Development and Evaluation of a Buprenorphine Diversion Protocol in Primary Care

Author: Shameka Brown, APRN, FNP-BC

DNP Project Advisors: Dr. Barbara Sartell and Dr. Joanne Fletcher

Abstract

- Buprenorphine/suboxone is a highly efficacious, safe, medication that has been approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder in 2002.
- The increased access to buprenorphine in office-based settings has increased the rate of diversion of the medication.
- According to the National Prescription Audit Plus, 9.1 million buprenorphine prescriptions were dispensed in the United States in 2012 and has drastically increased over the years (Drug Enforcement Administration, 2019).
- The use of routine urine drug testing or qualitative immunoassay testing can be a vital clinical tool for monitoring compliance with prescribed therapy, however some patients may conceal their diversion of buprenorphine by tampering with their urine specimens.
- Qualitative urine drug test provide semi-quantitative results which only indicate whether the result for buprenorphine is positive or negative but does not measure norbuprenorphine levels.
- Implementing the use of quantitative or definitive liquid chromatography-mass spectrometry urine drugs screenings in the primary care setting can be advantageous for the identification of urine specimen adulteration and non-compliance by analyzing the levels of buprenorphine and norbuprenorphine.

Introduction

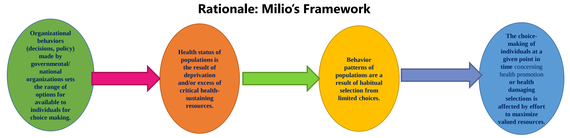
Problem Description

- Diversion presents a significant problem for healthcare providers, policymakers, and other individuals receiving treatment for opioid use disorder. Additionally, diversion negatively impacts the individual's recovery from addiction, treatment outcomes, and public health.
- The increased frequency of prescribing buprenorphine in the primary care setting has resulted in a significant increase in the reports of buprenorphine diversion.
- During the height of the opioid crisis in 2017, 14.6 million buprenorphine prescriptions were written, and 15.9 million prescriptions were sold to patients in 2017 (Drug Enforcement Administration, 2019).
- Diversion of buprenorphine negatively impacts the community by producing adverse effects on public health and crime (Wright, Agnone, Krajci, Littlewood, Alho, Reimer, Roncero, Somaini & Maremmani, 2015).
- Individuals that divert buprenorphine have higher mortality rates which result in a significant increase in healthcare expenditures associated with medical treatment of opioid overdose (Wright et al., 2015).
- The demand for diverted buprenorphine on the black market caused an increase in associated crimes such as home burglaries and pharmacy thefts.
- Mean price for black market/street sells is $3.95 per mg of buprenorphine (Hswen et al., 2018).

Available Knowledge

- Research suggests that patients in office-based treatment settings such as primary care clinics are at a higher risk of drug diversion (Jarvis, Williams, Hurford, Lindsay, Lincoln, Luongo, Giles & Safarian, 2017).
- Common methods of diversion include illegal sale of prescriptions, doctor shopping to obtain multiple prescriptions, and giving away/selling medications to others (Tripathi & Sarkar, 2018).
- Studies examining buprenorphine diversion suggests that some individuals divert the medication to get high, prevent withdrawal, share with peer who could not find treatment, lack access to affordable treatment, self-treatment of opioid dependence, unwillingness to engage in long-term and to make financial gains.
- The cost of buprenorphine when obtained by prescription or when illicitly purchased on the streets is much cheaper than purchasing heroin/fentanyl (Tripathi & Sakar, 2018).
- Quantitative urine drug screening tests are therapeutic tools which are beneficial for detecting the presence and concentration of both buprenorphine and norbuprenorphine in urine specimens. The interpretation of the buprenorphine and norbuprenorphine metabolism can help the provider determine whether the patient is diverting their medication (Barthwell et al, 2018).
- The accuracy of quantitative urine drug test can help guide clinicians with monitoring individual treatment plan adherence, minimize risks to their patients, and improve patient success in recovery (Accurso, 2017).

Rationale: Milio's Framework



Specific Aims

- Implement the use of quantitative liquid chromatography-mass spectrometry urine drug screenings to analyze buprenorphine and norbuprenorphine levels to identify patients who divert their prescribed buprenorphine within a six-week period.
- Develop a Buprenorphine Diversion Prevention Protocol to enhance the clinical monitoring of individual treatment plan adherence, minimize risks to their patients, and improve patient success in recovery.
- Increase in the use of long-acting monthly buprenorphine injections to prevent diversion.

PICOT Question and Methods

PICOT question: In primary care providers prescribing buprenorphine, how does monitoring the quantification of buprenorphine and its metabolite norbuprenorphine levels in urine drug screenings versus standard qualitative immunoassay drug screenings affect the identification of buprenorphine diversion within a six-week period.

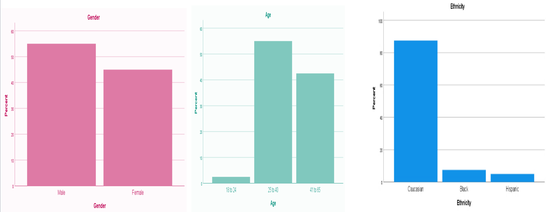
Methods

Context

- Clinical inquiry was focused primarily on determining the impact of implementing the use of quantitative urine drug screening test to analyze both buprenorphine and norbuprenorphine levels in individuals prescribed buprenorphine for treatment of opioid use disorder to identify diversion.

Setting

- Tri-State Health Inc., Cecil County, Elkton, MD. Founded in 2011 by Dr. Muhammed Niaz
- Primary care, office-based medication assisted treatment for substance abuse treatment for opioid addiction and alcohol, drug and alcohol counseling, sleep medicine and weight management.
- Two physicians, two nurse practitioners, in-house lab manager, four medical office assistants.
- 40 participants (55% males (n=22) and 45% females (n=18)), Mean age 37
- Race: 87% Caucasian (n=35), 7.5 % African-American (n=3), 5% Hispanic (n=2)



Intervention

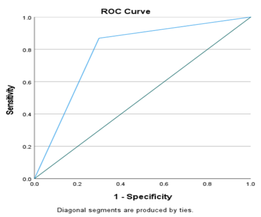
- Implementation of quantitative urine drug screening test or liquid chromatography-tandem mass spectrometry to analyze buprenorphine and norbuprenorphine and comparing test results with qualitative urine drug screening test over a six-week period.
- 240 routine urine drug test and quantitative urine drug test collected during the six-week project

Study of Intervention

- To study the intervention, a comparison of buprenorphine and its metabolite norbuprenorphine levels using the liquid chromatography-tandem mass spectrometry (LC-MS) and routine immunoassay or qualitative urine drug screenings were performed to assess the impact of the intervention.

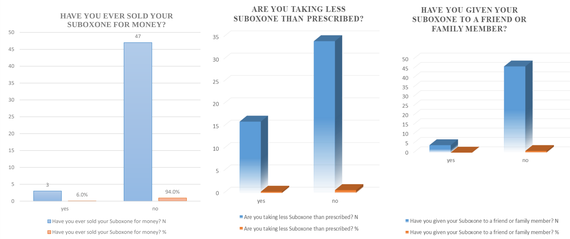
Data Analysis

A binomial logistic regression was performed utilizing IBM SPSS 27.0 to ascertain the effects of a buprenorphine screening test on the likelihood of a positive norbuprenorphine quantitative result. The logistic regression model was statistically significant, $X^2(1) = 66.7$, $p < .001$. The model explained 36% (Nagelkerke R^2) and correctly classified 83%. Sensitivity was 86.9%; specificity was 70.2%; positive predictive value was 90.3%; and negative predictive value was 62.5%. Buprenorphine screening was a statistically significant predictor of a norbuprenorphine quantitative result. A person with a positive buprenorphine screening has 15.6 times higher odds to have a positive norbuprenorphine quantitative result. The area under the ROC curve was .785. 95% CI [.710-.861] which is an acceptable level of discrimination according to Hosmer et al. (2013).

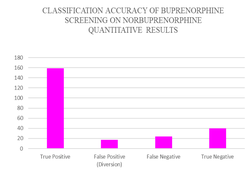


Results

Pre-intervention Survey Results



Utilizing Buprenorphine Screening only, 159/240 urine drug screenings were correctly classified and had positive norbuprenorphine quantitative values; 17 patients were misclassified and had negative norbuprenorphine quantitative results, indicating 7% were diverting.



Ethical Considerations

- CITI Training completed
- DNP project approved by Wilmington University Human Subjects Research Committee
- DNP project approval from Dr. Muhammed Niaz, owner of Tri-State Health Inc.

Application of DNP Essentials

- DNP Essential I: The evidence-based quality improvement DNP project exemplified the scientific underpinnings for practice by integrating nursing science, science-based theories, and concepts to address current and future practice issues with opioid addiction treatment in the primary care setting.
- DNP Essential II: The project demonstrated an understanding of organization and systems leadership for quality improvement and systems thinking by explicitly evaluating care delivery approaches that meet current and future needs of individuals with opioid use disorders based on scientific findings in advanced practice nursing and addiction medicine.
- DNP Essential III: Dissemination and translation of research in practice, evaluation of practice and the application of knowledge was integrated into the DNP project to solve current practice issues and implement the best evidence for practice.
- DNP Essential IV: Knowledge of information systems/technology was also used to analyze and interpret urine drug screening tests and to assess the efficacy of patient care. Information from web-based learning, clinical decision supports, and intervention tools were incorporated to implement quality improvement initiatives and support practice decision-making.
- DNP Essential V: Advocacy for health care policy was demonstrated by critically analyzing current health policies on buprenorphine diversion and advocating for policy change within the organization. In addition, a Buprenorphine Diversion Prevention Protocol was developed.
- DNP Essential VI: The DNP project exemplified effective interprofessional collaboration which is essential to quality improvements in healthcare. The integration of effective communication, collaborative skills and a high functioning team was essential to completing the project's tasks, overcoming barriers, and implementing a buprenorphine diversion prevention protocol to improve patient health outcomes.
- DNP Essential VII: Synthesized concepts of psychosocial dimensions related to buprenorphine diversion and evaluated interventions to address diversion, improved the health status of individuals with opioid use disorder and addressed gaps in care.
- DNP Essential VIII: Experiential engagement was incorporated to design, implement, evaluate the DNP project inventions based on nursing science and addiction medicine. Additionally, the DNP project encompassed therapeutic relationships and partnerships with other professional to facilitate optimal care and patient outcomes.

Dissemination

- Presented findings with project advisor, team mentor/stakeholder and project team
- Send abstract to the following journals: The Journal of Addictions Nursing, The Journal of Addiction Medicine, and Journal of Substance Abuse Treatment.
- National conference: Abstract was submitted to Delaware Nurses Association for the 16th Annual Nursing Research Conference. NAADAC and AANP

Implications for Advanced Practice Nursing

- The use of routine quantitative urine drug tests to analyze both buprenorphine and norbuprenorphine levels is imperative to detect diversion in the primary care setting (Holt et al., 2017).
- Advanced practice nurses and other buprenorphine providers are more capable of preventing diversion, modifying treatment plans, terminating treatment, reducing risk for potential harm, promoting treatment retention, and engagement by using quantitative urine drug screenings routinely for monitoring compliance (Holt et al., 2017).

Limitations

- sample size
- length of time
- limited research on buprenorphine diversion
- costs associated with quantitative urine drug screenings
- project focused on the diversion of suboxone films only, other buprenorphine products (Subutex or Zubsolv) were not included

Sustainability

- mutual adaptation between the evidence-based intervention and organization
- maintenance of workforce skills by continued provider training
- ongoing monitoring of the evidence-based intervention effectiveness

Conclusions

- Diversion presents a significant problem for patients, healthcare providers, policymakers, and other individuals receiving treatment for opioid dependence (Wright et al., 2015).
- The routine inclusion of quantitative buprenorphine and norbuprenorphine levels is invaluable for treatment monitoring; therefore, these tests should emerge as a standard of care (Accurso et al., 2017).
- The increased use of quantitative urine drug screening tests in the primary care setting can drastically improve patient compliance, reduce diversion, and black-market sells, prevent drug overdose and related death, and decrease societal crimes worldwide.

The results of implementing quantitative urine drug screening were as follows:

1. Clinicians were able to improve compliance
2. Patients were referred to a higher level of treatment at inpatient rehabilitation facilities and methadone clinics
3. The organization offered long-acting buprenorphine injections and Vivitrol
4. Non-adherent patients were terminated.

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