Adventures in Data Sharing

Health care providers collect data in an electronic health record during a patient visit.

Researchers have a study idea using those data, but discover there are not enough patients to do the study locally.

The researchers consider partnering with other sites to find more patients, but they are worried collaborating will be complicated.

Carolinias Collaborative Members have harmonized their patient data to allow researchers to query and obtain data across sites.

Carolinias Collaborative staff can help with data requests, identify co-investigators, and navigate the regulatory process.

With Carolinas Collaborative, our researchers kick off their research study—made better through collaboration!
Traditional clinical trials are valuable, but have limitations...

- Too expensive
- Too slow
- Do not answer questions the right questions
- Health outcomes and disparities are not improving
Research on clinical data can reduce these challenges.

Locally

Carolina Data Warehouse for Health (CDW-H)

i2b2

Regionally & Nationally

Clinical Data Research Networks (CDRNs)
EHR DATA & RESEARCH

HEALTH CARE PROVIDERS COLLECT DATA IN AN ELECTRONIC HEALTH RECORD DURING A PATIENT VISIT.
In the hospital/clinical context, YOU are data.
In the hospital/clinical context, YOU are data.
First and foremost, data about you is recorded by a provider in order to provide the best care for you. (Oh, and to bill you.)

Date: 8/16/2016
MRN: 888999222

Patient presents today with persistent cough and pain in left flank...
Not all that long ago, that data was recorded on paper. And there’s nothing really wrong with paper, per se...

100111101001001110010
0101001001011101011101
0100101101011101011001
0010111101101001000101
0110101001010111010100

Date: 8/16/2016
MRN: 888999222
Patient presents today with persistent cough and pain in left flank…
...until you want to start looking at many patients at once.

- Can’t find patterns and trends
- Can’t make complex comparisons
- Can’t query
- ...Flammable?
...until you want to start looking at many patients at once.

“You can serve an individual quite well; you can deliver excellent customer service if you wait for someone to walk through the door and then you go and pull their chart... What you can’t do with paper charts is ask the question, ‘Who DIDN’T walk in the door?’”

--Dr. Farzad Mostashari
Fmr. National Coordinator for Health IT
So how can we use EHRs to find the patients we want to study?
Developing a computable phenotype

Can you pull data from our EHR that will show me all patients between ages _____ and _____, who have been diagnosed with _______, but haven’t had a _________ in the last 6 months, but have had ___ visits in the ________________ clinic over the past year? I also need to know if they’re taking ________________, or have had any ___, ___, or ___ lab values over ___ mg/ml in the past year.
What do I do with my phenotype?

- NC TraCS offers “local” tools to support research on clinical data, where you can put your phenotype to the test:
  - **Carolina Data Warehouse for Health**
    - Central repository containing clinical, research and administrative data from the UNC Health Care System
    - Over 5 million patients, dating back to 2004
  - **i2b2@UNC**
    - Self-service tool that allows researchers to query CDWH for counts of patients
Now, what if you wanted to look at many patients at different health systems across the country?
Why look beyond UNC?

- Study rare diseases
- Increase generalizability
- Support study recruitment
- …it’s what your grant requires
But it can be hard...

- Study team may not know any potential collaborators at another site
- Data are formatted differently across sites making comparisons challenging
- Multi-site regulatory process is daunting and confusing
HOW CDRNS WORK

CAROLINAS COLLABORATIVE MEMBERS HAVE HARMONIZED THEIR PATIENT DATA TO ALLOW RESEARCHERS TO QUERY AND OBTAIN DATA ACROSS SITES.
CDRNs have common features:

1. Common Data Model (CDM)
2. Federated structure
3. Collaborator network
4. Shared governance

These features collectively reduce barriers and support inter-institutional data sharing and research.
CDMs allow data across sites to be compared.

- UNC’s data is optimized and coded for our organization. But what if we want to share it?
- If we just try to smash the data in our warehouse with, say, the data in the Duke warehouse, we’ll be...
CDMs allow data across sites to be compared.

- But if we could agree with one, two, three, or more organizations to spin up a special instance of our data where we all agree on structure...
- ...we’ll have an instance of our data that’s sharable in a number of ways.

(close enough)
CDMs allow data across sites to be compared.
Data federation allows for controlled data sharing.
Data federation allows for controlled data sharing.
Data federation allows for controlled data sharing.

Query for counts across sites

Federated Query Tool (Web-based)

Common data model

Data stored locally

Database 1

Database 2

Database 3

Database 4

UNC: 234 pts
Duke: 336 pts
HSSC: 502 pts
WF: 175 pts
CDRNs connect researchers to collaborators.

- Expand the expertise of your study team:
  - Content experts
  - Methodologists
  - Engagement experts

- CDRN staff can help you find collaborators at other institutions.
Each CDRN has its own processes for oversight and governance.

- Approval process for data requests
- IRB Reliance Agreements and guidance
- Templates for Data Use Agreements
Patient engagement occurs at all levels of the CDRNs.

- Patients serve on standing committees locally and within networks.
- Patient engagement encouraged in PCORnet projects.
- Local efforts to listen to and inform patients (e.g., discussion groups, patient newsletters)
National Projects

- **PCORnet Bariatric Study** – Observational study comparing outcomes of three common weight loss surgeries

- **PCORnet Antibiotics and Obesity Study** – Observational study comparing the relationship between antibiotic use in the first two years of life and weight gain in later childhood

- **ADAPTABLE, the Aspirin Study** – Pragmatic clinical trial that aims to determine the best dose to prevent heart disease while reducing side effects
Regional Projects

- **The HEART Pathway**— Pilot project that aims to evaluate the feasibility of disseminating a decision support tool for chest pain, developed at Wake Forest

- **Harmonization of Patient-Reported Outcomes**— Pilot project that aims to harmonize patient-reported outcomes across the four of the Carolinas Collaborative sites
CDRNS AND YOUR RESEARCH
## CDRNs at UNC

<table>
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<th>PCORnet</th>
<th>Mid-South CDRN†</th>
<th>Carolinas Collaborative</th>
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* Patient populations will include patients who receive care at multiple health systems
† Mid-South CDRN is part of PCORnet
What research can CDRNs support?

Pre-research
- Feasibility queries
- Engagement
- Match-making

Observational studies
- Cross-sectional
- Epidemiology
- Health services
- Comparative effectiveness or safety

Interventional studies
- Clinical trials
- Pragmatic randomized clinical trials
- Cluster randomization
Data Availability

Data availability vary by network and by institution. The CDMs will continue to be expanded.

- Patient Demographics
- Encounter Details
- Diagnoses
- Procedures
- Vitals
- Lab Results
- Medication
- Insurance Payor
Getting Started*

- Learn More: tracs.unc.edu/cdrn
- Request a consult http://tracs.unc.edu/consultation
- Create a computable phenotype
- Assess feasibility of project locally (i2b2)
- Connect with network for collaborators, counts, and data

* Order recommended but not required or appropriate for all studies.
Other ways NC TraCS Can Help

- Development and validation of computable phenotypes
- Linkages to claims data
- CER and Pragmatic interventions
- Regulatory support
- Stakeholder engagement consultations
More Information

http://pcornet.org/

https://midsouthcdrn.mc.vanderbilt.edu

https://carolinascarollaborative.org/