

# The Trauma Survivors Outcomes & Support (TSOS) Pragmatic Trial Targeting PTSD and Comorbidity: Design and Early Implementation

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Funded by Grant UH3 MH106338-02

# Trauma Survivors Outcomes & Support (TSOS)



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# Trauma Survivors Outcomes & Support (TSOS)



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# Overview

## A. TSOS Effectiveness-Implementation Hybrid Pragmatic Design

- 1) PRECIS scoring – high and low marks
- 2) Building towards pragmatic trial generalizable knowledge

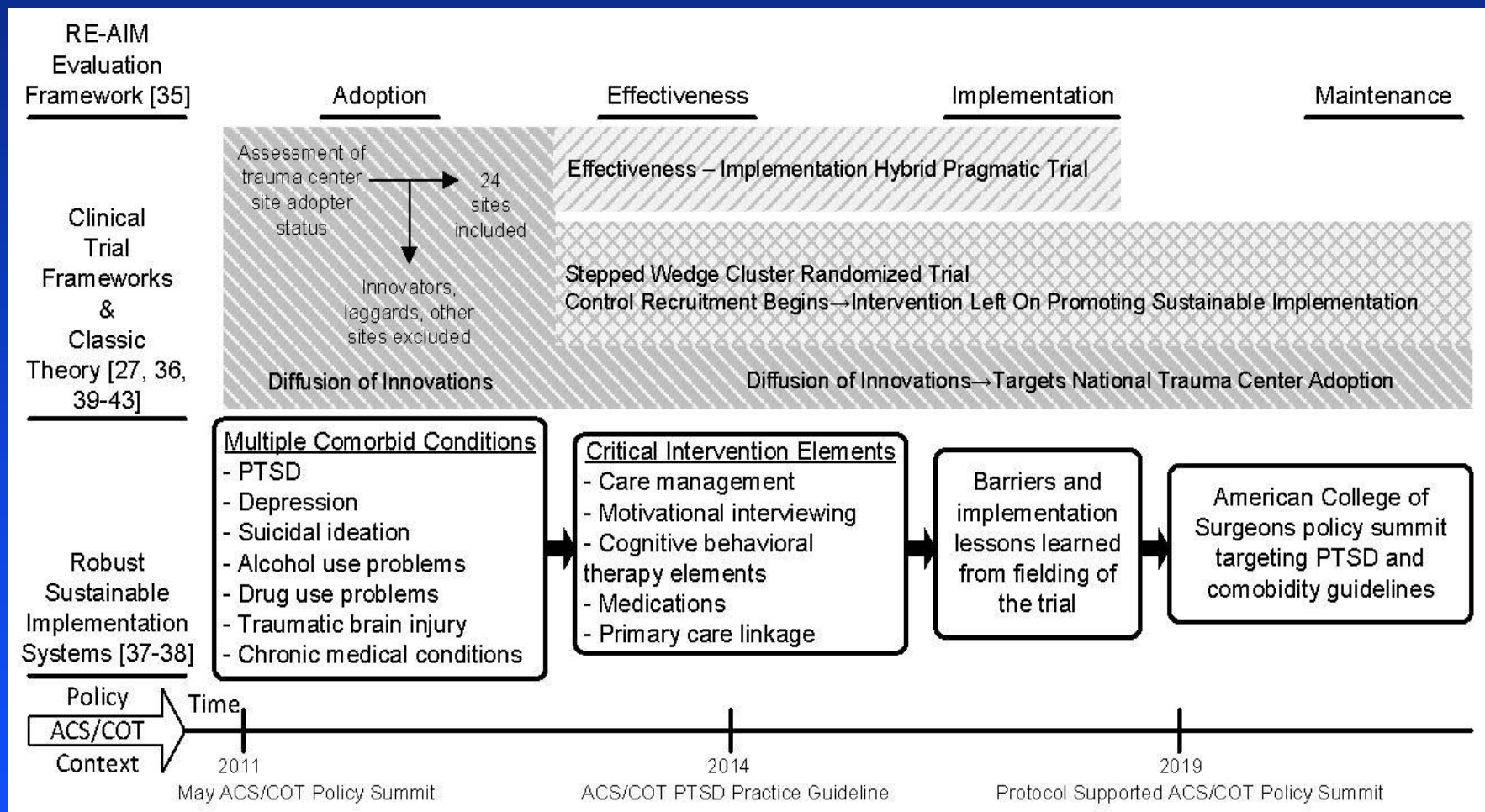
## B. TSOS Early Implementation

- 1) Aims
- 2) Recruitment & Follow-up
- 3) Milestones & Challenges

## C. Lessons Learned

- 1) Developing pragmatic behavioral interventions that target multiple comorbid conditions
- 2) Acute care pragmatic trials may include more intensive follow-up evaluations beyond routine visits
- 3) TSOS effectiveness-Implementation hybrid design informs data sharing that simultaneously targets treatment effectiveness & national trauma center practice change considerations

# Overview: TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework



# Overview: PRECIS Pragmatic Trial Domains & the TSOS Study - High Marks

- Broad site, provider and patient eligibility criteria, multiple comorbidities
- Intervention flexibly delivered
- Full range of providers included
- Comparison intervention - usual care
- Primary outcome objectively measured
- Intent to treat primary outcome analysis

# Overview: PRECIS Domains & TSOS Trial - Lower Marks

- Provider behavioral intervention fidelity assessment requires adjudication
- Greater intensity of outcome assessment given no single acute care administrative data base

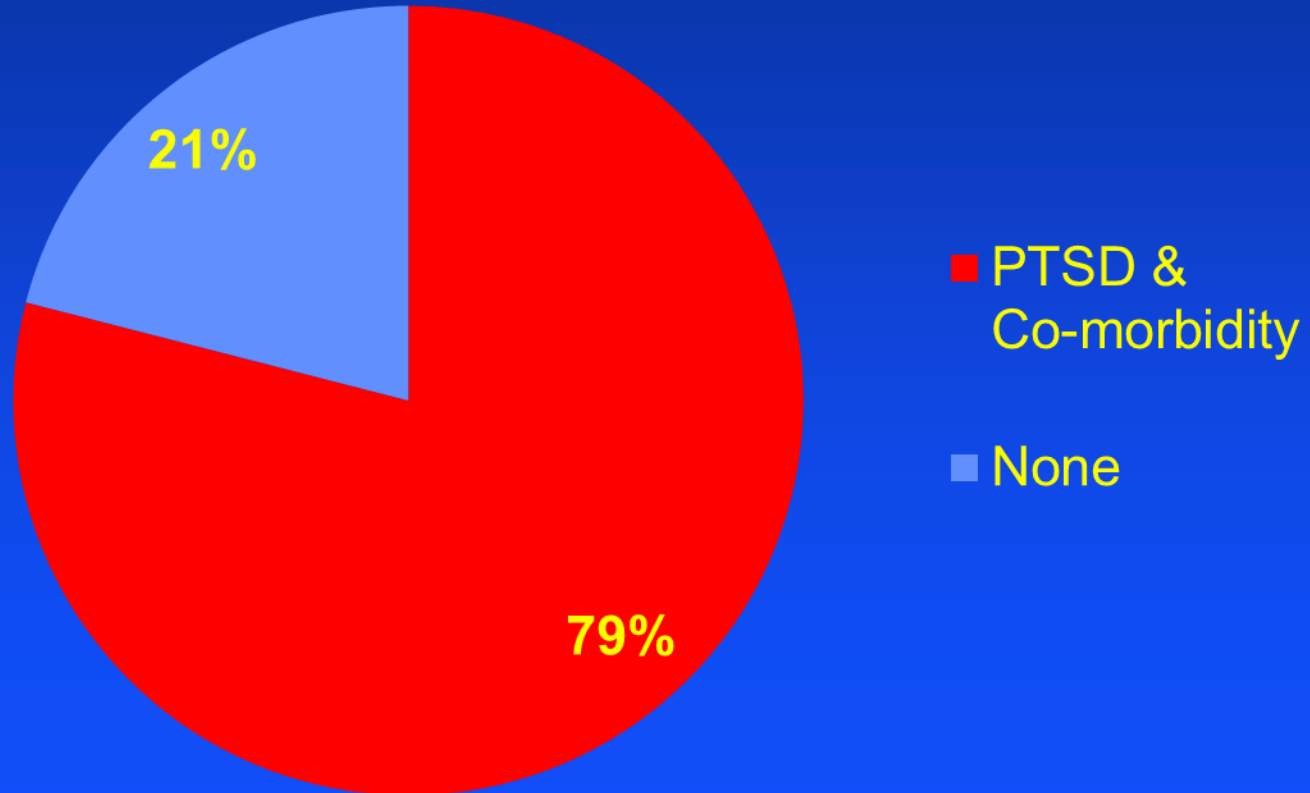


# Overview: Global Approach

- Work inductively from TSOS “lessons learned” to more generalizable knowledge regarding pragmatic trials
- Integration of pragmatic trial and implementation science conceptual frameworks

# TSOS Study Aims & Progress

# PTSD & Other Mental Health/Substance Disorders Among Randomly Selected Harborview Emergency/Trauma Surgery Patients (N=878)



# TSOS UH3 Aims

- 1) Conduct pragmatic trial
- 2) Understand trial implementation
- 3) Dissemination of results through American College of Surgeons policy

# TSOS Hypotheses: Aim 1

- The intervention group when compared to the control group will demonstrate:
  - 1) ↓ PTSD symptoms (primary hypothesis)
  - 2) ↓ Depressive symptoms
  - 3) ↓ Suicidal ideation
  - 4) ↓ Alcohol use problems
  - 5) Improved post-injury physical function
- Exploration of intervention effects in patients with/without chronic medical conditions & TBI

# TSOS Study Design

- Cluster randomized trial
- 24 US trauma centers
- 40 patients per site (960 patients total)
- Baseline PTSD & comorbidity assessment at trauma center
- 3, 6 and 12 month follow-up interview assessments

# TSOS US Level I Trauma Center Sites (N =24)



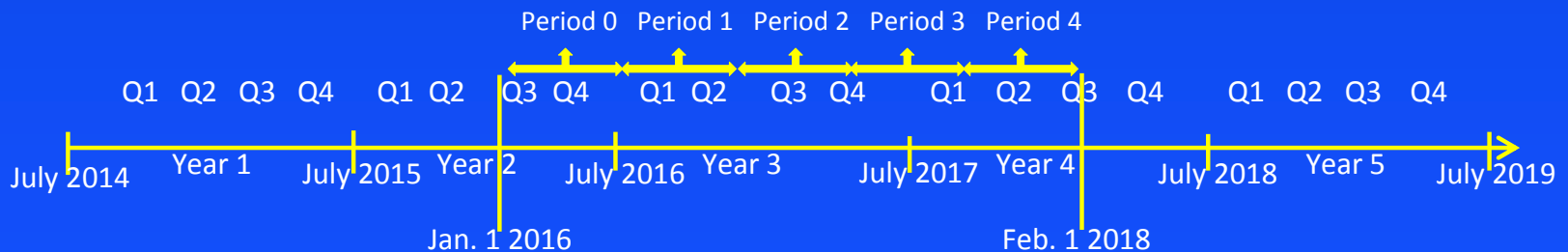
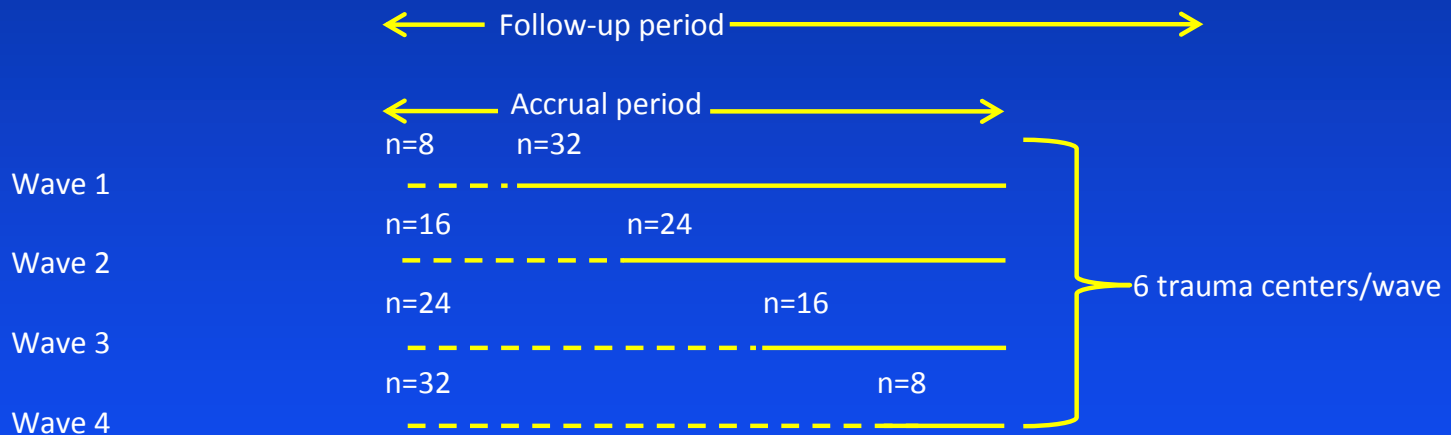
# Stepped Wedge Design

- Sites recruit control & intervention
- 24 sites randomized to 4 waves
- Begin with control recruitment
- Turn on intervention midway



# Stepped Wedge Cluster Randomized Trial Design and Timeline

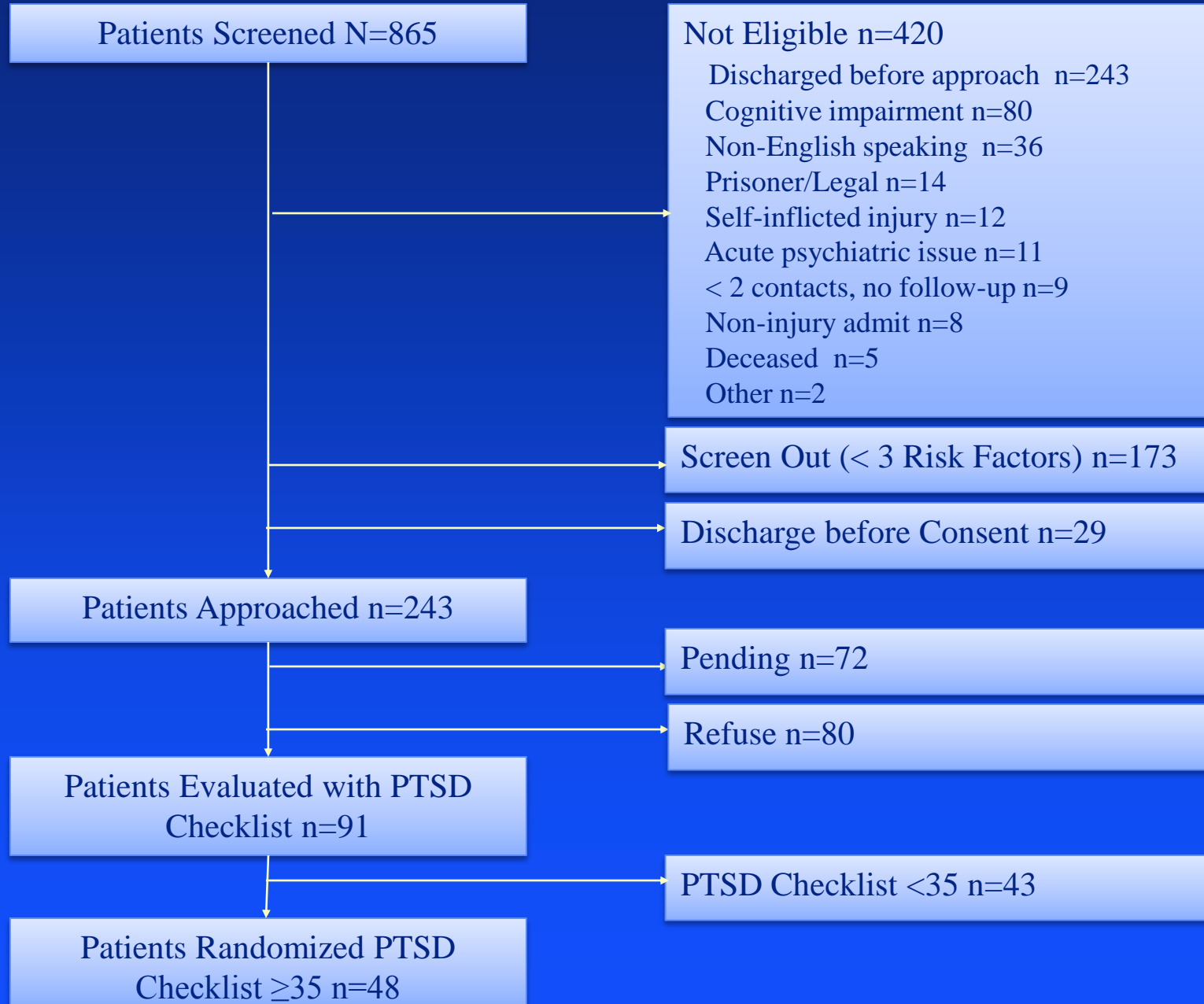
- - - - - Unexposed to intervention (n=480 patients)  
————— Exposed to intervention (n=480 patients)



# Recruitment Update

- 14 sites  $\geq$  1 patient recruited
- 6 additional sites with automated recruitment workbook data transfer
- 4 sites regulatory delays
  - 2 IRB re-review
  - 1 Centralized IRB coordination
  - 1 Indemnity review

# TSOS Study CONSORT (3-30-16)



# TSOS Recruited Patients (3-30-16)

- 91 Consented
- 43 Screen out: PTSD Checklist  $< 35$
- 48 Screen in: PTSD Checklist  $\geq 35$
- 48 Screen in April 1, 2016 Milestone

# Major Challenge: Variability in Site Recruitment Rates

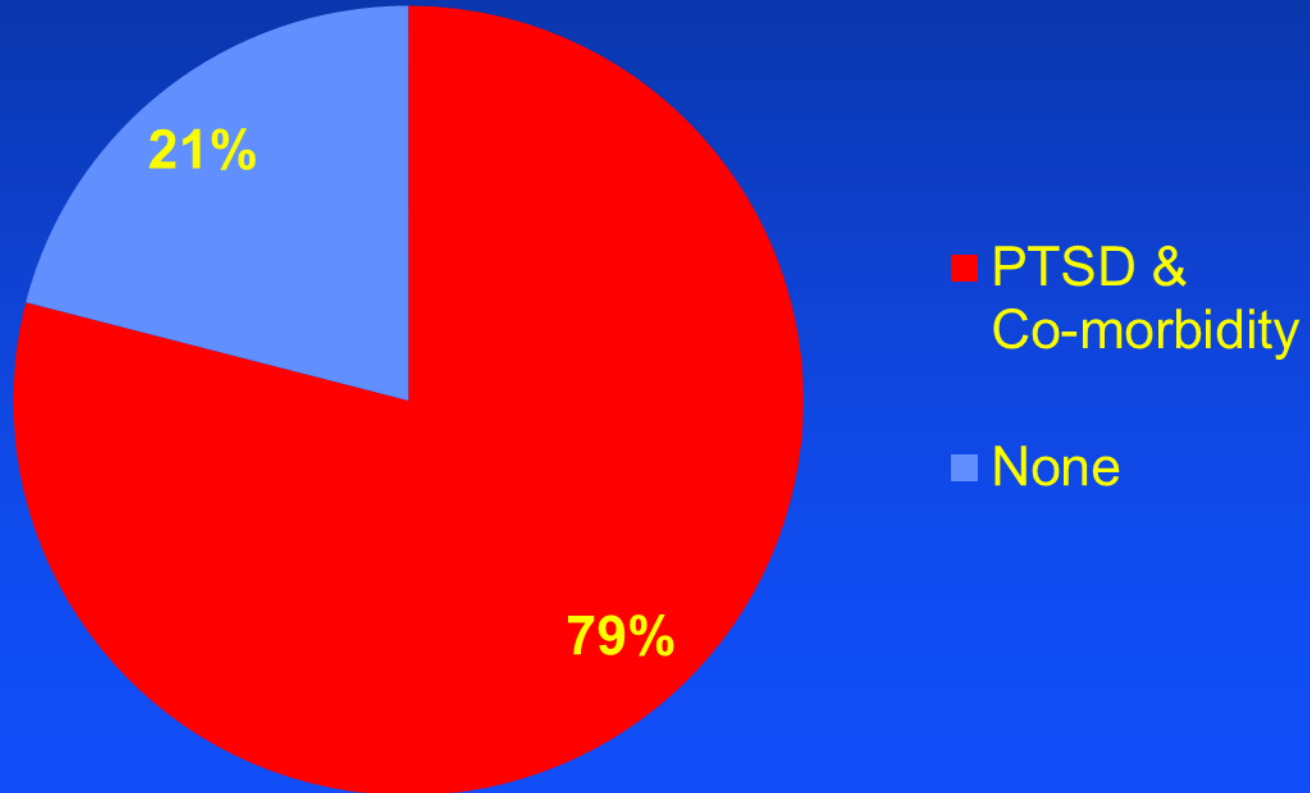
- Some sites rapid: wish to complete control recruitment all in one period
- Some sites slower may not complete recruitment of controls before switching on intervention
- Scientific tension between stepped wedge design integrity & site implementation flexibility
- Initial solution
  - 4 minimum patients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

# UH3 Participant Follow-up (As of 3-30-16)



# TSOS Intervention

# PTSD & Other Mental Health/Substance Disorders Among Randomly Selected Harborview Emergency/Trauma Surgery Patients (N=878)

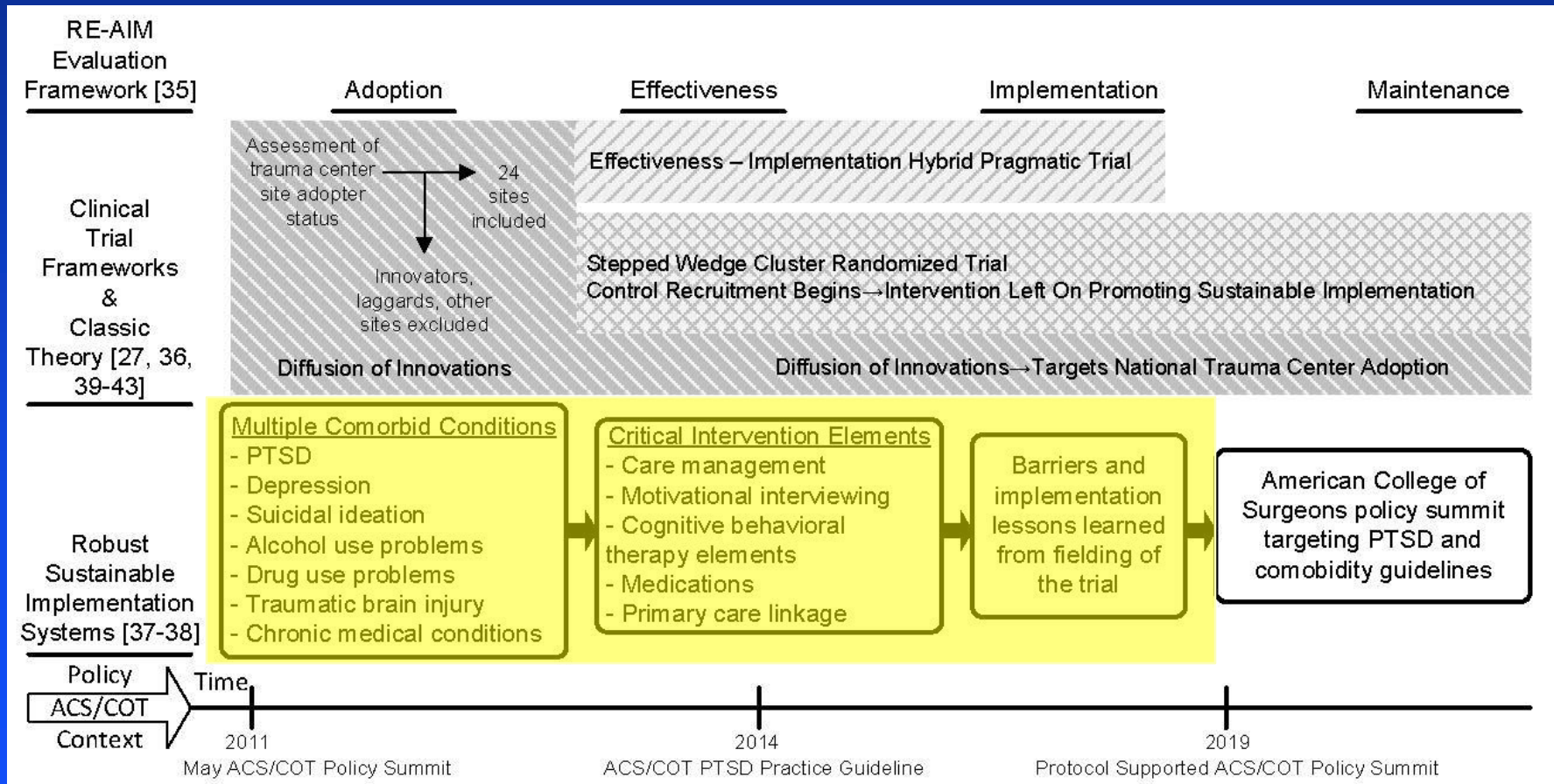




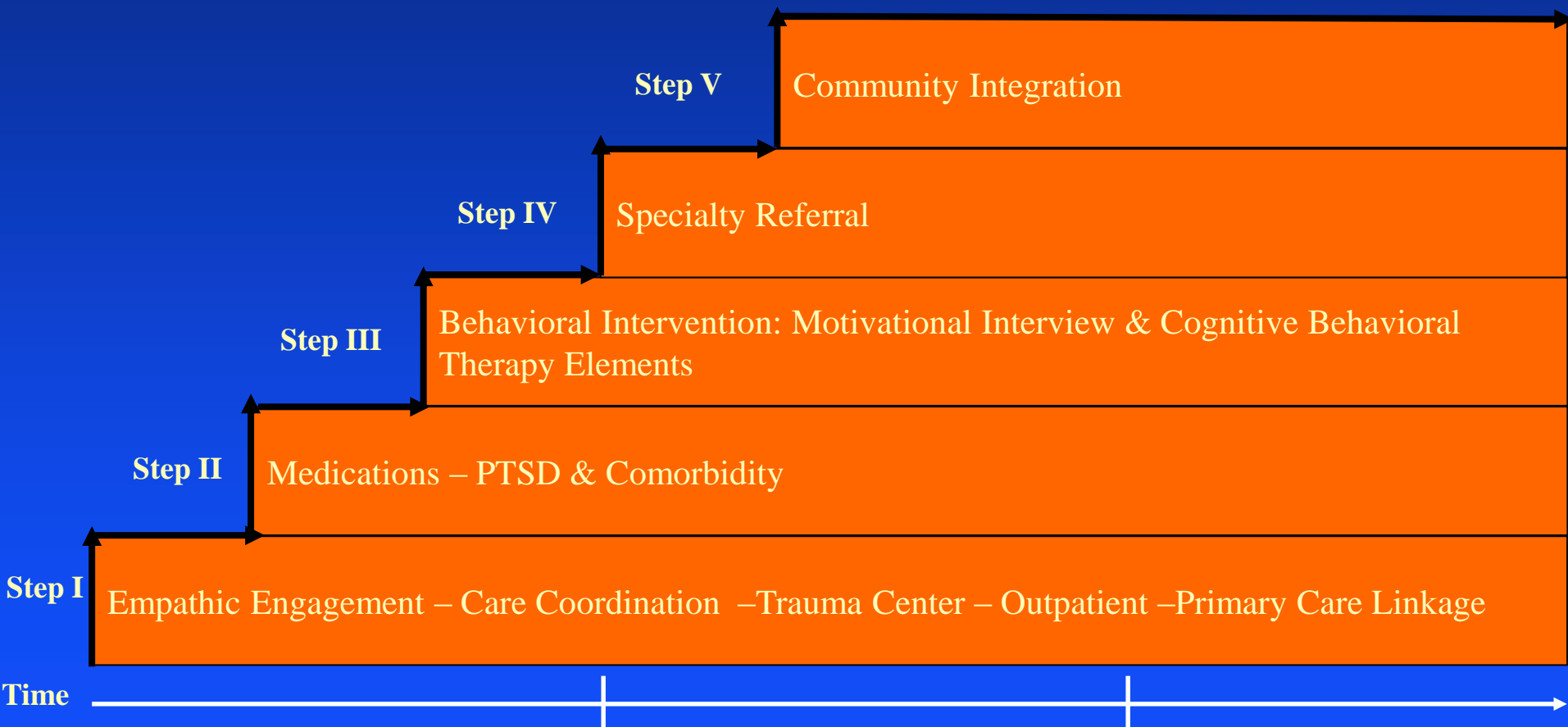
# PTSD & Comorbidity and the Multiple Chronic Condition Framework

- Mental health comorbidity: PTSD, depression and occult suicidal ideation (25-40%)
- Alcohol use problems (25%)
- Other substance use problems: Stimulants, opiates, benzodiazepines, MJ (20%)
- Chronic pain (10-20%)
- Traumatic Brain Injury (40-50%)
- Pre-injury chronic medical conditions (>50%)

# TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework



# Stepped Collaborative Care: Readily Implementable Elements



# Behavioral Interventions: Lessons Learned from Prior NIAAA funded Pragmatic Trial (DO-SBIS)

- Alcohol mandate and ACS/COT trainings
- 20 trauma centers in trial
- 878 alcohol Motivational interviewing (MI) targeting alcohol
- Front-line trauma providers trained in alcohol brief int.
- Variability in skills assessed with standardized patients
- Trained providers ↑ MI skills
- Sites with trained providers had greater effectiveness in reducing alcohol use

# Behavioral Interventions: UH2 Pilot & UH3 Implementation

- Extension of behavioral intervention to PTSD & comorbidity
- Motivational interviewing targets alcohol
- Behavioral activation targets PTSD and depression
- Front-line trauma center providers trained
- Fidelity again assessed with standardized patients

# Lessons Learned: Behavioral Interventions

- PRECIS criteria: more than minimal adjudication to assess provider fidelity
- Implementation science: ACS/COT stakeholder partnership could support feasibly implemented fidelity evaluation

# Lessons Learned Acute Care Pragmatic Trial Follow-up Beyond Routine Visits - TSOS

- TSOS trial 24 centers, 19 states
- No single administrative data base tracks patients over time
- 3, 6, 12 month follow-up interviews required
- Interviews are not part of trauma center routine follow-up

# Acute Care Pragmatic Trial Follow-up Beyond Routine Visits: Comprehensive Post-Acute Stroke Services Study (COMPASS)

- PCORI pragmatic trial
- Pamela Duncan, PhD PI
- Stroke survivors in acute care hospitals across North Carolina
- Primary outcome: PROs
  - Stroke impact scale PRO post-discharge
  - Caregiver strain also assessed
  - Readmissions and mortality also tracked

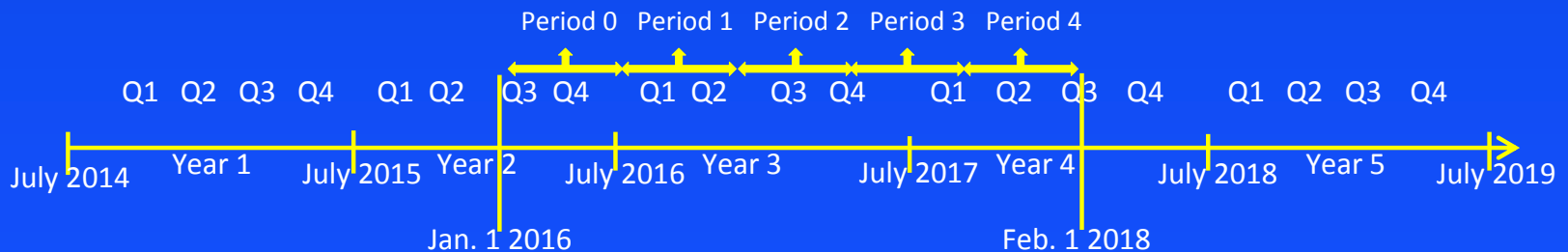
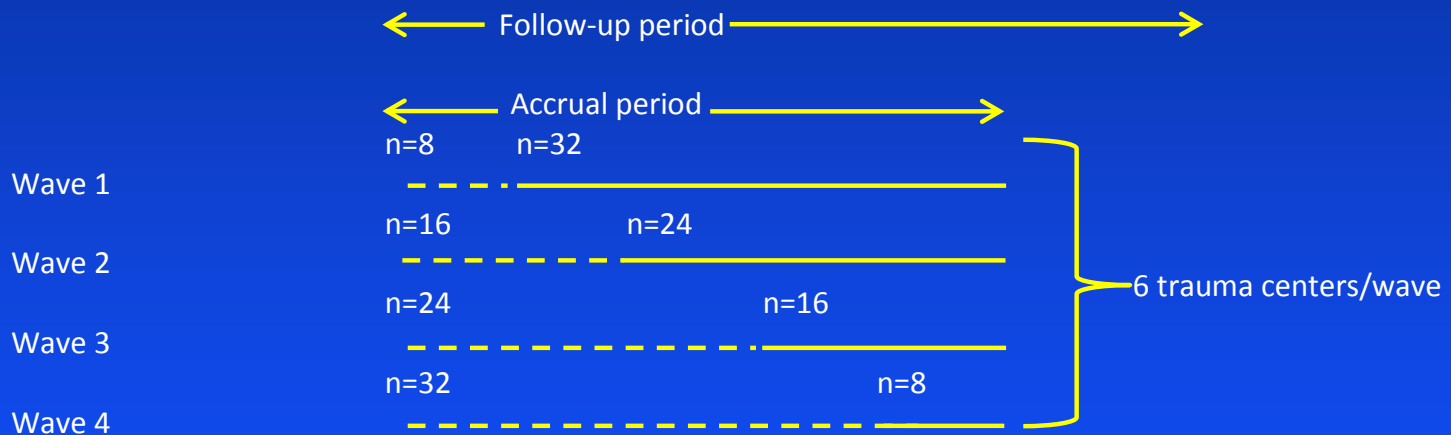


# Lessons Learned: Implementation Science, Stepped Wedge Designs, & Data Sharing

- Stated aim of TSOS is to generate knowledge for American College of Surgeons policy
- All 24 sites will have intervention “turned on” at the end of the trial
- Decision to leave intervention turned on temporally occurs months before composite 24 site results published

# Stepped Wedge Cluster Randomized Trial Design and Timeline

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- Decision to leave intervention turned on temporally occurs months before composite 24 site results published
- Sites integral part of study team academic products and will participate in publications

# Summary

- TSOS is being rolled out nationally
- Milestones achieved
- Challenges exist
- Multiple lessons learned that can facilitate knowledge generation at the interface of pragmatic trials and implementation science