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Do Not Miss Your Shot: Improving Follow-up in Patients Receiving Long-Acting Injectable Medications

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DOCUMENTATION OF MASTERY OF DNP PROGRAM: MANUSCRIPT

Do Not Miss Your Shot: Improving Follow-up in Patients

Receiving Long-Acting Injectable Medications

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ABSTRACT

Background: Serious mental illness including schizophrenia and bipolar disorder affects 1 in 24 adults in California. These chronic disorders are difficult to treat and often sabotaged by medication nonadherence. Long-acting injectable (LAI) medications are one strategy to combat medication nonadherence. Effectively providing treatment with LAI medications can be challenging at the clinic level.

Objectives: Reduce the number of days without medication by reducing the number of days between injection due date and injection administration for patients receiving LAI medications.

Design: Establish appointments for all injection visits. Standardize visit protocol for injection encounters to optimize provider time. Arrange immediate follow-up and prompt rescheduling of missed injections.

Results: Number of patients receiving an injection more than one week late decreased by 20%. Average number of days late decreased from 10 to 6.

Conclusions: Appointments and reminders reduced number days without medication in patients receiving LAI medications. Standardization of injection visits improved clinic productivity.

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Introduction

Problem Description

  Mental illnesses are among the most common health conditions in the United States. Serious mental illnesses (SMI) are those that cause significant impairment in the affected individuals' ability to perform one or more daily activities. SMI affects 4.5% of American adults and includes diagnoses of schizophrenia and bipolar disorder (Substance Abuse and Mental Health Services Administration, 2018). Schizophrenia affects 1.2% of American adults (Nemade & Dombeck, 2009) and bipolar disorder affects 2.8% of American adults (National Institute of Mental Health, 2016). In California 1 in 24 adults are diagnosed with SMI (California Health Care Foundation CHCF, 2018). These chronic diseases impact patients, families, healthcare systems and society as a whole.

  The clinical and financial burden of SMI is significant. According to a 2015 Global Burden of Disease study, the leading causes of disease burden in the United States are mental health and substance use disorders (Kamal, 2017). At 12.0 per 100,000 the U.S has the highest rate of deaths from mental health and substance use disorders. This is almost double the next highest country, France at 6.5, and more than double the comparative country average of 4.9. In 2010 the global cost of mental disorders was $2.5 trillion (Trautmann, Rehm, & Wittchen, 2016). This included both direct (e.g. hospitalizations) and indirect (e.g. income loss) cost considerations. Nationally, in 2013 total expenditures for mental illness in the United States was $89 billion (Kamal, 2017). On the state level, in 2011 of the 5% of Medi-Cal service users with the highest costs of care, over half of those individuals were treated for a mental health condition (CHCF, 2018). This was more than double the percent of individuals treated for hypertension or diabetes. Reports show increases over the years that are likely to continue.

Available Knowledge

One of the most troubling problems providers face in effectively treating individuals with SMI is achieving medication adherence. The issue of nonadherence is a common concern in medical and psychiatric populations alike. Nonadherence applies to any treatment recommendation (e.g. diet, exercise, medication) and occurs on a spectrum with the individual refusing all or some of the recommendations. This paper focuses on nonadherence as it applies to medications. Medication nonadherence can be overt, intentionally refusing medication, or accidental, forgetting to take medication. Estimates of medication nonadherence in patients with SMI vary widely depending on study design and reporting criteria. In studies of patients with schizophrenia or bipolar disorder where nonadherence was defined as taking medication 80% of the time or less, estimates of were about 50% (Haddad, Brain, & Scott, 2014; Jawad, Watson, Haddad, Talbot, & McAllister-Williams, 2018).

An individual's attitude, insight and cognition all impact their ability to adhere to medication regimens (Haddad et al., 2014; Jawad et al., 2018). Some patients believe medications do not work or are harmful. Others stop taking medications prematurely, believing they are no longer necessary once symptoms are alleviated. For many patients the shame and stigma associated with mental illness prevents them from taking medication. Complex medication schedules or unwanted side effects further intimidate patients from adherence. Often the course of a patient's illness or substance use alters their decision-making and inhibits their ability to follow medication regimens. When patients are willing to adhere to prescribed medications, they may have difficulty obtaining medications and refills.

Medication nonadherence can lead to symptom exacerbations that result in one or more of the following: unemployment, hospitalization, loss of personal relationships, homelessness,

danger to self (suicide), danger to others (violent crime), arrest, or incarceration (Haddad et al., 2014; Jawad et al., 2018). These risks are significant and should be avoided when possible.

Rationale

Long-acting injectable (LAI) medication formulations are a potential solution to medication nonadherence and its subsequent related complications. Second generation antipsychotic (SGA) medications are recommended by treatment guidelines for SMI and FDA approved for the treatment of schizophrenia and bipolar disorder (Llorca et al., 2013). Due to intramuscular administration, LAI SGA are potentially distributed at a more steady-rate as compared to oral formulations. The continuous release of medication through the body helps maintain therapeutic levels and sustain medication benefit. Comparatively, missed oral doses can cause fluctuations resulting in sub-therapeutic medication levels. Multiple studies have shown the effectiveness of LAI SGA in nonadherent patients. LAI SGA are associated with fewer hospitalizations, shorter hospital stays, and increased scores on measures of medication satisfaction, quality of life, and patient functioning (Joshi, Mao, Biondi, & Millet, 2018; Stip & Lachaine, 2018).

LAI SGA are dosed every 2, 4, or 12 weeks depending on the medication. For patients, these dosing intervals eliminate the burden of taking a pill every day or multiple times a day. For providers and care-partners, the burden of monitoring medication adherence is greatly reduced because missed injections are easier to track than daily behaviors. Providers are able to intervene quickly when they see an injection has been missed which helps prevent severe decompensation. Providers can assist patients in maintaining medication adherence by scheduling appointments when injections are due. Research shows that appointments accompanied by mobile reminders via phone-call or text message increase appointment

attendance in individuals with SMI (Filippidou, Lingwood, & Barnet, 2014; Gurol-Urganci, de Jongh, Vodopivec-Jamsek, Atun, & Car, 2013; Reda, S., Rowett, M., & Makhoul, S. 2012). Additionally, missed appointments elicit early detection of missed injections for prompt intervention.

  Framework. Successfully implementing an appointment system and subsequent follow-up protocol requires input and buy-in from multiple interdisciplinary team members. The IOWA model employs a multidisciplinary team approach to evidence-based practice that considers the patient, provider and organization throughout the implementation process (Schaffer, Sandau & Diedrik, 2012).   The steps of the model are mapped in a way that allows the user to move forward or backward as needed (Melnyk, & Fineout-Overholt, 2015).   Feedback loops permit continuous movement through the model and prevent stagnation at key points of transition and decision-making. The process begins with staff identifying a "trigger" such as a clinical problem or knowledge deficit. Next a literature search is conducted to determine what evidence exists that might support a change in practice. Then an intervention is piloted for a brief time and evaluated for its efficacy. Subsequent trials of the intervention are conducted, with necessary alterations, until an amenable and effective solution is reached. These trial periods allow the team to monitor and evaluate the process to determine goal attainment.

  In keeping with the IOWA model, the DNP student assembled a team consisting of a prescriber, a medical assistant (MA), a patient service representative (PSR) and an administrator. Later, staff from pharmacy and Information and Technology (IT) were included. The topic of medication adherence was discussed and strategies for improving treatment with LAI medications were contemplated. A small study was piloted. After evaluating outcome indicators additional changes were discussed for sustainability.

Specific Aims

The purpose of this evidence-based project was to improve medication adherence in patients receiving LAI SGA for the treatment of SMI, namely schizophrenia and bipolar disorder, by reducing the number of days without medication as calculated by number of days between injection due date and injection administration.

Methods

Context

In a Federally Qualified Health Center (FQHC) in San Diego county barriers to effectively providing treatment to the population of patients receiving LAI SGA were recognized. First, patient's receiving LAI treatment needed to be accurately and consistently identified. Once identified, staff needed to ensure that all patients receiving LAI treatment had appointments scheduled for injection administration. These patients were often told to return to the clinic as a "walk-in" to receive their injection. However, as walk-ins without appointments these patients did not have access to the benefits of appointment reminders. Adherence to injection schedules and timeliness of injections was uncertain. As a result of the clinic not having registered nursing (RN) staff it was also imperative to have consistency in how injection visits were conducted and what information was gathered. Lastly, the clinic was in need of a strategy for the prompt identification and intervention of patients that had missed injections.

Interventions

The foundation of this project would not have been possible without first creating an accurate and reliable list of patients receiving LAI medications. Collaborating with staff from the IT department an area of the chart was selected for the documentation of therapeutic injections. MAs were advised to document all administered injections in this section of the

Electronic Health Record (EHR). Documenting injections was already part of injection administration workflow, however by utilizing the same designated area of the EHR IT staff was able to generate a report of patients receiving LAI medications. After approximately 3 months, the report was accurate, consistent, and reliable.

Scheduling appointments for injections and reminding patients of those appointments was the second and most important intervention. In some cases, patients' follow-up visits coincided with their injection schedule, so every 4 weeks they received both services. For other patients, follow-up appointments were scheduled weeks before or after their next injection was due. These patients were prioritized for appointment scheduling. It was unrealistic in this busy FQHC to add appointments to providers' already packed schedules. Instead a place holder provider was created. This provider was named "Behavioral Health (BH) LAI." The BH LAI provider accepted up to six appointments per day; three in the morning between 8-10am and three in the afternoon between 1-3pm. These times were selected consciously with provider preference in mind as they were noted to be generally less busy and least disruptive. With appointments scheduled patients now had access to the clinic reminder system, which consisted of (1) A confirmation text message three-days prior to the appointment, (2) A phone call two-days prior to appointment, if text not confirmed, (3) A phone call one-day prior to appointment, if previous call not confirmed.

Due to a lack of RN staff at this clinic all injections were administered by MAs. This meant that whenever a patient came for an injection, walk-in or otherwise, a provider would need to be interrupted to verify the medication before it was administered. In light of this inevitable disruption a protocol was devised to standardize patient preparation and information gathering. A 10-question template was developed that ascertained the following information: (1)

Medication name, (2) Last medication dose given (amount mg), (3) Injection last given (date), (4) Location of last injection (anatomical), (5) Dosing interval (number of weeks), (6a) History of adverse reaction, answering 'yes' triggers follow-up question (6b) Type of reaction and severity, (7) Injection verified with (provider name), (8) Due for next injection (date), (9) Next visit scheduled (date), (10) Next injection scheduled (date). The first six questions provide a clinical snap-shot of the patient. These questions are particularly important in instances where the physician being asked to verify the medication is not the patient's usual provider, as may be the case if the primary provider is out of the office or busy with another client. The latter three questions ensure appropriate follow-up appointments are scheduled before the visit ends and the patient leaves.

Upon completion of the "LAI Visit Template" MAs were asked to inform the provider verifying the injection that the patient was waiting in the exam room. The provider would then meet with the patient face-to-face, do a brief assessment, confirm the appropriateness of the injection and verify the medication. At this point the visit was moved from the "BH LAI" provider schedule to the verifying provider's schedule and titled "BH Enhanced Medical Visit (EMV)"

As visit standards were established productivity opportunities emerged. The Evaluation and Management Services guide was used to obtain billing requirements for various CPT codes. Criteria for visit code 99212 requires (1) problem focused history, (2) problem focused exam, (3) straightforward decision-making/minimal risk (American Academy of Child and Adolescent Psychiatry, 2012). In ethical consideration of visit requirements and documentation it was determined that BH EMV could be billed using the 99212 CPT code. Per Medicare this code is worth 0.72 Relative Value Units (RVU) and eligible for financial compensation in the

Prospective Payment System (PPS) (Centers for Medicare & Medicaid Services, 2018). Previously these visits were listed as "Lab Only" or "Injection Only" which represent zero RVU and no reimbursement.

Lastly, a protocol was developed to address what to do when a patient missed an injection. PSRs were advised to contact the patient right away to facilitate prompt rescheduling. PSRs would attempt to contact the patient up to six times, if unsuccessful after these attempts a letter would be sent to the patient's address on file and a telephone encounter would be sent to the prescribing provider for further instruction.

Measures

The primary measure was number of days between injection due date and injection administration as this demonstrated number of days without medication. A de-identified excel sheet tracked injection schedule due dates and administration dates for each patient receiving LAI medications. Differences between these two data points was recorded in days (e.g. 0, 1, 2…) for future analysis.

Productivity was a secondary measure and required analysis of billing and coding behaviors pre and post intervention.

Analysis

SPSS software was used to generate descriptive statistics of pre and post data. A time frame of 3-months or 12-weeks was selected for both pre and post data collection. This time frame was selected because the longest interval between injections is 12 weeks. Pre data were collected from September to December. Post data were collected from December to March without overlap.

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Results

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During pre-data collection there were 38 patients identified as receiving treatment with a LAI SGA; paliperidone, risperidone, or aripiprazole. Five of these patients were removed from the analysis because they left the clinic or discontinued LAI treatment unrelated to this project. Of the remaining 33 patients 20 were late receiving the most recent injection by at least one day. Ten of the late patients, 50%, missed the injection by more than seven days or one week. The range of late days was 1 to 39. On average these 20 patients were late by 9.9 days, meaning they went almost 10 days without medication.

Post data analysis of the same 33 patients identified 19 patients as late to receive the most recent injection by at least one day. Eight of the late patients, 42%, missed their injection by more than seven days or one week. The range of days late was 1 to 56. On average these 19 patients were late 11.5 days. Post intervention data includes three outliers, which will be covered in more detail in the discussion section. Results from analysis of the data with the outliers removed is as follows: (1) 16 patients were late for the most recent injection by at least one day, (2) five patients, 31%, missed their injection by more than one week, (3) range of days late was 1 to 21, (4) average days late were six.

The number of patients that did not have an appointment scheduled to receive their next injection was 17 or 52% of pre-intervention patients. Post-intervention this number decreased to one or 3% of patients.

Analyzing visit type and coding pre data 11 visits were identified that had been coded by a zero RVU, no reimbursement label of "Lab Only" or "Injection only." Post intervention this number decreased by 36% with only four visits coded as "Lab Only" or "Injection Only." In addition to reducing loss, productivity increased in the form of 31 new appointments billed with the 99212 CPT code. This increased RVUs from 0 to 22.32. Of note the time frame for

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gathering post intervention billing data included the month of November, because one provider was piloting the intervention.

Discussion

Summary

The primary measure for this project was a reduction in days without medication. The results show that creating appointments for patients receiving LAI SGA can reduce the number of patients receiving injections late and the number of days injections are given late. There was also a significant change in clinic productivity. Though not formally measured the changes implemented during this project likely improved quality and access to care by altering work flow to include face-to-face time between providers and patients. Allowing providers to observe the relative stability of the patient. Provider efficiency potentially increased as a result of having the same baseline information for each patient. Likewise, MA efficiency may have improved by eliminating the waste and redundancy of unclear visit expectations.

One unanticipated issue that came from this project was the consideration of how LAI medications were ordered and stored for administration. It came to light that often samples were used because they were readily available and quicker than waiting for prescription delivery. In some cases when prescriptions were ordered in advance and stored in the clinic patients did not come in and the medications went to waste. Adding one step to the appointment reminder process addressed the issue of ordering and returning medications. Per current work-flow, appointment reminders stop as soon as the patient confirms they will be at the appointment. So, upon appointment confirmation the MA was tasked with requesting the medication from the pharmacy to ensure availability and timely delivery. The clinic made arrangements with a

pharmacy located nearby that offered same day delivery. This small adjustment reduced waste

from of unused injections and freed up sample stock for emergency situations.

Interpretation

Improvement is most successful when clinic strengths are highlighted, and current

practice is expounded upon. This FQHC was going above and beyond to provide treatment with

LAI medications despite a lack of RN staff. Clinic staff were flexible and accommodating to

patients receiving LAI treatment. These behaviors are a testament to the clinic's views on the

benefit and importance of LAI treatment options.

By creating a "BH LAI" provider, the clinic's tested and effective three-day appointment

reminder system, text – call – call, was expanded to include patients receiving LAI medications.

Excluding outliers, this intervention reduced the number of people receiving late injections from

20 to 16. Average number of days injections were missed decreased 40%, from about 10 to 6.

The number of patients missing injections by more than seven days or one week decreased 20%,

from 10 to 5.

The one-week marker is important to highlight for a couple of reasons. The first is

functional, in that it is not always possible to have patients return on the exact day their injection

is due. One week provides a realistic cushion for these situations. The second reason is clinical.

Thanks to pharmacy staff involvement, a color-coded, easy-to-read chart was created combining

recommendations and package insert information for each LAI SGA formulation and dose

offered by the FQHC. Chart headings included drug name, FDA approved indications, dosing

options for initiation, maintenance and adjustments, how early an injection can be administered

and what to do when an injection dose is missed. The clinical implications of this final column

are perhaps the most important to this project. Now prescribers have a reference to determine

best practice when a patient arrives late for an injection. In most cases no adjustment to treatment is needed as long as the patient is not more than one-week late. Beyond the one-week mark adjustments, such as oral supplementation, may be necessary to help the patient regain therapeutic medication levels.

By standardizing the work flow surrounding LAI visits, the provider is able to spend time with patients in a focused rather than distracted manner. The information gathered in the visit template provides a clinical snapshot for the prescriber verifying the medication. This change has been particularly helpful when prescribers are asked to verify injections for patients, they may know little about because they are not the primary provider. By improving access to LAI medications and reducing number of days without medication, it is possible these patients are more stable which could positively impact the clinic in other ways (e.g. fewer patients in-crisis, fewer hospitalizations). With little to no cost to the clinic functioning has improved, resulting in net benefit.

Limitations

As mentioned above, post intervention data analysis identified three individuals considered to be outliers. This determination was made because these individuals were not exposed to the intervention, as they each received their last injection prior to the project start date in early December. While these individuals were identified as high priority, staff were unable to contact them to schedule injection appointments. When the patients did come to the clinic it was not the result of any clinic intervention.

One of the outliers lost their phone, being homeless there was no way to contact them. This patient was brought to the clinic by a member of the Psychiatric Emergency Response Team (PERT) and reported a psychiatric hospitalization that coincided with their missed

injection. Another outlier had received the messages to come in but was too paranoid and disorganized to follow through. These select individuals demonstrate potential limitations of this intervention. Namely that appointments, reminders and contact after missed appointments is only possible if the patient has a way to be reached.

Patients that are homeless or without communication devices might be considered high-risk for medication nonadherence due to multiple barriers to receiving medications. One solution might be to connect these high-risk individuals with additional resources such as Assertive Community Treatment (ACT) that treat patients in the community or navigation services that can assist patients in getting items like government funded cellphones. This FQHC has navigation staff in house available to assist in these endeavors. Navigation can also help address housing, food, and transportation needs.

Future Implications.

Sustainability of project outcomes will depend on the extent to which staff are able to continue interventions independent of student orchestration. Currently the DNP student monitors the de-identified patient list weekly. The student determines which patients are expected for injections that week, notes absentee patients and tracks follow-up protocol. Thanks to the continued commitment and assistance from IT staff a formal report with this information has been created. This report can be accessed by MAs and generated weekly. A project champion (MA) has been identified who is willing to take on weekly monitoring tasks. Currently the DNP student is working with IT and the MA to assess report efficacy and ensure ease of use. This project champion is also interested in expanding the project population to include patients receiving LAI vivitrol for Opioid and Alcohol use disorder, as well as expanding to other clinic locations of this FQHC.

Conclusions

The primary intervention for this project was the creation of an injection visit that would trigger appointment reminders to help improve medication adherence and reduce number of days without medication in patients receiving LAI SGA for the treatment of chronic SMI of schizophrenia and bipolar disorder. Medication management is critical to maintain optimal functioning and to avoid risks associated with symptom exacerbation. Additionally, the productivity related outcomes made possible by this project could potentially to be applied to other clinic locations of this FQHC.

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