

Effectiveness of a discharge analgesia guideline on discharge opioid prescribing after a surgical procedure from a tertiary metropolitan hospital

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ABSTRACT

Objective: *The primary objective of this study was to evaluate the effectiveness of a discharge analgesia guideline on the number of days' supply of opioid analgesics provided among surgical patients upon hospital discharge. The secondary objective was to analyze the effect of this guideline on the provision of an analgesic discharge plan.*

Design: *A retrospective historical control cohort study.*

Setting: *A tertiary metropolitan hospital.*

Interventions: *A discharge analgesia guideline recommending the supply of opioid analgesics on discharge based on patient use in the 24 hours prior to discharge and the supply of an analgesic discharge plan.*

Main outcome measure(s): *The primary outcome measure was the number of days' supply of opioids. The secondary outcome measure was the proportion of patients receiving an analgesic discharge plan.*

Results: *There was no change in the number of days' supply of opioids provided on discharge (median, interquartile range: 5, 3-9.75 vs 6, 4-10; $p = 0.107$) and in the proportion of patients receiving an analgesic discharge plan (26 percent vs 22.2 percent; $p = 0.604$). The results of two multivariable regression models showed no change in the number of days' supply of opioids (adjusted incidence rate ratio, 95 percent confidence interval [CI]: 1.1, 0.9-1.2) and the provision of an analgesic discharge plan (adjusted odds ratio, 95 percent CI: 0.6, 0.2-1.4) after adjusting for confounding variables.*

Conclusion: *Overall, our study found no change in the number of days' supply of opioids provided on discharge and the provision of an analgesic discharge plan after implementation of a discharge analgesia guideline, but we also found that prescribing practices already aligned with the guideline before its implementation.*

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INTRODUCTION

Opioid analgesics are often prescribed upon hospital discharge for the management of acute post-operative pain.¹ A multicenter prospective cohort

study conducted in Australia in 2020 found that 56 percent of post-surgical patients were discharged with an opioid prescription.² Of these, 70 percent reported that they had leftover opioid medications 2 weeks post-discharge. Supplying too much opioids

on discharge can cause significant harm, such as persistent opioid use, dependence, and overdose.³ A prospective observational cohort study conducted in Australia in 2017 found that 10.5 percent of opioid-naïve patients were still using opioids 90 days post-surgery.⁴ Such long-term use increases the potential for tolerance, overdose, and even death.⁵ Furthermore, a surplus amount of prescription opioids remaining in the community also contributes to an opioid reservoir and poses a health risk due to the increased potential for misuse, diversion, and overdose.^{6,7}

Several strategies aimed at improving the appropriate supply of opioids upon hospital discharge have been implemented to reduce the opioid reservoir in the community.⁶ A systematic review of 43 studies identified that such strategies include the implementation of prescribing guidelines, prescriber education, and default quantity changes in electronic medical records.⁸ A common intervention was to supply opioids on discharge based on the amount of opioids the patient consumed in the 24 hours prior to discharge.^{9,10} These studies found a decrease of up to 57 percent in the median morphine milligram equivalents (MMEs) prescribed on discharge. Also, a couple of studies evaluated the effect of a multifaceted intervention on the provision of a pain management plan upon discharge in order to prevent unnecessary long-term opioid use.^{11,12} The systematic review found that many of the studies evaluating the effect of guideline implementation included no adjustment for potential confounding variables, thus significantly increasing the potential for bias.¹²⁻¹⁶ There were also no studies that evaluated the effect of a discharge analgesia guideline on the provision of an analgesic discharge plan. Thus, the primary objective of this study was to evaluate the effectiveness of a discharge analgesia guideline on the number of days' supply of opioid analgesics provided to surgical patients upon hospital discharge. A secondary objective was to analyze the effect of this guideline on the provision of an analgesic discharge plan.

MATERIALS AND METHODS

Study design and setting

A retrospective historical control cohort study examining the effects of a discharge analgesia guideline released between October and December 2019 was conducted at a tertiary metropolitan hospital in Sydney, Australia. The discharge analgesia guideline

(Appendix A) was developed in consultation with the Department of Pain Management and the hospital Narcotics Working Party. These guidelines directed prescribers to consider the patient's pain and analgesia requirements in the 24 hours prior to discharge and supply opioids based on these requirements. They also stated that all patients were to be provided with a written analgesic plan on discharge. Prior to implementation of these guidelines, there were no other discharge analgesia guidelines in place. Feedback was compiled from the Pharmacy Department, anesthesiologists, senior surgeons, and junior medical officers (JMOs). Once finalized, the guidelines were formatted into posters and were placed strategically in every ward where doctors would congregate. They were also emailed to all JMOs and registrars. Informal face-to-face education sessions regarding the guidelines were offered to nurses, JMOs, and pharmacists. The guidelines were also formally presented to the JMOs, at nursing grand rounds, and at nursing research symposium. These education sessions were held between October and December 2019.

Patient selection

Patients aged 18 years or over who underwent a surgical procedure and were discharged from hospital stay with an opioid analgesic were included in this study. Same-day surgery patients and repeat admissions were excluded. Patients who did not have opioid analgesics dispensed from the hospital pharmacy were also excluded, as information on the quantity of opioid analgesics supplied was required for the primary outcome analysis.

The preintervention group comprised patients discharged between October 1, 2018, and September 30, 2019. The post-intervention group comprised patients discharged between January 1, 2020, and December 31, 2020, thus excluding the 2 months of guideline release and allowing a month for the dissemination of the guidelines. As data such as medication information and pain scores needed to be collected manually, a random sample was generated using a random number generator in Excel[®] to create a list of unique numbers. A sample size calculation was made with G*Power Version 3.1.9.6 using a Mann-Whitney U test with a change in mean (standard deviation [SD]) the number of days' supply from 7 (4) to 5 (3) days, an α limit of 0.05, and a power of 0.8.¹⁷ The calculation showed that a total sample size of 106 with 52 in each group was required.

Data collection processes

Patient data were extracted from the electronic medical record (Millennium PowerChart, Cerner Corporation, North Kansas City, Missouri, USA) and the pharmacy dispensing software (iPharmacy, DXC Technology Company, Macquarie Park, NSW, Australia). Demographic data collected included patient age, gender, height, weight, and length of stay. The use of opioids prior to admission was also collected to determine whether patients were opioid naïve prior to hospital stay. Australian Classification of Health Intervention procedure codes were extracted for each patient.¹⁸ Patients who were readmitted within 30 days after discharge were also identified. International Classification of Diseases 10th Revision Australian Modification (ICD-10-AM) codes were collected to identify patient comorbidities.¹⁹ The Charlson Comorbidity Index was calculated using the corresponding weightings for each ICD-10-AM code established by previous studies.²⁰ Pain scores were collected from the last day of hospitalization. Scores were provided by the patient as a numeric rating of their pain between 0 and 10, where 0 indicated no pain, and 10 indicated severe pain. If more than one pain score was available, the average score was used.

Information about medications prescribed upon hospital discharge (including drug, form, dose, route, and quantity) and information on process outcomes (including the provision of a discharge analgesia plan) was collected. A discharge analgesia plan was considered to be provided if the doctor had provided instructions for their opioid analgesic in the discharge letter, such as tapering the opioid dose or ceasing the opioid after a certain number of days. Oral MMEs were calculated using established conversion factors.²¹ The primary outcome of the number of days' supply of opioids was calculated by dividing the total MME prescribed on discharge by the total MME consumed in the 24 hours prior to discharge, then by rounding to the nearest positive integer. If a patient had not received any opioids in the 24 hours prior to discharge, the number of days supplied was determined by using the smallest daily quantity possible from the opioids provided on discharge as the denominator. This amount was capped to 10 days as per the state policy for medications supplied on discharge.²²

Data analyses

Statistical analysis was performed using IBM SPSS Statistics Version 25 (IBM, Armonk, New York,

USA). Results were considered significant if the *p*-value was less than 0.05. Fisher's exact test was used to compare categorical variables. Independent *t*-tests were used to compare continuous normally distributed variables, and the Mann-Whitney *U*-test was used for continuous variables that were not normally distributed.

Multivariable regression models were developed to assess the effect of the guidelines on the primary and secondary outcomes. Negative binomial regression was performed for the primary outcome using the number of days' supply of opioids as the dependent variable. Independent variables were whether the guidelines were implemented or not and demographics that were identified as being statistically different before and after the implementation of the guidelines, including age,²³ length of stay, pain scores, comorbidity of circulatory or respiratory system disease, procedure type for the circulatory or respiratory system, and nonsteroidal anti-inflammatory drug supply on discharge. Other independent variables that were identified from the literature were also included in the models, namely, chronic pain,²⁴ mental and behavioral disorders,²³ opioid dependence or substance abuse,²³ and opioid use prior to admission.²³

The secondary outcome was assessed using a logistic regression with the dependent variable being the provision of an analgesic discharge plan. This model used the same independent variables, as listed for the primary outcome.

Multiple imputation was used to impute missing pain scores using age, sex, comorbidities, procedure types, and total MME used in the 24 hours prior to discharge as predictors in the model.

RESULTS

A random sample of 679 surgical patients was identified. Same-day surgery patients and patients who were not provided an opioid analgesic upon discharge were removed, leaving a total of 181 patients in the study. Of these, 100 patients were discharged during the preintervention period, and 81 patients were discharged during the post-intervention period (Appendix B).

Characteristics of surgical patients in the pre-intervention and post-intervention groups are presented in Tables 1 and 2. The post-intervention group was significantly older (mean, SD: 61.6, 20.1 vs 53.9, 18.7; *p* = 0.009) and had a longer length of

Table 1. Characteristics of surgical patients prescribed an opioid on discharge

	Overall (N = 181)	Preintervention (N = 100)	Post-intervention (N = 81)	p-Value
Age; years, mean (SD)	57.3 (19.7)	53.9 (18.7)	61.6 (20.1)	0.009*
Sex; female, n (percent)	81 (44.8 percent)	47 (47 percent)	34 (42 percent)	0.549
BMI, median (IQR)	26.2 (23.6-31.0)	27.0 (23.5-30.3) [†]	26.1 (23.7-32.4)	0.548
Opioids used prior to admission, n (percent)	27 (14.9 percent)	15 (15 percent)	12 (14.8 percent)	1.000
Length of stay; days, median (IQR)	6 (3-10)	4 (3-8)	7 (5-12.5)	<0.001*
30-Day readmission, n (percent)	12 (6.6 percent)	7 (7 percent)	5 (6.2 percent)	1.000
Pain scores on rest in 24 hours prior to discharge, [‡] median (IQR)	1.5 (0-3)	2 (0.02-3.6)	1 (0-2.8)	0.022*
Charlson Comorbidity Index, n (percent)				
0	136 (75.1 percent)	77 (77 percent)	59 (72.8 percent)	0.604
1	11 (6.1 percent)	5 (5 percent)	6 (7.4 percent)	0.544
2+	34 (18.8 percent)	18 (18 percent)	16 (19.8 percent)	0.849
Comorbidities, n (percent)				
Type 2 diabetes	32 (17.7 percent)	13 (13 percent)	19 (23.5 percent)	0.079
Kidney failure	11 (6.1 percent)	3 (3 percent)	8 (9.9 percent)	0.066
Circulatory system diseases [§]	39 (21.5 percent)	14 (14 percent)	25 (30.9 percent)	0.007*
Digestive system diseases	39 (21.5 percent)	23 (23 percent)	16 (19.8 percent)	0.717
Respiratory system diseases	19 (10.5 percent)	5 (5 percent)	15 (17.3 percent)	0.013*
Arthritis or osteoarthritis	12 (6.6 percent)	7 (7 percent)	5 (6.2 percent)	1.000
Osteoporosis	26 (14.4 percent)	15 (15 percent)	11 (13.6 percent)	0.834
Cancer	27 (14.9 percent)	17 (17 percent)	10 (12.3 percent)	0.410
Chronic pain	7 (3.9 percent)	5 (5 percent)	2 (2.5 percent)	0.462
Mental and behavioral disorders	19 (10.5 percent)	10 (10 percent)	9 (11.1 percent)	0.813
Opioid dependence or substance use disorder	34 (18.8 percent)	22 (22 percent)	12 (14.8 percent)	0.254
ACHI procedure type, n (percent)				
Nervous system	31 (17.1 percent)	21 (21 percent)	10 (12.3 percent)	0.165
Respiratory system	18 (9.9 percent)	5 (5 percent)	13 (16 percent)	0.022*
Cardiovascular system	36 (19.9 percent)	12 (12 percent)	24 (29.6 percent)	0.005*
Digestive system	26 (14.4 percent)	14 (14 percent)	12 (14.8 percent)	1.000
Musculoskeletal system	94 (51.9 percent)	51 (51 percent)	43 (53.1 percent)	0.881
Primary hip or knee replacement	19 (10.5 percent)	7 (7 percent)	12 (14.8 percent)	0.095

Table 1. Characteristics of surgical patients prescribed an opioid on discharge (continued)

	Overall (N = 181)	Preintervention (N = 100)	Post-intervention (N = 81)	p-Value
Other	76 (42.0 percent)	44 (44 percent)	32 (39.5 percent)	0.549
Dermatology and plastics	13 (7.2 percent)	6 (6 percent)	7 (8.6 percent)	0.569
Other	21 (11.6 percent)	12 (12 percent)	9 (11.1 percent)	1.000

SD: standard deviation; IQR: interquartile range; BMI: body mass index; ACHI: Australian Classification of Health Interventions.

*p-Value indicates statistical significance set at $p < 0.05$.

[†]n = 98.

[‡]Where multiple pain scores were available in the 24 hours prior to discharge, the average score was taken.

[§]Addition of subcategories will exceed 100 percent as patients may have had multiple comorbidities.

Table 2. Analgesics prescribed upon discharge among patients prescribed an opioid on discharge

	Overall (N = 181)	Preintervention (N = 100)	Post-intervention (N = 81)	p-Value
Total MME in 24 hours prior to discharge, median (IQR)	30 (15-61.3)	37.5 (15-76.5)	22.5 (15-50)	0.178
Total MME provided on discharge, median (IQR)	150 (75-280)	150 (75-266.3)	150 (97.5-290)	0.522
Prescribed an extended release opioid on discharge, n (percent)	71 (39.2 percent)	38 (38 percent)	33 (40.7 percent)	0.760
Opioids prescribed on discharge, n (percent)	181 (100 percent)	100 (100 percent)	81 (100 percent)	
Buprenorphine	4 (2.2 percent)	1 (1 percent)	3 (3.7 percent)	0.326
Codeine	1 (0.6 percent)	1 (1 percent)	0 (0 percent)	1.000
Hydromorphone	7 (3.9 percent)	4 (4 percent)	3 (3.7 percent)	1.000
Fentanyl	2 (1.1 percent)	1 (1 percent)	1 (1.2 percent)	1.000
Oxycodone	126 (69.6 percent)	80 (80 percent)	46 (56.8 percent)	0.001*
Tapentadol	50 (27.6 percent)	18 (18 percent)	32 (39.5 percent)	0.002*
Tramadol	5 (2.8 percent)	3 (3 percent)	2 (2.5 percent)	1.000
Methadone	1 (0.6 percent)	1 (1 percent)	0 (0 percent)	1.000
Morphine	2 (1.1 percent)	1 (1 percent)	1 (1 percent)	1.000
Nonopioid analgesics prescribed on discharge, n (percent)	165 (91.2 percent)	91 (91 percent)	74 (91.4 percent)	0.574
Paracetamol	163 (90.1 percent)	91 (91 percent)	72 (88.9 percent)	0.804
Gabapentinoids	13 (7.2 percent)	6 (6 percent)	7 (8.6 percent)	0.569
NSAIDs	37 (20.4 percent)	26 (26 percent)	11 (13.6 percent)	0.043*
Benzodiazepines	5 (2.8 percent)	3 (3 percent)	2 (2.5 percent)	1.000

MMEs: morphine milligram equivalents; NSAIDs: nonsteroidal anti-inflammatory drugs; IQR: interquartile range.

*p-Value indicates statistical significance set at $p < 0.05$.

stay (median, interquartile range [IQR]: 7, 5-12.5 vs 4, 3-8; $p < 0.001$). A greater proportion of patients were identified as having circulatory system diseases (30.9 percent vs 14 percent; $p = 0.007$) and respiratory system diseases in the post-intervention group (17.3 percent vs 5 percent; $p = 0.013$). There was no statistically significant difference in the proportion of patients with a Charlson Comorbidity Index greater than or equal to 2 in the pre- vs post-group (18 percent vs 19.8 percent; $p = 0.849$). Fewer patients in the preintervention group underwent respiratory system procedures (5 percent vs 16 percent; $p = 0.022$) and cardiovascular system procedures (12 percent vs 29.6 percent; $p = 0.005$). Pain scores in the last day of hospitalization were significantly lower for the post-intervention group (median, IQR: 1, 0-2.8 vs 2, 0.02-3.6; $p = 0.022$). There were 16.7 percent of pain scores for our sample missing at random. Fewer patients in the post-intervention group were given oxycodone on discharge (56.8 percent vs 80 percent; $p = 0.001$), but more patients were discharged with tapentadol (39.5 percent vs 18 percent; $p = 0.002$).

Information on the primary and secondary objectives of both the number of days' supply of opioids on discharge and provision of an analgesic discharge plan is provided in Table 3. There was no statistically significant change in the number of days' supply of opioids provided on discharge (median, IQR: 5, 3-9.75 vs 6, 4-10; $p = 0.107$). After adjusting for potential confounding factors, the multivariable negative binomial regression model still showed no significant association between guideline

implementation and the number of days' supply of opioids (adjusted incidence rate ratio, 95 percent CI: 1.1, 0.9-1.2). The provision of an analgesic discharge plan did not change significantly between the intervention groups (26 percent vs 22.2 percent; $p = 0.604$). The results of the multivariable logistic regression model showed no association between the guideline implementation and the proportion of patients receiving an analgesic discharge plan even after controlling for potential confounding factors (adjusted odds ratio, 95 percent CI: 0.6, 0.2-1.4). Of those who had discharge plans, the most common recommendation was to wean the opioid dose, with 73 percent of discharge plans in the pregroup and 56 percent of plans in the post-group containing these instructions. The other recommendation found was to cease the opioid analgesic after a specified number of days, with 7 percent of discharge plans in the pregroup and 9.9 percent in the post-group containing these instructions.

DISCUSSION

The results of this study show that there was no improvement in discharge opioid prescribing or the provision of analgesic discharge plans after the implementation of the discharge analgesia guideline. However, before the intervention, patients were already provided 5 days' supply of opioids, aligned with the guideline recommendations and hospital policy.²² As such, no improvements in opioid supply on discharge may have been considered necessary by clinicians. However, a large proportion

Table 3. Primary and secondary outcome data: Number of days' supply of opioids and analgesic discharge plan provided to patients on discharge

	Preintervention (N = 100)	Post-intervention (N = 81)	Adjusted incidence rate/ odds ratio (95 percent CI)*
Number of days' supply, [†] median (IQR)	5 (3-9.8)	6 (4-10)	1.1 (0.9-1.2)
Analgesic discharge plan provided, n (percent)	26 (26 percent)	18 (22.2 percent)	0.6 (0.2-1.4)
Recommendation to wean dose	19 (19 percent)	10 (12.3 percent)	N/A
Cease after a number of days	7 (7 percent)	8 (9.9 percent)	N/A

IQR: interquartile range; N/A: not applicable.

*Adjusted for age, length of stay, circulatory system diseases, respiratory system diseases, respiratory system procedures, cardiovascular system procedures, chronic pain, mental and behavioral disorders, opioid dependence or substance use disorder, opioids used prior to admission, pain on rest and nonsteroidal anti-inflammatory drugs supplied on discharge.

[†]Number of days' supply of opioids relative to the total MME consumed in the 24 hours prior to discharge.

of patients were still discharged without any written instructions on weaning or ceasing their opioid analgesic after the implementation of the discharge analgesia guideline.

This study found that opioid prescribing practices in the tertiary metropolitan hospital were already aligned with the guideline recommendations pre-intervention. The amount of opioids supplied on discharge before the implementation of the guidelines were lower than other studies before they implemented discharge analgesia guidelines.^{10,14} Like this study, studies by Peterman et al.¹⁰ and Linder et al.¹⁴ evaluated the effectiveness of guidelines on opioids supplied upon discharge in patients undergoing ventral hernia repair and surgery for pelvic organ prolapse, respectively. Both of these studies had a higher median total MME provided on discharge preintervention compared to our study (225 and 200 vs 150). This low MME in our study may have occurred due to other initiatives focused on improving opioid prescribing. For example, the Australian and New Zealand College of Anesthetists released a position statement on the use of extended-release opioids in the management of acute pain in March 2018, which may have led to other discussions on appropriate opioid prescribing on discharge.²⁵

The amount of opioids supplied post-intervention in this study was higher than previous studies after the implementation of prescribing guidelines.^{14,15} Studies by Sada et al.¹⁵ and Linder et al.¹⁴ evaluated the effectiveness of prescribing guidelines on patients who underwent surgery for endocrine conditions and pelvic organ prolapse, respectively. These studies had a lower median total MME post-intervention compared to our study (50 and 112.5 vs 150). This shows that further improvements can be made to lower the amount of opioids provided to patients on discharge. Providing specific recommendations based on patient use and procedure type has been shown to be effective in many of the studies mentioned previously.^{10,14,15} The Michigan Opioid Prescribing Engagement Network has developed opioid prescribing recommendations for specific procedure types based on published literature and expert opinion.²⁶ These recommendations could be applied to refine opioid prescribing guidelines and improve appropriate opioid prescribing on discharge.

The proportion of patients receiving an analgesic discharge plan was quite low both before (26 percent) and after (22 percent) guideline implementation. The proportion of patients instructed to cease

their opioid analgesic after a specified number of days was also low in both groups (7 percent and 9.9 percent). This highlights the need for further improvement in the number of patients provided with analgesic discharge plans following surgery. The current intervention involved implementation of a discharge analgesia guideline, along with education sessions about the guideline over a period of 3 months with no follow-up. A similar study conducted by Stanley et al. in an orthopedic specialty unit in a tertiary metropolitan hospital in Melbourne, Australia, found a significant increase in the proportion of patients receiving a weaning plan for their opioid analgesics after the intervention (6.9 percent to 87.4 percent).¹² Their intervention included implementation of a prescribing guideline, educational sessions, and an expert advisory group (EAG) to oversee opioid prescribing. The differences in outcomes between these two studies suggests that clinical champions such as the healthcare professionals in the EAG play a key component in attracting and engaging individuals in the intervention during the implementation process.²⁷ An integrative review of 199 articles found that clinical champions were one of the main factors contributing to implementation success in over 80 percent of the studies.²⁸ The success of the intervention in improving provision of an analgesic discharge plan in Stanley et al.'s study seems to have been driven by the formation of the EAG. This suggests that interventions aimed at improving provision of analgesic discharge plans are more likely to be successfully implemented when there are clinical champions advocating for and encouraging clinician involvement with the intervention.

There were several limitations to our study. We were unable to control for concurrent opioid educational interventions and initiatives, which may have been conducted during the study period. This may have had an impact on the potential magnitude of the effect resulting from the discharge analgesia guideline. There were also many baseline differences between the two intervention groups, which could have impacted the outcome and reduces the comparability of the groups. For example, due to the effect of the coronavirus disease 2019 pandemic and subsequent restrictions placed on elective surgery, patients who were considered higher risk were prioritized for surgical procedures during the post-intervention group. This may explain the significantly higher length of stay in this group. Furthermore, process measures to assess the adherence to the new

guidelines were not available, but may have highlighted the reason for poor uptake of the guidelines. This was also a single-center study, which limits the generalizability of our findings.

In conclusion, our study found no difference in the number of days' supply of opioids provided on discharge after the implementation of a discharge analgesia guideline, but we also found that prescribing practices already aligned with the guideline before its implementation. These guidelines had no impact on the provision of analgesic discharge plans. Results from previous studies have shown that guidelines may increase the proportion of patients receiving an analgesic plan on discharge when they are supported and overseen by clinical champions.

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APPENDIX A: DISCHARGE ANALGESIA GUIDELINES

- (1) Consider pain and analgesia use in the 24 hours prior to discharge and expected pain levels over the 3-5 days after discharge.
- (2) If analgesia is required, consider prescribing nonopioid analgesia such as paracetamol and nonsteroidal anti-inflammatory drugs (commencement of pregabalin and gabapentin were not recommended on discharge without specialist advice).
- (3) If the patient required any immediate-release opioids in the 24 hours prior to discharge, consider prescribing an immediate-release opioid such as oxycodone or tapentadol for short-term use (3-5 days' supply).
- (4) If the patient required extended-release opioids before discharge, consider ceasing the slow-release opioid before discharge or step down to a lower strength of slow-release opioid upon discharge.
- (5) Provide all patients with a written analgesic plan upon discharge, especially if discharged with opioid analgesics.

APPENDIX B: PATIENT INCLUSION FLOW DIAGRAM

