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Health Care Systems Research Collaboratory

Data Quality Assessment Recommendations for Pragmatic Clinical Trials

Rachel Richesson, PhD
Duke University
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of Pragmatic Clinical Trials

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About NIH Collaboratory

Our Mission: Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners.

Dr. David Shurtleff of the National Center for Complementary and Integrative Health (NCCIH) discusses the unique work of the Collaboratory.

Supported by the Common Fund at the National Institutes of Health (NIH), the NIH Health Care Systems Research Collaboratory aims to improve the way clinical trials are conducted by creating a new infrastructure for collaborative research with healthcare systems. The ultimate goal is to ensure that healthcare providers and patients can make decisions based on the best available clinical evidence.

The Collaboratory also supports the design and rapid execution of pragmatic clinical trial Demonstration Projects that address questions of major public health importance and engage healthcare delivery systems in research partnerships. These projects help to establish best practices and provide proof of concept for innovative

http://rethinkingclinicaltrials.org/about-nih-collaboratory

Demonstration Projects

Title	Principal Investigator	Sponsoring Institution
A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS])	Zatzick, Douglas	University of Washington
Active Bathing to Eliminate (ABATE) Infection	Huang, Susan	University of California, Irvine
Collaborative Care for Chronic Pain in Primary Care (PPACT)	DeBar, Lynn	Kaiser Foundation
Improving Chronic Disease Management with Pieces (ICD-Pieces)	Vazquez, Miguel	UT Southwestern Medical Center
Lumbar Imaging with Reporting of Epidemiology (LIRE)	Jarvik, Jeffrey	University of Washington
Pragmatic Trial of Video Education in Nursing Homes (PROVEN)	Mor, Vincent; Volandes, Angelo; Mitchell, Susan	Brown University School of Medicine
Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)	Coronado, Gloria	Kaiser Foundation Research Institute
Suicide Prevention Outreach Trial (SPOT)	Simon, Gregory	Kaiser Permanente Washington Health Research Institute
Time to Reduce Mortality in End-Stage Renal Disease (TiME)	Dember, Laura	University of Pennsylvania

New Projects

Title	Principal Investigator	Sponsoring Institution
Improving Advance Care Planning in Oncology: A Pragmatic, Cluster-Randomized Trial Integrating Patient Videos and Clinician Communication Training (ACP PEACE)	Tulsky, James; Volandes, Angelo	Dana-Farber Cancer Institute
Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis (HiLo)	Wolf, Myles	Duke University
Pragmatic Trial of Parent-Focused Prevention in Pediatric Primary Care: Implementation and Adolescent Health Outcomes in Three Health Systems (GGC4H: Guiding Good Choices for Health)	Catalano, Richard; Kuklinski, Margaret; Sterling, Stacy	University of Washington
Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder (EMBED)	Melnick, Edward; D'Onofrio, Gail	Yale University
Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)	Ho, Michael; Bull, Sheana	University of Colorado
Primary Palliative Care for Emergency Medicine (PRIM-ER)	Grudzen, Corita	New York University School of Medicine

EHR Data in PCTs

- Describing patient cohorts for analysis of existing data
- Identifying patients for prospective trials
- Presenting baseline characteristics or conditions to describe research populations for clinical trials
- Presenting primary outcomes to test the trial hypothesis

Data Quality Assessment Recommendations

- Identify variation between populations
- Recommend formal assessment of accuracy, completeness & consistency for key data
- Data quality should be described, reported & informed by workflows

https://www.nihcollaboratory.org/Products/Assessing-data-quality_V1%200.pdf

Recommendations

1) Key data quality dimensions should be assessed for data elements used in subject identification, outcome measures, and important covariates
2) Describe formal assessments for completeness, accuracy, consistency, and impact

Recommendations

3) Use of workflow and data flow diagrams to inform data quality assessment
   - “Talk though” (source, format) for each data element used in cohort identification
   - Describe all transformations from source data to final research repository
   - Are there differences in data capture, documentation, or transformation processes across sites?
   - Are there any subsets of data that may be collected or documented differently?

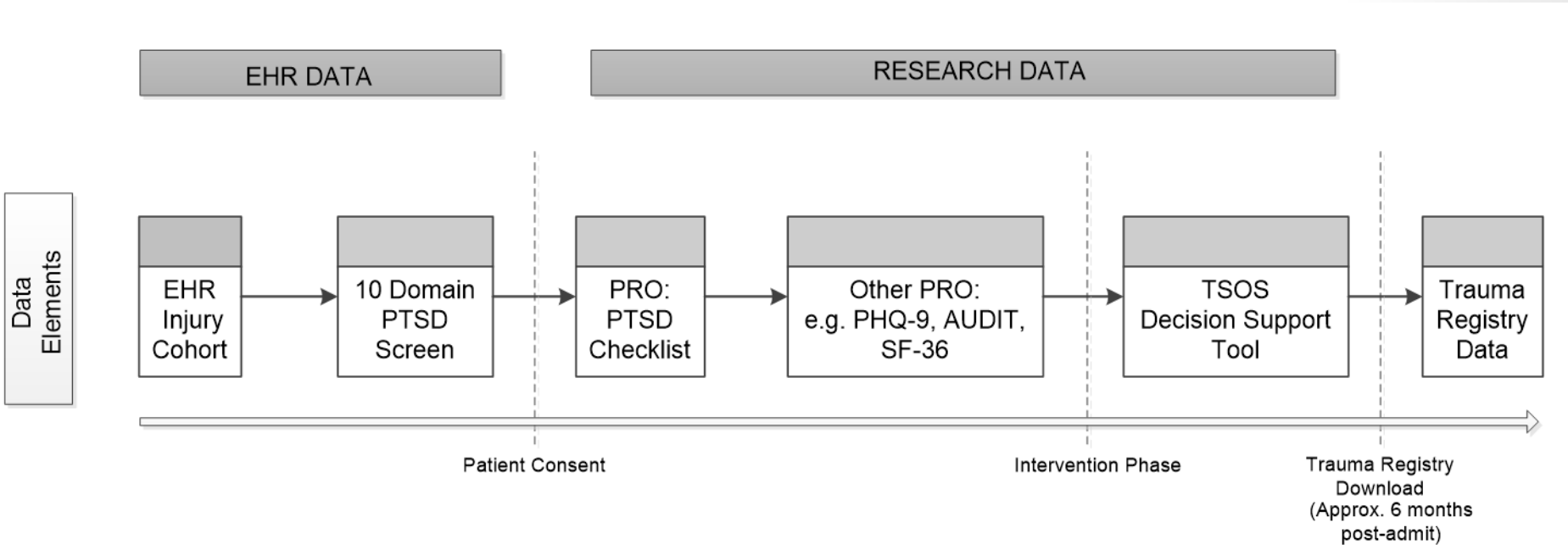
4) Reporting data quality assessment with research results

Trauma Survivors Outcomes and Support (TSOS) Pragmatic Trial

- targeting PTSD and comorbidity
- cluster-randomized trial employing a stepped-wedge design across 24 US trauma sites
- implements stepped collaborative care involving empathic engagement, medications, behavioral intervention, specialty referral, and community integration
- pragmatic design elements: broad eligibility criteria, multiple comorbidities, flexible intervention, comparison with usual care, and an intent-to-treat primary outcome analysis

Principal Investigator: Douglas Zatzick, MD

Data Flow for TSOS Study

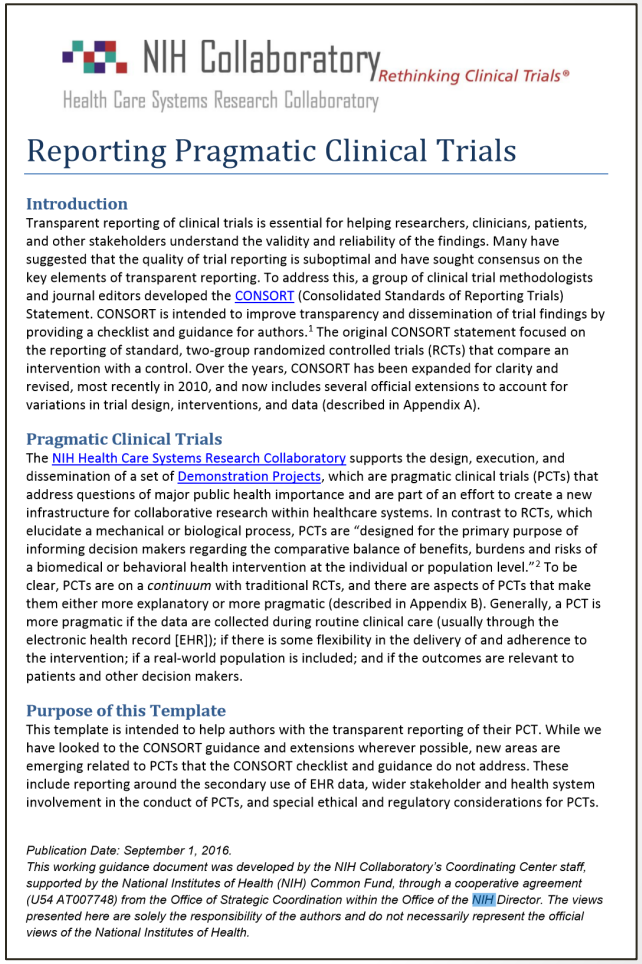


TSOS Data Management Plan

- Includes workflow analysis and interviews with all sites to understand data flow, process, staffing and IT capacity
- Identifies variation and data quality issues up-front
- Proposes strategies to alleviate them
- Includes monitoring (and action plans)

Benefits of Data Quality Assessment Plan

- A robust data quality assessment plan can improve value of data and to detect and address data issues.
- Data quality assessment results should be reported with final study results.
- Will enable readers to understand, interpret, and trust results.



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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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