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Enhancing Community Health Center PCORI Engagement (EnCoRE)

This work was partially supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (NCHR 1000-30-10-10 EA-0001).

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N^2 PBRN
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AHRQ

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Project Partners

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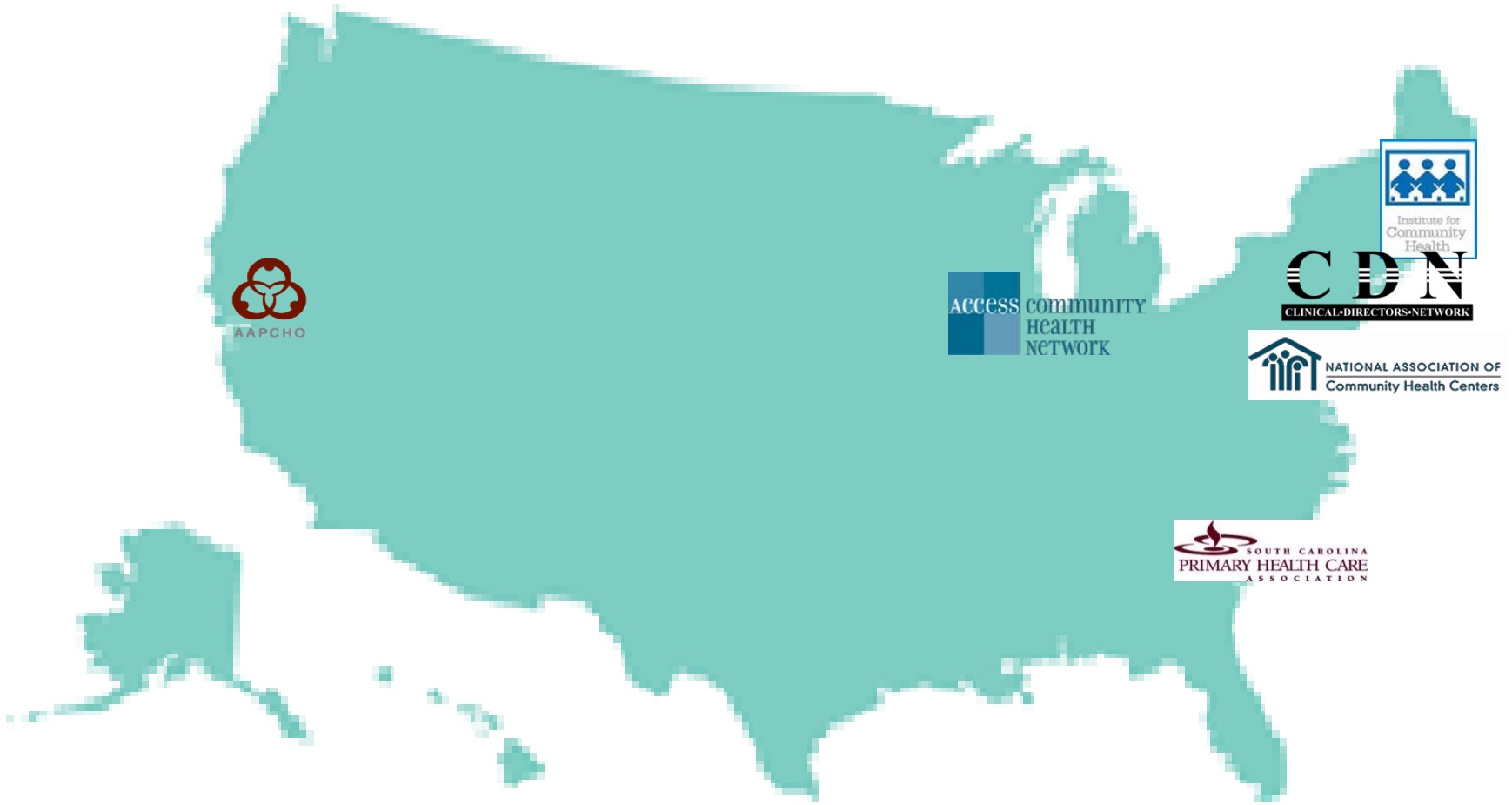
EnCoRE Partners' Geography 2014-2015



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EnCoRE: Enhancing Community Health Center PCORI Engagement

AIM: To build health center capacity to engage in patient-centered outcomes research through an interactive 12-month long training curriculum, walking health centers through the steps and skills needed to develop a patient-centered research proposal

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EnCoRE

Goal:

To adapt, enhance, and implement an existing year long training curriculum designed to educate and engage Health Center teams including patients, clinical and administrative staff in Patient Centered Outcomes Research (PCOR).

Objectives:

- Build infrastructure to strengthen the patient-centered comparative effectiveness research (CER) capacity of Health Centers as they develop or expand their own research infrastructure and engage in PCOR/CER
- Develop, implement, and disseminate an innovative online training, which will be targeted to and accessible at no cost to all Health Centers and other primary care practices. Content will prepare Health Center patients, staff, and researchers in the conduct of community-led PCOR
- Evaluate, refine, and disseminate training resources to Health Centers and other primary care practices nationally

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Sample Size, Power and Sampling Methods

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Senior Investigator, Kaiser Permanente Center for Health Research
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President/CEO CLINICAL DIRECTORS NETWORK, INC. (CDN)

Most Recent Homework Activity

- Define and finalize the testable hypothesis
- Are outcomes clinical outcomes or patient-centered outcomes (care delivery/systems)?
- Identify the main outcome (dependent variable), independent variable(s), and potential bias and confounders
- Has a database been identified?
- Has appropriate statistical software been identified?
- Determine appropriate descriptive statistics to perform

Acknowledgment

Material in this presentation was developed as part of the curriculum for the international **Methods in Epidemiologic, Clinical and Operations Research (MECOR)** program sponsored by the **American Thoracic Society (ATS)**

- Designed for physicians and health care professionals
- Intended to strengthen capacity and leadership in research related to respiratory conditions, critical care and sleep medicine in middle and low income countries

Testing a hypothesis

- We want to make inferences about a population from a sample.
  - i.e., we have a hypothesis we want to test

- We need to choose the number of observations to include in a study sample.
  - The larger the sample, the greater the power of the statistical test

=> Sample size determines statistical power

Testing a hypothesis

- What is (statistical) power?

⇒ It is the probability that we will observe an intervention effect (based on data from our sample) when an intervention effect actually exists.

Testing a hypothesis: Example

- Say we want to test a text messaging intervention to remind diabetes patients to take their meds on schedule, which should result in lower HbA1c levels.
  - We randomly assign patients to the **text message intervention** or to the "**usual care" control** groups.
  - Define the mean difference between HbA1c scores in the intervention and non intervention groups as our effect size:

$$\delta_{diff} = \delta_{tx} - \delta_{no\ tx}$$

δ_{diff} is the "effect size"

Testing a hypothesis: Example

- We specify mutually exclusive "null" and "alternative" hypotheses":
  - Null hypothesis: there is no difference in mean HbA1c between patients receiving the text messages and those not:

$$H_0: \delta_{diff} = 0$$

  - Alternative (2-sided) hypothesis : mean HbA1c differs between patients who do and do not get the text intervention:

$$H_A: \delta_{diff} = 0\backslash$$

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The truth vs what we observe

- What is the truth?
  - Either the intervention is effective or it isn't (we don't know which)
- What do we observe (we only do the study in a sample of the intended population)
  - Either we will observe an effect on HbA1c level when we analyze the data from our sample or we won't
- We want to optimize our chances of:
  - Observing an effect in our data **if** the truth is that the intervention really works.
  - NOT observing an effect **if** the truth is that the intervention really doesn't work

Testing a Hypothesis

What we see (in our sample)	The "Truth" (unknown to us) Our text intervention is: Effective	 Not Effective
We observe a difference in HbA1c	OK	error!
We don't observe a difference in HbA1c	error!	OK

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Testing a hypothesis

- Let's think about these possibilities in terms of probabilities

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Testing a Hypothesis

What we see (in our sample)	The "Truth" (unknown to us) Our text intervention: Works	 Doesn't Work
We observe a difference in HbA1c	Probability of deciding **there is an effect** when there really is one	Probability of deciding **there is an effect** when there really isn't one
We don't observe a difference in HbA1c	Probability of deciding **there is no effect**, when there really is one	Probability of deciding **there is no effect** when there really isn't one

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Testing a Hypothesis

What we see (in our sample)	The "Truth" (unknown to us) Our text intervention: Works	Doesn't Work
We observe a difference in HbA1c	Power = $1 - \beta$	Type I error = α
We don't observe a difference in HbA1c	Type II error = β	$1 - \alpha$

Testing a Hypothesis

What we see (in our sample)	The "Truth" (unknown to us) Our text intervention: Works	 Doesn't Work
We observe a difference in HbA1c	Power = 1- β Usually $\geq$ .80	Type I error = α Usually <.05
We don't observe a difference in HbA1c	Type II error = β Usually < .20	1- α Usually $\geq$ .95

Testing a Hypothesis

- Setting $\alpha = .05$ is traditional (and arbitrary)
  - i.e., we accept a 5/100 (or 1 in 20) chance of making type I error (i.e., deciding that there IS an effect when there really ISN'T)
- Setting power = .80, (i.e. $\beta = .20$) means we expect to have at least an 80% chance of detecting an effect when there really is one.

Testing a Hypothesis

- So… if we want to have 80% power and a 5% significance level how many patients do we need?

Sample Size (N) depends on

- Type I error = α
- Power =
- Effect size = Estimate of expected treatment effect, $\delta_{diff} = \delta_{tx} - \delta_{no\ tx}$
- Estimate of variability in treatment effect, σ
  - Will therapy affect everyone to the same degree or does the effect vary substantially, affecting some patients a lot and others very little?

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Sample Size

- Some common sample size applications assume that your data are normally distributed

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A simple sample size calculation:

$$2n = \frac{4(Z_{1-\alpha} + Z\quad)^2\ \sigma^2}{\delta^2}$$

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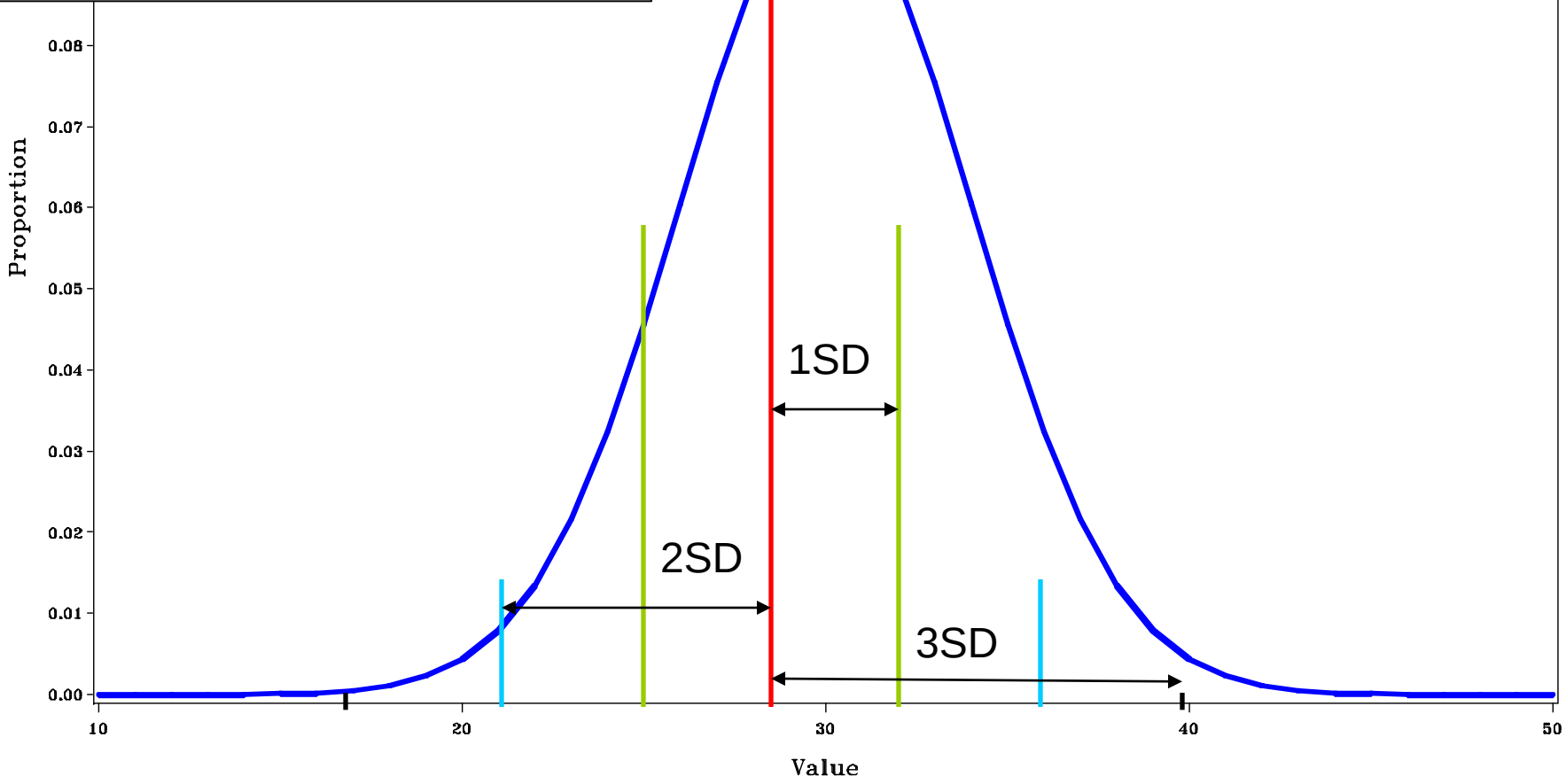
Normal Distribution

±1 SD, coverage=68.26%

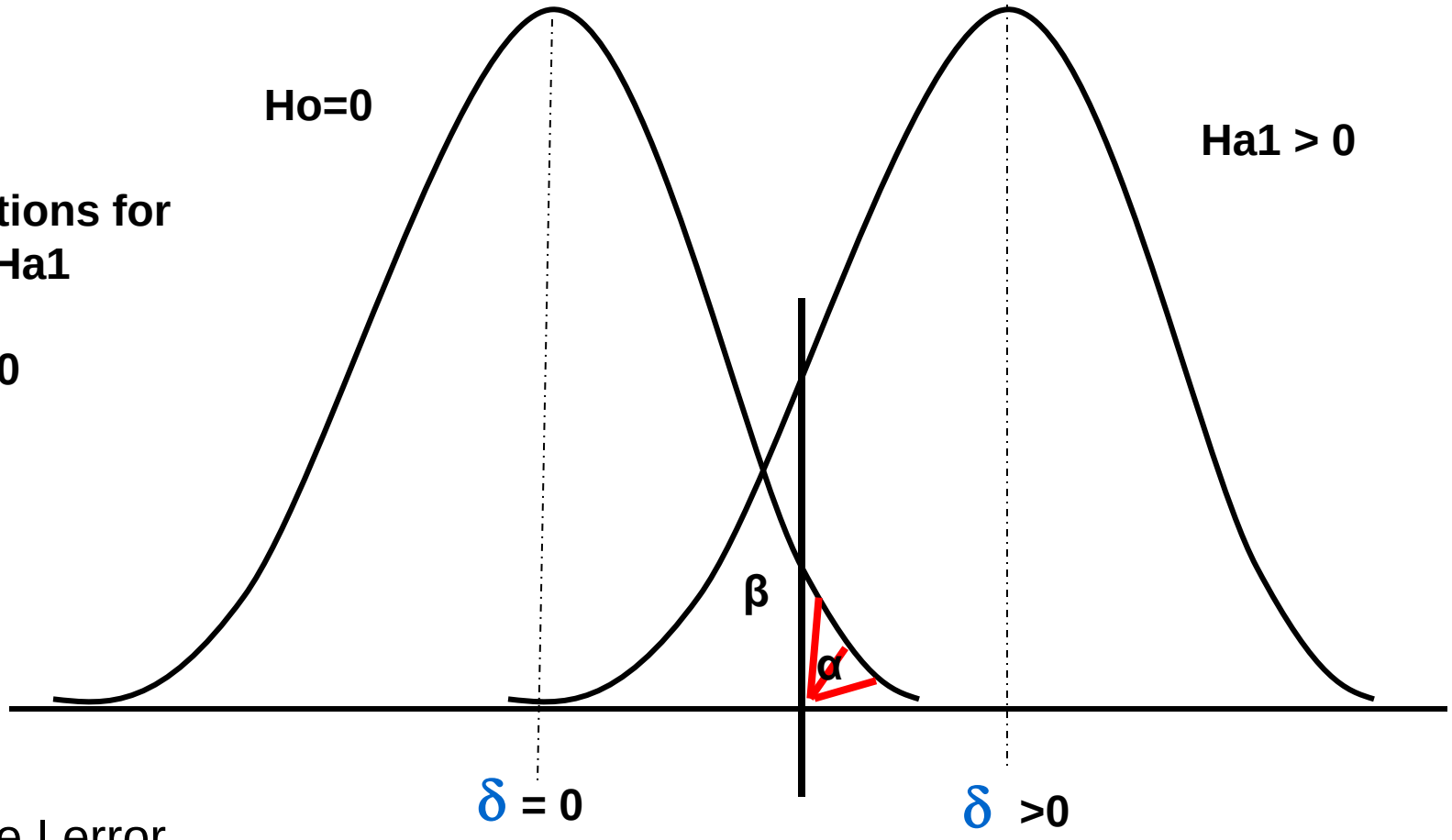
±2 SDs, coverage=95.46%

±1.96 SDs, coverage=95%

±3 SDs, coverage=99.73%

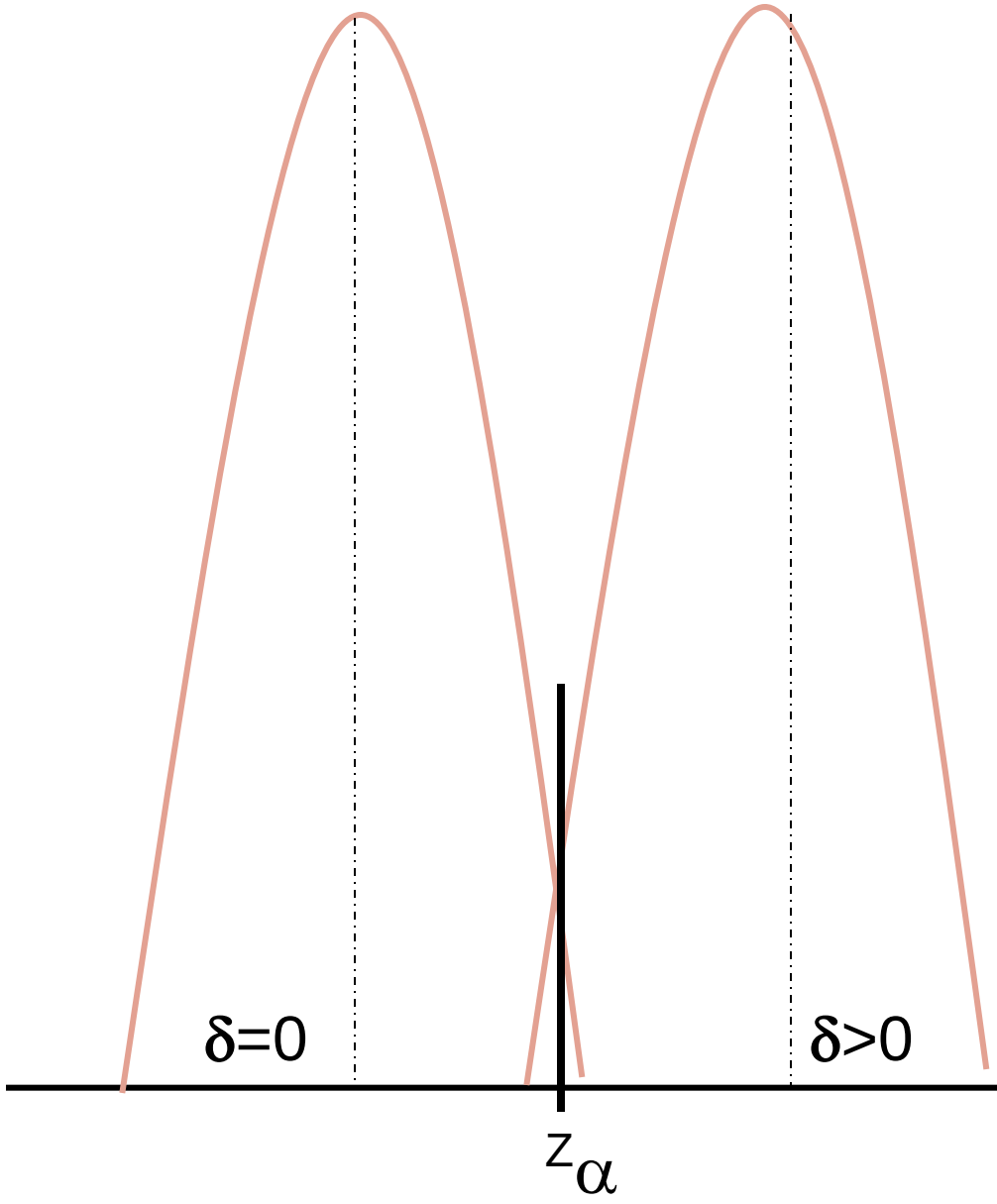


Distributions for Ho and Ha1
Ho: $\delta = 0$
Ha1: $\delta > 0$



α: Type I error
β: Type II error

Must choose cut point corresponding to α: Z_α



Increase in Sample Size
Tightens the Distributions
Decreases the Overlap

Both α and β are decreased

Trade-offs between sample size, power and effect size

- If we want to increase power, say from 80% to 90%, we must increase sample size
- If we want to detect a smaller effect size, say a 10% increase in survival instead of a 20% increase, we must increase sample size

Quiz

What is β?

- Type II error: The probability of failing to reject the null hypothesis when it is false

What is α?

- Type I error: The probability of rejecting the null hypothesis when it is true

What is 1-β?

- Power: the probability of accepting the alternative hypothsis when it is true.

Resources for power and sample size calculations

- http://davidmlane.com/hyperstat/power.html
- http://homepage.stat.uiowa.edu/~rlenth/Power/

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Sampling Methods

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Sampling

- Methods for selecting subjects for study e.g., people, organizations, trees, etc.) from a population of interest .
- Often we want to generalize results of study to the larger population.

Sampling

- Theoretical population vs accessible population
- Usually not feasible to sample full population.
  => Sample some members of a theoretical population as representative of the entire population
- Multi-step process
  - Identify population of interest
  - Identify accessible population
  - Develop sampling frame
  - Draw sample
  - Contact/recruit subjects/participants

Types of sampling

- Convenience sampling = identify a group of people you can get to "conveniently“
  - Examples: hospital staff, market women, senior housing
  - No "formal" sampling frame is used
  - Not able to calculate confidence intervals
  - Useful for many purposes

- Probability sampling = random selection
  - SRS (‘simple random sample’)
  - Stratified sample
  - CS (‘cluster sample’)

Random Sampling

- Involves creation of a "Sampling frame" (list of members of group to be sampled).
- Assures equal probability of selection for all members of the population.
- Estimates will be "unbiased" (precise statistical meaning: average of multiple samples will have population mean)
- Note: random does not mean "haphazard"

Simple Random Sampling (SRS)

- SRS Process:
  - Develop sampling frame: List accessible population of N subjects from which n subjects will be drawn (e.g., all individuals/HHs).
  - Use random process, e.g. random number table, to generate "n" numbers between 1 and N.
  - Identify "n" individuals in sample corresponding to the "n" numbers generated.

- Examples: phonebook - random digit dialing.

Simple Random Sampling (SRS)

- Advantages:
  - Most basic form of sampling
  - The gold standard to which other methods are compared.
- Disadvantages:
  - All individuals/HH must be identified prior to sampling
  - May be unrealistic - time, money.
  - Selected individuals/HHs may be highly dispersed. Visiting each may be very time consuming

Stratified Random Sampling

- Divide population in homogeneous (mutually exclusive) subgroups (i.e., “strata”) and do SRS within each group
- Advantages
  - Enough cases from each strata to make meaningful inferences on key subgroups (e.g., small minority groups).
  - Generally have more statistical precision than SRS **if** the strata are homogeneous:

    => the variability within-groups is lower than the variability for the population as a whole.

    => smaller sample sizes
- Examples of common strata: age, race, gender, educational attainment level, socioeconomic status, rare traits, diseases or conditions

Cluster Sampling (CS)

- CS Process
  - Construct sampling frame using groups or clusters of individuals (or HHs) without identifying or listing each one.
    - Cluster = villages, towns, districts, urban blocks, etc.
  - List clusters
  - Take a random sample of the clusters
  - Obtain list of individuals/HHs only for those clusters selected in the sample
  - Sample a random sample of individuals/HHs within each selected cluster

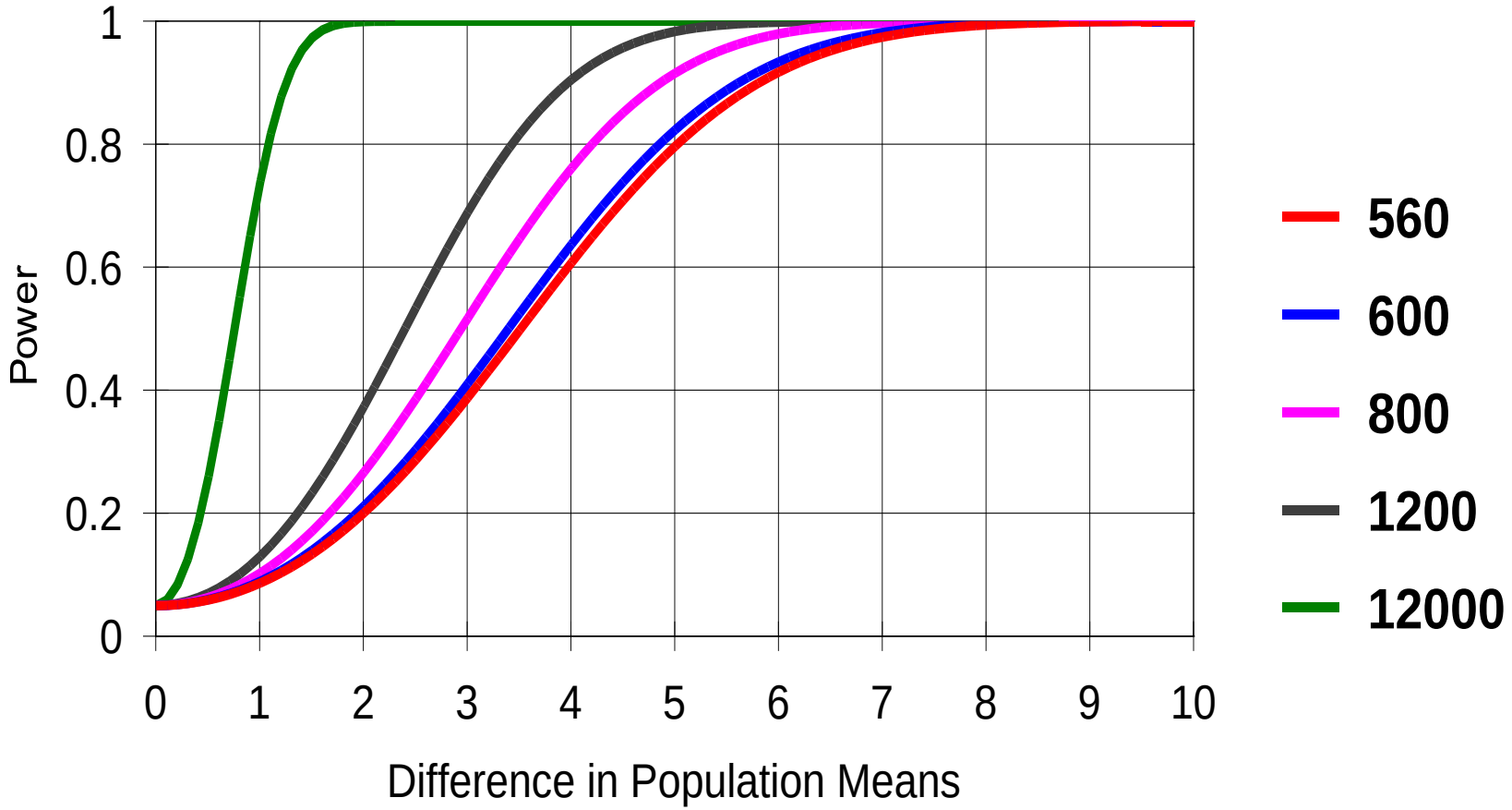
Cluster Sampling (CS)

- Advantages:
  - Economy: listing costs/travel costs.
  - Feasibility: most countries will have lists of population by groups (villages, towns)
  - Allows a larger sample size than SRS due to decreased costs
    - for same resources (money, person-time), it's possible to gain greater precision with cluster sampling
- Disadvantages:
  - Estimate not as precise as SRS for the same sample size.
    - Design Effect = Variance Cluster Sampling/Variance SRS. Factor by which to increase CS sample size to obtain same precision as for SRS
- Example: WHO Expanded Programme on Immunization (EPI) sampling method.

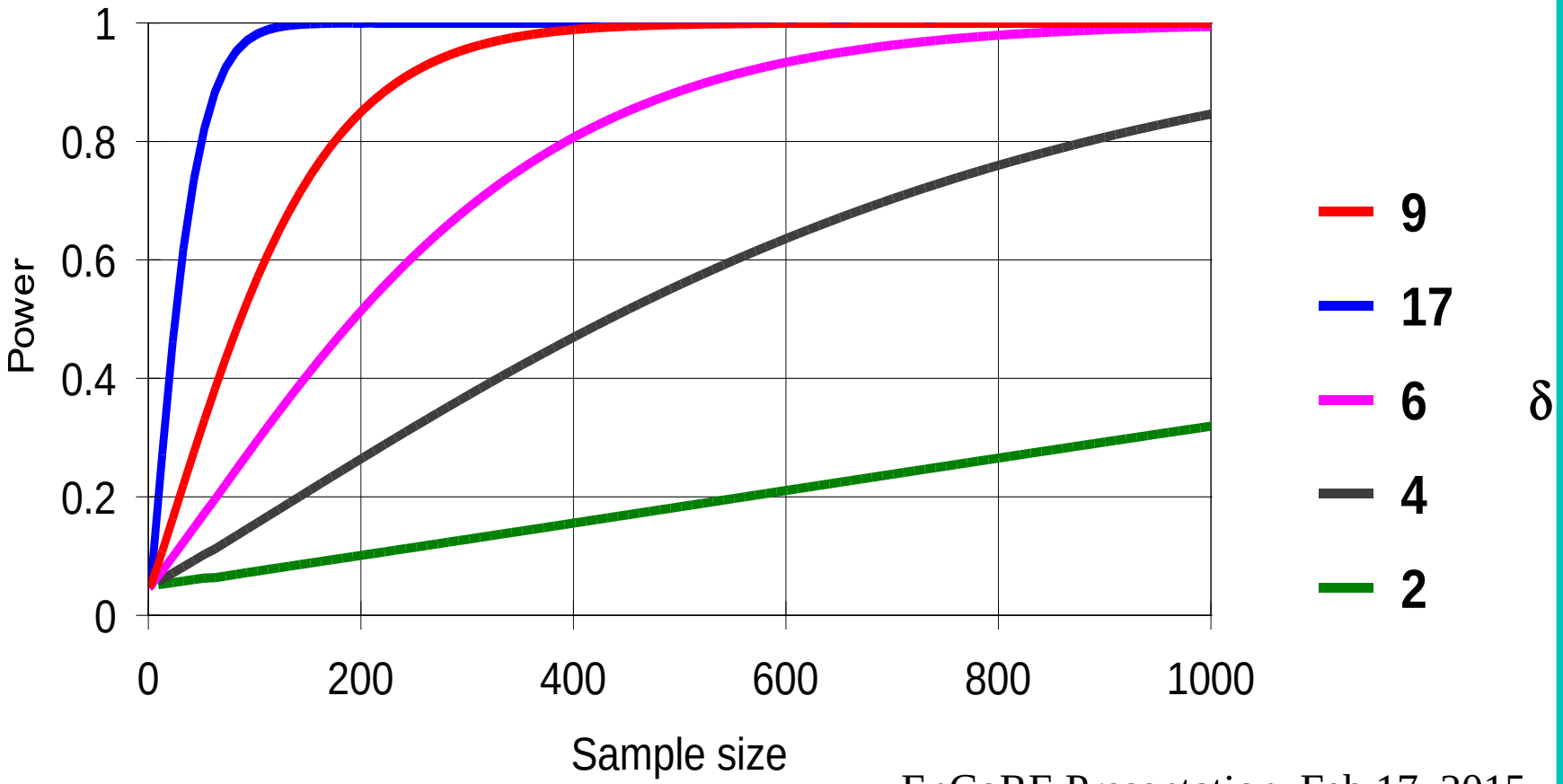
Cluster Sampling (CS)

- Considerations
  - Budget – transport costs can be high, esp. in rural areas
  - Travel/logistics
    - Define center/periphery of urban areas.
    - How to account for appartments vs houses – need to establish unambiguous methods, eliminate personal choice of researchers
    - Number of surveys in given area per day.
  - Supplies
  - Technical
    - Can estimate optimal cluster size if you know:
      - transport costs to each cluster
      - cost for interviewing each respondent
      - Roh

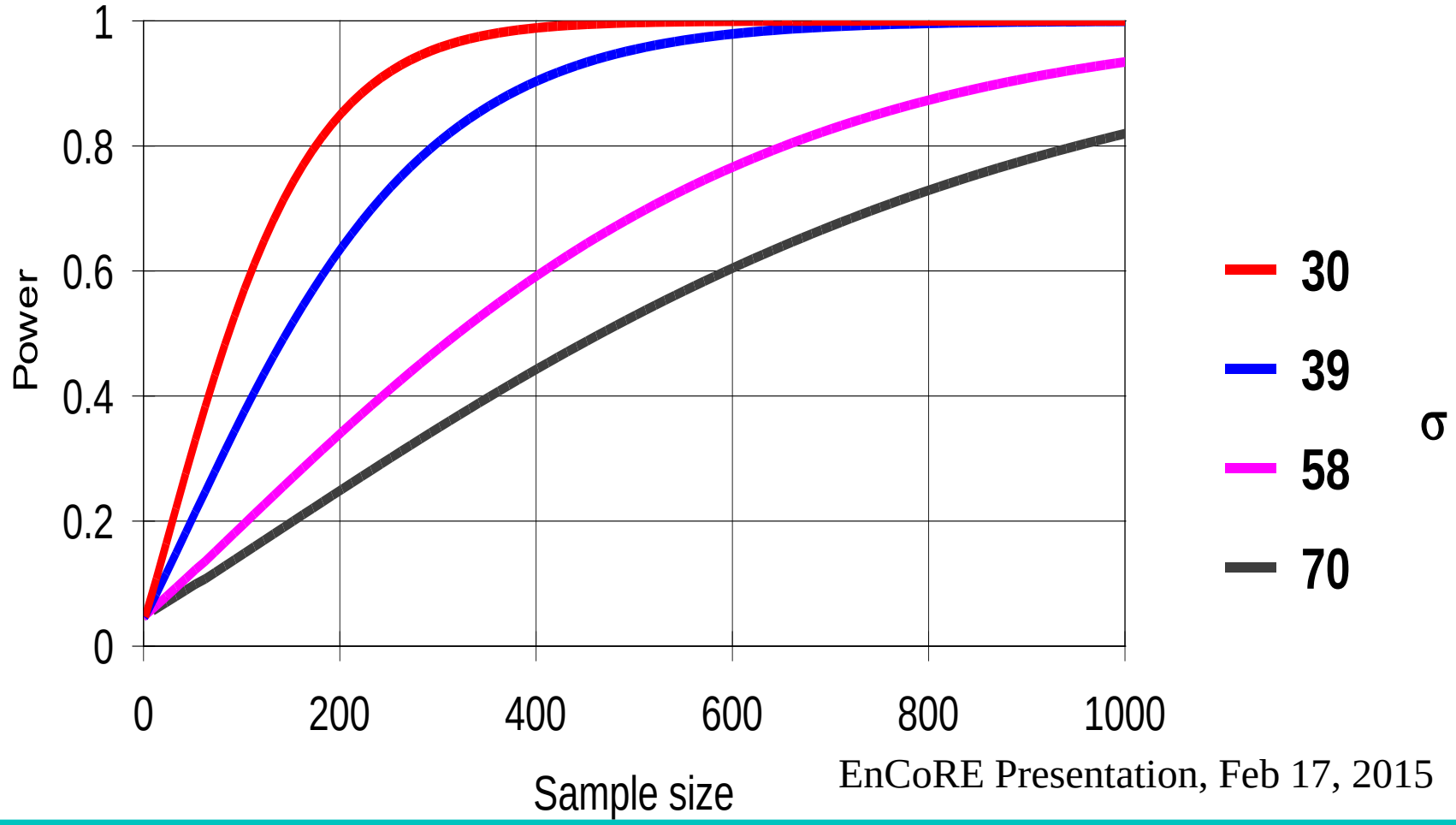
How sample size affects the power to detect differences



How δ affects the relationship between power and sample size



How variability affects the relationship between power and sample size



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Questions?

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Thank You!

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Need Identified / Approach

- SIHF first saw the need to examine mental health practices and started discussions with mental health providers at one of the busiest SIHF mental health sites and mental health providers at Touchette Regional Hospital, an affiliated hospital offering inpatient mental health services for SIHF patients as necessary.

- These mental health practitioners agreed that medication adherence was one of the biggest problems mental health patients face, and that getting information directly from patients would be extremely helpful in examining this issue and coming up with solutions.

- Patients have been recruited and discussions have begun as to how to address the issue of medication adherence and we are beginning the process of developing a specific research question in this area.

- In order to have a team that can work with patients every step of the way in this area, the SIUE School of Pharmacy was contacted and a partnership established. This partnership also gives SIHF access to academic support resources.

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PCORI RFA & LOI Requirements

- The LOI requirements were a brief description of the project. It is not a lengthy application process.
- The key points needed for submitting the LOI are to determine who will lead the project, which organizations are committed to developing the project, what patients will be included as research partners, and what will the first phase of the process cost, including both grant budgeted amounts and organizational support committed to the project.

How This Project Fits Requirements

Patient Participation

- Two patients have already attended organizational meetings and six additional patients are scheduled for an orientation meeting, making a total of eight patients recruited to participate in this research.
- The SIHF Project also fits the requirements by having a collaborative team that can look at each phase of the patient experience related to the issue selected (medication adherence by mental health patients).

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Acceptance Email

Dear Dale Fiedler,

We are pleased to inform you that your LOI, Behavioral Health Research Capacity Development, has been selected for a full proposal application. To access the application form please click on the link at the end of this message or you can log into the PCORI Pipeline to Proposal Awards Online Application System (https://pcori.submittable.com/login), using your previously created username (your email address) and password. Once you click your submission you will find the full proposal in the "PCORI-Pipeline to Proposal tab." Resources to help you complete your full application, including required templates, can be found here under Applicant Resources: http://www.pcori.org/announcement/pipeline-proposal-awards-tier-i-pre-engagementcommunity-projects.

Please keep in mind that the Pipeline to Proposal Award Initiative does not fund projects with the following emphasis:

- Cost-effectiveness
- Efficacy (Studies that ask "Does this work?" rather than "Which of these options works better?")
- Causes of disease or descriptive studies
- Implementation or measurement of care delivery interventions
- Conferences or training
- Pilot projects
- Product or app development or improvement
- Recruitment for clinical trials
- Social determinants of health
- Raising awareness for a given disease or health issue
- Development of clinical practice guidelines

The application is due Friday, February 20, 2015 at 5pm EST. We will provide award announcements within 45 days of the February 20th deadline.

You must complete a mandatory Pipeline to Proposal Tier I Applicant Training by February 20, 2015 at 5pm EST. The training will provide you with information on the Pipeline to Proposal Awards and how to complete your full application. The link to the training is: http://pcori.interactyx.com. The login information for the training is as follows:

Username: your email address
Password: Guest1 (case sensitive)

For questions or technical assistance, please contact us at p2p@pcori.org.

Sincerely,

Patient-Centered Outcomes Research Institute
http://www.pcori.org

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Next Steps/Challenges

Completion of the Tier I application is the next step

- Describe the Team in greater detail and add increased specificity to the work plan for building research capacity among the patients and practicing clinicians.
- Match local plans and capabilities with the specific nuances of the PCORI requirements for a Tier I proposal. **It will be important to carefully read all application materials and ensure directions are followed specifically.**
- Know the capabilities of what your entity can perform, i.e. patient recruitment / involvement
- Do not set your entity up to fail
- Allow enough time to do a quality proposal

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Upcoming Webinars

Webinar Date	Content	Activities	Presenters
March 17 2:00 – 3:30 pm EST	Study Design and Clinical Statistics	Preparing graphs and tables, logistics required for study design	Vicki Young and Mickey Eder
April 21 2:00 – 3:30 pm EST	Biostatistics	Exploration of statistical analyses, write research approach and protocol	MaryAnn McBurnie
May 19 2:00 – 3:30 pm EST	Bioinformatics	Data management and EHR data collection methods	Michelle Proser and Mickey Eder
June 16 2:00 – 3:30 pm EST	Research Ethics, IRB, and Good Clinical Practices	Creation of informed consent forms, plans for fair compensation of patient participants	Leah Zallman and Rosy Chang Weir

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Available Resources

- EnCoRE Website for Past Webinars and Materials
  - https://cdnencore.wordpress.com/live-session-library/
- Additional resources to build research capacity at health centers
  - www.CDNetwork.org/NACHC

Future Funding Opportunities from PCORI

Opportunity	Letter of Intent Due	Application Due
Addressing Disparities	March 3, 2015	May 5, 2015
Improving Healthcare Systems	March 3, 2015	May 5, 2015
Assessment of Prevention, Diagnosis, and Treatment Options	March 3, 2015	May 5, 2015
Communication and Dissemination Research	March 3, 2015	May 5, 2015
Clinical Management of Hepatitis C Infection	March 3, 2015	May 5, 2015
Improving Methods for Conducting PCOR	March 3, 2015	May 5, 2015
Engagement Award: Knowledge, Training and Development, and Dissemination Awards	April 1, 2015	April 1, 2015
Engagement Award: Research Meeting and Conference Support		April 1, 2015

Visit http://www.pcori.org/funding/opportunities for more information