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**Using Audit and Feedback to Improve Compliance to Medication-Assisted
Treatment Recommendations for Substance Use Disorder**

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Abstract

Background: In 2019, of the 111 opioid deaths reported in the State of Vermont, 30 were found to be prescription opioid-related and accidental. Medication Assisted Therapy (MAT) programs are used to treat patients with substance use disorders, promoting recovery and preventing overdose. Vermont uses the “Hub and Spoke” model to increase the availability of MAT for patients with OUD by increasing the number of primary care providers who prescribe buprenorphine. Hubs are the specialty opioid treatment programs while spokes are the office-based community settings where a patient receives ongoing follow up integrated into general medical care. Evidence-based documentation guidelines and clinical quality measures exist to improve the quality of care for these patients. Adherence to documentation guidelines at one office-based spoke practice setting was unknown. **Purpose:** This project sought to evaluate compliance to evidence-based documentation recommendations for patients being treated with MAT through evaluation of provider documentation. **Methods:** A documentation evaluation tool was created using the recommended American Academy of Addiction Psychiatry clinical quality measures and evidence-based practice recommendations. A retrospective review of electronic health record documentation was conducted to assess the presence or absence of 16 recommended quality measures within the provider clinical visit note. **Results:** Overall documentation was compliant with evidence-based documentation recommendations in the majority of documentation elements. A draft clinical progress note template with recommendations for improvement was created. **Conclusion:** Participation in audit and feedback of clinical records by providers may improve consistency of documentation and provide better outcomes for patients with substance use disorder.

Introduction

According to the Vermont Department of Health, opioid deaths slightly decreased from 130 in 2018 to 111 in 2019 (Vermont Department of Health, n.d.). Of these 111 deaths, 30 deaths were deemed to be prescription opioid related and accidental (Vermont Department of Health, n.d.). Valid prescribing/screening tools and evidence-based treatment guidelines are available to guide providers in lowering prescription-opioid-related sequelae and eliminating accidental deaths (American Academy of Addiction Psychiatry & Providers Clinical Support Systems, n.d.; American Society of Addiction Medicine, 2020; Centers for Disease Control and Prevention, 2020; Dowell et al., 2016; Vermont Department of Health, n.d.). Medication Assisted Therapy (MAT) programs are available to diagnose and treat patients with substance use disorders, promoting recovery and preventing overdose.

Vermont currently uses the “Hub and Spoke” model to increase the availability of MAT programs available to patients with opiate use disorder (OUD) by increasing the number of primary care providers who prescribe buprenorphine (State of Vermont, 2022; Tanzman & Nalley, 2020). Hubs are the specialty opioid treatment programs while spokes are the office-based setting where a patient is seen monthly or weekly for follow up. This system allows patients who require intensive treatment to begin their treatment in a hub facility which offer daily medication administration and support at the beginning of treatment. There are currently nine hubs in Vermont for this model of treatment (Tanzman & Nalley, 2020). For patients seeking ongoing treatment integrated into general medical care, the “spokes” provide ongoing treatment options in a primary care setting (State of Vermont, 2022). This approach provides ongoing treatment for the patient but requires specialized training for the primary care provider (SAMSHA, 2022; Tanzman & Nalley, 2020). Federal statutes, regulations and clinical practice

govern MAT for opioid addiction (SAMHSA, 2022). These guidelines require specialized training before prescribing of pharmacological agents to assist with the treatment of opioid use disorder as part of a comprehensive treatment plan (SAMHSA, 2022).

Medications such as methadone (Dolophine) and buprenorphine (Buprinex) are used for treatment of OUD. Prescribing these medications require waivers and training for providers to prescribe these medications in an office setting (SAMHSA, 2022). Methadone must be administered daily in an opioid treatment facility, while buprenorphine may be prescribed on a weekly or monthly basis for at-home use (SAMHSA, 2022). Methadone is considered to be a full agonist as it completely occupies the mu-opioid receptor and decreases the painful symptoms of opioid withdrawal. Methadone also simultaneously blocks the effect of other opioid drugs in the system (SAMHSA, 2022). Methadone lasts 24–36 hours so that patients will not experience the highs and lows that are common with heroin use. A 12-month treatment course is considered the minimum duration for methadone maintenance (SAMHSA, 2022). Buprenorphine is a partial agonist and does not completely occupy the mu-receptor, and it is commonly combined with naloxone (Narcan) to form the drug Suboxone. The optimal duration of treatment is patient-specific, and decreasing the dosage involves a taper that spans several months (SAMHSA, 2022). Patients attempting to stop using opioids are at an increased risk for overdose and relapse as the body has lowered tolerance levels to opioid; so, treatment and care must be monitored on an ongoing basis (Schuckit, 2016).

Available Knowledge

The Centers for Disease Control and Prevention (CDC) reported that opioids were involved in 46,000 deaths in the United States in 2018 (Centers for Disease Control and Prevention, 2020). Synthetic opioids, excluding methadone, were responsible for 31,335 of the reported deaths

(Centers for Disease Control and Prevention, 2020). The CDC report endorses increasing the provision of MAT and expanding the distribution of naloxone for overdose reversal (Centers for Disease Control and Prevention, 2020).

The use of primary care offices as spokes in a treatment program increases access to care for those seeking treatment. To ease the increasing public health crisis that the opioid epidemic has evolved into, primary care providers evaluate and treat patients for ongoing care that were previously seen at specialty clinics. The need for specialty care created a backlog of patients who sought treatment but were unable to begin without the oversight by an addiction specialty trained provider. Using the guidelines set forth by the CDC, primary care providers have begun treating OUD in the primary setting rather than in specialty addiction clinics (Dowell et al., 2016). In addition, recent legislation, The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act extends the privilege of prescribing buprenorphine to qualifying practitioners such as nurse practitioners (Congress, 2018).

To prescribe, administer, and dispense buprenorphine to treat opiate use disorder, nurse practitioner providers are required to complete X-waiver training (U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration [SAMHSA], 2022). MAT providers who obtain an X-waiver complete required training and education in regard to best practice standards and the use of evidence-based evaluation and treatment recommendations to guide practice.

Despite the development of best practice guidelines, some providers still fail to meet the recommended documentation guidelines (Khalid, et al., 2015). Improving adherence to these guidelines has proven successful in providing better outcomes for patients (Lasser, et al., 2016;

Liebschutz et al., 2017). Using tools and guideline adherence mechanisms increases provider accuracy and decreases patient dosages of opioids (Liebschutz et al., 2017). Huang et al. (2019) implemented a five-pronged intervention including 1) creating a patient registry, 2) standardization of chronic opioid prescribing policies, 3) development of a risk assessment algorithm, 4) team-based case management, and 5) an electronic health record dashboard. This five-pronged approach increased the number of appropriate primary care visits and increased the number of patients on opioid contracts for chronic pain.

Implementation of a quality dashboard to track metrics and monitor quality improvement provides access to real time information and increases the use of opioid treatment agreements, urine drug tests, pain and functional assessment questionnaires, and behavioral health visits (Anderson et al., 2015). Office visits should include informing the patient of risks and harms of opioid use to ensure that the patient understand the risks/benefits of treatment with opioids (Dowell et al., 2016). To aid primary care providers in improving the quality of care for patients with substance use disorder, Providers Clinical Support Systems recommends providers participate in performance in practice review activities based on American Academy of Addiction Psychiatry recommendations to identify areas for improvement (AAAP/Providers Clinical Support Systems, 2019). These activities assess practice according to performance measures. Additionally, X-waiver training includes a guide to assist a primary care practice in reviewing its processes for best practices in caring for patients in medically assisted treatment therapy.

Evidence-based documentation guidelines and clinical quality measures exist to improve the quality of care for these patients. Adherence to documentation guidelines at one office-based primary care spoke practice was unknown.

Project Aims

Global aim: This project sought to evaluate compliance to evidence-based documentation recommendations for patients being treated with MAT through evaluation of provider documentation.

Secondary AIM 1: Create a MAT/ODD clinical documentation evaluation tool based on best practice recommendations by October 2021.

Secondary AIM 2: Audit electronic health records for compliance with best practice recommendations for clinical documentation and provide audit feedback to X-waivered providers by February 2022.

Secondary AIM 3: Develop and disseminate recommended changes to current dot phrase for clinical documentation of best practices by April 2022.

Project Site

The project site is a nurse-practitioner led primary care clinic in New England. This clinic is affiliated with a state university and employs 8 nurse practitioners and one physician. There are currently two nurse practitioners at the site who are X-waivered with an active panel of 12 MAT patients. This spoke clinic participates in the hub and spoke program for opioid treatment. The site provides the community with primary care expertise on diabetes, chronic obstructive pulmonary disease (COPD), asthma, hypertension, behavioral health, hyperlipidemia, health promotion and disease prevention, geriatric issues, palliative care, and management of health-related transitions in all phases of life. The clinic is designated as a patient-centered medical home (PCMH) by the Agency for Research and Quality and focuses on comprehensive care for the whole patient. As a PCMH, the practice has a commitment to continuous quality

improvement and a patient centered approach to care. Providers at the clinic engage in performance measurement and outcome improvement activities to improve patient experience.

Methods

A MAT OUD documentation evaluation tool was developed by the project manager based on recommendations from the American Academy of Addiction Psychiatry /Providers Clinical Support System Performance Improvement Activity and current best practice guidelines (AAAP & PCCS, 2019; ASAM, 2020; Liebshcutz et al., 2017; Tanzman & Nalley, 2020) (see Appendix A). The project team, who consisted of 2 X-waivered NPs and a faculty advisor reviewed and approved use the audit tool. Patient records were de-identified, and collected de-identified chart data was stored on a password protected laptop at the clinic. Patient identifiers were not collected, and records were assigned a chart number at the time reviewed. The tool was pilot tested by the project manager through review of one de-identified patient record in summer 2021 to ascertain ease of use and time required to complete one chart audit. Each chart audit took approximately 45 minutes. The sample ($n=12$) included the electronic health record visit note of all established active patients who attended an acute visit for MAT medication management/OUD/opioid dependence in October, 2021. A retrospective review of 100% of the 12 MAT/OUD patient records occurred using the MAT/OUD documentation evaluation tool to record responses. Provider clinical progress notes and the patient dashboard in the electronic health record for the month were reviewed and each record required approximately 45 minutes to review. Raw data findings were recorded on an excel spreadsheet (see Appendix B). Note: Document is defined as providing reasonable evidence in the chart.

Data Analysis

Each clinical record represented one progress note and data for one patient for a monthly clinic visit. Data were reviewed to ascertain whether a metric was present or absent. Mean difference score values of attainment for documentation metric in the clinical note vs. missing documentation was computed. Sixteen discrete measurements were analyzed to understand the overall current state of documentation for patient visits in relation to achievement of recommended clinical quality measures (see Figure 1 and Figure 2). In addition, the electronic health record was reviewed for the presence of an annual wellness exam in the past 12 months.

Overall documentation was compliant with evidence-based documentation recommendations in the majority of documentation elements for patient evaluation and treatment. Six elements of documentation with room for improvement were identified including the completion of an annual wellness exam, HIV testing in the past year and status and Hepatitis C testing in the past year and status, assessment of readiness to change, pregnancy testing for women of childbearing age, and naloxone rescue kit being offered. Based on these findings, the current provider note template was revised to recommend inclusion of the missing elements and incorporate evidence-based recommendations for MAT prescribing documentation. (See Appendix C). This document was shared with the clinic providers for review and feedback.

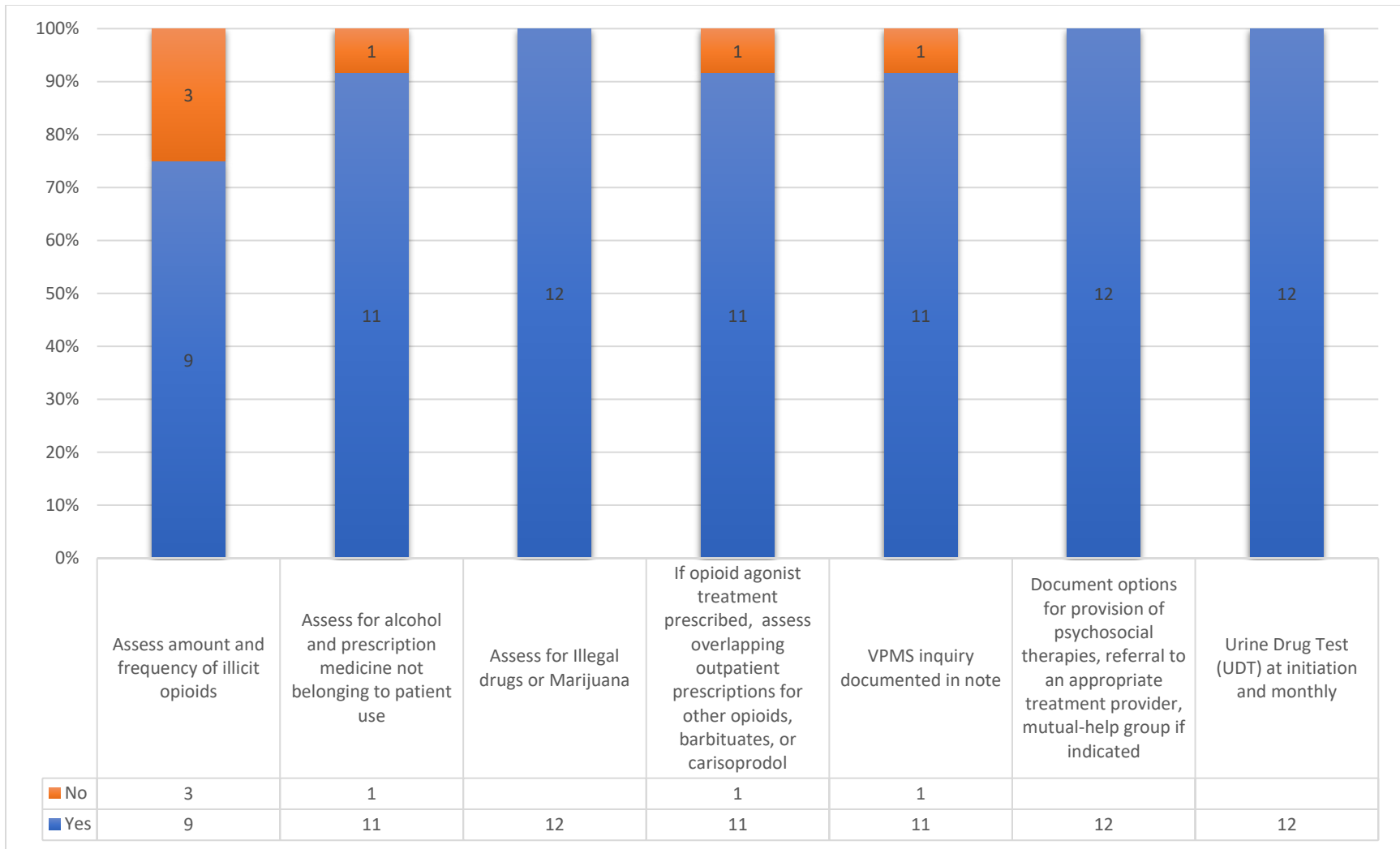


Figure 1. MAT/ODU documentation evaluation tool data. Provider documentation of recommended clinical quality measures in clinical visit vote and medical record. Note: Document is defined as providing reasonable evidence in the chart.

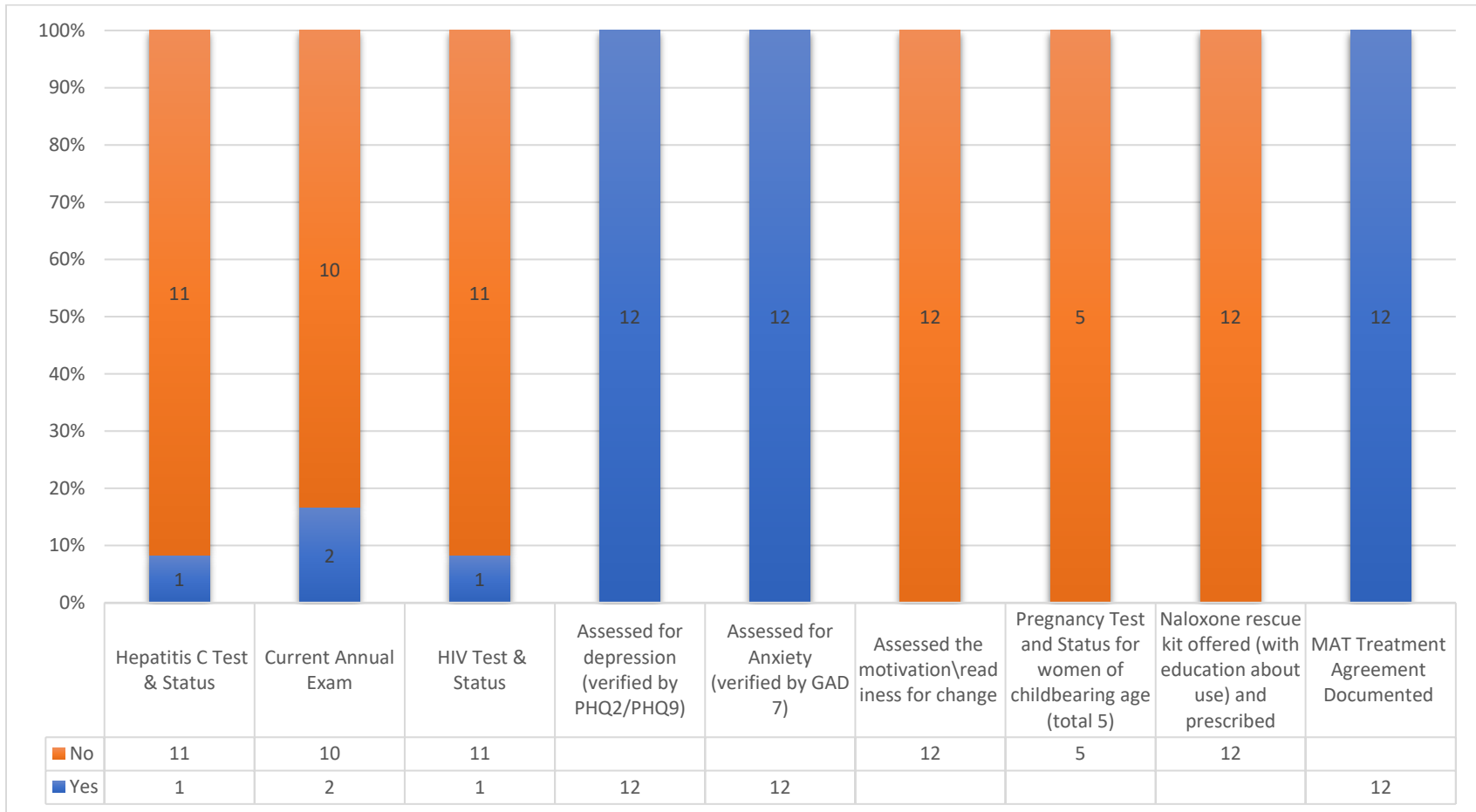


Figure 2. MAT/ODU documentation evaluation tool data. Provider documentation of recommended clinical quality measures in clinical visit note and medical record. Note: Document is defined as providing reasonable evidence in the chart.

Discussion

This project evaluated compliance to evidence-based documentation recommendations for MAT patients through a chart audit. The purpose of a chart audit is to measure how well something is being done and to understand if there is room for improvement. The audit demonstrated consistent documentation of evidence-based documentation recommendations in the majority of documentation elements.

Six elements of documentation with recommendations for improvement include: documentation of an annual wellness exam, HIV testing and status. Hepatitis C testing and status, assessment of readiness to change, pregnancy testing for women of childbearing age, and naloxone rescue kit *and* overdose prevention education being offered.

- Annual exam- The purpose of an annual yearly exam is to prevent illness based on a patient's current health status and risk factors. Clinicians should assure that a current annual examination is documented in medical record before or after starting or making changes to medication for substance use disorder (ASAM, 2020).
- HIV screening and status/Hepatitis C (HCV) screening and status- Opioid use has an increased risk for acquisition and transmission of both HIV and HCV due to engaging in unsafe behavior (ASAM, 2020; NIDA, 2020). Although opioid use has an increased risk for acquisition and transmission of HIV and HCV, gaps exist in HIV/HCV testing among individuals with OUD due to low testing uptake and testing refusal (Brown, 2019).

- Assessing readiness for change- motivational interviewing promotes and facilitates patient engagement in recovery-oriented activities (ASAM, 2020). Using tools such as a “readiness ruler” guides conversations about personal change (Case Western Reserve University Center for Evidence-based Practice, 2022; Moyer, 2009).
- Pregnancy testing- American College of Obstetrics and Gynecologists (ACOG) recommends that contraceptive counseling and access to contraceptive services should be a routine part of substance use disorder treatment among women of reproductive age to minimize the risk of unplanned pregnancy (ACOG, 2017).
- Naloxone ordered *and* overdose prevention education provided- To prevent overdose, families and patients should be counseled on the development to an “overdose plan” to share with friends, partners, and/or caregivers. Plan should include signs of overdose and how to administer naloxone and provide emergency care. Codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be used to bill time for counseling a patient about how to recognize overdose and how to administer naloxone (SAMHSA, 2018).

The results of the chart audit add to the understanding of how evidence-based evaluation and treatment recommendations are documented in the clinical progress notes by x-waivered providers. Ongoing review of electronic note templates is recommended to ensure the inclusion of appropriate elements of evaluation and treatment. Electronic documentation templates help capture complete and accurate reporting of the clinical encounter. Providers who participate in

audit and feedback activities and re-design and ongoing review of electronic note templates improve the clarity and consistency in documentation.

Limitations

Results of this quality improvement project are specific to one primary care clinic in a rural state. The results cannot be generalized to the population of SUD patients in clinics beyond this population. The study is limited by a small sample size ($n=12$) and the review of only one month's note as a snapshot. Quality improvement requires several cycles of audit and feedback to improve processes.

Conclusion

Evidence-based treatment guidelines and screening tools are available to guide providers in lowering prescription-opioid-related sequelae and eliminating accidental deaths in patients with substance use disorder. Using tools that promote guideline adherence provide opportunities to consistently document evidence-based evaluation and treatment recommendations and has potential to provide better outcomes for patients with substance use disorder. Participation in audit and feedback of clinical records by providers may improve consistency of behavior. Providers have a responsibility to participate in the development of best practices and a local standard of care. Development of a mechanism to audit and monitor best practices provides an opportunity to identify a performance improvement goal and seek to reach that goal to improve care processes and ultimately patient outcomes.

Funding

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Appendix C. Recommended updated MAT OUD Template

Patient ID: @NAME@ is a @AGE@ y.o. @SEX@

Subjective:

Chief Complaint: Medication Assisted Treatment Follow-up Office Visit

HPI:

General Health Today?

Any concerns:

Last annual wellness exam?

HIV status? Exposure?

History of hepatitis? Exposure? + Screen?

Any triggers or cravings?

If yes, **how are you managing them?**

Current Medication Assisted Therapy Medications and Dose:

Do you still have your Naloxone and have you received education on using it?

Experiencing any side effects?

Are you currently using any non-prescribed medications or substances?

Psychosocial Check-in:

PHQ-2

In the last two weeks, **how often have you felt down, depressed or hopeless?**

___ Not at all (0)

___ Several days (1)

___ More than half the days (2)

___ Nearly every day (3)

In the last two weeks, **how often have you had little interest or pleasure in doing things?**

___ Not at all (0)

___ Several days (1)

___ More than half the days (2)

___ Nearly every day (3)

Interpretation:

PHQ-2 score obtained by adding score for each question (total points) and ranges from 0-6. A score of 3 is the optimal cutpoint when using the PHQ-2 to screen for depression. If the score is ≥ 3 major depressive disorder is likely. Patients who screen positive should be further evaluated with the PHQ-9, other diagnostic instruments, or direct interview to determine whether they meet criteria for a depressive disorder.

GAD-2

In the last two weeks, **how often have you been bothered by feeling nervous, anxious or on edge?**

Not at all (0)

Several days (1)

More than half the days (2)

Nearly every day (3)

In the last two weeks, **how often have you been bothered by being unable to stop or control worrying?**

Not at all (0)

Several days (1)

More than half the days (2)

Nearly every day (3)

Interpretation:

GAD-2 score obtained by adding score for each question (total points) and ranges from 0-6. A score of 3 is the preferred cut-off for identifying possible cases and in which further diagnostic evaluation for generalized anxiety disorder is warranted. Using a cut-off of 3, the GAD-2 has a sensitivity of 86% and specificity of 83% for diagnosis generalized anxiety disorder.

Readiness for Change tool

Are you doing any **individual therapy/counseling**?

If you are doing therapy, **who do you see and how often**?

Are you participating in any **group therapy**?

Do you take part in any **peer support groups**?

Do you have **stable housing**?

Do you feel **safe at home**?

Are you **currently employed**?

Do you have **adequate social support**?

Do you feel **safe in your recovery**?

@PROBCOM@

@PSH@

@FAMHX@

@CMEDFASIMPLE@

@ALLERGY@

@SOCH@

@ROSNH@

Objective:

@VS@

@PHYSICALEXAM@

LABS:

@THISVISIT@

Assessment/Plan:

@NAME@ is a @AGE@ year old with h/o opioid use disorder here for **MAT follow-up visit**.

@ORDERSDX@

@FOLLOWUP@

Today's face-to-face visit time was *** minutes with *** minutes spent in counseling and/or coordination of care for the problems listed above.

@NPPTEDDONE@

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
<p>Anderson, D., et al (2015). https://doi.org/10.1097/AJP.00000000000000177</p>	<p>To evaluate the impact of a clinical dashboard for opioid analgesic management on opioid prescribing and adherence to opioid practice guidelines in primary care.</p>	<p>Qualitative Study Design</p>	<p>Community Health Center Inc. (CHCI) is a multisite FQHC in Connecticut providing comprehensive primary care services for over 140,000 medically underserved patients.</p>	<p>During the year before implementation 1309 patients had received COT or 3.4% of all CHCI patients aged 18 years and above with at least 1 medical primary care visit during that year compared with 1270 patients or 3.1% of all CHCI adult patients with at least 1 medical primary care visit in the post implementation year.</p>	<p>77% of PCPs felt that the dashboard was clinically useful. Implementation of the dashboard was associated with an increase in the use of OTAs, UDTs, pain and functional assessment questionnaires, and behavioral health visits.</p>	<p>Lack of a control group limits the ability to assert causality between the implementation of the dashboard and the changes observed in guideline adherence. Addition of intermittent opioid user from the 90 day user group.</p>	<p>JHNEBP Evidence Tool Level 3 Grade A</p>
<p>Dowell, D., et al.(2016). https://doi.org/10.15585/mmwr.rr6501e1</p>	<p>CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016</p>	<p>Practice guidelines</p>	<p>This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.</p>	<p>The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE)</p>	<p>CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee</p>	<p>http://www.cdc.gov/drugoverdose/prescribingresources.html</p>	<p>JHNEBP Evidence Tool Level 4 Grade B</p>

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation.			
Huang, K., et al. (2019). https://doi.org/10.5055/jom.2019.0535	A multicomponent intervention to improve adherence to opioid prescribing and monitoring guidelines in primary care.	Qualitative Study	Primary care practice affiliated with a tertiary care hospital in Boston serving over 40,000 patients and employing 35 PCPs.	The team implemented a five-pronged intervention. 1. Creating a patient registry 2. Standardization of chronic opioid prescribing policies 3. Development of a risk-assessment algorithm 4. Team-based case management 5. EHR dashboard	The percentage of patients chronically prescribed opioids in the practice decreased from 1.6 percent (n = 519) in September 2015 to 1.3 percent (n = 480) in September 2016. Of the patients who stopped receiving prescription opioids from our practice during	The single practice design limits generalizability to practices with several locations. During the course of the intervention, Massachusetts passed a law requiring providers to check the PMP every time opioids were prescribed, and this likely contributed to the increased rate of PMP usage. We therefore cannot assume all changes in opioid prescribing were associated with the	JHNEBP Evidence Tool Level 3 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					<p>this time period, the largest proportion (38 percent) had been weaned off due to symptom control via other modalities, patient preference, or resolution of pain. The second largest proportion (21 percent) was terminated due to pain agreement violations. The remaining patients were no longer a patient at our practice (17 percent), were now receiving opioid medication from another provider (7 percent), or</p>	<p>systematic changes we implemented. However, there were no concurrent interventions in our practice that may have influenced opioid prescribing practices. Lastly, clinicians may have been adhering to some guidelines pre-intervention, but without a structured field in the EHR to automatically document these practices, they were not uniformly captured beforehand.</p>	

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					<p>were deceased (5 percent) from nonopioid related etiologies.</p> <p>The percentage of patients on chronic opioid therapy with no primary care visit in the past year decreased from 9 to 0.2 percent ($p < 0.0001$). The percentage of patients on chronic opioid therapy who had signed a controlled substances agreement in the past year increased from 46 percent at baseline to 76 percent a year after program</p>		

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					implementation (p < 0.0001).		
<p>Kay, C., et al (2016). https://doi.org/10.5055/jom.2016.0350</p>	<p>Adherence to chronic opioid therapy prescribing guidelines in a primary care clinic. <i>Journal of opioid management</i>, 12(5), 333–345.</p>	<p>Retrospective chart review</p>	<p>Adults prescribed chronic opioids (three or more monthly prescriptions within a year) for CNCP between April 1, 2014 and April 1, 2015.</p>	<p>Patient demographics, medical diagnoses, tobacco status, provider status, documentation of guideline-recommended opioid-monitoring practices, pain agreement status, and opioid prescription. Univariate statistics were used to explore differences in patient demographics, comorbidities, and guideline-recommended opioid-monitoring practices by chronic pain and pain agreement status.</p>	<p>The clinic had 834 (9 percent) patients on chronic opioids, with 335 on a pain agreement. Documentation of opioid-monitoring practices was lacking. Logistic regression indicated that patients were significantly more likely to be on an agreement if they were Caucasian (adjusted odds ratio [OR] 2.17 [95% CI 1.41, 3.39]), had a baseline urine drug screen (adjusted OR 10.72 [95% CI</p>	<p>Limitations: Full article unavailable – does not state where study took place. Data table and results unavailable to be reviewed except for excerpts from pubmed/source Journal</p>	<p>Unable to determine based on pubmed information.</p>

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					6.16, 19.41)), were prescribed a schedule II controlled medication (adjusted OR 11.92 [95% CI 6.93, 21.62]), and had risk assessed to some degree (adjusted OR 3.06 [95% CI 1.90, 4.96]).		
Khalid, L., et al (2015). https://doi.org/10.1111/pme.12602	Adherence to prescription opioid monitoring guidelines among residents and attending physicians in the primary care setting. Pain medicine (Malden, Mass.), 16(3), 480–487	Retrospective Cross sectional study	Large primary care practice at a safety net hospital in New England. 18-99 yo patients with long-term opioid treatment for chronic noncancer pain	The primary outcomes were adherence to any one of two American Pain Society Guidelines by residents and attendings: (1) documentation of at least one opioid agreement (contract) ever and (2) any urine drug testing in the past year, and evidence	Similar proportions of resident and attending patients had a controlled substance agreement (45.1% of resident patients vs. 42.4% of attending patient, P = 0.47) or urine drug testing (58.6% of resident patients	With some variability, residents and attending physicians were only partly compliant with national guidelines. Residents were more likely to manage patients with a higher likelihood of opioid misuse. Limitations: Data were abstracted from the EMR and therefore mental health, tobacco	JHNEBP Evidence Tool Level 2 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				of potential prescription misuse defined as ≥ 2 early refills.	vs. 63.6% of attending patients, $P = 0.16$). Resident patients were more likely to have two or more early refills in the past year relative to attending patients (42.8% vs. 32.5%; $P = 0.004$). In the adjusted regression analysis, resident patients were more likely to receive early refills (odds ratio 1.82, 95% confidence interval 1.26-2.62) than attending patients.	use, alcohol use and substance use disorders were derived from billing information or ICD codes, which may be incomplete or unreliable. We did not have information about early refills provided by prescribers outside of the primary care practice. Thus, the prevalence of early refills in our study is likely an underestimate.	
Krebs, E. et al. (2018).	Effect of Opioid vs Nonopioid	RCT	Patients were recruited from	Eligible patients had moderate to severe	There was no significant	Treatment with opioids was not superior to	JHNEBP Evidence Tool

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
https://doi.org/10.1001/jama.2018.0899	Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial.		Veterans Affairs primary care clinics from June 2013 through December 2015; follow-up was completed December 2016.	chronic back pain or hip or knee osteoarthritis pain despite analgesic use. Of 265 patients enrolled, 25 withdrew prior to randomization and 240 were randomized.	difference in pain-related function between the 2 groups over 12 months	treatment with nonopioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain. Limits: Because primary outcomes were patient-reported, results are subject to potential reporting bias that would likely favor opioids. Second, there was an imbalance in prerandomization treatment preference. Any effect of this imbalance would likely favor opioids. Third, because this study was conducted in VA clinics, patient characteristics differ from those of the	Level 1 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
						general population, most notably in sex distribution. Fourth, patients with physiological opioid dependence due to ongoing opioid use were excluded, so results do not apply to this population.	
Kroenke, K., et al (2014). https://doi.org/10.1001/jama.2014.7689	Telecare collaborative management of chronic pain in primary care: a randomized clinical trial.	RCT	Patients were enrolled from 5 primary care clinics in a single Veterans Affairs medical center from June 2010 through May 2012, with 12-month follow-up completed by June 2013.	Patients were randomized either to an intervention group (n = 124) or to a usual care group whose members received all pain care as usual from their primary care physicians (n = 126). The intervention group received 12 months of telecare management that coupled automated symptom monitoring with an algorithm-guided stepped care	Overall, mean (SD) baseline BPI scores in the intervention and control groups were 5.31 (1.81) and 5.12 (1.80), respectively. Compared with usual care, the intervention group had a 1.02-point lower (95% CI, -1.58 to -0.47) BPI score at 12 months (3.57 vs 4.59). Patients in the intervention	Limitations: 1) The sample consists of veterans from a single center. 2) Many patients had pain for years that involved at least several bodily sites. 3) The comparator group was usual care rather than an attention control; thus, the relative effects of optimizing analgesics, automated monitoring, and nurse contacts cannot be unbundled. 4) Not have data on medications prescribed outside of the Veterans	JHNEBP Evidence Tool Level 1 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				approach to optimizing analgesics.	group were nearly twice as likely to report at least a 30% improvement in their pain score by 12 months (51.7% vs 27.1%; relative risk, 1.9 [95% CI, 1.4 to 2.7]), with a number needed to treat of 4.1 (95% CI, 3.0 to 6.4) for a 30% improvement.	Affairs system. 5) The trial did not include a formal cost analysis.	
Lasser, et al (2016). https://doi.org/10.1016/j.jsat.2015.06.018	A multicomponent intervention to improve primary care provider adherence to chronic opioid therapy guidelines and reduce opioid misuse: a cluster randomized controlled trial protocol	RCT	53 PCPs from three Boston-area community health centers and one urban safety-net hospital-based primary care practice who have at least four patients meeting inclusion criteria	PCPs were randomized to receive the intervention, which includes four components: 1) nurse care management, 2) use of a patient registry, 3) academic detailing, and 4) electronic tools, or a control condition, which includes only	Starting in July 2013, we piloted the intervention for five months with two PCPs and their 33 patients on chronic opioid therapy at the urban safety-net hospital based practice. In this initial pilot test,	It is not possible to determine the individual effect of each intervention component on quantitative study outcomes. Rather, we are only able to test the effectiveness of the entire, four-component intervention package against the electronic tools-only control condition.	JHNEBP Evidence Tool Level 1 Grade C

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				the use of the electronic tools.	we demonstrated feasibility and acceptability; the intervention was well received by the PCPs and patients. We observed a high frequency of aberrant behaviors among patients, with four of 33 patients having one of the following aberrant behaviors: they had incorrect numbers of opioid pills at pill counts with NCMs, had Tylenol in their opioid pill bottles instead of the prescribed opioid, cocaine		

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					on urine drug screens, and were not taking medication as prescribed.		
Liebschutz, , et al (2017) https://doi.org/10.1001/jamainternmed.2017.2468	Improving Adherence to Long-term Opioid Therapy Guidelines to Reduce Opioid Misuse in Primary Care: A Cluster-Randomized Clinical Trial	Cluster RCT	53 primary care clinicians (PCCs) and their 985 patients receiving long-term opioid therapy for pain	Intervention PCCs received nurse care management, an electronic registry, 1-on-1 academic detailing, and electronic decision tools for safe opioid prescribing. Control PCCs received electronic decision tools only.	At 1 year, intervention patients were more likely than controls to receive guideline-concordant care, to have a patient-PCC agreement, and to undergo at least 1 UDT. There was no difference in odds of early refill receipt between groups. Intervention patients were more likely than controls to have either a 10% dose reduction	Solely used EHR and did not capture patient experience of the intervention, including its potential impact on pain control, function, and disability. Furthermore, EHR data do not provide accurate substance use and mental health diagnoses. Also lacks ability to measure opioid prescribing outside of these practices (multifacility prescriptions)	JHNEBP Evidence Tool Level 2 Grade A

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Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					or opioid treatment discontinuation. In adjusted analyses, intervention patients had a mean mg lower than controls		
Manchikanti, L., et al. (2017)	Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. Pain physician.	Practice Guidelines -	In preparation of the current guidelines, we have focused on the means to reduce the abuse and diversion of opioids without jeopardizing access for those patients suffering from non-cancer pain who have an appropriate medical indication for opioid use.	These guidelines are intended to provide a systematic and standardized approach to this complex and difficult arena of practice, while recognizing that every clinical situation is unique.	These guidelines were developed based on comprehensive review of the literature, consensus among the panelists, in consonance with patient preferences, shared decision-making, and practice patterns with limited evidence, based on randomized controlled trials (RCTs) to	Conclusions: Chronic opioid therapy should be provided only to patients with proven medical necessity and stability with improvement in pain and function, independently or in conjunction with other modalities of treatments in low doses with appropriate adherence monitoring and understanding of adverse events.	JHNEBP Evidence Tool Level 4 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					improve pain and function in chronic non-cancer pain on a long-term basis.		
Parchman, M. L., et al. (2017). https://doi.org/10.3122/jabfm.2017.01.160183	Primary Care Clinic Re-Design for Prescription Opioid Management. Journal of the American Board of Family Medicine : JABFM, 30(1), 44–51.	Quality Improvement Redesign	Thirty primary care clinics across the United States selected for their use of team-based workforce innovations.	Site visits included interviews with leadership, clinic tours, observations of clinic processes and team meetings, and interviews with staff and clinicians. Data were reviewed to identify common attributes of clinic system changes around chronic opioid therapy (COT) management. These concepts were reviewed to develop narrative descriptions of key components of changes made to improve COT use.	Twenty of the thirty sites had addressed improvements in COT prescribing. Across these sites a common set of 6 Building Blocks were identified: 1) providing leadership support; 2) revising and aligning clinic policies, patient agreements (contracts) and workflows; 3) implementing a registry tracking system; 4) conducting planned, patient-	The practical steps and strategies represented in the 6 Building Blocks were used by innovative clinics to address the use of COT in their patient population and should be considered in designing improvement initiatives in other primary care settings. It is important to note, however, that these new guidelines and the associated workflow redesigns to implement them cause burdens of their own. Unless they can be demonstrated to significantly improve patient outcomes, while also decreasing provider and staff burnout, there may be resistance to	JHNEBP Evidence Tool Level 3 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					centered visits; 5) identifying resources for complex patients; and 6) measuring progress toward achieving clinic objectives. Common components of clinic policies, patient agreements and data tracked in registries to assess progress are described.	implementation. In addition, primary care clinics alone cannot stem the tide of opioid overuse within local communities; it will require community-wide initiatives that include all prescribers.	
Quanbeck, A., et al (2018). https://doi.org/10.1186/s13012-018-0713-1	A randomized matched-pairs study of feasibility, acceptability, and effectiveness of systems consultation: a novel implementation strategy for adopting clinical	Observational Prospective Case Control	The study took place in family medicine clinics that are part of UWHealth, the health system affiliated with the University of Wisconsin Department of Family Medicine	This pilot test of systems consultation used the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) evaluation framework. To assess reach , we compared characteristics of	The systems consultation implementation strategy demonstrated feasibility, acceptability, and effectiveness in a study of eight primary care clinics. Clinic	The problem of opioid prescribing received attention both locally and nationally during the intervention period, and notable secular changes in opioid prescribing outcomes were evident. The UWHealth system also introduced a new	JHNEBP Evidence Tool Level 3 Grade B/C

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Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
	guidelines for Opioid prescribing in primary care. Implementation science		and Community Health. The intervention was introduced to the four intervention clinics on staggered starting dates	intervention clinics, control clinics, and clinics that refused participation, including number of prescribers and characteristics of the patient panel. For effectiveness , we examined overall opioid prescribing rates; average morphine-equivalent daily dose for patients on long-term opioid therapy. For adoption , we examined the characteristics of clinic change teams, attendance at scheduled intervention activities, and ratings by staff participants on a satisfaction survey. Assessment of implementation focused on the cost of delivering the	teams actively participated in the intervention (attendance at scheduled implementation activities was 83% of consented staff members) and reported positive feedback in focus groups and satisfaction surveys.	opioid-prescribing policy in February 2016, concurrent with the beginning of the study period. The Centers for Disease Control and Prevention published guidelines for opioid prescribing in March 2016 that are based on the guidelines [24] used in this study.	

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				implementation strategy. Maintenance was assessed using 6-month follow-up data on the effectiveness measures described above.			
Saffore, C. D, et al. (2020). https://doi.org/10.3399/bjgp20X711737	Identification of barriers to safe opioid prescribing in primary care: a qualitative analysis of field notes collected through academic detailing	Qualitative Analysis	June 2018 to August 2018 to licensed PCPs with prescriptive authority within a large independent health system in the Chicago area.	Intervention involved visits by trained detailers to PCPs who contemporaneously documented details from each visit via field notes. Using qualitative analysis, field notes were analyzed to identify recurring themes related to opioid prescribing barriers.	Detailer-entered field notes from 186 AD visits with PCPs were analyzed. Barriers to safe opioid prescribing were organized into six themes: 1) gaps in knowledge; 2) lack of prescription monitoring program (PMP) utilization; 3) patient pressures to prescribe opioids; 4) insurance coverage	Barriers to safe opioid prescribing in primary care, identified through AD visits among this large group of PCPs. Over 75% of PCPs indicated at least 1 barrier, 50% indicated at least 2 barriers and 19% indicated at least 3 barriers.	JHNEBP Evidence Tool Level 3 Grade C

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					policies; 5) provider beliefs; and 6) health system pain management practices.		
Seal, K. et al (2019). https://doi.org/10.1016/j.cct.2018.12.006	Optimizing pain treatment interventions (OPTI): A pilot randomized controlled trial of collaborative care to improve chronic pain management and opioid safety- Rationale, methods, and lessons learned.	RCT	San Francisco VA Health Care System trial enrolling 100 veterans	A primary endpoint for this pilot study was increased self-efficacy among PCPs and the Care Managers in co-creating and encouraging the use of SMART goals captured in the Pain Care Plans with participants, since this formed the foundation for both the Collaborative Care and Attention Control conditions.	Overall, 90 participants (90% of those enrolled) completed the trial and all study assessments.	First, the study was implemented during their primary care clinics and they reported difficulties obtaining approval for and scheduling one-hour research study visits between regularly scheduled 30-minute patient visits. Second, despite training on Shared Decision-Making in which PCPs elicited participants' values and goals in order to construct SMART goals to develop the Pain Care Plan, some PCPs found it challenging to accomplish this task within the initial 60-minute visit, which also	JHNEBP Evidence Tool Level 2 Grade C

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
						<p>included detailed assessment and education about chronic pain and opioid safety. PCPs reported that some patients had difficulty articulating life values and goals and/or constructing “SMART” goals that were specific, measurable, action-oriented, etc. Third, study PCPs reported varying degrees of role confusion regarding their relationship with the participant’s own PCP when it came to making changes to patients’ pain regimens in accordance with the Pain Care Plans. Finally, study PCPs found it difficult to make referrals for non-pharmacological pain management services, especially complimentary and</p>	

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
						<p>integrative health services in VA (because of a dearth of services) as well as in the community (because of limited resources or prohibitive costs to veterans). As the study progressed, study PCPs were strongly encouraged to assist participants in developing more self-directed SMART goals. Examples of self-directed goals are walking, meditating at home or engaging in pleasurable activities; in other words, activities that align with participants' values, shift attention away from chronic pain to more enjoyable activities and rely less on referrals to VA or community resources.</p>	

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
Weller L. M. (2020). https://doi.org/10.1097/JXX.0000000000000487	Development and implementation of a primary care clinic workflow protocol to meet opioid prescribing guidelines.	Quality improvement project using an educational intervention was implemented	Ten Washington State primary care clinics	Primary care clinics viewed the project's instructional YouTube webinar that explained the project's primary care clinic workflow protocol, opioid prescribing best practice guidelines, and the organization's mandated EMR charting for chronic pain management.	Preintervention and postintervention measures, which included five different documented patient completion rates of the organization's best practices for opioid prescribing, were used to assess for improvement to guideline adherence. Additionally, participants completed a questionnaire regarding their perceptions of the webinar as an educational tool.	Postintervention data showed significantly ($p \leq .05$) increased completion rates for three of five outcome measures, indicating improvement in guideline adherence. Limitations: Generalizability, study was limited to ten Washington clinics. The study also utilized YouTube educational materials which may not be an effective form of teaching for some providers. Only addressed 5 areas of documentation.	JHNEBP Evidence Tool Level 3 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
Witt et al, 2018	To describe the steps taken and results obtained by a rural primary care practice to effectively implement opioid prescribing guidelines.	Qualitative Study Design	435 patients – Mayo Clinic health setting	Between December 1, 2014, and May 30, 2017, a quality improvement project was undertaken. Elements included prescribing registries, a nurse coordinator, and an Opioid Use Review Panel. Clinic workflow was redesigned to more consistently incorporate these and other guideline recommendations into practice. The effect on opioid prescribing was measured as well as patient outcomes.	Of the remaining 435 patients, 96 (22.1%; 95% CI, 18.4-26.2) had decreased prescribing below the threshold for inclusion or were no longer receiving opioid prescriptions. Originally, 64 patients (13.9%; 95% CI, 11.0-17.3) were using average daily doses equal to or greater than 90 morphine milligram equivalents. After implementation, 54 of 435 patients (12.4%; 95% CI, 9.6-15.8) were still using equal to or	Estimates for patients' decrease in use, in the absence of or before such a program's implementation, have not been well studied, so it is difficult to fully quantify the effects of this project. Data outcomes are currently available only in aggregate. This limits the type of analyses that can be performed (eg, unable to determine for most patients whether they had different starting vs ending use categories, unknown follow-up time per patient, and only presence or absence during the second phase) and the conclusions that can be drawn. For example, although the number of patients using greater than 90 MME/D	JHNEBP Evidence Tool Level 3 Grade B

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Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
					greater than 90 morphine milligram equivalents per day after accounting for death or loss to follow-up.	decreased, it is unknown whether they are not present in the greater than 90 MME/D group due to decreased usage, death, or loss to follow-up.	
Zgierska, A. E., et al (2020). https://doi.org/10.1186/s12875-020-01320-9	Increasing system-wide implementation of opioid prescribing guidelines in primary care: findings from a non-randomized stepped-wedge quality improvement project.	Quality Improvement Project	The academic health system in Wisconsin, USA included 35 primary care. The first 9 consenting clinics (convenience sample) were enrolled into a non-randomized stepped-wedge QI project.	The QI participants were volunteer clinical staff (prescribers, nurses and others) at each intervention clinic. The evaluation subjects (target patient population) were identified by the search of EHR-based data from the problem list, encounter, and billing records, using the health system-developed criteria: age \geq 18 years old; active-patient status (seen at the clinic in the past 3 years); primary care provider	A total of 215 unique health care providers, including 73 prescribers and 142 other clinic staff from the enrolled 4 family medicine and 5 internal medicine clinics completed at least one component of the QI intervention (QI participants; Table 1). Among the QI participants, 48.4% completed half or more of	Augmenting routine policy implementation with targeted QI intervention, delivered to volunteer clinic staff, did not additionally improve clinic-level, opioid guideline-concordant care metrics. However, the observed effect sizes suggested this approach may be effective, especially in higher-risk patients, if broadly implemented.	JHNEBP Evidence Tool Level 3 Grade B

Appendix D. Synthesis Table

Author, YEAR	Purpose/Objective	Design	Sample/Setting	Measurement Outcomes	Analysis and Findings	Limitations and conclusions	Level of Evidence
				<p>within the health system; no diagnosis of malignant neoplasm (except non-melanoma skin cancer) or palliative or hospice care status; and meeting at least one of the two criteria: 1) ≥ 1 opioid prescription issued in the prior 45 days and ≥ 3 opioid prescriptions issued in the prior 4 months; or 2) ≥ 1 opioid prescription issued in the prior 45 days, and presence of a chronic pain diagnosis and a controlled substance agreement.</p>	<p>the intervention components; 44.7% completed at least 4 of the 6 in-person practice facilitation sessions; 31.2% completed the opioid prescribing and 23.2% completed the shared decision making online modules</p>		