



Enhancing Community Health Center PCORI Engagement (EnCoRE)

Funded by: Patient Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award 2014-2015



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AHRQ















Enhancing Community Health Center PCORI Engagement (EnCoRE)

Session 1 Introduction to Patient Centered Outcomes Research (PCOR): Developing a Study and Study Questions

Presenter:

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Project Partners

Clinical Directors Network (CDN) New York, NY

National Association of Community Health Centers (NACHC) Washington D.C.

The Association of Asian Pacific Community Health Organizations (AAPCHO) Oakland, CA

Access Community Health Network Chicago, IL

Institute for Community Health (ICH) a Harvard Affiliated Institute Cambridge, MA

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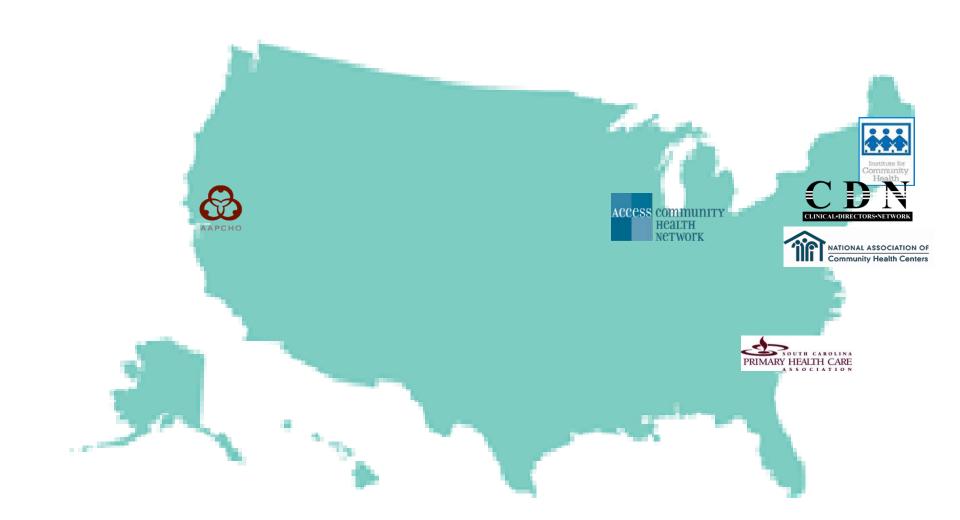
Vicki Young, PhD vickiy@scphca.org

Additional Faculty: Milton "Mickey" Eder, PhD, Assistant Professor at University of Minnesota Medical School



EnCoRE Partners' Geography 2014-2015







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
- 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













Introductions



- Name
- Responsibilities
- Community Health Center Affiliation
- Prior Research Experience
- What are you hoping to learn from EnCoRE?













Session Goals



- What is the EnCoRE project?
- What are patient-centered outcomes?
- Why is patient-centered outcomes research important to Health Centers?
- How to ask a question and form a testable hypothesis
- Types of variables
- Introduction to clinical epidemiology and types of study designs
- Introduction to human subjects research
- Introduction to literature search/PubMed













PCORI Pipeline to Proposal



- The Patient Centered Outcomes Research Institute (PCORI) <u>www.PCORI.org</u> is committed to funding research guided by patients, caregivers, and the broader healthcare community
- The "Pipeline to Proposal" program, part of the Eugene Washington Awards, program addresses the challenge of engaging stakeholders (such as patients, clinicians, and researchers) to create partnerships that lead to PCOR research proposals
- Using the award resources and PCORI patient engagement guidelines, this project aims to build a community of patients, stakeholders, and researchers who can participate in patient centered outcomes research (PCOR)

About Us	Research We Support	Funding Opportunities	Meetings & Events Get In	nvolved News Room
Blog				"Pipeline to Proposal
Pipeline	to Proposal Awards		606000	Awards
Up	Tierl to \$15,000 9-month term	000 Up to \$50,000	PCORI Funding Announcement	-CI
Proposal Awar Pipeline to Pr	rds for the Western Region of oposal Awards has been man	line to Proposal Awards prog the United States. This RFP i aged in collaboration with the pilot Intermediate Funder for	for the first cycle of Tier I e Colorado Foundation for Public	PCORI approved 30 projects totaling more tha \$400,000 under the pilot of its "Pipeline to Proposi awards program. These T
	tional Intermediate Funders to		eline to Proposal Awards and he to Proposal Awards in other	awards were initially offer the Western US to build communities around com health research interests.
believe in the	promise of patient-centered i	research. The awards will be	ealthcare research ideas and who used to help build capacity and se awards focus on building the	program will soon be exp nationwide.
research. This group of patie developing qu	award is open to any individu nts, stakeholders, or researche uestions that can be addressed	ual patient, other healthcare s ars—oriented around a particu d by comparative effectivenes	: in patient-centered outcomes takeholder, or researcher—or ilar health issue and interested in s research. It is targeted to those search funding sources, and the	Read Mo
	· · · · · · · · · · · · · · · · · · ·	mmunity and capacity building	u	Opening a Pipeline to Patient-Centered
for a research		t clinical issue that you would	keholder with a compelling idea I like to explore—the Pipeline to	Research Proposals With a new type of award invite individuals and gro build a community and
In December 2 program:	2013, PCORI approved the fo	bllowing 30 projects under the	pilot phase of this new awards	partnerships prepared to participate in patient-cen outcomes research.





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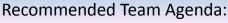


Training Curriculum



www.NACHC.com

- A year long structured program
 - Monthly training webcasts
 - Monthly "homework" assignments
 - Online clearinghouse of skill-building resources
- What will this series cover?
 - Basics of PCOR
 - Development of research questions
 - The structure of research design and protocols
 - Patient and community engagement
 - Human subjects protection
 - Data analysis and interpretation
 - Dissemination



,	Agenda:	
12:00-1:00 pm	Pre Lunch: Working team lunch meeting	
1:00-2:00 pm	Webcast/Virtual Classroom	
2:00-2:30 pm	Post Class Work: Team Meeting to Follow Up/Implement	
3:00 pm	Adjoum	
12:00-1:00 pm	Pre Lunch: Working team lunch meeting	
1:00-2:30 pm	Webcast/Virtual Classroom	
2:30-3:00 pm	Post Class Work: Team Meeting to Follow Up/Implement	
3:30 pm	Adjoum	

Specific CHC responsibilities will include:

- Commit the time for a Team of 3-5 clinicians and staff members and patient representatives to participate in this project and participate in monthly webcasts and pre and post webcast related activities
- Identify one staff champion to lead this group of 3-5 clinicians and staff members
- Identify one or more patient representatives to participate













Training Curriculum



Session I – Introduction to PCOR - Developing a Study and Study Questions

Session 2 – Patient Engagement in Selecting and Designing Interventions for Testing and Outcomes for Assessment

Session 3 – Community Engagement for Selecting and Designing Interventions for Testing

Session 4– Measurement, Defining Variables (dependent, independent, covariates)

Session 5 - Sample Size, Power Calculations, Sampling Methods, and Recruiting Plans Session 6–Study Design & Clinical Statistics

Session 7– Biostatistics/Univariate Data Analysis

Session 8 – Bioinformatics

Session 9 - Research Ethics, IRB, FDA Regulations, and Good Clinical Practices (GCP)

Session 10 - Grant Writing, Fundraising, Project Planning, Identifying Study Partners, and Funders

Session 11 - Preparing Budgets, Work Plans, and Timelines

Session 12–Dissemination and Presentation





www.accesscommunityhealth.net

i

pcor

www.PCORI.org



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AAPCHO www.aapcho.org



Training Curriculum (Cont'd)



- The partners will develop the training course by building on existing CDN/N2-PBRN, NACHC, and CTSA training programs and PCORI training resources and adding any content gaps identified by partners or learners
- The curriculum will incorporate previously developed and archived online training resources on research models and methodology using a "flipped classroom" learning model
- All webinars developed during the project period will be posted <u>on www.CDNetwork.org/</u>and <u>www.CDNetwork.org</u> for free global dissemination







Goals for your Health Center

Short Term Goals:

- To gain meaningful understanding of PCOR engagement, knowledge, and methods
- To become "research engaged"
- To become PCOR "research-ready"
- To successfully submit PCOR funding applications to PCORI as well as NIH, AHRQ, and CDC
- To become partners, stakeholders, collaborators, and leaders in PCORI applications

Long Term Goals:

- To receive PCORI funding
- To publish PCOR results in peer-reviewed journals
- To aligning and integrating research and QI efforts
- To be prepared to incorporate results into practice with measurable impact on clinical, patient-centered and population health outcomes
- To increase the number of Health Center patients, clinicians, and staff participating as PCORI grant reviewers, and to improve the quality of those reviews over time













What is PCOR? Why patient-centered outcomes?



Patient-Centered Outcomes Research (See www.PCORI.org)

- "...considers patients' needs and preferences and focuses on outcomes most important to them."
- "...can help patients and other healthcare stakeholders, such as caregivers, clinicians, insurers, policymakers and others, make better-informed decisions about their health and healthcare options."
- "...answers patient-centered questions, such as:"
 - "Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?"
 - "What are my options, and what are the potential benefits and harms of those options?"
 - "What can I do to improve the outcomes that are most important to me?"
 - "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?"













What is PCOR? Why are patient-centered outcomes important?



Patient Centered Outcomes Research (PCOR):

- "Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people"
- "Is inclusive of an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life"
- "Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination"

www.aapcho.org

 "Investigates optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives"





See <u>www.PCORI.org</u>











- Infrastructure
- Methodology Studies
- Observational Studies
- Individual Randomized Controlled Trials (RCTs)
- Cluster RCTs
- Pragmatic Clinical Trials (PCTs, Individual or Cluster)

For more information see www.PCORI.org http://www.pcori.org/content/research-we-support













Randomized Clinical Trials (RCT)



- Prospective treatment precedes outcome
- Randomized treatment assignment at random
- Controlled comparison group
 - Placebo
 - Standard treatment
 - Alternative treatments head to head comparison (cf. Comparative Effectiveness Research)
 - Single Blind- treatment group assignment is unknown to participant
- Double Blind treatment group assignment is unknown to both investigator and participant















Why is community-based collaborative work important for PCOR?

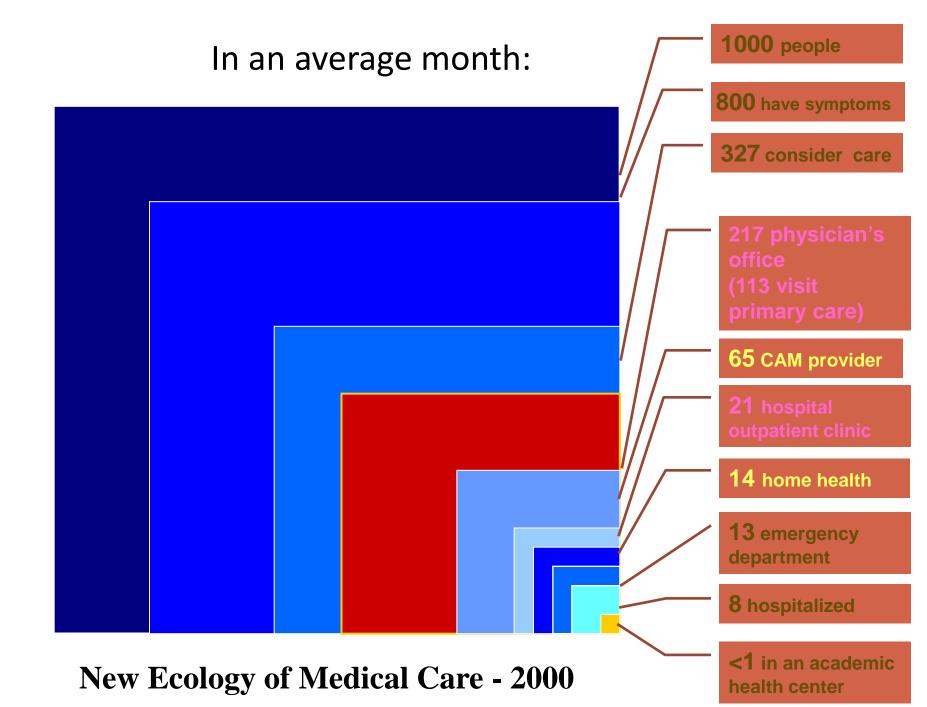














Clinical Epidemiology



Clinical Epidemiology

applies epidemiological principles and study designs in <u>clinical settings</u> using medically defined populations as opposed to <u>population settings</u>

Closely related to:

- Comparative Effectiveness Research (CER)
- Patient-Centered Outcomes Research (PCOR)















	Examples	
Nominal	Gender	
	 Eye color 	
Ordinal	• Size	
Interval	 Blood Pressure 	
	• A1c	
Ratio	HIV Viral Load	













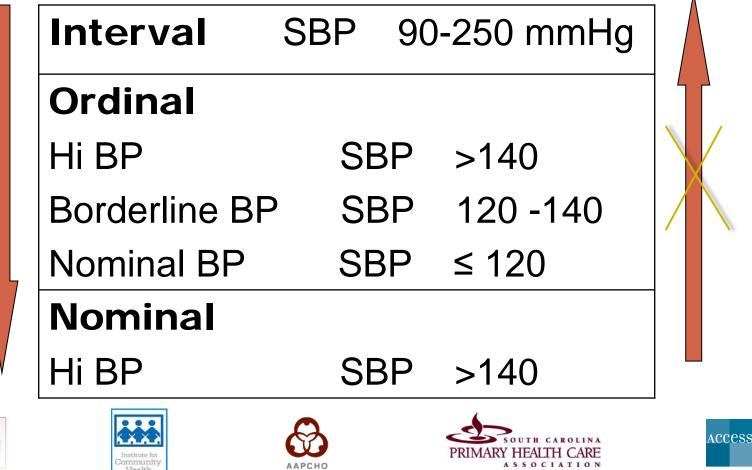
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www.PCORI.org

Recoding Measures



Example: Systolic Blood Pressure (mmHg)

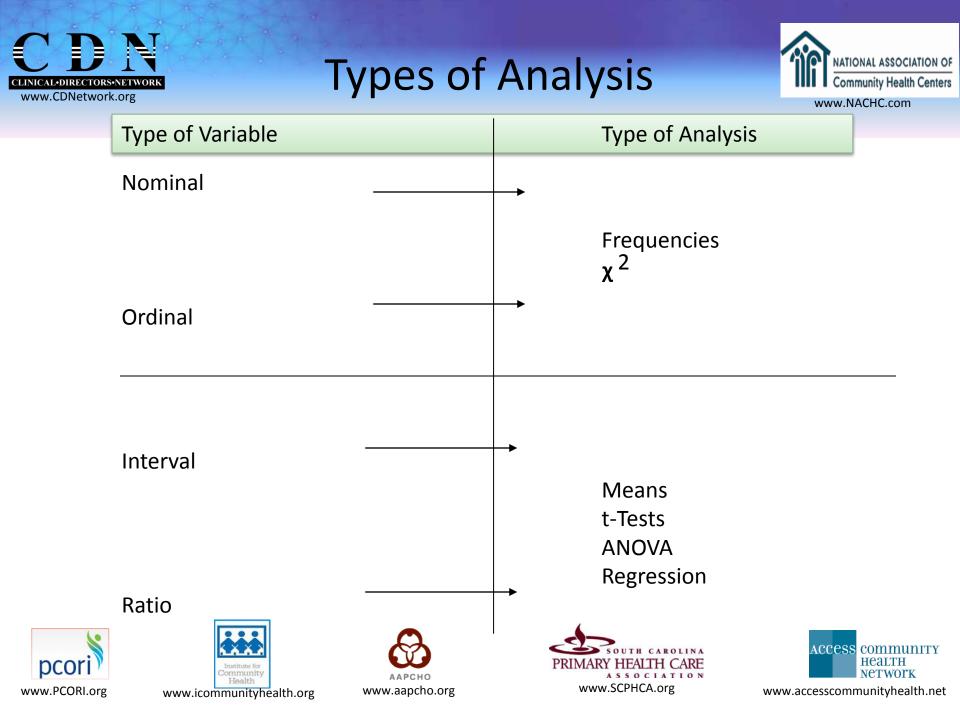


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www.aapcho.org

www.SCPHCA.org







Human Subjects Research



Governed by the Office of Human Research Protections (OHRP; www.hhs.gov)

The Belmont Report www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Human Subjects Protection Certification phrp.nihtraining.com/users/register.php

Collaborative Institutional Training Initiative (CITI) https://www.citiprogram.org/

















Self-Assessment

- 1) Does your Health Center have experience conducting any type of research?
- 2) Is your Health Center currently conducting PCOR?
- 3) Is your Health Center ready to conduct PCOR?
- 4) What would it take to get ready to conduct PCOR?
- 5) Why is participating in research important to my Health Center?













Exercise #2



Develop a patient-centered study question

What questions would your health center like answered?

Remember PCOR addresses... "Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?"

"What are my options, and what are the potential benefits and harms of those options?"

"What can I do to improve the outcomes that are most important to me?"

"How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?"

quoted from www.PCORI.org

















- 1) Who is your target patient or clinical population
- 2) Who are the most important patient and clinical subgroups?















Patient-centered CER of Home-based Interventions to Prevent CA-MRSA Infection Recurrence (CAMP-2)

Funding by:

Patient Centered Outcomes Research Institute (Grant # Pending)

The Rockefeller University Center for Clinical and Translational Science (CCTS) Pilot Grant and Administrative Supplement (NIH-NCATS Grant # 8-UL1-TR000043)

THE ROCKEFELLER UNIVERSITY HOSPITAL

AHRQ Grant # P30 HS 021667





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Convergence of CER/PCOR Interests

- <u>Patients</u>: Responses from the RPPS patient focus group indicated that many patients participated in the CAMP study in order to contribute to knowledge about CA-MRSA transmission and recurrence. Outcomes that patients were most concerned about include: **recurrence**, pain and inability to work.
- <u>Clinicians</u>: "[It is assumed that] colonization is ongoing, because we've had patients return with recurrent infections. ...If you just use systemic antibiotics, the nasal colonization persists. Another question to consider is if the source is in the house. We can take all measures to decolonize the person but if the infection is still in the house (pet, towel, sheets, etc), then it's a huge factor." – Dr. Balachandra
- <u>Laboratory Investigators</u>: "Does the MRSA recurrent phenotype reflect a single or multiple genotypes?
- <u>Clinical Investigators</u>: 31% of MRSA+ wounds and 28% of MSSA+ wounds are recurrent





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CAMP-2 Research Design

Incision & Drainage Oral Antibiotics

Home Assessment

Patient Decolonization & Environmental Decontamination (after Huang, 2014)



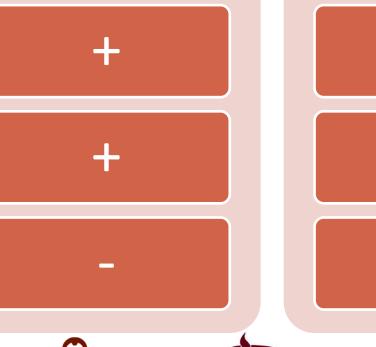


Usual Care

(CDC Guidelines-Directed) (n=139)

www.aapcho.org

Usual Care (CDC) + Experimental Intervention (n=139)









Exercise # 4



Identify measures: patient-centered vs. clinical

Example for Skin and Soft Tissue Infections:

	Patient Centered	Clinical
Dependent Variable(s)	Abscess, furuncle, folliculitis, boil, carbuncle, cellulitis (dermatological symptoms) Recurrence on self or family	MRSA+ vs. MSSA+ lab result (microbiology diagnosis)
Independent Variable(s) -Environmental Treatment (Home decontamination vs. usual care)	Prevention self-efficacy Decision-making autonomy	Environmental contamination
Independent Variable -Clinical Treatment (Incision and Drainage vs. Antibiotics vs. Both)	Pain Ability to work Quality of life	Clinical response to treatment
Covariates / Confounding Variable(s)	Illness burden Medication adherence	Comorbidity Antibiotic Treatment





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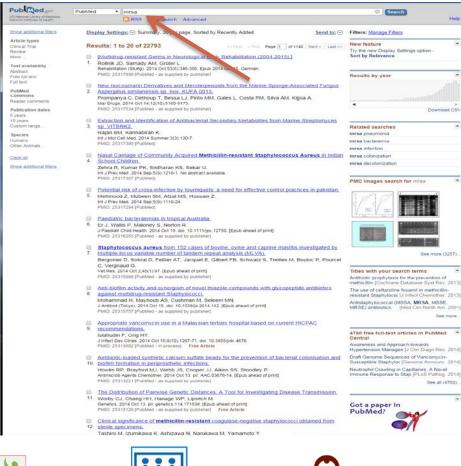






Introduction to Conducting Literature Searches using NLM PubMed.gov





www.pubmed.gov





www.icommunityhealth.org



PRIMARY HEALTH CAROLINA www.SCPHCA.org









Search www.PubMed.gov

- The use of asthma drugs in pregnancy
 - Type in search box *asthma drugs pregnancy*
- Use MeSH
 - with or w/o subheadings
- Combine using AND, OR
- Filters
 - limit to dates of publication, language, age, gender, etc.

















Engage other Health Center colleagues in Team formation

Lets make a list of other colleagues that might be interested in joining you and contact them this week...

Ideally your team would consist of 4-6 individuals from each Health Center: 1-2 clinicians, 1-2 individuals involved in Health IT/EHR work, 1 health educator, and a patient representative













Exercise #5



Role in Study	Role In CHC	Name	Credentials	Email	Phone













Homework



- Identify research interests
- Develop testable question
- Complete human subjects protection training (collect certificates)
- Begin literature search on PubMed.gov and compile relevant articles
- Engage team members (use template)

Due date October 4, 2014 Email to Project Coordinator: rtayler@CDNetwork.org













Supplement Online Training



Introduction to Collaborative Community-Based Research

https://cne.memberclicks.net/index.php?option=com_mc&view=mc&mcid=72&eventId=365790

Presenter:

Jonathan N. Tobin, PhD, FACE, FAHA President/CEO, CDN, Co-Director for Community-Engaged Research The Rockefeller University Center for Clinical and Translational Science (CCTS), Professor, Department of Epidemiology & Population Health, Albert Einstein College of Medicine of Yeshiva University













How to Sign Up for CDN ListServ



- Visit: <u>www.CDNetwork.org</u>
- Click on "Join Our Mailing List"
- Fill in your information

OR

Send an email to eLearning@CDNetwork.org













How to Get a CE Certificate



- Fill out SurveyMonkey.org link that launches in the window
- Complete survey
- Send an email to <u>eLearning@CDNetwork.org</u> with your name, the title of the session, and the date you completed it













Upcoming Sessions



SESSION
1. Introduction to PCOR
2. Patient Engagement
3. Community Engagement
4. Measurements and Descriptive Statistics
5. Sample Size and Sampling Methods
6. Study Design and Clinical Statistics
7. Biostatistics and Univariate Data Analysis
8. Bioinformatics
9. Research Ethics
10. Grant Writing and Fundraising
11. Preparing Budgets and Timelines
12. Dissemination and Presentation





ААРСНО www.aapcho.org







Suggested Resources



Primary Text:

 SB Hulley, SR Cummings et al., *Designing Clinical Research:* An Epidemiologic Approach (NY: Lippincott Williams & Wilkins; 2nd Ed. 2001)

Additional/Supplemental Texts & Resources:

- Leon Gordis *Epidemiology* (Philadelphia PA: Saunders Elsevier, 2009 4th Ed)
- N Krieger Epidemiology for the People (New York NY: Oxford, 2010)
- RS Greenberg, SR Daniels, WD Flanders, JW Eley, JR Boring III *Medical Epidemiology* (4th Ed) (New York NY: Lange/McGraw Hill, 2005)
- RM Merrill Introduction to Epidemiology (Boston MA: Jones and Bartlett, 2010, 5th Ed)
- Univ of Pittsburgh Epidemiology Super Course <u>www.pitt.edu/~super1</u>
- Univ of North Carolina Epidemiology eText <u>www.epidemiolog.net</u>
- CDN Clinical Research Training Webcast Library <u>www.CDNetwork.org</u>
- Rockefeller University Center for Clinical and Translational Science Webcast Library <u>www.CDNetwork.org/Rockefeller</u>





AAPCHO www.aapcho.org







Additional Suggested Resources



Application Exercises & Web-based Resources

Key Concepts www.pitt.edu/~super1 www.epidemiolog.net

NLM - PubMed www.ncbi.nlm.nih.gov/pubmed

CDC - NCHS www.cdc.gov/nchs/nhanes.htm www.cdc.gov/nchs/nhis.htm

Study Design

www.pitt.edu/~super1 www.epidemiolog.net





- Use Epidemiologic Vocabulary & Concepts

 Search, Retrieve, Review > 1 study in your area using the current design

Identify and explore
 <u>></u> 1 public data-set
 that measures your primary research interest

<u>Do</u> try this at home (& at work!)
 FOLLOW YOUR <u>OWN</u> NATURAL HISTORY !









Additional Suggested Resources



www.NACHC.com







www.accesscommunityhealth.net



DCO

www.PCORI.org



AAPCHO



Additional Suggested Resources



www.NACHC.com

www.CDNetwork.org/NACHC





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www.icommunityhealth.org











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