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Randomized Program Evaluation of Stratification Tool for Opioid Risk Mitigation

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Complete List of Authors:	Minegishi, Taeko; VA Boston Health Care System Jamaica Plain Campus, PEPReC; Northeastern University, Bouvé College of Health Sciences Garrido, Melissa; James J Peters VA Medical Center, GRECC; Icahn School of Medicine at Mount Sinai, Geriatrics & Palliative Medicine Pizer, Steven; VA Boston Health Care System Jamaica Plain Campus, PEPReC; Boston University, School of Public Health Frakt, Austin; VA Boston Health Care System Jamaica Plain Campus, PEPReC; Boston University, School of Public Health
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Title: Randomized Program Evaluation of Stratification Tool for Opioid Risk Mitigation

Authors: Taeko Minegishi, MS[1-2], Melissa M. Garrido, PhD[1,3-4], Steven D. Pizer, PhD[1,5], Austin B. Frakt, PhD[1,5-6]

Corresponding Author: Taeko Minegishi, 150 S. Huntington Avenue, 152H, Boston, MA, 02130. E-mail: taeko.minegishi@va.gov. Phone: 857-364-6065. Fax: 857-364-2259

Author affiliations:
1. Partnered Evidence-based Policy Resource Center, VA Boston Healthcare System, Boston, MA, USA
2. Bouvé College of Health Sciences, Northeastern University, Boston, MA, USA
3. Geriatrics Research, Education, and Clinical Center, James J Peters VA Medical Center, Bronx, NY, USA
4. Brookdale Department of Geriatrics and Palliative Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, USA
5. Department of Health Law, Policy & Management, Boston University of Public Health, Boston, MA, USA
6. Department of Health Policy and Management, Harvard T.H. Chan School of Public Health, Cambridge, MA, USA

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Abstract

Introduction: Opioid use related adverse events and deaths is an epidemic in the United States. The rates of chronic pain, mental illness, and substance use disorder are higher at the Veterans Health Administration (VHA) compared to the general U.S. population. The 2016 Comprehensive Addiction and Recovery Act (CARA) requires the VHA to improve opioid therapy strategies in treating patients, and to ensure responsible prescribing practices. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prioritizes review of VHA patients receiving opioids based on their risk. VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk.

Methods and analysis: This stepped-wedge cluster randomized control trial will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related serious adverse events (SAEs), relative to facilities not randomized to facilitation. 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed. Patients who receive an opioid prescription at VHA medical centers will be followed for a minimum of 3 months after their first opioid prescription. Follow-up will continue until the last day of the project or death. The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions.

Ethics and dissemination: Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069; Approval: March 27, 2017). Findings will be published in peer-reviewed journals and presentations at national conference meetings.

Trial registration number: ISRCTN16012111 (http://www.isrctn.com/ISRCTN16012111). Registered May 25, 2017.

Strength and limitations of this study

- Randomized program evaluation reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget.
- The stepped wedge design evaluates aspects of the VHA policy and a web-based dashboard to identify risk factors and risk mitigation strategies for patients with an opioid prescription.
- This study will only include Veterans Health Administration (VHA) patients and exclude opioid use disorder patients.

Introduction

Opioid overdose deaths reached 33,000 in 2015, an increase of about 16% from the prior year, and are the leading cause of injury death in the United States (1). The supply of opioid prescriptions remains high in the United States, with nearly 250 million opioid prescriptions written in 2013 or about one prescription per American adult (2). These statistics underlie the Centers for Disease Control and Prevention's (CDC's) characterization of opioid use related adverse events and deaths as an epidemic in the United States. The epidemic is potentially more acute in the Veterans Health Administration (VHA) patient population, which has higher rates of chronic pain, mental illness, and substance use disorder compared to the general U.S. population (3–5). In particular, VHA's prevalence of opioid use disorder is approximately seven times higher than among commercial health plans (6).

The epidemic in the U.S. in general, and in the VHA population in particular, has captured the attention of policymakers. For instance, the 2016 Comprehensive Addiction and Recovery Act (Pub.L.No. 114-198; CARA) outlines a coordinated effort to confront opioid mis- and over-use through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. In particular, CARA requires the VHA to improve opioid therapy strategies in treating patients, and to ensure responsible prescribing practices (Subtitle A Sec 911).

The VHA Office of Mental Health and Suicide Prevention (OMHSP; formerly Office of Mental Health Operations) developed a tool that is responsive to the CARA requirement that VHA opioid prescribers review existing adverse event risk characteristics for each patient before prescribing. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prospectively prioritizes review of VHA patients receiving opioids based on their risk for overdose-, accident-, or suicide-related events (collectively, serious adverse events or SAEs). The risk prioritization is determined by a predictive model based on the association of patient characteristics (i.e. age, race, prior history of mental illness) and opioid prescription with opioid related SAEs (7). Designed to be easily incorporated into clinical practice, VHA clinicians can use STORM to identify risk factors and risk mitigation strategies potentially relevant for each patient.

Although STORM has gone through validation and usability testing, more evidence is needed to guide its use. Validation and usability reviews indicate that the STORM dashboard is

an acceptable and efficient method of reviewing patient-specific risk information (Oliva et al., 2017). User feedback indicated high face-validity for the patients STORM identifies as high risk and appropriate for intensive monitoring. It also indicated that the STORM dashboard can reduce the time required to review risk factors, assist with monitoring and systematic use of risk mitigation strategies, and improve awareness of the care patients are receiving across providers and care settings. However, the impact of identifying patient risk through STORM on opioid related SAEs has not been rigorously evaluated. In addition, it is unclear how to best convey the CARA mandates to providers and ensure case-review of patients identified by STORM.

Therefore, the VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk. In the following sections, we describe the STORM dashboard and the design of a cluster randomized trial to evaluate the effect of an expanded risk threshold and variations in policy languages on time to opioid related SAEs. This timely, randomized evaluation of STORM reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget (8).

STORM Dashboard and Implementation

On any given day, approximately 400,000 to 500,000 VHA patients are prescribed opioids. Patients' information will be displayed in the STORM dashboard until their prescription expires. For credentialed users (including VHA prescribers), the dashboard automatically sorts patients at their medical center in descending order of predicted SAE risk. In this evaluation, we focus on patients prescribed an opioid who are in the top 5% of risk scores. Predicted risk is a function of demographics, comorbidities, prior history of mental illness and substance use disorders, and opioid prescription data. The dashboard also provides clinicians with a list of evidence-based clinical recommendations for risk mitigation, such as drug screening tests, bowel regimens, and treatment alternatives to opioid prescription. Once a clinician reviews a case, the dashboard records and saves case review notes and dates of review. The dashboard compactly displays a patient's name, age and gender, patient risk level classification (low, medium, high, or very high risk), diagnoses and medications that are relevant to opioid risk, and risk mitigation strategies and non-pharmacological pain treatment recommendations (Figure 1). In addition, to facilitate care coordination, recent and upcoming appointments and patient care provider names are listed.

In Fall of 2017, VHA Central Office will release a policy memo mandating that VHA clinicians to conduct case reviews and identify appropriate risk mitigation approaches for patients with opioid prescriptions who are identified by STORM as having a very high risk of SAEs. The specific language used in the memo is displayed in Figure 2.

Randomized Program Evaluation of STORM

Despite the benefits of randomized control trials, U.S. health care policies and programs are rarely tested with randomized designs (9). As a result, there is little evidence-based guidance for writing effective policy memos. The US Government Accountability Office has identified limitations in VHA policy memos, including a lack of clearly articulated accountability (10). Improving this aspect of VHA policy memos is a high priority. Therefore, two versions of the

policy memo have been prepared; half of the medical centers will receive a version that states that if fewer than 97 percent of their cases are reviewed, additional facilitation will be provided to help them increase their case review rate; the other half will receive a memo that only states that case reviews are mandated. Facilitation includes greater administrative oversight and a requirement to file an action plan. To our knowledge, no prior study has compared the effects of alternative accountability approaches in policy documents on uptake of delivery system innovations.

In addition to randomizing medical centers to different versions of the policy memo, we will rigorously evaluate the effect of the STORM dashboard on patient outcomes. To do this, we will use a randomized stepped wedge design (described in detail below) to create two cohorts of patients in a similar risk group, one for which case review is required (treatment) and another for which it is not (control). This risk group will be created by expanding the threshold for very high risk from 1% to 5%.

Hypotheses

We will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related SAEs, relative to facilities not randomized to facilitation. 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed.

Methods

Intervention 1: Effectiveness of VHA Policy

According to the policy memo, VHA medical centers are required to review the cases of very high risk patients. Half of facilities (randomly assigned) will be asked to complete an action plan and receive additional oversight and facilitation from OMHSP if at least 97% of cases are not reviewed (the policy treatment group). The other half of VHA medical centers will receive a version of the memo without any mention of action plans, oversight, or facilitation (the policy control group). Facilities that fail to meet the targeted rate for completing case reviews of very high risk patients will be tasked to review these patients and report quarterly to the OMHSP on progress toward executing an action plan to meet the metric.

Intervention 2: Effectiveness of STORM

Within the policy treatment and control groups, separately, the definition of very high risk patients will be altered over time in a stepped wedge manner. For the first 8 months all medical centers will be required to conduct case reviews for patients in the top one percent of risk for an SAE. In order to evaluate the effect of being targeted for case review by STORM, half of the medical centers will be randomly assigned to review patients identified as high risk under an expanded risk threshold. At month 9, half of the policy treatment and half of the policy control facilities will be randomly assigned to review patients in the top five percent of risk scores. At month 15, all facilities will be required to review patients in the top five percent of risk. This stepped wedge design creates a cohort of patients who have opioid prescriptions and are between the top one percent and top five percent of SAE risk. Half of these patients will have

mandated case review (the STORM treatment group) and half will receive usual care (the STORM control group). Figure 3 presents the two interventions and timeline.

Randomization and Blinding

Randomization was conducted in two steps, using permuted block randomization. Permuted block randomization allowed us to create groups with an even number of facilities. First, the 140 VHA medical centers were split into two groups with 70 medical centers each in the policy treatment and policy control groups. Then, to apply the stepped wedge design for analysis of STORM treatment vs control, the 70 medical centers in each group were split into two groups of 35 hospitals using permuted block randomization. The STORM dashboard will label patients as “very high risk” using the respective risk score cut-offs (top one percent and top five percent) at each VHA medical center. The risk scores will not be displayed and providers will be blinded to changes in the risk score threshold that defines “very high risk”.

Recruitment/Eligibility Criteria/Participant Timeline

Our analytic cohort will include all VHA patients with an opioid prescription in the top 10% of risk scores. Patients are eligible for inclusion in the study cohort for the first 18 months of the study. If a patient has an active opioid prescription on the day the policy memo is released and has a risk score in the top 10% of risk, he or she will automatically enter the study. Other patients will enter the cohort on the date of their first prescription that exceeds the 10% risk threshold. Patients will be followed for a minimum of 3 months after they are first prescribed an opioid. Follow-up will continue until the last day of the project (September 30, 2019) or date of death. Our primary analyses of the effect of policy language will focus on patients in the top 1% of risk, and our primary analyses of the effect of STORM will be analyzed among patients between the top 5% and top 1% of risk scores. Over the course of this study, we anticipate over 50,000 patients to have risk scores in the top 5% of risk.

Outcome Measures and Control Variables

Our primary outcome of interest is opioid-related SAEs (e.g., opioid overdose, accidental falls, and possible and confirmed suicide attempts, etc. [See Appendix A for ICD-9 and -10 codes]). The outcome measure is censored by death or end of study. The STORM risk score that a patient receives when they first enter the study (baseline risk score) will be used as a control variable, since it reflects the probability that a patient will have an opioid-related SAE outcome. The risk score also captures the risk associated with the general demographics (i.e. age, race, gender) and comorbidities (i.e. prior and current history of disease) characteristics. In addition, facility indicators and time in study (indicators for current and past months) will be used as control variables.

Although case review is mandated, it is unlikely that all providers will review all identified cases. In addition, the risk mitigation strategies suggested in the STORM dashboard are optional. If lower SAE rates in treatment facilities are achieved, this could be due to higher case review rates or to greater use of risk mitigation strategies. That is, the case review rate acts as a mediator of the relationship between risk identification and opioid-related SAEs. Additionally risk mitigation strategies are intended to reduce risk of adverse outcomes. Thus, the SAE rates should be lower if risk mitigation strategies are more frequently implemented. We will test

whether facility level rates of case review and patient level risk mitigation strategies implemented are mediators of the primary outcome.

Data Collection and Management

STORM risk scores are calculated and updated on a daily basis. Upon a patient's entry into the study cohort (i.e. at the date of the first opioid prescription on or after the release of the policy memo), his or her risk score will be recorded. VHA has a centralized corporate data warehouse (CDW) where all patient data, including demographics, appointments, visits, diagnoses, and prescriptions are stored. From these data, any opioid-related SAEs for study patients will be identified. The case review notes and case reviewed date will also be collected in CDW.

Sample Size/Power Calculation

Sample size was calculated using the data that informed the original STORM model (7). That dataset included 1,135,600 patients with an opioid prescription from VHA anytime in 2010. From these data, we expect our baseline monthly SAE rates to be 0.029 for the policy control group and 0.010 for the STORM control group.

Based on these baseline rates, with an alpha of 0.05, we can detect a difference between the policy treatment and control groups of 20% (i.e., a SAE rate difference at least as large as 0.035 or at least as small as 0.023) with 80% power. The evaluation can also detect a difference of 15% between the STORM treatment and control groups with 80% power (i.e., an SAE rate difference at least as large as 0.012 or at least as small as 0.009).

Statistical Analysis

The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions: 1) effectiveness of policy, and 2) effectiveness of STORM. For the effectiveness of policy analysis, a patient-level time-to-event Cox proportional hazards model will be used to evaluate the difference between facilities with and without facilitation language in the memo, controlling for the different targeted risk group at different times and facility fixed effects. Similarly, for the effectiveness of STORM analysis, the primary outcome will be modeled with a patient level time-to-event Cox proportional hazards model to evaluate the difference between the STORM treatment and control groups, controlling for difference in policy, and facility fixed effects. We will estimate the effect of the intervention during a single month as well as the cumulative effect of the intervention. In order to account for diminishing returns of additional months of exposure to policy or time in STORM, we estimate separate effects for one month before treatment, two months before treatment, and so on.

A statistically significant difference between the two policy groups suggests that the threat of facilitation modifies VHA providers' behavior to increase surveillance on very high risk opioid prescribed patients and to apply SAE risk mitigation strategies. A statistically significant effect of the STORM treatment group indicates that when opioid prescribed patients are required to be case reviewed, they are less likely to experience opioid-related SAEs.

Our intent-to-treat analysis assumes that patients' risk scores are relatively stable over the study period, and that baseline risk closely approximates the risk level of a patient at the time their facility is randomized to target an expanded risk threshold. However, it is possible that

risk scores may change over time for patients who receive long-term opioid therapy and/or frequent short-term opioid therapy. Risk scores at baseline may simultaneously predict prospective risk scores, likelihood of exposure to the intervention, and risk of SAEs. In addition, a patient's risk score at a given month may be affected by the version of policy or level of risk threshold in place at a facility in previous months. To account for this potential endogeneity, we can conduct a secondary survival analysis that treats the facility treatment indicator and interaction between baseline risk score and facility treatment as potential instrumental variables.

Ethics and Dissemination

Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069; approval date: 3/27/17). Randomized roll-out of STORM to medical centers is occurring as part of the OMHSP's activities and does not require IRB approval. This trial has been registered at ISRCTN (http://www.isrctn.com/ISRCTN16012111). In addition, our partner at the VHA Center for Health Equity Research and Promotion is conducting a complementary evaluation to identify strategies used to implement STORM across the two policy groups as well as barriers and facilitators to STORM implementation (https://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141704557).

PEPReC's protocol has been presented at the 2017 AcademyHealth National Health Policy Conference and a VHA cyberseminar. We are submitting abstracts about this protocol and randomized program evaluations to other national conferences. Once the study is completed, the following two papers will be prepared and submitted to peer-reviewed journals; 1) Reduction of opioid-related serious adverse events (SAEs) in VHA medical centers with and without facilitation, and 2) Effect of identification of high risk patients via the STORM dashboard on opioid-related serious adverse events (SAEs). Beyond providing rigorous evidence of the impact of STORM on patient outcomes, this study will provide insight to OMHSP and VHA leadership about how to optimize the STORM dashboard to reduce SAEs among high risk patients.

Contributors: SP and AF conceived the idea for the study. TM, MG, SP, and AF contributed to the study design, randomization, and analysis plan. TM wrote the first draft. AF and MG were involved in multiple revisions. The final version of the manuscript was approved by all co-authors.

Competing Interests: None

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Data sharing statement: Public disclosure of Veterans Health Administration data containing personally identifiable information is not allowed. No additional data available.

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STORM: Patient Detail Dashboard
Stratification Tool for Opioid Risk Mitigation

New Feature! Relevant diagnosis are now hyperlinked to display the ICD code and source.

Home | About | Definitions | Contact Us | Quick View Report | Export this view | Set Custom View

Patient Details	Suicide-related event or overdose 1yr	Relevant Diagnoses	Relevant Medications	Risk Mitigation Strategies	Non-pharmacological Strategies	Recent Appts	Upcoming Appts	Care Providers
John Doe Last Four: Age: Gender: Station:	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 **Recent Adverse Events:** Suicide Attempt/Ideation Vehicle Accident	**Active Opioids:** Tramadol (Dr. ABC) Oxycodone (Dr. ABC)	MEDD <=100 ☒ XX/XX/2017 Naloxone Kit ☐ Opioid Signed Informed Consent ☐ Timely Follow-up ☒ XX/XX/2017 Timely UDS ☒ XX/XX/2017 Psychosocial Assessment ☐ Psychosocial Tx ☒ XX/XX/2017 Active SUD Tx ☒ XX/XX/2017 Medication Assisted Therapy ☐ Med. Reconciliation ☐ PDMP ☐ Opioid Education Visit ☐ Data-based Opioid Risk Review ☐	Active Therapies ☐ CIH Therapies ☐ Chiropractic Care ☐ Occupational Therapy ☐ Pain Clinic ☒ XX/XX/2017 Physical Therapy ☒ XX/XX/2017 Special Therapy ☐ Other Therapy ☐	**Primary Care:** XX/XX/2017 **Mental Health:** XX/XX/2017 **Pain Clinic:** XX/XX/2017 **Other:** XX/XX/2017 Telephone Primary Care	**Primary Care:** XX/XX/2017 **Mental Health:** XX/XX/2017 **Pain Clinic:** XX/XX/2017 **Other:** None	**Recent Opioid Prescriber:** Dr. ABC **Primary Care Provider:** Dr. DEF **MH Tx Coordination:** Jane Doe **BHIP Team:** Team A

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Policy Memo for Treatment Facilities

"The STORM implementation team will review completion rates at the end of each quarter and notify the facility point(s) of contact of their completion rate. Facilities with scores at or above 97% on this metric are considered in compliance. This high target for completing reviews is justified given the serious risk of potentially fatal adverse events, and the need for careful and on-going use of risk mitigation efforts in this set of patients. Facilities are expected to sustain this high completion rate once they have reached it and to this end will continue to receive feedback on their completion rates.

Lack of compliance will be remediated starting in FY18QX. If the facility fails to meet the targeted rate for completing case reviews of very high risk patients by FY18QX+1 the STORM implementation team will notify the facility point(s) of contact. The goal of reviewing these patients will be added to the facility's existing improvement goals on the Psychotropic Drug Safety Initiative (PDSI), given facilities' familiarity with the existing PDSI action planning program. The facility point(s) of contact must then report quarterly to the PDSI team on progress toward executing an action plan to meet the metric. The action plan indicates that the case review program requires additional assistance, not that it is a failure."

Policy Memo for Control Facilities

"The STORM implementation team will review completion rates at the end of each quarter and notify the facility point(s) of contact of their completion rate. Facilities are expected to achieve scores above 97% on this metric by FY18QX+1. This high target for completing reviews is justified given the serious risk of potentially fatal adverse events, and the need for careful and on-going use of risk mitigation efforts in this set of patients. Facilities are expected to sustain this high completion rate once they have reached it and to this end will continue to receive feedback on their completion rates."

		Randomization t=0	Step 1 t=9 months	Step 2 t=15 months
VHA Policy	Treatment	top 1%	top 1%	top 5%
			top 5%	top 5%
	Control	top 1%	top 1%	top 5%
			top 5%	top 5%

Mediators from the STORM Dashboard
Risk Mitigation Strategies
Case Review

Clinical Outcomes
Serious Adverse Events

The recruitment will continue until 18 months and the study will continue until September 30, 2019. Clinical outcomes for patients will be measured monthly for at least 3 months.

Supplemental A ICD9/10 Code for Opioid-Related Serious Adverse Events (SAEs)

Serious Adverse Events	ICD9	ICD10
Involving acetaminophen	965.4; 967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E850.4; E851.; E852.0,.1,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E935.4; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.3	T39.1X1A,D,S; T39.1X2A,D,S; T39.1X3A,D,S; T39.1X4A,D,S; T39.1X5A,D,S; T39.8X1A,D,S; T39.8X2A,D,S; T39.8X3A,D,S; T39.8X4A,D,S; T39.8X5A,D,S; T39.91XA,D,S; T39.92XA,D,S; T39.93XA,D,S; T39.94XA,D,S; T39.95XA,D,S;
Opioid overdose	965.00,01,02,09; E850.0,.1,.2; E935.0,.1,.2; E908.0	T40.0X1A,D.S; T40.0X2A,D,S; T40.0X3A,D,S; T40.0X4A,D,S; T40.0X5A,D,S; T40.1X1A,D,S; T40.1X2A,D,S; T40.1X3A,D,S; T40.1X4A,D,S; T40.2X1A,D,S; T40.2X2A,D,S; T40.2X3A,D,S; T40.2X4A,D,S; T40.2X5A,D,S; T40.3X1A,D,S; T40.3X2A,D,S; T40.3X3A,D,S; T40.3X4A,D,S; T40.3X5A,D,S; T40.4X1A,D,S; T40.4X2A,D,S; T40.4X3A,D,S; T40.4X4A,D,S; T40.4X5A,D,S; T40.601A,D,S; T40.602A,D,S; T40.603A,D,S; T40.604A,D,S; T40.605A,D,S; T40.691A,D,S; T40.692A,D,S; T40.693A,D,S; T40.694A,D,S; T40.695A,D,S
Other drug poisoning	965.1,.6,.61,.69; 969.01,.02,.03,.04,.05, .09,.6,.72; 970.1; E850.3; E854.0,.1,.3; E855.0,.1,.2,.3,.4,.5,.6, .8,.9; E935.3,.6; E939.0,.6,.7; E940.1; E980.4,.5	T40.7X1A,D,S; T40.7X2A,D,S; T40.7X3A,D,S; T40.7X4A,D,S; T40.7X5A,D,S; T40.8X1A,D,S; T40.8X2A,D,S; T40.8X3A,D,S; T40.8X4A,D,S T44.901A,D,S; T44.902A,D,S; T44.903A,D,S; T44.904A,D,S; T44.991A,D,S; T44.992A,D,S; T44.993A,D,S; T44.994A,D,S; T44.995A,D,S; T50.7X1A,D,S; T50.7X2A,D,S; T50.7X3A,D,S; T50.7X4A,D,S; T50.7X5A,D,S
Falls	E880.0,.1,.9; E881.0,.1; E882.; E883.0,.1,.2,.9; E884.0,.1,.2,.3,.4,.5,.6, .9; E885.,.0,.1,.2,.3,.4,.9; E886.0,.9; E887.; E888.,.0,.1,.8,.9; E929.3;	R29.6; W00.0XXA,D,S; W00.1XXA,D,S; W00.2XXA,D,S; W00.9XXA,D,S; W01.0XXA,D,S; W01.10XXA,D,S; W01.110XXA,D,S; W01.111XXA,D,S; W01.118XXA,D,S; W01.119XXA,D,S; W01.190XXA,D,S; W01.198XXA,D,S; W03.XXXA,D,S; W04.XXXA,D,S; W05.0XXA,D,S; W05.1XXA,D,S; W05.2XXA,D,S; W06.XXXA,D,S; W07.XXXA,D,S; W08.XXXA,D,S; W09.0XXA,D,S; W09.1XXA,D,S; W09.2XXA,D,S; W09.8XXA,D,S; W10.0XXA,D,S; W10.1XXA,D,S; W10.2XXA,D,S; W10.8XXA,D,S; W10.9XXA,D,S; W11.XXXA,D,S; W12.XXXA,D,S; W13.0XXA,D,S; W13.1XXA,D,S; W13.2XXA,D,S; W13.3XXA,D,S; W13.4XXA,D,S; W13.8XXA,D,S; W13.9XXA,D,S; W14.XXXA,D,S; W15.XXXA,D,S; W16.011A,D,S; W16.012A,D,S; W16.021A,D,S; W16.022A,D,S; W16.031A,D,S; W16.032A,D,S; W16.111A,D,S; W16.112A,D,S; W16.121A,D,S; W16.122A,D,S; W16.131A,D,S; W16.132A,D,S;

	E987.0,.1,.2,.9	W16.211A,D,S; W16.212A,D,S; W16.221A,D,S; W16.222A,D,S; W16.311A,D,S; W16.312A,D,S; W16.322A,D,S; W16.331A,D,S; W16.332A,D,S; W16.41XA,D,S; W16.42XA,D,S; W16.511A,D,S; W16.512A,D,S; W16.521A,D,S; W16.522A,D,S; W16.531A,D,S; W16.532A,D,S; W16.611A,D,S; W16.612A,D,S; W16.621A,D,S; W16.622A,D,S; W16.711A,D,S; W16.712A,D,S; W16.721A,D,S; W16.722A,D,S;W16.811A,D,S; W16.812A,D,S; W16.821A,D,S; W16.822A,D,S; W16.831A,D,S; W16.832A,D,S; W16.91XA,D,S; W16.92XA,D,S; W17.0XXA,D,S; W17.1XXA,D,S; W17.2XXA,D,S; W17.3XXA,D,S; W17.4XXA,D,S; W17.81XA,D,S; W17.82XA,D,S; W17.89XA,D,S; W18.00XA,D,S; W18.01XA,D,S; W18.02XA,D,S; W18.09XA,D,S; W18.11XA,D,S; W18.12XA,D,S; W18.2XXA,D,S; W18.30XA,D,S; W18.31XA,D,S; W18.39XA,D,S; W18.40XA,D,S; W18.41XA,D,S; W18.42XA,D,S; W18.43XA,D,S; W18.49XA,D,S; W19.XXXA,D,S; X00.3XXA,D,S; X01.3XXA,D,S; X02.3XXA,D,S; X03.3XXA,D,S
Vehicle	E800.1,.2,.3,.8,.9; E801.0,.1,.2,.3,.8,.9; E802.0,.1,.2,.3,.8,.9; E803.0,.1,.2,.3,.8,.9; E804.0,.1,.2,.3,.8,.9; E805.0,.1,.2,.3,.8,.9; E806.0,.1,.2,.3,.8,.9; E807.0,.1,.2,.3,.8,.9, E810.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E811.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E812.0,.1,.2,.3,.4,.5,.6, .7,.8,.9 E813.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E814.0,.1,.2,.3,.4,.5,.6, .7..8,.9; E815.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E816.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E817.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E818.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E819.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E820.0,.1,.2,.3,.4,.5,.6,	V00.01XA,D,S; V00.02XA,D,S; V00.09XA,D,S; V00.111A,D,S; V00.112A,D,S; V00.118A,D,S; V00.121A,D,S; V00.122A,D,S; V00.128A,D,S; V00.131A,D,S; V00.132A,D,S; V00.138A,D,S; V00.141A,D,S; V00.142A,D,S; V00.148A,D,S; V00.151A,D,S; V00.152A,D,S; V00.158A,D,S; V00.181A,D,S; V00.182A,D,S; V00.188A,D,S; V00.211A,D,S; V00.212A,D,S; V00.218A,D,S; V00.221A,D,S; V00.212A,D,S; V00.228A,D,S; V00.281A,D,S; V00.282A,D,S; V00.288A,D,S; V00.311A,D,S; V00.312A,D,S; V00.318A,D,S; V00.321A,D,S; V00.322A,D,S; V00.328A,D,S; V00.381A,D,S; V00.382A,D,S; V00.388A,D,S; V00.811A,D,S; V00.812A,D,S; V00.818A,D,S; V00.821A,D,S; V00.822A,D,S; V00.828A,D,S; V00.831A,D,S; V00.832A,D,S; V00.838A,D,S; V00.891A,D,S; V00.892A,D,S; V00.898A,D,S; V01.00XA,D,S; V01.01XA,D,S; V01.02XA,D,S; V01.09XA,D,S; V01.10XA,D,S; V01.11XA,D,S; V01.12XA,D,S; V01.19XA,D,S; V01.90XA,D,S; V01.91XA,D,S; V01.92XA,D,S; V01.99XA,D,S; V02.00XA,D,S; V02.01XA,D,S; V02.02XA,D,S; V02.09XA,D,S; V02.10XA,D,S; V02.11XA,D,S; V02.12XA,D,S; V02.19XA,D,S; V02.90XA,D,S; V02.91XA,D,S; V02.92XA,D,S; V02.99XA,D,S; V03.00XA,D,S; V03.01XA,D,S; V03.02XA,D,S; V03.09XA,D,S; V03.10XA,D,S; V03.11XA,D,S; V03.12XA,D,S; V03.19XA,D,S; V03.90XA,D,S; V03.91XA,D,S; V03.92XA,D,S; V03.99XA,D,S; V04.00XA,D,S; V04.01XA,D,S; V04.02XA,D,S; V04.09XA,D,S; V04.10XA,D,S; V04.11XA,D,S; V04.12XA,D,S; V04.19XA,D,S; V04.90XA,D,S; V04.91XA,D,S; V04.92XA,D,S; V04.99XA,D,S; V05.00XA,D,S; V05.01XA,D,S; V05.02XA,D,S; V05.09XA,D,S; V05.10XA,D,S; V05.11XA,D,S; V05.12XA,D,S; V05.19XA,D,S; V05.90XA,D,S; V05.91XA,D,S; V05.92XA,D,S; V05.99XA,D,S; ; V06.00XA,D,S; V06.01XA,D,S; V06.02XA,D,S; V06.09XA,D,S; V06.10XA,D,S; V06.11XA,D,S; V06.12XA,D,S; V06.19XA,D,S; V06.90XA,D,S; V06.91XA,D,S; V06.92XA,D,S; V06.99XA,D,S; ; V09.00XA,D,S; V09.01XA,D,S; V09.02XA,D,S; V09.09XA,D,S; V09.1XXA,D,S; V09.20XA,D,S; V09.21XA,D,S; V09.29XA,D,S; V09.3XXA,D,S; V09.9XXA,D,S; V10.0XXA,D,S; V10.1XXA,D,S; V10.2XXA,D,S;V10.3XXA,D,S; V10.4XXA,D,S; V10.5XXA,D,S; V10.9XXA,D,S; V11.0XXA,D,S; V11.1XXA,D,S; V11.2XXA,D,S; V11.3XXA,D,S; V11.4XXA,D,S; V11.5XXA,D,S; V11.9XXA,D,S; V12.0XXA,D,S; V12.1XXA,D,S; V12.2XXA,D,S; V12.3XXA,D,S; V12.4XXA,D,S; V12.5XXA,D,S; V12.9XXA,D,S; V13.0XXA,D,S; V13.1XXA,D,S; V13.2XXA,D,S; V13.3XXA,D,S; V13.4XXA,D,S; V13.5XXA,D,S; V13.9XXA,D,S; V14.0XXA,D,S; V14.1XXA,D,S; V14.2XXA,D,S; V14.3XXA,D,S; V14.4XXA,D,S; V14.5XXA,D,S; V14.9XXA,D,S; V15.0XXA,D,S; V15.1XXA,D,S; V15.2XXA,D,S; V15.3XXA,D,S; V15.4XXA,D,S; V15.5XXA,D,S;

	.7,.8,.9; E821.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E822.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E823.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E824.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E825.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E826.0,.1,.2,.3,.4,.8,.9; E827.0,.2,.3,.4,.8,.9; E828.0,.2,.4,.8,.9; E829.0,.4,.8,.9; E830.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E831.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E832.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E833.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E834.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E835.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E836.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E837.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E838.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E840.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E841.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E842.6,.7,.8,.9; E843.0,.1,.2,.3,.4,.5,.6, .7,.8,.9;	V15.9XXA,D,S; V16.0XXA,D,S; V16.1XXA,D,S; V16.2XXA,D,S; V16.3XXA,D,S; V16.4XXA,D,S; V16.5XXA,D,S; V16.9XXA,D,S; V17.0XXA,D,S; V17.1XXA,D,S; V17.2XXA,D,S; V17.3XXA,D,S; V17.4XXA,D,S; V17.5XXA,D,S; V17.9XXA,D,S; V18.0XXA,D,S; V18.1XXA,D,S; V18.2XXA,D,S; V18.3XXA,D,S; V18.4XXA,D,S; V18.5XXA,D,S; V18.9XXA,D,S; V19.00XA,D,S; V19.09XA,D,S; V19.10XA,D,S; V19.19XA,D,S; V19.20XA,D,S; V19.29XA,D,S; V19.3XXA,D,S; V19.40XA,D,S; V19.49XA,D,S; V19.50XA,D,S; V19.59XA,D,S; V19.60XA,D,S; V19.69XA,D,S; V19.81XA,D,S; V19.88XA,D,S; V19.9XXA,D,S; V20.0XXA,D,S; V20.1XXA,D,S; V20.2XXA,D,S; V20.3XXA,D,S; V20.4XXA,D,S; V20.5XXA,D,S; V20.9XXA,D,S; V21.0XXA,D,S; V21.1XXA,D,S; V21.2XXA,D,S; V21.3XXA,D,S; V21.4XXA,D,S; V21.5XXA,D,S; V21.9XXA,D,S; V22.0XXA,D,S; V22.1XXA,D,S; V22.2XXA,D,S; V22.3XXA,D,S; V22.4XXA,D,S; V22.5XXA,D,S; V22.9XXA,D,S; V23.0XXA,D,S; V23.1XXA,D,S; V23.2XXA,D,S; V23.3XXA,D,S; V23.4XXA,D,S; V23.5XXA,D,S; V23.9XXA,D,S; V24.0XXA,D,S; V24.1XXA,D,S; V24.2XXA,D,S; V24.3XXA,D,S; V24.4XXA,D,S; V24.5XXA,D,S; V24.9XXA,D,S; V25.0XXA,D,S; V25.1XXA,D,S; V25.2XXA,D,S; V25.3XXA,D,S; V25.4XXA,D,S; V25.5XXA,D,S; V25.9XXA,D,S; V26.0XXA,D,S; V26.1XXA,D,S; V26.2XXA,D,S; V26.3XXA,D,S; V26.4XXA,D,S; V26.5XXA,D,S; V26.9XXA,D,S; V27.0XXA,D,S; V27.1XXA,D,S; V27.2XXA,D,S; V27.3XXA,D,S; V27.4XXA,D,S; V27.5XXA,D,S; V27.9XXA,D,S; V28.0XXA,D,S; V28.1XXA,D,S; V28.2XXA,D,S; V28.3XXA,D,S; V28.4XXA,D,S; V28.5XXA,D,S; V28.9XXA,D,S; V29.00XA,D,S; V29.09XA,D,S; V29.10XA,D,S; V29.19XA,D,S; V29.20XA,D,S; V29.29XA,D,S; V29.3XXA,D,S; V29.40XA,D,S; V29.49XA,D,S; V29.50XA,D,S; V29.59XA,D,S; V29.60XA,D,S; V29.69XA,D,S; V29.81XA,D,S; V29.88XA,D,S; V29.9XXA,D,S; V30.0XXA,D,S; V30.1XXA,D,S; V30.2XXA,D,S; V30.3XXA,D,S; V30.4XXA,D,S; V30.5XXA,D,S; V30.6XXA,D,S; V30.7XXA,D,S; V30.9XXA,D,S; V31.0XXA,D,S; V31.1XXA,D,S; V31.2XXA,D,S; V31.3XXA,D,S; V31.4XXA,D,S; V31.5XXA,D,S; V31.6XXA,D,S; V31.7XXA,D,S; V31.9XXA,D,S; V32.0XXA,D,S; V32.1XXA,D,S; V32.2XXA,D,S; V32.3XXA,D,S; V32.4XXA,D,S; V32.5XXA,D,S; V32.6XXA,D,S; V32.7XXA,D,S; V32.9XXA,D,S; V33.0XXA,D,S; V33.1XXA,D,S; V33.2XXA,D,S; V33.3XXA,D,S; V33.4XXA,D,S; V33.5XXA,D,S; V33.6XXA,D,S; V33.7XXA,D,S; V33.9XXA,D,S; V34.0XXA,D,S; V34.1XXA,D,S; V34.2XXA,D,S; V34.3XXA,D,S; V34.4XXA,D,S; V34.5XXA,D,S; V34.6XXA,D,S; V34.7XXA,D,S; V34.9XXA,D,S; V35.0XXA,D,S; V35.1XXA,D,S; V35.2XXA,D,S; V35.3XXA,D,S; V35.4XXA,D,S; V35.5XXA,D,S; V35.6XXA,D,S; V35.7XXA,D,S; V35.9XXA,D,S; V36.0XXA,D,S; V36.1XXA,D,S; V36.2XXA,D,S; V36.3XXA,D,S; V36.4XXA,D,S; V36.5XXA,D,S; V36.6XXA,D,S; V36.7XXA,D,S; V36.9XXA,D,S; V37.0XXA,D,S; V37.1XXA,D,S; V37.2XXA,D,S; V37.3XXA,D,S; V37.4XXA,D,S; V37.5XXA,D,S; V37.6XXA,D,S; V37.7XXA,D,S; V37.9XXA,D,S; V38.0XXA,D,S; V38.1XXA,D,S; V38.2XXA,D,S; V38.3XXA,D,S; V38.4XXA,D,S; V38.5XXA,D,S; V38.6XXA,D,S; V38.7XXA,D,S; V38.9XXA,D,S; V39.00XA,D,S; V39.09XA,D,S; V39.10XA,D,S; V39.19XA,D,S; V39.20XA,D,S; V39.29XA,D,S; V39.3XXA,D,S; V39.40XA,D,S; V39.49XA,D,S; V39.50XA,D,S; V39.59XA,D,S; V39.60XA,D,S; V39.69XA,D,S; V39.81XA,D,S; V39.89XA,D,S; V39.9XXA,D,S; V40.0XXA,D,S; V40.1XXA,D,S; V40.2XXA,D,S; V40.3XXA,D,S; V40.4XXA,D,S; V40.5XXA,D,S; V40.6XXA,D,S; V40.7XXA,D,S; V40.9XXA,D,S; V41.0XXA,D,S; V41.1XXA,D,S; V41.2XXA,D,S; V41.3XXA,D,S; V41.4XXA,D,S; V41.5XXA,D,S; V41.6XXA,D,S; V41.7XXA,D,S; V41.9XXA,D,S; V42.0XXA,D,S; V42.1XXA,D,S; V42.2XXA,D,S; V42.3XXA,D,S; V42.4XXA,D,S; V42.5XXA,D,S; V42.6XXA,D,S; V42.7XXA,D,S;

	E844.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E845.0,.8,.9; E846.; E847.; E848.; E929.0	V42.9XXA,D,S; V43.01XA,D,S; V43.02XA,D,S; V43.03XA,D,S; V43.04XA,D,S; V43.11XA,D,S; V43.12XA,D,S; V43.13XA,D,S; V43.14XA,D,S; V43.21XA,D,S; V43.22XA,D,S; V43.23XA,D,S; V43.24XA,D,S; V43.31XA,D,S; V43.32XA,D,S; V43.33XA,D,S; V43.34XA,D,S; V43.41XA,D,S; V43.42XA,D,S; V43.43XA,D,S; V43.44XA,D,S; V43.51XA,D,S; V43.52XA,D,S; V43.53XA,D,S; V43.54XA,D,S; V43.61XA,D,S; V43.62XA,D,S; V43.63XA,D,S; V43.64XA,D,S; V43.71XA,D,S; V43.72XA,D,S; V43.73XA,D,S; V43.74XA,D,S; V43.91XA,D,S; V43.92XA,D,S; V43.93XA,D,S; V43.94XA,D,S; V44.0XXA,D,S; V44.1XXA,D,S; V44.2XXA,D,S; V44.3XXA,D,S; V44.4XXA,D,S; V44.5XXA,D,S; V44.6XXA,D,S;V44.7XXA,D,S; V44.9XXA,D,S; V45.0XXA,D,S; V45.1XXA,D,S; V45.2XXA,D,S; V45.3XXA,D,S; V45.4XXA,D,S; V45.5XXA,D,S; V45.6XXA,D,S; V45.7XXA,D,S; V45.9XXA,D,S; V46.0XXA,D,S; V46.1XXA,D,S; V46.2XXA,D,S; V46.3XXA,D,S; V46.4XXA,D,S; V46.5XXA,D,S; V46.6XXA,D,S; V46.7XXA,D,S; V46.9XXA,D,S; V47.0XXA,D,S; V47.01XA,D,S; V47.02XA,D,S; V47.11XA,D,S; V47.12XA,D,S; V47.1XXA,D,S; V47.2XXA,D,S; V47.31XA,D,S; V47.32XA,D,S; V47.3XXA,D,S; V47.4XXA,D,S; V47.51XA,D,S; V47.52XA,D,S; V47.5XXA,D,S; V47.61XA,D,S; V47.62XA,D,S; V47.6XXA,D,S; V47.7XXA,D,S; V47.91XA,D,S; V47.92XA,D,S; V47.9XXA,D,S; V48.0XXA,D,S; V48.1XXA,D,S; V48.2XXA,D,S; V48.3XXA,D,S; V48.4XXA,D,S; V48.5XXA,D,S; V48.6XXA,D,S; V48.7XXA,D,S; V48.9XXA,D,S; V49.00XA,D,S; V49.09XA,D,S; V49.10XA,D,S; V49.19XA,D,S; V49.20XA,D,S; V49.29XA,D,S; V49.3XXA,D,S; V49.40XA,D,S; V49.49XA,D,S; V49.50XA,D,S; V49.59XA,D,S; V49.60XA,D,S; V49.69XA,D,S; V49.81XA,D,S; V49.88XA,D,S; V49.9XXA,D,S; V50.0XXA,D,S; V50.1XXA,D,S; V50.2XXA,D,S; V50.3XXA,D,S; V50.4XXA,D,S; V50.5XXA,D,S; V50.6XXA,D,S; V50.7XXA,D,S; V50.9XXA,D,S; V51.0XXA,D,S; V51.1XXA,D,S; V51.2XXA,D,S; V51.3XXA,D,S; V51.4XXA,D,S; V51.5XXA,D,S; V51.6XXA,D,S; V51.7XXA,D,S; V51.9XXA,D,S; V52.0XXA,D,S; V52.1XXA,D,S; V52.2XXA,D,S; V52.3XXA,D,S; V52.4XXA,D,S; V52.5XXA,D,S; V52.6XXA,D,S; V52.7XXA,D,S; V52.9XXA,D,S; V53.0XXA,D,S; V53.1XXA,D,S; V53.2XXA,D,S; V53.3XXA,D,S; V53.4XXA,D,S; V53.5XXA,D,S; V53.6XXA,D,S; V53.7XXA,D,S; V53.9XXA,D,S; V54.0XXA,D,S; V54.1XXA,D,S; V54.2XXA,D,S; V54.3XXA,D,S; V54.4XXA,D,S; V54.5XXA,D,S; V54.6XXA,D,S; V54.7XXA,D,S; V54.9XXA,D,S; V55.0XXA,D,S; V55.1XXA,D,S; V55.2XXA,D,S; V55.3XXA,D,S; V55.4XXA,D,S; V55.5XXA,D,S; V55.6XXA,D,S; V55.7XXA,D,S; V55.9XXA,D,S; V56.0XXA,D,S; V56.1XXA,D,S; V56.2XXA,D,S; V56.3XXA,D,S; V56.4XXA,D,S; V56.5XXA,D,S; V56.6XXA,D,S; V56.7XXA,D,S; V56.9XXA,D,S; V57.0XXA,D,S; V57.1XXA,D,S; V57.2XXA,D,S; V57.3XXA,D,S; V57.4XXA,D,S; V57.5XXA,D,S; V57.6XXA,D,S; V57.7XXA,D,S; V57.9XXA,D,S; V58.0XXA,D,S; V58.1XXA,D,S; V58.2XXA,D,S; V58.3XXA,D,S; V58.4XXA,D,S; V58.5XXA,D,S; V58.6XXA,D,S; V58.7XXA,D,S; V58.9XXA,D,S; V59.00XA,D,S; V59.09XA,D,S; V59.10XA,D,S; V59.19XA,D,S; V59.20XA,D,S; V59.29XA,D,S; V59.3XXA,D,S; V59.40XA,D,S; V59.49XA,D,S; V59.50XA,D,S; V59.59XA,D,S; V59.60XA,D,S; V59.69XA,D,S; V59.81XA,D,S; V59.88XA,D,S; V59.9XXA,D,S; V60.0XXA,D,S; V60.1XXA,D,S; V60.2XXA,D,S; V60.3XXA,D,S; V60.4XXA,D,S; V60.5XXA,D,S; V60.6XXA,D,S; V60.7XXA,D,S; V60.9XXA,D,S; V61.0XXA,D,S; V61.1XXA,D,S; V61.2XXA,D,S; V61.3XXA,D,S; V61.4XXA,D,S; V61.5XXA,D,S; V61.6XXA,D,S; V61.7XXA,D,S; V61.9XXA,D,S; V62.0XXA,D,S; V62.1XXA,D,S; V62.2XXA,D,S; V62.3XXA,D,S; V62.4XXA,D,S; V62.5XXA,D,S; V62.6XXA,D,S; V62.7XXA,D,S; V62.9XXA,D,S; V63.0XXA,D,S; V63.1XXA,D,S; V63.2XXA,D,S; V63.3XXA,D,S; V63.4XXA,D,S; V63.5XXA,D,S;

		V63.6XXA,D,S; V63.7XXA,D,S; V63.9XXA,D,S; V64.0XXA,D,S; V64.1XXA,D,S; V64.2XXA,D,S; V64.3XXA,D,S; V64.4XXA,D,S; V64.5XXA,D,S; V64.6XXA,D,S; V64.7XXA,D,S; V64.9XXA,D,S; V65.0XXA,D,S; V65.1XXA,D,S; V65.2XXA,D,S; V65.3XXA,D,S; V65.4XXA,D,S; V65.5XXA,D,S; V65.6XXA,D,S; V65.7XXA,D,S; V65.9XXA,D,S; V66.0XXA,D,S; V66.1XXA,D,S; V66.2XXA,D,S; V66.3XXA,D,S; V66.4XXA,D,S; V66.5XXA,D,S; V66.6XXA,D,S; V66.7XXA,D,S; V66.9XXA,D,S; V67.0XXA,D,S; V67.1XXA,D,S; V67.2XXA,D,S; V67.3XXA,D,S; V67.4XXA,D,S; V67.5XXA,D,S; V67.6XXA,D,S; V67.7XXA,D,S; V67.9XXA,D,S; V68.0XXA,D,S; V68.1XXA,D,S; V68.2XXA,D,S; V68.3XXA,D,S; V68.4XXA,D,S; V68.5XXA,D,S; V68.6XXA,D,S; V68.7XXA,D,S; V68.9XXA,D,S; V69.00XA,D,S; V69.09XA,D,S; V69.10XA,D,S; V69.19XA,D,S; V69.20XA,D,S; V69.3XXA,D,S; V69.40XA,D,S; V69.49XA,D,S; V69.50XA,D,S; V69.59XA,D,S; V69.60XA,D,S; V69.69XA,D,S; V69.81XA,D,S; V69.88XA,D,S; V69.9XXA,D,S; V70.0XXA,D,S; V70.1XXA,D,S; V70.2XXA,D,S; V70.3XXA,D,S; V70.4XXA,D,S; V70.5XXA,D,S; V70.6XXA,D,S; V70.7XXA,D,S; V70.9XXA,D,S; V71.0XXA,D,S; V71.1XXA,D,S; V71.2XXA,D,S; V71.3XXA,D,S; V71.4XXA,D,S; V71.5XXA,D,S; V71.6XXA,D,S; V71.7XXA,D,S; V71.9XXA,D,S; V72.0XXA,D,S; V72.1XXA,D,S; V72.2XXA,D,S; V72.3XXA,D,S; V72.4XXA,D,S; V72.5XXA,D,S; V72.6XXA,D,S; V72.7XXA,D,S; V72.9XXA,D,S; V73.0XXA,D,S; V73.1XXA,D,S; V73.2XXA,D,S; V73.3XXA,D,S; V73.4XXA,D,S; V73.5XXA,D,S; V73.6XXA,D,S; V73.7XXA,D,S; V73.9XXA,D,S; V74.0XXA,D,S; V74.1XXA,D,S; V74.2XXA,D,S; V74.3XXA,D,S; V74.4XXA,D,S; V74.5XXA,D,S; V74.6XXA,D,S; V74.7XXA,D,S; V74.9XXA,D,S; V75.0XXA,D,S; V75.1XXA,D,S; V75.2XXA,D,S; V75.3XXA,D,S; V75.4XXA,D,S; V75.5XXA,D,S; V75.6XXA,D,S; V75.7XXA,D,S; V75.9XXA,D,S; V76.0XXA,D,S; V76.1XXA,D,S; V76.2XXA,D,S; V76.3XXA,D,S; V76.4XXA,D,S; V76.5XXA,D,S; V76.6XXA,D,S; V76.7XXA,D,S; V76.9XXA,D,S; V77.0XXA,D,S; V77.1XXA,D,S; V77.2XXA,D,S; V77.3XXA,D,S; V77.4XXA,D,S; V77.5XXA,D,S; V77.6XXA,D,S; V77.7XXA,D,S; V77.9XXA,D,S; V78.0XXA,D,S; V78.1XXA,D,S; V78.2XXA,D,S; V78.3XXA,D,S; V78.4XXA,D,S; V78.5XXA,D,S; V78.6XXA,D,S; V78.7XXA,D,S; V78.9XXA,D,S; V79.00XA,D,S; V79.10XA,D,S; V79.19XA,D,S; V79.20XA,D,S; V79.29XA,D,S; V79.3XXA,D,S; V79.40XA,D,S; V79.49XA,D,S; V79.50XA,D,S; V79.59XA,D,S; V79.60XA,D,S; V79.69XA,D,S; V79.81XA,D,S; V79.88XA,D,S; V79.9XXA,D,S; V80.010A,D,S; V80.020A,D,S; V80.11XA,D,S; V80.12XA,D,S; V80.21XA,D,S; V80.22XA,D,S; V80.31XA,D,S; V80.32XA,D,S; V80.41XA,D,S; V80.42XA,D,S; V80.51XA,D,S; V80.52XA,D,S; V80.61XA,D,S; V80.62XA,D,S; V80.710A,D,S; V80.711A,D,S; V80.720A,D,S; V80.721A,D,S; V80.730A,D,S; V80.731A,D,S; V80.790A,D,S; V80.791A,D,S; V80.81XA,D,S; V80.82XA,D,S; V80.910A,D,S; V80.918A,D,S; V80.919A,D,S; V80.919A,D,S; V80.920A,D,S; V80.928A,D,S; V80.929A,D,S; V81.0XXA,D,S; V81.1XXA,D,S; V81.2XXA,D,S; V81.3XXA,D,S; V81.4XXA,D,S; V81.5XXA,D,S; V81.6XXA,D,S; V81.7XXA,D,S; V81.81XA,D,S; V81.82XA,D,S; V81.83XA,D,S; V81.89XA,D,S; V81.9XXA,D,S; V82.0XXA,D,S; V82.1 XXA,D,S; V82.2XXA,D,S; V82.3XXA,D,S; V82.4XXA,D,S; V82.5XXA,D,S; V82.6XXA,D,S; V82.7XXA,D,S; V82.8XXA,D,S; V82.9XXA,D,S; V83.0XXA,D,S; V83.1 XXA,D,S; V83.2XXA,D,S; V83.3XXA,D,S; V83.4XXA,D,S; V83.5XXA,D,S; V83.6XXA,D,S; V83.7XXA,D,S; V83.9XXA,D,S; V84.0XXA,D,S; V84.1XXA,D,S; V84.2XXA,D,S; V84.3XXA,D,S; V84.4XXA,D,S; V84.5XXA,D,S; V84.6XXA,D,S; V84.7XXA,D,S; V84.9XXA,D,S; V85.0XXA,D,S; V85.1 XXA,D,S; V85.2XXA,D,S; V85.3XXA,D,S; V85.4XXA,D,S; V85.5XXA,D,S; V85.6XXA,D,S; V85.7XXA,D,S; V85.8XXA,D,S;

		V85.9XXA,D,S; V86.01XA,D,S; V86.02XA,D,S; V86.03XA,D,S; V86.04XA,D,S; V86.09XA,D,S; V86.11XA,D,S; V86.12XA,D,S; V86.13XA,D,S; V86.14XA,D,S; V86.19XA,D,S; V86.21XA,D,S; V86.22XA,D,S;V86.23XA,D,S; V86.24XA,D,S; V86.29XA,D,S; V86.31XA,D,S; V86.32XA,D,S; V86.33XA,D,S; V86.34XA,D,S; V86.39XA,D,S; V86.41XA,D,S; V86.42XA,D,S; V86.43XA,D,S; V86.44XA,D,S; V86.49XA,D,S; V86.51XA,D,S; V86.52XA,D,S; V86.53XA,D,S; V86.54XA,D,S; V86.59XA,D,S; V86.61XA,D,S; V86.62XA,D,S; V86.63XA,D,S; V86.64XA,D,S; V86.69XA,D,S; V86.71XA,D,S; V86.72XA,D,S; V86.73XA,D,S; V86.74XA,D,S; V86.79XA,D,S; V86.91XA,D,S; V86.92XA,D,S; V86.93XA,D,S; V86.94XA,D,S; V86.99XA,D,S; V87.0XXA,D,S; V87.1XXA,D,S; V87.2XXA,D,S; V87.3XXA,D,S; V87.4XXA,D,S; V87.5XXA,D,S; V87.6XXA,D,S; V87.7XXA,D,S; V87.8XXA,D,S; V87.9XXA,D,S; V88.0XXA,D,S; V88.1XXA,D,S; V88.2XXA,D,S; V88.3XXA,D,S; V88.4XXA,D,S; V88.5XXA,D,S; V88.6XXA,D,S; V88.7XXA,D,S; V88.8XXA,D,S; V88.9XXA,D,S; V89.0XXA,D,S; V89.1XXA,D,S; V89.2XXA,D,S; V89.3XXA,D,S; V89.9XXA,D,S; V90.00XA,D,S; V90.01XA,D,S; V90.02XA,D,S; V90.03XA,D,S; V90.04XA,D,S; V90.05XA,D,S; V90.06XA,D,S; V90.08XA,D,S; V90.09XA,D,S; V90.10XA,D,S; V90.11XA,D,S; V90.12XA,D,S; V90.13XA,D,S; V90.14XA,D,S; V90.15XA,D,S; V90.16XA,D,S; V90.18XA,D,S; V90.19XA,D,S; V90.20XA,D,S; V90.21XA,D,S; V90.22XA,D,S; V90.23XA,D,S; V90.24XA,D,S; V90.25XA,D,S;V90.26XA,D,S; V90.27XA,D,S; V90.28XA,D,S; V90.29XA,D,S; V90.30XA,D,S; V90.31XA,D,S; V90.32XA,D,S; V90.33XA,D,S; V90.34XA,D,S; V90.35XA,D,S; V90.36XA,D,S; V90.37XA,D,S; V90.38XA,D,S; V90.39XA,D,S; V90.80XA,D,S; V90.81XA,D,S; V90.82XA,D,S; V90.83XA,D,S; V90.84XA,D,S; V90.85XA,D,S; V90.86XA,D,S; V90.87XA,D,S; V90.88XA,D,S; V90.89XA,D,S; V91.00XA,D,S; V91.01XA,D,S; V91.02XA,D,S; V91.03XA,D,S; V91.04XA,D,S; V91.05XA,D,S; V91.06XA,D,S; V91.07XA,D,S; V91.08XA,D,S; V91.09XA,D,S; V91.10XA,D,S; V91.11XA,D,S; V91.12XA,D,S; V91.13XA,D,S; V91.14XA,D,S; V91.15XA,D,S; V91.16XA,D,S; V91.18XA,D,S; V91.19XA,D,S; V91.20XA,D,S; V91.21XA,D,S; V91.22XA,D,S; V91.24XA,D,S; V91.25XA,D,S; V91.26XA,D,S; V91.29XA,D,S; V91.30XA,D,S; V91.31XA,D,S; V91.32XA,D,S; V91.33XA,D,S; V91.34XA,D,S; V91.35XA,D,S; V91.36XA,D,S; V91.37XA,D,S; V91.38XA,D,S; V91.39XA,D,S; V91.80XA,D,S; V91.81XA,D,S; V91.82XA,D,S; V91.83XA,D,S; V91.84XA,D,S; V91.85XA,D,S; V91.86XA,D,S; V91.87XA,D,S; V91.88XA,D,S; V91.89XA,D,S; V92.00XA,D,S; V92.01XA,D,S; V92.02XA,D,S; V92.03XA,D,S; V92.04XA,D,S; V92.05XA,D,S; V92.06XA,D,S; V92.07XA,D,S; V92.08XA,D,S; V92.09XA,D,S; V92.10XA,D,S; V92.11XA,D,S; V92.12XA,D,S; V92.13XA,D,S; V92.14XA,D,S; V92.15XA,D,S; V92.16XA,D,S; V92.19XA,D,S; V92.20XA,D,S; V92.21XA,D,S; V92.22XA,D,S; V92.23XA,D,S; V92.24XA,D,S; V92.25XA,D,S; V92.26XA,D,S; V92.27XA,D,S; V92.28XA,D,S; V92.29XA,D,S; V93.00XA,D,S; V93.01XA,D,S; V93.02XA,D,S; V93.03XA,D,S; V93.04XA,D,S; V93.09XA,D,S; V93.10XA,D,S; V93.11XA,D,S; V93.12XA,D,S; V93.13XA,D,S; V93.14XA,D,S; V93.19XA,D,S; V93.20XA,D,S; V93.21XA,D,S; V93.22XA,D,S; V93.23XA,D,S; V93.24XA,D,S; V93.29XA,D,S; V93.30XA,D,S; V93.31XA,D,S; V93.32XA,D,S; V93.33XA,D,S; V93.34XA,D,S; V93.35XA,D,S; V93.36XA,D,S; V93.37XA,D,S; V93.38XA,D,S; V93.40XA,D,S; V93.41XA,D,S; V93.42XA,D,S;V93.43XA,D,S; V93.44XA,D,S; V93.48XA,D,S; V93.49XA,D,S; V93.50XA,D,S; V93.51XA,D,S; V93.52XA,D,S; V93.53XA,D,S; V93.54XA,D,S; V93.59XA,D,S; V93.60XA,D,S; V93.61XA,D,S; V93.62XA,D,S; V93.63XA,D,S; V93.64XA,D,S; V93.69XA,D,S; V93.80XA,D,S;

		V93.81XA,D,S; V93.82XA,D,S; V93.83XA,D,S;V93.84XA,D,S; V93.85XA,D,S; V93.86XA,D,S; V93.87XA,D,S; V93.88XA,D,S; V93.89XA,D,S; V94.0XXA,D,S; V94.11XA,D,S; V94.12XA,D,S; V94.21XA,D,S; V94.22XA,D,S; V94.31XA,D,S; V94.32XA,D,S; V94.4XXA,D,S; V94.810A,D,S; V94.811A,D,S; V94.818A,D,S; V94.89XA,D,S; V94.9XXA,D,S; V95.00XA,D,S; V95.01XA,D,S; V95.02XA,D,S; V95.03XA,D,S; V95.04XA,D,S; V95.05XA,D,S; V95.09XA,D,S; V95.10XA,D,S; V95.11XA,D,S; V95.12XA,D,S; V95.13XA,D,S; V95.14XA,D,S; V95.15XA,D,S; V95.19XA,D,S; V95.20XA,D,S; V95.21XA,D,S; V95.22XA,D,S; V95.23XA,D,S; V95.24XA,D,S; V95.25XA,D,S; V95.29XA,D,S; V95.30XA,D,S; V95.31XA,D,S; V95.32XA,D,S; V95.33XA,D,S; V95.34XA,D,S; V95.35XA,D,S; V95.39XA,D,S; V95.40XA,D,S; V95.41XA,D,S; V95.42XA,D,S; V95.43XA,D,S; V95.44XA,D,S; V95.45XA,D,S; V95.49XA,D,S; V95.8XXA,D,S; V95.9XXA,D,S; V96.00XA,D,S; V96.01XA,D,S; V96.02XA,D,S; V96.03XA,D,S; V96.04XA,D,S; V96.05XA,D,S; V96.09XA,D,S; V96.10XA,D,S; V96.11XA,D,S; V96.12XA,D,S; V96.13XA,D,S; V96.14XA,D,S; V96.15XA,D,S; V96.19XA,D,S; V96.20XA,D,S; V96.21XA,D,S; V96.22XA,D,S; V96.23XA,D,S; V96.24XA,D,S; V96.25XA,D,S; V96.29XA,D,S; V96.8XXA,D,S; V96.9XXA,D,S; V97.0XXA,D,S; V97.1XXA,D,S; V97.21XA,D,S; V97.22XA,D,S; V97.29XA,D,S; V97.31XA,D,S; V97.32XA,D,S; V97.33XA,D,S; V97.39XA,D,S; V97.810A,D,S; V97.811A,D,S; V97.818A,D,S; V97.89XA,D,S; V98.0XXA,D,S; V98.1XXA,D,S; V98.2XXA,D,S; V98.3XXA,D,S; V98.8XXA,D,S; V99.XXXA,D,S
Sedative Poisoning	967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E851.; E852.0,.1,.2,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.2,.3	T41.0X1A,D,S; T41.0X2A,D,S; T41.0X3A,D,S; T41.0X4A,D,S; T41.0X5A,D,S; T41.1X1A,D,S; T41.1X2A,D,S; T41.1X3A,D,S; T41.1X4A,D,S; T41.1X5A,D,S; T41.201A,D,S; T41.202A,D,S; T41.203A,D,S; T41.204A,D,S; T41.205A,D,S; T41.291A,D,S; T41.292A,D,S; T41.293A,D,S; T41.294A,D,S; T41.295A,D,S; T41.3X1A,D,S; T41.3X2A,D,S; T41.3X3A,D,S; T41.3X4A,D,S; T41.3X5A,D,S; T41.41XA,D,S; T41.42XA,D,S; T41.43XA,D,S; T41.44XA,D,S; T41.45XA,D,S; T42.3X1A,D,S; T42.3X2A,D,S; T42.3X3A,D,S; T42.3X4A,D,S; T42.3X5A,D,S; T42.4X1A,D,S; T42.4X2A,D,S; T42.4X3A,D,S; T42.4X4A,D,S; T42.4X5A,D,S; T42.6X1A,D,S; T42.6X2A,D,S; T42.6X3A,D,S; T42.6X4A,D,S; T42.6X5A,D,S; T42.8X1A,D,S; T42.8X2A,D,S; T42.8X3A,D,S; T42.8X4A,D,S; T42.8X5A,D,S; T43.3X1A,D,S; T43.3X2A,D,S; T43.3X3A,D,S; T43.3X4A,D,S; T43.3X5A,D,S; T43.4X1A,D,S; T43.4X2A,D,S; T43.4X3A,D,S; T43.4X4A,D,S; T43.4X5A,D,S; T43.501A,D,S; T43.502A,D,S; T43.503A,D,S; T43.504A,D,S; T43.505A,D,S; T43.591A,D,S; T43.592A,D,S; T43.593A,D,S; T43.594A,D,S; T43.595A,D,S
Suicide-related	E950.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9,.91,.92; E951.0,.01,.02,.1,.11,.12,.8,.81,.82; E952.0,.01,.02,.1,.11,.12,.8,.81,.82,.9,.91,.92; E953.0,.01,.02,.1,.11,.	R45.851; T14.91; T36.0X2A,D,S; T36.1X2A,D,S; T36.2X2A,D,S; T36.3X2A,D,S; T36.4X2A,D,S; T36.5X2A,D,S; T36.6X2A,D,S; T36.7X2A,D,S; T36.8X2A,D,S; T36.92XA,D,S; T37.0X2A,D,S; T37.1X2A,D,S; T37.2X2A,D,S; T37.3X2A,D,S; T37.4X2A,D,S; T37.5X2A,D,S; T37.8X2A,D,S; T37.92XA,D,S; T38.0X2A,D,S; T38.1X2A,D,S; T38.2X2A,D,S; T38.3X2A,D,S; T38.4X2A,D,S; T38.5X2A,D,S; T38.6X2A,D,S; T38.7X2A,D,S; T38.802A,D,S; T38.812A,D,S; T38.892A,D,S; T38.902A,D,S; T38.992A,D,S; T39.012A,D,S; T39.092A,D,S; T39.1X2A,D,S; T39.2X2A,D,S; T39.312A,D,S; T39.392A,D,S; T39.4X2A,D,S; T39.8X2A,D,S; T39.92XA,D,S; T40.0X2A,D,S; T40.1X2A,D,S; T40.2X2A,D,S; T40.3X2A,D,S; T40.4X2A,D,S; T40.5X2A,D,S; T40.602A,D,S; T40.692A,D,S; T40.7X2A,D,S; T40.8X2A,D,S; T40.902A,D,S; T40.992A,D,S; T41.0X2A,D,S; T41.1X2A,D,S; T41.202A,D,S; T41.292A,D,S; T41.3X2A,D,S; T41.42XA,D,S; T41.5X2A,D,S; T42.0X2A,D,S; T42.1X2A,D,S; T42.2X2A,D.S; T42.3X2A,D,S; T42.4X2A,D.S; T42.5X2A,D,S;

	12,.8,.81,.82,.9; E954.,.1,.2; E955.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31..32,.4,.41,.42,.5,.51,.52,.6,.7,.9; E956.,.1,.2; E957.0,.01,.02,.1,.11,.12,.2,.21,.22,.9,.91,.92; E958.0,.01;.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9; E959.; E980.6,.8; E981.0,.1,.8; E982.0,.1,.8,.9; E983.0,.1,.8,.9; E984.; E988.0,.1,.2,.3,.4,.5,.6,.7,.8,.9; V62.84	T42.6X2A,D,S; T42.72XA,D,S; T42.8X2A,D,S; T43.012A,D,S; T43.022A,D,S; T43.1X2A,D,S; T43.202A,D,S; T43.212A,D,S; T43.222A,D,S; T43.292A,D,S; T43.3X2A,D,S; T43.4X2A,D,S; T43.502A,D,S; T43.592A,D,S; T43.602A,D,S; T43.612A,D,S; T43.622A,D,S; T43.632A,D,S; T43.692A,D,S; T43.8X2A,D,S; T43.92XA,D,S; T44.0X2A,D,S; T44.1X2A,D,S; T44.2X2A,D,S; T44.3X2A,D,S; T44.4X2A,D,S; T44.5X2A,D,S; T44.6X2A,D,S; T44.7X2A,D,S; T44.8X2A,D,S; T44.902A,D,S; T44.992A,D,S; T45.0X2A,D,S; T45.1X2A,D,S; T45.2X2A,D,S; T45.3X2A,D,S; T45.4X2A,D,S; T45.512A,D,S; T45.522A,D,S; T45.602A,D,S; T45.612A,D,S; T45.622A,D,S; T45.692A,D,S; T45.7X2A,D,S; T45.8X2A,D,S; T45.92XA.D.S; T46.0X2A,D,S; T46.1X2A,D,S; T46.2X2A,D,S; T46.3X2A,D,S; T46.4X2A,D,S; T46.5X2A,D,S; T46.6X2A,D,S; T46.7X2A,D,S; T46.8X2A,D,S; T46.902A,D,S; T46.992A,D,S; T47.0X2A,D,S; T47.1X2A,D,S; T47.2X2A,D,S; T47.3X2A,D,S; T47.4X2A,D,S; T47.5X2A,D,S; T47.6X2A,D,S; T47.7X2A,D,S; T47.8X2A,D,S; T47.92XA,D,S; T48.0X2A,D,S; T48.1X2A,D,S; T48.202A,D,S; T48.292A,D,S; T48.3X2A,D,S; T48.4X2A,D,S; T48.5X2A,D,S; T48.6X2A,D,S; T48.902A,D,S; T48.992A,D,S; T49.0X2A,D,S; T49.1X2A,D,S; T49.2X2A,D,S; T49.3X2A,D,S; T49.4X2A,D,S; T49.5X2A,D,S; T49.6X2A,D,S; T49.7X2A,D,S; T49.8X2A,D,S; T49.92XA,D,S; T50.0X2A,D,S; T50.1X2A,D,S; T50.2X2A,D,S; T50.3X2A,D,S; T50.4X2A,D,S; T50.5X2A,D,S; T50.6X2A,D,S; T50.7X2A,D,S; T50.8X2A,D,S; T50.902A,D,S; T50.902S,D,S; T50.992A,D,S; T50.A12A,D,S; T50.A12A,D,S; T50.A22A,D,S; T50.A92A,D,S; T50.B12A,D,S; T50.B92A,D,S; T50.Z12A,D,S; T50.Z92A,D,S; T51.0X2A,D,S; T51.1X2A,D,S; T51.2X2A,D,S; T51.3X2A,D,S; T51.8X2A,D,S; T51.92XA,D,S; T52.0X2A,D,S; T52.1X2A,D,S; T52.2X2A,D,S; T52.3X2A,D,S; T52.4X2A,D,S; T52.8X2A,D,S; T52.92XA,D,S; T53.0X2A,D,S; T53.1X2A,D,S; T53.2X2A,D,S; T53.3X2A,D,S; T53.4X2A,D,S; T53.5X2A,D,S; T53.6X2A,D,S; T53.7X2A,D,S; T53.92XA,D,S; T54.0X2A,D,S; T54.1X2A,D,S; T54.2X2A,D,S; T54.3X2A,D,S; T54.92XA,D,S; T55.0X2A,D,S; T55.1X2A,D,S; T56.0X2A,D,S; T56.1X2A,D,S; T56.2X2A,D,S; T56.3X2A,D,S; T56.4X2A,D,S; T56.5X2A,D,S; T56.6X2A,D,S; T56.7X2A,D,S; T56.812A,D,S; T56.892A,D,S; T56.92XA,D,S; T57.0X2A,D,S; T57.1X2A,D,S; T57.2X2A,D,S; T57.3X2A,D,S; T57.8X2A,D,S; T57.92XA,D,S; T58.02XA,D,S; T58.12XA,D,S; T58.2X2A,D,S; T58.8X2A,D,S; T58.92XA,D,S; T59.0X2A,D,S; T59.1X2A,D,S; T59.2X2A,D,S; T59.3X2A,D,S; T59.4X2A,D,S; T59.5X2A,D,S; T59.6X2A,D,S; T59.7X2A,D,S; T59.812A,D,S; T59.892A,D,S; T59.92XA,D,S; T60.0X2A,D,S; T60.1X2A,D,S; T60.2X2A,D,S; T60.3X2A,D,S; T60.4X2A,D,S; T60.8X2A,D,S; T60.92XA,D,S; T61.02XA,D,S; T61.12XA,D,S; T61.772A,D,S; T61.782A,D,S; T61.8X2A,D,S; T61.92XA,D,S; T62.0X2A,D,S; T62.1X2A,D,S; T62.2X2A,D,S; T62.8X2A,D,S; T62.92XA,D,S; T63.002A,D,S; T63.012A,D,S; T63.022A,D,S; T63.032A,D,S; T63.042A,D,S; T63.062A,D,S; T63.072A,D,S; T63.082A,D,S; T63.092A,D,S; T63.112A,D,S; T63.122A,D,S; T63.192A,D,S; T63.2X2A,D,S; T63.302A,D,S; T63.312A,D,S; T63.322A,D,S; T63.332A,D,S; T63.392A,D,S; T63.412A,D,S; T63.422A,D,S; T63.432A,D,S; T63.442A,D,S; T63.452A,D,S; T63.462A,D,S; T63.482A,D,S; T63.512A,D,S; T63.592A,D,S; T63.612A,D,S; T63.622A,D,S; T63.632A,D,S; T63.692A,D,S; T63.712A,D,S; T63.792A,D,S; T63.812A,D,S; T63.822A,D,S; T63.832A,D,S; T63.892A,D,S; T63.92XA,D,S; T64.02XA,D,S; T64.82XA,D,S; T65.0X2A,D,S; T65.1X2A,D,S; T65.212A,D,S; T65.222A,D,S; T65.292A,D,S; T65.3X2A,D,S; T65.4X2A,D,S; T65.5X2A,D,S; T65.6X2A,D,S; T65.812A,D,S; T65.822A,D,S; T65.832A,D,S; T65.892A,D,S;

		T65.92XA,D,S; T71.112A,D,S; T71.122A,D,S; T71.132A,D,S; T71.152A,D,S; T71.162A,D,S; T71.192A,D,S; T71.222A,D,S; T71.232A,D,S; X71.0XXA,D,S; X71.1XXA,D,S; X71.2XXA,D,S; X71.3XXA,D,S; X71.8XXA,D,S; X71.9XXA,D,S; X72.XXXA,D,S; X73.0XXA,D,S; X73.1XXA,D,S; X73.2XXA,D,S; X73.8XXA,D,S; X73.9XXA,D,S; X74.01XA,D,S; X74.02XA,D,S; X74.09XA,D,S; X74.8XXA,D,S; X74.9XXA,D,S; X75.XXXA,D,S; X76.XXXA,D,S; X77.0XXA,D,S; X77.1XXA,D,S; X77.2XXA,D,S; X77.3XXA,D,S; X77.8XXA,D,S; X77.9XXA,D,S; X78.0XXA,D,S; X78.1XXA,D,S; X78.2XXA,D,S; X78.8XXA,D,S; X78.9XXA,D,S; X79.XXXA,D,S; X80.XXXA,D,S; X81.0XXA,D,S; X81.1XXA,D,S; X81.8XXA,D,S; X82.0XXA,D,S; X82.1XXA,D,S; X82.2XXA,D,S; X82.8XXA,D,S; X83.0XXA,D,S; X83.1XXA,D,S; X83.2XXA,D,S; X83.8XXA,D,S

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_1_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1_____
	5b	Name and contact information for the trial sponsor	_7_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_2_____
	6b	Explanation for choice of comparators	_____
Objectives	7	Specific objectives or hypotheses	_4_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_3-4_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_2-3_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_5_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_4-5_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_5-6_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_Figure 3_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_6_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_5_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_5_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_5_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_5_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_5_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_6_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_6_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_6-7_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_6-7_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_7_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_7_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

The Effectiveness of Policy and Risk Targeting for Opioid-Related Risk Mitigation: A Randomized Program Evaluation

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Addiction, Mental health, Research methods
Keywords:	randomized program evaluation, opioids, united states veterans administration

Title: The Effectiveness of Policy and Risk Targeting for Opioid-Related Risk Mitigation: A Randomized Program Evaluation

Authors: Taeko Minegishi, MS[1-2], Melissa M. Garrido, PhD[1,3-4], Steven D. Pizer, PhD[1,5], Austin B. Frakt, PhD[1,5-6]

Corresponding Author: Taeko Minegishi, 150 S. Huntington Avenue, 152H, Boston, MA, 02130. E-mail: taeko.minegishi@va.gov. Phone: 857-364-6065. Fax: 857-364-2259

Author affiliations:
1. Partnered Evidence-based Policy Resource Center, VA Boston Healthcare System, Boston, MA, USA
2. Bouvé College of Health Sciences, Northeastern University, Boston, MA, USA
3. Geriatrics Research, Education, and Clinical Center, James J Peters VA Medical Center, Bronx, NY, USA
4. Brookdale Department of Geriatrics and Palliative Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, USA
5. Department of Health Law, Policy & Management, Boston University of Public Health, Boston, MA, USA
6. Department of Health Policy and Management, Harvard T.H. Chan School of Public Health, Cambridge, MA, USA

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Word count: 2895

Abstract

Introduction: There is an epidemic of opioid use related adverse events and deaths in the United States. The rates of chronic pain, mental illness, and substance use disorder are higher at the Veterans Health Administration (VHA) compared to the general U.S. population. The 2016 Comprehensive Addiction and Recovery Act (CARA) requires the VHA to improve opioid therapy strategies in treating patients and to ensure responsible prescribing practices. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prioritizes review of VHA patients receiving opioids based on their risk. The VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk.

Methods and analysis: This stepped-wedge cluster randomized controlled trial will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related serious adverse events (SAEs), relative to facilities not randomized to facilitation, and 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed. Patients who receive an opioid prescription at VHA medical centers will be followed for a minimum of 3 months after their first opioid prescription. Follow-up will continue until the last day of the project or death. The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions.

Ethics and dissemination: Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069; Approval: March 27, 2017).

Findings will be published in peer-reviewed journals and presentations at national conference meetings.

Trial registration number: ISRCTN16012111 (http://www.isrctn.com/ISRCTN16012111). Registered May 25, 2017.

Strength and limitations of this study

- Randomized program evaluation reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget.
- The stepped wedge design evaluates aspects of the VHA policy and a web-based dashboard to identify risk factors and risk mitigation strategies for patients with an opioid prescription.
- This study will only include Veterans Health Administration (VHA) patients and exclude patients with opioid use disorder.

Introduction

Opioid overdose deaths reached 33,000 in 2015, an increase of about 16% from the prior year, and are the leading cause of injury death in the United States (1). The supply of opioid prescriptions remains high in the United States, with nearly 250 million opioid prescriptions written in 2013 or about one prescription per American adult (2). These statistics underlie the Centers for Disease Control and Prevention's (CDC's) characterization of opioid use related adverse events and deaths as an epidemic in the United States. The epidemic is potentially more acute in the Veterans Health Administration (VHA) patient population, which has higher rates of chronic pain, mental illness, and substance use disorder compared to the general U.S. population (3–5). In particular, the prevalence of opioid use disorder in the VHA is approximately seven times higher than it is in commercial health plans (6).

The epidemic in the U.S. in general, and in the VHA population in particular, has captured the attention of policymakers. For instance, the 2016 Comprehensive Addiction and Recovery Act (Pub.L.No. 114-198; CARA) outlines a coordinated effort to confront opioid mis- and over-use through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. In particular, CARA requires the VHA to improve opioid therapy strategies in treating patients, and to ensure responsible prescribing practices (Subtitle A Sec 911).

The VHA Office of Mental Health and Suicide Prevention (OMHSP; formerly Office of Mental Health Operations) developed a tool that is responsive to the CARA requirement that VHA opioid prescribers review existing adverse event risk characteristics for each patient before prescribing. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prospectively prioritizes review of VHA patients receiving opioids based on their risk for overdose-, accident-, or suicide-related events (collectively, serious adverse events or SAEs). The risk prioritization is determined by a predictive model based on the association of patient characteristics (e.g., age, race, prior history of mental illness) and opioid prescription with opioid-related SAEs (7). Designed to be easily incorporated into clinical practice, VHA clinicians can use STORM to identify risk factors and risk mitigation strategies potentially relevant for each patient.

Although STORM has gone through validation and usability testing, more evidence is needed to guide its use. Validation and usability reviews indicate that the STORM dashboard is an acceptable and efficient method of reviewing patient-specific risk information (Oliva et al., 2017). User feedback indicated high face-validity for the patients STORM identifies as high risk and appropriate for intensive monitoring. It also indicated that the STORM dashboard can reduce the time required to review risk factors, assist with monitoring and systematic use of risk mitigation strategies, and improve awareness of the care patients are receiving across providers and care settings. However, the impact of identifying patient risk through STORM on opioid related SAEs has not been rigorously evaluated. In addition, it is unclear how to best convey the CARA mandates to providers and ensure case-review of patients identified by STORM.

Therefore, the VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk. In the following sections, we describe the STORM dashboard and the design of a cluster randomized trial to evaluate the effect of an expanded risk threshold and variations in policy language on time to opioid related SAEs. This timely, randomized evaluation of STORM reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget (8).

STORM Dashboard and Implementation

On any given day, approximately 400,000 to 500,000 VHA patients have active prescriptions for opioids. Patients' information will be displayed in the STORM dashboard until their prescription expires. For credentialed users (including VHA prescribers), the dashboard automatically sorts patients at their medical centers in descending order of predicted SAE risk. In this evaluation, we focus on patients prescribed an opioid who are in the top 5% of risk scores. Predicted risk is a function of demographics, comorbidities, prior history of mental illness and substance use disorders, and opioid prescription data. The dashboard also provides clinicians with a list of evidence-based clinical recommendations for risk mitigation, such as drug screening tests, bowel regimens, and treatment alternatives to opioid prescription. Once a clinician reviews a case, the dashboard records and saves case review notes and dates of review. The dashboard compactly displays a patient's name, age and gender, patient risk level classification (low, medium, high, or very high risk), diagnoses and medications that are relevant to opioid risk, and risk mitigation strategies and non-pharmacological pain treatment recommendations (Figure 1). In addition, to facilitate care coordination, recent and upcoming appointments and patient care provider names are listed.

In the near future, VHA Central Office will release a policy memo mandating that VHA clinicians conduct case reviews and identify appropriate risk mitigation approaches for patients with opioid prescriptions who are identified by STORM as having a very high risk of SAEs. Differences in the memo's key messages for the treatment and control groups are displayed in Table 1.

Table 1 The Policy Memo Language for the Treatment and Control Group

Policy Memo Language	Treatment	Control
Metric	Numerator: Patients with case review within the last 4 quarters. Denominator: Patients with an opioid prescription who are in the "Very High – Opioid Patients" risk category in STORM for at least 7 days in the last quarter.	
Monitoring	The STORM implementation team will review completion rates at the end of each quarter and notify facility point(s) of contact of their completion rate.	
Implementation	• Facilities with scores at or above 97% on this metric are considered fully implemented. • Lack of implementation will trigger technical assistance and action planning starting in FY18Q4.	Facilities are expected to achieve scores at or above 97% by the end of FY18Q3.
Oversight and Facilitation	• If the facility fails to meet the targeted rate for completing case reviews by the end of FY18Q3 the STORM implementation team will notify the facility point(s) of contact. • The goal of reviewing these patients will be added to the facility's existing improvement goals. • The facility point(s) of contact must then report quarterly on progress toward executing an action plan to meet the metric.	None

Randomized Program Evaluation of STORM

Despite the benefits of randomized controlled trials, US health care policies and programs are rarely tested with randomized designs (9). As a result, there is little evidence-based guidance for writing effective policy memos. The US Government Accountability Office has identified limitations in VHA policy memos, including a lack of clearly articulated accountability (10). Improving this aspect of VHA policy memos is a high priority. Therefore, two versions of the policy memo have been prepared; half of the medical centers will receive a version that states that if fewer than 97 percent of their cases are reviewed, facilitation, which includes technical assistance and action planning, will be provided to help them increase their case review rate; the other half will receive a memo that only states that case reviews are mandated. Sites that are required to develop action plans must:1) add the metric (i.e. >97% review of very high risk patients) to their existing improvement goals and 2) submit quarterly reports detailing progress toward executing an action plan to meet the metric.. To our knowledge, no prior study has compared the effects of alternative accountability approaches in policy documents on uptake of delivery system innovations.

In addition to randomizing medical centers to different versions of the policy memo, we will rigorously evaluate the effect of the STORM dashboard on patient outcomes. To do this, we will use a randomized stepped wedge design (described in detail below) to create two cohorts of patients in a similar risk group, one for which case review is required (treatment) and another for which it is not (control). This risk group will be created by expanding the threshold for very high risk from 1% to 5%.

Hypotheses

We will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related SAEs, relative to facilities not randomized to facilitation. 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed.

Methods

Intervention 1: Effectiveness of VHA Policy

According to the policy memo, VHA medical centers are required to review the cases of very high risk patients. Half of facilities (randomly assigned) will be asked to complete an action plan and receive additional oversight and facilitation from OMHSP if at least 97% of cases are not reviewed (the policy treatment group). Facilities that fail to meet the targeted rate for completing case reviews of very high risk patients will be tasked to review these patients and report quarterly to the OMHSP on progress toward executing an action plan to meet the metric. The other half of VHA medical centers will receive a version of the memo without any mention of action plans, oversight, or facilitation (the policy control group).

Intervention 2: Effectiveness of STORM

Within the policy treatment and control groups, separately, the definition of very high risk patients will be altered over time in a stepped wedge manner. This will allow us to evaluate the effect of being targeted for case review by STORM. For the first 8 months, all medical centers will be required to conduct case reviews for patients in the top 1% of risk for an SAE. At baseline, patients with risk scores between 1% and 5% are not displayed in STORM (control group). At month 9,, half of the policy treatment and half of the policy control facilities will be randomly assigned to review patients identified as high risk under an expanded risk threshold (up to 5%). At month 15, all facilities will be required to review patients in the top 5% of risk. This stepped wedge design creates a cohort of patients who have opioid prescriptions and are between the top 1% and top 5% of SAE risk. Half of these patients will have mandated case review (the STORM treatment group) and half will receive usual care (the STORM control group). Figure 2 presents the two interventions and timeline.

Randomization and Blinding

Randomization was conducted in two steps, using permuted block randomization. Permuted block randomization allowed us to create groups with an even number of facilities. First, the 140 VHA medical centers were split into two groups with 70 medical centers each in the policy treatment and policy control groups. Then, to apply the stepped wedge design for analysis of STORM treatment vs control, the 70 medical centers in each group were split into two groups of 35 hospitals using permuted block randomization. The STORM dashboard will label patients as “very high risk” using the respective risk score cut-offs (top 1% and top 5%) at each VHA medical center. The risk scores will not be displayed, and providers will be blinded to changes in the risk score threshold that defines “very high risk”.

Recruitment/Eligibility Criteria/Participant Timeline

Our analytic cohort will include approximately 100,000 VHA patients with an opioid prescription in the top 10% of risk scores. Patients are eligible for inclusion in the study cohort for the first 18 months of the study. If a patient has an active opioid prescription on the day the policy memo is released and has a risk score in the top 10% of risk, he or she will automatically enter the study. Other patients will enter the cohort on the date of their first prescription that exceeds the 10% risk threshold. Patients will be followed for a minimum of 3 months after they are first prescribed an opioid. Follow-up will continue until the last day of the project (September 30, 2019) or date of death. Our primary analyses of the effect of policy language will focus on patients in the top 1% of risk, and our primary analyses of the effect of STORM will be focused on patients between the top 5% and top 1% of risk scores. Over the course of this study, we anticipate over 50,000 patients will have risk scores in the top 5% of risk.

Outcome Measures and Control Variables

Our primary outcome of interest is opioid-related SAEs (e.g., opioid overdose, accidental falls, and possible and confirmed suicide attempts, etc. [See Supplementary A for ICD-9 and -10 codes]). The outcome measure is censored by death or end of study. The STORM risk score that a patient receives when he or she first enters the study (baseline risk score) will be used as a control variable, since it reflects the probability that the patient will have an opioid-related SAE outcome. The risk score also captures the risk associated with general demographic characteristics (i.e. age, race, gender) and comorbidities (i.e. prior and current history of disease). In addition, facility indicators and time in study (indicators for current and past months) will be used as control variables.

Although case review is mandated, it is unlikely that all providers will review all identified cases. In addition, the risk mitigation strategies suggested in the STORM dashboard are optional. If lower SAE rates in treatment facilities are achieved, this could be due to higher case review rates or to greater use of risk mitigation strategies. That is, the case review rate acts as a mediator of the relationship between risk identification and opioid-related SAEs. In addition, risk mitigation strategies are intended to reduce risk of adverse outcomes. Thus, the SAE rates should be lower if risk mitigation strategies are more frequently implemented. We will test whether facility level rates of case review and patient level risk mitigation strategies implemented are mediators of the primary outcome.

Data Collection and Management

STORM risk scores are calculated and updated on a daily basis. Upon a patient's entry into the study cohort (i.e. at the date of the first opioid prescription on or after the release of the policy memo), his or her risk score will be recorded. VHA has a centralized corporate data warehouse (CDW) where all patient data, including demographics, appointments, visits, diagnoses, and prescriptions are stored. From these data, any opioid-related SAEs for study patients will be identified. The case review notes and case review date, along with risk mitigation strategies implemented for each patient, will also be collected in CDW.

Sample Size/Power Calculation

Sample size was calculated using the data that informed the original STORM model (7). That dataset included 1,135,600 patients with an opioid prescription from VHA anytime in 2010.

The sample size calculation for the effectiveness of policy was completed using a baseline SAE rate of 0.029 per person-month for the policy control group, 140 medical centers with an average of 2,112 patient-months, and an intraclass correlation coefficient (ICC) of 0.01 in Stata's *clustersampsi* function (11). For the effectiveness of STORM, Stata's *steppedwedge* function was used to account for the changes in medical centers and patients included in the treatment group over time (12). To calculate sample size, we used an expected baseline SAE rate of 0.01 per person-month for the STORM control group with an average of 352 patients per medical center in the 1-5% risk group, and we assumed an ICC of 0.01.

Based on these baseline rates, with an alpha of 0.05, we can detect a difference between the policy treatment and control groups of 28% (i.e., a SAE rate difference at least as large as 0.037 or at least as small as 0.021) with 80% power. The evaluation can also detect a difference of 15% between the STORM treatment and control groups with 80% power (i.e., an SAE rate difference at least as large as 0.012 or at least as small as 0.009).

Statistical Analysis

The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions: 1) effectiveness of policy, and 2) effectiveness of STORM. For the effectiveness of policy analysis, a patient-level time-to-event Cox proportional hazards model will be used to evaluate the difference between facilities with and without facilitation language in the memo, controlling for the different targeted risk group at different times and facility fixed effects. Similarly, for the effectiveness of STORM analysis, the primary outcome will be modeled with a patient level time-to-event Cox proportional hazards model to evaluate the difference between the STORM treatment and control groups, controlling for difference in policy, and facility fixed effects. We will estimate the effect of the intervention during a single month as well as the cumulative effect of the intervention. In order to account for diminishing returns of additional months of exposure to time in STORM, we estimate separate effects for one month before treatment, two months before treatment, and so on.

Equations 1 and 2 represent the planned analyses for effectiveness of policy and effectiveness of STORM, respectively.

$$Outcome_{itk} = intercept + \propto_i + \beta_t + P_i\gamma + x_k\Phi + \varepsilon_{itk} \quad (1)$$

$$Outcome_{itk} = intercept + \propto_i + \beta_t + P_i\gamma + R_{it}\theta_t + R_{it-1}\theta_{-1} + R_{it-2}\theta_{-2} + \cdots + R_{it-n}\theta_{-n} + x_k\Phi + \varepsilon_{itk} \quad (2)$$

In these equations, i represents medical centers, t is time points (i.e. months), n is months before month t, and k is individuals. In addition, $\propto$ is a random medical center effect, β is a vector of fixed time effects, P is a policy indicator (P=1 if policy treatment medical center, 0 if policy control medical center), γ is a fixed effect for policy, R is a risk targeting indicator (1 if patient in the 1%-5% risk stratum in the treatment medical center i at time t, 0 otherwise), $\theta_t$is a fixed risk targeting effect at time t, θ_{-n} represents lagged risk targeting effects from targeting at time $t-n$, x_k represents baseline covariates, Φ represents fixed effects for baseline covariates, and ε is residual error. In Equation 1, we are interested in estimates of γ, the policy treatment effect. In Equation 2, we are interested in estimates of θ, the risk targeting effect at month t, as well as in estimates of $\theta + \theta_{-1} + \theta_{-n}$, the cumulative effect of months of risk targeting experienced prior to and including month t.

A statistically significant difference between the two policy groups (γ) suggests that the threat of facilitation modifies VHA providers' behavior to increase surveillance on very high risk

opioid prescribed patients and to apply SAE risk mitigation strategies. A statistically significant effect of the STORM treatment group (θ) indicates that when opioid prescribed patients are required to be case reviewed, they are less likely to experience opioid-related SAEs.

Our intent-to-treat analysis assumes that patients' risk scores are relatively stable over the study period, and that baseline risk closely approximates the risk level of a patient at the time their facility is randomized to target an expanded risk threshold. However, it is possible that risk scores may change over time for patients who receive long-term opioid therapy and/or frequent short-term opioid therapy. Risk scores at baseline may simultaneously predict prospective risk scores, likelihood of exposure to the intervention, and risk of SAEs. In addition, a patient's risk score at a given month may be affected by the version of policy or level of risk threshold in place at a facility in previous months. To account for this potential endogeneity, we plan to conduct a secondary survival analysis that treats the facility treatment indicator and interaction between baseline risk score and facility treatment as instrumental variables.

We will conduct a sensitivity analysis to evaluate the effect of facilitation during the study period on the policy treatment group. The time when each medical center is notified that they failed to meet the targeted case review rate will be tracked and the cohort will be stratified into three groups: policy control, policy treatment with facilitation, and policy treatment without facilitation. A statistically significant effect of treatment with facilitation compared to treatment without facilitation indicates facilitation may lead to greater reduction in patients' risk of opioid-related SAEs. We also will evaluate whether the effect of the threat of but not actual facilitation is associated with reduced risk of opioid-related SAEs.

Ethics and Dissemination

Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069; approval date: 3/27/17). Randomized roll-out of STORM to medical centers is occurring as part of the OMHSP's activities and does not require IRB approval. This trial has been registered at ISRCTN (http://www.isrctn.com/ISRCTN16012111). In addition, our partner at the VHA Center for Health Equity Research and Promotion is conducting a complementary evaluation to identify strategies used to implement STORM across the two policy groups as well as barriers and facilitators to STORM implementation (https://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141704557).

PEPReC's protocol has been presented at the 2017 AcademyHealth National Health Policy Conference and a VHA cyberseminar. We are submitting abstracts about this protocol and randomized program evaluations to other national conferences. Once the study is completed, the following two papers will be prepared and submitted to peer-reviewed journals; 1) Reduction of opioid-related serious adverse events (SAEs) in VHA medical centers with and without facilitation, and 2) Effect of identification of high risk patients via the STORM dashboard on opioid-related serious adverse events (SAEs). Beyond providing rigorous evidence of the impact of STORM on patient outcomes, this study will provide insight to OMHSP and VHA leadership about how to optimize the STORM dashboard to reduce SAEs among high risk patients.

Contributors: SP and AF conceived the idea for the study. TM, MG, SP, and AF contributed to the study design, randomization, and analysis plan. TM wrote the first draft. AF and MG were involved in multiple revisions. The final version of the manuscript was approved by all co-authors.

Competing Interests: None

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Data sharing statement: Public disclosure of Veterans Health Administration data containing personally identifiable information is not allowed. No additional data available.

Figure 1 Mock-up of STORM dashboard
Figure 2 Project timeline

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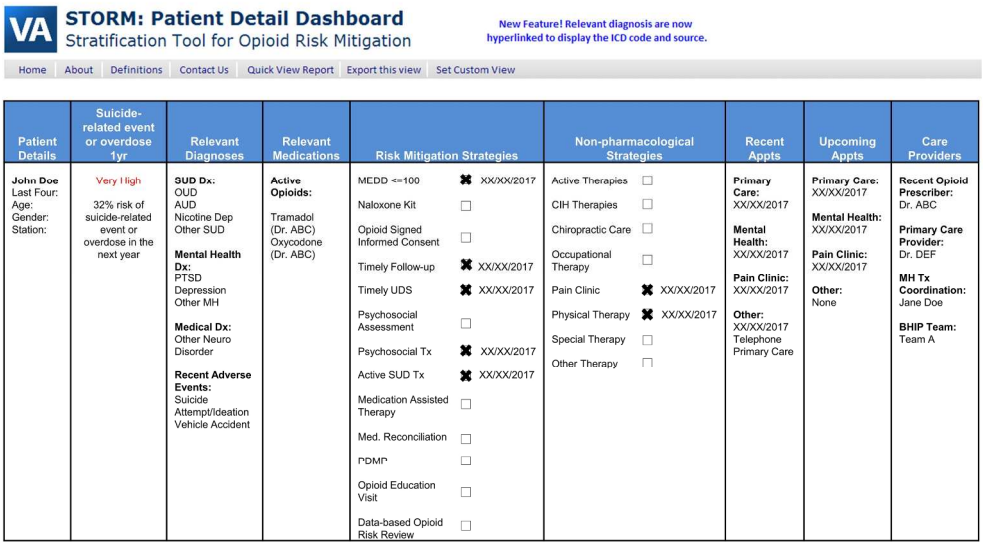

Figure 1 Mock-up of STORM dashboard

122x69mm (600 x 600 DPI)

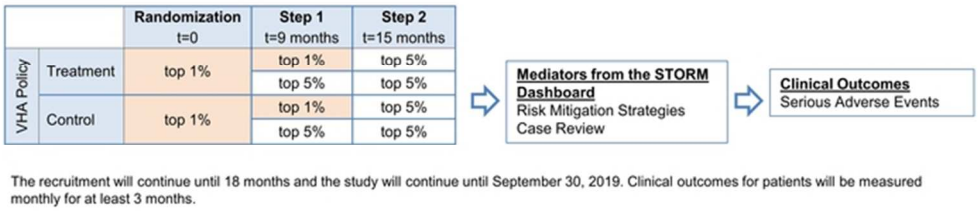

Figure 2 Project timeline

59x14mm (300 x 300 DPI)

Supplemental A ICD9/10 Code for Opioid-Related Serious Adverse Events (SAEs)

Serious Adverse Events	ICD9	ICD10
Involving acetaminophen	965.4; 967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E850.4; E851.; E852.0,.1,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E935.4; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.3	T39.1X1A,D,S; T39.1X2A,D,S; T39.1X3A,D,S; T39.1X4A,D,S; T39.1X5A,D,S; T39.8X1A,D,S; T39.8X2A,D,S; T39.8X3A,D,S; T39.8X4A,D,S; T39.8X5A,D,S; T39.91XA,D,S; T39.92XA,D,S; T39.93XA,D,S; T39.94XA,D,S; T39.95XA,D,S;
Opioid overdose	965.00,01,02,09; E850.0,.1,.2; E935.0,.1,.2; E908.0	T40.0X1A,D.S; T40.0X2A,D,S; T40.0X3A,D,S; T40.0X4A,D,S; T40.0X5A,D,S; T40.1X1A,D,S; T40.1X2A,D,S; T40.1X3A,D,S; T40.1X4A,D,S; T40.2X1A,D,S; T40.2X2A,D,S; T40.2X3A,D,S; T40.2X4A,D,S; T40.2X5A,D,S; T40.3X1A,D,S; T40.3X2A,D,S; T40.3X3A,D,S; T40.3X4A,D,S; T40.3X5A,D,S; T40.4X1A,D,S; T40.4X2A,D,S; T40.4X3A,D,S; T40.4X4A,D,S; T40.4X5A,D,S; T40.601A,D,S; T40.602A,D,S; T40.603A,D,S; T40.604A,D,S; T40.605A,D,S; T40.691A,D,S; T40.692A,D,S; T40.693A,D,S; T40.694A,D,S; T40.695A,D,S
Other drug poisoning	965.1,.6,.61,.69; 969.01,.02,.03,.04,.05, .09,.6,.72; 970.1; E850.3; E854.0,.1,.3; E855.0,.1,.2,.3,.4,.5,.6, .8,.9; E935.3,.6; E939.0,.6,.7; E940.1; E980.4,.5	T40.7X1A,D,S; T40.7X2A,D,S; T40.7X3A,D,S; T40.7X4A,D,S; T40.7X5A,D,S; T40.8X1A,D,S; T40.8X2A,D,S; T40.8X3A,D,S; T40.8X4A,D,S T44.901A,D,S; T44.902A,D,S; T44.903A,D,S; T44.904A,D,S; T44.991A,D,S; T44.992A,D,S; T44.993A,D,S; T44.994A,D,S; T44.995A,D,S; T50.7X1A,D,S; T50.7X2A,D,S; T50.7X3A,D,S; T50.7X4A,D,S; T50.7X5A,D,S
Falls	E880.0,.1,.9; E881.0,.1; E882.; E883.0,.1,.2,.9; E884.0,.1,.2,.3,.4,.5,.6, .9; E885.,.0,.1,.2,.3,.4,.9; E886.0,.9; E887.; E888.,.0,.1,.8,.9; E929.3;	R29.6; W00.0XXA,D,S; W00.1XXA,D,S; W00.2XXA,D,S; W00.9XXA,D,S; W01.0XXA,D,S; W01.10XXA,D,S; W01.110XXA,D,S; W01.111XXA,D,S; W01.118XXA,D,S; W01.119XXA,D,S; W01.190XXA,D,S; W01.198XXA,D,S; W03.XXXA,D,S; W04.XXXA,D,S; W05.0XXA,D,S; W05.1XXA,D,S; W05.2XXA,D,S; W06.XXXA,D,S; W07.XXXA,D,S; W08.XXXA,D,S; W09.0XXA,D,S; W09.1XXA,D,S; W09.2XXA,D,S; W09.8XXA,D,S; W10.0XXA,D,S; W10.1XXA,D,S; W10.2XXA,D,S; W10.8XXA,D,S; W10.9XXA,D,S; W11.XXXA,D,S; W12.XXXA,D,S; W13.0XXA,D,S; W13.1XXA,D,S; W13.2XXA,D,S; W13.3XXA,D,S; W13.4XXA,D,S; W13.8XXA,D,S; W13.9XXA,D,S; W14.XXXA,D,S; W15.XXXA,D,S; W16.011A,D,S; W16.012A,D,S; W16.021A,D,S; W16.022A,D,S; W16.031A,D,S; W16.032A,D,S; W16.111A,D,S; W16.112A,D,S; W16.121A,D,S; W16.122A,D,S; W16.131A,D,S; W16.132A,D,S;

	E987.0,.1,.2,.9	W16.211A,D,S; W16.212A,D,S; W16.221A,D,S; W16.222A,D,S; W16.311A,D,S; W16.312A,D,S; W16.322A,D,S; W16.331A,D,S; W16.332A,D,S; W16.41XA,D,S; W16.42XA,D,S; W16.511A,D,S; W16.512A,D,S; W16.521A,D,S; W16.522A,D,S; W16.531A,D,S; W16.532A,D,S; W16.611A,D,S; W16.612A,D,S; W16.621A,D,S; W16.622A,D,S; W16.711A,D,S; W16.712A,D,S; W16.721A,D,S; W16.722A,D,S;W16.811A,D,S; W16.812A,D,S; W16.821A,D,S; W16.822A,D,S; W16.831A,D,S; W16.832A,D,S; W16.91XA,D,S; W16.92XA,D,S; W17.0XXA,D,S; W17.1XXA,D,S; W17.2XXA,D,S; W17.3XXA,D,S; W17.4XXA,D,S; W17.81XA,D,S; W17.82XA,D,S; W17.89XA,D,S; W18.00XA,D,S; W18.01XA,D,S; W18.02XA,D,S; W18.09XA,D,S; W18.11XA,D,S; W18.12XA,D,S; W18.2XXA,D,S; W18.30XA,D,S; W18.31XA,D,S; W18.39XA,D,S; W18.40XA,D,S; W18.41XA,D,S; W18.42XA,D,S; W18.43XA,D,S; W18.49XA,D,S; W19.XXXA,D,S; X00.3XXA,D,S; X01.3XXA,D,S; X02.3XXA,D,S; X03.3XXA,D,S
Vehicle	E800.1,.2,.3,.8,.9; E801.0,.1,.2,.3,.8,.9; E802.0,.1,.2,.3,.8,.9; E803.0,.1,.2,.3,.8,.9; E804.0,.1,.2,.3,.8,.9; E805.0,.1,.2,.3,.8,.9; E806.0,.1,.2,.3,.8,.9; E807.0,.1,.2,.3,.8,.9, E810.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E811.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E812.0,.1,.2,.3,.4,.5,.6, .7,.8,.9 E813.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E814.0,.1,.2,.3,.4,.5,.6, .7..8,.9; E815.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E816.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E817.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E818.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E819.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E820.0,.1,.2,.3,.4,.5,.6,	V00.01XA,D,S; V00.02XA,D,S; V00.09XA,D,S; V00.111A,D,S; V00.112A,D,S; V00.118A,D,S; V00.121A,D,S; V00.122A,D,S; V00.128A,D,S; V00.131A,D,S; V00.132A,D,S; V00.138A,D,S; V00.141A,D,S; V00.142A,D,S; V00.148A,D,S; V00.151A,D,S; V00.152A,D,S; V00.158A,D,S; V00.181A,D,S; V00.182A,D,S; V00.188A,D,S; V00.211A,D,S; V00.212A,D,S; V00.218A,D,S; V00.221A,D,S; V00.212A,D,S; V00.228A,D,S; V00.281A,D,S; V00.282A,D,S; V00.288A,D,S; V00.311A,D,S; V00.312A,D,S; V00.318A,D,S; V00.321A,D,S; V00.322A,D,S; V00.328A,D,S; V00.381A,D,S; V00.382A,D,S; V00.388A,D,S; V00.811A,D,S; V00.812A,D,S; V00.818A,D,S; V00.821A,D,S; V00.822A,D,S; V00.828A,D,S; V00.831A,D,S; V00.832A,D,S; V00.838A,D,S; V00.891A,D,S; V00.892A,D,S; V00.898A,D,S; V01.00XA,D,S; V01.01XA,D,S; V01.02XA,D,S; V01.09XA,D,S; V01.10XA,D,S; V01.11XA,D,S; V01.12XA,D,S; V01.19XA,D,S; V01.90XA,D,S; V01.91XA,D,S; V01.92XA,D,S; V01.99XA,D,S; V02.00XA,D,S; V02.01XA,D,S; V02.02XA,D,S; V02.09XA,D,S; V02.10XA,D,S; V02.11XA,D,S; V02.12XA,D,S; V02.19XA,D,S; V02.90XA,D,S; V02.91XA,D,S; V02.92XA,D,S; V02.99XA,D,S; V03.00XA,D,S; V03.01XA,D,S; V03.02XA,D,S; V03.09XA,D,S; V03.10XA,D,S; V03.11XA,D,S; V03.12XA,D,S; V03.19XA,D,S; V03.90XA,D,S; V03.91XA,D,S; V03.92XA,D,S; V03.99XA,D,S; V04.00XA,D,S; V04.01XA,D,S; V04.02XA,D,S; V04.09XA,D,S; V04.10XA,D,S; V04.11XA,D,S; V04.12XA,D,S; V04.19XA,D,S; V04.90XA,D,S; V04.91XA,D,S; V04.92XA,D,S; V04.99XA,D,S; V05.00XA,D,S; V05.01XA,D,S; V05.02XA,D,S; V05.09XA,D,S; V05.10XA,D,S; V05.11XA,D,S; V05.12XA,D,S; V05.19XA,D,S; V05.90XA,D,S; V05.91XA,D,S; V05.92XA,D,S; V05.99XA,D,S; ; V06.00XA,D,S; V06.01XA,D,S; V06.02XA,D,S; V06.09XA,D,S; V06.10XA,D,S; V06.11XA,D,S; V06.12XA,D,S; V06.19XA,D,S; V06.90XA,D,S; V06.91XA,D,S; V06.92XA,D,S; V06.99XA,D,S; ; V09.00XA,D,S; V09.01XA,D,S; V09.02XA,D,S; V09.09XA,D,S; V09.1XXA,D,S; V09.20XA,D,S; V09.21XA,D,S; V09.29XA,D,S; V09.3XXA,D,S; V09.9XXA,D,S; V10.0XXA,D,S; V10.1XXA,D,S; V10.2XXA,D,S;V10.3XXA,D,S; V10.4XXA,D,S; V10.5XXA,D,S; V10.9XXA,D,S; V11.0XXA,D,S; V11.1XXA,D,S; V11.2XXA,D,S; V11.3XXA,D,S; V11.4XXA,D,S; V11.5XXA,D,S; V11.9XXA,D,S; V12.0XXA,D,S; V12.1XXA,D,S; V12.2XXA,D,S; V12.3XXA,D,S; V12.4XXA,D,S; V12.5XXA,D,S; V12.9XXA,D,S; V13.0XXA,D,S; V13.1XXA,D,S; V13.2XXA,D,S; V13.3XXA,D,S; V13.4XXA,D,S; V13.5XXA,D,S; V13.9XXA,D,S; V14.0XXA,D,S; V14.1XXA,D,S; V14.2XXA,D,S; V14.3XXA,D,S; V14.4XXA,D,S; V14.5XXA,D,S; V14.9XXA,D,S; V15.0XXA,D,S; V15.1XXA,D,S; V15.2XXA,D,S; V15.3XXA,D,S; V15.4XXA,D,S; V15.5XXA,D,S;

	.7,.8,.9; E821.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E822.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E823.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E824.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E825.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E826.0,.1,.2,.3,.4,.8,.9; E827.0,.2,.3,.4,.8,.9; E828.0,.2,.4,.8,.9; E829.0,.4,.8,.9; E830.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E831.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E832.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E833.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E834.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E835.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E836.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E837.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E838.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E840.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E841.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E842.6,.7,.8,.9; E843.0,.1,.2,.3,.4,.5,.6, .7,.8,.9;	V15.9XXA,D,S; V16.0XXA,D,S; V16.1XXA,D,S; V16.2XXA,D,S; V16.3XXA,D,S; V16.4XXA,D,S; V16.5XXA,D,S; V16.9XXA,D,S; V17.0XXA,D,S; V17.1XXA,D,S; V17.2XXA,D,S; V17.3XXA,D,S; V17.4XXA,D,S; V17.5XXA,D,S; V17.9XXA,D,S; V18.0XXA,D,S; V18.1XXA,D,S; V18.2XXA,D,S; V18.3XXA,D,S; V18.4XXA,D,S; V18.5XXA,D,S; V18.9XXA,D,S; V19.00XA,D,S; V19.09XA,D,S; V19.10XA,D,S; V19.19XA,D,S; V19.20XA,D,S; V19.29XA,D,S; V19.3XXA,D,S; V19.40XA,D,S; V19.49XA,D,S; V19.50XA,D,S; V19.59XA,D,S; V19.60XA,D,S; V19.69XA,D,S; V19.81XA,D,S; V19.88XA,D,S; V19.9XXA,D,S; V20.0XXA,D,S; V20.1XXA,D,S; V20.2XXA,D,S; V20.3XXA,D,S; V20.4XXA,D,S; V20.5XXA,D,S; V20.9XXA,D,S; V21.0XXA,D,S; V21.1XXA,D,S; V21.2XXA,D,S; V21.3XXA,D,S; V21.4XXA,D,S; V21.5XXA,D,S; V21.9XXA,D,S; V22.0XXA,D,S; V22.1XXA,D,S; V22.2XXA,D,S; V22.3XXA,D,S; V22.4XXA,D,S; V22.5XXA,D,S; V22.9XXA,D,S; V23.0XXA,D,S; V23.1XXA,D,S; V23.2XXA,D,S; V23.3XXA,D,S; V23.4XXA,D,S; V23.5XXA,D,S; V23.9XXA,D,S; V24.0XXA,D,S; V24.1XXA,D,S; V24.2XXA,D,S; V24.3XXA,D,S; V24.4XXA,D,S; V24.5XXA,D,S; V24.9XXA,D,S; V25.0XXA,D,S; V25.1XXA,D,S; V25.2XXA,D,S; V25.3XXA,D,S; V25.4XXA,D,S; V25.5XXA,D,S; V25.9XXA,D,S; V26.0XXA,D,S; V26.1XXA,D,S; V26.2XXA,D,S; V26.3XXA,D,S; V26.4XXA,D,S; V26.5XXA,D,S; V26.9XXA,D,S; V27.0XXA,D,S; V27.1XXA,D,S; V27.2XXA,D,S; V27.3XXA,D,S; V27.4XXA,D,S; V27.5XXA,D,S; V27.9XXA,D,S; V28.0XXA,D,S; V28.1XXA,D,S; V28.2XXA,D,S; V28.3XXA,D,S; V28.4XXA,D,S; V28.5XXA,D,S; V28.9XXA,D,S; V29.00XA,D,S; V29.09XA,D,S; V29.10XA,D,S; V29.19XA,D,S; V29.20XA,D,S; V29.29XA,D,S; V29.3XXA,D,S; V29.40XA,D,S; V29.49XA,D,S; V29.50XA,D,S; V29.59XA,D,S; V29.60XA,D,S; V29.69XA,D,S; V29.81XA,D,S; V29.88XA,D,S; V29.9XXA,D,S; V30.0XXA,D,S; V30.1XXA,D,S; V30.2XXA,D,S; V30.3XXA,D,S; V30.4XXA,D,S; V30.5XXA,D,S; V30.6XXA,D,S; V30.7XXA,D,S; V30.9XXA,D,S; V31.0XXA,D,S; V31.1XXA,D,S; V31.2XXA,D,S; V31.3XXA,D,S; V31.4XXA,D,S; V31.5XXA,D,S; V31.6XXA,D,S; V31.7XXA,D,S; V31.9XXA,D,S; V32.0XXA,D,S; V32.1XXA,D,S; V32.2XXA,D,S; V32.3XXA,D,S; V32.4XXA,D,S; V32.5XXA,D,S; V32.6XXA,D,S; V32.7XXA,D,S; V32.9XXA,D,S; V33.0XXA,D,S; V33.1XXA,D,S; V33.2XXA,D,S; V33.3XXA,D,S; V33.4XXA,D,S; V33.5XXA,D,S; V33.6XXA,D,S; V33.7XXA,D,S; V33.9XXA,D,S; V34.0XXA,D,S; V34.1XXA,D,S; V34.2XXA,D,S; V34.3XXA,D,S; V34.4XXA,D,S; V34.5XXA,D,S; V34.6XXA,D,S; V34.7XXA,D,S; V34.9XXA,D,S; V35.0XXA,D,S; V35.1XXA,D,S; V35.2XXA,D,S; V35.3XXA,D,S; V35.4XXA,D,S; V35.5XXA,D,S; V35.6XXA,D,S; V35.7XXA,D,S; V35.9XXA,D,S; V36.0XXA,D,S; V36.1XXA,D,S; V36.2XXA,D,S; V36.3XXA,D,S; V36.4XXA,D,S; V36.5XXA,D,S; V36.6XXA,D,S; V36.7XXA,D,S; V36.9XXA,D,S; V37.0XXA,D,S; V37.1XXA,D,S; V37.2XXA,D,S; V37.3XXA,D,S; V37.4XXA,D,S; V37.5XXA,D,S; V37.6XXA,D,S; V37.7XXA,D,S; V37.9XXA,D,S; V38.0XXA,D,S; V38.1XXA,D,S; V38.2XXA,D,S; V38.3XXA,D,S; V38.4XXA,D,S; V38.5XXA,D,S; V38.6XXA,D,S; V38.7XXA,D,S; V38.9XXA,D,S; V39.00XA,D,S; V39.09XA,D,S; V39.10XA,D,S; V39.19XA,D,S; V39.20XA,D,S; V39.29XA,D,S; V39.3XXA,D,S; V39.40XA,D,S; V39.49XA,D,S; V39.50XA,D,S; V39.59XA,D,S; V39.60XA,D,S; V39.69XA,D,S; V39.81XA,D,S; V39.89XA,D,S; V39.9XXA,D,S; V40.0XXA,D,S; V40.1XXA,D,S; V40.2XXA,D,S; V40.3XXA,D,S; V40.4XXA,D,S; V40.5XXA,D,S; V40.6XXA,D,S; V40.7XXA,D,S; V40.9XXA,D,S; V41.0XXA,D,S; V41.1XXA,D,S; V41.2XXA,D,S; V41.3XXA,D,S; V41.4XXA,D,S; V41.5XXA,D,S; V41.6XXA,D,S; V41.7XXA,D,S; V41.9XXA,D,S; V42.0XXA,D,S; V42.1XXA,D,S; V42.2XXA,D,S; V42.3XXA,D,S; V42.4XXA,D,S; V42.5XXA,D,S; V42.6XXA,D,S; V42.7XXA,D,S;

	E844.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E845.0,.8,.9; E846.; E847.; E848.; E929.0	V42.9XXA,D,S; V43.01XA,D,S; V43.02XA,D,S; V43.03XA,D,S; V43.04XA,D,S; V43.11XA,D,S; V43.12XA,D,S; V43.13XA,D,S; V43.14XA,D,S; V43.21XA,D,S; V43.22XA,D,S; V43.23XA,D,S; V43.24XA,D,S; V43.31XA,D,S; V43.32XA,D,S; V43.33XA,D,S; V43.34XA,D,S; V43.41XA,D,S; V43.42XA,D,S; V43.43XA,D,S; V43.44XA,D,S; V43.51XA,D,S; V43.52XA,D,S; V43.53XA,D,S; V43.54XA,D,S; V43.61XA,D,S; V43.62XA,D,S; V43.63XA,D,S; V43.64XA,D,S; V43.71XA,D,S; V43.72XA,D,S; V43.73XA,D,S; V43.74XA,D,S; V43.91XA,D,S; V43.92XA,D,S; V43.93XA,D,S; V43.94XA,D,S; V44.0XXA,D,S; V44.1XXA,D,S; V44.2XXA,D,S; V44.3XXA,D,S; V44.4XXA,D,S; V44.5XXA,D,S; V44.6XXA,D,S;V44.7XXA,D,S; V44.9XXA,D,S; V45.0XXA,D,S; V45.1XXA,D,S; V45.2XXA,D,S; V45.3XXA,D,S; V45.4XXA,D,S; V45.5XXA,D,S; V45.6XXA,D,S; V45.7XXA,D,S; V45.9XXA,D,S; V46.0XXA,D,S; V46.1XXA,D,S; V46.2XXA,D,S; V46.3XXA,D,S; V46.4XXA,D,S; V46.5XXA,D,S; V46.6XXA,D,S; V46.7XXA,D,S; V46.9XXA,D,S; V47.0XXA,D,S; V47.01XA,D,S; V47.02XA,D,S; V47.11XA,D,S; V47.12XA,D,S; V47.1XXA,D,S; V47.2XXA,D,S; V47.31XA,D,S; V47.32XA,D,S; V47.3XXA,D,S; V47.4XXA,D,S; V47.51XA,D,S; V47.52XA,D,S; V47.5XXA,D,S; V47.61XA,D,S; V47.62XA,D,S; V47.6XXA,D,S; V47.7XXA,D,S; V47.91XA,D,S; V47.92XA,D,S; V47.9XXA,D,S; V48.0XXA,D,S; V48.1XXA,D,S; V48.2XXA,D,S; V48.3XXA,D,S; V48.4XXA,D,S; V48.5XXA,D,S; V48.6XXA,D,S; V48.7XXA,D,S; V48.9XXA,D,S; V49.00XA,D,S; V49.09XA,D,S; V49.10XA,D,S; V49.19XA,D,S; V49.20XA,D,S; V49.29XA,D,S; V49.3XXA,D,S; V49.40XA,D,S; V49.49XA,D,S; V49.50XA,D,S; V49.59XA,D,S; V49.60XA,D,S; V49.69XA,D,S; V49.81XA,D,S; V49.88XA,D,S; V49.9XXA,D,S; V50.0XXA,D,S; V50.1XXA,D,S; V50.2XXA,D,S; V50.3XXA,D,S; V50.4XXA,D,S; V50.5XXA,D,S; V50.6XXA,D,S; V50.7XXA,D,S; V50.9XXA,D,S; V51.0XXA,D,S; V51.1XXA,D,S; V51.2XXA,D,S; V51.3XXA,D,S; V51.4XXA,D,S; V51.5XXA,D,S; V51.6XXA,D,S; V51.7XXA,D,S; V51.9XXA,D,S; V52.0XXA,D,S; V52.1XXA,D,S; V52.2XXA,D,S; V52.3XXA,D,S; V52.4XXA,D,S; V52.5XXA,D,S; V52.6XXA,D,S; V52.7XXA,D,S; V52.9XXA,D,S; V53.0XXA,D,S; V53.1XXA,D,S; V53.2XXA,D,S; V53.3XXA,D,S; V53.4XXA,D,S; V53.5XXA,D,S; V53.6XXA,D,S; V53.7XXA,D,S; V53.9XXA,D,S; V54.0XXA,D,S; V54.1XXA,D,S; V54.2XXA,D,S; V54.3XXA,D,S; V54.4XXA,D,S; V54.5XXA,D,S; V54.6XXA,D,S; V54.7XXA,D,S; V54.9XXA,D,S; V55.0XXA,D,S; V55.1XXA,D,S; V55.2XXA,D,S; V55.3XXA,D,S; V55.4XXA,D,S; V55.5XXA,D,S; V55.6XXA,D,S; V55.7XXA,D,S; V55.9XXA,D,S; V56.0XXA,D,S; V56.1XXA,D,S; V56.2XXA,D,S; V56.3XXA,D,S; V56.4XXA,D,S; V56.5XXA,D,S; V56.6XXA,D,S; V56.7XXA,D,S; V56.9XXA,D,S; V57.0XXA,D,S; V57.1XXA,D,S; V57.2XXA,D,S; V57.3XXA,D,S; V57.4XXA,D,S; V57.5XXA,D,S; V57.6XXA,D,S; V57.7XXA,D,S; V57.9XXA,D,S; V58.0XXA,D,S; V58.1XXA,D,S; V58.2XXA,D,S; V58.3XXA,D,S; V58.4XXA,D,S; V58.5XXA,D,S; V58.6XXA,D,S; V58.7XXA,D,S; V58.9XXA,D,S; V59.00XA,D,S; V59.09XA,D,S; V59.10XA,D,S; V59.19XA,D,S; V59.20XA,D,S; V59.29XA,D,S; V59.3XXA,D,S; V59.40XA,D,S; V59.49XA,D,S; V59.50XA,D,S; V59.59XA,D,S; V59.60XA,D,S; V59.69XA,D,S; V59.81XA,D,S; V59.88XA,D,S; V59.9XXA,D,S; V60.0XXA,D,S; V60.1XXA,D,S; V60.2XXA,D,S; V60.3XXA,D,S; V60.4XXA,D,S; V60.5XXA,D,S; V60.6XXA,D,S; V60.7XXA,D,S; V60.9XXA,D,S; V61.0XXA,D,S; V61.1XXA,D,S; V61.2XXA,D,S; V61.3XXA,D,S; V61.4XXA,D,S; V61.5XXA,D,S; V61.6XXA,D,S; V61.7XXA,D,S; V61.9XXA,D,S; V62.0XXA,D,S; V62.1XXA,D,S; V62.2XXA,D,S; V62.3XXA,D,S; V62.4XXA,D,S; V62.5XXA,D,S; V62.6XXA,D,S; V62.7XXA,D,S; V62.9XXA,D,S; V63.0XXA,D,S; V63.1XXA,D,S; V63.2XXA,D,S; V63.3XXA,D,S; V63.4XXA,D,S; V63.5XXA,D,S;

		V63.6XXA,D,S; V63.7XXA,D,S; V63.9XXA,D,S; V64.0XXA,D,S; V64.1XXA,D,S; V64.2XXA,D,S; V64.3XXA,D,S; V64.4XXA,D,S; V64.5XXA,D,S; V64.6XXA,D,S; V64.7XXA,D,S; V64.9XXA,D,S; V65.0XXA,D,S; V65.1XXA,D,S; V65.2XXA,D,S; V65.3XXA,D,S; V65.4XXA,D,S; V65.5XXA,D,S; V65.6XXA,D,S; V65.7XXA,D,S; V65.9XXA,D,S; V66.0XXA,D,S; V66.1XXA,D,S; V66.2XXA,D,S; V66.3XXA,D,S; V66.4XXA,D,S; V66.5XXA,D,S; V66.6XXA,D,S; V66.7XXA,D,S; V66.9XXA,D,S; V67.0XXA,D,S; V67.1XXA,D,S; V67.2XXA,D,S; V67.3XXA,D,S; V67.4XXA,D,S; V67.5XXA,D,S; V67.6XXA,D,S; V67.7XXA,D,S; V67.9XXA,D,S; V68.0XXA,D,S; V68.1XXA,D,S; V68.2XXA,D,S; V68.3XXA,D,S; V68.4XXA,D,S; V68.5XXA,D,S; V68.6XXA,D,S; V68.7XXA,D,S; V68.9XXA,D,S; V69.00XA,D,S; V69.09XA,D,S; V69.10XA,D,S; V69.19XA,D,S; V69.20XA,D,S; V69.3XXA,D,S; V69.40XA,D,S; V69.49XA,D,S; V69.50XA,D,S; V69.59XA,D,S; V69.60XA,D,S; V69.69XA,D,S; V69.81XA,D,S; V69.88XA,D,S; V69.9XXA,D,S; V70.0XXA,D,S; V70.1XXA,D,S; V70.2XXA,D,S; V70.3XXA,D,S; V70.4XXA,D,S; V70.5XXA,D,S; V70.6XXA,D,S; V70.7XXA,D,S; V70.9XXA,D,S; V71.0XXA,D,S; V71.1XXA,D,S; V71.2XXA,D,S; V71.3XXA,D,S; V71.4XXA,D,S; V71.5XXA,D,S; V71.6XXA,D,S; V71.7XXA,D,S; V71.9XXA,D,S; V72.0XXA,D,S; V72.1XXA,D,S; V72.2XXA,D,S; V72.3XXA,D,S; V72.4XXA,D,S; V72.5XXA,D,S; V72.6XXA,D,S; V72.7XXA,D,S; V72.9XXA,D,S; V73.0XXA,D,S; V73.1XXA,D,S; V73.2XXA,D,S; V73.3XXA,D,S; V73.4XXA,D,S; V73.5XXA,D,S; V73.6XXA,D,S; V73.7XXA,D,S; V73.9XXA,D,S; V74.0XXA,D,S; V74.1XXA,D,S; V74.2XXA,D,S; V74.3XXA,D,S; V74.4XXA,D,S; V74.5XXA,D,S; V74.6XXA,D,S; V74.7XXA,D,S; V74.9XXA,D,S; V75.0XXA,D,S; V75.1XXA,D,S; V75.2XXA,D,S; V75.3XXA,D,S; V75.4XXA,D,S; V75.5XXA,D,S; V75.6XXA,D,S; V75.7XXA,D,S; V75.9XXA,D,S; V76.0XXA,D,S; V76.1XXA,D,S; V76.2XXA,D,S; V76.3XXA,D,S; V76.4XXA,D,S; V76.5XXA,D,S; V76.6XXA,D,S; V76.7XXA,D,S; V76.9XXA,D,S; V77.0XXA,D,S; V77.1XXA,D,S; V77.2XXA,D,S; V77.3XXA,D,S; V77.4XXA,D,S; V77.5XXA,D,S; V77.6XXA,D,S; V77.7XXA,D,S; V77.9XXA,D,S; V78.0XXA,D,S; V78.1XXA,D,S; V78.2XXA,D,S; V78.3XXA,D,S; V78.4XXA,D,S; V78.5XXA,D,S; V78.6XXA,D,S; V78.7XXA,D,S; V78.9XXA,D,S; V79.00XA,D,S; V79.10XA,D,S; V79.19XA,D,S; V79.20XA,D,S; V79.29XA,D,S; V79.3XXA,D,S; V79.40XA,D,S; V79.49XA,D,S; V79.50XA,D,S; V79.59XA,D,S; V79.60XA,D,S; V79.69XA,D,S; V79.81XA,D,S; V79.88XA,D,S; V79.9XXA,D,S; V80.010A,D,S; V80.020A,D,S; V80.11XA,D,S; V80.12XA,D,S; V80.21XA,D,S; V80.22XA,D,S; V80.31XA,D,S; V80.32XA,D,S; V80.41XA,D,S; V80.42XA,D,S; V80.51XA,D,S; V80.52XA,D,S; V80.61XA,D,S; V80.62XA,D,S; V80.710A,D,S; V80.711A,D,S; V80.720A,D,S; V80.721A,D,S; V80.730A,D,S; V80.731A,D,S; V80.790A,D,S; V80.791A,D,S; V80.81XA,D,S; V80.82XA,D,S; V80.910A,D,S; V80.918A,D,S; V80.919A,D,S; V80.919A,D,S; V80.920A,D,S; V80.928A,D,S; V80.929A,D,S; V81.0XXA,D,S; V81.1XXA,D,S; V81.2XXA,D,S; V81.3XXA,D,S; V81.4XXA,D,S; V81.5XXA,D,S; V81.6XXA,D,S; V81.7XXA,D,S; V81.81XA,D,S; V81.82XA,D,S; V81.83XA,D,S; V81.89XA,D,S; V81.9XXA,D,S; V82.0XXA,D,S; V82.1 XXA,D,S; V82.2XXA,D,S; V82.3XXA,D,S; V82.4XXA,D,S; V82.5XXA,D,S; V82.6XXA,D,S; V82.7XXA,D,S; V82.8XXA,D,S; V82.9XXA,D,S; V83.0XXA,D,S; V83.1 XXA,D,S; V83.2XXA,D,S; V83.3XXA,D,S; V83.4XXA,D,S; V83.5XXA,D,S; V83.6XXA,D,S; V83.7XXA,D,S; V83.9XXA,D,S; V84.0XXA,D,S; V84.1XXA,D,S; V84.2XXA,D,S; V84.3XXA,D,S; V84.4XXA,D,S; V84.5XXA,D,S; V84.6XXA,D,S; V84.7XXA,D,S; V84.9XXA,D,S; V85.0XXA,D,S; V85.1 XXA,D,S; V85.2XXA,D,S; V85.3XXA,D,S; V85.4XXA,D,S; V85.5XXA,D,S; V85.6XXA,D,S; V85.7XXA,D,S; V85.8XXA,D,S;

		V85.9XXA,D,S; V86.01XA,D,S; V86.02XA,D,S; V86.03XA,D,S; V86.04XA,D,S; V86.09XA,D,S; V86.11XA,D,S; V86.12XA,D,S; V86.13XA,D,S; V86.14XA,D,S; V86.19XA,D,S; V86.21XA,D,S; V86.22XA,D,S;V86.23XA,D,S; V86.24XA,D,S; V86.29XA,D,S; V86.31XA,D,S; V86.32XA,D,S; V86.33XA,D,S; V86.34XA,D,S; V86.39XA,D,S; V86.41XA,D,S; V86.42XA,D,S; V86.43XA,D,S; V86.44XA,D,S; V86.49XA,D,S; V86.51XA,D,S; V86.52XA,D,S; V86.53XA,D,S; V86.54XA,D,S; V86.59XA,D,S; V86.61XA,D,S; V86.62XA,D,S; V86.63XA,D,S; V86.64XA,D,S; V86.69XA,D,S; V86.71XA,D,S; V86.72XA,D,S; V86.73XA,D,S; V86.74XA,D,S; V86.79XA,D,S; V86.91XA,D,S; V86.92XA,D,S; V86.93XA,D,S; V86.94XA,D,S; V86.99XA,D,S; V87.0XXA,D,S; V87.1XXA,D,S; V87.2XXA,D,S; V87.3XXA,D,S; V87.4XXA,D,S; V87.5XXA,D,S; V87.6XXA,D,S; V87.7XXA,D,S; V87.8XXA,D,S; V87.9XXA,D,S; V88.0XXA,D,S; V88.1XXA,D,S; V88.2XXA,D,S; V88.3XXA,D,S; V88.4XXA,D,S; V88.5XXA,D,S; V88.6XXA,D,S; V88.7XXA,D,S; V88.8XXA,D,S; V88.9XXA,D,S; V89.0XXA,D,S; V89.1XXA,D,S; V89.2XXA,D,S; V89.3XXA,D,S; V89.9XXA,D,S; V90.00XA,D,S; V90.01XA,D,S; V90.02XA,D,S; V90.03XA,D,S; V90.04XA,D,S; V90.05XA,D,S; V90.06XA,D,S; V90.08XA,D,S; V90.09XA,D,S; V90.10XA,D,S; V90.11XA,D,S; V90.12XA,D,S; V90.13XA,D,S; V90.14XA,D,S; V90.15XA,D,S; V90.16XA,D,S; V90.18XA,D,S; V90.19XA,D,S; V90.20XA,D,S; V90.21XA,D,S; V90.22XA,D,S; V90.23XA,D,S; V90.24XA,D,S; V90.25XA,D,S;V90.26XA,D,S; V90.27XA,D,S; V90.28XA,D,S; V90.29XA,D,S; V90.30XA,D,S; V90.31XA,D,S; V90.32XA,D,S; V90.33XA,D,S; V90.34XA,D,S; V90.35XA,D,S; V90.36XA,D,S; V90.37XA,D,S; V90.38XA,D,S; V90.39XA,D,S; V90.80XA,D,S; V90.81XA,D,S; V90.82XA,D,S; V90.83XA,D,S; V90.84XA,D,S; V90.85XA,D,S; V90.86XA,D,S; V90.87XA,D,S; V90.88XA,D,S; V90.89XA,D,S; V91.00XA,D,S; V91.01XA,D,S; V91.02XA,D,S; V91.03XA,D,S; V91.04XA,D,S; V91.05XA,D,S; V91.06XA,D,S; V91.07XA,D,S; V91.08XA,D,S; V91.09XA,D,S; V91.10XA,D,S; V91.11XA,D,S; V91.12XA,D,S; V91.13XA,D,S; V91.14XA,D,S; V91.15XA,D,S; V91.16XA,D,S; V91.18XA,D,S; V91.19XA,D,S; V91.20XA,D,S; V91.21XA,D,S; V91.22XA,D,S; V91.24XA,D,S; V91.25XA,D,S; V91.26XA,D,S; V91.29XA,D,S; V91.30XA,D,S; V91.31XA,D,S; V91.32XA,D,S; V91.33XA,D,S; V91.34XA,D,S; V91.35XA,D,S; V91.36XA,D,S; V91.37XA,D,S; V91.38XA,D,S; V91.39XA,D,S; V91.80XA,D,S; V91.81XA,D,S; V91.82XA,D,S; V91.83XA,D,S; V91.84XA,D,S; V91.85XA,D,S; V91.86XA,D,S; V91.87XA,D,S; V91.88XA,D,S; V91.89XA,D,S; V92.00XA,D,S; V92.01XA,D,S; V92.02XA,D,S; V92.03XA,D,S; V92.04XA,D,S; V92.05XA,D,S; V92.06XA,D,S; V92.07XA,D,S; V92.08XA,D,S; V92.09XA,D,S; V92.10XA,D,S; V92.11XA,D,S; V92.12XA,D,S; V92.13XA,D,S; V92.14XA,D,S; V92.15XA,D,S; V92.16XA,D,S; V92.19XA,D,S; V92.20XA,D,S; V92.21XA,D,S; V92.22XA,D,S; V92.23XA,D,S; V92.24XA,D,S; V92.25XA,D,S; V92.26XA,D,S; V92.27XA,D,S; V92.28XA,D,S; V92.29XA,D,S; V93.00XA,D,S; V93.01XA,D,S; V93.02XA,D,S; V93.03XA,D,S; V93.04XA,D,S; V93.09XA,D,S; V93.10XA,D,S; V93.11XA,D,S; V93.12XA,D,S; V93.13XA,D,S; V93.14XA,D,S; V93.19XA,D,S; V93.20XA,D,S; V93.21XA,D,S; V93.22XA,D,S; V93.23XA,D,S; V93.24XA,D,S; V93.29XA,D,S; V93.30XA,D,S; V93.31XA,D,S; V93.32XA,D,S; V93.33XA,D,S; V93.34XA,D,S; V93.35XA,D,S; V93.36XA,D,S; V93.37XA,D,S; V93.38XA,D,S; V93.40XA,D,S; V93.41XA,D,S; V93.42XA,D,S;V93.43XA,D,S; V93.44XA,D,S; V93.48XA,D,S; V93.49XA,D,S; V93.50XA,D,S; V93.51XA,D,S; V93.52XA,D,S; V93.53XA,D,S; V93.54XA,D,S; V93.59XA,D,S; V93.60XA,D,S; V93.61XA,D,S; V93.62XA,D,S; V93.63XA,D,S; V93.64XA,D,S; V93.69XA,D,S; V93.80XA,D,S;

		V93.81XA,D,S; V93.82XA,D,S; V93.83XA,D,S;V93.84XA,D,S; V93.85XA,D,S; V93.86XA,D,S; V93.87XA,D,S; V93.88XA,D,S; V93.89XA,D,S; V94.0XXA,D,S; V94.11XA,D,S; V94.12XA,D,S; V94.21XA,D,S; V94.22XA,D,S; V94.31XA,D,S; V94.32XA,D,S; V94.4XXA,D,S; V94.810A,D,S; V94.811A,D,S; V94.818A,D,S; V94.89XA,D,S; V94.9XXA,D,S; V95.00XA,D,S; V95.01XA,D,S; V95.02XA,D,S; V95.03XA,D,S; V95.04XA,D,S; V95.05XA,D,S; V95.09XA,D,S; V95.10XA,D,S; V95.11XA,D,S; V95.12XA,D,S; V95.13XA,D,S; V95.14XA,D,S; V95.15XA,D,S; V95.19XA,D,S; V95.20XA,D,S; V95.21XA,D,S; V95.22XA,D,S; V95.23XA,D,S; V95.24XA,D,S; V95.25XA,D,S; V95.29XA,D,S; V95.30XA,D,S; V95.31XA,D,S; V95.32XA,D,S; V95.33XA,D,S; V95.34XA,D,S; V95.35XA,D,S; V95.39XA,D,S; V95.40XA,D,S; V95.41XA,D,S; V95.42XA,D,S; V95.43XA,D,S; V95.44XA,D,S; V95.45XA,D,S; V95.49XA,D,S; V95.8XXA,D,S; V95.9XXA,D,S; V96.00XA,D,S; V96.01XA,D,S; V96.02XA,D,S; V96.03XA,D,S; V96.04XA,D,S; V96.05XA,D,S; V96.09XA,D,S; V96.10XA,D,S; V96.11XA,D,S; V96.12XA,D,S; V96.13XA,D,S; V96.14XA,D,S; V96.15XA,D,S; V96.19XA,D,S; V96.20XA,D,S; V96.21XA,D,S; V96.22XA,D,S; V96.23XA,D,S; V96.24XA,D,S; V96.25XA,D,S; V96.29XA,D,S; V96.8XXA,D,S; V96.9XXA,D,S; V97.0XXA,D,S; V97.1XXA,D,S; V97.21XA,D,S; V97.22XA,D,S; V97.29XA,D,S; V97.31XA,D,S; V97.32XA,D,S; V97.33XA,D,S; V97.39XA,D,S; V97.810A,D,S; V97.811A,D,S; V97.818A,D,S; V97.89XA,D,S; V98.0XXA,D,S; V98.1XXA,D,S; V98.2XXA,D,S; V98.3XXA,D,S; V98.8XXA,D,S; V99.XXXA,D,S
Sedative Poisoning	967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E851.; E852.0,.1,.2,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.2,.3	T41.0X1A,D,S; T41.0X2A,D,S; T41.0X3A,D,S; T41.0X4A,D,S; T41.0X5A,D,S; T41.1X1A,D,S; T41.1X2A,D,S; T41.1X3A,D,S; T41.1X4A,D,S; T41.1X5A,D,S; T41.201A,D,S; T41.202A,D,S; T41.203A,D,S; T41.204A,D,S; T41.205A,D,S; T41.291A,D,S; T41.292A,D,S; T41.293A,D,S; T41.294A,D,S; T41.295A,D,S; T41.3X1A,D,S; T41.3X2A,D,S; T41.3X3A,D,S; T41.3X4A,D,S; T41.3X5A,D,S; T41.41XA,D,S; T41.42XA,D,S; T41.43XA,D,S; T41.44XA,D,S; T41.45XA,D,S; T42.3X1A,D,S; T42.3X2A,D,S; T42.3X3A,D,S; T42.3X4A,D,S; T42.3X5A,D,S; T42.4X1A,D,S; T42.4X2A,D,S; T42.4X3A,D,S; T42.4X4A,D,S; T42.4X5A,D,S; T42.6X1A,D,S; T42.6X2A,D,S; T42.6X3A,D,S; T42.6X4A,D,S; T42.6X5A,D,S; T42.8X1A,D,S; T42.8X2A,D,S; T42.8X3A,D,S; T42.8X4A,D,S; T42.8X5A,D,S; T43.3X1A,D,S; T43.3X2A,D,S; T43.3X3A,D,S; T43.3X4A,D,S; T43.3X5A,D,S; T43.4X1A,D,S; T43.4X2A,D,S; T43.4X3A,D,S; T43.4X4A,D,S; T43.4X5A,D,S; T43.501A,D,S; T43.502A,D,S; T43.503A,D,S; T43.504A,D,S; T43.505A,D,S; T43.591A,D,S; T43.592A,D,S; T43.593A,D,S; T43.594A,D,S; T43.595A,D,S
Suicide-related	E950.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9,.91,.92; E951.0,.01,.02,.1,.11,.12,.8,.81,.82; E952.0,.01,.02,.1,.11,.12,.8,.81,.82,.9,.91,.92; E953.0,.01,.02,.1,.11,.	R45.851; T14.91; T36.0X2A,D,S; T36.1X2A,D,S; T36.2X2A,D,S; T36.3X2A,D,S; T36.4X2A,D,S; T36.5X2A,D,S; T36.6X2A,D,S; T36.7X2A,D,S; T36.8X2A,D,S; T36.92XA,D,S; T37.0X2A,D,S; T37.1X2A,D,S; T37.2X2A,D,S; T37.3X2A,D,S; T37.4X2A,D,S; T37.5X2A,D,S; T37.8X2A,D,S; T37.92XA,D,S; T38.0X2A,D,S; T38.1X2A,D,S; T38.2X2A,D,S; T38.3X2A,D,S; T38.4X2A,D,S; T38.5X2A,D,S; T38.6X2A,D,S; T38.7X2A,D,S; T38.802A,D,S; T38.812A,D,S; T38.892A,D,S; T38.902A,D,S; T38.992A,D,S; T39.012A,D,S; T39.092A,D,S; T39.1X2A,D,S; T39.2X2A,D,S; T39.312A,D,S; T39.392A,D,S; T39.4X2A,D,S; T39.8X2A,D,S; T39.92XA,D,S; T40.0X2A,D,S; T40.1X2A,D,S; T40.2X2A,D,S; T40.3X2A,D,S; T40.4X2A,D,S; T40.5X2A,D,S; T40.602A,D,S; T40.692A,D,S; T40.7X2A,D,S; T40.8X2A,D,S; T40.902A,D,S; T40.992A,D,S; T41.0X2A,D,S; T41.1X2A,D,S; T41.202A,D,S; T41.292A,D,S; T41.3X2A,D,S; T41.42XA,D,S; T41.5X2A,D,S; T42.0X2A,D,S; T42.1X2A,D,S; T42.2X2A,D.S; T42.3X2A,D,S; T42.4X2A,D.S; T42.5X2A,D,S;

	12,.8,.81,.82,.9; E954.,.1,.2; E955.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31..32,.4,.41,.42,.5,.51,.52,.6,.7,.9; E956.,.1,.2; E957.0,.01,.02,.1,.11,.12,.2,.21,.22,.9,.91,.92; E958.0,.01;.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9; E959.; E980.6,.8; E981.0,.1,.8; E982.0,.1,.8,.9; E983.0,.1,.8,.9; E984.; E988.0,.1,.2,.3,.4,.5,.6,.7,.8,.9; V62.84	T42.6X2A,D,S; T42.72XA,D,S; T42.8X2A,D,S; T43.012A,D,S; T43.022A,D,S; T43.1X2A,D,S; T43.202A,D,S; T43.212A,D,S; T43.222A,D,S; T43.292A,D,S; T43.3X2A,D,S; T43.4X2A,D,S; T43.502A,D,S; T43.592A,D,S; T43.602A,D,S; T43.612A,D,S; T43.622A,D,S; T43.632A,D,S; T43.692A,D,S; T43.8X2A,D,S; T43.92XA,D,S; T44.0X2A,D,S; T44.1X2A,D,S; T44.2X2A,D,S; T44.3X2A,D,S; T44.4X2A,D,S; T44.5X2A,D,S; T44.6X2A,D,S; T44.7X2A,D,S; T44.8X2A,D,S; T44.902A,D,S; T44.992A,D,S; T45.0X2A,D,S; T45.1X2A,D,S; T45.2X2A,D,S; T45.3X2A,D,S; T45.4X2A,D,S; T45.512A,D,S; T45.522A,D,S; T45.602A,D,S; T45.612A,D,S; T45.622A,D,S; T45.692A,D,S; T45.7X2A,D,S; T45.8X2A,D,S; T45.92XA.D.S; T46.0X2A,D,S; T46.1X2A,D,S; T46.2X2A,D,S; T46.3X2A,D,S; T46.4X2A,D,S; T46.5X2A,D,S; T46.6X2A,D,S; T46.7X2A,D,S; T46.8X2A,D,S; T46.902A,D,S; T46.992A,D,S; T47.0X2A,D,S; T47.1X2A,D,S; T47.2X2A,D,S; T47.3X2A,D,S; T47.4X2A,D,S; T47.5X2A,D,S; T47.6X2A,D,S; T47.7X2A,D,S; T47.8X2A,D,S; T47.92XA,D,S; T48.0X2A,D,S; T48.1X2A,D,S; T48.202A,D,S; T48.292A,D,S; T48.3X2A,D,S; T48.4X2A,D,S; T48.5X2A,D,S; T48.6X2A,D,S; T48.902A,D,S; T48.992A,D,S; T49.0X2A,D,S; T49.1X2A,D,S; T49.2X2A,D,S; T49.3X2A,D,S; T49.4X2A,D,S; T49.5X2A,D,S; T49.6X2A,D,S; T49.7X2A,D,S; T49.8X2A,D,S; T49.92XA,D,S; T50.0X2A,D,S; T50.1X2A,D,S; T50.2X2A,D,S; T50.3X2A,D,S; T50.4X2A,D,S; T50.5X2A,D,S; T50.6X2A,D,S; T50.7X2A,D,S; T50.8X2A,D,S; T50.902A,D,S; T50.902S,D,S; T50.992A,D,S; T50.A12A,D,S; T50.A12A,D,S; T50.A22A,D,S; T50.A92A,D,S; T50.B12A,D,S; T50.B92A,D,S; T50.Z12A,D,S; T50.Z92A,D,S; T51.0X2A,D,S; T51.1X2A,D,S; T51.2X2A,D,S; T51.3X2A,D,S; T51.8X2A,D,S; T51.92XA,D,S; T52.0X2A,D,S; T52.1X2A,D,S; T52.2X2A,D,S; T52.3X2A,D,S; T52.4X2A,D,S; T52.8X2A,D,S; T52.92XA,D,S; T53.0X2A,D,S; T53.1X2A,D,S; T53.2X2A,D,S; T53.3X2A,D,S; T53.4X2A,D,S; T53.5X2A,D,S; T53.6X2A,D,S; T53.7X2A,D,S; T53.92XA,D,S; T54.0X2A,D,S; T54.1X2A,D,S; T54.2X2A,D,S; T54.3X2A,D,S; T54.92XA,D,S; T55.0X2A,D,S; T55.1X2A,D,S; T56.0X2A,D,S; T56.1X2A,D,S; T56.2X2A,D,S; T56.3X2A,D,S; T56.4X2A,D,S; T56.5X2A,D,S; T56.6X2A,D,S; T56.7X2A,D,S; T56.812A,D,S; T56.892A,D,S; T56.92XA,D,S; T57.0X2A,D,S; T57.1X2A,D,S; T57.2X2A,D,S; T57.3X2A,D,S; T57.8X2A,D,S; T57.92XA,D,S; T58.02XA,D,S; T58.12XA,D,S; T58.2X2A,D,S; T58.8X2A,D,S; T58.92XA,D,S; T59.0X2A,D,S; T59.1X2A,D,S; T59.2X2A,D,S; T59.3X2A,D,S; T59.4X2A,D,S; T59.5X2A,D,S; T59.6X2A,D,S; T59.7X2A,D,S; T59.812A,D,S; T59.892A,D,S; T59.92XA,D,S; T60.0X2A,D,S; T60.1X2A,D,S; T60.2X2A,D,S; T60.3X2A,D,S; T60.4X2A,D,S; T60.8X2A,D,S; T60.92XA,D,S; T61.02XA,D,S; T61.12XA,D,S; T61.772A,D,S; T61.782A,D,S; T61.8X2A,D,S; T61.92XA,D,S; T62.0X2A,D,S; T62.1X2A,D,S; T62.2X2A,D,S; T62.8X2A,D,S; T62.92XA,D,S; T63.002A,D,S; T63.012A,D,S; T63.022A,D,S; T63.032A,D,S; T63.042A,D,S; T63.062A,D,S; T63.072A,D,S; T63.082A,D,S; T63.092A,D,S; T63.112A,D,S; T63.122A,D,S; T63.192A,D,S; T63.2X2A,D,S; T63.302A,D,S; T63.312A,D,S; T63.322A,D,S; T63.332A,D,S; T63.392A,D,S; T63.412A,D,S; T63.422A,D,S; T63.432A,D,S; T63.442A,D,S; T63.452A,D,S; T63.462A,D,S; T63.482A,D,S; T63.512A,D,S; T63.592A,D,S; T63.612A,D,S; T63.622A,D,S; T63.632A,D,S; T63.692A,D,S; T63.712A,D,S; T63.792A,D,S; T63.812A,D,S; T63.822A,D,S; T63.832A,D,S; T63.892A,D,S; T63.92XA,D,S; T64.02XA,D,S; T64.82XA,D,S; T65.0X2A,D,S; T65.1X2A,D,S; T65.212A,D,S; T65.222A,D,S; T65.292A,D,S; T65.3X2A,D,S; T65.4X2A,D,S; T65.5X2A,D,S; T65.6X2A,D,S; T65.812A,D,S; T65.822A,D,S; T65.832A,D,S; T65.892A,D,S;

		T65.92XA,D,S; T71.112A,D,S; T71.122A,D,S; T71.132A,D,S; T71.152A,D,S; T71.162A,D,S; T71.192A,D,S; T71.222A,D,S; T71.232A,D,S; X71.0XXA,D,S; X71.1XXA,D,S; X71.2XXA,D,S; X71.3XXA,D,S; X71.8XXA,D,S; X71.9XXA,D,S; X72.XXXA,D,S; X73.0XXA,D,S; X73.1XXA,D,S; X73.2XXA,D,S; X73.8XXA,D,S; X73.9XXA,D,S; X74.01XA,D,S; X74.02XA,D,S; X74.09XA,D,S; X74.8XXA,D,S; X74.9XXA,D,S; X75.XXXA,D,S; X76.XXXA,D,S; X77.0XXA,D,S; X77.1XXA,D,S; X77.2XXA,D,S; X77.3XXA,D,S; X77.8XXA,D,S; X77.9XXA,D,S; X78.0XXA,D,S; X78.1XXA,D,S; X78.2XXA,D,S; X78.8XXA,D,S; X78.9XXA,D,S; X79.XXXA,D,S; X80.XXXA,D,S; X81.0XXA,D,S; X81.1XXA,D,S; X81.8XXA,D,S; X82.0XXA,D,S; X82.1XXA,D,S; X82.2XXA,D,S; X82.8XXA,D,S; X83.0XXA,D,S; X83.1XXA,D,S; X83.2XXA,D,S; X83.8XXA,D,S

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_1_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1_____
	5b	Name and contact information for the trial sponsor	_8_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_2-3_____
	6b	Explanation for choice of comparators	_____
Objectives	7	Specific objectives or hypotheses	_4_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_3-5_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_3-4_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_5_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_4-5_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_5-6_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_Figure 3_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_6_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_5_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_5_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_5_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_5_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_5_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_6-7_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_6_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_6-7_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_6-7_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_8_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_7-8_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

The Effectiveness of Policy and Risk Targeting for Opioid-Related Risk Mitigation: A Randomized Program Evaluation with Stepped-Wedge Design

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Addiction, Mental health, Research methods
Keywords:	randomized program evaluation, opioids, united states veterans administration

Title: The Effectiveness of Policy and Risk Targeting for Opioid-Related Risk Mitigation: A Randomized Program Evaluation with Stepped-Wedge Design

Authors: Taeko Minegishi, MS[1-2], Melissa M. Garrido, PhD[1,3-4], Steven D. Pizer, PhD[1,5], Austin B. Frakt, PhD[1,5-6]

Corresponding Author: Taeko Minegishi, 150 S. Huntington Avenue, 152H, Boston, MA, 02130. E-mail: taeko.minegishi@va.gov. Phone: 857-364-6065. Fax: 857-364-2259

Author affiliations:
1. Partnered Evidence-based Policy Resource Center, VA Boston Healthcare System, Boston, MA, USA
2. Bouvé College of Health Sciences, Northeastern University, Boston, MA, USA
3. Geriatrics Research, Education, and Clinical Center, James J Peters VA Medical Center, Bronx, NY, USA
4. Brookdale Department of Geriatrics and Palliative Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, USA
5. Department of Health Law, Policy & Management, Boston University of Public Health, Boston, MA, USA
6. Department of Health Policy and Management, Harvard T.H. Chan School of Public Health, Cambridge, MA, USA

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Word count: 2895

Abstract

Introduction: There is an epidemic of opioid use related adverse events and deaths in the United States. The rates of chronic pain, mental illness, and substance use disorder are higher at the Veterans Health Administration (VHA) compared to the general U.S. population. The 2016 Comprehensive Addiction and Recovery Act (CARA) requires the VHA to improve opioid therapy strategies in treating patients and to ensure responsible prescribing practices. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prioritizes review of VHA patients receiving opioids based on their risk. The VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk.

Methods and analysis: This stepped-wedge cluster randomized controlled trial will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related serious adverse events (SAEs), relative to facilities not randomized to facilitation, and 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed. Patients who receive an opioid prescription at VHA medical centers will be followed for a minimum of 3 months after their first opioid prescription. Follow-up will continue until the last day of the project or death. The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions.

Ethics and dissemination: Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069). Findings will be published in peer-reviewed journals and presentations at national conference meetings.

Trial registration number: ISRCTN16012111 (http://www.isrctn.com/ISRCTN16012111). Registered May 25, 2017.

Strength and limitations of this study

- Randomized program evaluation reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget.
- The stepped wedge design evaluates aspects of the VHA policy and a web-based dashboard to identify risk factors and risk mitigation strategies for patients with an opioid prescription.
- This study will only include Veterans Health Administration (VHA) patients and exclude patients with opioid use disorder.

Introduction

Opioid overdose deaths reached 33,000 in 2015, an increase of about 16% from the prior year, and are the leading cause of injury death in the United States (1). The supply of opioid prescriptions remains high in the United States, with nearly 250 million opioid prescriptions written in 2013 or about one prescription per American adult (2). These statistics underlie the Centers for Disease Control and Prevention's (CDC's) characterization of opioid use related adverse events and deaths as an epidemic in the United States. The epidemic is potentially more acute in the Veterans Health Administration (VHA) patient population, which has higher rates of chronic pain, mental illness, and substance use disorder compared to the general U.S. population (3–5). In particular, the prevalence of opioid use disorder in the VHA is approximately seven times higher than it is in commercial health plans (6).

The epidemic in the U.S. in general, and in the VHA population in particular, has captured the attention of policymakers. For instance, the 2016 Comprehensive Addiction and Recovery Act (Pub.L.No. 114-198; CARA) outlines a coordinated effort to confront opioid mis- and over-use through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. In particular, CARA requires the VHA to improve opioid therapy strategies in treating patients, and to ensure responsible prescribing practices (Subtitle A Sec 911).

The VHA Office of Mental Health and Suicide Prevention (OMHSP; formerly Office of Mental Health Operations) developed a tool that is responsive to the CARA requirement that VHA opioid prescribers review existing adverse event risk characteristics for each patient before prescribing. The Stratification Tool for Opioid Risk Mitigation (STORM) is a web-based dashboard that prospectively prioritizes review of VHA patients receiving opioids based on their risk for overdose-, accident-, or suicide-related events (collectively, serious adverse events or SAEs). The risk prioritization is determined by a predictive model based on the association of patient characteristics (e.g., age, race, prior history of mental illness) and opioid prescription with opioid-related SAEs (7). Designed to be easily incorporated into clinical practice, VHA clinicians can use STORM to identify risk factors and risk mitigation strategies potentially relevant for each patient.

Although STORM has gone through validation and usability testing, more evidence is needed to guide its use. Validation and usability reviews indicate that the STORM dashboard is an acceptable and efficient method of reviewing patient-specific risk information (7). User feedback indicated high face-validity for the patients STORM identifies as high risk and appropriate for intensive monitoring. It also indicated that the STORM dashboard can reduce the time required to review risk factors, assist with monitoring and systematic use of risk mitigation strategies, and improve awareness of the care patients are receiving across providers and care settings. However, the impact of identifying patient risk through STORM on opioid related SAEs has not been rigorously evaluated. In addition, it is unclear how to best convey the CARA mandates to providers and ensure case-review of patients identified by STORM.

Therefore, the VHA Partnered Evidence-based Policy Resource Center (PEPReC) is coordinating a multi-year evaluation of STORM and aspects of the VHA policy that mandate case review of patients identified by STORM as very high risk. In the following sections, we describe the STORM dashboard and the design of a cluster randomized trial to evaluate the effect of an expanded risk threshold and variations in policy language on time to opioid related SAEs. This timely, randomized evaluation of STORM reflects VHA's commitment to rapid and rigorous evaluation of government programs, an ambition promoted by the Office of Management and Budget (8).

STORM Dashboard and Implementation

On any given day, approximately 400,000 to 500,000 VHA patients have active prescriptions for opioids. Patients' information will be displayed in the STORM dashboard until their prescription expires. For credentialed users (including VHA prescribers), the dashboard automatically sorts patients at their medical centers in descending order of predicted SAE risk. In this evaluation, we focus on patients prescribed an opioid who are in the top 5% of risk scores. Predicted risk is a function of demographics, comorbidities, prior history of mental illness and substance use disorders, and opioid prescription data. The dashboard also provides clinicians with a list of evidence-based clinical recommendations for risk mitigation, such as drug screening tests, bowel regimens, and treatment alternatives to opioid prescription. Once a clinician reviews a case, the dashboard records and saves case review notes and dates of review. The dashboard compactly displays a patient's name, age and gender, patient risk level classification (low, medium, high, or very high risk), diagnoses and medications that are relevant to opioid risk, and risk mitigation strategies and non-pharmacological pain treatment recommendations (Figure 1). In addition, to facilitate care coordination, recent and upcoming appointments and patient care provider names are listed.

In the near future, VHA Central Office will release a policy notice mandating that VHA clinicians conduct case reviews and identify appropriate risk mitigation approaches for patients with opioid prescriptions who are identified by STORM as having a very high risk of SAEs. Differences in the key messages for the treatment and control groups are displayed in Table 1.

Table 1 The Policy Notice Content for the Treatment and Control Group

Policy Notice	Treatment	Control

Content		
Metric	Denominator: Patients with an opioid prescription who are in the "Very High – Opioid Patients" risk category in STORM for at least 7 days in the last quarter. Numerator: Patients in the denominator with case review within the last 4 quarters.	
Monitoring	The STORM implementation team will review completion rates at the end of each quarter and notify facility point(s) of contact of their completion rate.	
Implementation	• Facilities with scores at or above 97% on this metric are considered fully implemented. • Lack of implementation will trigger technical assistance and action planning starting in FY18Q4.	Facilities are expected to achieve scores at or above 97% by the end of FY18Q3.
Oversight and Facilitation	• If the facility fails to meet the targeted rate for completing case reviews by the end of FY18Q3 the STORM implementation team will notify the facility point(s) of contact. • The goal of reviewing these patients will be added to the facility's existing improvement goals. • The facility point(s) of contact must then report quarterly on progress toward executing an action plan to meet the metric.	None

Randomized Program Evaluation of STORM

Despite the benefits of randomized controlled trials, US health care policies and programs are rarely tested with randomized designs (9). As a result, there is little evidence-based guidance for writing effective policy notices. The US Government Accountability Office has identified limitations in VHA policy notices, including a lack of clearly articulated accountability (10). Improving this aspect of VHA policy notices is a high priority. Therefore, two versions of the policy notice have been prepared; half of the medical centers will receive a version that states that if fewer than 97 percent of their cases are reviewed, facilitation, which includes technical assistance and action planning, will be provided to help them increase their case review rate; the other half will receive a notice that only states that case reviews are mandated. Sites that are required to develop action plans must:1) add the metric (i.e. >97% review of very high risk patients) to their existing improvement goals and 2) submit quarterly reports detailing progress toward executing an action plan to meet the metric. To our knowledge, no prior study has compared the effects of alternative accountability approaches in policy documents on uptake of delivery system innovations.

In addition to randomizing medical centers to different versions of the policy notice, we will rigorously evaluate the effect of the STORM dashboard on patient outcomes. To do this, we will use a randomized stepped wedge design (described in detail below) to create two cohorts of patients in a similar risk group, one for which case review is required (treatment) and another for which it is not (control). This risk group will be created by expanding the threshold for very high risk from 1% to 5%.

Hypotheses

We will test two hypotheses: 1) VHA medical centers randomized to facilitation for not meeting the targeted case review rate will achieve lower opioid-related SAEs, relative to

facilities not randomized to facilitation. 2) Patients whose cases are required to be reviewed will have a lower rate of opioid-related SAEs compared to comparable risk patients whose cases are not required to be reviewed.

Methods

Intervention 1: Effectiveness of VHA Policy

According to the policy notice, VHA medical centers are required to review the cases of very high risk patients. Half of facilities (randomly assigned) will be asked to complete an action plan and receive additional oversight and facilitation from OMHSP if at least 97% of cases are not reviewed (the policy treatment group). Facilities that fail to meet the targeted rate for completing case reviews of very high risk patients will be tasked to review these patients and report quarterly to the OMHSP on progress toward executing an action plan to meet the metric. The other half of VHA medical centers will receive a version of the notice without any mention of action plans, oversight, or facilitation (the policy control group).

Intervention 2: Effectiveness of STORM

Within the policy treatment and control groups, separately, the definition of very high risk patients will be altered over time in a stepped wedge manner. This will allow us to evaluate the effect of being targeted for case review by STORM. For the first 8 months, all medical centers will be required to conduct case reviews for patients in the top 1% of risk for an SAE. At baseline, patients with risk scores between 1% and 5% are not displayed in STORM (control group). At month 9, half of the policy treatment and half of the policy control facilities will be randomly assigned to review patients identified as high risk under an expanded risk threshold (up to 5%). At month 15, all facilities will be required to review patients in the top 5% of risk. This stepped wedge design creates a cohort of patients who have opioid prescriptions and are between the top 1% and top 5% of SAE risk. Half of these patients will have mandated case review (the STORM treatment group) and half will receive usual care (the STORM control group). Figure 2 presents the two interventions and timeline.

Randomization and Blinding

Randomization was conducted in two steps, using permuted block randomization. Permuted block randomization allowed us to create groups with an even number of facilities. First, the 140 VHA medical centers were split into two groups with 70 medical centers each in the policy treatment and policy control groups. Then, to apply the stepped wedge design for analysis of STORM treatment vs control, the 70 medical centers in each group were split into two groups of 35 hospitals using permuted block randomization. The STORM dashboard will label patients as “very high risk” using the respective risk score cut-offs (top 1% and top 5%) at each VHA medical center. The risk scores will not be displayed, and providers will be blinded to changes in the risk score threshold that defines “very high risk”.

Recruitment/Eligibility Criteria/Participant Timeline

Our analytic cohort will include approximately 100,000 VHA patients with an opioid prescription in the top 10% of risk scores. Patients are eligible for inclusion in the study cohort for the first 18 months of the study. If a patient has an active opioid prescription on the day the

policy notice is released and has a risk score in the top 10% of risk, he or she will automatically enter the study. Other patients will enter the cohort on the date of their first prescription that exceeds the 10% risk threshold. Patients will be followed for a minimum of 3 months after they are first prescribed an opioid. Follow-up will continue until the last day of the project (September 30, 2019) or date of death. Our primary analyses of the effect of policy language will focus on patients in the top 1% of risk, and our primary analyses of the effect of STORM will be focused on patients between the top 5% and top 1% of risk scores. Over the course of this study, we anticipate over 50,000 patients will have risk scores in the top 5% of risk.

Outcome Measures and Control Variables

Our primary outcome of interest is opioid-related SAEs (e.g., opioid overdose, accidental falls, and possible and confirmed suicide attempts, etc. [See Supplementary A for ICD-9 and -10 codes]). The outcome measure is censored by death or end of study. The STORM risk score that a patient receives when he or she first enters the study (baseline risk score) will be used as a control variable, since it reflects the probability that the patient will have an opioid-related SAE outcome. The risk score also captures the risk associated with general demographic characteristics (i.e. age, race, gender) and comorbidities (i.e. prior and current history of disease). In addition, facility indicators and time in study (indicators for current and past months) will be used as control variables.

Although case review is mandated, it is unlikely that all providers will review all identified cases. In addition, the risk mitigation strategies suggested in the STORM dashboard are optional. If lower SAE rates in treatment facilities are achieved, this could be due to higher case review rates or to greater use of risk mitigation strategies. That is, the case review rate acts as a mediator of the relationship between risk identification and opioid-related SAEs. In addition, risk mitigation strategies are intended to reduce risk of adverse outcomes. Thus, the SAE rates should be lower if risk mitigation strategies are more frequently implemented. We will test whether facility level rates of case review and patient level risk mitigation strategies implemented are mediators of the primary outcome.

Data Collection and Management

STORM risk scores are calculated and updated on a daily basis. Upon a patient's entry into the study cohort (i.e. at the date of the first opioid prescription on or after the release of the policy notice), his or her risk score will be recorded. VHA has a centralized corporate data warehouse (CDW) where all patient data, including demographics, appointments, visits, diagnoses, and prescriptions are stored. From these data, any opioid-related SAEs for study patients will be identified. The case review notes and case review date, along with risk mitigation strategies implemented for each patient, will also be collected in CDW.

Sample Size/Power Calculation

Sample size was calculated using the data that informed the original STORM model (7). That dataset included 1,135,600 patients with an opioid prescription from VHA anytime in 2010. The sample size calculation for the effectiveness of policy was completed using a baseline SAE rate of 0.029 per person-month for the policy control group, 140 medical centers with an average of 2,112 patient-months, and an intraclass correlation coefficient (ICC) of 0.01 in

Stata's *clustersampsi* function (11). For the effectiveness of STORM, Stata's *steppedwedge* function was used to account for the changes in medical centers and patients included in the treatment group over time (12). To calculate sample size, we used an expected baseline SAE rate of 0.01 per person-month for the STORM control group with an average of 352 patients per medical center in the 1-5% risk group, and we assumed an ICC of 0.01.

Based on these baseline rates, with an alpha of 0.05, we can detect a difference between the policy treatment and control groups of 28% (i.e., a SAE rate difference at least as large as 0.037 or at least as small as 0.021) with 80% power. The evaluation can also detect a difference of 15% between the STORM treatment and control groups with 80% power (i.e., an SAE rate difference at least as large as 0.012 or at least as small as 0.009).

Statistical Analysis

The data will be analyzed using an intent-to-treat approach with patient-month level Cox proportional hazards models for both interventions: 1) effectiveness of policy, and 2) effectiveness of STORM. For the effectiveness of policy analysis, a patient-level time-to-event Cox proportional hazards model will be used to evaluate the difference between facilities with and without facilitation language in the notice, controlling for the different targeted risk group at different times and facility fixed effects. Similarly, for the effectiveness of STORM analysis, the primary outcome will be modeled with a patient level time-to-event Cox proportional hazards model to evaluate the difference between the STORM treatment and control groups, controlling for difference in policy, and facility fixed effects. We will estimate the effect of the intervention during a single month as well as the cumulative effect of the intervention. In order to account for diminishing returns of additional months of exposure to time in STORM, we estimate separate effects for one month before treatment, two months before treatment, and so on.

Equations 1 and 2 represent the planned analyses for effectiveness of policy and effectiveness of STORM, respectively.

$$Outcome_{itk} = intercept + \propto_i + \beta_t + P_i\gamma + x_k\phi + \varepsilon_{itk} \quad (1)$$

$$Outcome_{itk} = intercept + \propto_i + \beta_t + P_i\gamma + R_{it}\theta_t + R_{it-1}\theta_{-1} + R_{it-2}\theta_{-2} + \cdots + R_{it-n}\theta_{-n} + x_k\phi + \varepsilon_{itk} \quad (2)$$

In these equations, i represents medical centers, t is time points (i.e. months), n is months before month t, and k is individuals. In addition, $\propto$ is a random medical center effect, β is a vector of fixed time effects, P is a policy indicator (P=1 if policy treatment medical center, 0 if policy control medical center), γ is a fixed effect for policy, R is a risk targeting indicator (1 if patient in the 1%-5% risk stratum in the treatment medical center i at time t, 0 otherwise), $\theta_t$is a fixed risk targeting effect at time t, θ_{-n} represents lagged risk targeting effects from targeting at time $t-n$, x_k represents baseline covariates, ϕ represents fixed effects for baseline covariates, and ε is residual error. In Equation 1, we are interested in estimates of γ, the policy treatment effect. In Equation 2, we are interested in estimates of θ, the risk targeting effect at month t, as well as in estimates of $\theta + \theta_{-1} + \theta_{-n}$, the cumulative effect of months of risk targeting experienced prior to and including month t.

A statistically significant difference between the two policy groups (γ) suggests that the threat of facilitation modifies VHA providers' behavior to increase surveillance on very high risk opioid prescribed patients and to apply SAE risk mitigation strategies. A statistically significant effect of the STORM treatment group (θ) indicates that when opioid prescribed patients are required to be case reviewed, they are less likely to experience opioid-related SAEs.

Our intent-to-treat analysis assumes that patients' risk scores are relatively stable over the study period, and that baseline risk closely approximates the risk level of a patient at the time their facility is randomized to target an expanded risk threshold. However, it is possible that risk scores may change over time for patients who receive long-term opioid therapy and/or frequent short-term opioid therapy. Risk scores at baseline may simultaneously predict prospective risk scores, likelihood of exposure to the intervention, and risk of SAEs. In addition, a patient's risk score at a given month may be affected by the version of policy or level of risk threshold in place at a facility in previous months. To account for this potential endogeneity, we plan to conduct a secondary survival analysis that treats the facility treatment indicator and interaction between baseline risk score and facility treatment as instrumental variables.

We will conduct a sensitivity analysis to evaluate the effect of facilitation during the study period on the policy treatment group. The time when each medical center is notified that they failed to meet the targeted case review rate will be tracked and the cohort will be stratified into three groups: policy control, policy treatment with facilitation, and policy treatment without facilitation. A statistically significant effect of treatment with facilitation compared to treatment without facilitation indicates facilitation may lead to greater reduction in patients' risk of opioid-related SAEs. We also will evaluate whether the effect of the threat of but not actual facilitation is associated with reduced risk of opioid-related SAEs.

Patient and Public Involvement

Patients and public were not involved in the development, design, recruitment and randomization of this study.

Ethics and Dissemination

Evaluation of the randomized roll-out was approved by the VA Boston Healthcare System IRB and R&D Committees (Protocol # 3069; approval date: 3/27/17). Randomized roll-out of STORM to medical centers is occurring as part of the OMHSP's activities and does not require IRB approval. This trial has been registered at ISRCTN (http://www.isrctn.com/ISRCTN16012111). In addition, our partner at the VHA Center for Health Equity Research and Promotion is conducting a complementary evaluation to identify strategies used to implement STORM across the two policy groups as well as barriers and facilitators to STORM implementation (https://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141704557).

PEPReC's protocol has been presented at the 2017 AcademyHealth National Health Policy Conference and a VHA cyberseminar. We are submitting abstracts about this protocol and randomized program evaluations to other national conferences. Once the study is completed, the following two papers will be prepared and submitted to peer-reviewed journals; 1) Reduction of opioid-related serious adverse events (SAEs) in VHA medical centers with and without facilitation, and 2) Effect of identification of high risk patients via the STORM dashboard on opioid-related serious adverse events (SAEs). Beyond providing rigorous evidence of the impact of STORM on patient outcomes, this study will provide insight to OMHSP and VHA leadership about how to optimize the STORM dashboard to reduce SAEs among high risk patients.

Contributors: SP and AF conceived the idea for the study. TM, MG, SP, and AF contributed to the study design, randomization, and analysis plan. TM wrote the first draft. AF and MG were involved in multiple revisions. The final version of the manuscript was approved by all co-authors.

Competing Interests: None

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Data sharing statement: Public disclosure of Veterans Health Administration data containing personally identifiable information is not allowed. No additional data available.

Figure 1 Mock-up of STORM dashboard
Figure 2 Project timeline

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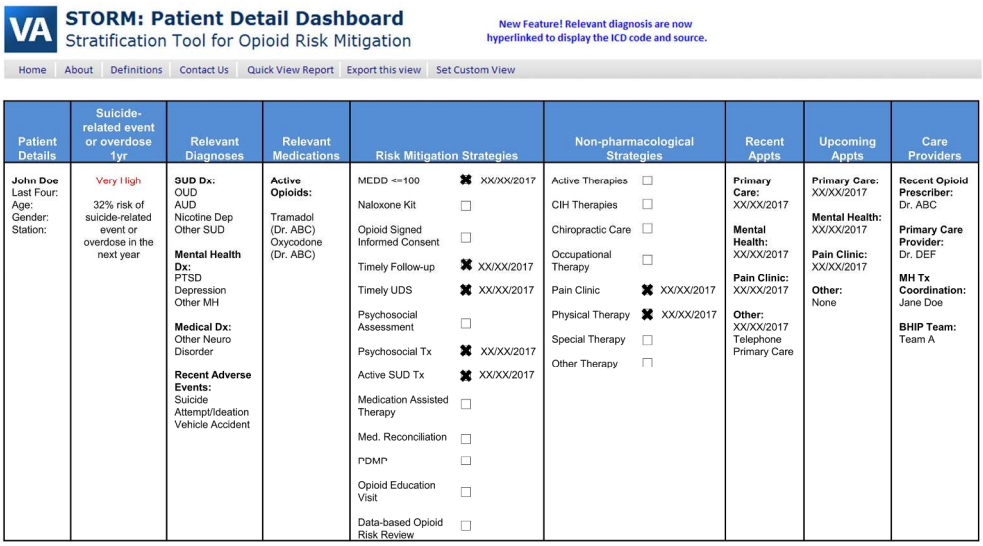

Figure 1 Mock-up of STORM dashboard

122x69mm (600 x 600 DPI)

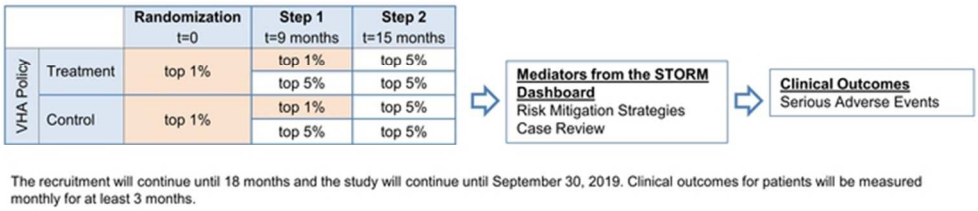

Figure 2 Project timeline

59x14mm (300 x 300 DPI)

Supplemental A ICD9/10 Code for Opioid-Related Serious Adverse Events (SAEs)

Serious Adverse Events	ICD9	ICD10
Involving acetaminophen	965.4; 967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E850.4; E851.; E852.0,.1,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E935.4; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.3	T39.1X1A,D,S; T39.1X2A,D,S; T39.1X3A,D,S; T39.1X4A,D,S; T39.1X5A,D,S; T39.8X1A,D,S; T39.8X2A,D,S; T39.8X3A,D,S; T39.8X4A,D,S; T39.8X5A,D,S; T39.91XA,D,S; T39.92XA,D,S; T39.93XA,D,S; T39.94XA,D,S; T39.95XA,D,S;
Opioid overdose	965.00,01,02,09; E850.0,.1,.2; E935.0,.1,.2; E908.0	T40.0X1A,D.S; T40.0X2A,D,S; T40.0X3A,D,S; T40.0X4A,D,S; T40.0X5A,D,S; T40.1X1A,D,S; T40.1X2A,D,S; T40.1X3A,D,S; T40.1X4A,D,S; T40.2X1A,D,S; T40.2X2A,D,S; T40.2X3A,D,S; T40.2X4A,D,S; T40.2X5A,D,S; T40.3X1A,D,S; T40.3X2A,D,S; T40.3X3A,D,S; T40.3X4A,D,S; T40.3X5A,D,S; T40.4X1A,D,S; T40.4X2A,D,S; T40.4X3A,D,S; T40.4X4A,D,S; T40.4X5A,D,S; T40.601A,D,S; T40.602A,D,S; T40.603A,D,S; T40.604A,D,S; T40.605A,D,S; T40.691A,D,S; T40.692A,D,S; T40.693A,D,S; T40.694A,D,S; T40.695A,D,S
Other drug poisoning	965.1,.6,.61,.69; 969.01,.02,.03,.04,.05, .09,.6,.72; 970.1; E850.3; E854.0,.1,.3; E855.0,.1,.2,.3,.4,.5,.6, .8,.9; E935.3,.6; E939.0,.6,.7; E940.1; E980.4,.5	T40.7X1A,D,S; T40.7X2A,D,S; T40.7X3A,D,S; T40.7X4A,D,S; T40.7X5A,D,S; T40.8X1A,D,S; T40.8X2A,D,S; T40.8X3A,D,S; T40.8X4A,D,S T44.901A,D,S; T44.902A,D,S; T44.903A,D,S; T44.904A,D,S; T44.991A,D,S; T44.992A,D,S; T44.993A,D,S; T44.994A,D,S; T44.995A,D,S; T50.7X1A,D,S; T50.7X2A,D,S; T50.7X3A,D,S; T50.7X4A,D,S; T50.7X5A,D,S
Falls	E880.0,.1,.9; E881.0,.1; E882.; E883.0,.1,.2,.9; E884.0,.1,.2,.3,.4,.5,.6, .9; E885.,.0,.1,.2,.3,.4,.9; E886.0,.9; E887.; E888.,.0,.1,.8,.9; E929.3;	R29.6; W00.0XXA,D,S; W00.1XXA,D,S; W00.2XXA,D,S; W00.9XXA,D,S; W01.0XXA,D,S; W01.10XXA,D,S; W01.110XXA,D,S; W01.111XXA,D,S; W01.118XXA,D,S; W01.119XXA,D,S; W01.190XXA,D,S; W01.198XXA,D,S; W03.XXXA,D,S; W04.XXXA,D,S; W05.0XXA,D,S; W05.1XXA,D,S; W05.2XXA,D,S; W06.XXXA,D,S; W07.XXXA,D,S; W08.XXXA,D,S; W09.0XXA,D,S; W09.1XXA,D,S; W09.2XXA,D,S; W09.8XXA,D,S; W10.0XXA,D,S; W10.1XXA,D,S; W10.2XXA,D,S; W10.8XXA,D,S; W10.9XXA,D,S; W11.XXXA,D,S; W12.XXXA,D,S; W13.0XXA,D,S; W13.1XXA,D,S; W13.2XXA,D,S; W13.3XXA,D,S; W13.4XXA,D,S; W13.8XXA,D,S; W13.9XXA,D,S; W14.XXXA,D,S; W15.XXXA,D,S; W16.011A,D,S; W16.012A,D,S; W16.021A,D,S; W16.022A,D,S; W16.031A,D,S; W16.032A,D,S; W16.111A,D,S; W16.112A,D,S; W16.121A,D,S; W16.122A,D,S; W16.131A,D,S; W16.132A,D,S;

	E987.0,.1,.2,.9	W16.211A,D,S; W16.212A,D,S; W16.221A,D,S; W16.222A,D,S; W16.311A,D,S; W16.312A,D,S; W16.322A,D,S; W16.331A,D,S; W16.332A,D,S; W16.41XA,D,S; W16.42XA,D,S; W16.511A,D,S; W16.512A,D,S; W16.521A,D,S; W16.522A,D,S; W16.531A,D,S; W16.532A,D,S; W16.611A,D,S; W16.612A,D,S; W16.621A,D,S; W16.622A,D,S; W16.711A,D,S; W16.712A,D,S; W16.721A,D,S; W16.722A,D,S;W16.811A,D,S; W16.812A,D,S; W16.821A,D,S; W16.822A,D,S; W16.831A,D,S; W16.832A,D,S; W16.91XA,D,S; W16.92XA,D,S; W17.0XXA,D,S; W17.1XXA,D,S; W17.2XXA,D,S; W17.3XXA,D,S; W17.4XXA,D,S; W17.81XA,D,S; W17.82XA,D,S; W17.89XA,D,S; W18.00XA,D,S; W18.01XA,D,S; W18.02XA,D,S; W18.09XA,D,S; W18.11XA,D,S; W18.12XA,D,S; W18.2XXA,D,S; W18.30XA,D,S; W18.31XA,D,S; W18.39XA,D,S; W18.40XA,D,S; W18.41XA,D,S; W18.42XA,D,S; W18.43XA,D,S; W18.49XA,D,S; W19.XXXA,D,S; X00.3XXA,D,S; X01.3XXA,D,S; X02.3XXA,D,S; X03.3XXA,D,S
Vehicle	E800.1,.2,.3,.8,.9; E801.0,.1,.2,.3,.8,.9; E802.0,.1,.2,.3,.8,.9; E803.0,.1,.2,.3,.8,.9; E804.0,.1,.2,.3,.8,.9; E805.0,.1,.2,.3,.8,.9; E806.0,.1,.2,.3,.8,.9; E807.0,.1,.2,.3,.8,.9, E810.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E811.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E812.0,.1,.2,.3,.4,.5,.6, .7,.8,.9 E813.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E814.0,.1,.2,.3,.4,.5,.6, .7..8,.9; E815.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E816.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E817.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E818.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E819.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E820.0,.1,.2,.3,.4,.5,.6,	V00.01XA,D,S; V00.02XA,D,S; V00.09XA,D,S; V00.111A,D,S; V00.112A,D,S; V00.118A,D,S; V00.121A,D,S; V00.122A,D,S; V00.128A,D,S; V00.131A,D,S; V00.132A,D,S; V00.138A,D,S; V00.141A,D,S; V00.142A,D,S; V00.148A,D,S; V00.151A,D,S; V00.152A,D,S; V00.158A,D,S; V00.181A,D,S; V00.182A,D,S; V00.188A,D,S; V00.211A,D,S; V00.212A,D,S; V00.218A,D,S; V00.221A,D,S; V00.212A,D,S; V00.228A,D,S; V00.281A,D,S; V00.282A,D,S; V00.288A,D,S; V00.311A,D,S; V00.312A,D,S; V00.318A,D,S; V00.321A,D,S; V00.322A,D,S; V00.328A,D,S; V00.381A,D,S; V00.382A,D,S; V00.388A,D,S; V00.811A,D,S; V00.812A,D,S; V00.818A,D,S; V00.821A,D,S; V00.822A,D,S; V00.828A,D,S; V00.831A,D,S; V00.832A,D,S; V00.838A,D,S; V00.891A,D,S; V00.892A,D,S; V00.898A,D,S; V01.00XA,D,S; V01.01XA,D,S; V01.02XA,D,S; V01.09XA,D,S; V01.10XA,D,S; V01.11XA,D,S; V01.12XA,D,S; V01.19XA,D,S; V01.90XA,D,S; V01.91XA,D,S; V01.92XA,D,S; V01.99XA,D,S; V02.00XA,D,S; V02.01XA,D,S; V02.02XA,D,S; V02.09XA,D,S; V02.10XA,D,S; V02.11XA,D,S; V02.12XA,D,S; V02.19XA,D,S; V02.90XA,D,S; V02.91XA,D,S; V02.92XA,D,S; V02.99XA,D,S; V03.00XA,D,S; V03.01XA,D,S; V03.02XA,D,S; V03.09XA,D,S; V03.10XA,D,S; V03.11XA,D,S; V03.12XA,D,S; V03.19XA,D,S; V03.90XA,D,S; V03.91XA,D,S; V03.92XA,D,S; V03.99XA,D,S; V04.00XA,D,S; V04.01XA,D,S; V04.02XA,D,S; V04.09XA,D,S; V04.10XA,D,S; V04.11XA,D,S; V04.12XA,D,S; V04.19XA,D,S; V04.90XA,D,S; V04.91XA,D,S; V04.92XA,D,S; V04.99XA,D,S; V05.00XA,D,S; V05.01XA,D,S; V05.02XA,D,S; V05.09XA,D,S; V05.10XA,D,S; V05.11XA,D,S; V05.12XA,D,S; V05.19XA,D,S; V05.90XA,D,S; V05.91XA,D,S; V05.92XA,D,S; V05.99XA,D,S; ; V06.00XA,D,S; V06.01XA,D,S; V06.02XA,D,S; V06.09XA,D,S; V06.10XA,D,S; V06.11XA,D,S; V06.12XA,D,S; V06.19XA,D,S; V06.90XA,D,S; V06.91XA,D,S; V06.92XA,D,S; V06.99XA,D,S; ; V09.00XA,D,S; V09.01XA,D,S; V09.02XA,D,S; V09.09XA,D,S; V09.1XXA,D,S; V09.20XA,D,S; V09.21XA,D,S; V09.29XA,D,S; V09.3XXA,D,S; V09.9XXA,D,S; V10.0XXA,D,S; V10.1XXA,D,S; V10.2XXA,D,S;V10.3XXA,D,S; V10.4XXA,D,S; V10.5XXA,D,S; V10.9XXA,D,S; V11.0XXA,D,S; V11.1XXA,D,S; V11.2XXA,D,S; V11.3XXA,D,S; V11.4XXA,D,S; V11.5XXA,D,S; V11.9XXA,D,S; V12.0XXA,D,S; V12.1XXA,D,S; V12.2XXA,D,S; V12.3XXA,D,S; V12.4XXA,D,S; V12.5XXA,D,S; V12.9XXA,D,S; V13.0XXA,D,S; V13.1XXA,D,S; V13.2XXA,D,S; V13.3XXA,D,S; V13.4XXA,D,S; V13.5XXA,D,S; V13.9XXA,D,S; V14.0XXA,D,S; V14.1XXA,D,S; V14.2XXA,D,S; V14.3XXA,D,S; V14.4XXA,D,S; V14.5XXA,D,S; V14.9XXA,D,S; V15.0XXA,D,S; V15.1XXA,D,S; V15.2XXA,D,S; V15.3XXA,D,S; V15.4XXA,D,S; V15.5XXA,D,S;

	.7,.8,.9; E821.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E822.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E823.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E824.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E825.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E826.0,.1,.2,.3,.4,.8,.9; E827.0,.2,.3,.4,.8,.9; E828.0,.2,.4,.8,.9; E829.0,.4,.8,.9; E830.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E831.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E832.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E833.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E834.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E835.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E836.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E837.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E838.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E840.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E841.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E842.6,.7,.8,.9; E843.0,.1,.2,.3,.4,.5,.6, .7,.8,.9;	V15.9XXA,D,S; V16.0XXA,D,S; V16.1XXA,D,S; V16.2XXA,D,S; V16.3XXA,D,S; V16.4XXA,D,S; V16.5XXA,D,S; V16.9XXA,D,S; V17.0XXA,D,S; V17.1XXA,D,S; V17.2XXA,D,S; V17.3XXA,D,S; V17.4XXA,D,S; V17.5XXA,D,S; V17.9XXA,D,S; V18.0XXA,D,S; V18.1XXA,D,S; V18.2XXA,D,S; V18.3XXA,D,S; V18.4XXA,D,S; V18.5XXA,D,S; V18.9XXA,D,S; V19.00XA,D,S; V19.09XA,D,S; V19.10XA,D,S; V19.19XA,D,S; V19.20XA,D,S; V19.29XA,D,S; V19.3XXA,D,S; V19.40XA,D,S; V19.49XA,D,S; V19.50XA,D,S; V19.59XA,D,S; V19.60XA,D,S; V19.69XA,D,S; V19.81XA,D,S; V19.88XA,D,S; V19.9XXA,D,S; V20.0XXA,D,S; V20.1XXA,D,S; V20.2XXA,D,S; V20.3XXA,D,S; V20.4XXA,D,S; V20.5XXA,D,S; V20.9XXA,D,S; V21.0XXA,D,S; V21.1XXA,D,S; V21.2XXA,D,S; V21.3XXA,D,S; V21.4XXA,D,S; V21.5XXA,D,S; V21.9XXA,D,S; V22.0XXA,D,S; V22.1XXA,D,S; V22.2XXA,D,S; V22.3XXA,D,S; V22.4XXA,D,S; V22.5XXA,D,S; V22.9XXA,D,S; V23.0XXA,D,S; V23.1XXA,D,S; V23.2XXA,D,S; V23.3XXA,D,S; V23.4XXA,D,S; V23.5XXA,D,S; V23.9XXA,D,S; V24.0XXA,D,S; V24.1XXA,D,S; V24.2XXA,D,S; V24.3XXA,D,S; V24.4XXA,D,S; V24.5XXA,D,S; V24.9XXA,D,S; V25.0XXA,D,S; V25.1XXA,D,S; V25.2XXA,D,S; V25.3XXA,D,S; V25.4XXA,D,S; V25.5XXA,D,S; V25.9XXA,D,S; V26.0XXA,D,S; V26.1XXA,D,S; V26.2XXA,D,S; V26.3XXA,D,S; V26.4XXA,D,S; V26.5XXA,D,S; V26.9XXA,D,S; V27.0XXA,D,S; V27.1XXA,D,S; V27.2XXA,D,S; V27.3XXA,D,S; V27.4XXA,D,S; V27.5XXA,D,S; V27.9XXA,D,S; V28.0XXA,D,S; V28.1XXA,D,S; V28.2XXA,D,S; V28.3XXA,D,S; V28.4XXA,D,S; V28.5XXA,D,S; V28.9XXA,D,S; V29.00XA,D,S; V29.09XA,D,S; V29.10XA,D,S; V29.19XA,D,S; V29.20XA,D,S; V29.29XA,D,S; V29.3XXA,D,S; V29.40XA,D,S; V29.49XA,D,S; V29.50XA,D,S; V29.59XA,D,S; V29.60XA,D,S; V29.69XA,D,S; V29.81XA,D,S; V29.88XA,D,S; V29.9XXA,D,S; V30.0XXA,D,S; V30.1XXA,D,S; V30.2XXA,D,S; V30.3XXA,D,S; V30.4XXA,D,S; V30.5XXA,D,S; V30.6XXA,D,S; V30.7XXA,D,S; V30.9XXA,D,S; V31.0XXA,D,S; V31.1XXA,D,S; V31.2XXA,D,S; V31.3XXA,D,S; V31.4XXA,D,S; V31.5XXA,D,S; V31.6XXA,D,S; V31.7XXA,D,S; V31.9XXA,D,S; V32.0XXA,D,S; V32.1XXA,D,S; V32.2XXA,D,S; V32.3XXA,D,S; V32.4XXA,D,S; V32.5XXA,D,S; V32.6XXA,D,S; V32.7XXA,D,S; V32.9XXA,D,S; V33.0XXA,D,S; V33.1XXA,D,S; V33.2XXA,D,S; V33.3XXA,D,S; V33.4XXA,D,S; V33.5XXA,D,S; V33.6XXA,D,S; V33.7XXA,D,S; V33.9XXA,D,S; V34.0XXA,D,S; V34.1XXA,D,S; V34.2XXA,D,S; V34.3XXA,D,S; V34.4XXA,D,S; V34.5XXA,D,S; V34.6XXA,D,S; V34.7XXA,D,S; V34.9XXA,D,S; V35.0XXA,D,S; V35.1XXA,D,S; V35.2XXA,D,S; V35.3XXA,D,S; V35.4XXA,D,S; V35.5XXA,D,S; V35.6XXA,D,S; V35.7XXA,D,S; V35.9XXA,D,S; V36.0XXA,D,S; V36.1XXA,D,S; V36.2XXA,D,S; V36.3XXA,D,S; V36.4XXA,D,S; V36.5XXA,D,S; V36.6XXA,D,S; V36.7XXA,D,S; V36.9XXA,D,S; V37.0XXA,D,S; V37.1XXA,D,S; V37.2XXA,D,S; V37.3XXA,D,S; V37.4XXA,D,S; V37.5XXA,D,S; V37.6XXA,D,S; V37.7XXA,D,S; V37.9XXA,D,S; V38.0XXA,D,S; V38.1XXA,D,S; V38.2XXA,D,S; V38.3XXA,D,S; V38.4XXA,D,S; V38.5XXA,D,S; V38.6XXA,D,S; V38.7XXA,D,S; V38.9XXA,D,S; V39.00XA,D,S; V39.09XA,D,S; V39.10XA,D,S; V39.19XA,D,S; V39.20XA,D,S; V39.29XA,D,S; V39.3XXA,D,S; V39.40XA,D,S; V39.49XA,D,S; V39.50XA,D,S; V39.59XA,D,S; V39.60XA,D,S; V39.69XA,D,S; V39.81XA,D,S; V39.89XA,D,S; V39.9XXA,D,S; V40.0XXA,D,S; V40.1XXA,D,S; V40.2XXA,D,S; V40.3XXA,D,S; V40.4XXA,D,S; V40.5XXA,D,S; V40.6XXA,D,S; V40.7XXA,D,S; V40.9XXA,D,S; V41.0XXA,D,S; V41.1XXA,D,S; V41.2XXA,D,S; V41.3XXA,D,S; V41.4XXA,D,S; V41.5XXA,D,S; V41.6XXA,D,S; V41.7XXA,D,S; V41.9XXA,D,S; V42.0XXA,D,S; V42.1XXA,D,S; V42.2XXA,D,S; V42.3XXA,D,S; V42.4XXA,D,S; V42.5XXA,D,S; V42.6XXA,D,S; V42.7XXA,D,S;

	E844.0,.1,.2,.3,.4,.5,.6, .7,.8,.9; E845.0,.8,.9; E846.; E847.; E848.; E929.0	V42.9XXA,D,S; V43.01XA,D,S; V43.02XA,D,S; V43.03XA,D,S; V43.04XA,D,S; V43.11XA,D,S; V43.12XA,D,S; V43.13XA,D,S; V43.14XA,D,S; V43.21XA,D,S; V43.22XA,D,S; V43.23XA,D,S; V43.24XA,D,S; V43.31XA,D,S; V43.32XA,D,S; V43.33XA,D,S; V43.34XA,D,S; V43.41XA,D,S; V43.42XA,D,S; V43.43XA,D,S; V43.44XA,D,S; V43.51XA,D,S; V43.52XA,D,S; V43.53XA,D,S; V43.54XA,D,S; V43.61XA,D,S; V43.62XA,D,S; V43.63XA,D,S; V43.64XA,D,S; V43.71XA,D,S; V43.72XA,D,S; V43.73XA,D,S; V43.74XA,D,S; V43.91XA,D,S; V43.92XA,D,S; V43.93XA,D,S; V43.94XA,D,S; V44.0XXA,D,S; V44.1XXA,D,S; V44.2XXA,D,S; V44.3XXA,D,S; V44.4XXA,D,S; V44.5XXA,D,S; V44.6XXA,D,S;V44.7XXA,D,S; V44.9XXA,D,S; V45.0XXA,D,S; V45.1XXA,D,S; V45.2XXA,D,S; V45.3XXA,D,S; V45.4XXA,D,S; V45.5XXA,D,S; V45.6XXA,D,S; V45.7XXA,D,S; V45.9XXA,D,S; V46.0XXA,D,S; V46.1XXA,D,S; V46.2XXA,D,S; V46.3XXA,D,S; V46.4XXA,D,S; V46.5XXA,D,S; V46.6XXA,D,S; V46.7XXA,D,S; V46.9XXA,D,S; V47.0XXA,D,S; V47.01XA,D,S; V47.02XA,D,S; V47.11XA,D,S; V47.12XA,D,S; V47.1XXA,D,S; V47.2XXA,D,S; V47.31XA,D,S; V47.32XA,D,S; V47.3XXA,D,S; V47.4XXA,D,S; V47.51XA,D,S; V47.52XA,D,S; V47.5XXA,D,S; V47.61XA,D,S; V47.62XA,D,S; V47.6XXA,D,S; V47.7XXA,D,S; V47.91XA,D,S; V47.92XA,D,S; V47.9XXA,D,S; V48.0XXA,D,S; V48.1XXA,D,S; V48.2XXA,D,S; V48.3XXA,D,S; V48.4XXA,D,S; V48.5XXA,D,S; V48.6XXA,D,S; V48.7XXA,D,S; V48.9XXA,D,S; V49.00XA,D,S; V49.09XA,D,S; V49.10XA,D,S; V49.19XA,D,S; V49.20XA,D,S; V49.29XA,D,S; V49.3XXA,D,S; V49.40XA,D,S; V49.49XA,D,S; V49.50XA,D,S; V49.59XA,D,S; V49.60XA,D,S; V49.69XA,D,S; V49.81XA,D,S; V49.88XA,D,S; V49.9XXA,D,S; V50.0XXA,D,S; V50.1XXA,D,S; V50.2XXA,D,S; V50.3XXA,D,S; V50.4XXA,D,S; V50.5XXA,D,S; V50.6XXA,D,S; V50.7XXA,D,S; V50.9XXA,D,S; V51.0XXA,D,S; V51.1XXA,D,S; V51.2XXA,D,S; V51.3XXA,D,S; V51.4XXA,D,S; V51.5XXA,D,S; V51.6XXA,D,S; V51.7XXA,D,S; V51.9XXA,D,S; V52.0XXA,D,S; V52.1XXA,D,S; V52.2XXA,D,S; V52.3XXA,D,S; V52.4XXA,D,S; V52.5XXA,D,S; V52.6XXA,D,S; V52.7XXA,D,S; V52.9XXA,D,S; V53.0XXA,D,S; V53.1XXA,D,S; V53.2XXA,D,S; V53.3XXA,D,S; V53.4XXA,D,S; V53.5XXA,D,S; V53.6XXA,D,S; V53.7XXA,D,S; V53.9XXA,D,S; V54.0XXA,D,S; V54.1XXA,D,S; V54.2XXA,D,S; V54.3XXA,D,S; V54.4XXA,D,S; V54.5XXA,D,S; V54.6XXA,D,S; V54.7XXA,D,S; V54.9XXA,D,S; V55.0XXA,D,S; V55.1XXA,D,S; V55.2XXA,D,S; V55.3XXA,D,S; V55.4XXA,D,S; V55.5XXA,D,S; V55.6XXA,D,S; V55.7XXA,D,S; V55.9XXA,D,S; V56.0XXA,D,S; V56.1XXA,D,S; V56.2XXA,D,S; V56.3XXA,D,S; V56.4XXA,D,S; V56.5XXA,D,S; V56.6XXA,D,S; V56.7XXA,D,S; V56.9XXA,D,S; V57.0XXA,D,S; V57.1XXA,D,S; V57.2XXA,D,S; V57.3XXA,D,S; V57.4XXA,D,S; V57.5XXA,D,S; V57.6XXA,D,S; V57.7XXA,D,S; V57.9XXA,D,S; V58.0XXA,D,S; V58.1XXA,D,S; V58.2XXA,D,S; V58.3XXA,D,S; V58.4XXA,D,S; V58.5XXA,D,S; V58.6XXA,D,S; V58.7XXA,D,S; V58.9XXA,D,S; V59.00XA,D,S; V59.09XA,D,S; V59.10XA,D,S; V59.19XA,D,S; V59.20XA,D,S; V59.29XA,D,S; V59.3XXA,D,S; V59.40XA,D,S; V59.49XA,D,S; V59.50XA,D,S; V59.59XA,D,S; V59.60XA,D,S; V59.69XA,D,S; V59.81XA,D,S; V59.88XA,D,S; V59.9XXA,D,S; V60.0XXA,D,S; V60.1XXA,D,S; V60.2XXA,D,S; V60.3XXA,D,S; V60.4XXA,D,S; V60.5XXA,D,S; V60.6XXA,D,S; V60.7XXA,D,S; V60.9XXA,D,S; V61.0XXA,D,S; V61.1XXA,D,S; V61.2XXA,D,S; V61.3XXA,D,S; V61.4XXA,D,S; V61.5XXA,D,S; V61.6XXA,D,S; V61.7XXA,D,S; V61.9XXA,D,S; V62.0XXA,D,S; V62.1XXA,D,S; V62.2XXA,D,S; V62.3XXA,D,S; V62.4XXA,D,S; V62.5XXA,D,S; V62.6XXA,D,S; V62.7XXA,D,S; V62.9XXA,D,S; V63.0XXA,D,S; V63.1XXA,D,S; V63.2XXA,D,S; V63.3XXA,D,S; V63.4XXA,D,S; V63.5XXA,D,S;

		V63.6XXA,D,S; V63.7XXA,D,S; V63.9XXA,D,S; V64.0XXA,D,S; V64.1XXA,D,S; V64.2XXA,D,S; V64.3XXA,D,S; V64.4XXA,D,S; V64.5XXA,D,S; V64.6XXA,D,S; V64.7XXA,D,S; V64.9XXA,D,S; V65.0XXA,D,S; V65.1XXA,D,S; V65.2XXA,D,S; V65.3XXA,D,S; V65.4XXA,D,S; V65.5XXA,D,S; V65.6XXA,D,S; V65.7XXA,D,S; V65.9XXA,D,S; V66.0XXA,D,S; V66.1XXA,D,S; V66.2XXA,D,S; V66.3XXA,D,S; V66.4XXA,D,S; V66.5XXA,D,S; V66.6XXA,D,S; V66.7XXA,D,S; V66.9XXA,D,S; V67.0XXA,D,S; V67.1XXA,D,S; V67.2XXA,D,S; V67.3XXA,D,S; V67.4XXA,D,S; V67.5XXA,D,S; V67.6XXA,D,S; V67.7XXA,D,S; V67.9XXA,D,S; V68.0XXA,D,S; V68.1XXA,D,S; V68.2XXA,D,S; V68.3XXA,D,S; V68.4XXA,D,S; V68.5XXA,D,S; V68.6XXA,D,S; V68.7XXA,D,S; V68.9XXA,D,S; V69.00XA,D,S; V69.09XA,D,S; V69.10XA,D,S; V69.19XA,D,S; V69.20XA,D,S; V69.3XXA,D,S; V69.40XA,D,S; V69.49XA,D,S; V69.50XA,D,S; V69.59XA,D,S; V69.60XA,D,S; V69.69XA,D,S; V69.81XA,D,S; V69.88XA,D,S; V69.9XXA,D,S; V70.0XXA,D,S; V70.1XXA,D,S; V70.2XXA,D,S; V70.3XXA,D,S; V70.4XXA,D,S; V70.5XXA,D,S; V70.6XXA,D,S; V70.7XXA,D,S; V70.9XXA,D,S; V71.0XXA,D,S; V71.1XXA,D,S; V71.2XXA,D,S; V71.3XXA,D,S; V71.4XXA,D,S; V71.5XXA,D,S; V71.6XXA,D,S; V71.7XXA,D,S; V71.9XXA,D,S; V72.0XXA,D,S; V72.1XXA,D,S; V72.2XXA,D,S; V72.3XXA,D,S; V72.4XXA,D,S; V72.5XXA,D,S; V72.6XXA,D,S; V72.7XXA,D,S; V72.9XXA,D,S; V73.0XXA,D,S; V73.1XXA,D,S; V73.2XXA,D,S; V73.3XXA,D,S; V73.4XXA,D,S; V73.5XXA,D,S; V73.6XXA,D,S; V73.7XXA,D,S; V73.9XXA,D,S; V74.0XXA,D,S; V74.1XXA,D,S; V74.2XXA,D,S; V74.3XXA,D,S; V74.4XXA,D,S; V74.5XXA,D,S; V74.6XXA,D,S; V74.7XXA,D,S; V74.9XXA,D,S; V75.0XXA,D,S; V75.1XXA,D,S; V75.2XXA,D,S; V75.3XXA,D,S; V75.4XXA,D,S; V75.5XXA,D,S; V75.6XXA,D,S; V75.7XXA,D,S; V75.9XXA,D,S; V76.0XXA,D,S; V76.1XXA,D,S; V76.2XXA,D,S; V76.3XXA,D,S; V76.4XXA,D,S; V76.5XXA,D,S; V76.6XXA,D,S; V76.7XXA,D,S; V76.9XXA,D,S; V77.0XXA,D,S; V77.1XXA,D,S; V77.2XXA,D,S; V77.3XXA,D,S; V77.4XXA,D,S; V77.5XXA,D,S; V77.6XXA,D,S; V77.7XXA,D,S; V77.9XXA,D,S; V78.0XXA,D,S; V78.1XXA,D,S; V78.2XXA,D,S; V78.3XXA,D,S; V78.4XXA,D,S; V78.5XXA,D,S; V78.6XXA,D,S; V78.7XXA,D,S; V78.9XXA,D,S; V79.00XA,D,S; V79.10XA,D,S; V79.19XA,D,S; V79.20XA,D,S; V79.29XA,D,S; V79.3XXA,D,S; V79.40XA,D,S; V79.49XA,D,S; V79.50XA,D,S; V79.59XA,D,S; V79.60XA,D,S; V79.69XA,D,S; V79.81XA,D,S; V79.88XA,D,S; V79.9XXA,D,S; V80.010A,D,S; V80.020A,D,S; V80.11XA,D,S; V80.12XA,D,S; V80.21XA,D,S; V80.22XA,D,S; V80.31XA,D,S; V80.32XA,D,S; V80.41XA,D,S; V80.42XA,D,S; V80.51XA,D,S; V80.52XA,D,S; V80.61XA,D,S; V80.62XA,D,S; V80.710A,D,S; V80.711A,D,S; V80.720A,D,S; V80.721A,D,S; V80.730A,D,S; V80.731A,D,S; V80.790A,D,S; V80.791A,D,S; V80.81XA,D,S; V80.82XA,D,S; V80.910A,D,S; V80.918A,D,S; V80.919A,D,S; V80.919A,D,S; V80.920A,D,S; V80.928A,D,S; V80.929A,D,S; V81.0XXA,D,S; V81.1XXA,D,S; V81.2XXA,D,S; V81.3XXA,D,S; V81.4XXA,D,S; V81.5XXA,D,S; V81.6XXA,D,S; V81.7XXA,D,S; V81.81XA,D,S; V81.82XA,D,S; V81.83XA,D,S; V81.89XA,D,S; V81.9XXA,D,S; V82.0XXA,D,S; V82.1 XXA,D,S; V82.2XXA,D,S; V82.3XXA,D,S; V82.4XXA,D,S; V82.5XXA,D,S; V82.6XXA,D,S; V82.7XXA,D,S; V82.8XXA,D,S; V82.9XXA,D,S; V83.0XXA,D,S; V83.1 XXA,D,S; V83.2XXA,D,S; V83.3XXA,D,S; V83.4XXA,D,S; V83.5XXA,D,S; V83.6XXA,D,S; V83.7XXA,D,S; V83.9XXA,D,S; V84.0XXA,D,S; V84.1XXA,D,S; V84.2XXA,D,S; V84.3XXA,D,S; V84.4XXA,D,S; V84.5XXA,D,S; V84.6XXA,D,S; V84.7XXA,D,S; V84.9XXA,D,S; V85.0XXA,D,S; V85.1 XXA,D,S; V85.2XXA,D,S; V85.3XXA,D,S; V85.4XXA,D,S; V85.5XXA,D,S; V85.6XXA,D,S; V85.7XXA,D,S; V85.8XXA,D,S;

		V85.9XXA,D,S; V86.01XA,D,S; V86.02XA,D,S; V86.03XA,D,S; V86.04XA,D,S; V86.09XA,D,S; V86.11XA,D,S; V86.12XA,D,S; V86.13XA,D,S; V86.14XA,D,S; V86.19XA,D,S; V86.21XA,D,S; V86.22XA,D,S;V86.23XA,D,S; V86.24XA,D,S; V86.29XA,D,S; V86.31XA,D,S; V86.32XA,D,S; V86.33XA,D,S; V86.34XA,D,S; V86.39XA,D,S; V86.41XA,D,S; V86.42XA,D,S; V86.43XA,D,S; V86.44XA,D,S; V86.49XA,D,S; V86.51XA,D,S; V86.52XA,D,S; V86.53XA,D,S; V86.54XA,D,S; V86.59XA,D,S; V86.61XA,D,S; V86.62XA,D,S; V86.63XA,D,S; V86.64XA,D,S; V86.69XA,D,S; V86.71XA,D,S; V86.72XA,D,S; V86.73XA,D,S; V86.74XA,D,S; V86.79XA,D,S; V86.91XA,D,S; V86.92XA,D,S; V86.93XA,D,S; V86.94XA,D,S; V86.99XA,D,S; V87.0XXA,D,S; V87.1XXA,D,S; V87.2XXA,D,S; V87.3XXA,D,S; V87.4XXA,D,S; V87.5XXA,D,S; V87.6XXA,D,S; V87.7XXA,D,S; V87.8XXA,D,S; V87.9XXA,D,S; V88.0XXA,D,S; V88.1XXA,D,S; V88.2XXA,D,S; V88.3XXA,D,S; V88.4XXA,D,S; V88.5XXA,D,S; V88.6XXA,D,S; V88.7XXA,D,S; V88.8XXA,D,S; V88.9XXA,D,S; V89.0XXA,D,S; V89.1XXA,D,S; V89.2XXA,D,S; V89.3XXA,D,S; V89.9XXA,D,S; V90.00XA,D,S; V90.01XA,D,S; V90.02XA,D,S; V90.03XA,D,S; V90.04XA,D,S; V90.05XA,D,S; V90.06XA,D,S; V90.08XA,D,S; V90.09XA,D,S; V90.10XA,D,S; V90.11XA,D,S; V90.12XA,D,S; V90.13XA,D,S; V90.14XA,D,S; V90.15XA,D,S; V90.16XA,D,S; V90.18XA,D,S; V90.19XA,D,S; V90.20XA,D,S; V90.21XA,D,S; V90.22XA,D,S; V90.23XA,D,S; V90.24XA,D,S; V90.25XA,D,S;V90.26XA,D,S; V90.27XA,D,S; V90.28XA,D,S; V90.29XA,D,S; V90.30XA,D,S; V90.31XA,D,S; V90.32XA,D,S; V90.33XA,D,S; V90.34XA,D,S; V90.35XA,D,S; V90.36XA,D,S; V90.37XA,D,S; V90.38XA,D,S; V90.39XA,D,S; V90.80XA,D,S; V90.81XA,D,S; V90.82XA,D,S; V90.83XA,D,S; V90.84XA,D,S; V90.85XA,D,S; V90.86XA,D,S; V90.87XA,D,S; V90.88XA,D,S; V90.89XA,D,S; V91.00XA,D,S; V91.01XA,D,S; V91.02XA,D,S; V91.03XA,D,S; V91.04XA,D,S; V91.05XA,D,S; V91.06XA,D,S; V91.07XA,D,S; V91.08XA,D,S; V91.09XA,D,S; V91.10XA,D,S; V91.11XA,D,S; V91.12XA,D,S; V91.13XA,D,S; V91.14XA,D,S; V91.15XA,D,S; V91.16XA,D,S; V91.18XA,D,S; V91.19XA,D,S; V91.20XA,D,S; V91.21XA,D,S; V91.22XA,D,S; V91.24XA,D,S; V91.25XA,D,S; V91.26XA,D,S; V91.29XA,D,S; V91.30XA,D,S; V91.31XA,D,S; V91.32XA,D,S; V91.33XA,D,S; V91.34XA,D,S; V91.35XA,D,S; V91.36XA,D,S; V91.37XA,D,S; V91.38XA,D,S; V91.39XA,D,S; V91.80XA,D,S; V91.81XA,D,S; V91.82XA,D,S; V91.83XA,D,S; V91.84XA,D,S; V91.85XA,D,S; V91.86XA,D,S; V91.87XA,D,S; V91.88XA,D,S; V91.89XA,D,S; V92.00XA,D,S; V92.01XA,D,S; V92.02XA,D,S; V92.03XA,D,S; V92.04XA,D,S; V92.05XA,D,S; V92.06XA,D,S; V92.07XA,D,S; V92.08XA,D,S; V92.09XA,D,S; V92.10XA,D,S; V92.11XA,D,S; V92.12XA,D,S; V92.13XA,D,S; V92.14XA,D,S; V92.15XA,D,S; V92.16XA,D,S; V92.19XA,D,S; V92.20XA,D,S; V92.21XA,D,S; V92.22XA,D,S; V92.23XA,D,S; V92.24XA,D,S; V92.25XA,D,S; V92.26XA,D,S; V92.27XA,D,S; V92.28XA,D,S; V92.29XA,D,S; V93.00XA,D,S; V93.01XA,D,S; V93.02XA,D,S; V93.03XA,D,S; V93.04XA,D,S; V93.09XA,D,S; V93.10XA,D,S; V93.11XA,D,S; V93.12XA,D,S; V93.13XA,D,S; V93.14XA,D,S; V93.19XA,D,S; V93.20XA,D,S; V93.21XA,D,S; V93.22XA,D,S; V93.23XA,D,S; V93.24XA,D,S; V93.29XA,D,S; V93.30XA,D,S; V93.31XA,D,S; V93.32XA,D,S; V93.33XA,D,S; V93.34XA,D,S; V93.35XA,D,S; V93.36XA,D,S; V93.37XA,D,S; V93.38XA,D,S; V93.40XA,D,S; V93.41XA,D,S; V93.42XA,D,S;V93.43XA,D,S; V93.44XA,D,S; V93.48XA,D,S; V93.49XA,D,S; V93.50XA,D,S; V93.51XA,D,S; V93.52XA,D,S; V93.53XA,D,S; V93.54XA,D,S; V93.59XA,D,S; V93.60XA,D,S; V93.61XA,D,S; V93.62XA,D,S; V93.63XA,D,S; V93.64XA,D,S; V93.69XA,D,S; V93.80XA,D,S;

		V93.81XA,D,S; V93.82XA,D,S; V93.83XA,D,S;V93.84XA,D,S; V93.85XA,D,S; V93.86XA,D,S; V93.87XA,D,S; V93.88XA,D,S; V93.89XA,D,S; V94.0XXA,D,S; V94.11XA,D,S; V94.12XA,D,S; V94.21XA,D,S; V94.22XA,D,S; V94.31XA,D,S; V94.32XA,D,S; V94.4XXA,D,S; V94.810A,D,S; V94.811A,D,S; V94.818A,D,S; V94.89XA,D,S; V94.9XXA,D,S; V95.00XA,D,S; V95.01XA,D,S; V95.02XA,D,S; V95.03XA,D,S; V95.04XA,D,S; V95.05XA,D,S; V95.09XA,D,S; V95.10XA,D,S; V95.11XA,D,S; V95.12XA,D,S; V95.13XA,D,S; V95.14XA,D,S; V95.15XA,D,S; V95.19XA,D,S; V95.20XA,D,S; V95.21XA,D,S; V95.22XA,D,S; V95.23XA,D,S; V95.24XA,D,S; V95.25XA,D,S; V95.29XA,D,S; V95.30XA,D,S; V95.31XA,D,S; V95.32XA,D,S; V95.33XA,D,S; V95.34XA,D,S; V95.35XA,D,S; V95.39XA,D,S; V95.40XA,D,S; V95.41XA,D,S; V95.42XA,D,S; V95.43XA,D,S; V95.44XA,D,S; V95.45XA,D,S; V95.49XA,D,S; V95.8XXA,D,S; V95.9XXA,D,S; V96.00XA,D,S; V96.01XA,D,S; V96.02XA,D,S; V96.03XA,D,S; V96.04XA,D,S; V96.05XA,D,S; V96.09XA,D,S; V96.10XA,D,S; V96.11XA,D,S; V96.12XA,D,S; V96.13XA,D,S; V96.14XA,D,S; V96.15XA,D,S; V96.19XA,D,S; V96.20XA,D,S; V96.21XA,D,S; V96.22XA,D,S; V96.23XA,D,S; V96.24XA,D,S; V96.25XA,D,S; V96.29XA,D,S; V96.8XXA,D,S; V96.9XXA,D,S; V97.0XXA,D,S; V97.1XXA,D,S; V97.21XA,D,S; V97.22XA,D,S; V97.29XA,D,S; V97.31XA,D,S; V97.32XA,D,S; V97.33XA,D,S; V97.39XA,D,S; V97.810A,D,S; V97.811A,D,S; V97.818A,D,S; V97.89XA,D,S; V98.0XXA,D,S; V98.1XXA,D,S; V98.2XXA,D,S; V98.3XXA,D,S; V98.8XXA,D,S; V99.XXXA,D,S
Sedative Poisoning	967.0,.8; 968.0; 969.1,.2,.3,.4,.5; E851.; E852.0,.1,.2,.3,.4,.5,.8,.9; E853.0,.1,.2,.8,.9; E937.0,.8; E938.0; E939.1,.2,.4,.5; E980.1,.2,.3	T41.0X1A,D,S; T41.0X2A,D,S; T41.0X3A,D,S; T41.0X4A,D,S; T41.0X5A,D,S; T41.1X1A,D,S; T41.1X2A,D,S; T41.1X3A,D,S; T41.1X4A,D,S; T41.1X5A,D,S; T41.201A,D,S; T41.202A,D,S; T41.203A,D,S; T41.204A,D,S; T41.205A,D,S; T41.291A,D,S; T41.292A,D,S; T41.293A,D,S; T41.294A,D,S; T41.295A,D,S; T41.3X1A,D,S; T41.3X2A,D,S; T41.3X3A,D,S; T41.3X4A,D,S; T41.3X5A,D,S; T41.41XA,D,S; T41.42XA,D,S; T41.43XA,D,S; T41.44XA,D,S; T41.45XA,D,S; T42.3X1A,D,S; T42.3X2A,D,S; T42.3X3A,D,S; T42.3X4A,D,S; T42.3X5A,D,S; T42.4X1A,D,S; T42.4X2A,D,S; T42.4X3A,D,S; T42.4X4A,D,S; T42.4X5A,D,S; T42.6X1A,D,S; T42.6X2A,D,S; T42.6X3A,D,S; T42.6X4A,D,S; T42.6X5A,D,S; T42.8X1A,D,S; T42.8X2A,D,S; T42.8X3A,D,S; T42.8X4A,D,S; T42.8X5A,D,S; T43.3X1A,D,S; T43.3X2A,D,S; T43.3X3A,D,S; T43.3X4A,D,S; T43.3X5A,D,S; T43.4X1A,D,S; T43.4X2A,D,S; T43.4X3A,D,S; T43.4X4A,D,S; T43.4X5A,D,S; T43.501A,D,S; T43.502A,D,S; T43.503A,D,S; T43.504A,D,S; T43.505A,D,S; T43.591A,D,S; T43.592A,D,S; T43.593A,D,S; T43.594A,D,S; T43.595A,D,S
Suicide-related	E950.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9,.91,.92; E951.0,.01,.02,.1,.11,.12,.8,.81,.82; E952.0,.01,.02,.1,.11,.12,.8,.81,.82,.9,.91,.92; E953.0,.01,.02,.1,.11,.	R45.851; T14.91; T36.0X2A,D,S; T36.1X2A,D,S; T36.2X2A,D,S; T36.3X2A,D,S; T36.4X2A,D,S; T36.5X2A,D,S; T36.6X2A,D,S; T36.7X2A,D,S; T36.8X2A,D,S; T36.92XA,D,S; T37.0X2A,D,S; T37.1X2A,D,S; T37.2X2A,D,S; T37.3X2A,D,S; T37.4X2A,D,S; T37.5X2A,D,S; T37.8X2A,D,S; T37.92XA,D,S; T38.0X2A,D,S; T38.1X2A,D,S; T38.2X2A,D,S; T38.3X2A,D,S; T38.4X2A,D,S; T38.5X2A,D,S; T38.6X2A,D,S; T38.7X2A,D,S; T38.802A,D,S; T38.812A,D,S; T38.892A,D,S; T38.902A,D,S; T38.992A,D,S; T39.012A,D,S; T39.092A,D,S; T39.1X2A,D,S; T39.2X2A,D,S; T39.312A,D,S; T39.392A,D,S; T39.4X2A,D,S; T39.8X2A,D,S; T39.92XA,D,S; T40.0X2A,D,S; T40.1X2A,D,S; T40.2X2A,D,S; T40.3X2A,D,S; T40.4X2A,D,S; T40.5X2A,D,S; T40.602A,D,S; T40.692A,D,S; T40.7X2A,D,S; T40.8X2A,D,S; T40.902A,D,S; T40.992A,D,S; T41.0X2A,D,S; T41.1X2A,D,S; T41.202A,D,S; T41.292A,D,S; T41.3X2A,D,S; T41.42XA,D,S; T41.5X2A,D,S; T42.0X2A,D,S; T42.1X2A,D,S; T42.2X2A,D.S; T42.3X2A,D,S; T42.4X2A,D.S; T42.5X2A,D,S;

	12,.8,.81,.82,.9; E954.,.1,.2; E955.0,.01,.02,.1,.11,.12,.2,.21,.22,.3,.31..32,.4,.41,.42,.5,.51,.52,.6,.7,.9; E956.,.1,.2; E957.0,.01,.02,.1,.11,.12,.2,.21,.22,.9,.91,.92; E958.0,.01;.02,.1,.11,.12,.2,.21,.22,.3,.31,.32,.4,.41,.42,.5,.51,.52,.6,.61,.62,.7,.71,.72,.8,.81,.82,.9; E959.; E980.6,.8; E981.0,.1,.8; E982.0,.1,.8,.9; E983.0,.1,.8,.9; E984.; E988.0,.1,.2,.3,.4,.5,.6,.7,.8,.9; V62.84	T42.6X2A,D,S; T42.72XA,D,S; T42.8X2A,D,S; T43.012A,D,S; T43.022A,D,S; T43.1X2A,D,S; T43.202A,D,S; T43.212A,D,S; T43.222A,D,S; T43.292A,D,S; T43.3X2A,D,S; T43.4X2A,D,S; T43.502A,D,S; T43.592A,D,S; T43.602A,D,S; T43.612A,D,S; T43.622A,D,S; T43.632A,D,S; T43.692A,D,S; T43.8X2A,D,S; T43.92XA,D,S; T44.0X2A,D,S; T44.1X2A,D,S; T44.2X2A,D,S; T44.3X2A,D,S; T44.4X2A,D,S; T44.5X2A,D,S; T44.6X2A,D,S; T44.7X2A,D,S; T44.8X2A,D,S; T44.902A,D,S; T44.992A,D,S; T45.0X2A,D,S; T45.1X2A,D,S; T45.2X2A,D,S; T45.3X2A,D,S; T45.4X2A,D,S; T45.512A,D,S; T45.522A,D,S; T45.602A,D,S; T45.612A,D,S; T45.622A,D,S; T45.692A,D,S; T45.7X2A,D,S; T45.8X2A,D,S; T45.92XA.D.S; T46.0X2A,D,S; T46.1X2A,D,S; T46.2X2A,D,S; T46.3X2A,D,S; T46.4X2A,D,S; T46.5X2A,D,S; T46.6X2A,D,S; T46.7X2A,D,S; T46.8X2A,D,S; T46.902A,D,S; T46.992A,D,S; T47.0X2A,D,S; T47.1X2A,D,S; T47.2X2A,D,S; T47.3X2A,D,S; T47.4X2A,D,S; T47.5X2A,D,S; T47.6X2A,D,S; T47.7X2A,D,S; T47.8X2A,D,S; T47.92XA,D,S; T48.0X2A,D,S; T48.1X2A,D,S; T48.202A,D,S; T48.292A,D,S; T48.3X2A,D,S; T48.4X2A,D,S; T48.5X2A,D,S; T48.6X2A,D,S; T48.902A,D,S; T48.992A,D,S; T49.0X2A,D,S; T49.1X2A,D,S; T49.2X2A,D,S; T49.3X2A,D,S; T49.4X2A,D,S; T49.5X2A,D,S; T49.6X2A,D,S; T49.7X2A,D,S; T49.8X2A,D,S; T49.92XA,D,S; T50.0X2A,D,S; T50.1X2A,D,S; T50.2X2A,D,S; T50.3X2A,D,S; T50.4X2A,D,S; T50.5X2A,D,S; T50.6X2A,D,S; T50.7X2A,D,S; T50.8X2A,D,S; T50.902A,D,S; T50.902S,D,S; T50.992A,D,S; T50.A12A,D,S; T50.A12A,D,S; T50.A22A,D,S; T50.A92A,D,S; T50.B12A,D,S; T50.B92A,D,S; T50.Z12A,D,S; T50.Z92A,D,S; T51.0X2A,D,S; T51.1X2A,D,S; T51.2X2A,D,S; T51.3X2A,D,S; T51.8X2A,D,S; T51.92XA,D,S; T52.0X2A,D,S; T52.1X2A,D,S; T52.2X2A,D,S; T52.3X2A,D,S; T52.4X2A,D,S; T52.8X2A,D,S; T52.92XA,D,S; T53.0X2A,D,S; T53.1X2A,D,S; T53.2X2A,D,S; T53.3X2A,D,S; T53.4X2A,D,S; T53.5X2A,D,S; T53.6X2A,D,S; T53.7X2A,D,S; T53.92XA,D,S; T54.0X2A,D,S; T54.1X2A,D,S; T54.2X2A,D,S; T54.3X2A,D,S; T54.92XA,D,S; T55.0X2A,D,S; T55.1X2A,D,S; T56.0X2A,D,S; T56.1X2A,D,S; T56.2X2A,D,S; T56.3X2A,D,S; T56.4X2A,D,S; T56.5X2A,D,S; T56.6X2A,D,S; T56.7X2A,D,S; T56.812A,D,S; T56.892A,D,S; T56.92XA,D,S; T57.0X2A,D,S; T57.1X2A,D,S; T57.2X2A,D,S; T57.3X2A,D,S; T57.8X2A,D,S; T57.92XA,D,S; T58.02XA,D,S; T58.12XA,D,S; T58.2X2A,D,S; T58.8X2A,D,S; T58.92XA,D,S; T59.0X2A,D,S; T59.1X2A,D,S; T59.2X2A,D,S; T59.3X2A,D,S; T59.4X2A,D,S; T59.5X2A,D,S; T59.6X2A,D,S; T59.7X2A,D,S; T59.812A,D,S; T59.892A,D,S; T59.92XA,D,S; T60.0X2A,D,S; T60.1X2A,D,S; T60.2X2A,D,S; T60.3X2A,D,S; T60.4X2A,D,S; T60.8X2A,D,S; T60.92XA,D,S; T61.02XA,D,S; T61.12XA,D,S; T61.772A,D,S; T61.782A,D,S; T61.8X2A,D,S; T61.92XA,D,S; T62.0X2A,D,S; T62.1X2A,D,S; T62.2X2A,D,S; T62.8X2A,D,S; T62.92XA,D,S; T63.002A,D,S; T63.012A,D,S; T63.022A,D,S; T63.032A,D,S; T63.042A,D,S; T63.062A,D,S; T63.072A,D,S; T63.082A,D,S; T63.092A,D,S; T63.112A,D,S; T63.122A,D,S; T63.192A,D,S; T63.2X2A,D,S; T63.302A,D,S; T63.312A,D,S; T63.322A,D,S; T63.332A,D,S; T63.392A,D,S; T63.412A,D,S; T63.422A,D,S; T63.432A,D,S; T63.442A,D,S; T63.452A,D,S; T63.462A,D,S; T63.482A,D,S; T63.512A,D,S; T63.592A,D,S; T63.612A,D,S; T63.622A,D,S; T63.632A,D,S; T63.692A,D,S; T63.712A,D,S; T63.792A,D,S; T63.812A,D,S; T63.822A,D,S; T63.832A,D,S; T63.892A,D,S; T63.92XA,D,S; T64.02XA,D,S; T64.82XA,D,S; T65.0X2A,D,S; T65.1X2A,D,S; T65.212A,D,S; T65.222A,D,S; T65.292A,D,S; T65.3X2A,D,S; T65.4X2A,D,S; T65.5X2A,D,S; T65.6X2A,D,S; T65.812A,D,S; T65.822A,D,S; T65.832A,D,S; T65.892A,D,S;

		T65.92XA,D,S; T71.112A,D,S; T71.122A,D,S; T71.132A,D,S; T71.152A,D,S; T71.162A,D,S; T71.192A,D,S; T71.222A,D,S; T71.232A,D,S; X71.0XXA,D,S; X71.1XXA,D,S; X71.2XXA,D,S; X71.3XXA,D,S; X71.8XXA,D,S; X71.9XXA,D,S; X72.XXXA,D,S; X73.0XXA,D,S; X73.1XXA,D,S; X73.2XXA,D,S; X73.8XXA,D,S; X73.9XXA,D,S; X74.01XA,D,S; X74.02XA,D,S; X74.09XA,D,S; X74.8XXA,D,S; X74.9XXA,D,S; X75.XXXA,D,S; X76.XXXA,D,S; X77.0XXA,D,S; X77.1XXA,D,S; X77.2XXA,D,S; X77.3XXA,D,S; X77.8XXA,D,S; X77.9XXA,D,S; X78.0XXA,D,S; X78.1XXA,D,S; X78.2XXA,D,S; X78.8XXA,D,S; X78.9XXA,D,S; X79.XXXA,D,S; X80.XXXA,D,S; X81.0XXA,D,S; X81.1XXA,D,S; X81.8XXA,D,S; X82.0XXA,D,S; X82.1XXA,D,S; X82.2XXA,D,S; X82.8XXA,D,S; X83.0XXA,D,S; X83.1XXA,D,S; X83.2XXA,D,S; X83.8XXA,D,S

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_1_____
	2b	All items from the World Health Organization Trial Registration Data Set	_NA_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1_____
	5b	Name and contact information for the trial sponsor	_8_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_None_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_NA_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_2-3_____
	6b	Explanation for choice of comparators	_2-3_____
Objectives	7	Specific objectives or hypotheses	_4_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_3-5_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_3-4_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_5_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_4-5_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_ NA _____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_ NA _____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_NA_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_5-6_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_Figure 2_____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_6_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_5_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_5_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_5_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_5_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_5_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_NA_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_6-7_____

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Patient outcomes can be followed as long as they continue to use any VHA medical centers.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_6_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_6-7_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_6-7_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Patients who stop coming to VHA medical centers cannot be followed or identified. For these patients no adverse outcomes will be identified and can bias the results toward the null. Limitation of this study.

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Data collected for this trial is VHA administrative data therefore DMC is not needed.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_NA_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_NA_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_NA_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_8_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Any modifications to the protocol will be updated in our protocol registered in ISRCTN (http://www.isrctn.com/ISRCTN16012111).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Randomization is conducted at medical center level and does not require patient consent.

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_NA_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	All patient data and analysed are secured behind VHA IT firewalls
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_None_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	VHA data are only accessible by personnel with appropriate security clearance from the VHA.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_NA_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_7-8_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_NA_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	VHA data cannot be shared with the public.
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_NA_____

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_NA_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.