



# Implementation of a Prenatal Naloxone Distribution Program to Decrease Maternal Mortality from Opioid Overdose

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Accepted: 22 November 2021

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## Abstract

**Introduction** Maternal mortality rates have been increasing in the United States for decades. For several years, opioid overdoses have been a leading cause of maternal mortality in several states. New Hampshire (NH) is a particularly severe case, with 50% of all maternal deaths being caused by drug-related overdoses from 2016 to 2017. We report on the implementation of a point-of-care naloxone distribution program for an Ob/Gyn clinic in NH.

**Methods** Naloxone distribution was tracked to measure program implementation. Proportion of patients screened for naloxone need was calculated monthly. Proportion of patients with which discussions about naloxone took place was calculated quarterly. Patient and provider perspectives on the program were captured periodically. Statistical process control charts monitored change over time and evaluated for special-cause variation.

**Results** The clinic has distributed 12 doses of naloxone since program implementation in April 2020. Despite the challenges posed by the COVID-19 pandemic, screening for naloxone need has remained at pre-pandemic rates (moving average: 73%), except for a decrease in April–May 2020. Patient-provider discussions about naloxone have also remained at pre-pandemic rates (moving average: 51%). Qualitative feedback from patients and providers has indicated that the program has been well-received by both groups.

**Discussion** The purpose of this description is to provide a framework for other Ob/Gyn clinics to use in implementing similar naloxone distribution programs. Although too early to determine whether this intervention will result in a significant decrease in maternal mortality due to opioid overdose in our patients, this measure will continue to be tracked annually. Implementation of a naloxone program in the obstetrical context provides an important way to improve outcomes for a vulnerable perinatal population.

**Keywords** Naloxone · Narcan · Quality improvement · Maternal mortality · Overdose

## Significance Statement

Overdoses are a primary driver of maternal mortality rates in several states. Current American College of Obstetrics and Gynecology recommendations advise that naloxone be distributed to pregnant and postpartum women with opioid use disorders. In an effort to make naloxone more accessible to pregnant and postpartum patients, we have implemented a point-of-care naloxone distribution program at an

ambulatory Ob/Gyn clinic at a New Hampshire academic medical center. This article outlines the processes in designing this program, in addition to early results in tracking its success.

## Introduction

Maternal mortality, or death during pregnancy or the postpartum year, has nearly doubled in the United States since 1990 (CDC, 2020). Calculations of maternal mortality rates have historically excluded deaths attributed to substance use disorders (SUDs), such as opioid overdoses. For example, the Maternal Mortality Review Information Application (MMRIA) only began collecting data on mental health and SUDs in 2018 (Brantley et al., 2018). Therefore,

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the already staggering statistics on maternal mortality are likely underestimations, and a comprehensive picture of overdose-related deaths among this population fails to exist. However, overdoses have been indicated as a leading cause of maternal deaths in several states, including California (Goldman-Mellor & Margerison, 2019), Colorado (Metz et al., 2016), Illinois (Koch & Geller, 2017), Massachusetts (Schiff et al., 2018), Texas (DSHS, 2017) Virginia (Bronson & Reviere, 2017), and New Hampshire (NH) (Collins & Laflamme, 2019). The majority of these deaths have occurred postpartum.

Naloxone is an opioid antagonist medication that reverses the effects of an opioid overdose (Walsh, 2020). The American College of Obstetricians and Gynecologists (ACOG) recommends that naloxone be used when a pregnant person experiences opioid overdoses (ACOG, 2017). Additionally, the Alliance for Innovation in Maternal Health consensus bundle for the Care of Pregnant and Postpartum People with Substance Use Disorder includes a national level recommendation to provide access to naloxone to all postpartum people with SUD at the time of discharge following delivery (Krans et al., 2019).

When administered during pregnancy, naloxone crosses the placenta, and therefore may affect the fetus (Hibbard et al., 1986). However, teratogenicity has not been reported (Bailey, 2003). Concern has been raised that naloxone administration may cause acute withdrawal to both the pregnant person and the fetus, with potentially serious consequences for the fetus (Erickson et al., 2007, p. 17). However, it remains an established part of clinical practice, and ACOG has stated that, “although induced withdrawal may possibly contribute to fetal stress, naloxone should be used in pregnant women in the case of maternal overdose in order to save the woman’s life” (“Committee Opinion No. 711,” 2017). Naloxone administration to a breastfeeding person is unlikely to affect the breastfeeding infant, as it is not orally bioavailable (“Naloxone,” 2006). Additionally, the drug does not affect suckling-induced oxytocin or prolactin secretion in postpartum persons (Cholst et al., 1984; Johnson et al., 1990).

New Hampshire has a high rate of maternal mortality due to overdose, with 50% of all maternal deaths being reported as overdoses during the years 2016–2017 (Collins & Laflamme, 2019). In response to this, our ambulatory Ob/Gyn clinic implemented a provider checklist to facilitate evidence-based care practices for women with opioid use disorder (OUD) in 2017 (D. Goodman et al., 2019). The checklist included discussing and providing access to naloxone by prescription. While this initiative saw these discussions with patients increase from 10.9% to an average of 55.6% between 2017 and 2019, the improved rate was still felt to be deficient. To address the ongoing risk of overdose

among our patients, we implemented a point-of-care naloxone distribution program within our clinic.

Our clinic is located within a rural academic medical center in NH, which serves several million individuals annually, including approximately 1400 deliveries per year. Our practice provides all levels of obstetric and gynecologic care. Care is provided by maternal–fetal medicine specialists, generalist Ob/Gyn physicians, advanced practice nurses (APRNs), certified nurse midwives (CNMs), and resident physicians. The practice also includes a sub-specialty clinic which provides comprehensive services for pregnant people with SUD diagnoses, including OUD.

The program we describe here aims to improve the rate of naloxone discussions with prenatal patients with OUD, at risk of experiencing an overdose, and/or at risk of witnessing an overdose to 100%. This paper outlines the implementation of this program, identifies contextual factors impacting implementation, proposes process, outcome, and balancing measures to track program success, and describes early results of this initiative.

## Methods

### Context

Birthing patients at our institution are primarily insured by private insurance (51%) or Medicaid (40%). The majority identify as white, non-Hispanic (91%) and do not report prenatal substance use (88%). Between 4–5% of these patients are diagnosed with OUD. Among these, the majority are insured by Medicaid (89%), and identify as white (99%), non-Hispanic (98%) (Goodman et al., 2021).

### Intervention

Implementing a point-of-care naloxone distribution program in our clinic was a complex process. The key steps of the project launch included: securing a source for naloxone, assessing barriers and opportunities utilizing standard quality improvement tools, developing clinic policies and procedures, training providers and nursing staff, integrating the program into the clinic flow, and determining how to measure and track success.

### Naloxone Source

To obtain a supply of naloxone for distribution, we pursued a relationship with The NH Doorways Program. Doorways provides state-funded naloxone, which allowed us to distribute it without charge. Once a relationship was formed,

contact persons were determined for Doorways and the clinic. State law requires that recipients are provided with overdose response training, and also requires that anonymous data is collected from each recipient. Processes involving state requirements, returning completed data collection forms, ordering, and kit delivery were considered when creating policies and procedures for the program.

## Policies and Procedures

Quality improvement tools were utilized to understand contextual factors which might impact our ability to distribute naloxone in the clinic. Through direct observation of encounters in our sub-specialty SUD clinic, we developed a process map of the current clinic flow (Fig. 1). This analysis was used to identify opportunities to introduce the elements of the naloxone distribution program.

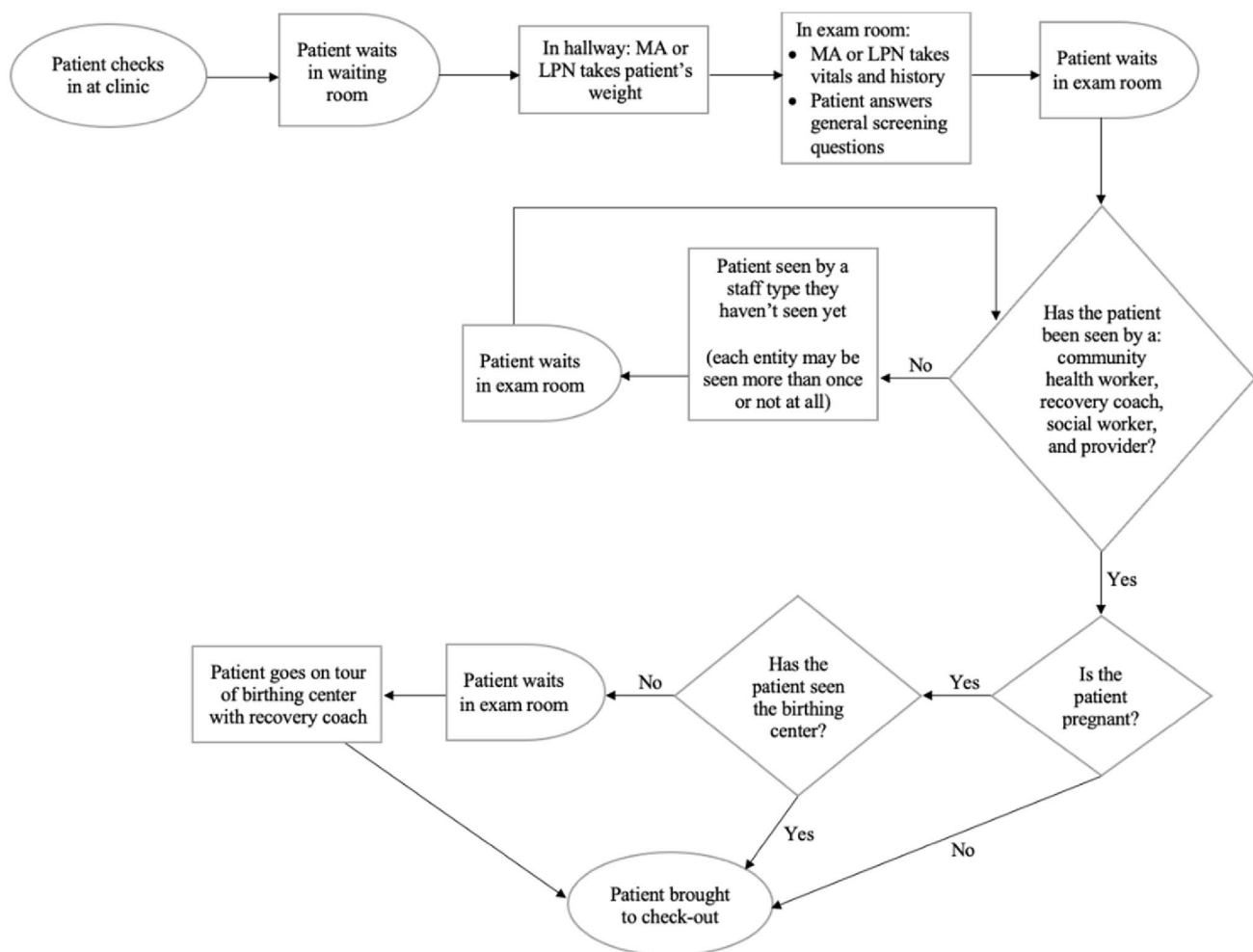
Additionally, we created a fishbone diagram outlining anticipated barriers to implementing the program (Fig. 2).

One barrier identified was that key staff members were under the impression that point-of-care naloxone distribution was prohibited, as is the case for other medications. This concern was addressed through the medical center's Pharmacy and Therapeutics Committee, which approved the final policy defining roles and responsibilities of staff.

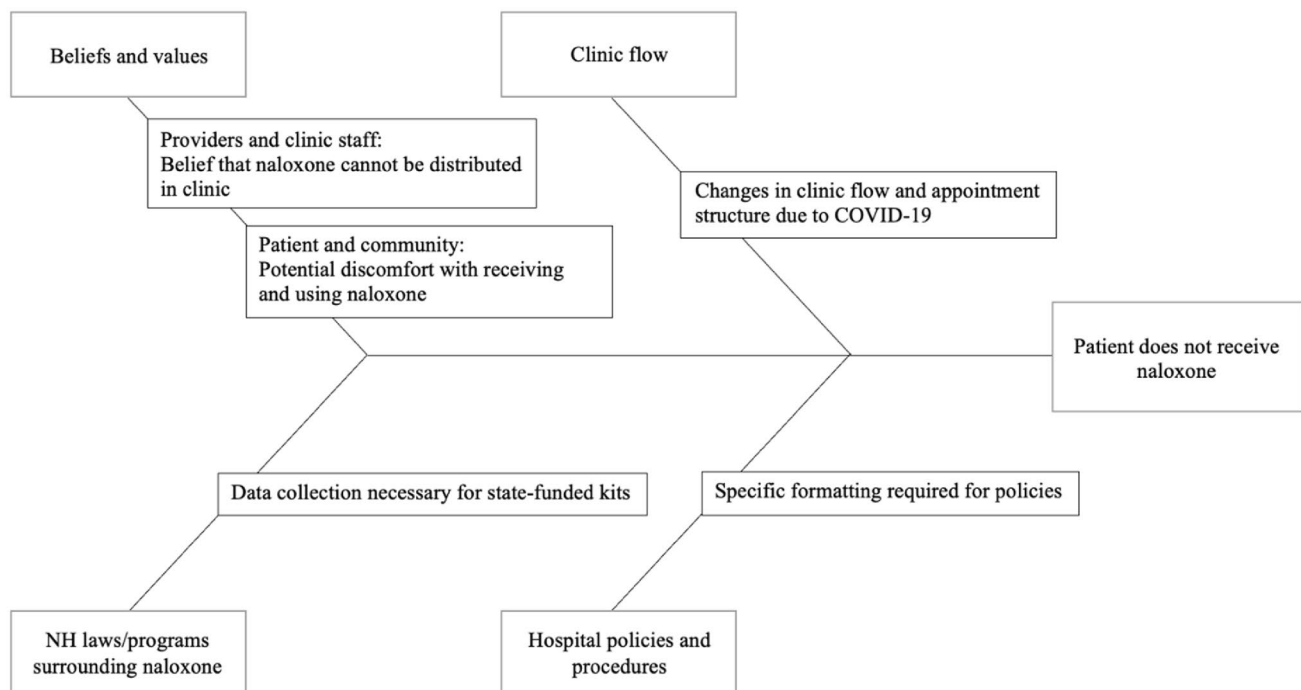
Ultimately, only providers (physicians and APRNs) were permitted to dispense the medication, but naloxone education and harm reduction counseling could also be provided by a registered nurse (RN) with appropriate training. The naloxone is stored in compliance with state and federal rules regarding medication security for non-scheduled drugs.

## Staff Training and Education

Opioid overdose response training and naloxone education was offered to providers and RNs by the regional public health and overdose prevention network. Training topics included assessing scene safety, identifying an overdose,



**Fig. 1** Ambulatory Ob/Gyn clinic process map, before implementation of the point-of-care naloxone distribution program



**Fig. 2** Fishbone diagram of barriers to point-of-care naloxone distribution program at ambulatory Ob/Gyn clinic

administering naloxone, calling 911, rescue breathing, possible side-effects of reviving someone with naloxone, and the importance of aftercare.

### Integration into Clinic Flow

Using the process map created at the onset of the project (Fig. 1), we modified our process to include the naloxone distribution program (Fig. 3). During a clinical encounter, patients are escorted to the exam room by a medical assistant (MA) or licensed practical nurse (LPN). Patients are then administered screening questions about substance use. This seemed like a natural place to add in a question to assess the patient's need for naloxone.

To determine language for our screening question, we reviewed the literature for best practices in single-question screening for naloxone, which did not yield any results. We ultimately formulated our question as: "Are you, or is someone you know, at risk of witnessing or experiencing an opioid overdose? Would you like to talk with someone about naloxone?" An answer of "yes" to this question triggers a response from the clinical team.

The response begins with the MA or LPN alerting a provider or RN, who then discusses naloxone with the patient. If accepted, the patient is provided with a naloxone kit in a discrete brown paper bag by the provider. The state-mandated data collection form is then completed by either the provider or RN, or the patient themselves. If a patient declines

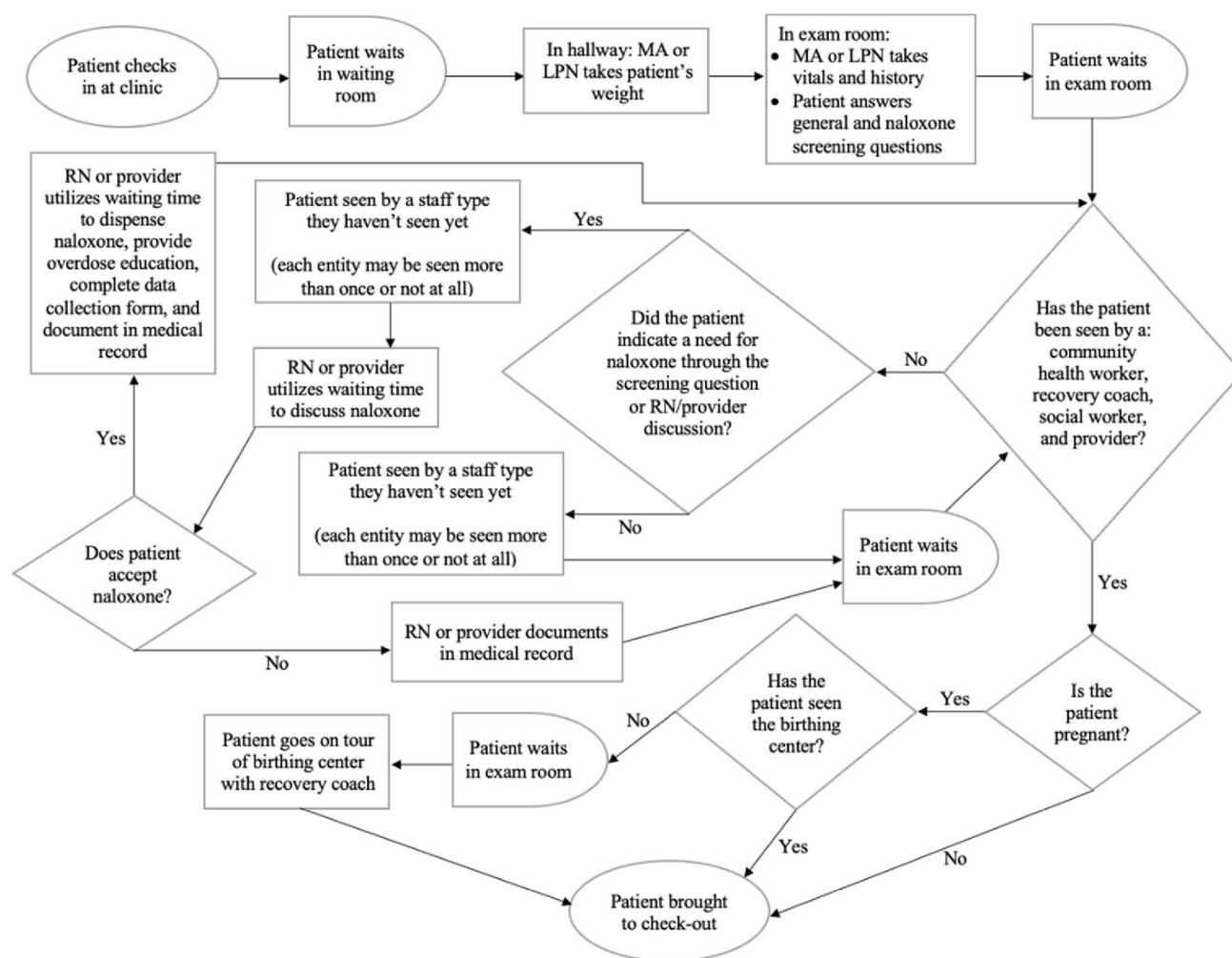
naloxone, the provider or RN documents this in the patient's electronic medical record.

When a naloxone kit is taken from the storage shelf to give to a patient, the provider or RN documents the lot number on an inventory sheet. After dispensing, the provider or RN files the completed data collection form in a designated secure location. The forms are then sent to the Doorways Program by fax.

### Measures

Outcome, process, and balancing measures were identified using the clinical value compass (Ogrinc et al., 2012). Statistical process control (SPC) charts (QI Macros) were utilized to monitor change in our process measures over time. Data was collected and plotted on either a monthly or quarterly basis. A moving average, upper control limit (UCL), and lower control limit (LCL) were calculated and plotted over time, providing a measure of expected versus unexpected ("special cause") variation in performance, the latter marked by points outside of the area between UCL and LCL.

Our proximal outcome measure is the number of naloxone doses distributed, which measures the success of the implementation of this program. Process measures included: 1) the proportion of patients screened for interest in discussing naloxone at their first prenatal visit, and, 2) to align with the Alliance for Innovation in Maternal Health recommendations, the proportion of patients with diagnosed OUD



**Fig. 3** Ambulatory Ob/Gyn clinic process map, after implementation of the point-of-care naloxone distribution program

with whom providers discussed naloxone. Additionally, we evaluated the overall acceptability of the program to patients and providers as balancing measures.

Finally, the main clinical outcome is prevention of maternal mortality. Moving forward, this will be measured through the NH maternal mortality review process. This includes notification of the program which provided prenatal care for the decedent. Due to the reporting intervals of this data, it is not included in our current results.

### Ethical Considerations

This unfunded improvement project was reviewed by the medical center's institutional review board and was determined not to be human subjects research. The SQUIRE 2.0 guidelines for reporting healthcare quality improvement initiatives were followed in preparation of this manuscript (SQUIRE, 2020).

## Results

### Implementation Checklist

One purpose of our program was to design and implement a model for other point-of-care Ob/Gyn naloxone distribution programs. Given this, we created a checklist for other healthcare settings to use when implementing similar programs (Fig. 4). The checklist identifies key steps in planning for, implementing, and measuring the success of a clinical point-of-care naloxone distribution program. It is intended to be adaptable enough to implement such programs in a variety of healthcare settings.

### Outcome, Process, and Balancing Measure Data

Our program was implemented in April 2020. To date, the program has dispensed a total of 12 doses of naloxone



- Secure naloxone source:
  - Establish relationship with state-based distribution program
  - Determine logistics with partner organization
    - Contact persons
    - Ordering
    - Delivery
    - Data collection
- Develop policies and procedures:
  - Fishbone diagram
    - Identify potential barriers
  - Clinic policy
    - Identification of patients
    - Electronic medical record documentation
    - Inventory, ordering, and data collection
    - Integration of program into clinic flow
  - Pharmacy and Therapeutics Committee Review
- Provide training and education:
  - Existing providers and nursing staff
    - Initial
    - Refresher
  - New providers and nursing staff
    - Onboarding
- Integrate into clinic flow:
  - Process map
    - Before program implementation
    - After program implementation
  - Identification of at-risk patients
  - Documentation in medical record
  - State reporting requirements
- Identify measures:
  - Outcome
  - Process
  - Balancing

**Fig. 4** Key activities checklist for implementation of a point-of-care naloxone distribution program in an ambulatory Ob/Gyn clinic

during 6 clinical encounters. No changes have been observed in our clinic's screening rate for naloxone need since the implementation of this program. This rate has occurred at an average of 73% of encounters each month since February 2020 (Fig. 5).

Similarly, naloxone discussions with pregnant and postpartum patients have been maintained at pre-pandemic rates, occurring with an average of 51% of pregnant patients each quarter (Fig. 6). No increase in discussion frequency has occurred since implementing the naloxone distribution program.

Providers have expressed universally positive feedback about the distribution program, specifically linking this with efforts to reduce maternal mortality from opioid overdose. Patients with OUD have also been unanimously positive about the program. Responses ranged from those who declined, saying that “I stay away from anyone who might need that these days, but I appreciate that you are doing this,” to patients who accepted, expressing concern about a partner or other family member who was actively using opioids. Additionally, a number of patients described experiences when they had been revived with naloxone in the past.

## Discussion

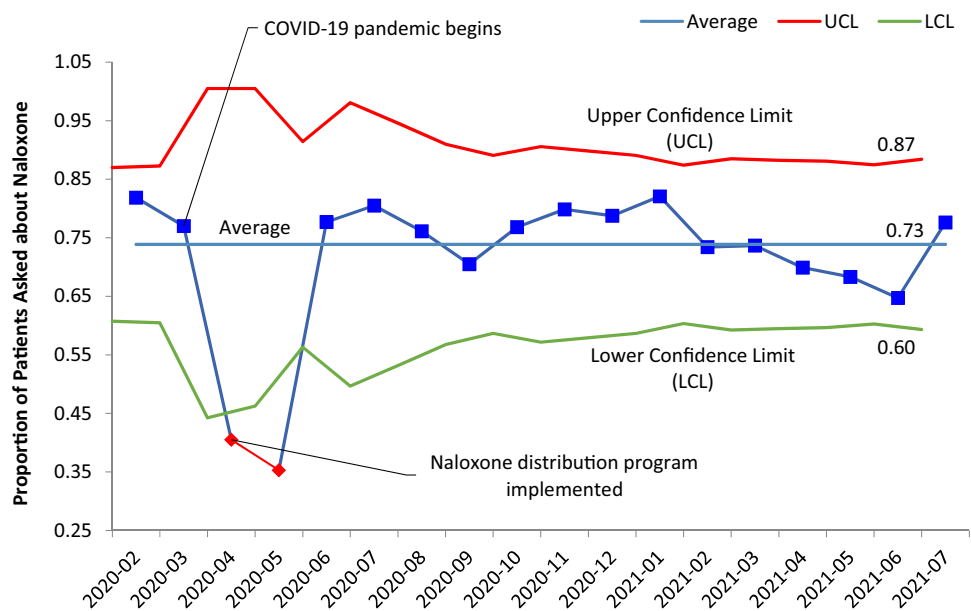
### Summary

We implemented a point-of-care naloxone distribution program at our institution's ambulatory Ob/Gyn clinic. The need for this program has been demonstrated by the high rates of opioid related maternal mortality in the State of NH (Collins & Laflamme, 2019). This program is supported by ACOG recommendations, which state that naloxone should be distributed during antepartum care (Krans et al., 2019), and administered when a pregnant person experiences an overdose (ACOG, 2017). To our knowledge, this is the first publication describing the implementation of a naloxone distribution program in an ambulatory Ob/Gyn clinic, although programs serving pregnant women have previously demonstrated success in distributing naloxone ultimately used in overdose reversals (Katzman et al., 2020).

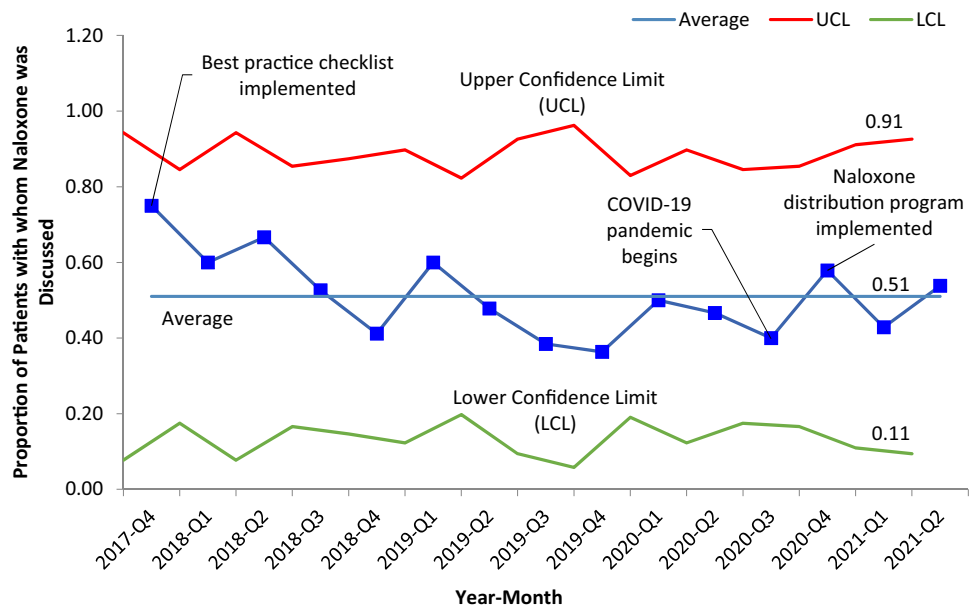
### Interpretation

The greatest implementation barrier of our program was the COVID-19 pandemic. It caused immense changes to prenatal care delivery, including a rapid transition to telehealth for a significant portion of prenatal visits. Our clinic policies state that screening for sensitive topics, such as substance use and domestic violence, must be done in person. Therefore, our screening process was disrupted, and our data was likely impacted. For example, prior to the COVID-19 pandemic, screening for prenatal substance use had occurred at close to 90% of all new obstetric visits. This dropped drastically due to pandemic-related practice changes in April and May of 2020, before recovering to a rate of approximately 80% of new visits. This disruption may have contributed to the absence of any observable change in our clinic's rates of screening for naloxone need and patient-provider discussions after program implementation. However, it was positive that we were able to maintain consistent screening for and discussions of naloxone, despite these challenges.

**Fig. 5** Proportion of pregnant patients screened for desire to have a naloxone kit at first prenatal visit (2020–2021)



**Fig. 6** Proportion of pregnant patients with opioid use disorder with whom naloxone was discussed by a provider (2017–2021)



We plan to collect data on pregnant and postpartum clinic patients experiencing fatal overdoses, as a long term outcome measure. Because the number of pregnancy-associated maternal overdose deaths in our service area is low, we do not anticipate a statistically detectable decrease in the rate fatal overdoses among pregnant and postpartum clinic patients. However, preventing any maternal death is significant from a personal, social, and clinical perspective. We hope that describing our process will be useful to others undertaking similar work. Wide-spread implementation of such programs among Ob/Gyn clinics has the potential to meaningfully contribute to a decrease in maternal mortality

rates, and subsequently decrease trauma for all who are affected by these deaths. Although the number of naloxone kits distributed so far has been low, the program has generated universally positive feedback, and importantly has increased knowledge about harm reduction among staff as well as patients. Successful implementation in the clinic has also inspired the inpatient obstetrics unit at our hospital to develop a parallel program for patients at time of discharge.

### Limitations

The program described here was implemented at a single obstetric specialty clinic in rural New England.

Comparison of results with larger samples will be necessary to evaluate the feasibility and efficacy of these programs in reducing overdose-related maternal mortality within and across states. Additionally, it was made possible by the availability of free naloxone to clinical providers in NH. Therefore, it may not be feasible to implement similar programs in all states, depending on current legislation and access to supply. However, our approach can be modified to provide prescriptions when free naloxone kits are not available. Additionally, we did not formally survey staff and patients regarding acceptability of and satisfaction with the program. Finally, as noted above, the onset of the COVID-19 pandemic had enormous impact on clinic workflow, which likely impacted our results.

## Conclusions

Although published data is lacking regarding the effectiveness of naloxone access in preventing maternal mortality, ample data supports the efficacy of naloxone programs in preventing mortality in the general population. Based on the assumption that maternal deaths can similarly be prevented with naloxone, the Alliance for Innovation in Maternal Health recommends that naloxone be provided to all postpartum people with SUD. Ob/Gyn clinics provide a unique opportunity to make naloxone more accessible to a vulnerable population and their families.

**Acknowledgements** The authors gratefully acknowledge the dedication of the Dartmouth-Hitchcock Medical Center ambulatory Ob/Gyn clinic staff, especially Deborah Fabry, RN, MSN, who developed the nursing protocols and training program, and NH Doorways program for providing naloxone.

**Author Contribution** MKD performed literature reviews, developed policies and procedures for the intervention, wrote the initial draft of the manuscript, and provided copy editing and formatting. DG conceived of the intervention, collected and analyzed data, and contributed substantially to manuscript development.

**Funding** No funding sources to report – this is an unfunded quality improvement project.

## Declarations

**Conflict of interest** None to disclose by either author.

**Ethics Approval** This project was reviewed by the medical center's institutional review board and was determined not to be human subjects research.

**Consent to Participate** N/A

**Consent for Publication** N/A

**Data Availability** Patient demographic data is available through NH Vital Records (David.laflamme@unh.edu). Data on naloxone discussion and distribution was extracted from electronic health records for quality improvement purposes.

**Code Availability** N/A.

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