

A Policy Relevant US Trauma Care System Pragmatic Trial for PTSD & Comorbidity: Trauma Survivors Outcomes & Support (TSOS)

Douglas Zatzick

Erik Van Eaton

Doyanne Darnell

Jeff Love

Gregory Jurkovich

UH2 MH106338-01

Overview: Lessons Learned

- Unique US Trauma Care System
Context for MCC Pragmatic Trials
- UH3 Research Plan & Implementation
 - Dialogues with Collaboratory Cores
- Potential Barriers
- UH3 Dissemination/Sustainability
- Questions & Discussion

Lessons Learned - Unique Pragmatic Context: Trauma Care Systems Are Open Systems with Marked Patient Diversity & Health Care Delivery Heterogeneity



**Paramedic/
Pre-Hospital**



**Emergency &
Trauma Center**



**Primary
Care and
Community**

Lessons Learned MCC Heterogeneity: PTSD & Comorbidity and the Multiple Chronic Condition Framework

- Mental Health/ PTSD, depression, suicide (25-40%)
- Alcohol use problems (25%)
- Other substance use problems (20%)
- Chronic pain (10-20%)
- Traumatic Brain Injury (40-50%)
- Pre-injury chronic medical conditions (> 50%): HTN, Diabetes, CAD, Pulmonary, Liver, Neoplasm, Renal
- Evidence-based collaborative care interventions exist

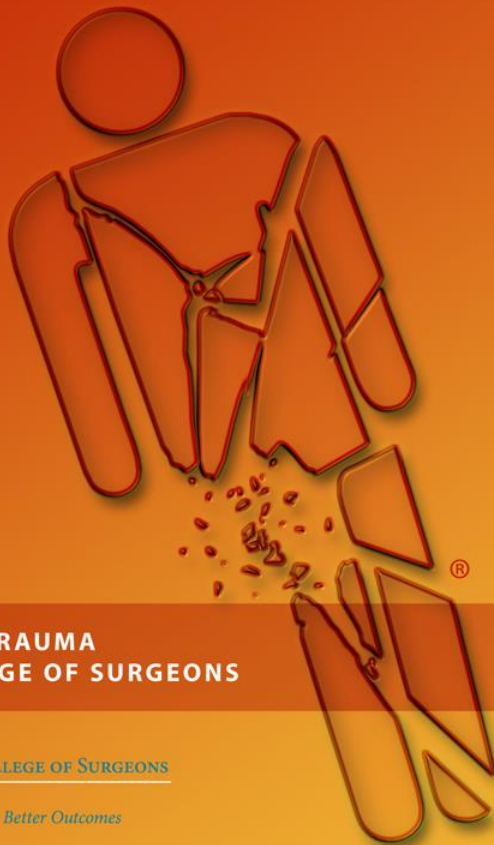
Lessons Learned: The Importance of Stakeholder Partnerships in Pragmatic Trials

- Collaboratory Health Care Systems Core BMJ 2014
- American College of Surgeons' Policy Partnership
- Implementation science "Make it Happen" approach to dissemination of pragmatic trial results
- Trauma care system pragmatic trial generalizability therefore includes:
 - Patients
 - Providers
 - Sites

RESOURCES

FOR OPTIMAL CARE
OF THE INJURED PATIENT

2014



COMMITTEE ON TRAUMA
AMERICAN COLLEGE OF SURGEONS



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

100+ years

PTSD

PTSD screening &
intervention best
practice guideline
recommendation

UH3 Research Plan: Aims & Hypotheses

Aims

- 1) Conduct pragmatic trial
- 2) Understand process of trial implementation
- 3) Disseminate results

Hypotheses

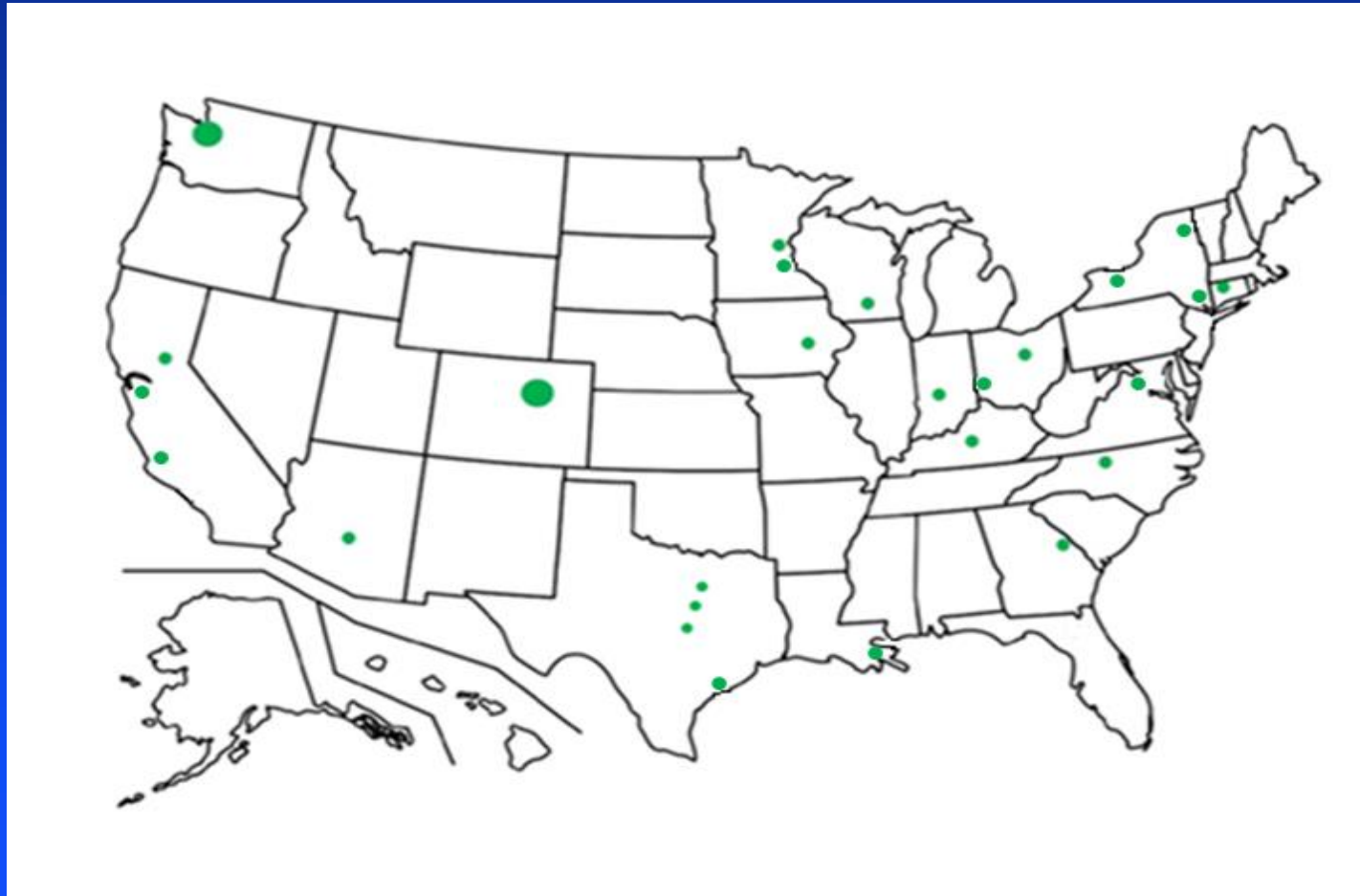
- 1) Intervention improves PTSD symptoms
- 2) Improved alcohol, depression & function
- 3) Explore intervention effect in patients with pre-injury chronic medical conditions

UH3 Study Design

Biostatistics Core Lessons Learned: Increased Numbers of Trauma Centers & Patients

- Cluster randomized trial
- Increase from 20 to 24 trauma centers
- 800 to 960 patients (40 patients/site)

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



UH3 Study Design

Biostatistics Core Lessons Learned: Proposed Stepped Wedge Cluster Randomized Design

- Stepped wedge design addresses site variability
- 24 sites randomized to 4 waves
- All sites recruit both control and intervention patients
- All sites begin recruiting controls
- Intervention “turned on” at each site
- Implementation advantage: all sites trained
- Design adds analytic complexity

Lessons Learned - Phenotypes Core: Data Quality Approaches for Trauma Centers with Heterogeneous EHR Capacity

- Reliance on phenotypes core materials
- 10 domain EHR screen identifies PTSD risk
- Patient reported outcome PTSD Checklist score ≥ 35 defines cohort
- EHR methods for sites that:
 - Standardizes data quality method
 - Overcomes gaps in automation ability



Automated Process
Generates Cohort
with EHR Data

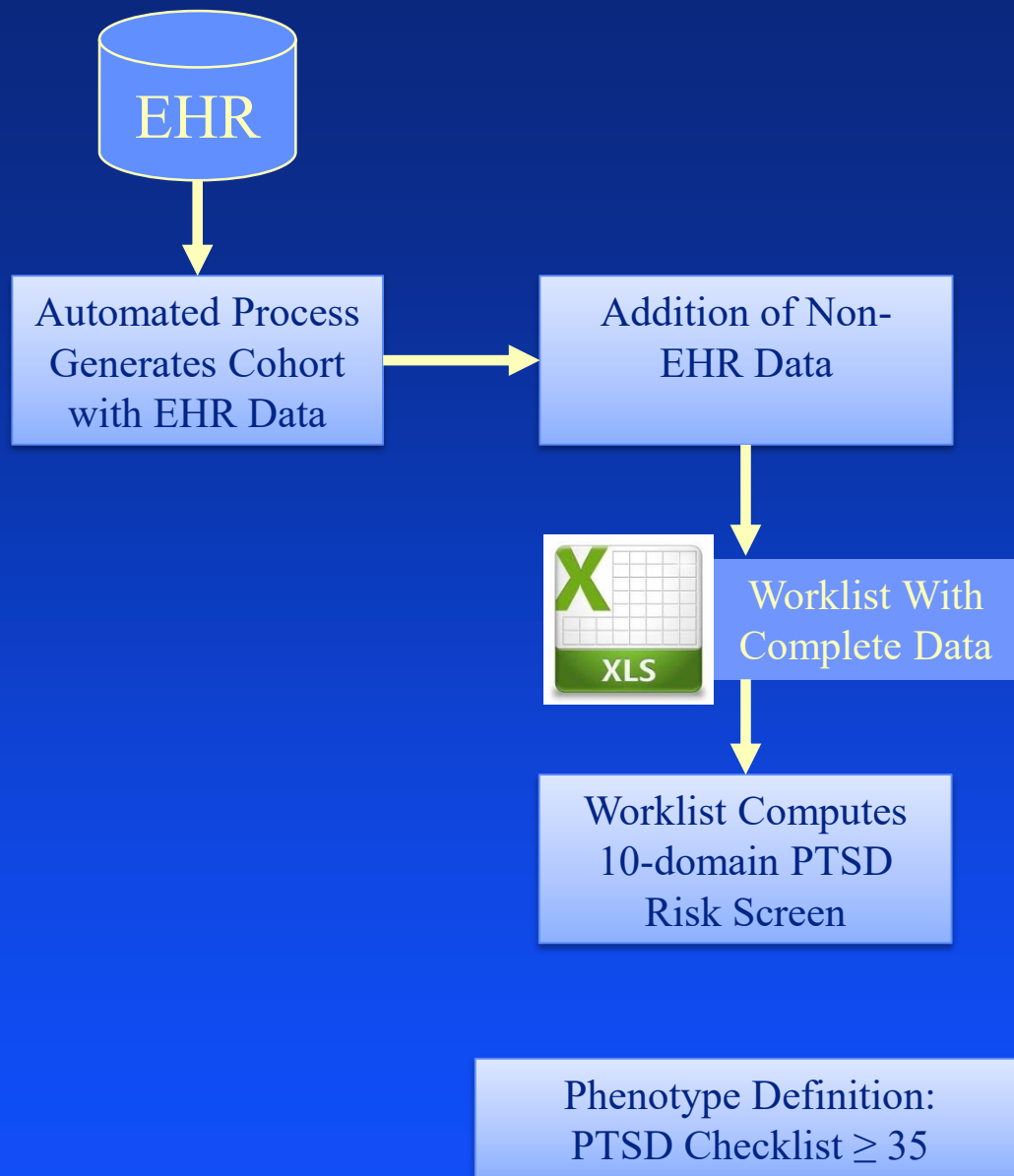


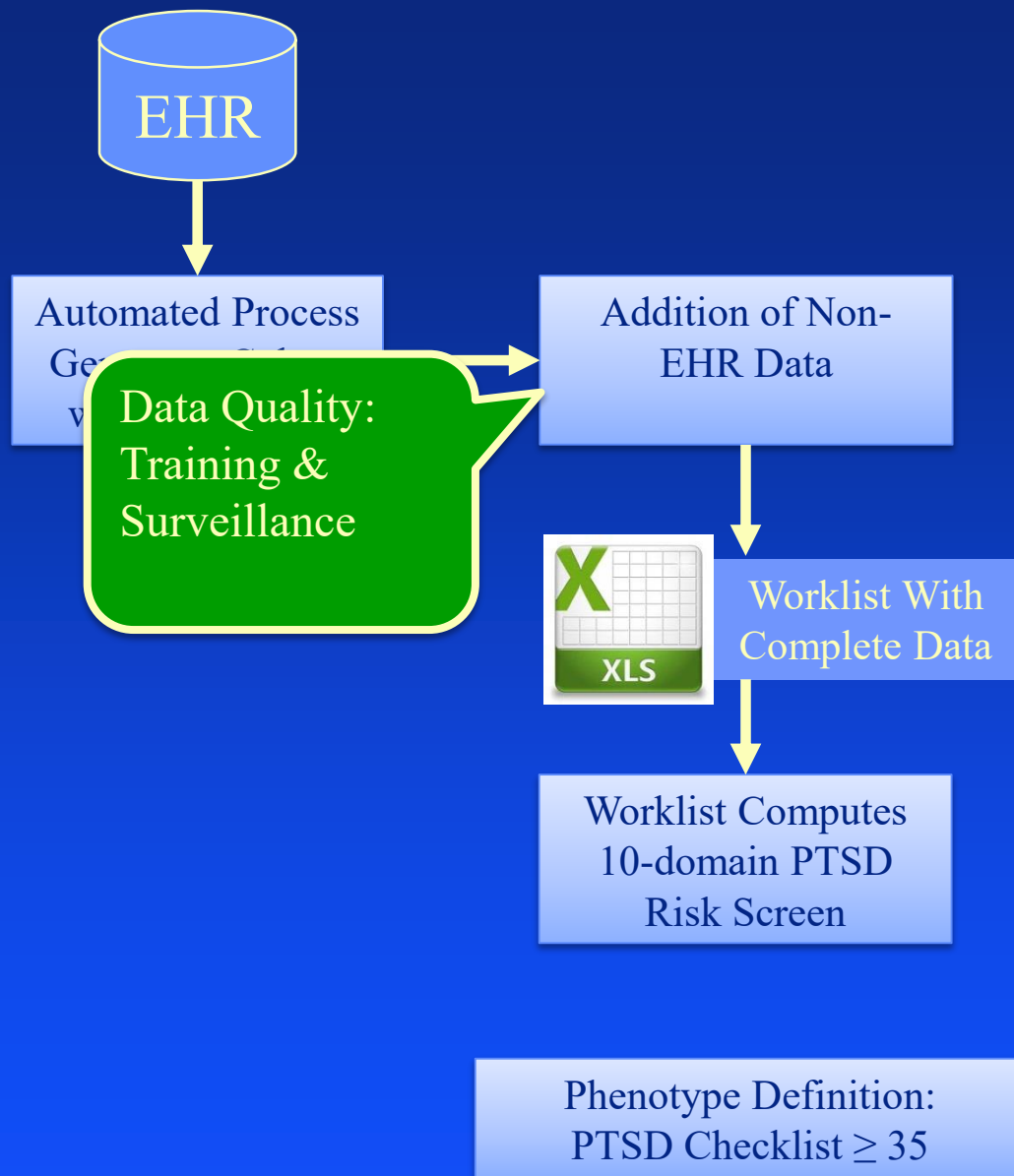
Worklist With
Complete Data

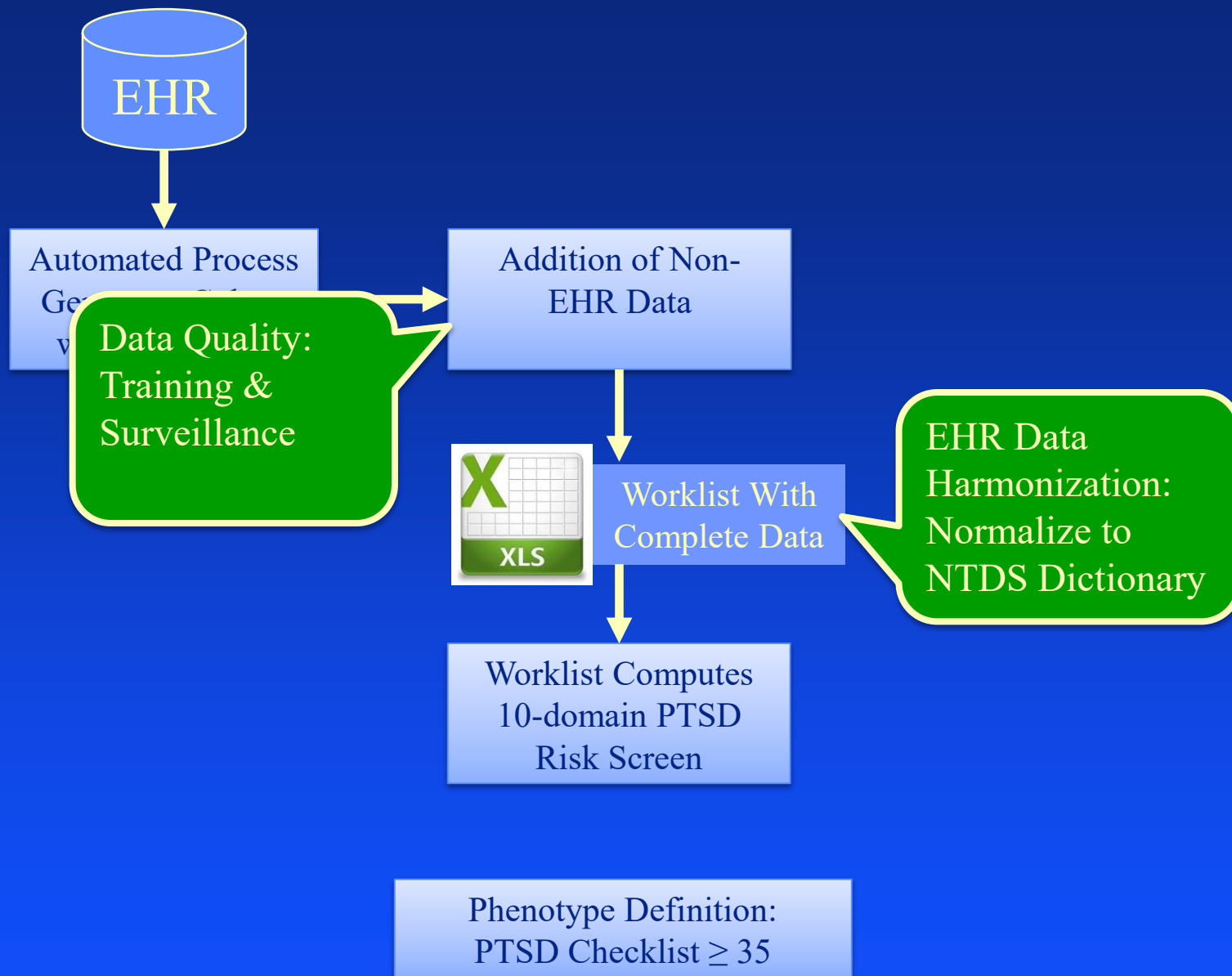


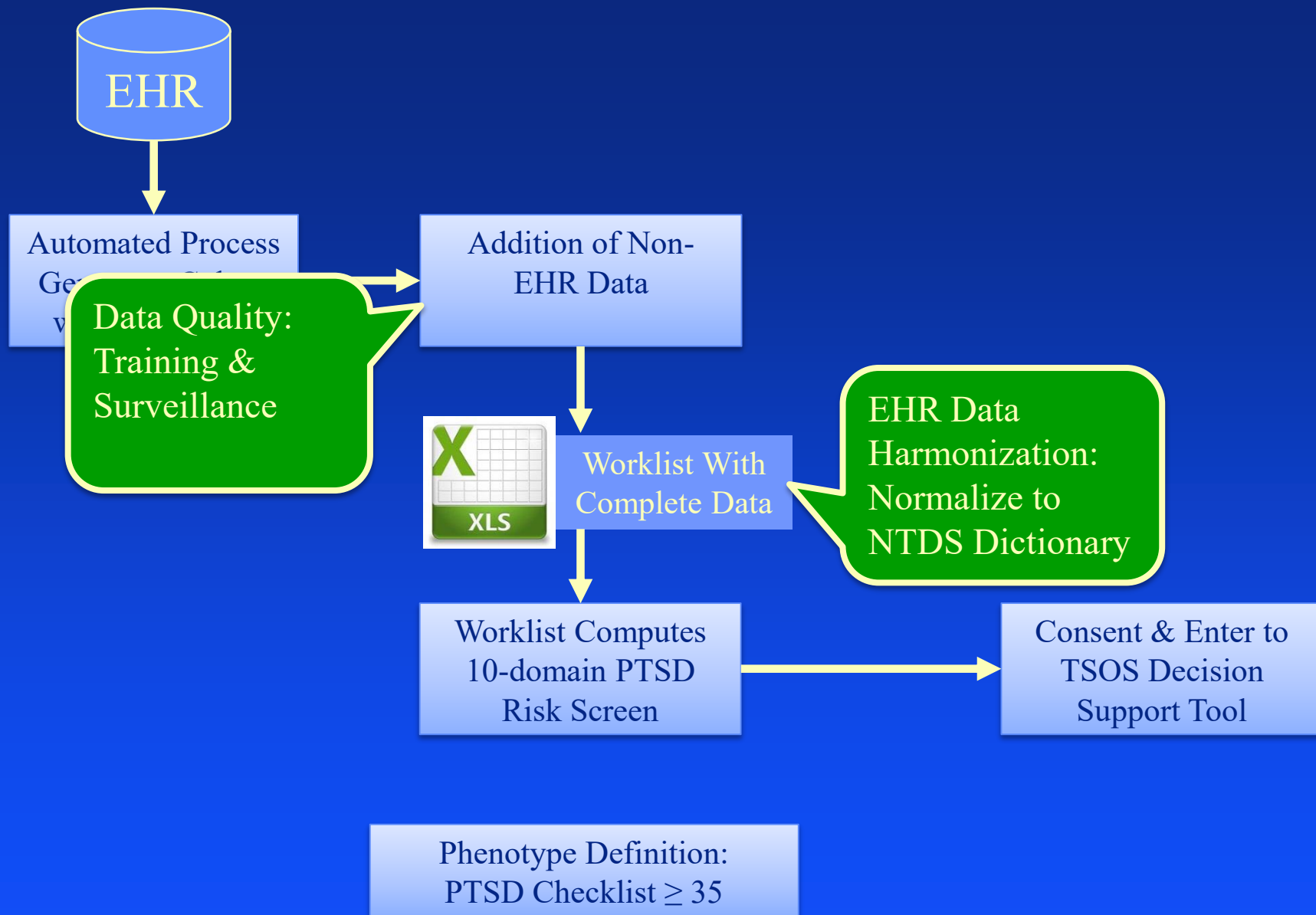
Worklist Computes
10-domain PTSD
Risk Screen

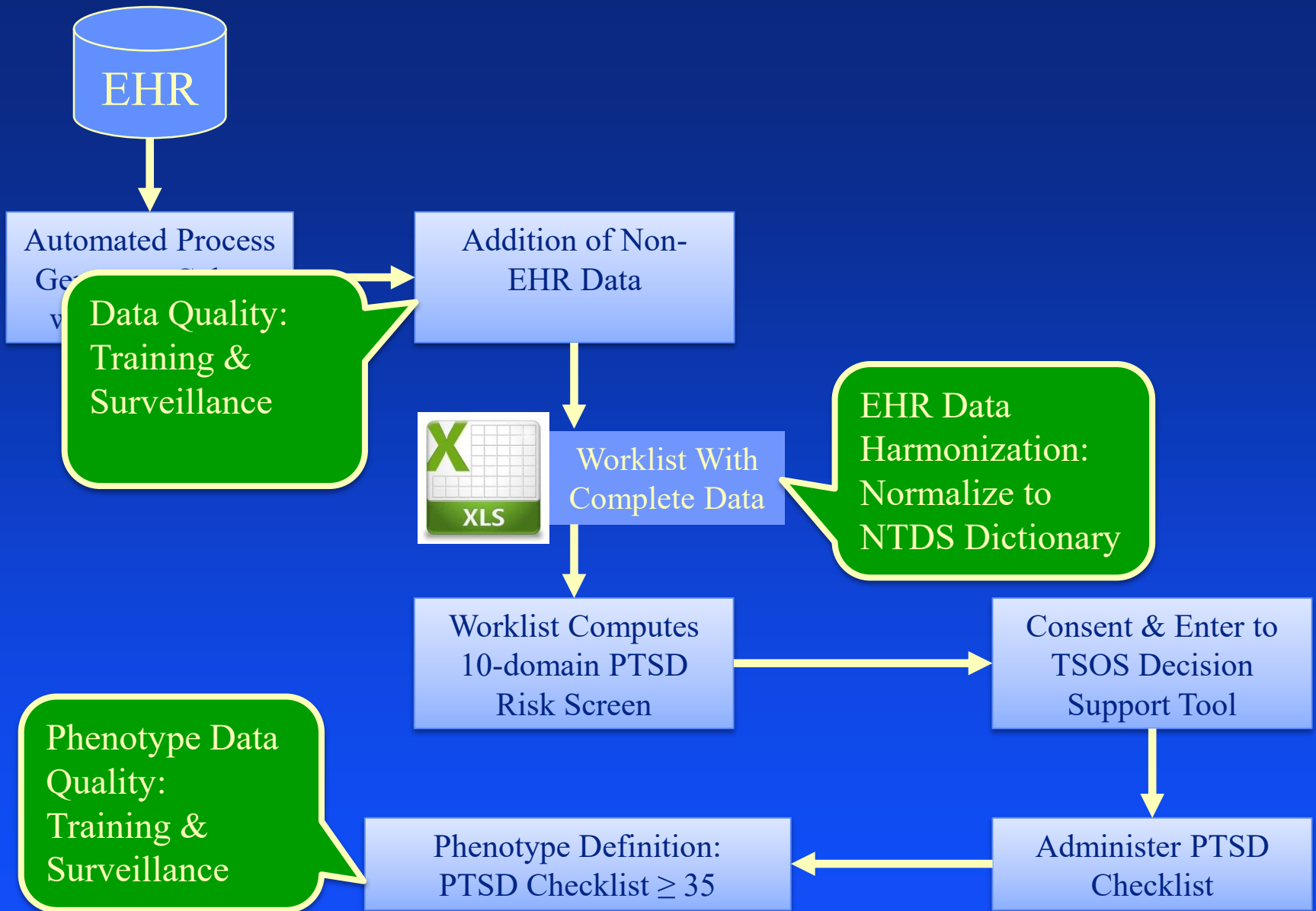
Phenotype Definition:
PTSD Checklist ≥ 35













EHR

Addition of Non-EHR Data

Data Quality:
Training &
Surveillance



Worklist With
Complete Data

EHR Data
Harmonization:
Normalize to
NTDS Dictionary

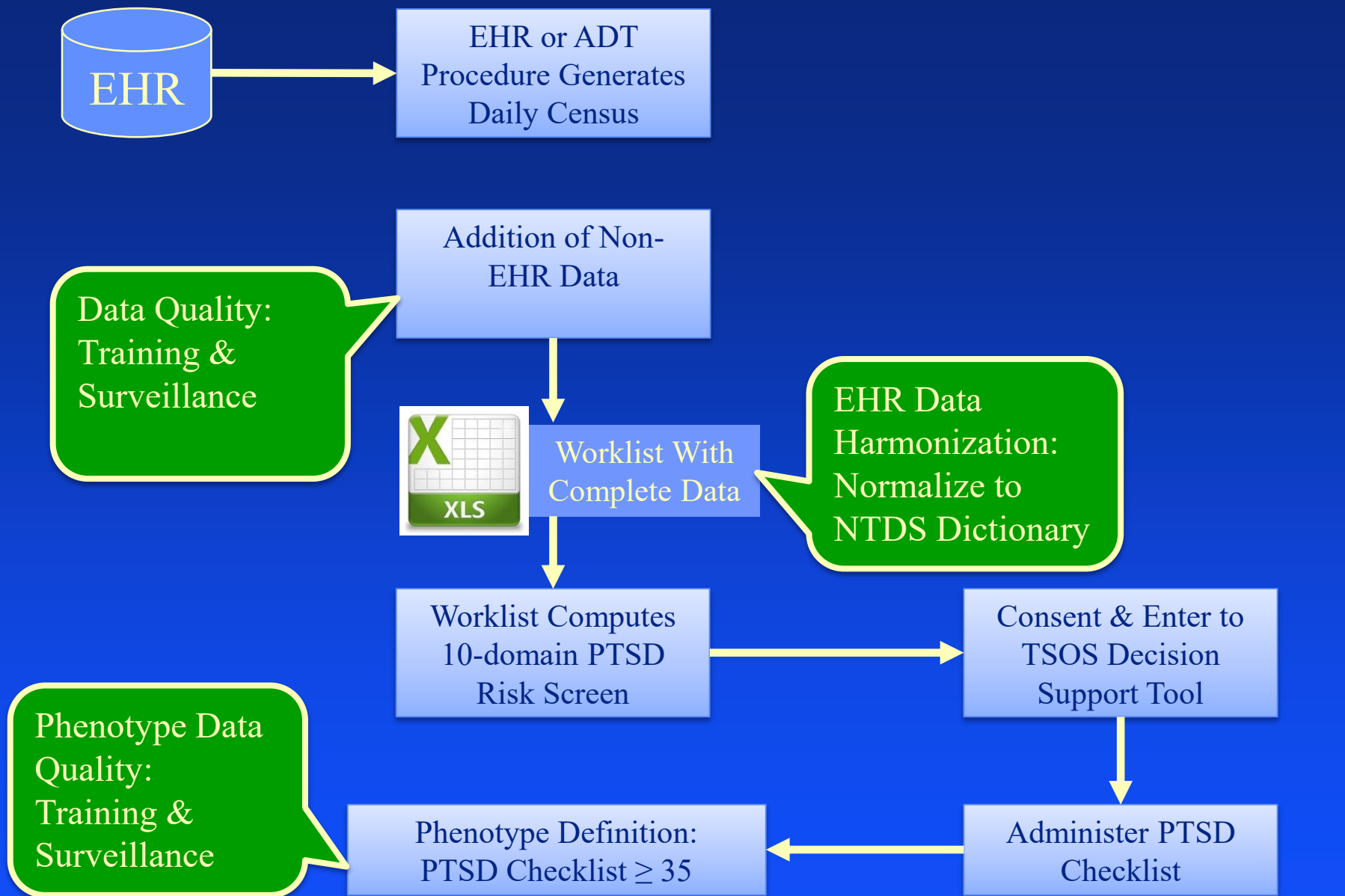
Worklist Computes
10-domain PTSD
Risk Screen

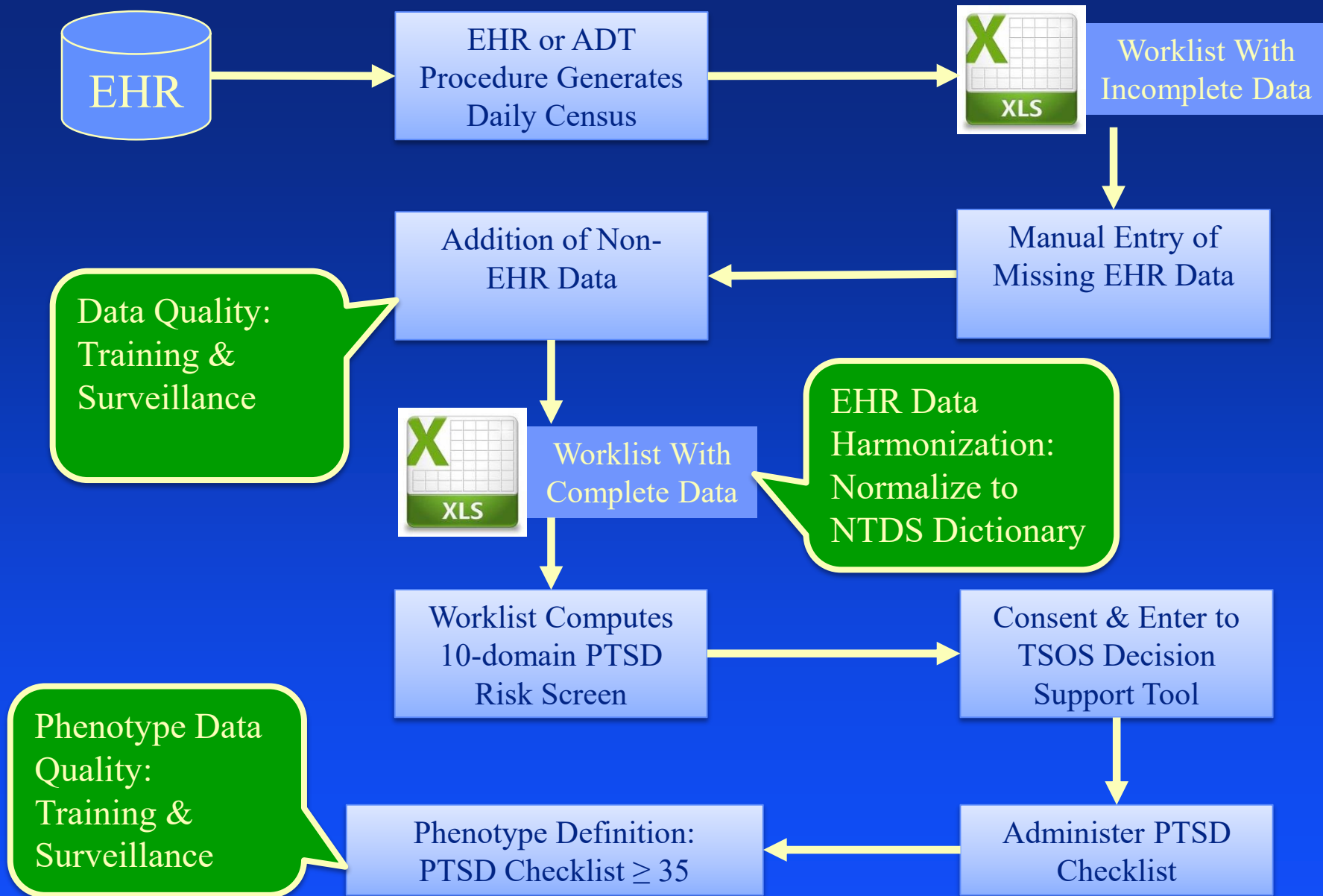
Consent & Enter to
TSOS Decision
Support Tool

Phenotype Data
Quality:
Training &
Surveillance

Phenotype Definition:
PTSD Checklist ≥ 35

Administer PTSD
Checklist





Lessons Learned PRO Assessments at Baseline 3-, 6- & 12-months Post-injury: Targeted, Common & Harmonized

- PTSD (PTSD Checklist)
- Depression (PHQ-9)
- Alcohol use problem (AUDIT)
- Physical function (SF-36 PCS)
- Brief pain inventory (BPI)

Lessons Learned UH2 Pilot: Control Condition

- Enhanced usual trauma center care
- Nurse notification of patients with PTSD checklist ≥ 35

Stepped Collaborative Care Intervention: Decision Support Tool Supported Readily Implementable Elements



Regulatory/IRB Considerations & Potential Barriers

- Consolidated IRB structure
- WIRB approval March 2014
- 24 individual IRB submissions progressing
 - 8 approved
 - 12 under review
 - 4 to be submitted
- 19/24 sub-awards processed
- NIMH DSMB Review June 2015
- IRB modifications post-DSMB
- Delays possible with major protocol changes

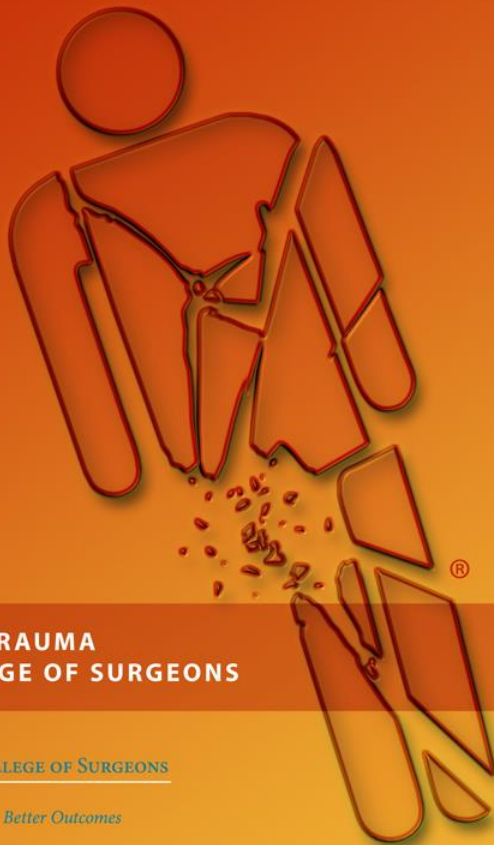
Potential IT Barriers

- Participant site resource availability to create EHR queries
- Tool refinements required for expansion to 24 sites

RESOURCES

FOR OPTIMAL CARE
OF THE INJURED PATIENT

2014



COMMITTEE ON TRAUMA
AMERICAN COLLEGE OF SURGEONS



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

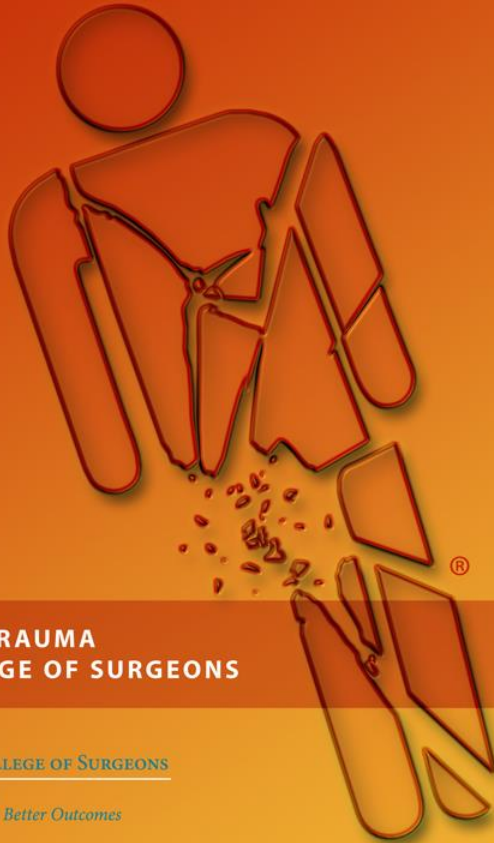
100+ years

Dissemination Year 5 American College of Surgeons Policy Summit

RESOURCES

FOR OPTIMAL CARE
OF THE INJURED PATIENT

2014



COMMITTEE ON TRAUMA
AMERICAN COLLEGE OF SURGEONS



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

100+ years

PTSD

PTSD screening &
intervention best
practice guideline
recommendation

PRO

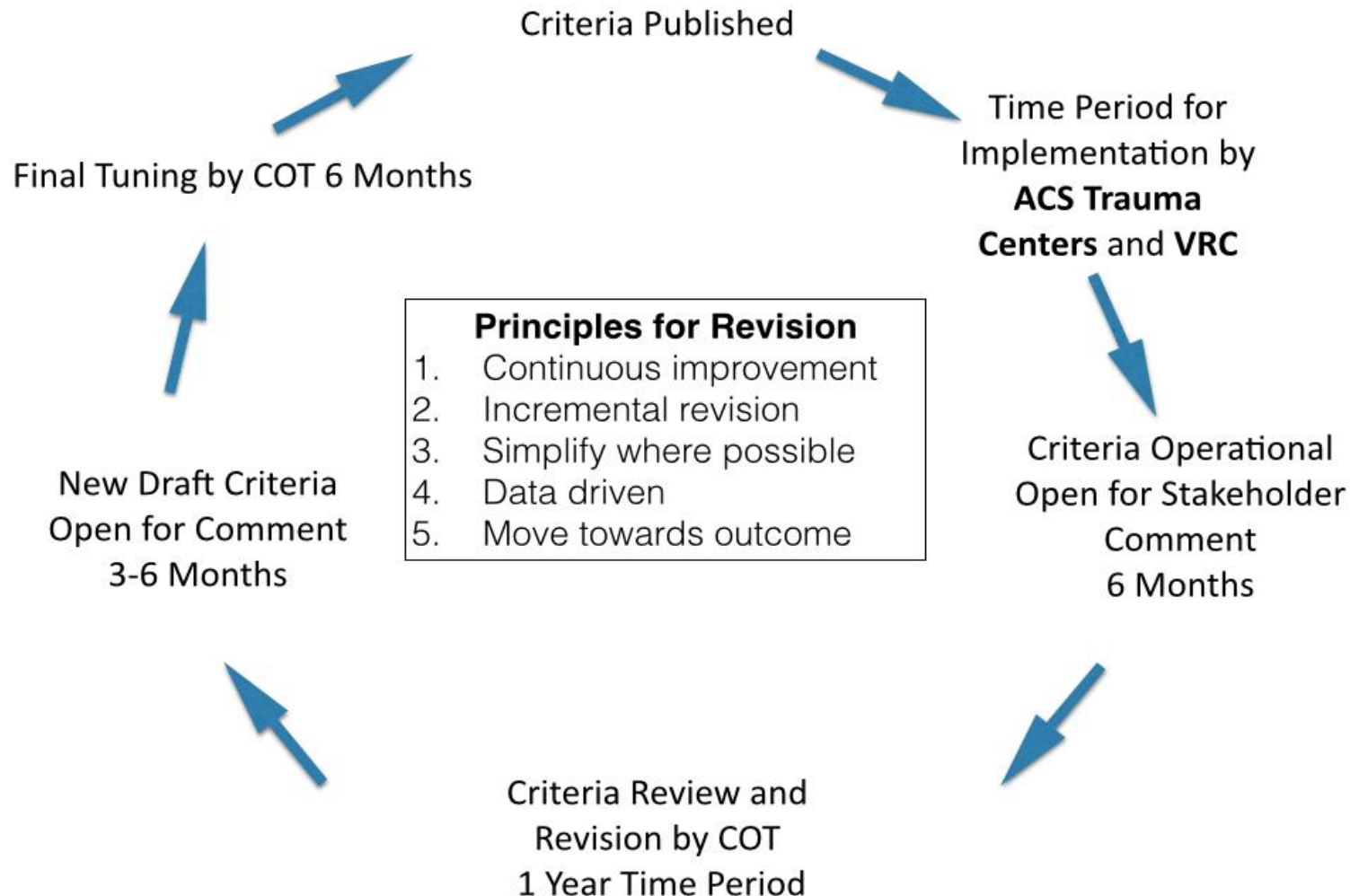
PTSD Checklist
Recommended

American College of Surgeons' Committee on Trauma

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



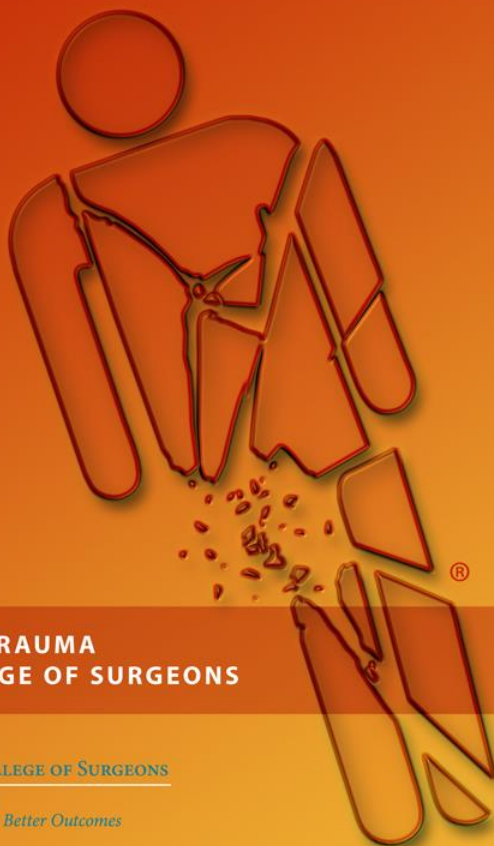
American College of Surgeons' Resources Guide Revision Process



RESOURCES

FOR OPTIMAL CARE
OF THE INJURED PATIENT

2014



COMMITTEE ON TRAUMA
AMERICAN COLLEGE OF SURGEONS



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

100+ years

Next Steps

“The incorporation of routine trauma center based screening and intervention for PTSD and depression is an area that could benefit from the ongoing integration of emerging data and evolving expert opinion”

Questions & Discussion

