Enhancing the Budget Impact Model for Institutional Use: A Tool with Practical Applications for the Hospital Oncology Pharmacy

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ABSTRACT

Background: The cost of cancer care is increasing, and tools are needed to understand the economic impact of new drugs on the hospital pharmacy budget.

Objective: To develop an interactive budget impact model (BIM) through a collaborative effort of industry, academia, and modeling experts to evaluate the use of a new agent in non-small cell lung cancer (NSCLC); this BIM included an institutional module specific to the needs of practices that purchase medications for use in institutional settings.

Methods: Treatment regimens, doses, duration of therapy, toxicity, and cost data are from published sources. All input data may be modified to match the local population. Outputs include cost of care, reimbursement, and margin overall and by treatment regimen.

Results: The base case assumes 20 NSCLC patients progressing after initial therapy (3 receiving ramucirumab+docetaxel, 2 bevacizumab+erlotinib, 3 docetaxel, 6 erlotinib, and 6 pemetrexed), wholesale acquisition cost (WAC) purchase price, and reimbursement at WAC+4.3%. The model estimated the total cost and reimbursement for the institutional oncology pharmacy to be \$699,413 and \$729,487, respectively, resulting in a margin of \$30,075 (difference due to rounding) for the year for regimens utilized in the treatment of NSCLC in the post-progression setting. Results will vary depending on the input data.

Conclusions: There is an increasing need for institutional pharmacies to plan ahead and anticipate the impact of new drugs on their oncology budgets. This interactive Excel-based institutional BIM may provide evidence-based support for pharmacy decision making.

Key Words—budget impact, economics, hospital, non-small cell lung cancer, pharmacy

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The cost of cancer care is a growing concern in the United States, which spends more on cancer care than any other nation in the world.¹ In fact, the increase in cost of care over time is more than double that of most other OECD (Organization for

Economic Cooperation and Development) nations. Despite the potentially unsustainable cost increase, the United States has demonstrated improved cancer outcomes compared with other developed areas of the world.¹ For the hospital to anticipate the growing

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costs of care with new agents entering the market, tools are needed to understand their impact on the pharmacy budget.

The change in reimbursement rates may have contributed to a decrease in the number of community oncology practice sites. In 2013, the Moran Company produced a report demonstrating that over time there has been a shift in the proportion of chemotherapy infusions from private community practice settings to hospital-based outpatient infusion centers.² An analysis of Truven MarketScan data,³ an insurance claims database covering more than 98 million patient lives in the United States, demonstrated a similar trend at the per-patient level (Figure 1). In this analysis of 546,217 lung cancer patients from January 2006 through June 2014, approximately 4% of patients received chemotherapy in the hospital (eg, licensed outpatient infusion centers and/or inpatient settings) in early 2006 compared with more than 45.1% by mid 2014. This trend toward hospital-based cancer care is expected to continue.

Guidelines recommend that budget impact analyses (BIA) include details of the treatment condition, treatments available, and outcomes of those treatments.^{4,5} A BIA “predicts how a change in the mix of drugs and other therapies used to treat a particular

health condition will impact the trajectory of spending on that condition.”^{4(p337)} These analyses are the foundation of a budget impact model (BIM), which typically uses an Excel-based user interface, to help a decision maker conduct a BIA without the need for complex programming skills. This allows a decision maker to conduct their own “point-in-time” analysis of what may occur to a health care budget with the introduction and use of the new treatment option.⁴

The development and structure of a typical BIM takes the perspective of a single-payer system. In the United States, the majority of these models are created to represent the perspective of an insurance company. Due to changing health care policy, shifts in site of care, and cost-sharing arrangements, insurers are not the only decision makers who are evaluating the economic impact of new health care products in oncology.

With the trending shift to care within the hospital system, the pharmacy has increasing responsibility for potential financial loss or gain with the inclusion or exclusion of new oncology products on the hospital or institutional formulary. The information used to aid in decision making about these new products may be obtained from published sources (eg, clinical trial data and other drug-specific publications), AMCP

Figure 1. Monthly rate of lung cancer patients receiving chemotherapy in the hospital setting, January 2006 to June 2014 (light gray = hospital setting; dark gray = private practice setting).

(Academy of Managed Care Pharmacy) dossiers, or summaries of published literature reviews.^{6,7} Work to tailor economic analyses to the perspective of the institutional pharmacy decision maker has been limited.

In December 2014, ramucirumab, in combination with docetaxel, received US Food and Drug Administration (FDA) approval for treatment of patients with NSCLC who experience disease progression on or following platinum-based chemotherapy. This approval follows ramucirumab's initial FDA approvals as a single agent and in combination with paclitaxel in gastric cancer after prior platinum or fluoropyrimidine use (April 2014 and November 2014, respectively),⁸ and this was followed by a more recent approval for use in colorectal cancer after treatment with FOLFOX and bevacizumab (May 2015).

In the NSCLC registration trial, ramucirumab plus docetaxel demonstrated statistically significant improvements in overall survival (hazard ratio [HR], 0.86; 95% confidence interval [CI], 0.75-0.98; $p = .023$), progression-free survival (HR, 0.76; 95% CI, 0.68-0.86; $p < .0001$), and greater overall response rate (odds ratio [OR], 1.89; 95% CI, 1.41-2.54; $p < .0001$) versus docetaxel alone.⁹ This regimen was subsequently included in the NCCN (National Comprehensive Cancer Network) guidelines with a level of evidence rating of 2A.¹⁰

In response to the gap in value of the single payer BIM and the increasing shift in care to the hospital outpatient setting, a Microsoft Excel-based interactive BIM was developed with an institutional module specific to the needs of the hospital oncology pharmacy or other community-based practice that purchases medications to enable these practices to evaluate the use of a new agent (in this case, ramucirumab plus docetaxel) in NSCLC. This institutional BIM was developed in accordance with the International Society of Pharmacoeconomic and Outcomes Research (ISPOR) guidelines⁴ through a collaborative effort of academic pharmacy directors, industry, and experts in modeling. The institutional BIM and user guide is included in the ramucirumab AMCP dossier.

METHODS

Setting

A BIM was developed by a cross-functional team (industry scientists, health outcomes specialists, academic pharmacists, and expert economic modelers) to facilitate analyses that will enable a decision maker to quantify the economic consequences of including ramucirumab and docetaxel as a therapeutic option in the treatment of NSCLC after progression

on platinum-based therapy. This study presents the institutional BIM, which was specifically developed for a pharmacy decision maker to assist in the formulary assessment of an FDA-approved treatment option – ramucirumab plus docetaxel in second-line NSCLC. The model was designed to enable the pharmacy/institution to enter the number of patients they expect to treat in a given year as well as any site-specific negotiated cost or reimbursement rates so that the results are tailored to the institution's unique drug acquisition practices and payer reimbursement mix.

Development

The concept and interactive functionality of the institutional BIM were developed through an iterative process.¹¹ This incremental development process allows for multiple revisions and adaptations through cyclic development, correction, and refinement. First, ideation occurs through interaction between health outcomes scientists and clinical/administrative pharmacists. Second, the concept is brought to modeling teams and is operationalized in a base framework. The concept is returned to the scientists, refined by the modeling team, and brought back to the pharmacists for feedback. This process is continued until the model is considered to be reflective of the setting and needs of the institutional/hospital pharmacist.

Population

The population specific to the hospital- or community-based pharmacy differs from an insurer's population. The population demographics of patients cared for at a site level are often highly tailored to the surrounding community. Whereas the modules for the commercial insurance and Medicare payers are based on Surveillance, Epidemiology, and End Results (SEER) data, the institutional BIM reflects the reality that most patients present at the hospital when it is time to be treated for chemotherapy (Figure 2A). NSCLC is associated with different treatment patterns and outcomes in the squamous and nonsquamous histological types; therefore, the BIM incorporates the 26% squamous/74% nonsquamous breakdown of this overall population (Figure 2B).¹² Values in the white cells in Figures 2A and 2B may be modified as needed; the default entries are shown.

Treatment Options

Input data are provided based on analyses of electronic medical record (EMR) data from community-based practices for treatment patterns following disease progression in NSCLC.¹³ The distribution

A

Overview Population Market Share Adverse Events Costing Results Documentation

Hospital: Combined Population Save Scenario Delete Scenario Reset All Inputs Reset Sheet Save File

Scenario Name: Base Case

☐ Manually Enter 2nd Line: Patients Receiving Chemotherapy

Hospital Covered Lives	150,000
Plan Annual Incidence Rate of Lung Cancer per 100,000	66.70
Proportion Non-Squamous	74.00%
Proportion Squamous	26.00%
Proportion Receiving 2nd Line Chemotherapy: Non-Squamous	21.00%
Proportion Receiving 2nd Line Chemotherapy: Squamous	16.00%
Proportion Receiving 2nd Line Chemotherapy: Non-Squamous + Squamous	19.70%
NSCLC Patients Receiving 2nd Line Therapy: Non-Squamous + Squamous	20

Population
☒ Combined
☐ Non-squamous
☐ Squamous

Perspective
☐ Commercial
☐ Medicare
☒ Hospital

B

Gender, Age and Ethnicity Distribution		
	Male	Female
Non-Hispanic White		
Age < 25	9.76%	9.36%
Age 25-44	8.17%	8.13%
Age 45-64	9.46%	9.72%
Age 65+	4.50%	5.69%
Non-Hispanic Black		
Age < 25	2.87%	2.86%
Age 25-44	1.68%	1.98%
Age 45-64	1.40%	1.71%
Age 65+	0.45%	0.70%
Hispanic		
Age < 25	3.98%	3.67%
Age 25-44	2.66%	2.33%
Age 45-64	1.40%	1.43%
Age 65+	0.40%	0.53%
Asian		
Age < 25	0.91%	0.90%
Age 25-44	0.79%	0.87%

Annual Incidence Rate of Lung Cancer per 100,000		
	Male	Female
Non-Hispanic White		
Age < 25	0.10	0.09
Age 25-44	3.58	3.95
Age 45-64	87.72	73.49
Age 65+	451.46	324.33
Non-Hispanic Black		
Age < 25	-	-
Age 25-44	3.91	3.43
Age 45-64	129.48	77.96
Age 65+	511.57	265.49
Hispanic		
Age < 25	-	-
Age 25-44	1.65	1.72
Age 45-64	33.33	28.96
Age 65+	257.59	152.97
Asian		
Age < 25	-	-
Age 25-44	2.45	2.68

(Plan Members x Distribution % x Annual Incidence)/100,000		
	Male	Female
Non-Hispanic White		
Age < 25	0	0
Age 25-44	0	0
Age 45-64	12	11
Age 65+	30	28
Non-Hispanic Black		
Age < 25	-	-
Age 25-44	0	0
Age 45-64	3	2
Age 65+	3	3
Hispanic		
Age < 25	-	-
Age 25-44	0	0
Age 45-64	1	1
Age 65+	2	1
Asian		
Age < 25	-	-
Age 25-44	0	0

Figure 2. Institutional budget impact model interface; patient number may be manually entered (top, panel A) or estimated based on community population demographics (bottom, panel B).

from this study is applied to the annual number of NSCLC patients treated through the institutional pharmacy after first progression as follows: single-agent pemetrexed, 37%; single-agent erlotinib, 40%; single-agent docetaxel, 21%; and combination therapy for the remaining patients. It is important to note that the treatment regimen distribution inputs may be overwritten to reflect practice patterns in settings that differ from the prepopulated data. Bevacizumab use in real-world treatment pattern studies was found to be 11% in the post-progression setting,¹³ but clinical trial data are limited to bevacizumab plus erlotinib¹⁴; therefore, the use of this regimen is reduced to 2% in the model to avoid overestimation of comparator costs. Only those agents/regimens with sufficient clinical trial data were included in this BIA to ensure adherence to the ISPOR standards. All values are modifiable to explore the budget impact at different utilization rates for ramucirumab or any of the comparators.

Dose and Duration of Treatment

Dose and duration of treatment inputs are the primary drivers of both costs and gross profit (ie, margin) to an institution's oncology pharmacy. The dose, duration, and outcomes associated with each of the regimens available in the institutional BIM are presented in Table 1.

Costs and Reimbursement Rates

The costs included in the institutional model are limited to those incurred by the hospital- or community-based pharmacy. These costs include drug costs per treatment cycle (based on expected patient body weight, vial size needed, and dose used) multiplied by the duration of treatment from the supporting clinical trials of each regimen included in the model.^{9,14,15} Unlike the insurance payer, toxicity costs are not directly paid for through an institutional pharmacy budget and are not included in the cost calculations for the institutional BIM. The institutional BIM also

Table 1. Dose and duration of treatment

Comparators	Dosing	Average dose	Vials or pills, dose (quantity)	Doses per cycle	Median duration of therapy, months
Ram+Doc ⁹	10 mg/kg	736 mg	500 mg (1) + 100 mg (3)	1	4.22
	75 mg/m ²	142 mg	80 mg (1) + 20 mg (4)	1	
Bev+Erl ¹⁴	15 mg/kg	1104 mg	400 mg (2) + 100 mg (4)	1	3.40
	150 mg	150 mg	150 mg (1)	21	
Docetaxel ⁹	75 mg/m ²	142 mg	80 mg (1) + 20 mg (4)	1	3.72
Erlotinib ¹⁴	150 mg	150 mg	150 mg (1)	21	1.70
Pemetrexed ¹⁵	500 mg/m ²	945 mg	500 mg (1) + 100 mg (5)	1	3.10

Note: Bev+Erl = bevacizumab plus erlotinib; Ram+Doc = ramucirumab plus docetaxel.

includes chair time (the time per patient in the infusion chair at the center) needs for each treatment regimen. For oral agents, this time is set to zero; for the infused agents, the time of the infusion is included in the model.

The price of drugs is an important factor. However, each hospital may utilize very different pricing structures that affect the purchase costs for drugs. The institutional BIM is pre-populated with wholesale acquisition costs (WAC) (Table 2), but there is a 340B option available to either enter specific drug prices or apply a discount rate to the WAC (Figure 3). The 340B option was added to enable sites that qualify under Section 340B of the Veteran's Health Care Act of 1992 for discounted rates of outpatient medications. The added 340B functionality enables sites that qualify for this discounted pricing program to tailor the acquisition costs of medications to the unique situation of their organization. Although survival

outcomes are not included in the calculations of an institutional BIA, they are presented in the model and adjusted to match the distribution of squamous versus nonsquamous histology in a real-world setting.¹²

Outputs

There are profits and losses within the institutional pharmacy with the addition of a new health care product; reimbursement rates may increase margin as well as the cost of drugs, reducing the available budget. The institutional BIM includes both a cost output as well as a reimbursement margin output. Costs are calculated as total cost for the pharmacy based on the cost inputs noted above and number of patients selected by the user. Costs are calculated both with and without the use of ramucirumab plus docetaxel. The expected reimbursement rate plus the WAC is then used to project the total reimbursement margin to the institutional pharmacy. Reimbursement

Table 2. Treatment costs and chair time

Comparators	Wholesale acquisition cost per vial ²⁰	Vial size	Chair time per cycle, minutes
Ramucirumab	\$5,100.00	500 mg/50 mL	60
	\$1,020.00	100 mg/10 mL	
Bevacizumab	\$2,655.00	400 mg/16 mL	30 ^b
	\$663.75	100 mg/4 mL	
Docetaxel	\$386.60	80 mg/2 mL	60
	\$96.65	20 mg/0.5 mL	
		160 mg/16 mL	
Erlotinib	\$223.63 ^a	150 mg	0
	\$197.72	100 mg	
Pemetrexed	\$2,979.20	500 mg/20 mL	10
	\$595.84	100 mg/4 mL	

^aAfter the initial several infusions with longer chair times (eg, 90 minutes), time may be reduced to 30 minutes.

Drug Related Costs - Combined Population					
Drug Name	Edit Drug Pricing	Month(s)		Tx Cost per Patient per Month	Adverse Event Cost per Patient
		Duration of Tx (median)	Overall Survival (median)		
Ramucirumab + Docetaxel		4.22	10.68	\$ 12,948	\$ 15,943
Bevacizumab + Erlotinib		3.40	9.10	\$ 18,351	\$ 2,707
Docetaxel		3.72	9.31	\$ 1,121	\$ 12,127
Erlotinib		1.70	8.21	\$ 6,807	\$ 975
Pemetrexed		3.10	9.30	\$ 8,636	\$ 1,951

Figure 3. Interface that allows for institution-specific inputs related to drug costs and reimbursement rates. Adverse event costs are provided in the institutional budget impact model for informational purposes only and are not included in the total costs to the institution.

margin is calculated with and without the use of ramucirumab plus docetaxel, based on WAC+4.3% (Medicare rate) or using specific rates relevant to an institution as described above.

Use of the Institutional Module and Exemplar Scenario

The institutional BIM as used in this study was applied with the following settings: 20 patients treated for NSCLC post-progression per year¹³; drugs are purchased at WAC and reimbursement is estimated at WAC+4.3%. The estimated first year market share of ramucirumab plus docetaxel is 15% and the number of patients who switch to the ramucirumab regimen is proportionally taken from the docetaxel, erlotinib and pemetrexed cohorts. No assumption is made of any switch between VEGF inhibitors. These and all other assumptions are modifiable (Figures 2 and 3).

RESULTS

Costs

Assuming the pharmacy pays WAC for all drugs without discount, the cost of adding ramucirumab to the hospital formulary for the care of 20 patients treated after first progression is provided in Figure 4. The overall costs to the pharmacy shift across the regimens used by physicians due to the increased use of ramucirumab and the proportional decrease from other available treatment options. The total annual costs to

the institutional pharmacy for the treatment of post-progression NSCLC are estimated to be \$699,413.

Reimbursement

Assuming a WAC+4.3% reimbursement rate to the institutional oncology pharmacy for the care of 20 patients treated post-progression, annual reimbursement is shown in Figure 5. Due to a lack of publicly available reimbursement rates for commercial insurers, a default reimbursement rate for both Medicare patients and commercially insured patients was set at WAC+4.3%. It is widely known that commercial payers may provide higher percentage reimbursement than 4.3%, but the BIA presented assumes equal reimbursement across payer segments to ensure transparency. The base case analysis assumes 60% and 40% across commercial and Medicare insurers, respectively.

The total reimbursement is provided in Figure 5. There is an increase in total reimbursement received by the pharmacy with the increased use of ramucirumab. The total annual reimbursement to the institutional oncology pharmacy from the post-progression treatment of NSCLC patients is estimated to be \$729,487.

Margin

An analysis exploring the tradeoff between expenditures for drug costs and the reimbursement

Figure 4. Annual cost of adding ramucirumab plus docetaxel to the formulary for non-small cell lung cancer.

Figure 5. Annual reimbursement from adding ramucirumab plus docetaxel to the formulary for non-small cell lung cancer.

provided to the center is provided. The institutional BIM will automatically generate a similar table based on the unique patient distribution of the institution to reflect actual costs and reimbursement for the site-specific treatment patterns and number of patients based on the inputs selected by the institution. The per-patient level data are provided in **Table 3** for demonstrative purposes only. However, for the scenario above with 20 patients, the expected annual margin would be the difference between costs and reimbursement, or \$30,075. This would result in an incremental gain of \$6,261 before the addition of ramucirumab to the hospital formulary. This is a hypothetical scenario only and the institutional BIM allows for tailoring to the institutional setting.

DISCUSSION

The addition of an institutional module to a Microsoft Excel-based BIM provides an interface that allows institutions to manually input a population they are intending to treat versus having to know a percentage of their patient demographic or composition of patients they treat within a respective disease and line of therapy. The institutional BIM was designed to allow hospital pharmacies to estimate the impact a novel therapy would have on pharmacy and hospital budgets. As the therapeutic landscape is constantly changing, the BIM will be updated to include the more recently approved immunotherapy agents. These new agents, nivolumab and pembrolizumab, have demonstrated improved survival outcomes in NSCLC,

Table 3. Per-patient summary of annual costs, reimbursement, and margin

Treatment	No. of patients treated	Total chair time, hours	Drug acquisition costs	Commercial reimbursement (WAC+4.3%)	Medicare reimbursement (WAC+4.3%)	Total reimbursement	Projected margin
Ramucirumab + docetaxel	1	15.19	\$67,847	\$42,459	\$28,306	\$70,764	\$2,917
Bevacizumab + erlotinib	1	6.49	\$82,220	\$51,453	\$34,302	\$85,756	\$3,535
Docetaxel	1	6.95	\$5,372	\$3,362	\$2,241	\$5,603	\$231
Erlotinib	1	0	\$16,569	\$10,369	\$6,913	\$17,281	\$712
Pemetrexed	1	1.01	\$35,984	\$22,519	\$15,013	\$37,531	\$1,547

Note: WAC = wholesale acquisition cost.

particularly among patients with high levels of PDL-1 protein expression.^{16,17}

According to ISPOR, the results of a BIM should be presented across various aspects of care (eg, pharmacy, physician visits, outpatient visits, inpatient care).⁵ While this is very appropriate for a single payer setting or for larger insurers, these values generally do not translate well from the perspective of an institutional pharmacy budget. The institutional BIM for the treatment of NSCLC after progression described above was developed to address the current gap in economic information provided to institutional pharmacy decision makers.

In 2014, it was estimated that 30% of spending for drugs was from oncology agents.¹⁸ Consistent with many other analyses in the United States, trends in drug spending show a greater than 10% increase, with most of those costs related to new agents entering the market.¹⁸ As a result, the pharmacy must plan ahead and anticipate these costs and understand the impact of new drugs both in terms of costs and reimbursement margin.

The institutional BIM may help the pharmacy anticipate upcoming costs and facilitate budgetary decision making as new agents become available for patient care. The utilization of new agents is highly influenced by oncology clinical pathways.¹⁹ For institutions that use pathway programs, the inclusion or exclusion of new agents influences the resultant cost/reimbursement ratio in the pharmacy budget. The institutional BIM may assist the institution's pharmacy to predict these economic consequences by entering anticipated costs and reimbursement rates for future years.

As with any model, the structure may be limited in that it does not account for all costs or margin for the institutional pharmacy. The costs are limited to those associated with acquiring chemotherapy and to the costs of infusion, and reimbursement is limited to that associated with the drugs used. There may be other sources of profit and cost to the pharmacy budget that are not included here. The scenario presented for the oncology pharmacy is for demonstrative purposes and is not intended to be representative of any specific pharmacy (eg, arbitrary patient population size, assuming no discounts or incentives either on the drug cost or reimbursement rate), and the results presented here must be considered with this limitation.

The ability to tailor the costs, comparators, and reimbursement details to the unique setting of any particular hospital enhances the value of a single payer-based BIM to the management of the budget of the institutional pharmacy. Individual pharmacy users of the BIM are able to enter specifics to tailor the model to their own population. It is anticipated that the addition of this institutional module to an interactive Microsoft Excel-based BIM in NSCLC was designed to aid pharmacies regarding decision making for formulary considerations in the post-progression setting.

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