

NIH Collaboratory Coordinating Center Overview and Goals

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Today's Presentation

1. What Are the Goals of the Collaboratory Coordinating Center?
2. How Are We Doing It?
3. How Do We Share What We Have Learned?
4. Conclusions



1

What Are the Goals of the Coordinating Center?



Millions



Patients **walk through the doors** of hospitals and clinics each year **with questions** about their health and their care.



How do we **study their experiences** to **find answers** and **create solutions** that **change care** and **improve outcomes**?

Increasing System-ness

Hospitals and physicians in US health systems

2000: 5810 hospitals

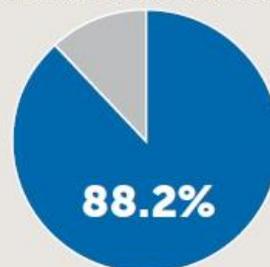
2016: 626 health systems

2020: ?

By the end of 2016, there were **626 health systems*** in the United States.

U.S. hospitals and physicians in health systems

Percentage of U.S. hospital beds in systems

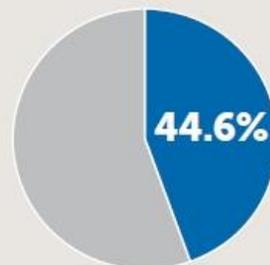


69.7% of U.S. hospitals are in health systems



91.6% of U.S. hospital discharges are from system hospitals

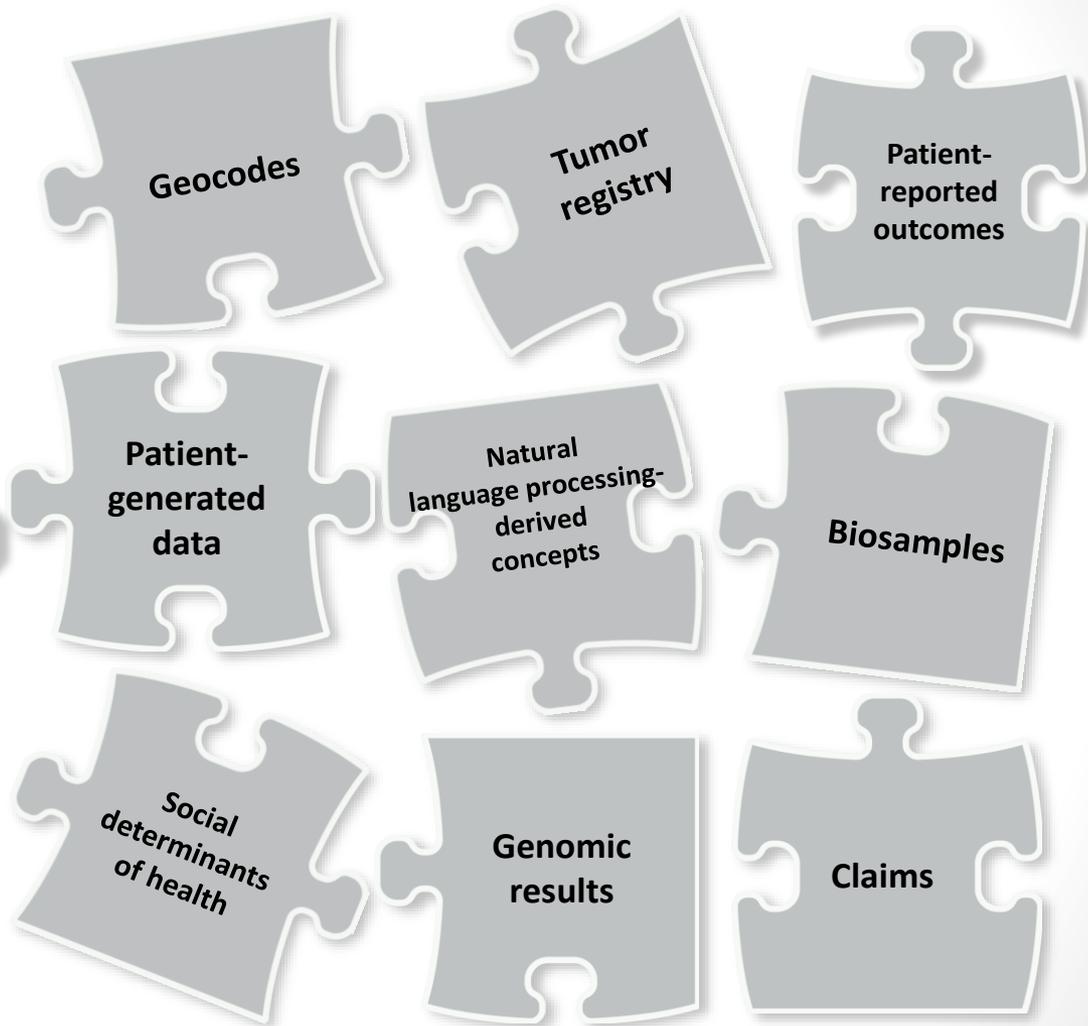
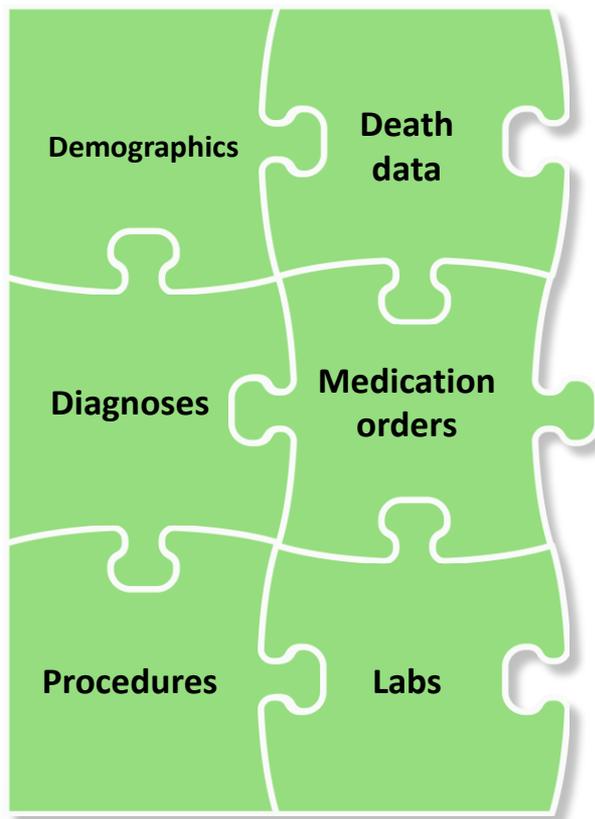
Percentage of U.S. physicians in health systems



42.7% of U.S. primary care physicians are in health systems

Note: The hospital figures represent all non-Federal general acute care hospitals in the United States.

Data Everywhere



The NIH Collaboratory Story



National Institutes
of Health

Initiated through the NIH Common Fund in 2012

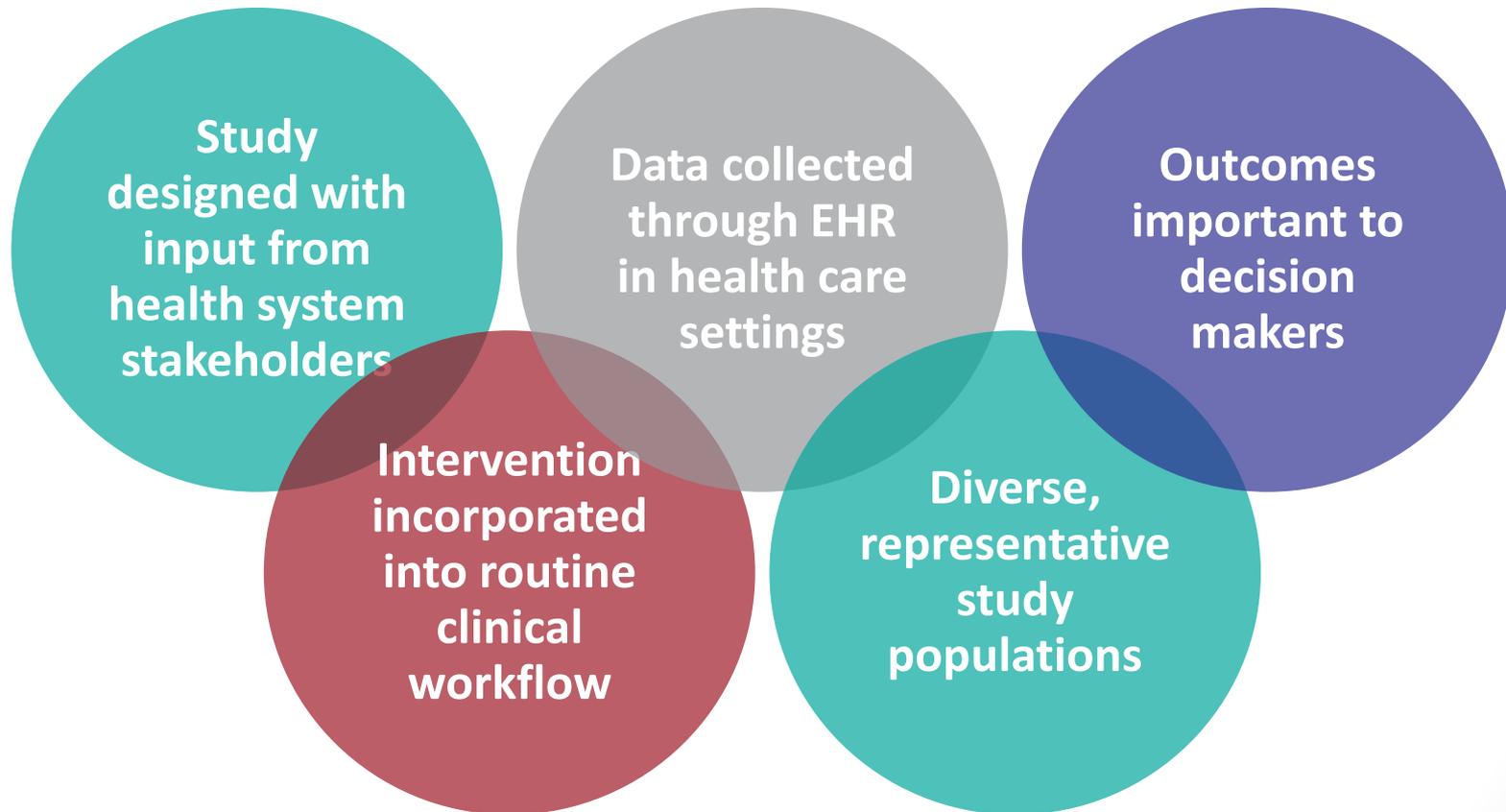


Goal: Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners



Vision: Support the design and execution of innovative pragmatic clinical trial Demonstration Projects to establish best practices and proof of concept

Embedded PCTs Bridge Research Into Clinical Care

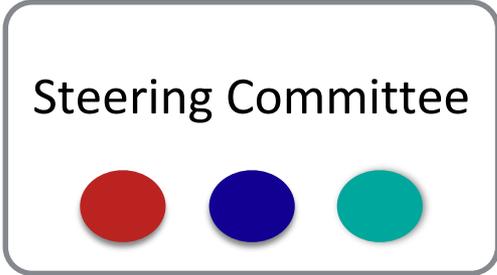




2

How Are We Doing It?
Structure of the Coordinating Center

Collaboratory Structure



Core Working Groups

- Guide and support Demonstration Projects
- Disseminate knowledge
- Chair from Coordinating Center and representatives from NIH and Demonstration Projects

Biostatistics and Study Design

Electronic Health Records

Health Care Systems
Interactions

Patient-Reported Outcomes

Regulatory/Ethics

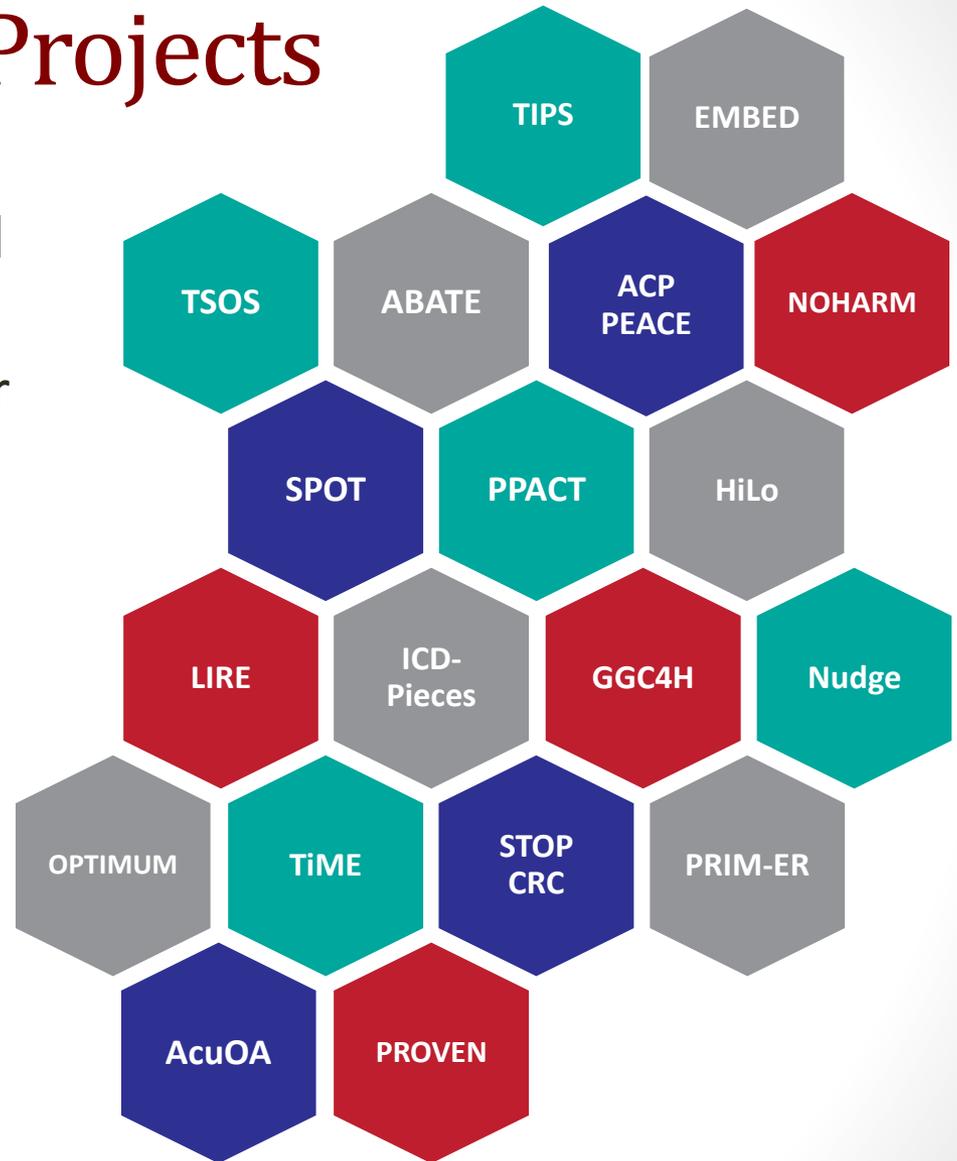


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How Are We Doing It?
Demonstration Projects

Demonstration Projects

- Pragmatic trials embedded in healthcare systems to address questions of major public health importance
- Projects span multiple NIH Institutes, Centers, and Offices
- One-year planning phase followed by implementation phase



Completed Demonstration Projects

Project	Population	Intervention	Outcome
ABATE	Non-ICU patients	Decolonization strategies	MRSA and VRE clinical cultures
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
STOP CRC	Adults aged 50-75 years	Direct mail CRC screening program (FIT kit)	CRC screening rates
TiME	Patients initiating dialysis	Dialysis session of at least 4.25 hours	All-cause mortality, hospitalization



Ongoing Projects

Project	Population	Intervention	Outcome
ACP PEACE	Older adults with advanced cancer	Advance care planning program	Completed advance care plans, resuscitation preference orders, palliative care consults, hospice enrollment
EMBED	Opioid use disorders	Computerized clinical decision support for ED-initiated BUP, referral for ongoing treatment	Rates of ED-initiated BUP
GGC4H	Parents of early adolescents	Universal evidence-based anticipatory guidance curriculum	Drug use, depression, delinquent behavior
HiLo	Patients with ESRD receiving maintenance hemodialysis	Higher vs lower serum phosphate target	Hospitalization, mortality
ICD-Pieces	Comorbid diabetes, CKD, hypertension	Collaborative primary care program	Hospitalization for 3 conditions

Ongoing Projects (continued)

Project	Population	Intervention	Outcome
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	RVU for spine-related interventions
Nudge	Chronic cardiovascular conditions	Text message reminders and AI-based interactive chat	Medication adherence
PRIM-ER	Older adults in EDs with serious, life-limiting illness	Primary palliative care program in EDs	ICU and hospital admissions; inpatient days; discharge to home and palliative care service; use of home health and hospice; survival
PROVEN	Nursing home patients	Advance care planning video (behavioral program)	Hospitalization, presence of advance directive
SPOT	Suicidal ideation or depression	Collaborative care behavioral program (care management and skills training)	Suicide attempts
TSOS	Traumatic injury	Collaborative care management program	PTSD checklist, PHQ-9, alcohol use disorders, SF-12/-36

PRISM Demonstration Projects

Project	Population	Intervention	Outcome
AcuOA	Older adults with low back pain	Standard and enhanced 12-week courses of acupuncture	Back-related function at 26 week, cost-effectiveness
NOHARM	Postoperative pain	EHR-embedded tools to aid shared decision making about pain management	Postoperative opioid use, pain, function
OPTIMUM	Chronic low back pain	Group-based mindfulness in outpatient clinical settings	Pain, physical and psychological function, opioid prescriptions for chronic low back pain
TIPS	Fibromyalgia	Addition of transcutaneous electrical nerve stimulation to physical therapy	Fibromyalgia symptoms, adherence to therapy, meeting therapeutic goals, medication use

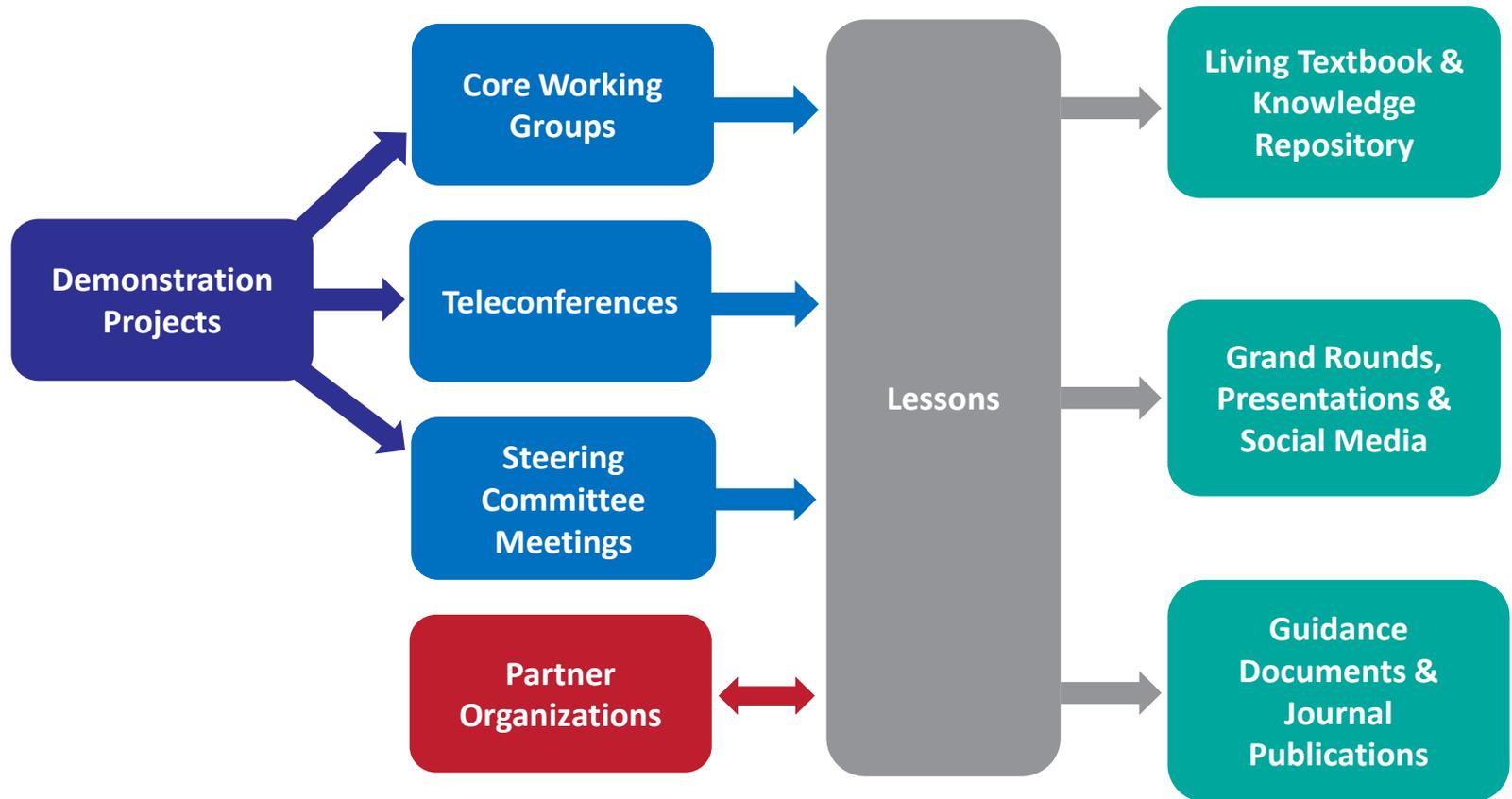




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How Are We Doing It?
*Process for Identifying and
Responding to Issues*

Flow of Information



Issue Tracker

Challenge	Raised by (PI)	Category	Date Reported	Status Updated	Status at Last Check In
Culture: Beginning second set of site visits; culture change is needed around beliefs about infection control.	Huang	Practice norms & workflow	9/12/14	2/25/15	Ongoing – Investigators continuing follow up site visits for facilities struggling with compliance and overuse of CHG.
A radiologist unhappy with the intervention and how it changes the format of radiology reports. This might lead to a site withdrawing.	Jarvik	Engagement	4/24/15	4/24/15	New challenge: We're currently doing what we can to work through this issue.

Sharing Challenges & Solutions

Teleconferences, SC Meetings,
Collaboratory Videos & Interviews



Advice to New Pragmatic Trial Investigators

from NIH Research Collaboratory **PRO** 1 month ago

AN INTERVIEW WITH DR. JERRY JARVIK
Principal Investigator, Lumbar Imaging with Reporting of Epidemiology (LIRE) Trial
conducted April 20, 2015

Dr. Jarvik provided an update on the Lumbar Imaging with Reporting of Epidemiology (LIRE) Trial at the April 2015 Collaboratory Steering Committee Meeting (view slides). The LIRE trial is about halfway through its initial enrollment period with over 52,000 patients enrolled.

Background
Over 15 years ago, Dr. Jarvik was involved in a Veteran's Affairs (VA) study in which they obtained lumbar spine magnetic resonance image (MRI) reports of 148 asymptomatic patients (no back pain) and followed them longitudinally to see who developed back pain. They generated, in essence, a "normal range" of MRI findings in patients without back pain. Shortly thereafter, a paper was published by Martin Roland and Maurits van Tulder that questioned the clinical importance of MRI spine imaging findings and urged radiologists to include prevalence information in their imaging reports of the lumbar spine. Inspired by the paper, Dr. Jarvik incorporated the information from the VA cohort study—the normal range—into the routine imaging at the University of Washington Medical center. This information was available as a template that could be inserted into the radiologist report. As it turned out, only a few of the radiologists used this template, giving Dr. Jarvik the opportunity to investigate the data to determine if epidemiologic information

had any effect on patient outcomes. He was surprised by the results. Even though they had relatively small numbers, there was evidence that the inclusion of the epidemiological information decreased utilization of spine-related interventions, and even more importantly, decreased opioid prescription rates.

That was the spark of the LIRE trial, a pragmatic trial to answer this question: Does inserting prevalence information decrease downstream spine-related utilization or opioid prescribing rates by primary care physicians?

Design
LIRE is a cluster randomized trial with a stepped-wedge crossover design. The primary unit of randomization is the clinic (cluster) rather than the primary care provider or the patient. They are randomizing 100 clinics in 4 health systems (Kaiser Permanente Northern California, Henry Ford Health Systems, Group Health in Seattle, and the Mayo Clinic). For the stepped wedge design, they have five waves (steps) of randomization: a fifth of the 100 clinics are exposed to the intervention during each wave (see Figure 1). By the end of the study, all 100 clinics will have had the intervention — hence a "crossover" design: all clinics eventually crossover from the control arm (no intervention)

Even the simplest ideas are complex to implement and rigorously study.

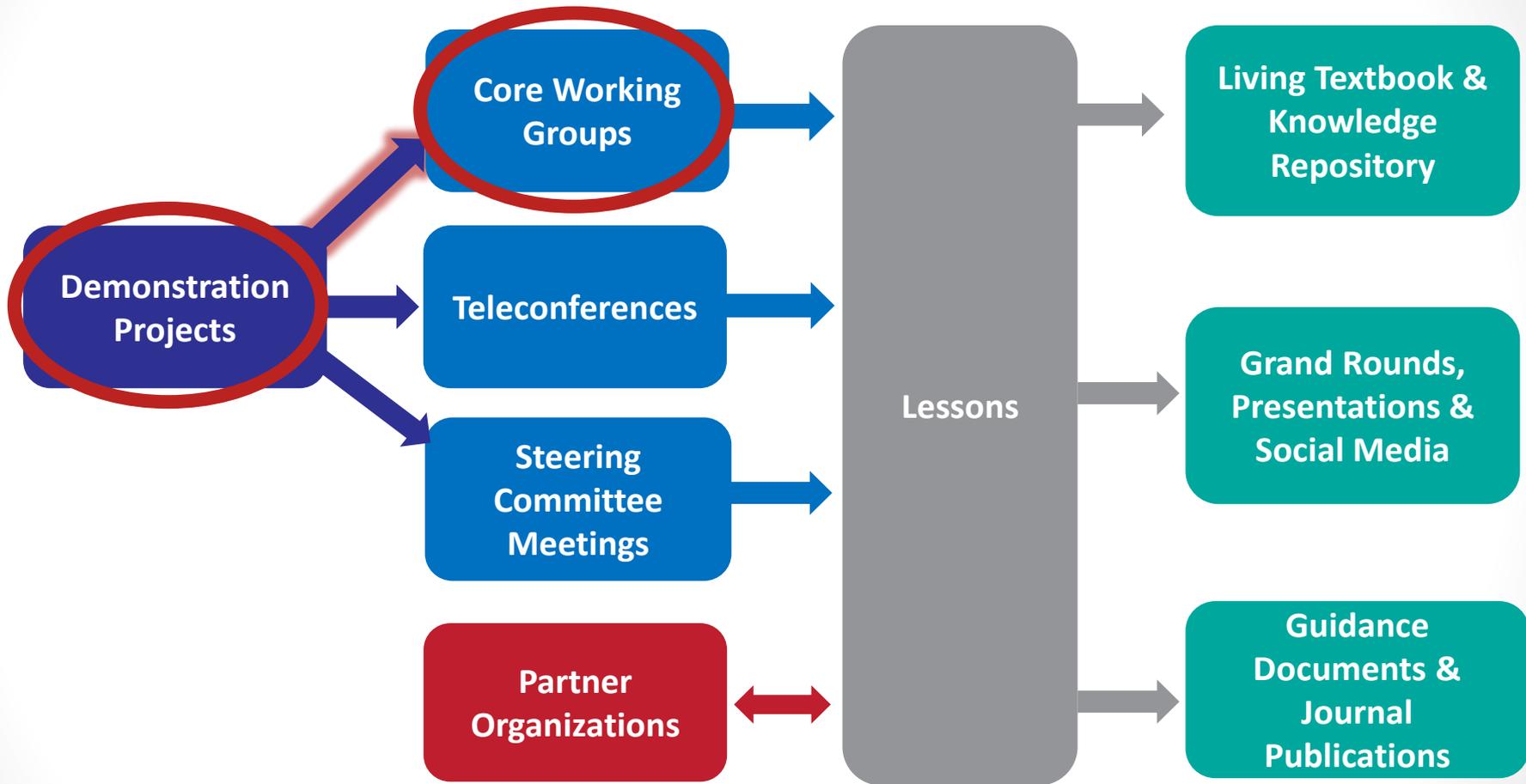
NIH Collaboratory
Health Care Systems Research Collaboratory



3

How Do We Share
What We Learn?
Process for Dissemination

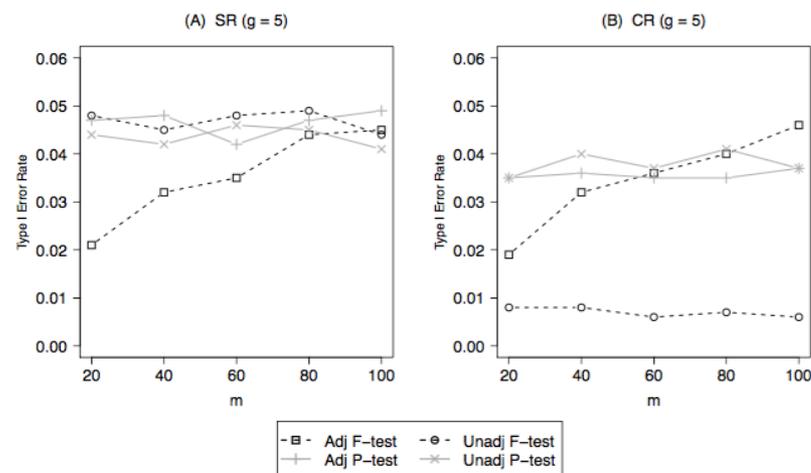
Flow of Information



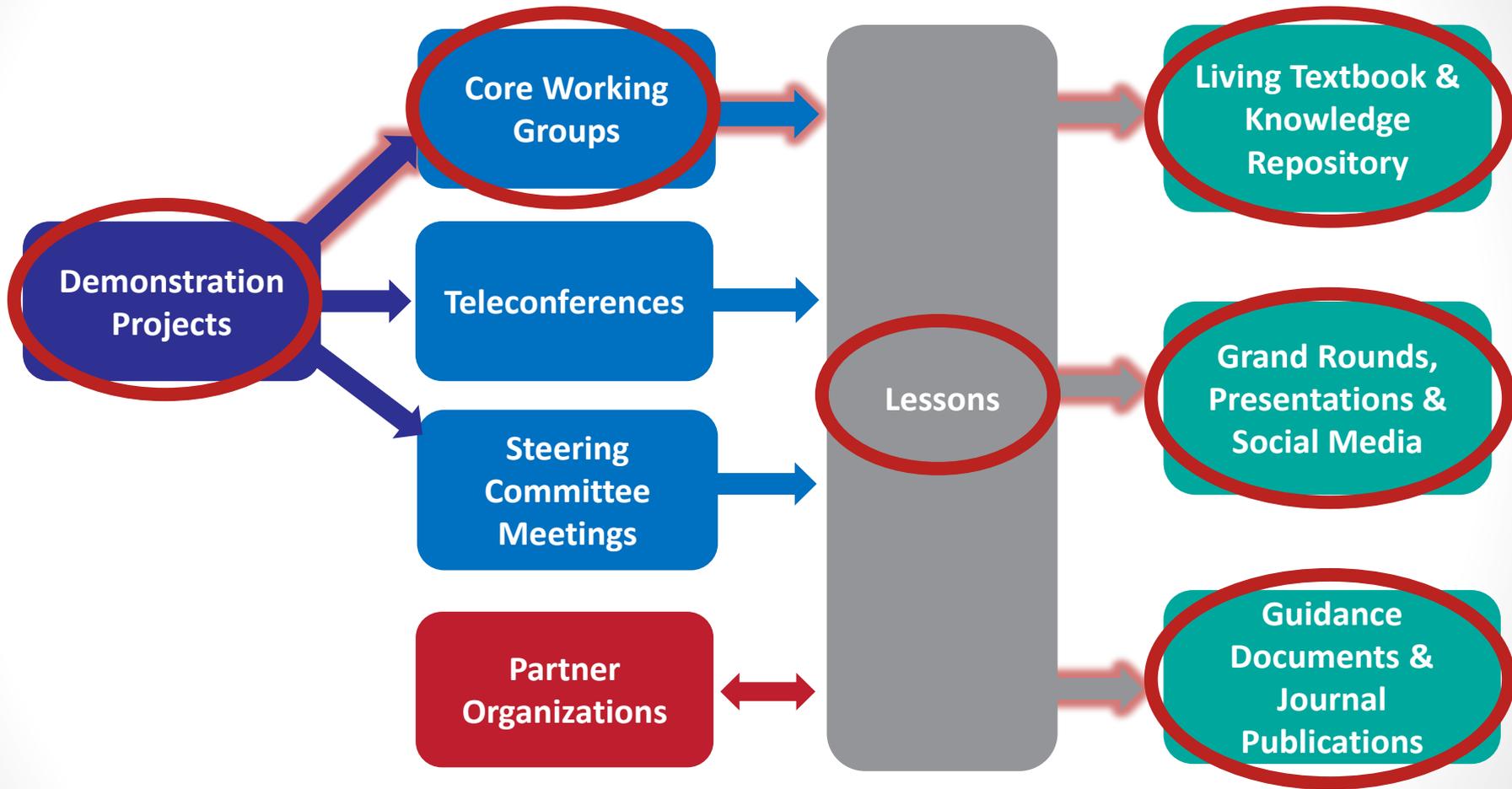
Simulation Studies



Lessons re: Design & Analysis



Flow of Information



The Living Textbook *of Pragmatic Clinical Trials*



knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost and time needed to conduct a traditional clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than are typically encountered with traditional clinical trials. The Living Textbook reflects a collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of pragmatic

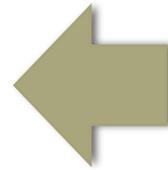
ENGAGING STAKEHOLDERS ▶
and building partnerships to ensure a
successful trial

What is the
NIH COLLABORATORY? ▶

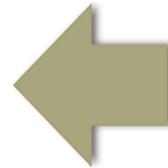
www.rethinkingclinicaltrials.org

PCT Training Workshops

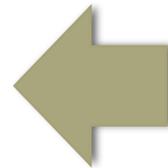
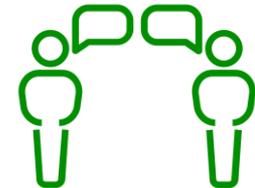
- What are Embedded PCTs?
- Engaging All Stakeholders & Aligning With HCS Partners
- Designing With Implementation in Mind
- Design & Analytic Considerations
- Regulatory & Ethical Challenges
- Measuring Outcomes
- Pilot & Feasibility Testing
- Dissemination
- ePCT Team Composition
- Developing a Compelling Application



Case Studies



Interactive Exercises



Living Textbook Content



PCT Grand Rounds Presentations

- Weekly webinars on a wide range of research topics
- >300 presentations since inception
- Podcasts of expert interviews available on iTunes and Soundcloud



Grand Rounds

Join our weekly webinars on Fridays from 1-2 pm ET.
Open to the public; no registration required.

[Join our mailing list](#)

Upcoming Webinars

- Grand Rounds March 16: Straight from the Source: Clinicians' Views on Participating in CER/PCOR (Ellen Tambor, MA; Rachael Moloney, MHS; Sean Tunis, MD, MSc)
- Grand Rounds March 23: Data Science in the Era of Data Ubiquity (Robert M. Califf, MD)
- Grand Rounds March 30: HHS-DoD-VA Pain Management Collaboratory (Robert Kerns, PhD)

[View Calendar of All Events](#)

Podcasts

- [Podcast February 16, 2018: Considerations for the Return of Genomic Results](#)

Last Week's Grand Rounds



Jeff Brown, Lesley Curtis, and Richard Platt give a status report on the Distributed Research Network

Tweets by [@PCTGrandRounds](#)

For More Information

Living Textbook

- Comprehensive, searchable information on design, conduct, and dissemination of embedded PCTs
- rethinkingclinicaltrials.org

Monthly
Newsletter

- Convenient monthly wrap-up of NIH Collaboratory news, Demonstration Project spotlights, and new Living Textbook content
- rethinkingclinicaltrials.org/newsletter-subscribe

Twitter

- @Collaboratory1



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Conclusions

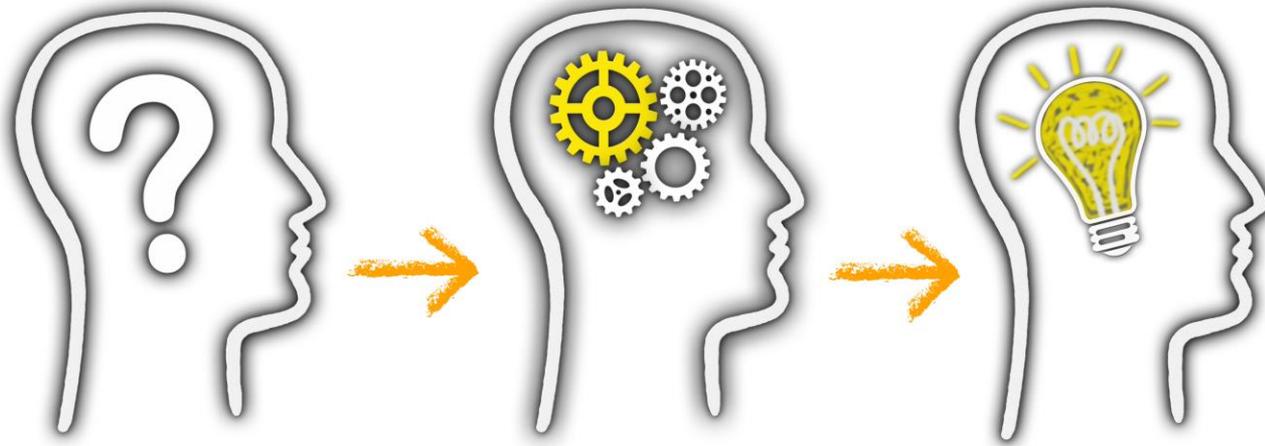
What's been contributed

- Significant body of knowledge on ethical & regulatory issues in PCTs
 - Consulted with OHRP
 - Conducted research on clinician & participant attitudes
 - Published special journal issue on challenges & best practices
- Biostatistical guidance in area of cluster randomized trials
- Created functional distributed research network
- Established policies and culture for data sharing
- Developed resources and guidance to support re-use of EHR data, integration of patient-reported outcomes, and partnerships with healthcare systems
- Shared case studies from our Demonstration Projects

What's Next: Expanded Knowledge

- Develop and disseminate guidelines and lessons learned from the PRISM projects
- Promote synergies with newer Collaboratory programs
 - NIA Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory
 - NIH-DoD-VA Pain Management Collaboratory
- Advance the quality and impact of patient-centered outcome measures
 - Using patient engagement activities
 - By understanding and disseminating best practices for assessing pain and related constructs in the context of ePCTs
- Study innovative dissemination and implementation science approaches

What will you contribute...



LESSONS LEARNED

Conclusions

- Take advantage of continued interest in real-world evidence and learning health systems
- Multiple lessons learned from rethinking research integrated with practice
- Cost-effective, large-scale research is possible, and we have the charge to scale it...
 - By learning, sharing, and helping the ecosystem evolve

