Disability Claims as a Pathway to Pain Treatment in Veterans: Screening, Brief Intervention and Referral to Treatment for Pain Management (SBIRT-PM)

> Marc Rosen, MD Steve Martino, Ph.D.

Yale School of Medicine – Department of Psychiatry
VA Connecticut Healthcare System
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UG3 AT012262



Disclosures

- Employees of VA and Yale University
- Research funding from NIH and VA
- Members of the NIH-DoD-VA Pain Management Collaboratory Coordinating Center (PMC3)
- The views expressed in this presentation are those of the authors and do not necessarily reflect the official policy or position of the Department of Veterans Affairs, the U.S. Government, or the PMC3



Partnership



- Compensation & Pension
- Addictions Treatment
- SUD Assessment
- VA Trial Methodology



- Motivational Interviewing
- Clinician Training and Fidelity
- Multisite Effectiveness Trials
- Implementation Science



C&P as an Intervention Opportunity

- Over half of post-9/11 Veterans treated at VA are service-connected for a musculoskeletal disorder. Comorbid substance misuse is common.
- In FY 2023, 1,453,400 awards were made for lumbosacral or cervical sprain
- 116,810 new lumbo/cervical claims awarded during FY 2023.
- Opportunity for early intervention.





Screening Brief Intervention Referral to Treatment-Pain Management (SBIRT-PM)

Grant- type	Dates	Grant focus	Therapy Delivery	Key Investigators
R34	2014-2017	Therapy Development (efficacy)	Yale staff, post-doc (MacLean)	Anne Black, Will Becker, Robert Kerns, Carine Sakr, Ellen Edens, Ross McLean
UG3/UH3	2017-2024	Pragmatic Trial (effectiveness)	Yale staff West Haven hub to 8 sites in New England	Site Investigators, Qing Zeng (NLP), Paul Barnett (economist), Kathryn Gilstad-Hayden (stats), Kristin Mattocks (qualitative interviews), John Sellinger (pain health psych)
UG3 (UH3 pending)	2023-2028	Implementation (hybrid)	VA MSWs and RNs in Military2VA Transition Care Program	M2VA leadership (Weede, Perez) and staff (Sullivan-Tibbs), Kristin Mattocks (qualitative interviews), John Sellinger (pain health psych), Gabriela Garcia Vassallo (patient simulations), Amos Turner (addiction), Ajay Manhapra (chronic pain), Ellen Edens (pain/addiction) Liam Rose (health economics)



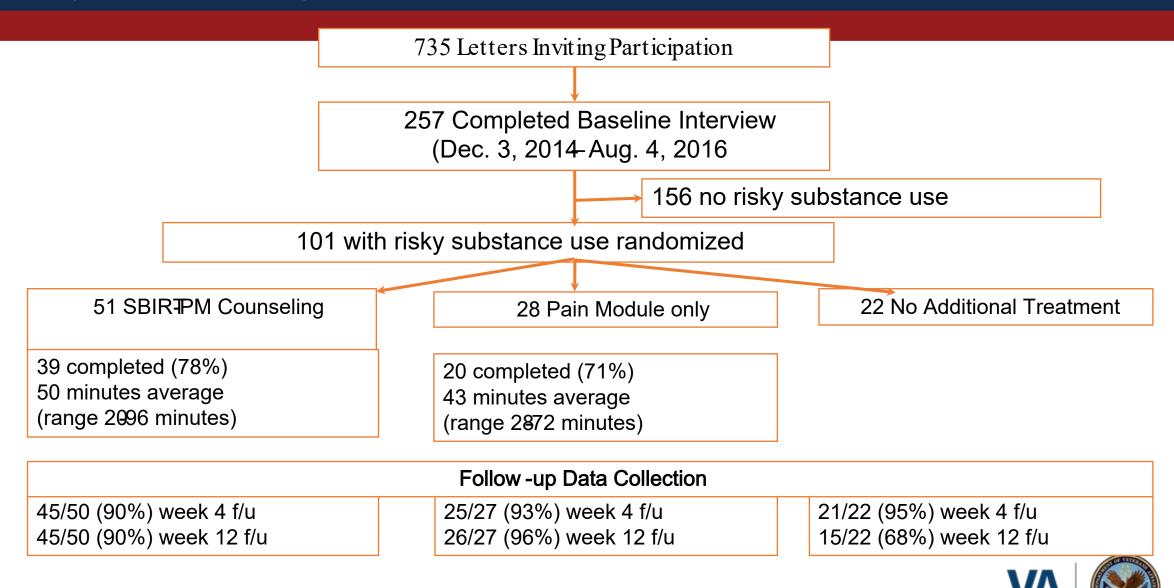
SBIRT-PM Counseling 1.0; In-person, single site

Key Features

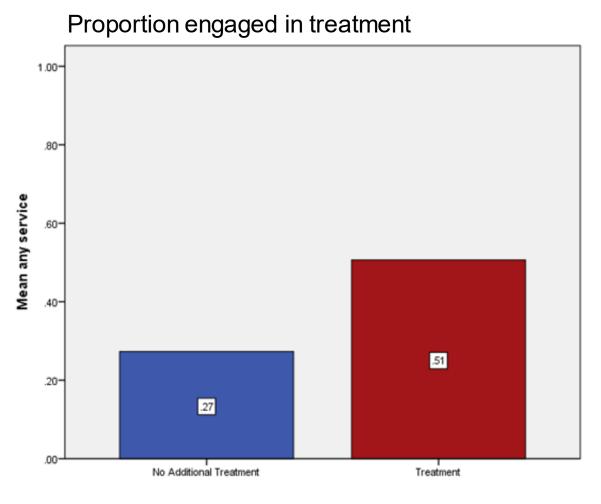
- Veterans contacted around time of C&P exam.
- Motivational Interviewing-based counseling over 12 weeks
- First session delivered in-person (60 mins)
 - Inquire about pain and motivations for pain treatment engagement
 - Explain pain treatments at VACHS
 - Screen for risky substance use; brief intervention; referral to treatment (SBIRT)
 - Enhance motivation to engage in treatment
 - Develop change plan
- One or Two brief phone follow-ups (5-10 mins)
 - Enhance motivation and follow-up on change plan



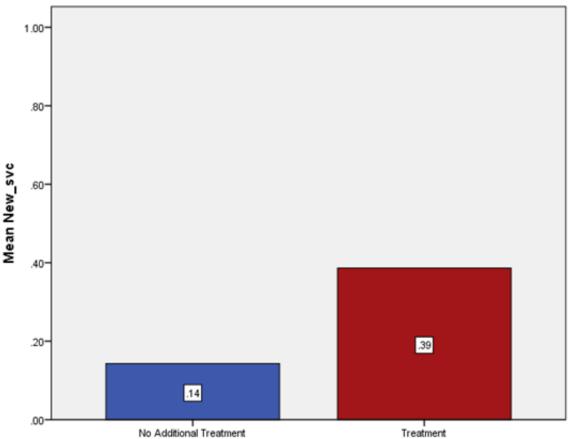
Study Flow Diagram



Study Results: Chart-Extracted VA Pain Treatment



Proportion newly-engaged in treatment





Findings from 101 Veteran RCT

- Veterans filing musculoskeletal disorder claims were hurting
 - Mean pain interference 5.0
 - 39% with risky substance use within 28 days
- Veterans were receptive to SBIRT counseling around time of C&P
- Counseling associated with
 - Less self-reported substance use
 - More use of VA pain services
 - No significant change in pain severity
- Implications
 - C&P as a gateway to treatment
 - Benefits of early intervention targeting pain and substance use

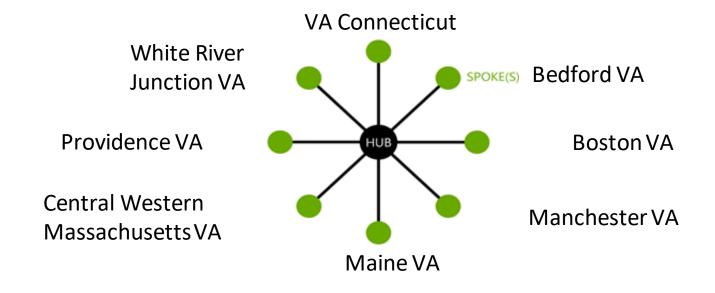


Scaling Up SBIRT-PM

VA often uses a hub-and-spoke approach to scale up innovations

- Pragmatic
- Broad reach
- VISNs, Clinical Resource Hubs, and Centers of Excellence have hub-and-spoke configurations



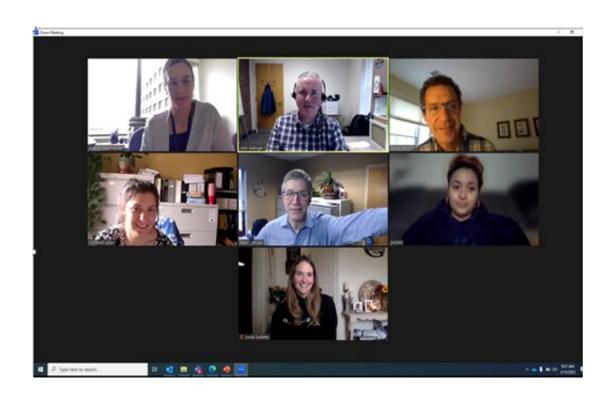




Next Study: Pragmatic Trial in VISN 1

Investigative Team

- Marc Rosen & Steve Martino (Co-Pls)
- Kate Gilstad-Hayden (Biostatisticians)
- Christina Lazar (Project Director)
- John Sellinger (Co-I)
- Kimberly Ross & Lisa Navarra (SBIRT-PM Counselors)
- Linda Guillette & Jessenia Medina (Research Assistants)
- Paul Barnett (Consultant for Health Economics)





Pragmatic Trial in VISN 1 Partners

- Site Investigators
 - Tu Ngo (VA Bedford)
 - Diana Higgins & Nick Livingston (VA Boston)
 - Brad Brummett (VA Central Western Mass)
 - John Sellinger (VA Connecticut)
 - Brad Schimelman & Todd Stapley (VA Maine)
 - Alicia Semiatin & Jennifer Ault (VA Manchester)
 - Thom Reznik (VA Providence)
 - Carolyn Solzhenitsyn & Paul Holtzheimer (VA White River Junction)
- Comp & Pen/VBA: Cathy Popp, Glen Gechlik, Amir Mohammad
- VISN 1 MIRECC, Mental Health Clinical Trials Network, PRIME Center
- NCCIH/NIDA



Pragmatic Trial Study Aims

- Aim 1 SBIRT-PM vs Usual Care
 - Primary outcome: Pain severity
 - Secondary outcomes: Number of nonpharmacological pain modalities used, pain interference, health-related quality of life
- Aim 2 SBIRT-PM vs Usual Care
 - Primary outcome: Number of misused substances requiring intervention (measured by the ASSIST)
 - Secondary outcome: Severity of use for individual substances
- Aim 3 SBIRT-PM vs. Usual Care
 - Cost-effectiveness and budget impact



Study Progress so far...

Recruitment/Enrollment

- After sending letters, we contact 64% of veterans by phone
- 8% of potential participants are randomized
- 1101 (100 % of goal) have been randomized

Retention

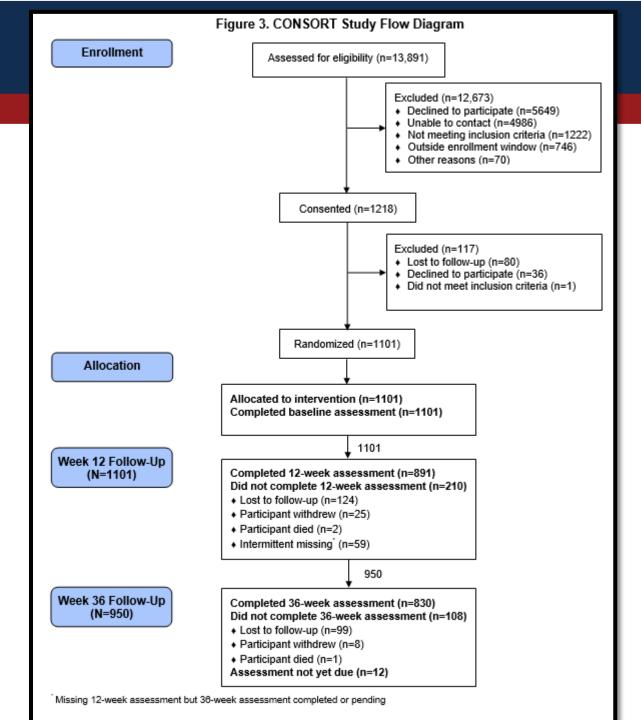
- 12 week = 81%
- 36 week = 76%

Counseling

- 86% allocated to SBIRT received at least 1 session.
- 73% allocated to SBIRT received at least 2 sessions

Sample Characteristics

- 86% male, 79% white, 14% Hispanic
- 51% w problematic substance use
- Mean PEG = 5.7(2.0 SD)
- 18% with suicidality on PHQ-9



Publications to date...

- Lazar, et al., Counseling veterans with chronic pain during the COVID-19 pandemic: a secondary analysis of a randomized controlled trial. Pain Medicine, 2022; 23 (8): 1434-144.
- Sellinger et al., The Acceptability and Feasibility of Screening, Brief Intervention, and Referral to Treatment for Pain Management among New England Veterans with Chronic Pain: A Pilot Study.
 Pain Practice, 2021 May 1.
- Martino et al., Screening, Brief Intervention and Referral to Treatment for Pain Management for Veterans Seeking Service-Connection Payments for Musculoskeletal Disorders: SBIRT-PM Study Protocol. Pain Medicine, 2020; 21: S110-S117.
- Rosen et al., Access to Pain Care from Compensation Clinics: A Relational Coordination Perspective. Federal Practitioner July 2020; 336-341.
- Mattocks et al., Pain Care in the Department of Veterans Affairs: Understanding How a Cultural Shift in Pain Care Impacts Provider Decisions and Collaboration. Pain Medicine 2019; 21: 970-977.



Other findings coming your way

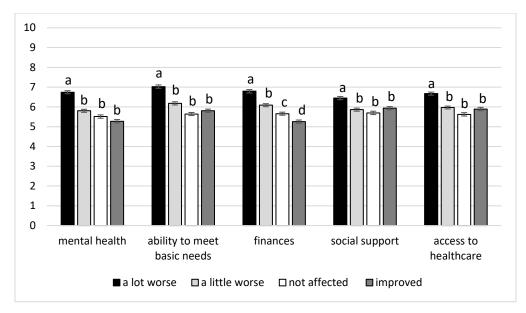
VALUE / INNOVATION / NEW PRODUCTS KNOWLEDGE) (CREATIVITY) SERENDIPITY



Which patients with pain were most impacted by COVID-19?

COVID-19 impacts on different domains rated by 2333 Veterans from 4 pragmatic trials. Veterans with higher PEG scores were more likely to have "a lot worse" impact in each domain.





Notes: PEG= Pain, Enjoyment of Life and General Activity scale; Scores range from 0 to 10 with higher scores indicating more severe pain. Results of post-hoc ANOVA Tukey-Kramer tests are shown with letters. Means not statistically different at p<0.05 share a letter: those that are significantly different do not share a letter. Error bars show 95% confidence interval around mean PEG scores.

More pandemic impact on:

- Younger
- Black or Latino
- Female
- More educated
- Unemployed
- Screened positive for depression



Sellinger JJ, Gilstad-Hayden K, Lazar C, Seal K, Purcell N, Burgess DJ, Martino S, Heapy A, Higgins D, Rosen MI. "Impact of the COVID-19 Pandemic on Participants in Pragmatic Clinical Trials for Chronic Pain: Implications for Trial Outcomes and Beyond"



Do Veterans with Risky Substance Use (RSU) use Distinct Pain Treatment Modalities?

- Sample: Veterans (N=924) who filed serviceconnected benefit claims related to musculoskeletal conditions and rated their pain >= 4 on the Numeric Rating Scale
- Method: Self-reported use of 25 different pain services in the preceding 90 days. Recent Substance Use (RSU) was identified via ASSIST cutoffs and/or nail sample toxicology.
- Pain treatment utilization did not differ based on Risky Substance Use.
 - Destigmatizing finding
- Overall, the most commonly used modalities were:
 - Over-the-counter medications (71%)
 - Self-structured exercise (69%)
 - Non-opioid prescription medications (38%)



	No Substance	Misuse of	
	Misuse	≥1 Substance	
	N=404	N=520	P-value ¹
Count of pain treatment modalities			
utilized, Mean (SD)			
Provider-delivered modalities	1.1 (1.2)	1.0 (1.2)	0.224
Self-delivered modalities	1.6 (1.2)	1.6 (1.3)	0.975

Meshberg-Cohen S, Gilstad-Hayden K, Martino S, Lazar CM, Sellinger J, Rosen MI. "Do Veterans with Substance Misuse (SM) use Distinct Pain Treatment Modalities."



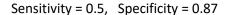
Sensitivity, specificity and discordance with self-report of nail sample testing for alcohol and cannabis

- 707 of 1101 respondents mailed in nail clippings. Those with returned nails were disproportionately married, white race, older, and less depressed.
- False positive nails for THC-related problems were associated with being African American, Hispanic, and having had legal problems.
- Conclusions: Nail measures had low sensitivity and higher specificity. The groups who
 disproportionately submit positive nails/negative self-report could self-report inaccurately due to
 social pressures, have substance use patterns not captured by self-report, or have distinct drug
 metabolism.





		Self-Report	=			
		+	-			
ETG ≥8pg/mg	+	123	57			
in nail sample	-	122	387			



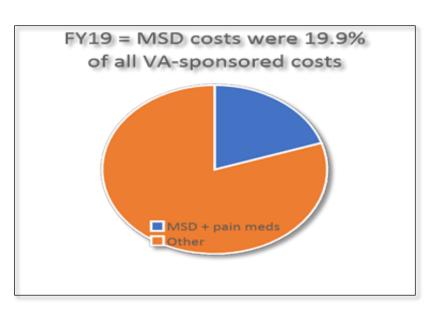


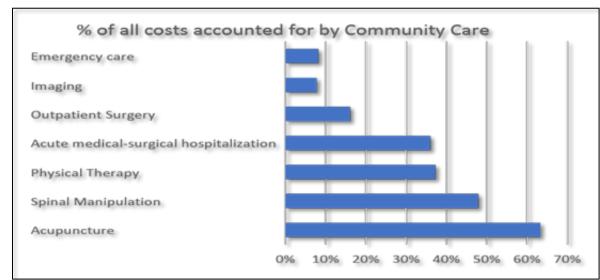
Morie KP, Gildstad-Hayden K, Martino S, Lazar CM, Rosen MI. "Sensitivity, specificity and discordance with self-report of nail sample testing for alcohol and cannabis."



High proportions of CIH costs are Community Care

- 1,068,327 Veterans had a request for a C&P examination for a back, neck, knee, or shoulder condition between 2000 and 2018.
- Most of them (799,836) received VA sponsored care in FY19. This care cost \$10.9 billion (mean \$13,615 per person).
- Community care was >35% of total costs for
 - Physical therapy
 - Spinal manipulation
 - Acupuncture







HSR&D Annual Conference. "VHA-sponsored Musculoskeletal Disorder (MSD) Treatment Costs: VA-delivered vs. Community Care", Poster Presentation, Feb 8-10, 2023. Baltimore, MD.



Costs of care for MSD conditions

Annual cost of VHA provided services

conditions	All care	% of care for musculoskeletal conditions					
\$1,186	\$6,567	18.1%					
\$436	\$1,364	32.0%					
\$206	\$2,299	9.0%					
\$1,828	\$10,230	17.9%					
	\$1,186 \$436 \$206	\$1,186 \$6,567 \$436 \$1,364 \$206 \$2,299					



Back to the main attraction...





Implementing SBIRT-PM in the VA

- Why a Hybrid Effectiveness-Implementation Study?
- Implement with whom? By whom?
- Design of Hybrid Effectiveness-Implementation Trial
- Implementation Strategy
 - Theoretical framework
 - Components of Strategy



Why an Effectiveness-Implementation Study?

- Target Young Veterans fresh out of the military
 - Each year about 200,000 personnel leave U.S. military service
 - 51% of those seen at VHA receive service-connected disability for an MSD
 - C&P is private...need VBA-VHA liaisons to reach Veterans with private C&P exams
 - Pragmatic trial participants
 - Averaged 39 years old
 - Most had re-filed MSD claims
- Have real VA clinicians deliver intervention instead of Yale-hired therapists
- Nationwide roll-out, not just VISN 1
- Sustainable roll-out not dependent on NIH \$
- Will it work if done this way?



Why an Effectiveness-Implementation Study?

- More need for outreach to Veterans at C&P
- More privatization of C&P exams.
- Best strategy to implement SBIRT-PM needs investigation







Implementation by Whom?

Poll Question:

Do you know about the Post-9/11 Military2VA (M2VA) Case Management Program?

No

Yes



Implementation by Whom? Answer: Military-to-VA (M2VA, OEF/OIF Coordinators)

- Every VHA medical center has a Post-9/11 Military to VA (M2VA) Team of social workers (mostly) and nurses
- M2VA contacts <u>all</u> separating service members and Post-9/11 era Veterans who are new to their VA health care system
 - Some separating service members get additional case management
- These case managers are uniquely situated to implement SBIRT-PM
 - No specific training in Motivational Interviewing, pain care, addiction
 - No specific organizational support for MI, pain care navigation
- M2VA national leadership wants them to learn SBIRT-PM





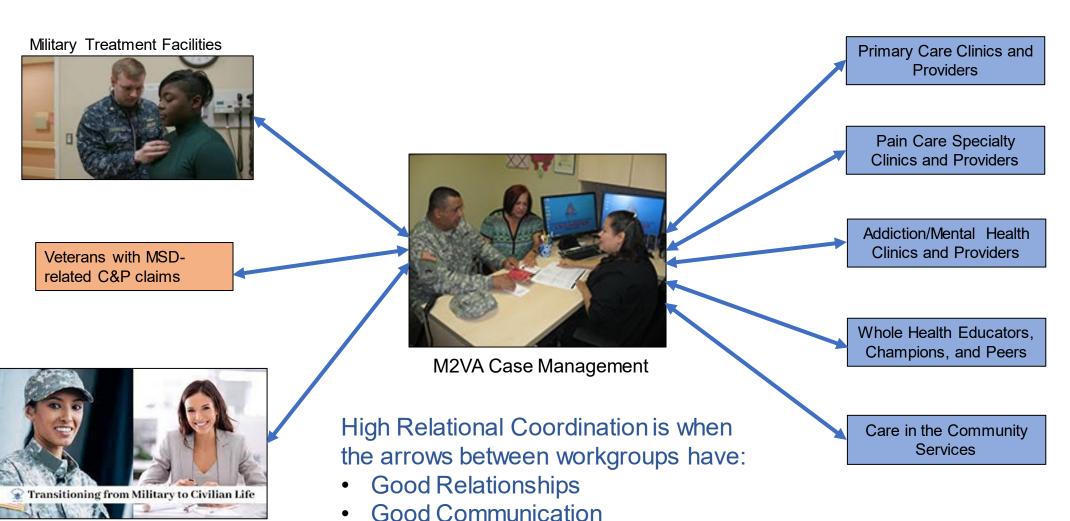








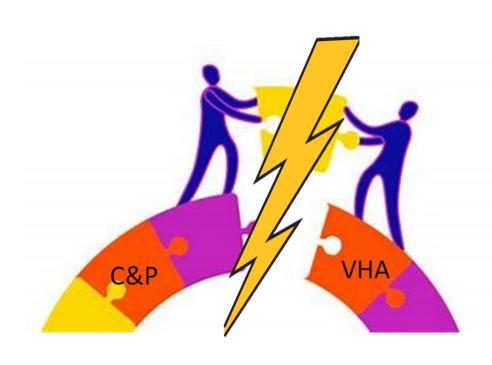
Implementation by M2VA needs Relational Coordination with other Partners



Veterans new to VA



Implementation by M2VA needs Relational Coordination with other Partners



- More privatization of C&P exams.
- More outreach to Veterans at C&P
- More involvement of M2VA Case Managers
- Requires more relational coordination



Who is Participating?





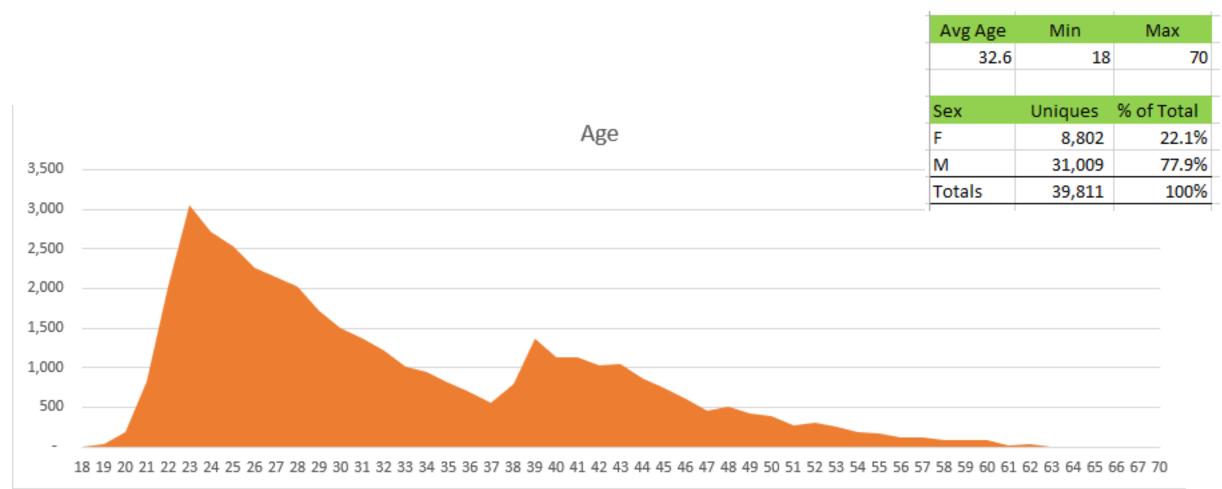


Implementation by Whom? Partners

Group	Comments								
M2VA Leadership, Broader Transition Care Management Teams	Implementers. Operational Partners. Interface with numerous other DoD and VA groups								
Primary Care	Pain care goes through primary care. Sites vary on how much they use M2VA input								
Care-in-the-Community Programs	Pain care pathways vary by site, some sites provide care in the community instead of on-site								
VHA Pain Care Apparatus	Recruiting PMOP coordinators to be internal facilitators. Research vs. Clinical Care role.								
Research Community	Health Services Research, PRIME Center, MIRECC, Painiacs								
Addictions	OIG report on need for OUD treatment in recently separated military personnel. Increase use of non-opioid pain treatments								
Veterans	Veterans Engagement Board								
VHACO Patient Centered Care and Cultural Transformation	Increasingly the pathway to complementary/alternative pain care								
VBA Medical Disability Examination Office and Contracted Exams	Performance Analysis and Integrity provides C&P claimant lists. Case finding for intervention.								



Implement to whom? Age of Veterans with M2VA case management separated in the past year





Hybrid Effectiveness-Implementation Trial Study

- Implementation Clinical Trial components
 - Intervention: SBIRT-PM
 - Implementation Strategy: Implementation Facilitation
 - Theoretical Framework for Implementation: Relational Coordination
- Study Design:
 - 28 sites in 2 cohorts randomized to
 - SBIRT-PM Training or
 - SBIRT-PM Training plus Implementation Facilitation
- Hybrid Type 2 Effectiveness-Implementation Clinical Trial with <u>two</u> <u>primary</u> aims
 - Coprimary Aim: Determine effectiveness of an implementation strategy
 - Coprimary Aim: Determine effectiveness of a clinical intervention



Randomization to Implementation-Facilitation:

- 1 year to plan the implementation in collaboration with the Post-9/11 M2VA Case Management Program
- 4 years to run a 2-cohort (14 sites each) staggered, cluster randomized, type 2 hybrid trial
- Within cohorts, sites randomized to Training or Training plus Implementation Facilitation
- 1848 Veterans enrolled in an observational study with assessments at baseline, 3 months, 9 months,
- 3-part formative evaluation

Cohort	Sites	Task	UG3 Planning Phase				UH3 Research Execution Phase															
			Year One				Year Two				Year Three				Year Four				Year Five			
			1-3	4-6	7-9	10-12	1-3	4-6	7-9	10-12	1-3	4-6	7-9	10-12	1-3	4-6	7-9	10-12	1-3	4-6	7-9	10-12
		Formative Eval																				
	1-7	Training + IF																				
	1-7	Recruit																				
1		Follow-up																				
	ı	Training Only																				
		Recruit																				
		Follow-up																				
		Formative Eval																				
	15-21	Training + IF																				
		Recruit																				
2		Follow-up																				
		Training Only																				
	22-28	Recruit																				
		Follow-up																				



Study Aims

- <u>Implementation Aim</u>: Training as Usual vs. Implementation Facilitation
 - Primary implementation outcome will be the proportion of participants who receive any SBIRT-PM (Reach).
 - Other implementation outcomes:
 - Proportion of case managers who receive training in SBIRT-PM and proportion of those trained who used SBIRT-PM with at least three participants (Adoption)
 - Integrity of case managers' use of Motivational Interviewing in SBIRT-PM sessions (Implementation).
 - Qualitative analyses of implementation process.
- Clinical Aim: Training as Usual vs. Implementation Facilitation:
 - The primary clinical outcome is the PEG measure of pain.
 - Secondary outcomes: ASSIST-3 measure of substance use (with biochemical verification of alcohol report using fingernails)
 - EHR-derived number of non-pharmacologic pain management services used
- <u>Cost Aim</u>: Cost-effectiveness and budget impact of implementation facilitation relative to trainingas-usual

Training-as-Usual Group (virtual workshop and SP actors)

Virtual Experiential Workshop for M2VA staff

- Motivational Interviewing as "a way of doing what you do"
- Description of VA approach to pain care
- Screening for substance use
- Integrate motivational interviewing approach to address pain and substance use and engage Veterans in multimodal pain care/SUD services during M2VA encounters
- 8 hours over 2 days
- Multiple offerings across time zones



Training-as-Usual Group (virtual workshop and SP actors)

Post-Workshop Simulated Patient Encounters

- 8 cases involving recently separated Veterans with musculoskeletal disorders, service-connected ratings, chronic pain, and in some cases problematic substance use
- Cases vetted by the CORE Veterans Engagement Panel
- Hiring 8 Veterans who will be trained to enact the simulations
- Performance feedback from actors to case managers
- One baseline SP encounter following workshop followed by up to 7 follow-up SP practice encounters during 21-month implementation phase (opportunity once every 3 months)



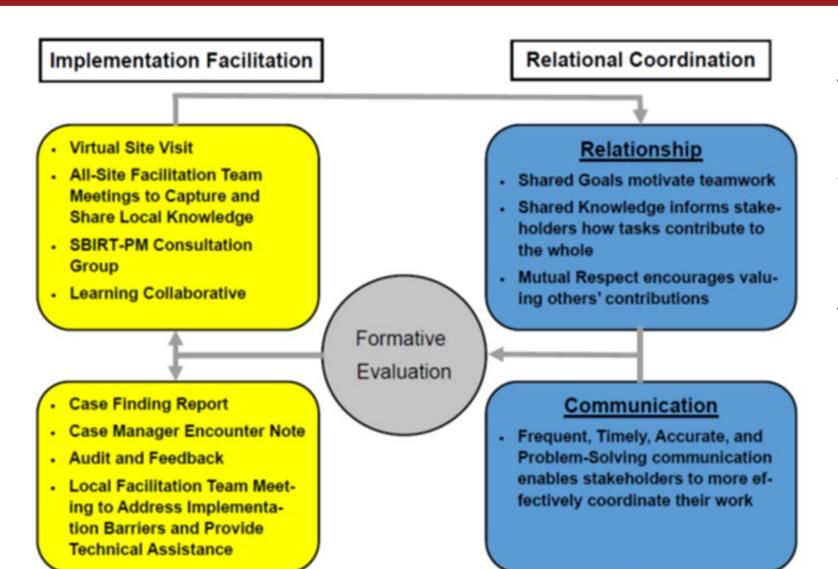
Training-as-Usual Group (SP case example)

Justin is a 25-year-old Coast Guard Veteran

- Left the military 11 months ago
- Worked as a Damage Controlman maintaining vessel systems
- Chronic pain resulted from an injury in 2018
 - A swell crashed into his cutter (boat) dropping him hard to the floor
 - Leg trapped in a door that crashed closed
 - Muscle injuries, no fractures
- Pain persisted
 - Briefly prescribed oxycodone but stopped due to side effects (light-headedness, constipation, and dry mouth)
 - Pain is 4/10 on most days but pushes to a 7 or 8 when taxed at work (contractor)
- Received a 50% service-connection rating for multiple musculoskeletal disorders involving his back, leg, and shoulder



Implementation Facilitation Guided by Relational Coordination



External Facilitation Team consisting of experts in pain care, addiction treatment, case management, implementation facilitation, and motivational interviewing.

<u>Internal Facilitators i</u>deally will be PMOP Coordinators at each site



Simulated patients call case managers for training sessions...

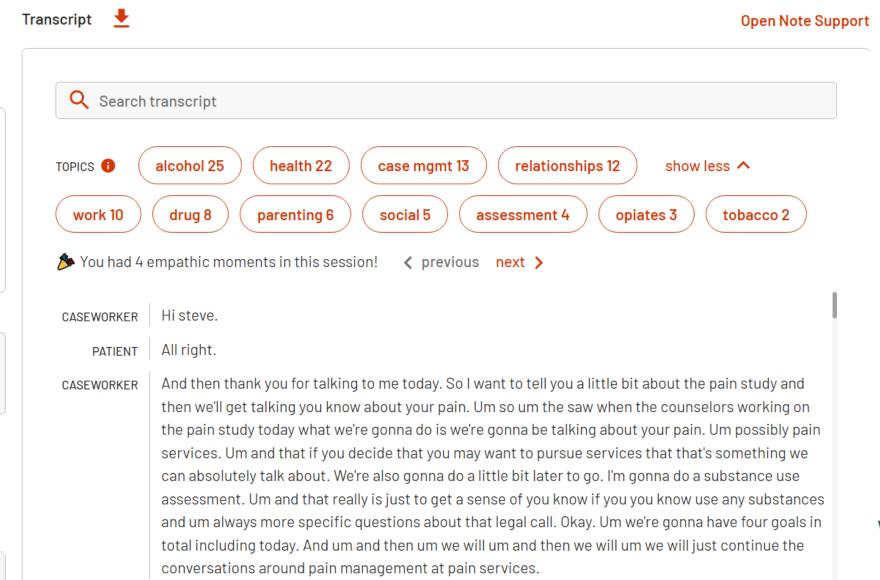




Maria Gabriela Garcia Vassallo, M.D.

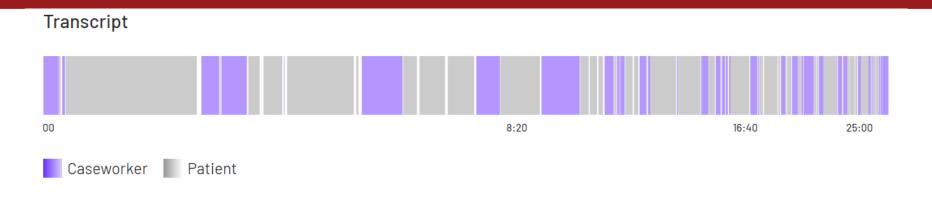


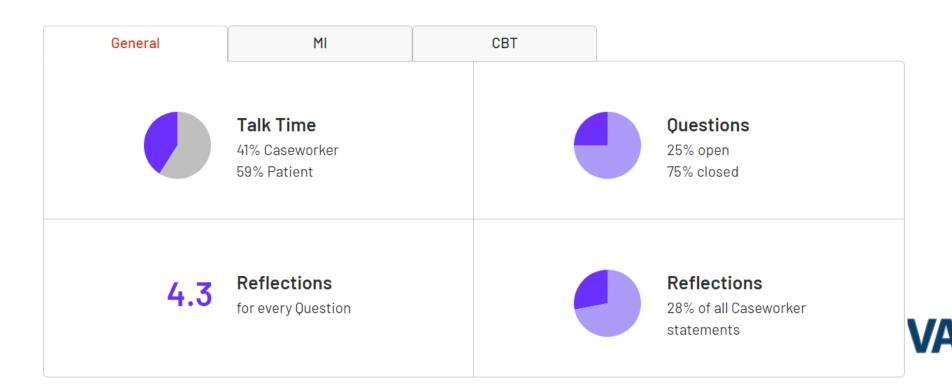
LYSSN Software Using Artificial Intelligence to Train M2VA Case Managers



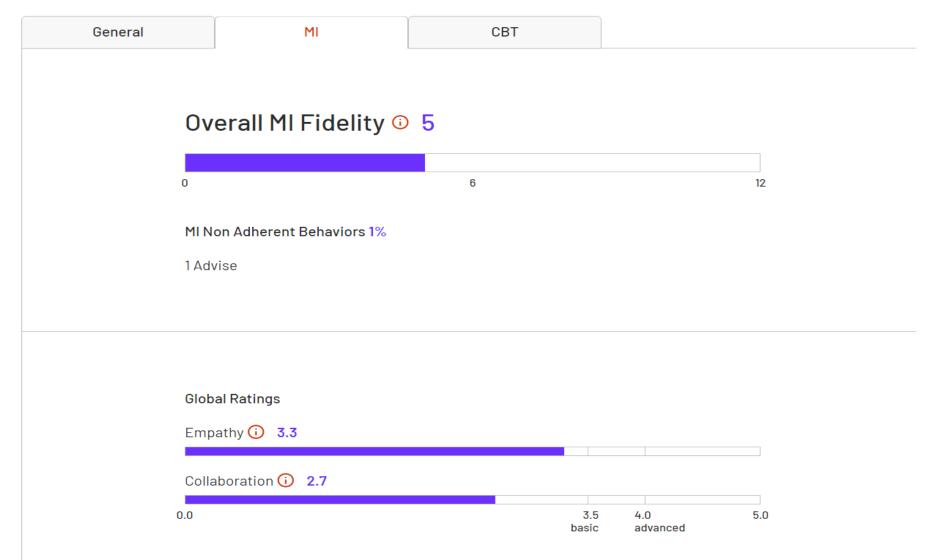


LYSSN Software Using Artificial Intelligence to Train M2VA Case Managers





LYSSN Software Using Artificial Intelligence to Train M2VA Case Managers





Summary

- Veterans seeking compensation for MSD
 - Are numerous (half of post-9/11 VHA patients)
 - Have high pain severity and high rates of comorbidities
 - Usually attended proffered counseling
 - Appear to benefit from the counseling
 - More pain service use
 - Other studies have found benefits of MI and patient care navigation approaches
- Project combines quantitative and qualitative science and implementation work science work
 - Relational Coordination framework driving mixed methods formative evaluation and implementation facilitation strategy
 - Primary test is about effectiveness of implementation strategy
 - Controlled data: RCT data, costs of implementing SBIRT-PM under both implementation strategies

- Implementation work requires close work with key partners
 - NIH/NCCIH
 - VBA
 - Military 2VA Transition Care Managers
 - CORE Veterans Engagement Panel
 - Comp and Pen services
 - Primary Care
 - Pain care providers/PMOP
 - Addiction/Mental Health providers



Questions or Comments



Marc.Rosen@yale.edu Marc.Rosen@va.gov Steve.Martino@yale.edu Steve.Martino@va.gov

