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Running head: ED-INITIATED BUPRENORPHINE

A Pilot of Emergency Department-Initiated Buprenorphine for
Opioid Withdrawal and Opioid Use Disorder: A Quality Improvement Project

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Abstract

Background: Emergency department (ED) visits for opioid related visits have increased dramatically during the opioid epidemic. Buprenorphine is an evidence-based therapy for treating opioid use disorder (OUD) and withdrawal. Unfortunately, lack of access to pharmacotherapy for OUD, including buprenorphine, remains a challenge. Research supports ED-initiated buprenorphine as a practical, cost-effective strategy which engages patients in treatment better than non-pharmacologic alternatives.

Purpose: The aims of this improvement project were to 1) develop a pilot process in an ED for providing buprenorphine to patients in opioid withdrawal or for OUD; 2) recruit and train a cohort of ED staff on the process; and 3) track the process as it was offered to patients.

Methods/Interventions: Based on protocols from national and regional examples, a process for ED-initiation of buprenorphine was developed. Using a Diffusion of Innovation model, the project trained an influential cohort of staff. Buprenorphine waiver training was facilitated for ED physicians. In-person and virtual trainings on the process were conducted by the project leader. Written case reports for patient encounters were completed by providers/staff.

Results: Guidelines were vetted and approved by hospital committees. 6 out of 10 full-time ED physicians (60%) obtained buprenorphine waivers. Pilot program trainings were provided to 34 staff directly and a recorded training was distributed. Within the first month of implementation, 16 unique case reports of encounters were collected. Case reports showed high rates of adherence to the following steps of the process: COWS scores performed (87.5%), buprenorphine administered for COWS score ≥8 (100%) discharged with prescription after ED dosing (77.8%), home induction prescriptions for COWS<8 (100%), cases discharged with prescription (87.5%), and referral to care coordination services (81.25%). Lower rates of adherence to process steps of involvement of recovery coaches (56.25%) and provision of overdose education/naloxone (33.3%) were noted. Process barriers included difficulties with entries in electronic medical record (EMR), a patient who did not get relief, and a patient who declined buprenorphine. Suggestions for improvement included easier order entry, clearer documentation of COWS score and challenges in locating forms.

Conclusion: This project resulted in a new ED process affording access to buprenorphine where it was previously unavailable. A majority of ED physicians (60%) became waivered to prescribe buprenorphine. This percentage is well above a targeted 13.5% to reach a critical mass hypothesized to sustain a diffusion of this innovation. The odds of improved outcomes resulting from buprenorphine exposure including sustained recovery and reduced overall morbidity and mortality for patients exposed in this project are improved. Despite limitations in data accuracy, lessons learned about the process including barriers and opportunities for improvement may be valuable to other organizations as they develop their own systems. Further analysis of the project including future statistical process control measures and collection of more data using the electronic record will be valuable.

Keywords: opioid use disorder, opioid withdrawal, buprenorphine, emergency department, quality improvement

A Pilot of Emergency Department-Initiated Buprenorphine for Opioid Withdrawal and Opioid Use Disorder

Problem Description

The United States is facing an ongoing opioid epidemic responsible for shocking societal complications, including historically high numbers of overdose deaths. In 2017, the CDC reported nearly 72,000 overdose deaths, of which over two-thirds were linked to opioids (Ahmad, Rossen, Spencer, Warner & Sutton, 2018). To make matters worse, overdose deaths represent only the tip of the proverbial iceberg of numerous other opioid-related health, social and economic costs. These include high healthcare burden related to infectious diseases and non-fatal healthcare for opioid related problems, lost work productivity, criminal justice costs, and generational trauma related to loss of loved ones to name only a few. In a recent report, the White House Council of Economic Advisers (November 2017) estimated that the total costs of the epidemic for 2015, were \$504 billion.

In the face of this public health crisis, consideration of evidence-based treatment for people who develop opioid use disorder is paramount. Research supports the use of pharmacotherapy including opioid agonist therapy (methadone and buprenorphine) as effective lifesaving treatment for opioid use disorder (OUD). Buprenorphine in particular has been shown to be an effective tool for both maintenance treatment (Mattick, Breen, Kimber, & Davoli, 2014) and management of opioid withdrawal symptoms (Gowing, Ali, White, & Mbewe, 2017). Given the increased prevalence and urgency of the epidemic, wider access to pharmacotherapy is called for and non-traditional venues for initiating and accessing treatment are necessary. Emergency departments (ED) in hospitals frequently serve as the healthcare venue for opioid related visits

and thus represent a setting where expanded access to pharmacotherapy including buprenorphine should be considered. High quality research supports ED-initiated buprenorphine as a practical, cost-effective strategy which engages patients in short-term treatment better than non-pharmacotherapy alternatives (Busch et al., 2017, D'Onofrio et al., 2015, D'Onofrio et al., 2017). **Available Knowledge**

The opioid epidemic and emergency departments. The tragic number of drug-related overdose deaths in the U.S. are dismaying. In 2017, the total number of overdose deaths totaled more than the number of all soldiers killed in the entire Vietnam war, more than the number of peak annual HIV/AIDS or gun deaths in the 1990's, and more than annual peak motor vehicle accident deaths in the 1970's (Lopez, 2017). In 2016, New Hampshire ranked 2nd in the nation for per capita rate of overall overdose deaths and 1st for fentanyl related overdose deaths (Centers for Disease Control and Prevention (CDC), 2017).

Over a one-year period from 2015-2016, the CDC found that the number of ED visits for opioid overdose, which represents only a fraction of total opioid-related visits, increased nationwide by nearly 30% (Vivolo-Kantor et al., 2018). In New Hampshire, opioid-related visits to EDs increased 9.8% from 2016-2017 to over 50 visits per month per 10,000 population statewide (NH Drug Monitoring Initiative [NH DMI], 2018). Also, in 2016-2017, in Strafford County, where the project site (Wentworth Douglass Hospital: Mass General Subsidiary [WDH]) is located, the number of opioid-related ED visits per capita of 71.22 visits per 10,000 population was the highest of all counties in NH (NH DMI, 2018). The combined high prevalence of opioid related health problems in NH and the frequency of ED visits related to opioids, suggest that the ED is an ideal setting for improved interventions aimed at enhancing outcomes for patients.

Pharmacotherapy for OUD. It is widely accepted that pharmacotherapy (often referred

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to as "medication assisted treatment") for opioid use disorder is an evidence-based and lifesaving treatment. Both methadone and buprenorphine are listed on the World Health Organization's (WHO) (2005) list of essential medication, citing their success in reducing heroin use as well as being associated with numerous other public health and societal benefits such as reduced rates of HIV, hepatitis, and criminal activity. Of the three current approved medications for treatment of opioid use disorder in the US, buprenorphine, a partial opioid agonist, has some practical advantages over methadone and naltrexone. Pharmacologically, buprenorphine, unlike methadone, poses less risk of overdose due to its ceiling effect where larger doses do not suppress respiratory drive. Moreover, whereas current federal law requires daily observed dosing of methadone in licensed treatment facilities, buprenorphine may be prescribed by any provider who has received a Drug Enforcement Agency waiver after completing a training (Substance Abuse and Mental Health Services Administration (SAMHSA), 2018). Unlike naltrexone, a full opioid antagonist, buprenorphine can be used for symptomatic relief of opioid withdrawal symptoms. In a Cochrane Review metanalysis, Gowing, Ali, White, & Mbewe (2017) found buprenorphine to be more effective than non-opioid clonidine or lofexidine for management of opioid withdrawal. Buprenorphine resulted in less severity of withdrawal symptoms, shorter duration of withdrawal treatment and increased likelihood of completing treatment (Gowing et al., 2017). This review also found buprenorphine to be as effective as methadone for managing withdrawal (Gowing et al., 2017). There is also evidence that repeated exposure to buprenorphine, even if initial treatment is not successful in long-term treatment retention, may result in better treatment retention in subsequent buprenorphine treatment (Cunningham, Roose, Starrels, Giovanniello, & Sohler, 2013). This finding is key to address the myth that ED-initiated buprenorphine should only be prescribed when a comprehensive follow

up plan is in place before discharge.

A recent systematic review and meta-analysis showed that buprenorphine for OUD is effective for reducing illicit drug use, improving physical and mental health morbidity and reducing overall mortality (Sordo et al., 2017). Buprenorphine has been shown to be an effective and relatively safe medication for both opioid withdrawal as well as maintenance treatment for OUD (Gowing et al, 2017; Mattick et al., 2014). In a 2016 study of 150,000 National Health Service patients treated for OUD and followed for over 400,000 patient years, treatment with buprenorphine reduced the risk for opioid overdose death by 50% compared to patients with no treatment or psychosocial treatment alone (Pierce et al., 2016).

The efficacy and relative safety profile of buprenorphine, combined with its availability outside of specialty addiction treatment clinics, makes it the principal tool to combat the devastating effects of the opioid epidemic. Although relatively new within the US, buprenorphine's benefits have been demonstrated in other countries. To address a worsening opioid epidemic in 1995, France lifted prescribing restrictions for buprenorphine which led to dramatic increases in patients treated with buprenorphine and a 79% reduction of overdose deaths between 1995-2004 (Auriacombe, Fatséas, Dubernet, Daulouède, & Tignol, 2004).

Buprenorphine in the emergency department. Because the opioid crisis has resulted in numerous ED opioid-related visits, utilizing buprenorphine for opioid withdrawal management and as initiation of OUD treatment in the ED is a clear fit. In a currently unpublished systematic review, Hale and Lucey (2018) identified three studies that assessed ED-initiated buprenorphine including a randomized control trial (RCT) (D'Onofrio et al., 2015), a cohort follow-up study (D'Onofrio et al., 2017) and a cost-effectiveness analysis of the RCT (Busch et al., 2017). Using a validated Downs and Black checklist, the authors independently

and then jointly assessed the quality of the included studies and determined quality to be high despite some limitations and a risk of attrition bias in two of the studies (Hale & Lucey, 2018). D'Onofrio et al. (2015; 2017) demonstrated that ED initiation of buprenorphine resulted in improved retention in treatment compared to both a psychosocial brief intervention and referral to treatment resources without motivational counseling. ED initiation of buprenorphine was found to be cost-effective and superior to brief intervention and referral at all willingness-to-pay values above zero dollars (Busch et al., 2017).

Across these 3 studies, ED-initiated buprenorphine resulted in higher treatment retention at 30 days and 2 months compared to both brief intervention and referral to treatment without psychosocial intervention. Although the intended N of 360 for the RCT (D'Onofrio et al., 2015) was not achieved resulting in a slightly underpowered study, the significantly improved retention rates for the buprenorphine group at 30 days and 2 months is convincing evidence that ED initiation of buprenorphine results in better outcomes than non-pharmacologic ED care. Although improvements were also seen in both non-medication arms of the study, it is important to consider that both control arms received more attention to OUD than current standard in US ED's (D'Onofrio et al., 2015).

ED-initiation of buprenorphine was found to be significantly more cost-effective, than both non-pharmacological ED interventions (Busch, et al., 2017). Compared to non-pharmacologic interventions, ED-initiated buprenorphine had significantly lower patient time costs (\$97 versus \$283–322; P < 0.001) (Busch, et al., 2017). Additionally, the initial cost of training ED providers to receive waivers to prescribe is also low. The cost effectiveness analysis did not include factors such as labor market improvements, reduced disease transmission from patients engaged in treatment, and family benefits of patients engaged in treatment. Therefore,

the overall cost benefits of ED-initiated buprenorphine are likely underestimated (Busch, et al., 2017).

Although studies specific to ED initiated buprenorphine are few, the significant positive results of higher treatment retention and cost-effectiveness of ED-initiated buprenorphine warrant larger scale implementation and further research. There is strong evidence showing buprenorphine as a safe, lifesaving, and effective treatment for both opioid withdrawal and OUD. This evidence asserts that more hospitals and ED providers should innovate and begin to use this proven medication in ED venues where patients with OUD often present for care. In fact, in a consensus report released during this project's timeline, the National Academies of Sciences, Engineering, and Medicine (2019) concluded that "withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment (p. 88)." In other words, failure to provide pharmacotherapy for OUD is unethical.

Efforts to expand ED-initiated buprenorphine are ongoing in several areas across the U.S. in response to the opioid crisis and the evidence in support of ED-initiated buprenorphine. In California, ED-Bridge is a program through the SAMHSA State Targeted Response to the Opioid Crisis Grant to the California Department of Health Care Services (ED-Bridge, 2018). This program aims to increase the number of California ED's that offer 24/7 access to buprenorphine and offers several resources for starting and sustaining a program to initiate buprenorphine in the ED.

While California's efforts have thus far consisted of pilot programs in select hospitals, a 2018 Massachusetts law mandated that all emergency departments have the capacity to initiate opioid agonist therapy (buprenorphine or methadone) to patients after an opioid-related overdose

(Bebinger, 2019). In response to the law, the Massachusetts Health and Hospital Association (MHA) (2019) published "Guidelines for Medication for Addiction Treatment for Opioid Use Disorder within the Emergency Department."

On a national level, in September 2018, the National Institute on Drug Abuse (NIDA), in collaboration with researchers at Yale University, launched a web-based resource to help guide ED providers in best practices for use of buprenorphine in the ED setting (NIDA, 2018). Resources include tools for identifying OUD, training resources for interacting with and motivating patients towards treatment and a simple algorithm for buprenorphine initiation for eligible patients in the ED.

Unfortunately, although the prevalence of substance use disorders including opioid use disorder is high, lack of access to proper treatment remains a national challenge. According to the 2018 report, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, only about 1 in 4 people with opioid use disorder received specialty treatment within the last year (US Department of Health and Human Services, 2018). Development and expansion of ED-initiated buprenorphine programs is an important component of expanded access aimed at reducing this treatment gap.

Rationale

The rate of OUD and complications such as infectious disease and fatal opioid overdoses both in the US and in New Hampshire, where this project was conducted, is staggering. There is a need for low-barrier access to readily available treatment for patients with OUD, of which pharmacotherapy is a cornerstone. Buprenorphine is a practical, lifesaving outpatient treatment that may be prescribed by trained providers across multiple settings including the ED. Expansion

of access to buprenorphine in ED settings is a critical component of a comprehensive public health approach to mitigating the enormous costs of the opioid epidemic. Expansion of pharmacotherapy requires change within organizations to train prescribers, nurses, and staff and to overcome historical stigma and regulatory restrictions that have preferred less effective abstinence-only and psychosocial treatment modalities over pharmacotherapy.

The theoretical framework guiding this project was the Rogers Diffusion of Innovation Theory (Rogers, 2003). Because ED-initiated buprenorphine was a new process for the WDH ED, it represented an innovative strategy that will undergo a process of diffusion before being widely used and accepted. Diffusion is defined as a social process that occurs as people learn about a new evidence-based approach for improving healthcare (Dearing and Cox, 2018). Diffusion occurs over time and, as illustrated in Appendix A, typically follows an S-Shaped curve with an initial slow rate of adoption of the innovation and progressing to more rapid acceleration which eventually slows as less non-adopters remain and the innovation has become the standard (Dearing and Cox, 2018). With clinical practice changes that rely on voluntary adoption of certain practices, the rate of adoption can be accelerated by influential members of the social system of interest (early adopters) who then communicate the benefits of the innovation to others who follow their lead (Dearing and Cox, 2018). It was the intent of this project to train and utilize a critical mass (greater than 13.5%) of ED provider "early adopters" to begin offering ED-initiated buprenorphine in the hopes that a "tipping point" would be reached and subsequent ED access to evidence based pharmacotherapy would then become standard over time as the innovation diffuses over the entire social system of ED providers.

The success of an innovation's diffusion generally relies on 3 sets of variables: the inherent pros and cons of the innovation, the characteristics of the adopters, and the larger social

and political context in which the innovation arises (Dearing & Cox, 2018). For this project, the convincing evidence in support of ED-initiated buprenorphine pointed to it as a likely successful innovation. The characteristics of the ED early adopter providers, which included the medical director, the nurse manager and several respected ED physicians and nurses, suggested that these members of the social system would be successful in influencing their peers towards adoption. Lastly, because of the overwhelming urgency of the opioid epidemic and the sociopolitical attention being paid to improving the health of the community affected by opioids, this innovation was highly timely and pertinent.

As a quality improvement effort, this project was also guided by the Institute for Healthcare Improvement Model for Improvement (Appendix B). IHI guiding principles of forming a team, setting aims, establishing measures, and selecting/ testing/ implementing/ spreading changes were used. Because this project aimed to establish a new process for the WDH ED, traditional statistical process control techniques to measure the process over an extended period were not indicated. The project leader communicated regularly with WDH and ED leadership, providers, nurses and staff. Based on the analysis of case report data, adjustments and improvements were made, through multiple PDSA (Plan, Do, Study, Act) cycles as the process of ED-initiated buprenorphine was developed and implemented.

Specific Aims

The goals of this project were to develop and pilot a process for ED-initiated buprenorphine, to train early adopter providers and staff to administer and prescribe buprenorphine in the ED, and to track the process as buprenorphine was offered. The project's specific aims were as follows:

- By December 30, 2018, in collaboration with WDH behavioral health and ED leadership,
 ED staff, and select community buprenorphine providers, develop a pilot process for initiating buprenorphine treatment for ED patients presenting with opioid withdrawal or requesting outpatient OUD treatment.
- 2. By January 30, 2019, at least 3 full-time ED physician providers would be trained and waivered to prescribe buprenorphine. At least 6 ED nursing staff would also be trained on buprenorphine and the WDH process for ED initiation.
- 3. By March 8, 2019, tracking of the ED buprenorphine initiation process would be initiated using case report data where buprenorphine was offered or provided to patients.
 Descriptive statistics on process steps as well as reported barriers and opportunities for improvement would be assessed and reported.

Methods

Context

Wentworth Douglass Hospital-Massachusetts General Hospital Subsidiary (WDH) is a 178-bed community Magnet® Recognized hospital located in Dover, NH. In 2017, WDH joined the Massachusetts General Hospital family and Partners HealthCare system. WDH serves the NH and southern Maine Seacoast and in addition to the hospital operates several walk-in clinics, primary care and specialty offices, a dental clinic, a fitness center and a philanthropic foundation (WDH, n.d.). The community of Dover and the state of NH have been dramatically affected by the opioid epidemic which has had several adverse effects including a strain on emergency services with over 6500 emergency visits in NH and nearly 900 visits in Strafford County (where WDH is one of 2 hospitals) related to opioids in 2017 alone. (NH DMI, 2018)

This project not only met the need for an evidence-based response to the New Hampshire and Strafford County opioid crisis but also fit in to specific strategic planning measures documented by WDH: The hospital system's long-range plan includes "strengthening, enhancing, and growing programs and services to meet the health care needs of the communities we serve" (WDH, 2018, p.3). More specific to OUD and the importance of pharmacotherapy, the mission of WDH strives to partner with patients to "attain their highest level of health" by promoting "patient-centered and evidence-based" approaches (WDH, 2018, p.4). Additionally, within its identified strategic priorities, WDH looks to "optimize, coordination and improve transitions of care across the continuum" and "strengthen access to and coordination of behavioral health services" (WDH, 2018, p.7). Efforts to expand access to pharmacotherapy for OUD fit clearly in these goals. Another strategic priority for WDH is to "boldly innovate health care delivery" with a focus on exploring, designing and testing new models of consumer-centric care (WDH, 2018, p.7). This project represents a key innovation in consumer-centric care.

In addition to its long-range strategic plan, in its 2016 Community Health Needs

Assessment and Implementation Plan, WDH identified substance use disorder treatment access
and resources as one of 10 of the community's priority health needs and frequently references
goals and initiatives in line with this project. WDH (2016) commits to continuing the provision
and expansion of behavioral health services and identifies a need to develop and implement
educational trainings around behavioral health needs and resources for its providers and staff.

Specifically targeting substance misuse and access to treatment, WDH reported a need for
program initiatives exploring community partnerships for substance use treatment and increased
access to specialists trained in addiction treatment. Additionally, WDH (2016) committed to
exploring the expansion of outpatient treatment options for substance use disorder and

implementing additional trainings about substance misuse for staff. This ED-initiated buprenorphine project compliments these goals by training ED staff and by establishing connections with community buprenorphine providers.

Primary stakeholders involved in this improvement project included ED providers/ nurses/ staff, behavioral health leadership and staff, ED leadership (nursing and medicine), the Strafford County Integrated Delivery Network (IDN), outpatient community buprenorphine providers, social work services, and recovery coach services provided by SOS Recovery, the local recovery community organization.

Intervention(s)

To achieve the above stated aims, the following interventions were carried out:

Pre-implementation (**August-November**). Initial concepts of the project began after the project leader, an ED nurse practitioner with expertise in addiction, was approached by the WDH behavioral health director and ED leadership. After reports of patient dissatisfaction with opioid withdrawal management were expressed by staff of the recovery coaching program within the hospital, a meeting to discuss options for improving care for opioid withdrawal was convened by the director of behavioral health. Attendees of this initial meeting included the project leader, ED leadership (nurse manager and medical director), the behavioral health medical director, hospitalist medical director, and outpatient practices medical director. From this discussion, it was decided that piloting a program for ED-initiated buprenorphine would be an important step towards improved care for patients with opioid withdrawal.

An organizational readiness assessment tool produced by the Network for the Improvement of Addiction Treatment (NIATx) at the University of Wisconsin–Madison (Appendix C) completed by the project leader confirmed that the WDH context represented an excellent site for buprenorphine implementation.

Implementation (December-April).

Process development. The project leader arranged multiple meetings/communications with the WDH behavioral health director, ED leadership, early adopters, community providers, and the Strafford county IDN to develop the WDH ED-initiated buprenorphine process.

Guidelines were produced describing step-by-step plan for ED-initiation including inclusion/exclusion criteria, an initiation protocol consistent with expert recommendations and NIDA (references), and instructions for outpatient referral and follow-up. The project leader obtained examples of Mass General Hospital's ED-initiation protocols to serve as reference for adaptation to a WDH-specific process. Two guidelines were extensively reviewed by stakeholders, revised and ultimately approved by hospital Standardization and Pharmacy and Therapeutics Committee (Appendices D and E).

Trainings. In collaboration with partners and stakeholders, the project leader facilitated buprenorphine waiver trainings for early adopter prescribers. After encountering multiple challenges in coordinating schedules for an in-person federal DEA waiver training, asynchronous online trainings for individual providers were determined to be the most effective way of obtaining waivers. The project leader distributed information to all ED providers directing them to online trainings or regionally available in-person trainings. Many ED providers opted for the nationally-offered approved trainings at https://pcssnow.org/medication-assisted-treatment/.

Once the process for ED-initiation was finalized and approved, the project leader developed and delivered in-person and virtual trainings on the process to ED and allied staff. A binder including copies of the approved guidelines, and supporting resources such as criteria for

diagnosing OUD, patient handouts, and a nursing guide for buprenorphine was placed in a central location in the ED. A list of all training resources with links to specific documents is included in Appendix F.

Case reporting. After the WDH process was approved and trainings were completed, data about the process was collected via written case report forms (Appendix G) filled out by staff after patient encounters involving buprenorphine initiation. Case report forms were deposited into a locked collection box and collected for analysis by the project leader/author only. Although the ability to access medical records for auditing of encounters was desired, it was not permitted during the quality improvement project approval process.

Budget. There were minimal economic costs to carry out this project. Online waiver trainings were federally-sponsored and free of charge. Process trainings were available as an asynchronous recorded training or delivered as drop-in trainings during ED shifts thus relieving the need to pay staff for extra training time.

Measures

To measure the outcomes of this project the following instruments were used:

Process development. An organizational readiness assessment tool created by the Network for the Improvement of Addiction Treatment (NIATx) at the University of Wisconsin–Madison (Appendix C) indicated that WDH was an organization well-suited to implementation of a buprenorphine program with a total relative score of 18 or "Excellent". Approval of the written process guidelines through the hospital Standardization and Pharmacy and Therapeutics Committees served as the final outcome measure of process development.

Training. Descriptive data on numbers of providers obtaining buprenorphine waivers and numbers/ types of staff receiving in-person process trainings were collected.

Case Reporting. Data on patient encounters was measured using case report forms (Appendix G). Data collected included: initials of staff involved to avoid duplication of data if multiple staff compete forms on same encounter, date/time of patient encounter, questions about the process algorithm points (whether patient was in withdrawal, if a Clinical Opioid Withdrawal Scale (COWS) was used, if buprenorphine was dosed in ED, if a prescription was given at discharge, and if overdose education was provided), where the patient was referred, and if a follow-up appointment was made. Additionally, respondents were asked to comment on barriers encountered and to suggest potential improvements to the process.

Analysis

A description of process development steps and descriptive statistics on the training phase of the project were summarized for review. Case report data were compiled at the end of the pilot project timeline and summaries of descriptive statistics (i.e. number of encounters reported, number of times buprenorphine was initiated, locations of community referrals) were reviewed. Evaluation of the fidelity to the treatment algorithm steps was performed with attention to calculation of COWS scores and appropriate induction dosing (ED or home induction) (Table 2). Data on barriers and suggestions for improvement was tallied and reported. Because the process is new, traditional statistical process control reporting (i.e. run charts, p-charts) was not possible during the project timeline as numbers of encounters were not sufficient and access to all ED records for analyzing total numbers of patients seen for opioid-related visits was not permitted.

In addition to analysis of written case reports, the project leader met with multiple stakeholders (ED providers, staff, Doorway staff, recovery coaches, and pharmacists) during

project implementation and received feedback which guided adjustments and suggestions for potential future process improvements.

Ethical Considerations

This project was approved by WDH as a quality improvement project by the WDH Nurse Scientist and Director of Nursing Education, Research & Innovation (Appendix H). The University of New Hampshire (UNH) School of Nursing's Quality Review Committee reviewed and recognized this project as a quality improvement project not requiring IRB approval (Appendix I). As a quality improvement project, no personally identifying patient information was collected. Any review of patient/staff information was conducted by personnel with permission to access data for provision of clinical care. All data presented as part of this project is aggregated data. Staff initials collected on case report forms were only used by the project leader to determine if multiple encounter forms were completed on the same patient encounter and are de-identified in reporting of results. The risks and benefits to patients participating in this project were no different from the risks/benefits of patients receiving standard emergency department care.

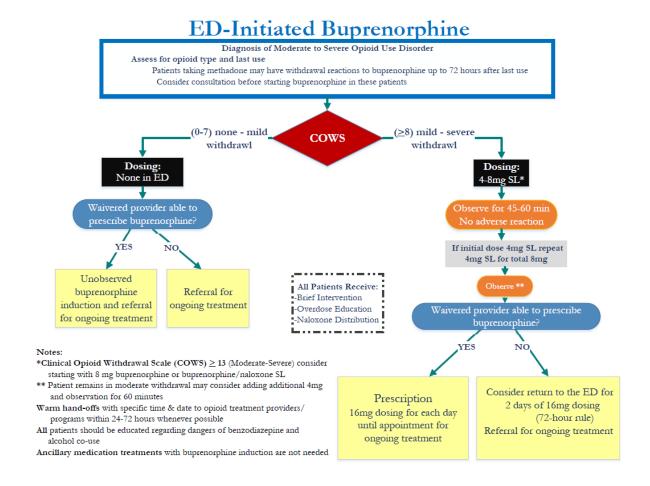
Results

Process Development

Guidelines for opioid withdrawal and OUD treatment with buprenorphine (Appendices D and E) were approved in March 2019. Although the original timeline of this project estimated approval by December 2018, several delays in achieving stakeholder consensus extended the timeline. Formal approval by the WDH Standardization Committee (end of February 2019) and then the WDH Pharmacy and Therapeutics Committee (mid-March 2019) was required, which

was not originally anticipated. The first patient encounter resulting in ED buprenorphine initiation occurred one day after guidelines were approved in March 2019.

Process development consisted of multiple meetings between stakeholders, consultants and the project leader, which are further described in methods. Expert colleagues from Mass General Hospital, the first Massachusetts hospital to offer ED initiated buprenorphine (Bebinger, 2018), shared protocols with the project leader which served as a foundation for the WDH guidelines. To enhance outpatient support and follow-up, recovery coaches were utilized during encounters for ED-initiated buprenorphine. Guidelines specify definitions of patients appropriate for buprenorphine initiation and include detailed assessment steps such as diagnostic criteria for OUD and a validated opioid withdrawal assessment tool (Clinical Opioid Withdrawal Scale [COWS]). Medication orders for buprenorphine and discharge process steps are specified. The guidelines utilized the NIDA recommended algorithm for ED-Initiated Buprenorphine (Figure 1). Two separate guidelines, representing the 2 main branches of the NIDA algorithm, were approved. One for use with patients in acute withdrawal (COWS score >8) who would require buprenorphine dosing in the ED and another for patients who would qualify for home induction by outpatient prescription (COWS scores <8).



 $Figure\ 1-\ From:\ \underline{https://www.drugabuse.gov/nidamed-medical-health-professionals/discipline-specific-resources/initiating-buprenorphine-treatment-in-emergency-department/buprenorphine-treatment-algorithm$

Coinciding with this project, in January 2019, WDH became one of 9 state "hubs" and opened The Doorway, a service to assist anyone seeking treatment for substance use (Early, 2019). Whereas the original intent of the project was to have several options of community buprenorphine providers available to refer patients to at discharge, the Doorway made it possible to refer patients to one location where care coordination of follow-up (i.e. insurance coverage, transportation needs, preferences of location for follow-up) was addressed by Doorway staff.

Trainings

As of February 2019, a total of 6 full-time ED physician providers had been trained and

waivered to prescribe buprenorphine. This represents 60% of the full-time ED physician staff at WDH, a percentage above the originally targeted 13.5% based on the Diffusion of Innovation theory (Dearing and Cox, 2018). As indicated in Table 1, multiple ED staff including 14 nurses and 17 interdisciplinary staff trained onsite. A recorded training was distributed to all other ED, behavioral health and social work staff.

Table 1

ED Buprenorphine Trainings	
Buprenorphine Waiver Trainings	
Type of Training	Number/Type of Staff
In-person Buprenorphine Waiver	1 Physician
Training (offered by regional trainers)	
Online Buprenorphine Waiver training	5 Physicians
WDH Process Trainings	
Drop-in onsite trainings by Project	6 MAT Waivered Physicians
Leader	14 Nurses
	4 Physician Assistants
	4 Social Workers
	3 Recovery Coaches
	2 Psychiatric Nurse Practitioners
	2 Pharmacists
	1 Behavioral Health Clinician
	1 Paramedic
Recorded Process Training	Distributed by email to <u>all</u> ED/ Behavioral

Health/ Social Work staff

Tracking

Beginning March 2019, tracking of ED-initiated buprenorphine was initiated to track when buprenorphine was offered or provided to patients. In the first month of the process, 16 unique case reports were collected. Additionally, one case report was filed where a patient was offered buprenorphine but declined. Table 2 illustrates various steps of the algorithmic process and the rates of compliance with the process. COWS scores were performed on 14 patients (87.5%). Nine case report forms documented a COWS score of ≥ 8 , five documented a COWS <8, and two did not have a COWS score reported. As EMR access was not allowed by the project site, it is unknown whether a COWS score was documented in the patient's chart but omitted from the case report form. Buprenorphine was administered in the ED for all nine patients with a recorded COWS score $\ge 8 (100\%)$. One patient received ED dosing, but a waivered provider was unavailable to write a discharge prescription. One patient was administered buprenorphine in the ED but eloped prior to receiving a prescription. Home induction prescriptions were provided for seven patients total, including the five with a documented COWS <8 (100%) and the two patients who did not have a COWS score reported. Discharge prescriptions for buprenorphine were provided to 14 of the 16 patients with case reported filed (87.5%). Of the nine encounters that documented whether overdose education/naloxone was provided, three of the nine (33.3%) indicated that it was. The Doorway was the only referral source with 13 patients (81.25%) referred to its care coordination services. Recovery coaches were involved in nine out of 16 encounters (56.25%).

Table 2

ED Buprenorphine Initiation Process Compliance Analysis

Process Step	n	Total applicable cases	Percent Compliant
COWS Performed and Documented on Case Report	14	16	87.5
Buprenorphine Dosed in ED (COWS >8)	9	9	100
Discharged with Prescription (RX) After ED Induction	7	9	77.8
Home Induction RX Provided for COWS <8	7	7	100
Cases Where RX Given at Discharge (Waivered Provider)	14	16	87.5
Overdose Education/ Naloxone Provided	3	9	33.3
Referred to Doorway	13	16	81.25
Recovery Coach Involved	9	16	56.25

Table 3 includes reported barriers encountered by staff as well as suggestions for process improvements. Barriers to the process identified by staff included difficulties with inputting orders and writing prescriptions within the existing electronic medical record (EMR), a patient who did not get relief, and a patient who was not interested in medication for treatment. Suggestions for improvement included easier inputting of orders and prescriptions in the EMR, clearer documentation of COWS score in the EMR, locating forms in a central location, and ensuring follow-up arrangements.

Table 3

Barriers Encountered and Potential Improvements

Barriers Encountered	 "Patient stated did not get relief from dosing in ED" "Patient actively using (while in ED no less) and not ready to start med or accept change in lifestyle. Left AMA (against medical advice)." "Putting in RX in ED electronic record was laborious" "Computerized Physician Order Entry (CPOE) one-time orders are not well-built" (2 instances) "None" (5 instances)
Potential Improvements	 "It would be great if it was easier for providers to order" "Easier entry of RX into ED electronic record" "Clear documentation of COWS score in EMR. As a pharmacist, I would like to know the score and symptoms in case any additional treatment/symptom care can be recommended" "All forms in one location" "Assuring follow-up appointment as soon as possible" "Patient also received Ativan in ED. Patient qualified for 8mg dose. Will send email as to whether to add 8mg tabs, because we only have 2mg tabs in ED." "Not sure if possible but definite follow-up arrangement would be helpful"

Continuous improvement adjustments during implementation

During implementation, the project leader collected feedback from case report forms and post-encounter conversations with staff to guide process improvement. Examples of process issues that arose and adjustments are listed in Table 4.

Table 4

Continuous Improvements During Implementation		
Issue	Adjustment/Improvement	
Original phone number listed for after-hours Doorway messages was changed.	Guidelines updated with correct numbers. Binder updated.	
Order entry system did not allow for ordering buprenorphine films although films were stocked in Pyxis.	IT was contacted, and films were added to the order options.	

Inputting long instructions into home induction RX's was laborious.	Project leader printed "cheat sheets" at provider workstations and worked with IT to
induction KA's was laborious.	create "favorites" for easy input.
Referrals coming from Doorway created concern about whether a waivered provider	Instructed Doorway to call ahead to ensure a waivered provider available.
would always be available.	warvered provider available.
Patient who did not get an appointment before	Discussion with providers/ Doorway/
initial RX ran out, Doorway called to see if a	Behavioral Health director plan for bridge
refill could be issued. ED provider expressed	clinic, enhanced messaging to patients that
discomfort in issuing refills and becoming a	ED bridge is intended to be short term and
long-term bridge clinic. ED provider	ideally one-time. Discussed ED provider
expressed concern that refill requests would	flexibility for instances of legitimate repeat
deter ED providers to prescribe initial	visits. Follow-up meeting with ED providers/
prescription.	Doorway planned.
Hospital outpatient pharmacist expressed	Edited guidelines/ "cheat sheets" to allow for
concerns about challenges filling RXs that	interchange of tabs/ films and induction
indicate films or tabs as insurances often	instructions scaled to fit pill bottle.
prefer one over the other. Also concerned	
about length of home induction instructions.	

Discussion

Summary

This project achieved all its specific aims of developing a process for ED buprenorphine initiation including training a cohort of providers/ staff and tracking the new process. This project is an example of a successful diffusion of innovation and continuous improvement project that addressed a pressing clinical need for rapid access to evidence-based treatment for opioid withdrawal and OUD. The project achieved an overarching goal of creating the availability of buprenorphine in the ED, where it had not been available to patients before. Given the current regional and national opioid epidemic and its associated tragic burdens, this project may serve as a model for other organizations looking to implement rapid access to buprenorphine for OUD.

Particular strengths of this project include the work and dedication of the early adopter staff at WDH who showed enthusiasm and compassion towards a patient population that historically has not had easy access to care and evidence-based treatment. In just over a month of

data collection, at least 14 patients were started on buprenorphine. Because data collection in this project was restricted to voluntary written case reports, true numbers of patient initiations are likely higher. High rates of compliance with several steps of the process algorithm (Performance of COWS, Buprenorphine dosing in ED for COWS \geq 8, Home Induction RX's, RX's at discharge, referrals to Doorway) demonstrate fidelity to the process as developed and implemented. However, other steps in the process with lower rates of compliance, namely overdose education, naloxone distribution, and recovery coach involvement, highlight the need for continued process improvement.

Barriers identified by staff involved challenges with order entry and use of the EMR system. Similarly, several suggestions for improvement involved efficiency or clarification of order entry and documentation within the EMR. Other suggestions included stocking of different medication formulations in the hospital pharmacy and enhancement of follow-up appointments coordination. Additionally, the project leader was able to establish effective relationships with practice partners and seek continual feedback during implementation. The project leader was able to work with staff to successfully address each barrier identified.

Interpretation

This de novo process for initiating buprenorphine in the ED allowed providers and staff to offer a previously unavailable treatment that more effectively manages withdrawal, enhances engagement in treatment, and quickly connects patients to ongoing outpatient treatment in the community. After the Doorway had been able to send multiple patients to the ED for buprenorphine, the Doorway program manager provided feedback that "those are people we otherwise would have had essentially tell to go and use (illicit opioids)" to avoid severe withdrawal as they waited for access to community treatment services (P. Fifield, personal communication,

4/10/2019). The simple fact that there is now a safer alternative option for managing withdrawal and treating OUD available to patients in this community is a significant accomplishment.

Training of a cohort of early adopter ED providers, who model the benefits and use of this new ED process to other providers, is expected to result in continued and expanded use of this innovative intervention. It is hoped that with more universal use and experience with the process that more providers will become trained and waivered. Subsequently, opportunities for ED patient engagement and treatment for OUD will be increased. Continual collaboration with recovery coaches and behavioral health care coordination services (the Doorway) to ensure prompt and sustained outpatient engagement will be critical to the success.

While this project did not intend to measure or replicate longer term outcome results of other research, based on previous studies of ED-initiated buprenorphine, the intervention that is now available at WDH increases the odds for patients remaining in treatment (D'Onofrio et al., 2015). This should in turn, decrease their overall risk of morbidity and mortality (Sordo et al., 2017). Further research to confirm this hypothesis is needed. Another potential benefit of this project is that with repeated exposure to buprenorphine, even if patients do not engage in follow up, odds of retention in treatment are increased over time and exposures (Cunningham et al., 2013).

This project represents a concrete action within the organization to improve the care of patients with opioid use disorder, which is consistent with WDH's stated strategic plans for improving community health. The advent of WDH opening the Doorway as a centralized referral site and the availability of recovery coaches in the ED were beneficial to the success of this project. As this intervention continues, it will be important for the WDH system to ensure prompt follow-up for ongoing treatment after ED-initiation to minimize repeat ED visits for buprenorphine refills as some ED providers expressed an unwillingness to refill and if asked to do so, this might

jeopardize their willingness to prescribe at all.

Limitations

This project does have several limitations. Generalizability to other organizations may be limited as this project was conducted at one community hospital. Access to addiction expert consultants (i.e. project leader, Mass General colleagues) may not be readily available to all other organizations. Additionally, specialized services such as on-call recovery coaches and the Doorway referral site may not be available in other organizations. Waiver training of providers was voluntary and while a majority of ED providers participated, the same result may not be expected in other organizations as the project leader had a longstanding relationship with providers.

Unfortunately, several written case reports in this project were incomplete. Missing data on case reports could have either a positive or negative effect on results. Because case reports were isolated from EMR documentation and there was not constant oversight to ensure completion, voluntary completion of reports in a very busy ED environment likely resulted in incomplete and missed reports. To minimize the effect of missing data, the project leader gave several reminders to enhance reporting during multiple site visits as well as via email to providers. Ideally, a strategy for maximizing reporting via consistent reminders either embedded within the EMR or access to a web-based survey may improve reporting.

The inability to access data within the EMR also limited capacity for gathering more accurate and detailed data and prohibited the use of statistical process control measures. Because this was a brand-new process with only a limited number of encounters recorded, data was insufficient to assess long-term trends. Moreover, because EMR access was not granted, an accurate count of the total number of opportunities for buprenorphine initiation was not possible.

Without being able to assess the true denominator, it is not possible to assess the proportion of cases where the process was appropriately offered. It would be ideal to audit the EMR for presenting complaints, discharge diagnoses, and buprenorphine orders (in ED and discharge RXs) to get more accurate data. For future projects and/or research, understanding of other variables surrounding visits for buprenorphine initiation (demographics, comorbid health conditions, frequency of ED utilization, number of repeat visits, etc.) would also be valuable.

Conclusions

This project addressed a pressing need for the expansion of access to buprenorphine for patients with opioid withdrawal or seeking treatment for OUD. The development of an ED buprenorphine initiation process created access to an evidence-based treatment for patients in the ED that was previously not available. Training of a significant cohort of early adopters (60% of ED physicians, and multiple nursing and ancillary staff), larger than the targeted percentage, is expected to result in sustainability and continued diffusion of this innovative intervention.

Tracking of the process revealed that multiple patients over a short period of time were exposed to buprenorphine, which according to previous research, is a safe, practical, effective treatment. It is hoped that outcomes for patients exposed will be similar to research outcomes showing improved rates of treatment as well as reduced morbidity and mortality.

Given the nationwide epidemic of OUD with calls for the expansion of access to pharmacotherapy, including instances of legislated requirements like those in Massachusetts (MHA, 2019), it is probable that other organizations will pursue similar projects to offer ED-initiated buprenorphine. This project represents an example of one organization's experiences with process development, training, and tracking. While generalizability is limited in some

regards, the resources produced and experiences including lessons learned about barriers and suggestions for improvement may be valuable to other organizations.

Next steps for further development of this project should strive to enhance efficiency and ensure sustainability. In addition to targeting a goal for more ED providers to become waivered, it will be important to assess whether providers who are already waivered continue to offer buprenorphine. An expected change to a new EMR in the next several months will require attention to process details like order entry and discharge information to ensure the process is better integrated within the new EMR. Continued tracking of encounters through EMR audits would have improved accuracy and allow the ability to assess total numbers of eligible patients presenting to the ED to apply statistical process control measures for further improvement.

Future related research might include evaluation of other outcomes such as patient satisfaction, patient demographics, short and long-term engagement in outpatient treatment, provider satisfaction, provider utilization of buprenorphine, rate of return ED visits, subsequent hospitalizations, and overdose rates.

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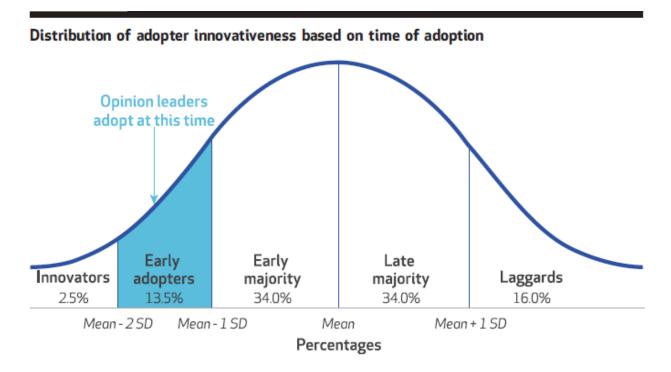
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Appendix A
Roger's Diffusion of Innovation Model



SOURCE Modified from Rogers EM, Diffusion of innovations (see note 9 in text). **NOTES** This exhibit is based on Everett Rogers's meta-review of empirical diffusion studies. SD is standard deviation.

(Dearing & Cox, 2018)

Appendix B

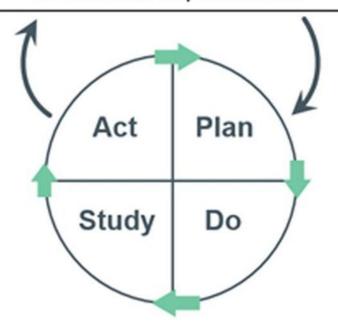
Institute for Healthcare Model for Improvement

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?



Appendix C Buprenorphine Readiness Assessment Tool

University of Wisconsin-Madison Prepared by Organizational Readiness Assessment

Readiness Tool 1: Buprenorphine Organizational Readiness Inventory

An executive champion supports buprenorphine	☐ Check if Yes List person below:	Relative Score Circle the Most Appropriate # for each Asset Very Supportive 5 4 3	List Examples/Details 1 WDH director of BH very receptive. Project m
treatment.	WDH director of BH	3 Minimal Support 1 No executive champion 0	
Influences outside the organization support	< < < < < < < < < < < < < < < < < < <	Significant Influences Exist 2	County and State highly focused on improving continuum of care during
buprenorphine treatment.	Strafford County IDN NH Hub and Spoke model	Modest Influences Exist 1 No Influence 0	2
Influential clinical champion (change leader) supports	List person below:	Very Supportive 5	Many ED providers open and supportive to id
buprenorphine treatment.	ED med director ED RN director ED MDs (x3) ED NP	Minimal Support 1	² ED leadership highly supportive
		No clincial champion 0	

Assets	□Check if (Yes)	Relative Score Circle the Most Appropriate # for each Asset	List Examples/Details
Front line staff support	List person below:	Very supportive 5	1
buprenorphine treatment	•	4	Multiple RN staff and CPLs supportive and int
		3	٠
		2	2
	Identified at least 6 RI Minimal support	Minimal support 1	
		No support 0	
Clinical staff	✓	Very supportive 5	List MAT already being used
support buprenorphine treatment	same as above	3	comfort meds for withdrawal only currently
Court Part II		2 Minimal support 1	2
		No support 0	ω

Total Relative Score=
Excellent (17+)
Good (13-16)
Poor (9-12)
Very Poor (<9)

		Operational Environment	
Support	☐ Check if (Yes)	List Primary Assets	Check if located on-site
Patients have funding source (e.g., commercial insurance,	<	Social work services available in ED to assist with insurance	✓
government, self-pay).		2. With advent of Doorway, care coordination services will be available	
We have physicians or other prescribers willing to prescribe buprenorphine.	<	Multiple ED docs interested 2.	<
We have a plan in place to educate staff, patients, and families about buprenorphine.	<	Project leader to provide process trainings for all interested 2.	<
We have a physician available to administer the buprenorphine implant.		1. N/A 2.	
We have strategies in place to reduce potential buprenorphine misuse or diversion.	<	1. ED initiation intended to be one-time event with arrangement of comm. f/ 2. NH PDMP and EDIS will allow providers to recognize repeat encounters	<

Scoring = "0"s or No's = targets for process improvement.

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Appendix D

Guideline:	ED buprenorphine for Opioid Withdrawal Protocol
Applies to:	Department of Emergency Medicine
Effective Date:	3/20/19
Reviewed and	Standardization Committee (Approved 2/26/19), P and
Approved by:	T (Approved 3/20/19)
Last Revision:	3/20/19

Standards/Definitions:

The following guideline has been developed to manage patients' opioid withdrawal symptoms while being treated in the Emergency Department. The guideline applies to patients who are actively going through opioid withdrawal. The active management of withdrawal symptoms is based on individual assessment and may vary based on specific clinical presentations.

Recommendations in this guideline derived from:

ASAM Clinical Practice Guideline: https://www.asam.org/docs/default-source/practice-guideline-supplement.pdf
NIDA-Initiating Buprenorphine Treatment in the Emergency Department:

 $\underline{https://www.drugabuse.gov/nidamed-medical-health-professionals/initiating-buprenorphine-treatment-in-emergency-department}$

Details:

Federal regulations permit the use of buprenorphine for a maximum of 72 hours for the purpose of relieving acute withdrawal symptoms while arranging for a patient's referral to treatment. Patients who are eligible for the opioid withdrawal guideline must show active signs of withdrawal and be equal to or greater than 18 years old. Appropriate conditions *may* include any of the following:

- 1. Patients in the ED for an extensive period of time who meet Clinical Opioid Withdrawal Scale (COWS) criteria (Score > 8) for opioid withdrawal
- 2. Patients in moderate-severe withdrawal (COWS >8) who are seeking assistance accessing treatment for their substance use and identified to have an opioid use disorder (OUD) in the course of their ER stay
- 3. Pregnant women in withdrawal (COWS >8) –an OB consult is required for any pregnant patient. Inpatient induction recommended for gestational age >20 weeks.

Assessment

- a. Medical exam
- b. Identify patients with possible OUD ("How many times in the last year have you used heroin, fentanyl or prescription opioids for nonmedical reasons?" Any response more than "never" is a positive screen and warrants further assessment.)
- c. Assess eligibility for ED-initiated buprenorphine by meeting following criteria:
 Recent regular opioid use (i.e. daily/almost daily use including within last 7 days)

- o Meets DSM-5 criteria for moderate to severe OUD (4 or more criteria)
- o Opioids are often taken in larger amounts or over a longer period of time than intended.
- o There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- o A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- o Craving, or a strong desire to use opioids.
- o Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
- o Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- o Important social, occupational or recreational activities are given up or reduced because of opioid use.
- o Recurrent opioid use in situations in which it is physically hazardous
- o Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
- o *Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
- o *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms
- o Needs treatment (i.e. not already engaged in formal medication treatment program)
- d. Assess for signs and symptoms of withdrawal

o Opioid withdrawal symptoms include:

Signs	Symptoms
Lacrimation	Yawning
Rhinorrhea	Sweating
Dilated pupils	Anxiety
Piloerection	Restlessness
Tachycardia	Insomnia
Hypertension	Chills
Diarrhea	Nausea
Vomiting	Cramping
	Abdominal pains
	Muscle aches

Utilize COWS scale (https://www.mdcalc.com/cows-score-opiate-withdrawal (also attached to end of this document) to determine if patient is in active withdrawal. If COWS score is >8, consider ED induction. If COWS<8, patient may be considered for Home Induction (See ED Buprenorphine/naloxone Home Induction Guideline).

e. Consider: Urine tox screen, pregnancy test. Lab testing not required but urine tox can confirm opioid use and exclude recent methadone if concerned. Consider LFT's, HIV and Hep screens as these are recommended in early treatment.

- f. Patient education should be conducted, ensuring patient makes an informed decision to take buprenorphine products to manage withdrawal symptoms/OUD. Provider will document that this discussion took place.
- g. SOS recovery coach (800-864-9040) to be called in while arranging ED induction or Home induction- Recovery Coach will offer their services to the patient while patient is in the ED. (If patient declines Recovery Coach services after coach arrives, this *does not* preclude patient from receiving buprenorphine or Rx at discharge.)
- h. Consider other prescribed or recreational substances and interactions as withdrawal/comfort meds are prescribed
- i. Consider complicating factors and potential contraindications:
 - o Recent methadone or long-acting opioid use (risk for precipitated withdrawal)
 - o Unstable alcohol, benzodiazepine or other sedative use
 - o Medical, psychiatric, or surgical instability or decompensated liver/lung/heart/kidney disease
 - o Prisoner- consult with jail medical staff
 - Pregnancy (buprenorphine not contraindicated but MUST be managed with OB consult)

Medication orders

- 1. Buprenorphine products (either buprenorphine ("Subutex" ${\mathbb R}$) or buprenorphine/naloxone
 - a) Please Note:
 - Use with caution in patients requiring opioid analgesics for pain management
 - Do not use in patients who may require surgery in the next seven days
 - IF AFTER CONSULTATION WITH OB, a decision is made to start buprenorphine in pregnant patient, buprenorphine without naloxone (Subutex), may be used.
 - b) Do not administer buprenorphine until patient objectively demonstrates signs and symptoms of opioid withdrawal (COWS score >8) or precipitated withdrawal may occur.
 - c) Withdrawal typically begins: 12 hours after last dose of short-acting opioid (heroin, oxycodone, Vicodin, etc.) or 24-48 hours after last dose of long-acting opioid (methadone)
 - d) First dose:
 - Wait until COWS score >8 before giving initial buprenorphine dose
 - Administer buprenorphine SL 4mg or buprenorphine/naloxone SL 4mg/1mg (may consider initial dose of 8mg if COWS score >12).
 - e) Observe for 45-60 minutes and if no adverse reaction, administer second dose of 4mg buprenorphine or 4mg/1mg buprenorphine/naloxone.
 - f) Observe for 60 minutes. If patient remains in moderate withdrawal (COWS >8), may consider adding additional 4mg buprenorphine or 4mg/1mg buprenorphine/naloxone and additional 60-minute observation. Do not exceed 16 mg in first 24 hours.

2. Clonidine

- a) May be given instead of buprenorphine for opioid withdrawal or to supplement treatment (not needed if able to bridge to appointment for continued buprenorphine treatment).
- b) Administer 0.1mg every 6 hours PRN signs and symptoms of withdrawal
- c) Do not exceed 0.4mg in 24 hours
- d) Hold any doses if:
 - SBP < 90 or DBP < 50 mm Hg
 - HR < 50
 - Excessive sedation
 - Orthostatic hypotension (drop of 20 mm Hg in SBP or 10 mm Hg in DBP)
- 3. To augment opioid withdrawal treatment, consider symptom-targeted treatment as below:
 - a) Mild-moderate pain management options
 - Acetaminophen 650mg PO every 6 hours PRN mild to moderate pain, not to exceed 4000mg in 24 hours in patients with normal hepatic function or 2000mg in patients with hepatic disease/cirrhosis
 - Ibuprofen 400mg PO PRN every 6 hours for mild pain, OR 600mg PO PRN every 6 hours for moderate pain, or 800mg PO every 8 hours PRN for moderate pain, not to exceed 2400mg in 24 hours; avoid in patients with renal impairment (eGFR < 30 mL/min/1.73m²)
 - b) Abdominal cramps
 - Dicyclomine 10mg PO every 6 hours PRN for mild stomach cramps, or 20 mg PO every 6 hours for moderate stomach cramps
 - c) Diarrhea
 - Loperamide 4mg PO after first loose stool, then 2mg PO each additional loose stool, not to exceed 16mg in 24 hours
 - d) Nausea
 - Ondansetron 4 mg PO every 8 hours PRN or 2 mg IV every 6 hours PRN Nausea or vomiting (CAUTION: Combination of buprenorphine and ondansetron may prolong QT interval) OR
 - Promethazine (Phenergan)-25mg PO every 6 hours PRN
 - e) Dyspepsia
 - Famotidine 40mg every 8 hours PRN
 - f) Muscle cramping
 - Methocarbamol 750mg PO every 6-8 hours PRN muscle cramps
 - g) Insomnia
 - Melatonin –over the counter
 - o 5mg PO every night before bed for mild insomnia, OR 10mg PO every night before bed for moderate insomnia
 - Trazadone
 - o 50mg every night before bed for mild insomnia, OR 100mg PO every night before bed for moderate insomnia

Discharge

- Prior to prescribing buprenorphine, providers should check NH Prescription Drug Monitoring Program.
- Provide short term (2-7 day Rx for buprenorphine/naloxone 8mg/2mg (tabs or films) OR buprenorphine SL 8mg tabs, take 2 tabs or films SL one time daily). Write RX as follows:
 - Buprenorphine/Naloxone 8mg/2mg Films (interchange with tabs as needed per insurance coverage)
 - o Instructions: Take 2 films (or tabs) sublingually one time daily.
 - O Dispense: 2- 7 day supply (duration can depend on when Doorway is able to secure f/u appt for patient)
- If patient was not in withdrawal (COWS <8) then follow **Buprenorphine Home Induction Guideline** for prescription dosing.

Take home Naloxone and Overdose prevention-

 Ensure all patients are educated on and given intranasal naloxone kit/instructions to take home.

Treatment and Harm Reduction Referral:

- RN or recovery coach will make direct phone call to **WDH Doorway** (603-740-2253) so care coordinators can arrange f/u within 2-7 days for patient with ongoing outpatient treatment. After hours, message to be left with patient contact information and Doorway care coordinator will contact patient next business day. Secure fax with patient information may also be sent to Doorway at fax 603-609-6691.
- Options for ongoing care may include the following WDH community buprenorphine partners:

Addiction Recovery Services- Intensive Outpatient Program

Office: 603-433-6250 Fax: 603-433-6350

1145 Sagamore Ave. Portsmouth, NH 03801

Cell: 814-515-9896 Website: arsnh.com Email: info@arsnh.com

o Groups

40 Winter St., # 204, Rochester, NH New Members: (800)683-8313

Info@joinGroups.com

- Referral to SOS Recovery (603) 841-2350- if patient declined to speak to on-call recovery coach during encounter.
- Also refer to Hand-Up Health Services- (http://nhhrc.org/resources/handup/) ((207) 370-7187) for syringes/naloxone refills/other harm reduction services in case of continued use or return to use.
- As needed, involve social work services for housing/financial assistance/PCP linkage

COWS Score

Resting Pulse Rate: beats/minute	GIUpset: over last 1/2 hour
Measured after patient is sitting or lying for one minute	0 no GI symptoms
0 pulse rate 80 or below	1 stomach cramps
1 pulse rate 81-100	2 nausea or loose stool
2 pulse rate 101-120	3 vomiting or diarrhea
4 pulse rate greater than 120	5 multiple episodes of diarrhea or vomiting
Sweating: over past 1/2 hour not accounted for by room temperature or patient activity.	Tremor observation of outstretched hands 0 no tremor
0 no report of chills or flushing	1 tremor can be felt, but not observed
1 subjective report of chills or flushing	
2 flushed or observable moistness on face	2 slight tremor observable
3 beads of sweat on brow or face	4 gross tremor or muscle twitching
4 sweat streaming off face	Variation Of an all their annual
Restlessness Observation during assessment	Yawning Observation during assessment
0 able to sit still	0 no yawning
1 reports difficulty sitting still, but is able to do so	1 yawning once or twice during assessment
3 frequent shifting or extraneous movements of legs/arms	2 yawning three or more times during assessment
5 unable to sit still for more than a few seconds	4 yawning several times/minute
Pupil size	Anxiety or Irritability
0 pupils pinned or normal size for room light	0 none
1 pupils possibly larger than normal for room light	1 patient reports increasing irritability or anxiousness
2 pupils moderately di lated	2 patient obviously irritable or anxious
5 pupils so dilated that only the rim of the iris is visible	4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches If patient was having pain	Gooseflesh skin
previously, only the additional component attributed	0 skin is smooth
to opiates withdrawal is scored	3 piloerrection of skin can be felt or hairs standing up
0 not present	on arms
1 mild diffuse discomfort	5 prominent piloerrection
2 patient reports severe diffuse aching of joints/muscles	
4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	
Runny nose or tearing Not accounted for by cold	
symptoms or allergies	Total Score
0 not present	
1 nas al stuf finess or unusually moist eyes	The total score is the sum of all 11 item
2 nose running or tearing	Initials of person
4 nose constantly running or tears streaming down cheeks	completing assessment:

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Appendix E

Guideline:	ED Buprenorphine/naloxone Home Induction Guideline
Applies to:	Department of Emergency Medicine
Effective Date:	3/20/19
Reviewed and Approved	Standardization Committee (Approved 2/26/19), P and T
by:	(Approved 3/20/19)
Last Revision:	3/20/19

Standards/Definitions:

The following guideline has been developed to provide guidance initiating treatment with buprenorphine/naloxone (Suboxone) for Emergency Department (ED) patients with opioid use disorder. The management of opioid use disorder (OUD) is based on individual assessment and may vary based on specific clinical presentations. The guideline applies to patients equal to or greater than 18 years old and have an opioid use disorder based on meeting at least four of the DSM-5 criteria (see Assessment below).

Recommendations in this guideline derived from:

ASAM Clinical Practice Guideline: https://guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf
NIDA-Initiating Buprenorphine Treatment in the Emergency Department:
https://www.drugabuse.gov/nidamed-medical-health-professionals/initiating-buprenorphine-treatment-in-emergency-department

Note: The provision of buprenorphine/naloxone from the ED for at home induction is <u>intended to be a one-time event</u> to transition the patient to outpatient treatment.

Details:

Providers MUST:

- Possess a DEA DATA X-waiver to prescribe buprenorphine for home induction
- <u>Check Prescription Drug Monitoring Program (PDMP) to check for prescriptions not reported</u>

Patients should NOT:

- Have acute/chronic pain requiring opioid management
- Need higher levels of care/admission due to advanced psychiatric illness or polysubstance use prior to induction
- Be on methadone maintenance

Assessment:

- a) Medical exam
- b) Identify patients with possible OUD ("How many times in the last year have you used heroin, fentanyl or prescription opioids for nonmedical reasons?" Any response more than "never" is a positive screen and warrants further assessment.)

- c) Assess eligibility for ED-initiated buprenorphine by meeting following criteria:
 - o Recent regular opioid use (i.e. daily/almost daily use including within last 7 days)
 - o Meets DSM-5 criteria for moderate to severe OUD (4 or more criteria)
 - Opioids are often taken in larger amounts or over a longer period of time than intended.
 - There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
 - A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
 - o Craving, or a strong desire to use opioids.
 - Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
 - Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
 - o Important social, occupational or recreational activities are given up or reduced because of opioid use.
 - o Recurrent opioid use in situations in which it is physically hazardous
 - Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
 - Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
 - o *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms
- d) Needs treatment (i.e. not already engaged in formal medication treatment program)
- e) Assess for signs and symptoms of withdrawal
 - o Opioid withdrawal symptoms include:

Utilize Clinical (COWS)

Signs	Symptoms
Lacrimation	Yawning
Rhinorrhea	Sweating
Dilated pupils	Anxiety
Piloerection	Restlessness
Tachycardia	Insomnia
Hypertension	Chills
Diarrhea	Nausea
Vomiting	Cramping
	Abdominal pains
	Muscle aches

Opioid Withdrawal Scale

(https://www.mdcalc.com/cows-score-opiate-withdrawal or see end of this document) to determine if patient is in active withdrawal. If COWS score is >8, consider ED induction (see WDH Opioid Withdrawal Guideline). If COWS<8, patient may be considered for Home Induction.

- f) Consider: Urine tox screen, pregnancy test. Lab testing not required but urine tox can confirm opioid use and exclude recent methadone if concerned. Consider LFT's, HIV and Hep screens as these are recommended in early treatment.
- g) Patient education should be conducted, ensuring patient makes an informed decision to take buprenorphine products to manage OUD. Provider will document that this discussion took place.
- h) **SOS recovery coach (800-864-9040) to be called in** while arranging Home Induction/plan for discharge- Recovery Coach will offer their services to the patient while patient is in the ED. (If patient declines Recovery Coach services after coach arrives, this *does not* preclude patient from receiving buprenorphine or Rx at discharge).
- i) Consider other prescribed or recreational substances and interactions as withdrawal/comfort meds are prescribed
- j) Consider complicating factors and potential contraindications:
 - Recent methadone or long-acting opioid use (risk for precipitated withdrawal
 - o Unstable alcohol, benzodiazepine or other sedative use
 - Medical, psychiatric, or surgical instability or decompensated liver/lung/heart/kidney disease
 - o Prisoner- consult with jail medical staff
 - Pregnancy (buprenorphine not contraindicated but MUST be managed with OB consult. Inpatient induction recommended for gestational age >20 weeks.)

Medication orders:

- For non-pregnant patients without other contraindications, ED Provider will prescribe the following RX:
 - Buprenorphine/Naloxone 8mg/2mg Films (interchange with tabs as needed per insurance coverage)
 - Instructions: On day 1, take 4mg sublingually experiencing at least 3 withdrawal symptoms. Wait 45 minutes and if still having symptoms, take another 4mg.
 Wait 6 hours and if still having symptoms, take additional 4mg. On day 2 and beyond, take 16mg sublingually one time daily.
 - O Dispense: 2- 7 day supply (duration can depend on when Doorway is able to secure f/u appt for patient)

- Provide patient with detailed handout: "Guide for Patients Beginning Buprenorphine Treatment at Home" (See Handout at end of this document. Copies will also be stored in ED buprenorphine binder)
- If it is decided that a pregnant patient is appropriate for outpatient induction and that buprenorphine *without naloxone* product is to be used, the following RX would be provided:
 - o Buprenorphine SL tablet 8mg.
 - o Instructions: On day 1, take ½ tablet(4mg) when you are experiencing at least 3 withdrawal symptoms. Wait 45 minutes and if still feeling withdrawal symptoms, take ½ tablet. Wait 6 hours, and if still feeling withdrawal symptoms, take an additional ½ tablet. On day 2, take 2 tablets (total 16 mg buprenorphine) once daily. Repeat this 16 mg dose once daily until follow-up appointment. (2-7 day supply provided, depending on arranged day of follow-up with community buprenorphine provider)
 - Provide patient with detailed handout: "Guide for Patients Beginning Buprenorphine Treatment at Home" (See Handout at end of this document. Copies will also be stored in ED buprenorphine binder)

Take home Naloxone and Overdose prevention-

• Ensure all patients are educated on and given intranasal naloxone kit to take home.

Discharge:

Treatment and Harm Reduction Referral:

- RN or recovery coach will make direct phone call to **WDH Doorway** (603-740-2253) so care coordinators can arrange f/u within 2-7 days for patient with ongoing outpatient treatment. After hours, message to be left with patient contact information and Doorway care coordinator will contact patient next business day. **Secure fax** with patient information may also be sent to Doorway at **fax 603-609-6691**.
- Options for ongoing care may include the following WDH community buprenorphine partners:
 - Addiction Recovery Services- Intensive Outpatient Program

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o Groups

40 Winter St., # 204, Rochester, NH New Members: (800)683-8313

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- Referral to **SOS Recovery** (603) 841-2350—especially if patient declined to speak to on-call recovery coach during encounter.
- Also refer to **Hand-Up Health Services** (http://nhhrc.org/resources/handup/) ((207) 370-7187) for syringes/naloxone refills/other harm reduction services in case of continued use or return to use.
- As needed, involve social work services for housing/financial assistance/PCP linkage

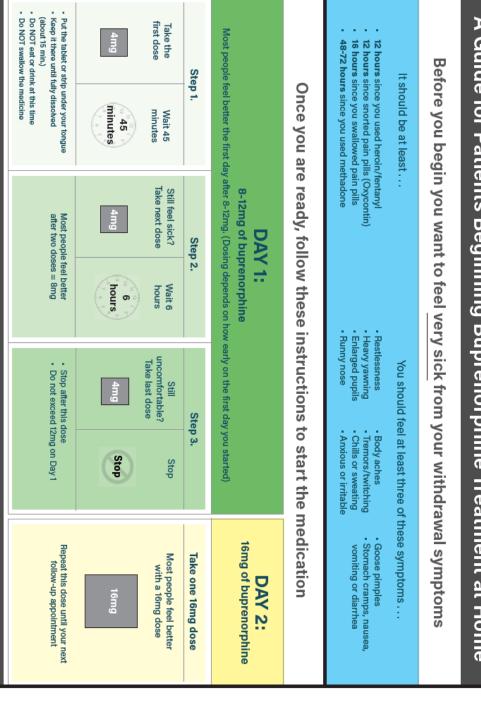
COWS Score

Resting Pulse Rate:beats/minute	GIUpset: over last 1/2 hour
Measured after patient is sitting or lying for one minute	0 no GI symptoms
0 pulse rate 80 or below	1 stomach cramps
1 pulse rate 81-100	2 nausea or loose stool
2 pulse rate 101-120	3 vomiting or diarrhea
4 pulse rate greater than 120	5 multiple episodes of diarrhea or vomiting
Sweating: over past 1/2 hour not accounted for by room temperature or patient activity.	Tremor observation of outstretched hands 0 no tremor
0 no report of chills or flushing	1 tremor can be felt, but not observed
1 subjective report of chills or flushing	2 slight tremor observable
2 flushed or observable moistness on face	4 gross tremor or muscle twitching
3 beads of sweat on brow or face	
4 sweat streaming off face	
Restlessness Observation during assessment	Yawning Observation during assessment
0 able to sit still	0 no yawning
1 reports difficulty sitting still, but is able to do so	1 yawning once or twice during assessment
3 frequent shifting or extraneous movements of legs/arms	2 yawning three or more times during assessment
5 unable to sit still for more than a few seconds	4 yawning several times/minute
Pupil size	Anxiety or Irritability
0 pupils pinned or normal size for room light	0 none
1 pupils possibly larger than normal for room light	1 patient reports increasing irritability or anxiousness
2 pupils moderately di lated	2 patient obviously irritable or anxious
5 pupils so dilated that only the rim of the iris is visible	4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches If patient was having pain	Gooseflesh skin
previously, only the additional component attributed	0 skin is smooth
to opiates withdrawal is scored	3 piloerrection of skin can be felt or hairs standing up
0 not present	on arms
1 mild diffuse discomfort	5 prominent piloerrection
2 patient reports severe diffuse aching of joints/muscles	
4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	
Runny nose or tearing Not accounted for by cold symptoms or allergies	Total Score
0 not present	
1 nas al stuf finess or unusually moist eyes	The total score is the sum of all 11 item
2 nose running or tearing	Initials of person
4 nose constantly running or tears streaming down cheeks	completing assessment:

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

If you develop worsening symptoms while starting buprenorphine before your scheduled outpatient appointment return to the emergency department

Þ **Guide for Patients Beginning Buprenorphine Treatment at Home**



Appendix F

Buprenorphine waiver trainings:

Regional in-person trainings-

https://www.bmcobat.org/training/

Online trainings-

https://pcssnow.org/medication-assisted-treatment/

Process training materials:

Presentation slides-

https://docs.google.com/presentation/d/1dcuAqTrrWlKT6PrPhU8VY-

4J_Ay_MMFUkDjETd6Z4dg/edit?usp=sharing

Recorded presentation-

https://hosting2.desire2learncapture.com/mgh/1/Watch/8189.aspx

ED Buprenorphine Binder documents:

WDH approved ED guidelines-

a. Opioid Withdrawal-

 $\underline{https://docs.google.com/document/d/1pjcDf69gOeSdgRU8zqUnreKkH8eXeuZdGRFin1t}$

HcNo/edit?usp=sharing

b. Home Induction-

 $\underline{https://docs.google.com/document/d/1BQs7G8GxkwRujbyE670mTO6FwwwqSMF6ZET}$

QdT04JMg/edit?usp=sharing

Case Report Form-

https://docs.google.com/document/d/1br0XgZGwGCbYlv1Jinfvu37BoFOVji5wVdOxb8mvIpM/edit?usp=sharing

Diagnosis of OUD (DSM 5 Criteria)-

https://docs.google.com/document/d/1Tmfu2FeZTTjiWFXqBSmNaeFTGXm7m3dnipWEFF6qh CM/edit?usp=sharing

NIDA ED Buprenorphine Academic Detailing brochure-

https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/edbuprenorphinehandout.pdf

NIDA Home Initiation of Buprenorphine Patient Handout-

https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/home_buprenorphine_initiation.pdf

NIDA ED Buprenorphine Initiation Algorithm-

https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/algorithm.pdf

Buprenorphine: A Guide for Nurses-

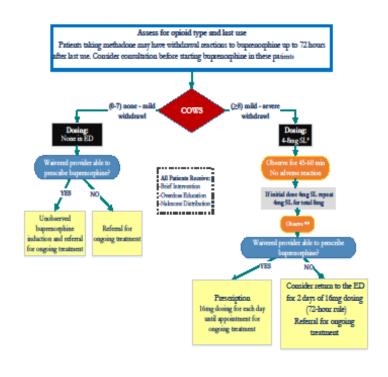
https://www.naabt.org/documents/TAP30.pdf

Appendix G

ED-Initiated Buprenorphine Pilot- Case Reporting Form

Initials of reporter:	_		
Date/Time of Patient Encounter:			
Other staff/nartners involved in this rase?	□ Rehavioral Health	☐ Social Worker	□ Decovery Coach

Was patient in withdrawal?	Y/N
If yes, was COWS performed?	Y/N
COWS score?	
Buprenorphine dosed in ED?	Y/N
Buprenorphine RX given?	Y/N
Overdose education/naloxone kit provided?	Y/N
How many days supply?	
Referral?(circle one)	
Groups	
Addiction Recovery	
Services	
Appointment? (circle one)	
RN or staff spoke directly and confirmed appt?	Appt date:
 Left voicemail or message for clinic to contact patient? 	



Please comment on the following:

What were <u>barriers</u> you encountered in delivering ED initiated buprenorphine for this patient (i.e. insurance issues, transportation, patient reluctance, staff support)?

What do you see as potential improvements to the process of initiating a patient on buprenorphine?

Appendix H WDH Letter



December 5, 2018

Jason R. Lucey, MSN, FNP-BC 101 Belknap Street Dover, NH 03820

Dear Mr. Lucey,

Thank you for your proposal, "A Pilot of Emergency Department-Initiated Buprenorphine for Opioid Withdrawal and Opioid Use Disorder," dated 12/05/2018. We have reviewed your proposal and it meets the criteria for a Quality Improvement Project.

We appreciate the time and attention you have invested in this excellent project. It is timely, relevant, and addresses a vital need for our patients and community. We are eager to provide any assistance you may require throughout the process. Please don't hesitate to reach out.

Sincerely,

Kate Sullivan Collopy, PhD, RN

Director, Nursing Education, Research & Innovation

kate.collopy@wdhospital.com

(603) 609-6919

Pager: (603) 517-8491

Kelly Grady, PhD, RN-BC

Nurse Scientist, Nursing Education Research & Innovation

External Faculty Nurse Scientist, The Yvonne L. Munn Center for Nursing Research, MGH

edgk@wdhospital.com

(603)740-3389

Appendix I UNH Quality Improvement Approval Letter



College of Health and Human Services Department of Nursing

Hewitt Hall 4 Library Way Durham, NH 03824

V: 603.862.2271 F: 603.862.4774

December 6, 2018

Dear Jason

The UNH Department of Nursing Quality Review committee has reviewed your DNP proposal.

Titled: "A Pilot of Emergency Department-Initiated Buprenorphine for Opioid Withdrawal and
Opioid Use Disorder" Based on the SQUIRE 2.0 guidelines for determination of quality
improvement and research activities, the proposal meets the standards for a quality improvement
project. The Quality Review committee determined that this project does not constitute research,
and therefore does not need review by the UNH Institutional Review Board for the Protection of
Human Subjects, and there are no potential conflicts of interest (financial, professional, or

Good Luck,

Pamela P DiNapoli PhD, RN.CNL

Assistant Professor and Graduate Programs Coordinator

institutional). You may implement your project as proposed.

247 Hewitt Hall

Durham NH 03824

cc. K. Nolte

J. Dufresne