Data Quality Assessment Recommendations for Pragmatic Clinical Trials

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November 4, 2018
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.

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...
# Demonstration Projects

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

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<td>Improving Advance Care Planning in Oncology: A Pragmatic, Cluster-Randomized Trial Integrating Patient Videos and Clinician Communication Training (ACP PEACE)</td>
<td>Tulsky, James; Volandes, Angelo</td>
<td>Dana-Farber Cancer Institute</td>
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<td>Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis (HiLo)</td>
<td>Wolf, Myles</td>
<td>Duke University</td>
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<td>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)</td>
<td>Catalano, Richard; Kuklinski, Margaret; Sterling, Stacy</td>
<td>University of Washington</td>
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<td>Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder (EMBED)</td>
<td>Melnick, Edward; D’Onofrio, Gail</td>
<td>Yale University</td>
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<td>Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)</td>
<td>Ho, Michael; Bull, Sheana</td>
<td>University of Colorado</td>
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<td>Primary Palliative Care for Emergency Medicine (PRIM-ER)</td>
<td>Grudzen, Corita</td>
<td>New York University School of Medicine</td>
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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
Data Flow for TSOS Study

- **EHR DATA**
  - EHR Injury Cohort
  - 10 Domain PTSD Screen
  - PRO: PTSD Checklist

- **RESEARCH DATA**
  - Other PRO: e.g. PHQ-9, AUDIT, SF-36
  - TSOS Decision Support Tool
  - Trauma Registry Data

- **Stages**
  - Patient Consent
  - Intervention Phase
  - Trauma Registry Download (Approx. 6 months post-admit)
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.