Original Article

Healthcare Utilization and Expenditures Associated With Appropriate and Inappropriate Implantable Defibrillator Shocks

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Background—In patients with implantable cardioverter–defibrillators, healthcare utilization (HCU) and expenditures related to shocks have not been quantified.

Methods and Results—We performed a retrospective cohort study of patients with implantable cardioverter–defibrillators identified from commercial and Medicare supplemental claims databases linked to adjudicated shock events from remote monitoring data. A shock event was defined as ≥1 spontaneous shocks delivered by an implanted device. Shock-related HCU was ascertained from inpatient and outpatient claims within 7 days following a shock event. Shock events were adjudicated and classified as inappropriate or appropriate, and HCU and expenditures, stratified by shock type, were quantified. Of 10 266 linked patients, 963 (9.4%) patients (61.3±13.6 years; 81% male) had 1885 shock events (56% appropriate, 38% inappropriate, and 6% indeterminate). Of these events, 867 (46%) had shock-related HCU (14% inpatient and 32% outpatient). After shocks, inpatient cardiovascular procedures were common, including echocardiography (59%), electrophysiology study or ablation (34%), stress testing (16%), and lead revision (11%). Cardiac catheterization was common (71% and 51%), but percutaneous coronary intervention was low (6.5% and 5.0%) after appropriate and inappropriate shocks. Expenditures related to appropriate and inappropriate shocks were not significantly different.

Conclusions—After implantable cardioverter–defibrillator shock, related HCU was common, with 1 in 3 shock events followed by outpatient HCU and 1 in 7 followed by hospitalization. Use of invasive cardiovascular procedures was substantial, even after inappropriate shocks, which comprised 38% of all shocks. Implantable cardioverter–defibrillator shocks seem to trigger a cascade of health care. Strategies to reduce shocks could result in cost savings. (***Circ Cardiovasc Qual Outcomes*. 2017;10:e002210. DOI: 10.1161/CIRCOUTCOMES.115.002210.)**

Key Words: cardiac arrhythmias ■ defibrillators ■ electrophysiology ■ hospitalization

The implantable cardioverter–defibrillator (ICD) improves survival in populations at high risk for sudden death.[1–3] While potentially life-saving, ICD shocks, both appropriate and inappropriate, can also increase long-term morbidity and mortality.[4,5] Trials of device programming to reduce shocks have been shown to improve survival.[6,7]

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However, there is limited information on healthcare utilization (HCU) associated with ICD shocks and whether inappropriate and appropriate shocks have differences in type, intensity, or cost of care. Moreover, detailed knowledge of utilization following an appropriate versus inappropriate shock may elucidate downstream patterns of care and potential mediators of the differences in patient survival following shocks. We therefore evaluated HCU and expenditures after inappropriate and appropriate shock events by linking ICD remote monitoring data to healthcare administrative data.

Methods

Study Design and Data Sources

We performed a retrospective cohort study of patients with ICDs from national (United States) implant registration and remote monitoring data linked to healthcare claims. Cohort structure and patient selection are detailed in Figure 1. Data, stripped of personal identifiers of name, date of birth, medical record number, and social security, were first obtained from the Medtronic Data Warehousing and Analytics Service (DWAS; Medtronic plc, Mounds View, MN). DWAS is a device implant record data set containing patient demographics (age, sex, 3-digit zip codes for patient location, and implant site location), implant date, device information (device type, model, and leads),

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WHAT IS KNOWN

- Randomized trials have shown that the ICD can improve survival, but ICD shocks are also associated with increased morbidity and mortality.
- The HCU and expenditures following ICD shocks have not been quantified.

WHAT THE STUDY ADDS

- In patients with ICDs, 46% of shock events had shock-related HCU.
- After shocks, inpatient cardiovascular procedures were common, and expenditures were not significantly different following inappropriate versus appropriate shocks.
- ICD shocks seem to trigger a cascade of health care, and strategies to reduce shocks could result in cost savings.

and records from remote monitoring transmissions, including programmed device settings, arrhythmia detection and classification, electrocardiograms for episodes detected as ventricular tachycardia/ventricular fibrillation, and delivered therapies.

We identified patients in DWAS with ICDs and cardiac resynchronization therapy defibrillator (CRT-D) devices implanted between January 1, 2008 and December 31, 2010. To minimize survival and other biases that could be associated with generator replacement or lead or device upgrades (eg, ICD to CRT-D), the cohort was restricted to patients receiving de novo devices.

Next, patients with ICD and CRT-D implants were identified in the Truven Health MarketScan Commercial Claims and Encounters Database and MarketScan Medicare Supplemental and Coordination of Benefits Database (Truven Health Analytics, Ann Arbor, MI). These data sources contain nationally representative, deidentified medical, and pharmacy claims data on the inpatient, outpatient, and prescription drug experience of over 45 million enrolled employees, dependents, and retirees annually who are covered under a variety of fee-for-service and managed care health plans.[8] Patients in the MarketScan database were identified based on the presence of procedure codes for ICD or CRT-D implant (*International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM] codes 37.94 and 00.51 or Current Procedural Terminology [CPT] codes 33249 and 33225) between January 1, 2008 and December 31, 2010. Follow-up data for these patients were available through December 31, 2011.

Linking Patient Data

A deterministic matching algorithm was used to link patients who had data in both DWAS and MarketScan. The linked patients therefore represent individuals who have a device manufactured by Medtronic and who have commercial or Medicare supplemental insurance coverage through a health plan that contributes to the MarketScan databases. We followed a strict matching algorithm on 6 of 6 criteria with 1-to-1 matching: implant date, device type (ICD or CRT-D), patient sex, patient age, patient location (3-digit zip code), and implant procedure location (3-digit zip code). All variables used in the linkage were HIPAA (Health Insurance Portability and Accountability Act of 1996) compliant. In other words, no identifiable protected health information (PHI) was used in the linkage. Patients who matched to multiple devices or devices matching to multiple patients were

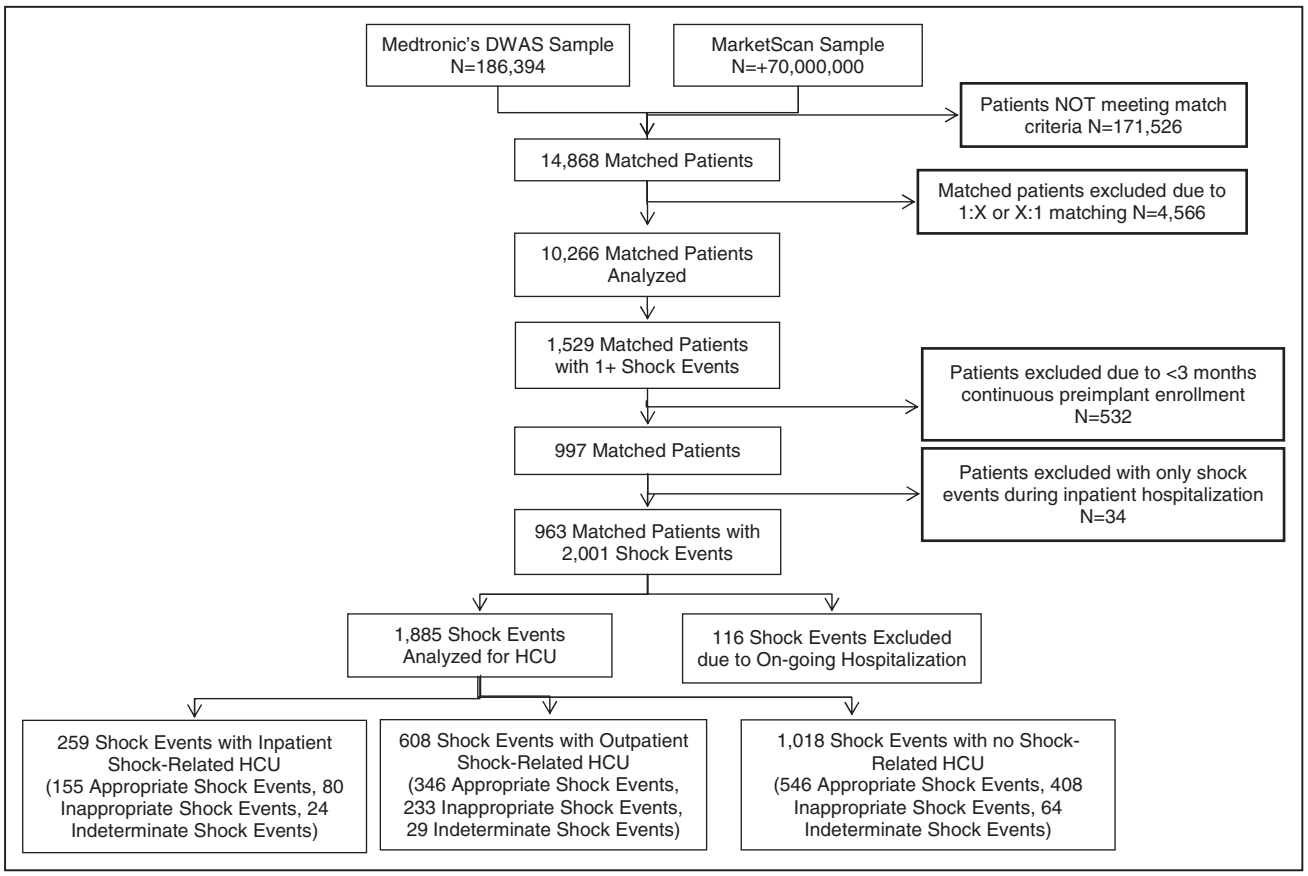

Figure 1. Patient and shock event CONSORT diagram. DWAS indicates Medtronic Data Warehousing and Analytics Service (Medtronic plc); and HCU, healthcare utilization.

excluded. This technique is similar to previous studies linking patients from registry data sets to insurance claims.[9,10] For comorbidity ascertainment, we further required continuous medical and drug benefit coverage for the 3-month period before the implant date.

From this matched data set, patients with evidence of at least 1 shock event were identified from DWAS data. Shock events were defined as 24-hour periods in which ≥1 shocks were delivered by the implanted device. Patients with shock events occurring during a concomitant inpatient stay, defined as a shock event occurring ≥1 days after the admission date but on or before the discharge date, were excluded. We also excluded nonspontaneous shocks such as for defibrillation threshold testing. Baseline characteristics were ascertained for each patient from claims within 3 months before the implant date via outpatient and inpatient diagnosis codes (Appendix Table I in the Data Supplement).

Shock Event Adjudication

All shock episodes electrograms were adjudicated to determine whether they were appropriate or not. Appropriate shocks were defined as those delivered for true ventricular tachyarrhythmias (ventricular tachycardia/ventricular fibrillation), and inappropriate shocks were defined as those delivered for any other type of detected rhythm (atrial fibrillation, supraventricular tachycardia, T-wave oversensing, or noise). We used a sequential method of adjudication. First, for all shocks, we used a proprietary Medtronic electrogram classification algorithm that was developed against physician adjudication from 1255 shocks in 346 patients in the OMNI observational registry.[11] In validation, the algorithm resulted in a 2% relative increase in inappropriate shock classification compared with physician adjudication (Patel et al, unpublished data [poster presented at Heart Rhythm Society Scientific Sessions], 2011). Seventy percent of shock episodes were classified by the proprietary episode classification algorithm, and the remaining 30% were manually reviewed by at least 2 Medtronic technical experts (scientists and engineers). In the event the manual review by the technical experts resulted in disagreement, one author (S.Z.), a board certified and practicing clinical cardiac electrophysiologist, performed the final adjudication. Shock episodes with insufficient electrocardiogram (ECG) data for adjudication or for which technical experts could not agree were considered indeterminate. Physician adjudication was performed for 6% of all shock episodes and 19% of manual reviewed episodes.

Outcomes

The primary outcomes were shock-related HCU and expenditures. Shock-related diagnoses were defined as ICD-9-CM codes for cardiac dysrhythmia, syncope, dizziness, palpitations, tachycardia, or mechanical complication of cardiac device, based on a prespecified analysis plan by the investigators (Appendix Table II in the Data Supplement). The rationale was to conservatively only consider hospitalizations that would likely be directly and proximately related to arrhythmia triggering the shock or to the shock itself, rather than any number of cardiac or noncardiac causes that might or might not have been potentially related to a shock. For example, we did not include heart failure or myocardial infarction diagnoses in our shock-related definition. Because the majority of patients with ICDs have reduced systolic function, it would not be possible to know whether a hospitalization coded with a diagnosis of heart failure was necessarily a result of the shock, or if it was coded because no other reasons for the shock were documented. Therefore, inclusion of heart failure could overestimate the attribution of post shock care to being shock related.

Shock-related HCU was defined via shock-related diagnoses reported as the primary diagnosis of any inpatient hospitalization or shock-related diagnoses reported as any diagnosis for outpatient service(s) that occurred during the postshock period, defined as the shorter of the 7-day period following the date of shock or the time to a subsequent shock. We selected a 7-day window based on clinical face validity. Because we used shock data extracted from remote monitoring records, it is possible for there to have been a delay in patients seeking HCU after receiving a shock because of delays across the care pathway from remote data transmission to clinician interpretation and recommendation of seeking medical care. Outpatient services included office visits, emergency room care, and emergency medical transport that did not result in a subsequent inpatient stay. Inpatient and outpatient procedures were ascertained using ICD-9-CM and CPT codes (Appendix Table III in the Data Supplement).

Healthcare expenditures for shock-related HCU were based on adjudicated claims from the postshock period, including insurer and health plan payments and patient cost sharing in the form of copayment, deductible, and coinsurance. Expenditures for services provided under capitated arrangements were estimated by using payment proxies that were computed from paid claims at the procedure level within the MarketScan databases.[8] Healthcare expenditures were inflated to 2011 dollars based on the Medical Care Consumer Price Index. For this analysis, the unit of analysis was the shock event (defined as a day [24 hours] with ≥1 shocks), and an individual patient could contribute multiple events. All reimbursement claims are fully adjudicated in the cost data set. Therefore, we included encounters with $0 claims because they do not represent missing data but rather claims of a covered visit with no actual associated expenditures. Outliers were not discarded for the same reason.

Statistical Analysis

Shock-related expenditures among those with shock-related HCU are reported, and *t* tests were used to compare hospital length of stay and expenditures between appropriate and inappropriate shock events. Predictors of expenditures were determined using a multivariable generalized linear model on the log expenditure scale with generalized estimating equations to account for multiple shocks per individual. This allowed estimation of a cost ratio for each covariate in the model which included patient characteristics at baseline (including age, sex, primary insurer, health plan type, comorbidities, and medication use), device type, the number of days from the ICD implant to the shock event, the number of shocks in the shock event, patient preshock expenditures (both cardiac and noncardiac), and for those with multiple shocks, the shock event number and the proportion of previous shocks for which the patient sought treatment. These covariates were included because they were either statistically significant in univariate models or they were deemed clinically significant for inclusion by the study team. Preshock expenditures were included in the model because past HCU sought by a patient can predict future HCU and expenditures. To be as conservative as possible, we included both preshock cardiac and noncardiac expenditures to try and attribute, as closely as possible, current expenditures with the shock-related HCU, as opposed to the patient being a high utilizer in general. EXP(β) was used to convert the regression coefficients into the ratios of the geometric means. Analyses were conducted using SAS (Cary, NC). Physician investigators did not directly perform the analysis and could not retain access to the linked data set. M.P.T. worked directly with the data analysts and reviewed the raw data output of all models and statistical code. The study was a retrospective analysis of data recorded in such a manner that the subjects cannot be identified, and thus the research was exempt from institutional review board (IRB) review under 45 CFR 46.101(b)(4).

Results

Patient Characteristics

Of 186 394 patients in the DWAS data set, 10 266 patients were successfully linked to patients in the MarketScan databases (Figure 1). Among these, there were 1529 (14.9%) with at least 1 shock event. After excluding patients without continuous preimplant enrollment (n=532) and those with shock events during a hospitalization stay (n=34), there were 963 linked patients with 1885 shock events. Baseline characteristics are shown in Table 1. Patients with shock events (aged 61.3±13.7 years) were predominantly male (81%), and 41% had Medicare supplemental coverage. There were high rates of preimplant ischemic heart disease or previous myocardial infarction (60%), ventricular

Table 1. Baseline Characteristics for All Patients With a Shock Event (n=963)

Characteristics	Count
Age at implant, mean (SD)	61.29 (13.65)
Sex, n (%)	
Male	778 (80.79)
Female	185 (19.21)
Health plan, n (%)	
Comprehensive/indemnity	194 (20.15)
EPO/PPO	516 (53.58)
POS/POS w/capitation	69 (7.17)
HMO	117 (12.15)
Other/unknown	67 (6.96)
Primary insurance, n (%)	
Commercial	573 (59.50)
Medicare	390 (40.50)
Preimplant comorbid conditions, n (%)	
Acute myocardial infarction or ischemic heart disease	574 (59.61)
Conduction disorder	116 (12.05)
Chronic kidney disease	66 (6.85)
Arrhythmia (atrial)	354 (36.76)
Arrhythmia (ventricular)	394 (40.91)
Cardiac arrest	91 (9.45)
Arrhythmia (dysrhythmia)	170 (17.65)
Heart failure	488 (50.68)
Cardiomyopathy	468 (48.60)
Valvular heart disease	246 (25.55)
Stroke/transient ischemic attack	35 (3.63)
Congenital heart disease	28 (2.91)
Hypertension	329 (34.16)
CHADS2 score, mean (SD)	1.30 (1.07)
Preimplant medication use, n (%)	
Antidiabetic medications	160 (16.61)
β-blockers	482 (50.05)
Oral anticoagulants	201 (20.87)
Shock events	
Total shock events, mean (SD)	1.96 (1.77)
Device type, n (%)	
VR	219 (22.74)
CRT-D	269 (27.93)
DR	475 (49.33)
Shock type, n (%)	
Appropriate shock(s) only	416 (43.20)
Inappropriate shock(s) only	403 (41.85)
Indeterminate shock type(s) only	30 (3.11)
Mixed shock types	114 (11.84)

CRT-D indicates cardiac resynchronization therapy defibrillator; DR, dual-chamber implantable cardioverter–defibrillator; EPO, exclusive provider organization; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization; SD, standard deviation; and VR, single-chamber implantable cardioverter–defibrillator.

arrhythmias (41%), and atrial arrhythmias (37%). In this cohort, 23% had single chamber, 49% had dual chamber, and 28% had cardiac resynchronization ICDs. Most patients had only appropriate shocks (43%) or only inappropriate shocks (42%), whereas 12% had both types.

Shock-Related HCU

Of the 1885 shock events, 259 (13.7%) were followed by inpatient HCU, and 608 (32.2%) were followed by outpatient HCU only, whereas 1018 (54.0%) had no shock-related HCU. Figure 2 shows the distribution of shock-related HCU (inpatient, outpatient, and none) stratified by shock type (appropriate, inappropriate, and indeterminate). These distributions were similar across shock types.

The most frequently reported procedures (primary or secondary procedures) during shock-related inpatient HCU were ECG (85.3%), chest x-ray (75.7%), cardiac catheterization (75.7%), echocardiogram (58.7%), and electrophysiology study/ablation (33.6%; Table 2). Compared with appropriate shock events, utilization of cardiovascular procedures after inappropriate shock events was generally reduced, but still substantial, and included catheterization (51.3% versus 79.4%), echocardiography (51.3% versus 60.6%). However, lead or device revision (28.8% versus 5.2%) was more common after inappropriate shock events. Despite substantial use of catheterization in both groups, percutaneous coronary intervention was performed in only 6.5% of appropriate shock events and 5.0% of inappropriate shock events. The most frequently reported primary procedures after all shock events with related inpatient HCU were cardiac catheterization (12.7% after any shock events and 12.9% after appropriate shock events) and lead or device revision (11.3% after inappropriate shock events).

Length of stay was slightly longer following appropriate than inappropriate shock events, 3.6±3.2 days versus 2.8±2.2 days (P=0.02; Table 3). Inpatient HCU was most commonly associated with Medicare Severity-Diagnosis Related Groups (MS-DRG) related to cardiac arrhythmias or conduction disorders or to circulatory disorders with cardiac catheterization (excluding acute myocardial infarction [MI]), with and without complicating comorbidities (Appendix Table IV in the Data Supplement).

In the outpatient setting, the most common procedures included device interrogations (76.1%), ECG (73.4%), and chest x-ray (40.7%). About 61.4% of outpatient shock-related HCU included ambulance transportation, and 45.6% included an emergency room visit. Among outpatient-only

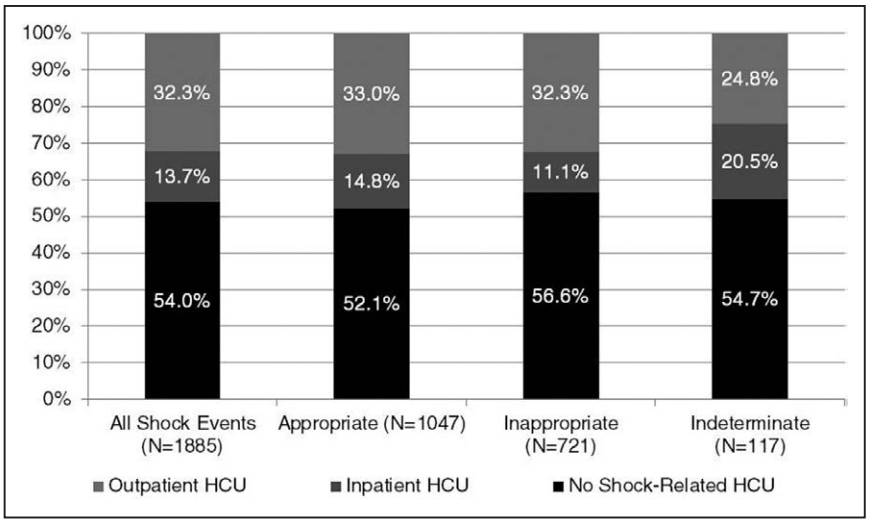

Figure 2. Healthcare utilization (HCU) after shock event, stratified by shock type.

shock-related HCU, 56.9% of visits were due to appropriate shock events, and procedures were similar between shock types (Table 4).

Table 2. Inpatient Shock-Related Procedures

	All Inpatient Visits (n=259)*	Appropriate (n=155)	Inappropriate (n=80)
Any procedure (primary or secondary)			
ECG	221 (85.3%)	144 (92.9%)	58 (72.5%)
Chest x-ray	196 (75.7%)	124 (80.0%)	54 (67.5%)
Cardiac catheterization	196 (75.7%)	123 (79.4%)	41 (51.3%)
Echocardiography	152 (58.7%)	94 (60.6%)	41 (51.3%)
Emergency room visit	103 (39.8%)	67 (43.2%)	28 (35.0%)
Electrophysiology study/ ablation	87 (33.6%)	61 (39.4%)	9 (11.3%)
Device interrogation	67 (25.9%)	47 (30.3%)	15 (18.8%)
Stress test	42 (16.2%)	29 (18.7%)	7 (8.8%)
Lead or device revision	28 (10.8%)	8 (5.2%)	23 (28.8%)
Percutaneous coronary intervention	17 (6.6%)	10 (6.5%)	4 (5.0%)
Circulatory support	9 (3.1%)	7 (4.5%)	0 (0.0%)
Heart/pericardium operations	5 (1.9%)	3 (1.9%)	2 (2.5%)
Cardioversion	4 (1.5%)	1 (0.6%)	2 (2.5%)
Primary procedure			
Cardiac catheterization	33 (12.7%)	20 (12.9%)	6 (7.5%)
Electrophysiology study/ ablation	21 (8.1%)	15 (9.7%)	2 (2.5%)
Percutaneous coronary intervention	8 (3.1%)	4 (2.6%)	5 (2.5%)
Lead or device revision	11 (4.2%)	2 (1.3%)	9 (11.3%)
Heart/pericardium operations	5 (1.9%)	3 (1.9%)	2 (2.5%)
Circulatory support	5 (1.9%)	4 (2.6%)	0 (0.0%)

*Includes shock events of indeterminate type.

Expenditures for Shock-Related HCU

Table 5 shows aggregate expenditure data stratified by inpatient versus outpatient-only and by shock type. Across all shock events, mean and median expenditures were $5887±$19 836 and $901±$6106, respectively. The mean and median expenditures for HCU following appropriate shock events were $5592±$13 831 and $940±$6021, respectively, whereas for inappropriate shock events, they were similar at $4470±$5283 and $681±$5283 (P=0.11). Across all shock events, expenditures for patients with inpatient HCU were substantially higher than for patients with only outpatient HCU (inpatient: mean $15 756±$33 178, median $8561±$8648 versus outpatient: mean $1300±$4706, median $304±$1010). Expenditures were similar for inappropriate compared with appropriate shocks in the inpatient and outpatient settings (Table 5).

In the multivariable analysis of patients with inpatient and outpatient shock-related HCU, the number of shocks during the event was associated with higher expenditures (inpatient ratio, 1.018; 95% confidence interval [CI], 1.008–1.028; and outpatient ratio, 1.037; 95% CI, 1.003–1.072; Table 6). There was no significant association of device type (inpatient CRT-D

Table 3. Shock-Related Healthcare Utilization Detail

	No. of Claims		Length of Stay*	
Shock-Related HCU Type	Mean±SD	Median	Mean±SD	Median
Inpatient visits				
All (n=259)†	1.01±0.11	1	3.47±3.09	3
Appropriate (n=155)	1.01±0.11	1	3.60±3.21	3
Inappropriate (n=80)	1.00±0.00	1	2.79±2.18	2
Outpatient visits				
All (n=608)†	2.51±2.06	2	NA	NA
Appropriate (n=346)	2.57±2.13	2	NA	NA
Inappropriate (n=233)	2.37±1.96	2	NA	NA

HCU indicates healthcare utilization; NA, not applicable; and SD, standard deviation.

*P value for difference in mean between inappropriate and appropriate length of stay 0.02.

†Shock events of indeterminate type are included here, but not in subsequent rows.

Table 4. Outpatient Shock-Related Procedures

Procedure	All Outpatient Visits (n=608)*	Appropriate (n=346)	Inappropriate (n=233)
Device interrogation	599 (76.1%)	362 (80.8%)	231 (78.3%)
ECG	578 (73.4%)	316 (70.5%)	220 (74.6%)
Ambulance transportation	483 (61.4%)	254 (56.7%)	185 (62.7%)
Emergency room visit	359 (45.6%)	183 (40.8%)	152 (51.5%)
Chest x-ray	320 (40.7%)	175 (39.1%)	124 (42.0%)

*Shock events of indeterminate type are included here, but not in subsequent columns.

ratio, 1.040; 95% CI, 0.745–1.452; inpatient DR [dual chamber ICD] ratio, 0.849; 95% CI, 0.630–1.145; outpatient CRT-D ratio, 1.281; 95% CI, 0.876–1.873; and outpatient DR [dual chamber ICD] ratio, 0.854; 95% CI, 0.596–1.223; Ref=VR [single chamber ICD]) or shock event type (inappropriate versus appropriate) to inpatient (ratio, 0.944; 95% CI, 0.756–1.165) or outpatient (ratio 1.042; 95% CI, 0.770–1.410) shock-related expenditures. All covariates are detailed in Table 6.

Discussion

Using novel matching of ICD registration and remote monitoring data to healthcare claims, we found that almost one half of the shock events were associated with HCU, and 1 in 7 shock events was followed by inpatient HCU. Use of cardiovascular procedures, including cardiac catheterization, echocardiography, electrophysiology study or ablation, and lead or device revision, was common, even following inappropriate shock events. Expenditures were similar for appropriate and inappropriate shock events. These data indicate: (1) substantial HCU is triggered by a device shock, regardless of the underlying cause of shock and (2) substantial utilization of cardiovascular procedures that may not improve outcomes, such as the high observed rate of cardiac catheterization but relatively low observed rate of percutaneous coronary intervention.

The findings from this study have several implications. From a methodology standpoint, we demonstrate that linking across multiple deidentified data sets is feasible and can enable health services and outcomes research that otherwise would not be possible. To our knowledge, this is the first published study to link HCU and expenditure data with individual arrhythmia event data collected via remote monitoring. Although there is an increasing interest to link big data across a variety of sources,[12] the balance between data access and privacy remains an active area of discussion and policy development.[13] Although all of our data sources were stripped of protected identifiers before data manipulation or linkage, our analysis demonstrates that one could effectively reidentify data through linkage, even if protected identifiers were not used in the linkage process. Therefore, protection of human subjects and their data remains paramount.

This study also shows that both appropriate and inappropriate shocks initiate a cascade of HCU that frequently includes invasive procedures, many with uncertain effects on patient outcomes. Two recent trials have demonstrated that an ICD programming strategy of high-rate cutoff with extended detection can improve survival,[6] reduce inappropriate therapies,[6,14] and reduce the risk of hospitalization.[14] In this study, it was found that cardiac catheterization was performed in 75% of all shock-related hospitalizations (including 51% after inappropriate shock event hospitalizations), yet percutaneous coronary intervention was uncommon (6.6% in all and 5.1% in inappropriate shock event hospitalizations). Electrophysiology studies and cardiac ablation were also common. These invasive procedures, along with the associated risks of significant near-term and long-term complications, could have untoward effects on survival in patients who experience a shock event. As a result, it could be the HCU following a shock event, rather than the shock event itself, that has the greatest impact on survival. Further study is needed to better understand the role of healthcare interventions (including changes to drug therapy) in mediating survival rates,

Table 5. Shock-Related Healthcare Expenditures

Shock Event Type	Mean±SD	Median±IQR	Min	Max	P1	P5	P95	P99
All visit healthcare expenditures*								
All shock events (n=867)	$5887±$19 836	$901±$6106	$0	$442 706	$6.13	$32.91	$21 897.52	$74 323.49
Appropriate (n=501)	$5592±$13 831	$940±$6021	$0	$164 245	$7.27	$25.79	$18 897.54	$47 554.32
Inappropriate (n=313)	$4470±$5283	$681±$5283	$0	$103 966	$6.13	$43.33	$21 903.88	$52 882.77
Inpatient healthcare expenditures*								
All shock events (n=259)	$15 756±$33 178	$8561±$8648	$182	$442 690	$231.26	$2434.47	$45 604.85	$146 001.90
Appropriate (n=155)	$14 914±$21 452	$8697±$8805	$182	$164 245	$1176.59	$3115.49	$35 677.50	$74 210.42
Inappropriate (n=80)	$11 383±$11 475	$7316±$7767	$1177	$74 210	$231.26	$2381.69	$45 604.85	$133 277.99
Outpatient healthcare expenditures*								
All shock events (n=608)	$1300±$4706	$304±$1010	$0	$103 966	$5.50	$26.75	$4736.89	$13 320.59
Appropriate (n=346)	$1094±$2645	$314±$968	$0	$36 809	$1.80	$20.09	$5409.61	$31 676.29
Inappropriate (n=233)	$1656±$6935	$286±$1034	$0	$103 966	$5.50	$29.97	$4220.87	$9899.16

IQR indicates interquartile range; P1, first percentile; P5, fifth percentile; P95, ninety-fifth percentile; P99, ninety-ninth percentile; and SD, standard deviation.
*P value for difference in mean between appropriate and inappropriate expenditures: all visits 0.11, inpatient 0.08, outpatient 0.94.

Table 6. Multivariable Analysis for Shock-Related Healthcare Expenditures

	Inpatient HCU			Outpatient HCU		
Variables	Ratio*	*P* Value	95% CI for Ratio	Ratio*	*P* Value	95% CI for Ratio
No. of days post-implant	1.000	0.656	1.000–1.000	1.000	0.848	1.000–1.001
Proportion of previous shocks with HCU	1.170	0.313	0.863–1.585	1.307	0.174	0.888–1.922
Shock event number	1.033	0.332	0.968–1.102	0.948	0.127	0.885–1.015
No. of shocks in current event	1.018	0.001†	1.008–1.028	1.037	0.032†	1.003–1.072
Age	1.006	0.478	0.989–1.024	0.973	0.012†	0.952–0.994
Age (squared)	1.000	0.881	1.000–1.000	1.000	0.386	0.999–1.000
Sex, female	0.818	0.084	0.652–1.027	0.720	0.082	0.498–1.042
Primary insurance, Medicare	0.975	0.895	0.664–1.430	1.063	0.814	0.637–1.775
Health plan (ref: HMO)						
Comprehensive/FFS	0.636	0.029†	0.423–0.955	2.246	0.001†	1.391–3.628
EPO/PPO	0.898	0.432	0.686–1.175	1.119	0.550	0.773–1.621
POS	1.318	0.256	0.818–2.125	1.355	0.351	0.716–2.564
Comorbid conditions						
Acute MI or IHD	0.930	0.527	0.741–1.166	1.385	0.031†	1.030–1.864
Conduction disorder	0.810	0.211	0.583–1.127	1.368	0.151	0.892–2.098
Chronic kidney disease	0.898	0.514	0.649–1.241	0.908	0.807	0.417–1.975
Arrhythmia (atrial)	0.923	0.501	0.730–1.166	0.680	0.017†	0.495–0.935
Arrhythmia (ventricular)	1.018	0.889	0.789–1.315	1.133	0.439	0.826–1.554
Cardiac arrest	1.256	0.153	0.919–1.717	0.930	0.800	0.529–1.634
Arrhythmia (dysrhythmia)	0.860	0.362	0.621–1.190	1.166	0.392	0.821–1.655
Preimplant medication use						
Antidiabetic medications	0.784	0.049†	0.615–0.999	0.900	0.562	0.631–1.284
β-blockers	1.053	0.632	0.852–1.302	1.008	0.954	0.755–1.347
Oral anticoagulants	1.023	0.855	0.798–1.312	0.777	0.157	0.547–1.102
Device type (ref: VR)						
CRT-D	1.040	0.818	0.745–1.452	1.281	0.202	0.876–1.873
DR	0.849	0.284	0.630–1.145	0.854	0.390	0.596–1.223
Total cardiac related preshock expenditures	1.000	0.078	1.000–1.000	1.000	0.441	1.000–1.000
Total noncardiac related preshock expenditures	1.000	0.013†	1.000–1.000	1.000	0.498	1.000–1.000
Shock type (ref: appropriate)						
Inappropriate	0.944	0.593	0.765–1.165	1.042	0.790	0.770–1.410
Indeterminate	1.510	0.078	0.955–2.387	1.310	0.328	0.763–2.247

CI indicates confidence interval; CRT-D, cardiac resynchronization therapy defibrillator; DR, dual-chamber implantable cardioverter–defibrillator; EPO, exclusive provider organization; FFS, fee-for-service; HCU, healthcare utilization; IHD, ischemic heart disease; MI, myocardial infarction; POS, point of service; PPO, preferred provider organization; and VR, single-chamber implantable cardioverter–defibrillator.

*Values <1 indicate that variable is associated with lower costs; values >1 indicate that variable is associated with higher costs.

†Significant predictor of expenditures.

particularly with respect to reprogramming devices to use a high-rate, extended detection strategy or use improved algorithms to reduce ICD shocks.

Lead or device revision procedures were performed in 29% of inappropriate shock-related hospitalizations. This suggests a potentially high proportion of lead sequelae or complications (such as lead fracture) as a cause of inappropriate shock. It is of note that this analysis included data from 2008 to 2010, which was after the recall of the Sprint Fidelis defibrillation lead (Medtronic, Inc, Minneapolis, MN) that had been shown to be related to a higher likelihood of lead fracture.

Finally, the quantification of HCU and expenditures demonstrates alignment of cost reduction with the clinical benefits for reducing shocks. In our analysis, 9.4% of patients experienced ≥1 shock events, which is similar to a previously reported 1-year shock incidence rate in a primary prevention cohort.[15] Although there was wide variation in expenditures, there were relatively small absolute differences in median expenditures between appropriate and inappropriate shock events. Recent evidence suggests that strategic programming of devices can reduce the 1-year incidence of all-cause shocks to <10%,[14] and arrhythmia discrimination algorithms in modern ICDs further minimize the risk of inappropriate shocks.[12] In context, our findings underscore the opportunity to improve both the clinical care and the economic burden associated with shocks through the implementation of shock reduction strategies.

Our study has several limitations associated with the use of retrospective anonymized data. First, results may be affected by confounding factors that are not readily available from the data sources used, such as health status beyond what can be represented by diagnoses of comorbid conditions, including ejection fraction and New York Heart Failure classification, patient behaviors and lifestyle, additional medical or pharmaceutical interventions, or the indication for the ICD (eg, primary versus secondary prevention). Second, the population included in this study may not be a representative of all patients, such as those who are uninsured, have ICDs from a different manufacturer, or do not use remote monitoring (which was required in our analysis to ascertain shock events). Because remote monitoring itself has been associated with decreased HCU, our study may underestimate utilization and costs.[16,17] Third, our data come from linked remote monitoring data from devices of a single vendor (Medtronic) linked to commercial claims (rather than Medicare), and our cohort seems to be slightly younger than observational studies from the ICD Registry.[18] Fourth, HCU was defined as shock related only if the primary diagnosis was related to arrhythmias, ICD complications, or relevant symptoms within the prespecified 7-day window. As our goal was to conservatively consider HCU that have a high likelihood of being arrhythmia or device related, we did not consider HCU for other causes, such as heart failure or myocardial infarction, if these primary ICD-9-CM codes were not part of the encounter. As a result, this could underestimate HCU and expenditures, especially if HCU occurred after the 7-day window. For example, inclusion of heart failure HCU in the absence of the prespecified shock-related diagnoses would have added 8% to 9% more HCU episodes. Because of the potential for over attribution of heart failure to the shock-related event, we chose to be more conservative with our estimates of shock-related care. However, once care was identified as shock related, then all expenditures for that HCU were included. These may include costs associated with conditions discovered during the visits which were not specifically shock related. The cumulative costing could therefore potentially overestimate the attributable risk of shock reduction on overall healthcare expenditures.

Conclusions

In patients with Medtronic ICDs and remote monitoring that were linked to commercial claims data, we found 14.9% of patients experienced at least 1 shock event, and 46% were associated with any HCU and 14% with inpatient care. HCU and expenditures, including use of invasive cardiovascular procedures, were substantial, even after inappropriate shock events. Strategies to reduce the incidence of ICD shocks may result in significant reductions in HCU and expenditures. Further investigation is warranted to determine the impact on survival of these procedures after appropriate and inappropriate shocks.

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Disclosures

Dr Turakhia is a consultant to Medtronic plc and St. Jude Medical, Inc, and has received honoraria for speaking for Medtronic plc. Dr Zweibel is a consultant to Medtronic plc and has received honoraria for speaking for Medtronic. Dr Reynolds is a consultant to Medtronic plc. A.L. Swain and S.A. Mollenkopf (at the time the study was conducted) are employees of Medtronic plc.

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Healthcare Utilization and Expenditures Associated With Appropriate and Inappropriate Implantable Defibrillator Shocks

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SUPPLEMENTAL MATERIAL

Appendix Table 1. Codes for Baseline Characteristics

Chronic Kidney Disease	403.xx	Hypertensive chronic kidney disease
	404.xx	Hypertensive heart and chronic kidney disease
	585.x	Chronic kidney disease (ckd)
Conduction disorder	426.xx	Conduction disorders
Cardiac arrest	427.5	Cardiac arrest
Arrhythmia (atrial)	427.0	Paroxysmal supraventricular tachycardia
	427.31	Paroxysmal ventricular tachycardia
	427.32	Atrial flutter
Arrhythmia (ventricular)	427.1	Paroxysmal ventricular tachycardia
	427.41	Ventricular fibrillation
	427.42	Ventricular flutter
Arrhythmia (dysrhythmia)	427.89	Other specified cardiac dysrhythmias
	427.9	Cardiac dysrhythmia, unspecified
Acute myocardial infarction or ischemic heart disease	410.xx	Acute myocardial infarction
	412	Old myocardial infarction
	411.xx	Other acute and subacute forms of ischemic heart disease
	413.xx	Angina pectoris
	414.xx	Other forms of chronic ischemic heart disease
ICD	37.94	Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]
	37.94+33249	Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD] Insertion or repositioning of electrode leads(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator
	33249	Insertion or repositioning of electrode

		leads(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator
CRT-D	00.51	Implantation Of Cardiac Resynchronization Defibrillator, Total System [Crt-D]
	00.51+33225	Implantation Of Cardiac Resynchronization Defibrillator, Total System [Crt-D] Insertion of left ventricular pacing electrode
	00.51+33249	Implantation Of Cardiac Resynchronization Defibrillator, Total System [Crt-D] Insertion or repositioning of electrode leads(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator
	33249+33225	Insertion or repositioning of electrode leads(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator Insertion of left ventricular pacing electrode

Appendix Table 2. Codes to Identify Shock-Related Healthcare Utilization

Primary diagnosis for Inpatient; Any diagnosis for Outpatient	427.xx	Cardiac dysrhythmias
	780.2	Syncope and collapse
	780.4	Dizziness and giddiness
	996.00	Mechanical complication of unspecified cardiac device, implant, and graft
	996.01	Mechanical complication due to cardiac pacemaker (electrode)
	996.04	Mechanical complication of automatic implantable cardiac defibrillator
	996.09	Other mechanical complication of cardiac device, implant, and graft
	996.72	Other complications due to other cardiac device, implant, and graft
	785.1	Palpitations
	785.0	Tachycardia, unspecified

Appendix Table 3. Procedure Groupings by CPT and ICD-9 Codes - organize by inpatient and outpatient

Ambulance Transportation	Outpatient A0425 A0427 A0422 A0426 A0429	 Ground mileage, per statute mile Als1-emergency Ambulance (als or bls) oxygen and oxygen supplies, life sustaining situation Ambulance service, advanced life support, non-emergency transport, level 1 (als 1) Ambulance service, basic life support, emergency transport (bls-emergency)
Chest X-ray	71010 71020	Chest x-ray 1 view frontal Chest x-ray 2 view frontal & latl
Electrocardiogram	Outpatient 93010 93005 93000 93042 3120F 93041 93012 93230	 Interpretation and report of routine ECG with at least 12 leads Tracing of routine ECG with at least 12 leads Routine ECG with at least 12 leads with interpretation and report Interpretation and report of rhythm ECG, 1-3 leads 12-Lead ECG Performed Tracing of rhythm ECG, 1-3 leads Telephonic transmission of post-symptom electrocardiogram rhythm strip(s), 24-hour attended monitoring, per 30 day period of time; tracing only Wearable electrocardiographic rhythm derived monitoring for 24 hours by continuous original waveform recording and storage without superimposition scanning, physician review and interpretation
Emergency Room Visit	Outpatient 99285 99284 99283 99282 99281	 Emergency department visit, problem with significant threat to life or function Emergency department visit, problem of high severity Emergency department visit, moderately severe problem Emergency department visit, low to moderately severe problem Emergency department visit, self-limited or minor problem
Device Interrogation	Outpatient 93295 93296 93283 93284 93297 93289	 Remote evaluations of defibrillator up to 90 days with analysis, review and report Remote evaluations of defibrillator up to 90 days with analysis, technical component Prgrmg eval implantable in prsn dual lead dfb Prgrmg eval implantable in person multi lead dfb Interrogation eval remote </30 d cv mntr sys Interrog eval f2f 1/dual/mlt leads impltbl dfb

	93282	Prgrmng dev eval implantable in persn 1 ld dfb
	93290	Interrogation eval f2f implantable cv mntr sys
	93743	Analyze heart pace device sngl
	93741	Analysis of pacing cardioverter-defibrillator dual chamber, w/o reprogramming
	93744	Analysis of pacing cardioverter-defibrillator single or wearable, w/o reprogramming
	93299	Interrogation eval remote </30 d tech review
	93742	Interrogation eval remote </30 d tech review
	93280	Program eval implantable in persn dual ld pacer
	93288	Interrogation eval in person 1/dual/mlt lead pm
	93294	Interrogation eval remote </90 d 1/2/mlt lead pm
Cardiac Catheterization	Inpatient	
	37.21	Coronary arteriography using two catheters
	37.22	Right heart cardiac catheterization
	37.23	Left heart cardiac catheterization
	88.53	Angiocardiography of left heart structures
	88.56	Combined right and left heart cardiac catheterization
	88.57	Other and unspecified coronary arteriography
	Outpatient	
	36620	Arterial catheterization or cannulation for sampling, monitoring or transfusion
	93451	Right heart catheterization including oxygen saturation & cardiac output measurements
	93454	Catheter placement in coronary artery for coronary angiography
	93458	Catheter placement in coronary artery for coronary angiography
	93459	Catheter placement in coronary artery for coronary angiography
	93460	Right & left heart catheterization with coronary angiography
	93501	Right heart catheterization
	93503	Insertion flow directed catheter for monitoring
	93508	Catheter placement in coronary artery(s), angiography
	93510	Left heart catheterization, retrograde
	93526	Combined right heart and retrograde left heart catheterization
	93539	Injection procedure during cardiac catheterization
	93540	Injection procedure during cardiac catheterization
	93543	Injection procedure during cardiac catheterization
	93545	Injection procedure during cardiac catheterization
	93555	Imaging, cardiac cath
	93556	Imaging, cardiac cath
	93567	Inject supravalvular aortography

Electrophysiology Study / Ablation	Inpatient 37.26 37.33 37.34 Outpatient 93609 93612 93613 93620 93621 93622 93623 93642 93650 93652 93662 93724	 Cardiac electrophysiologic stimulation and recording studies Excision or destruction of other lesion or tissue of heart, open approach Excision or destruction of other lesion or tissue of heart, endovascular approach Add-on code for mapping tachycardia Intraventricular pacing Intracardiac electrophysiologic 3D mapping Comprehensive electrophysiologic arrhythmia induction Comprehensive electrophysiologic w/ Lt ventr pacing/rec Comprehensive electrophysiologic w/ Lt ventr pacing/rec Programmed stimulation/pacing after intravenous infusion Evaluation of single/dual chamber pacing cardioverter-defibrillator w/ programming or reprogramming Insertion of catheters for creation of complete heart block Intracardiac catheter ablation of arrhythmogenic focus Ultrasound evaluation of heart blood vessel Electronic analysis antitachy pacemaker system
Lead / Device Revision	Inpatient 00.52 37.75 37.76 37.87 37.94 37.95 Outpatient 71090 33215 33216 33224 33225 33241 33249 93641	 Implant/replace of transvenous lead into left ventricular coronary venous system Revision of lead [electrode] Replacement of transvenous atrial and/or ventricular lead(s) [electrode] Replacement of any type pacemaker device with dual-chamber device Implantation or replacement of automatic cardioverter/defibrillator, total system [aicd] Implantation of automatic cardioverter/defibrillator lead(s) only Insertion pacemaker, fluoroscopy and radiography Rpsg prev implted pm/dfb r atr/r ventr electrode Insj 1 transvns eltrd perm pacemaker/impltbl dfb Insj eltrd car ven sys attch prev pm/dfb pls gen Insj eltrd car ven sys tm insj dfb/pm pls gen Removal implantable defib pulse generator only Insj/rplcmt perm dfb w/trnsvns lds 1/dual chmbr Ephys eval pacg cvdfb lds w/tstg of pulse gen
Percutaneous Coronary	Inpatient	

Intervention	00.66 Outpatient 92980	Percutaneous transluminal coronary angioplasty [PTCA] Transcatheter placement of an intracoronary stent(s), percutaneous
Heart/pericardium operations NEC	Inpatient 37.99	Other operations on heart and pericardium
Circulatory Support	Inpatient 37.66	Implant of an implantable, pulsatile heart assist system

NEC = Not Elsewhere classified.

Appendix Table 4. Inpatient Shock-Related MS-DRG Detail

MS-DRG		All Inpatient Visits (N=259)*	Appropriate (N=155)	Inappropriate (N=80)
309	Cardiac arrhythmia and conduction disorders with CC	113 (43.6%)	73 (47.1%)	31 (38.8%)
310	Cardiac arrhythmia and conduction disorders without CC or MCC	43 (16.6%)	26 (16.8%)	16 (20.0%)
287	Circulatory disorders except AMI, with card cath without MCC	23 (8.9%)	13 (8.4%)	4 (5.0%)
308	Cardiac arrhythmia and conduction disorders with MCC	20 (7.7%)	12 (7.7%)	7 (8.8%)

* Shock events of 'indeterminate' type are included here, but not in subsequent columns.

AMI = acute myocardial infarction; CC = complication or comorbidity; MCC = major complication or comorbidity; MS-DRG: Medicare Severity Diagnosis Related Group