A Policy Relevant US Trauma Care System Pragmatic Trial for PTSD and Comorbidity

(1UH2MH106338-01)

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Overview of Core Discussion

- UH2-UH3 Proposal
  - PTSD & MCC framework
    - Collaborative care “elements”
    - US trauma care systems & policy
- UH2 Milestones
  - Timeline
  - Current UH2-UH3 milestone progress
  - Potential barriers
  - Collaborative brainstorming of optimal UH2-UH3 milestone approaches

Other Discussion Points (as time permits)

- Background: Prior DO-SBIS multisite alcohol screening and brief intervention pragmatic trial
- Prior nationwide PTSD & Comorbidity screening & intervention assessments
- Prior nationwide IT assessments
- Other implementation science considerations
- American College of Surgeons' policy

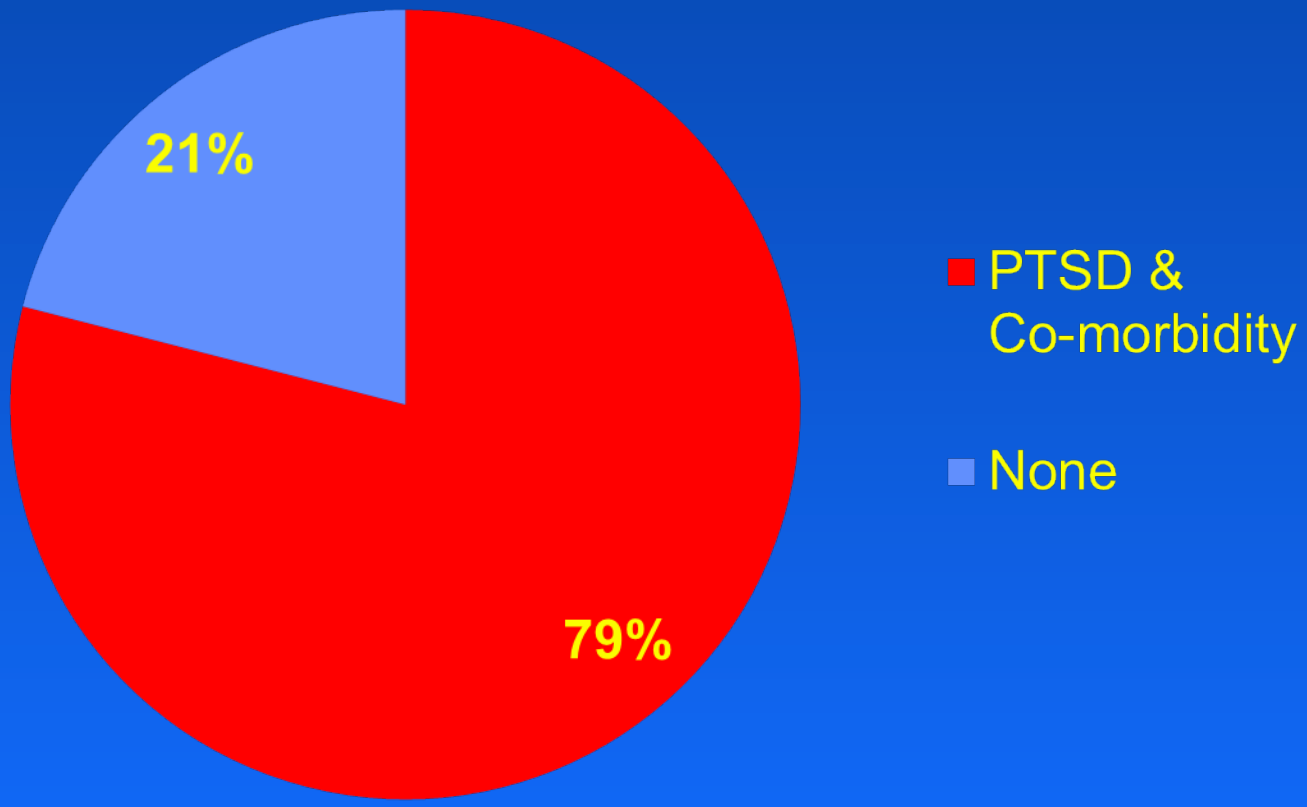
Study Design

- Cluster randomized trial
- 24 US trauma centers
- 12 intervention sites receive training in PTSD & comorbidity
- Control sites care as usual
- 40 patients per site (960 patients total)
- Baseline pre-randomization evaluation
- 3, 6, 12 month follow-up

UH2-UH3 Hypotheses

- The intervention group when compared to the control group will demonstrate:
- 1) ↓ PTSD symptoms
- 2) ↓ Alcohol use problems
- 3) Improved post-injury physical function
- 4) Intervention will be equally effective among patients with and without traumatic brain injury
- 5) Intervention will be equally effective among injury survivors with and without pre-existing chronic medical conditions

Background MCC Framework: PTSD & Comorbidty Among Randomly Selected Emergency/Trauma Surgery Patients (N=878)



Zatzick et al JSAT 2012

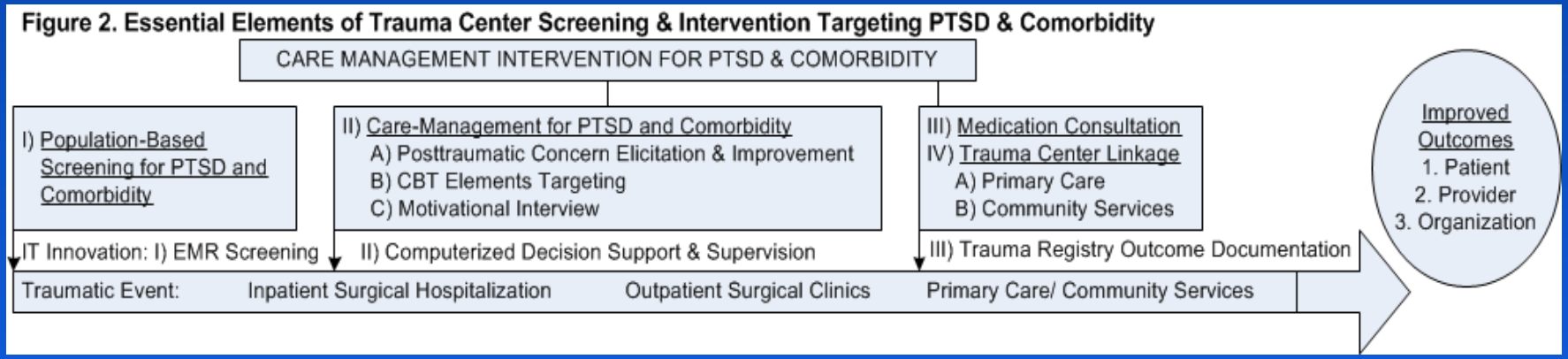
PTSD & Comorbidity and the MCC Framework: Heterogeneity

- Mental health comorbidity: PTSD, depression, occult suicidal ideation, pain and somatic symptoms
- Substance abuse comorbidity: alcohol, stimulants, opiates, benzodiazepines, MJ
- Medical comorbidity: HTN, CAD, Diabetes, Pulmonary, Hepatic, Renal, Obesity, HIV, Epilepsy
- Injury: Traumatic Brain Injury (TBI)

PTSD & Comorbidity and the MCC Framework: Frequencies

- 63% ≥ 3 comorbidity
- 20%-40% high PTSD/depression
- 25% alcohol use problems
- 21% other substance use problems
- 40-50% Traumatic brain injury
- 50-60% ≥ 1 Chronic medical condition

Intervention Model: Stepped Measurement-Based Collaborative Care



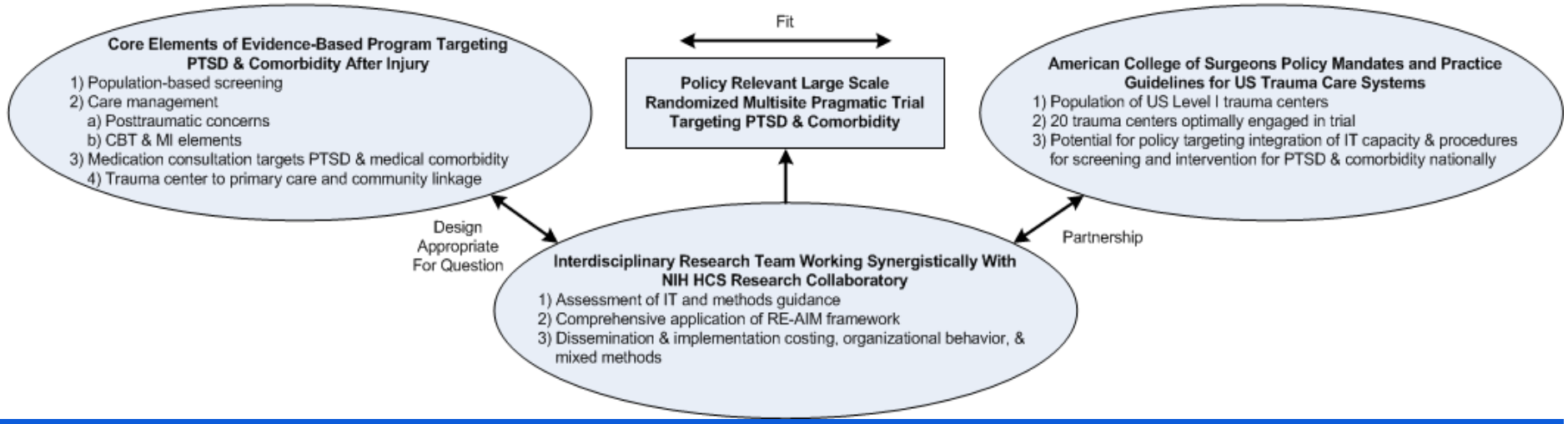
Core Intervention Elements Targeting MCC After Injury

Essential Element	Which of multiple (≥ 3) MCC Targeted	MCC strategic framework goals addressed*
Population-based EMR PTSD & comorbidity risk prediction	PTSD, depression, alcohol & drug use problems, pain and somatic symptoms, & chronic medical conditions after acute injury	Goal 1 Objective D, Implement and efficiently use health information technology; Automated screening efficiently identifies constellation of PTSD and comorbidity in injured populations
Care management with trauma center to primary care linkage	Coordination of acute injury mental health and pre-existing chronic medical condition care	Goal 2 Facilitate use of community based services and self-care management
Early post-injury medication history, reconciliation, and care coordination	PTSD, depression, pain, somatic symptom amplification & TBI symptoms prevention. Chronic medical condition (e.g. HTN, CAD, Diabetes) reconciliation and coordination	Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions & Goal 2 Objective C, Provide tools for medication management
Evidence-based MI embedded within care management	Targets alcohol and drug use problems and enhanced patient engagement	Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions
Evidence-based CBT embedded within care management	Targets PTSD, depression, pain, somatic symptom amplification and TBI sequelae. Also targets enhanced patient self-efficacy	Goal 1 Objective E Prevent occurrence of new chronic conditions and mitigate the consequences of existing conditions, & Goal 2 Objective A Facilitate self-care management
Patient and caregiver-centered posttraumatic concern elicitation and improvement	Patient-centered concerns elicitation and improvement targets patient and family engagement in care of full MCC constellation	Goal 2 Optimize self-care management and coordinated use of services by patient and caregivers
Caseload supervision & stepped measurement-based care implementation	PTSD, depression & associated suicidal ideation, alcohol & drug use problems, chronic medical conditions & acute physical injury	Goal 3 Provide better information and education on treatment of MCCs to health-care workers

* All study elements address MCC Goal 4 Enhancing Research Knowledge on MCCs

Integration of Pragmatic Trial, Robust Implementation and Policy Conceptual Frameworks for US Trauma Care Systems

Figure 3. Integration of Large-Scale Pragmatic Trials, Robust Implementation, & Policy Relevance Conceptual Frameworks for Trauma Care Systems



Derived from Glasgow and Chambers CTS 2012

UH2-UH3 Transition Milestones

- 1. Establish collaborative relationships and a scientific exchange: 7-2014
- 2. Implementation of Collaboratory approved policies and practices: 7-2014
- 3. Obtain IRB Approval: 10-2014
- 4. Finalized outcome assessments: 11-2014
- 5. Finalize incentives for participation with the American College of Surgeons: 12-2014
  - Research participation
  - Alcohol screening & brief intervention waiver

UH2-UH3 Transition Milestones

- 6. Develop detailed UH3 budget: 3-2015
- 7. Final revised 24 site statistical plan: 4-2015
- 8. Obtain final commitment from 24 sites: 5-2015
- 9. Decision support tool able to be used at 24 sites: 6-2015
- 10. UH2 Pilot
  - IRB approvals by 1-2015
  - Subject recruitment begins 2-2015
  - Recruitment ends 5-2015
  - Pilot complete 6-2015

UH2 Milestone Timeline

UH2 Milestone Timeline

UH2 Project Completion Aim	July 2014	Aug. 2014	Sept. 2014	Oct. 2014	Nov. 2014	Dec. 2014	Jan. 2015	Feb. 2015	March 2015	April 2015	May 2015	June 2015
1. Collaboratory scientific exchange	x											
2. Collaboratory policy acceptance	x											
3. Centralized IRB approval				x								
4. Finalized outcome assessments					x							
5. Surgical College incentives final						x						
6. UH3 budget developed									x			
7. Revised statistical plan										x		
8. Obtain final 24 site commitment											x	
9. Decision support tool deployed												x
10. Pilot at 2 non-UH3 sites												
A. Site IRB approval granted							x					
B. Recruitment begins								x				
C. Recruitment ends											x	
D. Pilot complete												x

UH2-UH3 Milestones Progress: Site Recruitment

- Broad criteria
- Approach derived from DO-SBIS
- Inclusion: 3 Champions
  - Trauma surgery
  - PTSD recruitment/intervention
  - Information technology
- Exclusion: Well developed PTSD screening/intervention capacity

UH2-UH3 Milestones Progress: Site Recruitment

- 2 UH2 pilot sites identified and feasibility discussions have begun
- 24 UH3 sites required
- 14 sites meet criteria & progressing
- 12 sites in-depth discussions
- Ongoing contact nationally

Potential Barriers: IRB Approvals

- Centralized versus local IRB
- Tradeoffs: Centralized – potential loss of excellent sites
- Tradeoffs: Local – delays with modifications
- Brainstorming feasible solutions

Potential Barriers: Site Payments

- Direct payment to trauma service
- Subcontract (more lengthy process)

Potential Barriers: Scale Consensus

Study Measure	Ward	3-Mo	6-Mo	12-Mo
EMR 10 Item PTSD Evaluation	X			
ICD injury severity	X			
ICD TBI severity	X			
ICD Chronic Medical Conditions	X			
EMR & Self-reported demographics	X			
Consciousness/Glasgow Coma Scale	X			
PTSD (PTSD Checklist DSM-IV & DSM-5)	X	X	X	X
Depression (PHQ-9)	X	X	X	X
Alcohol (AUDIT)	X	X	X	X
Illegal and Prescription Drug Use (DAST)	X	X	X	X
Pain (McGill Pain Short Form)	X	X	X	X
Postconcussive/Somatic Sympt. (NSCOT)	X	X	X	X
Functioning (MOS SF12/36)	X	X	X	X
Work, Disability & Legal ADL/IADL (NSCOT)	X	X	X	X
Utilization, & Medication (NSCOT)	X	X	X	X
Satisfaction with Care (NSCOT)	X	X	X	X
Pre-Injury Trauma (NCS)	X			
Recurrent Traumatic Events (NSC)			X	X
Reactions to Research Participation (RRPQ)	X	X	X	X
EMR/Trauma Registry Utilization Data		Ongoing - Automated Data		

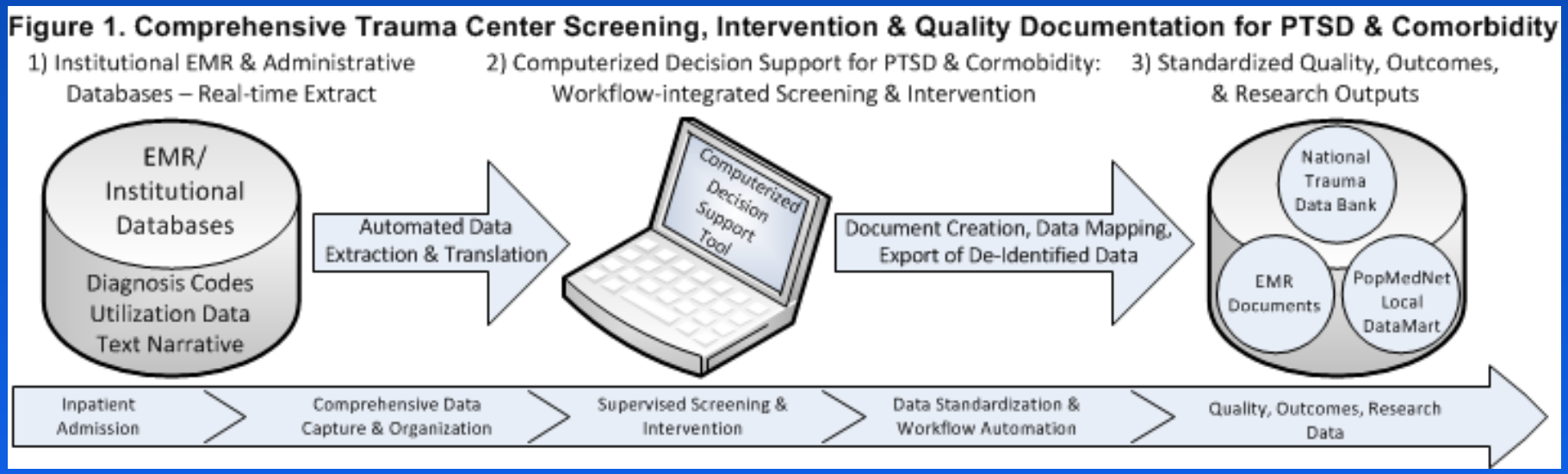
Potential Barriers: Power, Sample Size & Other Statistical Issues

- Spring 2014 discussions with D. Murray
- Power considerations increases site N from 20 to 24
- P. Heagerty joins team oversees UH2-UH3 transition statistical planning

Thank You!
We look forward to ongoing brainstorming

Other Topics (as time permits)

Comprehensive Acute Care Medical IT Approach for PTSD & Comorbidity Targeting Real Time Work-flow Integration of Clinical Care

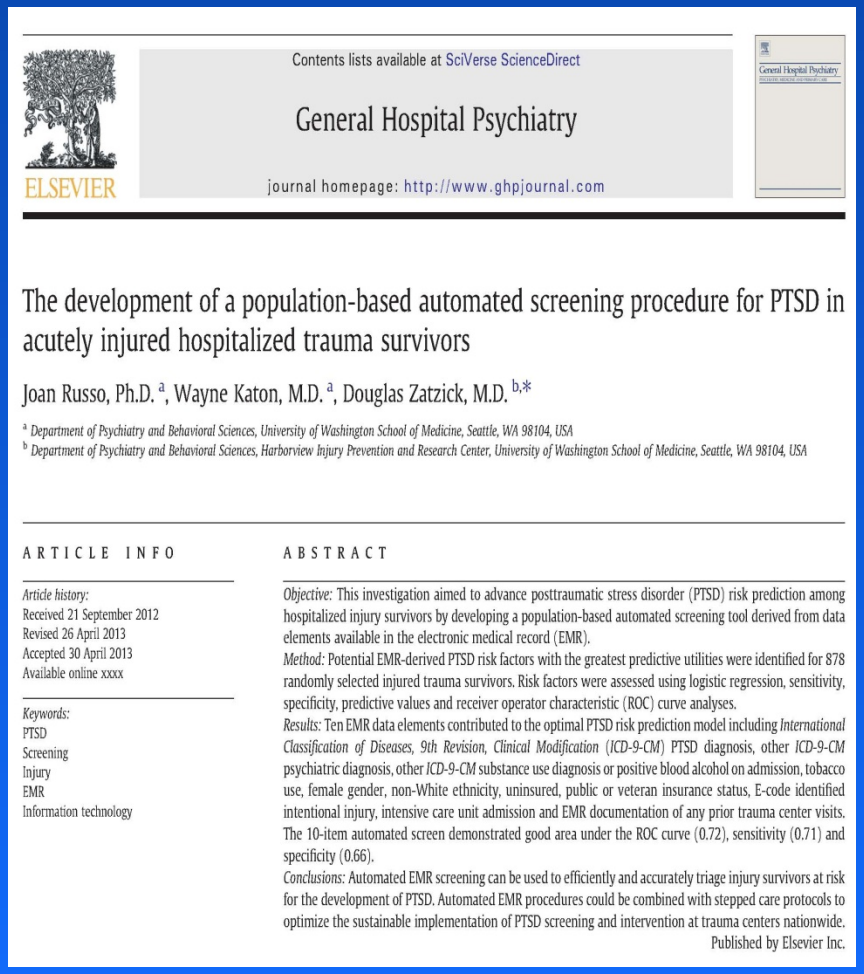


Van Eaton, Zatzick, Gallagher, Tarczy-Hornoch, Rivara, Flum, Peterson & Maier
Accepted for Publication Journal of the American College of Surgeons'

IT Milestones & Goals

- Decision support tool can be deployed to 24 sites (Mandatory)
- EMR PTSD evaluation options
  - Automated
  - Manual

Population-based Electronic Medical Record PTSD & Comorbidity Evaluation



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The development of a population-based automated screening procedure for PTSD in acutely injured hospitalized trauma survivors

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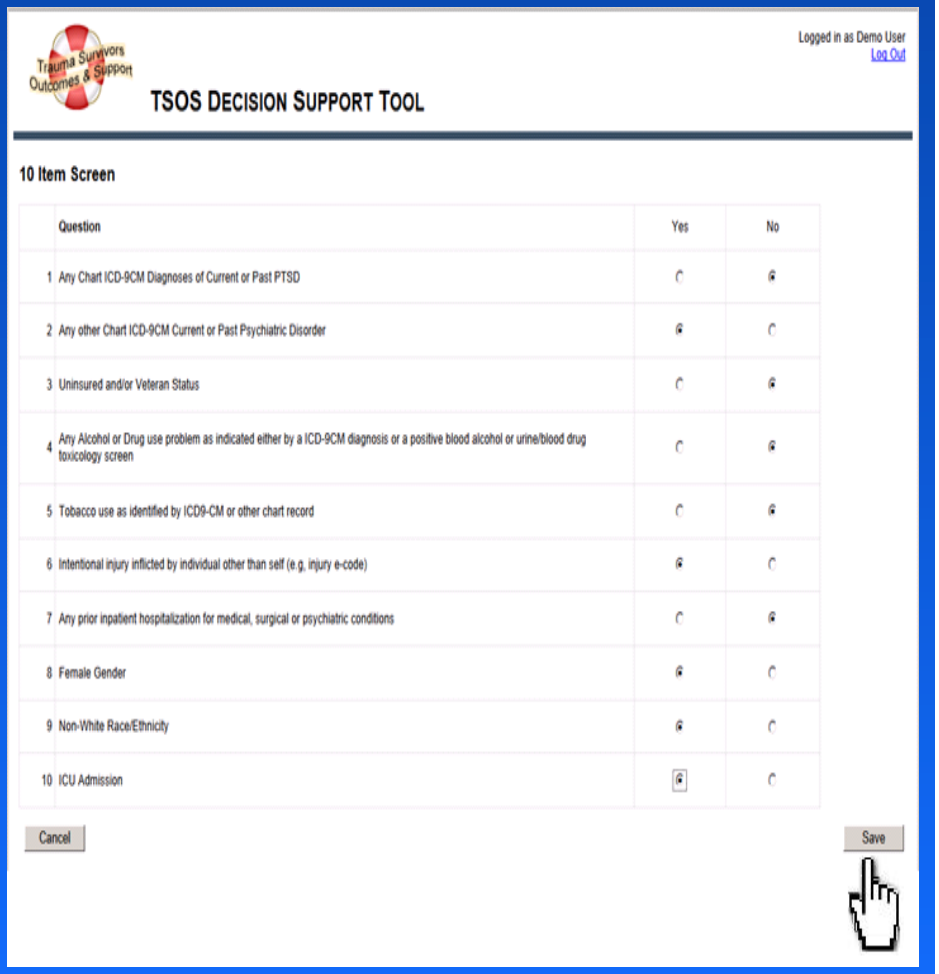
ABSTRACT

Objective: This investigation aimed to advance posttraumatic stress disorder (PTSD) risk prediction among hospitalized injury survivors by developing a population-based automated screening tool derived from data elements available in the electronic medical record (EMR).
Method: Potential EMR-derived PTSD risk factors with the greatest predictive utilities were identified for 878 randomly selected injured trauma survivors. Risk factors were assessed using logistic regression, sensitivity, specificity, predictive values and receiver operator characteristic (ROC) curve analyses.
Results: Ten EMR data elements contributed to the optimal PTSD risk prediction model including *International Classification of Diseases, 9th Revision, Clinical Modification* (*ICD-9-CM*) PTSD diagnosis, other *ICD-9-CM* psychiatric diagnosis, other *ICD-9-CM* substance use diagnosis or positive blood alcohol on admission, tobacco use, female gender, non-White ethnicity, uninsured, public or veteran insurance status, E-code identified intentional injury, intensive care unit admission and EMR documentation of any prior trauma center visits. The 10-item automated screen demonstrated good area under the ROC curve (0.72), sensitivity (0.71) and specificity (0.66).
Conclusions: Automated EMR screening can be used to efficiently and accurately triage injury survivors at risk for the development of PTSD. Automated EMR procedures could be combined with stepped care protocols to optimize the sustainable implementation of PTSD screening and intervention at trauma centers nationwide.



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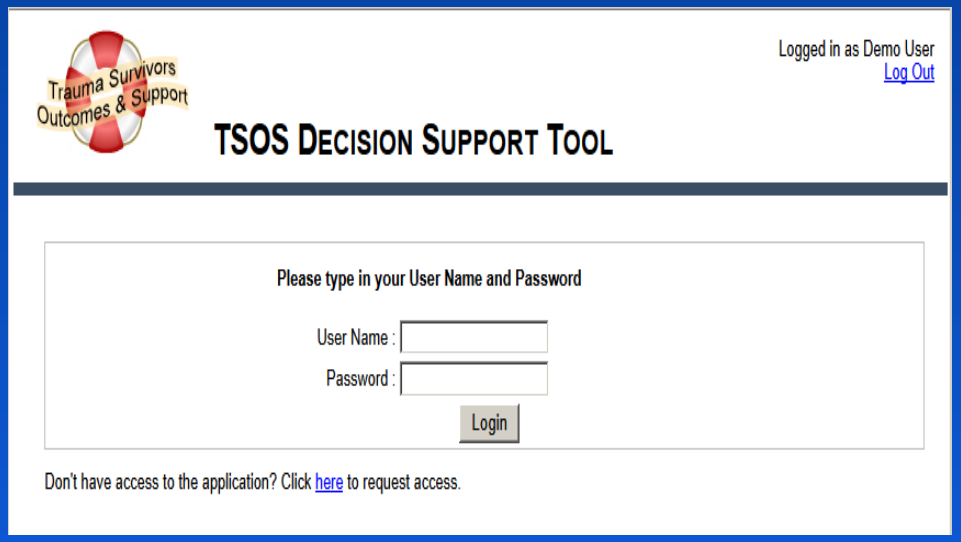
TSOS DECISION SUPPORT TOOL

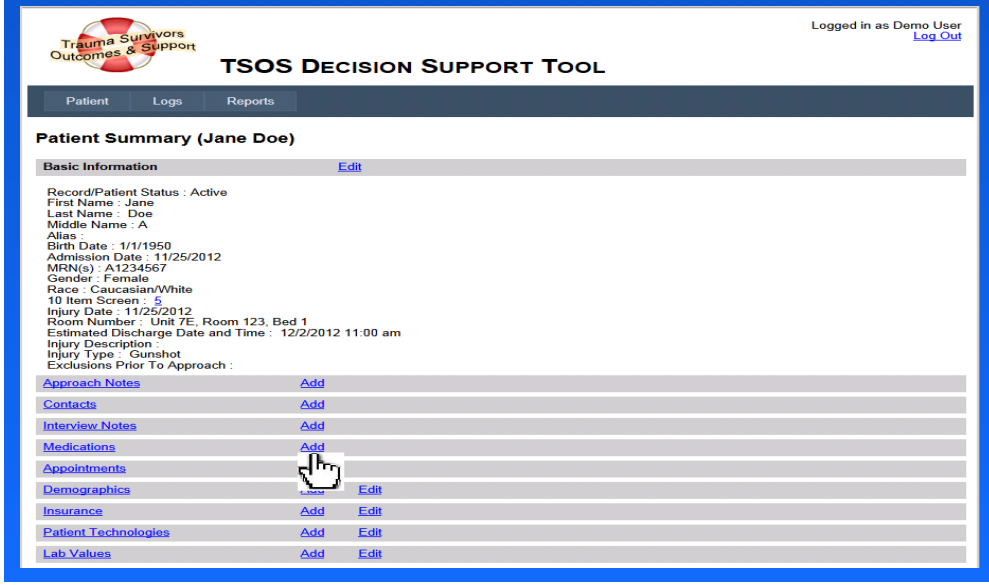
10 Item Screen

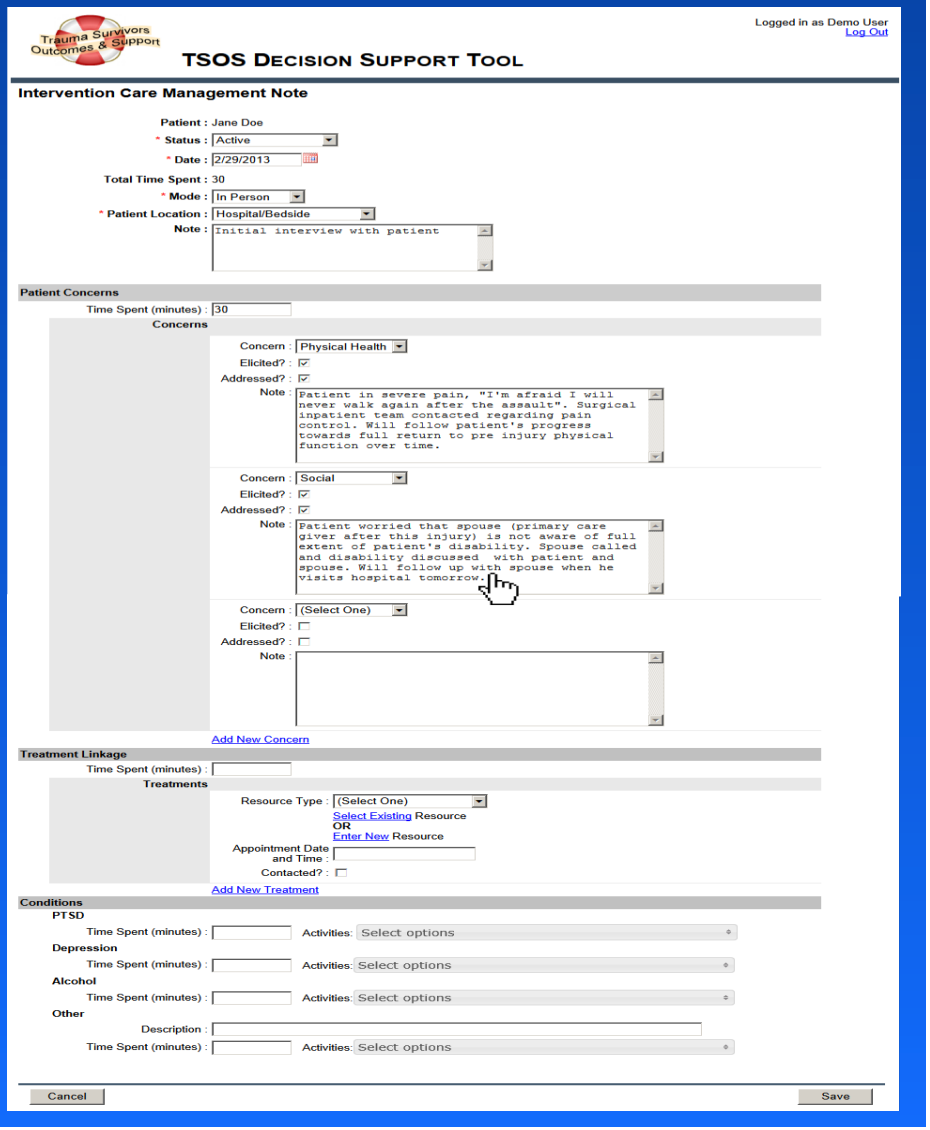
	Question	Yes	No
1	Any Chart ICD-9CM Diagnoses of Current or Past PTSD	○	●
2	Any other Chart ICD-9CM Current or Past Psychiatric Disorder	●	○
3	Uninsured and/or Veteran Status	○	●
4	Any Alcohol or Drug use problem as indicated either by a ICD-9CM diagnosis or a positive blood alcohol or urine/blood drug toxicology screen	○	●
5	Tobacco use as identified by ICD9-CM or other chart record	○	●
6	Intentional injury inflicted by individual other than self (e.g, injury e-code)	●	○
7	Any prior inpatient hospitalization for medical, surgical or psychiatric conditions	○	●
8	Female Gender	●	○
9	Non-White Race/Ethnicity	●	○
10	ICU Admission	●	○

Cancel Save

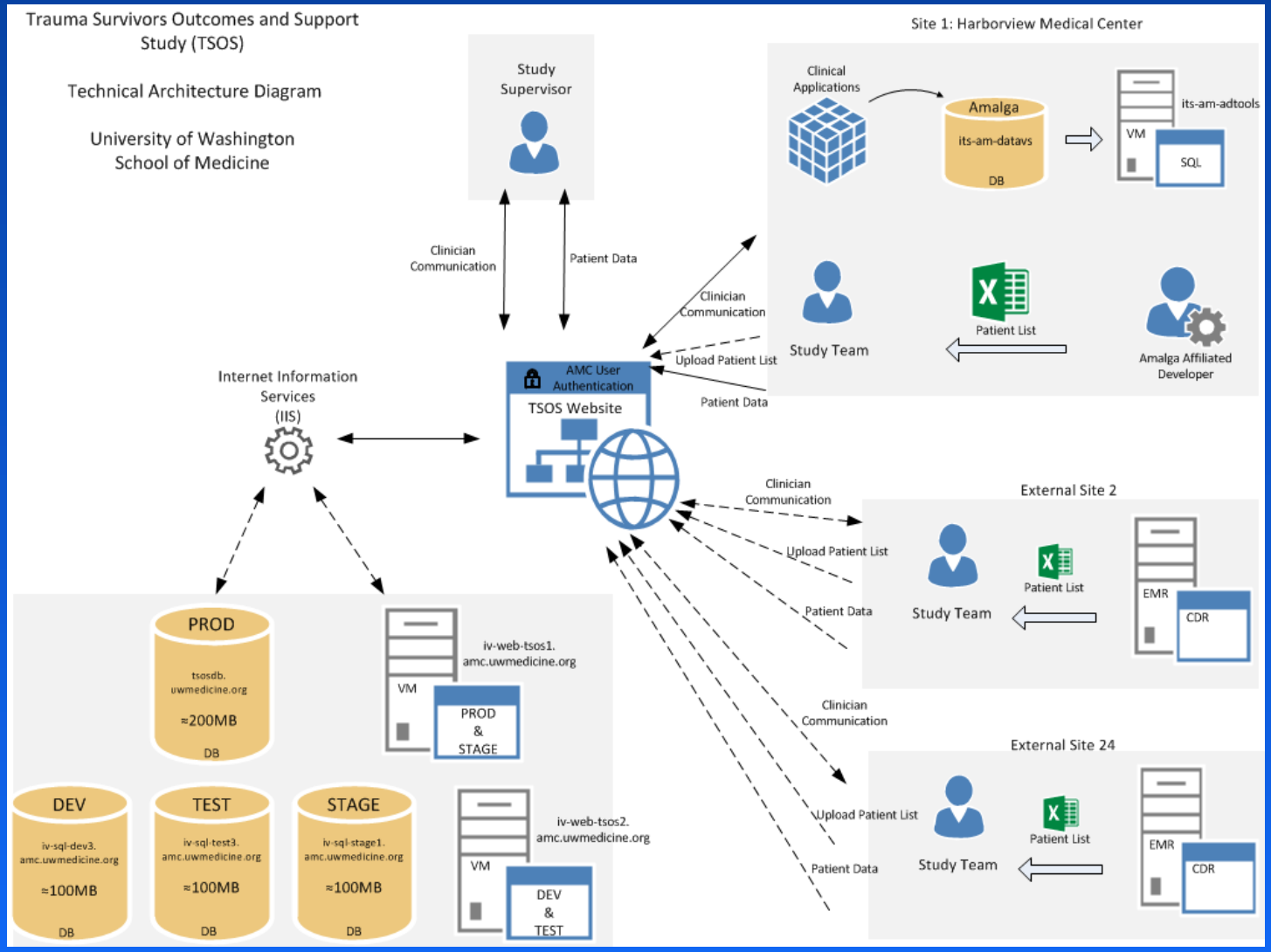
Computerized Decision Support for PTSD & Comorbidty (Derived from “CORES” Van Eaton et al 2005)





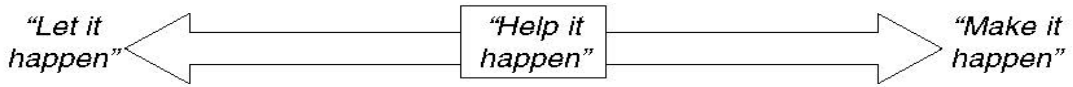


IT Architecture



Implementation Science "Make It Happen" Research to Policy Partnership with The American College of Surgeons

(Greenhalgh et al 2004, Milbank Quarterly)



Defining Features

Unpredictable, unprogrammed, uncertain, emergent, adaptive, self-organizing	Negotiated, influenced, enabled	Scientific, orderly, planned, regulated, programmed, systems "properly managed"

Assumed Mechanism

Natural, emergent	Social	Technical	Managerial

Metaphor for Spread

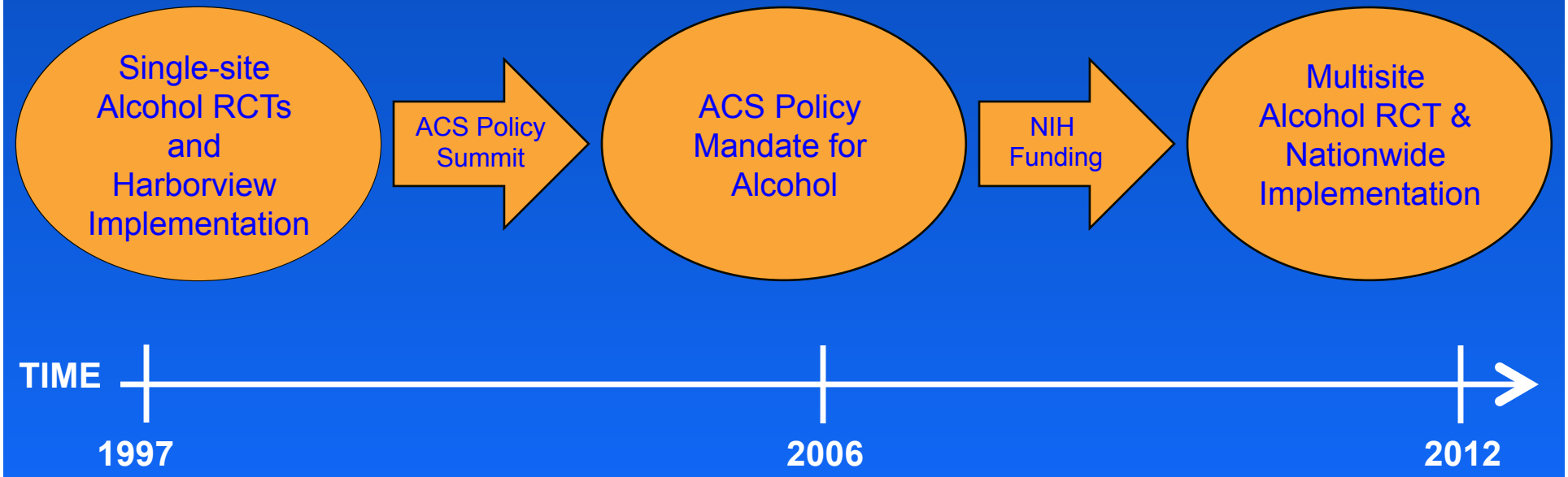
Emergence, adaptation	Knowledge construction, making sense	Diffusion	Negotiation	Knowledge transfer	Dissemination, cascading	Re-engineering

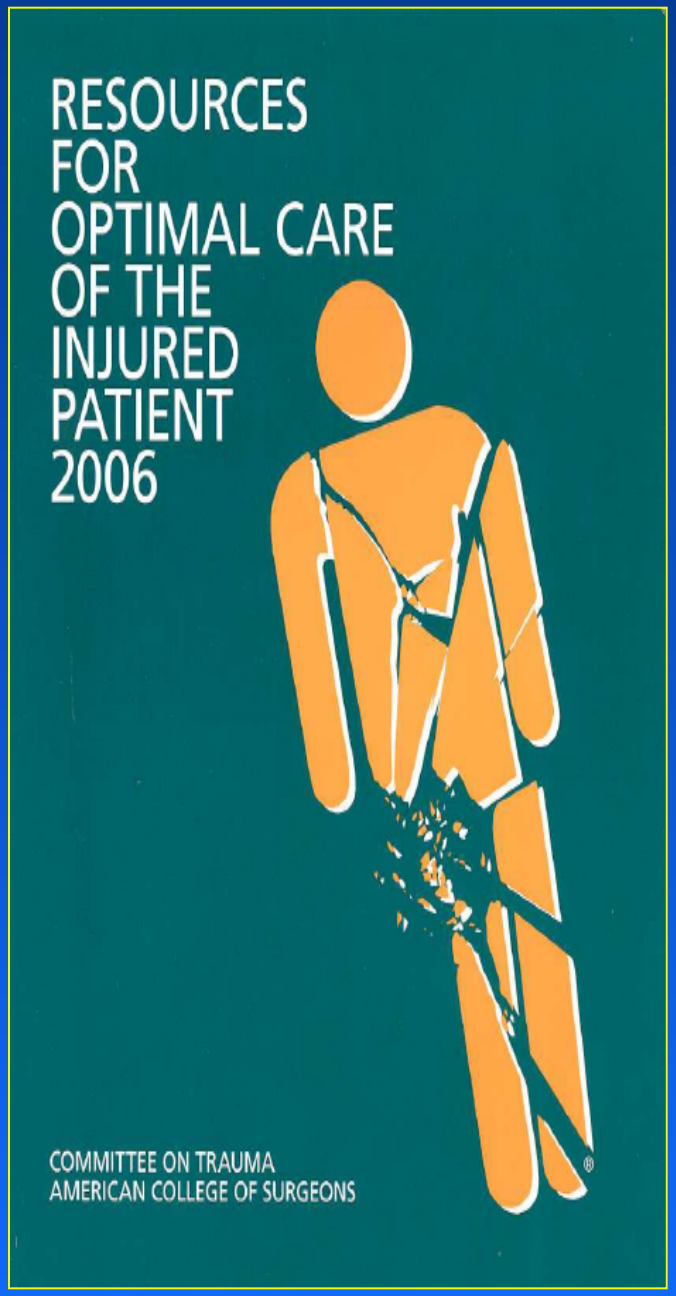
FIGURE 2. Different Conceptual and Theoretical Bases for the Spread of Innovation in Service Organizations

Implementation Science/RE-AIM Outcome Framework

UH2-UH3 Phase	Patient, Provider or Site Assessment	N	How Assessed	Measures/ Assessment	RE-AIM Domain/Level
UH2	Site Recruitment	20	CONSORT	Characteristics of 20 sites versus all other US sites	Reach Site
UH2	Trauma Surgeon Provider	20-40	Phone	Middle adopter status interview assessment	Adoption Site/Provider
UH2	Care Manager Champion	20-40	Phone	Middle status interview assessment	Adoption Site/Provider
UH2	Medication Champion	20-40	Phone	Middle adopter status interview assessment	Adoption Site/Provider
UH2	IT Expertise	20-40	Phone	Middle adopter status interview assessment	Adoption Site/Provider
UH2-UH3	Trauma Center Providers	10* 20	Web	Organizational change, culture, & climate surveys	Implementation Provider
UH3	Intervention Champion	20	Web	Weekly recruitment log activity	Implement. Provider/Site
UH3	Intervention Champion	20	Provid. logs	Logging of intervention procedures	Impl.Provider Adherence
UH3	Patient Flow	800	CONSORT	Patient flow through protocol	Reach Patient
UH3	Patient Outcomes	800	Web/Phone	PTSD,& comorbidity, gender & ethnicity subgroups	Effectiveness, Patient
UH3	Patient Outcomes	800	Multiple	EMR, trauma registry self-report, cost & work, logs	Implementation Patient
UH3	Patient 3,6, &12-Mo. F/U	800	Web/Phone	≥ 6 months follow-up after intervention complete	Maintenance Patient
UH3	Intervention Champion	20	Phone	Semi-structured key informant interviews	Implement/Maintenance
UH3	Policy Summit Participant	20	Phone	Semi-structured key informant interviews	Implement/Maintenance
UH3	All US Level I Centers	204	Web	Questionnaire	Maintenance, Site

American College of Surgeons Partnership: Orchestration of Pragmatic Trials & Policy

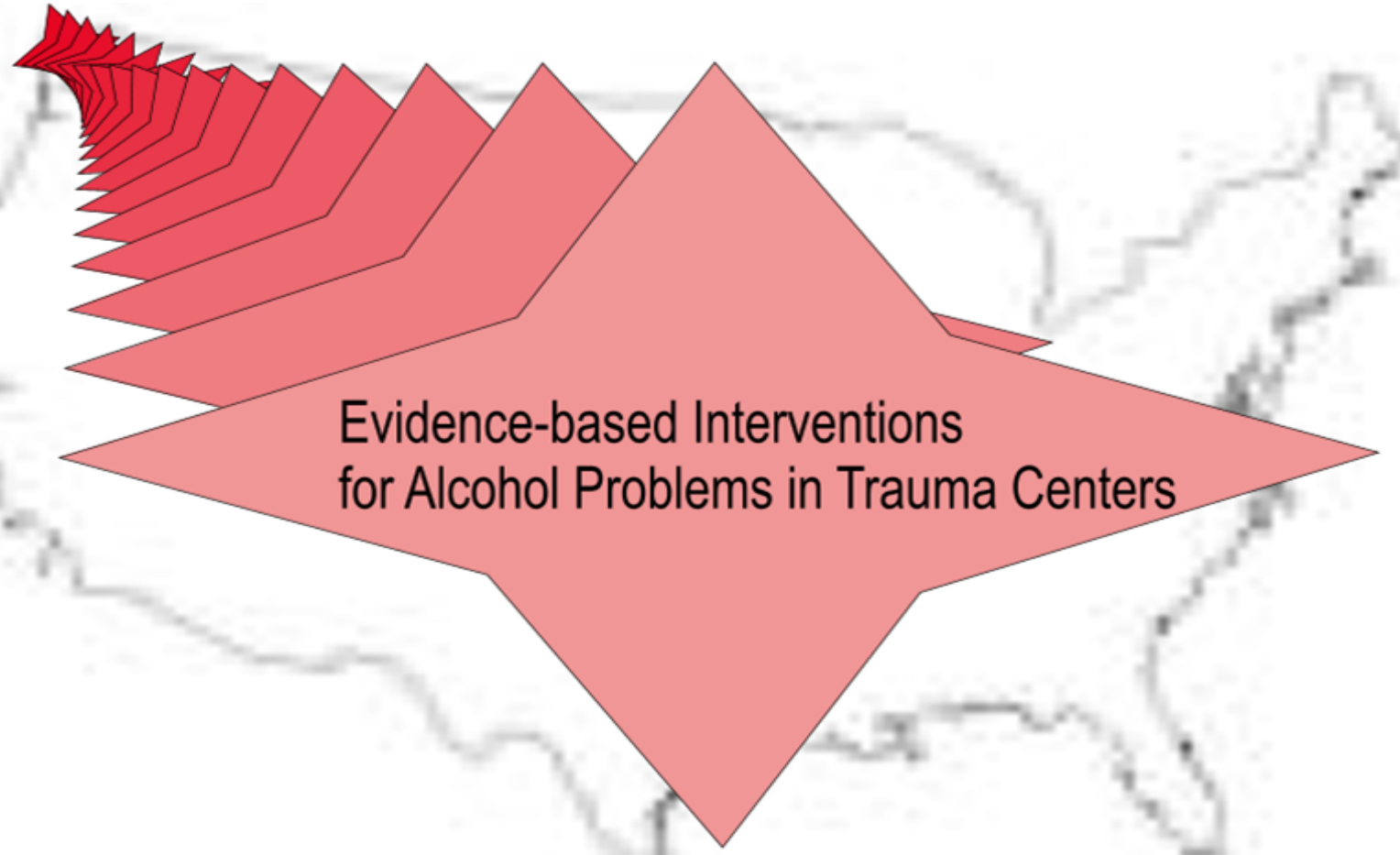


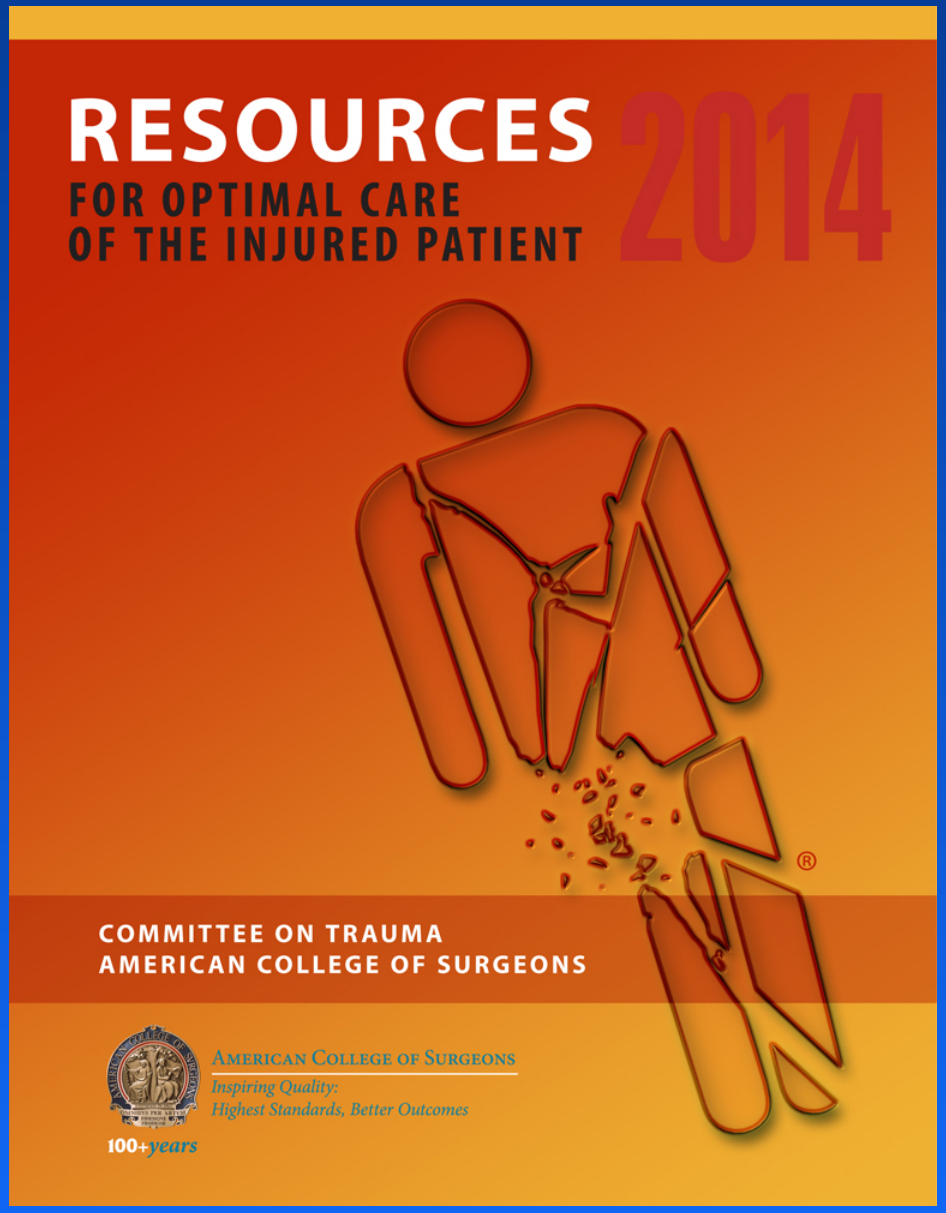


Prevention
Chapter 18

"Alcohol is such a significant associated factor and contributor to injury that it is vital that level I and level II trauma centers have a mechanism to identify patients who are problem drinkers."

"In addition, level I centers must have the capability to provide an intervention for patients identified as problem drinkers."

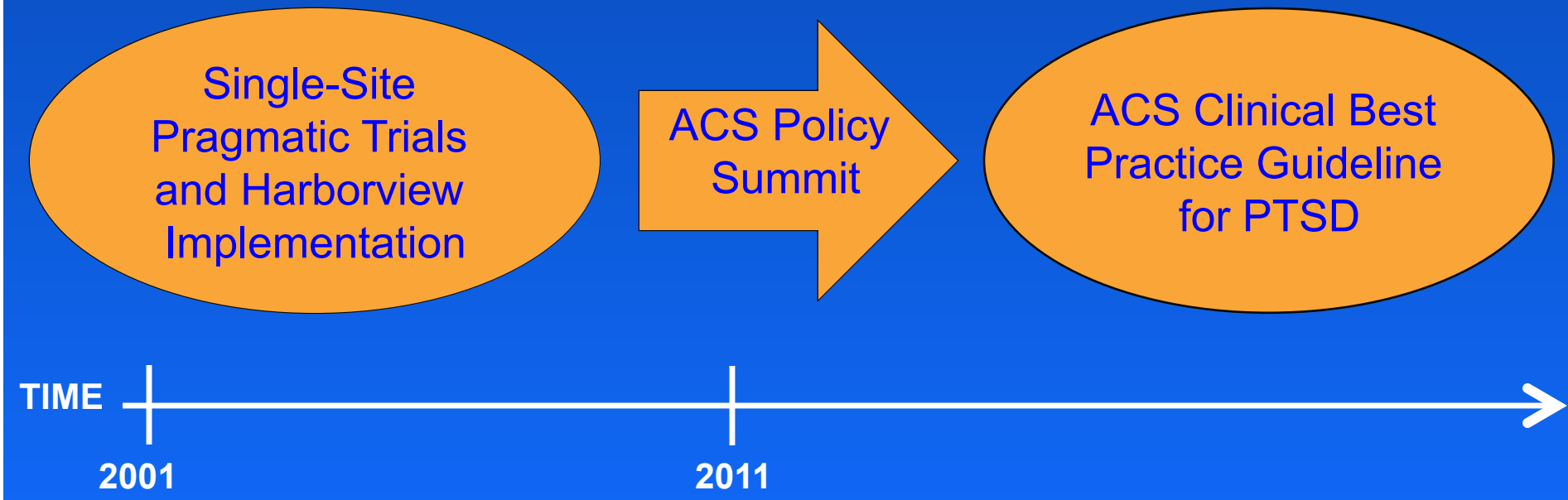

Evidence-based Interventions
for Alcohol Problems in Trauma Centers

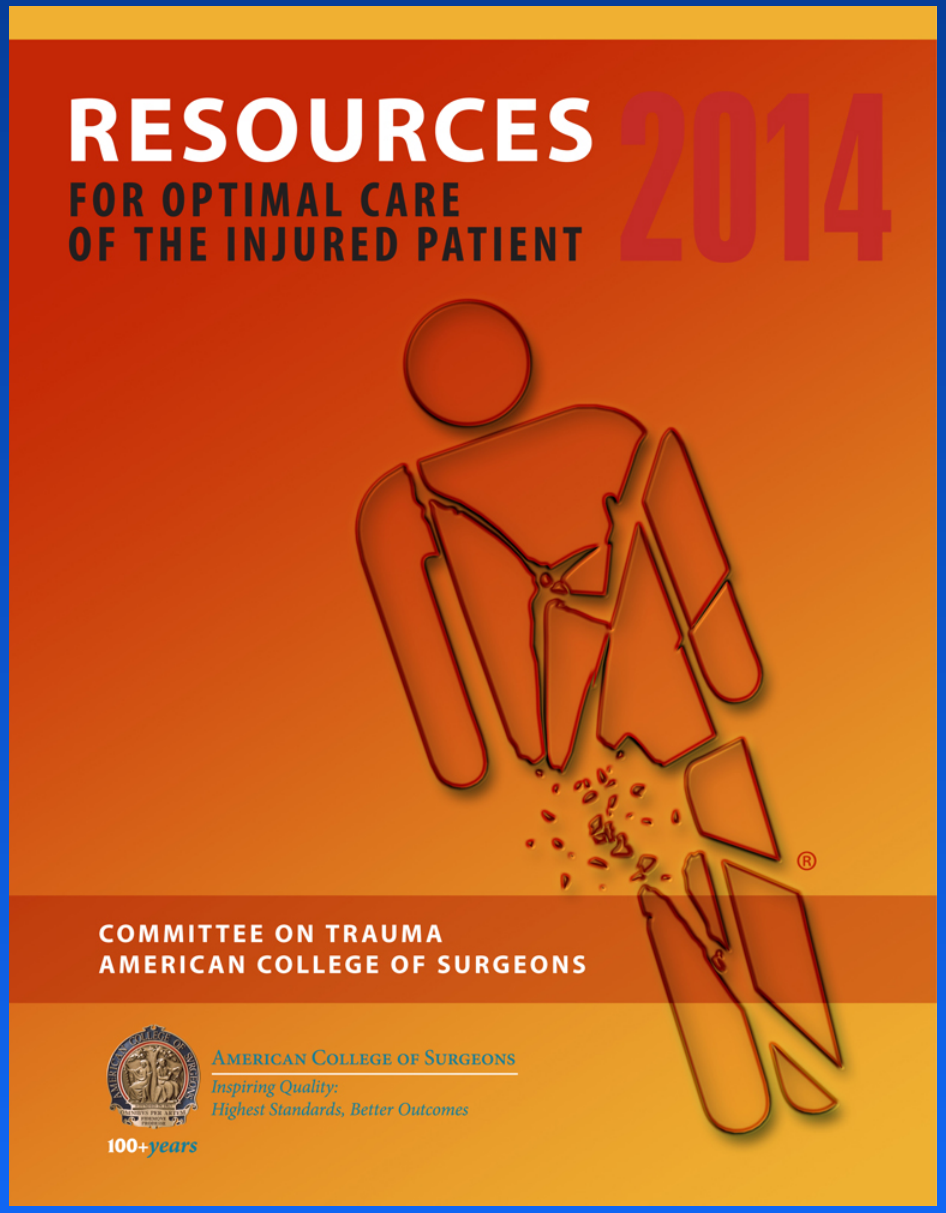


Alcohol

Universal Screening & Intervention at Level I & II trauma centers

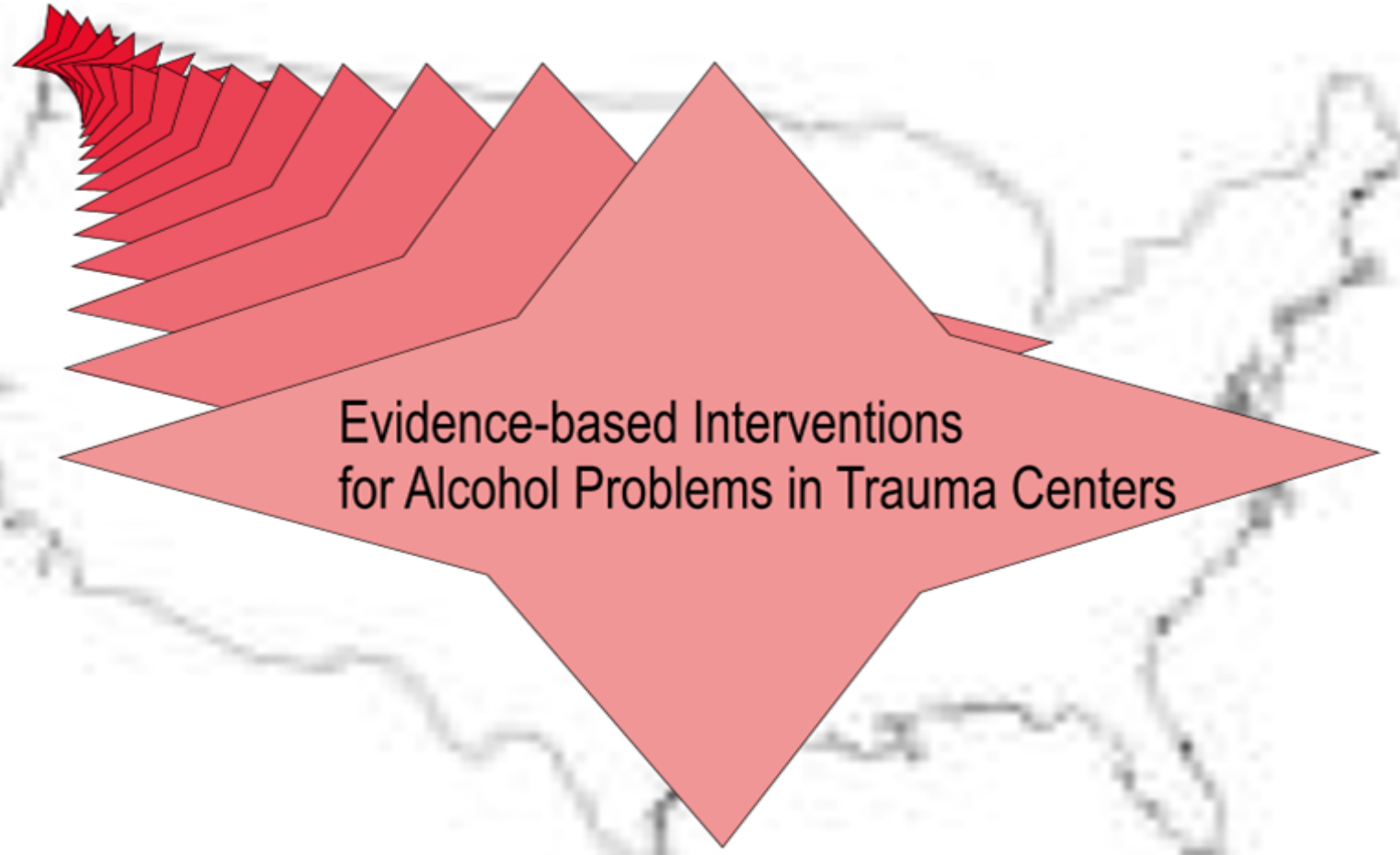
Orchestration of Pragmatic Trials & ACS Policy: PTSD





PTSD

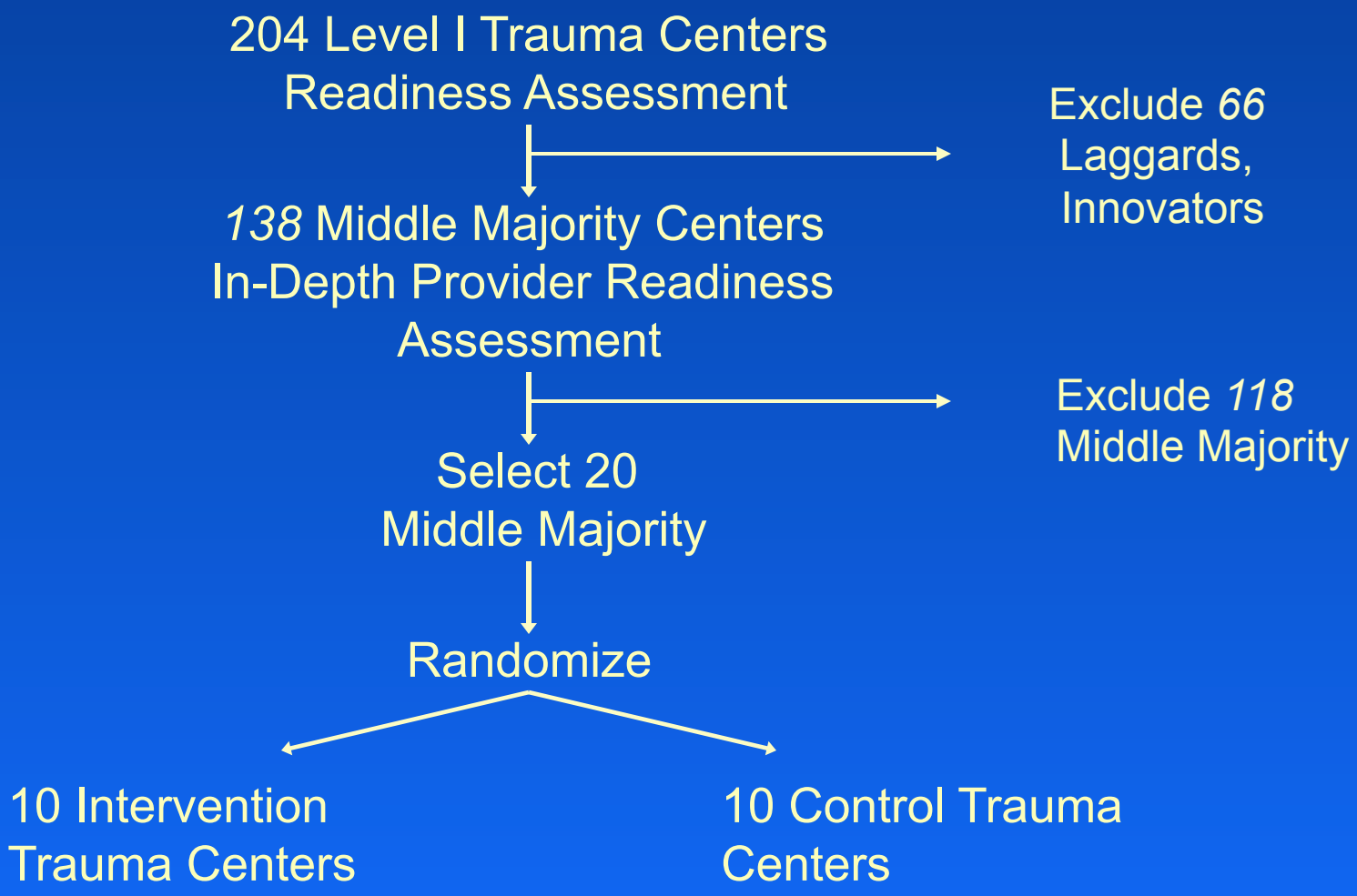
PTSD screening & intervention best practice guideline recommendation

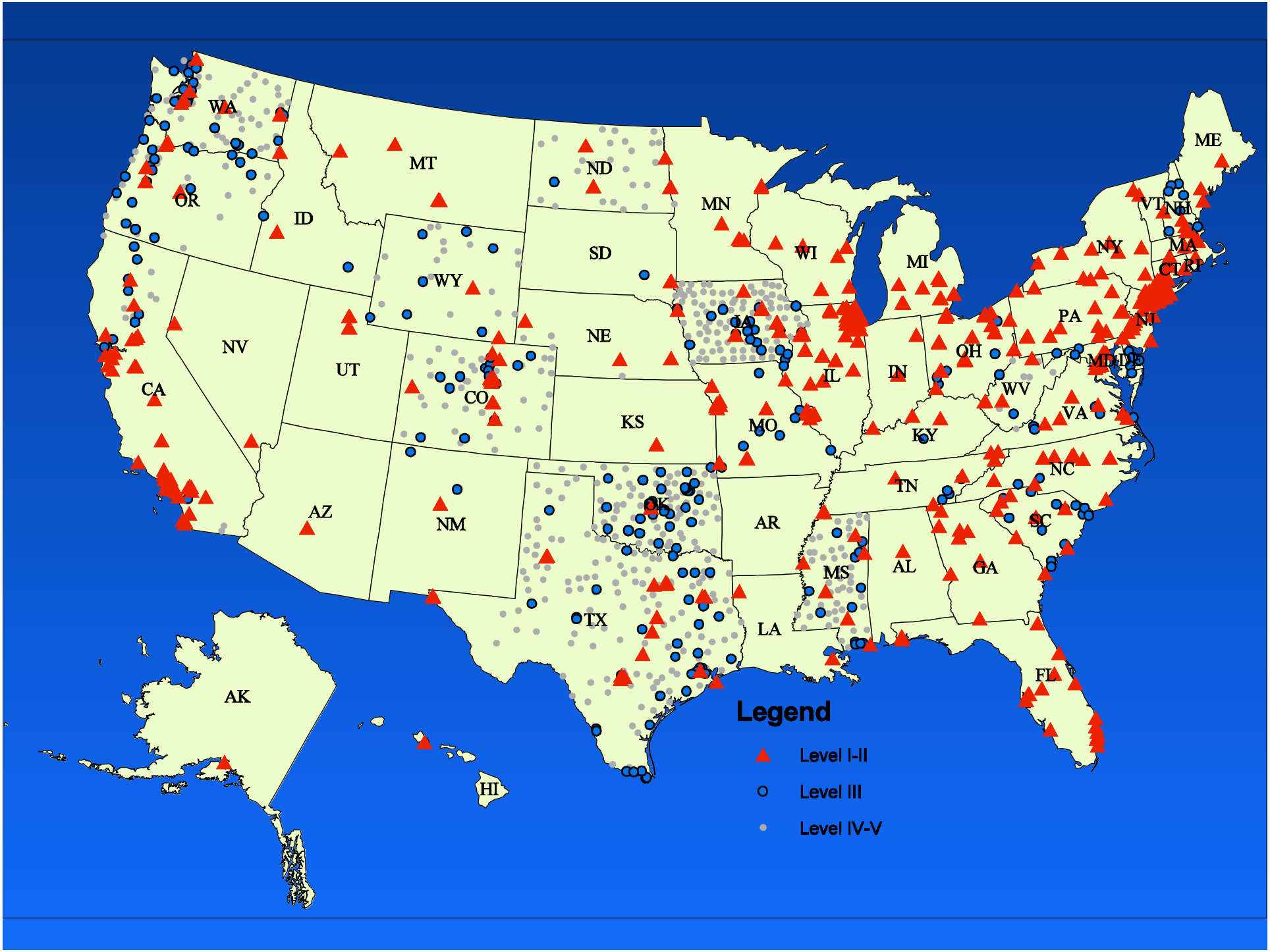

Evidence-based Interventions
for Alcohol Problems in Trauma Centers

DO-SBIS RCT

- 20 Middle Majority sites randomized
- 10 sites receive organizational intervention and SBI training
- 10 Control sites
- 878 patients
- 76% 6 month follow-up
- 72% 12 month follow-up

DO-SBIS Multisite RCT

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HI
Legend
Level I-II
Level III
Level IV-V

Implementation Science Methods: Organizational Adopter Status & Individual Readiness

Category	Color	Surgeon Champion	Other Champion (eg RN)	NIH Funded Alcohol Research	FTE Allocation	Prior Training	Blood Alcohol Drawn	Responses to ACS Survey	ACS Survey Response
Innovator		Yes	Yes	Yes	Yes	Yes	Yes	Mean of 4 items <7	Yes
Early Majority		Yes/No	Yes/No	No	Yes/No	Yes/No	Yes	Mean of 4 items >7	Yes
Middle Majority		Yes/No	Yes/No	No	Yes/No	No	Yes	Mean of 4 items >7	Yes
Late Majority		Yes/No	Yes/No	No	Yes/No	No	Yes	No mean specified	Yes
Laggard		No	No	No	No	No	No	Mean of 4 items <7	No

Zatzick C. & Zatzick D. Health Care Management Review 2012