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Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients With Stage IV Non–Small-Cell Lung Cancer

David M. Jackman, Yichen Zhang, Carole Dalby, Tom Nguyen, Julia Nagle, Christine A. Lydon, Michael S. Rabin, Kristen K. McNiff, Belen Fraile, and Joseph O. Jacobson

QUESTION ASKED: Did the implementation of a clinical pathway for patients with stage IV non–small-cell lung cancer (NSCLC) impact cost and survival?

SUMMARY ANSWER: After implementation of a clinical pathway for stage IV NSCLC, there was a significant decrease in the average 1-year cost of care, with no compromise in survival.

WHAT WE DID: We created customized lung cancer pathways and partnered with a commercial vendor to provide a Web-based platform for real-time decision support and post-treatment data aggregation. Dana-Farber Cancer Institute Pathways for NSCLC were introduced in January 2014. We identified all Dana-Farber patients who were diagnosed and treated for stage IV NSCLC in 2012 (before pathways) and 2014 (after pathways). Costs of care were determined for 1 year from the time of diagnosis.

WHAT WE FOUND: After implementation of a clinical pathway for stage IV NSCLC, the total 12-month cost of care had a mean decrease of \$15,013 (\$67,050 before pathways v

\$52,037 after pathways). Clinical outcomes were not compromised, with similar median overall survival times (10.7 months before v 11.2 months after pathways; $P = .08$).

BIAS, CONFOUNDING FACTOR(S), REAL-LIFE IMPLICATIONS: Our assessment of the value of a cancer pathway is the most rigorous to date. However, we recognize several important limitations to our study. Among standard quasi-experimental designs, uncontrolled before-and-after analysis is open to several potential sources of error. Such analyses are vulnerable to secular trends that may be confused for a treatment effect. This may be particularly true for guidelines and, by extension, clinical pathways. Another limitation of the analysis is that only ambulatory oncology costs were included as a result of limitations in obtaining extramural utilization of emergency and inpatient services. In an era where comparative outcomes analysis and value assessment are increasingly important, the implementation of clinical pathways may provide a means to coalesce and disseminate institutional expertise and track and learn from care decisions. **JOP**

Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients With Stage IV Non–Small-Cell Lung Cancer

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Abstract

Purpose

Increasing costs and medical complexity are significant challenges in modern oncology. We explored the use of clinical pathways to support clinical decision making and manage resources prospectively across our network.

Materials and Methods

We created customized lung cancer pathways and partnered with a commercial vendor to provide a Web-based platform for real-time decision support and post-treatment data aggregation. Dana-Farber Cancer Institute (DFCI) Pathways for non–small cell lung cancer (NSCLC) were introduced in January 2014. We identified all DFCI patients who were diagnosed and treated for stage IV NSCLC in 2012 (before pathways) and 2014 (after pathways). Costs of care were determined for 1 year from the time of diagnosis.

Results

Pre- and postpathway cohorts included 160 and 210 patients with stage IV NSCLC, respectively. The prepathway group had more women but was otherwise similarly matched for demographic and tumor characteristics. The total 12-month cost of care (adjusted for age, sex, race, distance to DFCI, clinical trial enrollment, and EGFR and ALK status) demonstrated a \$15,013 savings after the implementation of pathways (\$67,050 before pathways v \$52,037 after pathways). Antineoplastics were the largest source of cost savings. Clinical outcomes were not compromised, with similar median overall survival times (10.7 months before v 11.2 months after pathways; $P = .08$).

Conclusion

After introduction of a clinical pathway in metastatic NSCLC, cost of care decreased significantly, with no compromise in survival. In an era where comparative outcomes analysis and value assessment are increasingly important, the implementation of clinical pathways may provide a means to coalesce and disseminate institutional expertise and track and learn from care decisions.

ASSOCIATED CONTENT



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INTRODUCTION

Today's oncologists face an environment of spiraling costs and increasing medical complexity. In non-small-cell lung cancer (NSCLC), for example, the emergence of genomically driven targeted therapies, vascular endothelial growth factor inhibitors, and more recently checkpoint inhibitors has dramatically altered the diagnostic and therapeutic landscape. Successfully translating these scientific advances into improved patient outcomes requires timely genomic and immunohistochemical screening, with a nuanced understanding of whom to test, what test to use, and how to interpret the results. These findings then drive selection of increasingly costly treatment regimens within the growing armamentarium of therapeutics.¹ Medical expenditures for cancer care are projected to reach at least \$158 billion by 2020, with some estimates going as high as \$207 billion.² Cancer drugs have been associated with the largest increase in costs,³ and recent studies show that the value obtained per dollar spent on cancer drugs in the United States lags behind other countries.⁴ These factors pose an urgent need to develop tools to support and inform care delivery and manage resource utilization in an appropriate and timely fashion to increase the value that we provide to our patients and to society.

Clinical pathways may be a way to harness medical expertise to optimize cancer care delivery. Prior studies have suggested that clinical pathways can reduce costs by 15% to 35% while achieving the same patient outcomes and clinical quality.^{5,6} Although analyses of pathways implementations remain limited, national support for their use is growing. Pathways have been proposed as critical tools in the movement to value-based care.⁷

At our academic cancer center, the Dana-Farber Cancer Institute (DFCI), we consider pathways to be a mechanism to capture the expertise and achieve consensus of our disease center clinician-scientists to ensure that diagnostic and therapeutic resources are applied most appropriately. The pathways project team supported each disease center in creating highly detailed care algorithms that define the optimal management for patients at each point in their care. Pathways were created in a series of semistructured meetings facilitated by one of the authors (D.M.J.). Engagement of all clinicians was strongly encouraged to maximally tap the expertise of the faculty and to create a strong sense of ownership. Prioritization of clinical options was based on efficacy, toxicity, and cost, in that order. We partnered with a commercial pathways vendor to create a Web-based platform to house our customized

content. The resulting pathways tool provides focused, real-time decision-making support across the continuum of cancer care.

A crucial advantage of a computer-based platform is the ease of aggregating data on treatment decisions and care delivery. In this analysis, we explore the clinical and financial impact of the creation and implementation of a lung cancer pathway.

MATERIALS AND METHODS

This project met DFCI's Institutional Review Board requirements for a quality improvement exemption and, therefore, did not require Institutional Review Board review.

Patients

The DFCI lung cancer pathways were created in late 2013 and implemented in January 2014. For this analysis, we focus on patients who were diagnosed with stage IV NSCLC and were treated within our network. The prepathway group consists of patients who were diagnosed in calendar year 2012, assuring at least 12 months of follow-up prior to the pathways implementation date. The postpathway cohort consists of patients diagnosed in calendar year 2014, after the rollout of the NSCLC pathway.

From the Dana-Farber Cancer Tumor Registry database, we identified all DFCI patients who were newly diagnosed with and treated for stage IV NSCLC during the time period of January 1, 2012, to December 31, 2012 (before pathways), and during the time period of January 1, 2014, to December 31, 2014 (after pathways). Demographics, clinical characteristics, treatments, charges, and utilization were captured from the Enterprise Performance System, a DFCI internal administrative cost accounting database. Clinical outcomes, including all results of *EGFR* and *ALK* testing, were extracted by a clinical team through review of the medical record. We also tracked the participation of patients in therapeutic clinical trials through our Clinical Operations and Research Information System.

The total payment of care for each patient was calculated, giving an estimated actual payment for 1 year after the time of diagnosis. The cost analysis was limited to DFCI-based activities and does not include data from any outside institution. Considering the inflation of the US dollar over time, we adjusted the 2012 dollar value to the 2014 dollar value by applying the Consumer Price Index.

Statistics and Cost Analysis

Four of the authors (D.M.J., C.A.L., J.N., and T.N.) reviewed the full medical record of each patient using a structured process to assure the accuracy of all treatment and outcomes data. For statistical consideration, in the descriptive analyses, the sociodemographic and clinical characteristics of participants are estimated as proportions for categorical variables and means with standard deviations for continuous variables. We conducted *t* test comparisons for continuous variables between the prepathway and postpathway groups with respect to age and distance between residence and DFCI. We performed χ^2 tests for categorical variables, such as sex, race (white *v* other), genetic profile (*EGFR* or *ALK* positive), and clinical trial enrollment. Kaplan-Meier survival curves were generated to explore patterns of survival between prepathway and postpathway groups, and a log-rank test was used to compare statistical distributions of the two groups. Cox regression was adopted to estimate the hazard ratio and 95% CI for the difference between the prepathway and postpathway implementation groups, adjusting for demographic and clinical covariates. For prepathway and postpathway implementation cost estimation, we compared average total cost and cost of each major service category by *t* test and multivariable regression models, with adjustment for the demographic and clinical covariates described. All tests were considered statistically significant at the *P* = .05 level, and all analyses were completed using Stata13 (STATA, College Station, TX).

RESULTS

We identified a total of 160 patients with stage IV NSCLC diagnosed in the year 2012 and 210 patients with stage IV NSCLC diagnosed in 2014. The prepathway group contained more women than the postpathway group (61% *v* 50%, respectively), but the groups were otherwise similar in terms of smoking status and presence of targetable genomic changes in *EGFR* and *ALK* (Table 1). The unadjusted regression shows a reduction of \$15,993 per patient (*P* = .03) for the total 12-month cost of care. By adjusting for age, sex, race, distance to DFCI, clinical trial enrollment, and *EGFR* and *ALK* status, the model demonstrated a \$17,085 (*P* = .01) savings after the implementation of pathways (\$69,122 before pathways *v* \$52,037 after pathways; Table 2). Pre- and postpathways itemization of outpatient payments identified chemotherapy as the single largest contributor to savings (Appendix Table A1, online only). Clinical outcomes remained consistent, with no significant difference in median overall

survival (10.7 months before *v* 11.2 months after pathways; *P* = .08; Fig 1).

DISCUSSION

Neubauer et al⁶ demonstrated a cost savings for patients with lung cancer treated between July 2006 and December 2007 on a clinical pathway compared with those treated off pathway over that same period. Lung cancer care has continued to evolve since that time, with a dozen new US Food and Drug Administration drug approvals or initial lung cancer labels in the past decade. We see clinical pathway development as an opportunity to define best practice and manage resource utilization within this increasingly complex landscape. With the implementation of a clinical pathway in NSCLC, we have documented a significant cost savings after pathway implementation with no adverse effects on clinical outcomes. Our findings echo those reported by Shapiro et al,⁸ with our data demonstrating the cost savings over a larger cohort encompassing a broader population (all patients with stage IV NSCLC, not just patients with nonsquamous disease).

Beyond the data, this study supports the notion that clinical pathways are feasible for creation and use within an academic network. One of the most critical yet least discussed aspects of clinical pathways is the intellectual consensus development process required for pathways development. The value of convening expert clinicians and scientists in a structured, ongoing process to discuss evolving issues around optimal cancer management cannot be understated.

The passing of the 2015 Medicare Access and Children's Health Insurance Program Reauthorization Act in part reflects a need to address the spiraling costs of health care. In its wake, providers and practices have been exploring a variety of possible alternative payment models. Although there remains uncertainty regarding the specific direction that payment reform may ultimately take, there will almost certainly be an increasing emphasis on comparative outcomes, value, and standardization. These three elements are at the heart of what clinical pathways can bring to cancer care.

Our assessment of the value of a cancer pathway is the most rigorous to date. To ensure accuracy and completeness, we combined administrative data with a structured record review for each patient. We performed a regression analysis that controlled for multiple covariates and found that the results fully supported the findings of the unadjusted analysis. However, we recognize several important limitations to our study. Among standard quasi-experimental designs,

Table 1. Characteristics of Pre- and Postpathway Cohorts of Patient With Stage IV Non–Small-Cell Lung Cancer

Characteristic	Prepathway Cohort (n = 160)	Postpathway Cohort (n = 210)	P
Sex, No. (%)			.03
Male	62 (39)	105 (50)	
Female	98 (61)	105 (50)	
Race, No. (%)			.39
White	142 (89)	192 (91)	
Other	18 (11)	18 (9)	
Median distance between patient residence and DFCI, miles (range)	29 (1-192)	27 (1-178)	.71
Median age, years (range)	63 (31-90)	64 (42-98)	.14
Genetic profile: <i>EGFR</i> or <i>ALK</i> positive, No. (%)	25 (16)	26 (12)	.37
Clinical trial enrollment, No. (%)	27 (17)	23 (11)	.15

Abbreviation: DFCI, Dana-Farber Cancer Institute.

uncontrolled before-and-after analysis is open to several potential sources of error. Such analyses are vulnerable to secular trends that may be confused for a treatment effect. This may be particularly true for guidelines and, by extension, clinical pathways.⁹

Another limitation of the analysis is that only ambulatory oncology costs were included. Because the majority of DFCI adult inpatient care is delivered at a second independent hospital (Brigham and Women’s Hospital), inpatient costs (including emergency department services) could not be captured as part of this analysis. To be as robust as possible, pathways decisions should be based on total cost of care, not just drug costs. Capturing extramural service usage rates and costs is challenging and requires collaboration with payers. To begin to address this issue, as a next step, we have established a program of data sharing with major Massachusetts payers and plan to obtain more comprehensive total usage data.¹⁰

Table 2. Cost Analysis for Patients With Stage IV Non–Small-Cell Lung Cancer Before and After Pathways

Pathways Cohort	Mean Cost (\$)	95% CI (\$)	P
Unadjusted cost			.03
Prepathway	64,508	53,140 to 75,876	
Postpathway	48,515	41,421 to 55,608	
Adjusted cost			.01
Prepathway	69,122	33,242 to 105,001	
Postpathway	52,037	25,200 to 48,849	

Most cancer pathways efforts to date have focused primarily, if not exclusively, on antineoplastic drug decision making. Future pathways should focus on optimizing other aspects of cancer care. This could include standardizing supportive medications, indicating optimal use of colony-stimulating factors, and providing palliative care pathways for management of common toxicities and cancer-related symptoms.

Finally, developing and deploying cancer pathways is a multifaceted process that includes a series of technical (eg, electronic pathway platform) and adaptive changes (eg, bringing clinicians together to discuss care patterns and potential best practices); which of these interventions resulted in

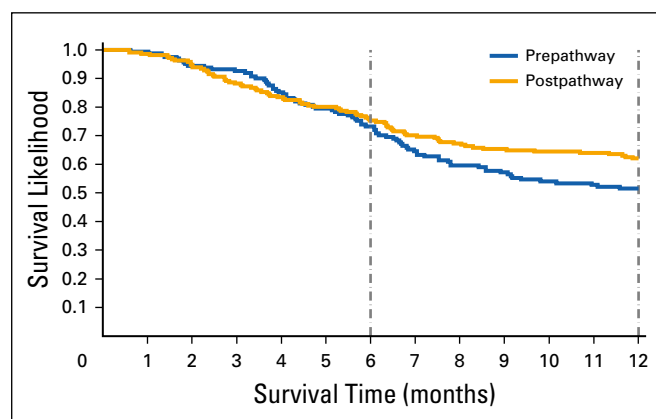


FIG 1. One-year Kaplan–Meier survival estimates comparing prepathway and postpathway groups of patients with stage IV non–small-cell lung cancer.

the reduction in spending cannot be ascertained. We report encouraging preliminary results of a large institutional program to build medical oncology clinical pathways in a large comprehensive cancer hospital. While maintaining consistent outcomes, the design and deployment of a locally developed pathway for stage IV NSCLC have been associated with significant cost savings. We view these findings as hypothesis generating. To determine the true benefits of cancer pathways, additional study is needed. Considerations include a rigorous design, such as a multi-institution cluster randomized controlled trial, or a more pragmatic assessment of costs and outcomes achieved by different pathways programs implemented across comparable practice settings. **JOP**

Authors' Disclosures of Potential Conflicts of Interest

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Appendix

Table A1. Estimated Payment Comparison for Non–Small-Cell Lung Cancer, Before and After Pathway

Service	Average Payment Before Pathway (\$)		Average Payment After Pathway (\$)		P
	Mean	95% CI	Mean	95% CI	
Chemotherapy, biologics, and other antineoplastic	44,237	44,084 to 44,390	31,846	31,726 to 31,966	.00
Radiology	5,409	5,354 to 5,464	3,870	3,827 to 3,913	.70
Radiation therapy	5,175	421 to 9,928	3,975	711 to 8,662	.00
Nonchemotherapy infusion, transfusion, and blood products	3,764	2,880 to 4,648	3,082	1,859 to 4,305	.74
Other diagnostic tests	2,882	2,335 to 3,429	3,031	2,466 to 3,595	.39
Evaluation and management	2,855	2,533 to 3,176	2,537	2,255 to 2,819	.15
Procedures	183	138 to 228	172	125 to 219	.76
Other	3	1 to 5	2	0.28 to 3.25	.37