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Sensitivity of Medicare Claims Data for Measuring Use of Standard Multi-Agent Chemotherapy Regimens

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Abstract

Purpose—We sought to determine the accuracy with which Medicare billing data documents elderly Medicare cancer patients' receipt of common multi-agent chemotherapy regimens.

Methods—We merged gold-standard clinical trial data from 406 elderly cancer patients known to be treated on one of six Cancer and Leukemia Group B (CALGB) breast, colorectal, and lung cancer trials (trial numbers; 9344, 9730, 9235,9732, 80203, 89803) with their Medicare claims data from Centers for Medicare and Medicaid Services (CMS). Comparing CMS chemotherapy codes to gold-standard CALGB treatment data, we estimated Medicare data's sensitivity at measuring the correct drugs and schedule for each of the multi-agent chemotherapy regimens.

Results—Overall 92% (375/406) of CALGB patients had contemporaneous CMS claims indicating receipt of chemotherapy. The overall sensitivity of CMS ambulatory claims for documenting treatment with the correct drugs and on the correct schedule (i.e., all drugs had to be billed on the same day) for the five common multi-agent chemotherapy regimens was 78% (275/354) for those potentially treated in the ambulatory setting. The sensitivity was similar for all treatment regimens: carboplatin and paclitaxel 83%, 5FU and leucovorin 80%, FOLFIRI 76%, doxorubicin and cyclophosphamide 75%, and cisplatin and etoposide 75%.

Conclusions—We identified at least three-quarters of elderly Medicare cancer patients treated on a clinical trial with standard first-line multi-agent chemotherapy regimens in the ambulatory setting by applying coding algorithms. The algorithms may be useful in identifying cohorts of elderly Medicare patients for observational studies of the comparative effectiveness of standard multi-agent chemotherapy regimens.

Keywords

Elderly; Cancer; Medicare; Chemotherapy; Comparative Effectiveness Research

Background

Medicare spent nearly a billion dollars in 2002 on chemotherapy for newly diagnosed breast, colorectal, and lung cancer patients alone, but surprisingly little is known about the extent to which cancer chemotherapies help or harm such elderly patients.[1] This unsettling paradox is the direct result of the well-described under-enrollment of elderly on the clinical trials of chemotherapy.[2–4] In the absence of trials with representative patients, treating

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oncologists, patients, and policy-makers must extrapolate results of clinical trials that were conducted on younger and comparatively healthier individuals. Surprisingly, basic results of this common extrapolation are unknown.

Because Medicare reimburses for intravenous administration of chemotherapy, Medicare claims are a potential source of observational data that could be used to begin to fill this knowledge gap. Other sources of potential information include other large data sources like National Cancer Data Base (NCDB) [5] and smaller sources like individual hospital cancer registry information linked to medical record and billing information.[6] Prior work has shown that CMS claims are highly valid measures of a number of cancer therapies [7,8] including intravenous chemotherapy use among elderly Medicare beneficiaries and that the Health Care Financing Administration Common Procedure Code (HCPC) J codes are highly valid markers of individual chemotherapy agents administered to these patients. [9,10] However, it is not known if standard chemotherapy regimens that are composed of multiple drugs administered on specific schedules (i.e., on relative days) are equally as well reflected in Centers for Medicare and Medicaid Services (CMS) claims.

We sought to determine the sensitivity of Medicare claims at detecting five standard multi-agent chemotherapy regimens among elderly Medicare patients who were known to have been treated with the regimens on clinical trials.

Methods

Data and Cohorts

CALGB Studies Data—We used clinical trial data from the CALGB to identify cancer site, stage, and treatment-specific cohorts of clinical trial patients treated in the experimental setting with one of five standard first-line chemotherapy regimens. The CALGB, now a part of the Alliance for Clinical Trials in Oncology, was an NCI-sponsored cooperative oncology research group which represents a network of over 3,000 physicians from 29 academic medical centers and 225 community hospitals. Members of multi-modality treatment programs in seven disease areas develop therapeutic trials, which may then be opened for patient accrual at CALGB institutions. Data from the trials were collected and maintained centrally at the CALGB Statistical Center. Trial data were analyzed and results disseminated in manuscripts published in medical journals. Among the variables common to all therapeutic trials is registration information which includes: study number, subject identifiers, demographic and disease information, treatment information (e.g., drugs administered, dates of treatment, doses of therapy) and survival endpoints.

Medicare Data—Medicare is a federally sponsored health insurance program administered by the CMS whose beneficiaries include more than 96% of all US citizens aged 65 and older.[11] CMS maintains billing records of outpatient, inpatient, home health, hospice, durable medical equipment and other claims for all beneficiaries not enrolled in risk contract health maintenance organizations (HMOs). In order to determine the study population's use of chemotherapy, we studied five types of Medicare files: the denominator file, the Medicare Provider Analysis and Review (MEDPAR) file; the Outpatient Standard Analytic File (OUTPT); the National Claims History (NCH) file, and the Durable Medical Equipment (DME) file. Of note, Medicare reimburses providers for costs associated with clinical trials including those of drugs and drug combinations that have been previously established to be standards of care. All regimens we studied were standard chemotherapy regimens at the time of trial enrollment.

Cohort Construction

We identified all 837 study subjects aged 65 or older at the time of enrollment onto one of six CALGB trials that contained one of the multi-drug chemotherapy regimens of interest. Table 1 lists the six study numbers, drugs and schedules as well as the tumor site-, stage-, and histology-specific cohorts. The cohorts represent patients with limited and extensive stage small cell lung cancers (ES SCLC) treated with cisplatin and etoposide (CDDP/VP16); stage IIIB or IV non-small cell lung cancer (NSCLC) treated with carboplatin and paclitaxel; stage II or III colon cancer treated with fluorouracil and leucovorin (5FU/LV); stage IV colorectal cancer (CRC) treated with a combination of fluorouracil, leucovorin and irinotecan (FOLFIRI); and locoregional breast cancer treated with adjuvant doxorubicin and cyclophosphamide (AC).

We linked the cohorts' CALGB clinical trial data (e.g., demographic information, information pertaining to chemotherapy administration) to their CMS Medicare claims files (i.e., denominator, NCH, OUTPT, MEDPAR, and DME files) from the corresponding calendar period using social security numbers. We were able to match 80% (673/837) of the participants to Medicare files. Among these 673 eligible patients, 128 were removed because they were not eligible for Medicare parts A and B during the observation period; 94 because of enrollment in HMOs whose claims were not processed through CMS; 42 because they were treated at facilities that do not bill Medicare; three because they were never treated on the CALGB trial following randomization; and 52 because their first chemotherapy was delivered in the inpatient setting, a situation in which individual agents are not discernible. The final analytic sample consisted of 354 elderly Medicare patients treated on six CALGB clinical trials with five standard first-line multi-agent chemotherapy regimens who were at risk for potential ambulatory chemotherapy treatment. Figure 1 represents a schema of the cohort formation.

Variables

We developed coding algorithms that utilized specific Medicare files, codes and data fields to determine whether or not individual drugs were administered (Table 2) and if so the drug billing date. Because all five of the standard-multi drug regimens of interest required that more than one drug be given on the same day (i.e., day 1 of each cycle), we similarly required that the chemotherapy agents identified in Medicare files be billed on the same day for the multi-drug regimen to be considered "received". The focus on day 1 is consistent with an "intent to treat" approach to clinical care. The observation period was the first day of the month and year in which the patient was registered onto the CALGB trial (or the first day treated according to CALGB if that date preceded registration) plus 90 days. Prior to online registration for specific studies, patients were allowed to receive protocol treatment before registering if treatment needed to occur immediately and the registration line was closed. The sensitivity of the claims using 30, 60, 90, and 120 day time windows (from the date of registration) were each empirically evaluated and the 90 day time window was associated with a slightly higher sensitivity than the 30 and 60 day windows, but not lower than the 120 day window. We also used CALGB and Medicare data to obtain information pertaining to patients' demographic and disease attributes.

Statistical Analyses

The CALGB treatment information was considered the gold standard to calculate the sensitivity of the CMS multi-agent chemotherapy algorithms. *Sensitivity* is defined as the proportion of the patients known (according to CALGB data) to have been treated with the multi-agent chemotherapy regimen of interest who are correctly identified through CMS claims as having received it during the observation period. We calculate sensitivity by dividing the number of patients with Medicare claims indicating receipt of the chemotherapy

of interest by the number patients who actually received the chemotherapy of interest as determined by CALGB files. Exact binomial confidence intervals were calculated for each estimate. Because all patients were treated with chemotherapy, we cannot calculate specificity of CMS multi-agent chemotherapy algorithms. However, prior research has shown Medicare chemotherapy claims, including individual agents, to be highly specific. [12]

This research was approved by Duke University, Harvard Medical School and Massachusetts General Hospital institutional review boards and conducted in compliance with their regulations. All analyses were done using STATA 10, College Station, Texas.

Results

Table 3 describes the demographic and disease characteristics of the sample. Using a broad algorithm of chemotherapy ascertainment, [13] we found that 92% (375/406) of patients at risk for having Medicare chemotherapy claims had a least one claim for “chemotherapy” during the observation period. Thirteen percent (52/406) of patients appeared to have received their first chemotherapy in the hospital setting, a situation in where individual drugs are not observable. As shown in Table 3, patients who received their first cycle of clinical trial therapy in the inpatient setting had a poorer performance status than those who were first treated in the ambulatory setting and were also more likely to be receiving CDDP/VP16 for small cell lung cancer than other therapies. The remaining patients (N=354) were considered “at risk” for having Medicare claims documenting the specific multi-agent chemotherapy regimens delivered through the clinical trial.

Table 4 describes the sensitivity of CMS-based algorithms for ascertaining administration of each multi-agent regimen in the ambulatory setting. The overall sensitivity of CMS ambulatory claims for documenting treatment with the correct drugs and on the correct schedule (i.e., all drugs had to be billed on the same day) was 78% (275/354). The sensitivity varied little by treatment regimen. For carboplatin and paclitaxel the sensitivity was 83% (49/59), 5FU/LV 80% (73/91), FOLFIRI 76% (26/34), AC 75% (33/44), and CDDP/VP16 75% (94/126).

The Appendix also contains a detailed breakdown of the counts of the CALGB Medicare patients according to setting of treatment with chemotherapy, drugs ascertained for each regimen and the Medicare file sources of the patient counts.

Discussion

This study shows that for elderly Medicare beneficiaries with breast, CRC, and lung cancer who were treated with one of five standard multi-agent chemotherapy regimens on six phase III CALGB trials, contemporaneous Medicare claims files reflect the clinical trial therapies, on average, 78% of the time, with very consistent results across a variety of regimens. Our findings suggest that an algorithmic approach to identify multi-agent treatment regimens, requiring specific drugs (and routes of administration) that appear in the claims on the same day (or in the case of continuous infusion 5FU within a defined billing interval surrounding day may be useful in identifying at least three quarters of patients treated with the standard multi-agent chemotherapy regimens in CMS-based data sources. The algorithms could allow researchers to identify Medicare patients who were treated with standard multi-drug combination chemotherapy regimens to ask and answer a variety of questions relevant to population health and health care policy. For example, researchers may compare survival of cancer site, stage, and histology-matched cohorts of patients treated with one common multi-agent chemotherapy regimen versus another. As such our findings may accelerate

comparative effectiveness research which in turn may inform clinical care and health care policy.

There are important caveats to this work. The results show that the sensitivity is not perfect. For example, the HCPC-based FOLFIRI algorithm we developed will miss 26% of patients treated with FOLFIRI. Among those FOLFIRI patients we "missed" with our algorithm 2 of the 34 (0.06%) patients appeared to have received a different regimen entirely, IFL (day 1 irinotecan, fluorouracil, and leucovorin without the addition of 48 hours of continuous infusion 5FU) which is a more toxic and less efficacious regimen. [14] More importantly, if we had ignored the DME files entirely (i.e., not evaluated for evidence of 48 hours of continuous infusion 5FU that is a part of the FOLFIRI regimen), fully 82% of the CALGB FOLFIRI patients would have appeared to have received IFL instead. This finding raises caution regarding studies that seek to compare outcomes of patients receiving pharmacologically similar regimens as exposures may be difficult to delineate in such instances.

Our results apply to elderly Medicare patients who are receiving their first treatment in the ambulatory setting and therefore may not apply to all elderly Medicare patients receiving the multi-agent chemotherapy regimen of interest. This selection bias is introduced by the fact that individual chemotherapy agents are not discernible within inpatient Medicare claims, only treatment with "chemotherapy" broadly defined. Elderly Medicare patients with poorer performance statuses and more biologically aggressive tumors may be less likely to be represented in the ambulatory samples of patients receiving multi-agent chemotherapy regimens as their care may be more often initiated in the inpatient setting (Table 3). Thus the prognostic estimates associated with the multi-agent chemotherapy regimens will apply only to those Medicare patients who begin their treatment in the ambulatory setting (i.e., not all Medicare patients who receive the given multi-agent chemotherapy regimen).

In conclusion, our results suggest that CMS files are highly but not perfectly sensitive at identifying elderly Medicare patients who are treated with standard multi-agent chemotherapy regimens. As such, the findings may accelerate studies of the comparative effectiveness of specific multi-agent chemotherapy regimens in elderly cancer patients. Such studies may allow population scientists and policy makers to understand the benefits and risks of various standard multi-agent chemotherapy regimens that were developed in clinical trial settings when they are applied to elderly Medicare patients with cancer who are treated in the usual care setting.

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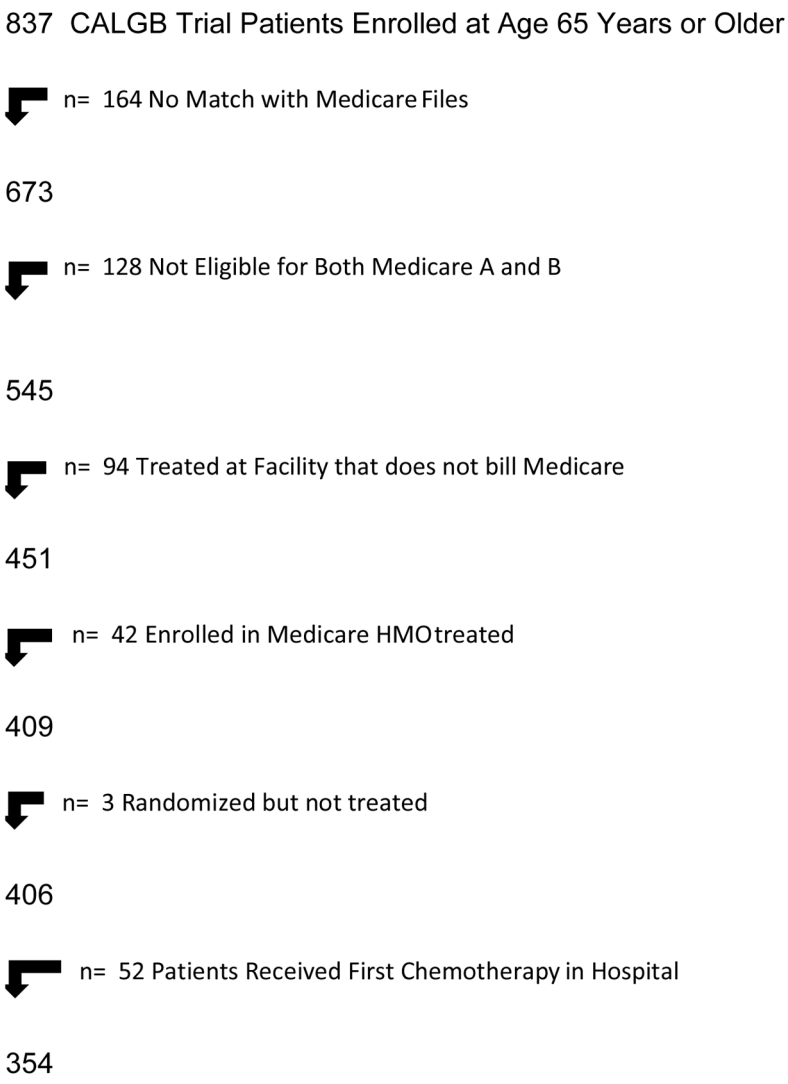

Figure 1.
Analytic CALGB-Medicare Cohort Construction N=354

Table 1

CALGB Trials, Study Cohorts, and Treatment Regimens and Schedules

Study	Accrual Years	Tumor	Stage or Extent	Drugs and Schedule	Frequency	Reference
9344	**1994 – 1997**	Breast	LN positive	Day 1 Doxorubicin Day 1 Cyclophosphamide	q 21 days	11
89803	**1999 – 2001**	CRC	II or III	Day 1 5FU Day 1 Leucovorin	q 7 days	12
80203	**2004**	CRC	IV	FOLFIRI = Day 1 5FU Day 1 Leucovorin Day 1 CPT-11 Day 1–2 5FU2	q 14 days	13
9235	**1993– 1999**	SCLC	Limited	Day 1 CDDP Day 1 VP16	q 21 days	14
9732	**1998– 2001**	SCLC	Extensive			15
9730	**1997– 2000**	NSCLC	Stage IIIB/IV	Day 1 Carboplatin Day 1 Paclitaxel	q 21 days	16

CALGB study number, tumor type, and treatment regimen including specific drugs and schedules (i.e., timing and frequency of administration).

LN=lymph node; CRC=colorectal cancer; SCLC=small cell lung cancer; NSCLC=non-small cell lung cancer; 5FU=fluorouracil; 5FU2 = 48 hour continuous infusion 5FU q=“every”; CDDP=cisplatin; VP16=etoposide; CPT-11=irinotecan

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Table 2

Coding of Taxonomy Measuring Ambulatory Administration of Multi-Agent Chemotherapy Regimens in Medicare Claims Files

	Types of Medicare Claims Files			
Standard Multi-Agent Regimen	**NCH & OUTPT Drug 1 HCPC(s)**	**NCH & OUTPT Drug 2 HCPC(s)**	**NCH & OUTPT Drug 3 HCPC**	**DME Drug 4 HCPCS(s)**
AC	J9000, J9001, or J9010 (doxorubicin)	J9070, J9080, or J9090–J9097 (cyclophosphamide)	-	-
FOLFIRI	J9190 (5FU)	J9206 (CPT-11)	J0640 (leucovorin)	≥1 code for A4221, A4222, E0781, or J9190 (5FU2)
5FU/LV	J9190 (5FU)	J0640 (leucovorin)	-	No HCPCS for A4221, A4222, or E0781 or J9190 (No 5FU2)
CDDP/VP16	J9060 or J9062 (cisplatin)	J8560, J9181, or J9182 (VP16)	-	-
Carboplatin/Paclitaxel	J9045 (carboplatin)	J9265 (paclitaxel)	-	-

AC=doxorubicin and cyclophosphamide; 5FU/LV=5FU and leucovorin; CDDP/VP16= cisplatin and etoposide; 5FU= fluorouracil; 5FU2 = 48 hour continuous infusion fluorouracil; CPT-11=irinotecan; FOLFIRI=Day 1 fluorouracil, leuvocorin, irinotecan and Day 1–2 continuous infusion fluorouracil. For each of the three standard multi-agent regimens listed above, all the drugs in the regimen were required to be administered on day 1. For FOLFIRI drugs 1–3 needed to appear on day 1, but the requisite DME codes could occur anytime between Day 1–30 days to D1 +7 days to receive credit. Conversely, for 5FU/LV there may not be the described DME codes between Day 1 –30 days to D1 +7 days to receive credit for drugs 1 and 2. HCPC=Health Care Financing Administration Common Procedure Codes; NCH = National Claims History; OUTPT = Outpatient; DME = Durable Medical Equipment

Table 3

Demographic and Disease Characteristics of the Analytic Sample (N=406)

Variable (proportions)	Inpatient Tx N=52	Ambulatory Tx N=354	p-value
Mean age (years)	71.6	71.5	<0.01
Sex			
Female	0.54	0.50	0.63
Male	0.46	0.50	
Race			
White	0.96	0.94	0.81
Black	0.04	0.05	
Hispanic	0.00	0.01	
Unknown	0.00	0.00	
Median HH Income	$42,415	$43,738	<0.01
Marital Status			
Single (never married)	0.00	0.02	0.72
Married	0.33	0.28	
Divorced	0.02	0.04	
Widowed	0.10	0.09	
Unknown	0.55	0.57	
Performance Status			<0.01
“Normal”	0.29	0.42	
“Ambulatory”	0.58	0.40	
“Less 50% Day in Bed”	0.13	0.04	
“Unknown”	0.00	0.14	
CALGB Protocols			<0.01
9344	0.00	0.12	
9730	0.04	0.17	
9235 & 9732	0.96	0.36	
80203	0.00	0.10	
89803	0.00	0.26	
Tumor Site			**<0.01**
Breast	**0.00**	**0.12**	
Colorectal	**0.00**	**0.35**	
Lung	**1.00**	**0.52**	

Comparison of attributes of elderly Medicare patients treated on Cancer and Leukemia Group B trials according to whether or not they received their first cycle of trial treatment in the inpatient setting.

Table 4

Sensitivity of HCPC-Based Coding Algorithms at Measuring Treatment with Standard Multi-Agent Chemotherapy Regimens in CMS Files

Treatment	Ambulatory Analytic N	All Drugs Day 1	Sensitivity	95% CI
AC	44	33	0.75	0.60–0.87
FOLFIRI	34	26	0.76	0.59–0.89
5FU/LV	91	73	0.80	0.71–0.88
CDDP/VP16	126	94	0.75	0.66–0.82
Carboplatin/paclitaxel	59	49	0.83	0.71–0.92
TOTAL	354	275	0.78	0.73–0.82

Sensitivities of HCPC-based coding algorithms for measuring receipt of five common multi-agent chemotherapy regimens in CMS files. HCPC= Health Care Financing Administration Procedure Codes; AC=doxorubicin and cyclophosphamide; FOLFIRI=Day 1 fluorouracil, leucovorin, irinotecan and Day 1–2 CI fluorouracil. 5FU/LV= fluorouracil and leucovorin; CDDP/VP16= cisplatin and etoposide

Appendix

Counts of Eligible Trial Patients for Whom CMS Files Document Receipt of Multi-Agent Chemotherapy Regimens

		CMS Files of Interest								
		ALL	**MEDPAR**	**NCH/OUTPT**	**NCH/OUTPT**	**NCH/OUTPT**	**NCH/OUTPT**	**NCH/OUTPT**	**DME**	
Treatment	**At Risk Any Chemo**	**Any Chemo**	**Inpatient Chemo Only**	**At Risk Outpatient Chemo**	**Any Outpatient Codes Day 1**	**Drug 1**	**Drug 2**	**Drug 3**	**Drug 4**	**All Drugs Day 1**
A/C	44	39	0	44	39	36	34	-	-	33
FOLFIRI*	34	32	0	34	32	28	29	29	27	26
5FU/LV	91	85	0	91	85	84	74	-	0	73
CDDP/VP16	176	164	50	126	114	96	106	-	-	94
carboplatin/paclitaxel	61	55	2	59	53	49	53	-	-	49
Total	**406**	**375**	**52**	**354**	**323**	**-**	**-**	**-**	**-**	**275**

*="All Drugs of Interest" = 1 if Drugs 1–4 positive CMS=Centers for Medicare and Medicaid Services; ALL=MEDPAR, NCH, and OUTPT; MEDPAR = Medicare Provider Analysis and Review; NCH = National Claims History; OUTPT = Outpatient; DME = Durable Medical Equipment; AC=doxorubicin and cyclophosphamide; 5FU/LV=5FU and leucovorin; CDDP/VP16= cisplatin and etoposide; LN=lymph node; CRC=colorectal cancer; SCLC=small cell lung cancer; NSCLC=non-small cell lung cancer; 5FU=fluorouracil; 5FU2 = 48 hour continuous infusion 5FU; VP16=etoposide; CPT-11=irinotecan; FOLFIRI=Day 1 5FU, leuvocorin, irinotecan and Day 1–2 CI 5FU.