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Considerations for Observational Study Design: Comparing the Evidence of Opioid Use between Electronic Health Records and Insurance Claims

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Abstract

Purpose: Pharmacoepidemiology studies often use insurance claims and/or electronic health records (EHR) to capture information about medication exposure. The choice between these data sources has important implications.

Methods: We linked EHR from a large academic health system (2015–2017) to Medicare insurance claims for patients undergoing surgery. Drug utilization was characterized based on medication order dates in the EHR, and prescription fill dates in Medicare claims. We compared opioid use measured in EHR orders to prescription claims in 4 time periods: 1) Baseline (182-d before surgery); 2) Perioperative period; 3) Discharge date; 4) Follow-up (90-d after surgery).

Results: We identified 11,128 patients undergoing surgery. During baseline, 34.4% (EHR) vs 44.1% (claims) had evidence of opioid use, and 56.9% of all baseline use was reflected only in one data source. During the perioperative period, 78.8% (EHR) vs 47.6% (claims) had evidence of use. On the day of discharge, 59.6% (EHR) vs 45.5% (claims) had evidence of use, and 51.8% of all discharge use was reflected only in one data source. During follow-up, 4.3% (EHR) vs 10.4% (claims) were identified with prolonged opioid use following surgery with 81.4% of all prolonged use reflected only in one data source.

Conclusions: When characterizing opioid exposure, we found substantial discrepancies between EHR medication orders and prescription claims data. In all time periods assessed, most patients' use was reflected only in the EHR, or only in the claims, not both. The potential for misclassification of drug utilization must be evaluated carefully, and choice of data source may have large impacts on key study design elements.

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Ethics Approval: This project was approved by the University of North Carolina at Chapel Hill Institutional Review Board (IRB #18-1248).

Plain Language Summary:

Observational studies of large populations often use insurance claims and / or electronic health records (EHR) to efficiently examine medication use. Claims and EHR are both extremely valuable for enabling timely research, and each data source has different advantages and disadvantages. We examine how the choice between claims and EHR can impact estimates of opioid exposure before, during, and after surgery. For a population of Medicare patients undergoing surgery, we linked their insurance claims with their EHR. We then summarize the percent of patients with evidence of opioid use documented in the EHR, and the percent with opioid use documented in the insurance claims. We found that there were substantial discrepancies between EHR and claims data. For most patients who had evidence of opioid use, the use was documented in only 1 data source, not both. This suggests that in certain scenarios, the choice of dataset may provide different conclusions when trying to understand the percent of surgical patients who are using opioids. Researchers will need to be thoughtful when using these data and must understand how to choose which datasource is most appropriate for the research question at hand.

Keywords

opioids; pharmacoepidemiology; insurance claims; EHR; data linkage

Introduction

Health insurance claims and electronic health records (EHR) have long been used to conduct timely epidemiology research in large populations. As the opioid crisis in the United States continues to have devastating consequences across the country, researchers have leveraged insurance claims and EHR for a wide array of prescription opioid focused work ranging from evaluations of opioid prescribing trends,[1,2] potentially inappropriate prescribing,[3] risks of opioid medications,[4] development of screening tools,[5] and changes in access to adequate pain management.[6] While both insurance claims and EHR are widely used, the impact of choosing between them to define prescription drug use is not well understood.

EHR are generated prospectively at the time of healthcare delivery, generally including information documenting inpatient and outpatient visits, medical diagnoses, medical procedures, and medications prescribed, as well as clinical details, laboratory findings, and notes. EHR vary widely in scope and types of information available for research, ranging from single institution studies to large multi-institutional EHR consortiums. EHR from Health Maintenance Organizations for example usually have access to enrollment data, often have access to dispensed prescriptions, and have more comprehensive coverage of medical services, as out-of-system care is rare. However, EHR data are often limited to records within a specific health system, which can make longitudinal research challenging in patients who may receive care at unaffiliated institutions.[7]

Insurance claims derive from electronic health records and include data elements necessary to provide payment to the original provider and therefore do not include vitals, lab results, or inpatient medications. Because claims capture all health care services reimbursed through

a patient's insurance, encounters across different health systems are expected to be included (if they are submitted for reimbursement), better enabling longitudinal follow-up. Monthly enrollment data in an insurance plan equip researchers with concrete time windows during which longitudinal research can be conducted – information which is often unavailable in EHR.

Understanding pain management in the perioperative setting and how opioids are prescribed in patients undergoing major surgeries is one of many key components to understanding how opioid prescribing is contributing to and impacted by the opioid crisis. Many studies have focused on the risk of postoperative opioid prescribing, using either insurance claims or EHR.[8] These datasets each have different limitations with specific implications for inferences. To examine the potential impact of data source choice on observational studies, we linked EHR from a large academic health system to Medicare Part D insurance claims to characterize opioid use as it relates to study eligibility criteria, exposure and outcome assessment.

Methods

This work builds on a prior study evaluating prolonged opioid use following surgery. We used EHR from a large academic health care system in the Southeast to identify Medicare patients undergoing major surgery between January 1, 2015 and September 30, 2017.[9] These patients were deterministically linked to Medicare insurance claims using a crosswalk provided by the Centers for Medicaid and Medicare Services which mapped non-identifiable patient IDs in the EHR system to encrypted Medicare beneficiary IDs. We included both outpatient and inpatient surgeries. Inpatient surgeries were included only if the admission was three nights or fewer, and patients were discharged home (not to a rehab facility, long-term care, etc.), consistent with the original aim of understanding prolonged opioid use in patients not under direct medical supervision after surgery. Patients were required to have at least 182 days (approximating 6 months or half of a calendar year) of continuous enrollment in Medicare Parts A, B, and D prior to surgery admission and at least 90 days of continuous enrollment following discharge.

The EHR data for this academic health care system does not reliably capture medication fill dates, thus drug utilization was characterized based on medication order dates. Orders were classified as inpatient, outpatient, or discharge medications. In the Medicare claims, drug utilization was characterized using prescription fill dates from the Medicare Part D claims. In this population of surgical patients, we examined measurement of opioid use during four time periods surrounding surgery (Figure 1): baseline, perioperative, discharge date, and follow-up.

Baseline Period

The baseline period to assess outpatient opioid use was defined as the 182-days before surgery. The baseline period is generally used for study selection, eligibility, and identifying opioid naïve patients. We examined the presence of any outpatient or discharge opioid orders in the EHR, and any opioid prescription fills in the Medicare Part D claims during this period. Because it is known that claims do not include inpatient medications reliably due to

the bundled nature of inpatient payments, we limit EHR orders to outpatient and discharge orders, mirroring what we expect to be picked up in insurance claims.

Perioperative Period

We assessed opioid use during surgery, defined as the day of surgery for outpatient surgeries, and the entire hospitalization spanning from the day of admission to the day of discharge for inpatient surgeries. We examined the presence of any opioid order (inpatient, outpatient, or discharge) in the EHR, or any opioid prescription fill in the Medicare Part D claims during this time.

Discharge Date

We assessed opioid use on day of discharge from surgery, defined as the day of surgery for outpatient surgeries, and the day of discharge from the hospital for inpatient surgeries. Because the focus is on take-home opioid medications intended for use after discharge, we examined the presence of any outpatient or discharge opioid orders in the EHR, and any prescription fill in the Medicare Part D claims on this day.

Follow-up Period

Our evaluation of opioid use during the follow-up period focused on prolonged opioid use, the main outcome of interest in the prior study that motivated this work.[10] We defined prolonged opioid use as evidence of opioid use in each of three consecutive 30-day windows (e.g., months) immediately following discharge. To meet the definition of prolonged opioid use in the EHR, patients had to have at least one active opioid order (outpatient or discharge) based on order date and day supply in each of the three consecutive 30-day windows following discharge. The focus on outpatient and discharge orders is consistent with our intention to study prolonged opioid use in patients not under direct medical supervision after surgery. Similarly, to meet the definition of prolonged opioid use in the Medicare Part D claims, patients had to have at least one active prescription based on the prescription fill date and day supply in each of the three consecutive 30-day windows following discharge.

In response to concerns regarding the impact that timing between medication orders and prescription fills could have on the main definition of prolonged opioid use, we conducted a post-hoc analysis aimed at comparing follow-up use. We relaxed the time periods and examined the number of patients with at least three outpatient or discharge medication orders in the EHR occurring at any point in the 90-day follow-up after discharge, and at least 3 prescription fills in the Medicare Part D claims at any point in the 90-day follow-up after discharge.

We quantified the proportion of surgical patients with evidence of opioid use during each of the four time periods separately for claims and EHR orders, and assessed concordance. This project was approved by the University of North Carolina at Chapel Hill Institutional Review Board (IRB #18-1248). Informed consent was waived, as we relied on preexisting data and did not conduct any recruitment or intervention.

Results

We identified 18,069 patients undergoing surgery between 2015 and 2017 in the EHR. We were able to deterministically link 18,054 (99.9%) to the claims, of which 11,128 (61.6%) had continuous enrollment in Medicare Part A, B, and D for the 182 days prior to surgery and the 90 days following surgery. The mean age was 74 years, 57% were female, and the most common surgeries were total knee arthroplasty (10.3%), total hip arthroplasty (6.4%), and laparoscopic cholecystectomy (4.6%).

Baseline Period

Among the 11,128 patients undergoing surgery, 34.4% had an opioid order (outpatient or discharge) in the EHR, while 44.1% of patients had an opioid prescription fill during the same 182-day baseline period prior to surgery (Table 1). Combining the two data sources, 54.8% of patients had records of opioid use in either. However, only 23.6% of patients had evidence of use in both the EHR and claims (Table 1). Among the 5,691 patients with evidence of baseline use in either data source, 56.9% of all baseline use was reflected only in one data source (Figure 2, Supplemental Table 1).

Perioperative Period

When focusing on evidence of opioid use during the perioperative period, 78.8% of the 11,128 patients undergoing surgery had opioid orders in the EHR (inpatient, outpatient, or discharge). Meanwhile, 47.6% of patients had a prescription fill in the claims during this period. Combining the two data sources, 88.6% had evidence of use in at least one data source, but only 37.8% had use reflected in both the EHR and claims. Among the 9,862 patients with evidence of perioperative use in either data source, 57.4% of perioperative use was reflected only in one data source (Table 1, Figure 2, Supplemental Table 2).

Discharge Date

On the day of discharge from surgery, 59.6% of the 11,128 patients undergoing surgery had a discharge or outpatient opioid order in the EHR. Meanwhile 45.5% had a prescription fill in the insurance claims. Combining the two data sources, 70.9% had use in at least one data source, but only 34.2% had evidence of use in both. Among the 7,893 patients with any evidence of opioid use on the day of discharge from surgery, 51.8% of discharge use was detected in only one data source (Table 1, Figure 2, Supplemental Table 3).

Follow-up Period

Among the 11,128 patients undergoing surgery, 4.3% met the definition of prolonged opioid use using EHR orders, while 10.4% met this definition using claims. Combining data sources, 12.3% met this definition in at least one data source, but only 2.3% met this definition in both the EHR and the claims concordantly. Among the 1,374 who met the definition in at least one data source, 81.4% met the definition in only one data source (Table 1, Figure 2, Supplemental Table 4).

Our post-hoc analysis evaluating the percent of patients with at least three medication orders (EHR) or prescription fills (claims) found very similar results (Supplemental Table 5).

Discussion

We observed little concordance between EHR medication orders and Medicare Part D prescription claims, even for the simple question of whether patients received any opioid analgesic. During the baseline period, perioperative period, and day of discharge, more than 50% of patients had evidence of opioid use in one of the data sources. Among patients with use documented in either the EHR or claims, less than half had documented use in both. Concordance between the two data types varied based on timing, whether before, during, or after major surgery. The largest relative difference we saw was in the assessment of prolonged opioid use following surgery, an outcome requiring longitudinal follow-up for 90 days. We found that the proportion of patients with evidence of prolonged opioid use in the claims was more than double that of the EHR orders. This may be due in part to the definition of prolonged use, requiring three orders (EHR) or fills (claims) in subsequent 30-day windows, but likely also reflects health system fragmentation between surgical facility and outpatient follow-up between provider networks. Our post-hoc analysis relaxed the timing of follow-up prescriptions and compared the proportion of patients who had at least 3 orders or fills in the 90 days following surgery, and results were very similar.

We highlight three important differences between EHR orders and claims that may impact the measurement of medication use in each data source. First, the EHR only reflect care delivered within the contributing health system, which can result in underestimation of opioid use if a patient receives an opioid prescription from an unaffiliated provider. In fact, a prior study linking Medicare insurance claims with two EHR networks found that only 22%−27% of outpatient and inpatient encounters found in the claims data were captured in the EHR systems evaluated.[11] In our current work, we focused on prescriptions instead of encounters and found that in the baseline and follow-up periods surrounding surgery, the Medicare claims data identified higher proportions of patients with evidence of opioid use. This is consistent with the scenario where patients receive routine baseline and follow-up care from providers outside of the health system where surgery was performed. Surgical procedures may be a particularly common setting for patients to travel for a specific procedure, while receiving routine care elsewhere. In these scenarios where a patients routine health care provider is outside of the health system where surgery was performed, baseline prescriptions would not be reflected in the EHR. Similarly, if follow-up care is managed by a physician outside of the EHR system, follow-up opioids will not be reflected. Meanwhile, insurance claims cover all prescriptions paid for via a patient's insurance benefit, regardless of provider. Of note, if a prescription is paid for out-of-pocket, this would not show up in the dispensed medication insurance claims. With this limitation in mind, we selected a study population enrolled in Medicare Part D where we expect most patients choose to use their insurance benefit.

Second, the EHR used in this analysis include outpatient medication *orders*, while the claims reflect outpatient prescription *fills*. If a provider writes a prescription for an opioid after surgery, but the patient decides not to pick this medication up from the pharmacy, this order would appear in the EHR, but would not be recorded in the prescription claims. This is referred to as primary nonadherence and could result in overestimating opioid use in the EHR.[12] Among Medicare beneficiaries in a study using survey data from 2004,

4.4% responded that they had chosen not to fill prescriptions due to cost, doubts about medical necessity, and fear of reactions.[13] This reported rate of primary nonadherence is lower than other findings and may be due in part to self-report. Primary nonadherence may be an increasing issue given rising costs of pharmaceuticals. A more recent meta-analysis estimated a primary nonadherence rate for chronic disease medications of 14.6%,[14] and in a similar study to ours linking claims and EHR, one-in-five orders for prescriptions for pediatric primary care patients were not filled, with white patients more likely than African-American and Hispanic patients to have unfilled prescriptions.[15] Specific to analgesics, patient-level opioid hesitancy can reduce the propensity to fill a prescription and consume the medication after surgery. One study of emergency department patients showed 9.2% chose not to fill opioid analgesic prescriptions.[16] Other factors influencing opioid fill behaviors that have been documented are: concerns about interference with daily activities, dissatisfaction with the type of analgesic prescribed, family interference, fear of dependence, pharmacy pickup logistics, and availability of complementary and alternative medicine.[17] Unfilled prescriptions have been recognized as a threat to validity in opioid utilization studies by others.[18] Our analysis provides quantitative evidence that prescriber behavior studies using claims may be muddled by patient fill behaviors.

Third, non-trivial discrepancies in perioperative medications are to be expected between EHR and claims data. EHR may be the more accurate measure of opioid use during surgical admission, as these data include inpatient medication orders and administrations. While insurance pays for these services and drugs, they are often represented as bundled procedure-based packages in claims, such as a “surgery kit”, and individual inpatient medications are not recorded. Thus, assessing drug exposures during a surgical admission would be more valid in EHR than claims. On a related point, our comparisons of opioid use in the baseline period, day of discharge, and follow-up period focused on outpatient and discharge orders in the EHR and did not include inpatient orders. This enabled comparison of opioid use occurring outside of inpatient admissions during periods when patients are not under direct medical supervision. The decision of whether to use inpatient medication orders to measure opioid use at different points in a patient’s timeline will depend on the clinical context and nature of the research question. In contexts where biologic exposure to medications is important to measure, inpatient administrations will be helpful. For studies focused on everyday management of pain in patients who are not hospitalized, outpatient prescriptions will be more relevant.

EHR and insurance claims are both useful data sources for epidemiologic research, providing the opportunity to examine trends and medication effects in large, diverse populations. EHR have become increasingly available as the utility of these detailed clinical data in informing and improving patient care has been more widely recognized.[19,20] However, it is important to understand that both EHR and claims data have important limitations to consider.

Our study in patients undergoing major therapeutic surgery found that data source choice directly impacts critical study design considerations. To limit the threat of selection-bias and time-varying risks, many pharmacoepidemiologic studies of medication use are conducted among “new users”, or patients without evidence of medication use in a baseline period.[21,22]

We found that measurement of baseline outpatient use of opioids in surgical patients differed between EHR and claims, impacting which patients would be considered eligible for study inclusion. Measurement error in baseline use can lead to bias in comparative studies if the unintentional inclusion of prevalent users is more likely to occur in one group of interest. Furthermore, if baseline use is measured as a confounder of interest, measurement error in the baseline period can also contribute to poor control for baseline differences.[23]

We also found that for exposure assessment of opioid use during surgical admission or discharge, insurance claims identified far fewer patients who were exposed compared to the EHR. This reflects the bundled inpatient payment structure resulting in a lack of inpatient medication data recorded in claims. Studies intending to study medication use during inpatient admissions will drastically underestimate use if relying on claims. The lack of medication data during inpatient admissions also has implications for baseline and follow-up periods, as drug exposures during admissions at any point in a longitudinal study will be incomplete during inpatient admissions.

Finally, for outcome ascertainment of prolonged opioid use, claims identified more than double the percent of patients with prolonged opioid use compared to EHR orders. For estimation of unbiased relative effect measures, near-perfect specificity is critical and any imperfections in sensitivity should be similar across the groups to be compared. The use of EHR alone would imply that sensitivity is poor, and specificity is unlikely to be near perfect given the potential for unfilled prescriptions that have been ordered in the EHR. The result would be a treatment effect that could be biased either toward or away from the null.

This study has limitations to consider. First, we focused on evidence of opioid use across one EHR system and Medicare claims data and did not evaluate concordance of other classes of medications. It is likely that the amount of out-of-system care and primary nonadherence varies widely across medication classes, and medication hesitancy and primary non-adherence may be more pronounced for opioids than other medications. Second, we were limited to a single healthcare system. While this is a large academic healthcare system with multiple hospitals and practices across the state, it may not generalize to other systems and regions where prescribing practices may differ. EHRs from health maintenance organizations where patients typically receive all healthcare services with a single network will have more comprehensive coverage of care, with minimal loss due to out-of-system services. Third, the EHR system did not have medication fills, so we were only able to observe medication orders, however this is not uncommon in studies using EHR. There may be timing discrepancies between order dates in the EHR and prescription fill dates in the claim. We expect the impact of these timing discrepancies to be small in the baseline period where we evaluated any prescription in the prior 182 days. For the analysis of opioid use on the day of discharge, it is possible that the percentage of patients with a prescription fill in the claims data is underreported if patients filled the prescription the in the days following discharge. In post-hoc analyses we combined the day of discharge with the first 7 days following discharge and found that the proportion of patients with orders in the EHR still exceeded the proportion of patients with prescription fills during this time, but the results were less dramatic (Supplemental Table 6). Our post-hoc analysis for the follow-up period also relaxed time windows for the definition of prolonged use,

finding similar results to the main analysis for prolonged opioid use. Fourth, we required that patients had continuous enrollment in Medicare Parts A, B, and D, excluding almost 40% of patients who were initially linked between the EHR and claims. This is largely driven by requiring Part D enrollment. The population with parts A, B, and D coverage may differ from those with Medicare Advantage plans. Additionally, there may be differences in prescription fill patterns in other types of claims data, and differences between medication filling behavior in older adults compared to the general population. Finally, both EHR and claims are proxy measures for biological opioid exposure. Patients have complex reasons for not completing prescribed courses of opioids, including side effects and resolution of pain. Diversion is also possible. Attributing opioid exposure in individual patient records is further complicated by poorly understood patient-level opioid sparing behaviors.

Data source choice depends heavily on specific research questions, but in practice, the existence of a data source may be the starting point for research conceptualization. If a hypothesis requires long periods of baseline health history or long periods of follow-up for outcome assessment, insurance claims are preferred. It will also be important to consider whether detailed clinical information (smoking history, body mass index, pain scores, lab results) that are not included in claims are necessary for confounder control, while assessing the impact of inpatient exposure on the causal contrast. Furthermore, the degree to which primary non-adherence, out-of-pocket payments, and care across unaffiliated institutions will impact measurement of study constructs will vary depending on the clinical populations and medication classes under research.

Combining linked EHR and claims can be illuminating, offering both clinical detail and longitudinal assessment. However there has been little attention in opioid research as to how discrepancies should be reconciled. Our results suggest that data source choice can impact key aspects of observational studies, such as the proportion of surgical patients with opioid use prior to, during, at discharge, and following surgery, leading to different conclusions. Each distinct data source may present different challenges and each source must therefore be validated separately. We caution that researchers leveraging these large data sets will need to understand the data generating mechanism (e.g., medication orders versus reimbursed prescription fills) behind the data, and how the data generating mechanism may influence measurement of key study definitions and the research question at hand.

With the increasing availability of large claims and EHR data and the ability to link the two data sources, the scientific research community will need to find ways to leverage these data in innovative ways while addressing discrepancies between data sources.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Conflicts of Interest:

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5 Key Points:

- Less than half of opioid prescriptions were present in both EHR orders and prescription claims.
- Using either EHR orders or prescription claims leads to substantial variation in measuring opioid use.
- Neither EHR orders nor prescription claims are a gold-standard. When linked, discrepancies are common.
- EHR are valuable in inpatient contexts; claims are valuable in longitudinal contexts.
- EHR orders and prescription claims should not be considered interchangeable for opioid ascertainment.

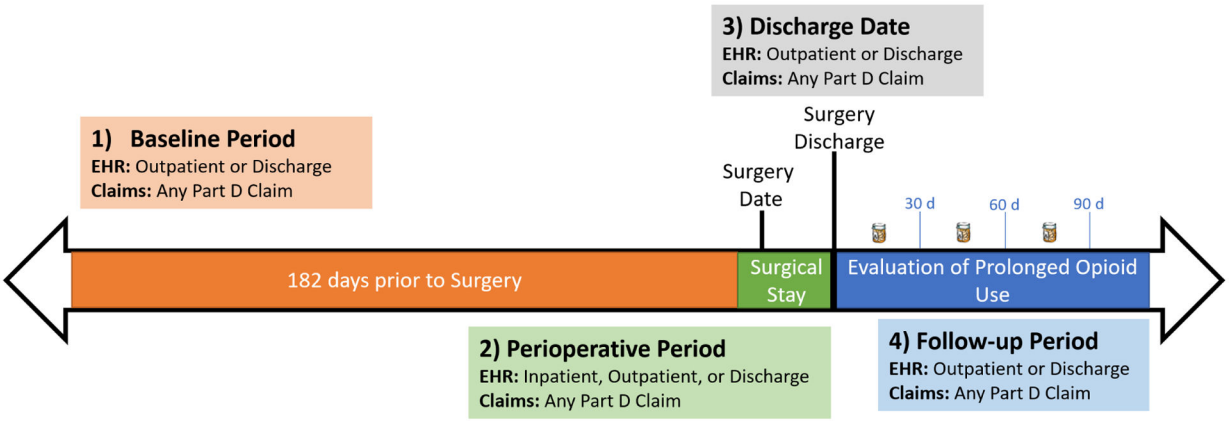

Figure 1.
Time windows for assessment of opioid use using EHR and Medicare Part D claims.

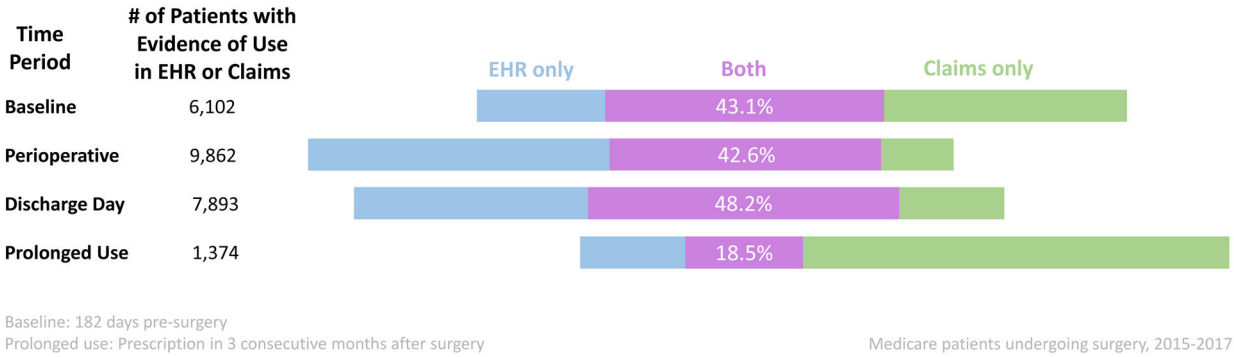

Figure 2.
Agreement between EHR and claims among patients with evidence of opioid use.

Table 1.

Number and percent of patients with evidence of opioid use in varying time windows (N=11,128).

Data source	Baseline Period		Perioperative Period		Day of Discharge		Prolonged Opioid Use (90-day Follow-up)	
	N	%	N	%	N	%	N	%
EHR Orders	3,825	34.4%	8,774	78.8%	6,635	59.6%	473	4.3%
Claims	4,905	44.1%	5,293	47.6%	5,064	45.5%	1,155	10.4%
Both EHR & claims	2,628	23.6%	4,205	37.8%	3,806	34.2%	255	2.3%
Either source	6,102	54.8%	9,862	88.6%	7,893	70.9%	1,373	12.3%
Total Number of Surgical Patients	11,128							