



Using VA Data to Inform the Design of Partnered Randomized Program Evaluations

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Overview of PEPRReC

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- Objective: Provide timely, rigorous data analysis to support the development of high-priority policy, planning, and management initiatives and quantitative program evaluations with strong potential to improve the quality and efficiency of VA healthcare
- Director: Austin Frakt, PhD
- QUERI PEC 16-001; HSR&D SDR 16-196

Randomized Program Evaluations

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- Veteran-Directed Home and Community Based Services (VD-HCBS)
- Randomized Program Evaluation of Stratification Tool for Opioid Risk Management (RPE-STORM)

Poll Question #1

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- Have you ever been involved in a partnered program evaluation?
 - a) Yes
 - b) No
 - c) Not sure

Veteran-Directed Home and Community Based Services (VD-HCBS)

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- Goal: Reduce risk of unwanted placement in nursing home or other long-term care facility



VD-HCBS Evaluation Partners

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- VHA Office of Geriatrics & Extended Care
- Administration for Community Living
- PEPReC
- Center of Innovation in Long Term Services and Supports
- Center for Health Services Research in Primary Care
- VA Caregiver Support Evaluation Initiative (VA-CARES)
- The Lewin Group
- Applied Self Direction

VD-HCBS Evaluation Goals

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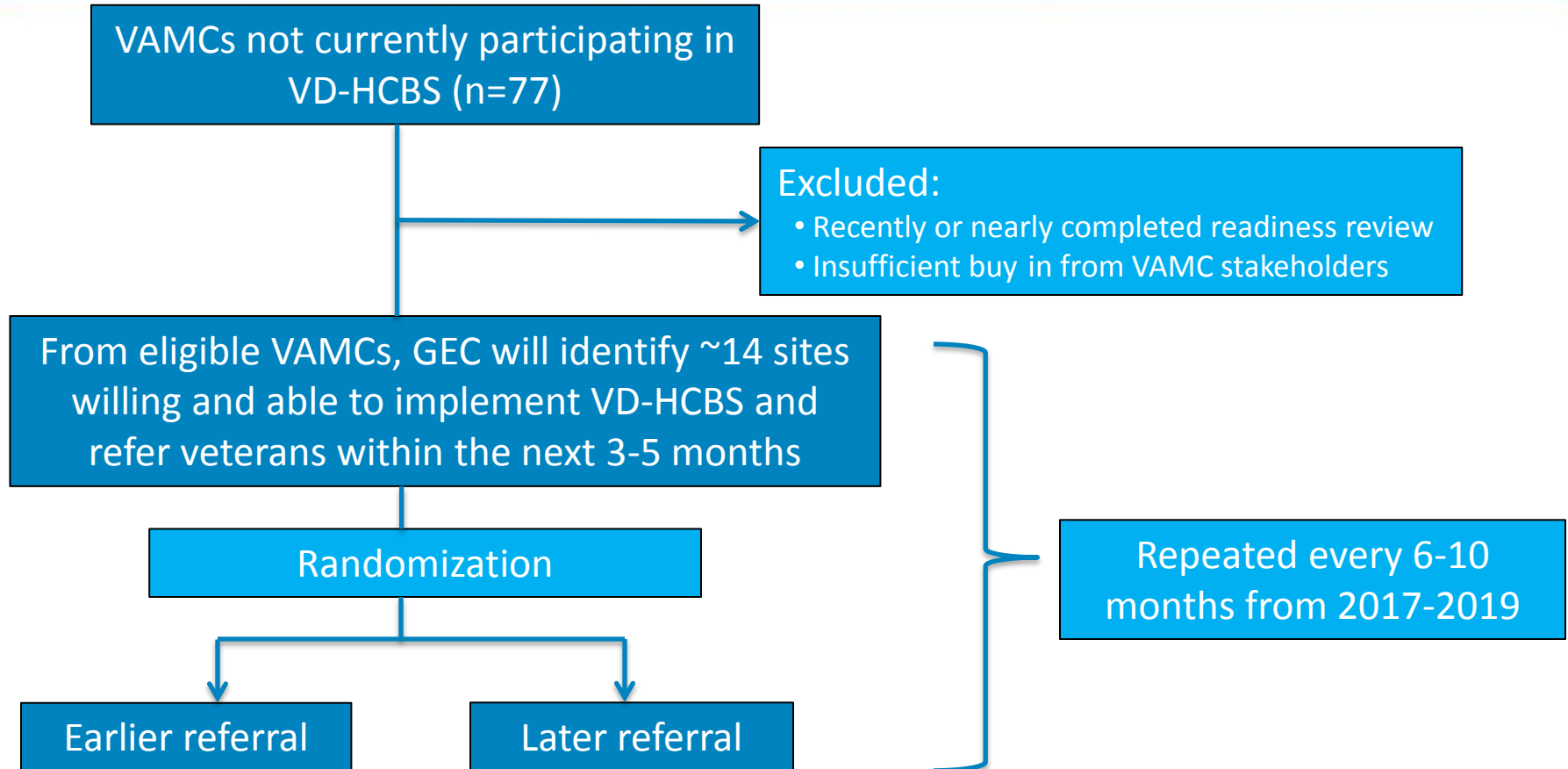
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- Rigorously evaluate effects of VD-HCBS on health outcomes and costs
- Work with operations and research partners to produce evidence that will inform GEC's decisions about the best ways to prevent unnecessary institutionalization of older Veterans

VD-HCBS Evaluation: Cluster Randomization

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VD-HCBS Evaluation: Stepped Wedge Design

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Every eligible site will participate in VD-HCBS during the evaluation

VAMCs	3/2017	6/2017	9/2017	12/2017	3/2018	6/2018	9/2018	12/2018	3/2019	6/2019	9/2019	12/2019
1-7												
8-14												
15-21												
22-28												
29-35												
36-42												
43-49												
50-56												
57-63												
64-70												
71-77												

Start times and exact number of sites in each step subject to change

Unique Data Considerations for VD-HCBS Evaluation

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- Covariate Constrained Randomization
- Analysis Plan

Unique Data Considerations for VD-HCBS Evaluation

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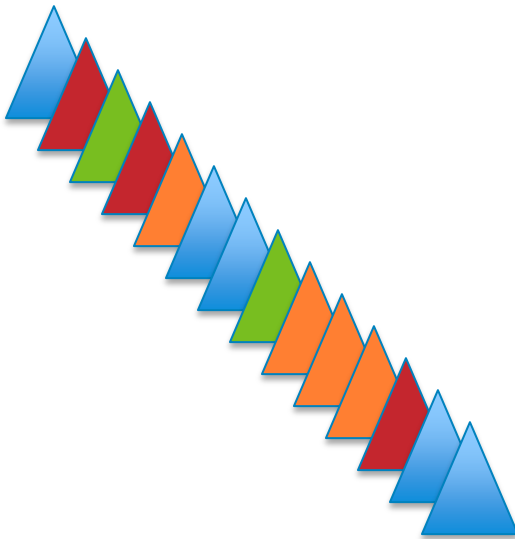
- Covariate Constrained Randomization
- Analysis Plan

Simple Randomization

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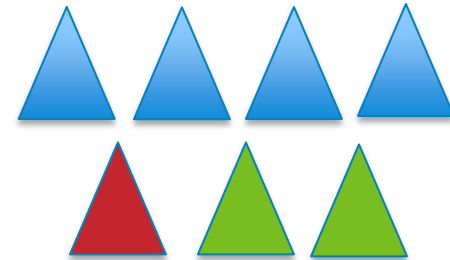
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Eligible Sites

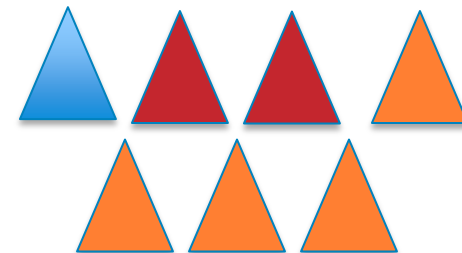


Simple Randomization

Early Enrollment



Late Enrollment



Covariate Constrained Randomization

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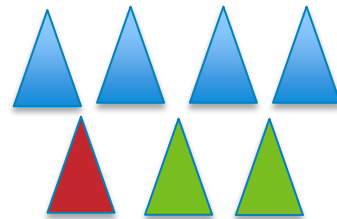
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Eligible Sites

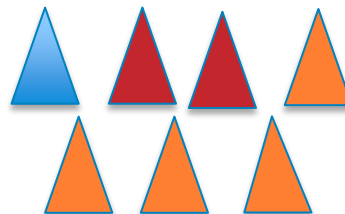
Covariate Constrained Randomization

Option 1

Early Enrollment

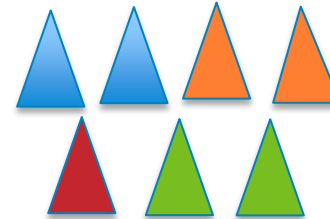


Late Enrollment

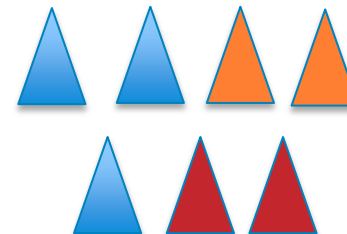


Option 2

Early Enrollment

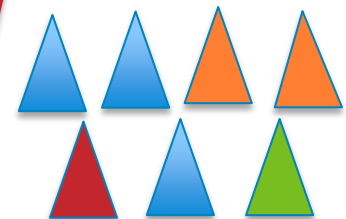


Late Enrollment

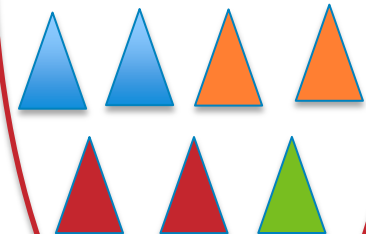


Option 3

Early Enrollment



Late Enrollment



VD-HCBS Evaluation: Covariate Constrained Randomization

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Patient Case-Mix

Size of patient
population

CAN scores

Jen Frailty Index
scores

Prospective NOSOS
scores

Site-Specific Patterns of Caring for Older Patients

VAMC spending on
HCBS

VAMC has CLC on
campus

Market penetration
of HCBS

State or County Access to HCBS

Urban/rural location

State participation in
early participant-
directed care
initiatives

State Medicaid
spending on HCBS

Data Sources: Covariate Constrained Randomization

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- Geriatrics and Extended Care Data Analysis Center (GEC-DAC)
 - VHA CDW data
- Veterans Health Administration Support Service Center (VSSC)
 - Non-institutional care report
 - VHA Site Tracking (VAST) snapshots and quarterly summaries
- Reports and publications
 - Administration on Aging
 - Truven Health Analytics report
 - Journal articles

Unique Data Considerations for VD-HCBS Evaluation

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- Covariate Constrained Randomization
- Analysis Plan

VD-HCBS Evaluation: Outcomes

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Outcome	Primary	Secondary
Hospital admission	Any admission	Any admission for an ambulatory care sensitive (ACS) condition Number of any and ACS admissions Length of stay
Emergency department admission	Any admission	Number of admissions
Nursing home admission	Any admission	Days at home Length of stay
Health care costs	Total costs	Costs associated with HCBS, nursing home care, hospitalization, outpatient care

VD-HCBS Evaluation: Planned Analyses

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- Primary: Intent-to-treat
 - Among patients potentially eligible for VD-HCBS, what is the average change in outcomes that occurs when VD-HCBS services are available at the facility?
- Secondary: Instrumental variable
 - Among patients whose chance of receiving VD-HCBS varies with random assignment and ADNA readiness, what is the average change in outcomes that occurs with receipt of VD-HCBS?

Data Sources: Planned Analyses

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	Intent-to-treat	Instrumental Variable
GEC-DAC	✓	✓
CDW	✓	✓
VSSC	✓	✓
Published reports	✓	✓
Medicare	✓	✓
Medicaid Analytic eXtract	✓	✓
Program data from GEC and Administration for Community Living		✓

VD-HCBS Summary

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- Data from partners useful for informing study design and evaluation
- This evaluation is benefitting from GEC-DAC's systematic data on older veterans
- Main challenge is systematically collecting data from outside VA (ADNA data)

Opioid Crisis

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91
AMERICANS

die ever
an **opio**
(that inc
opioids



Nearly
HALF

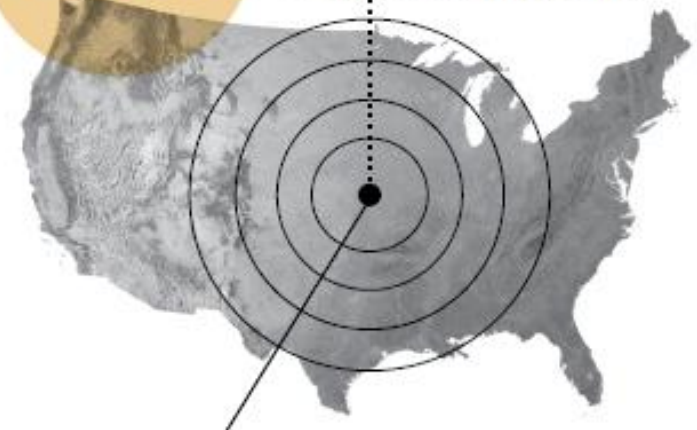
of all opioid ove
deaths involve a
prescription o



Rx

249M

prescriptions for opioid pain
medication were written by
healthcare providers in 2013



enough prescriptions were written for every
American adult to have a bottle of pills

Poll Question #2

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Approximately 9 million veterans are enrolled at VHA. What percentage of veterans are prescribed opioids?

- <1%
- 1 - 5%
- 5 - 10%
- **10 - 20%**
- > 20%

STORM Dashboard

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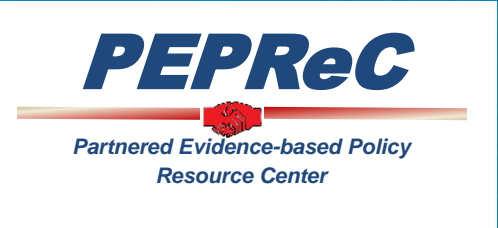
VA STORM: Patient Detail Dashboard Stratification Tool for Opioid Risk Mitigation

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 Information ⓘ	What is my patient's risk level? (Click + for details)			What factors contribute to my patient's risk?		How can I reduce my patient's risk?			How can I follow-up with this patient?		
	Suicide-related event, overdose, falls or accident 3 yr	Suicide-related event or overdose 1 yr	Overdose or opioid-induced respiratory depression	Relevant Diagnoses	Relevant Medications	Risk Mitigation Progress	Risk Mitigation Strategies		Non-pharmacologic al Pain Tx	Recent Appts ⓘ	Upcoming Appts ⓘ
<div>Patient Name</div> <div>Last Four: [REDACTED]</div> <div>Age: [REDACTED]</div> <div>Gender: [REDACTED]</div> <div>Station: [REDACTED]</div> <div>Chart Review Note</div>	<div>Very High</div> <div>94% hypothetical risk* of suicide-related event, overdose, falls or accidents in the next three years</div>	<div>Very High</div> <div>75% hypothetical risk* of suicide-related event or overdose in the next year</div>	<div>Risk Class: 7</div> <div>RIOSORD Score: 52</div>	<div>SUD Dx:</div> <div>OUD</div> <div>AUD</div> <div>Nicotine Dep.</div> <div>Mental Health Dx:</div> <div>PTSD</div> <div>Depression</div> <div>Bipolar</div> <div>Other MH</div> <div>Medical Dx:</div> <div>Osteoporosis</div> <div>Other Neuro Disorder</div> <div>Paralysis</div> <div>Arrhythmia</div> <div>Recent Adverse Events:</div> <div>Suicide Attempt/Ideation</div> <div>Fall</div>	None	<div>6</div> <div>4</div> <div>0</div>	<div>Naloxone Kit</div> <div><input checked="" type="checkbox"/> 1/17/17</div> <div>Timely UDS</div> <div><input type="checkbox"/> 2/17/17</div> <div>Psychosocial Assessment</div> <div><input checked="" type="checkbox"/> 2/22/17</div> <div>Psychosocial Tx</div> <div><input checked="" type="checkbox"/> 2/23/17</div> <div>Active SUD Tx</div> <div><input type="checkbox"/></div> <div>Opioid Agonist Tx</div> <div><input checked="" type="checkbox"/> 10/1/16</div>	<div>Active Therapies</div> <div><input checked="" type="checkbox"/> 2/8/17</div> <div>CIH Therapies</div> <div><input type="checkbox"/></div> <div>Chiropractic Care</div> <div><input type="checkbox"/></div> <div>Occupational Therapy</div> <div><input checked="" type="checkbox"/> 2/14/17</div> <div>Pain Clinic</div> <div><input type="checkbox"/></div> <div>Physical Therapy</div> <div><input checked="" type="checkbox"/> 3/1/17</div> <div>Specialty Therapy</div> <div><input checked="" type="checkbox"/> 3/2/17</div> <div>Other Therapy</div> <div><input type="checkbox"/></div>	<div>Primary Care:</div> <div>[REDACTED]</div> <div>Mental Health:</div> <div>[REDACTED]</div> <div>Pain Clinic:</div> <div>[REDACTED]</div> <div>Other:</div> <div>[REDACTED]</div>	<div>Primary Care:</div> <div>None</div> <div>Mental Health:</div> <div>None</div> <div>Pain Clinic:</div> <div>None</div> <div>Other:</div> <div>None</div>	<div>Recent Opioid Prescriber:</div> <div>[REDACTED]</div> <div>Primary Care Provider:</div> <div>[REDACTED]</div> <div>MH Tx Coordinator:</div> <div>[REDACTED]</div> <div>BHIP Team:</div> <div>[REDACTED]</div>
<div>Patient Name</div> <div>Last Four: [REDACTED]</div> <div>Age: [REDACTED]</div> <div>Gender: [REDACTED]</div> <div>Station: [REDACTED]</div> <div>Chart Review Note</div>	<div>Very High</div> <div>96% hypothetical risk* of suicide-related event, overdose, falls or accidents in the next three years</div>	<div>Very High</div> <div>68% hypothetical risk* of suicide-related event or overdose in the next year</div>	<div>Risk Class: 10</div> <div>RIOSORD Score: 70</div>	<div>SUD Dx:</div> <div>OUD</div> <div>AUD</div> <div>Nicotine Dep.</div> <div>Mental Health Dx:</div> <div>PTSD</div> <div>Depression</div> <div>Bipolar</div> <div>Medical Dx:</div> <div>Chronic Pulm Dis.</div> <div>Electrolyte Disorder</div> <div>Hypertension</div> <div>Liver Disease</div>	None	<div>6</div> <div>4</div> <div>0</div>	<div>Naloxone Kit</div> <div><input type="checkbox"/></div> <div>Timely UDS</div> <div><input checked="" type="checkbox"/> 4/11/17</div> <div>Psychosocial Assessment</div> <div><input checked="" type="checkbox"/> 5/10/17</div> <div>Psychosocial Tx</div> <div><input checked="" type="checkbox"/> 6/29/17</div> <div>Active SUD Tx</div> <div><input checked="" type="checkbox"/> 5/10/17</div> <div>Opioid Agonist Tx</div> <div><input type="checkbox"/></div>	<div>Active Therapies</div> <div><input type="checkbox"/></div> <div>CIH Therapies</div> <div><input type="checkbox"/></div> <div>Chiropractic Care</div> <div><input type="checkbox"/></div> <div>Occupational Therapy</div> <div><input checked="" type="checkbox"/> 4/21/17</div> <div>Pain Clinic</div> <div><input type="checkbox"/></div> <div>Physical Therapy</div> <div><input checked="" type="checkbox"/> 2/7/17</div> <div>Specialty Therapy</div> <div><input type="checkbox"/></div> <div>Other Therapy</div> <div><input type="checkbox"/></div>	<div>Primary Care:</div> <div>[REDACTED]</div> <div>Mental Health:</div> <div>[REDACTED]</div> <div>Pain Clinic:</div> <div>[REDACTED]</div> <div>Other:</div> <div>[REDACTED]</div>	<div>Primary Care:</div> <div>None</div> <div>Mental Health:</div> <div>None</div> <div>Pain Clinic:</div> <div>None</div> <div>Other:</div> <div>None</div>	<div>Recent Opioid Prescriber:</div> <div>[REDACTED]</div> <div>Primary Care Provider:</div> <div>[REDACTED]</div> <div>MH Tx Coordinator:</div> <div>[REDACTED]</div> <div>BHIP Team:</div> <div>[REDACTED]</div>

Randomized Program Evaluation of STORM (RPE-STORM)



In Summer/Fall of 2017, a VHA policy memo will be released that mandates case review of patients identified by STORM as being very high risk for an opioid-related adverse event

Randomize roll-out of policy memo and risk threshold

RPE-STORM Targets

- Policy Evaluation
 - Two versions of policy memo will be randomly assigned to VA medical centers
- Risk Threshold Evaluation
 - Evaluate impact on patient outcomes when facilities are required to review patients who fall under an expanded risk threshold

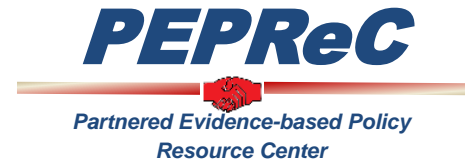
RPE-STORM Partners



- Office of Mental Health and Suicide Prevention (OMHSP)
 - Creators and implementation of STORM dashboard and policy memo
- Center for Health Equity Research Promotion (CHERP)
 - Quantitative and qualitative analysis of strategies used for implementation of STORM use at VHA facilities
- PEPReC
 - Quantitative analysis of clinical outcome rates to evaluate the effectiveness of VHA policy and STORM dashboard

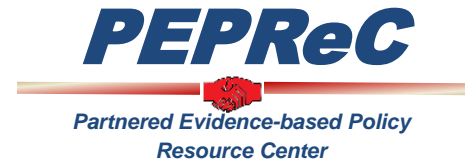
Bi-weekly calls on project updates

Policy Evaluation



- GAO's high risk list includes ambiguous VHA policies
 - Inconsistencies in care processes across facilities
 - Weak accountability
- The VHA's Veterans Engineering Resource Center (VERC) developed a framework to address these issues
 - Policies should be consistent, complete, feasible, verifiable, validated, unambiguous, and concise
- Focus on completeness: justification for requirement, identify responsible party, describe implementation process, specify how it will be verified

Policy Evaluation



- Two versions of policy memo randomly assigned to each VHA facility

Treatment

If case review rate is less than 97%,
facilities may receive facilitation

Control

No mention of facilitation

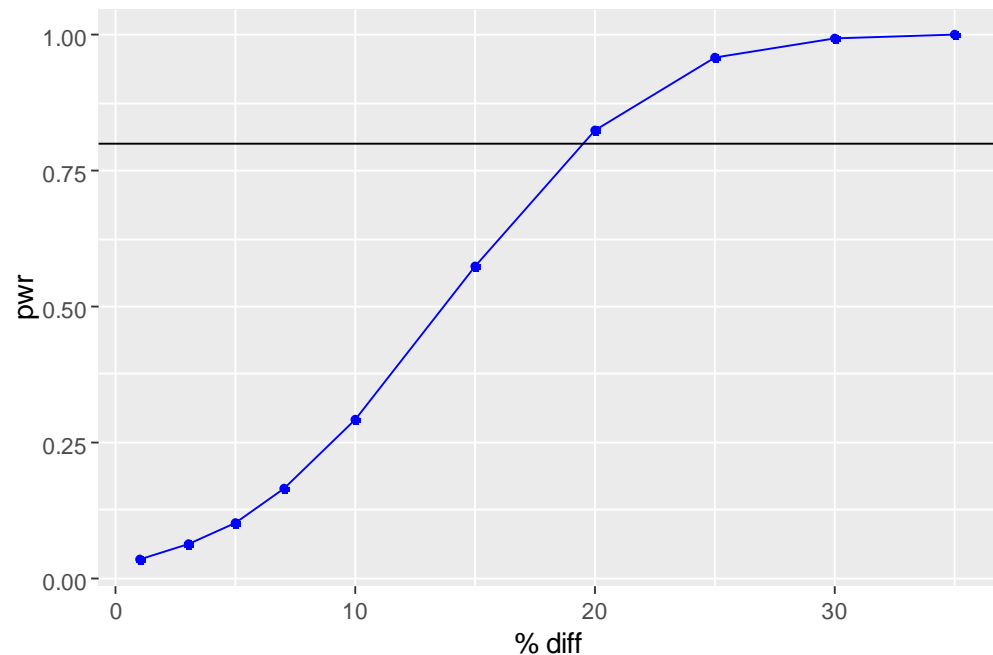
- Simple randomization of VHA facilities
- Compare clinical outcomes (i.e. opioid-related serious adverse events) between treatment and control

Hypothesis:

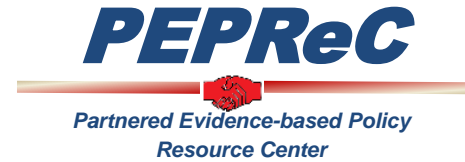
VHA facilities randomized to facilitation will achieve lower opioid-related SAEs, relative to facilities not randomized to facilitation

Power Calculation

- Stata's -clustersampsi- package
- 140 VHA facilities with 2,112 patient-months
- Baseline risk rate of 2.9% for any opioid-related SAEs
- Difference in risk rate of 20% can be detected with alpha of 0.05 and 80% power among patients with a risk level of top 1st percentile



Data Type



- Random assignment
- Patient STORM risk score
 - Baseline
 - Any changes in the course of study
- Case review notes
 - Clinicians' notes date stamped in STORM dashboard
- Patient demographics
- Patient clinical outcomes

Data Sources

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- Excel Spreadsheet
 - Randomization (using block randomization) conducted in R
 - Exported into MS EXCEL spreadsheet
- STORM Dashboard
 - Calculated risk score
 - Clinicians access dashboard via Sharepoint (website)
 - Back-end data stored in SQL tables owned by OMHSP
- CDW
 - Patient demographics
 - Clinical outcomes

Data Challenges



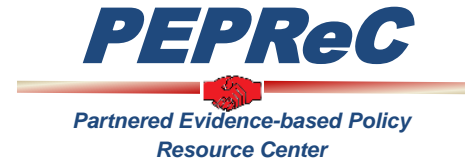
- Data sharing across different operational groups
 - Data Use Agreement
 - Basecamp - Outbox
- Saving data that gets updated on a daily basis
 - Running SQL using Windows task scheduler
 - Writing executable code
 - Being mindful of data storage capacity
- Creating cohort data
 - Updates from STORM dashboard
 - Patient demographics and comorbidities
 - Outcomes

RPE-STORM Summary



- Policy memo is planned to be release in Summer/Fall of 2017 and evaluation to be conducted in Winter of 2019
- Goals of evaluation include:
 - Enhance the understanding of strategies for writing an effective VHA policy
 - Rigorously evaluate how the policy affects SAEs
- Lessons learned on challenges of implementing a randomized evaluation on real on-going programs

Summary



- Unique data considerations for each partnered evaluation
- Partnerships between researchers and operations stakeholders facilitate rapid, rigorous evaluation of relevant data and evidence-based decision-making about how to best sustain or improve delivery system interventions

Questions?

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VD-HCBS: <http://www.isrctn.com/ISRCTN12228144>
[clinicaltrials.gov](http://www.clinicaltrials.gov): NCT03145818

STORM: <http://www.isrctn.com/ISRCTN16012111>

PEPReC: <https://www.peprec.research.va.gov>

The views expressed in this presentation do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

Next Partnered Research Presentation

Tuesday, September 19, 2017
12 pm ET

**The Enhancing Mental and Physical Health of Women
through Engagement and Retention (EMPOWER) QUERI**

Alison Hamilton, PhD
VA Greater Los Angeles

Erin Finley, PhD
South Texas Veterans Health Care System