Examining Opioid Risk Mitigation Practices in a Rural Pain Management Clinic: A Quality Improvement Project

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The United States (US) has the highest usage of opioids globally, leading to significant opioid-related deaths and a public health crisis (National Institute on Drug Abuse [NIDA], 2022). According to the Centers for Disease Control and Prevention (CDC, 2021), 91,799 people in the U.S. died from opioid-related overdoses in 2020. Addictions to prescription opioids and overdoses have led to increased mortality rates that exceed HIV-related mortality and motor vehicle accidents (Rudd et al., 2016).

Opioid misuse, abuse, and addiction are concerning public health issues in Virginia. Drug addiction is on the rise in Virginia and causing an increase in multiple public health issues, including blood-borne infections (Hepatitis C) and overdoses (Virginia Department of Health [VDH], 2021). In Virginia, 1,193 drug overdose deaths involved opioids in 2018 (NIDA, 2020). Opioid-related emergency room visits and overdose deaths are rising locally. In 2020, Virginia had 1,478 overdose deaths, a 17% increase from 2019, and hospitals recorded 9,901 emergency room visits, a 33% increase from 2019 (VDH, 2021). Given the national and local opioid crisis, providers must understand opioid use disorder and related clinical guidelines and apply this knowledge to their specific area of practice to better ensure patient safety. Thus, this quality improvement project addressed the following question with providers in a rural pain management clinic: "Will implementation of the ORT-OUD as a screening tool in adult who meet inclusion criteria result in 80% of eligible patients being screened by the second iterative plan-do-study-act (PDSA) implementation cycle?"

Background

Several diagnostic and general terms are important to understanding the opioid crisis. "Opioid misuse" is the use of an illegal drug or using a prescription medication in a manner other than as directed by the prescriber (Agency for Healthcare Research & Quality, 2019; CDC, 2021). This may include taking a higher dose, more often, or longer than prescribed (Agency for Healthcare Research & Quality, 2019; CDC, 2021). Addiction is a disease that affects a person's brain and leads to the inability to control the use of a drug or medication. Symptoms can include intense urges for that drug or medication. The preferred term for addiction is substance use disorder (SUD) (CDC, 2021) and when referring to opioids, the preferred term is opioid use disorder (OUD). OUD is a specific type of SUD characterized by a problematic pattern of using opioids resulting in distress or significant impairment (CDC, 2021).

The national problem of opioid misuse is widespread and complex. Approximately 10.1 million people aged 12 years and older misused opioids in 2019, and 9.7 million misused prescription pain relievers (US Department of Health and Human Services, 2021). A summary article highlighted many identified risk factors for opioid misuse and OUD, including the inability to function, exaggeration of pain, poor social support, stress, trauma, and mood swings (Webster, 2018). The author also identified risk factors related to the healthcare system, including healthcare provider prescribing practices.

Unsafe opioid prescribing is a vital provider factor related to the SUD problem in the U.S. An explanatory longitudinal cohort study identified that a higher prescribed opioid dose was strongly associated with opioid-related death (Gomez et al., 2011). Moreover, a study of opioid treatment dosing guidance demonstrated significant declines in doses prescribed, suggesting that baseline dosing was higher than needed (Sullivan et al., 2016). Finally, variations in opioid-related death rates of different states indicate that state laws related to prescribing practices of healthcare providers are relevant to patient outcomes (Morbidity and Mortality Weekly Report, 2019). According to Volkow et al. (2019), efforts to address the opioid crisis must include prevention programs and focus on risk factors of opioid misuse and OUD, as well as inappropriate prescribing.

In a rural Virginia pain management clinic, no screening protocol for patients on chronic opioid therapy existed. Thus, given this national and local problem, this quality improvement project aimed to screen 80% of eligible patients. Prior to implementing the project and addressing the clinical question, a review of the literature was completed.

Opioid Clinical Guidelines

In 2016, the CDC issued 12 evidence-based guidelines covering such topics as when to initiate or continue opioids, best practices for prescribing specifics, treatment goals relative to risks, and discussing opioid-related risks with patients (Dowell et al., 2016). The CDC also recommended that prescribers who manage chronic opioid therapy screen patients for misuse, abuse, and risk for opioid-related harm. However, when the CDC issued the guidelines in 2016, insufficient evidence existed to determine whether screening tools effectively reduced harm. Thus, the guidelines did not recommend specific tools or implementation strategies, such as screening frequency. Moreover, the guidelines are less helpful for some practice settings, such as pain management clinics. For instance, the guidelines have been less practical for providers managing complex and often long-standing patient pain, as described in the next section.

The CDC developed their 2016 guidelines for primary care providers, and pain management specialist providers considered them controversial. These guidelines were not intended for pain management providers treating chronic pain patients already managed with chronic opioids, as these patients often benefit from the high doses, as evidenced by improved quality of life and pain control (Downes et al., 2018). For example, higher morphine milligram equivalents (MME) are correlated to increased opioid-related risks, including respiratory depression. For this reason, the 2016 CDC guidelines recommended limiting prescribed doses to 50 MME, with a maximum of 90 MME per day for most patients and no limits per dose. However, it is sometimes challenging to achieve these limits when managing individuals with chronic pain, as these patients have often failed conservative treatments or interventional injections and may not have been eligible for or responded to surgery (Downes et al., 2018). Moreover, these patients may require higher opioid doses to maintain function and quality of life, making the CDC's MME recommendations infeasible for this population (Downes et al., 2018). Given the specific needs of the pain management patient group in terms of higher doses and lack of other treatment options, it is vital to monitor this population for opioid risk as part of their treatment plan.

Opioid Risk Screening in Pain Management

Evidence to support risk screening in pain management is relatively new. A 2017

systematic review found a lack of high-quality evidence to guide pain management clinics to treat patients with chronic pain and opioid misuse, and the authors specifically cautioned about inconsistencies with screening tools (Voon et al., 2017). Since 2017, there has been growing support and evidence available to guide opioid risk screening in pain management clinics and more generally. For instance, Cheatle et al. (2018) conducted a prospective study examining the process of screening patients before prescribing opioids for chronic pain. The researchers found that aberrant behavior is low in pre-screened patients with no history of a SUD, minimal psych history, and good social support. In a community study, Strand et al. (2019) created a community pharmacy toolkit to prevent opioid misuse, including the opioid risk tool (ORT). The pharmacists who implemented the toolkit valued having an objective measure of potential misuse and reported improved patient conversations (Strand et al., 2019). Thus, within the last five years, evidence has grown to support screening.

Specifically, there is evidence for using the ORT and a revised version of the ORT, the ORT-OUD. A longitudinal study of four screening questionnaires concluded that providers should use the ORT to screen patients before beginning opioids (Vargas-Schaffer & Cogan, 2018). Cheatle et al. (2019) further studied the ORT and tested a revised version that removed the question regarding pre-adolescent sexual abuse for patients with chronic nonmalignant pain (CNMP) on long-term opioid therapy. The same authors examined a 10-item weighted scale including the pre-adolescent sexual abuse question, a nine-item ORT without the pre-adolescent sexual abuse question, and a 9-item unweighted scale with yes or no responses. Their analysis showed that the patient's age, personal and family history of substance abuse, and psychological disease determined the risk level without including the pre-adolescent sexual abuse question (Cheatle et al., 2019). The authors found that the ORT could discriminate between patients with and without OUD ($OR = 1.624$) and that removing the item about sexual abuse produced similar results ($OR = 1.648$). Cheatle et al. (2019) reported Cronbach's alpha (CA) of .72 and .73 in two respective samples. When they tested an unweighted version of the ORT without the question about sexual abuse, it produced stronger results ($OR = 3.085$, 95% CI [2.725, 3.493], $p < .001$) than the original ORT and the weighted ORT without the question about sexual abuse. Since removing the item about sexual abuse simplified the process and produced similar results, the researchers considered the ORT-OUD a superior tool (Cheatle et al., 2019). Given the complexities of the pain management patient population and growing evidence to support screening for opioid misuse risk, it is reasonable for pain management clinics to initiate screenings using the ORT-OUD. Screenings will give providers additional knowledge to make clinical decisions and establish a baseline for future patient assessments.

A theoretical and implementation framework further supported this project. Lewin's (1974) unfreeze-change-refreeze change management model guided this project. Unfreezing prepares an organization for change, the change occurs, and once people are ready to embrace the change, refreezing occurs (Lewin, 1947). The Institute for Healthcare Improvement's (2022) model for improvement and Plan-Do-Study-Act (PDSA) approach provided the implementation framework for this two-cycle project (IHI, 2022).

The primary objective of this quality improvement project was to implement an evidence-based risk screening tool in patients receiving long-term oral opioid therapy in a rural pain management clinic to improve the

identification of patients at high risk for opioid misuse and abuse. Each PDSA cycle lasted three weeks with the primary aim of describing the risk level of screened patients and the secondary aim of quantifying the number/percent of patients who met eligibility criteria. PDSA Cycle 1 specifically aimed to identify barriers and levers to implementation of the ORT-OUD. The goal was to screen 80% of eligible patients for opioid risk in Cycle 2. The following methods supported achieving the aims.

Methods

This project took place in a local, rural interventional pain management clinic staffed by five providers: one medical doctor (MD), one doctor of osteopathic medicine (DO), two physician assistants (PA), and one nurse practitioner (NP). Two to four providers see patients in the clinic daily and providers rotate to complete procedures and to other offices in the health system. The practice sees an average of 1,000 patients monthly; 260 of these patients are treated in the procedural suite.

Intervention

This project was a quality improvement project with a primarily quantitative design augmented by narrative feedback about implementation. The Institutional Review Board at James Madison University and the participating institution approved the project before the interdisciplinary team implemented an addiction risk screening tool.

ORT-OUD Description

The implemented screening tool was the ORT-OUD, a brief questionnaire easily self-administered by the patient within one to two minutes and used with permission from the developers. The ORT-OUD is a nine-item instrument that asks yes or no questions about family history of substance abuse (alcohol, illegal drugs, and prescription drugs), personal history of substance use (alcohol, illegal drugs, and prescription drugs), age (16 to 45 years), and history of psychological diseases (attention deficit disorder, obsessive-compulsive disorder, bipolar, schizophrenia, and depression) (Cheatle et al., 2019). Patients can score from 0-9, and their total scores are summed, with a score of ≤ 2 indicating low risk and ≥ 3 indicating high risk (Cheatle et al., 2019). Psychometric testing of the ORT-OUD is robust with a sensitivity of .854, a specificity of .851 (both high), and strong negative and positive predictive values, .914 and .757, respectively (Cheatle et al., 2019). The ORT-OUD was implemented over two PDSA cycles lasting three weeks each.

PDSA Cycle 1

Procedures (Cycle 1). During PDSA Cycle 1, the interdisciplinary team implemented the ORT-OUD with one provider whose patients met the inclusion criteria. The inclusion criteria consisted of adult patients (age 18 and older) who presented with CNMP and received chronic opioid therapy ($\geq$6 months) during the study period. The primary investigator (PI) reviewed the participating provider's schedule daily with the nurses and front desk staff to identify eligible patients. The front desk staff and all nurses were given a list of eligible patients. The registration clerical staff gave an ORT-OUD paper form to each patient that met the criteria at check-in. No patient identifiers were used on the form.

The nurse rooming the patient collected the form, verified it was complete, and gave it to the provider for review. Similar to other intake paperwork, if the form was incomplete, the nurse asked the questions and completed the form, noting this on the document. After the visit, the nurse placed the form into a securely locked box at the nurses' work area and the PI collected the forms daily. The PI kept records of the

provider's total number of patients seen that day, the number of eligible patients seen, and the number of completed ORT-OUD forms at the end of each day. The PI collected and noted feedback from staff, the implementing provider, and the participating patients during and at the end of the first three weeks. The first PDSA cycle ended with an email to all providers, nursing staff, and clerical staff describing the results of Cycle 1. During this phase, the team noted early successes and approved the process, which increased the likelihood that the unfreezing of prior behavior occurred, a necessary step for change according to the theory (Lewin, 1947).

PDSA Cycle 1 Sample. All patients scheduled to see the participating provider and who met the inclusion criteria (Table 1) received the ORT-OUD form for completion. One of the aims of PDSA Cycle 1 was to determine the number of eligible patients. This information allowed for better planning for Cycle 2.

Table 1

Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Adults aged 18 and older	Not prescribed oral opioids
Long-term (≥6 months) oral opioid therapy	Pain related to cancer
Chronic non-cancer pain	Short-term (<6 months) opioid therapy

PDSA Cycle 2

Procedures. During PDSA Cycle 2, the PI and the interdisciplinary team implemented the ORT-OUD with four providers whose patients met the same inclusion criteria used in Cycle 1. The four providers included in this study (1 MD, 1 DO, and 2 PAs) treat chronic pain and prescribe oral opioids. The NP in the group was the PI. Patients seen by the NP were excluded to minimize bias. All patients seen by the four providers who met inclusion criteria were given the ORT-OUD for completion. The ORT-OUD was implemented in the same manner as PDSA Cycle 1. The only procedural change was that a number indicating the provider seen was added to each completed ORT-OUD form. Implementation dates were adjusted to accommodate days the clinic was closed for holidays. Related to the theory of change, the final phase is refreezing, when the goal is to sustain the change, becoming a new habit (Lewin, 1947). At the end of PDSA Cycle 2, the PI shared the results and presented recommended plans to maintain the change.

Analysis

The PI analyzed data at the end of Cycles 1 and 2. The PI entered data collected from the ORT-OUD forms and implementation data into a spreadsheet and calculated the total number of patients seen, number and percent of eligible, and screened patients. The risk level was calculated for

each screened patient, and then rates and percentages were calculated to describe the risk level of the screened group. The PI made these calculations for each cycle and for the project total. De-identified qualitative data were analyzed using qualitative descriptive methods.

Results

During the project implementation period, the four participating providers saw 544 patients. In PDSA Cycle 1, the participating provider saw a total of 118 patients, and the four participating providers in Cycle 2 saw 426 patients. Of the 544 total patients, 78 (14% of the total) met the inclusion criteria (18 years of age or older, ≥6 months oral opioid therapy, and chronic non-cancer pain diagnosis). All 78 patients who met the inclusion criteria (100% of eligible) completed the ORT-OUD screening. The nurse completed two ORT-OUD forms during telehealth visits where there is no protocol for completing intake paperwork individually. One ORT-OUD form was completed verbally during the office visit with a patient that did not complete it as part of the intake paperwork. If this person is excluded from the screening rates, the completion rate is 99% of eligible patients. Therefore, the project met the goal of screening greater than 80% of eligible patients by Cycle 2.

ORT-OUD Responses by Item and Reliability

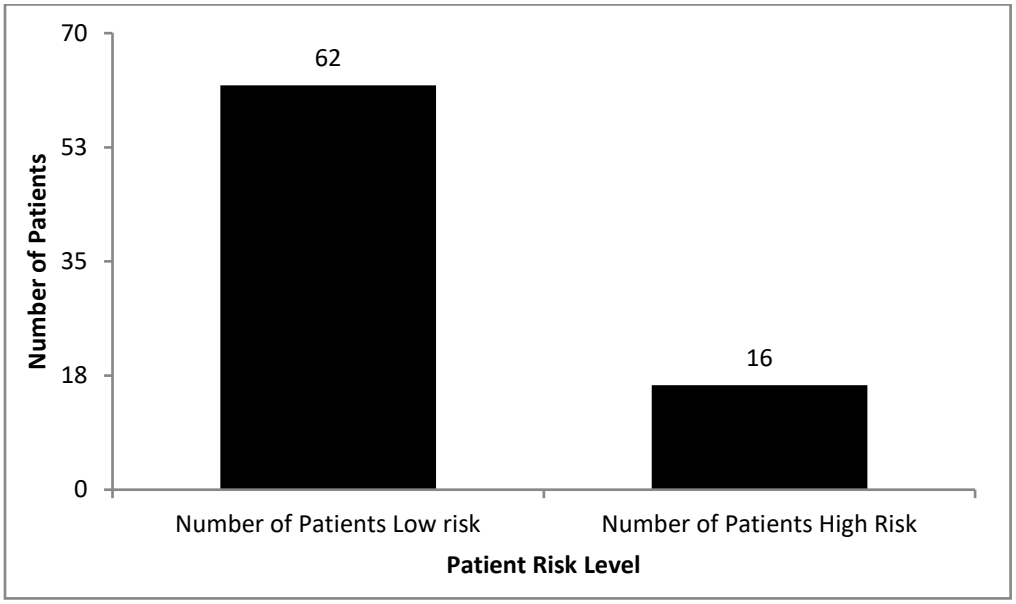
A total of 78 patients completed the ORT-OUD. Of those, 26 (33%) had a family history of alcohol abuse, nine (12%) had a personal history of alcohol abuse, 10 (13%) had a family history of illegal drug use, four (5%) had a personal history of illegal drug use, 12 (15%) had a family history of prescription drug abuse, and four (5%) had a personal history of prescription drug abuse. Of the 78 patients screened, six (8%) fell into the high risk age range of 16-45, 16 (21%) had a history of psychological disorders other than depression (attention deficit disorder, obsessive-compulsive disorder, bipolar, and schizophrenia), and 36 (46%) had a history of depression. In the current study, our CA was 0.65. CA for this sample would be slightly higher (0.66) with the item regarding age removed.

Number of Patients Screened by Risk Level

Of the 78 patients that were screened during the project, 16 (21%) were high risk and 62 (79%) were low risk (see Figure 1)

Figure 1

Number of Patients by High- and Low-Risk Designation



Implementing the intervention with one provider in Cycle 1 resulted in five patients over three weeks being identified as high risk. Implementing the intervention with four providers in Cycle 2 resulted in 11 patients being identified as high risk. The screening identified a total of 16 patients (21% of screened patients, 3% of total) as high risk throughout the 6-week intervention. Table 2 provides a week-by-week breakout of the high-risk patients identified through screening.

Table 2

Number of Screened Patients Identified High Risk by Week

Screening Period	Number (% of screened that week) of Patients Identified as High Risk
Week 1 Cycle 1	1 (33)
Week 2 Cycle 1	3 (43)
Week 3 Cycle 1	1 (33)
Week 4 Cycle 2	3 (27)

Week 5 Cycle 2	2 (12)
Week 6 Cycle 2	6 (16)
Total (% of total)	16 (21)

Barriers and Levers

The interview data revealed two barriers related to implementing the ORT-OUD screening form. First, one day during PDSA Cycle 2, a float nurse worked in the clinic. That day, the nurse did not give five ORT-OUD screening forms to the provider for review but instead gave them directly to the PI. Second, one provider was less interested in reviewing the ORT-OUD screening forms.

A lever of this project was that the providers and staff were overwhelmingly supportive of the implementation during the project. Three providers stated they were especially interested in using the ORT-OUD results to inform their practice. The providers also noted that the ORT-OUD was helpful because it establishes a baseline that can be used to evaluate changes in patient status over time.

The project raised several implications for future implementation. During the interviews, the PI and providers discussed frequency of screening. Providers and staff reported they supported implementing the ORT-OUD screening form at least annually in patients receiving chronic opioid therapy. Providers also noted that they needed to take time to calculate their patients' risk level by looking at the individual responses. While the calculation was simple, a future improvement would be to have the risk score calculated for the provider.

Discussion

This quality improvement project builds on prior evidence that suggests it is feasible to implement ORT-OUD screening in a pain management clinic (Downes, et al., 2018; Vargas-Schaffer & Cogan, 2018). Other studies about chronic opioid therapy focused on assessing risks only at the initiation of opioid use (Dowell et al., 2016). The response rate in this study exceeded the benchmark of 80%, which suggests that patients in this sample were willing and able to complete such screening. Exploring staff and provider attitudes further supported that this evidence-based opioid risk screening tool is implementable with patients receiving chronic oral opioid therapy. Almost one-quarter (21%) scored in the high-risk range. This information would have been unknown to providers before this project. These findings suggest that ORT-OUD screening gives providers additional clinical knowledge for care. Implementing the ORT-OUD in pain management clinics is therefore recommended.

Regarding the paper format of the ORT-OUD used in this study, staff and providers identified a few barriers to implementing the ORT-OUD in paper format. Whether a digital format would be more straightforward or challenging to implement is unknown. One potential benefit of the digital format would be that the risk score would be calculated automatically and recorded as part of the medical record for comparison. Moreover, digital screening may also address the issue of float staff not knowing and following the exact process.

Providers identified screening frequency as an important consideration. Evaluation at one point in time is a limitation as noted in the Cheatle et al. (2019) study, as there may be events that occur after the one-time evaluation that could contribute to OUD at a later time. Cheatle et al. (2019) suggested that screening could also potentially take place during the initial visit and when opioid medication changes are initiated. Additional research is needed to understand the ideal frequency of screening and how the specific modalities affect risk screening. Given the benefits of identifying previously unknown high-risk patients, an additional PDSA cycle in the study clinic should implement the screening tool in the electronic health record (EHR).

Limitations

This project was conducted in a small, local pain management practice. Implementation was studied over six weeks using paper screening, limiting the potential applicability of these specific findings in other settings. The clinic plans to sustain and expand the screening, which will likely include implementation in the EHR. This project gathered no information, beyond informal feedback, about whether the pain management providers used the information gained through the ORT-OUD screening. Although the ORT-OUD identified similar rates of high-risk patients in this project as seen in previous research, it is impossible to assess whether this project's screening potentially missed some high-risk patients or if patients responded accurately to the questions. More research is needed to determine if providers use this screening information in practice decisions and how those changes ultimately affect patient outcomes.

CA is a measure of internal reliability and estimates reliability of responses to questionnaires. The ORT-OUD CA for this sample was .65, which is lower than previous samples and lower than the benchmark of .70 for a "good" CA (Lavrakas, 2008). However, it may be less relevant whether the ORT-OUD measures a consistent construct than whether each item individually measures a known risk factor and the total provides a clinically relevant understanding of those risk factors. Further, the ORT-OUD screening form asks dichotomous yes or no responses. The use of CA is convenient but is limited in testing the reliability of tools with dichotomous values (Napolitano et al., 2013).

The CA brings up an interesting point about age in our sample. The lower CA in this sample may be because of an age difference between the project sample and prior ones, although removing the question about age would only minimally elevate the CA in this sample. Although this study did not assess the participants' specific age, 92% of participants in this sample were over 45. Our sample was likely older than others who validated the ORT-OUD as a screening tool and reported a mean age of 40 (SD 10.92) for those who screened positive, and a mean age of 54 (SD 12.65) for those who screened negative (Cheatle et al., 2019). Yet, a clinically important number and percent of patients screened positive in our sample, suggesting that the ORT-OUD tool is clinically relevant. It is possible that the demographics of addiction risk are changing or that risk factors by age are different for those being treated with opioids for CNMP. This could be explored in future research. Despite these limitations, the project accomplished the stated aims and identified important implications for practice based on the clinical significance of the results.

Implications for Practice

This project supports the use of the ORT-OUD as a screening instrument in the pain management setting, as the ORT-OUD successfully identified a clinically significant

number of high-risk patients in this setting. Specifically, opioid risk screening should be part of care for patients receiving chronic opioid therapy for CNMP. Those who wish to implement the ORT-OUD in clinical practice should plan for and iteratively evaluate screening frequency. Lewin's theory of change is a helpful theory for guiding the implementation of the ORT-OUD in this setting.

Conclusion

Opioid risk screening as part of a comprehensive evaluation to identify patients at high risk for opioid misuse and abuse is an evidence-based practice for several populations, including those treated for chronic pain (Vargas-Schaffer & Cogan, 2018). The lack of opioid risk screening is a problem in many practices, including pain management (Downes et al., 2018). Given this problem, this project aimed to implement an evidence-based opioid risk screening tool, the ORT-OUD (Cheatle et al., 2019), in a rural pain management practice. The project completed two PDSA cycles implementing the ORT-OUD screening tool with eligible patients, identifying high-risk patients who would have otherwise not been identified.

Implementing an opioid risk screening tool in patients receiving chronic oral opioid therapy can identify high-risk patients, potentially improving outcomes. These findings can guide future practice in the pain management clinic where the project took place. The results may also change care in the complicated health system and serve as an example to other clinics looking to implement the evidence-based ORT-OUD in their practice.

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