Model Facts

Model Name: ***Duke Opioid and Sedation Assessment (DOSA)***
Locale: Duke University Health System

Approval Date: **Last Update:** 09/13/2023	**Creator:** Dr. Padma Gulur Department of Anesthesiology **Version**: 1.0

Summary: This model uses EHR input data from a patient's Duke Health history initiated at the time of first opioid administration following inpatient admission. Upon meeting inclusion requirements, the model runs hourly and estimates the probability that the patient will experience an opioid induced respiratory depression (OIRD) event requiring rescue naloxone administration and provides recommendations for level of monitoring to prevent such events. It was developed in 2021 and 2022 by the Department of Anesthesiology, Duke Institute for Healthcare Innovation, and approved by the Algorithm-Based Clinical Decision Support (ABCDs) committee in 2023.

Opioid induced respiratory depression was defined as intravenous or intramuscular administration of naloxone outside of the operating room as end respiratory depression requires resuscitation with rescue naloxone

Mechanism

- **Outcomes** ……OIRD event requiring rescue naloxone administration
- **Output** …0-100% predicted probability of event and risk strata for preventative monitoring recommendations
- **Outcome Prevalence** ……[0.50% - 1.02%]
- **Model Thresholds**…….Score ranges from 0-29, Risk categorized as Low (0-8), Moderate (9-11), or High (12-29)
- **Target population** ……..all adult inpatients who have received opioids during admission
- **Time of prediction**…… hourly following inpatient admission and opioid administration
- **Input data source**……..electronic health record (EHR data)
- **Input data type** ……..demographics, encounter data, comorbidities, medication administrations
- **Dashboard display software**……Tableau
- **Model Type**……..Logistic Regression to produce risk scores and risk strata
- **Action Mechanism**……BPA based notification to the provider. The dashboard is for monitoring purposes only

Validation and Performance

Results were determined by training on data from January 2017 to June 2020. We undertook a 2:1 split-sample analysis approach to avoid over fit and over optimization in the primary DUH cohort. The derivation set was identified via simple random sampling, and all risk score specifications were completed on the derivation set alone. The DUH validation set was reserved for diagnostic performance and calibration assessments and are reported in the table below. We further investigated the generalizability of our findings to two additional Duke practices (DRaH, DRH).

The selected model formulation was determined by backwards selection from multivariable logistic regression models based on AIC and model inclusion frequency across 1,000 bootstrap samples from the derivation cohort. Once the final model was determined, a simplified score was derived among the selected terms by standardizing the regression coefficients by the smallest beta value then rounding down to the nearest whole integer.

Using the ROC and Youden's index, which identifies cut points that maximize both sensitivity and specificity performance, we divided the simplified score range into a low and high interval. Then, as interventions need to be tailored for those at especially high risk, we restricted the derivation cohort to those with a score in the high interval to identify a second cut point via Youden's index to split the score range into moderate and high risk.

A silent evaluation was conducted between 10/20/2022 and 1/31/2023 for model testing and additional evaluation.

Table 1: Demographic and Characteristic Distributions

	DUH Derivation	DUH Validation	DRH	DRAH
n	45810	22786	29436	21820
Sex Male (%)	22805 (49.8)	11541 (50.6)	9935 (33.8)	9887 (45.3)
Age (mean (SD))	57.43 (17.00)	57.63 (16.90)	53.15 (19.35)	62.01 (15.36)
Race (%)				
Black or African American	13451 (29.4)	6597 (29.0)	10911 (37.1)	5976 (27.4)
Caucasian/White	29168 (63.7)	14620 (64.2)	16365 (55.6)	14487 (66.4)
Other	2472 (5.4)	1189 (5.2)	1631 (5.5)	1012 (4.6)
Unknown	719 (1.6)	380 (1.7)	529 (1.8)	345 (1.6)
Admission Type (%)				
Elective	16501 (36.0)	8417 (36.9)	8567 (29.1)	9259 (42.4)
Emergency	20872 (45.6)	10292 (45.2)	13465 (45.7)	11652 (53.4)
Trauma Center	7 (0.0)	3 (0.0)	3 (0.0)	2 (0.0)
Urgent	8430 (18.4)	4074 (17.9)	7401 (25.1)	907 (4.2)
Surgical Admission (%)	40164 (87.7)	19996 (87.8)	24494 (83.2)	17197 (78.8)
DRG Weight (mean (SD))	2.81 (3.19)	2.79 (3.15)	1.64 (1.24)	2.25 (1.60)
Opioid Tolerant (%)	5722 (12.5)	2929 (12.9)	2560 (8.7)	3152 (14.4)
Current Lung Cardiac (%)	22565 (49.3)	11304 (49.6)	11602 (39.4)	9904 (45.4)
Renal Hepatic Impair (%)	8041 (17.6)	3916 (17.2)	4258 (14.5)	3979 (18.2)
Recent Surgery 48H (%)	10288 (22.5)	5028 (22.1)	7751 (26.3)	6501 (29.8)
Polypharmacy (%)	16573 (36.2)	8251 (36.2)	7776 (26.4)	8714 (39.9)
Previous Narcan (%)	541 (1.2)	252 (1.1)	396 (1.3)	240 (1.1)

Table 2. Selected DOSA Model and Simplified Score Coefficients

Effect	Selected Model OR (95% CI)	Selected Model Beta Coefficient	Simplified Score Points
Current Lung Cardiac Dx	2.74 (2.25, 3.37)	1.0088	5
Renal Hepatic Impair Dx	1.70 (1.39, 2.08)	0.5335	2
Recent Surgery 48H	3.68 (3.05, 4.43)	1.3036	7
Previous Rescue Narcan	5.14 (3.44, 7.42)	1.6366	8
Polypharmacy	2.42 (2.02, 2.89)	0.8826	4
Age > 65	1.20 (1.00, 1.44)	0.1831	1
Opioid Tolerance at Adm	1.58 (1.26, 1.97)	0.4573	2

Table 3. Model Performance Characteristics

Location	Incidence	AUROC	Low (0-8) vs Moderate/High Risk (9+)		
			PPV	Sensitivity	Specificity
DUH Validation Set (January 2017 – June 2020)	1.02%	0.75 (0.72, 0.79	0.02 (0.02, 0.03)	0.71 (0.64, 0.76)	0.69 (0.69, 0.70)
DraH (January 2017 – June 2020)	0.70%	0.73 (0.69, 0.76)	0.01 (0.01, 0.02)	0.71 (0.63, 0.78)	0.65 (0.64, 0.65)
DRH (January 2017 – June 2020)	0.50%	0.74 (0.70, 0.78)	0.01 (0.01, 0.01)	0.58 (0.50, 0.66)	0.75 (0.74, 0.75)
All Sites Silent Evaluation (10/20/2022 – 1/31/2023)	0.75%	0.82 (0.79, 0.86)	0.03 (0.02, 0.04)	0.58 (0.47, 0.68)	0.85 (0.85, 0.86)

Uses and Directions

§ **Benefits:** Detection of a patient's declining respiratory status before progression to respiratory depression can help avert transfers to ICU and undesirable outcomes such as anoxic brain injury or death. Averting incidents of Opioid-related respiratory depression can increase patient safety and improve patient outcomes. Postoperative respiratory failure is rated as the fourth most common patient safety event by the Agency for Healthcare Research and Quality and is associated with increased mortality and hospital length of stay. DOSA was developed as a tool to assist clinicians in identifying patients requiring additional monitoring with the goal of reducing the rate of OIRD events.

§ **Target population and use case:** Adult inpatient cases where opioids are administered

§ **General use:** This model and dashboard are intended to be used by surgeons, anesthesiologists, surgical residents, surgical nurse practitioners, or surgical physician assistants to identify patients at risk for and requiring additional monitoring for OIRD. The model and dashboard are not a diagnostic for OIRD and are not meant to directly drive clinical care. They are intended to complement other patient information related to OIRD as well as a physical or tele- evaluation to determine the need for preventative monitoring.

§ **Appropriate decision support:** The model identifies patient X likelihood of OIRD based on calculated DOSA score and corresponding risk strata. Monitoring recommendations are made corresponding to the predicted level of risk and clinicians may decide to increase the level of monitoring based on these recommendations. Patients will be assigned a score based on the calculated DOSA score that can trigger a Best Practice Advisory in the patient's Storyboard that includes contributing factors and medications as well recommendation for continuous pulse ox monitoring. If the BPA is not addressed from the Storyboard, it will pop up when signing orders.

§ **Phenotype retrospective evaluation:** OIRD was identified via rescue naloxone administration in the training dataset and model building was conducted to derive a risk score. We identified all intravenous and intramuscular administrations of naloxone outside of the operating room as representing rescue use. The administration of naloxone in the operating room was excluded as it is commonly used as routine care. Similarly oral administrations were excluded because this route of administration is uncommon for OIRD resuscitation during inpatient admissions.

§ **Safety and efficacy evaluation:** Review of the model and dashboard tool occurs throughout the build and testing phases to ensure accuracy of model and underlying data, as well as clinical relevance and actionability of the output. This process culminated in a "silent go live" period wherein the clinical team prospectively evaluated model output on patients and adjudicate their evaluation of model's decision-making and was completed in Winter of 2023. The DOSA tool will be evaluated for efficacy following a "go live" period at DUH during which the team will monitor rates of OIRD, operational characteristics of the DOSA score, and the use of continuous monitoring based on identified risk strata.

Warnings

§ **Risks:** Even if used appropriately, clinicians using this model can fail to detect risk of OIRD or entire lack thereof. Delays in response to clinical deterioration can lead to morbidity and mortality.

§ **Inappropriate Settings:** This model was not trained or evaluated on outpatients nor patients who do not receive an opioid during care at Duke. Do not use this for pediatric patients.

§ **Clinical Rationale:** Clinical end users are expected to place model output in context with other clinical information to make final determination of clinical need for respiratory monitoring.

§ **Inappropriate decision support:** This model may not be accurate outside of the target population, primarily pediatrics, outpatients, and those not administered opioids. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment.

§ **Generalizability:** This model was primarily evaluated within the local settings of Duke University Health Systems. Do not use this model in an external setting without further evaluation.

§ **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

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