Health Care Systems Research Collaboratory Grand Rounds:

"Health Care Systems Interactions Core"

Eric B. Larson, MD, MPH

January 11, 2013

A Virtual Home for Knowledge about Pragmatic Clinical Trials using Health Systems: www.theresearchcollaboratory.org

The Collaboratory

Health Care Systems Research Collaboratory Grand Rounds:

General Instructions for our viewers during today's call:

- To enhance audio quality, all users have been muted.

- During the presentation (at any time), type your questions for our speaker in the Chat Pod. Address your chat to "Everyone." Questions will be answered by the speaker at the end of the presentation.

- For technical support, type a private chat message to "Technical Support."

Health Care Systems Interactions Core

January 11, 2013 | Eric B. Larson, MD, MPH

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Vision for Health Care System Research Partnerships

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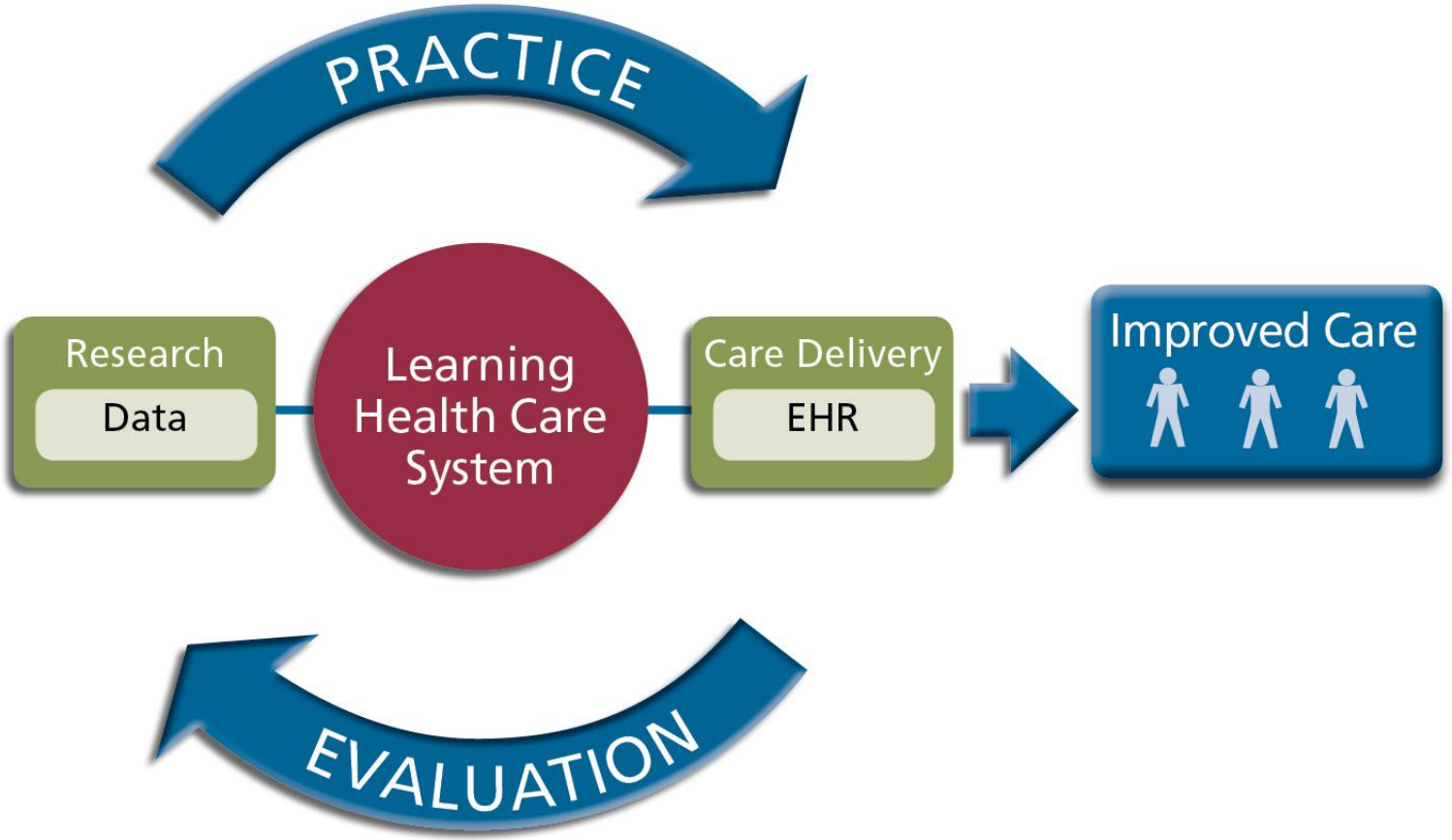
Research with and within real world delivery systems has the potential to close the gap between research and translation



Source: Developing an HMO Collaboratory CRN Administrative Supplement, 2010-2011

Health Care Systems Interactions: Core Purpose

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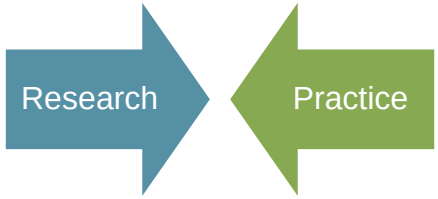
The Health Care System Interactions (HCS) Core exists to:

- Support and facilitate productive collaboration between researchers, health care systems, and clinical partners
- Discover and develop generalizable knowledge in the conduct of pragmatic clinical trials

Process will involve identifying barriers, problem solving, and developing generalizable knowledge



Health Care Systems Interactions: Typical Issues

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From experience we know what is often most troublesome for researchers and those responsible for care

- Building trust and relationships
- Engaging health care systems and clinics across multiple sites and staffing layers
- Incentivizing and educating providers
- Altering provider behavior and workflows to implement research
- Methodologically addressing site variability and the possibility of contamination in less controlled settings

Health Care Systems Interactions: Typical Issues (cont.)

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- Interpreting non-standard clinical data for research purposes
- Efficiently handling multiple IRB reviews, business contracts
- Transferring research data, events and findings back to HCS
- Consenting issues (e.g., clusters vs. patients at participants)
- Understanding HCS business concerns
    - Proprietary
    - Privacy
    - Financial
    - Operational disruption
    - Billing compliance

Foundational Work

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Coordinated Clinical Studies Network (CCSN)

- NIH Roadmap Initiative contract: Re-engineering the Clinical Trials Enterprise
- Aimed to remove barriers to conducting multisite research across health systems
- CCSN environment was the HMO Research Network (HMORN), a confederation of 19 health plans with embedded research departments
- Key outcome = The HMORN Collaboration Toolkit (40+ resources)
- PRISM Toolkit to increase readability, use of plain language in study materials

Since the CCSN, the Toolkit has continued to be updated and expanded. It includes:

- Multisite IRB review processes
- Standardizing data extraction across multiple systems and EMR
- Best practices for multi-site data collection, recruitment and retention
- Contractual and DUA templates for additional efficiencies
- Best practices for collaborative research (e.g., authorship and publication, ancillary study requests, multisite project communications)
- Tools for geographically dispersed grant writing teams

Overarching Challenges

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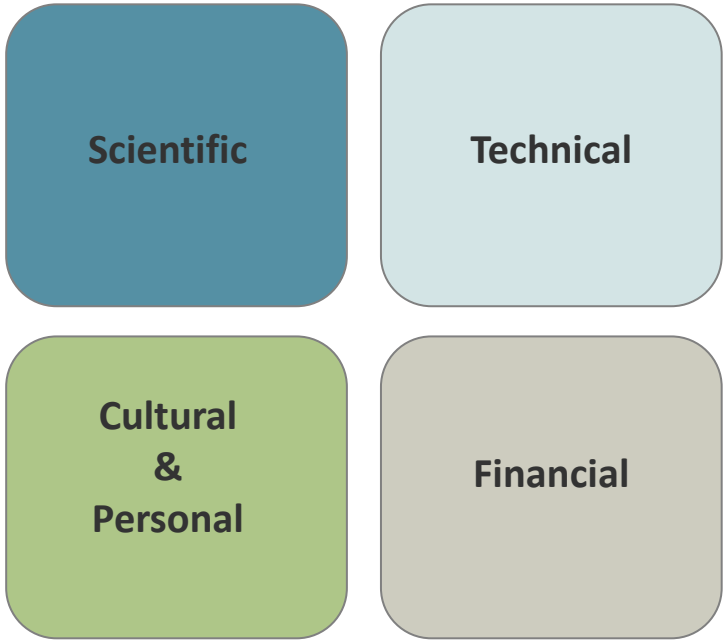
Four domains of collaboration



Technical and scientific are easiest to address

Financial can be challenging, but not insurmountable

Transforming the research enterprise will require transforming behaviors and cultural norms of the U.S. health and health research environments

Transforming Behaviors and Norms

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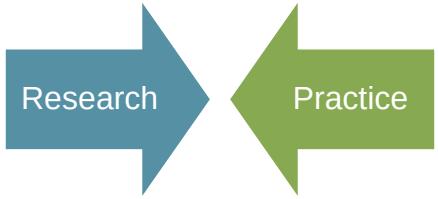
First steps to accomplishing this goal:

- Creating a safe environment to share challenges across projects and learn from one another
- Building trust among individuals in research settings and partnering health systems
- Developing more global shared values and building trust between diverse organizations (e.g., IRB ceding)

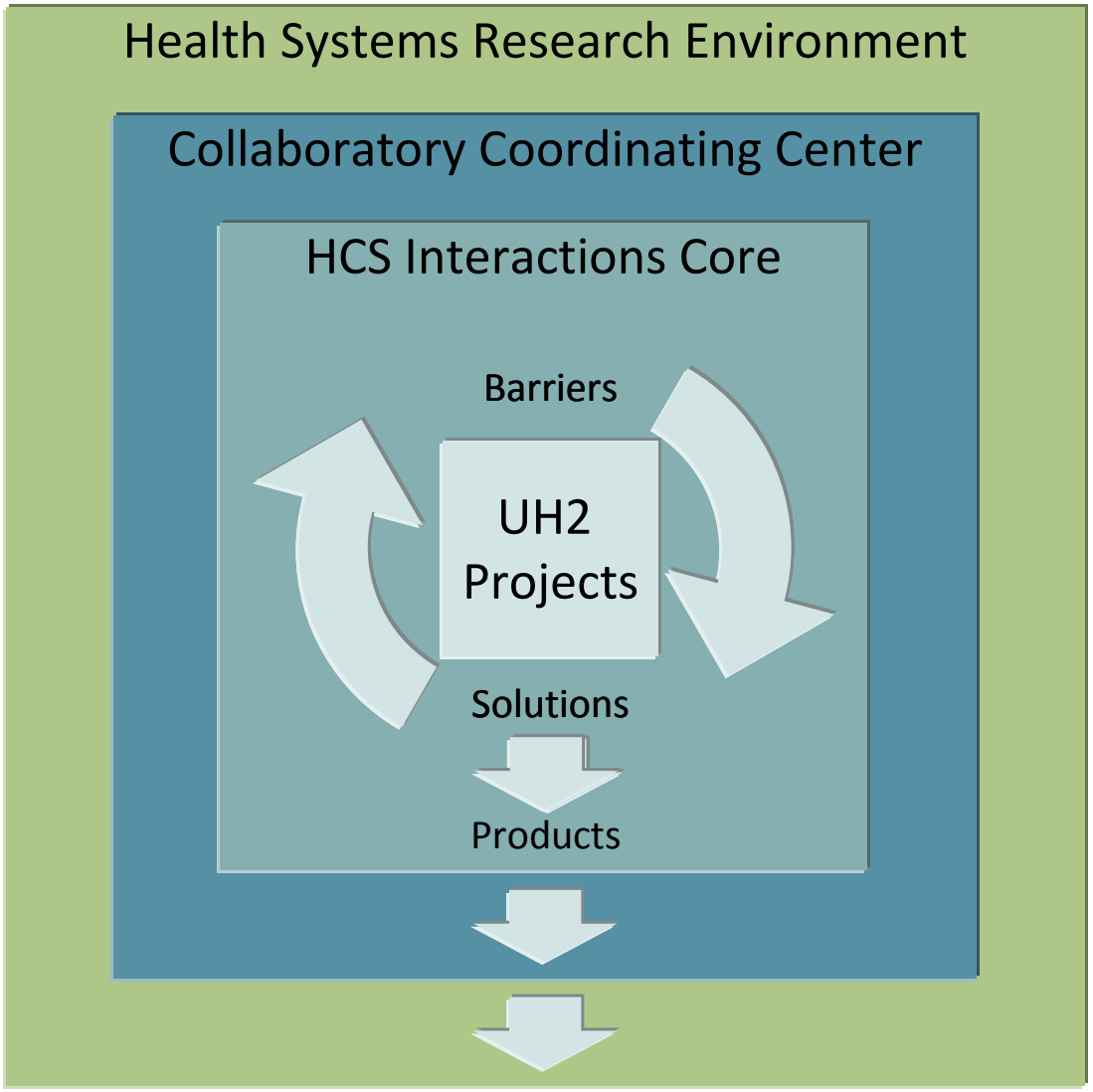
The ultimate challenge

- Overarching issues include public policy and the regulatory environment. Both affect the health care systems based research environment

Our work can lead to improving the climate for research in health care systems



Health Care Systems Interactions: Process and Context



Core Leadership

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Core Chair – Eric B. Larson, MD, MPH

- Vice President for Research, Group Health
- Executive Director, Group Health Research Institute
- PI of Common Fund Admin Supplement to ‘scale up’ for Collaboratory
- PI of past NIH Roadmap Coordinated Clinical Studies Network (CCSN)
- Collaborative research experience in multiple types of health systems across multiple therapeutic areas

Project Leader – Ella Thompson, BS

- HMORN manager; develops and maintains HMORN process efficiencies
- Past CCSN and UW’s CTSA CE core project manager. Project director of CTSA’s CE-KFC effort that developed www.ResearchToolkit.org

Andrea Cook, PhD *(Design and Biostatistics Core)*

- Biostatistician with extensive experience in delivery system-based clinical trials and related methodological issues

HCS Committee Members

Christine Nelson, RN, PhD

- Senior Research Associate, OCHIN (Coronado UH2)

Gary Rosenthal, MD

- Director, Institute for Clinical and Translational Sciences, UI (UH2 PI)

Greg Simon, MD, MPH

- Senior Investigator, Group Health (UH2 PI)

Jeffrey “Jerry” Jarvik, MD, MPH and Kathryn James, PA-C, MPH

- Director, Radiology HSR Section (UH2 PI) and Research Manager, UW

Lynn DeBar, PhD

- Senior Investigator, KP Northwest (UH2 PI)

Ravi Thadhani, MD, MPH

- Director, Clinical Research in Nephrology, MGH (Dember UH2)

Susan Huang, MD, MPH and Adrijana Gombosev, BS

- Medical Director, Epidemiology and Infection Control (UH2 PI) and Clinical Research Coordinator, UC - Irvine

Committee Member Roles

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Chair

- Provide overall leadership for the HCS core and its activities.
- Offer consultation to demonstration project PIs, as needed for operational issues relating to HCS interactions

Project leader

- Manage core activities (e.g., meetings, work plan, timelines, evaluation, reporting, etc.)

Committee members

- Share demonstration project challenges, solutions and priorities
- Inform and participate in development of generalizable knowledge to advance research in health systems and promote learning health systems

Workgroup members

- Contribute knowledge and expertise to the development of generalizable tools and knowledge relating to the work of the core

Organization

HCS Core Meetings

- Monthly group call: Plan activities, review progress toward goals, share solutions
- Monthly office hours call-in time: Consult on project specific operational challenges; discuss priorities, core processes, etc. (optional)
- Workgroups (TBD, varied): Contribute expertise to develop generalizable work products on identified priority topics

Core Evaluation

- Monthly: Feedback solicited for continuous meeting and process improvement
- Annually: Formal HCS core evaluation conducted

Communications

- Primary modes – email, Collaboratory CC SharePoint site
- Products will be added to Collaboratory CC Knowledge Base

Reaching Out and Assessing Needs

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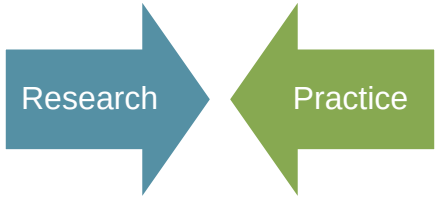
The HCS core has met individually with UH2 Project PIs in order to:

- Start building relationships and set a tone of trust, openness, and support
- Share expectations regarding transparency, sharing and updating of challenges and solutions employed
- Clarify the HCS core's role in helping resolve on-the-ground operational issues in working with and within health systems
    - vs. the CC's role in informing higher level policy change
    - vs. the Stakeholder core's role engaging patients, purchasers, etc
- Assess immediate HCS core consultation needs and challenges facing UH2 projects
- Gather ideas for generalizable knowledge and tools to improve the ability for themselves and others to partner successfully with health care systems on pragmatic research projects



Example Current Challenges
Clinical Data

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ABATE Trial to Reduce Health Care Assoc Infections and Readmissions

(PI – Huang, UC-Irvine) *Cluster trial, randomizing 50 Hospital Corporation of America facilities to evaluate whether daily bathing non-ICU patients with antimicrobial soap prevents healthcare-associated infections and the readmissions they cause*

- Heterogeneity across large number of hospitals and data entered into EHR
- Working at corporate level to modify the common EHR to incorporate a standardized e-prompt regarding daily bathing for each patient

STOP CRC in Priority Populations

(PI – Coronado, Kaiser Permanente-NW) *Cluster trial, randomizing 18 Federally Qualified Health Centers (FQHCs) to test an intervention to improve rates of colorectal cancer screening in priority populations*

- Lack of standardization across clinics in capturing and defining the disease condition, and in current screening practices
- Variable experience and buy-in regarding use of a common EHR

Topics Proposed for HCS Core Related to Clinical Data

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Utilizing non-standard clinical data to conduct rigorous research

- Understanding how to recognize and interpret incongruities in non-standard clinical data in order to develop protocols, identify patients, and understand data
- Working with systems to develop a common IT approach in order to standardize the collection of key clinical data measures
- Standardizing data across clinics may be needed, even within a single system

- Possible benefit to health systems, patients, and researchers alike

Potential generalizable products

- Protocol for standardizing the data checking process
- Strategies to promote standard clinical data collection to all clinics routinely (e.g., baseline measures, numeric pain rating scale)
- Improved and debugged EPIC Reporting Workbench tool (collective Collaboratory voice to up-prioritize EPIC's efforts)

Example Current Challenges
Consent and IRB

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Nighttime Dosing of Anti-hypertensives

(PI – Rosenthal, UI) *Simple and practical RCT to determine if taking medication for high blood pressure at night, as opposed to in the morning, leads to a lower risk of cardiovascular disease in patients with hypertension*

- Regulations for patient-level electronic consent vary across states, complicating planned implementation of an innovative web-based consent protocol

LIRE Project – Lumbar Image Reporting with Epidemiology

(PI – Jarvik, UW) *Cluster trial to determine if insert epidemiological benchmarks into lumbar spine imaging reports reduces subsequent tests and treatments*

- Differing institutional opinions regarding whether consent is needed, and if it is needed – who should consent (patient, provider, health plan)
- Variability across sites in willingness to cede to a central IRB – even given little to no risk to human subjects
- HMO Research Network's (HMORN) IRB ceding process could be used for some partner sites, but the prime site (UW) is not an HMORN member

Topics Proposed for HCS Core Related to Consent and IRB

GroupHealth

Consent and IRB Challenges

- Navigating variable state regulations for web-based, electronic consent
- Willingness of sites to cede IRB authority to a lead IRB
- Determining if consent is needed for a cluster randomized trial and if so, who is consented

NIH Expectations

- NIH may begin compelling UH2 projects to use some form of streamlined IRB review

Ongoing efforts to address challenges

- Rob Califf and Collaboratory CC's Ethics core are beginning work at a policy level to gain consensus around cluster randomized trial consent issues
- HCS core is connecting Jarvik to HMORN IRB ceding materials, and internal experts regarding its use

Example Current Challenges
Business Concerns and Contracting

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TiME Trial in Maintenance Hemodialysis

(PI – Dember, UPenn) *Cluster trial evaluating the systematic implementation of prolonged hemodialysis session duration for individuals with irreversible kidney failure initiating maintenance hemodialysis treatment within 2 dialysis provider orgs*

- Business needs drive decision making; motivations regarding participation often differ from those of academic medical centers
- Proprietary concerns related to submitting data to NIH repository

PPACT Trial – Collaborative Care for Chronic Pain in Primary Care

(PI – DeBar, Kaiser Permanente-NW) *Cluster trial evaluating psychosocial service integration in the primary care environment for chronic pain patients in 3 KP regions*

- Conservative nature of covered entities with respect to contracting due to perceived compliance risks (e.g., patient privacy and HIPAA) and proprietary interests
- Communicating billing info correctly to FQHC patients for study CRC screening
- Coding study visits in such a way as to address billing compliance concerns

Topics Proposed for HCS Core Related to Business Concerns and Contracting

GroupHealth

Navigating business-driven risks and requirements

- Clarifying and negotiating roles in working with and within systems and clinics
- Understanding business and data privacy concerns of covered entities
- Contracting with for- and non-profit business entities
- Ensure correct and up-to-date billing info is given (mix of insured vs. non-insured)
- Building trust, relationships, and understanding the business POV in order to negotiate solutions (e.g., submitting health plan data to NIH repository)

Potential generalizable products

- Compare/contrast – working with for-profit, non-profit and academic entities
- Strategies for balancing research benefits with burdens to the health systems and clinical operations
- Models to help health systems become less conservative in nature while remaining fully compliant
- Educational materials for understanding business related concerns, motivators, expectations, budgeting norms, etc (business vs. academic POV)

Example Current Challenges
Variability Across Research Sites

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Population-based Programs to Prevent Suicide Attempt

(PI – Simon, Group Health) *Cluster trial, evaluating the effectiveness of two programs to prevent suicide attempts among patients reporting suicidal ideation on routine depression questionnaires*

- One partner is a less well defined health "system" (e.g., practice integration, work standards); presenting challenges relating to data needs, ability to track outcomes

STOP CRC in Priority Populations

(PI - Coronado, KPNW)

- Study relevant screening is already beginning to roll out at some clinics; need to operationally and methodologically address possible contamination
- Creating image only FIT-kit instructions to address low literacy and multi-linguistic needs of portions of the population
- Use of different EHR at SeaMar clinics

Topics Proposed for HCS Core Related to Variability Across Research Sites

GroupHealth

Managing inherent differences across systems, clinics, and populations

- Different EHRs across partners
- Systems changing EHR systems during the study period
- Variable literacy levels and linguistic needs across regions
- Degree to which all partners are health “systems”

Potential generalizable products

- Methodological approaches for addressing when study relevant practice changes roll out at different times at different clinical sites, and possible contamination of the intervention
- Decision support tool mapping out needed health system elements (e.g., data, outcome tracking, practice standards) to help researchers select viable partners
- Practical considerations for conducting research in large business chains (e.g., dialysis centers, nursing homes, pharmacies)

Example Current Challenges
Engagement and Education

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TiME Trial in Maintenance Hemodialysis

(PI – Dember, UPenn)

- Incentivizing providers to carry out intervention protocols when they already have multiple time and performance pressures
- Building trust and relationships and gaining buy in across nearly 400 relatively independent facilities, each with its own layers of administration, etc

PPACT Trial – Collaborative Care for Chronic Pain in Primary Care

(PI – DeBar, Kaiser Permanente-NW)

- Need to educate clinicians about how pragmatic trials intervene on the system, not simply in the system; differences between pragmatic and traditional RCTs

Topics Proposed for HCS Core Related to Engagement and Education

GroupHealth

Fostering relevance, understanding and buy-in among non-researcher stakeholders

- Engaging and educating diverse groups about pragmatic trials
- Gaining buy-in and addressing training needs across multiple clinic sites and/or partners

Potential generalizable products

- Communication strategies educating clinics and clinicians about pragmatic trials vs. traditional RCTs (i.e., research in vs. research on the health system)
- Systematic, standardized, and ongoing process for interacting and engaging with health care leaders
- Strategies for addressing layers of buy-in and training needed across many clinic sites and/or partners

Example Current Challenges Integrating Protocols into Clinical Practice

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Population-based Programs to Prevent Suicide Attempt

(PI – Simon, Group Health)

- Low local capacity to deliver intervention at one site; exploring possibility of centralized delivery of intervention for that site – however, would require non-employees be granted remote access to local EHR

ABATE Trial to Reduce Health Care Assoc Infections and Readmissions

(PI – Huang, UC-Irvine)

- Institutionalize across 50 hospitals use of EHR-based prompt to document whether daily bathing (intervention) was administered by nursing staff

PPACT Trial – Collaborative Care for Chronic Pain in Primary Care

(PI – DeBar, Kaiser Permanente-NW)

- Scope of practice limitations for physical therapists prevent group visits for intervention patients

Topics Proposed for HCS Core Related to Integrating Protocols into Clinical Practice

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Institutionalizing study procedures at both the systems and practice levels

- Working with systems to alter EHRs and clinician practices to meet study needs
- Centralizing intervention delivery to address low capacity for local delivery
- Training large numbers of clinics and practice teams on study protocols
- Disconnects for some potentially-eligible patients from referral patterns

Potential generalizable products

- EHR tools for embedding study protocols (e.g., intelligent eligibility algorithms)
- Practical ways to galvanize behavior changes needed to implement new protocols
- Sharable methods (for Epic users) for implementing EHR based intervention
- Best practices to minimize workflow impacts on clinics delivering study interventions
- Special considerations when conducting research on patients with severe chronic illness and/or multiple co-morbidities

Example Current Challenges
Sharing PROs and Research Findings

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Nighttime Dosing of Anti-hypertensives

(PI – Rosenthal, UI)

- Communicating any adverse reactions to study drug protocol to physician, EHR

LIRE Project – Lumbar Image Reporting with Epidemiology

(PI – Jarvik, UW) **Challenge**

- Gaining health system buy-in on the advantages of routinely collecting standardized intensity of pain measure (pain NRC) for back pain patients

Topics Proposed for HCS Core Related to Sharing PROs and Research Findings

GroupHealth

Enabling information flow between researchers, clinicians and systems

- Process needed to report research data (e.g., patient reported outcomes), adverse drug reactions, and other relevant data back to the patient's physican and EHR record
- Often a lack of standardized measures in EHR systems (e.g., pain NRC) to collect research derived data
- Health systems and their IT departments have other demands and priorities for new EHR functionality

Potential generalizable products

- Best practices for the effective and parsimonious transfer of research derived data and adverse events back to EHRs and physicians
- Communication strategies for sharing study findings to health system decision makers (not just academic audiences); address not only effectiveness but cost and ROI, clinician burden, and other business-related concerns and motivators

Priority Setting and Work Products

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Priorities

- Number of potential products already identified far exceeds capacity of the core; need to prioritize what to work on first

Process

- Each demonstration project asked to identify their single top priority for any on the list
- Work collectively to narrow down to a realistic number to take on at once
- Capacity issues will depend on what is picked (complexity, extant materials to draw from, desired product, etc.)
- Augment our capacity by drawing from other cores where topical intersections and overlaps exist

Products

- Practical tools
- Citable publications (generalizable knowledge)

Cross Core Coordination

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A number of topics cross multiple projects or domains or extend beyond the HCS alone. We are managing this by:

- Transparently tracking challenges and work products, and where needs and issues overlap across projects and cores
- Regular conference calls with Collaboratory CC leaders (Rob Califf, Rich Platt, Kathy Fox) to ensure efforts are not duplicated across cores
- Working with Collaboratory CC leaders to identify a single core to ‘own’ those issues of overlapping scope, when needed. Some issues and needs identified by the HCS core may fit better under another core
    - e.g., IRB and cluster consent challenges: Ethics core
    - e.g., EHR data, Epic tools: EHR core
- Collaborating across cores to draw out expertise to address challenges and develop products in a robust manner

Creating Learning Health Care Systems

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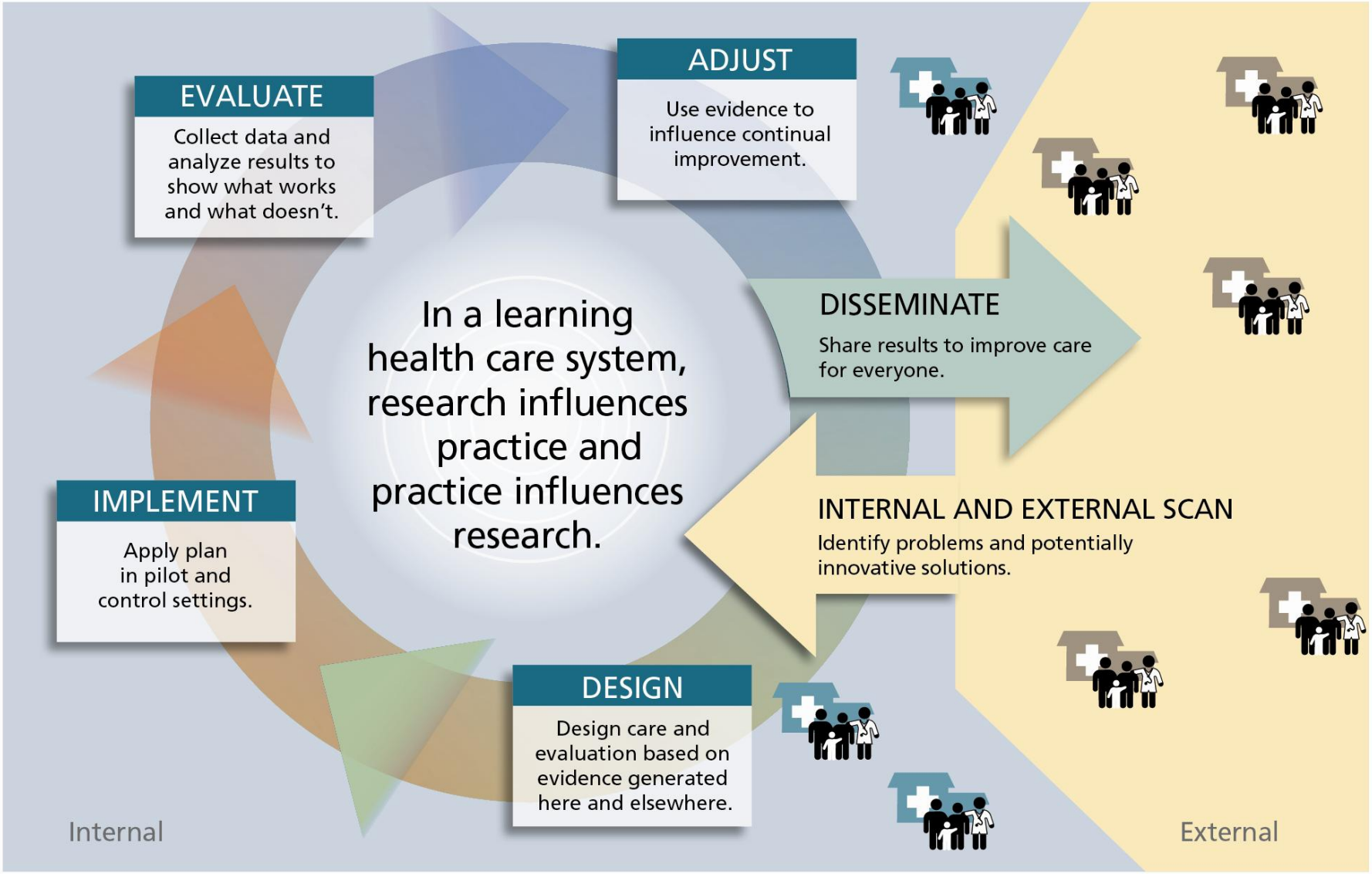

Questions?

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