HHS Public Access

Author manuscript

J Trauma Nurs. Author manuscript; available in PMC 2020 May 01.

Published in final edited form as:

J Trauma Nurs. 2019 ; 26(3): 113–120. doi:10.1097/JTN.0000000000000435.

Evaluation of a Safer Opioid Prescribing Protocol (SOPP) for Patients Being Discharged from a Trauma Service

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Abstract

The aims of this study were to evaluate the effects on opioid medication prescribing, patient opioid safety education, and prescribing of naloxone following implementation of a safer opioid prescribing practice protocol (SOPP) as part of the electronic health record (EHR) system at a Level I Trauma Center.

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Contributors: All authors contributed to the original study design, development and writing of the submitted manuscript

Conflict of Interest: No conflict declared

This was a prospective observational study of the EHR of trauma patients pre (n = 191) and post (n = 316) SOPP implementation; between 2014 and 2016. At a comparison Level I trauma site not implementing SOPP, EHR for the same time period were assessed for any historical trends in opioid and naloxone prescribing.

After SOPP implementation, the implementation site increased the use of non-narcotic pain medication; decreased dispensing high opioid dose (≥ 100 MME), significantly increased the delivery of opioid safety education to patients and initiated prescribing naloxone. These changes were not found in the comparison site

Opioid prescribing for acute pain can be effectively reduced in a busy trauma setting with a guideline intervention incorporated into an EHR. Guidelines can increase the use of non-narcotic medications for the treatment of acute pain and increase naloxone co-prescription for patients with a higher risk of overdose.

Keywords

Opioid medication safety; pain management; overdose prevention

BACKGROUND

Although there has been an increase globally in opioid prescribing the United States has the world's highest rate of dispensing opioid analgesic medications (Berterame et al., 2016), with a prescribing rate in 2017 of 58.5 opioid prescriptions per 100 of the population and with individuals receiving on average 3.4 prescriptions per annum (Centers for Disease Control and Prevention, 2017). Although most patients who are prescribed opioid medications do not misuse them, the increase in the use of these drugs presents a potentially serious risk to patient safety, due to the risk of medication misuse, addiction and overdose (Centers for Disease Control and Prevention, 2012). Opioid prescribing practices are an important focus as a mechanism for reducing this serious public health issue.

Factors associated with misuse, abuse and addiction to opioids include an ongoing or history of a substance abuse disorder, undiagnosed or untreated psychiatric disorder, age 25-34, traumatic experience (Rosenthal et al., 2018), and social or family factors associated with substance use disorder (Webster et al., 2011). Access to prescribed opioids, dose and continued prescribing of opioids has also been linked to misuse (Sehgal, Manchikanti, & Smith, 2012). Patients prescribed opioid pain medication with pre-existing medical co-morbidities such as renal and hepatic diseases, respiratory disease, congestive heart failure, and psychiatric disorders have an increased risk of opioid overdose (Darke, Kaye, & Duflou, 2006; Wyne, Rai, Cuerden, Clark, & Suri, 2011). Other situational factors such as co-prescription of an opioid with benzodiazepines or other sedative drugs (O'Brien et al., 2017), and concurrent or recent use of alcohol or other drugs (Kandel, Hu, Griesler, & Wall, 2017), are also predictive of increase risk of opioid overdose (Sun et al., 2017). Additionally, an increased risk of fatal opioid overdose has also been associated with high daily doses of opioids, defined as daily intake at or exceeding 100 milligram morphine equivalent (MME) dose (Bohnert et al., 2011)

The use of opioid medication for pain management during admission and on discharge from trauma care is almost ubiquitous (Wunsch, Wijeysundera, Passarella, & Neuman, 2016). Recent research has found that among injured trauma patients discharged to home with prescribed opioids, continued use of prescription opioids four-months after discharge could be predicted from the amount of continued pain experienced and the patients' self-reported ability to cope with their pain (Rosenbloom, McCartney, Canzian, Kreder, & Katz, 2017). Field and colleagues, reported that the non-medical use of prescription opioids by injured at-risk drinkers continued for up to 12 months following discharge from a Level I trauma care facility. They also found that pre-admission non-medical use of prescription opioids and/or other drug misuse was predictive of non-prescribed opioid use following discharge (Field, Cochran, Caetano, Foreman, & Brown, 2014). While estimates of substance misuse are around 8.4% in the general population (Lipari & Van Horn, 2013), among injured patients this rises to between 40 and 60% (Alam et al., 2012).

The Centers for Disease Control and Prevention (CDC) guidelines for opioid prescribing for chronic pain (Dowell, Haegerich, & Chou, 2016) include: avoiding high daily dose (i.e. daily dose ≥ 90 Morphine Milligram Equivalent [MME; – the metric used to define the potency of an opioid dose, which allows us to compare potency across different types of prescribed opioids] (Eder et al., 2005)); co-prescription with naloxone (an effective opioid agonist that can reverse overdose) for daily dose ≥ 50 MME (or for any opioid overdose risk factors); avoiding co-prescription of benzodiazepines; and combining opioids with non-pharmacological and non-opioid therapy. Other recommendations include limiting the number of days of prescribing for acute pain and assessing patients' total opioid use before repeat prescribing. The challenge, for the health care professional in a trauma setting, is to adequately control acute pain without increasing the burden of misuse, morbidity, and mortality among those prescribed opioid analgesics.

PURPOSE

The primary objective of the current study was to evaluate the Safer Opioid Prescribing Practice (SOPP) protocol implemented at a Level 1 trauma center for patients discharged to home with a prescription for opioid medication after an inpatient admission

RESEARCH QUESTIONS

Does the implementation of a SOPP protocol increase patient education around opioid medication, and increase naloxone prescribing for patients at increased risk for an opioid overdose? Additionally, does a SOPP protocol reduce prescribed MME opioid dose at discharge and increase the use of non-opioid pain management approaches?

METHODS

Study sample

This study was conducted at a Level I adult trauma center in New England that admits over 2,900 adult patients annually. Study data and reporting were handled in accordance with the guideline on the Transparent Reporting of Evaluations with Nonrandomized Designs (Des

Jarlais, Lyles, Crepaz, & Group). The Institutional Review Board at the site approved the study protocol and provided a waiver of informed patient consent for the EHR data extraction.

The EHR of patients admitted and discharged to home from the SOPP implementation site between July 1, 2014 and May 31, 2016 were included. Study inclusion criteria were: patient discharged to home; discharged with a prescription for opioid analgesic medication; age ≥ 18. Exclusion criteria were age < 18 years and discharged to continued care services other than patients' home.

Patient EHR across the same time period was extracted from a Level I trauma center from a nearby New England state to determine if changes in the implementation site were due to historical factors, that influenced the opioid prescribing practices at a site not exposed to SOPP implementation. This comparison trauma center site admits approximately 1,800 adult patients annually.

Measures

The data for the EHR review were collected for three non-sequential patient cohorts, each of three-month's duration: cohort 1: July 1, 2014 to September 30, 2014, representing pre-SOPP implementation; cohort 2: September 1 to November 30, 2015, representing early SOPP implementation, and cohort 3: March 1 to May 31, 2016, representing the maintenance phase of SOPP.

We extracted the following information from patients' EHRs at each of these three-time points: patient demographic information; admission history, including primary diagnosis; injury severity; length of hospital inpatient stay; medication on discharge; home medication; and, comorbid medical conditions. The opioid MME discharge dose was calculated by multiplying the frequency of daily dose by the strength of dose (or maximum, if a range of frequency was recorded). A classification system for drug types of discharge and home medication (opioid analgesic, benzodiazepines, other sedatives, and non-opioid analgesic) was developed by the research study pharmacist.

The study investigators developed the data extraction procedures and the principal investigator trained the research assistants (RAs) in this protocol. The protocol, training approaches and validation approaches have previously been reported (Baird et al., 2017).

From the extracted EHR, an opioid risk factor score was developed based on prior research. (Dunn et al., 2010; Green, Grau, Carver, Kinzly, & Heimer, 2011; Silva, Schrager, Kecojevic, & Lankenau, 2013; Webster et al., 2011) The following risk factors were scored as present 1, versus not present or not documented 0: a. comorbid medical condition risk (COPD, congestive heart failure, end stage renal or liver disease); b. prior to admission home medication risk (opioid and/or benzodiazepine medication); c. discharge benzodiazepine co-prescription risk; d. discharge opioid medication ≥ 100 MME risk (MME dose was calculated for the discharge opioid dose by multiplying the frequency of daily dose by the strength of dose or maximum if a range of frequency was recorded).; e. positive illicit drug toxicology on admission or positive alcohol behavioral screen; f. prior treatment for

substance use disorder in past 12 months; and, g. opioid overdose in the past 12 months. The summed opioid overdose risk score potential range was 0 to 7. The number of doses of opioid analgesic medication as well as the use of non-narcotic medication prescribed were also collected.

SOPP Implementation

The SOPP protocol was developed as part of clinical care, and integrated into the implementation site's EHR, and functioned as an electronic best practice alert (BPA), triggered when a trauma patient was discharged to home with an opioid medication. The trauma staff (prescribers and nurses) were trained in the SOPP protocol and BPA prior to the implementation. The prescriber BPA displayed a pre-calculated table that presented the maximum daily MME of the opioid prescribed at discharge. The prescriber indicated if the discharge dose was ≥ 100 MME. If affirmed, or if there was another identified risk factor, the prescriber was advised to prescribe naloxone. If naloxone was not prescribed, a reason for this was requested. A link to the state Prescription Drug Monitoring Program was also made available.

Following the prescriber BPA, the nurse discharging the patient also received up to two BPAs. First, a universal BPA indicated that the nurse should provide opioid medication safe use education to all patients discharged with a prescribed opioid. Patient brochures were developed to standardize this education about safe use of opioid medication (i.e. not using with alcohol, using only amount prescribed, not using with other medications unless medically advised); safe storage of opioids, and information on safer disposal of unused opioids. If the patient was prescribed naloxone, the second BPA was implemented. In this BPA, the nurse printed a patient education brochure on overdose recognition and administration of naloxone. The nurse was also prompted to use the naloxone demonstration kits with the patient and their family member to provide a visual aid for instructing how to administer naloxone. All educational materials were available in English, Spanish, and Portuguese.

Data analysis

Statistical power analysis was performed to estimate the required number of EHRs of eligible patients to be reviewed to identify at least one identified opioid overdose risk factor in at least 30% of the reviewed charts. A minimum of 161 EHRs pre and post implementation was required to detect this preponderance of opioid overdose risk; this assumed a 5% error in our estimated proportion of positive charts.

The data were imported into Statistical Analysis Software (SAS) (Version 9.4, Carey, NC) for analyses. For descriptive analyses, means, counts and proportions are reported with 95% confidence intervals (CIs) (Laupacis, Sackett, & Roberts), and medians with inter-quartile range (IQR). The inter-rater reliability of the extracted EHR data was calculated using Cohen's Kappa. The rater agreement coefficients were determined for six identified categories: patient demographics, comorbid medical conditions, positive toxicology or substance use screen, home medication, discharge medications, and discharge opioid medication MME. These agreement rates are reported with 95% CIs.

The focus of the analyses was on changes in clinical practice related to the BPA at the SOPP implementation trauma site. The data from the comparison site were used to determine if changes at the implementation site were attributable to historical or secular trends, rather than the SOPP protocol. We compared the frequency and change in frequency (with 95% CIs) of naloxone prescribing and opioid safety education across the three-time cohorts.

To address the secondary aim of the study we examined change in the discharge prescribing across two metrics: medication dosage (odds dichotomized as < 100 MME daily and ≥ 100 MME daily), and number of opioid analgesic pills dispensed, as well as the use of non-opioid pain management approaches. A logistic regression, adjusting for gender, age and injury severity, was conducted to estimate the change in likelihood of receiving a higher medication dosage following SOPP implementation.

RESULTS

Rater Agreement

Across the three patient EHR data collection cohorts, collapsed across both sites, the inter-rater agreement were: a. patient descriptive data = 100%; b. comorbid medical conditions = (kappa 0.93 95% CI =.0.89, 0.97; c. positive substance use screen (kappa = 0..83, 95% CI = 0.78, 0.88.); d. home medications = (kappa=0.94, 95% CI= .0.91 ,.0.98); e. discharge medications type= (kappa =1.00); and, f. discharge medication MME ≥ 100 (kappa = 0.89, 95% CI=0.85, 0.93).

Patient Characteristics

Table 1 details the characteristics of the patients observed across cohorts at the SOPP implementation site. Most were male, white and not Hispanic. The median length of stay for the trauma admission was 3 days for all cohorts; length of stay ranged from 1 to 49 days; the three most common injury mechanisms for the admitted trauma patients were motor vehicle crash (34.5%), falls (34.1%), or cutting/piercing (18.1%), with these mechanisms accounting for 87% of all admissions. Median length of stay at the comparison site was also 3 days and 79% of admissions were due to motor vehicle crash, falls, or cutting/piercing.

Opioid safety education and naloxone prescribing

A substantial proportion of patients across the cohorts at the implementation site had at least one of the seven defined opioid overdose risk factors (Table 2). The most frequently identified risk factors were the discharge opioid medication dose ≥ 100 MME, and positive screen for alcohol or drug use at the time of admission. After the implementation of SOPP, prescribers' response rate to the MME dose alert in the EHR was 92% for patients discharged with an opioid for cohort 2 and 99% of cohort 3 patients (Table 3).

Table 3 indicates the outcome of the BPA for naloxone co-prescribing, patient opioid safety education given, and education provided if naloxone was prescribed. We found that the BPA identified 23 patients from cohort 2 that had an opioid risk factor resulting in 21 prescriptions for naloxone given (91%), and 11 naloxone BPAs for cohort 3 with 11 prescriptions for naloxone given (100%). Nurses documented they trained 12 patients on

naloxone use in cohort 2 who were prescribed naloxone (57%) and trained five of the patients prescribed naloxone in cohort 3 (45%). For the 168 patients discharged during cohort 2 we found EHR documentation of a nurse led opioid safety education being provided to 58 patients (34.5%) and for 57 of the 150 patients discharged to home with an opioid prescription for cohort 3 (38%).

Prescribed Opioid Dose and Pain Management

At the implementation site, 94% of cohort 1 trauma patients were discharged to home with a prescription for opioid medication; this decreased to 89% for cohort 2 and 84 % for cohort 3 (Table 4: Δ = 10% 95% CI: 5, 15%). The most commonly prescribed discharge opioid analgesic medication was oxycodone, at a 5mg dose and a frequency of up to four-hourly as needed, across sites and cohorts (Table 4); the median number of pills prescribed also significantly decreased. The median dose of 90MME did not change after SOPP implementation; however, the likelihood of a prescribed dose ≥100MME at discharge did significantly decrease (AOR = 0.36; 95%CI; 0.18, 0.72). The use of non-narcotic medication prescribed for pain control at the implementation site significantly increased after SOPP; cohort 1 73% to 93% (cohort 3) (Δ = 18%; 95% CI: 13; 23).

Comparison Site

At the comparison site the proportion of patients who were discharged home with a prescription for opioid medication remained consistently lower than at the implementation site across the three cohorts, at between 62-63% (p = 0.02) but did not change over time. There were site differences in the median MME discharge dose: the intervention site prescribed a median of 90 MME at all cohorts, while the comparison site prescribed a median of 45 MME, across all cohorts. The proportion of patients discharged to home with a high dose of opioids (≥ 100MME) did not change across the cohorts at the comparison site. The proportion of patients discharged to home with a non-opioid pain medication also increased at the comparison site across the cohorts (Δ = 13%; 95% CI: 9; 17) but was significantly less than at the SOPP implementation site. No patient opioid safety education or co-prescription for naloxone was found in the review of the EHR at the comparison site across the time-periods of the study.

DISCUSSION

The purpose of this study was to evaluate implementation of clinical protocol for opioid prescribing, SOPP, at a Level I Trauma Center. There is evidence that the SOPP protocol changed practices within the implementation Trauma Center site by decreasing the number of prescription that had a high daily dose of opioids (≥100 MME), the quantity of opioids prescribed at discharge, prescribing naloxone to patients with an identified opioid overdose risk, and in providing safer opioid medication use education to trauma patients. These effects were found, when we compared the Trauma Center initiating the SOPP protocol across time, and in comparison, to a Trauma Center site not utilizing this protocol.

Positive steps to decrease both the quantity and dose of opioids prescribed have been advocated by many institutions as essential to reduce the morbidity and mortality associated

with prescribed opioid use (Dowell et al., 2016; Sehgal et al., 2012). Increasing patient accesses to the opioid reversal medication, naloxone, through provider co-prescribing has also been recommended (Davis, Ruiz, Glynn, Picariello, & Walley, 2014; Dowell et al., 2016; Doyon, Aks, & Schaeffer, 2014). The results of the SOPP implementation evaluation study indicates that the EHR can be utilized to identify patients risk factors for opioid overdose, and that a clinical protocol for trauma service prescribers and medical staff can be in implemented in response to those risks. These results were consistent with other opioid guideline and opioid reduction prescribing efforts (Fulton-Kehoe et al., 2015) and current state guidelines recommend lower upper limits for opioid prescribing. However, our data also demonstrated that there is room for improvement given the number of patients who did not receive all or some of the elements of the BPAs that comprise the SOPP protocol.

The BPA for identifying patients with an opioid overdose risk factor used EHR information that was easily available but was not always consistent with the information found during the extraction of EHR data by the RAs. Research staff were able to extensively review all available data fields, such that information on a patient's past substance use disorder history that may not be documented in the physician's or nurse's record, may have been found in the notes of the social worker or psychiatrist conducting consultation.

The BPA was designed to use data fields readily available to the physician or nurse who wanted to check any medical information, and the differences between the identification of patients through the BPA versus the RA review may indicate either an over-inclusion of the research review or the limits of a BPA based only on electronic record review. Also, the prescriber may have discussed naloxone with the patient who refused it being prescribed; but this was not documented. The BPA alerted the physician that the patient had an opioid overdose risk and that naloxone prescribing should be considered, but the specific risk type was not given, and if the prescribed dose was < 100 MME the prescriber may have evaluated the risk as less than was indicated by the BPA. Similarly, the nursing BPA was triggered to provide patients general safety education about prescribed opioid use, yet less than 60% were documented as receiving the education. This may represent poor documentation or discomfort of the nursing staff in delivering opioid safety and naloxone use education to patients.

Future analyses could explore the reasons for these differences between the BPA responses and data extracted from the EHR to determine the potential provider perceptions that underpin naloxone prescribing.

LIMITATIONS

This was an evaluation of a new clinical protocol for patients discharged from the trauma services of a busy urban Level I Trauma Center. As patients were not randomized to receive the SOPP intervention differences in patient characteristics and medical practices at the two sites may have contributed to the differences found in prescribing practices and may have affected the internal validity and conclusions of this study. Also, there were changes in recommendations for opioid prescribing that were being developed by the implementation site state Department of Health during the period of SOPP implementation that could have

confounded these results. Although these prescribing regulations were not instituted into practice until after the final cohort of data collection had been completed; knowledge of these impending changes could have affected opioid prescribing.

CONCLUSIONS

In summary, the SOPP study demonstrated that the additional BPA to identify patients at risk for harm from their opioid medication could be integrated into an existing EHR system. This safety protocol was successfully used to identify patients at increased risk for opioid overdose and provide general education around safer prescribed opioid use for these discharged patients. More work is needed to improve the frequency at which these services can be provided to trauma patients who are prescribed opioids. These findings have important implication for shaping public health policy decisions on opioid prescribing safety across health care services.

Acknowledgment:

We acknowledge the invaluable contribution in electronic medical record review of Miriam Okero, Vera Bernardino; Jheraldines Gonzalez, and Daniel Chiou.

Role of Funding Source: Funding for this study was obtained from the Centers for Disease Control and Prevention. Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

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KEY POINTS

- Opioid prescribing is almost ubiquitous among severely injured trauma patients
- An EHR guided intervention can reduce high dose prescribing of opioid pain medications, increase patient medication education, and increase co-prescribing of naloxone.
- Further studies are needed to evaluate approaches to increases the issue of safer opioid prescribing practices across patient groups

Table 1:

Demographic characteristics of Trauma Patients at SOPP Implementation Site

Demographic characteristics	Cohort 1 n = 191	Cohort 2 n = 166	Cohort 3 n = 150
Median age, years (IQR), range	43 (25, 60) 18-96	45 (28, 58) 18-93	47 (30,62) 18-94
Female n (%)	43 (22.5)	55 (32.7)	32 (20.7)
Hispanic n (%)	22 (11.5)	26 (15.5)	21 (14)
White n (%)	148 (77.5)	119 (71.7)	108 (72)
Black/African-American n (%)	19 (10)	17 (10.2)	12 (8)
Other n (%)	24 (12.5)	30 (18.1)	30 (20)

Table 2:

Opioid Overdose Risk Factors Across SOPP Implementation Cohorts

Risk Factor Type n (%)	Cohort 1 N = 191	Cohort 2 N=168	Cohort 3 N= 150
1. Medical co-morbidity	29 (15.2)	38 (22.6)	32 (21.3)
2. Prior Treatment Past 12 months			
Alcohol/Substance	8 (4.2)	9 (5.4)	5 (3.3)
Major psychiatric disorder	0	3 (1.7)	2 (1.3)
3. Opioid 0verdose past 12 months	0	1 (< 1)	0
4. Pre-admission home medication (opioid/benzodiazepine	45 (23.6)	30 (17.9)	38 (25.3)
5. Discharge opioid ≥ 100MME daily	53 (27.7)	45 (26.7)	40 (26.6)
6. Benzodiazepine co-prescribed at discharge	18 (9.4)	11 (6.5)	26 (17.3)
7. Positive for alcohol and/or drug screen on admission	126 (66)	91 (54.2)	94 (62.7)
Calculated unintentional opioid overdose risk factors	0 =79 (41.4) 1= 76 (38) 2= 22 (10.7) 3= 3 (11) 4= 1 (7.3) >4 = 0	0 =37 (22) 1= 64 (38.1) 2= 30 (18) 3= 24 (14.3) 4= 7 (4.2) 5= 6 (3.6) > 6 = 0	0 =40 (26.7) 1= 62 (41.3) 2= 36 (24) 3= 10 (6.7) 4= 6 (4) 5= 2 (1) > 5 = 0

Table 3.

Best Practice Alert Response Cohort 2 and 3 at SOPP Implementation Site

	Cohort 2 N = 168	Cohort 3 N = 150
*MME Table responded to by prescriber n (%)	155 (92)	149 (99)
BPA alert for daily MME ≥ 100 or other risk factor n (%)	23 (14.4%)	11 (7.4%)
Naloxone prescribed if indicated	21 (91)	11 (100)
BPA opioid safety education n (%)	58 (34.5)	57 (35)
BPA naloxone education (if prescribed) n (%)	12 (57)	5 (45)

* Prescriber had to indicate if MME table indicated prescribed discharge dose of opioid ≥ 100 Morphine Milligram Equivalent (MME)

* BPA = Best Practice Alert

Table 4:

Opioid Medication at Discharge at SOPP Implementation Site

Discharge Medication	**Cohort 1**	**Cohort 2**	**Cohort 3**
Implementation Site	**n = 191**	**n=168**	**n= 150**
Frequent Rx Type/Dose (%)	Oxycodone/5 mg (87.8)	Oxycodone/5 mg (70.3)	Oxycodone/5 mg (77.3)
Median daily MME opioid discharge dose (IQR)	90 (45,120)	90 (45,120)	90 (45,120)
Median number dispensed (IQR)	60 (30,60)	50 (30,60)	40 (30,60)
Frequency of non-narcotic pain medication n (%)	144 (75)	151 (90)	139 (93)

Rx = Prescription; IQR=interquartile range