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Construct Validity of Medicare Chemotherapy Claims

The Case of 5FU

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BACKGROUND. The elderly are under represented in clinical trials of cancer therapy and the elderly who are enrolled may be unrepresentative.

OBJECTIVE. To assess whether Medicare claims data might be used to understand the benefits and tolerance of chemotherapy in the general elderly population, the construct validity of Medicare 5FU claims for elderly colon cancer patients within the SEER-Medicare data set was determined.

METHODS. In this validation study of Medicare chemotherapy claims from the linked the SEER-Medicare data set, the patterns of 5FU chemotherapy claims were evaluated for an incident cohort of elderly colon cancer patients (n = 15,039) during the 13 months following their diagnosis. Patterns of Medicare National Claims History (NCH) 5FU claims were evaluated with respect to prespecified patient-level disease and demographic factors from the data set.

RESULTS. Twenty-two percent of patients had at least one detectable 5FU claim during the observation period. Among those patients, the median dose of 5FU was 1000 mg, the median interval between 5FU claims was 7 days, and the median number of claims during this period was 24. Multivariate regression revealed expected associations between demographic and disease factors and the likelihood of having a Medicare NCH 5FU claim. With increasing cancer stage, patients' likelihood of having a 5FU claim increased. Younger patients, married patients, white patients, patients with low comorbidity, and patients living in urban and less impoverished regions were each more likely to have 5FU claims.

CONCLUSION. Because their pattern is consistent with the standard of medical care and with previously described associations with disease and demographic factors, it was concluded that Medicare NCH claims for 5FU administration in the SEER-Medicare data set exhibit construct validity. Criterion validation studies with an external gold standard should be pursued to determine the sensitivity and specificity of chemotherapy codes in the Medicare NCH files.

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Elderly Americans with cancer are under represented in the clinical trials that seek to establish the benefits and tolerance of anti-cancer therapy.[1,2] Also, clinical trials often exclude participants with comorbidities, which are common among the elderly. Thus, the results of these studies may not

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be applicable to the general population of elderly Americans with cancer. Solutions to this problem that have been proposed include increasing the number of elderly participants on clinical trials and collecting observational data. The latter solution, however, requires a valid data source, which includes accurate information regarding chemotherapy agent, dose, schedule, and date of administration and outcomes.

Because the Health Care Financing Administration (HCFA) Medicare program reimburses chemotherapy administration, Medicare billing claims are a potential source of such observational data. Medicare claims data are complete and accurate for specific categories of procedures and diagnoses to varying extents.[3–7] Before these data can be used in analytic studies of Medicare claims, their validity must be evaluated. Such validity studies seek to address the extent to which the Medicare claims reflect the relevant aspects of a patient's health care encounter—here, administration of chemotherapy.[3]

Among the types of validation amenable to administrative data sources are studies ascertaining "construct validity." With its origins in the psychology literature,[8,9] construct validation is commonly used in health care research[10,11] and can be thought of as determining the extent to which a specified measure from a data source varies with other measures within the same data source in a manner consistent with theories and hypotheses related to the construct, or the putative object of measurement.[11]

Here, we seek to determine the construct validity of chemotherapy claims appearing in the SEER-Medicare data set. Our construct is "chemotherapy administration to elderly colon cancer patients." Our measures of interest are patient 5FU chemotherapy claim codes from the SEER-Medicare data set and our queried associated measures are patient demographic and disease variables from the same data set. The specified associations between measures that we seek are consistent with theories, hypotheses, and prior empirical work related to the construct of 5FU administration in elderly colon cancer patients. We chose to focus on colon cancer and 5FU because this agent offers the advantage of more precise expectations of patterns of receipt as it was the standard first line chemotherapy agent for the treatment of both locally advanced and metastatic colon cancer during our observation period.

Based on results of relevant clinical trials that have established a standard of care within the medical community, we expect defined associations between 5FU claims and colon cancer stage, and we expect the 5FU claims to reflect a standard administration. During the study period, the recommended standard of care with respect to 5FU therapy[12] was based on results of randomized-controlled trials that revealed a survival advantage for patients who received adjuvant chemotherapy with 5FU following resection of stage III disease.[13–15] In patients with metastatic disease,[16] 5FU was shown in a randomized trial to confer a small survival advantage. The relevant adjuvant regimen was oral levamisole and intravenous 5FU 425 to 500 mg/m^2 daily for 5 days followed 28 days later by 48 weekly doses of intravenous 5FU at the same dose. The relevant metastatic regimen was weekly 5FU at a similar dose and leucovorin. Thus, if the Medicare claims are valid representations of clinical care and if the recommended standard of care was generally followed, we would expect to find higher proportions of patients with stage III and IV disease with claims for 5FU than patients with stage I and II disease.

Additionally, we would expect to find most 5FU claims to indicate a dose in the range of 1000 mg (assuming a distribution of body surface area in the elderly of 1.5–2.0), to repeat at 7 day intervals, and to describe up to 53 administrations for stage III patients. We would expect fewer repeat administrations for stage III patients who are unable to tolerate the therapy caused by toxicity or who die before completion, and fewer repeat administrations for stage IV patients, who have a median survival of less than 1 year. Because comorbidity has been shown to be negatively associated with receipt of adjuvant chemotherapy in elderly colon cancer patients,[17,18] we would also expect to see a decrease in proportion of patients of having claims for 5FU as patients' comorbidity increases.

There are also several previously described associations between patient demographic factors and anti-cancer therapy. Specifically, age, race, marital status, and urban region have each been shown to be associated with receipt of anti-cancer therapy. Age is negatively associated with adjuvant chemotherapy use in elderly patients with colon cancer.[17–19] Black persons are less likely to receive curative colon cancer surgeries[20–21] and, therefore, may be less likely to receive other types of anti-cancer therapy. Marital status has been shown to be associated with treatment of patients with a

variety of medical conditions including cancer; married patients are more likely to receive treatment.[22,23] Geographic variation in cancer care has been described with patients residing in urban regions more likely to receive standard of care.[24] Thus, we would expect to find these associations between 5FU claims and patient demographic factors if the claims accurately reflect clinical practice. Hence, to determine construct validity of the Medicare NCH 5FU claims in the SEER-Medicare data set, we evaluated the associations between clinical and demographic variables and 5FU claims among elderly Medicare beneficiaries with colon cancer.

Materials and Methods

Data Sources

We studied Medicare beneficiaries with colon cancer from the 11 geographically diverse tumor registries that participate in the NCI's SEER program using the NCI's SEER-Medicare data set. It is estimated that patients in the SEER program constitute approximately 14% of the American population with cancer[25] and prior research has shown that patients in these registries are demographically representative of the general population.[26] The SEER program collects detailed information about initial diagnosis and treatment, including date of diagnosis, site, histology, stage of tumor at diagnosis, and date of death and demographic information (eg, age, sex, race, census-based socioeconomic indicators). The mortality data reported by SEER are provided by the National Center for Health Statistics through linkage to death certificates. The SEER program conducts annual audits of their data to ensure data quality and completeness and hold the standard of ascertainment at 98%.[27]

Medicare is a federally sponsored health insurance program administered by the Health Care Financing Administration (HCFA) whose beneficiaries include more than 96% of all US citizens aged 65 and older.[28] HCFA maintains billing records of outpatient, inpatient, home health, hospice, and other claims for all beneficiaries not enrolled in risk contract health maintenance organizations (HMOs). Outpatient medical care is documented in the Outpatient Standard Analytic File (SAF) and the National Claims History (NCH) file. The NCH file contains all Medicare Part B (physician/supplier) claims for each calendar year. The NCH file can contain multiple records per visit and each record includes up to one procedure and five diagnoses. The procedures fields are coded with Medicare procedure codes and the diagnosis fields are coded with ICD-9-CM codes. Although we know of no prior work focused on questions of data quality of NCH chemotherapy claims, others have examined Medicare part B files against a gold-standard of clinical data (ie, medical record) for other claims and found certain codes were associated with a high likelihood of the presence of the disease described or procedure rendered.[29,30]

The SEER-Medicare data set is the result of an NCI-sponsored linkage of the clinical data collected by the SEER registries with health services billing claims collected by Medicare for administrative purposes. NCI releases files where linkage is possible through the use of a unique number for each elderly cancer patient that is visible in both files and thereby allows SEER files and Medicare files to be matched and merged, although persons are not identifiable. The SEER-Medicare data set is widely used by researchers studying outcomes, clinical epidemiology, and health services factors among elderly cancer patients.

Cohort Development

Our incidence cohort (n = 15,589) consisted of all patients in the SEER file diagnosed with pathologically confirmed stage I-IV adenocarcinoma of the colon; diagnosed at or after age 67 between the period 1/1/93 and 12/30/96; entitled to Medicare parts A and B during the observation period so that evaluation of both outpatient care (covered by Medicare part B) and inpatient care (covered by Medicare part A) was possible; and not enrolled in an HMO (for whom individual claims may not be submitted to Medicare because of capitated payment) during the observation period. Patients were excluded if they had Medicare ICD-9-CM codes for colon cancer that preceded the SEER date of colon cancer diagnosis by more than 2 months (n = 304); if they had not undergone cancer surgery (restriction applied only to patients with stage I-III disease) (n = 229); if their colon cancer was diagnosed at autopsy (n = 17). The analytic sample thus consisted of 15,039 patients.

Outcome Ascertainment

Although the SEER program routinely collects information regarding certain anti-cancer therapies (ie, surgery, radiation therapy) occurring within 4 months of diagnosis, SEER does not report information pertaining to chemotherapy administration because of concerns regarding data quality. However, the Medicare program reimburses chemotherapy administration, and we have found that specific agents, routes, and total dose of chemotherapy billed may be reconstructed from NCH files by using a constellation of three NCH file fields. The relevant fields are the "HCPCS code" field, the "carrier miles/time/units/serv indicator" field, and the "carrier miles/time/units/serv count" field. The HCPCS code is the HCFA Common Procedure Code. When the HCPC begins with a "J9", the following three numbers indicate the chemotherapy drug, the route of administration, and a base dose value. For example, the HCPC code J9190 indicates 5FU, intravenously administered with a base dose of 500 mg. The "carrier miles/time/units/serv indicator" field and the "carrier miles/time/units/serv count" field modify the J code base dose, providing complete information about dose. Specifically, when the number "3"—indicating "Services"—appears in the "carrier miles/time/units/serv indicator" field, the billed dose is the J code base dose multiplied by the numeric value—"unit count"—reported in the "carrier miles/time/units/serv count" field. When the number "3" appears in the "carrier miles/time/units/serv indicator" field and the number "2" appears in the "carrier miles/time/units/serv count" field, this constellation of codes indicates that the patient was billed for 1000 mg of intravenous 5FU (two times the base dose). Table 1 contains a description of this coding system.

We evaluated the cohort's NCH files for these three chemotherapy-related fields for the 13 months following colon cancer diagnosis. The choice of the observation period stems from the recommended clinical practice for patients with stage III and IV disease. With respect to stage III disease, until 1997,[31] standard adjuvant therapy consisted of daily 5FU for five doses, followed 4 weeks later by 48 weekly doses of 5FU therapy after surgical resection[13] that was typically initiated within 3 to 4 weeks following surgical resection. With respect to stage IV patients, the median survival associated with 5FU therapy is approximately 1 year.[16,32–35] Thus, the 13 months following diagnosis will likely contain most 5FU chemotherapy information for most stage III and IV patients who began treatment soon after diagnosis.

Finally, we were also interested in ascertaining whether dates of NCH Medicare chemotherapy claims plausibly reflected dates of patient treatment. Medicare NCH files contain variables that indicate the beginning and end of a given claim's treatment interval. Because later use of these data for studies of causal inference would be aided by the ability to pinpoint date of chemotherapy administration, we sought to describe the treatment interval for the cohort's NCH 5FU claims. A finding of a single date of treatment in the claims would support, but clearly not prove, an informative role for dates.

Definition of Explanatory Variables

Patients' cancer related variables of tumor stage, histology, and grade were ascertained from the SEER file. To evaluate for the impact of patient comorbidity on propensity to have claims for 5FU, we used an application of the Charlson comorbidity score.[36–38] The Charlson comorbidity score is a convenient method of making operational cooccurring medical illness in cancer patients and is often used for risk adjustment. The score, ranging from 0 to 33, consists of a weighted sum of 17

TABLE 1. Methodology for Ascertainment of Billed Dose of Chemotherapy From Medicare NCH Files

Field	Value	Description of Code
HCPC	J9XXX	Chemotherapy drug, base dose, route of administration (eg, J9190 = intravenous fluorouracil 500 mg)
Carrier Indicator	Services	Indicates that Carrier Count Field contains the number count of units of the HCPC code
Carrier Count	Integer	Indicates the multiples of the HCPC code

different illnesses that have been shown to be associated with increased mortality. We used a variation of the Charlson comorbidity score that relies on diagnosis codes (ICD-9-CM) within the Medicare files, and we applied it to the patients' inpatient (MEDPAR) files in the 24 months preceding diagnosis (thus the requirement that incident cases be age 67 or older). Patient demographics were ascertained from the SEER file including age at diagnosis, sex, race, marital status, metropolitan zip code, and whether the patient lived in a census tract with greater than 20% of residents living below the poverty level.

Statistical Analyses

To evaluate for associations between the presence or absence of NCH 5FU claims and categorical and continuous variables, we used χ^2 tests and analysis of variance respectively. We used logistic regression to model the multivariate impact of patient demographic and disease variables on the likelihood of having claims for 5FU in the 13 months following colon cancer diagnosis. All analyses were performed in STATA 7.0 (Stata, College Station, Texas).

Results

Cohort Characteristics

Table 2 contains a description of the demographic and disease characteristics of the analytic sample (n = 15,039). The median age was 77 years and 58% of patients were female. For 14,857 cases (99%) in the cohort there were matching NCH Medicare files within the period of observation.

5FU Utilization Analyses

Table 3 contains a description of the 5FU claims incurred by the cohort during the 13 months following SEER date of diagnosis of colon cancer, stratified by stage at diagnosis. Among the group of patients with NCH claims (n = 14,857), 3,246 patients (22%) had at least one NCH claim for 5FU in the follow up period. The likelihood of claims for 5FU varied with patients' stage of disease in expected pattern, with only 1% of stage I patients and 42% of stage III patients having 5FU claims. For those patients with claims for 5FU (n = 3,246), 82,464 5FU claims were detected (ie, a mean of 25.4 claims/person). Ninety-five percent of 5FU claims indicated a billing dose of 1000 mg

TABLE 2. Characteristics of Analytic Sample of Elderly Colon Cancer Patients From SEER-Medicare Files Diagnosed 1/93–12/96

Variable	Proportion
Age ≥77 years	0.50
Female sex	0.58
Race	
White	0.88
Black	0.07
Asian Pacific Islander	0.04
Native American	<0.01
Other/unknown	<0.01
Marital status	
Married	0.49
Single	0.08
Separated	<0.01
Divorced	0.04
Widowed	0.37
Unknown	0.02
Living in census tract with ≥20% residents below poverty level	0.05
Living in a metropolitan county	0.57
Year of diagnosis	
1993	0.24
1994	0.26
1995	0.25
1996	0.25
AJC Stage	
Stage I	0.21
Stage II	0.36
Stage III	0.24
Stage IV	0.19
Histologic grade	
Well differentiated	0.09
Moderately differentiated	0.61
Poorly differentiated	0.21
Undifferentiated	<0.01
Unknown	0.08
Comorbidity	
Charlson Score = 0	0.09
Charlson Score = 1	0.09
Charlson Score > 1	0.10
No prior hospitalization	0.72

N = 15,039.

TABLE 3. Characteristics of the Cohort's 5FU NCH Claims

Colon Cancer AJCC Stage	Proportion Patients with NCH 5FU Claims	Number Patients with NCH 5FU Claims	Total Number NCH 5FU Claims	Number NCH 5FU Claims Filed in the Observation Period/Patient		Survival Adjusted Number Weekly NCH 5FU Claims Filed in Observation Period/Patient		Billed Dose 5FU (mg)/Claim	
				Median	IQR	Median	IQR	Median	IQR
I	0.01	40	752	14	6–29.5	0.29	0.12–0.56	1000	500–1000
II	0.15	776	20,493	25	10–40.5	0.50	0.21–0.78	1000	500–1000
III	0.42	1514	43,326	29	14–43	0.56	0.31–0.84	1000	1000–1000
IV	0.32	884	17,893	15	6–30	0.40	0.22–0.61	1000	1000–1000
Total	0.22	3246	82,464	24	10–39	0.50	0.24–0.76	1000	1000–1000

N = 82,464

The table shows that the characteristics of NCH 5FU claims vary with patients' colon cancer AJCC stage. While the billed dose is constant across stages, the proportion of patients with claims increases as tumor stage increases and the median number of claims filed during the observation period is largest for patients with stage III disease.

or less: 76% 1000 mg, 19% 500 mg. Ninety-nine point nine percent of 5FU claims were indexed to a single day of treatment. The median number of 5FU claims per patient during the observation period was 24 claims (interquartile range: 10 claims–39 claims). The survival-adjusted number of 5FU claims/wk for all patients with 5FU claims was 0.50 (interquartile range: 0.24–0.76). The median interval between 5FU claims per patient was 7 days (interquartile range: 1 days–7 days). Figure 1 describes the distribution of time intervals between claims. Table 4 describes the characteristics of patients who did and did not have detectable NCH claims for 5FU. Because of the large sample size, even modest differences in characteristics between patients who did and did not have claims for 5FU achieved statistical significance (eg, metropolitan ZIP code).

Using a multivariate logistic regression model, we combined significant variables from the bivariate analyses, standard patient demographic variables, and variables in which we had substantive interest. The model, reported in Table 5, revealed that patient tumor stage was strongly positively associated with the likelihood of having 5FU claims in the observation period. Patients with stage III colon cancer had 69 times the odds of those with stage I cancer to have 5FU claims (OR 68.83, 95% CI: 49.14–96.41). Similarly, patients with stage IV disease had 42 times the odds of having 5FU claims than patients with stage I disease (OR 41.69, 95% CI: 29.64–58.63). In addition, patient comorbidity had a strong negative association with the likelihood of having 5FU claims. For example, compared to those with Charlson comorbidity scores of zero, patients with scores greater than one had a 59% reduction in their odds of having 5FU claims (OR, 0.41; 95% CI, 0.32–0.53).

Finally, patient demographic variables were also associated with likelihood of having 5FU claims during the surveillance period. Each 1-year increase in patient age was associated with an 11% decrease in odds of having a 5FU claim (OR 0.89 95% CI: 0.88–0.89). Compared to white patients, black patients had 55% the odds and Asian/Pacific Islander patients 53% of having 5FU claims during the observation period (black; OR, 0.55; 95% CI, 0.44–0.68; Asian/Pacific Islander; OR, 0.53; 95% CI, 0.42–0.68). Compared to patients who were married, patients who were unmarried were less likely to have 5FU claims. For example, patients who were single were 37% less likely (OR, 0.63; 95% CI, 0.52–0.76), patients who were widowed were 31% less likely (OR, 0.69; 95% CI, 0.61–0.78), and patients who were divorced were 24% less likely (OR, 0.76; 95% CI, 0.60–0.95) than patients who were married to have 5FU claims. Finally, patients living in Metropolitan counties were 37% more likely than those living in less urban counties to have claims for 5FU (OR, 1.37; 95% CI, 1.25–1.51) and patients living in census tracts with greater than 20% of residents below the poverty level were 25% less likely to have claims for 5FU (OR, 0.75; 95% CI, 0.58–0.97).

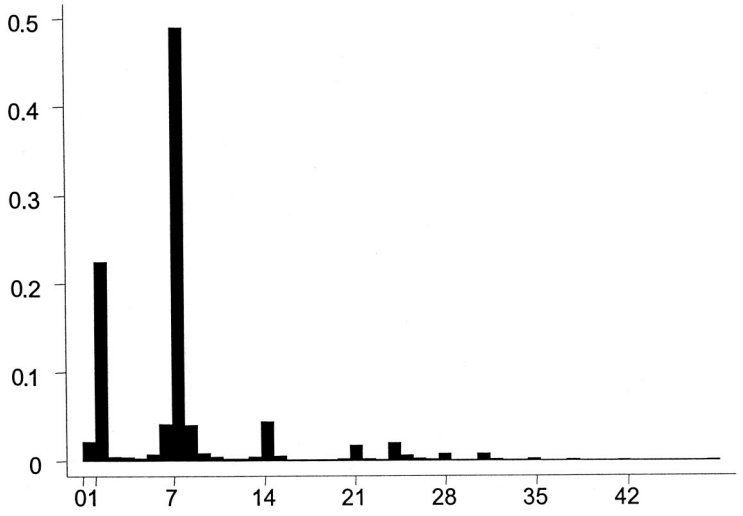

FIG. 1. Distribution of days between NCH 5FU claims for those patients with more than one claim.

Discussion

We found that the Medicare NCH 5FU claims for elderly colon cancer patients from the SEER-Medicare data set in the 13 months following colon cancer diagnosis exhibit construct validity. That is, the pattern of Medicare NCH 5FU claims vary with other disease and demographic variables within the data set in a manner consistent with clinical practice and with previously described associations.

With respect to consistency with clinical practice, the descriptive statistics of the 5FU NCH claims and the multivariate associations between 5FU claims and patient malignant disease factors are highly suggestive that the data may be a valid representation of the clinical encounter. First, the odds of having a 5FU claim increased with stage of cancer in a pattern consistent with the standard of clinical care (ie, lower odds for early stages where chemotherapy has not been proven to prolong life and higher odds for later stages where chemotherapy has been proven to prolong life). Second, the dose billed (ie, 500–1000 mg) and the billing frequency (ie, weekly) are consistent with clinical care. On two fronts the results suggest possible under-treatment of the elderly with curable colon cancer. First, less than half of all stage III patients (all whom had undergone surgical resection) had claims for 5FU. Similarly, in the stage III patients who did have claims for 5FU, the median number of 5FU claims was 29, slightly more than half the expected 53 doses described in the 1990 NCI Consensus statement as an appropriate standard and the survival adjusted number of weekly doses was 0.56, again slightly more than half of the expected one dose/wk.[12] Whether these findings represent relapsed disease among patients (leading to cessation of therapy), true under-treatment, or are spurious, the result of incompleteness of Medicare claims, we cannot know until a study with external validation data are undertaken. However, both results of prior randomized trials of adjuvant 5FU in younger stage III patients that described fewer than the intended number of doses,[13,39] and prior research on the toxicity of 5FU in the elderly[40] suggest that the number of 5FU claims may be correct because the elderly may be more likely to incur toxicities requiring abbreviation of therapy. Additionally, the relatively high percentage of stage II patients with 5FU claims may represent adjuvant treatment of patients with higher risk tumors, a clinical practice for some physicians, and progression of some stage II patients to metastatic disease that was treated during the observation period.

With respect to associations within the claims related to nonmalignant disease factors, the findings that the likelihood of detecting 5FU claims decreased with increasing comorbidity and age is consistent with prior studies of chemotherapy use in the elderly.[41] Similarly, the finding that, compared to white patients, black patients were less

TABLE 4. Characteristics of Patients With and Without Medicare NCH 5FU Claims in the 13 Months Following Colon Cancer Diagnosis

Variable	+ 5FU Claims N = 3,246	− 5FU Claims N = 11,611	*P* value
Age (mean)	74.2 (SD 5.0)	78.7 (SD 6.9)	$P < 0.001$
Female	0.54	0.60	$P < 0.001$
Race			$P < 0.001$
White	0.91	0.88	
Black	0.05	0.07	
Asian Pacific Islander	0.03	0.04	
Native American	<0.01	<0.01	
Other/unknown	<0.01	<0.01	
Marital status			$P < 0.001$
Married	0.63	0.46	
Single	0.06	0.08	
Divorced	0.04	0.04	
Widowed	0.26	0.41	
Census tract with >20% below poverty level	0.03	0.05	$P < 0.001$
Metropolitan ZIP code	0.60	0.56	$P < 0.001$
Charlson Score	0.9 (SD 1.1)	1.4 (SD 1.5)	$P < 0.001$
Year of diagnosis			NS
1993	0.24	0.24	
1994	0.26	0.26	
1995	0.25	0.25	
1996	0.24	0.24	
TNM stage			$P < 0.001$
Stage I	0.01	0.26	
Stage II	0.24	0.40	
Stage III	0.47	0.18	
Stage IV	0.28	0.16	
Tumor grade			$P < 0.001$
Well differentiated	0.05	0.10	
Moderately differentiated	0.63	0.61	
Poorly differentiated	0.27	0.19	
Undifferentiated	0.01	0.01	
Unknown	0.05	0.09	

N = 14,857.

likely to have 5FU claims is also consistent with prior research examining the clinical care of colon cancer patients by race.[20,21] The finding that patients living in urban regions were more likely to have 5FU claims is consistent with prior research on the regional variation of cancer care.[24] Finally, being married was strongly associated with likelihood of having detectable 5FU claims, a finding consistent with the prior work on the effects of marriage on health care use.[22,23]

A promising feature of the claims regarding possible future use of these data are that the treatment interval for nearly all the doses of 5FU for nearly all the patients with 5FU claims was 1 day. Also, the treatment intervals (Fig. 1) were consistent with clinical care. If this precision is

TABLE 5. Adjusted Odds of Medicare NCH 5FU Claims Within Thirteen Months of Colon Cancer Diagnosis

Variable	OR	95% CI
Age	0.89	0.88–0.89
Female Sex	0.97	0.88–1.08
Race		
White	1.00	(referent)
Black	0.55	0.44–0.68
Asian Pacific Islander	0.53	0.42–0.68
Native American	0.24	0.05–1.15
Other/unknown	1.05	0.43–2.56
Marital status		
Married	1.00	(referent)
Single	0.63	0.52–0.76
Widowed	0.69	0.61–0.78
Divorced	0.76	0.60–0.95
Separated	0.85	0.35–2.03
Living in census tract with ≥20% residents below the poverty level	0.75	0.58–0.97
Metropolitan county	1.37	1.25–1.51
Comorbidity		
Charlson Score = 0	1.00	(referent)
Charlson Score = 1	0.84	0.67–1.05
Charlson Score >1	0.41	0.32–0.53
No prior hospitalizations	1.00	0.85–1.18
TNM stage		
Stage I	1.00	(referent)
Stage II	14.75	10.54–20.66
Stage III	68.83	49.14–96.41
Stage IV	41.69	29.64–58.63
Tumor grade		
Poorly differentiated	1.02	0.92–1.14

This table gives odds ratios and 95% confidence intervals ("CI") for the effect of various patient demographic and disease factors on the likelihood of having NCH claim for 5FU in the 13 months following diagnosis. All dichotomous variables are coded as 0 = absent and 1 = present.

accurate, then future studies that seek to make causal inferences regarding initiation of therapy, delays of therapy, and therapy-related toxicities may be possible using Medicare NCH claims.

To date, there are few studies[42–45] of Medicare chemotherapy claims, and we are unaware of any previous validation studies. However, Dr. Warren et al at the NCI have studied the percentage agreement between enriched SEER data and Medicare data in small samples of elderly cancer patients. They report percentage agreement for 5FU claims to be approximately 90% (Warren J: Identification of chemotherapy administration from Medicare claims data. Unpublished data presented at the SEER-Medicare Data Users Workshop, Bethesda, MD; November 16–17, 2000). With respect to the consistency of our results with those of prior studies of Medicare chemotherapy claims, we report an approximately 13% lower apparent rate of 5FU treatment within the NCH files for stage III patients than investigators who evaluated for evidence of any "chemotherapy" use in multiple Medicare files (inpatient MEDPAR and outpatient SAF and NCH) of a slightly younger group of elderly SEER stage III colon cancer patients in the 3 months following surgical resec-

tion.[45] This suggests that at least part of the apparent under-treatment we report may be secondary to under-ascertainment related to our use of only the NCH file. For example, the NCH file will not capture 5FU administered to patients exclusively in the inpatient setting; the inpatient claims for such patients would indicate "chemotherapy administration," but the actual agent would not be identifiable.

In summary, the elderly are under represented in clinical trials of anti-cancer therapy and, therefore, the expected benefits and toxicities of chemotherapy in the general population of elderly Americans may not be the same as the study population. Medicare claims are a potential source of observational data from which to make inferences regarding chemotherapy outcomes for the population of elderly cancer patients. The cumulative evidence of our analyses suggests that Medicare NCH 5FU claims within the SEER-Medicare data set exhibit construct validity. Thus, formal sensitivity and specificity analyses that utilize a gold standard of chemotherapy administration should be undertaken to determine the test characteristics of NCH Medicare chemotherapy claims.

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