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Brooks, Delora, "Evaluating Controlled Substance Documentation in an Electronic Medical Record" (2019). *Dissertations*. 885.

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Evaluating Controlled Substance Documentation in an Electronic Medical Record

Doctor of Nursing Practice Project Presented to the
Faculty of Graduate Studies
University of Missouri – St. Louis

In Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice
by
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December 2019

Evaluating Controlled Substance Documentation in an Electronic Medical Record

Abstract

The Centers for Disease Control and Prevention (CDC) directives issued in 2016 gave guidelines for safely prescribing opiates; however, primary source discussions about methods used for documenting opioid and controlled substance monitoring within an electronic medical record (EMR) are limited (Hussain, Nelson, Polston & Zheng, 2019).

This leaves individual providers to determine the appropriate way to document.

Inconsistent documentation may not protect providers or organizations from regulatory, civil or criminal liability. As stated by Raveesh, Nayak & Kumbar (2016), “The best way to handle medico-legal issues is by preventing them”. Even with the advent and widespread use of EMRs, documentation is still often limited to basics: diagnosis, medication, dosage, procedures, referrals, and follow up (Schneider, 2014). The purpose of this project was to implement a practice improvement change which included creation of a standardized template and a central location for documentation of controlled substance monitoring. This allowed providers to document, see the dates and results for urine drug screens (UDS) or pill counts, review any concurrent schedule II or III medications, and log prescription drug monitoring database (PDMD) checks. Data indicated an improvement in documentation frequency for UDS and PDMD checks at both 30 and 60 days; however, this increase was only statistically significant for UDS at 30 days with $p = 0.004$. The increase was not found to be statistically significant for either UDS or PDMD checks at 60 days.

Introduction

The state of the science for opioid use in primary care is publicly being debated on a frequent basis. Proof of this is available every time we turn on the news or view our social media accounts; there are numerous individuals, families, and healthcare providers sharing how opioid addiction and substance abuse impacts them daily (Green, 2017). Opioid overdoses have become so commonplace that many states now permit laypersons to carry the injectable opiate antagonist, Narcan (National Institute on Drug Abuse [NIDA], 2019; Substance Abuse and Mental Health Services Administration, 2018).

According to the Centers for Disease Control and Prevention (CDC), more than 11 million Americans admit to abusing opiates (CDC, 2016 para. 3). Medical providers have recognized that the prescription of opiate-based pain medication has become a significant health concern due to the high risk of addiction, over-dose related illnesses and numerous deaths. As a result, providers and health care organizations have rushed to change their prescribing habits based on the CDC's directives, which detail the appropriate management of opioid pain medications and list other medications that should not be prescribed in conjunction with them (Clinical Advisor, 2016; Dowell, Haegerich, & Chou, 2016). In response, some providers have drastically cut the number of opiates they are prescribing, others have begun referring patients out to pain management centers, while yet others have stopped prescribing opiates entirely (Lagisetty, Healy & Garpestad, 2019). However, the documentation of all controlled substances remains inconsistent.

Every state in the U.S. now has a law or regulation requiring the creation and use of a prescription monitoring database (PDMD) for providers to track what controlled

substances patients receive, how often, and from whom (Gudoski, 2015). Nationwide, the comprehensiveness and usability of PDMDs appears to vary significantly (Davis, 2018; Gudoski, 2015; Inzerro, 2018). The robustness of the databases has changed over time with varying levels of impact on overdose-related illnesses and deaths (Smith et al., 2019). Much closer to home, Missouri still does not have a functioning state-wide PDMD (Erickson, 2019). This means that providers and organizations cannot track the prescriptions of any particular patient across the state and may be unknowingly further contributing to the crisis.

The purpose of this project was to implement a practice improvement change which included the creation of a standardized form within an electronic medical record (EMR) on which providers could document all aspects of controlled substance monitoring. This template included dates/results of urine drug screens (UDS) and pill counts, any concurrent Schedule II-IV prescriptions, and PDMD reviews. The PICOT and project objectives are as follows: **(p)opulation**--providers in specified family practice groups who prescribe controlled substances; **(i)ntervention**--implementation of new controlled substance documentation template; **(c)omparison**--comparison of pretest documentation frequency with post-test frequency; **(o)utcomes**--increased provider documentation from pretest rate of less than 20%; and **(t)ime**--demonstrable improvement in documentation compliance at 30 days and 60 days after implementation.

Literature Review

Healthcare provider education is centered on ensuring providers learn to properly diagnose and treat illness and disease, but providers are often left to their own devices in learning how to appropriately document that treatment (Balestra, 2017). Standard

documentation, even with the advent and widespread use of EMRs, is still often limited to the basics: exams, diagnosis, medication, dosage, procedures, referrals, and follow up dates (Schneider, 2014). Except in very egregious circumstances, regulatory penalties associated with substandard documentation are limited to fines and licensure penalties, but do not normally result in criminal prosecution. However, even the perceived over-prescription of opiates or other controlled substances may result in investigation by insurance carriers, the Drug Enforcement Agency (DEA), or law enforcement (Schneider, 2014).

The existing literature focuses very heavily on the importance of patient compliance and monitoring of individuals taking opiate-based pain medications and other controlled substances. There are also numerous studies and articles with reams of data indicating recommendations for appropriate prescribing of opiates in nearly every population including geriatrics, adolescents, pregnant women, postoperative adults and children. The literature supports the CDC recommendations for regular drug screens, pill counts, avoidance of concurrent opiate-benzodiazepine or hypnotic prescriptions, and regular checks of state-wide PDMD databases (Dowell, et. al, 2016). However, the literature does not show that these tools have been particularly successful in reducing the number of overdoses or overdose-related deaths (Davis, 2018; Inzerro, 2018). Nor does it adequately address the potential liability of prescribers associated with such adverse outcomes (Kawi, 2016). Very recently, national news outlets published stories regarding a physician found to be criminally liable in the overdose death of an opiate-addicted patient; resulting in a life sentence for the physician (Associated Press, 2019). Part of the case against this physician was predicated on the lack of an appropriate medical exam, no

documentation of drug screening, no checks of the PDMD, and no medication reviews.

Most large organizations and private practices utilize some form of EMR, but there is no consistent method for documenting controlled substances within any of them, or method to transfer data across platforms. While the CDC guidelines from 2016 gave suggestions and methods to more safely and appropriately prescribe opiates, there were no recommendations for documentation standards. Primary source discussions about effective methods for documenting the monitoring of opiates and other controlled substances within an EMR continues to be limited (Hussain, Nelson, Polston & Zheng, 2019). The majority of the conversation surrounding the efficacy and deficiencies of the existing methods is happening in blogs, online professional discussion boards, and editorial articles, many of which are not formally published in scholarly journals. Nor does there appear to be significant literature dedicated to addressing the need for documentation that can be quickly reviewed and transmitted to other providers or electronic systems. Since the opioid crisis remains front page news, and was even mentioned by President Trump during the State of the Union Address (The White House, 2019), the likelihood of some form of regulatory ruling being issued by the DEA, Centers for Medicare and Medicaid (CMS), or Office of the Surgeon General will only increase.

Poor documentation of monitoring tasks can be linked to barriers and challenges experienced by providers in day-to-day practice (Davis, 2018; Kelly, 2014). In some cases, organizations and providers were not fully utilizing all features of the EMR to ease the burden of documentation. One example is providers not being able to electronically prescribe (e-scribe) controlled substances. E-scribing provides an additional layer of security, eliminating the risk of diversion by removing access to the providers' DEA

number on a written prescription or the ability to change the prescription (DEA, 2010). Additional barriers include: lack of organizational policies, lack of a consistent documentation format, data not being transferable amongst EMRs, separate logins for each PDMD, and the need to check more than one PDMD for cities on state borders. The inefficiency of the PDMDs is exacerbated by requiring providers to leave the EMR they are working in, login to an entirely different system to complete searches (Kelly, 2014). This lack of easily recognizable, reproducible, transmissible documentation increases the likelihood that patients who are abusing or misusing controlled substances will not be identified; thereby also increasing the medicolegal risks to the providers, practices, and organizations.

According to Brummond, et al. (2017), the American Journal of Health-System Pharmacy responded to the increasing risks and liability with recommendations that all health care organizations develop a comprehensive framework for preventing the diversion of controlled substance medications and improving documentation. Developing a comprehensive framework for controlled substance management may be easier said than done. Quality and process improvement initiatives can often be difficult to implement, especially in larger organizations where there may be issues of complexity and cost, questions of causality, policy or regulatory considerations, and substantially differing opinions amongst stakeholders (Sollecito & Johnson, 2013). However, the framework for appropriate documentation already exists in the form of guidelines for prescribing and monitoring (CDC, 2016), existing PDMDs (Gudoski, 2015), and EMRs that are capable of submitting controlled substance prescriptions electronically (DEA, 2010). The challenge will be to integrate the individually limited tools into a streamlined

procedure that providers will find usable and implementable in daily practice.

The organization and practice group where this project took place had no existing corporate policy to set the frequency of documenting drug screens, pill counts, and checks of the PDMD; nor were there any specific tools to ensure consistent, reproducible, researchable documentation of monitoring tasks within the EMR. This left the individual providers to determine the most appropriate way to document, which may not be enough to protect them or the organization from regulatory, civil, or criminal penalties. The goal was to improve the documentation of identified providers and practices without losing sight of the need to have improved outcomes for individual patients.

Framework

The framework for this project was the plan-do-study-act (PDSA) cycle which provides a scientific method to apply single or multiple process changes to real-world situations in an organizational setting once an aim has been set (Agency for Healthcare Research and Quality [AHRQ], 2013; CMS, 2017). PDSA cycles allow for (P) planning the method of observation and collection of data prior to the intervention, (D) initiation of the intervention on a small scale, (S) analyzation of the pre and post intervention data, (A) and determination of future actions based on the outcomes. The PDSA cycle was originally developed for use in industrial processes, but has been shown to be amenable to application in clinical settings (Upshaw, Steffen and McLaughlin, 2013).

Method

Design

This project was designed to be a quality process improvement. The problem was identified as a barrier to health care providers utilizing the EMR to monitor controlled

substance compliance. The goal was improvement in EMR documentation frequency with respect to UDS and PDMD checks. Process change was implemented via creation of a controlled substance template in the EMR. The proposed template was based on a medication documentation tool for warfarin already available in the EMR.

Setting/Sample

The setting for this project consisted of four family practice offices with a total of seven providers. The practices treat all age ranges--children, adult, adolescent and geriatric patients. The samples included any chart with a controlled substance prescription. The selected charts were chosen based on EMR-generated controlled substance reports. The pretest sample size was 270 charts. The post-test samples were 188 charts and 201 charts at 30 and 60 days respectively. All charts meeting the criteria within the given time frames were reviewed.

Approval Processes

Administrative approval was obtained from the director of clinical practice management. The project plan and details were submitted to the DNP project chairperson, capstone committee, and UMSL IRB for review and approved. IRB approval was granted based on exemption category 4 as no patient risks were identified. Potential benefits of the project included the reduction of provider and organizational risk management profiles due to improved documentation. Ethical considerations of the project included the avoidance of any identifying information and avoidance of a perception of bias in data analysis.

Data Collection/Analysis

No identifiable data was collected on individual patients. Collected data was

numerical only and applied to individual markers as to whether a UDS or PDMD check was performed during the established timeframe. Data regarding pill counts and concurrent Schedule II-IV prescriptions was excluded. The project focus was narrowed to evaluate UDS and PDMD checks based on literature which identified those as most useful in preventing overdose, misuse, and abuse. The resulting data was collated in tables utilizing IBM Statistical Package for the Social Sciences (SPSS). Direct comparisons of compliance data before and after implementation of the template was utilized. Compliance data was reevaluated at 30 and 60 days after implementation. Six-month post-intervention data was collected and reviewed after completion of the project; however, the results were not completed in time to be included here. Final results, including the six-month post-test data, will be submitted to the organization for evaluation and consideration of additional PDSA cycle implementation.

Procedures

The documentation tool was created by the corporate IT department and integrated into the EMR. The new documentation process was implemented at all four practice locations. Compliance rates were evaluated 30-days after implementation and again at 60-days via EMR-generated controlled substance reports. Statistical analysis of pretest and post-test data was completed using IBM SPSS software.

Planning

Organizational approval for this project was obtained. DNP committee and university IRB committee approval obtained. Pretest rates of compliance were established and evaluated. Post-test compliance was established and evaluated.

Results

The purpose of this project was to evaluate provider documentation of controlled substance monitoring. The question posed was whether providers would be more compliant with documentation of controlled substance monitoring if they had a template within the EMR. The data was based on retrospective chart reviews of seven family practice providers from four offices. The data included pretest and post-test evaluations of provider documentation of UDS and checks of the PDMD. Pill counts were not included in the data collection as the providers stated pill counts were not part of their routine compliance checks unless diversion/misuse was suspected.

The pretest data evaluated a 6-month time span from June 2018 through December 2018. The initial report included 492 charts. Charts in which the patient received a one-time only controlled substance prescription were eliminated. The final chart reviews yielded 270 charts for pretest evaluation. Data was recorded as yes = 1, no = 2 to answer whether or not the chart in question contained a UDS and/or a check of the PDMD during the specified time period. The frequency distribution of the pretest data indicated that UDSs were performed at a rate of 23.3% and PDMD checks were performed at a rate of 9.3%, as illustrated in the frequency tables (see Appendix I).

Providers began using the new documentation template on April 11, 2019. The first post-test data collection occurred 30 days later. The 30-day posttest chart reviews were conducted in a similar manner to the pretest reviews. Charts with one-time only controlled substance prescriptions were eliminated, yielding an $N = 188$. At the 30-day mark the frequency distribution showed UDS were performed at a rate of 46.3% and PDMD checks were performed at a rate of 17.6%, as illustrated in the 30-day posttest

frequency table (see Appendix I). When compared to the pretest data via the use of the Independent Samples Kruskal-Wallis Test, the null hypothesis for 30-day UDS is rejected as $p = .004$, which is less than the .05 threshold (see Appendix II) representing a statistical change in provider compliance. When comparing pre and post-test PDMD checks, the means were also evaluated using the Independent Samples Kruskal-Wallis Test. The findings were acceptance of the null hypothesis at 30-days with a $p = .252$ (see Appendix II), indicating there was no statistically significant change in provider compliance.

At the 60-day mark, the charts were again reviewed with the same exclusion criteria previously established, yielding an $N = 201$. The frequency distribution at 60-days reveals drug screens were performed at a rate of 19.9% and PDMD checks were performed at a rate of 45.8% as found in the frequency tables (see Appendix I). The 60-day data were then compared to the pretest data using the Independent Samples Kruskal-Wallis test. The resulting 60-day UDS had a $p = .339$, affirming the null hypothesis and indicating no change in provider compliance from the pretest comparison (see Appendix II). At 60-days, the means were also evaluated with the Independent Samples Kruskal-Wallis Test, yielding a nonsignificant p value of .505, again indicating no change to provider compliance.

Discussion

In evaluating the pre and post-test comparisons, it was found that the null hypothesis was rejected at 30 days for UDS checks, but accepted at the 60-day mark, indicating there was improvement in documentation at 30-days, but not at 60-days. The discrepancy in improvement can be explained by timing of the UDS. If a patient had a

UDS at 30-days, they likely did not need one at the 60-day mark. It was also found that the statistical evaluation for the PDMD checks at both the 30-day and 60-day marks was not considered statistically significant despite a much higher frequency at both. Part of the lack of statistical significance may be due to PDMD checks mostly occurring during face-to-face encounters. A substantial number of the prescriptions were written as the result of patient's calling in for refills. Additionally, the 30-day, 60-day data only looked at the dates matching those for written prescriptions.

Due to proprietary software constraints, the corporate IT team was unable to create the documentation template as it was originally proposed. In order for the template to be built as requested, the changes needed to be approved by the software owners, then built by their application development team, likely at a substantial cost. Despite multiple requests, no one from the EMR owner group was able to commit to being interviewed for this project. Instead, the corporate IT team created a template to be used in the physical exam portion of the chart. Feedback from the participating providers indicated that they were forgetting to utilize the template during encounters because it was not easily accessible, and they often had to go back to the encounter to document in the template later. Having it only accessible during face-to-face encounters prevented providers from utilizing the template for call-in refill requests. Providers also indicated that the tool was "clunky" because it (a) required too much typing, (b) was only accessible in the physical examination section of the EMR, (c) only accessible to the providers, (d) was not easily found. Repeating the study with an improved, more accessible template might yield different results. It might also be beneficial to add in excluded monitoring tasks, such as checks for other scheduled medications, to further

evaluate compliance.

Since completion of the project, the EMR has added additional functions making it easier for providers to safely prescribe controlled substances. Providers can now electronically prescribe all Schedule II-IV drugs. Patients no longer have to pick up their prescriptions in person from the office, fewer prescriptions get lost/stolen, and providers can be assured that the prescription they have written has not been altered in any way. The EMR also now links directly with the state PDMD from the individual patient's chart, allowing the provider to see what controlled substances the patient is receiving, from whom, when the prescriptions were written/filled, and the number of morphine milligram equivalents (MMEs) the patient is receiving daily. The PDMD link also contains a dashboard indicating how at-risk the patient is for overdose/misuse/abuse based on the prescriptions they are receiving and the number of MMEs per day. Each time the patient's chart is opened, the PDMD link is immediately visible indicating when the last check was performed and which provider checked it. It is likely that evaluation of the same data at the 6-month mark will indicate a statistically significant improvement in compliance as the tools are much easier access and utilize.

Conclusion

The participating providers showed substantial frequency improvement in documentation at both the 30 and 60-day checks. Statistically, the only significant improvement of their controlled substance monitoring was with UDS at 30-days. The lack of statistical improvement in the PDMD checks may be attributed to the need to leave the chart to check the database as well as lack of functionality in the template. It may also have been due to the relatively small sample size and short time frame. The

template that was created by the corporate IT team, was less than ideal for several reasons: (a) only accessible in one section of the chart, (b) only accessible to the providers, (c) required too much typing by providers, (d) was not searchable in the chart. Based on the PDSA framework, the recommendation would be to abandon the current template, have a new template created, and run the cycle again.

Despite the improved functionality of some tools since the end of the project, there is still no single chart section or template where providers can document their controlled substance monitoring tasks. When other areas of monitoring such as pill counts and concurrent prescriptions of other scheduled medications are added, the need for an easy to use template may become more obvious. While the template used for this project was not ideal, it did set a framework for the type of template that might be needed. Having accessible and effective documentation tools not only aids providers in providing better, more appropriate care for their patients, but also reduces the risk of liability for the individual providers and organizations.

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Appendix I: Frequency Distribution Tables

Pretest UDS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	63	23.3	23.3	23.3
	2	207	76.7	76.7	100.0
	Total	270	100.0	100.0	

Pretest PDMD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	9.3	9.3	9.3
	2	245	90.7	90.7	100.0
	Total	270	100.0	100.0	

30-Day Posttest UDS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	87	46.3	46.3	46.3
	2	101	53.7	53.7	100.0
	Total	188	100.0	100.0	

30-Day Posttest PDMD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	33	17.6	17.6	17.6
	2	155	82.4	82.4	100.0
	Total	188	100.0	100.0	

60-Day Posttest UDS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	40	19.9	19.9	19.9
	2	161	80.1	80.1	100.0
	Total	201	100.0	100.0	

60-Day Posttest PDMD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	92	45.8	45.8	45.8
	2	109	54.2	54.2	100.0
	Total	201	100.0	100.0	

Appendix II: Post-test Statistical Analysis (Nonparametric Tests)

<i>Null Hypothesis</i>	<i>Test</i>	<i>Significance</i>	<i>Decision</i>
<i>Comparison of 30-Day UDS mean to Pretest UDS mean.</i>	Independent-Samples Median Test	All test values are less than or equal to the median.	Unable to compute.
<i>Distribution of 30-Day UDS v Pretest UDS.</i>	Independent-Samples Kruskal-Wallis Test	.004	Reject the null hypothesis.
<i>Comparison of 60-Day UDS mean to Pretest UDS.</i>	Independent-Samples Median Test	All test values are less than or equal to the median.	Unable to compute.
<i>Distribution of 60-Day UDS mean to Pretest UDS.</i>	Independent-Samples Kruskal-Wallis Test	.339	Retain the null hypothesis.
<i>Null Hypothesis</i>	<i>Test</i>	<i>Significance</i>	<i>Decision</i>
<i>Comparison of 30-Day PDMD mean to Pretest PDMD mean.</i>	Independent-Samples Median Test	All test values are less than or equal to the median	Unable to compute.
<i>Distribution of 30-Day PDMD v Pretest PDMD.</i>	Independent-Samples Kruskal-Wallis Test	.252	Retain the null hypothesis.
<i>Comparison of 60-Day PDMD to mean to Pretest PDMD mean.</i>	Independent-Samples Median Test	All test values are less than or equal to the median	Unable to compute.
<i>Distribution of 60-Day PDMD v Pretest PDMD</i>	Independent-Samples Kruskal-Wallis Test	.505	Retain the null hypothesis.