

Welcome to the 2015 LEC

Introduction:

Reviewed schedule and logistics

Prairie Chickens – Etsy Hand Crochet’s prairie chickens Controversy – different colored cheeks. Endangered one is the red cheeked one. Throw the chicken if you don’t understand what we are talking about.

Break out groups – PE, IRB,

Discussion of Trials/Studies – how do we do a better job at this?

Fishing Trip – looking at data that already exists. Here for a data interest and want to try out what’s available. We will serve people on an abbreviated fishing trip for data.

Cohort Characterization – Each network had to tackle three diseases. Discuss what they learned with each other.

Collaborator Identification Process

World Café – Kim Kimminau leading – talked at all day long and then fried out. This afternoon the world café will give people a chance to rotate around to each section and what’s happening in each section. Think about what table you would like to sit at or visit.

Friday

Role play, what does it mean to be engaged in a trial or work with study data. Visitors – how do we take data from different people when there are concerns about privacy?

Data Sharing and Record Linkage

Data Request Oversight

Project Management Meeting

Sustainability and Terms for Commercial Use for Data Access and Data Use.

How do we approach/approve projects?

How we work and why we’re here. Get and give energy with others. Seek answers and solutions. Actively engage & learn from another. PCORnet vision back home to engage your teams. Plan and design with patients. We are moving from building to operating. There are a lot of large networks. Main point, when you write PCOR grants/contracts. Have big ideas. Planning to do something that you may need help in designing and implementing. Looking for your input on how to better plan and design the network. Something that patients and dr are going to want to experience. Project started 3 years ago. Phase 1 is about building phase 2 is about operating. Built the house and now start occupying the house.

In healthcare is a system. You plan on something then adjust those plans as you work through the process. This will be better for patients and science. Right now this is a meeting to bring people together to develop the network, in the future we will advance patient care and research. How do we get feedback and get people to use the network.

Questions?

We don't want to change healthcare, but sometimes you need a new roof and a remodel. Spruce up the research system for patients.

Institutional engagement – most of us have academic partners that are not extensively engaged. We have to be thinking across all of the activities we do and how do we engage them and interested and involved. This is a network of networks. Multiple institutions, academic, hospitals and clinics. How does everyone stay engaged to help advance health? This is a great conference to bring those concerns and talk to people. Kaiser Permanente has a more homogeneous system. This is a good spot to think about that issue.

If we succeed at this, we are directly addressing this issue for everyone. CTSA award, big focus on working with other spokes of clinical activity. There are some people increasing our network that will have leadership and exchange across the regions.

IRB People are going to split off. Common rule.

Background: - Russ Waitman

What is PCORnet? Talk about our network that are involved in NIH activities. CTSA

One clinical Data Research Network: GPC leveraging NIH

One year post-funding examples:

Example Observations

Our National clinical research system is well-intentioned but flawed:

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

Notes: why should I get involved with this activity, it's an intrusion.

Both researchers and funders now recognize the value in integrating clinical research networks

- Linking existing networks – both coasts – make it a community of research. How does the information get stored

PCORnet embodies a community of research by uniting systems – Goal – ambitious project. Interesting challenge to build the ability to support different diseases. Multiple networks for a large highly representative example of the country. Not treating but looking at the data that comes from treating people. Create a system - Institute of Medicine – get leaders across the field to think about where healthcare needs to be. Every patient is an opportunity to learn. PCORnet is part of the vision to create resources where we can learn from patient care.

- Create
- Utilize
- Engage – plains data – bill gets paid by insurance company. How do we look at claims data across sites? This can tell you what kind of procedures are done. Possible use health records. Patients manage their health, talk to one another. A lot of data about your health is carried by devices. Patients, clinicians and health system leaders working together and pulling the data together.
- Support
- Enable
- Sustain = don't want this to be a network club and if you're not in the club you don't get to use the data. Build a club for us but anyone nationally can use it. There are a lot organizations that want to help cure a disease – ALS.

I wish my doctor had a way to get my heart rate when I'm not nervous at the Dr.'s office. Marry clinical data with billable data. Data that takes care of the patient, paying for the care, dr. office, pharmacy and then patient data on how to manage my care. Sometimes we want to do observational studies. Interventional or clinical trial – tell the patient or inform people that this practice would be better than that practice.

There is not a hepatitis network but they could benefit from this network.

PCORI map –

CDRN Map – what are we doing? Our goal was to have data on at least 1 million people that we manage securely and it be comprehensive. The goal is to have data from the -EHR-EMR. How do I organize clinical data – centralized dataset?

- Getting patients involved in creating and running the network.
- Involve patients – deep into doing science but we've all been patients. – Cheryl Jernigan – we want the voice of the patient. Create a resource that can treat all diseases. WE need patients bringing their perspective.

- Develop the ability to run a clinical trial – make sure the system works for clinicians; want to integrate it into the regular healthcare operations.
- Identify 3 cohorts of patients

CDRN Highlights – even though we are a network of networks

Patient Powered Research so they can get together with others that have the same issues. People may be very focused on one but with broad conditions it's harder to get our arms around that community. Their goal is to collect patient-reported data.

PPRN Highlights – mixture of people involved, Make a real difference for people.

GPC Size, goals and structure in phase 1 – flow chart

WE have a lot of physicians that are specialists. Learning engagement Kickoff.

Interventional Information – ALS Example. Collect data consistently. RB has been working with others across the country that are doing the ALS research.

Addressing complete and comprehensive care for tertiary academic med centers – Create a research-ready dataset of at least 1 million patients. – Tumor Registry – someone diagnosed then all of the care they have received for the next year. Lots of COMPREHENSIVE data. Across time and lots of procedures. Not many people have a breast MRI done until they are diagnosed. Before this diagnoses we don't have much information. KU is a referral treatment facility. How do we know their baseline? Our goal is trying to figure out how to work with other people to pull data. Come to Nebraska, treated, then go back home. What happens then? We would like to know what happens to those people that go back to their rural homes.

Common Data Mapping model – we make sure we are comparing apples to apples. Begin with simple tables – then add more data to get a more complete picture. Want a system to be able to store data beyond what is in the tables.

PCORi was smart – ADAPTABLE – Aspirin Dosing-A Patient Centric Table Assessing Benefits and Long-term Effectiveness Trial – ADAPTABLE – Build it and then test it with an early trial. Case Scenario – person who led was the initial leader of PCORnet.

Case Scenario of Saul taking a baby aspirin. Compare effectiveness of stuff that is out there every day. This was a PCORi type of trial. Which dose is most effective? Did people die or have another heart attack/stroke; did they have a bleeding issue. To answer all these questions you need enough people to answer the question. Enroll 20,000 people across the country. \$15 mill dollars to answer a question. Can't do a trial that cheap. The plan is to bring the networks together.

Normal clinical trial you have to set up data – this has a unique feature is that the data was collected by PCORnet.

Closing Phase 1 thoughts - GPC we are one network in the middle of the country. Support observational and perspective

Phase 2 Focus Area Highlights

- Address concerns needed for the project.
- What can we add?
- Home page: www.gpcnetwork.org

Structure – Modify Structure based on Learning and challenges – Flow chart – we thought we would do a better job on restructuring how we work. Broke it down into two types of sausage. Divided the house into two types of activities. Data = how are we going to share that data. Functions = how do we operate this network. We had funding to build this network – can build this and let people use it but it doesn't cost any extra money for more people to use it. How do we balance the cost, sustain the network and allow people to use it. Want to make sure everyone is comfortable about how we are using our data. As a patient in the room, when we were building this, have patients get together with Cheryl so she could advise us on their ideas and solutions for the network. We want formal involvement over phase 2 to come together and give updates on how we are doing; where do we have success; what do we need to change.

Demonstration projects to bring together health system leaders. We are learning, getting patient input and redesigning the system.

Collaborator Database – We need to figure out how to bring together data of potential institutions. We already know the clinical researchers – database we can call upon to see who the clinicians and investigators are. We need to link it to who the providers are. Find clinicians who publish / research and provide care. A lot of focus on recruiting patients to trials. Lot of concern around a normal population of patients. A lot of protections on how you sign someone up. Similar to social media, get people who are interested in helping with research here is my name. How do we do this kind of match making.

Better data – New sources of data that we are trying to bring together. Structure data – richer types of studies. Collect survey data, different types of trials – that answer the same questions –

Over view – not a lot of questions – not too many people fell asleep. AS we are collecting data and doing trials, what is the downstream of data? What happens once the trials is done and the data is available. We want to think about that and bring this concern. How do we give feedback data back to providers, clinicians, researchers? We start building systems within – we want to think about how to do this.

PPRN – list of established PPRN's – yes, www.pcornet.org – all networks are listed here. You can see who is involved in the network.

Break –