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ASSESSMENT OF THE USE OF OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION BY MAINE BUPRENORPHINE/NALOXONE PRESCRIBERS

A Capstone Report Stephen Kirsch, MD

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Abstract

Background: Overdose deaths, specifically related to opioids, have been identified as a public health problem both nationally and in the state of Maine. Overdose Education and Naloxone Distribution (OEND) is an innovative model of patient education that has been shown to be effective in increasing knowledge of overdose risk and has the potential to help reduce opiate related overdose deaths.

Methods: A 28-item web-based survey examining clinician attitudes, OEND practices and characteristics was distributed to 196 Maine based physicians with a Drug Enforcement Agency waiver to prescribe buprenorphine/naloxone. Facilitators and barriers to the provision of OEND were also assessed. Surveys were sent via regular and email with follow up surveys sent at 2-4 week intervals. Responses were received from 28 of the 196 physicians with valid addresses (14.4% response rate).

Results: The majority of respondents reported providing OEND in their clinical settings and attitudes and beliefs of respondents are consistent with ongoing diffusion of OEND in Maine. The major facilitators to the provision of OEND were the interest in providing an agreement with the importance of OEND. Identified barriers included the "time" required to provide education and the cost of naloxone as well as lack of insurance coverage for the medication.

Conclusions: Many physicians are providing OEND in their clinical settings. Addressing identified facilitators and barriers to delivering OEND is essential to the further spread of patient education and prescribing of naloxone. The diffusion of this innovative patient education and naloxone has the potential to reduce opiate related drug deaths in the future.

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Introduction

A. Description of Problem

Opiate related overdose deaths have received national attention as a worsening public health crisis. Between 2000 and 2014, the national rate of drug overdoses involving opioids has increased 200% and nearly 500,000 individuals have died from drug overdoses during that period (Rudd, Aleshire, Zibbell, & Gladden, 2016). In 2014, approximately 29,000 deaths were related to opioid overdose nationwide (Dunlap and Cifu, 2016). In the state of Maine, one in four overdose deaths in 2014 were related to heroin or morphine (Diomede, 2014).

The statistics for drug related deaths highlight the breadth and scope of the opioid crisis here in Maine. Data available on drug related death rate in each of Maine's eight Public Health Districts illustrates the increased problem of opioid use and related overdoes in the state. Between 2013 and 2015, the drug related death rate per 100,000 individuals varied by Public Health District between 10.6 to 20.4 per 100,000 individuals (See Figure 1). To provide context, the drug overdose death rate in 2014, nationally was 14.7 deaths per 100,000 (Rudd et al., 2016). The highest death rates were seen in Public Health District 2 (Cumberland County) at 20.4 deaths per 100,000 and in Public Health District 5 (Somerset and Kennebec Counties) at 19.6 deaths per 100,000. The lowest death rate per 100,000 individuals was 10.6 in Public Health District 8 (Aroostook County) ("Substance Abuse Trends," 2016). The variability of drug related death rates between Public Health Districts highlights the need to improve access to physicians that provide treatment for OUD in the areas with the highest drug related death rates.

COMBINED YEARS 2013-15 District 8 Aroostook 10.6 deaths per 100,000 District 6 Penquis 14.5 deaths District 5 per 100,000 Central 19.6 deaths per 100,000 District 7 Downeast District 3 14.3 deaths Western per 100,000 15.6 deaths per 100,000 District 4 Midcoast 12.8 deaths per 100,000 District 2 Cumberland 20.4 deaths per 100,000 District I York 16.3 deaths per 100,000

FIGURE 1. DRUG-RELATED DEATH RATE PER 100,000 BY PUBLIC HEALTH DISTRICT

In response to the increasing public health crisis, the state of Maine has responded in a variety of ways. Local education has been provided at a Portland Needle Exchange center and the City of Portland started the Overdose Prevention Project in 2002. Larger statewide projects

such Maine Quality Counts "Caring for ME" and the Maine Opiate Collaborative have combined the expertise from multiple stakeholders to improve knowledge and shape a comprehensive response to this crisis. In April 2016, the Maine state legislature passed a law that allows the distribution of Naloxone at the pharmacy without a physician's order.

B. Overview of Opioid Use Disorder Prevention and Treatment

Treatment is crucial to reducing the morbidity and mortality associated with OUD. Medication Assisted Treatment (MAT) using the supervised prescription of opioid agonist treatments has been identified as the preferred first-line evidenced-based treatment of OUD (Dunlap and Cifu, 2016). MAT utilizes agonist and/or antagonist medication in association with psychosocial interventions such as individual therapy, group therapies and the comanagement of physical and behavioral health conditions. The use of mediation with counseling services has been found to be more effective than when either component is used alone. (Chou. Korthuis, Weimer, Bougatsos, Blazina, Zakher, Grusing, Devine, and McCarty, 2016) Despite this recommendation, fewer than half of individuals affected by OUD have access to MAT and the full spectrum of recommended behavioral, social supports and recovery services. Given the high rates of relapse associated with OUD, even individuals who receive treatment services remain at risk of overdose. In addition to MAT, the literature supports the effectiveness of interventions such as educational efforts around overdose prevention and the distribution of naloxone, an overdose reversal medication, in reducing the number of overdose deaths.

Overdose Education and Naloxone Distribution (OEND) is an innovative set of educational elements such as instruction on initiating rescue breathing, performing a sternal rub. providing cardiopulmonary resuscitation and activating the Emergency Medical System (EMS). An Assessment of OEND by Maine Buprenorphine/Naloxone Prescribers

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OEND also includes discussion of naloxone, a high affinity antagonist medication with a favorable safety profile. Naloxone has been used acutely to reverse the effects opiate related overdoses (Wermeling, 2015). Discussion of the indications for the use of this medication, the safety profile, and instruction on intranasal or intramuscular administration are important aspects of OEND. Education related to naloxone also includes the provision of information about the medication, routes of administration and possible side effects. Another essential element of OEND is the physician providing a prescription for naloxone to have available in the event of an overdose. Additional aspects of OEND described by Bowman, Eiserman, Beletsky, Stancliff, & Bruce, (2013) include the emergency treatment of initiation of rescue breathing, administration of naloxone and staying with the person until help arrives. Wermeling (2015) included education regarding overdose recognition.

Interventions such as Overdose Education and Naloxone Distribution (OEND) have resulted in the reported reversals of opiate related overdoses (Wheeler, Davidson, & Jones, 2012). In addition, a recent meta-analysis of 41 studies by Mueller, Walley, Calcaterra, Glanz, & Binswanger (2015) concluded the use of education and prescribing naloxone may reduce overdoses and overdose related deaths. Finally, Doe-Simkins and Bell (2014) highlight the benefits of these educational discussions to include enhancing patient-provider relationships, reducing harm and improving survival.

One of the principal challenges associated with providing OEND has been identifying those individuals most likely to benefit from the education. The American College of Emergency Physicians (ACEP) identified the importance of bystander use of naloxone. Per an ACEP policy statement, healthcare providers can play an integral role in promoting "education An Assessment of OEND by Maine Buprenorphine/Naloxone Prescribers Kirsch 7 | P a g e

of the overdose recognition and safe naloxone administration by non-medical providers" ("ACEP Policy Statement," 2015). The policy identifies individuals completing detoxification or abstinence programs as potential recipients of naloxone. However, the ACEP policy does not include a discussion of providing OEND to individuals actively engaged in MAT.

The literature details the evaluation of OEND in multiple settings including primary care. Educational efforts have been provided to different audiences such as individuals treated with methadone (Walley, Doe-Simkins, Quinn, Pierce, Xuan, & Ozonoff, 2013), bystanders (Jones, Roux, Stancliff, Matthews, & Comer, 2014), family members (Bagley, Peterson, Cheng, Jose, Quinn, O'Connor, & Walley, 2015), and non-paramedic first responders (Davis, Ruiz, Glynn, Picariello, & Walley, 2014). The duration of the educational component varied from 5-10 minutes (Behar, Santos, Wheeler, Rowe, & Coffin, 2015) to 4 hours (Walley et al., 2013). Although OEND has been assessed in multiple settings and can be presented in brief encounters with demonstrated benefits to individuals with OUD, little is known about the diffusion of this innovative education approach among Maine physicians prescribing buprenorphine/naloxone based MAT.

This study was designed to assess the adoption of OEND by Maine based physicians with a Drug Enforcement Agency waiver to prescribe buprenorphine/naloxone in their clinical settings. The principal aims of this study were twofold: 1) to assess current practices related to OEND and; 2) to examine provider attitudes and beliefs related the delivery of OEND in their clinical practice. A provider survey was used to assess the current level of provision of education intended to reduce overdoses as well as providers' recommendations to patients regarding naloxone. Given the provision of OEND is a recent innovation in patient education and care,

Maine based providers of MAT were assessed for their attitudes and beliefs toward the delivery of OEND. Finally, barriers and facilitators to delivering OEND were also assessed.

Methods

This project was initiated to assess the degree to which Maine based buprenorphine/naloxone prescribing physicians are educating their patients regarding acute responses to drug related overdoses using resuscitation techniques and administration of naloxone. As a primary care physician prescribing buprenorphine/naloxone, understanding the use of this innovative education technique among providers in Maine was of great interest to me. The initial proposal included a mix-methods approach that included the use of interviews with subject matter experts to guide the development of the provider survey of Maine based physicians. The Capstone Committee expressed concern regarding the scope of the project and the risk of a poor response rate to a survey. To address these recommendations, the scope of this project was narrowed to include the creation and use of survey without the series of qualitative structured interviews with key informants. Key informants were utilized on an informal basis to guide survey development. Additionally, to increase participation, the attention was paid to designing a short user-friendly survey to help obtain a best response and completion rates. The final instrument, a 28-item survey, was distributed to Maine based providers of buprenorphine/naloxone.

The survey was designed to assess provider attitudes and current practices related to OEND by providers in Maine. The design of the questionnaire was largely informed by the primary constructs associated with the Diffusion of Innovation theoretical framework. The

concise survey assessed current practices of OEND and physician's attitudes and beliefs regarding OEND.

A. Survey Design: A web-based survey was designed using the SNAP survey software tool. The questionnaire included yes/no response items, 5-point Likert scales as well as open-ended questions on topics of interest. Background information collected on key provider domains of interest including: years since medical school graduation, medical specialty, years with a Drug Enforcement Agency (DEA) waiver, patient limit, and if the individual was currently prescribing Buprenorphine/naloxone.

Survey questions were modeled on the constructs used in the Pankratz, Hallfors, & Cho (2002) study. Pankratz et al. (2002) provide a framework for assessing the constructs of the Diffusion of Innovation Theory (Rogers, 2003). Specifically asking providers their attitudes and beliefs regarding the following:

- Relative Advantage (Overdose education and naloxone distribution will increase the quality of MAT provided and the provider would like to implement OEND);
- Compatibility (Overdose education and naloxone distribution is compatible with other patient education provided);
- Complexity (Overdose education and naloxone distribution will not be too complicated to integrate);
- Trialability (It is acceptable to provide OEND on a limited basis) and;
- Observability (Implementing OEND will have an impact on rates of overdose).

Survey questions also included a section regarding attitudes and beliefs surrounding overdose education and naloxone distribution. Responses to these questions were formatted on a 5 answer Likert scale. Other questions in this survey assessed the communication channels by which prescribers have been exposed to the innovation of overdose education and naloxone distribution. Finally, respondents were asked for information on potential barriers and facilitators to providing overdose education and naloxone distribution. A PDF version of the survey is included in Appendix A.

B. Institutional Review Board (IRB): This research protocol was reviewed and approved by the University of Southern Maine Institutional Review Board (IRB). The review deemed the study to be Non-Research; the determination letter is available for review in Appendix B.

C. Data Collection: Maine based providers of buprenorphine/naloxone were identified through the Substance Abuse and Mental Health Services Administration (SAMHSA)

Buprenorphine Provider locator website. Information from the SAMHSA provider locator was cross-referenced with other Internet based listings of providers in Maine to ensure our sample captured the maximum number of identified providers in the state and to verify the accuracy of addresses of primary clinical site. A total of 196 providers were identified with a mailing address; providers were sent survey invitations via standard mail in September of 2016. Four weeks later 145 providers were sent follow-up reminders via standard mail. In addition, the 52 providers with identified email addresses received three email invitations over a 5-week period from October 2016 to early November 2016. One letter was returned as an invalid address. The

final sample consisted of 195 physicians, of which 28 physicians responded to the survey, for response rate was 14.4%.

D. Data Analysis: Results were analyzed using SPSS Version 10. Descriptive statistics, including frequencies and means, were generated to examine characteristics of respondents: frequency and format of OEND provided; aspects of OEND provided; groups provided with OEND and; sources of OEND information for physicians. Physicians were surveyed regarding the elements of overdose education and naloxone information provided. Frequencies and percentages of each of ten educational elements provided were calculated. Physicians were provided with an "other" category to provide qualitative input. Frequencies and percentages of subgroupings including: None, 1-3 educational elements and 4 or more elements, were calculated. Response to the qualitative questions were analyzed for the most frequently described categories. This information provides general themes of barriers and facilitators for the implementation of OEND. Finally, provider's zip codes were utilized to map the 196 physicians with a waiver to prescribe buprenorphine/naloxone in each of the eight Public Health District of Maine using Arc GIS. This analysis provides the density of physicians with a waiver in each Public Health District and allows assessment of the aspect of access to MAT providers in geographic areas throughout the state.

Results

A. Characteristics of Respondents

Respondent characteristics are displayed below in Table 1. Of the 28 respondents, 89% reported currently prescribing buprenorphine/naloxone to patients, with a mean duration for prescribing of 6.5 years. The majority of respondents specialized in Family Medicine (57%) followed by Internal Medicine (18%), Psychiatry (18%) and Pediatrics (4%). Only three of the 28 respondents reported receiving specialty training in Addiction Medicine (11%) and two were Board certified by the American Board of Addiction Medicine (7%). Most providers reported a waiver to treat up to 100 patients (71%); fewer providers reported a 30-patient limit waiver (18%) or a 275-patient limit waiver (11%).

TABLE 1. OVERVIEW OF PROVIDER CHARACTERISTICS AND PRESCRIBING PRACTICES (N=28)

Characteristics		
Provider Education	Mean	Range
Years since Graduation from Medical School	24.36	48 (4 – 52)
Provider Specialty	N	Percent
Family Medicine	16	57.1%
Internal Medicine	5	17.9%
Pediatrics	1	3.6%
Psychiatry	5	17.9%
Specialty Training in Addiction Medicine	3	10.7%
American Board of Addiction Medicine Certified	2	7.1%
Other	1	3.6%
Provider Buprenorphine/Naloxone Certification & Prescribing History	Mean	Range
Years with Prescribing Waiver for Buprenorphine/Naloxone	6.79	15 (1-16)
Years Prescribing Buprenorphine/Naloxone	6.50	15 (1-16)
Current Provider Buprenorphine/Naloxone Prescribing Practices	N	Percent
Currently Prescribing Buprenorphine/Naloxone	25	89.3%
Currently NOT Prescribing Buprenorphine/Naloxone	3	10.7%
Waiver Panel Size	N	Percent
30 Patients	5	17.9%
100 Patients	20	71.4%
275 Patients	3	10.7%

B. Provision of OEND

Overdose education and Naloxone distribution includes multiple elements that can be provided variably either all at once or on separate occasions. In addition, these elements could be provided by different members of the health care team over time. Table 2 includes data regarding the frequency and format of OEND being provided by survey participants. Of the respondents, 79% reported provided education regarding overdose and a smaller proportion, 57%, reported providing education regarding naloxone. The mean years of providing this type of

education was 4.24 years. Of those physicians providing OEND, 24% presented this education in a formal format such as an educational session, lecture and/or group therapy. Of those physicians who were not providing OEND in a formal format such as an educational session, lecture and/or group therapy, these respondents were asked if they were providing OEND as part of a routine office visit. Of these 18 respondents, two thirds reported offering OEND as part of routine office visits. In addition, 38% of respondents reported providing education to family members and 38% reported also providing prescriptions for naloxone.

TABLE 2. FREQUENCY & FORMAT OF OVERDOSE EDUCATION & NALOXONE DISTRIBUTION

Characteristics		
Frequency of OEND	Mean	Range
Years Providing OEND Education	4.24	15 (1-16)
Type of OEND Provided	N=28	Percent
Education Regarding Overdose	22	78.6%
Education Regarding Naloxone	16	57.1%
Format for Providing OEND*	N=21	Percent
Formal Format	5	23.8%
Part of Routine Office Visit	12	42.9%
Provided to Family Members	8	38.1%
Naloxone Distribution*	N=21	Percent
Currently Prescribing Naloxone	8	28.6%

^{*}NOTE: Only individuals who reported providing Overdose Education and Naloxone Distribution responded to this Question (n=21).

In response to the open-ended question regarding "other ways OEND is provided" in the clinical setting, three respondents reported utilizing non-physician staff members to provide education, such as medical assistants (MA), registered nurses (RN) and/or licensed alcohol and drug abuse counselors (LADC). One respondent described creating a training module to present

the information to their patients. Respondents also described providing OEND during individual appointments (n=5), group visits (n=4), inpatient consultations and appointments with family members. One respondent integrated information regarding the loss of drug tolerance associated with MAT in introductory patient paperwork that the practice requires to be reviewed and signed during intake appointments.

The aspects of OEND education reported by respondents are reported below in Table 3. Nine specific elements were queried with an additional option of "other." Most respondents endorsed providing educational information on treatment options such as counseling, intensive outpatient programs and support groups in the area (61%). Physicians reported providing naloxone education (46%), indication for naloxone use (43%) and instruction on use of naloxone (39%). Discussion of "Activation of Emergency Medical System (EMS)" was endorsed by 39% of respondents. Topics listed as "Other" included using online or video educational resources with patients.

TABLE 3: ASPECTS OF OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROVIDED

Aspects of Education Provided	N=28	Percent
Rescue Breathing	2	7.1%
Sternal Rub	4	14.3%
Initiate CPR	4	14.3%
Activate EMS	11	39.3%
Provide Naloxone	13	46.4%
Indications for Naloxone	12	42.9%
Safety Profile of Naloxone	7	25.0%
Instruction on use	11	39.3%
Information of Treatment options	17	60.7%
Other	3	10.7%

Information on the individual types of OEND provided by respondents was used to create a scale of the total number of interventions provided by each respondent. Overall, 39% of respondents did not provide any of the listed educational elements of OEND, 25% of respondents provided education containing 1-3 of the queried OEND elements and 39% provided 4 or more OEND educational elements (See Table 4).

TABLE 4. SUBGROUP ANALYSIS BASED ON NUMBER OF EDUCATIONAL ELEMENTS PROVIDED

Educational Interventions Provided	N=28	Percentage
None	11	39.3%
1-3 Interventions	7	25.0%
4 or More Interventions	10	35.7%

Respondents were also asked to report on their target populations for OEND educational training which is summarized below in Table 5. with OEND. Individuals being treated with buprenorphine/naloxone (57%), individuals being treated with chronic opiates (43%) and family members (36%) are the primary recipients of OEND. Providers also reported offering OEND to individuals contemplating buprenorphine/naloxone treatment (18%) and friends (18%).

Approximately 11% of providers also reported providing OEND to individuals treated for other substances. Finally, the single respondent, noting an "Other" category, identified the other recipients of OEND to be "any family or friend that is available".

TABLE 5: GROUPS PROVIDED WITH OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION

Groups Provided OEND	N=28	Percent
Individuals treated with Buprenorphine/naloxone	16	57.1%
Contemplating treatment	5	17.9%
Individuals treated with chronic opiates	12	42.9%
Family members	10	35.7%
Friends	5	17.9%
Individuals treated with other substances	3	10.7%
Other	1	3.6%

C. Diffusion of Innovation Theory Analysis

The constructs of the Diffusion of Innovation theory were utilized to examine how physicians learned about the innovation of OEND. This theory includes the use of communication channels and social systems such as peer to peer network and/or through the mass media. Table 6 highlights the source of information for physicians identified in this survey regarding OEND. The primary sources cited were colleagues (39 %) and continuing medical education (36%). Journal articles (21%) and residency/fellowship training (7%) were noted less frequently as sources of information about OEND. Medical school was not identified as source of OEND by any respondent. The "other" category included: mentors, list serves and pharmacists, which could be considered in the most cited category of colleagues. The "publications and conferences" from the specialty based website of American Society of Addiction Medicine (ASAM) and "hospital sponsored" activities were offered as "Other" category entries.

Other resources reported by respondents included Electronic Medical Record (EMR)-based naloxone presentation and web based education. The sites identified by respondents were "Prescribe to Prevent", "PCSS online module" and the "SAMHSA Opioid Toolkit" ("Prescribe to Prevent", "Provider's Clinical Support System", "SAMHSA Opioid Overdose Prevention Toolkit", 2016).

TABLE 6. SOURCES OF INFORMATION FOR PHYSICIANS REGARDING OEND

Sources of Information	N=28	Percent
Medical school	0	0%
Residency/Fellowship training	2	7.1%
Continuing Medical Education (CME)	10	35.7%
Colleagues	11	39.3%
Journal articles	6	21.4%
Other	5	17.9%

D. Facilitators and Barriers

The survey included open ended questions related to facilitators and barriers to the provision of OEND. Many respondents identified the assistance from local pharmacies as a facilitator to providing overdose education and naloxone distribution (N=5). Respondents also described hospital and community-based pharmacies as sources of information. Five respondents cited their "experience" with patients with opioid use disorder and overdose deaths in the community. Examples of this "experience" included exposure to "several overdose deaths", "increased press" related to the opioid use disorder problem and drug "using" friends who have had overdoses. Other respondents identified utilizing local and online resources. One provider had grant funds to facilitate this type of educational effort. Another physician reported displaying information "regarding naloxone and intervention in case of an overdose" to facilitate education.

The most frequently cited barriers to providing overdose education and naloxone distribution was lack of financial resources such as cost and insurance constraints. Respondents also mentioned time constraints and having competing patient demands as barriers to providing office-based education. One respondent stated they had a "focus on recovery" as opposed to a focus on the risk of relapse. Others mentioned that offering OEND "was not as pressing" nor An Assessment of OEND by Maine Buprenorphine/Naloxone Prescribers

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was it "in my 'checkbox' of things to do." Three respondents identified access to naloxone as a significant barrier to providing OEND. Another respondent identified having difficulty contacting individuals to be provided the education. Finally, one respondent identified Maine based policies that serve as a barrier and cited other states such as Massachusetts in which pharmacies have standing orders allowing for access to naloxone without provider intervention.

E. Attitudes and Beliefs

Figure 3 outlines respondent's attitudes and beliefs regarding the implementation of OEND. The domains assessed included: Compatibility, Trialability, increasing quality, and interest in implementing OEND. The questions about increasing quality and interest in implementing OEND are closely aligned with the construct of Relative Advantage of the diffusion of innovation framework. Most providers strongly agreed (54%) or agreed (29%) that offering OEND was compatible with other education provided in their clinical practice. Additionally, most providers agreed that OEND increases the quality of MAT provided in the clinical setting, with 54% of respondents strongly agreed and 32% agreed. Regarding the acceptability of trialing OEND before fully implementing the education in their practice, 25% of respondents strongly agreed and 61% agreed. Finally, regarding those expressing interest in implementing OEND into their clinical practice, 54% of respondents strongly agreed and 25% agreed.

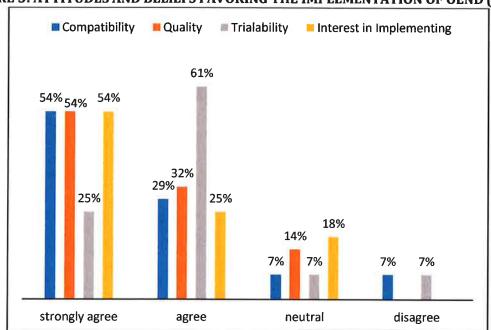


FIGURE 3: ATTITUDES AND BELIEFS FAVORING THE IMPLEMENTATION OF OEND (N=28)

Figure 4 displays the attitudes and beliefs that inhibit implementation of OEND in clinical settings. When asked if OEND is too complicated to integrate into their clinical setting, 11% strongly disagreed and 43% disagreed. Regarding OEND having "no impact on rates of overdose", 21% respondents strongly disagreed and 46% disagreed.

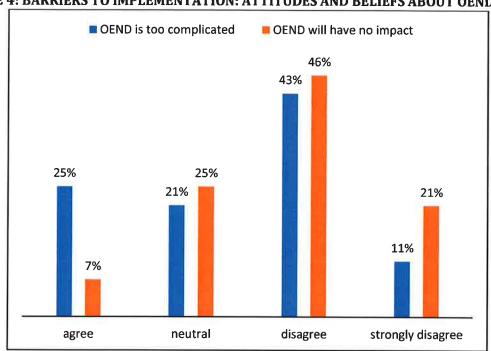


FIGURE 4: BARRIERS TO IMPLEMENTATION: ATTITUDES AND BELIEFS ABOUT OEND (N=28)

Figure 5 displays respondent's attitudes and beliefs about the amount of time and effort required to provide OEND as being a barrier to implementing this type of education in the clinical setting. The majority of respondents (57%) strongly disagreed (4%) or disagreed (54%) that time and effort are barriers to implementing OEND into their clinical practice. However, nearly 33% or respondents strongly agreed (4%) or agreed (29%) and an additional 11% were ambivalent that the time and effort required to implement OEND is a barrier to providing OEND in general practice.

54% 29% 11% 4% 4%

strongly agree

agree

FIGURE 5: BARRIERS TO IMPLEMENTATION OF OEND: TIME AND EFFORT REQUIREMENTS (N=28)

The assessment of the time required for OEND was also cited in responses to open ended questions about barriers to OEND implementation. In addition to time constraints and competing demands, respondents mentioned other barriers. Two other responses illustrating challenges to implementation included: "volume of patient visits" and "productivity pressures."

neutral

disagree

When asked to "share any additional thoughts" pertaining to providing OEND in their clinical setting respondents mentioned both facilitators and barriers to implementation. Three respondents expressed interest in providing OEND education and other respondents noted that providing the education was "easy and patients appreciate it" and one respondent was "happy to do" the education. Providers mentioned costs and insurance barriers to delivering OEND with one respondent noting the medication (naloxone) and the auto-injector device to administer naloxone needs to be "covered by insurance carriers." Similarly, one respondent noted patients may not fill the prescription for naloxone. One respondent emphasized the need to teach elements of overdose education to "family members and loved ones who have an opioid dependent person in their lives." Only one respondent noted "I do not perceive the problem."

strongly

disagree

F. Provider Distribution

To show the distribution of available physicians eligible to provide buprenorphine/naloxone in the state, a GIS map including all of the 196 physicians identified as prescribers was created. Figure 6 shows the distribution of physicians eligible to prescribe buprenorphine/naloxone across the eight Maine Public Health District. The more urban settings are included in Public Health Districts One, Two, Five and Six. The number of providers per Public Health District varied from 12 providers offering MAT in Public Health District Eight to 60 in Public Health District Two. This map displays the variable distribution of providers in the Public Health Districts. Population data per county was obtained via the United States Census Bureau website. The 2010 census data was utilized for calculation of number of providers per 100,000 individuals. When the number of MAT providing providers per 100,000 individuals was analyzed, the number of providers/100,000 population varied from 6.6 in Public Health District 1 to 21.7 in Public Health District 2. The mean number of providers/100,000 individuals was 14.9 with a standard deviation of 5.7. Public Health Districts 2, 6 and 7 were noted to have the highest provider density at 21.7, 20.4 and 19.5 providers/100,000 individuals, respectively. The lowest provider densities were in Public Health District 1 with 6.6 providers/100,000 (z-score of -1.5) and Public Health District 3 with 7.6 providers/100,000 (zscore of -1.3).

The variation in number of providers/100,000 in different Public Health Districts reveals the difference in providers is not related to the population in those areas but rather due to a fewer treating providers in Public Health Districts 1 (York County) and 3 (Androscoggin, Franklin, and

Oxford Counties). This analysis does not provide information on the optimal number of buprenorphine/naloxone providers/100,000 individuals.

District 8 Aroostook 16.7 Providers District 5 Central per 100,000 14.9 Providers per 100,000 District 6 Penquis 20.4 Providers per 100,000 District 3 Western District 7 Downeast 7.6 Providers 19.5 Providers per 100,000 per 100,000 District 4 Midcoast 12.1 Providers per 100,000 District 2 Cumberland 21.7 Providers per 100,000 District I York 6.6 Providers per 100,000

FIGURE 6: NUMBER OF PROVIDERS/100,000 INDIVIDUALS BY PUBLIC HEALTH DISTRICT

DISCUSSION

The results of this study show that the majority of respondents are currently providing education regarding overdose prevention and the use of naloxone. Most surveyed physicians reported providing between 1-3 elements of education or multiple elements (4 or more) of OEND. However, this survey identified 39% of respondents not providing any components of OEND. This represents an opportunity for ongoing diffusion of this educational innovation.

Despite discussing naloxone with patients, only 28.6% of respondents were providing patients with a prescription for naloxone. This highlights a discrepancy between providers taking the time to discuss information about overdose and the medication used to treat an overdose yet failing to prescribe naloxone. Some of the respondents identified the high cost of naloxone and the lack of insurance coverage as potential limits to use. Despite the concern regarding cost and health insurance coverage, these issues should not preclude the provision of the naloxone prescription. Providing a prescription for naloxone would serve to reinforce the importance of this medication in the event of an overdose.

In this survey, the majority of respondents were trained in a primary care specialty, such as in Family Medicine, Internal Medicine or Pediatrics. Only a small number of respondents reported training in psychiatry or specialty training and/or board certification in Addiction Medicine. This differed from the national trends noted by Rosenblatt, Andrilla, Catlin, & Larson (2015). Rosenblatt et al. (2015) found 37% of individuals with a DEA waiver nationally, had primary care specialty training. This information highlights both a strength and an opportunity for future care of patients with OUD in Maine. The strength is the important current role Maine primary care physicians for the provision of MAT. Further utilization of more primary care An Assessment of OEND by Maine Buprenorphine/Naloxone Prescribers

providers may be the best response to this public health crisis. Due to the availability of primary care providers in rural settings, they may be called on to provide MAT care in the rural settings. The opportunity arises from the low number of Addiction specialty trained physicians in Maine. Recognizing this discrepancy with national trends, this factor may prompt health systems in Maine to recruit more Addiction specialty trained providers to assist in the provision of MAT care.

Of note, most respondents reported having a 100-patient limit waiver. This level of patient limit is an improvement for the 30-limit waiver and displays the physician's commitment to providing MAT services in Maine. Physicians may further improve access for buprenorphine/naloxone treatment by increasing to a 275-patient limit.

The most frequently cited audiences of OEND were individuals treated with buprenorphine/naloxone and individuals treated with chronic opiates. Both groups are at high risk groups due to the risk of relapse for the actively treated cohort and accidental overdoses for those on chronic opiate therapy. Family members and friends are also important audiences because these groups may be the first responder to an overdose. Ideally, support persons for high risk individuals would also be provided with this information.

This study examined the use of OEND among providers in Maine using the framework of the Diffusion of Innovation theory. One key aspect of this theory is how people learn about the innovation. Those channels of communication were examined by asking how physicians were exposed to OEND. The innovation examined in this study, OEND, was found to be more likely spread through the communication channels between colleagues and publications, as opposed to medical school training. The responses identified as "other" highlights the influence of mentors,

listserv "communities" and specialty based organizations such as the American Society of Addiction Medicine. In order to promote the further diffusion of this innovation, utilizing the professional networks and exposure via continuing medical education will be essential. In addition, internet based resources such as specialty publications are important.

The majority of study participants agreed that OEND is an acceptable innovation. Responding physicians believe this education is compatible with other education provided in their practice, can improve the quality of MAT care provided and is something that can be implemented on a trial basis in their clinical setting. Respondents do not feel that OEND is too complicated nor do they think that implementing OEND will be fruitless. The majority of respondents expressed interested in implementing this innovation. In addition, most respondents did not feel that the time and effort required to provide education would serve as a barrier to the provision of OEND in their clinical settings. Some opinions identified in the qualitative responses highlight the competing interests on provider time and effort, such as "focus on recovery" as opposed to a focus on relapse, physician time constraints and "another box to check off." These qualitative responses characterize the myriad of expectations placed on a physician to provide the optimal level of evidence based medical care. Despite the agreement of respondents with the attitudes and beliefs for providing OEND, physicians continue to make judgements regarding their priorities for these educational efforts. Some physicians have highlighted the use of other staff members such as their medical assistants and/or registered nurses to assist in providing OEND. Some providers have utilized premade training videos and patient educational tools to overcome these barriers.

This project adds to the existing literature by assessing the provision and diffusion of OEND in a rural state. Maine offers unique challenges to the diffusion of innovation. The number of physicians is relatively low and they are mostly distributed in distinct, small clusters throughout the state. Thus, providers in rural communities across the state may have little or no interaction with providers who are utilizing OEND. Moreover, Maine does not have a comprehensive network for buprenorphine/naloxone providers nor is there an overarching institution that would promote the diffusion of OEND. In order to increase the use of OEND and improve the provision of MAT in the state, Maine can explore the option of implementing evidenced-based models from other rural communities. For example, Vermont has implemented a network system to provide care for OUD. The "Hub and Spoke" system as offered in Vermont provides an integrated delivery method that would allow a central Hub that performs initial consultation and ongoing support ("Integrated Treatment Continuum," 2012). The spokes or primary treatment location described in this model are the Patient Centered Medical Homes, i.e. primary care offices with comprehensive care models. This central resource of a health care system could promote an innovation such as OEND. Rogers discussed the "top down" more authoritarian approach as being effective for the spread of innovation. For example, a strong central hub can provide information and serve as an influential source of evidence based guidelines. A central source can also provide and disseminate tools to be used by the "spoke" practices. This may be highly effective at providing a uniform recommendation to all practices and removes the barrier for each practice to create the resources for themselves.

The results of this survey indicate that Maine based buprenorphine/naloxone prescribers favor the provision of OEND. Local efforts underway in the City of Portland via the Needle

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Exchange and the Overdose Prevention Program offer promising outlets to where physicians can work to expand the use of OEND in the state. Unfortunately, to implement a comprehensive statewide system of OEND, these types of services would need to be duplicated throughout the state and would likely be difficult to replicate in the rural areas of Maine. The larger statewide initiatives such as "Caring for ME" and the Maine Opiate Collaborative could use the results of this study as a basis for ongoing education of the aspects of OEND to Maine based MAT providers. Furthermore, additional populations such as individuals receiving high dose opiate analgesics on a chronic basis would benefit from OEND given their high risk of opiate related overdose.

Figure 1 and Figure 6 provide the framework for comparison of drug related death rate by Public Health District with the number of providers per Public Health District. This comparison identified some variation in the availability of MAT providers. For example, Public Health Districts Two and Five had the highest death rates/100,000 individuals at 20.4 and 19.6, respectively. However, when considering number of providers per 100,000 individuals, these two Public Health Districts are at or above average for providers at 21.7 and 14.9, respectively. Alternatively, Public Health Districts 1 and 3 have the third and fourth highest death rates in the state, at 16.3 and 15.6 deaths/100,000 individuals. Both districts have a lower than average numbers of providers. Therefore, a direct link between provider density and death rate cannot be established based on the Maine data. However, it would be expected that increased provider density would improve access to MAT and the educational efforts such as Overdose Education and Naloxone Distribution.

Study Limitations

The primary limitation of this study was the lack of a complete list of buprenorphine/naloxone providers in the state. Participation in the SAMHSA Buprenorphine Provider Locator is voluntary therefore, it is likely that the list is incomplete and the number of physicians is underreported. This list also represents an online source of information regarding available providers and is not reflective of the actual number of providers offering MAT services in Maine. In addition, many providers obtain the necessary DEA waiver but do not actually provide MAT.

The most critical limitation of the current study is the poor survey response rate. Although multiple attempts were made via mail and electronic mail, the response rate of 14.4% was low. One factor that may have impacted the response rate was the lack available email addresses; electronic mail addresses were available for approximately one quarter of the MAT providers surveyed. Thus, the majority of the potential study sample received a letter that included a URL link to the survey that respondents needed to be type in manually into their Internet browser to access the survey. This required respondents to take multiple steps to access the survey which may have deterred response rate.

A final limitation of the analysis includes the potential for selection bias. Providers who are currently discussing overdose education and naloxone distribution, may have self-selected to respond to a survey that reinforces an innovation that is already established in their practice. Respondents, that would be considered "early adopters" in the Diffusion of Innovation theory, may have responded in higher numbers.

Conclusions

The findings of this study indicate that Maine physicians with a waiver to prescribe buprenorphine/naloxone are providing education regarding overdose and naloxone however, only a minority of physicians reported providing prescriptions for naloxone. Given these findings, future emphasis should be placed on promoting the provision of a naloxone prescription at the same time as other educational elements are administered to patients. Providers report that even after naloxone prescriptions are provided, patients may not fill them due to a pharmacy not having the medication or because of cost or lack of insurance coverage of the medication.

Therefore, further efforts to enhance the prescription of naloxone would be of benefit until this medication becomes more widely available at the pharmacy without a physician's prescription.

Responses to the questions regarding attitudes and beliefs section of this survey were favorable with the diffusion of innovation of OEND amongst providers. Therefore, providers are likely to continue discussing this innovative patient education with their patients. This action will further enhance the diffusion of innovation if these discussions are also shared through the communication channels among physicians.

When examining the supply of physicians with the Drug Enforcement Agency Waiver to prescribe buprenorphine/naloxone, especially when compared with drug related death rate in Public Health Districts, there is an unclear association between increased death rate from OUD and available physicians to provide treatment. Future efforts to reduce drug related deaths should include a statewide analysis of available providers, with a plan to improve access to MAT in all Public Health Districts. In addition, an assessment of the optimal number of MAT providers

would facilitate manpower planning strategies. A centralized comprehensive healthcare system approach would be the most beneficial and promote the innovative patient education such as OEND.

This study provided the status of provision of OEND. Additional research will be necessary to identify if overdose education and naloxone distribution diffuses further amongst the medical community and become a standard of care over time. Many states including Maine have passed legislation that will make it easier for individuals to obtain naloxone without a physician's prescription. This legislation may future increase awareness of this innovation. Further work will be required to reduce costs, improve insurance coverage and increase the availability of naloxone.

Conclusions garnered from this survey can be used by healthcare providers who are providing MAT or primary care services, specifically individuals receiving treatment for Opioid Use Disorder and their families. Additionally, public health experts and legislators can utilize information from these survey results to advise future legislation or public health policy to reduce the risk of opioid related overdose deaths.

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Appendix A: Survey Instrument

Overdose Education and Naloxone Distribution Survey

Introduction:

As a fellow buprenorphine provider, primary care physician, and Master's in Public Health student at the University of Southern Maine, I am interested in learning what education is being provided regarding the risk of opioid overdose and naloxone distribution. The goal of this survey is to gain a better understanding of the factors that facilitate and/or hinder the provision of overdose education and naloxone distribution in Maine based practice settings offering Medication Assisted Treatment (MAT) services.

Participation:

This survey should take approximately 5-10 minutes of your time. The survey is completely voluntary; your participation will have no impact on your relationship with the University of Southern Maine Masters in Public Health Program. You can choose to answer all, some or none of the questions. Individual responses will be kept confidential to the maximum extent permitted by law.

Risks and Benefits of Participation:

There are no anticipated risks associated with participating in this survey, all survey results will be reported in the aggregate, individual respondent names will not be identified. However, by participating, you will be providing important feedback that could help better understand the factors that facilitate and/or hinder the provision of overdose education and naloxone distribution in Maine.

Contacts and Questions:

For questions or more information concerning this study you may contact Dr. Stephen Kirsch at Stephen Kirsch@maine.edu or (207) 653-3018.

If you have any questions or concerns about your rights as a research participant, you may call the USM Human Protections Administrator at (207) 228-8434 and/or email usmorio@maine.edu.

By clicking next and continuing to the survey you consent to participation.

Demographic Information

QI	rears since graduation from medical school:
Q2	Zip code of your primary practice settling in Maine:
Q3	What is your specialty? (Select all that apply) Internal Medicine Pediatrics Family Medicine Psychiatry Specialty trained in Addiction Medicine Certified by the American Board of Addiction Medicine (ABAM)
Q4	How many years have you had a waiver to provide or dispense buprenorphine/naloxone?
Q5	Select the option that reflects the patient limit associated with your waiver. 30 patients 100 patients 275 patients
Q6	Are you currently prescribing buprenorphine/naloxone? Yes No
Q7	How many years have you been prescribing buprenorpine/naloxone?
Quest	ions regarding overdose education and naloxone distribution,
Q8	Are you providing education regarding the risk of overdose? Yes No
Q 9	Are you providing education regarding naloxone? Yes No

If no to questions 8 AND 9, survey will proceed to question 19.

Q10	How many years have you been providing education regarding the risk of overdose and/or regarding naloxone?
Q11	Is the education you provide about overdose risk and the use of naloxone presented in a formal format, such as an educational session, lecture and/or group therapy? Yes No
Q12	If no to question 11, is the education provided as part of your routine office visit? ⊘ Yes ⊘ No
Q13	Are you providing education to family members regarding the risk of overdose and naloxone? ⊘ Yes ⊘ No
Q14	List other ways overdose education and naloxone distribution is presented in your clinical setting.
Q15	Identify the aspects of overdose education and naloxone distribution covered in your clinical setting. (Select all that apply.) Instruction regarding rescue breathing Stemal rub Initiating cardiopulmonary resuscitation Activating the Emergency Medical System (EMS) Providing naloxone (Intramuscular and/or intranasal) Indication for naloxone use Safety profile of naloxone Instructions on use of naloxone Instructions on use of naloxone Instructions on treatment options (counseling, intensive outpatient programs) or support groups (12 step programs) in your area Other Other, please explain:
216	What individuals in your clinical setting are provided with overdose education and natoxone distribution? (Select all that apply) Patients who are prescribed buprenorphine/natoxone. Patients who are contemplating treatment with buprenorphine/natoxone. Patients who are on chronic opiate therapy. Family members. Individuals using other substances other than opiates. Other Other, please explain:
217	Do you provide the individuals with a prescription for naloxone?
Q18	How did you learn about overdose education and naloxone distribution? (Select all that apply.) Medical school Residency/Fellowship training Continuing medical education Colleagues Journal articles Other Other, please explain:
19	Describe any internal or external factors that have facilitated the provision of overdose education and naloxone distribution in your clinical setting.
20	Describe any internal or external factors that have hindered the provision of overdose education and naloxone distribution in your clinical setting.

Attitudes and Beliefs regarding overdose education and naloxone distribution.

Rate the following on the scale with 1 being Strongly Agree and 5 being Strongly Disagree.

Q21	Providing education regarding overdose education and naloxone is compatible with other patient education provided in my clinical setting.						
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
		*	0	#	@;		
Q22	Utilizing overdose education and naloxone	distribution will increase	the quality of medication as	ssisted therapy provided in	my clinical setting.		
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	∜.	5	F,	0	(²⁵)		
Q23	It will be complicated to integrate overdose	It will be complicated to integrate overdose education and naloxone distribution into my clinical setting.					
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	0	5	Ö	C	₹ħ		
Q24	It is acceptable to provide aspects of overdose education and naloxone distribution on a limited basis before fully implementing this type of education in my clinical setting.						
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	347	8	<i>(*)</i>	to the second	6		
Q25	Implementing overdose education and naloxone distribution will have no impact on rates of overdose in my community.						
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	6	C	8	©	Ð		
Q26	The amount of time and effort necessary to provide education overdose education and natoxone distribution is a barrier to implementing this type of education in my clinical setting.						
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	8	6	©	0	•		
Q27	I would like to implement overdose education and naloxone distribution in my clinical setting.						
	1-Strongly Agree	2-Agree	3-Neutral	4-Disagree	5-Strongly Disagree		
	E.	Ô	6	8	\mathcal{O}		
Q28	Please share any additional thoughts you distribution in your clinical setting.	may have about prescribi	ing buprenorphine/naloxone	or providing overdose ed	ucation and naloxone		
				44			

Thank you for your time. Please click the SUBMIT button below.

Appendix B: IRB Determination



NOTICE OF EVALUATION-EXEMPT

DATE:

August 25, 2016

TO:

Stephen Kirsch, Muskie School of Public Service

Mary-Lindsey Smith, Muskie School of Public Service

FROM:

Casey Webster, Human Protections Administrator, USM IRB

PROTOCOL TITLE:

Assessment of the Use of Overdose Education and Naloxone Distribution by Maine Buprenorphine/Naloxone

Prescribers

FUNDING SOURCE:

NONE

PROTOCOL NUMBER: 16-07-759

The Office of Research Integrity and Outreach (ORIO) has evaluated the project named above. This study has been granted an exemption from USM IRB review per Title 45 CFR Part 46. This designation is based on the assumption that the materials that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

This exemption is given with the following terms:

- 1. You will conduct the project according to the plans and protocol you submitted;
- 2. No further contact with the ORIO is necessary unless you make changes to your project or adverse events or injuries to subjects occur;
- 3. If you propose to make any changes to the project, you must submit the changes to the ORIO for review; you will not initiate any changes until they have been reviewed and approved by the ORIO;
- 4. If any adverse events or injuries to subjects occur, you will report these immediately to the ORIO;
- 5. As applicable, you will comply with the University of Maine Information Security Policy and Standards and/or the Muskie School of Public Service Securing Protected Information Policies and Procedures and any other applicable USM polices or procedures; and
- 6. You will close the project upon completion (or discontinuation).

The University appreciates your efforts to conduct research in compliance with the federal regulations that have been established to ensure the protection of human subjects in research.

Sincerely,

Careyx E. Webstoo

Casey Webster