Original Contribution

Opening the Black Box: The Impact of an Oncology Management Program Consisting of Level I Pathways and an Outbound Nurse Call System

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Abstract

Purpose: The Innovent Oncology Program aims to improve the value of cancer care delivered to patients. McKesson Specialty Health and Texas Oncology (TXO) collaborated with Aetna to launch a pilot program. The study objectives were to evaluate the impact of Innovent on Level I Pathway compliance, implement the Patient Support Services program, and measure the rate and costs associated with chemotherapy-related emergency room (ER) visits and hospital admissions.

Patients and Methods: This was a prospective, nonrandomized evaluation of patients enrolled in Innovent from June 1, 2010, through May 31, 2012. Data from the iKnowMed electronic health record, the McKesson Specialty Health financial data warehouse, and Aetna claims data warehouse were analyzed.

Results: A total of 221 patients were included and stratified according to disease and age groups; 76% of ordered regimens were on pathway; 24% were off pathway. Pathway adherence improved from TXO baseline adherence of 63%. Of the 221 patients, 81% enrolled in PSS. Within the breast, colorectal, and lung cancer groups, 14% and 24% of patients had an ER visit and in-patient admission (IPA; baseline) versus 10% and 18% in Innovent, respectively; average in-patient days decreased from 2.1 to 1.2 days, respectively. Total savings combined for the program was $506,481.

Conclusion: Implementation of Innovent positively affected patient care in several ways: Fewer ER visits and IPAs occurred, in-patient days decreased, cancer-related use costs were reduced, and on-pathway adherence increased.

Introduction

Declining reimbursement, sequester cuts, and reimbursement advantages for hospitals threaten community oncology practice.[1-4] We present results of a pilot study involving Texas Oncology (TXO), a community oncology practice; the Innovent Oncology Program (supported by McKesson Specialty Health [MSH] and the US Oncology Network); and Aetna.

To address the rising costs of cancer treatment while emphasizing evidence-based medicine, the US Oncology Network developed the Innovent Oncology Program. Program goals address three drivers of high cost: variable use of drugs,[4-6] deterioration of patient health status between treatments, and ineffective interventions near the end of life.[7] Innovent incorporates three programs: Level I Pathways, Patient Support Services (PSS), and Advance Care Planning.[7] In this report, we focus on Level I Pathways and PSS.

Level I Pathways are treatment guidelines established for an evidence-based oncology program. Published data are evaluated to assess efficacy, toxicity, and cost. Treatment choices are based on lines of therapy and integrated into the iKnowMed (iKM) electronic health record. Pathway adherence is calculated from patient- and disease-specific data elements, line of therapy, and regimen prescribed. Adherence is measured for each regimen (*v* patient) at the time of treatment order based on physician intent in iKM. The mission of Level I Pathways is to provide treatment options that maximize survival, minimize toxicity, and provide cost-saving opportunities for patients and payers.[7]

PSS is a telephonic nursing intervention program to support patients throughout chemotherapy. Oncology-certified nurses contact, assess, and educate patients between treatments. Proactive calls occur before chemotherapy initiation to establish patient clinical and psychosocial baseline measures. Post-treatment call timing is based on frequency of chemotherapy administration, patient comorbidities, and risk of adverse events throughout treatment. GI toxicities, infection, thromboembolic events, pain, and depression are specific required queries during each call, as are patient-reported outcomes measured by the Edmonton Symptom Assessment Scale. Calls occur when adverse effects are identified and require clinical monitoring or when intervention is needed. New or uncontrolled symptoms are reported to the patient's physician for assessment and treatment to direct the patient to the oncologist for adverse effect management, reducing emergency room (ER) visits and hospitalizations.

Patient education is regimen specific and reinforces education received from the clinic. Nursing interventions are documented directly in the patient's medical record, providing continuity of care across the patient treatment continuum. Patient surveys report patient satisfaction with the program. Surveys are mailed to each PSS patient after program participation.

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To evaluate the impact of Innovent, MSH and TXO, a single tax identification group of more than 350 cancer specialists practicing in a US Oncology Network–affiliated practice in Texas, collaborated with Aetna to launch a pilot program. Multidisciplinary cancer centers (medical, radiation, surgical oncology) span the state and include rural, suburban, and urban centers. The study objectives were to evaluate the impact of Innovent on Level I Pathway compliance within TXO, implement PSS, measure the rate and costs associated with chemotherapy-related ER visits and in-patient use, and assess chemotherapy costs.

Patients and Methods

This was a prospective, nonrandomized evaluation of patients enrolled in Innovent seen by TXO physicians from June 1, 2010, to May 31, 2012. The program was conducted over 2 years: Program year 1 (PY1) was from June 1, 2010, to May 31, 2011, and program year 2 (PY2) was from May 1, 2011, to April 30, 2012. The study was institutional review board approved. No attempt was made to direct patients to particular physicians based on practice patterns. All TXO physicians were on the Aetna provider panel, and patients had unrestricted physician choice.

Patient Characteristics

Four groups of patients enrolled in an eligible Aetna insurance plan were compared: two TXO groups (baseline and Innovent) and two non-TXO groups (concurrent control [CC] baseline and CC active). Patients were included in the Innovent group for PY1 or PY2 if they had an Innovent cancer diagnosis treated by a TXO physician and initiated chemotherapy during the active Innovent period, PY1/PY2.

Patients were excluded if they had an initial chemotherapy claim in the last month of PY1 or had no chemotherapy claim within the program year. Patients beginning chemotherapy the month before PY2 were excluded from analysis to minimize overlap of data from PY1 to PY2 but were managed by Innovent.

Chemotherapy included oral and intravenous routes of immunotherapy, biologics, and targeted therapies, identified by Healthcare Common Procedure Coding System codes. Supportive agents, such as RBC and WBC growth factors, and bone agents (bisphosphonates) were included as chemotherapy-related drug costs (CRDCs). Hormonal agents were excluded.

Diagnoses were grouped into breast, colorectal, lung, ovarian, pancreatic, hematologic, and prostate cancers, which were all included in pathway adherence determination. Disease categories were divided by age at program entry (age 18-50 and ≥51 years) for 14 final cohorts. All patients and regimens were included in pathway adherence analysis; however, because numbers of patients in most of the 14 cohorts were small, only breast, colorectal, and lung cancers were included in the Innovent study cohort for additional performance metric analyses.

Patients with breast, colorectal, or lung cancer meeting these clinical, diagnostic, and payer-specific criteria in the 12 months before initiation of Innovent and seen by TXO physicians were identified for comparison of metrics with the Innovent study cohort and were included as the TXO baseline population. Two additional populations were identified for study inclusion and comprised patients in Texas seen outside of TXO who had Aetna coverage. They were classified as follows: CC baseline population, comprising Texas patients meeting the inclusion criteria the year before the program years, and CC active population, comprising Texas patients meeting inclusion criteria during the program years. Neither the CC baseline nor CC active group was managed by Innovent. The CC baseline and CC active populations were identified through Aetna claims data and matched with the TXO cohorts by diagnosis and age. Clinical information, including stage, line of therapy, and disease-specific information, was not available. These two non-TXO populations were used to assess drug costs only.

Performance Metrics

Data obtained from iKM, the US Oncology MSH financial data warehouse; and the Aetna claims data warehouse were analyzed to include clinical and claims elements and to evaluate the predetermined performance metrics. Pathway adherence was defined as the percentage of regimens ordered in each population on pathway. PSS use was calculated as the percentage of active treatment members engaged in PSS. CRDCs (chemotherapy plus select supportive care agents) were determined from a fee schedule agreed on before Innovent initiation. Acute care use and costs from Aetna claims data (chemotherapy-related in-patient admissions [IPAs] and ER visits) were also predetermined from an agreed-on fee schedule. IPAs and ER visits were defined as events that could occur as a result of chemotherapy administration and included toxicities like GI-related events, infection, thromboembolic events, and nutrition and fluid abnormalities, among others. Only events captured within 30 days of treatment were included as chemotherapy related. Pain scores, patient satisfaction, and referrals to Aetna case management were also collected.

Population Comparison and Analysis

Pathway adherence, ER visits, IPAs, and in-patient days (IPDs) were measured by comparing metrics in the TXO baseline versus Innovent populations. ER visits, IPAs, and IPDs were assessed by count and costs. IPAs, IPDs, and ER visits were included when the date of service (ER) or date of admission (IPA) fell on or after the first chemotherapy administration and on or before 30 days after the last chemotherapy administration. CRDCs were evaluated using a concurrent control comparison, measuring the rate of change from TXO baseline to Innovent versus the rate of change from CC baseline to CC active.

Statistical Evaluation

Patient characteristics including diagnosis, sex, stage at diagnosis, and age were assessed for differences between TXO baseline and Innovent groups (PY1 and PY2 collectively). Statistical significance was set at 5%. No adjustments were made for mul-

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tiplicity of testing. Categorical variables were evaluated using χ^2 or Fisher's exact test[8]; Wilcoxon rank sum test[9] was used to compare age and time on treatment as continuous variables.

Poisson regression analyses[10,11] were used to assess outcomes, ER visit and IPA counts, and length of stay in days. A model was fit using the covariates, population (baseline or Innovent), and diagnosis (breast, colorectal, or lung cancer) as predictors to model response outcomes. Because population is the primary factor of interest, it was retained in the model regardless of a statistically significant difference between groups. However, diagnosis was kept in the model only if statistically significant at the 5% level.

Goodness-of-fit χ^2 tests were conducted to evaluate the Poisson regression model; Pearson χ^2 statistic was used to assess overdispersion. Incident rate ratio (IRR) was calculated. If evidence of poor fit was found, negative binomial regression analysis was used as an alternative, and similar methods were implemented to assess goodness of fit. Extreme values for total length of stay were assessed for IPA analysis.

Pathway adherence (on *v* off pathway) was assessed using a two-sample test to compare the proportions of pathway adherence, and 95% CIs were constructed. All computations were executed in SAS software for Windows (version 9.2; SAS Institute, Cary, NC).

Results

Patient Characteristics

Innovent (PY1, n = 100; PY2, n = 121) included 221 patients. Each disease cohort was dichotomized by age: 18 to 50 years (PY1, n = 31; PY2, n = 47) and ≥ 51 years (PY1, n = 69; PY2, n = 74). Median age at diagnosis for PY1 and PY2 groups was 55 and 53 years, respectively. Pathway adherence was evaluated for all Innovent cohorts (N = 221), whereas pathway adherence plus ER visits, IPAs, IPDs, and costs included breast, colorectal, and lung cancer cohorts only (n = 169; breast cohort, age 18-50 and ≥ 51 years; colorectal cancer, age ≥ 51 years; lung cancer, age ≥ 51 years).

Table 1 shows characteristics for patients in the Innovent and TXO baseline groups. Of the 221 total Innovent patients, 169 were analyzed for ER visits, IPAs, IPDs, and costs: 99 patients in the breast (PY1, n = 39; PY2, n = 60), 41 in the colorectal (PY1, n = 20; PY2, n = 21), and 29 in the lung cancer cohorts (PY1, n = 19; PY2, n = 10). Patients were matched regarding age, stage at diagnosis, and time on treatment between Innovent and baseline. There were more women and more patients with breast cancer in the baseline group (P = .005 and P = .027, respectively). Excluded from the analysis were 52 Innovent patients because of diagnoses other than breast, colorectal, or lung cancer.

Pathway Adherence and PSS

In the Innovent population, 76% of ordered regimens were on pathway, 24% were off pathway, with 4% of off-pathway regimens nonassessable (ie, insufficient discrete data to assess compliance). Overall adherence improved from the TXO baseline evaluation of 63%. In the breast, colorectal, and lung cancer cohorts, pathway adherence improved from 69% (569 of 821 regimens ordered) during the baseline year to 79% (211 of 266 regimens ordered) in the Innovent population (95% CI, 0.04 to 0.16; P = .002).

Of the 221 Innovent patients, 81% enrolled in PSS, with 1,118 outbound calls placed. Pain was assessed during 93% of patient contacts. To evaluate overall patient satisfaction with the nursing intervention, surveys were sent to patients at the completion of the program. There was a 26% (n = 64) response rate, and 83% of responders reported being satisfied with PSS interventions.

Table 1. Clinical Characteristics of Baseline and Innovent Populations

	Baseline (n = 656)		Innovent (n = 169)		
Characteristic	**No.**	**%**	**No.**	**%**	***P***
Sex					.005*
Female	531	81.0	120	71.0	
Male	125	19.0	49	29.0	
Diagnosis					.027*
Breast cancer	435	66.0	99	59.0	
CRC	102	16.0	41	24.0	
NSCLC	119	18.0	29	17.0	
Stage at diagnosis†					.24*
I to III	421	76.3	122	80.8	
IV	131	23.7	29	19.2	
Time on treatment, days					.70‡
Median		106.0		105.0	
SD		82.3		80.6	
Age at diagnosis, years					.96*
18 to 50	189	28.8	49	29.0	
≥ 51	467	71.2	120	71.0	
Median		56.0		54.0	.07‡
SD		9.1		8.3	

Abbreviations: CRC, colorectal cancer; NSCLC, non–small-cell lung cancer; SD, standard deviation.
* χ^2 test.
† One hundred four patients in the baseline group (16%) and 18 patients in the Innovent population (11%) had an unknown stage at diagnosis.
‡ Wilcoxon rank sum test.

Acute Care Use and Cost Analysis

Chemotherapy-related IPAs, IPDs, and ER visits were assessed for breast, colorectal, and lung cancer cohorts. In the baseline population, 14% of patients (n = 90) had an ER visit and 24% (n = 158) had an IPA versus 10% (n = 17) and 18% (n = 31) in Innovent, respectively. Significant variability occurred in the number of IPAs, ER visits, and IPDs for all patients. Of 825 patients in the baseline and Innovent groups, ranges were zero to nine ER visits, zero to four IPAs, and zero to 56 IPDs (standard deviation, 4.83). Average ER visits, IPAs, and IPDs were 0.21, 0.38, and 2.08 days in the baseline population versus 0.11, 0.25, and 1.16 in the Innovent group, respectively.

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Population was an independent predictor of ER visits (P = .006), whereas population and diagnosis were independently associated with IPAs (P = .03 and P < .001, respectively). Patients in the baseline population had a higher incidence of both ER visits and IPAs than Innovent patients (IRR, 1.90; P = .006 and 1.46; P = .03, respectively). Additionally, Innovent patients had 50% fewer IPDs per patient (2.1 *v* 1.0 days; IRR, 0.47; P = .018) than baseline population patients (Table 2).

One IPA from each group was excluded as an outlier (47 days in Innovent and 56 days in TXO baseline), because these observed events were more than nine standard deviations from the mean. Both population and diagnosis were independent predictors for IPDs (P = .018 and P = .010, respectively). Table 2 lists results for the analysis of PY1 and PY2 collectively. The same methodology was applied and similar analyses were performed on PY1 and PY2 separately. These results are summarized in Appendix Table A1 (online only).

To estimate the variance of expected savings with this population, a bootstrap was applied. For each member, costs were compared with expected costs to determine total member-level savings. From this, 169 members were drawn, with replacement, and savings for this resampled group was computed. To estimate the probability density of savings, 10,000 such scenarios were produced.

Because the observed incidence of ER visits and IPAs decreased in the Innovent population, savings increased. Baseline IPAs, ER visits, and CRDCs per member for lung cancer were $12,968, $853, and $23,027 and for one program year per member were $4,926, $338, and $18,063, respectively. The resulting IPA, ER visit, and CRDC total savings were $80,217, $5,147, and $46,180, respectively. Total savings for breast, colorectal, and lung cancer cohorts were $441,452, $31,628, and $33,401, respectively, for the program (Fig 1); 1% of scenarios produced negative savings.

Table 2. Acute Care Assessments (PY1 and PY2 combined)

Outcome Response	Observed Average	Predicted Count	IRR	*P*
Total ER visits				
Population				.006*
Baseline	0.21	0.21	1.90	
Innovent	0.11	0.11	Ref.	
Total IPAs				
Population†				.03*
Baseline	0.38	0.41	1.46	
Innovent	0.25	0.28	Ref.	
Total IPDs				
Population†				.018‡
Baseline	2.08	2.09	—	
Innovent	1.16	0.99	0.47	

Abbreviations: ER, emergency room; IPA, in-patient admission; IPD, in-patient day; IRR, incident rate ratio; PY, program year; Ref., reference.
* Poisson regression analysis.
† Results after controlling for diagnosis.
‡ Negative binomial regression analysis

Discussion

This report presents the first prospective evaluation to our knowledge of a pathway and disease management program associated with cost and acute care use data. Cost reduction was substantial for hospital admissions, hospital days, and ER visits, with usage reductions of 34%, 44%, and 48%, respectively.

The relative impact of each Innovent component is uncertain. Previous studies have reported geographic variation in chemotherapy-related hospitalization rates (hospital admits per patient per year) in a commercial population, ranging from 0.223 to 0.484.[3] Incidence of chemotherapy-related ER visits also varied from 0.465 to 1.626 per patient per year. Another study[6] reported a trend of fewer hospital and ER visits for an on-pathway group. Notable in our study is the progressive reduction in IPAs and ER visits from year 1 to 2, with a second-year rate of IPAs of 0.19 and an ER visit rate of 0.1, with a ≥ 50% reduction in all parameters when PY2 is compared with baseline. These numbers are unprecedented in the current literature.[12] This suggests that Innovent may improve on-pathway–alone strategies. PSS is differentiated from other management programs by proactive and targeted intervention before chemotherapy administration and use of systematic symptom assessment throughout treatment. Our patient satisfaction survey response was lower than anticipated. We believe several factors were contributory: (1) PSS nurses did not inform patients that surveys would be sent, (2) no incentive was provided to participants, and (3) no follow-up was conducted among nonresponders. To increase survey responses, we will address these issues. In an older population with complex comorbidities, PSS will be critical to high-quality, integrated care.

To meet the needs of this program, significant changes occurred within TXO. Quality committees at each cancer center were launched in February 2011, focusing on pathway adherence, and monthly reviews of practice site performance were reported. The committees provided performance feedback to physicians regarding data completeness and regimen selection.

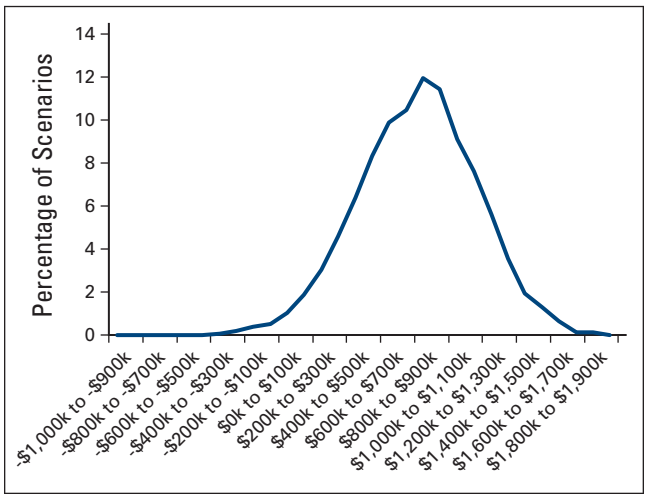

Figure 1. Bootstrap: cumulative 24-month gross savings using 10,000 scenarios.

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These reports provided information on individual physician and peer performance to promote collaborative exchange and learning. As a result of this broad-based education effort, pathway performance improved among all sites and physicians.

This study reinforces the notion that collaboration between providers and payers is key to understanding the total cost effects of care management. It is critical to measure drug and hospital costs over time. Our study demonstrated year-over-year improvement, with nonsignificant findings after PY1 but significant changes in PY2 and cumulatively.

Although all pathway diagnoses were included in the program, numbers of patients were small in some cohorts; therefore, most patients fell into the breast, colorectal, or lung cancer cohort. There was a predominance of young patients receiving adjuvant chemotherapy for breast cancer. This may be tempered by the overall comparison between the groups being well matched. There was some overlap of patients between the baseline and Innovent populations, making a clean assessment of program impact challenging. Only CRDCs and acute care occurring during the respective timelines were included in the analysis. We studied four populations: two within TXO for comparison of acute care use and two in Texas, outside of TXO, for evaluation of CRDCs. Because these latter two were identified within a claims database, limited clinical data were available. Although program study objectives were identified prospectively, statistical analysis was conducted ad hoc.

In conclusion, Innovent was feasible to implement and deliver. Patients were identified and calls were delivered to assist patients with management of toxicities as directed by the primary oncology physicians. Pathway adherence significantly improved. A decrease occurred in ER visits, IPAs, and IPDs in breast, colorectal, and lung cancer populations during PY1 and PY2. These data suggest that Innovent contributed to fewer ER visits and hospital admissions, shorter length of stay, overall cost reduction, and a greater likelihood of patients receiving evidence-based treatment.

Acknowledgment

We thank Cindy Taniguchi and John Ciaglo for their contributions to the development of this study and manuscript and Ann Morcos for writing and editorial assistance.

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Author's Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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DOI: 10.1200/JOP.2013.001210

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Appendix

Table A1. Acute Care Assessments (PY1 and PY2 separately)

Outcome Response	Observed Average	Predicted Count	IRR	*P*
		PY1		
Total ER visits				.23*
Baseline	0.21	0.21	—	
PY1	0.13	0.13	0.61	
Total IPAs				.84*
Baseline	0.34	0.34	—	
PY1	0.32	0.32	0.95	
Total IPDs				.51*
Baseline	2.08	1.75	—	
PY1	1.33	1.33	0.76	
		PY2		
Total ER visits				.014†
Baseline	0.21	0.21	—	
PY2	0.10	0.10	0.47	
Total IPAs‡				.011†
Baseline	0.38	0.40	1.77	
PY2	0.19	0.23	—	
Total IPDs‡				.009*
Baseline	2.08	2.04	—	
PY2	1.01	0.64	0.31	

Abbreviations: ER, emergency room; IPA, in-patient admission; IPD, inpatient day; IRR, incident rate ratio; PY, program year.
* Negative binomial regression analysis.
† Poisson regression analysis.
‡ Results after controlling for diagnosis.

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