make up the scores, this means that anywhere between 2 and 4 abilities make up the difference. These three outcomes represent a worsening of the elders' health. None of the outcomes in these two Panels are significant.

Outcomes related to chronic diseases are presented in Panel D. They are systolic blood pressure where the average is 131 and 135 mmHg for Control Areas and Treated Areas respectively. Glycated hemoglobin's average percentage is 7.32 for Control Areas and 7.37 for Treated Areas. Both measures are objectively measured and are not significantly different. The final measure is for cholesterol and it is 195 and 178 mg for Control and Treatment Areas. Cholesterol measurements show a small statistically significant decrease. In general, these results support the notion that the groups are comparable (random treatment distribution).

3.5.2 Areas after treatment

The graphs plotted in Figure 3.2 show that after treatment (year 0), the difference between the Treatment and Control Areas across all the variables increases each year and separates itself from 0. In fact, even considering the standard errors, the Treatment and Control groups are no longer the same. For instance, after the treatment the difference between the groups increases by 21 percent in year 2 for the number of 1st time patients. This translates into the difference between groups increasing by 1,234 first time patients from the second to third year post treatment.

The increase in the difference happens in all the variables presented here showing that healthcare utilization changed after the treatment occurred, and that the number of visits (quantity of use) in Treated Areas exceeded that of Control Areas, with the results being significant at a five percent level.

Regarding Figure A3.1, the same pattern is observed for the number of prescriptions, laboratory tests and x-rays. For both the figures however, it should be noted that the errors widen towards the final years observed. While the coefficients remain distinct from 0, this opens the possibility that the growth is not as sustained as it appears. It should also be noted that ER visits increase less

than the other variables, the highest change for them being 30.6 percent, while for general consults it is 0.666, for first time patients 0.710, and for valid ER visits 0.757. It is interesting that valid visits increased just as fast as the other variables, but no so all visits.

The large changes translate to treated Areas having significantly higher increases over control Areas overtime. This is consistent to a larger network of providers allowing for higher access and therefore use by the population. Additionally, as lag happens it can be expected that use increases further. The slopes are generally constant for all variables; this means that the increase in difference between the number of visits in Treated minus Control Areas is similar each year. For instance, for general physician consults the yearly increase in difference post-treatment is 1,018 visits during the first year, and 1,325 the third year. Afterwards, the increase is larger, reaching 1,947 visits during the final year observed. This suggests that the difference between the utilization levels between Treated and Control Areas is increasingly expanding.

Taking the final year's increase, this translates into an additional 5 visits per day for the treated network versus the control network. Considering that the treatment consists in adding a Team, this number is plausible. A similar approach with ER visits shows that the differences increase yearly between the Areas by 1,039 to 1,358 visits over all the post-period. This means that the final year the additional visits are 4 per day for the treated over the control networks. When looking at laboratory tests, the final year shows an additional 6 tests indicated in the treated network over the control ones.

Returning to Figure 3.3, it is observed that the change in the ratio appears to return to 0 two years after the treatment. However, it should be noted that these results have large standard errors.

3.5.3 Individual level health outcomes

In Table 3.4 the results from running difference-in-differences models for the health indicators with individual fixed effects. Nutritional outcomes are presented in the first 5 columns. First, there is a small increase in BMI by 0.291 points in the treated areas', this difference is significant at an five percent level. Considering the mean BMI for treated Areas is 25.99, the mean increase would result in a BMI of 26.28, which does not change the BMI from being classified as overweight. Also, compared to the control Area's mean that is 25.93, the difference is only 0.35 which is very small.

The CCSS does not cover nutrition services but the Teams are required to conduct routing

Table 3.4: Effects on health outcomes estimated from differences-in-differences model

	Time	Treated	DiD	Individual FE	Obs
<i>Panel A. Nutritional Outcomes</i>					
BMI	-0.1222 (0.3318)	0.0676 (0.2451)	0.2905* (0.0727)	X	4,367
Calorie Intake (kcal)	-29.0396 (51.4907)	-39.3644 (32.3822)	68.6766 (58.1080)	X	4,550
Protein Intake (g)	-0.5789 (1.8373)	-0.9789 (1.0979)	1.8668 (2.0521)	X	4,550
Alcohol Intake (g)	1.2557 (1.5861)	-0.7790* (0.3218)	-0.7796 (1.6033)	X	4,550
Blood Iron Intake (mcg)	-0.6280 (0.3397)	-0.0657 (0.2272)	0.5077 (0.3871)	X	4,550
<i>Panel B. Mental Health Outcomes</i>					
Cognitive State Scale	0.5455 (0.8353)	-1.0852 (0.5720)	-0.2669 (0.9501)	X	4,563
Depression Index	-0.0128 (0.0181)	0.0222 (0.0141)	0.0049 (0.0215)	X	3,435
<i>Panel C. Functional Outcomes</i>					
Functional Disability Score	2.8479 (2.1228)	4.0337* (1.5222)	-3.5528 (2.4238)	X	4,557
General Disability Score	2.1289 (1.6628)	2.5218* (1.2024)	-2.2587 (1.9002)	X	4,557
Daily Life Activities Index	0.0910* (0.0299)	0.0481* (0.0208)	-0.0633 (0.0342)	X	4,457
<i>Panel D. Chronic Diseases Related Outcomes</i>					
Systolic Blood Pressure (mmHg)	-0.2210* (0.0548)	0.0664 (0.0475)	-0.4733* (0.0632)	X	4,521
Glycated Hemoglobin (%)	-0.0209 (0.0443)	0.0462 (0.0334)	0.0813 (0.0513)	X	4,282
Cholesterol (mg)	27.6206* (11.9211)	6.0388 (6.8915)	11.9748* (5.3450)	X	4,550

Significance: $p < 0.05$ shown as *. *DiD*, difference-in-differences; *Obs*, number of observations; *FE*, fixed effects. Standard errors in parentheses.

Notes: Regression of treatment, timing, their interaction and sociodemographic controls on each health outcome.

health promotion education regarding adequate nutritional behaviors. Therefore, nutrition services are affected by preventive services affecting people's actions, not by direct primary care. For caloric intake there is an increase of 69 kilocalories in the treated areas. This change is not very relevant considering this is less than an apple a day would have. More so, considering that the means for the groups are around 2,100, less than 100 kilocalories per day will most likely not change health outcomes.

There is an increase in protein intake by 1.87 grams daily and a decrease of 0.78 grams of

alcohol daily for the treated areas. Both changes are interesting and would support the idea that if behavioral changes are occurring they are in a direction that would help elder's well-being. Neither of these variables are significant at a five percent level.

Regarding levels of blood iron, the model in column 5 shows an increase by 0.51 micromoles per liter. Considering that these levels are measured objectively by blood tests, it is interesting to note that there is a change in a direction supporting increased food consumption by the surveyed elders in the Treated Areas, consistent with the observed changes in BMI and calorie intake.

For the mental health outcomes, there is no change in the index representing the Geriatric Depression Scale (0.00) and a worsening in the Cognitive State Scale by 0.27 points (out of a scale of 0 to 100). Considering the regular aging expected from this population it is not unexpected to see deterioration. On the other hand, it would have been expected that having more contact with health services would decrease depression or improve mental health. Again, neither of these measures are significant.

All three variables measuring disability showed a decrease in the scores and deterioration of the index. The magnitudes of the changes are very small considering the scores come from a 0 to 100 scale, and for the index from 0-1. The decrease in score for Functional Disability is 3.55 points in Treated Areas; for General Disability it is a decrease of 2.26 points; and for the Daily Life Activities Index the decrease is by 0.06. None of these are significant, and as was described earlier do not represent a large change in the abilities elders can perform.

Finally, in the last three columns the results for the models for systolic blood pressure, glycated hemoglobin and cholesterol are shown. The measures for systolic blood pressure showed a decrease of 0.47 mmHg in the treated areas. Glycated hemoglobin percentages decreased by 0.08 percent in treated areas. These two results are particularly interesting considering that improvements in both variables are important results for improving health, for two of the most common chronic diseases, hypertension and diabetes mellitus. The coefficient for blood pressure are significant at a five percent level, but not so for glycated hemoglobin.

Even though the change in systolic blood pressure is small, it is in the direction of lowering levels which is in the direction of improving health outcomes. Glycated hemoglobin is particularly interesting considering that making it decrease is difficult, and the difference between a normal level (below 5.7) and diabetes (6.4) is less than 1 point. Additionally, because it represents the

glycemic control of over the last 3 months, it objectively measures food intake and glucose levels for the person over time, even if the means for both groups would not change their classification given their means being 7.32 and 7.37 for control and treated areas respectively.

Cholesterol means for the groups were 195 and 178 mg for control and treated areas which makes then normal by therapeutic standards, however the means are significantly different making any further results questionable. Still, the difference-in-differences coefficient for this measure shows a significant increase of 11.98 mg for the treated areas. This change would still not place the level out of normal range. Also, it would be consistent with the BMI increase reported earlier.

3.6 Discussion

This paper evaluates the impact of increased healthcare providers on the elderly population's health. Regarding the treated and control Area's healthcare utilization patterns prior to treatment, I find no distinct difference between the groups. With regards to their baseline sociodemographic characteristics, aggregate data shows that Control Areas are more rural and cover a larger surface area, but when considering population and people over age 65, the Areas are the same. Furthermore, the HDL is the same for both groups.

In previous studies a barrier to measuring the effect of increasing access to healthcare is the fact that said increase does not guarantee utilization which is necessary for a people's health to be impacted (Chun Chen et al. 2013; Cheng et al. 2015; Hsieh and Shing-Jong 1997; Hsiou and Pylypchuk 2012; Parente et al. 2005). I find that, after the increase in the number of providers in an Area's healthcare network, utilization clearly changed. It increased in treated Areas with respect to control Areas significantly in every measure analyzed. This means that not only were services available, but they were being used.

Additionally, and in accordance to previous literature (Dolton and Pathania 2016; Kolstad and Kowalski 2012), emergency care visits considered valid increased after treatment confirming the notion that unnecessary emergency room visits decreased when primary care is increased, thus making more efficient use of resources.

Published literature has focused on identifying the effect of one service when regarding preventive care and of measuring specific outcomes prevented, finding conflicting evidence ranging from no effect in elder's health to an effect that is overshadowed by other complications (Cheng et al. 2015;

Eric De Jonge et al. 2014; Gandjour 2009; Irvine et al. 2010; Mangin et al. 2007; McConnell 2013; Müller et al. 2015; Pihl et al. 2011; Shigeoka 2014). I find some evidence that there are changes happening in health outcomes, changes in both directions for health, improvement and worsening. Either way, the results are very small in magnitude, and considering the large investment required this could support the argument that any gain is not cost-effective (Maciosek et al. 2010).

Self-reported measures for nutritional outcomes and standardized –but still dependent on self-assessment- outcomes such as mental health and disability measures are more difficult to find a pattern with. There appears to be evidence that disability and mental health are responding to the aging process, but worsen slightly. As for nutrition outcomes, their effects are too small in magnitude to be relevant health wise. BMI the nutrition outcome that is not self-reported, but directly measured, is significant. However, it changes in a direction that is detrimental to health, even if the magnitude of the change makes it not be relevant clinically.

I find that glycated hemoglobin and systolic blood pressure change in a direction that improves health. The magnitude of the change is not large enough to change the values from abnormal to normal for glycated hemoglobin and blood pressure, but the reduction happens (even if only significant for blood pressure). This in of itself is relevant as both values are directly related to ample morbidities and an increased mortality (Basile and Bloch 2017; McCulloch et al. 2017).

In sum, I find that objective health outcomes support the notion that increasing healthcare access improves health given an increase in healthcare services utilization. However, there is an important caveat, the survey data only allows for one or two observations before or after the treatment. So, this only gives a glimpse of what being exposed to the treatment for one to three years at the most cause on health outcomes. This limitation stems from the way the survey data was collected and cannot be remedied. Even so, the findings certainly show how a different setup to measure the effects on health more objectively should be considered when exploring future avenues of research regarding the impact of preventive and primary care.

Regarding the policy itself, since the goal within the system was to improve coverage and access by expanding the network, I find evidence that this was achieved in the clear increase of utilization. Of course, a targeted approach in distributing the Teams based on actual conditions would maximize any health effects that could be observed. Regardless it would seem that given the current system increasing supply is shifting consumption, without any further investments begin

necessary (such as advertising, education, or promotion).

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Appendix

Table A3.1: Costa Rican health areas, their treatment status and timing

<i>Health Area</i>	<i>Treatment Status</i>	<i>Timing</i>	<i>Report Submission Date</i>
Alfaro Ruiz	No		
Abangares	No		Dec 05
Acosta	Yes	Dec 06	Jan 07
Aguas Zarcas	Yes	Jan 06	
Alajuela Central	No		Jan 06
Alajuela Norte	No		
Alajuela Oeste	No		Feb 06
Alajuela Sur	Yes	Dec 06	
Alajuelita	Yes	Feb 06	
Aserrí	No		Jun 05
Atenas	No		
Bagaces	No		
Barranca	No		Sep 05
Belen-Flores	No		
Cañas	Yes	May 06	Apr 06
Cariari	No		
Carrillo	No		
Cartago	No		Jan 06
Catedral Noreste	No		
Chacarita	No		
Chomes Monteverde	No		
Ciudad Quesada	Yes	Jan 06	Nov 05
Colorado	No		Aug 05
Coronado	Yes	Jun 06	Feb 07
Corralillo	No		
Corredores	No		
Coto Brus	No		Sep 06
Curridabat	No		
Desamparados	Yes	May 06	Jun 06
Desamparados 3	Yes	Jun 06	
El Guarco	No		Mar 06
Esparza	No		
Florencia	No		Mar 06
Garabito	Yes	Dec 06	Jun 05
Goicochea	No		
Golfoito	No		
Grecia	No		
Guácimo	No		
Guapiles	No		
Guatuso	No		
Hatillo Dr. Solón Nuñez	No		Sep 07
Heredia-Cubujuquí	No		Oct 05
Heredia-Virilla	No		
Hojancha	No		Nov 05
Horquetas-Rio Frío	No		
Hospital Los Chiles	Exclude		
Hospital San Carlos	Exclude		
Hospital San Fco. Asís	Exclude		
La Cruz	Yes	Jan 07	Aug 06
La Union	No		
Liberia	No		Nov 06
Limón	No		Oct 05
Los Chiles	No		
Los Chiles 2	No		Sep 06
Los Santos	No		

Continued in the next page.

Table A3.1 Continued: Costa Rican health areas, their treatment status and timing

<i>Health Area</i>	<i>Treatment Status</i>	<i>Timing</i>	<i>Report Submission Date</i>
Mata Redonda	Yes	Mar 06	Dec 05
Matina	Yes	Sep 06	
Montes de Oro	Yes	May 07	
Mora-Palmichal	No		Dec 06
Moravia	No		
Nandayure	No		Sep 07
Naranjo	Yes	Jan 07	
Nicoya	Yes	Feb 06	Aug 06
Oreamuno-Pacayas-Tierra Blanca	Yes	Jan 07	Mar 07
Orotina-San Mateo	No		
Osa	Yes	Feb 07	Apr 07
Palmares	No		
Paraíso-Cervantes	Yes	Jun 06	
Parrita	No		Nov 05
Peninsular	Yes	Feb 07	
Perez Zeledón	Yes	Oct 06	Sep 06
Pital	No		Mar 06
Poas	Yes	May 06	Sep 06
Puerto Viejo-Sarapiquí	No		
Puriscal-Turrubares	No		
Quepos	No		Aug 05
San Isidro	Yes	Nov 06	
San Juan-San Diego-Concepción	Yes	Feb 07	Dec 06
San Rafael de Heredia	No		
San Rafael de Puntarenas	No		
Santa Barbara	Yes	Jul 06	Mar 06
Santa Cruz	No		
Santa Rosa	Yes	Mar 07	
Santo Domingo	No		Oct 06
Siquirres	No		
Talamanca	No		Nov 05
Tilarán	No		Dec 06
Turrialba-Jimenez	No		
Upala	Yes	Apr 06	Jan 06
Valle La Estrella	Exclude		
Valverde Vega	No		Feb 06
Zapote Catedral	No		
<i>No. of Areas</i>			
Excluded	4		
Treated	27		
Total	93		

Notes: List of Health Areas and treatment status from the Costa Rican Social Security System from 2005 to 2008. Treatment timing confirmed using Costa Rican newspapers and/or health center websites. Excluded areas are due to the opening of other types of health centers that would confound the effect of a single care center. Report submission date comes from directly asking the Areas for the date of submitting the Special Needs Reports.

Table A3.2: Results from predicting treatment status using health area sociodemographic characteristics

<i>Model Statistics</i>			
Multiple R	0.231		
R ²	0.053		
Adj. R ²	0.045		
Std. Error	0.490		
Observations	676		
<i>Parameter</i>	<i>Coefficients</i>	<i>Std. Error</i>	<i>p-value</i>
Intercept	0.759	0.050	0.000
Population	0.000	0.000	0.097
Population Density	0.000	0.000	0.057
Urbanization Percentage	-0.000	0.001	0.759
Percent Over 65	-0.008*	0.002	0.002
HDI	-0.134*	0.059	0.023
Area (km ²)	-0.000*	0.000	0.004

Adj., adjusted; *Std.*, standard; *HDI*, Human Development Index.

Notes: List of Health Areas and treatment status from the Costa Rican Social Security System from 2005 to 2008. Treatment timing confirmed using Costa Rican newspapers and/or health center websites. Excluded areas are due to the opening of other types of health centers that would confound the effect of a single care center. Report submission date comes from directly asking the Areas for the date of submitting the Special Needs Reports.

Table A3.3: Summary statistics for health area sociodemographic characteristics during treatment

	<i>Control Areas</i>		<i>Treated Areas</i>		<i>t-test</i> ¹
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	
Population (1,000s)	17.65	1.46	15.88	2.77	1.69
Population Density	77.64	73.29	73.81	41.53	0.24
HDI ²	0.72	0.09	0.73	0.09	-0.20
Monthly Income (log USD)	2.33	1.04	2.42	1.19	0.99
Population Over 65 (<i>per capita</i>)	0.06	0.01	0.05	0.00	1.73
Area (square km <i>per capita</i>)	0.02	0.00	0.02	0.01	-1.23
Urban (area <i>per capita</i>)	0.01	0.01	0.01	0.01	-1.87
Observations	28		27		

Significance levels are shown as * for a $p < 0.05$.

¹ Two sample t-test for means of control and treatment areas.

² HDI, Human Development Index.

Sources: Sociodemographic characteristics come from the National Institute of Statistics (INEC) from 2005.

Table A3.4: Summary statistics for health area measures of health care utilization *per capita* during treatment

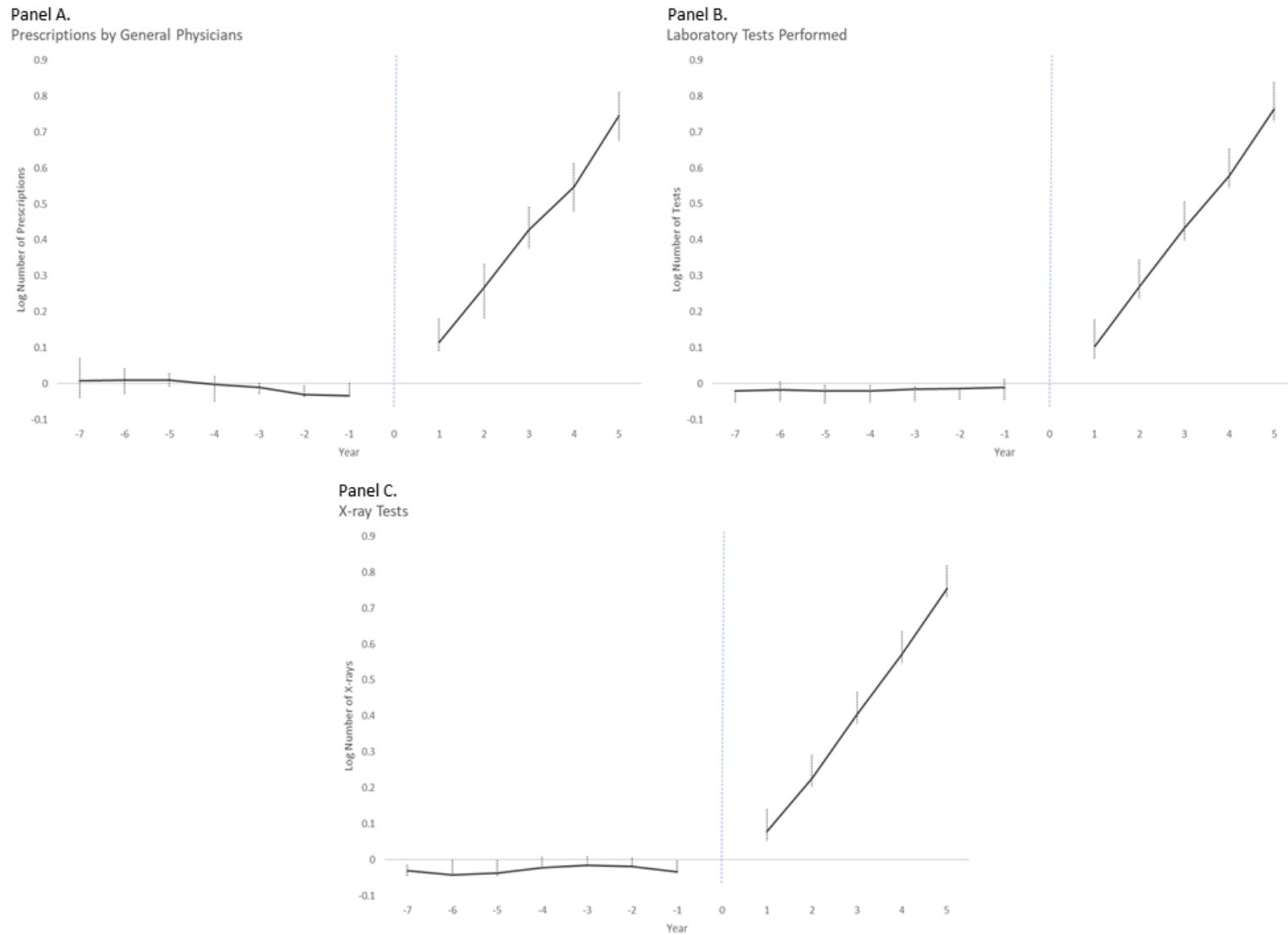
	<i>Control Areas</i>		<i>Treated Areas</i>		<i>t-test</i> ¹
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	
General Physician Consults	3.11	1.45	3.14	2.18	-1.95
First Time Patient Consults	1.14	0.59	1.35	0.87	-1.90
Emergency Room (ER) Visits	0.44	0.42	0.68	0.44	0.25
Valid ER Visits	0.26	0.24	0.44	0.29	-0.85
Ratio Valid to All ER Visits	0.61	0.26	0.66	0.13	-3.66*
General Physician Visits	2.59	5.62	6.96	12.29	-1.71
Laboratory Tests	5.85	13.18	15.27	31.38	-1.46
X-rays	3.78	7.78	10.11	17.65	-1.73
Observations	28		27		

Significance levels are shown as * for a $p < 0.05$.

¹ Two sample t-test for means of control and treatment areas.

Notes: Variables are *per capita* according to each Area. *Sources:* Health care utilization data comes from the CCSS's statistical yearbooks from 2002 to 2004.

Figure A3.1: Additional health care utilization measures over time for treated relative to control health areas



Notes: Regressions for healthcare utilization variables overtime including year dummies. Prescriptions, laboratory tests and x-rays refer to the number of prescriptions, tests and x-rays indicated to patients by general practitioners. Year represents when the treatment occurs for each health area (normalized at 0, represented by the dashed vertical line). The standard errors are shown by the vertical dotted lines perpendicular to the main line.