NIH Collaboratory

Health Care Systems Research Collaboratory

Achievements and Sustainability

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Collaboratory: A National Experiment to address 'missing data'

- High percentage of decisions not supported by evidence*
- Health outcomes and disparities are not improving
- Current system is great **except**:
  - Too slow, too expensive, and not reliable
  - Doesn't answer questions that matter most to patients
  - Unattractive to clinicians & administrators

We are not generating the evidence we need to support the healthcare decisions that patients and their doctors have to make every day.

*Tricoci P et al. JAMA 2009;301:831-41.

Collaboratory: Shifting the Paradigm

- Explanatory
  - Mechanisms and biological explanations
- Pragmatic (or Practical)
  - Informing decision makers
  - Broad range of practices
  - Broad range of participants/patients
  - Either very streamlined and focused or answering broad range of outcome issues of interest to patients

Re-engineering the Clinical Research Enterprise

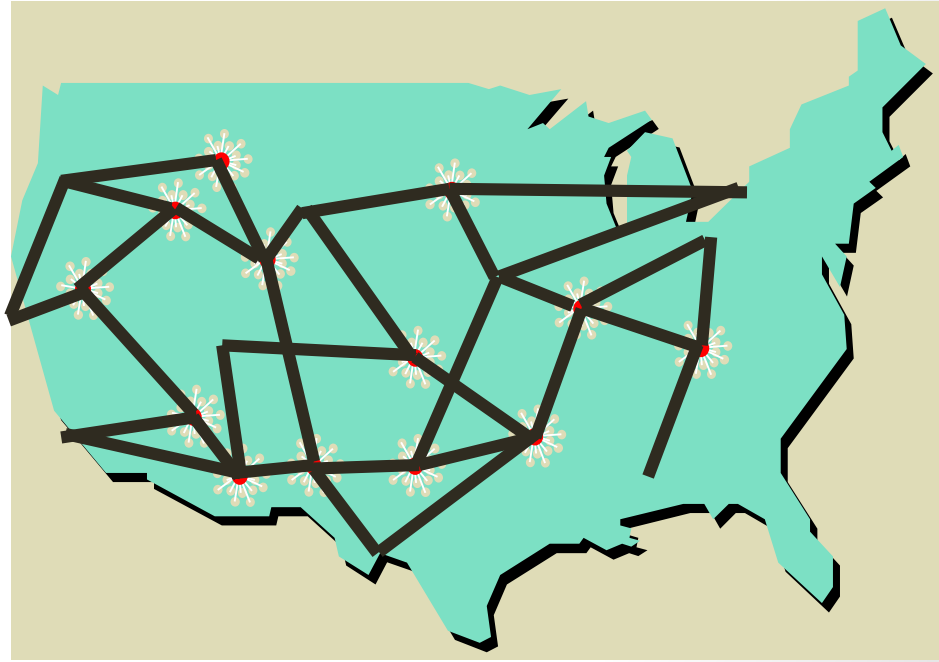
Increasing Level of Difficulty

Plan and start a few demonstration networks Simplify complex regulatory systems – demonstration projects Plan for networks in place for all institutes	Funding mechanism to sustain national system through consensus of all constituents ("1% solution") Simplified regulatory system in place for networks	**National Clinical Research System creates effectiveness data that moves rapidly into the community AND data on outcomes and quality of care; sustained efficient infrastructure to rapidly initiate large clinical trials; scientific information for patients, families, advocacy groups**
Establish repositories of biological specimens and standards for collection Standardize nomenclature, data standards, core data, forms for most major diseases Start a library of these elements shared between institutes and NLM Develop efficient network administration infrastructure at NIH Develop standards for capturing images for research	Data standards shared across NIH institutes Funding mechanisms evaluated to determine which are most efficient	**ONE medical nomenclature with national data standards (agreed to by NIH, CMS, FDA, DOD, CDC)** **Data standards updated 'in real time" through networks** **National repository of images and samples** **Critical national "problem list"** **Most efficient network funding mechanisms in place across NIH**
Create NIH standards to provide "safe haven" for clinical research Inventory and evaluate existing public-private partnerships, networks, CR institutions, and regulatory systems Establish FORUM(S) of all stakeholders Establish standards for and pilot creation of a National Clinical Research Corps Demonstration/planning grants to enhance/evaluate/develop model networks	NIH standards for safe haven in place Regulations and ethics harmonized with FDA, CMS Public private partnership mechanisms in place 100,000 members of certified "Clinical Research Corps" Standards shared across NIH	**Participation in research is a professional standard (taught in all health professions schools)** **Study, evaluation and training regarding clinical research a part of every medical school, nursing school, pharmacy school** **Clinical research practices documented and updated regularly to maintain safe haven** **Networks provide detailed training about network specific issues**
1-3 years	4-7 years	8-10 years

Time

Integration of Clinical Research Networks

- Link existing networks so clinical studies and trials can be conducted more effectively
- Ensure that patients, physicians, and scientists form true "Communities of Research"



Collaboratory: What will be the legacy?

- *Rethinking Clinical Trials*
  - Distributed Research Network/Electronic Health Records
  - Biostatistics and Study Design
  - Phenotype, Data Quality and Data Standards
  - Patient Reported Outcomes
  - Healthcare System Interactions
  - Stakeholder Engagement
  - Regulatory & Ethics
- Generalizable Demonstration Projects
- …..Others

Example #1
How do you make soup better?

- If we were all eating from the same pot, the soup would get better
- Greg Simon

Example #2: Reusable platforms

- The NIH Collaboratory DRN facilitates research partnerships with organizations (Data Partners) that possess **electronic health data that have been quality checked and formatted** to support multi-site biomedical research
  - **300 million person-years** of observation time and detailed information for **billions** of medical encounters and outpatient pharmacy dispensings

" It only takes a couple of days… Thurs night to Tues"

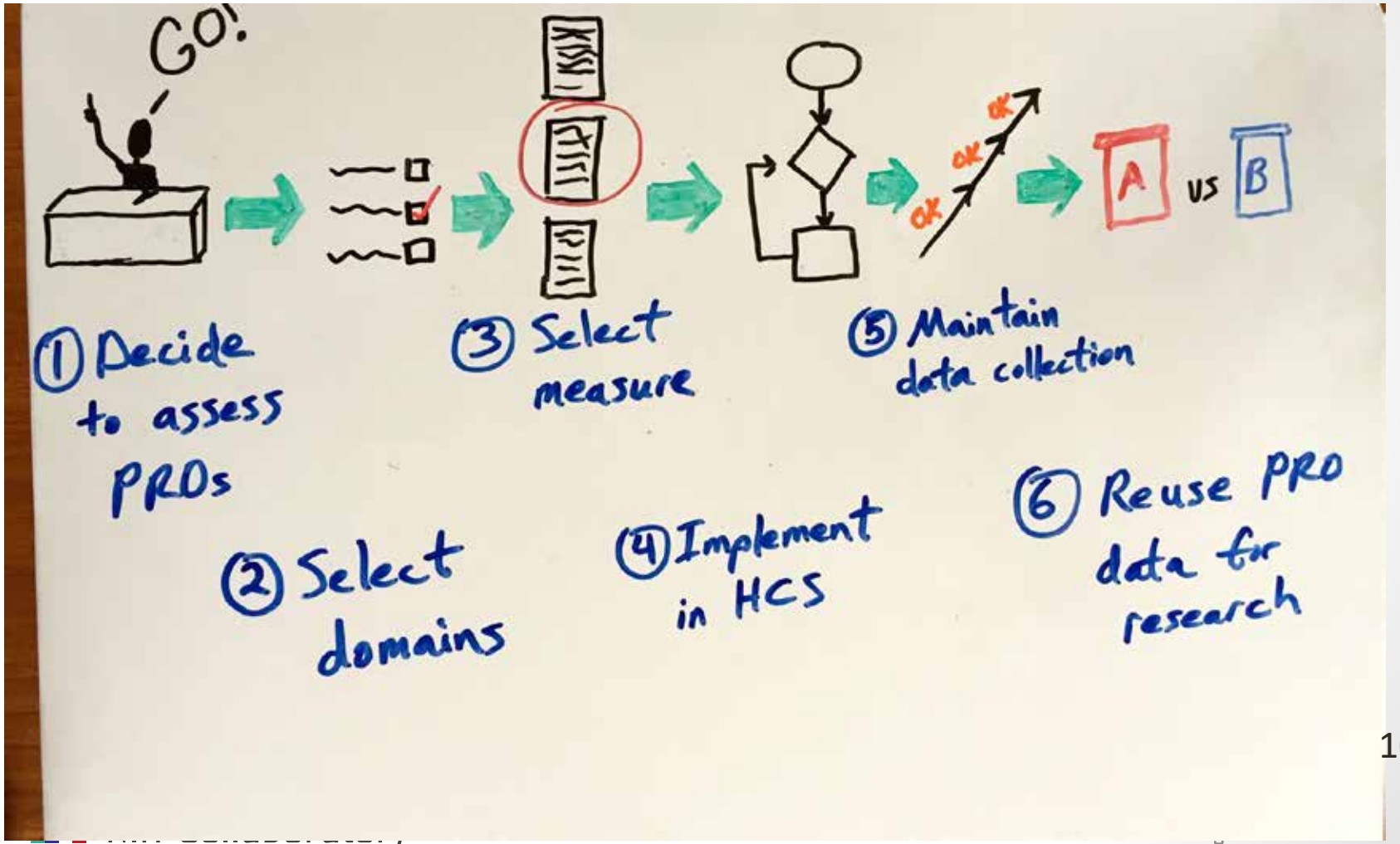
-Jeff Brown

Example #3: A Jamboree

Ethical and Regulatory Issues in Pragmatic Clinical Trials

1. Overview
2. Minimal risk
3. Waiver or modification of consent
4. Research/QI distinction in practice
5. Data monitoring in PCTs
6. Achieving IRBs harmonization and efficiency in PCTs
7. Vulnerable subjects in CRTs
8. Gatekeepers in PCTs
9. Identifying direct and indirect subjects in CRTs
10. FDA regulated products and PCTs
11. Ethics and the nature of interventions in PCTs
12. Privacy

Example #4: Keeping it Simple



Collaboratory Themes

- Simple, pragmatic studies integrated into routine care
- Shift the research paradigm
  - By study design
  - By leveraging 'real-world' data
  - By re-useable tools and approaches
  - By healthcare system engagement
  - By sharing
- Driving administrative simplicity
  - Raising and addressing bioethics and regulatory issues
  - "Collaborating"
- Identifying challenges and needs
  - Changing healthcare environment
  - Alignment with clinicians, regulatory bodies

Collaboratory: Leave a lasting legacy