



The Trauma Survivors Outcomes & Support: UH2-UH3 Lessons Learned

Douglas Zatzick, MD

Professor Department of Psychiatry & Behavioral Sciences
University of Washington School of Medicine

Funded by Grant UH3 MH106338-02

Trauma Survivors Outcomes & Support (TSOS)



Trauma Surgery Policy Core

Gregory Jurkovich

Erik Van Eaton

Ron Maier

David Hoyt

Trauma Survivors Outcomes & Support (TSOS)



Biostatistics Core

Patrick Heagerty

Joan Russo

Jin Wang

Bryan Comstock

Trauma Survivors Outcomes & Support (TSOS)



Other Collaborators

Doyanne Darnell (Behavioral Interventions)

Larry Palinkas (Implementation Science)

Lauren Whiteside (Emergency Medicine)

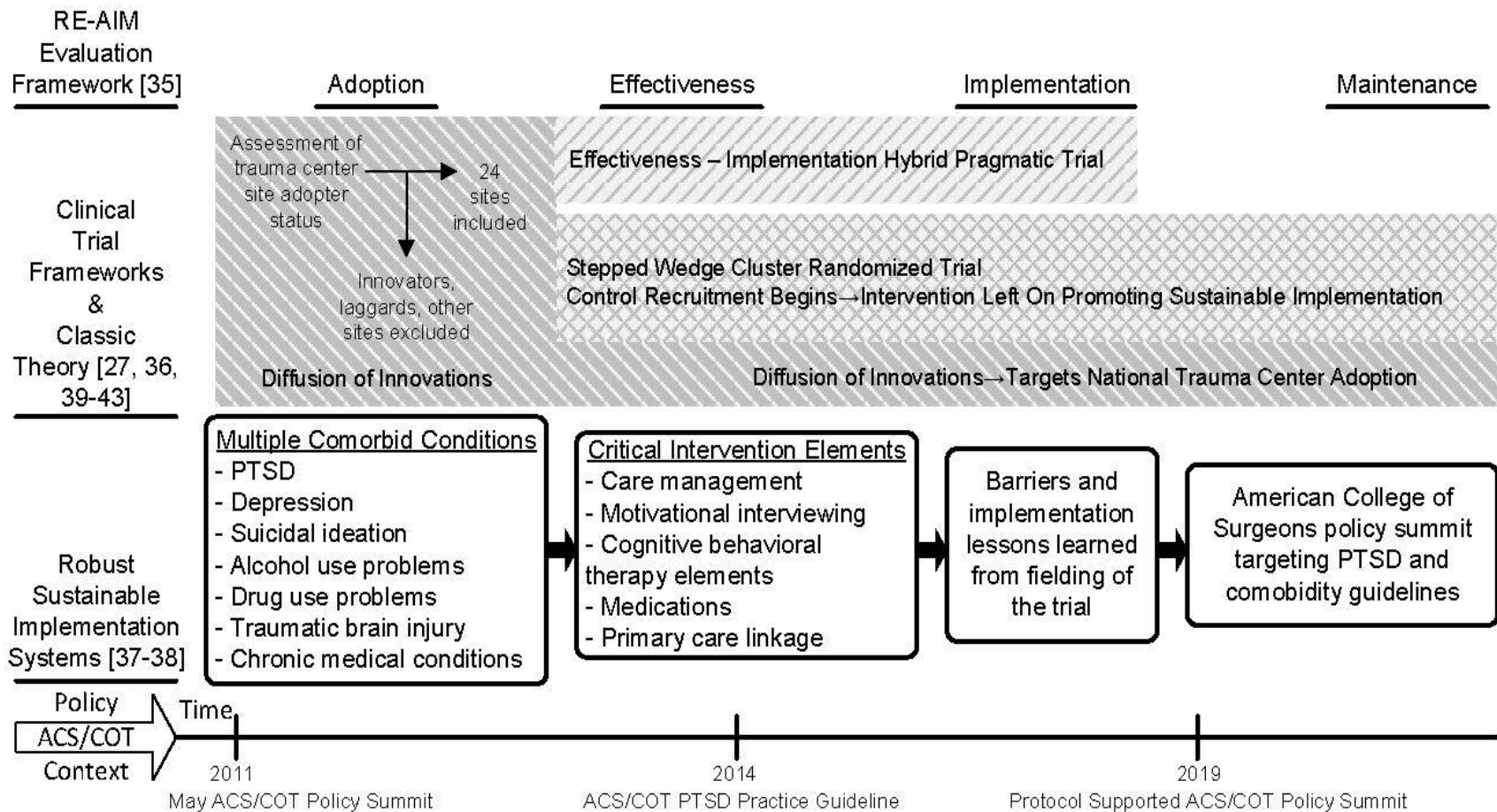
TSOS Barriers Scorecard

Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and Health Systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)				X	
Stability of control intervention	X				
Implementing/Delivering Intervention Across Healthcare Organizations			Anticipated		

TSOS UH3 Update

- Recruitment update and lessons learned
- Major challenge: Site variability/regulatory delays and stepped wedge design
- Anticipating site intervention implementation variability

Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework

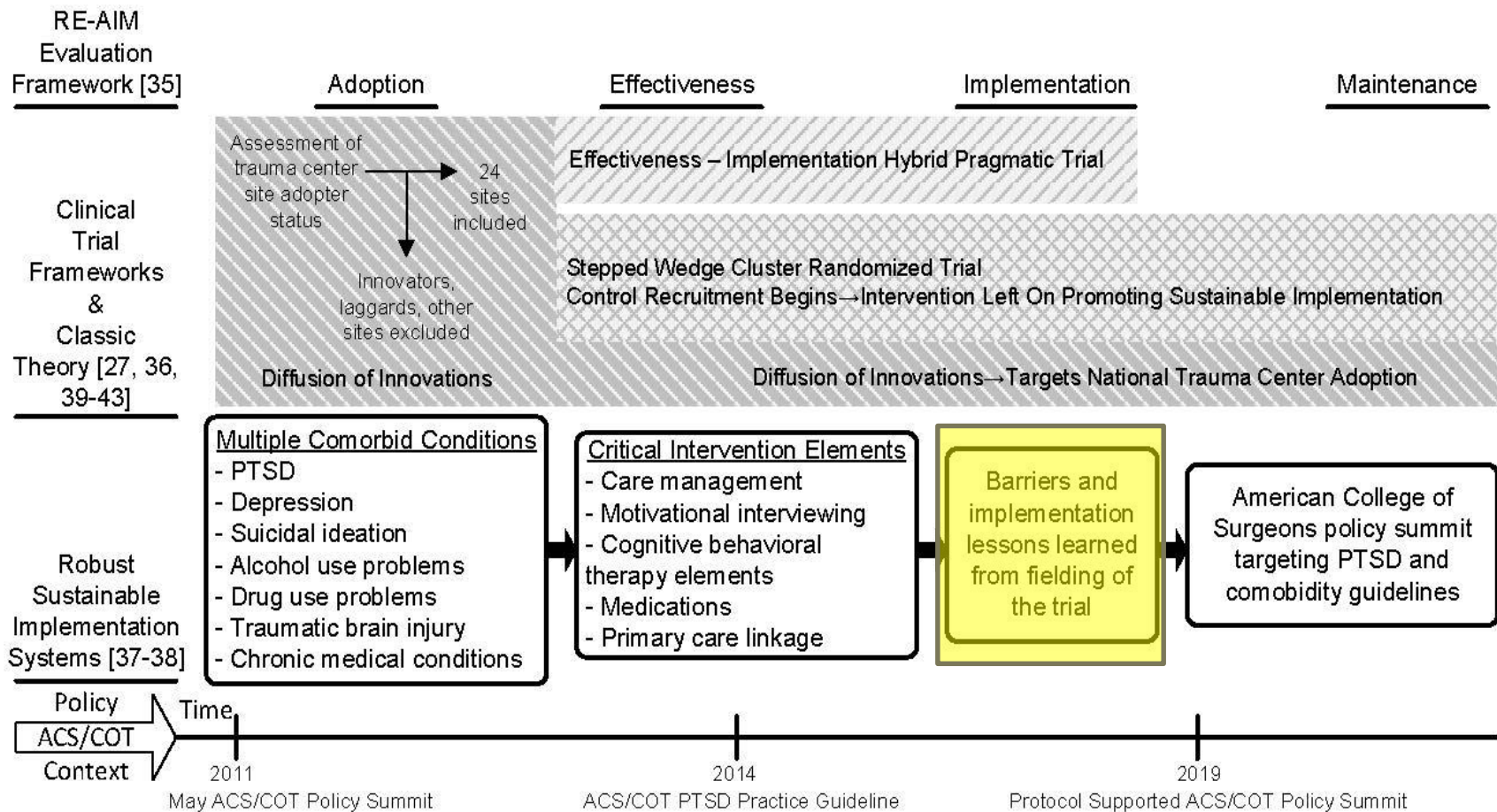


Zatzick Russo Darnell Chambers Palinkas Van Eaton Wang Ingraham Guiney Heagerty Comstock Whiteside & Jurkovich: *Implementation Science* 2016

NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework

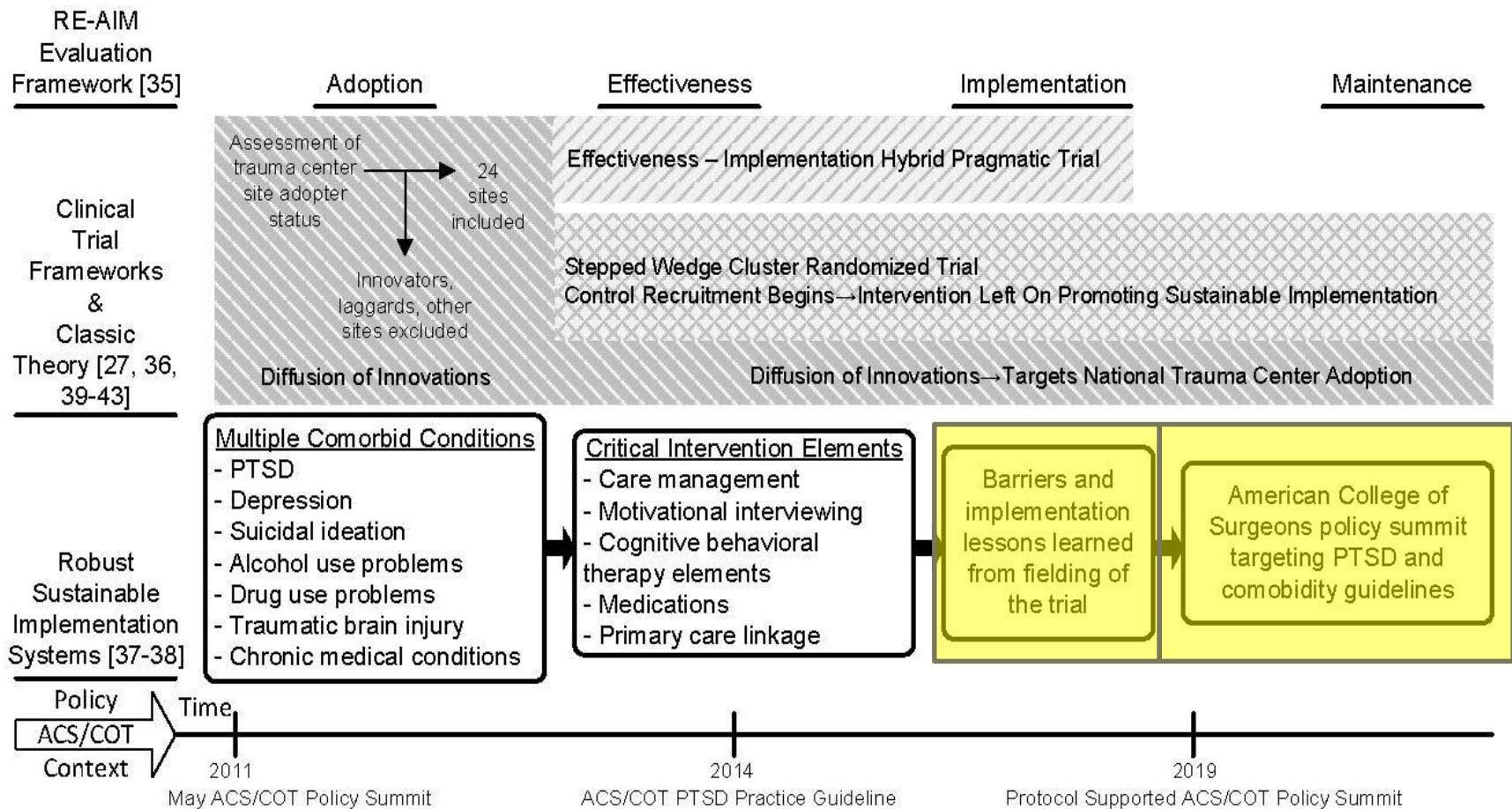


Zatzick Russo Darnell Chambers Palinkas Van Eaton Wang Ingraham Guiney Heagerty Comstock Whiteside & Jurkovich: *Implementation Science* 2016

NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework



Zatzick Russo Darnell Chambers Palinkas Van Eaton Wang Ingraham Guiney Heagerty Comstock Whiteside & Jurkovich: *Implementation Science* 2016

Recruitment Update & Lessons Learned

- 20 sites \geq 1 patient recruited
- 2 additional sites with automated recruitment workbook data transfer
- 2 sites regulatory delays: IRB re-review

TSOS EHR PTSD Screen Domains

- Female gender
- Non-White race/ethnicity
- Low income (insurance status as proxy)
- Intentional injury (e.g., assault, gunshot)
- ICU admit
- History of PTSD diagnosis
- History of other mental health diagnosis
- History of alcohol/drug use problems, positive BAC
- Tobacco use
- Prior inpatient admissions

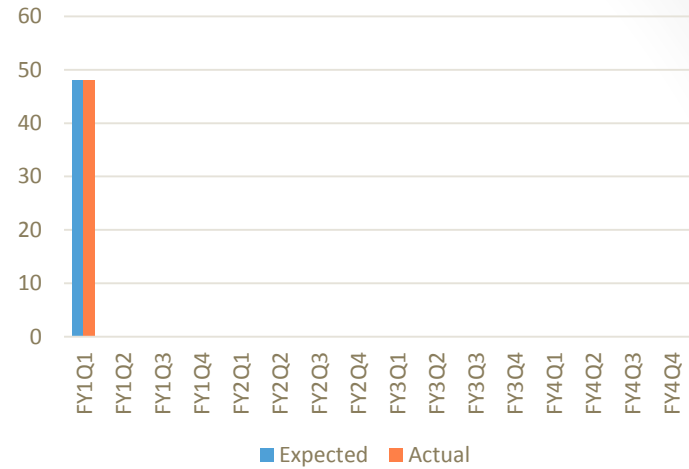
Study: UH3 Project: Trauma Survivors Outcomes and Support

Principal Investigator: Douglas Zatzick, MD

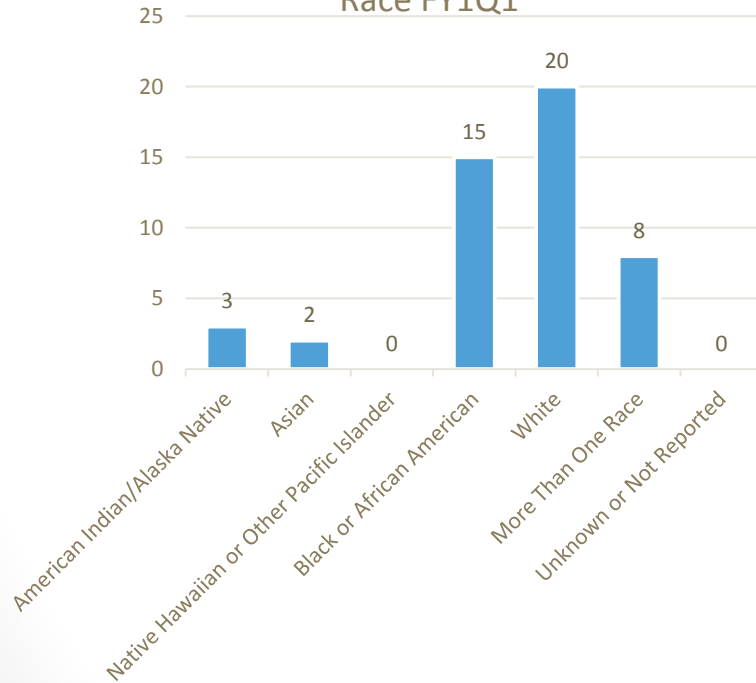
NIH Grant Number: UH3 MH106338-02

UH3 Award Date: August 2015

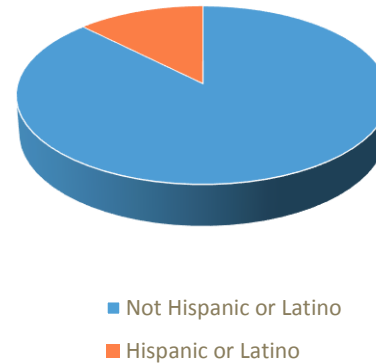
Total Active Subjects to Date



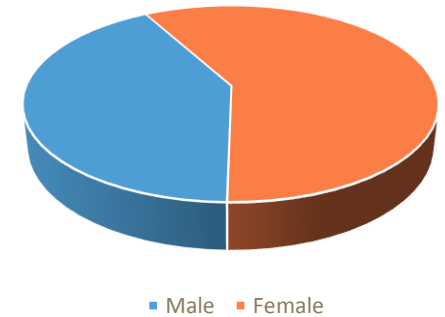
Race FY1Q1



Ethnicity FY1Q1



Gender FY1Q1



TSOS Minority & Gender Recruitment (N = 48)

	<u>Anticipated %</u>	<u>Actual %</u>
Minority	21%	58%
Female	24%	58%

Major Challenge: Regulatory & Other Delays Contribute to Site Recruitment Variability

- Some sites rapid: Complete control recruitment all in one period
- Some sites delayed may not complete control recruitment before intervention switched on
- Scientific tension between stepped wedge design integrity & site implementation flexibility
- Initial solution
 - 4 minimum patients per period
 - 12 maximum patients per period

Additional Modifications to Address Site Start-up Variability

- 25th site randomized from wait-list
- First period extended by 2 months
- High performance site(s) asked to recruit more control patients

TSOS Barriers Scorecard

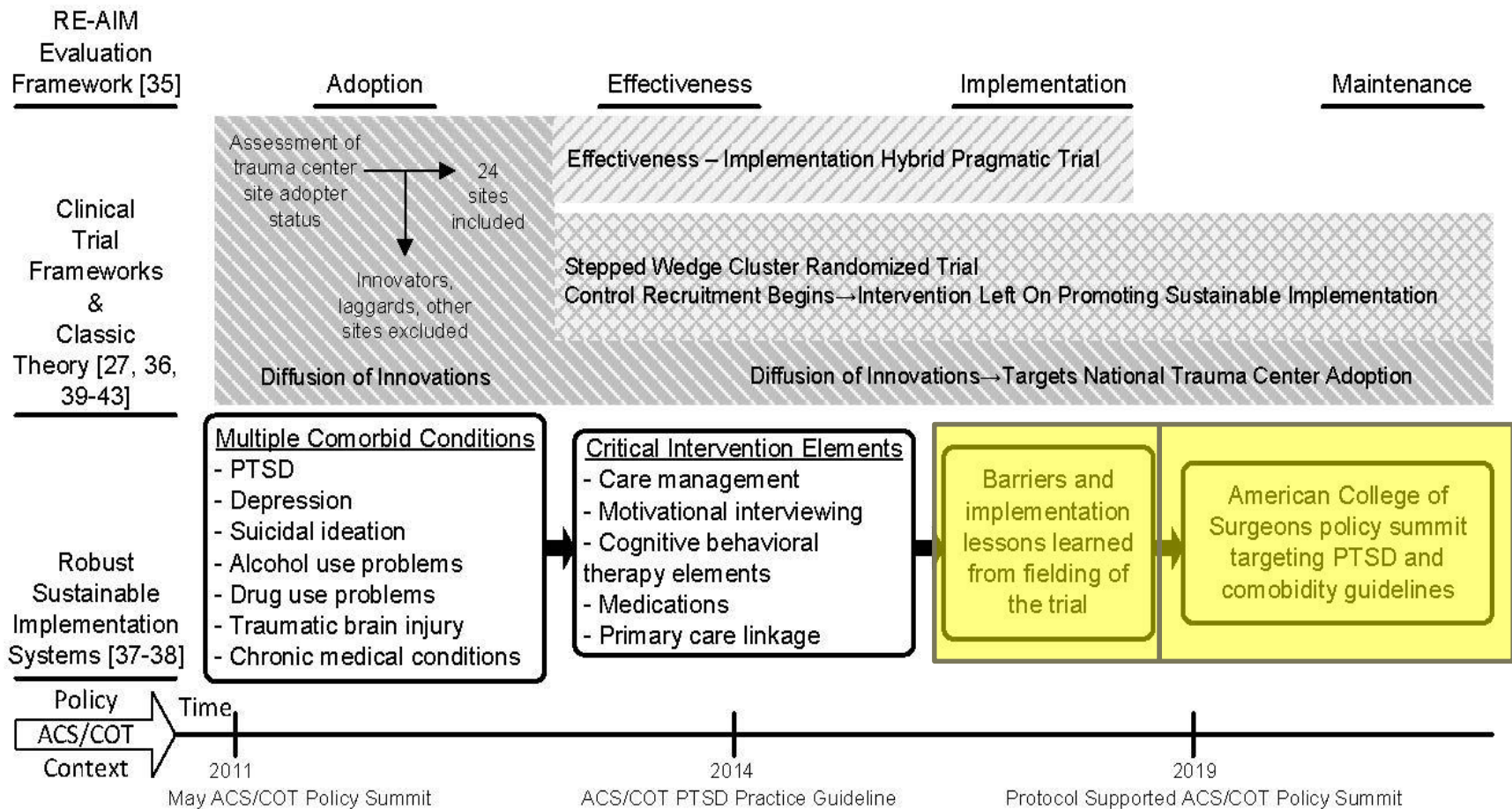
Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and Health Systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)				X	
Stability of control intervention	X				
Implementing/Delivering Intervention Across Healthcare Organizations			Anticipated		



Emerging Scientific Issue for Effectiveness-Implementation Hybrid Pragmatic Trial Design

- Anticipating site variability in intervention implementation and related sustainable maintenance of screening and intervention procedures

Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework



Zatzick Russo Darnell Chambers Palinkas Van Eaton Wang Ingraham Guiney Heagerty Comstock Whiteside & Jurkovich: *Implementation Science* 2016