

Development and Applications of the Veterans Health Administration's Stratification Tool for Opioid Risk Mitigation (STORM) to Improve Opioid Safety and Prevent Overdose and Suicide

Elizabeth M. Oliva, Thomas Bowe,
and Sara Tavakoli

Veterans Affairs (VA) Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California, and VA Center for Innovation to Implementation, VA Palo Alto Health Care System, Menlo Park, California

Eleanor T. Lewis

VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California, and VA Center for Innovation to Implementation, VA Palo Alto Health Care System, Menlo Park, California

Ilse Wiechers

VA Northeast Program Evaluation Center, VA Office of Mental Health Operations, West Haven, Connecticut, and Yale School of Medicine

Michael Harvey

VA Academic Detailing Program, VA Pharmacy Benefits Management Services, Minneapolis, Minnesota

Amanuel Medhanie

Parsimony, Inc., Blaine, Minnesota

Susana Martins

VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California

Meenah Paik

VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California

Patricia Henderson

VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California

Tigran Avoundjian

VA Center for Innovation to Implementation, VA Palo Alto Health Care System, Menlo Park, California

Jodie A. Trafton

VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California, VA Center for Innovation to Implementation, VA Palo Alto Health Care System, Menlo Park, California, and Stanford University School of Medicine

Concerns about opioid-related adverse events, including overdose, prompted the Veterans Health Administration (VHA) to launch an Opioid Safety Initiative and Overdose Education and Naloxone Distribution program. To mitigate risks associated with opioid prescribing, a holistic approach that takes into consideration both risk factors (e.g., dose, substance use disorders) and risk mitigation interventions

Elizabeth M. Oliva, Thomas Bowe, and Sara Tavakoli, Veterans Affairs (VA) Program Evaluation and Resource Center, VA Office of Mental Health Operations, Menlo Park, California, and VA Center for Innovation to Implementation, VA Palo Alto Health Care System, Menlo Park, California; Susana Martins, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations; Eleanor T. Lewis, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, and VA Center for Innovation to Implementation, VA Palo Alto Health Care System; Meenah Paik, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations; Ilse Wiechers, VA Northeast Program Evaluation Center, VA Office of Mental Health Operations, West Haven, Connecticut, and Department of Psychiatry, Yale School of Medicine; Patricia Henderson, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations; Michael Harvey, VA Academic Detailing Program, VA Pharmacy Benefits Management Services, Minneapolis, Minnesota; Tigran Avoundjian, VA Center for Innovation to Im-

plementation, VA Palo Alto Health Care System; Amanuel Medhanie, Parsimony, Inc., Blaine, Minnesota; Jodie A. Trafton, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations, VA Center for Innovation to Implementation, VA Palo Alto Health Care System, and Department of Psychiatry, Stanford University School of Medicine.

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Correspondence concerning this article should be addressed to Elizabeth M. Oliva, VA Program Evaluation and Resource Center, Center for Innovation to Implementation, 795 Willow Road (152 Menlo Park Division), Menlo Park, CA 94025. E-mail: elizabeth.oliva@va.gov

(e.g., urine drug screening, psychosocial treatment) is needed. This article describes the Stratification Tool for Opioid Risk Mitigation (STORM), a tool developed in VHA that reflects this holistic approach and facilitates patient identification and monitoring. STORM prioritizes patients for review and intervention according to their modeled risk for overdose/suicide-related events and displays risk factors and risk mitigation interventions obtained from VHA electronic medical record (EMR)-data extracts. Patients' estimated risk is based on a predictive risk model developed using fiscal year 2010 (FY2010: 10/1/2009–9/30/2010) EMR-data extracts and mortality data among 1,135,601 VHA patients prescribed opioid analgesics to predict risk for an overdose/suicide-related event in FY2011 (2.1% experienced an event). Cross-validation was used to validate the model, with receiver operating characteristic curves for the training and test data sets performing well ($>.80$ area under the curve). The predictive risk model distinguished patients based on risk for overdose/suicide-related adverse events, allowing for identification of high-risk patients and enrichment of target populations of patients with greater safety concerns for proactive monitoring and application of risk mitigation interventions. Results suggest that clinical informatics can leverage EMR-extracted data to identify patients at-risk for overdose/suicide-related events and provide clinicians with actionable information to mitigate risk.

Keywords: opioids, risk mitigation, opioid safety, decision support, risk model

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The Centers for Disease Control and Prevention reports that 259 million prescriptions for opioid or narcotic pain relievers (opioid analgesics) were written in the United States in 2012, with 46 people dying every day from opioid analgesic overdose (Centers for Disease Control and Prevention, 2014). Drug overdose is now the leading cause of injury death in the United States (Centers for Disease Control and Prevention, 2012; Jones et al., 2013) with most drug overdoses unintentional and related to opioids (Centers for Disease Control and Prevention, 2016; Chen et al., 2015). The Veterans Health Administration (VHA) serves a patient population with higher rates of chronic pain, mental health, and substance use disorders compared to the general U.S. population (Agha et al., 2000; Clark, 2002; Gironda et al., 2006; Hoglund & Schwartz, 2014; Seal et al., 2011; Toblin et al., 2014) due to both military-related trauma exposure and eligibility requirements for Veterans' use of VHA services; these conditions may put patients at greater risk of overdose-related adverse events. For example, the rate of accidental poisoning mortality in the VHA is nearly twice that of the general U.S. population (Bohnert et al., 2011) and the prevalence of opioid abuse is almost 7 times higher among VHA patients compared to commercial health plan patients (Baser et al., 2014). Patients treated by VHA also have an increased risk for suicide compared to the general population, and opioids could be used for intentional overdoses (Blow et al., 2012).

Concerns about opioid safety and overdose have led the VHA to develop an Opioid Safety Initiative (OSI) and Opioid Overdose Education and Naloxone Distribution (OEND) program. As part of the OSI, VHA "closely monitors VA's dispensing practices system-wide and coordinates pain management to include patient and provider education, testing and tapering programs, and alternative therapies like acupuncture and behavior therapy" (Department of Veterans Affairs, 2014). OEND provides patients at risk for an overdose with education on risk factors for and identification of, prevention of, and response to opioid overdose plus a naloxone rescue kit to use in case of an overdose (akin to epinephrine injector kits used for anaphylaxis, except containing naloxone; Oliva, 2015; Oliva et al., 2016). Identifying patients who may be at risk for a serious adverse event can be challenging; thus, one of the goals of the OSI is to develop tools to identify high-risk

patients to facilitate the identification and care "of patients who will require more intensive monitoring of opioid therapy, or more intensive consideration of non-opioid treatment plans as outlined in the clinical guidance recommendations and the VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (<http://www.healthquality.va.gov/guidelines/Pain/cot/>)" (Goal 5; Department of Veterans Affairs, 2014). The STORM model was developed to address this OSI goal.

Numerous studies have examined factors associated with risk for overdose- or suicide-related events in the VHA patient population. These risks include maximum daily dose (Bohnert et al., 2011; Paulozzi et al., 2012; Zedler et al., 2014), mental health conditions (Bohnert et al., 2012; Seal et al., 2011), substance use disorder (Bohnert et al., 2012; Zedler et al., 2014), opioid duration (Miller et al., 2015), coprescribing with benzodiazepines (Im et al., 2015; Park et al., 2015), and medical diagnoses (Zedler et al., 2014). Zedler et al. (2015) present a Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression among VHA patients prescribed opioids that incorporates 15 variables. Similar risk factors have been identified in the non-VHA population (e.g., Dunn et al., 2010). Based on these findings, a variety of clinician-administered screening tools have been developed to identify high-risk patients for intervention (summarized by Zedler et al., 2015). In addition to screening tools, clinical practice guidelines (Chou et al., 2009; VA/DoD, 2010) specify opioid risk mitigation strategies, including universal urine drug screening, timely follow-up after new prescription or dose changes, prior and concurrent use of nonopioid pain treatments, psychosocial assessment, treatment of mental health and substance use disorder comorbidities, avoiding high doses and coprescription with sedatives, side effect management, informed consent, and regular medication reconciliation.

Identifying patients at elevated risk for an overdose or suicide-related event can be difficult in clinical practice. Complex patients may be receiving care from multiple providers for multiple conditions that independently increase their risk, and staff making opioid prescribing decisions (e.g., in emergency departments or primary care clinics) may lack the time needed to conduct com-

prehensive medication reconciliation and biopsychosocial risk assessments. While screening tools are useful for informing clinical decision making, they require clinical time and resources to implement. Thus, screening tools may not be incorporated into standard clinical practice and may be difficult to implement in the settings in which many patients receive opioid analgesics (e.g., primary care). Moreover, concerns have been raised regarding the lack of evidence to support the predictive validity of risk assessment instruments for opioid misuse (Chou et al., 2015). In addition, use of risk mitigation strategies also requires clinical time and resources. Overdose- or suicide-related events are extremely serious when they occur but rare in the context of the high volume of opioids prescribed. Universal implementation of all risk mitigation strategies may not be efficient or feasible in current medical practice settings. Thus, a holistic approach is needed that addresses both risk factors and risk mitigation strategies relevant for specific patients in a manner that can be easily incorporated into clinical processes (Zedler et al., 2015).

In health care systems with electronic medical records (EMR), many of the risk factors and risk mitigation strategies listed above are readily available from EMR-based data warehouses that contain structured EMR-data extracts. The reason that EMR-data extracts are used is because EMRs are designed with a focus on maintaining the richness and detail of clinical notes and the integrity of the historic record, intentions at odds with summarizing and transforming data. To allow rapid analysis of EMR-based big data, one requires consolidated and highly structured health information, and the ability to transform health information into summary indicators. Health care systems will typically create and utilize separate data systems based on EMR-data extracts for billing, quality improvement, program monitoring, and research (i.e., EMR-data extracts). To help providers improve opioid safety, the VHA Office of Mental Health Operations (OMHO) sought to use national VHA EMR-data extracts to prioritize review of patients receiving opioids based on their risk for overdose- or suicide-related events and to inform providers of the risk factors and risk mitigation strategies for each patient. To accomplish this goal—that is, to help providers both identify patients at increased risk for overdose- or suicide-related events and provide them with patient-centered risk mitigation strategies—OMHO staff developed the VHA Stratification Tool for Opioid Risk Mitigation (STORM).

STORM is a clinical decision support tool that uses VHA EMR-data extracts to (a) estimate patient risk for an overdose- or suicide-related event and (b) provide actionable information for risk-stratified intervention, thus serving as a platform to help providers visualize and implement a much-needed patient-centered approach to address opioid safety. STORM estimates patient risk for an overdose- or suicide-related event in order to help providers prioritize review of patients prescribed opioids. OMHO staff developed a predictive model to estimate patients' risk for an overdose- or suicide-related event based on readily available and easily processed VHA EMR-data extracts, allowing for automated identification of higher-risk patients. To provide actionable information for risk-stratified intervention within STORM, OMHO staff developed an efficient and feasible strategy for presenting the most relevant risk- mitigation strategies for a specific patient. This article describes the development of STORM and its applications.

Method

This was a quality improvement project conducted by the VHA Office of Mental Health Operations. We describe STORM, including the predictive risk model that STORM uses to estimate risk for an overdose- or suicide-related event among patients who received an outpatient opioid prescription from VHA, and its clinical applications. The predictive risk model used VHA EMR-data extracts for patients with an outpatient opioid prescription in fiscal year 2010 (FY2010; October 1, 2009, to September 30, 2010) who had outcome data—that is, VHA encounters based on VHA EMR-data extracts or overdose- or suicide-related causes of death based on National Death Index data—in FY2011 (October 1, 2010, through September 30, 2011). Parameters from the risk model are applied to nightly updated VHA EMR-data extracts (i.e., FY2016 data) to calculate risk scores daily. STORM incorporates and visually represents the risk scores along with clinically useful and actionable information regarding patient risk factors and risk mitigation strategies.

Participants

All patients with an active short- or long-acting opioid analgesic prescription from VHA are included in STORM. STORM is updated nightly using VHA EMR-data extracts from the VHA Corporate Data Warehouse; thus the number of patients included varies day to day but as of March 25, 2016, there were 545,042 patients with an active opioid analgesic prescription from VHA included in STORM. Thus, while the predictive model included all patients with an opioid prescription in the index year (described below), STORM presents data only for patients with a current active opioid prescription. Because most opioid prescriptions are temporary treatments, most patients who receive opioids will have active prescriptions for only a limited period of time—a time during which they will be displayed in STORM.

The risk estimate included in STORM is based on a predictive model that uses FY2010 data to estimate patient risk for an overdose- or suicide-related event in FY2011. The population of interest for the predictive model was all patients who had outcome data in FY2011—that is, VHA encounters based on VHA EMR data or overdose- or suicide-related causes of death based on National Death Index data—who had received an outpatient opioid analgesic prescription from VHA in FY2010 ($N = 1,220,922$). Thus, we excluded patients who (a) had no VHA encounters in FY2011 and no data to suggest they had died in FY2011 ($n = 54,660$) or (b) died and the cause of death was not opioid-related and they had no other overdose or suicide events prior to their death ($n = 30,661$). The final sample of participants for the predictive model was 1,135,601 (90% male; $M_{\text{age}} = 59$ years, $SD = 14$ years; race/ethnicity—not mutually exclusive—was 77% White, 20% Black, 6% Hispanic, 1% Asian, and 1% American Indian). Opioid analgesic prescriptions included short- and long-acting opioids and tramadol. *Short-acting opioids* were defined as butorphanol, codeine, dihydrocodeine, hydrocodone, hydromorphone, meperidine, morphine, opium/belladonna, oxycodone, oxymorphone, pentazocine, and tapentadol. *Long-acting opioids* were defined as fentanyl, hydromorphone, methadone, sustained-release morphine, sustained-release oxycodone, sustained-release oxymorphone, and sustained-release tramadol.

Procedures

Identifying which patients may be in greatest need of risk-mitigation strategies requires knowing patients' total estimated risk for adverse events, specific risk factors for clinical intervention, and whether the patient has received specific risk-mitigation strategies. STORM was designed to combine the data elements needed to calculate risk score with use of risk-mitigation strategies, and to update this information nightly using VHA EMR-data extracts. Selection of the VHA EMR-data extracts used to calculate risk scores in STORM was based on the variables included in the predictive risk model (see below). To match the predictive risk model, diagnosis and adverse event information were pulled using the same criteria and time frame (e.g., diagnoses in the past year) as the risk model. Prescription data were based on active prescriptions released to the patient. These raw data were transformed into variables that matched those in the risk model. Parameter values from the model were applied to these variables and summed to generate the estimated risk score (ranges from 0 to 100), and risk scores were stored as a VHA data extract.

The predictive risk model used to estimate STORM risk scores was a multivariate mixed-effects logistic regression formulated to predict the occurrence of an overdose- or suicide-related event (overdose/suicide) using VHA EMR-data extracts in conjunction with National Death Index data that included cause of death codes. FY2010 VHA EMR-data extracts were used to predict overdose/suicide in FY2011. September 30, 2010—the end of FY2010—was considered the index date for the sample. Each participant had at least one outpatient opioid analgesic prescription prior to this date during FY2010. Participants were followed for 1 year (FY2011) to identify any overdose/suicide-related events.

Variables included in the risk model were selected based on published literature, *VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain* (VA/DoD Opioid Therapy for Chronic Pain Working Group, 2010), and recommendations from the VHA National Pain Workgroup. The predictor variables came from FY2010 data; the outcome variable of any overdose/suicide-related event came from FY2011 data. Design of the predictive model was guided by its intended use in the clinical decision support system, which was to pull historical data during a nightly data pull and estimate risk for the subsequent year to guide current clinical decision making. FY2010 predictor variables were designed to match that which would be pulled nightly, and outcomes variables were examined after that pull date (i.e., FY2011 for the model). Thus, adverse events that occurred after a FY2010 opioid prescription but before FY2011 were included as predictors of FY2011 risk, not adverse outcomes.

The outcome variable in the predictive model, overdose/suicide-related events, was a binary variable defined as having any drug overdose (i.e., drug poisoning including opioid, sedative, acetaminophen, or other drug poisoning) or suicide-related event (ideation or attempt) in FY2011 (see Table A1 in the online supplemental material for definitions). This variable also included deaths due to overdose or suicide—including causes of death identified with International Classification of Diseases (ICD)-10-CM codes X40-X45, X60-65, X85, Y10-15, and Y45—from National Death Index (NDI) data drawn from the Veterans Affairs/Department of Defense (VA/DoD) Suicide Data Repository, and followed established NDI search procedures (McCarthy et al., 2009). The pre-

dictor variables included in the predictive model were drawn from VHA EMR-data extracts and addressed the following domains in FY2010: (a) demographics; (b) previous overdose/suicide and treatment risk indicators; (c) prescriptions; (d) substance use and mental health disorder diagnoses; and (e) medical comorbidities.

Demographics. Demographic predictor variables for the predictive model were FY2010 sex and age. Sex was a binary variable with females as the reference group. Age was classified into four groups: ages 30 or younger, 31 to 50 years old, 51 to 65 years old, and 66 or older (reference group).

Previous overdose/suicide and treatment risk indicators. It was expected that previous overdose/suicide-related events, adverse events influenced by impulsivity or sedation (e.g., falls and accidents), and emergency treatments would be risk indicators for future overdose/suicide-related events. Thus, we included predictor variables for FY2010 health care encounters for overdose or suicide attempts or ideation, falls or accidents, detoxification, inpatient mental health treatment, and emergency room visits (see Table A2 in the online supplemental material for definitions).

Prescriptions. There were four main FY2010 prescription-related predictor variables included in the predictive model: (a) opioid therapy type, (b) opioid dose, (c) coprescribed contraindicated sedative medications, and (d) number of classes of prescribed medications that are evidence-based for pain management but are sedating.

1. *Opioid therapy type* was defined in consultation with an expert panel (including authors of the *VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain*, VA/DoD Opioid Therapy for Chronic Pain Working Group, 2010, and clinical experts from the VHA National Pain Workgroup) and involved a hierarchical classification of patients into four tiers based on opioid type and the length of time patients were prescribed opioids within FY2010: Tier 1—prescribed long-acting opioids; Tier 2—prescribed chronic, short-acting opioids (≥ 90 -day supply of any short-acting opioid medication) but no long-acting opioids; Tier 3—prescribed acute, short-acting opioids (< 90 -day supply of any short-acting opioid medication) but no long-acting opioids; and Tier 4—prescribed tramadol only (Midboe et al., 2012). The expert panel suggested this hierarchical classification to reflect potential differences in risk (e.g., long-acting medications may pose greater risk for adverse events and are typically prescribed by specialists and in nonprimary care settings). In addition, a recent study found that patients initiating long-acting opioid therapy were more than twice as likely to overdose compared to patients initiating short-acting opioid therapy (Miller et al., 2015).

2. *Opioid dose* was calculated by converting medications into morphine equivalent daily dose (MEDD). This is the method used by VHA Pharmacy Benefits Management and higher MEDD has been associated with greater risk for overdose/suicide (Bohnert et al., 2011; Paulozzi et al., 2012; Zedler et al., 2014). However, opioid dose may change over the course of treatment and patients may have overlapping prescriptions to ensure coverage. Thus, to avoid overestimating MEDD during these overlap periods, the 90% percentile of the distribution of daily calculated MEDD over FY2010 was used for the *opioid dose* variable in the model (see Table A3 in the online supplemental material for more information). To address infrequent data entry errors in the source pre-

scription data, any MEDD over 1,000 were deleted. MEDD between 500 and 1,000 were set to 500.

3. Coprescribed contraindicated sedative medication.

4. *Evidence-based but sedating medication prescriptions* were defined in consultation with the same expert panel described above. These variables have been associated with increased risk for overdose/suicide-related events (Im et al., 2015; Park et al., 2015). *Coprescribed contraindicated sedative medication* was a binary variable defined as having overlapping prescriptions of opioids and sedative medications in FY2010 (e.g., benzodiazepines, barbiturates, sedative hypnotics, SOMA; see Table A4 in the online supplemental material for definitions). *Number of classes of prescribed medications that are evidence-based for pain management but sedating* in FY2010 was a count variable of classes prescribed (i.e., tricyclic antidepressants, SNRI's, and anticonvulsants; see Table A4 in the online supplemental material for definitions) and ranged from 0 (reference group) to 3.

Substance use and mental health disorder diagnoses. Prior literature suggests that individuals with substance use and mental health disorder diagnoses are at greater risk for overdose/suicide-related events compared to individuals without those diagnoses (Bohnert et al., 2012; Seal et al., 2012; Zedler et al., 2014). Based on the literature, binary predictor variables for the following disorders were included in the model: opioid, alcohol, and tobacco use disorders as well as posttraumatic stress, major depressive, bipolar, and any other mental health disorders. To examine whether other substance use disorders may relate to overdose/suicide, we included exploratory binary predictor variables for sedative use disorder (including barbiturates), stimulant use disorder, cannabis or hallucinogen use disorders, and any other substance use disorder (see Table A5 in the online supplemental material for definitions).

Medical comorbidities. The inclusion of FY2010 medical comorbidities as predictor variables was seen as exploratory and we started from the list of comorbidities as defined by Elixhauser (Elixhauser et al., 1998). Based on suggestions from the expert panel, sleep apnea and osteoporosis were added to the list (see Table A5 in the online supplemental material for definitions).

Data Analysis

STORM displays relevant VHA EMR-data extracts—that is, estimated risk scores, risk factors included in the predictive model (e.g., prescription related factors, substance use and mental health disorder diagnoses, medical comorbidities), risk mitigation strategies, nonpharmacological pain treatments, appointments, and providers—designed to support opioid risk consideration, monitoring, and mitigation with prioritization of patients based on estimated risk (see Figure 1). Design and usability of the initial interface was guided based on feedback from multiple clinical experts in opioid safety, including VHA Pain Management leadership, a chair of the VA/DOD Clinical Practice Guideline for Chronic Opioid Therapy, leads of VHA pain management education and consultation efforts, clinical pharmacists, and interested providers. The STORM Patient Report allows for identification and filtering of patients by risk mitigation strategies (see Table A6 in the online supplemental material), opioid prescriber, and risk score. STORM requires locally granted protected health information and personally identifiable information data access; thus, only VHA staff with approved access to view patient-level health record data can view and interact with the report.

For the predictive model, a multivariate mixed-effects logistic regression using FY2010 predictor variables was used to predict overdose- or suicide-related health care events or deaths in FY2011 using data from the entire sample. The model included random effects for VHA facility and Veterans Integrated Service Network (VISN) to account for the clustering of patients within facilities and VISNs. Because our predictor variables might interact to predict overdose/suicide-related event risk (e.g., a patient with opioid use disorder admitted for inpatient mental health treatment), we conducted exploratory analyses testing all two-way interactions, except for interactions between medical comorbidities, and retained only those that were significant in the final model. Univariate analyses of the predictor variables were conducted to estimate the effect of each predictor by itself on the outcome. The multivariate mixed effects logistic regression was conducted using SAS GLIMMIX (Version 9.2).

VA STORM: Patient Detail Dashboard Stratification Tool for Opioid Risk Mitigation										
Home Definitions Contact Us Summary Report										
Patient Details	Suicide-related event or Overdose Risk Estimate	Clinical Detail on Risk Factors		Risk Mitigation Strategies		Non-pharmacological Pain Tx		Appointments		Care Providers
		Relevant Diagnoses	Relevant Medications	Strategy	Status	Therapy	Status	Recent	Upcoming	
John Doe Last Four: 0000 Gender: M Station: Facility A	Very High 32% risk of suicide-related event or overdose in the next year	SUD Dx: OUD AUD Nicotine Dep. Other SUD Mental Health Dx: PTSD Depression Other MH Medical Dx: Other Neuro Disorder	Active Opioids: Tramadol (Dr. ABC) Sedating Evidence-based Pain Meds: Vendofexine (Dr. ABC)	MEDD >= 200** Naloxone Rx Opioid Signed Informed Consent Timely Follow-up Timely UDS Psychosocial Assessment Psychosocial Tx Active SUD Tx Opioid Agonist Tx Bowel Regimen Med Reconciliation	☒ MEDD: 20 ☐ ☒ 6/20/15 ☒ 10/31/15 ☒ 10/23/15 ☒ 10/22/15 ☒ 10/22/15 ☒ 10/31/15 ☒ 10/31/15 ☐	Active Therapies CAM Therapies Chiropractic Care Occupational Therapy Pain Clinic Physical Therapy Specialty Therapy	☒ 1/16/16 ☐ ☐ 1/16/16 ☐ ☒ 1/16/16 ☐ 7/12/2015 ☐	Primary Care 10/23/2015 Mental Health 10/31/15 Substance Use Disorder - Gp Pain Clinic 7/12/2015 Other 10/23/2015 Telephone Primary Care	Primary Care 10/21/16 Mental Health 1/18/2015 11:00 AM Substance Use Disorder - Ind Pain Clinic 10/21/16 Other None	Recent Opioid Prescriber Dr. ABC Primary Care Provider Dr. DEF SUD Tx Coordinator Jane Doe SHIP Team Team A

Figure 1. Sample patient-level report. VA = Veterans Affairs; STORM = Stratification Tool for Opioid Risk Mitigation. See the online article for the color version of this figure.

Two-fold cross-validation was used to validate the model. This method involves dividing the sample into two random halves (R1 and R2) and then (a) using R1 as a training dataset and validating it with R2 and (b) using R2 as a training dataset and validating it with R1. Receiver operating characteristic (ROC) curves were used to assess model fit. ROC curves plot the probability of detecting an actual overdose- or suicide-related event (sensitivity) and a false overdose- or suicide-related event (1-specificity) for an entire range of possible cut points. A common measure of fit in a logistic regression model is the area under the ROC curve (AUC). AUC is a measure of how well the model predicts overdose/suicide-related events and is reported as a *c* statistic. AUC corresponds to the likelihood that a person who will have an overdose- or suicide-related event will have a higher predicted probability than a person who will not have an overdose- or suicide-related event. This provides a measure of the model's ability to discriminate between patients who experience an overdose/suicide-related event versus those who do not.

Results

As mentioned earlier, the number of patients included in STORM varies on a day-to-day basis, but as of March 25, 2016, there were 545,042 patients with an active opioid analgesic prescription from VHA included in STORM. In terms of the predictive risk model used to estimate risk scores for these patients, Table 1 includes descriptive information about the sample included in the risk model. The risk model sample was primarily male (91.9%) and of older age (77.6% were 51 years or older). In terms of *previous overdose/suicide and treatment risk indicators* in FY2010, 43.2% had a previous emergency room visit, 2.9% had a previous inpatient mental health treatment encounter, 1.8% had a previous fall/accident, 1.2% had a previous overdose/suicide event, and .2% had a previous detoxification encounter. With regard to *prescription-related factors* in FY2010, 16.3% of the sample was coprescribed opioids and sedatives. In terms of opioid therapy type, 41.7% were prescribed acute, short-acting opioids; 30.8% were prescribed chronic, short-acting opioids; 20.4% were prescribed tramadol only; and 7.1% were prescribed long-acting opioids. And in terms of number of classes of other sedating pain medications, the majority of the sample (67.3%) was not prescribed any, 25.9% were prescribed one, 6.2% were prescribed two, and 0.6% were prescribed three. Regarding *substance use disorders* in FY2010, 23.1% were diagnosed with a tobacco use disorder, 10.2% were diagnosed with alcohol use disorder, 3.2% were diagnosed with a stimulant use disorder, 2.7% were diagnosed with cannabis/hallucinogen use disorder, 1.8% were diagnosed with opioid use disorder, 0.4% were diagnosed with a sedative use disorder and 3.6% were diagnosed with any other substance use disorder. In terms of *mental health disorders* in FY2010, 18.0% were diagnosed with posttraumatic stress disorder, 6.7% were diagnosed with major depressive disorder, 3.9% were diagnosed with bipolar disorder, and 45.8% were diagnosed with some other mental health disorder. With regard to *medical comorbidities* in FY2010, the most frequent to least frequent diagnoses were hypertension (59.5%), diabetes—uncomplicated (26.8%), obesity (19.9%), chronic pulmonary disease (17.7%), sleep apnea (11.2%), solid tumor without metastasis (11.0%), cardiac arrhythmia (8.3%), deficiency anemia (7.9%), diabetes—complicated

(7.7%), peripheral vascular disorder (6.5%), hypothyroidism (5.9%), renal failure (5.9%), congestive heart failure (4.5%), electrolyte disorders (3.7%), other neurological disorder (3.6%), liver disease (3.4%), rheumatoid arthritis (2.6%), valvular disease (2.4%), osteoporosis (2.0%), peptic ulcer disease (1.4%), coagulopathy (1.3%), paralysis (1.0%), lymphoma (0.7%), AIDS (0.6%), metastatic cancer (0.5%), pulmonary circulation disorder (0.5%), weight loss (0.1%), and blood loss anemia (0.1%).

Among the 1,135,601 patients in the sample with an outpatient opioid prescription in FY2010 who had outcome data in FY2011, there were 23,790 who had an overdose- or suicide-related event (2.1%). Table 1 displays the predictors used in the risk model, including the odds ratios (*ORs*) for the univariate analyses and the parameter estimates in the final model. The interactions included in the final model and their parameter values are displayed in Table 2.

Demographics

Males were less likely than females (*OR* = .8) and all age groups below age 66 were more likely than the age 66 or older group to have an overdose- or suicide-related event (*ORs* ranged from 2.5 to 3.7).

Previous Overdose/Suicide and Treatment Risk Indicators

As expected, having a previous overdose- or suicide-related event (*OR* = 23.1), detoxification (*OR* = 18.5), inpatient mental health treatment (*OR* = 16.6), emergency room visit (*OR* = 3.4), or fall or accident (*OR* = 2.9) in FY2010 was associated with increased risk for an overdose or suicide-related event in FY2011.

Prescription-Related Predictors

Compared to patients prescribed tramadol only, patients prescribed short-acting and long-acting opioids in FY2010 were more likely to have an overdose- or suicide-related event in FY2011 (*ORs* = 1.1 and 1.5, respectively). Patients with acute (less than 90 days' supply) prescriptions for short-acting opioids in FY2010 were as likely to have an overdose or suicide-related event in FY2011 as were patients with chronic short-acting opioid therapy. Patients coprescribed opioid and sedative medications in FY2010 were more likely than those without a coprescription (*OR* = 1.4) to have an overdose or suicide-related event in FY2011. Compared to patients with no other sedating pain medication prescriptions in FY2010, patients with any sedating, but evidence-based, pain medication prescriptions were more likely to have an overdose or suicide-related event in FY2011 (*ORs* = 2.1, 3.6, and 6.1 for 1, 2, and 3 classes of sedating pain medications, respectively). Increasing opioid dose in FY2010 was related to overdose or suicide-related event risk in FY2011; in the final model, each additional milligram in MEDD increased risk by 0.3%.

Substance Use Disorder (SUD) Diagnoses

All SUD diagnoses in FY2010 were associated with increased risk for an overdose or suicide-related event in FY2011, including hypothesized diagnoses (i.e., opioid [*OR* = 8.0], alcohol [*OR* = 5.3], or tobacco use disorder [*OR* = 2.2]) and exploratory diagnoses (i.e., sedative [*OR* = 11.2], stimulant [*OR* = 8.1], cannabis or hallucinogen

Table 1

Descriptive Information for FY2010 Predictor Variables Included in Risk Model Predicting Any FY2011 Overdose/Suicide-Related Event, Including Odds Ratios From Univariate Analyses and Final Model Parameter Estimates

Variable	Overall sample 1,135,601	No overdose/suicide-related event (FY2011)	Any overdose/suicide-related event (FY2011)	Odds ratio	Final model parameter estimate
Demographics					
Sex					
Female (reference)	92,207	89,861 (97.5%)	2,346 (2.5%)		
Male	1,043,394	1,021,950 (97.9%)	21,444 (2.1%)	0.8	.17
Age (years)					
≤30	45,702	44,186 (96.7%)	1,516 (3.3%)	3.7	.94
31–50	208,230	201,649 (96.8%)	6,581 (3.2%)	3.5	.71
51–65	553,592	540,953 (97.7%)	12,639 (2.3%)	2.5	.38
≥66 (reference)	328,077	325,023 (99.1%)	3,054 (.9%)		
Previous overdose/suicide and treatment risk indicators (FY2010)					
Overdose/suicide					
No (reference)	1,122,431	1,102,520 (98.2%)	19,911 (1.8%)		
Yes	13,170	9,291 (70.5%)	3,879 (29.5%)	23.1	2.62
Fall/accident					
No (reference)	1,115,222	1,092,603 (98.0%)	22,619 (2.0%)		
Yes	20,379	19,208 (94.2%)	1,171 (5.8%)	2.9	.44
Detoxification					
No (reference)	1,133,303	1,110,153 (98.0%)	23,150 (2.0%)		
Yes	2,298	1,658 (72.2%)	640 (27.9%)	18.5	.06
Inpatient mental health treatment					
No (reference)	1,102,882	1,085,861 (98.5%)	17,021 (1.5%)		
Yes	32,719	25,950 (79.3%)	6,769 (20.7%)	16.6	1.00
ER visit					
No (reference)	644,647	637,904 (99.0%)	6,743 (1.1%)		
Yes	490,954	473,907 (96.5%)	17,047 (3.5%)	3.4	.72
Prescription related (FY2010)					
Opioid therapy type					
Tier 1 (long acting)	80,511	78,217 (97.2%)	2,294 (2.8%)	1.5	-.03
Tier 2 (chronic, short acting)	349,890	342,411 (97.9%)	7,479 (2.1%)	1.1	.07
Tier 3 (acute, short acting)	473,461	463,909 (98.0%)	9,552 (2.0%)	1.1	-.04
Tier 4 (tramadol only; reference)	231,739	227,274 (98.1%)	4,465 (1.9%)		
Opioid dose		Not applicable, continuous variable			.003
Coprescription of opioids and sedatives					
No (reference)	950,124	931,285 (98.0%)	18,839 (2.0%)		
Yes	185,477	180,526 (97.3%)	4,951 (2.7%)	1.4	.10
Number of classes of other sedating pain medications					
0 (reference)	764,124	753,181 (98.6%)	10,943 (1.4%)		
1	293,655	284,884 (97.0%)	8,771 (3.0%)	2.1	.25
2	70,963	67,449 (95.0%)	3,514 (4.0%)	3.6	.40
3	6,859	6,297 (91.8%)	562 (8.2%)	6.1	.77
Substance use disorders (FY2010)					
Opioid use disorder					
No (reference)	1,114,730	1,093,719 (98.1%)	21,011 (1.9%)		
Yes	20,871	18,092 (86.7%)	2,779 (13.3%)	8.0	.31
Alcohol use disorder					
No (reference)	1,019,998	1,004,780 (98.5%)	15,218 (1.5%)		
Yes	115,603	107,031 (92.6%)	8,572 (7.4%)	5.3	.36
Tobacco use disorder					
No (reference)	873,755	859,360 (98.4%)	14,395 (1.7%)		
Yes	261,846	252,451 (96.4%)	9,395 (3.6%)	2.2	.18
Sedative use disorder					
No (reference)	1,131,316	1,108,335 (98.0%)	22,981 (2.0%)		
Yes	4,285	3,476 (81.1%)	809 (18.9%)	11.2	.23
Stimulant use disorder					
No (reference)	1,098,884	1,079,707 (98.3%)	19,177 (1.8%)		
Yes	36,717	32,104 (87.4%)	4,613 (12.6%)	8.1	.73

Table 1 (continued)

Variable	Overall sample 1,135,601	No overdose/suicide-related event (FY2011)	Any overdose/suicide-related event (FY2011)	Odds ratio	Final model parameter estimate
Cannabis/hallucinogen use disorder					
No (reference)	1,105,261	1,084,536 (98.1%)	20,725 (1.9%)		
Yes	30,340	27,275 (89.9%)	3,065 (10.1%)	5.9	.27
Other substance use disorders					
No (reference)	1,094,245	1,075,518 (98.3%)	18,727 (1.7%)		
Yes	41,356	36,293 (87.8%)	5,063 (12.2%)	8.0	.33
Mental health disorders (FY2010)					
Posttraumatic stress disorder					
No (reference)	931,449	916,248 (98.4%)	15,201 (1.6%)		
Yes	204,152	195,563 (95.8%)	8,589 (4.2%)	2.6	.34
Major depressive disorder					
No (reference)	1,059,817	1,041,819 (98.3%)	17,998 (1.7%)		
Yes	75,784	69,992 (92.4%)	5,792 (7.6%)	4.8	.61
Bipolar disorder					
No (reference)	1,090,945	1,071,431 (98.2%)	19,514 (1.8%)		
Yes	44,656	40,380 (90.4%)	4,276 (9.6%)	5.8	.82
Other mental health disorder					
No (reference)	615,457	611,238 (99.3%)	4,219 (.7%)		
Yes	520,144	500,573 (96.2%)	19,571 (3.8%)	5.7	.73
Medical comorbidities (FY2010)					
AIDS					
No (reference)	1,128,392	1,104,923 (97.9%)	23,469 (2.1%)		
Yes	7,209	6,888 (95.6%)	321 (4.5%)	2.2	.20
Blood loss anemia					
No (reference)	1,134,280	1,110,519 (97.9%)	23,761 (2.1%)		
Yes	1,321	1,292 (97.8%)	29 (2.2%)	1.0 (ns)	-.13
Cardiac arrhythmia					
No (reference)	1,040,784	1,019,027 (97.9%)	21,757 (2.1%)		
Yes	94,817	92,784 (97.9%)	2,033 (2.1%)	1.0 (ns)	.08
Chronic obstructive pulmonary disease					
No (reference)	934,738	916,155 (98.0%)	18,583 (2.0%)		
Yes	200,863	195,656 (97.4%)	5,207 (2.6%)	1.3	.08
Congestive heart failure					
No (reference)	1,084,838	1,062,211 (97.9%)	22,627 (2.1%)		
Yes	50,763	49,600 (97.7%)	1,163 (2.3%)	1.1	.16
Coagulopathy					
No (reference)	1,120,678	1,097,311 (97.9%)	23,367 (2.1%)		
Yes	14,923	14,500 (97.2%)	423 (2.8%)	1.4	.18
Deficiency anemia					
No (reference)	1,045,495	1,023,871 (97.9%)	21,624 (2.1%)		
Yes	90,106	87,940 (97.6%)	2,166 (2.4%)	1.2	.09
Diabetes—complicated					
No (reference)	1,048,388	1,026,401 (97.9%)	21,987 (2.1%)		
Yes	87,213	85,410 (97.9%)	1,803 (2.1%)	1.0 (ns)	.08
Diabetes—uncomplicated					
No (reference)	831,100	812,964 (97.8%)	18,136 (2.2%)		
Yes	304,501	298,847 (98.1%)	5,654 (1.9%)	.8	.003
Electrolyte disorders					
No (reference)	1,093,650	1,071,559 (98.0%)	22,091 (2.0%)		
Yes	41,951	40,252 (96.0%)	1,699 (4.0%)	2.0	.19
Hypertension					
No (reference)	460,226	449,429 (97.7%)	10,797 (2.4%)		
Yes	675,375	662,382 (98.1%)	12,993 (1.9%)	.8	-.03
Hypothyroidism					
No (reference)	1,068,123	1,045,755 (97.9%)	22,368 (2.1%)		
Yes	67,478	66,056 (97.9%)	1,422 (2.1%)	1.0 (ns)	.05
Liver disease					
No (reference)	1,096,628	1,074,538 (98.0%)	22,090 (2.0%)		
Yes	38,973	37,273 (95.6%)	1,700 (4.4%)	2.2	.15
Lymphoma					
No (reference)	1,127,763	1,104,126 (97.9%)	23,637 (2.1%)		
Yes	7,838	7,685 (98.1%)	153 (1.9%)	.9 (ns)	.08

(table continues)

Table 1 (continued)

Variable	Overall sample 1,135,601	No overdose/suicide-related event (FY2011)	Any overdose/suicide-related event (FY2011)	Odds ratio	Final model parameter estimate
Metastatic cancer					
No (reference)	1,129,388	1,105,762 (97.9%)	23,626 (2.1%)		
Yes	6,213	6,049 (97.4%)	164 (2.6%)	1.3	.30
Obesity					
No (reference)	909,163	890,234 (97.9%)	18,929 (2.1%)		
Yes	226,438	221,577 (97.9%)	4,861 (2.1%)	1.0 (ns)	-.05
Osteoporosis					
No (reference)	1,112,632	1,089,304 (97.9%)	23,328 (2.1%)		
Yes	22,969	22,507 (98.0%)	462 (2.0%)	1.0 (ns)	.01
Other neurological disorder					
No (reference)	1,095,213	1,073,101 (98.0%)	22,112 (2.0%)		
Yes	40,388	38,710 (95.9%)	1,678 (4.2%)	2.1	.18
Paralysis					
No (reference)	1,123,721	1,100,277 (97.9%)	23,444 (2.1%)		
Yes	11,880	11,534 (97.1%)	346 (2.9%)	1.4	.14
Peptic ulcer disease					
No (reference)	1,119,762	1,096,436 (97.9%)	23,326 (2.1%)		
Yes	15,839	15,375 (97.1%)	464 (2.9%)	1.4	.15
Peripheral vascular disorder					
No (reference)	1,061,817	1,039,324 (97.9%)	22,493 (2.1%)		
Yes	73,784	72,487 (98.2%)	1,297 (1.8%)	.8	-.03
Pulmonary circulation disorder					
No (reference)	1,129,812	1,106,174 (97.9%)	23,638 (2.1%)		
Yes	5,789	5,637 (97.4%)	152 (2.6%)	1.3	.16
Renal failure					
No (reference)	1,068,744	1,046,127 (97.9%)	22,517 (2.1%)		
Yes	66,857	65,684 (98.3%)	1,173 (1.8%)	.8	.03
Rheumatoid arthritis					
No (reference)	1,105,449	1,082,242 (97.9%)	23,207 (2.1%)		
Yes	30,152	29,569 (98.1%)	583 (1.9%)	.9	-.03
Sleep apnea					
No (reference)	1,008,884	988,238 (98.0%)	20,646 (2.0%)		
Yes	126,717	123,573 (97.5%)	3,144 (2.5%)	1.2	-.03
Solid tumor without metastasis					
No (reference)	1,011,030	989,184 (97.8%)	21,846 (2.2%)		
Yes	124,571	122,627 (98.4%)	1,944 (1.6%)	.7	-.04
Valvular disease					
No (reference)	1,108,153	1,084,890 (97.9%)	23,263 (2.1%)		
Yes	27,448	26,921 (98.1%)	527 (1.9%)	.9	.02
Weight loss					
No (reference)	1,133,889	1,110,167 (97.9%)	23,722 (2.1%)		
Yes	1,712	1,644 (96.0%)	68 (4.0%)	1.9	.002

Note. All effects significant at $p < .05$ unless otherwise noted by *ns*. FY = fiscal year; ER = emergency room.

($OR = 5.9$), and other substance use disorders [$OR = 8.0$]). Similarly, all *mental health disorders* in FY2010 were associated with increased risk for an overdose or suicide-related event in FY2011, including posttraumatic stress ($OR = 2.6$), major depressive ($OR = 4.8$), bipolar ($OR = 5.8$), and other mental health disorders ($OR = 5.7$).

Medical Conditions

Our exploratory analysis of medical conditions included in the predictive model found that 22 of the 28 FY2010 medical conditions were significant predictors of an overdose- or suicide-related event in FY2011. The largest odds ratios were for FY2010 AIDS and liver disease being associated with increased risk for an overdose- or suicide-related event in FY2011 ($OR = 2.2$) and for FY2010 uncomplicated diabetes, hypertension, peripheral vascular disorder, and renal failure being associated with lower risk for an overdose- or suicide-

related event in FY2011 ($OR = .8$). With regard to sleep apnea and osteoporosis, comorbidities recommended for inclusion in our project, sleep apnea was among the 22 medical conditions that were significantly related ($OR = 1.2$) to increased risk and osteoporosis was among the six medical comorbidities not significantly related to risk.

The final model—which uses data from the entire sample—had a c statistic of .83, 95% confidence interval (CI) of [.83, .83] (see Figure 2 for the final model's AUC), and the c statistics for the cross-validation models were all good ($>.80$).

Table 3 displays the mean predicted risk scores, actual overdose- and suicide-related event rates, and sensitivity and specificity for varying risk cohorts. This table displays the results of different risk stratification cut points. For example, the mean risk score among the 1,000 patients with the highest risk scores was 57.9 with 53.7% (approximately 1 out of every 2 patients in this

Table 2
Interactions Between FY2010 Predictor Variables Included in Risk Model Predicting any FY2011 Overdose/Suicide-Related Event

Interaction	Final model parameter estimate
Dosage × Age Group < 30	-.00124
Dosage × Age Group 30–49	-.00226
Dosage × Age Group 50–64	-.00169
Dosage × Age Group 65+	0
Dosage × Opioid Use Disorder	-.00089
Dosage × Major Depressive Disorder	-.00097
Male × Long-Acting Opioid (Tier 1)	.08278
Male × Chronic Short-Acting Opioid (Tier2)	-.08085
Male × Non-Chronic Short-Acting Opioid (Tier3)	.03228
Male × Tramadol Only (Tier 4)	0
Overdose/Suicide × Age Group < 30	-.3079
Overdose/Suicide × Age Group 30–49	-.07174
Overdose/Suicide × Age Group 50–64	.05094
Overdose/Suicide × Age Group 65+	0
Falls/Accidents × Age Group < 30	-.7376
Falls/Accidents × Age Group 30–49	-.1763
Falls/Accidents × Age Group 50–64	-.1997
Falls/Accidents × Age Group 65+	0
ER visit × Age Group <30	-.3381
ER visit × Age Group 30–49	-.1927
ER visit × Age Group 50–64	-.09916
ER visit × Age Group 65+	0
Male × PTSD	-.2822
Overdose/Suicide × Other SUD Diagnosis	-.4755
Overdose/Suicide × ER Visit	-.937
Major Depressive Disorder × 3 Other Sedating Pain Medications	-.3726
Major Depressive Disorder × 2 Other Sedating Pain Medications	-.1103
Major Depressive Disorder × 1 Other Sedating Pain Medication	-.06741
Major Depressive Disorder × No Other Sedating Pain Medication	0
Other SUD × 3 Other Sedating Pain Medications	-.0414
Other SUD × 2 Other Sedating Pain Medications	.3233
Other SUD × 1 Other Sedating Pain Medication	.4747
Other SUD × No Other Sedating Pain Medication	.4651
Cannabis/Hallucinogen Use Disorder × 3 Other Sedating Pain Medications	-.6252
Cannabis/Hallucinogen Use Disorder × 2 Other Sedating Pain Medications	-.2242
Cannabis/Hallucinogen Use Disorder × 1 Other Sedating Pain Medication	-.1703
Cannabis/Hallucinogen Use Disorder × 0 Other Sedating Pain Medication	0
Alcohol Use Disorder × Major Depressive Disorder	-.08746
Alcohol Use Disorder × Cannabis/Hallucinogen Use Disorder	-.1786
Alcohol Use Disorder × Stimulant Use Disorder	-.1783
Inpatient Treatment × Nicotine Dependence	-.2984
Inpatient Treatment × ER Visit	.3336
Affective Psychosis × PTSD	-.1339
Affective Psychosis × Major Depressive Disorder	-.2216
Affective Psychosis × Stimulant Use Disorder	-.3871
PTSD × Major Depressive Disorder	-.05239
Nicotine Dependence × Other SUD	-.2087
Inpatient Treatment × Coprescription of Opioids and Sedatives	-.1253
Other SUD × Stimulant Use Disorder	-.2159

Note. FY = fiscal year; ER = emergency room; PTSD = posttraumatic stress disorder; SUD = substance use disorder.

cohort) having an overdose or suicide-related event in FY2011. Interventions targeted at this risk cohort (.09% of 1,135,601 patients) would identify 2.5% of the patients who had an overdose or suicide-related event in FY2011, but would incorrectly identify only 0.04% of that risk cohort. Targeting the top 100,000 patients with the highest risk scores (8.8% of full sample) would identify 50.2% of the patients who would had an overdose or suicide-related event in FY2011, while incorrectly identifying only 7.9% of that risk cohort. This demonstrates that the predictive model

successfully enriches cohorts for patients who would have a future overdose or suicide-related event, thereby allowing providers to prioritize patients for review and intervention.

Case Examples

To illustrate what a typical patient for each risk cohort might look like, we provide hypothetical patient profiles at the mean predicted risk score for each risk cohort (see Table 4). An average

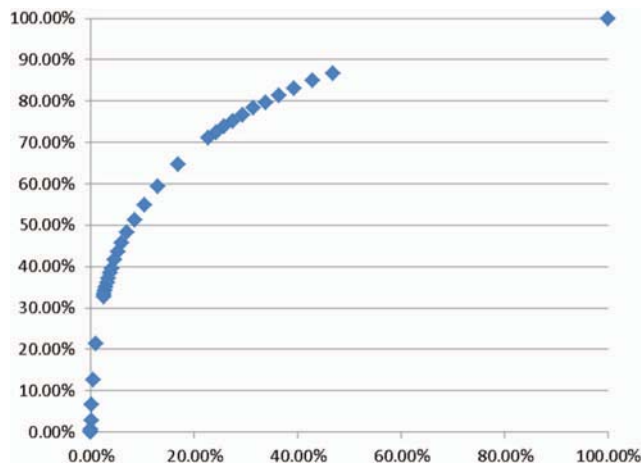


Figure 2. Area under the curve for the final predictive risk model (c statistic = .83). See the online article for the color version of this figure.

patient among the highest 1,000 risk scores has a complex clinical presentation that includes multiple mental health and substance use disorder diagnoses plus significant medical comorbidities that, for example, increase risk for respiratory depression or cardiac problems. This clinical case complexity is paired with relatively high-risk prescriptions (e.g., a high-dose long-acting opioid prescription plus a sedative), health care events that increase risk (e.g., inpatient detoxification which can reduce opioid tolerance and increase risk of overdose), and a history of prior adverse events (e.g., falls). The combination of behavioral, medical, and treatment-related risk factors and a history of prior recent adverse events identifies such patients as extremely high risk.

Patient cases within the top 10,000 risk scores are still highly complex with similar risk factors, though risk factors are slightly fewer or less severe in total. The average patient among the top 100,000 risk scores is somewhat less complex, though still at substantial risk; while this patient still has substantial mental health and substance use disorder severity, medical comorbidities and treatment related risks are less severe. The average patient in the top 500,000 has substantially fewer risk factors, for example, with less mental health and substance use comorbidity and no history of recent adverse health care events. While these are only examples of clinical presentations that would elicit each of the mean predicted scores for each risk cohort, they illustrate how risk factors in different domains combine to differentiate risk among

patients. Note that all of the case examples represent risk scores above the mean risk for the entire sample (i.e., all are at above average risk).

Risk Approaches—Comparison of Predictive Risk-Model Versus Individual Risk-Factor Methods

In the absence of comprehensive predictive models, individual risk factors could be targeted for case review and intervention. For example, one could identify patients with a specific modifiable risk factor, such as with an opioid prescription greater than 200 mg MEDD or who are coprescribed opioids and sedatives. Table 5 illustrates the improvement in efficiency obtained by using the risk model as opposed to individual risk factors for targeting risk mitigation strategies. Based on the FY2010 cohort of VHA patients prescribed opioid medications, reviewing and addressing risk in all patients prescribed over 200 mg MEDD would require intervention on roughly 20,000 patients. Of those patients, only 4.5% had an overdose or suicide-related event in FY2011 (vs. 28.9% of the top 20,000 STORM-identified patients), and these patients accounted for only 3.7% of all FY2011 overdose or suicide-related events in VHA (vs. 24.3% for the top 20,000 STORM-identified patients).

Comparing the top 20,000 STORM-identified patients to patients with opioid use disorder diagnoses who are also prescribed opioids (similar sample size; $n = 20,871$), also finds that the risk-based STORM approach outperforms individual risk-factor based approaches. Identifying all patients with opioid use disorders diagnoses who are prescribed opioids suggests that 13.3% will have an overdose or suicide-related event (less than half as many identified by a similar-sized STORM cohort), comprising 11.7% of such events in the overall population (less than half as many identified by a similar-sized STORM cohort). Notably, consistent with the lower rates of adverse events observed in these individual risk-factor based cohorts, calculated risk scores varied widely among patients with MEDD greater than 200 mg, opioid use disorders, and sedative coprescription. A substantial proportion of patients in each individual risk-factor-based approach have low estimated risk, and thus may not be high priority for intervention.

Figure 1 displays a sample patient-level report from STORM. The estimated risk score is juxtaposed with information on specific patient risk factors, current pain-relevant prescriptions, tailored risk mitigation strategy recommendations, nonpharmacological pain treatments, and information on care providers and past and scheduled health care utilization. Note that only information rele-

Table 3
Mean Predicted Risk Scores, Actual Overdose- or Suicide-Related Event Rates, and Sensitivity and Specificity for Varying Risk Cohorts

Risk cohort (N subjects with the highest risk scores)	Mean predicted risk score (range 0–100)	Actual overdose-/suicide-related event rate in FY2011	True positive sensitivity for this cut point	False negative 1 – specificity for this cut point
1,000	57.9	53.7% (~1 in 2)	.025	.00041
10,000	38.1	36.2% (~1 in 3)	.152	.0057
100,000	11.8	11.9% (~1 in 10)	.502	.079
500,000	4.0	4.1% (~1 in 25)	.850	.432
1,000,000	2.3	2.3% (~1 in 50)	.985	.878

Note. 23,790 total overdose- or suicide-related events in FY2011 among 1,135,601 patients (2.1%). FY = fiscal year.

Table 4
Case Examples for Risk Cohorts

Risk cohort (<i>N</i> subjects with the highest risk scores)	Risk score	Clinical detail on risk factors		
		Diagnoses	Medications	Other
1000	58.0%	<u>SUD</u> Opioid use disorder Sedative use disorder Tobacco dependence Mixed drug use disorder <u>Mental health</u> Posttraumatic stress disorder Bipolar disorder Attention deficit hyperactivity disorder <u>Medical</u> Cardiac arrhythmia Hypertension Sleep apnea	Extended-release morphine MEDD: 240 mg Zolpidem	Age: 31–49 Gender: male Injuries related to fall Recent inpatient Detoxification ER visit for suicide ideation
10,000	38.0%	<u>SUD</u> Alcohol use disorder Other SUD <u>Mental health</u> Posttraumatic stress disorder Major depressive disorder Agoraphobia with panic disorder <u>Medical</u> Huntington's Chorea	Fentanyl patch MEDD: 90 mg Diazepam Gabapentin	Age: 50–64 Gender: male ER visit for suicide attempt
100,000	11.8%	<u>SUD</u> Tobacco dependence Cannabis use disorder <u>Mental health</u> Bipolar disorder Anxiety disorder <u>Medical</u> Hypertension Obesity	Extended release morphine MEDD: 60 mg	Age: 50–64 Gender: male Recent inpatient mental health treatment ER visit
500,000	4.0%	<u>SUD</u> Tobacco use disorder <u>Mental health</u> Fear of injury <u>Medical</u> Chronic obstructive pulmonary disease	Extended release morphine MEDD: 270 mg Duloxetine	Age: ≥65 Gender: male
1,000,000	2.3%	<u>Mental health</u> Bipolar disorder <u>Medical</u> Cardiac arrhythmia Hypertension Uncontrolled diabetes Nonmetastatic tumor Iron deficiency anemia	Tramadol MEDD: 20 mg	Age: 50–64 Gender: male ER visit

Note. ER = emergency room; MEDD = morphine equivalent daily dose; SUD = substance use disorder.

vant to opioid risk mitigation is displayed to bring attention to elements of the patient's case and treatment that need to be considered in pain management decision making. End users can filter the data by risk scores as well as specific locations, patients, or prescribers. This complex example case was chosen to demonstrate all domains in which data are presented; a typical patient report will have fewer diagnoses, fewer medications, and fewer risk mitigation strategies listed. The report only presents risk factors for which the patient is positive and risk mitigation strategies that are clinically applicable to the patient. For example, a patient with no mental health diagnoses

would not show the “MH dx” category under relevant diagnoses, and a patient without an opioid use disorder would not have “opioid agonist treatment” listed as a risk mitigation strategy.

Not depicted, the report also provides hypothetical risk scores for patients if their clinician were to make specific prescription adjustments (e.g., reducing opioid dose by 50%, discontinuing a sedative), generated by replacing actual prescription data with hypothetical prescription data in the model calculation. This feature was added to help clinicians distinguish between patients for whom current prescriptions contribute substantially to risk, where prescription changes might be a

Table 5

Comparison of Different Risk Approaches (Risk-Model Based [STORM] Versus Individual Risk-Factor Based)

Risk approaches for VA patients prescribed opioids	Risk-model based (STORM top 20,000 patients)	MEDD > 200 mg	Opioid use disorder diagnosis	Coprescribed sedative medication
Total number in VA in FY2010	20,000	19,496	20,871	185,477
Total number of opioid- or suicide-related events in FY2011	5780	882	2779	4951
% of all opioid- or suicide-related events in FY2011 (<i>N</i> = 23,790)	24.3%	3.7%	11.7%	20.8%
% risk cohort with an opioid- or suicide-related event in FY2011	28.9%	4.5%	13.3%	2.7%
Minimum risk score in cohort	17.3%	.3%	.4%	.1%
Median risk score in cohort	26.8%	2.5%	6.5%	1.3%
Maximum risk score in cohort	79.8%	78.2%	79.8%	79.8%

Note. VA = Veterans Affairs; STORM = Stratification Tool for Opioid Risk Mitigation; MEDD = morphine equivalent daily dose; FY = fiscal year.

high priority for intervention, versus patients for whom diagnoses and past health care events elevate risk. In the latter, risk mitigation strategies targeting the comorbid conditions (e.g., substance use disorder treatment for patients with substance use, or continuous positive airway pressure treatment for patients with sleep apnea) might be more important. Additional tailored reports and interfaces can and will be developed to support specific clinical uses (e.g., planning by primary care teams, targeting of educational support for prescribers, proactive scheduling, or renewal of risk-mitigation interventions).

Discussion

The goals of this quality improvement project were to develop a clinical decision support tool that would help identify patients who may be at greater risk for overdose or suicide-related events and that would provide clinically meaningful and actionable information to providers to help prevent overdose and suicide events and improve care. Results suggest that clinical informatics can leverage EMR-extracted data to identify patients at risk for overdose or suicide-related events and provide clinicians with comprehensive, actionable information to mitigate risk.

In terms of STORM's ability to identify patients who may be at greater risk for overdose or suicide-related events, the predictive model corroborates previously identified risk factors for overdose or suicide-related events among patients prescribed opioids (e.g., mental health and substance use disorders; high-dose, long-acting prescriptions; and sedative coprescription), and suggests some novel markers of risk which are readily identifiable in EMR-data extracts. Specifically, prior adverse events (including previous overdose- or suicide-related events, accidents, and falls) and health care events indicative of risk (including previous detoxification treatments, emergency department encounters, and inpatient stays) were highly predictive of future risk of overdose- or suicide-related events in this population. While this finding is not surprising, the strong associations between these events and future overdose- or suicide-related event risk do emphasize the importance of considering these events in clinical case review and decision support systems.

The data indicate that the number of classes of evidence-based but sedating medications for pain management that a patient was

prescribed was associated with overdose- and suicide-related event risk. While the relative contributions of opioids versus sedating medications are impossible to tease out here, we speculate that this risk represents a combination of overdose risk related to the cumulative sedating properties of prescribed medications and suicide-related event risk due to unmanaged pain (Braden & Sullivan, 2008; Breslau et al., 2012; Hakansson, Schlyter, & Berglund, 2008; Ilgen et al., 2010; Magni et al., 1998; Ratcliffe et al., 2008; Theodoulou et al., 2005), as indicated by clinician use of multiple medications to treat pain conditions. We expect clinicians would not prescribe multiple medications unless the initial medication(s) failed to successfully manage pain individually, making increasing numbers of classes of pain medications a proxy for lack of successful pain management.

We also found that patients prescribed any short-acting opioid, regardless of length of time prescribed, had similar risk for an overdose- or suicide-related event compared to patients prescribed tramadol only. These findings suggest that appropriate risk mitigation strategies should be considered for all patients prescribed short-acting opioids, regardless of the length of time patients are expected to be prescribed these medications. Last, exploratory analysis of medical conditions suggests some additional comorbidities with substantial associations with risk (e.g., liver disease, AIDS, and electrolyte disorders).

Importantly, our predictive risk-model-based approach to identifying patients at risk for overdose- or suicide-related events substantially improves on use of individual risk-factor-based approaches. While individual risk factors such as dose and diagnoses do identify populations that are at greater average risk for overdose- or suicide-related events, they are not very specific, and include many patients our model indicates are low risk. This could result in both inefficient use of limited clinical resources and potential negative clinical consequences. Identifying patients for risk mitigation if they have specific prescriptions or diagnoses that increase average risk may encourage changes in treatment plans for relatively low-risk patients for whom the benefits of the prescription may outweigh the risks. For example, higher doses of opioids may provide more pain relief, reducing risk of suicide-related events from unmanaged pain, but increase risk for overdose. The dose at which potential risks begin to outweigh benefits for an individual patient will depend on the mix of clinical comor-

bidities and the availability of alternative effective pain management options. Any chosen cut-off will be too high for some patients and too low for others. Highlighting patients based only on dose may encourage unnecessary and potentially harmful changes in treatment for some low-risk patients, and unintentionally imply that doses are safe and do not need to be considered in complex high-risk patients. STORM's estimated risk scores direct attention to patients with combinations of risk factors, each of which may slightly increase risk. Consideration of these factors as a whole both improves identification of patients who are likely to have adverse events without intervention, and improves clinical decision making by helping clinicians think about the interaction of risk factors in risk–benefit assessments, treatment, and risk-mitigation planning.

Use of clinical decision support systems that integrate predictive modeling to improve the delivery of clinical care is a relatively new and not widely adopted practice. Initial pilot testing of STORM with volunteer clinicians suggests various strategies for using the information may be helpful for clinicians. However, for it to be used efficiently, clinical practice patterns, work flow, and organization may need to be restructured to provide time and support for its efficient use. Feedback from pilot testers suggests the comprehensiveness of STORM may actually save clinicians time. For instance, a pharmacist pilot tester commented that “this dashboard is REALLY useful for the naloxone kit outreach (chart review and CPRS documentation went from 1 hour per person to 15 minutes)” (Kangwon Song, personal communication, June 6, 2015).

Notably, the estimated risk score reflects on the patient clinical history, and not on the quality of care or use of risk-mitigation strategies used by the patient's providers. Patients with elevated risk scores that receive high-quality, comprehensive health care services, using all recommended strategies to address medical, mental health, and treatment-related risk will still show up as having elevated risk of adverse events by virtue of their clinical history and conditions. This is intentional, as patients at elevated risk should be monitored closely over time to ensure all appropriate risk-mitigation efforts are used and continued. Having patients with high risk scores on a provider's panel or in a facility in no way implies poor quality of care, and number of patients with elevated risk scores should not be considered a quality or performance measure.

This project does have limitations. Because of the lag in the availability of cause of death data, there is a multiple-year lag in terms of applying the risk parameters from the FY2011 model to nightly updated data (FY2016). We do plan to update the model and adjust parameters annually when death data become available. This may not be a substantial limitation, however, as the relationships among clinical diagnoses, prescriptions, and health care events, with overdose or suicide, are likely to be relatively stable. Notably, however, the transition from use of ICD-9 to ICD-10 coding of diagnoses in electronic medical records starting in FY2016 means that the exact definitions used for diagnostic variables in FY2011 can no longer be replicated in FY2016 databases. We have generated ICD-10 definitions for each predictor variable, matched as closely as possible with the original ICD-9-based categories, but this unavoidable change in source data does create room for error in application of the model. Given a desire to limit complexity,

both because the clinical decision support system was designed to apply the predictive risk model parameters to nightly updated data (with data updates spanning a few hours) and to make the data understandable for clinicians, we did not develop and use multiple tailored risk models targeting specific subpopulations; it is possible that this strategy might improve the accuracy of risk predictions. For instance, although there were 92,207 women included in our sample, they comprised only 8.1% of our sample; a separate model for women might optimize estimates further. With increasingly rapid advancements in technology, applications of more refined precision modeling may be possible in the future. Our outcome measure was a combination of accidental overdoses and suicide-related events, chosen because they may be difficult to distinguish clinically and they share overlapping risk factors (e.g., substance use and mental health disorders) and risk-mitigation strategies. Future applications may find it helpful to separate these outcomes, for example, for a tool to guide application of suicide prevention efforts. Lastly, risk models based on EMR-data extracts are efficient, but do not include nuanced contextual information about the patient that might greatly improve accuracy of risk prediction or data captured only in providers' free-text notes. The model could be expanded to include additional patient or provider generated data, which might improve the accuracy of model predictions.

Our project describes the development and applications of a clinical decision support tool—STORM—that uses a predictive risk model to identify patients at risk for overdose- or suicide-related events and that displays patient risk factors and risk-mitigation strategies in a patient-centered way. This tool meets one of the second-phase goals of the VHA Opioid Safety Initiative by improving upon individual risk-factor based approaches to identifying at-risk patients. The STORM model suggests that risk stratification can help direct resource-intensive risk-mitigation interventions to patients in greatest need. Future research should examine health care delivery models that optimize proactive use of modeled risk information to improve the safety of patients in general, and safety for patients who receive opioids specifically. Although initial piloting of STORM in clinical practice settings suggests that the tool is easy to use and interpret by clinicians, broader application across the system may identify additional opportunities to improve the user interface.

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