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Prescribing Protocol for Postoperative Opioids in an Orthopedic Spine Practice

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Ensuring effective post operative pain management for patients is a crucial aspect of surgical practices. Typically, this is achieved through the prescription of opioids. Providers need to strike the right balance to adequately address patients' pain while simultaneously taking measures to mitigate the risk of opioid misuse or addiction. Pharmacies fill 153 million opioid prescriptions in a year, according to the National Center for Drug Abuse Statistics (2023). More than 932,000 people have died since 1999 from drug overdoses (Centers for Disease Control and Prevention [CDC], 2022). This project was a change in opioid prescribing practices at a private orthopedic spine practice in California. A surgeon and a nurse practitioner work in this small practice, in addition to nine ancillary staff. The practice did not have a protocol in place defining the amount or length of time refills were provided. However, state and federal prescribing laws were followed. The purpose of this paper is to describe the identified problem, describe and analyze the data and evidence that supported the change project, and discuss the details of the project.

Problem Statement and Gap Analysis

Opioids are a necessary part of pain management for this practice, both as a measure to treat preexisting pain and as a method of managing post operative pain. It is well documented that opioid misuse is an epidemic in the United States, with variability in prescribing practices being a major contributor (CDC, 2022; California Department of Public Health [CDPH], 2022). Furthermore, studies have shown that patients with spine pathology needing surgical intervention are at high risk for opioid misuse or addiction, especially if they are opioid naïve (Orosz et al., 2022). This project site did not have a standardized prescribing protocol to prevent overprescribing opioids after surgery but did follow state and federal guidelines. The CDC

(2022) issued guidelines regarding prescribing opioids. Opioid prescribing best-practice guidelines must be addressed, implemented, and followed by prescribers for the safety of patients. The introduced prescribing protocol serves as the project site's strategic approach to enhance patient safety and well being.

Research indicated that overprescribing practices are correlated with an increase in opioid overdose cases. A gap analysis was conducted in the project site from June through November 2022, to identify if overprescribing was occurring. A chart audit from the practice identified that on average 38 surgeries were performed monthly, and 50% of these patients received two or more PO opioid prescription refills beyond the initial one prescribed on the day of surgery. In addition, 5% of patients received four or more refills following surgery. The gaps were analyzed using a fishbone diagram in order to gain a deeper understanding of the problem. Factors identified by the gap analysis included lack of staff education, provider overscheduling, the electronic health record, pharmacies, and the patients themselves. The financial impact to this project site came from patients having multiple appointments for refills post operatively that took away time from new higher coded incoming patient spots, along with potential treatments for addiction. According to the data collected from the project site, an evidence-based intervention was required to reduce the number of opioid prescriptions being refilled.

Background and Significance of the Problem

Spine surgery can be painful, and providers prescribe pain medications to patients post operative for at-home use. Because surgical advances have made more procedures outpatient instead of inpatient, providers have to be more aggressive in prescribing post operative opioids to ensure patient comfort (Arwi et al., 2022; Goyal et al., 2021). The project sites's data analysis revealed that prescription refills for opioid medications post-surgery surpassed the guidelines set

forth by the state of California (CDPH, 2022; Medical Board of California, 2022). The problem stems from the lack of a site policy that details for patients the dosage, length of pharmacologic therapy, and the number of refills that will be provided. The two outside facilities where surgery is performed need a more defined prescribing plan for patient education upon discharge. A gap was also identified that providers rely on staff to verify refills before sending over the request.

Background

The method of prescribing opioids for post operative pain control was established by the surgeon based on his medical education. He established prescribing criteria when the practice began but did not develop specific workflow. When patients were scheduled for spine surgery, they were provided an initial prescription for an opioid that allows the medication to be taken every six hours for the first two weeks. If the patient requested a refill of their pain medication at any point after that time, the medical assistant (MA) would take the message and leave a note on the provider's desk. Studies show that MAs taking shortcuts to check refills by not following policy can place patients at risk (Gold & Harmes, 2022; Mambrey et al., 2022). Research indicates that busy practices might take shortcuts and not follow the best workflows recommended for best practices in opioid prescribing and refilling (Quanbeck, 2021; Weller, 2021). The National Institute on Drug Abuse (2023) statistics show that patients who take prescription opioids for more than 30 days after initiation of medication therapy have a 47% chance of continuing for three years or longer. A policy change was indicated, given the background of the problem. The opioid epidemic in the United States represents one of the most pressing public health crises in recent history. The medical community had good intentions of managing pain, but the proliferation of prescription opioids has led to widespread misuse.

Significance of the Problem

The opioid crisis in the United States has reached epidemic levels over the last decade. The CDC (2022) estimated that drug overdose deaths increased by nearly 15% in 2021, with 107,622 deaths recorded. The National Center for Drug Abuse Statistics Report (2023) stated that over 96,700 people in the United States die each year from drug overdoses. Seven out of every 10 overdose deaths are caused by opioids. The CDC stated that, in 2020, on average, 44 people died daily from overdoses provided by prescriptions, totaling more than 16,000 deaths annually (2022). The staggering numbers serve as a clarion call for action and policy reform to address this crisis.

In the ongoing battle against the opioid crisis, it is crucial to understand the multifaceted factors that contribute to the misuse of these potent pain-relieving medications. Reasons that increase the risk for opioid misuse include patients being prescribed higher doses of opioids, being on other prescription drugs, including benzodiazepines and muscle relaxants, and long-term opioid use that often starts with acute pain (National Institute of Drug Abuse [NIDA], 2023). The ethical considerations for this project included the fine line between prescribing patients' opioids to control pain and the risk of multiple refills that can lead to addiction. Current recommendations include prescribing immediate-release opioids versus extended-release options and establishing opioid treatment goals that include risks, benefits, and therapy timelines (CDC, 2022). The project site did not track the number of opioid refills requested per patient and allowed patients to receive refills up to six months after surgery. The impact of not limiting opioid refills can increase the risk of misuse or addiction affecting both the patients and their families. The project site did not want to continue adding to the opioid epidemic in this country and embraced the necessary change.

Overarching Aim of the Project

The primary aim of this project was to implement a prescribing protocol to lower the number of opioid refills provided to post-surgical patients. One challenge is that orthopedic spine patients have experienced long-term chronic pain before surgery and report the highest pain scores post operative (Lovecchio et al., 2019; Orosz et al., 2022; Sanford et al., 2020). The project sites' desired result was to reduce the number of opioid refills provided to patients after surgery. Evidence-based guidelines were determined to be an appropriate intervention.

Review of the Evidence

Evidence-based guidelines are pivotal for driving change within a practice. A thorough review of the evidence was conducted to identify the most effective intervention to facilitate the required transformation in the practice. The purpose of this evidence-based project was to answer the compelling clinical question or PICO(t): In adults undergoing elective spine surgery, what is the effect of an evidence-based opioid prescribing protocol with a time-based weaning plan compared to current practice in an twelve-week time frame?

The opioid epidemic in the United States has been a growing problem for many years, with a significant part of the problem coming from overprescribed medications. In searching for evidence to support the proposed prescribing protocol, guidelines from the CDC (2022) and the CDPH (2022) for safer opioid prescribing were identified. The National Institute of Health has also issued statements identifying the need for evidence-based opioid prescribing using prescription databases to verify patients' medication usage (NIDA, 2023). The unchecked rise of the opioid epidemic in the United States fueled largely by overprescribing, calls for action. Trusted health organizations like the CDC, CDPH, and National Institute of Health emphasize the importance of evidence-based approaches in opioid prescribing.

Evidence to Support Project

An abundance of evidence exists to support an opioid prescribing protocol for this practice. According to evidence, prescribing opioids in the post-surgical setting with a specific process, rather than without a specific methodology, may be associated with a reduction in opioid use and/or refilled after surgery (Berardino et al., 2021; Bicket et al., 2022; Holte et al., 2019). The CDC's (2022) opioid prescribing guidelines for chronic pain include not using extended-release options, always starting with the lowest dosages, making Naloxone available, and providing proper education on taking opioids. Studies have shown that following a systemic approach can lead to decreased opioid consumption and the need for refills. The convergence of this evidence solidifies the call for adopting and adhering to such protocols in medical practices.

Guidelines recommend good prescribing practices, including an outlined protocol with defined parameters. There are also indications from guidelines that an opioid-weaning plan should be included in a prescribing protocol (Arwi et al., 2019; Joo et al., 2020; Lovecchio et al., 2019). It is evident that structured guidelines advocate for a comprehensive approach to opioid prescribing. Uhrbrand et al. (2019) recommended that opioids be tapered by 10-20% in the first two weeks of the post operative period, then tapering by an additional 5-10% every two weeks following. Recent literature has also shown that a prescribing protocol can allow shared decision-making between the provider and the patients leading to a better and safer patient experience (Incze, 2023). The implemented protocol for this practice included these evidence-based guidelines to help taper the post operative patients from opioids in an eight-week period and/or offer referral to a pain management physician or primary care provider past that point. The protocol was fashioned after the patient agreement created for the University of Michigan’s Pain

Management Toolkit (2023) that offers free adaptation of their protocol on their website. The project was designed taking into consideration the evidence presented.

Project Design

Every medical practice holds potential spaces for refinement, all aimed at bettering patient outcomes. Quality improvement (QI) acts as the structured route through which such transformative changes are realized. Whether undertaken by a lone individual or a collaborative team regardless of scale, the essence of a QI project is to instigate positive change. Recognizing a specific care deficiency, the project site embarked on a QI initiative to bridge this identified gap.

In any QI project, there needs to be a guide or process to evaluate the effectiveness of the change. The framework used for this project was the Institute for Healthcare Improvement (IHI) Model Plan-Do-Study-Act (PDSA) (Bradshaw & Vitale, 2021; Institute of Healthcare Improvement [IHI], 2022). Four PDSA cycles were conducted two weeks apart during the implementation of the prescribing protocol. After each cycle, the team met to review the data collected for improvement. Brainstorming sessions were held to analyze barriers to improvement, followed by the development processes to overcome the barriers to change and implemented the new processes.

The first PDSA cycle was evaluation of the implementation of the prescribing protocol to all surgical patients and occurred following two weeks of staff education and preparation in week three of the project. The surgical patients were provided with the prescribing protocol prior to surgery and signed the acknowledgment. The expectations for weaning were explained to the patients and altervative modalities for pain relief were offered.

In the initial PDSA cycle, an evaluation revealed a care gap for patients who were not native English speakers. To address this, the project was modified for the second PDSA cycle to enhance its effectiveness. The test of change (TOC) for this cycle involved offering the protocol either in English or translated to Spanish or Armenian, catering to the majority of the patient demographics. However, by the end of the second cycle, it became evident that even those patients who had the protocol discussed with them during the preoperative visit remained uncertain about its various facets on the day of surgery. This led to another round of adjustments in the project process, propelling it into the third PDSA cycle.

In the third PDSA cycle, the TOC centered on a joint review of the protocol between the provider and the patient on the day of surgery, aiming to reinforce understanding. Analysis of this cycle highlighted the persistent need for enhanced patient education, promting modifications for the fourth PDSA cycle. The TOC for this final cycle involved supplying patients with a handout detailing alternative pain control methods. This handout, distributed alongside the post operative discharge paperwork, equipped patients with various pain management strategies, encouraging them to explore these alternatives before resorting to opioids.

During the implementation phase, staff gathered three crucial data points. Firstly, they determined whether patients received the protocol. Secondly, they checked if patients were tapering their opioid use in accordance with the timeline recommended by the protocol. Lastly, they ascertained if patients had fully weaned off the medications by the eight-week post operative mark. This data collection was a collaborative effort, undertaken jointly by the providers and staff within the practice. Change can be challenging, but having a model for change makes the transition easier to navigate.

Effecting a change in policy or practice necessitates a structured approach to ensure that team leaders maintain organization and oversight, avoiding oversights in crucial details. Numerous change management models are available, designed for application in QI projects across a spectrum of scales, from local initiatives to large scale healthcare systems (Harrison et al., 2021). This particular project employed the OhioHealth Change Management Model, tapping into several of its provided tools. Possessing these ready to use resources eased some of the inherent pressures associated with project execution. These tools included the Key stakeholder Identification and Assessment, the Change Readiness Survey, and the Change Readiness Plan in both the planning and implementation phases of the project (Anderson, 2023). To gauge the staff's collective willingness and preparedness to embrace the forthcoming change, the Change Readiness Survey was administered during the planning phase. It was then re-administered midway through the project's roll-out to spot and address any unforeseen requriements or challenges. The biggest concern of all 11 staff members was how communication would be during all phases of the project. Concerns were first addressed in the initial change plan and then reinforced throughout all project planning and implementation phases. Regular staff meetings ensured that everyone's perspectives were considered, reinforcing project planning and implementation. This inclusive approach ensured that all team members felt heard and involved. Once a project has a design in place and resources to facilite the change, the implementation of the project begins.

Project Implementation

The project took place in a surgical practice, which, until that point, had no formal in-office policy to prevent opioid overprescribing for post operative pain management. A new protocol for prescribing opioids was intergrated into the practice, grounded in evidence-based

research from various peer-reviewed sources. The prescribing protocol included a designated weaning plan to help patients find alternative methods of pain control to help them reduce the amount of opioids taken following surgery. For the duration of the project, all surgical patients identified were considered for inclusion. However, patients under 18 years of age and those who underwent a return to surgery within 48 were excluded. This project did not require an institutional review board from either the practice site or Franklin University.

The providers explained the prescribing protocol to surgical patients at the preoperative appointment, obtained the acknowledgment signature, and the MAs scanned the forms into the electronic health record. On the day of surgery, the providers reminded the patients and their caregivers of the protocol and follow-up in the office at two, four, six-, and eight-week post operatively.

At the onset of each visit, the MAs provided patients with a survey focused on opioid consumption and the weaning timeline. Once filled out, the MA integrated this into the electronic health record and subsequently transferred the data to a designated spreadsheet crafted for this purpose. The protocol's adherence was cross-checked against the survey outcomes sourced from patients during their two-, four-, six-, and eight-week post-operative appointments. These surveys handed out by the MAs to every post-operative patient, inquired about their opioid intake, the count of remaining pills, and the deployment of any non-opioid pain relief strategies. To systemize and safeguard this data, an Excel spreadsheet was fashioned and fortified with security measures to deter any data manipulation. Once the surveys were completed, they were passed to a specific staff member responsible for populating the data collection spreadsheet. The team lead took charge of the continuous data gathering and subsequent analysis throughout the projects lifecycle. Futhermore, in line with protocol, providers introduced patients to non-opioid

pain managagment alternatives. By the time of the eight-week appointment, if a patient's situation necessitated prolonged opioid therapy, the provider ensured a referral to either pain management or back to the primary care provider.

Communication was essential for the successful implementation of the protocol, ensuring a smooth transition of the policy change. This project depended on the receptionist to inform patients about refills and schedules when they contacted the office. Medical assistants played a role by surveying patients during their post operative visits to assess opioid usage. Most crucially, the providers were responsible for clarifying the protocol's guidelines and setting expectations about opioid consumption post-surgery.

There were key stakeholders in the practice and in the outside health systems where surgery was performed. The entire staff of the practice had identified roles in the project with input from the hospital and outpatient surgical centers where the surgeries were performed. The recovery room staff reiterated the instructions for taking medications at home and stressed the importance of weaning upon patient discharge. Patient support systems at home after surgery helped to keep the patients on track with medications and weaning. Diversity was a large part of this project as the staff in the practice and health systems and the patients have individuals from various backgrounds, genders, sexes, and national origins. Patient preferences and chronic opioid use were considered for the type of initial medication prescribed. Alternative pain control modalities were be offered to patients by the providers in a printed document and sent home in discharge paperwork.

Outcomes and Data Analysis

In assessing the effectiveness of the intervention implemented for this project site, a rigorous data analysis was conducted to evaluate the outcomes. Throughout the project, the

medical assistants recorded the gathered data into the spreadsheet designed by the team lead for each patient visit. Leveraging both quantitative and qualitative methods, the subsequent analysis provides a comprehensive understanding of the results and the implecations for nursing practice. To assess the impact of the newly implemented prescribing protocol in this practice, a meticulous data analysis was undertaken. This analysis not only evaluated adherence to the protocol but also gauged the effectiveness in improving patient outcomes. The methods employed for data collection and analysis, and insights garnered from the evidence, allowed the results to serve as a cornerstone for refining the prescribing policy in this practice.

There were three measures were tracked during the change project, one process measure and two outcome measures. The first outcome measure was to reduce by the number of opioid refills prescribed by 75%. The success of the project was gauged by counting the total number of surgical patients who still needed opioid medication for pain management eight weeks after surgery compared to the number who still needed opioid therapy.

The process measure included in this project was to track if each surgical patient was educated on the prescribing protocol and signed acknowledgment prior to surgery. The desired outcome was to have 100% of all surgical patients sign the protocol prior to the surgery day. The total number of surgical patients who signed the protocol was divided by the total number of surgical patients and then multiplied by 100.

The second outcome measure involved monitoring whether patients who had not tapered off opioids by the eight-week mark were subsequently referred to either pain management or a primary care physician. The desired outcome was to have 100% of these patients referred for future medication prescribing to pain management or primary care physicians. This was

measured by the total number of patients who were not completely weaned divided by the total number of patients multiplied by 100.

Data for these measures were tracked from the beginning of project implementation through the final week. All the aggregate data was collected and analyzed by the team lead. Results of this analysis was the basis of recommendations for project sustainability going forward. This data underwent thorough analysis and represented visually through run and bar charts to pinpoint trends and anomalies. The insights derived from this analysis played a pivotal role in shaping recommendations for the enduring success of the project.

Results/Findings

Data was gathered from every surgical patient scheduled during the project's duration, spanning from May 22, 2023 to August 4, 2023. This included patients undergoing a wide range of spinal procedures, from outpatient surgeries to complex inpatient interventions.

A notable outlier that influenced the data was the project lead's temporary absence for two initial weeks of the project. This resulted in two patients not receiving the protocol or signing the acknowledgement. Data was collected from week one of project implementation from each surgical patient scheduled. The only identified outlying factor that changed any of the data was the project lead being out of town during two of the initial project weeks.

Documentation of protocol adherence by staff, providers, and patients resulted in 76 patients tracked during the project period. Adherence to the protocol occurred in 74 out of the 76 patients, resulting in a 97% compliance rate.The sole outlying factor that impacted this metric was the earlier mentioned absence of the team lead during the initial phase of implementation. The oversight with the two patients, who neither received the protocol nor signed the acknowledgment, led to results surpassing the established benchmark. This achievement

demonstrates the robustness of the protocol and its successful implementation within the practice, surpassing initial expectations despite the challenges faced during the project lead's absence.

The data revealed that patients who adhered to the protocol and the provided weaning plan experienced a substantial reduction in opioid consumption post surgery. This reduction in opioid use not only contributed to a decrease in potential opioid dependency but also led to fewer side effects and a quicker recovery period. Ninety seven percent of these patients were completely weaned off of opioid medications by eight weeks post operative, therefore reducing the number of refills significantly within the practice. The few that were not completely weaned off opioids at the eight-week mark were referred out to pain management.

When barriers to protocol compliance were identified, a systemic approach to correction was implemented. For instance, during the project lead's absence, it became evident that the primary provider and surgeon occasionally forgot to obtain patient signatures and review the protocol prior to surgery. This oversight led to the exclusion of two patients from the project's data pool, which accounted for the 97% compliance rate. The other tracked process measures showed a 100% compliance rate for referral at eight weeks when needed. Only two patients were still taking opioids at the eight-week visit, and both were referred to pain management for continuation of medication management. Two surgical patients were excluded from the project as they were return to surgery patients and did not meet inclusion requirements.

Preoperative opioid education played a pivotal role in patient acceptance of the protocol. Patients responded positively to the educational materials provided, which detailed the risks associated with opioids and alternative pain management strategies. Many of the patients reported feeling more informed and in control of their pain management. This informed

perpective empowered many patients, bolstering their confidence in managing pain and enhancing their commitment to the tapering plan.

An important observation gleaned from this project was that when patients received preoperative opioid education and had clear expectations set before surgery, they demonstrated a higher level of adherence to the weaning plan than initially anticipated. Before this project, patients were not adequately informed about the appropriate guidelines for using opioids and the procedure for obtaining refills.This lack of information sometimes resulted in patients requesting refills, even if they didn't necessarily need them, due to the ease of access.

All data that was verified and analyzed at project completion has shown better than predicted outcomes, indicating that the protocol significantly decreased the number of opioid refills provided to patients after surgery for this practice. The recommendation for this project would be that this protocol become a permanent part of practice policy and be utilized for every surgical patient in the future. The data clearly shows that there was a significant decrease in the number of opioid refills past the initial one provided on surgery day compared to the data collected in the planning phase gap analysis.

The entire office staff, including both providers, are excited about project outcomes. Everyone is fully committed to this change in policy and practice. Any barriers that arose were identified and corrected throughout the project implementation for better process flow. These changes have made the protocol seamless in preoperative education and preparation. The front office staff have also become aware of post operative time frames and have no issue telling patients who call in for refills that they are outside of the protocol parameters and referring them to the appropriate site for pain management. Additionally, staff members have been trained to

communicate the protocol parameters to patients effectively, resulting in seamless preoperative education and preparation.

The introduction of the prescribing protocol in this practice showed marked improvements in managing post-operative pain and curbing opioid refills for surgical patients. Supported by peer reviewed literature, this approach underscores the effectiveness of evidence-based opioid prescription after surgery. With the high compliance rate from the desired outcome measure and a tangible drop in opioid refills, this projects data serves as a compelling testament for the protocol's eduring integration into regular practice, offering patients a more informed approach to pain management post surgery.

Implementing this change requires little in terms of resources and additional costs, and the staff's evident preparedness only amplifies the seamless adoption into this orthopedic spine practice. This project's triumph can be attributed to a blend of in-depth patient education, consistent oversight, and the option of alternative pain management strategies. Moving forward, solidifying this protocol as a staple policy emerges as the next rational progression. By doing so, the practice not only minimizes opioid refills but also resonates with the ethos of effective quality improvement. Aligning with the Institute of Medicine's six crucial healthcare quality domains ensures that the care provided remains safe, efficient, timely, patient-focused, effective, and equitable (Agency for Healthcare Research and Quality, 2022). Looking forward to the future, integrating this protocol as a fixed policy becomes the discernible next step. This not only curtails the distribution of opioid refills but also aligns with the fundamental pillars of quality improvement.

Discussion

The implementation of the prescribing protocol into this practice yielded promising results in improving post operative pain management and reducing opioid refills among the surgery patients. The literature supports the use of an evidence-based prescribing protocol to reduce the amount of opioids patients take after surgery (Berardino et al., 2021; Peterman et al., 2020; Thuener et al., 2020). The data collected in this project provided compelling evidence for the need to permanently incorporate the prescribing protocol into everyday practice. With a 97% compliance rate and a significant reduction in opioid refills, it is clear that the patients will benefit from this evidence-based approach to post operative pain management.

The change in practice can be achieved with. Minimal resource utilization or additional costs. The staff has demonstrated their readiness to sustain the use of the protocol, further facilitating the integration of this policy change into this orthopedic spine practice. The combination of thorough education, regular monitoring, and the availability of alternative modalities for pain relief contributed to the projects success. The next logical step for this practice is to formalize the protocol as a permanent policy change. This will not only reduce the number of opioid refills provided to patients but will also align with the principles of a successful quality improvement change.

Summary

The opioid crisis underscores an urgent need for medical establishments to take decisive actions. Over prescribing has been identified as one of the critical factors feeding into the opioid epidemic. The project in this practice embarked on an evidence-driven approach targeting post-operative spine surgery patients, a group often vulnerable to prolonged opioid use. This project followed the six vital domains of healthcare quality of the Institute of Medicine. The six vital

domains include safe, effective, patient-centered, timely, efficient and equitable care (Agency for Healthcare Research and Quality, 2022). Each domain is crucial for ensuring that healthcare services meet the highest standards and prioritize the well-being of patients promoting a healthcare system that strives for excellence in every aspect of care delivery.

The project strategy was anchored in patient education. By illuminating the intricate balance of opioid therapy's advantages against its risks,coupled with a structured weaning plan, the practice sought to empower patients in their post operative recovery. The path ahead for this practice is clear with the well being of the patients the top priority. By tempering the reliance on opioids and accuentuating alternative pain modalities, this practice is safeguarding not just the individual patient but also contributing to a broader societal change. The successful reduction of opioid refills reflects more than just numbers for this project, it also symbolizes a proactive and conscious effort by the practice to combat a critical national issue. The projects success in this endeavor speaks volumes about its dedication to patient safety and its responsibility towards the broader community.

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