

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Introducing the ePCT Case Studies

Gloria Coronado, PhD, Kaiser Permanente Center for Health Research Doug Zatzick, MD, University of Washington School of Medicine

Collaboratory ePCT Training Workshop

Featuring 2 of the 9 NIH Collaboratory Demonstration Projects

STOP CRC:

- Strategies and Opportunities to Stop Colorectal Cancer in Priority Populations
- Gloria Coronado, Co-Principal Investigator

TSOS:

- A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support)
- Doug Zatzick, Principal Investigator

STOP CRC overview

Question: Does an evidence-based, culturally tailored approach increase colorectal cancer (CRC) screening in clinics that serve minority and low-income populations?

Setting: 26 federally qualified health center clinics

Population: 40,000 adults aged 50-74 with no evidence of recent CRC screening

Intervention: Cluster-randomized, EHR-linked, data-driven program tracks eligibility, mails fecal immunochemical test kits, tracks patient test results & follow-up

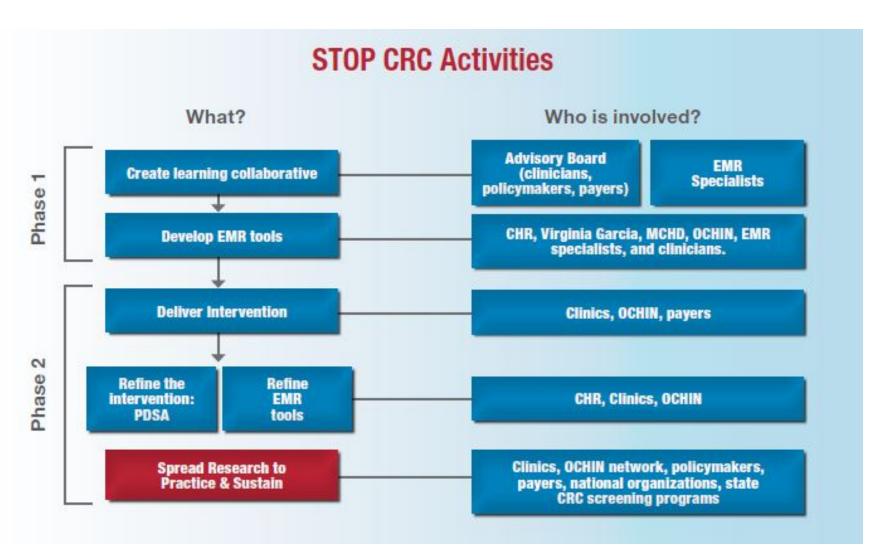
Outcome measures: CRC screening rates by age, sex, insurance status, ethnicity, race

Relevance: Results will provide valuable information on how to use EHR resources to optimize guideline-based screening

STOP CRC ePCT characteristics

- Goal: Increase rate of CRC screening in underserved patients
- Pragmatic design:
 - Broad patient eligibility
 - Comparative effectiveness intervention
 - Cluster randomization
- Embedded across 26 federally qualified health centers
- Data driven:
 - Uses EHR to identify eligible patients & generate test kit mailings
 - Uses EHR to track CRC-related outcomes using routine processes of care
- Leverages existing clinic staff

Study snapshot



TSOS overview

Question: Is a collaborative care intervention more effective than usual care in reducing PTSD and related symptoms and improving physical function?

Setting: 25 level I trauma centers across United States

Population: 960 adult patients with PTSD and related conditions

Intervention: Intervention training & support targets trauma center-based screening and treatment for PTSD and related conditions as well as care coordination from trauma center to primary care & community settings

Outcome measures: Change in scores on civilian PTSD checklist, patient health questionnaire depression scale, alcohol use disorders scale & short form physical function scale

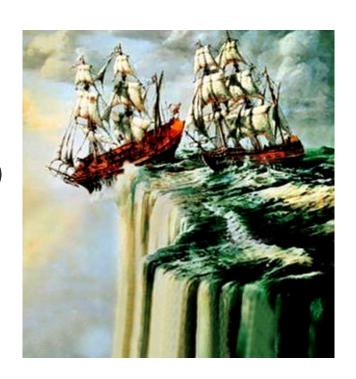
Relevance: Results will be incorporated in the American College of Surgeons' regulatory policy for trauma care

TSOS: multiple potentially chronic conditions & the need for trauma center-to-community linkage

Traumatic injury:

- PTSD, depression, suicidal ideation
- High-risk behaviors (eg, alcohol)
- traumatic brain injury, all common

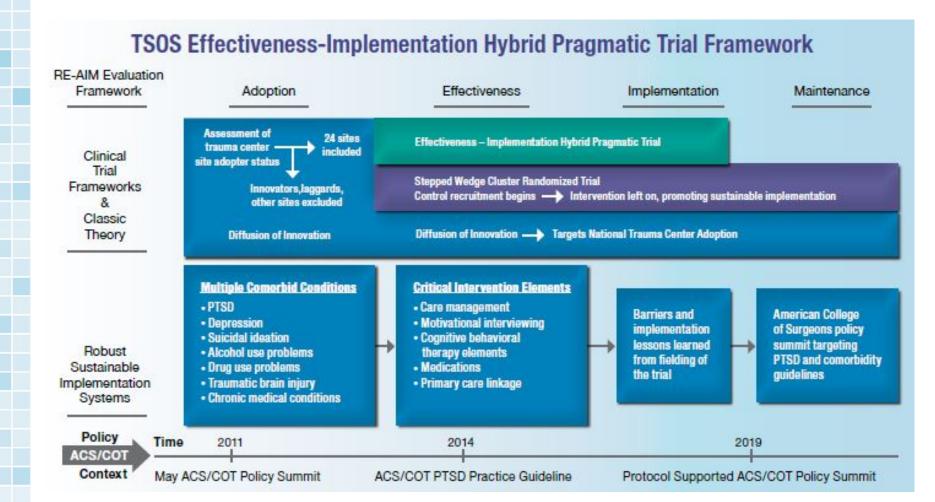
Patients "sail off of a flat earth" after trauma center care



TSOS ePCT characteristics

- Goal: Directly inform national trauma care system policy
- Pragmatic design:
 - Comparative effectiveness intervention
 - Stepped-wedge cluster randomization
 - Hybrid effectiveness-implementation framework, emphasizing sustainability
- Embedded in 25 U.S. level I trauma center sites
- Data driven: Uses EHR to conduct high-quality screening of patients

TSOS study snapshot



American College of Surgeons Regulatory Policy Targeting PTSD & Comorbidity

