THURS 10:00 - 12:00: Cohort Characterization

- PCORI CDRN and PPRN funded separately without knowing how they would be connected.
- PCORnet can be driven by both data collection and clinical research development.
- Some studies will be able to span multiple CDRNs.
  - Still need to figure out how best to do this.
- Medicare integration could help with cohort characterization.
- GPC could really help junior faculty do research at a national level

Russ Waitman presents initial slides

- Not all data registries aid in trial recruitment (i.e. cancer tumor registry).
  - tumor registry produce first clinical signal of breast cancer.
  - could potentially tease earlier signals out of unstructured notes data using natural language processing.

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  - As you expand your sources of clinical data you increase your potential of capturing signals of interest.
  - Hoes do the sources of data at different sites affect data quality.
  - PCORI interested to see how CDRNs innovate how data is moved from novel sources to the CDM.
  - Use ResDAC (Research Data Assistance Center) as a test platform for cohort characterization.
    - ResDac contains both Medicare and Medicaid data.
    - GPC will buy ResDac from 2011-2013 as an addition data source.
  - Is it possible to track patient as they move between sites? Yes.
  - Ann: Is it possible to link child/parent record relationship? We do have some mother/child linkages?
    - Street address, insurance benefit guarentor, emergency contact info.
    - Familial linkages are broody applicable.
    - Mei is working on integrating geocoding information.
    - Data linkage quality questions: Observational study vs. prospective
  - Build support model for clinical intervention.

(Dan C's notes; perhaps redundant)
Ann Davis: how can I connect health records of parents with children?
Dan Hale: we did some of that for the obesity survey; it was messy
Alex B: we used emergency contact, …
Dan C: I thought it was street address

Ann: how does funding work?
Russ: talk with Tamara and Li (KUMC honest brokers) to explore HERON, babel...
Russ: we have a data request form (linked from www.gpcnetwork.org) to facilitate collecting data from other sites; for maybe 5 sites would be willing to run the query for $200/site, so for $1K you might have pretty good preliminary data for a grant proposal.

Russ: pilot funding from CTSA is a possibility

… setup Google doc for collaboration…

- GCP member begin investigation at their local site to determine feasibility, and expand to other sites as needed.
- Now with phase 2 we want to start seeing pilot studies which begin to use GPC resources.
- Want to make sure GPC is the hub of data requests vs. “ping-ponging” requests among sites.

<u>Russ hands off to Dan Hale…</u>
We know where breast cancer is
Where is ALS?

- Challenges with reliance agreements and IRB
- Took till April to get REDCap up and running
- Last site IRB approve Sept. 2015
- “has not been an easy process”
- A lot of site specific customization on how to interface with patients
    - Not all patients diagnosed by physicians patients are highly symptomatic
- Surveys have been sent out.
- 40% did not respond well to callbacks (sometimes due to interaction w/ spose).
- UT Southwestern having the worst response (all electronic)
- Best responses from site with human interaction.
- Concern for easy-of-use for patient population of electronic and written resources.
- Change of address/phone number presented challenge to many sites.

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- Alex B: The may be disease specific patterns that a clinician could help define to aid with cohort characterization.

Russ: Where is Obesity at?

- Dan reviews Lessons Learned slides…

Russ: Patient motivation varies among disease popuations:

- Breast cancer vs. obesity (highly motivated vs. less motivated)

Brian: Concern about how REDCap email is recieved (bounces/spam filters)

- Dan: We can detect bounces, but not those mail marked as spam.

DanC: How about breast cancer?

- Brian: what question do people have?
- What about consent forms?
    - Many ALS folks did not return consent form.

- Brian: walk through survey
    - All mail survey
    - If you used windowed envelopes you don't have to worry about matching letters with envelopes
    - Brian reviewsedBC survey composition
    - Attached $10 bill or giftcard as appreciation/incentive for paticipants
        - Alex concerns about institutional financial resources in addtion to participant corrersion.
        - Brian: research shows there's a dose/response relationship between [gift card amount and response rate]
        - Dan meantions IRS's $600 income reporting requirement.
    - Brian shared Survey and Consent Report.
    - Brian: Each site comes to the tables with different resources.
    - Russ: We could/should leverage the strength of each of the sites.
    - Where is the status of the accumulated BC data?
        - Sites will receive data about their patients
        - Brian briefly detailed data-entry/form handle of recieved surveys
        - Dan: when will investigators be contacted about the status?
            - Brian: Plan to have a group call with site investigators the week of November 7th.

Dan: The is not currently any literature on qualitative patient recruitment, so there is potential to fill of space.
Dan: Glitches with studies between institutions have not generally originated from IRB issues, but instead from other institutional policy differences (accounting, administration, other local obligations, etc.).
Dan: It was difficult to find who was the lead for a given study at a given site.

(Dan C.'s notes, to integrate:)
Q/Alex: …?
Laura H.: ALS is a disease of exclusion; there is no test for it; you rule everything out
San Antonio: … often they present with weakness. So I searched for peg[?]: and found 5. I knew that's not right. So I looked for peg referrals and found 3000
Alex: wouldn't that ALS diagnosis disappear…?
[several]: no.
Russ: While there is a possibility of marking a diagnosis "resolved" in a problem list, that's not relevant to billing.

Russ: how about Breast cancer? [How accurate was the data in finding patients?]
Brian: we had just 3 that we managed to explain… I was surprised at the accuracy, given the level (complexity?) of coordination between sites etc.

THURS 1:00 - 3:00 : Cohort Characterization

Dan: What are the ALS strengths weaknesses?

- Rick: 30% response rate
- Jeff: over 54% response rate include “Do not want to participate”
- Rick: Part. would send in survey with first page (with identifier) removed.
- Rick: HERON search discovered additional patients (260 patients total).
- Additional challenge with ALS short lifespan after onset.
- Alex: I would like to see the initial deid dump to compare with final dump.
    - Could use datasets to train predictive models to use with future work.

General discussion:

- Dan: If there are disease specific drug, there use could be used to identify potential participants.
- Alex: Indentifiers could be buried in EHR free text fields.
- Jeff: It seemed at times like it was more work to use EHR data than to go without.
- Dan: Our participant list needed to be cleaned up manually (i.e. addresses, etc.) before materials were mailed out.
- Dan: Guarantor's address seem to be the cleanest and most accurate.
- Karen: Difference between REDCap instances caused some issues.
    - Dan: When projects are being design, it is important to specify version control.
    - DanC: It was less expensive to troubleshoot versioning issues, than wait for sites to update versions.
- Dan: We discovered our associated corporate physicians organization required
- Dan: Did you have to contact individual physicians to get buy in for their patient?
    - Rick: There are four ALS docs in Kansas, wasn’t an issue. What about obesity?
    - Ann: Certainly, but we didn’t have a problem with this at KU.
- Jeff: Currently we cannot use our EMR to determine if the SOC is used with a particular patient.
- Jeff: How to integrate forms/surveys into EMRs.
- Rick: Infrastructure doesn’t exist to disseminate additions/modification to EMR.
- Brain: What are the incentives to do so?
- Dan: there are five types up teams at each site:
    - Clinical
    - Informatics
    - …
- Rick: Our goal was to get patient report added into MyChart.
    - Brian: Has a research team successfully added a form to MyChart
    - Rick: Yes, …
    - RIck: University and hospital informatics teams need to collaborate to get this to happen. It’s been a problem. We don’t have the authority to demand it of the hospital.
- Jeff: We thought to add a REDCap link to the (EMR/MyCharts?).

- RIck: Where are we at with study site completion?
    - ALS: 3 sites left to go
    - BC: all 8 sites
    - obesity: 3 sites left to go
- Rick: When can we close this and look at the data?
    - Dan: I feel if they haven't finished by the end of Oct I don't think they will. The money has been spent.
    - Rick: I think we should wrap this up Jan 1
    - Dan: I agree.
    - Ann: <affirmative>
    - Alex: 1) Desire to declare victory 2) Desire to analyze data
        - These are not the same. We can begin analysis on the existing data, allowing time to troubleshoot issues along the way.
    - Dan: A preliminary look at the data is help to develop/refine process. Needs to be done in such a way that new data can just be dumped in.
    - Brian: Since we did a mailing we could have survey trickling in for quite sometime.
- Dan: I'd like to go over "lessons learned" with obesity.
    - Concern at some sites about adverse publicity.
    - It wasn't clear who owned the project at each institution.
    - Rick: Our ALS docs had difficulty knowing who the relevant GPC contact was.
    - DanC (to Dan): Have you seen this done better elsewhere? What could have been done better? More face to face meetings?
    - Laura: Our protocol was done a long time ago. Then IRB came back and we had to redo it. Nobody seemed to know what everyone else was doing, which resulted in having to go back and redo work.
    - Dan: We need project manager/study coordinators that are thinking about/know how organize research studies.
    - Laura: It would have been nice if the three different studies would have worked together more to find commonalities and cost savings.
    - Ann: We could have had site meeting covering each group, then those folks have take aways to their group specific meetings
    - Dan: Once we had Rhona on the calls we had IRB questions answered immediately.
    - Does anyone else know what their employee time estimates are?
        - Rick: It's amazing we were able to get people to work on this without funding.
        - Dan: Not sustainable in the long run.
        - Rick: This wouldn't have been possible without Laura, and she didn't get paid a dime for it.
    - Alex: Just like brick and mortar infrastructure, the product of phase one, will crumble and collapse without maintenance.
    - Ann: Does anyone one know of a major study that it using a CDRN?

        - There seems to some in the pipeline.
        - RICK: XO2 is a proposed interventional study we have proposed.

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    Dan: At KUMC are your institutional partners supportive/interested?
        - Rick: Passive indifference
        - Dan: <affirmation>
        - Rick: Still trying to get ALS forms into Epic.
        - Dan: Other institutions in town?
            - Rick: Only Children's Mercy.
            - Ann: CM being much more wary than KUMC.
            - Rick: DROC seems to be working well for KU

- Dan/Rick: Amount of time spent:
    - survey prep: 5 hours a week. We were underestimating at times.
    - project managers: 8 hours a week
- Alex: 100% of two faculty between 50% GPC infrastructure and 50% study support.
- Rick: Were you (Sarah) and Kiren funded by GPC?
    - Sarah: Yes we were.
- Dan: I feel we're not ready for primetime, but are be pushed to be ready.
- DanC: Russ is trying to a universal data sharing agreement.
- Dan: It's my feeling that we a central IRB for the GPC (i think) ???

- Alex presents his i2b2 cohort characterization tool:
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