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Health Policy Analysis

Illustrating Potential Efficiency Gains from Using Cost-Effectiveness Evidence to Reallocate Medicare Expenditures

James D. Chambers, MPharm, MSc, PhD^{1,2,*}, Joanne Lord, MSc, PhD¹, Joshua T. Cohen, PhD², Peter J. Neumann, ScD², Martin J. Buxton, BA¹

¹Health Economics Research Group, Brunel University, Uxbridge, UK; ²Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, Boston, MA, USA

ABSTRACT

Objectives: The Centers for Medicare & Medicaid Services does not explicitly use cost-effectiveness information in national coverage determinations. The objective of this study was to illustrate potential efficiency gains from reallocating Medicare expenditures by using cost-effectiveness information, and the consequences for health gains among Medicare beneficiaries. **Methods:** We included national coverage determinations from 1999 through 2007. Estimates of cost-effectiveness were identified through a literature review. For coverage decisions with an associated cost-effectiveness estimate, we estimated utilization and size of the “unserved” eligible population by using a Medicare claims database (2007) and diagnostic and reimbursement codes. Technology costs originated from the cost-effectiveness literature or were estimated by using reimbursement codes. We illustrated potential aggregate health gains from increasing utilization of dominant interventions (i.e., cost saving and health increasing) and from reallocating expenditures by decreasing investment in cost-ineffective interventions and increasing investment in relatively cost-effective interventions. **Results:** Complete information

was available for 36 interventions. Increasing investment in dominant interventions alone led to an increase of 270,000 quality-adjusted life-years (QALYs) and savings of \$12.9 billion. Reallocation of a broader array of interventions yielded an additional 1.8 million QALYs, approximately 0.17 QALYs per affected Medicare beneficiary. Compared with the distribution of resources prior to reallocation, following reallocation a greater proportion was directed to oncology, diagnostic imaging/tests, and the most prevalent diseases. A smaller proportion of resources went to cardiology, treatments (including drugs, surgeries, and medical devices), as opposed to nontreatments such as preventive services, and the least prevalent diseases. **Conclusions:** Using cost-effectiveness information has the potential to increase the aggregate health of Medicare beneficiaries while maintaining existing spending levels. **Keywords:** cost-effectiveness, disinvestment, Medicare, resource allocation.

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Introduction

It is well documented that US health care spending growth is unsustainable [1,2]. Compared with other developed countries, return on health care spending in the United States is poor, with a significant proportion of the American population lacking health insurance and the health care system performing poorly across key metrics such as life expectancy and infant mortality [3]. In many countries, cost-effectiveness analysis is used to prioritize scarce health care resources among competing interventions. Despite the immediate need to increase the value of health care spending, however, decision makers in the United States have resisted this approach [4].

More than 46 million Americans, including those 65 years and older and those with certain disabilities, receive health insurance through Medicare. The Centers for Medicare & Medicaid Services (CMS) does not operate with a fixed budget, and program cost has increased annually at a relatively rapid rate. The program's

current annual cost is estimated at upwards of \$600 billion, approximately 3.5% of the gross domestic product, and may reach \$1 trillion by 2020 [5]. Research indicates that approximately 30% of Medicare spending may be inappropriate or unnecessary [6–10].

The CMS issues approximately 10 to 15 national coverage determinations (NCDs) each year for interventions deemed to have a significant impact on the Medicare program [11]. With respect to cost-effectiveness evidence, CMS states that it “is not a factor CMS considers in making NCDs” [12]. While research suggests that coverage decisions made in NCDs are broadly consistent with cost-effectiveness evidence—that is, technologies associated with favorable cost-effectiveness estimates tend to be covered—a number of covered interventions are not cost-effective by traditional standards, with incremental cost-effectiveness ratios (ICERs) greater than \$250k per quality-adjusted life-year (QALY) gained [13]. Thus, efficiency gains are possible through disinvestments in cost-ineffective interventions and investments in relatively cost-effective interventions.

* Address correspondence to: James D. Chambers, Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, 800 Washington St #63, Boston, MA 02111, USA.

E-mail: jchambers@tuftsmedicalcenter.org.

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The objective of this research was to estimate potential aggregate health gains from increasing utilization of dominant (i.e., cost-saving and health increasing) interventions, and from a hypothetical reallocation of expenditures among interventions subject to NCDs, through the use of a cost-effectiveness decision rule. We also sought to estimate the impact of reallocation on the distribution of expenditures across diseases and types of intervention. We acknowledge that this is an illustrative exercise, but we believe that it is important as the first of its kind to demonstrate the consequences of using cost-effectiveness information to inform resource allocation. We highlight the research challenges, particularly with regards to data limitations.

Methods

National Coverage Determinations

We created a database of NCDs issued by the CMS from 1999 through 2007. We excluded incomplete NCDs or those pertaining to minor coding or language changes, as well as those pertaining to off-label treatments, coverage in clinical trials, coverage with evidence development policies, or treatment facilities. Frequently, NCDs include multiple coverage decisions, often for different interventions or patient populations. Furthermore, on occasion coverage is permitted only for patient subgroups that meet certain conditions and restrictions. An entry was made in the database for each separate coverage decision implied within each NCD. We have previously used this database to evaluate factors that predict positive CMS coverage decisions for interventions [14].

Reallocation of Expenditures

To facilitate our analysis, we limited our sample to NCDs in which we could find available estimates of: cost-effectiveness; incremental cost; cost of intervention and comparator in the first year of use; incremental health gain; number of Medicare beneficiaries currently receiving the intervention; and the size of the unserved eligible population, that is, Medicare beneficiaries who were eligible for the intervention but did not receive it. Each parameter will be discussed further.

Cost-Effectiveness

On occasion we were able to identify the cost-effectiveness estimate from CMS's decision memo, which comprises the agency's public communication about the NCD, including the evidence featured in its review. In the majority of the cases, we identified cost-effectiveness evidence through a literature search by using the PubMed database, the Tufts Medical Center Cost-Effectiveness Analysis Registry, the Health Economic Evaluations Database, and the National Health Service Economic Evaluation Database [15–18]. The findings of the literature search have been published elsewhere [13]. Most frequently, the reported ICER was in the form of a cost per QALY gained. On occasion, the ICER was presented in the form of a cost per life-year (LY) gained, and we adjusted incremental survival gain with a utility weight for Americans aged 65 to 69 years to create an estimate of incremental QALY gained [19]. This adjustment may underestimate the incremental QALY gain as only the years of life extended by the treatment (incremental LYs gained) are accounted for when adjusting for quality of life, not prior years of treatment during which patient quality of life may have been improved. In sensitivity analyses, we included cost-effectiveness studies that estimated the intervention to be “dominant”—that is, more effective and less costly than the comparator—even if the study reported health outcome using disease-specific units, for example, tumors

detected, rather than QALYs or LYs. The majority of cost-effectiveness studies were performed in a US health care system setting (26 of 34, 67%), and of those 63% (15 of 26) incorporated Medicare costs. Occasionally, a US study was unavailable and we included a non-US study. In these instances, we converted the ICER into US dollars by using purchasing power parities, and indexed to the year the coverage decision was made by using the health component of the consumer price index [20,21].

Utilization Rate—Served and Unserved Population

We estimated intervention utilization rates by using a database of Medicare inpatient and outpatient claims [22]. We used *International Classification of Diseases, Ninth Revision (ICD-9)* diagnostic codes reported in the database to identify Medicare beneficiaries eligible for an intervention, as defined by the parameters of the NCD. The database also includes Common Procedural Terminology (CPT) codes used for physician reimbursement. We estimated utilization rates by calculating the number of beneficiaries who had matching relevant ICD-9 diagnostic and CPT codes. We estimated the size of the unserved eligible population by calculating the difference between the number of beneficiaries who were a match for both ICD-9 diagnostic and CPT codes and those who were a match solely with ICD-9 diagnostic codes.

Incremental Cost Data

We extracted incremental cost data, that is, the net present value of future expenditures (the numerator of the ICER), from the included cost-effectiveness study, and when necessary adjusted it to 2007 USDs.

Cost of Intervention and Comparator in First Year of Use

We included the cost of the intervention and the comparator in the first year of use when it was reported in the cost-effectiveness study (64% of cases). When not reported, we estimated the cost of the intervention and the comparator in the year following first use from Medicare and physician reimbursement codes (36% of cases). Pertinent reimbursement codes were identified from Medicare documentation, the included cost-effectiveness study, or the manufacturer's website. For interventions subject to non-coverage decisions, we obtained the relevant information from the cost-effectiveness study.

Categorization of Interventions

To analyze the effect of the reallocation exercise on the distribution of expenditures, we categorized interventions with respect to disease (cardiology, oncology, and other), type of intervention (treatment, diagnostic, and other, i.e., education, preventative care, and mobility assistive equipment), and size of the eligible population (>1 million beneficiaries, 50,000–1 million beneficiaries, and <50,000 beneficiaries).

Reallocation of Expenditures

In the first analysis, we illustrated the effects of increasing the utilization of dominant interventions, while maintaining the existing utilization of nondominant interventions. That is, for dominant interventions we decreased by 50% the size of the unserved population, that is, Medicare beneficiaries who were eligible for the intervention but did not receive it. We assumed a 50% shift for the reallocation, reasoning that shifting all beneficiaries from one intervention to another would be infeasible in practice. To illustrate the possible range of aggregate health gains, we repeated this analysis by adjusting utilization by 10% and 90%, respectively.

In the second analysis, we reallocated existing resources by using an iterative process. First, we ranked interventions in order

of cost-effectiveness. Second, to generate resources for investment in more cost-effective interventions, we “disinvested” in the least cost-effective intervention. Disinvestment was achieved by reducing the existing utilization of the least cost-effective intervention by 50%. Third, with the resources generated from the disinvestment, we increased investment in the most cost-effective intervention. This was achieved by decreasing the size of the unserved eligible population by up to 50%. We continued this process by repeating the second and third steps, that is, disinvesting in the next least cost-effective intervention and investing in the next most cost-effective intervention, until no further reallocation of expenditures was possible and there was no net change in expenditure. We also repeated this analysis by adjusting utilization by 10% and 90%, respectively. Finally, we compared the existing and “ideal” distributions of resources across indications, types of technology, and conditions of different prevalence.

Assumptions

The reallocation exercise adhered to the assumptions necessary for the league table approach described by Johannesson and Weinstein [23]: perfect divisibility; that is, a partially implemented health care program will maintain the characteristics of the entire program; and constant returns to scale; that is, costs and effects are proportional to the scale of implementation. Our analysis required additional assumptions. First, all Medicare beneficiaries eligible for care, as defined by the parameters of the NCD, received an intervention. Second, the comparator included in the cost-effectiveness study was the alternative intervention received in all cases. Third, we ordered interventions by using the net present value of their total costs (including downstream costs) and assumed that for interventions with a

high upfront cost, for example, surgeries, resources were available to fund that “initial investment.”

Results

Figure 1 shows the process by which we arrived at the final sample of interventions. Thirty-six of 64 interventions associated with an estimate of cost-effectiveness were included (Table 1). Twenty-six of the 28 excluded interventions were removed because of incomplete data, for which the most common reason was our inability to accurately identify the utilization rate for the intervention in the indicated patient population. For example, for ultrasound stimulation for nonunion fracture healing, no beneficiaries had a combination of the necessary ICD-9 codes, that is, ICD-9 code for nonunion fracture healing (733.82) and for fractures of the relevant bones (tibial [823], scaphoid [814], and radius [813]). We excluded two interventions because they were dominated by another intervention in the sample.

We included both positive and noncoverage decisions included in NCDs made from 1999 through 2007. Of the 36 coverage decisions, 29 (81%) were positive and 7 (19%) were noncoverage decisions. We included noncoverage decisions to maximize the sample size and to evaluate the consequences of reallocation when using cost-effectiveness evidence as the sole criterion for resource allocation. While our previous research has demonstrated that covered technologies tend to be more cost-effective than non-covered ones, this was not necessarily the case for the technologies included here [13]. Indeed, the least cost-effective technologies in our sample were covered, while noncovered technologies were typically associated with favorable ICERs (e.g., the noncovered intervention acupuncture for osteoarthritis had a reported ICER

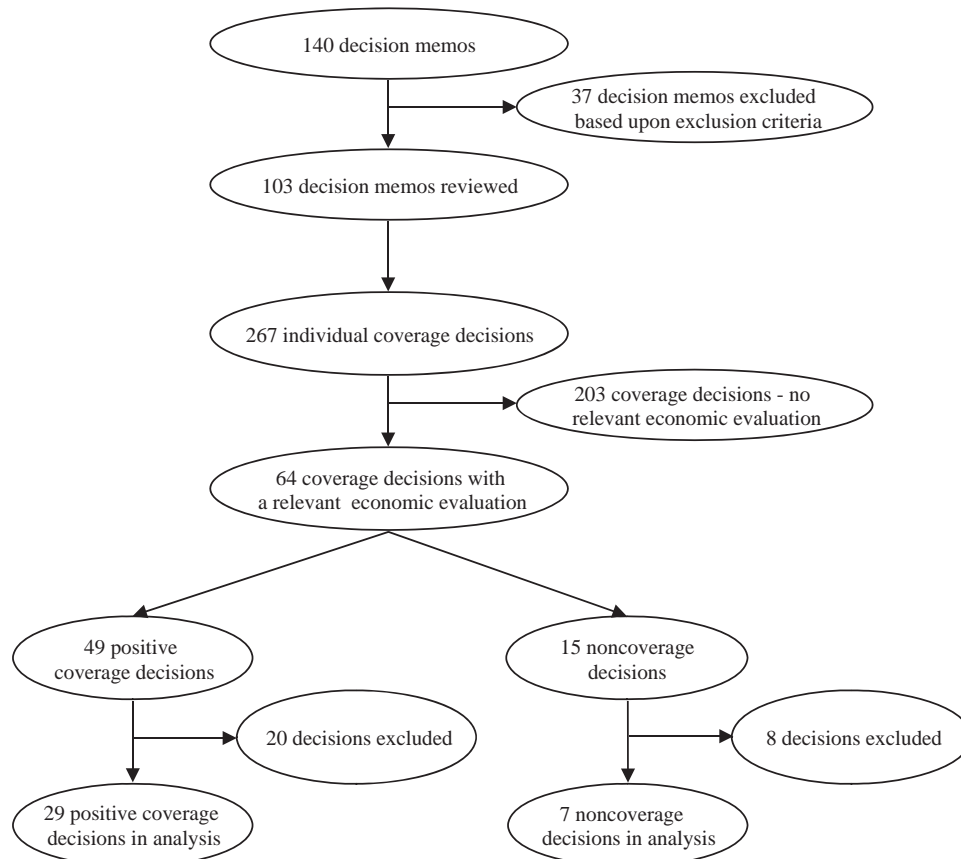


Fig. 1 – Process of identifying final set of coverage decisions for analysis.

Table 1 – Interventions included in reallocation of expenditures.

Intervention	Population	Coverage status	Utilization (per annum)	
			Received Tx for diagnosis	Eligible but did NOT receive tx
Ventricular assist devices	Destination therapy—patients with chronic end-stage heart failure who meet specified criteria	Covered	20	1,474,400
Transmyocardial revascularization	Patients with severe angina (stable or unstable), which has been found refractory to standard medical therapy	Covered	40	143,140
Liver transplantation	Patients suffering from hepatitis B	Covered	40	14,280
Ocular photodynamic therapy with verteporfin	Macular degeneration—predominately classic subfoveal CNV lesions	Covered	1,200	72,200
Lung volume reduction surgery	Severe upper-lobe emphysema	Covered	120	109,060
Implantable cardioverter defibrillators (ICDs)	Patients with documented familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias	Covered	28,180	1,276,880
Pancreas transplantation	Pancreas transplants—patients who meet the specified criteria (type 1 diabetes etc.)	Covered	720	67,200
Positron emission tomography	Esophageal cancer	Covered	200	80,200
ICDs	NIDCM, documented prior MI, class II and III heart failure	Covered	0	3,240
Deep brain stimulation	Parkinson's disease	Covered	39,860	687,940
ICDs	Documented sustained ventricular tachyarrhythmia	Covered	28,040	931,020
Autologous stem cell transplantation (AuSCT)	Patients suffering from multiple myeloma	Covered	80	1,520
Acupuncture	Osteoarthritis	Noncovered	0	744,860
Lumbar artificial disc replacement	Back pain	Noncovered	0	140,700
Laparoscopic adjustable gastric banding (LAGB)—bariatric surgery	Treatment of morbid obesity	Covered	6,600	5,976,900
Cochlear implantation	Postlingually hearing impaired patients	Covered	1,120	31,220
Hyperbaric oxygen therapy	Hypoxic wounds and diabetic wounds of the lower extremities—diabetic wounds of the lower extremities	Covered	43,800	1,196,800
Electrical bioimpedance for cardiac output monitoring	Hypertension	Noncovered	0	1,429,060
External counterpulsation (ECP) therapy	Various cardiac conditions	Noncovered	0	5,018,500
Positron emission tomography	Head and neck cancers	Covered	800	575,200
Screening immunoassay fecal-occult blood test—hemoccult II	Screening for colon cancer	Covered	56,400	476,800
Ultrasound image guidance	Breast cancer—breast biopsy	Covered	49,600	1,937,000
Foot care	Diabetic peripheral neuropathy with loss of protective sensation	Covered	400	473,200
Cardiac rehabilitation programs	Acute MI	Covered	46,400	153,800
Cardiac rehabilitation programs	Percutaneous transluminal coronary angioplasty	Covered	152,400	479,000
Positron emission tomography (FDG)	Breast cancer—initial staging of axillary lymph nodes	Noncovered	0	1,257,240
Positron emission tomography	Lung cancer (non-small cell)	Covered	3,000	835,400
Positron emission tomography (FDG)	Breast cancer—staging and restaging	Covered	2,400	1,948,800
Ambulatory BP monitoring	White coat hypertension	Covered	1,800	249,000
Positron emission tomography (FDG)	Colorectal cancer	Covered	800	604,200
Positron emission tomography (FDG)	Melanoma	Covered	600	388,000
Cryosurgery ablation	Primary treatment for clinically localized prostate cancer (stages T1–T3)	Covered	5,000	1,383,600
Positron emission tomography (FDG)	Ovarian cancer	Noncovered	0	230,500
Warm-up wound therapy aka noncontact normothermic wound therapy (NNWT)	Stage III and IV ulcers	Noncovered	0	1,119,120
Intravenous immune globulin	Bullous pemphigoid	Covered	200	8,200
Intravenous immune globulin	Pemphigus vulgaris	Covered	200	3,400

BP, blood pressure; CNV, choroidal neovascularisation; FDG, fludeoxyglucose (18F); ICER, incremental cost-effectiveness ratio; MI, myocardial infarction; NA, not applicable/available; NIDCM, nonischemic dilated cardiomyopathy; QALY, quality-adjusted life-years; Tx, most effective therapeutic option.

* Reallocation through disinvestment in less cost-effective interventions by 50%, and investment in relatively cost-effective interventions by decreasing the size of the unserved eligible population by up to 50%.

Table 1 – continued

Cost-effectiveness			Costs in year following first use		Spending on intervention	
Inc. cost (\$)	Inc. QALY	ICER (\$)	Cost of intervention (\$)	Cost of comparator (\$)	Existing spending (million) (3.s.f) (\$)	Reallocated spending* (million) (3.s.f) (\$)
416,545	0.42	986,630	331,878	65,177	9.63	4.82
19,777	0.04	489,417	18,123	4,086	1.02	0.511
150,967	0.74	204,186	117,624	8,558	10.9	5.45
14,504	0.03	195,566	9,570	0	18.7	9.36
60,243	0.50	120,460	87,905	28,727	16.3	8.17
21,102	0.16*	99,782	92,783	65,846	3,610	1,800
198,351	2.20	90,159	227,788	4,218	267	134
5,598	0.07	81,485	4,192	1,438	12.0	6.00
77,113	1.01	76,244	37,474	7,090	0	0
47,121	0.72	65,970	53,853	5,988	24,300	12,100
34,375	0.65*	39,971	101,310	73,912	4,360	2,180
83,123	1.69*	37,275	2,396	106	6.96	3.48
536	0.02	20,383	97	0	0	0
7,625	0.39	18,939	25,986	16,547	0	0
8,100	0.45	18,028	3,366	142	53.5	10,300
41,520	3.80	11,653	26,748	0	46.5	695
1,771	0.27	6,649	524	0	394	5,770
314	0.05	6,408	628	515	0	17,000
820	0.26	3,264	5,343	0	0	2,060
1,425	0.44	3,224	6,022	4,597	4.82	1,740
400	0.13*	1,318	5	0	22.6	118
–358	NA	Dominates	613	972	30.4	624
–386	0.05	Dominates	207	0	2.26	1,340
–470	0.60	Dominates	69	0	803	2,130
–470	0.60	Dominates	69	0	2,560	6,580
609	NA	Dominates	901	0	0	2,680
–698	NA	Dominates	2,038	2,736	6.11	857
–759	NA	Dominates	953	0	22.2	9,050
–915	NA	Dominates	110	14	16.7	1,170
–892	NA	Dominates	2,038	2,929	1.63	617
–906	NA	Dominates	2,038	2,943	1.22	396
–2,189	NA	Dominates	6,017	8,206	30.1	4,190
–3,467	NA	Dominates	2,956	0	0	341
–14,706	0.12	Dominates	5,753	8,431	0	3,810
–157,773	NA	Dominates	44,613	105,321	18.2	391
–217,840	NA	Dominates	102,656	165,777	47.4	450

Table 2 – Estimated gains in aggregate health and cost-savings.

Reallocation	Net present value of future commitments			Year following first use of the intervention		
	Additional beneficiaries receiving most effective intervention (millions) (3.s.f)	Cost savings (millions) (3.s.f) (\$)	QALY gain (millions) (3.s.f)	Additional beneficiaries receiving most effective intervention (millions) (3.s.f)	Cost savings (millions) (3.s.f) (\$)	QALY gain (millions) (3.s.f)
All interventions (all health outcome units)						
Increased utilization of dominant interventions*	5.54 (1.11– 9.96)	13,000 (2,590– 23,300)	0.269 (0.0538–0.484)	5.54 (1.11–9.96)	2,540 (507–4,560)	0.269 (0.0538–0.484)
Reallocation of expenditures†	11.1 (2.22–20.0)	NA	1.86 (0.373–3.35)	6.73 (1.35–12.1)	NA	0.580 (0.116–1.04)
Interventions with QALY data						
Increased utilization of dominant interventions*	1.11 (0.223–2.00)	8,470 (1,690– 15,200)	0.269 (0.0538– 0.484)	1.11 (0.222–2.00)	1,430 (286– 2,570)	0.269 (0.0538–0.484)
Reallocation of expenditures†	6.14 (1.23–11.1)	NA	1.61 (0.323–2.91)	2.10 (0.420–3.78)	NA	0.527 (0.105–0.949)

NA, not applicable/available; QALY, quality-adjusted life-year; 3.s.f, three significant figures.

* Increased utilization of dominant interventions through decreasing the size of the unserved population, i.e., Medicare beneficiaries who were eligible for the intervention but who did not receive it, by 50% (10%–90%).

† Reallocation through disinvestment in less cost-effective interventions, achieved by decreasing the utilization of the intervention by 50% (10%–90%) and investment in relatively cost-effective interventions, achieved by decreasing the size of the unserved eligible population, i.e., Medicare beneficiaries who were eligible for the intervention but who did not receive it, by up to 50% (10%–90%).

of \$18,383) (Table 1). Prior to reallocation, 470,000 beneficiaries received the most effective of the interventions included in the cost-effectiveness analysis, at a cost of approximately \$8 billion. Notably, the most cost-ineffective interventions were already in general used least frequently, with interventions associated with ICERs greater than \$100,000 per QALY associated with negligible utilization rates (Table 1).

For the first analysis, increasing utilization of dominant interventions had a substantial impact on aggregate health gain and cost-savings. When we considered the net present value of future commitments, and included dominant interventions without an estimate of incremental QALY gain, increasing the utilization of dominant interventions while maintaining the existing utilization of interventions associated with a positive ICER resulted in an additional 5.5 million beneficiaries receiving the most effective intervention, an additional 0.27 million QALYs gained, and approximately \$12.9 billion of cost-savings (Table 2).

For the second analysis, when we considered the net present value of future commitments and included dominant interventions without an estimate of incremental QALY gain, reallocation of expenditures resulted in an additional 11.1 million beneficiaries receiving the most effective intervention (Table 2). This corresponded to an additional 1.86 million QALYs, approximately 0.17 QALYs per beneficiary affected by the reallocation. The ICER of the marginal technology, that is, the least cost-effective intervention for which utilization was increased, was approximately \$18,000 per QALY (bariatric surgery for the treatment of morbid obesity). When we reallocated expenditures in the year following the first use of the intervention, the findings were similar, although the magnitude of changes was smaller. The ICER of the marginal technology was approximately \$3,300 per QALY (external counterpulsation therapy).

When we considered only interventions with an available estimate of incremental QALY gain, 25 interventions were

included in the reallocation. Findings were broadly consistent with the analysis including interventions without a QALY gain estimate, although the magnitude of gain was smaller (Table 2).

The reallocation had a notable impact on the distribution of expenditures across diseases (Table 3). Following reallocation, a greater proportion of expenditures was directed to beneficiaries receiving an oncology-related intervention (approximately 43%), for example, positron emission tomography for various cancers. In contrast, a decreased proportion was directed to those receiving a cardiology-related intervention (approximately 34%), for example, implantable cardioverter defibrillators. Furthermore, a decreased proportion was directed to interventions categorized as *other* (approximately 24%), for example, warm-up wound therapy for ulcers. With respect to intervention type, following reallocation the proportion of beneficiaries receiving an intervention categorized as *treatment*, for example, ocular photodynamic therapy with verteporfin for macular degeneration, or diagnostic, for example, screening immunoassay fecal-occult blood test for colorectal cancer, increased (approximately 50% and 44%, respectively), while the proportion of beneficiaries receiving interventions categorized as *other*, for example, foot care for diabetic peripheral neuropathy with loss of protective sensation, decreased (approximately 7%). Following reallocation, a much greater proportion of expenditures was directed to beneficiaries receiving interventions with an eligible population of more than 1 million beneficiaries (approximately 78%), for example, external counterpulsation therapy, while a decreased proportion was directed to beneficiaries receiving an intervention with an eligible population of 50,000 to 1 million beneficiaries (approximately 22%), for example, cardiac rehabilitation programs for acute myocardial infarction and percutaneous transluminal coronary angioplasty, and less than 50,000 beneficiaries (0.2%), for example, intravenous immune globulin for bullous pemphigoid, respectively.

Table 3 – Distribution of resources before and after reallocation* of expenditures.

	Prior to reallocation		Following reallocation	
	Beneficiaries receiving most effective therapeutic option (3.s.f)	Distribution (%)	Beneficiaries receiving most effective therapeutic option (millions) (3.s.f)	Distribution (%)
Disease area				
Cardiology	256,880	54.7	3.89	33.6
Oncology	118,880	25.5	4.94	42.6
Other disease area	94,260	20.1	2.76	23.8
Type of intervention				
Treatment	155,220	33.0	5.75	49.7
Diagnostic	115,600	24.6	5.08	43.8
Other type of intervention	199,200	42.4	0.752	6.5
Size of untreated patient population				
Large	135,600	28.8	9.03	78.0
Medium	332,780	70.8	2.53	21.8
Small	1,640	0.3	0.0230	0.2

3.s.f, three significant figures.

* Reallocation through disinvestment in less cost-effective interventions, achieved by decreasing the utilization of the intervention by 50% (10%–90%), and investment in relatively cost-effective interventions, achieved by decreasing the size of the unserved eligible population, i.e., Medicare beneficiaries who were eligible for the intervention but who did not receive it, by up to 50% (10%–90%).

Discussion

Coverage of cost-ineffective interventions generates relatively little health gain for the expenditure and suggests that existing resources could provide greater benefits if directed toward more cost-effective alternative interventions. As others have shown, using cost-effectiveness evidence can lead to more efficient resource allocation [24]. For this research we used an empirical approach to estimate efficiency gains by reallocating expenditures among interventions considered in NCDs by using a cost-effectiveness decision rule. This approach differs from studies that highlight inefficiencies by comparing expenditures across jurisdictions when adjusting for differences in populations [25,26]. While these studies highlight opportunities for efficiency gains, they do not suggest an approach to making care more efficient. In contrast, this study illustrates the potential to increase the aggregate health of Medicare beneficiaries while maintaining existing spending levels.

Our findings suggest that substantial efficiency gains are achievable by reallocating expenditures in accordance with cost-effectiveness evidence. Simply increasing the utilization of dominant interventions increases aggregate health gain, while generating additional resources, an approach in which no patients would receive a less effective therapeutic option. Reallocating expenditures in accordance with a broader definition of the cost-effectiveness evidence increases the number of beneficiaries receiving the most effective therapeutic option—though inevitably some patients would then receive a less effective option than their current therapy—and results in sizeable aggregate health gains. As we included dominant interventions without an estimate of incremental QALY gain in the analysis, aggregate population health gain estimates are likely conservative.

Reallocation also affects the distribution of expenditures across diseases. Following reallocation, a greater proportion of resources was directed to beneficiaries receiving *oncology*-related interventions and a lesser proportion to beneficiaries receiving *cardiology*-related interventions and diseases categorized as *other*. Interestingly, many cost-effective, oncology-related interventions in our sample were diagnostic imaging modalities (e.g., positron emission tomography for various cancers) and tests, rather than chemotherapies, which are often associated with high ICERs [27].

Limitations and Challenges

Many of the challenges of this research pertain to data limitations. Unlike other health technology assessment agencies—for example, the National Institute of Health and Clinical Excellence in the United Kingdom—the CMS does not independently perform cost-effectiveness analyses, nor does it require submission of cost-effectiveness evidence. Consequently, few of the cost-effectiveness estimates we used originated from CMS decision memos, and for the most part we relied on estimates identified in the cost-effectiveness literature. As a result, there may have been a lack of consistency among cost-effectiveness studies with respect to methodology, perspective, costing, country of study, and so on.

While necessary, we used ICD-9 diagnostic codes to identify eligible beneficiaries, though this approach was somewhat crude, as such codes do not sufficiently capture all factors that inform patient management in practice, for example, patient preference. The Medicare claims database provides a “snapshot” of interventions received by Medicare beneficiaries and does not distinguish between incident and prevalent cases. Without this information, identifying eligible beneficiaries is imprecise; for example, identifying a beneficiary with Parkinson’s disease is insufficient to confirm his or her eligibility for deep brain

stimulation, as this treatment is indicated only once pharmaceutical management is no longer effective. For other interventions, this is less problematic (e.g., foot care for diabetic patients suffering from diabetic peripheral neuropathy with loss of protective sensation), as the ICD-9 diagnostic codes were sufficient to identify this patient population.

An important assumption was that eligible patients who did not receive the intervention instead received the study comparator. While we attempted to ensure that CMS deemed the comparator relevant by affirming that CMS discussed it in the decision memo, this assumption introduces potential bias. In many cases, despite eligibility, Medicare beneficiaries are likely to receive no therapy or an alternative therapy not included in the cost-effectiveness analysis. Thus, there is potential for the ICER to be either overestimated or underestimated. In future research, we plan to explore and try to validate this assumption, potentially utilizing clinical opinion.

The requirement to integrate data from various sources limits the accuracy of study findings. Indeed, our study highlights the challenges of using currently available data for this type of analysis. While US-based recommendations for the performance cost-effectiveness analyses exist, evidence suggests that they are followed inconsistently [28].

Policy Significance and Next Steps

In the United States, cost-effectiveness is often conflated with “rationing” and a reduction in health care provision. This research shows that rather than using it to reduce spending, it can identify how to increase aggregate population health while maintaining existing spending levels. Despite the limited number of considered interventions, our analysis illustrated that an additional 1.86 million QALYs (0.17 QALYs per affected beneficiary) were achievable, suggesting substantial gains in aggregate health if the policy were implemented on a larger scale.

The least cost-effective intervention to which more expenditure was allocated after reallocation was associated with an ICER of \$18,000 per QALY (bariatric surgery for the treatment of morbid obesity), less than the often used benchmarks of value in the United States, for example, \$50,000 to \$100,000 per QALY [29]. This finding suggests that there is much potential for Medicare to increase spending on interventions associated with ICERs judged highly cost-effective by traditional standards, while reducing spending on interventions deemed comparatively cost-ineffective [30].

Our research is not offered as a precise accounting exercise, but rather as an illustration of the potential of this approach, which, while incorporating a number of assumptions, underscores the substantial aggregate health gains potentially achievable from using cost-effectiveness evidence to inform resource allocation. Indeed, gains may be even greater if one could better account for patient heterogeneity and if beneficiaries who would benefit most were prioritized for treatment.

For a number of included dominant interventions, positive expenditure was required in their first year of use, with aggregate cost-savings achieved in subsequent years, for example, foot care for diabetic patients with neuropathy. This finding emphasizes that considering interventions over a short time horizon may not adequately account for the potential positive financial impact on the entire health care system. The apparent underutilization of dominant interventions provides an opportunity for policymakers. Research suggests that underutilization may be due to a lack of physician referral, insufficient physician reimbursement, and perceived clinical benefits of the intervention, among other factors [31–33].

Ideally, data available for the research in this article would be more abundant, and of higher quality and greater consistency. Preferably, available cost-effectiveness studies would

include Medicare-specific direct costs and account for all relevant competing interventions. Costs would meet the specifications necessary to facilitate potential legislative action, for example, meet the standards of the Congressional Budget Office and CMS's Office of the Actuary [34,35]. Technologies should be evaluated over a time horizon for which costs and consequences, in terms of QALYs, are likely to differ, and reported on an annual basis. Ideally, studies would account for patient heterogeneity, with data available on the effectiveness of the intervention across beneficiaries in the indicated population.

Using a cost-effectiveness decision rule for resource allocation will impact the distribution of resources across Medicare beneficiaries. Despite the small number of included coverage decisions, the findings underscore the trade-offs inherent in resource allocation decisions, for example, the opportunity cost of prioritizing resources to a particular patient group. Indeed, the objective of maximizing aggregate health subject to a budget constraint is not entirely consistent with CMS's decision-making criteria. Other factors including the nature, strength, and uncertainty of the available evidence; the availability of alternative interventions; potential impact of the decision on access to health care; statutory mandates to cover certain services; and political considerations are important as well [36,37].

It is important to highlight that a minority of CMS's coverage decisions for interventions are made at the national level in NCDs and that we included only coverage decisions associated with cost-effectiveness estimates. Consequently, this research is limited to a relatively small, and potentially unrepresentative, selection of interventions. Included interventions may not be those for which a reallocation of expenditures would yield the greatest efficiency gains. Indeed, targeting interventions with the largest potential health gains may be impractical if they reflect widely used and accepted services, despite poor cost-effectiveness. Rather, targeting interventions for which a change in therapeutic management is more feasible may be a more appropriate approach. We chose arbitrarily to use a 50% (range 10%–90%) change in utilization to simulate resource allocation. Accounting for the relative ease of investing/disinvesting in interventions would be one approach for advancing this research and may produce more realistic efficiency gain estimates.

As an illustrative exercise this research could be furthered by focusing on a select group of interventions for which high-quality data are available, potentially interventions from the same class or for the same indication. Having data of sufficient quality would allow the adoption of alternative approaches, for example, integer programming, or a stochastic process to account for uncertainty in the parameter estimates and for disease incidence.

A larger sample would allow a more comprehensive categorization of interventions and facilitate a more thorough examination of the consequences of using cost-effectiveness evidence to guide resource allocation. For example, as research has shown that society has a preference for the treatment of severe diseases, a variable to capture disease severity would be valuable [38–41]. By better understanding Medicare beneficiaries' resource allocation preferences, the appropriateness of alternative resource use patterns could be evaluated.

Conclusions

While the US health care system has not embraced the use of cost-effectiveness evidence to inform health care resource allocation, this research illustrates the potential value and consequences of such an approach. While it is apparent that available data present challenges with this methodology, our research

illustrates that substantial health gains are achievable from a reallocation of expenditures within existing spending levels.

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REFERENCES

- [1] Keehan SP, Sisko AM, Truffer CJ, et al. National health spending projections through 2020: economic recovery and reform drive faster spending growth. *Health Aff (Millwood)* 2011;30:1594–605.
- [2] Organisation for Economic Co-operation and Development. OECD Health Data 2010: How Does the United States Compare? Paris, France: OECD Publishing.
- [3] Davis K, Schoen C, Stremikis K. Mirror, mirror on the wall. How the performance of the US health care system compares internationally. 2010 update. 2010. Available from: http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/Jun/1400_Davis_Mirror_Mirror_on_the_wall_2010.pdf. [Accessed June 8, 2012].
- [4] Bryan S, Sofaer S, Siegelberg T, Gold M. Has the time come for cost-effectiveness analysis in US health care? *Health Econ Policy Law* 2009;4(Pt 4):425–43.
- [5] Centers for Medicare & Medicaid Services. National health expenditure data. Available from: <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>. [Accessed June 8, 2012].
- [6] Bentley TG, Effros RM, Palar K, Keeler EB. Waste in the U.S. health care system: a conceptual framework. *Milbank Q* 2008;86:629–59.
- [7] Fisher ES, Wennberg DE, Stukel TA, et al. The implications of regional variations in Medicare spending, part 1: the content, quality, and accessibility of care. *Ann Intern Med* 2003;138:273–87.
- [8] Garber A, Goldman DP, Jena AB. The promise of health care cost containment. *Health Aff (Millwood)* 2007;26:1545–7.
- [9] United States General Accounting Office. Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives. Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities. Apr 11, 2003, GAO-03-175. Available from: <http://www.gao.gov/assets/240/237841.pdf>. [Accessed June 8, 2012].
- [10] Berwick DM, Hackbarth AD. Eliminating waste in US health care. *JAMA* 2012;307:1513–6.
- [11] Medicare Program; Revised Process for Making Medicare National Coverage Determinations; Notice of proposed rulemaking, 68 Federal Register 187 (26 September 2003), pp 55634–41.
- [12] Centers for Medicare & Medicaid Services. Guidance for the public, industry and CMS staff: factors CMS considers in opening a national coverage determination. Available from: <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=6&McdName=Factors+CMS+Considers+in+Opening+a+National+Coverage+Determination&mcldtypename=Guidance+Documents&MCDIndexType=1&bc=BAAIAAAAAA&>. [Accessed June 8, 2012].
- [13] Chambers JD, Neumann PJ, Buxton MJ. Does Medicare have an implicit cost-effectiveness threshold? *Med Decis Making* 2010;30:E14–27.
- [14] Chambers JD, Morris S, Neumann PJ, Buxton MJ. Factors predicting Medicare national coverage: an empirical analysis. *Med Care* 2012;50:249–56.
- [15] U.S. National Library of Medicine. PubMed: U.S. National Library of Medicine, National Institutes of Health. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/>. [Accessed June 8, 2012].
- [16] CEA Registry. Tufts Medical Center Cost-Effectiveness Analysis (CEA) Registry. Available from: <http://www.cearegistry.org>. [Accessed June 8, 2012].
- [17] Health Economic Evaluation Database. Health Economic Evaluation Database. Available from: <http://www3.interscience.wiley.com/cgi-bin/mrwhome/114130635/HOME>. [Accessed June 8, 2012].
- [18] Centre for Reviews and Dissemination. National Health Service-Economic Evaluation Database. Available from: <http://www.crd.york.ac.uk/crdweb/>. [Accessed June 8, 2012].
- [19] Erickson P, Wilson R, Shannon I. Years of healthy life. *Healthy People 2000 Stat Notes* 1995;7:1–15.
- [20] Organisation for Economic Co-operation and Development. Purchasing power parity (PPP) statistics. 2010. Available from: <http://www.oecd.org/dataoecd/61/56/39653523.xls>. [Accessed February 27, 2013].
- [21] U.S. Bureau of Labor Statistics. Measuring Price Change for Medical Care in the CPI. Available from: <http://www.bls.gov/cpi/cpifact4.htm>. [Accessed June 8, 2012].
- [22] Centers for Medicare & Medicaid Services. Research, statistics, data and systems: limited data sets. Available from: http://www.cms.gov/LimitedDataSets/01_Overview.asp#TopOfPage. [Accessed June 8, 2012].
- [23] Johannesson M, Weinstein MC. On the decision rules of cost-effectiveness analysis. *J Health Econ* 1993;12:459–67.

- [24] Lord J, Laking G, Fischer A. Health care resource allocation: is the threshold rule good enough? *J Health Serv Res Policy* 2004;9:237–45.
- [25] Matlock DD, Peterson PN, Heidenreich PA, et al. Regional variation in the use of implantable cardioverter-defibrillators for primary prevention: results from the National Cardiovascular Data Registry. *Circ Cardiovasc Qual Outcomes* 2011;4:114–21.
- [26] Song Y, Skinner JS, Bynum JPW, et al. Regional variations in diagnostic practices. *New Engl J Med* 2010;363:45–53.
- [27] Greenberg D, Earle C, Fang CH, et al. When is cancer care cost-effective? A systematic overview of cost-utility analyses in oncology. *J Natl Cancer Inst* 2010;102:82–8.
- [28] Phillips KA, Chen JL. Impact of the U.S. panel on cost-effectiveness in health and medicine. *Am J Prev Med* 2002;22:98–105.
- [29] Greenberg D, Neumann PJ. Is it cost-effective? It depends on who you ask. In: Rosen B, Israeli A, Shortell S, eds. *Improving Health and Healthcare. Who is Responsible? Who is Accountable?* Tel Hashomer, Israel: The Israel National Institute for Health Policy Research; 2011.
- [30] Weinstein MC, Skinner JA. Comparative effectiveness and health care spending—implications for reform. *N Engl J Med* 2010;362:460–5.
- [31] Daly J, Sindone AP, Thompson DR, et al. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. *Prog Cardiovasc Nurs* 2002;17:8–17.
- [32] Parkosewich JA. Cardiac rehabilitation barriers and opportunities among women with cardiovascular disease. *Cardiol Rev* 2008;16:36–52.
- [33] Thomas RJ. Cardiac rehabilitation/secondary prevention programs: a raft for the rapids: why have we missed the boat? *Circulation* 2007;116:1644–6.
- [34] Congressional Budget Office. Our processes. Available from: <http://www.cbo.gov/about/our-processes> [Accessed June 8, 2012].
- [35] Centers for Medicare & Medicaid Services. CMS's Office of the Actuary. Available from: http://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_OACT.html [Accessed June 8, 2012].
- [36] Keenan PS, Neumann PJ, Phillips KA. Biotechnology and Medicare's new technology policy: lessons from three case studies. *Health Aff (Millwood)* 2006;25:1260–9.
- [37] Griffin S, Claxton K, Palmer S, Sculpher MJ. Dangerous omissions: the consequences of ignoring decision uncertainty. *Health Econ* 2011;29:212–24.
- [38] Coast J. Is economic evaluation in touch with society's health values? *BMJ* 2004;329:1233–6.
- [39] Dolan P, Cookson R. A qualitative study of the extent to which health gain matters when choosing between groups of patients. *Health Policy* 2000;51:19–30.
- [40] Nord E, Richardson J, Street A, et al. Maximizing health benefits vs egalitarianism: an Australian survey of health issues. *Soc Sci Med* 1995;41:1429–37.
- [41] Ubel PA. *Pricing Life: Why It's Time for Health Care Rationing*. Cambridge, MA: MIT Press, 2001.