What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a ‘one-stop shop’ for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally

ACCORDS Upcoming Events – mark your calendars!

April 2, 2025 12-1pm MT AHSB Room 2200/2201	**Transforming and Advancing a Learning Health System: Multiple Perspectives for Mutual Gain** *Next Steps for Learning Health Systems in Colorado* **Presented by: Jean Kutner, MD, MSPH**
April 4, 2025 11am-1pm Krugman Conference Hall	**ACCORDS & CCTSI Community Engagement Showcase** *Connect with community and academic partners!*
April 30 + May 1, 2025 9am-3pm MT Zoom	**Strengthening the Application of Theories, Models, and Frameworks in Implementation Research** *Back by popular demand! Registration is now live!*
May 12, 2025 12-1pm MT AHSB Room 2200/2201	**Emerging Topics in Digital Health & Clinical Informatics** *Real World Augmented Supportive Care: Tech to Touch* Presented by: Matt Loscalzo, MSW
Annual Conference June 4-5, 2025 9-4pm MT	**Colorado Pragmatic Research in Health Conference** Future of Pragmatic Research: Team Science to Enhance Innovation and Impact *Registration now open → Visit COPRHcon.com for more information!*

Building Synergy Across Academic and Operational Programs in a Learning Health System

Presented by:
Sunil Kripalani, MD, MSc

Building Synergy Across Academic and Operational Programs in a Learning Health System

Sunil Kripalani, MD, MSc
Professor of Medicine
Vice President, Health System Sciences
Director, Center for Health Services Research
Associate Director, Nashville VAQS

VANDERBILT UNIVERSITY
MEDICAL CENTER

University of Colorado, ACCORDS
March 5, 2025

Learning Objectives

1. Review the promise and major functions of a learning health system.
2. Provide examples of research embedded in clinical operations at VUMC.
3. Discuss key infrastructure components bridging academic and operational programs at VUMC.

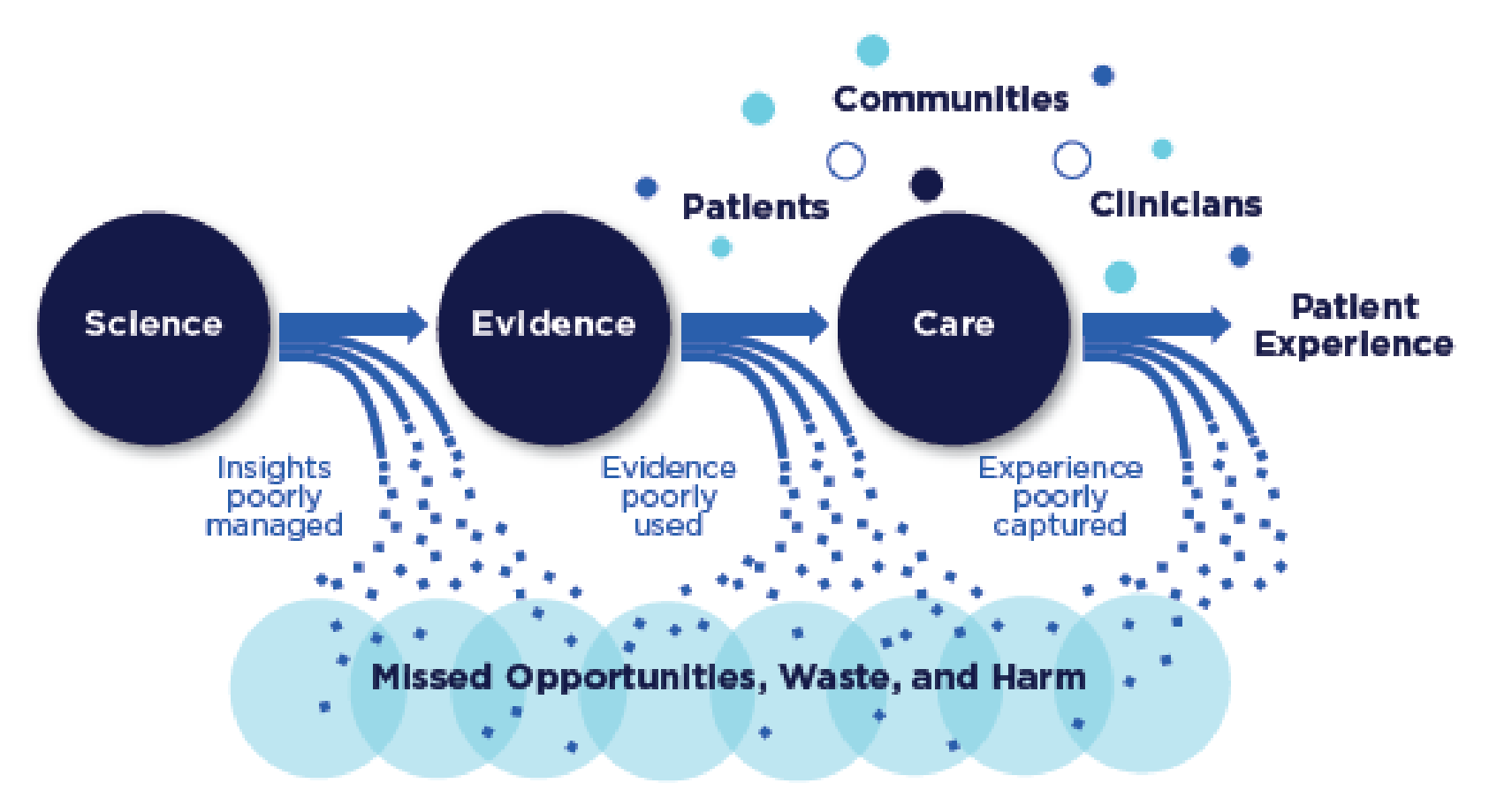
How much blood to transfuse?

Which empiric antibiotic regimen to use?

What are the best ventilator settings?

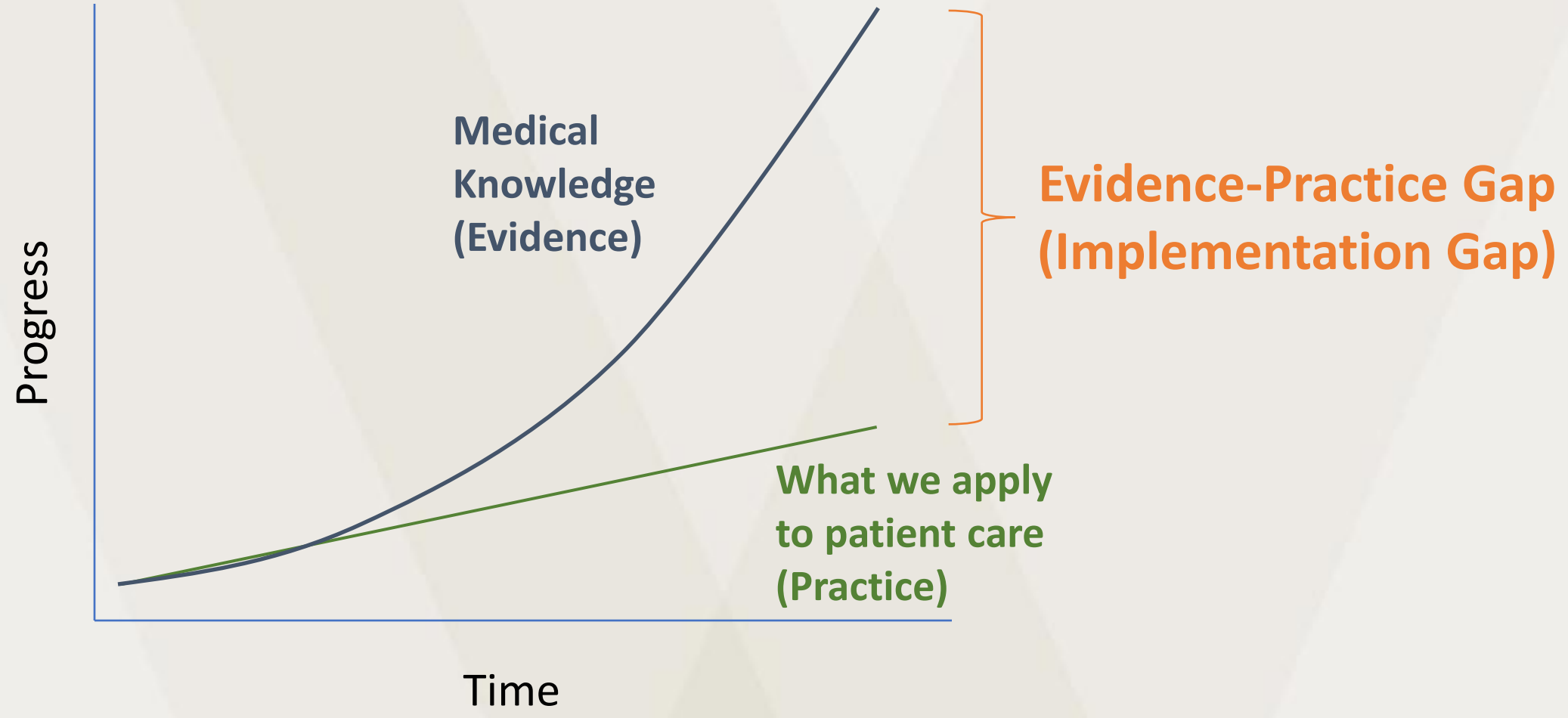
What are early warning signs of decompensation?

Traditional Approach: Separation of Research and Practice, Slow and Leaky Pipeline



Institute of Medicine 2013

Implementation Gap

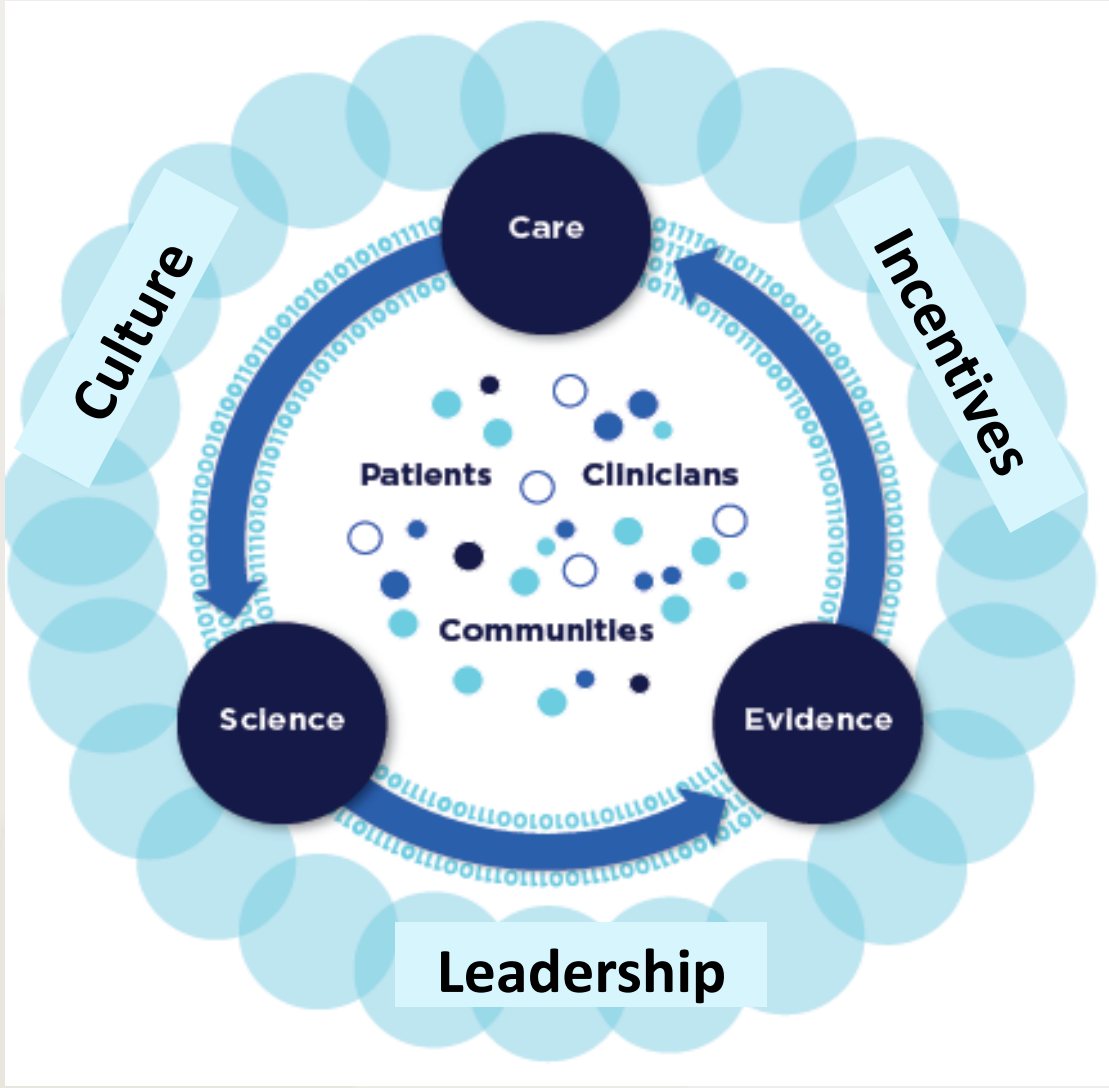


Bloomstone, 2016

Learning Health System

- *National Academy of Medicine*

- “in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity — with best practices and discovery seamlessly embedded in the delivery process, individuals and families as active participants in all elements, and new knowledge generated as an integral by-product of the delivery experience.”

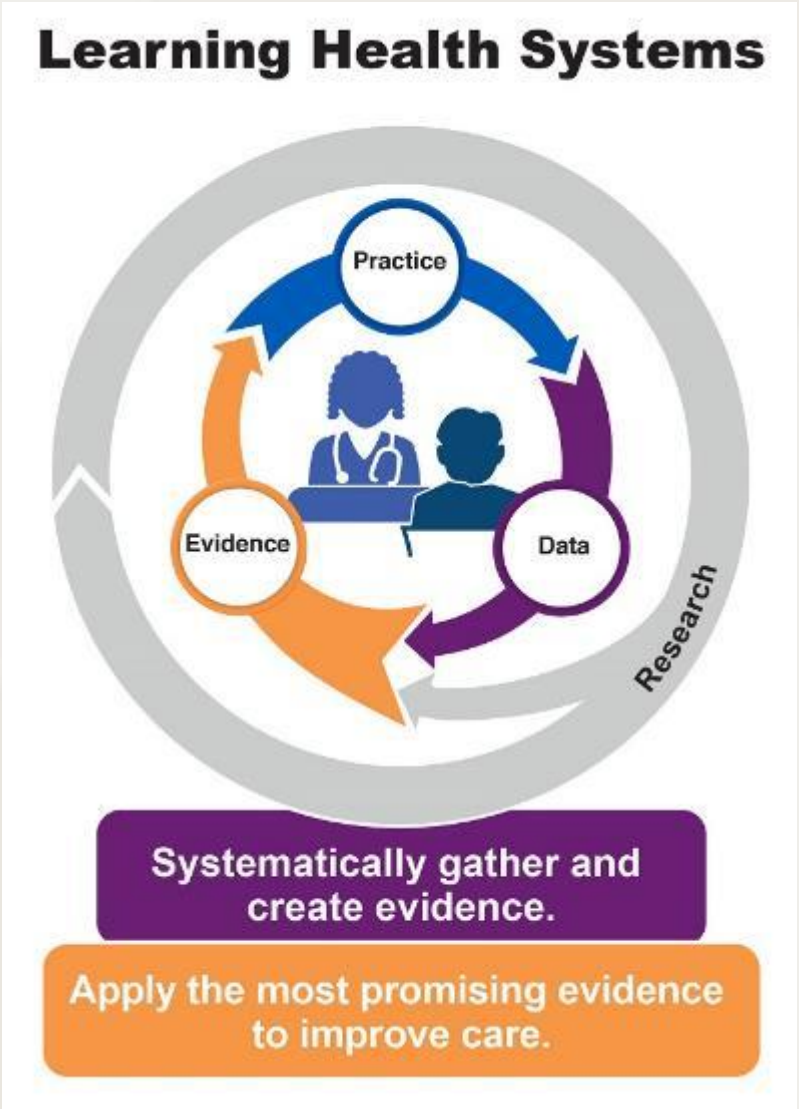


NAM Leadership Consortium: collaboration for a value and science-driven health system https://nam.edu/programs/value-science-driven-health-care/

Learning Health System

- Agency for Healthcare Research and Quality (AHRQ)

"a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice."

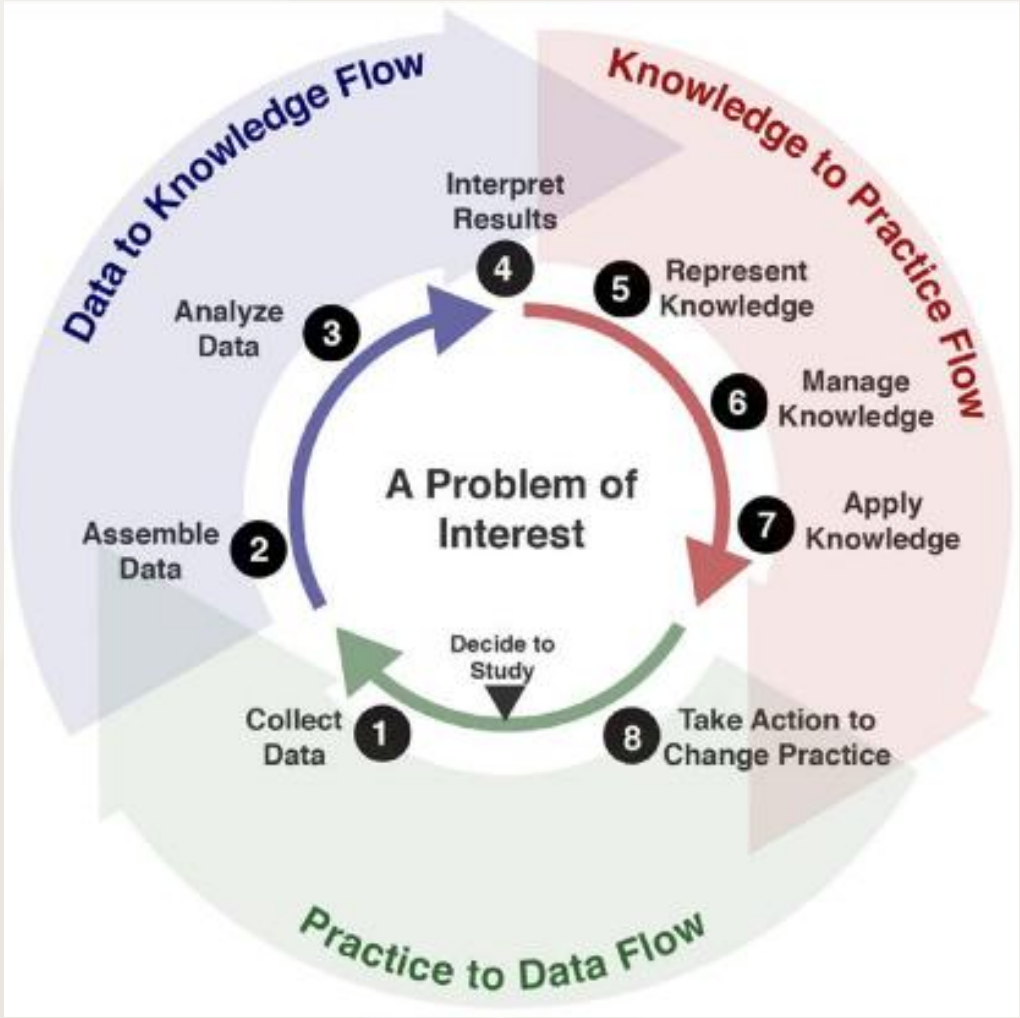


https://www.ahrq.gov/learning-health-systems/about.html

Characteristics of a Learning Health System

- ✓ Characteristics, events, and context are captured as data to learn from
- ✓ Trusted knowledge generated from analysis of the data is rapidly available to support strategies and decisions
- ✓ Improvement is continuous and enduring through ongoing cyclic activity
- ✓ An infrastructure creates a system that enables improvement to occur routinely and with economy of scale
- ✓ All of this is part of the culture

What a Learning Health System **IS**



What Are Basic LHS Capabilities?

1. Ability to gather and integrate data
2. Real-time or rapid data access
3. Tools to analyze data and generate knowledge
4. Design and implement interventions to generate evidence
5. Iterative quality improvement
6. Patient and health system stakeholder engagement
7. Ethics and privacy safeguards
8. Education and training for health care providers
9. Policies and governance to support operations
10. Scalability and sustainability

Learning Objectives

1. Review the promise and major functions of a learning health system.
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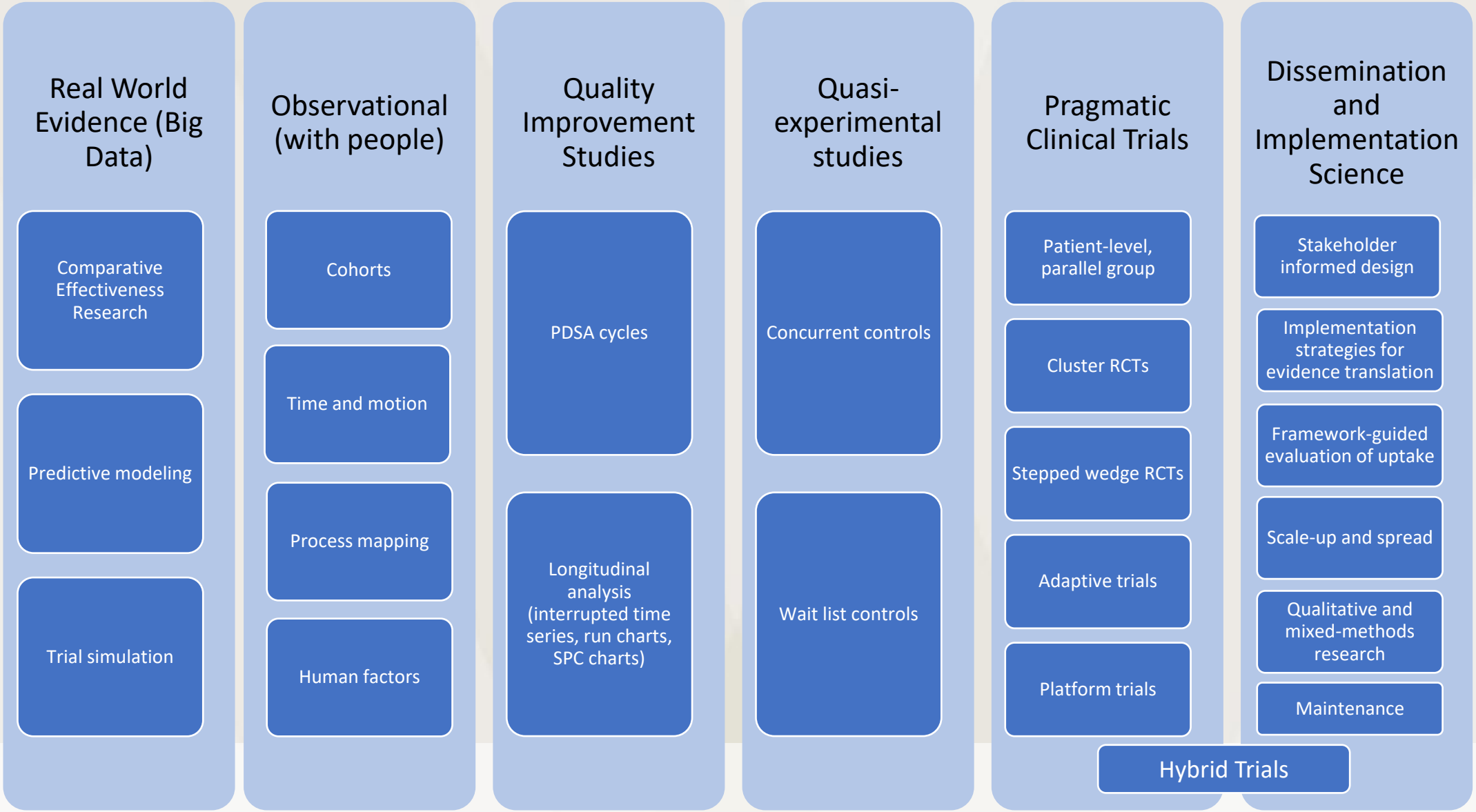
Spectrum of Methods in Learning Health Systems



Improvement Science

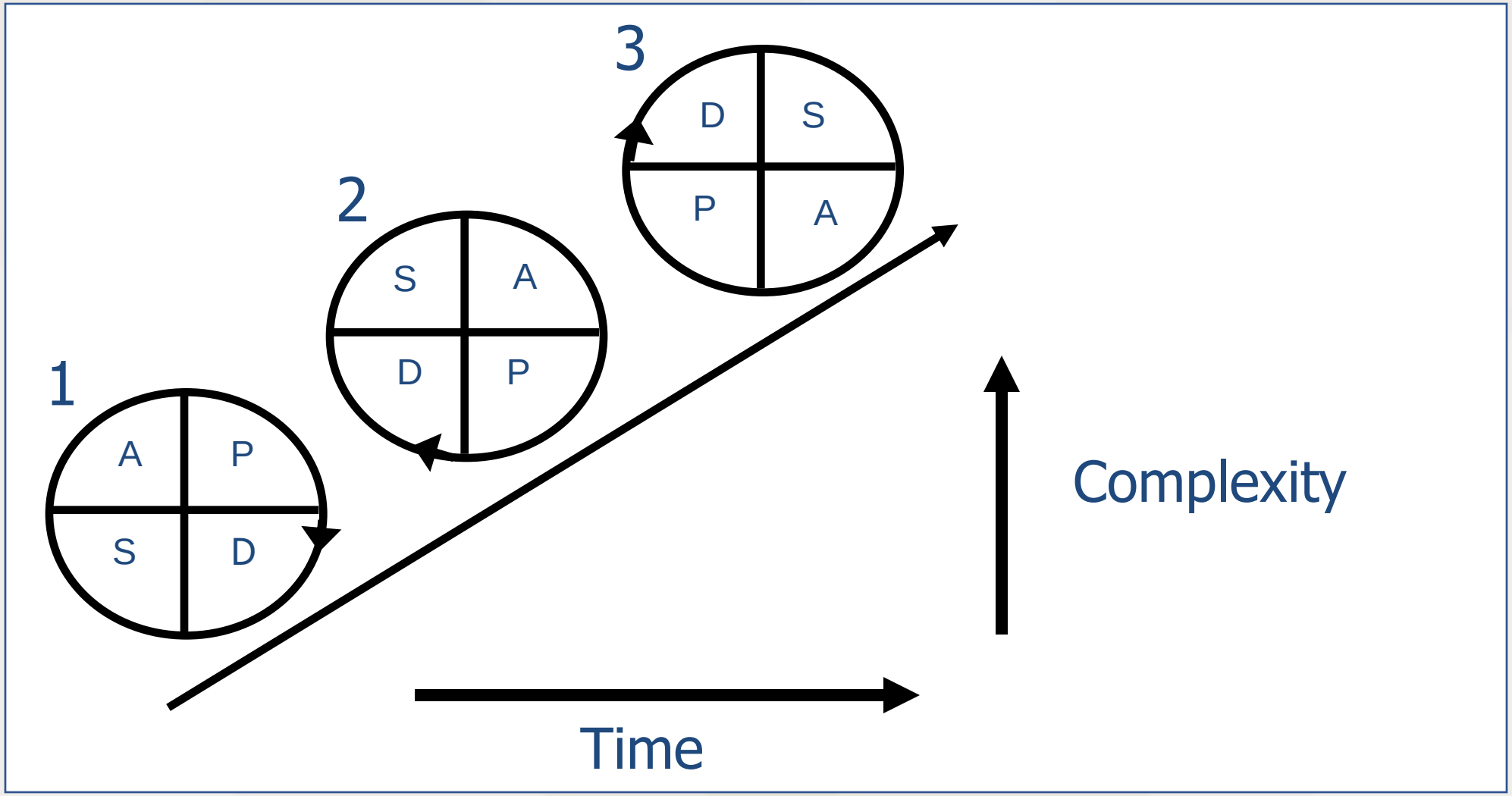
Aims
What are we trying to accomplish?

Measures
How will we know if a change is an improvement?

Process Analysis
What changes can we make that will result in improvement?

PDSA Cycle

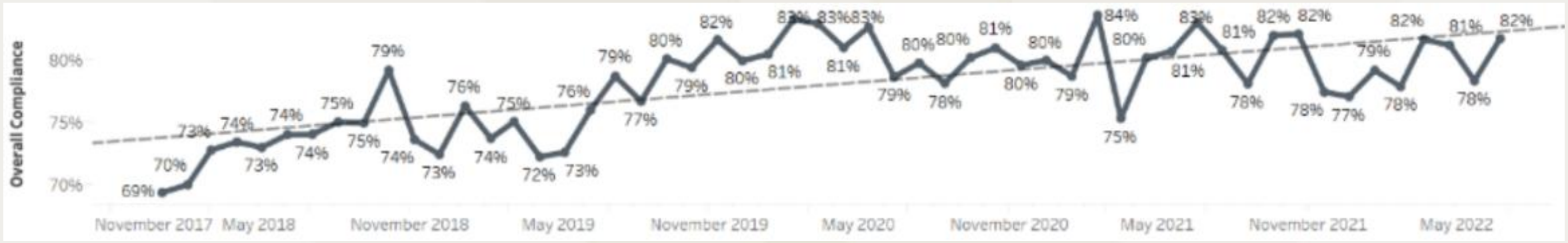
Multiple Small Interventions



Joiner and Nolan

Enhanced Recovery After Surgery (ERAS)

- Multi-component peri-operative care pathway to promote faster recovery
- Implemented at VUMC across 7 surgical lines
- Steering committee, engagement of stakeholders, health IT, pt education
- Continuous quality improvement model
- Colorectal outcomes: ↓ postop complications, ↓ length of stay



VANDERBILT UNIVERSITY MEDICAL CENTER

King AB 2016. Hawkins AT 2019.

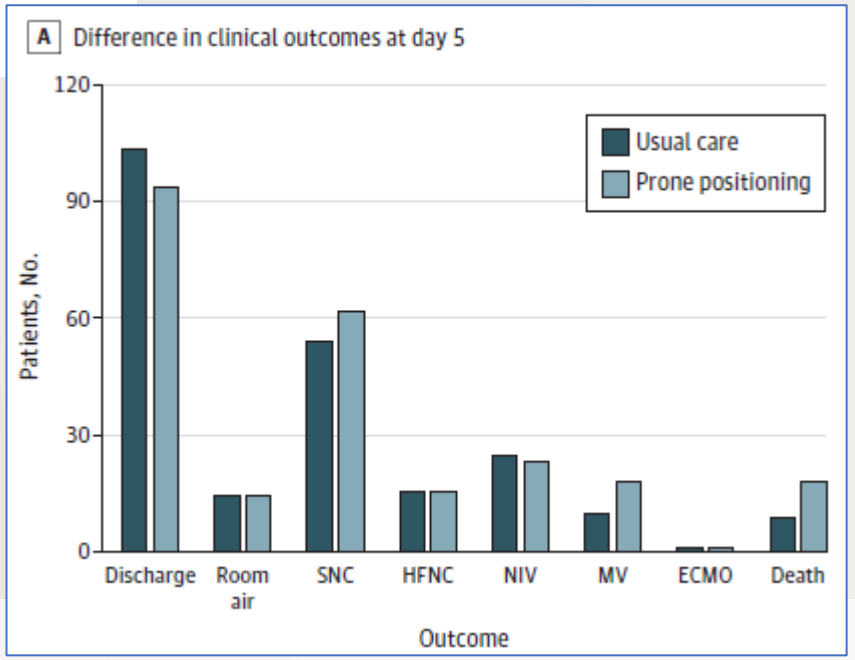
Quasi-Experimental Studies

JAMA Internal Medicine | Original Investigation

Assessment of Awake Prone Positioning in Hospitalized Adults With COVID-19

A Nonrandomized Controlled Trial

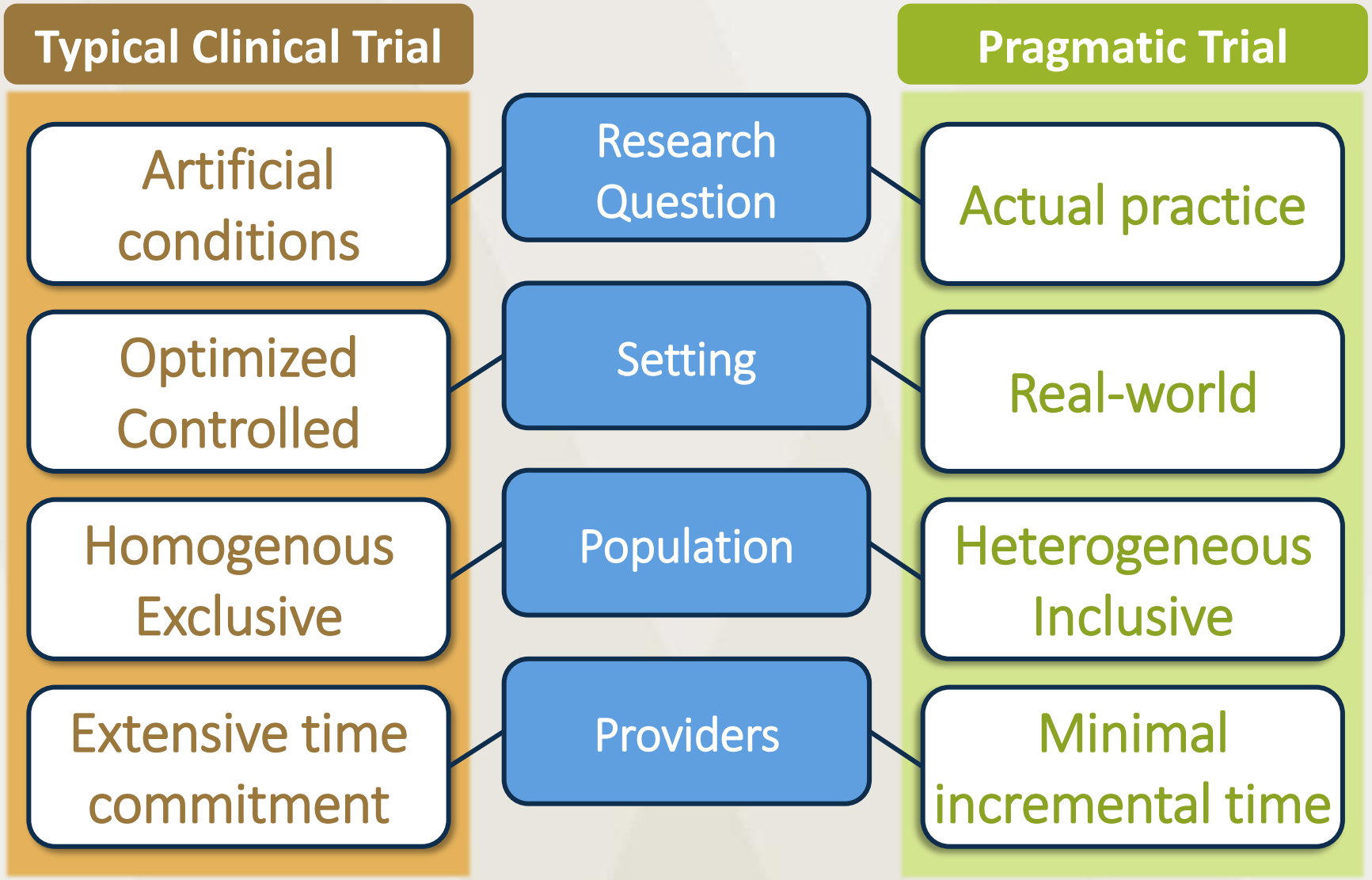
Edward Tang Qian, MD; Cheryl L. Gatto, PhD; Olga Amusina, DNP; Mary Lynn Dear, PhD; William Hiser, BA; Reagan Buie, MHA; Sunil Kripalani, MD; Frank E. Harrell Jr, PhD; Robert E. Freundlich, MD, MS, MSCI; Yue Gao, MS; Wu Gong, MD, MS; Cassandra Hennessy, MS; Jillann Grooms, MSN; Megan Mattingly, MSN; Shashi K. Bellam, MD; Jessica Burke, MD; Arwa Zakaria, DO; Eduard E. Vasilevskis, MD; Frederic T. Billings IV, MD, MSc; Jill M. Pulley, MBA; Gordon R. Bernard, MD; Christopher J. Lindsell, PhD; Todd W. Rice, MD, MSc; for the Vanderbilt Learning Healthcare System Platform Investigators



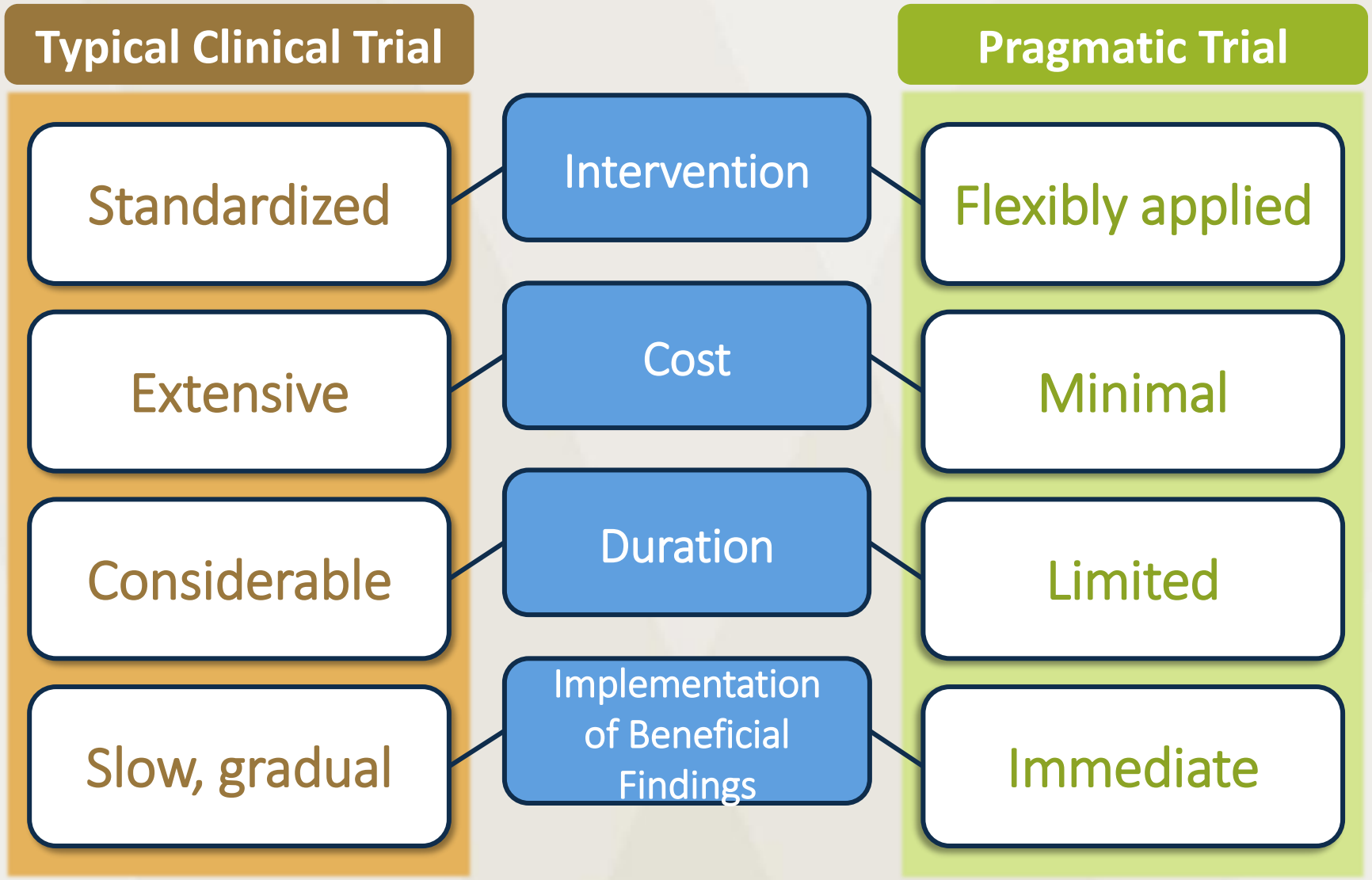
Quasi-randomized controlled trial

- Study assignment by medical record number (odd/even)

Pragmatic Randomized Controlled Trials



Pragmatic Randomized Controlled Trials



LHS Randomized Trial Designs

Pragmatic Clinical Trials

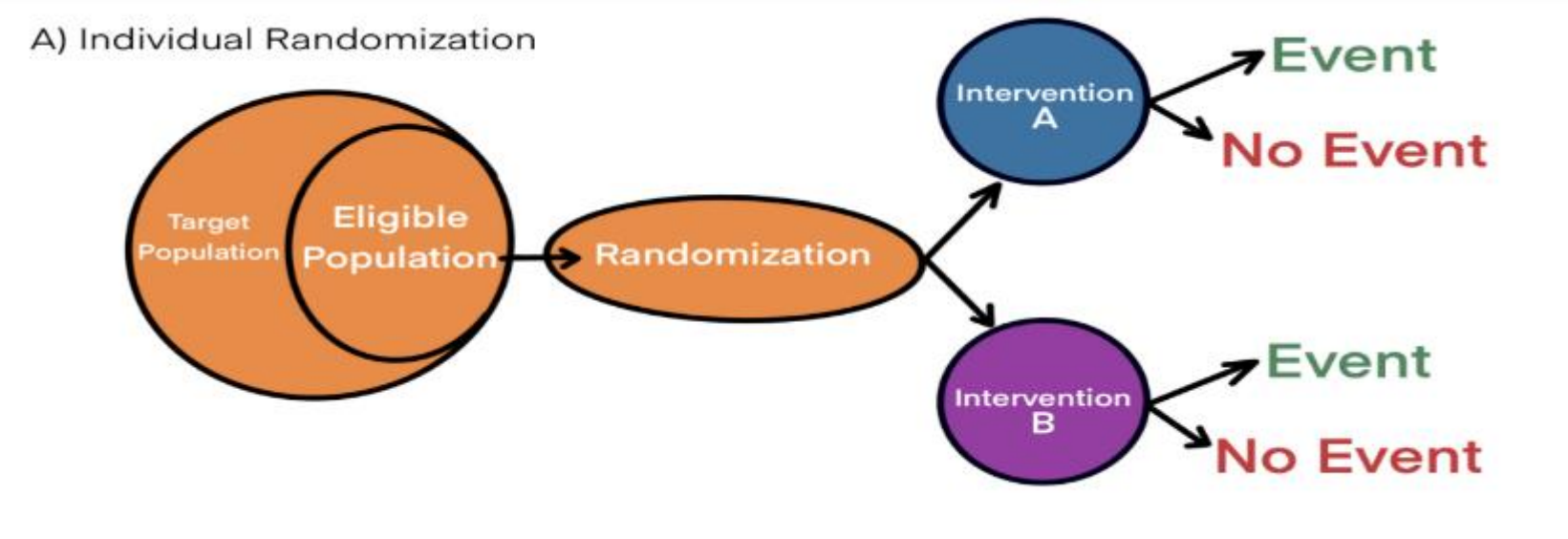
- Patient-level, parallel group
- Cluster RCTs
- Stepped wedge RCTs
- Adaptive trials
- Platform trials

Point of care Studies

Unit of Randomization is the person analyzed

Alert at time of the decision tells you do intervention A or B Provider has patients on both A and B

Outcomes collected based on alert for A or B (ITT)



LHS Randomized Trial Designs

Pragmatic Clinical Trials

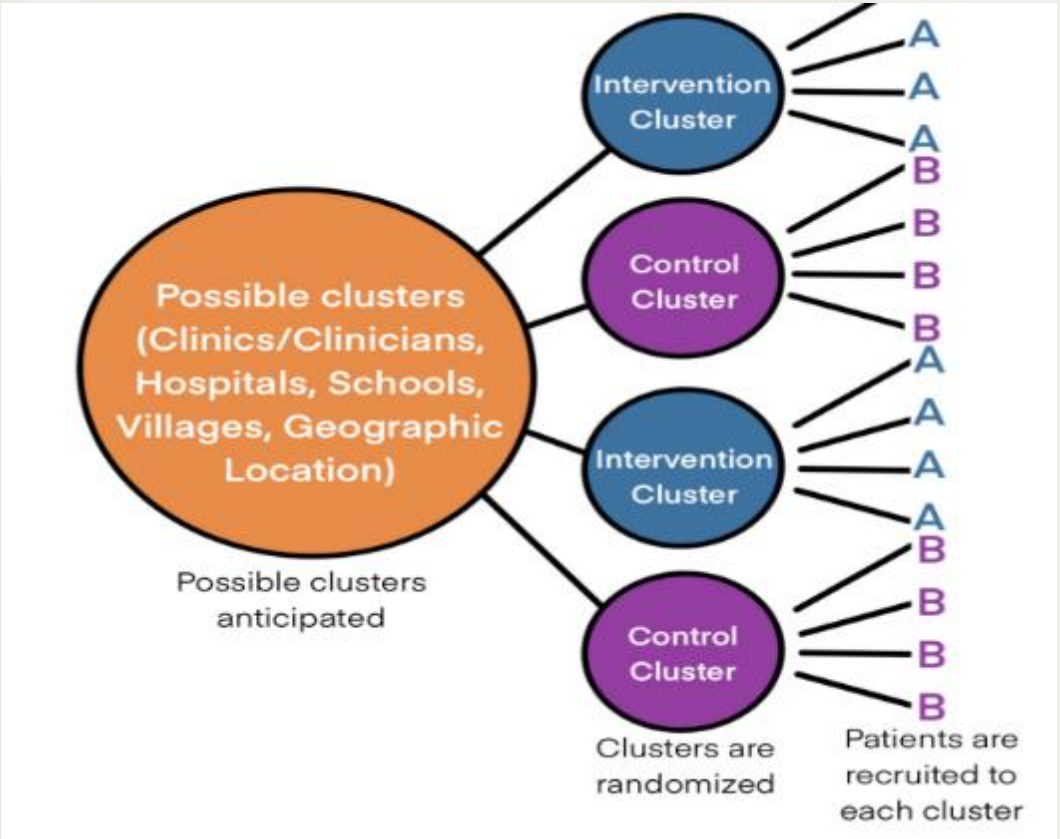
- Patient-level, parallel group
- Cluster RCTs
- Stepped wedge RCTs
- Adaptive trials
- Platform trials

Clinic or Unit studies

Unit of Randomization is a unit that contains many interrelated patients

Each Provider gets intervention A or B
All their patients then follow A or B

Outcomes collected based on Provider assigned as
A or B (ITT)



LHS Randomized Trial Designs

Pragmatic Clinical Trials

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- Cluster RCTs
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- Adaptive trials
- Platform trials

Stepped Wedge

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cluster 1	C	C	I	I	I	I	I	I	I	I	I	I
Cluster 2	C	C	C	C	I	I	I	I	I	I	I	I
Cluster 3	C	C	C	C	C	C	I	I	I	I	I	I
Cluster 4	C	C	C	C	C	C	C	C	I	I	I	I
Cluster 5	C	C	C	C	C	C	C	C	C	C	I	I

Incomplete or Modified Stepped Wedge

	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cluster 1	C	C	I	I	I	I	I	I								
Cluster 2	C	C	C	C	I	I	I	I	I	I						
Cluster 3			C	C	C	C	I	I	I	I	I	I				
Cluster 4					C	C	C	C	I	I	I	I	I	I		
Cluster 5							C	C	C	C	I	I	I	I	I	I

Unit studies ALL become Intervention

Unit of Randomization is a unit randomization is about WHEN

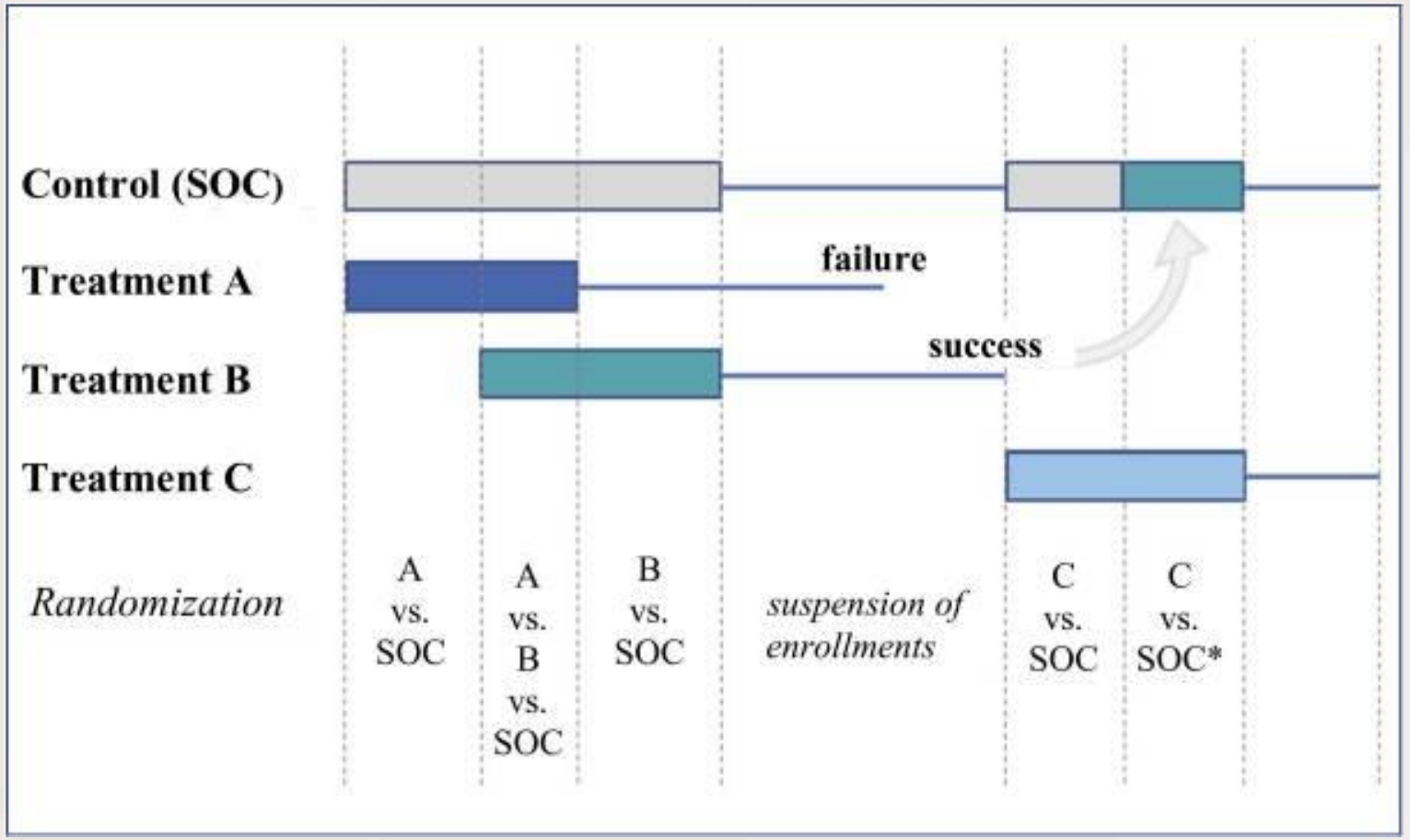
Each Unit eventually gets intervention B; Unit serves as both Control time (A) and Intervention time (B)

Outcomes collected based on Crossover time from A to B (ITT)

LHS Randomized Trial Designs

Pragmatic Clinical Trials

- Patient-level, parallel group
- Cluster RCTs
- Stepped wedge RCTs
- Adaptive trials
- Platform trials



Ability to make scheduled changes based on accumulated data

Change intervention, dose, population or introducing arms
Unit is typically person analyzed

Randomized to A vs B
B stops then next patients randomized to C

Outcomes collected based on Arm you are randomized to

JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Cefepime vs Piperacillin-Tazobactam in Adults Hospitalized With Acute Infection

The ACORN Randomized Clinical Trial

Edward T. Qian, MD, MSc; Jonathan D. Casey, MD, MSc; Adam Wright, PhD; Li Wang, MS; Matthew S. Shotwell, PhD; Justin K. Siemann, PhD; Mary Lynn Dear, PhD; Joanna L. Stollings, PharmD; Brad D. Lloyd, RRT-ACCS; Tanya K. Marvi, MD; Kevin P. Seitz, MD, MSc; George E. Nelson, MD; Patty W. Wright, MD; Edward D. Siew, MD, MSc; Bradley M. Dennis, MD; Jesse O. Wrenn, MD, PhD; Jonathan W. Andereck, MD, MBA; Jin H. Han, MD, MSc; Wesley H. Self, MD, MPH; Matthew W. Semler, MD, MSc; Todd W. Rice, MD, MSc; for the Vanderbilt Center for Learning Healthcare and the Pragmatic Critical Care Research Group

QUESTION Does the choice between cefepime and piperacillin-tazobactam affect the risks of acute kidney injury or neurological dysfunction in adults hospitalized with acute infection?

CONCLUSION Among hospitalized adults, the risk of acute kidney injury did not differ between cefepime and piperacillin-tazobactam, but neurological dysfunction was more common with cefepime.

POPULATION

1439 Men 1071 Women

Adults hospitalized with acute infection

Median age: 58 years

LOCATION

1 Medical center in Nashville, Tennessee

INTERVENTION

2634 Patients randomized
2511 Patients analyzed

1214 **Cefepime**
Administered as an intravenous push over 5 minutes

1297 **Piperacillin-tazobactam**
Administered as a bolus for the initial administration and then extended infusion over 4 hours for subsequent doses

PRIMARY OUTCOME

Highest stage of acute kidney injury or death by day 14 (measured on a 5-level ordinal scale; range: no acute kidney injury to death)

FINDINGS

Highest stage of acute kidney injury or death by day 14

Cefepime

Survived with stage 3 acute kidney injury	7.0% (85 of 1214 patients)
Died	7.6% (92 of 1214 patients)

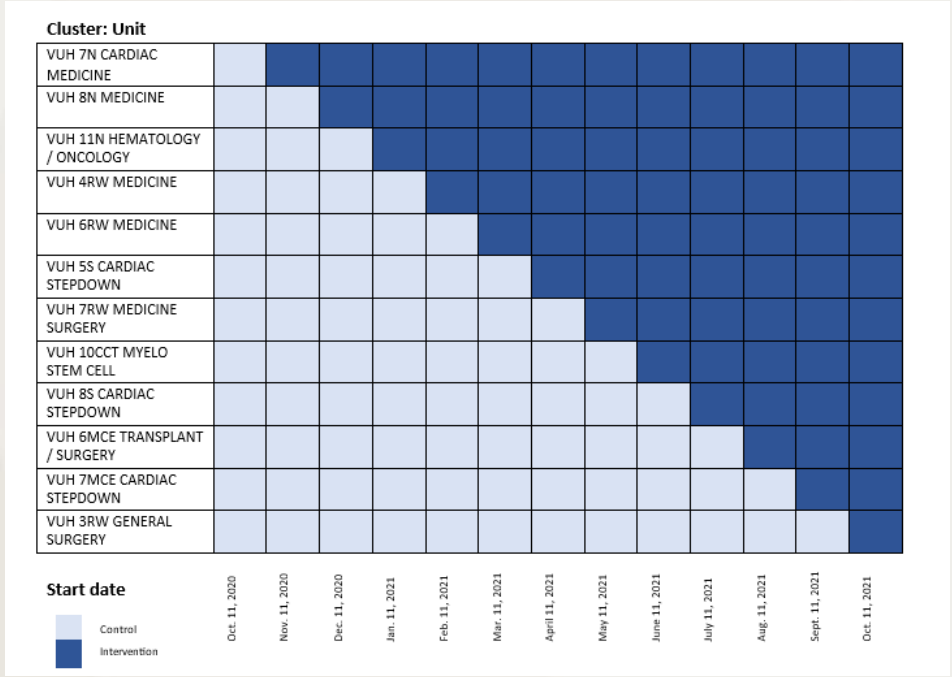
Piperacillin-tazobactam

Survived with stage 3 acute kidney injury	7.5% (97 of 1297 patients)
Died	6.0% (78 of 1297 patients)

There was no significant between-group difference:
Odds ratio, 0.95 (95% CI, 0.80 to 1.13); $P = .56$

PROPEL: Pragmatic Removal of Penicillin Electronic Health Record Labels

- Examined the safety, effectiveness, and impact of a single dose oral amoxicillin challenge as a testing strategy to remove low-risk penicillin allergy labels
- Stepped-wedge RCT
- 1018 patients exposed to intervention, 1034 control
- Delabeled PCN allergy: 4.4% vs. 3.0%, p<0.05

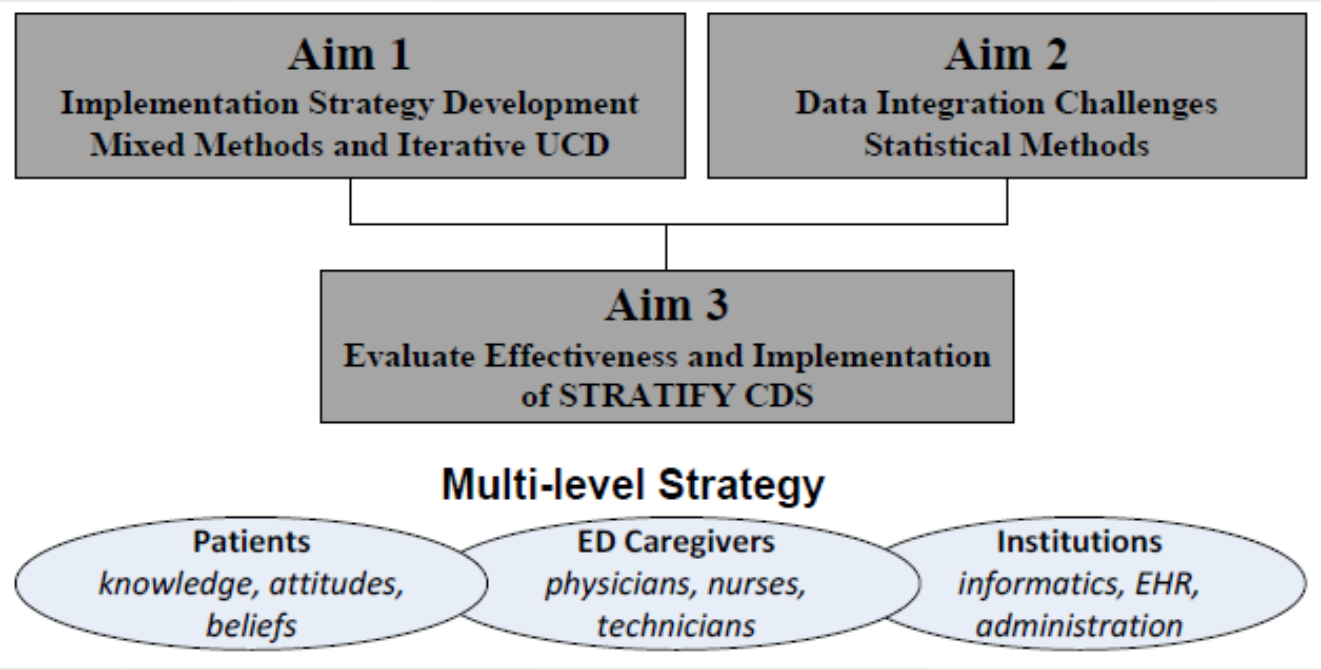


Stone CA (under review)

stratify
ED Heart Failure

Multi-center Implementation Trial of STRATIFY Decision Support Tool

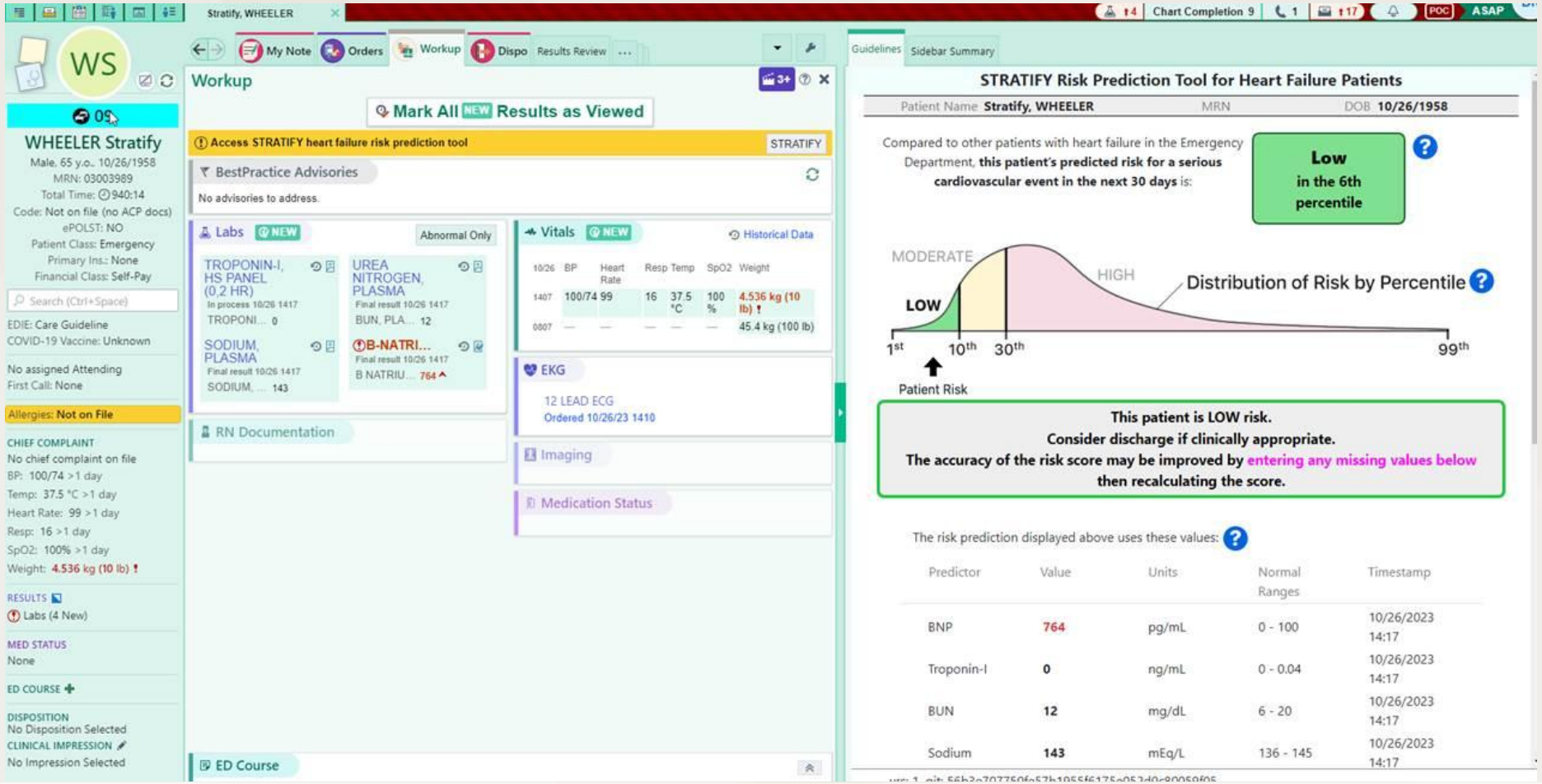
- 80-90% of patients in the ED with heart failure are admitted to the hospital
- Validated prediction model to identify low-risk patients
- 10-site study
- Aims to curb hospitalizations for heart failure



VANDERBILT UNIVERSITY MEDICAL CENTER

Funded by R01 HL157596 (Storrow, Liu, Kripalani)

STRATIFY CDS tool brings validated risk stratification score into clinical workflow



VANDERBILT UNIVERSITY MEDICAL CENTER

Funded by R01 HL157596 (Storrow, Liu, Kripalani)

Multi-level implementation strategies

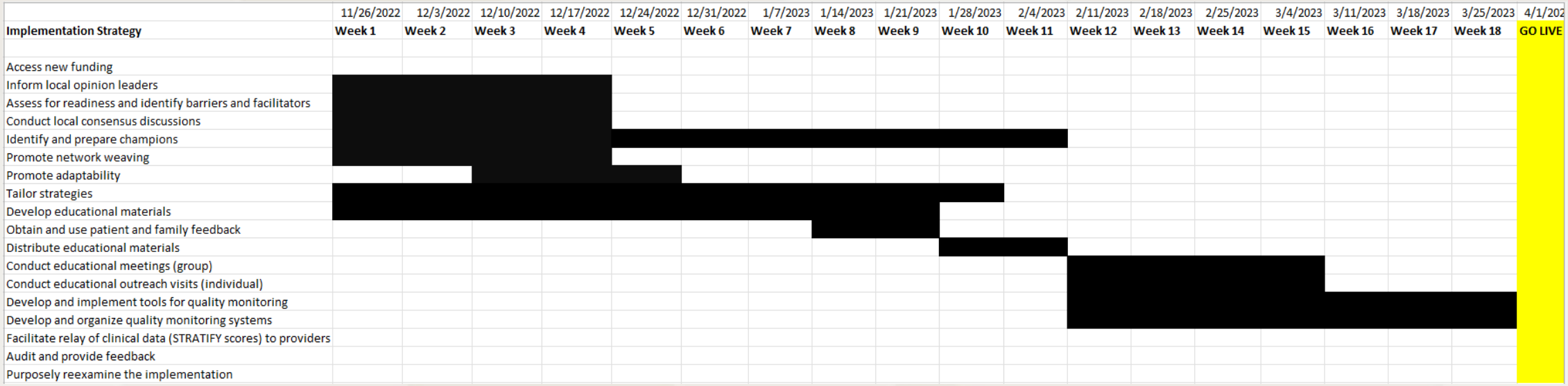
Pre-Implementation Phase

- Engage stakeholders
  - Inform local opinion leaders
  - Conduct local consensus discussions
  - Identify and prepare champions
  - Promote network weaving
- Site visits
  - Identify barriers and facilitators
  - Promote adaptability
  - Tailor strategies
- Develop educational materials
  - Obtain and use patient and family feedback
  - Conduct educational meetings (group and individual)

Implementation Phase

- Develop and implement tools for quality monitoring
  - Primary, secondary, and balancing measures
- Facilitate relay of clinical data (STRATIFY scores) to providers
  - Clinical decision support with user centered design
- Purposely re-examine implementation
- Audit and provide feedback

Details of each implementation strategy are timed and specified

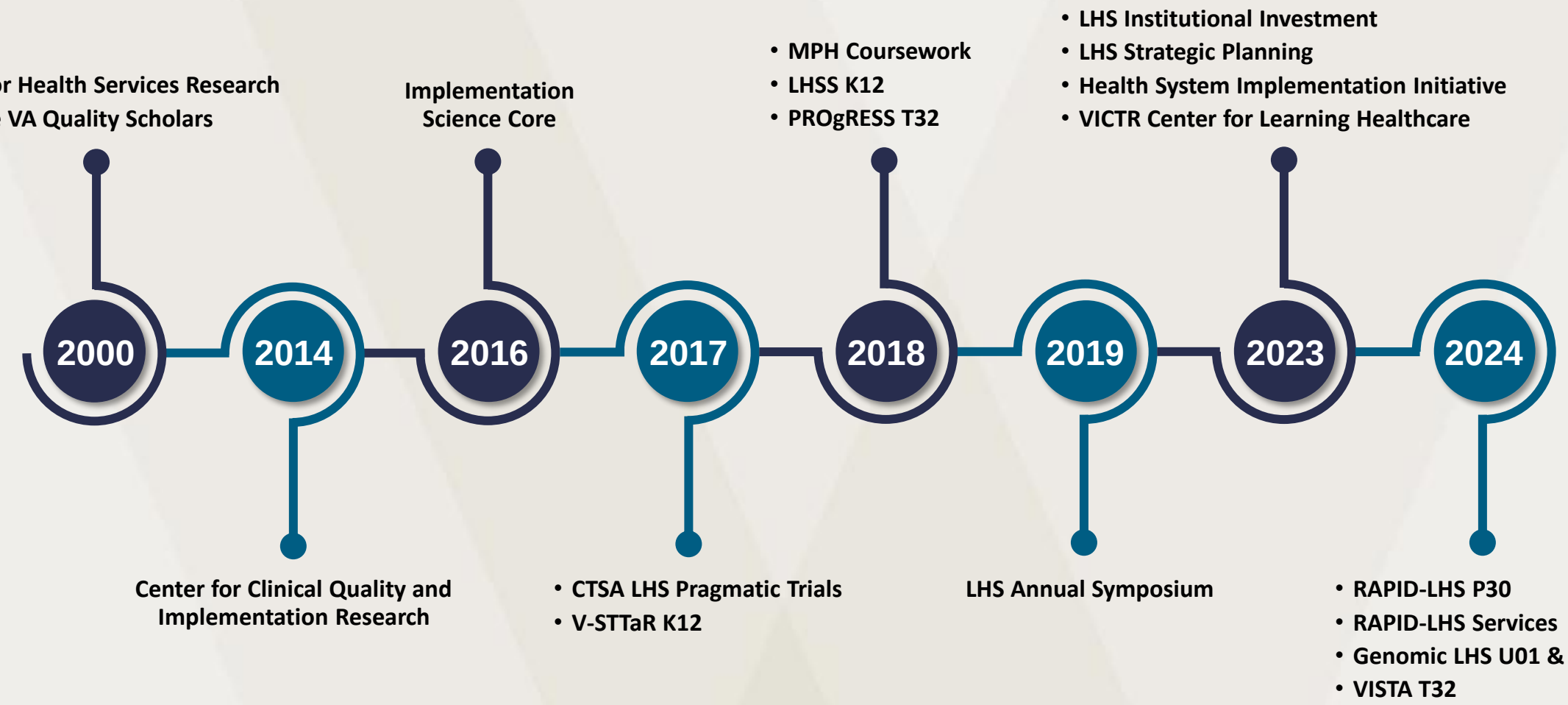


Implementation Strategy	Definition	Specification of Strategy					Mechanism/Justification	Implementation Outcome Affected	Time Frame
		Actor	Action	Action Target	Temporality	Dose			
Identify and prepare champions	Identify and prepare individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization	Site PIs; Storrow, Kripalani, Stolldorf	Site PIs identify champions; Storrow, Kripalani, and Stolldorf provide 2-hour webinar training (walkthrough of CDS, calculations, integration into workflow, planned monitoring, how to describe)	Clinicians, nurses	Pre-implementation, end of design phase, before study launch	Once for each site	Providing centralized training to site champions who will then lead education at each site provides some consistency while also engaging local assets	Reach, adoption	~one month before go-live

Learning Objectives

1. Review the promise and major functions of a learning health system.
2. Provide examples of research embedded in clinical operations at VUMC.
3. Discuss key infrastructure components bridging academic and operational programs at VUMC.

Building a Learning Health System



Center for Health Services Research (2000–)

>200

Supports more than 200 faculty and trainees

>1800

Over 1800 peer-reviewed publications annually related to HSR

~$230 M

Faculty PIs on ~$230 million in annual awarded funding

(NIH, PCORI, AHRQ, CMS, CDC, Industry)

50 K

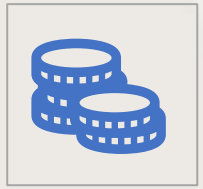
More than 50,000 square feet shared space

3 CORES

- Implementation/ Quality Improvement
- Qualitative Research
- Health Communication

ENGAGES 4 VUMC/VU SCHOOLS AND 14 VUMC DEPARTMENTS

Center for Clinical Quality and Implementation Research (2014–)


- Academic home for improvement and implementation sciences
- 40+ affiliated faculty
- $50M+ annual awarded grants
- Vanderbilt Quality Improvement and Implementation Core (2016–)

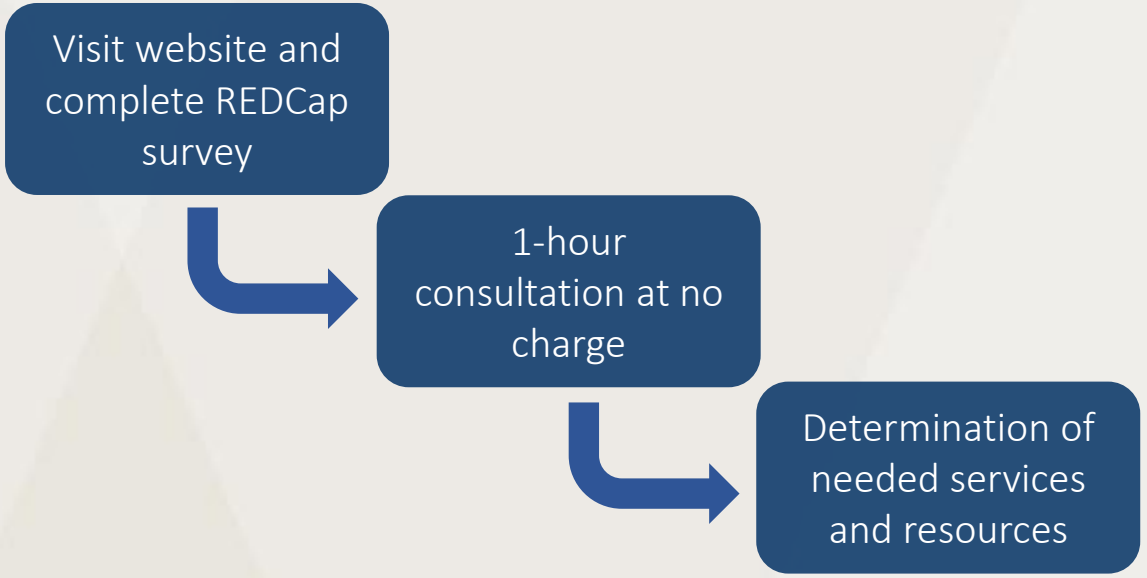
- Centralized support for training
  - Faculty career development
    - V-STTaR K12, LHSS K12, RAPID-LHS P30
  - Postdoctoral
    - VA Quality Scholars, PROgRESS T32, VISTA T32
- Weekly Seminar Series
- MPH coursework

Vanderbilt Implementation and Quality Improvement (VIQI) Core

Consultative Services

- ☑ Implementation science: theories and frameworks, barriers/facilitators, strategies, outcomes
- ☑ Improvement science: QI frameworks and tools
- ☑ Study design (hybrid designs, quasi-experimental and pragmatic clinical trials)
- ☑ Selection of appropriate measures and metrics
- ☑ Mixed methods program evaluation
- ☑ Systems-level process change
- ☑ Data visualization
- ☑ Grant and manuscript preparation

VIQI Request



vumc.org/implementation/VIQIcore

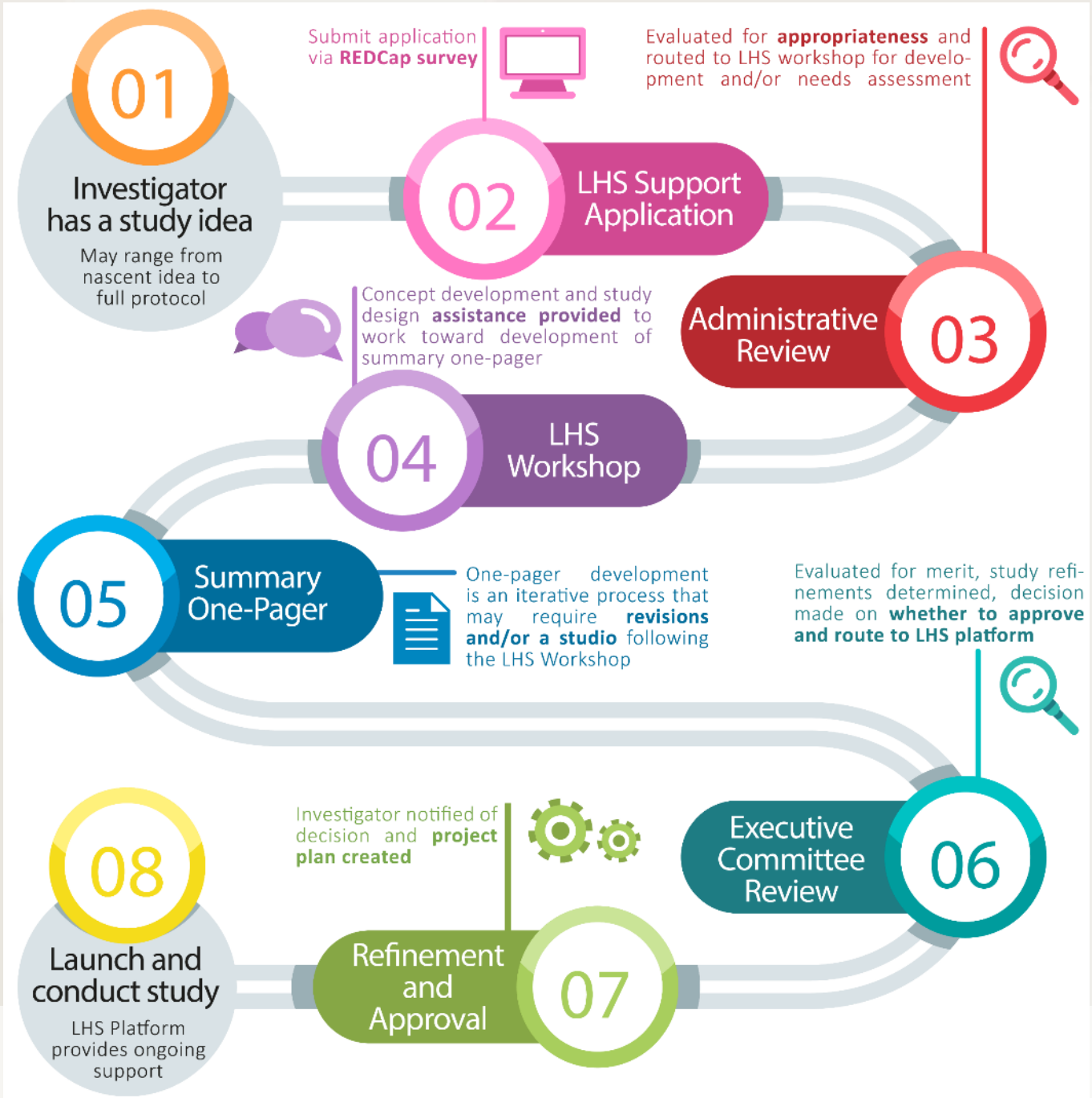
redcap.link/VIQIcoreRequest

VIQI Core Director: Amanda Mixon, MD, MS, MSPH

VICTR Learning Healthcare (2017–)

Platform for Pragmatic Randomized Controlled Trials

Center for Learning Healthcare (2023–)

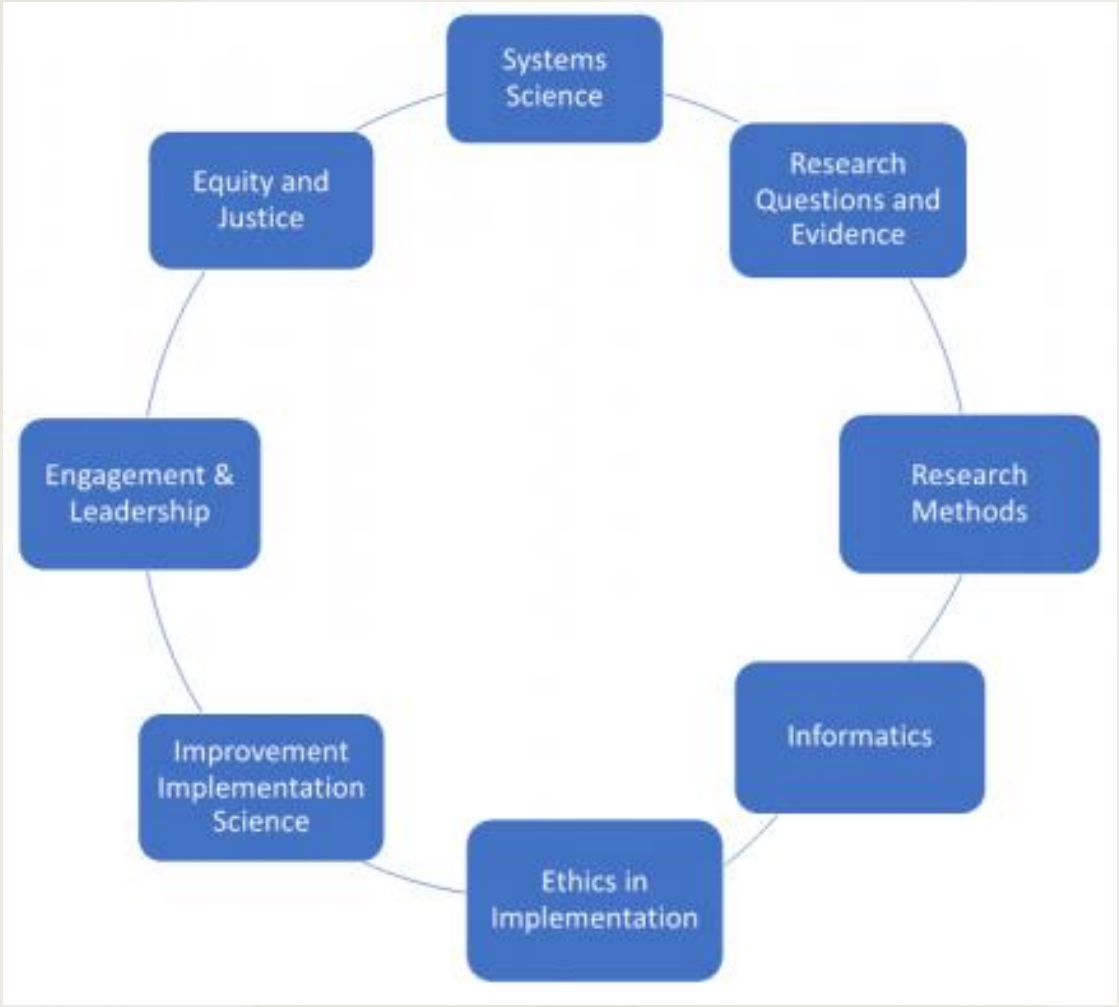


Education & Training Programs

Supporting CHSR Programs

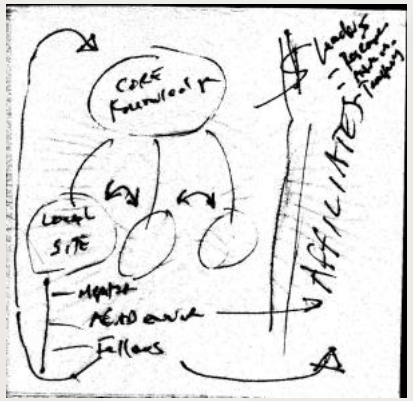
- Work In Progress Seminar Series
- Implementation Science Scholarly Series
- HSR/LHS Methods Seminars
- Peer Grant Reviews in Implementation Research
- Learning Health Systems Symposium

Learning Health System Science Competencies



https://www.ahrq.gov/learning-health-systems/building-workforce.html

VA Quality Scholars (2000-)



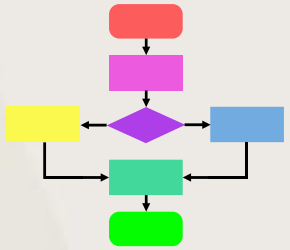
- Funded by Veterans Affairs health system
- Director: Robert Dittus; Deputy Director: Christianne Roumie
- Supports 2-3 postdoctoral fellows per year
- 2-3 year program in HSR, improvement/implementation sciences, leadership
- Multidisciplinary scholars (medicine, nursing, psychology)
- VA-based clinical work

Quality Academy (2016–)

- 11-month, in-person course, designed for clinical or administrative leaders
- Monthly didactic sessions (4 hrs each) – comprehensive overview of QI
- Conceptualize, design, and lead a mentored QI project
- Began in 2016, based at Monroe Carrell Jr. Children's Hospital
- Now open application process – due Feb 28

Application Link and QR code:

https://redcap.link/QualityAcademy2025Application



EQIC

Essentials in Quality Improvement Certificate

(2024–)

Didactic pre-work, asynchronous

(20-45 min)

Institute for Healthcare Improvement (IHI) Modules

Didactic teaching, live-virtual - 9 sessions

(1 hr)

- History of quality improvement (QI) and evidence-based practice (EBP)
- Literature review for EBP and Model of Improvement
- Process analysis and QI Tools
- Metrics, types, selection; Understanding variation
- Run charts, histogram, Pareto charts, control charts
- PDSA testing and change concepts
- Leading through change management
- Spreading and scaling projects
- Project presentation by participants

Optional 30-min office hours after each live session

Learning/skills practice, self-directed

(30-60 min)

Work-related QI project

PROgRESS T32 (2018-)

Patient/ pRactice Outcomes Research in Effectiveness and Systems Science

- Funded by Agency for Healthcare Research and Quality (AHRQ)
- MPIs: Christianne Roumie, Carlos Grijalva
- Supports 3-4 postdoctoral fellows per year
- 2-3 year program in patient-centered outcomes research, implementation science, health policy and community health

VISTA (2024–)

Vanderbilt **I**nterdisciplinary Hospital-based
Systems of Care T32 Research **T**raining prog**r**A**m**

- Funded by NIH/NHLBI
- MPIs: Michael Ward, Alan Storrow, Sunil Kripalani
- Supports 2-3 postdoctoral fellows per year
- 2 years of mentored research training in HSR and learning health systems
- Hospital-based care of heart, lung, blood, or sleep disorders
- Anchored in Emergency Medicine and Hospital Medicine

Learning Health System Symposium (2019–)

110 attendees

35 departments

29 posters

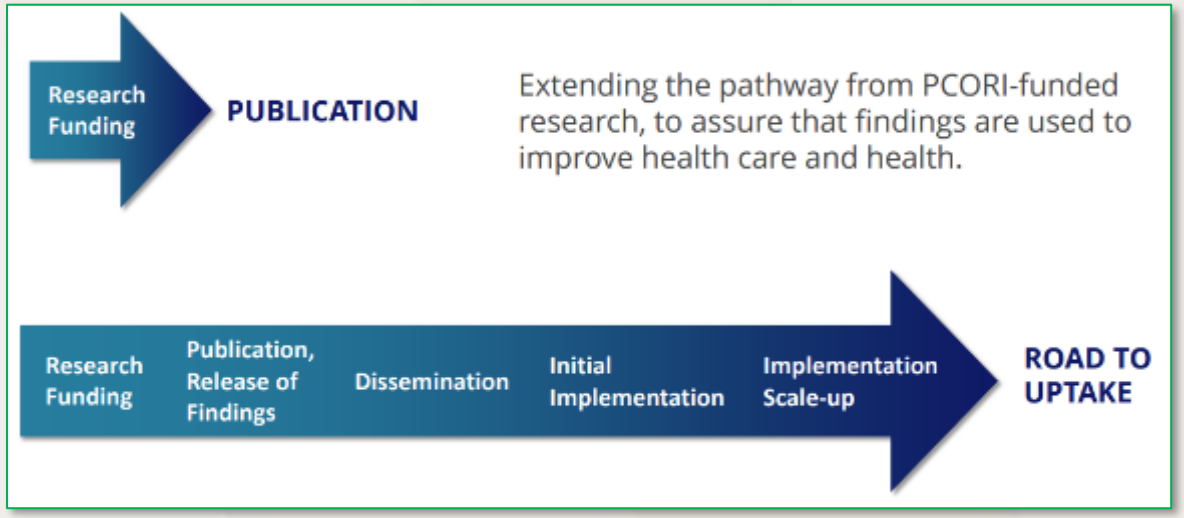
Poster Award Winners

- **Cristin Fritz, MD, MPH** "Evaluating a Novel Mobile Health Intervention for Food Insecurity"
- **Joseph Starnes, MD, MPH** "Effect of Pulse Oximetry Screening for Critical Congenital Heart Disease: A National Policy Evaluation"
- **Kevin Seitz, MD** "Effect of Ventilator Mode on Ventilator-free Days in Critically Ill Adults: A Randomized Clinical Trial"

Operational Partner Award

Cathy Ivory, PhD, NI-BC, NEA-BC, FAAN

PCORI Health Systems Implementation Initiative (2023–)



MPIs: Sunil Kripalani, Jenny Slayton

Capacity Building Projects

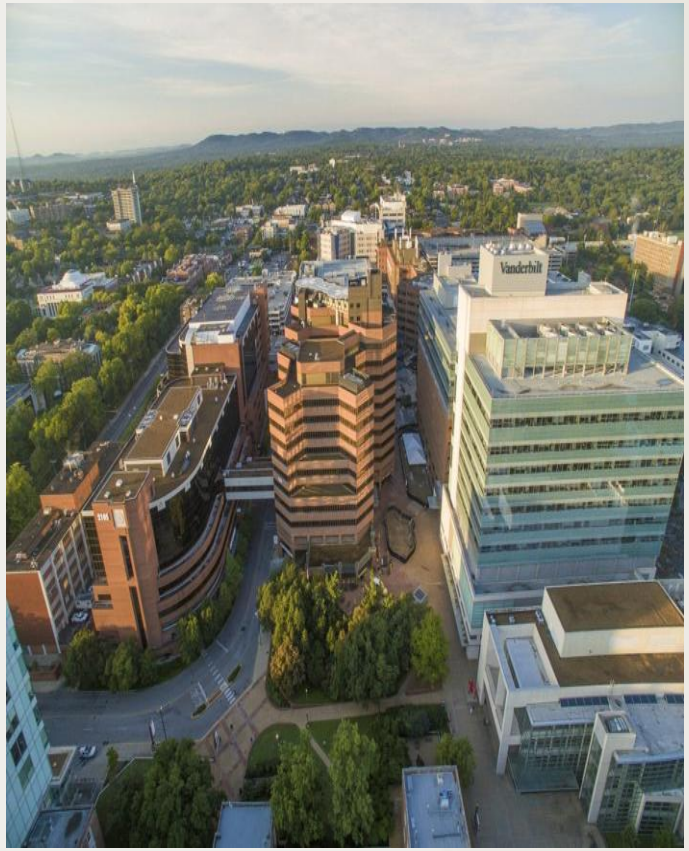
- Improvement Methods Training
  - EQIC
- Implementation Strategies
- IT Data Integration and Training

Implementation Project #1

Appropriate Antibiotic Prescribing for Children with Acute Respiratory Tract Infections (ARTIs)

Leads: Sophie Katz and Ritu Banerjee

LHS Needs Assessment and Strategic Planning (2023)

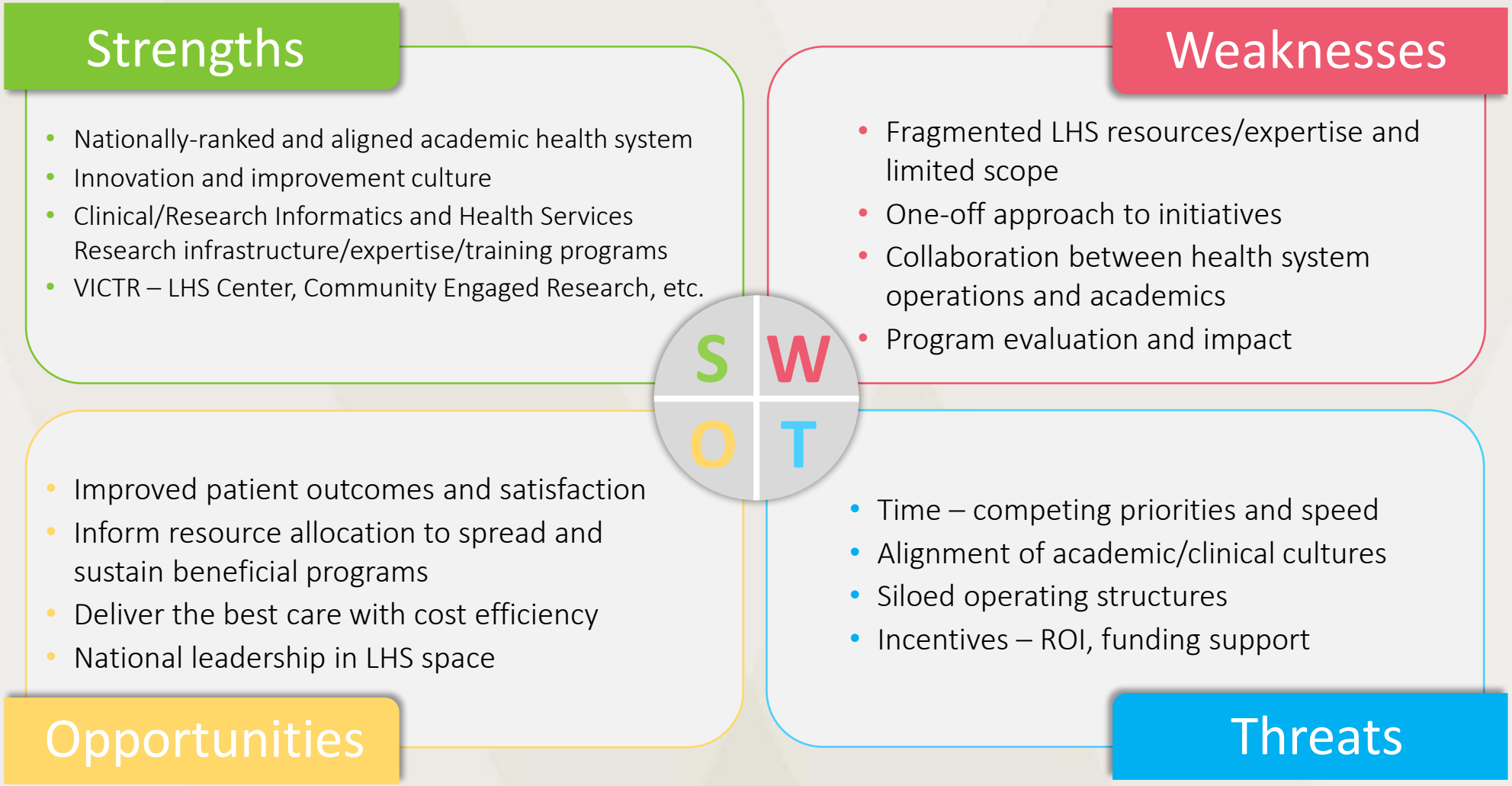


- Conducted interviews with VUMC leaders (Fall 2023)
- Asked participants to identify:
  - Key gaps / opportunities related to LHS activities
  - Needs or services desired related to LHS
  - Ideas for specific projects that could be conducted
- Strategic planning workshop (Dec 2023)

LHS Needs Assessment: Desired Capabilities

- Place to bring projects to get feedback/consultation/support on
  - Project design
  - Strategies for implementing practice change
  - Selection of leading and lagging measures, data sources, informatics
  - Evaluation techniques balancing rigor, feasibility, and timeliness
  - Ability to dial in subject matter expertise
- Rapid: within 3-12 months
- Mechanisms to
  - Prioritize potential projects for patient/system benefit
  - Disseminate innovations

SWOT Analysis of LHS at VUMC



RAPID-LHS (2024–)

Realizing Accelerated Progress, Investigation, Implementation, and Dissemination in Learning Health Systems

Christianne Roumie, MD, MPH | Sunil Kripalani, MD, MSc
Peter Embí, MD, MS | Russell Rothman, MD, MPP

Supported by:
P30 HS029767 AHRQ/PCORI
Center for Health Services Research
Institute for Medicine and Public Health

1. Support and train faculty as operational or academic scholars in LHS.
2. Support core services to assist health system and scholar projects.
3. Provide consultation and collaboration services for health system and academic initiatives.

RAPID-LHS Consult Services

1 IDEA

Challenge or opportunity recognized by academic or health system leader

2 REQUEST

Complete RAPID-LHS Intake Form

3 REVIEW

RAPID-LHS Services administrative review of Intake Form

4 WORKSHOP

Meet with tailored group of academic experts for discussion of design, implementation, evaluation, or dissemination

5 ADVICE

Identification of next steps for project team and referral to research cores and health system resources

6 FOLLOW-UP

Additional workshops or guidance as needed by project lead

RAPID-LHS Consultation Workshops

Key features

- Focus on the intersection of health system priorities and academic resources
- Held at two regular times a month on different days/times
- Standing roster of Academic Experts and Ad-hoc list to meet specific project needs
- Dedicated project manager
- Intake form and participant list is circulated to attendees in advance
- AI-generated discussion summary

LHS Methods
Implementation Science
Clinical Informatics
Biostatistics
Quasi-experimental
Quality Improvement
Health Services Research
Clinical Trials
Partner Engagement
Health Equity

Patient Centered Outcomes
Patient Experience
Population Health
Digital Health Interventions
Qualitative Methods
Surgical Sciences Research
Evidence-based Practice
Artificial Intelligence
Pediatric Health Services Research
Ethics

RAPID-LHS Collaboration Services

1 IDENTIFY

RAPID-LHS Leadership identifies health system initiatives that could benefit from an operational/academic partnership

2 PRIORITIZE

RAPID-LHS Review Panel discusses and prioritizes projects

3 WORKSHOP

Initial Consultation with academic experts to identify specific needs and opportunities for collaboration

4 DEVELOP

Identification of deliverable(s), project team, and development of a project plan

5 SUPPORT

Ongoing collaboration between RAPID-LHS and project team to meet deliverables

6 DISSEMINATE

Collaborate with project teams on publications and executive summaries

Considerations for Prioritizing Collaboration Projects

R

Relevant

to health system priorities

A

Aligned

with academic interests and opportunities

P

Patron

supported by health system sponsor or workgroup

I

Impactful

to quality, safety, value, equity for many patients or the health system

D

Duration

feasible to accomplish in a rapid timeframe

RAPID-LHS Services to Date

An academic and health system partnership to support health system initiatives and investigator-initiated studies by applying rigorous methods to integrate evidence-based practices into patient care delivery and evaluate their impact.

vumc.org/hsr/RAPID-LHS-Services

11 Months (Feb – Dec 2024)

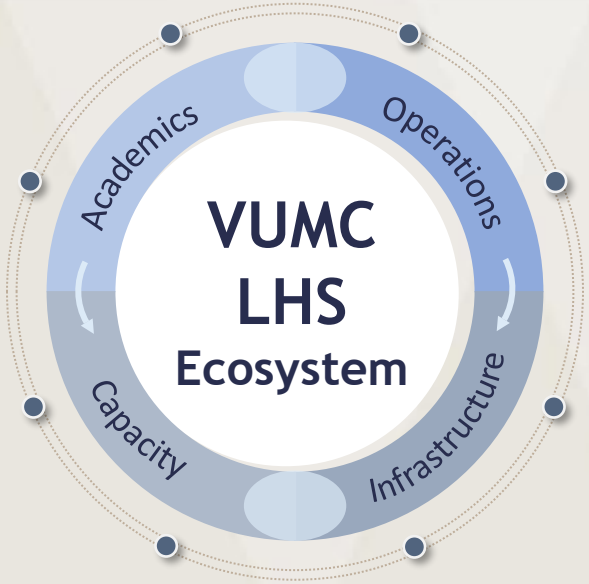
18 Project Supported

7 Consultation

11 Collaboration

11 Departments/Divisions

VUMC Learning Health Ecosystem



Clinical Informatics
- Department of Biomedical Informatics
- Clinical Informatics Core
- Research Informatics
- Clinical Analytics

Quality Improvement
- Quality, Safety, and Risk Prevention
- Nursing Magnet Program
- Quality Academy
- Essentials in Quality Improvement Certificate

Stakeholder Engagement
- Learning Healthcare Steering Committee
- RAPID-LHS Review Panel
- Clinical Enterprise Executive Committee
- Patient and Family Advocacy Councils
- Community Engaged Research Core
- Recruitment Innovation Center

Effectiveness Research
- VICTR Center for Learning HealthCare
- Center for Health Services Research
- Research Networks

Health Equity
- Office of Health Equity
- Program in Health Equity Research
- Meharry-Vanderbilt Alliance

Implementation Science
- Center for Clinical Quality & Implementation Research
- Health Systems Implementation Initiative

Training
- VA and Vanderbilt Quality Scholars
- PROgRESS and VISTA T32s
- RAPID-LHS P30
- CTSA KL2 & TL1

Practice Implementation
- Clinical Quality Committees
- Office of Population Health
- Vanderbilt Health Affiliated Network

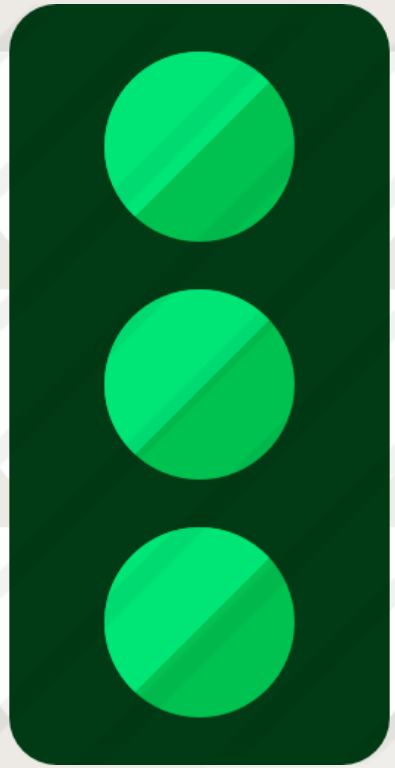
Questions/Discussion

sunil.kripalani@vumc.org

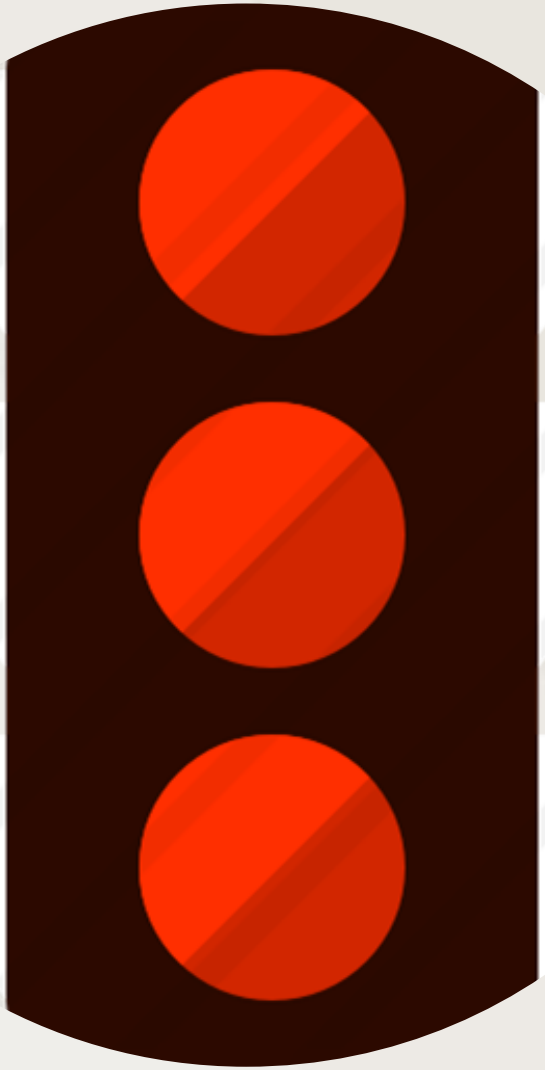
VANDERBILT UNIVERSITY
MEDICAL CENTER

Learning Health System Facilitators

- Obtain buy-in from the highest levels of leadership
- Develop leadership and system change strategy
- Identify priority areas for work
- Define clear and agreed upon interventions
- Drive with evidence-based recommendations
- Define resource requirements
- Establish performance measures and set goals
- Ensure data collection is feasible and pragmatic
- Collaborate and facilitate
- Discuss implementation (or de-implementation) early



Learning Health System Barriers



- Competing priorities
- Resistance to change
- Lack of resources
- Inability to coordinate/leverage existing programs
- Data not available or burdensome
- Gaps in skills and training of workforce
- Lack of patient engagement
- Tackling too much at once
- Unwillingness to compare treatments or methods of care delivery
- Failing to build sustainable models

RAPID-LHS Services Request | Intake Form

Project Information

Project Title

a few identifying words - e.g. Hospital Medicine Discharge Efficiency

Provide a brief description of the initiative that includes:

- **goal of the project**
- **clinical area**
- **patient population**
- **potential impact on the health system and patients**

Expand

What is the current status of the initiative?

Who are the key people or groups already involved in the initiative?

- **Operational/clinical personnel or leaders:**

if none, enter "none"

- **Research/academic faculty or trainees:**

if none, enter "none"

Is this initiative externally funded?

- ○ Yes
- ○ No

Assistance Request Information

Select the type of assistance requested: (select all that apply)

- ☐ design an intervention
- ☐ refine a question to guide evaluation of an intervention
- ☐ identify strategies for implementing the intervention
- ☐ evaluate the effectiveness of an initiative
- ☐ clinical informatics support to implement an intervention in the EHR
- ☐ help extracting data from the EHR to support evaluation
- ☐ evaluate cost-effectiveness
- ☐ scale up an effective program
- ☐ adapt a program to a new setting
- ☐ develop a manuscript for publication
- ☐ develop a grant application for external funding
- ☐ Unsure/Other

List specific questions or challenges that you would like help with.

RAPID-LHS Collaboration Project Management

Milestone	Task	Assigned To	Progress	Status	Due Date	January	February	March	April	Notes
Planning Meeting										
	Decide on Deadline	Kelsey Rodriguez	Completed	Complete	01/31/25	●				
	Determine Tasks	Kelsey Rodriguez	Completed	Complete	01/31/25	●				
	Assign Tasks/Timeline	Kelsey Rodriguez	Completed	Complete	01/31/25	●				
	Plan Check-in Meetings	Kelsey Rodriguez	Completed	Complete	01/31/25	●				
Research Focus										
	Research Question	Sara Horst/Sunil Kripalani	Completed	Complete	01/31/25	●				"How does the provider adoption of eVisits impact the number of patient messages in their practice over time while adjusting for baseline time trends?"
Data Preparation										
	Data Access	Kelsey Rodriguez	Completed	Complete	01/31/25	●				
	Data Extraction	Isaac Brewer	In Progress	On Track	02/28/25		●			
	Data Validation	Isaac Brewer/Sunil Kripalani	In Progress	On Track	02/28/25		●			Isaac to validate his extracted data query with Dr. Horst's known message volumes over specific time frames / Dr. Kripalani to validate the list of providers for control group (have never done eVisits and have been with VUMC for the entire analysis period)
	Data Cleaning	Andrew Guide	Not Started	On Track	03/31/25			●		Rate limiting step - if there are issues with missingness or complex data cleaning
Data Analysis								●		
	Baseline Summary Statistics	Andrew Guide	Not Started	On Track	03/31/25			●		
	Secondary Summary Tables	Andrew Guide	Not Started	On Track	03/31/25			●		
	Univariate Analysis (visualizations)	Andrew Guide	Not Started	On Track	03/31/25			●		
	Time Trends (visualizations)	Andrew Guide	Not Started	On Track	03/31/25			●		
	Primary Data Analysis	Andrew Guide	Not Started	On Track	03/31/25			●		
	Sensitivity/Secondary Data Analysis	Andrew Guide	Not Started	On Track	03/31/25			●		
Reporting										
	Present Findings	Andrew Guide	Not Started	On Track	04/03/25				●	
	Decide whether to Publish	Sara Horst/Sunil Kripalani	Not Started	On Track	04/03/25				●	

VUMC Learning Health Ecosystem
for Discovery, Innovation, Implementation, and Scholarship

Quality Improvement
- Quality, Safety, and Risk Prevention (QSRP)
- Nursing Magnet Program
- Quality Academy
- Essentials in Quality Improvement Certificate (EQIC)

Effectiveness Research
- VICTR Center for Learning Healthcare
- Center for Health Services Research
- Networks: Stakeholders Technology and Research (STAR), Pragmatic Critical Care Research Group (PCCRG)

Implementation Science
- Center for Clinical Quality & Implementation Research
- Vanderbilt Implementation and Quality Improvement (VIQI) Core
- Health Systems Implementation Initiative (HSII)

Cross-Cutting Elements

Stakeholder Engagement	• Learning Healthcare Steering Committee • Patient and Family Advisory Councils	• Community Engaged Research Core (CERC) • Recruitment Innovation Center (RIC)	
Informatics	• Dept of Biomedical Informatics (VCLIC, CPM, CIPHI, AVAIL) • Research Informatics/IT (REDCap, Research Derivative, Data Lake)	• Analytics teams: Quality, Enterprise, Finance • Vanderbilt Anesthesiology and Perioperative Informatics Research (VAPIR)	
Practice Implementation	• Clinical Quality Committees, Adult & Pediatric • Clinical Decision Support	• Office of Population Health • Vanderbilt Health Affiliated Network (VHAN)	
Health Equity	• Office of Health Equity • Meharry-Vanderbilt Alliance	• Program in Health Equity Research	
Training	• VA and Vanderbilt Quality Scholars • PROgRESS and VISTA T32s in HSR/LHS	• AHRQ/PCORI P30 RAPID Learning Health Systems • Seminars, MPH courses	• CTSA KL2 • CTSA TL1

Evolution of LHS

- Advancements
- How “pragmatic” is it?
- How to specify interventions for replicability?
- What about complex healthcare interventions?

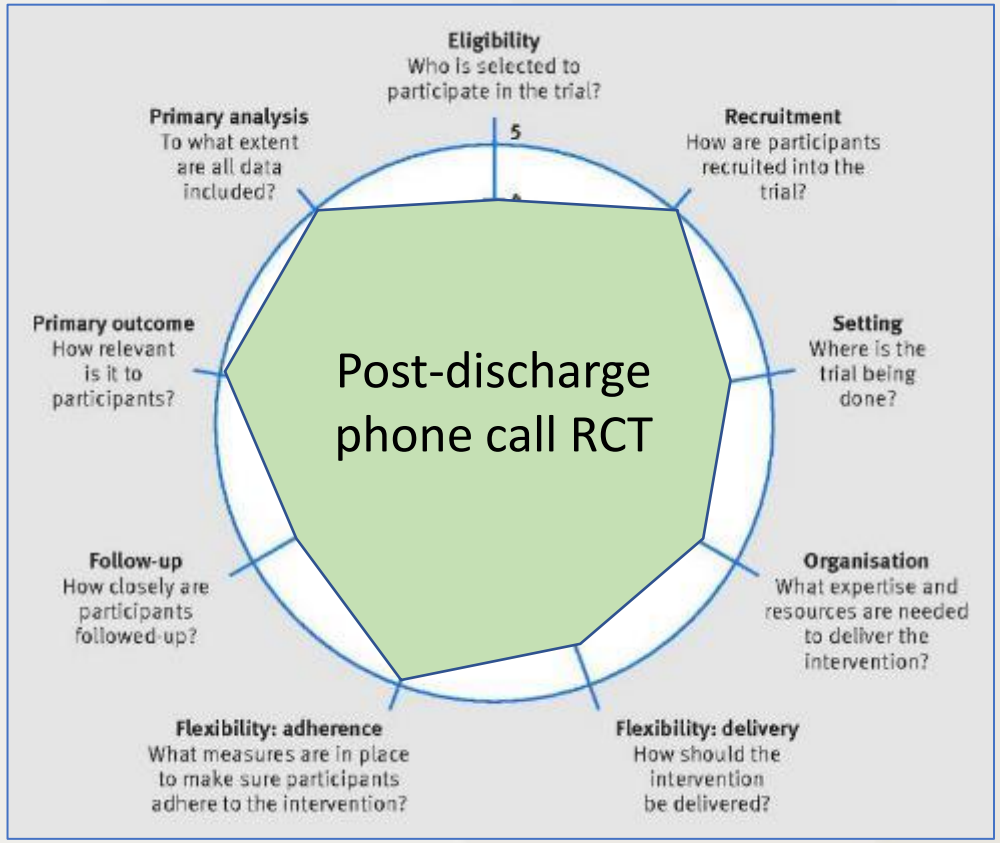
Current/Future Directions

- Implementation science
- Additional areas

How "Pragmatic" Is It?

PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2)

- 9 domains, rate pragmatic (5) to explanatory (1)



Practically, we focus on 4 areas:

1. Is it feasible to randomize at the patient, provider, unit, or system level?
2. Will the approach require detailed, individual level informed consent?
3. Are relevant, reliable, and valid data readily available for
   a. identifying patients of interest, and
   b. evaluating outcomes?
4. Is patient volume sufficient for a study to have the power to draw meaningful conclusions within a reasonable timeframe, typically a year or less?

Loudon et al. *BMJ* 2015;350:h2147
https://www.precis-2.org/

Yiadom et al. *BMJ Open* 2018
Yiadom et al. *Med Care* 2020

Template for Intervention Description and Replication (TIDieR)

- Useful schema for specifying details of intervention
- Extension of CONSORT (2010) and SPIRIT (2013) guidance for reporting trials
- 12-item checklist

1) Brief name	7) Where
2) Why – rationale, theory	8) When, how much
3) What – materials	9) Tailoring – if adapted, how
4) What – procedures	10) Modifications
5) Who provides, expertise, training	11) How well – fidelity plans
6) How – modes of delivery	12) How well – actual fidelity

Hoffmann et al, *BMJ* 2014

Complex Interventions

Complexity

- Multiple interacting components, multiple causal pathways
- Intervention adaptable, flexible, multi-level
- Real world: contextual factors at play, health care staff carry out intervention

Challenges in studying

- Heterogeneity: patients, microsystems, context, intervention
- Variability/adaptability: intervention targets, context, intervention content
- Causal complexity: multiple components, multi-step causal chains, strength of contextual vs main effects
- Contextual factors affect implementation strategies, processes, and outcomes

Craig et al, *BMJ* 2008;337:a1655
Guise et al, *J Clin Epidemiol* 2017

PCORI Standards for Studies of Complex Interventions

SCI-1: Fully describe the intervention and comparator and define their core functions.

- Functions, forms, intervention target

SCI-2: Specify the hypothesized causal pathways and their theoretical basis.

- Include contextual factors that may influence impact

SCI-3: Specify how adaptations to the form of the intervention and comparator will be allowed and recorded.

- What is allowable, how managed and measured, maintain fidelity to core functions

SCI-4: Plan and describe a process evaluation.

- Fidelity, dose actually delivered, reach, mediators, moderators

SCI-5: Select patient outcomes informed by the causal pathway.

https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Complex

Current and Future Directions

Further Incorporation of Implementation Science

- Hybrid effectiveness-implementation trials
  - Type 1: Primary focus on effectiveness, also evaluate implementation
  - Types 2 and 3: Test implementation strategies
- Intervention fidelity: run-in period and monitoring
  - Example: COVID-19 proning study
- Dissemination
  - Toolkit of resources for dissemination
  - QuizTime asynchronous learning platform
- After trial completion: disseminate, implement, sustain
  - Example: SMART, SALT-ED studies
  - Dashboard monitoring of practice, clinical decision support tools

RAPID-LHS Center | Realizing Accelerated Progress, Investigation, Implementation, and Dissemination in Learning Health Systems

- Train faculty in the science and practice of LHS
- AHRQ and PCORI Learning Health System Embedded Scientist Training and Research Centers (P30) – LHS E-STaR
  - $5M, 5 years
- Institute for Medicine and Public Health
  - Scientist effort
  - Administrative, project management, and statistical support

Resources

- National Academy of Medicine (book series) https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/
- AHRQ https://www.ahrq.gov/learning-health-systems/index.html
- Learning Health Community (toolkits and more) https://lhstoolkit.learninghealthcareproject.co.uk/
- *Learning Health Systems* (journal) https://onlinelibrary.wiley.com/journal/23796146