NIH Collaboratory

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Topic 8: Dissemination

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Collaboratory ePCT Training Workshop

Dissemination research defined

The scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

Source: NIH Dissemination and Implementation Research in Health PAR-16-238

Implementation research reviewed

The scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health

Source: NIH Dissemination and Implementation Research in Health PAR-16-238

Putting it together: NIH Collaboratory dissemination case examples

- REDUCE MRSA/ABATE
- STOP CRC
- TSOS

Source: NIH Collaboratory Workshop Demonstration Projects May 24, 2017

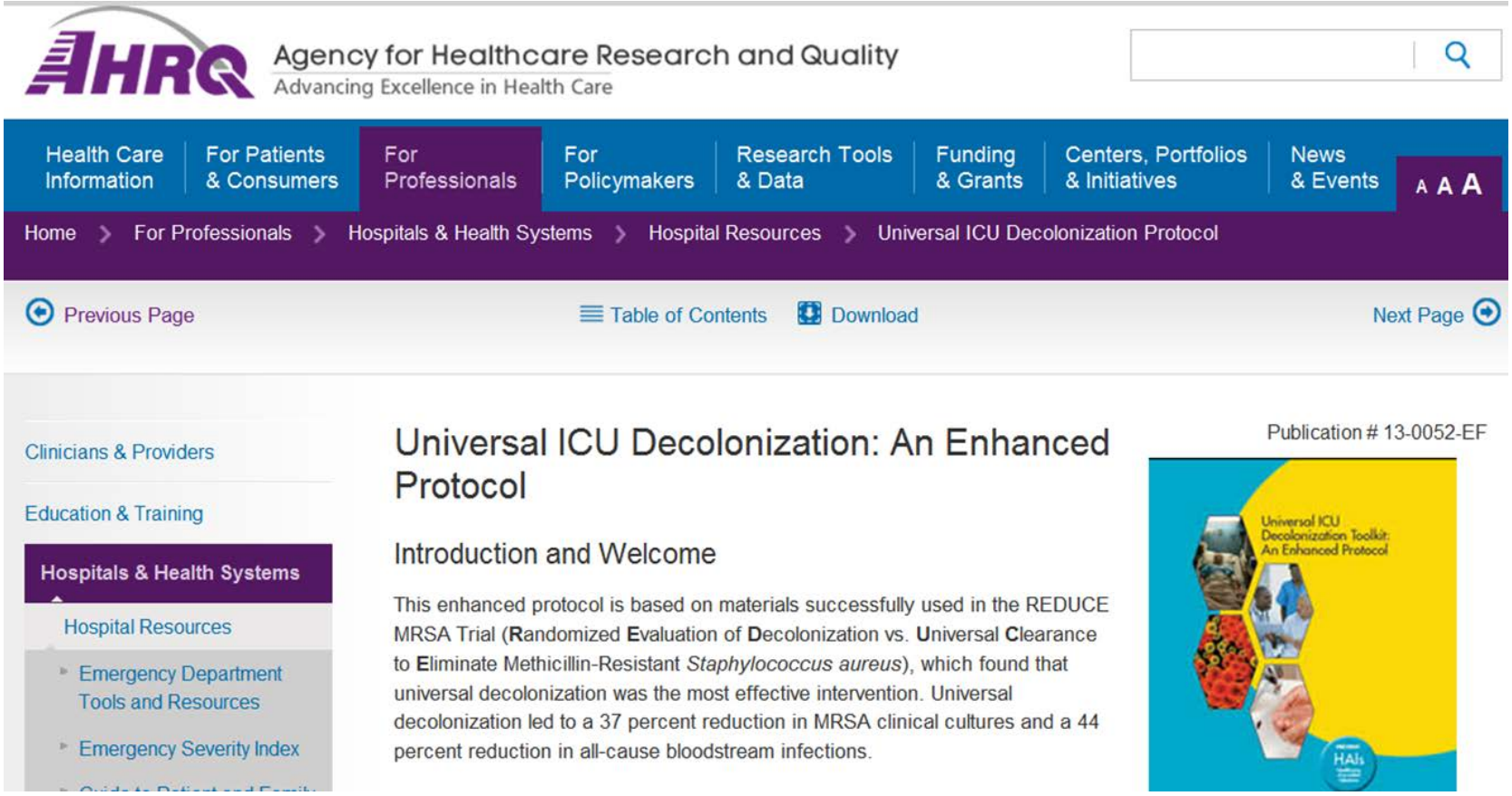
REDUCE MRSA dissemination lessons learned

- REDUCE MRSA trial: decolonization in ICUs
  - 37% reduction in MRSA clinical cultures
  - 44% reduction in bloodstream infections

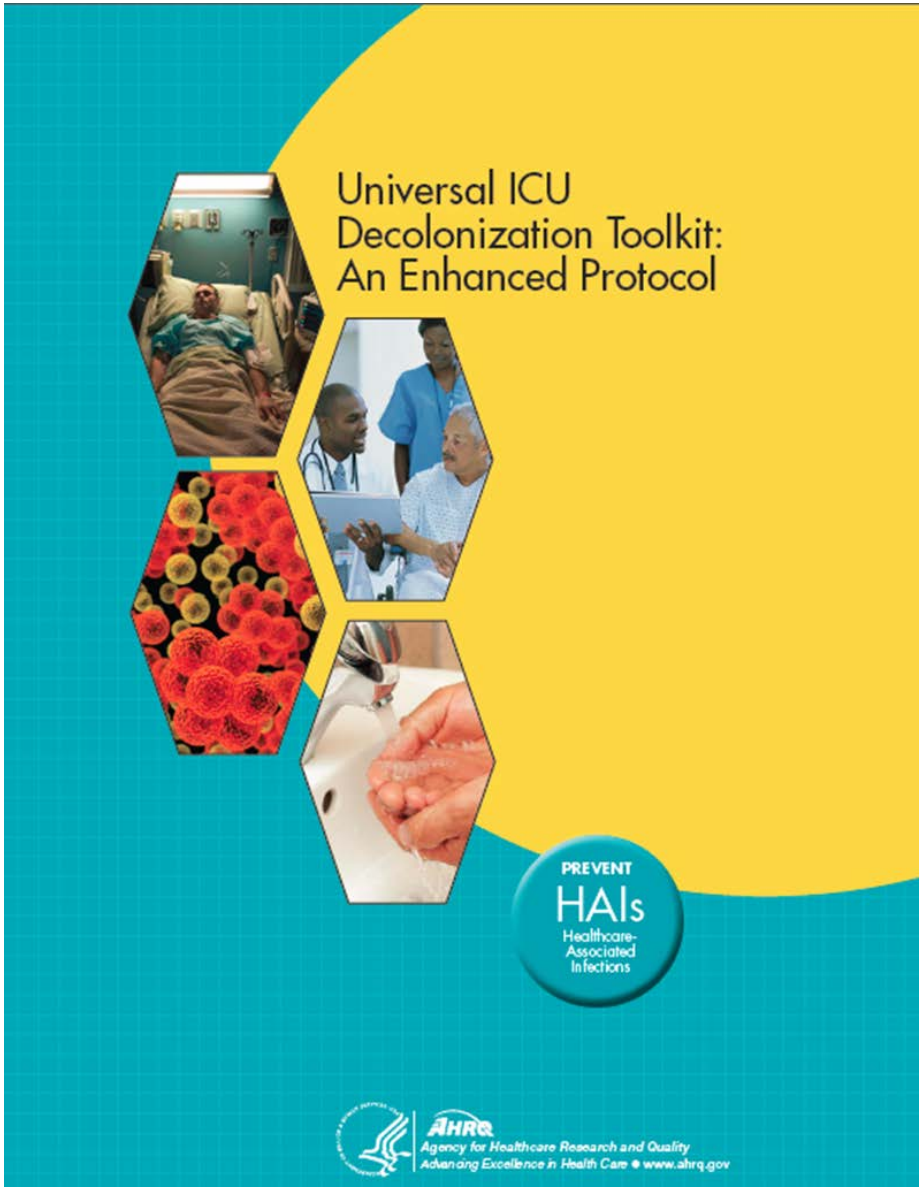
- Post-publication response
  - Protocol inquiries
  - Detailed implementation issues not in paper

Source: Huang, Septimus et al NEJM 2013

REDUCE MRSA toolkit on AHRQ website



Source: http://www.ahrq.gov/professionals/systems/hospital/universal_icu_decolonization.html


Universal ICU
Decolonization Toolkit:
An Enhanced Protocol
PREVENT
HAIs
Healthcare-
Associated
Infections
AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

REDUCE dissemination manuscript

Clinical Infectious Diseases

MAJOR ARTICLE

Closing the Translation Gap: Toolkit-based Implementation of Universal Decolonization in Adult Intensive Care Units Reduces Central Line–associated Bloodstream Infections in 95 Community Hospitals

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Background. Challenges exist in implementing evidence-based strategies, reaching high compliance, and achieving desired outcomes. The rapid adoption of a publicly available toolkit featuring routine universal decolonization of intensive care unit (ICU) patients may affect catheter-related bloodstream infections.

Methods. Implementation of universal decolonization—treatment of all ICU patients with chlorhexidine bathing and nasal mupirocin—used a prerelease version of a publicly available toolkit. Implementation in 136 adult ICUs in 95 acute care hospitals across the United States was supported by planning and deployment tactics coordinated by a central infection prevention team using toolkit resources, along with coaching calls and engagement of key stakeholders. Operational and process measures derived from a common electronic health record system provided real-time feedback about performance. Healthcare-associated central line–associated bloodstream infections (CLABSIs), using National Healthcare Safety Network surveillance definitions and comparing the preimplementation period of January 2011 through December 2012 to the postimplementation period of July 2013 through February 2014, were assessed via a Poisson generalized linear mixed model regression for CLABSI events.

Results. Implementation of universal decolonization was completed within 6 months. The estimated rate of CLABSI decreased by 23.5% (95% confidence interval, 9.8%–35.1%; $P = .001$). There was no evidence of a trend over time in either the pre- or postimplementation period. Adjusting for seasonality and number of beds did not materially affect these results.

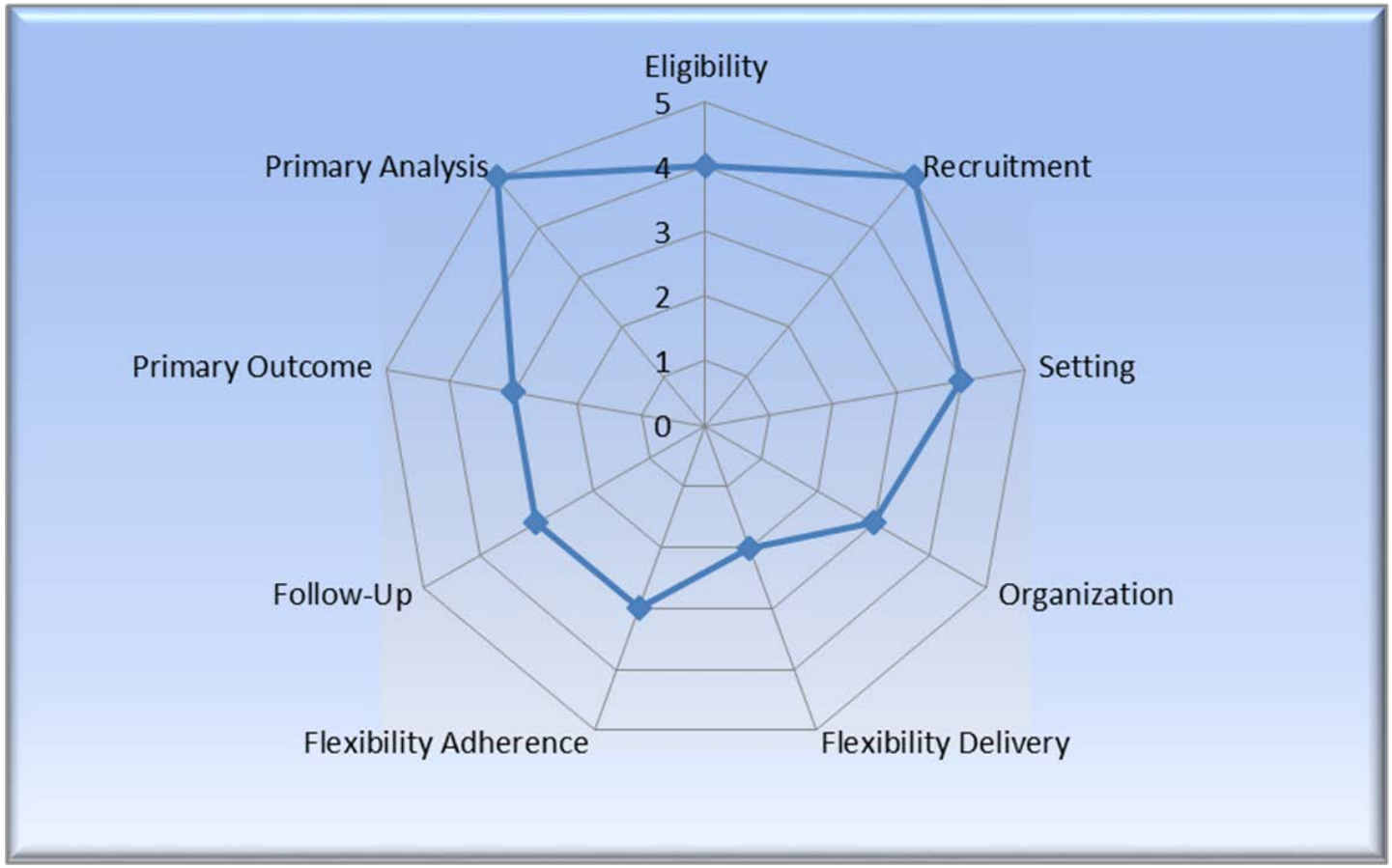
Conclusions. Dissemination of universal decolonization of ICU patients was accomplished quickly in a large community health system and was associated with declines in CLABSI consistent with published clinical trial findings.

Keywords. universal decolonization; decolonization; healthcare-associated central line–associated bloodstream infections (CLABSI); quality improvement; learning health system.

Toolkit contents

- Introduction and Welcome
- Universal ICU Decolonization Protocol Overview
- Scientific Rationale
- References
- Appendices include training and educational materials

Active Bathing to Eliminate Infection (ABATE) PRECIS-2 wheel

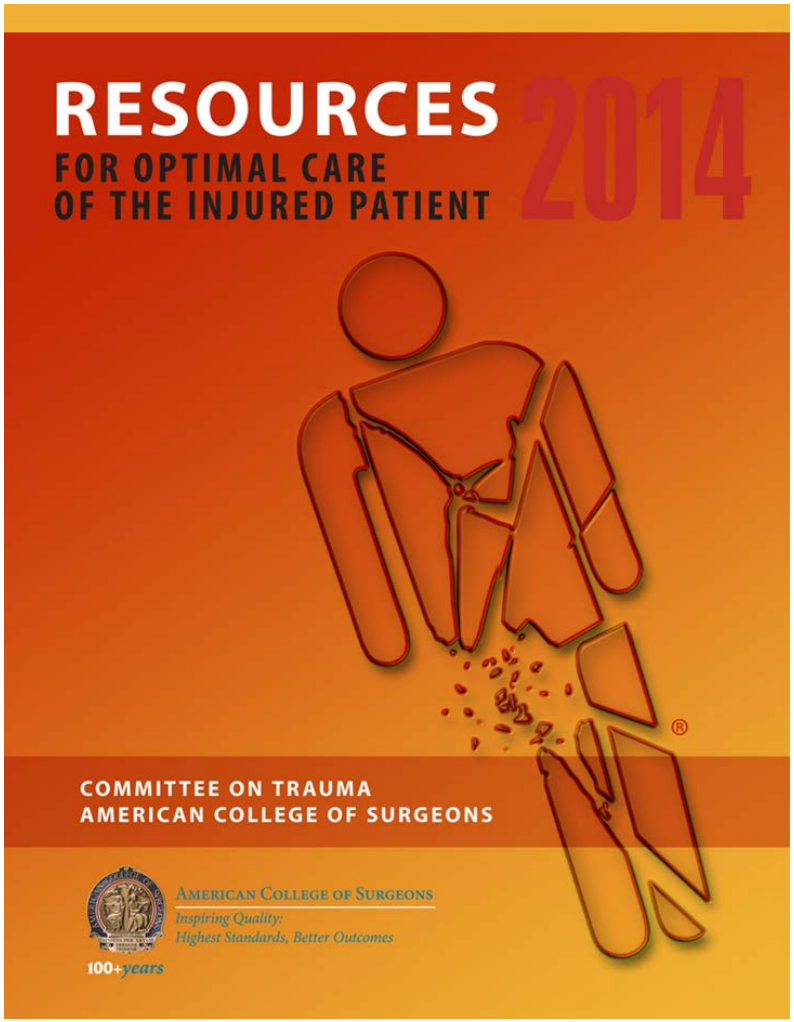


STOP CRC

Dissemination

Implementation

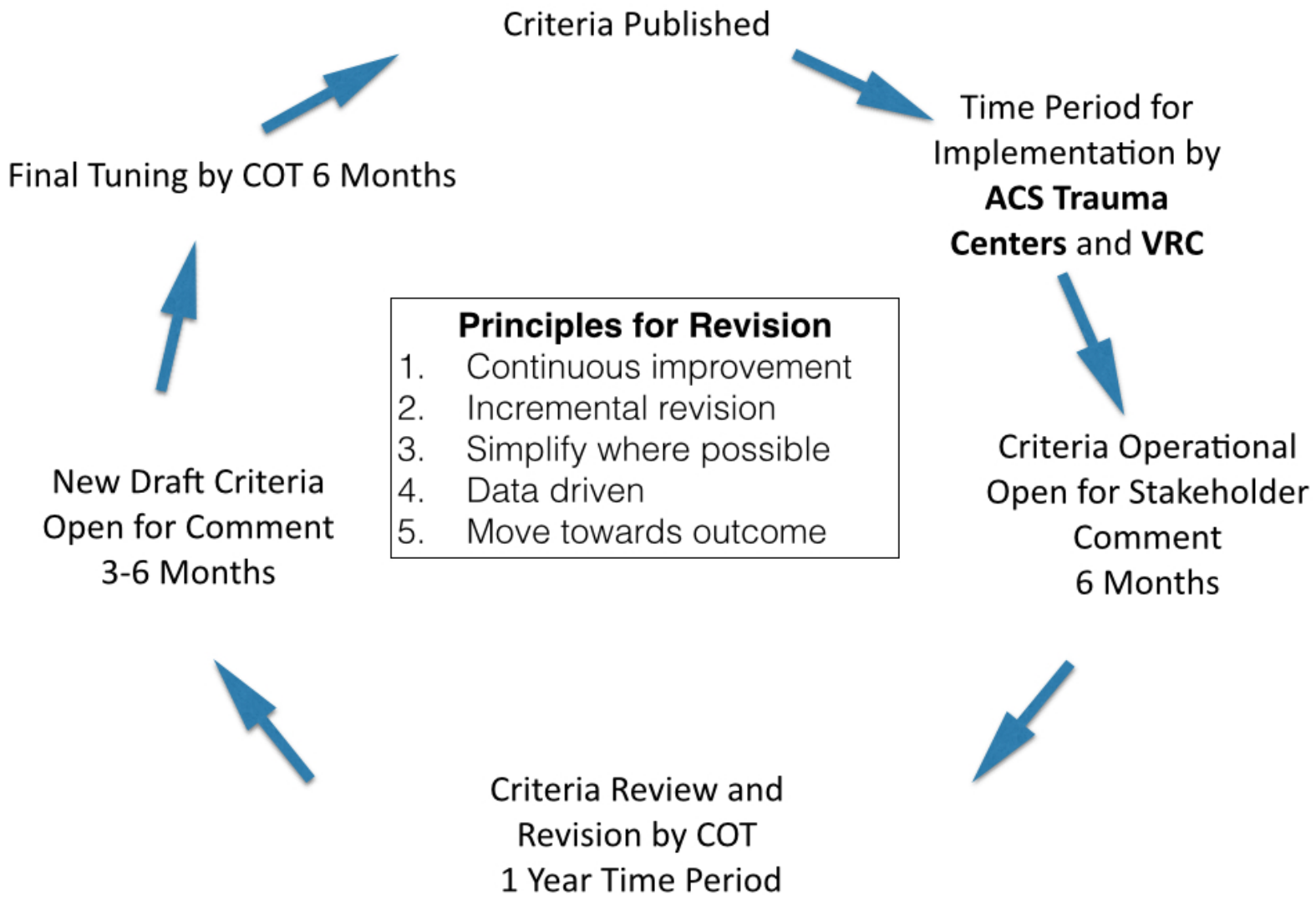
TSOS dissemination



American College of Surgeons Committee on Trauma Guideline Dissemination & Verification Process

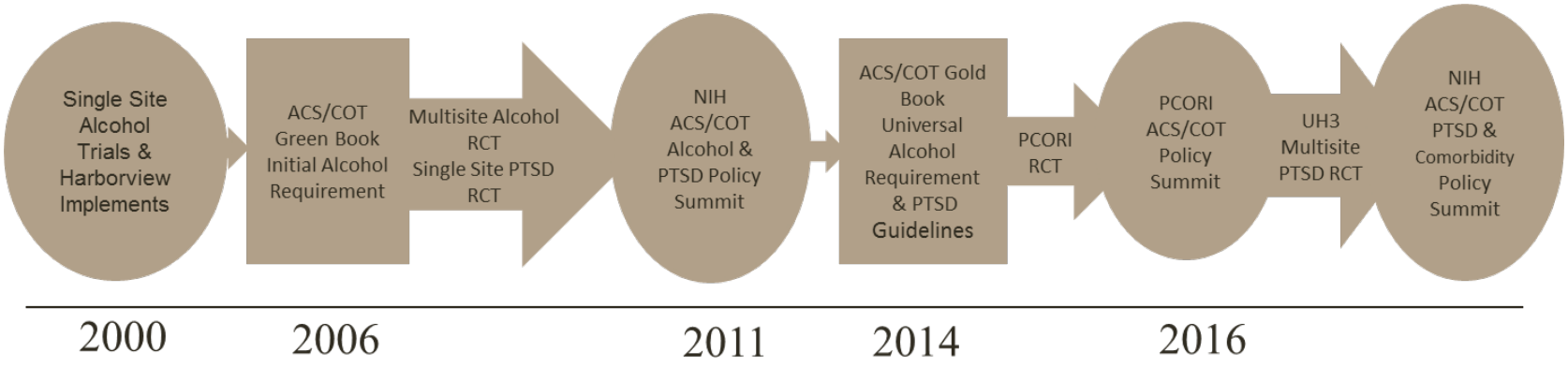
- 1976 1st Book
- 2006 “Green Book”
- 2014 “Orange Book”

American College of Surgeons Resources Guide revision process



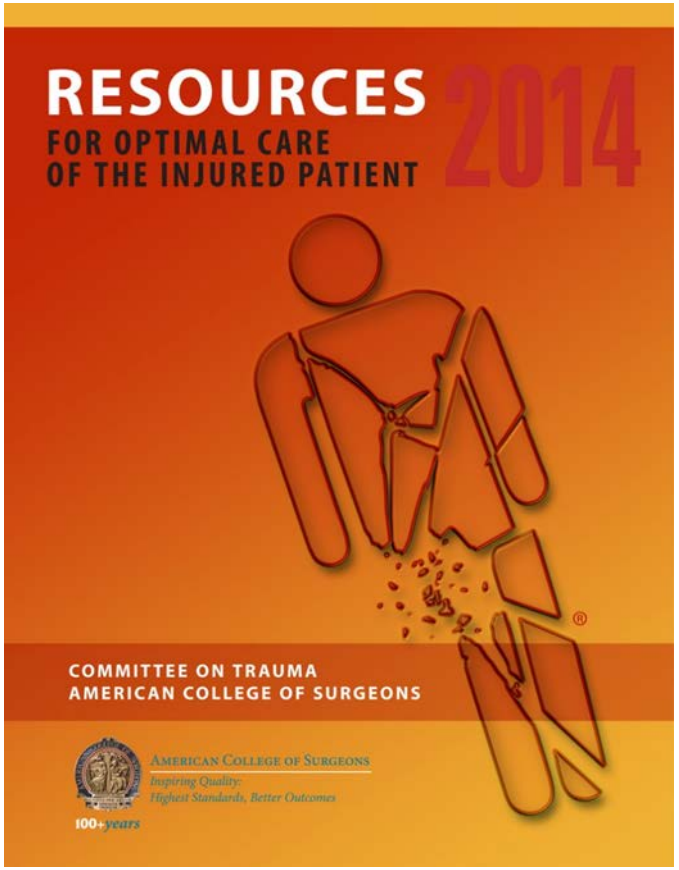
TSOS end-of-study policy summit

Two decades of orchestrated clinical trials & American College of Surgeons policy partnership builds practice change momentum into ePCT design & implementation



American College of Surgeons Resources Guide

PTSD & comorbidity: "The incorporation of routine trauma center–based screening and intervention for PTSD & depression is an area that could benefit from the ongoing integration of emerging data and evolving expert opinion."



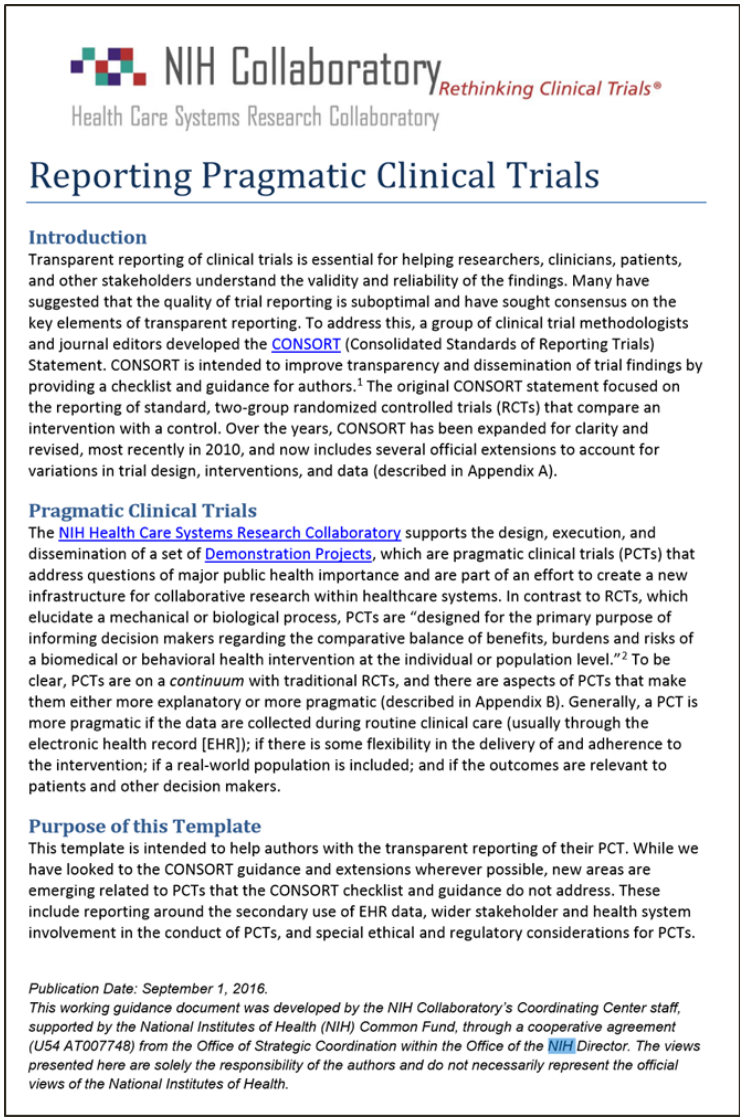
TSOS publications: dissemination aims to "nudge" practice change through regulatory policy

American College of Surgeons guidelines

- Main outcome paper & other publications aim to be cited in College Resources Guide
- End-of-study policy summit aims to integrate findings into College regulatory/verification processes

PCT reporting guidelines

Considerations specific to ePCTs



NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Reporting Pragmatic Clinical Trials

Introduction

Transparent reporting of clinical trials is essential for helping researchers, clinicians, patients, and other stakeholders understand the validity and reliability of the findings. Many have suggested that the quality of trial reporting is suboptimal and have sought consensus on the key elements of transparent reporting. To address this, a group of clinical trial methodologists and journal editors developed the CONSORT (Consolidated Standards of Reporting Trials) Statement. CONSORT is intended to improve transparency and dissemination of trial findings by providing a checklist and guidance for authors.[1] The original CONSORT statement focused on the reporting of standard, two-group randomized controlled trials (RCTs) that compare an intervention with a control. Over the years, CONSORT has been expanded for clarity and revised, most recently in 2010, and now includes several official extensions to account for variations in trial design, interventions, and data (described in Appendix A).

Pragmatic Clinical Trials

The NIH Health Care Systems Research Collaboratory supports the design, execution, and dissemination of a set of Demonstration Projects, which are pragmatic clinical trials (PCTs) that address questions of major public health importance and are part of an effort to create a new infrastructure for collaborative research within healthcare systems. In contrast to RCTs, which elucidate a mechanical or biological process, PCTs are "designed for the primary purpose of informing decision makers regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level."[2] To be clear, PCTs are on a *continuum* with traditional RCTs, and there are aspects of PCTs that make them either more explanatory or more pragmatic (described in Appendix B). Generally, a PCT is more pragmatic if the data are collected during routine clinical care (usually through the electronic health record [EHR]); if there is some flexibility in the delivery of and adherence to the intervention; if a real-world population is included; and if the outcomes are relevant to patients and other decision makers.

Purpose of this Template

This template is intended to help authors with the transparent reporting of their PCT. While we have looked to the CONSORT guidance and extensions wherever possible, new areas are emerging related to PCTs that the CONSORT checklist and guidance do not address. These include reporting around the secondary use of EHR data, wider stakeholder and health system involvement in the conduct of PCTs, and special ethical and regulatory considerations for PCTs.

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Important things to know

- Dissemination & implementation science can inform the translation of ePCT results into HCS practice change
- Case examples from NIH Collaboratory trials suggest a number of possible approaches to the dissemination of trial results
- Data sharing can be an essential element of dissemination

Important things to do

- Consider plans for dissemination of ePCT results
- How do these dissemination plans meld with NIH data sharing guidelines?