Evaluation of a Veterans Health Administration tool and policy to reduce patients' risk of adverse events from opioid prescriptions

Submission date 03/05/2017	Recruitment status No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/05/2017	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
10/06/2025	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims:

Opioids are drugs that act on the nervous system to relieve pain. There is growing concern about abuse, misuse and addiction related to opioids and opioid use related serious side effects (serious adverse events, SAEs) and deaths have been called an epidemic by the Centers for Disease Control and prevention (CDC) in the United States. The issue is a particular issue within the Veteran Health Administration (VHA) as well, in part because it has a patient population with higher rates of long-term pain, mental health, and substance use disorder compared to the general U.S. population. The VHA Office of Mental Health Operations (OMHO) developed the Stratification Tool for Opioid Risk Mitigation (STORM) which works by reviewing VHA patients receiving opioids based on their risk for overdose, accident, or suicide-related events (collectively, serious adverse events or SAEs) and to inform providers of the risk factors and risk reduction strategies potentially relevant for each patient. In June 2017, VHA central office plans to release a policy memo mandating the review of cases for patients identified by STORM to be at high risk of opioid related problems. This study aims to find out whether the use of the STORM tool decreases the rate of opioid related SAEs and whether the inclusion of consequences for failing to meet a target case review rate in a policy memo affects the behavior of providers in VHA hospitals and the SAE rate.

Who can participate?

All patients of VHA facilities with an opioid prescription who are at risk of SAE.

What does the study involve?

In the first part of the study, participating facilities are required to review cases in different levels of risk of SAEs using the STORM tool, starting with cases of patients predicted to be in the top 1% of risk. After 9 months half of the facilities are randomly selected to increase their load of case reviews to include cases of patients in the top 5% of risk. All participants are followed up after 18 months by reviewing VHA administrative data.

In the second part of the study, participating facilities are randomly allocated to one of two groups. Those in the first group receive a policy memo indicating there will be consequences (requirement of an action plan and additional oversight) if case review completion targets are

not met. Those in the second group receive a policy memo without any mention of consequences. All participants are followed up after 18 months by reviewing VHA administrative data.

What are the possible benefits and risks of participating? There are no known benefits or risks to participating patients.

Where is the study run from?

The study is being run by the Partnered Evidence-based Policy Resource Center (PEPReC) at the VA Boston Healthcare System in Boston and takes place in 140 VHA facilities (USA)

When is study starting and how long is it expected to run for? June 2017 to September 2019

Who is funding the study?
U.S. Department of Veterans Affairs (USA)

Who is the main contact?

- 1. Dr Austin Frakt (scientific)
- 2. Ms Taeko Minegishi (scientific)

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Evaluation of a Veterans Health Administration tool and policy to reduce patients' risk of adverse events from opioid prescriptions: A stepped wedge cluster randomized trial

Acronym

STORM

Study objectives

Hypotheses:

- 1. The use of the U.S. Veterans Health Administration (VHA) risk assessment tool the Stratification Tool for Opioid Risk Mitigation (STORM) will reduce opioid-related serious adverse events
- 2. Facilities that face consequences (i.e. requirement to file action plans, greater administrative oversight) for not meeting the targeted rate of reviews of cases of high-risk patients (as identified by STORM) achieve lower rates of serious adverse events among their patients, relative to facilities that do not face consequences

Ethics approval required

Old ethics approval format

Ethics approval(s)

VA Boston Healthcare System IRB and R&D Committees, 27/03/2017 ref: Protocol # 3069

Study design

Multi-centre stepped wedge cluster randomised interventional trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Opioid use

Interventions

The VHA Office of Mental Health Operations (OMHO) developed the Stratification Tool for Opioid Risk Mitigation (STORM) to prioritize review of patients receiving opioids based on their risk for overdose, accident, or suicide-related events and to inform providers of the risk factors and risk mitigation strategies potentially relevant for each patient. STORM is holistic tool that

addresses both risk factors and risk mitigation strategies in a manner that can be easily incorporated into clinical practice. The dashboard identifies high-risk patients and presents to providers actionable information to mitigate risk.

Intervention 1:

Stepped wedge design requiring facilities to review cases in different strata of risk of serious adverse events, as predicted by the STORM tool. Starting with all facilities mandated to review the cases of patients predicted to be in the top 1% of risk, after 9 months half of the facilities (randomly selected) will be mandated to increase their load of case reviews to include cases of patients in the top 5% of risk. At month 15, all facilities will review the cases of patients in the top 5% of risk. Providers are blinded to the risk levels of patients.

Intervention: Patients prescribed an opioid with a risk of adverse event between top 1% and 5% and at a facility required to review cases in that range of risk.

All patients are followed-up to 18 months using VHA administrative data. Such data are automatically collected by the VHA into a single database system. All patient visits and reason for visit can be retrieved from this system.

Intervention 2:

VHA central office will release a policy memo mandating the use of the STORM tool. Participating facilities are then randomly allocated to one of two groups by using block randomization.

Intervention group: Facilities receive a policy memo indicating there will be consequences (requirement of an action plan and additional oversight) if case review completion metrics are not met.

Control group: Facilities receive a policy memo without any mention of consequences.

All patients are followed-up to 18 months using VHA administrative data. Such data are automatically collected by the VHA into a single database system. All patient visits and reason for visit can be retrieved from this system.

Intervention Type

Behavioural

Primary outcome(s)

Opioid-related serious adverse events (SAEs) are determined using ICD9 and ICD10 codes using VA Corporate Data Warehouse in daily increments from baseline to 180 days.

Key secondary outcome(s))

Number of case reviews and the number of completed risk mitigation strategies using VA Corporate Data Warehouse in daily increments from baseline to 180 days.

Completion date

30/09/2019

Eligibility

Key inclusion criteria

- 1. Veterans Health Administration (VHA) patients with opioid prescription
- 2. Identified by STORM to have a risk of SAE in the top 10% of all VHA patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Patients who are in palliative care or hospice care.

Date of first enrolment

01/06/2017

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

United States of America

Study participating centre Partnered Evidence-Based Policy Resource Center

VA Boston Boston United States of America 02130

Sponsor information

Organisation

Department of Veterans Affairs Health Services Research & Development

ROR

https://ror.org/05rsv9s98

Funder(s)

Funder type

Government

Funder Name

U.S. Department of Veterans Affairs

Alternative Name(s)

Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons. Data will be stored on a secure server behind the Department of Veterans Affairs firewall.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type Results article	Details		Date added 03/05/2022	Peer reviewed? Yes	Patient-facing? No
Results article	secondary analysis	10/12/2022	15/06/2023	Yes	No
Results article	Randomized policy evaluation	17/06/2022	10/06/2025	Yes	No
Protocol article	protocol	18/01/2019	21/01/2019	Yes	No
Protocol article	protocol	27/06/2018	23/09/2019	Yes	No
Other publications	strategy evaluation	23/06/2020	25/06/2020	Yes	No
Other publications	article commentary	01/01/2019	15/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes