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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

Registration date
25/05/2017

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2016

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

Age group
Mixed

Sex
Both

Target number of participants
All 140 VHA facilities (clusters) in the United States. Approximately 100,000 patients (approximately 700 patients per cluster) are expected to meet inclusion criteria.

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

Sponsor details
1100 1st Street NE
Suite 6
Washington DC
United States of America
20002

Sponsor type
Government

Website
https://www.hsrd.research.va.gov/default.cfm

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

Publication and dissemination plan
Planned publication of the following papers after completion of the study:
1. Effectiveness of VA policy on prevention of opioid induced SAEs
2. Effectiveness of STORM tool in prevention of opioid induced SAEs
3. Change in practice of opioid mitigation strategies pre and post STORM

Intention to publish date
31/12/2018

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Results article		02/05/2022	03/05/2022	Yes	No
Other publications	article commentary	01/01/2019	15/06/2023	Yes	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