

Improving Implementation of Digital Tools Developed in ePCTs

Moderator: Steve George
Coordinating Center



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Key Topics

- What was the decision process regarding whether to integrate digital tools into the EHR or not?
- How do we account for the human factors that affect intervention uptake, fidelity, and sustainability?



Panelists



Keith Marsolo
EHR Core



Mike Ho
Nudge



Andrea Cheville
NOHARM



Michele Balas
BEST-ICU

Overviews

Trial	Population	Design	Intervention	Primary Outcome
BEST-ICU	Critically ill adults	Hybrid type 3, stepped-wedge CRT	Strategies to increase adoption of ventilation liberation approach	Effectiveness of intervention adoption
NOHARM	Postoperative pain	Effectiveness stepped-wedge CRT	EHR-embedded tools to aid shared decision-making about pain management	Postoperative pain and function
Nudge	Patients with chronic CV conditions	Hybrid with patient-level randomization	Text messages and chat bot	Adherence to CV medications

A Brief Introduction



**NIH PRAGMATIC TRIALS
COLLABORATORY**

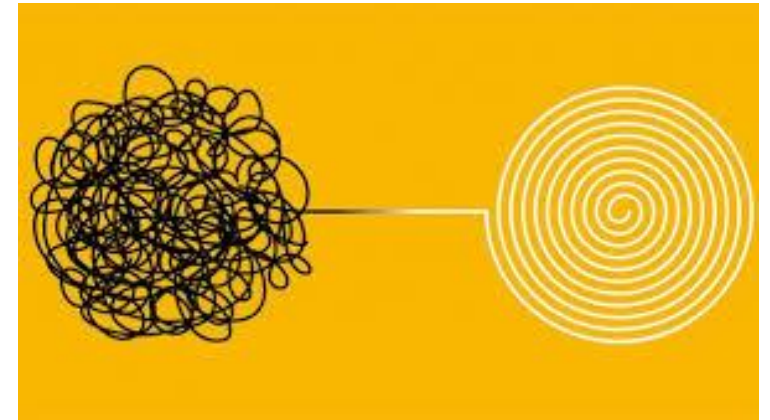
Rethinking Clinical Trials®

Theme #1

- Key decisions made in each trial about whether to integrate digital tools into the EHR or not

Deciding whether to integrating tools into the EHR

- Complexity depends on a variety of factors
 - Number of participating health systems
 - Type of health system (e.g., private clinic, FQHC, AMC)
 - Number of EHR vendors
 - Level of integration
 - Sending a result / message
 - Creating EHR-based data collection tools
 - Embedding a decision support application within a screen



Deciding whether to integrating tools into the EHR

- Will need to navigate institutional governance, which will vary by health system
 - Review committees (single, multiple?)
 - Queues for implementation and deployment (centralized vs. departments have flexibility to prioritize)
 - Approval by “Corporate”
 - Engaging with vendors, as opposed to local IT resources
- Does the trial / intervention require EHR integration, or is it just a nice-to-have?
 - If EHR integration is required, are there pieces that could be removed / deferred if implementation timelines are delayed?
- Remember: what works for one “phenotype” of institution, may be a complete non-starter for another



Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)



Mike Ho, MD, PhD
University of Colorado



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

NUDGE Study Setting



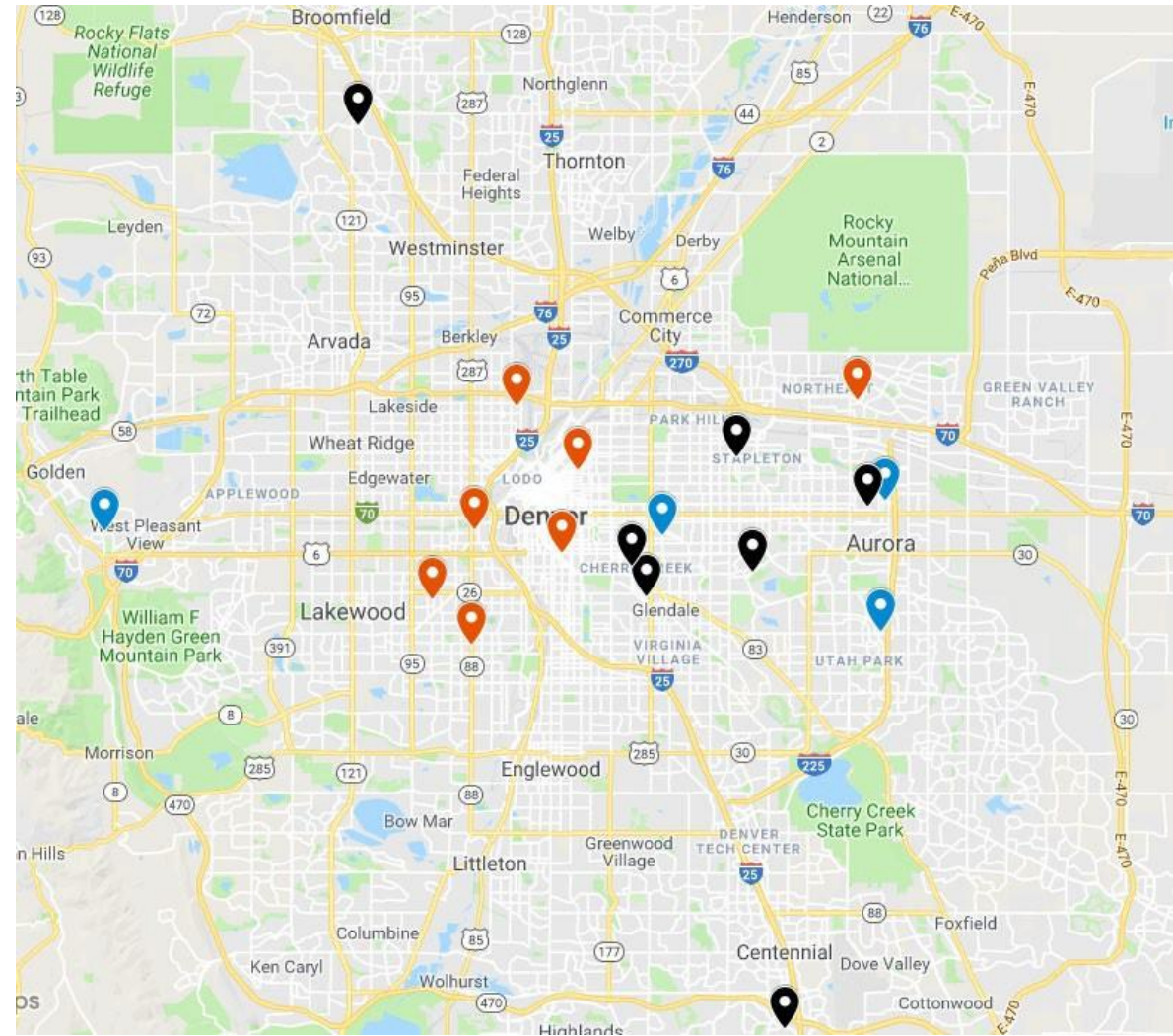
UCHealth Clinics: Epic EHR;
text messaging for clinic
appointment reminders



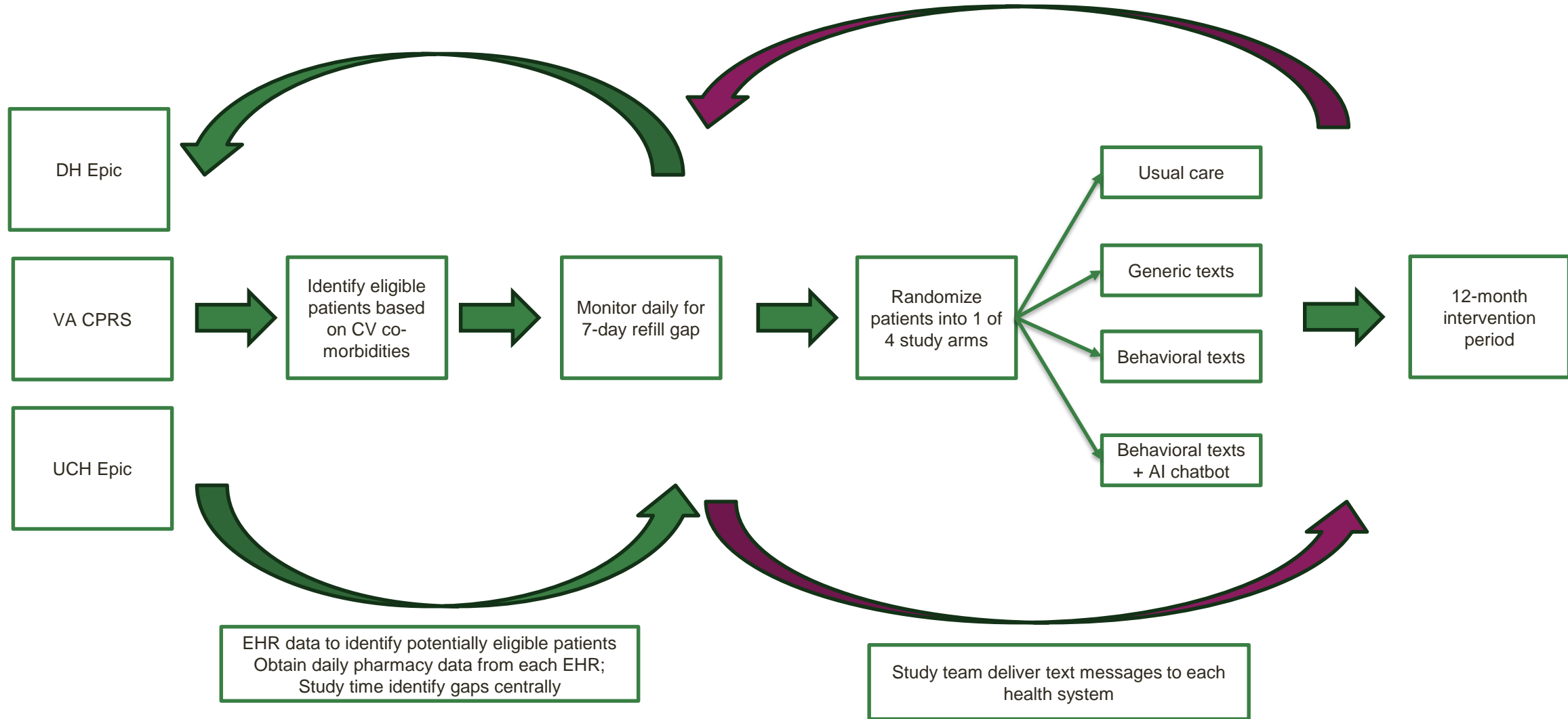
Denver Health Clinics: Epic EHR;
text messaging for clinic
appointment reminders



VA Eastern Colorado HCS
Clinics: CPRS EHR; some text
messaging capabilities including
patient messaging



Intervention Process



Centralized process for message delivery

Pros

- Study team about to control process to identify, deliver and monitor intervention fidelity
- Shorter timelines to initial deployment
- Bypass IT/EHR committees at each site

Cons

- More difficulty with addressing technical issues when they arose
- Competing pharmacy texting systems
- Systems integration and sustainability

NOHARM: Nonpharmacological Options in post-operative Hospital-based And Rehabilitation pain Management pragmatic trial



Andrea Cheville, MD, MSCE
Professor of Physical Medicine and
Rehabilitation
Mayo Clinic

Jon Tilburt, MD
Professor of Medicine
Mayo Clinic



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Objective

- Intervention:
 - Portal-based conversation guide
 - Epic Clinical decision support (CDS)
 - Suite of NPPC self-management materials
- Outcome:
 - Primary, PROMIS pain interference, PROMIS physical function
 - Secondary, PROMIS anxiety, HC utilization, opioid use
- Design:
 - Step-wedge, Cluster-randomized
 - 6 campuses, 4 - 6 procedures/campus
 - Pragmatic, standard of care trial – pt consent waived

Nonpharmacological pain care (NPPC)

Movement

- Walking
- Yoga
- Tai Chi

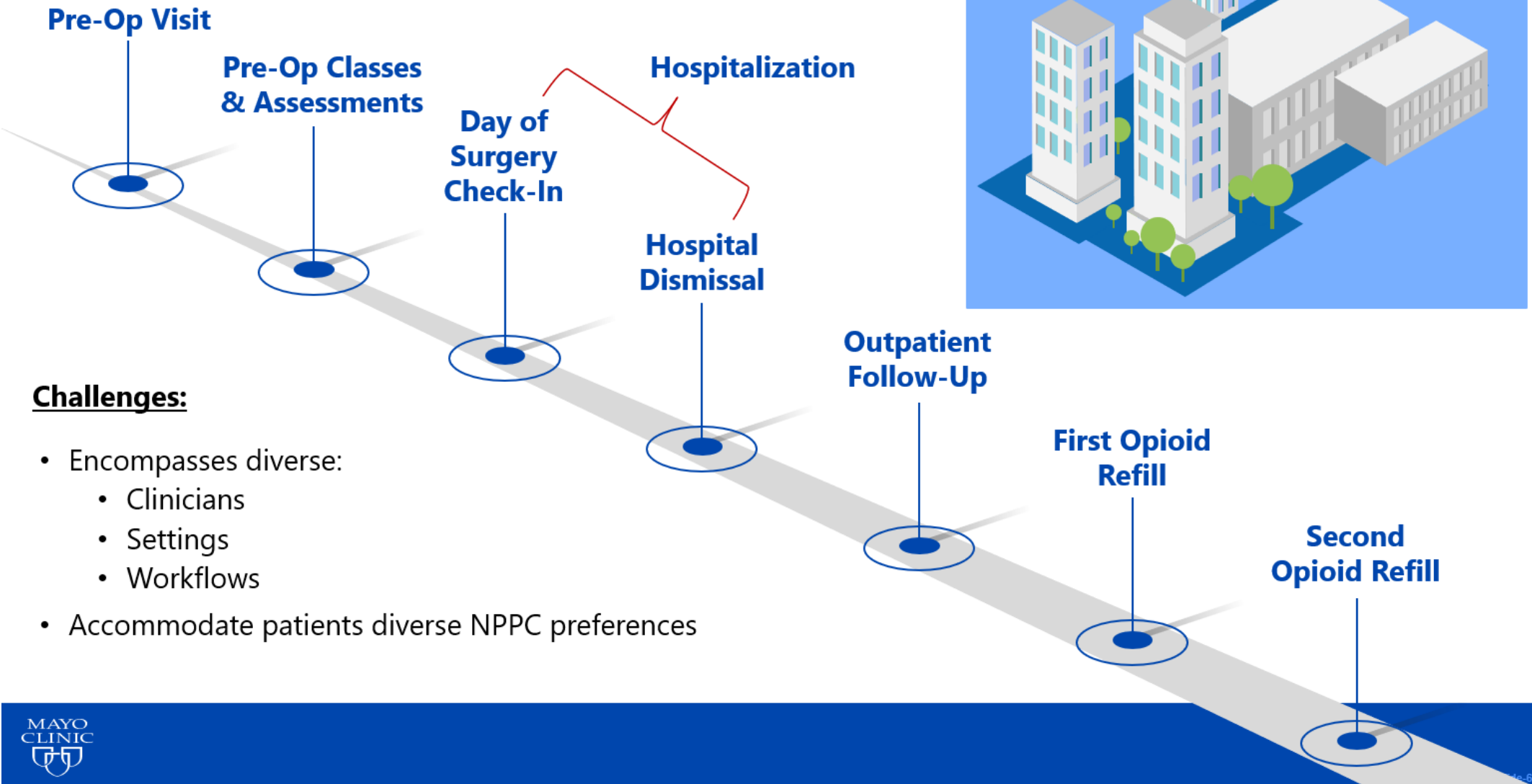
Relaxation

- Meditation
- Relaxed breathing
- Music listening
- Guided imagery
- Muscle relaxation
- Aromatherapy

Physical

- Acupressure
- Massage
- Cold or heat
- TENS

EHR to integrate NPPC use



Challenges:

- Encompasses diverse:
 - Clinicians
 - Settings
 - Workflows
- Accommodate patients diverse NPPC preferences

Discussion

- Key decisions made in each trial about whether to integrate digital tools into the EHR or not

Theme #2



- Accounting for the human factors that affect intervention uptake, fidelity, and sustainability

What about the human factors?



- We are not (yet) in the age of AI agents in healthcare, so we still need to rely on humans to do things!
- If the intervention requires someone to push a button or click on something, does that role / person exist at each institution?
- Has there been buy-in from sites to assess whether the intervention is compatible with clinical workflows to ensure fidelity?
- What types of updates or modifications are necessary over time? Will sites need to do additional work after the initial implementation? If so, are there plans for handling site IT staff turnover?

Behavioral Economic and Staffing Strategies to Increase Adoption of the ABCDEF Bundle in the ICU (BEST-ICU)



Michele Balas, PhD, RN, CCRN-K, FCCM, FAAN
University of Nebraska



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®



BEST-ICU

NIH-FUNDED STUDY

IRB# 0794-23-FB

A Stepped Wedge Cluster Randomized Controlled Trial

Improving Implementation of EHR-
Based Tools Developed in ePCTs: A
Case Report

BEST ICU Intervention Arm 1: Real-Time Audit & Feedback (A&F) Dashboard

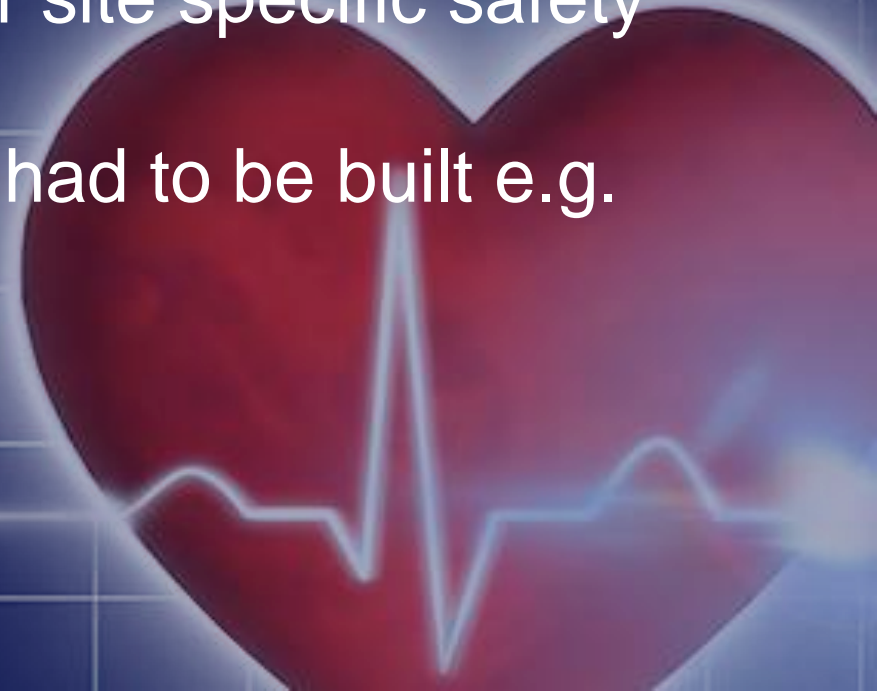
- Initial plans for integration
 - Provide real-time A&F displayed on centrally placed dashboard
 - All ICU providers have dashboard access
 - Implement in 6 ICUs located in 3 discrete safety net hospitals
 - Build off of existing EPIC® ABCDEF (ICU Liberation) bundle reporting
 - Include daily bundle element completion status by ICU room using “Red, Yellow, Green light” coding

ICU ROOM NUMBER	A Pain Assessment	B1 SAT	B2 SBT	C Level of Arousal Assessment	D Delirium Assessment	E Early Mobility	F Family Engagement Empowerment
5001	Green	Green	Yellow	Green	Green	Green	Green
5002	Green	Green	Red	Green	Green	Red	Green
5003	Green	Blue X	Blue X	Red	Green	Red	Green

Dashboard Development: UG3 Phase

Challenges

- Differences existed in study & EPIC foundation definitions related to ABCDEF bundle compliance
- Compliance definitions also needed to be standardized across each bundle element & site while allowing for site specific safety screen differences
- Some new nursing documentation elements had to be built e.g. addition of bundle element “E”



Dashboard Development: UG3 Phase


Challenges

- Different starting lines & EPIC build variability
 - Only 1 site implemented the EPIC ICU Liberation Bundle; 1 site had a home-built ABCDE (missing F) bundle reporting; 1 site was performing ABCDEF, but did not have reporting built
- Previous mistakes in bundle reporting
 - e.g. independence vs. dependence of SAT & SBT
- Varying workflows & documentation
 - Data entry
 - Data consumption & visualization



Dashboard Development: UG3 Phase

Solutions

- Address bundle process & policy gaps
 - Standardized definitions for bundle process elements:
 - Safety screen criteria; Pass/failure criteria
 - Ensure independence of each bundle element
 - Engage EPIC developers & clinicians
 - Weekly collaborative workgroup to share definitions, code, & ideas
 - Use of test environment
- 

Dashboard Development UH3 Phase

The screenshot shows an Epic dashboard for the 8CNW SICU. The dashboard is titled "8CNW SICU - Best ICU Dashboard (10 Patients)" and displays a table of patient status. The table has columns for "Room/Bed", "A (Pain) Completed", "B (SAT) Completed", "B (SBT) Completed", "C (Sedation) Completed", "D (Delirium) Completed", "E (Mobility) Completed", and "F (Family) Completed". Each cell in the table contains a colored circle (green, yellow, or red) or a white 'x' to indicate the status of that metric for each patient. The time shown is 8:50 AM.

Room/Bed	A (Pain) Completed	B (SAT) Completed	B (SBT) Completed	C (Sedation) Completed	D (Delirium) Completed	E (Mobility) Completed	F (Family) Completed
8851/8851-0	●	●	●	●	●	●	●
8853/8853-0	●	●	●	●	●	●	●
8854/8854-0	●	●	●	●	●	●	●
8855/8855-0	●	●	●	●	●	●	●
8856/8856-0	●	●	●	●	●	●	●
8857/8857-0	●	●	●	●	●	●	●
8858/8858-0	●	●	●	●	●	●	●
8860/8860-0	●	●	●	●	●	●	●
8861/8861-0	●	●	●	●	●	●	●
8862/8862-0	●	●	●	●	●	●	●

Discussion



- Accounting for the human factors that affect intervention uptake, fidelity, and sustainability