A Quality Improvement Project: Developing a Controlled Substance Review Committee at a Federally Qualified Health Center

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NURS703: DNP Project

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Abstract

Discussions about controlled substance medications can cause distress because patients may feel frustrated and abandoned as practice changes, while providers struggle with the responsibility of safely managing symptoms. This distress can negatively impact the therapeutic relationship, lead to high levels of provider burn-out and distress, and contribute to patient dissatisfaction. Controlled substance review committees (CSRCs) focus on providing support for difficult cases involving controlled substance (CS) prescribing. Evidence has shown these committees decrease strain placed on patient-provider relationships and improve health outcomes. This quality improvement (QI) project details the development of a CSRC including coordinating interested participants and formalizing logistics for case referral and review process at a metropolitan nonprofit community health organization. The aim of this QI project was to provide clinical support for challenging cases involving CS treatment planning through a committee of interprofessional staff offering individualized evidence-based recommendations and resources. Identified project aims included improving therapeutic relationships, decreasing staff burnout and workplace distress, and improving safety related to CS treatment planning. The clinic expressed strong interest in continuing with the CSRC and will be evaluating the effectiveness of the case referral and review process on project aims as important next steps. This project also adds to the limited evidence for interventions aimed at improving health outcomes related to controlled substance prescriptions and addressing a public health crisis.

Introduction

Problem Description

Controlled substance (CS) prescribing is a challenging part of clinical practice because these medications are highly effective at managing symptoms but capable of causing significant harm. The opioid epidemic first brought attention to CS prescribing as the nation grappled with high rates of dependence and overdose (Bourgeois et al., 2020; Gernant et al., 2015; Zeigler et al., 2016). More recently, benzodiazepines are gaining attention for causing patient harm and are often referred to as the "hidden epidemic" as a comparison to the opioid epidemic (Blazes, 2021) resulting in a recent Federal Drug Administration (Federal Drug Administration [FDA], 2020) black box warning. As awareness grows of risks associated with these medications, practice swiftly changes leaving patients with undertreated symptoms and providers to navigate challenging clinical cases not adequately addressed by changing guidelines (Zeigler et al., 2016). In the clinical setting, discussions about CS medications can cause distress as patients may feel frustrated and abandoned while providers struggle with the responsibility of safely managing symptoms (Zeigler et al., 2016). This distress can negatively impact the therapeutic relationship, lead to high levels of provider burn-out and distress, and contribute to patient dissatisfaction (Gernant et al., 2015; Zeigler et al., 2016).

Available Knowledge

Clinical ethics committees (CECs) are supported by evidence to navigate complex ethical issues that arise in clinical settings as well as, improve collaborative decision and patient outcomes (American Society for Bioethics and Humanities [ASBH], 2011; Rasoal et al., 2017;). Moral distress which often arises from ethical issues in patient care can be decreased through the support of CECs (Rasoal et al., 2017). CECs are interprofessional groups who provide supportive

services when requested by patients and or care teams (ASBH, 2011; Rasoal et al., 2017). Primary goals are to protect patient's rights and well-being, support clinical decision making, provide education, and update organizational policies (ASBH, 2011; Rasoal et al., 2017). Despite many commonalities CECs may differ for example, in structure or function (Rasoal et al., 2017).

Controlled substance review committees (CSRCs) are similar to CECs but focus on providing support and resources for difficult cases involving CS prescribing (Bourgeois et al., 2020; Gernant et al., 2015; Zeigler et al., 2016). Evidence has shown these committees decrease strain placed on patient-provider relationships from CS prescribing by having the institution share responsibility with the provider and assuring consistent, safe, and evidence-based prescribing (Gernant et al., 2015). CSRCs consist of interprofessional members (such as primary care and psychiatric providers, counselors, pharmacists, and nurses) who meet regularly to review patient cases and provide recommendations (Bourgeois et al., 2020; Gernant et al., 2015; Zeigler et al., 2016).

Similar to ethics committees CSRCs have differences in their structure and function. For example, proactively searching charts for high risk prescribing versus referring cases for review (Genrnat et al., 2015; Zeigler et al., 2016). However, there are consistencies seen in the literature including an electronic referral process, thorough chart review, case presentation and discussion among the CSRC, providing recommendations back to referring persons, and documentation in the electronic health record (EHR) (Bourgeois et al., Gernant et al., 2015; 2020; Zeigler et al., 2016). The presence of referring providers and the patient's care team for the case review was found to be of significant value for providing insight otherwise, the CSRC must rely entirely on the EHR (Bourgeois et al., 2020; Zeigler et al., 2016). Also, like CECs members of CSRCs benefit from having education related to current evidence on CS prescribing including alternative

evidence-based treatment options, current practice guidelines, and communication strategies to promote therapeutic alliances between patients and providers (ASBH, 2011; Zeigler et al., 2016). Additional responsibilities for CSRCs include updating institutional policies that support evidence-based practice and providing healthcare staff with current educational materials (Bourgeois et al., 2020; Gernant et al., 2015; Zeigler et al., 2016).

Rationale

Patients are often left feeling frustrated and abandoned by their treatment teams as practice changes around CS prescribing. Providers have been engaged in an important discussion about how to best support their patients with CS prescribing through practice that is evidence-based and safe while not undertreating symptoms. The framework used for demonstrating the importance of improving CS prescribing is from the Institute of Medicine's (IOM) impactful paper, *Crossing the Quality Chasm: Healthcare in the 21st Century*, that identified six aims for quality improvement essential to healthcare (Institute for Health Improvement [IHI], 2020). The six aims identified by the IOM include safe, timely, effective, efficient, equitable, patient centered (IHI, 2020). Improving CS prescribing practice through the support of a CSRC is relevant to the safe, effective, and patient centered aims identified by the IOM.

The Model for Improvement developed by the Associates in Process Improvement is the method used for this project because of its proven efficacy at supporting sustained change that produces improved outcomes (IHI, 2020). The model uses a strategy called Plan-Do-Study-Act (PDSA) cycles to test the effectiveness of interventions on desired outcomes of quality improvement. PDSA cycles are used to quickly test a change in a system, data are collected to determine effectiveness of the change on desired outcomes, the plan is adjusted based on these

observations, and to the adjustment is evaluated (IHI, 2020). A single QI project may involve multiple PDSA cycles.

Specific Aims

Interested staff will participate in the CSRC and a referral and review process for complex cases involving controlled substance treatment planning will be developed. Through shared responsibility with the institution and access to supportive resources, provider distress and burnout will be decreased and therapeutic relationships with patients will be enhanced. The impact of the CSRC will be examined using data from surveys and field notes.

Methods

Context

This QI project was completed at a metropolitan nonprofit organization providing comprehensive health services to chronically marginalized and vulnerable populations in Oregon. The organization is a Federally Qualified Health Center (FQHC) addressing health disparities by providing services regardless of ability to pay. The organization serves over 18,000 individuals across the lifespan. The services provided include mental health and substance use treatment, primary care, affordable housing, permanent supportive housing, and crisis support. There are over 900 employees providing these services at over 75 locations.

aff support individuals living with complex physical and mental health needs including those managed with CS prescriptions. CS prescribing guidelines change when evidence indicates risks are greater than initially suggested for example, as seen with opioids and pain management. Currently, prescribing guidelines for benzodiazepines are changing because of the accumulation of data showing the significant harm they may cause when prescribed or used inappropriately. As practice changes, treatment planning involving CSs becomes complicated for several reasons

including available guidelines not adequately addressing symptom management for all patients or tension created in the therapeutic relationship between patients and providers. At this organization there has been frequent discussion about how additional supports may be provided with these clinically challenging cases. Evidence shows CSRCs provide valuable support in clinical cases while significantly reducing the impact of CS prescribing on the therapeutic relationship, patient grievances, and provider burnout (Bourgeois et al., 2020; Gernant et al., 2015; Zeigler et al., 2016).

Interventions

A strength of CSRCs is the interprofessional team approach that expands insight on a case from that of a single provider. To identify interested participants at the selected location a document briefly outlining the project aims with supportive evidence was shared with staff through the employee email list serves. An interprofessional CSRC was coordinated consisting of primary care and behavioral health providers, a nurse, therapists, substance use and addictions counselors, peer support specialists, and pharmacists. At the first CSRC meeting members formalized logistics of future meetings and the case review process.

For cases to be elevated for CSRC review a referral system is being developed within the EHR; a process requiring collaboration with and support from the organization's Information Technology (IT) department. The electronic referral contains a form to be completed by the referring person and provides relevant information to inform the CSRC review. The referral form with the CSRCs review notes and recommendations will be saved in the patient's chart for easy accessibility by the patient and their treatment team (see Appendix A).

For clinical cases experiencing challenges related to CS prescribing the treatment team or the patient may elevate the case for CSRC review using the electronic referral system. Once a

case has been elevated the committee performs a thorough chart review, the case is presented to the CSRC for interprofessional discussion, and recommendations and notes are documented in the EHR as well as, shared with the treatment team.

Study of the Intervention

To assess the impact of this QI project's intervention on staff, patients, and systems at the clinic field notes were taken at CSRC meetings to collect observations and feedback from members. These notes and themes informed understanding of the impact of the intervention. Surveys were given to individuals who refer cases and treatment team members to reflect on their experience with CSRC. Surveys were to be given to members of the CSRC. Data collection will inform the impact of this project including opportunity costs (known as other factors and opportunities impacted by intervention than those intended) and unexpected benefits (see Appendix B).

To identify whether observed changes are due to the CSRC or were influenced by unrelated factors, participants will be asked to reflect on cultural influences (e.g., the culture at their clinic or current related societal views), external pressures (e.g., policy or practice changes), and any other potential influences.

Measures

The Model for Improvement uses a set of metrics known as, 'the Whole System Measures' to understand overall impact of a QI project on health care including outcome, process, and balancing measures (IHI, 2020). Outcome measures reflect impact of intervention on identified project aims. Process measures reflect the impact crucial parts of the intervention's process has on project outcomes. Balancing measures assess for inadvertently created problems by the project's intervention (IHI, 2020).

Outcome measures for this QI project include impact of CSRC on provider burnout and therapeutic relationships as measured by survey responses collecting qualitative and quantitative data. Process measures include number of referred cases to the CSRC, total number of cases reviewed, and completeness of reviews. Time staff dedicate in support of this project is considered a balancing measure due to adding to staff workload or using a limited resource such as clinical staffing. In addition, feedback from participants will be collected to better understand the project's impact and inform the improvement process.

Data Analysis

PDSA cycles were done at one location. This location served as the pilot run for CSRC case referral and review. Collection of data occurred at the start of and throughout the project and included field notes at CSRC meetings, survey responses from treatment teams that utilized the CSRC review process, and members of the CSRC. Surveys were mixed quantitative (Likert Scale) and qualitative (short answer responses and thematic analysis of field notes).

Ethical Considerations

Information for the project was shared with staff via employee emails to identify interested participants for the CSRC. Participation was emphasized as voluntary. Announcements were shared with staff about the availability of the CSRC as a resource for clinical support once the committee was formed via employee emails and treatment team meetings. Announcements emphasized use of resource as entirely voluntary and elective and intended to support improved outcomes in challenging clinical cases involving CS prescribing. Survey links sent via employee emails to CSRC members and those who used CSRC as a resource. Completion of surveys done anonymously and are voluntary. Verbal consent given by

CSRC members for observational field notes collected during meetings. No collection of identifying information of either patients or staff was performed for this project.

An important ethical consideration for this project is time taken away from patient care (a valuable and limited resource) to participate in or use the CSRC. Evidence shows that the time spent is worth the benefits seen on clinical outcomes including patient satisfaction and safety, therapeutic relationships, and provider distress and burn-out. Also, important to consider accessibility including who is accessing/benefitting from the project, communication facilitators and barriers such as language, and organizational resources to support CSRC function and goals. Steps are being taken to share information with patients and make easily accessible including having information available in various formats and languages throughout clinics. Resources were provided to support the CSRC pilot run including evidence-based educational materials and peer-reviewed references relevant to CSRCs, CS prescribing, and strengthening therapeutic relationships.

Of note there are no conflicts of interest to disclose. Finally, this QI project has been reviewed formally and approved by Oregon Health and Science University's (OHSU) Internal Review Board, Study00023315 (see Appendix C).

Results

After several discussions with clinical staff and administration over the summer of 2022 the project's aims shifted to better meet identified needs. Knowledge of best practice and current guidelines for CS prescribing was not the issue impacting quality of care and patient outcomes, but rather a lack of clinical support for challenging cases. During this period meetings were held with the clinic's Chief Medical Officer (CMO) and the quality management (QM) department to

discuss project goals and implementation including approved time for staff to dedicate to CSRC participation.

Throughout the winter months of 2022 staff were educated about the project and those interested in participation were identified. Employee emails were used as the primary method for communicating project information with overall good response rates. Development of the referral process for staff to elevate challenging cases for CSRC review was done with the support of the QM and IT departments. The first CSRC meeting was coordinated using an online scheduling tool, the meeting link was sent via employee emails, and the meeting was facilitated using videoconferencing software with recording capabilities. Recording of meetings was done to collect meeting notes and share with participants unable to attend (see Appendix C). The objective of the first meeting was to outline the case review process.

The pilot PDSA cycle was delayed due to unforeseen challenges including the ripple effects of COVID on the clinic. Specifically, COVID created staffing shortages from virus-related illnesses and concerns resulting in hired staff having to learn a new system slowing down overall productivity. Due to these obstacles, the case review process was delayed preventing collection of data from individuals who refer to CSRC. However, data (observational field notes from the first CSRC meeting and survey responses from staff) were collected that supported moving forward with the development of the CSRC.

Surveys links were sent to staff and CSRC participants. However, due to staffing shortages and time constraints survey completion was poor with only one partially completed. Responses from this survey included strongly agreeing that CS treatment planning contributes to workplace distress and reporting a long-held desire for additional clinical support. Field notes

were collected from the first CSRC meeting and the following quote exemplifies the importance of this project for staff: “there has been interest in such a resource for years” at the clinic.

Discussion

Summary

This quality improvement project set out to provide clinical support for challenging cases involving CS treatment planning through a committee of interprofessional staff offering individualized evidence-based recommendations and resources. Identified project aims included improving therapeutic relationships, decreasing staff burnout and workplace distress, and improving safety related to CS treatment planning. Despite the obstacles encountered preventing a pilot case review, the clinic’s staff have shown significant interest in having this support and are continuing to move forward with this project.

Interpretation

Baseline data from the organization were 172,000 active CS prescriptions for 18,000 patients. This volume emphasizes the significance of these medications in treatment planning for the organization. Providers at this organization often inherit patients who have been taking CS prescriptions for periods of time much longer than recommended by the Federal Drug Administration (FDA) (FDA, 2020). Discontinuing these prescriptions can be dangerous if not done thoughtfully and is contrary to harm reduction approaches of practice which support improved patient outcomes. Being a major community health provider in a metropolitan area the organization is well situated to coordinate patients with resources for any needs identified by the CSRC such as treatment for substance use disorders, which Zeigler et al. (2016) reported as an unexpected gain. As a consequence of current guidelines, many patients’ symptoms are

undertreated and providers at this organization recognize the importance of individualized treatment planning.

Available evidence shows interprofessional committees provide necessary clinical support for complex cases involving CS prescribing. Stakeholders at this organization have expressed a strong interest in having a CSRC and have volunteered time and voiced their support toward moving this project forward. Interest in this project persists despite the obstacles due to the recognition of the value a committee providing clinical support for CS treatment planning. In recognition of the overwhelming support this project has received, the CMO commented, “a good idea trumps low staffing”. The organization will continue with the case review process and complete at least one PDSA cycle to prepare for organization-wide implementation of this valuable resource as a resource aimed at improving patient outcomes, decreasing staff distress and burnout, and improving therapeutic relationships.

Limitations

Limitations to this QI project include not having a PDSA cycle completed at the time of this writing. The PDSA cycle was intended to test the impact of the CSRC as a clinical resource to address workplace related distress, staff burnout, and therapeutic relationships. Data came from meeting notes and one partially completed self-report survey resulting in poor reliability and validity and no ability to generalize findings.

Conclusions

This QI project demonstrated one process to establish a committee related to improving CS treatment planning at a metropolitan community health organization. Collected information supports moving forward with this project by completing at least one PDSA cycle of the case referral and review process. The CSRC will be implemented organization wide after the PDSA

cycle and stakeholders are satisfied with the case referral and review process. Future evaluation will include the usefulness of the CSRC as a clinical resource. Implementation will also involve increasing CSRC awareness and accessibility for patients. Data will be continuously collected examining impact of CSRC on identified outcomes. Next steps in this QI project will include collecting information on patients' perspectives, acceptance rates of CSRC recommendations, patients' appeals, themes of recommendations including looking at referral rates to specialty services, and changes in baseline data such as number of patient grievances and active CS prescriptions.

Evidence suggests, as the CSRC becomes available as a clinical resource, data will show a decrease in staff burnout, CS related work distress, and improvements in therapeutic relationships. In addition to benefits for this organization, there is potential to add to the limited evidence for interventions aimed at improving health outcomes related to CS prescriptions and addressing a public health crisis. There are often unforeseen costs and benefits of QI projects and close attention will be paid to capture data reflecting these such as referral rates to specialty services which may reflect under- diagnosed and treated conditions, improve care coordination, and identify unmet needs in the community. These data support findings from Zeigler et al. (2016) that many cases referred for review have underlying and often undiagnosed mental health conditions or substance use disorders and require referral to appropriate services for treatment to progress however, this requires these services to be readily accessible in the community.

References

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Appendix A: CSRG Referral Form Template

Provider Submission Template

1. Medical/behavioral condition for which patient is receiving or requesting a controlled substance?

2. Current controlled substance and dosage (if applicable)?
3. Substance Use/Addiction History:
Your question for the committee?

Committee Response Template

The Controlled Substances Review Committee met with regard to [patient name's] case on [date]. The Committee addressed the following questions:

1. Does the patient have a verifiable medical/behavioral diagnosis that warrants treatment with a controlled substance? Have other modalities been attempted and failed?
2. Does the patient have a high-risk history that makes controlled substances absolutely or relatively contraindicated?
3. Has the patient previously violated a controlled substances agreement at [clinic name], been reviewed before by the CSRC, or been discharged from by another clinic for violation of a controlled substances agreement?
4. Does the patient have a mental health diagnosis? Is it being treated appropriately?
5. Is the controlled substance and dosage appropriate?

Based on the above findings, the CSRC recommends the following:
[recommendation for prescribing.
if yes, discuss parameters for ongoing care, monitoring, etc.
if no, provide alternatives (Rx and non-Rx)

consider recommendations for communication strategies

***end of doc

Appendix B: Field Notes

CSRC meeting 1

Date 2.25.22
Time 1700 - 1745

*Hoping to get participation from peer support specialists in the future d/t valuable insight they could provide. Will continue to pursue

PowerPoint presentation (uploaded to Teams channel)
Content:

- Why a committee for controlled substance treatment planning?
    - Public health crisis r/t CS prescribing & call for development of interventions to improve outcomes
    - Specifically in clinical setting- undertreated symptoms, unsafe/inconsistent practice, adverse impact on therapeutic relationships/tx progress, high rates of grievances & prover distress/burnout
    - Limited evidence but what is available supports use of controlled substance committees as a strategy to significantly improve identified problems
- How these committees have been done effectively (improved patient safety & satisfaction and decreased provider distress & burnout) in other clinical settings?
    - 3 clinics published improved outcomes w/ CS committees including 1 in Maine and 2 in OR!! Context about setting & case review process provided on slides
    - Unique setting qualities bolded on slides to bring attention to differences for consideration
- What has been done and what is in the future
    - Identification of problem impacting clinical outcomes & stakeholder buy-in assessed → there is significant staff interest!!
    - Coordination of interested interprofessional staff
    - Development of electronic referral process (examples of templates for referral forms found at end of slides)
    - First CSRC meeting w/ primary agenda to discuss logistics of next meeting & pilot case review
    - In the future: pilot run of case review process (next meeting!!), refining process, making CSRC resource equitable resource available across organization and to patients/staff, collecting data to examine impact on clinical outcomes
    - This project is an opportunity for organization to:
        - solidify OR as a leader in addressing an identified public health crisis by adding to a limited body of evidence & filling a gap in the data (large community health clinic in urban setting providing whole health care)

- Improve health outcomes for our clients, staff, and community

- Additional resources including support with therapeutic relationships, difficult conversations, and controlled substance prescribing

Group Discussion (meeting recorded and saved to Teams channel)

Questions about electronic referral process & documenting recommendations in client's EHR chart
Specifically, moving forward pathway for primary care, behavioral health, and SUDs to "provide information and review charts"
Based on conversations with QM & known processes credible allows improved accessibility between departments
SUDs/BH use credible & would require Epic training to use
PC can access both credible & Epic
*Goal with use of electronic referral is to improve accessibility to CSRC and information sharing between departments

accessing ppt, meeting notes, resources:
Plan is to have shared location for documents/resources found on Teams channel
*Email sent to IT for CSRC channel

Voiced recognition of value for clinical staff and patients of having CSRC available at CBH including mentioning staff "interest in such a resource for years". Emphasized support w/difficult conversations & therapeutic relationships as a valuable resource for CSRC to provide staff b/c these conversations can be challenging and to improve consistency in the way recommendations/topics are communicated.

CSRC Meeting logistics
Frequency: 1x per month
Time expected for meetings: 60 – 90 minutes
Meeting agenda for March: pilot run for case review!!! Aim is to review 1 – 2 cases.
*a doodle poll will be sent out soon to coordinate this meeting

Pilot case review process
Cases electively referred to CSRC vs. charts flagged
Case referred → chart review & case presentation → interprofessional group discussion → formulation of recommendations including support with communication/therapeutic relationships & alternative interventions → recommendations communicated to referring tx team
*Ideally completed referral form and CSRC recommendations can be documented w/in client's chart to improve communication/consistency among care providers about tx planning. Discussed putting additional CSRC related tasks beyond case review on hold at this time d/t staffing shortages and recognizing staff time as a very limited/valuable resource.

Appendix C: Institutional Review Board (IRB) Application Determination

NOT HUMAN RESEARCH

July 26, 2021

Dear Investigator:

On 7/26/2021, the IRB reviewed the following submission:

Title of Study:	Education for providers to improve safety in benzodiazepine prescribing and deprescribing at a Federally Qualified Health Center: A quality improvement project
Investigator:	Constance Henderson
IRB ID:	STUDY00023315
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office