Workshop Overview

• Introduction to FSU CoM’s Clinical Research Network

• OneFlorida Clinical Research Consortium overview

• Future research workshop ideas
FSU Clinical Research Network

MISSION

• Build capacity for community based research with diverse and underserved patient populations
• Translation of findings to impact clinical practice

VISION

• Improve the health of Florida residents through high quality research in community based settings
What is the network?

• Statewide, multidisciplinary, collaborative

• Community-based faculty of healthcare professionals

• Supports practice-based translational research

• Based on FSU CoM’s distributed educational model

• More information: FSU’s Clinical Research Network
Florida State University College of Medicine
Regional and Rural Campuses

Regional campuses:
1: Daytona Beach
2: Fort Pierce
3: Orlando
4: Pensacola
5: Sarasota
6: Tallahassee

Rural training sites:
7: Immokalee
8: Marianna

Clinical training site:
9: Thomasville, Ga.
Why Practice-based Research?

• Occurs where patients receive the majority of their care

• Identifies problems in every day practice that create gaps between care recommendations & health care delivery

• Tests interventions in “real world” settings

• Functions as “laboratories” to test system improvements in medical care
Benefits of Participation

• Enhanced research expertise & capacity

• Improved quality of care & patient outcomes

• Training & professional development

• Access to FSU IRB oversight
Opportunities for Investigators

Community-based research studies
- Grant searches and writing guidance to fund research
- Site recruitment and training
- Study implementation support at the practice level
- Data collection assistance

Access to diverse patient populations

Education & training
- MOC, CME
- Research methods & logistics

Publications & presentations
- Guidance on research dissemination
Network Research Studies

Health Information Technology
• Pediatric sports-related concussion management
• Adolescent health risk assessment
• HPV Vaccination

Specimen Collection and Application
• Hypertension
  • Assessed PRA level to optimize BP medications
• Genomics
  • Buccal swab to assess genetically-driven metabolism of opioid pain medications
Network Practice Locations

Affiliated Practice Locations

- Primary Care (n=100)
- Specialty (n=94)
Current Network Membership

- 197 FSU-affiliated practice entities
- 52% are primary care practices (n=103)
- How does your practice join the network?
  - Contact your RCD or a member of the network team
How can you participate?

As a Research Site
• Allow access to your patients for research study participation
• Study implementation, patient consenting & data collection assistance via FSU Clinical Research Associates

As a Site Level Investigator
• Implement another PI’s study in your practice
• Practice facilitation

As a Principal Investigator or Co-PI
• Design or collaborate on a study to execute in the network
The Team

Main Campus

Jeffrey Joyce, PhD (2/1/17)
Senior Associate Dean for Research and Graduate Programs

Donna O’Neal, MA
Assistant Dean for Research Activities

Jessica De Leon, PhD
Assistant in Research

Meadridth Pooler, MSPH
Clinical Research Associate

Orlando Campus

Michael Muszynski, MD
Associate Dean for Clinical Research Chair, Research Advisory Committee

Michelle Vinson, MS, RDN
Director, FSU Clinical Research Network

Lori Drum, LMHC, CCRC
Clinical Research Associate

Jennifer Mauck, MPH
Clinical Research Associate
Partners & Scope

Statewide partnership

• Academic institutions: UF, FSU, UM
• Healthcare institutions
• Third party payers / pediatric claims data

Create enduring infrastructure

• Comparative effectiveness research
• Practice-based network research studies

One of 13 Clinical Data Research Networks (CDRN) nationwide
Statewide Partner Locations

- University of Florida and UF Health
- Florida State University and the Regional Campus Practice Partners
- University of Miami and UHealth
- Orlando Health
- Florida Hospital
- Tallahassee Memorial HealthCare
- Health Choice Network
- Bond Community Health Center Inc.
- Miami Children’s Health System
- WellFlorida Council
PCORI & PCORnet

Patient-Centered Outcomes Research Institute (PCORI)

- Funds comparative clinical effectiveness research (CER) & supports work that will improve methods to conduct such studies

Patient-Centered Outcomes Research Network (PCORnet)

- Integrates health data studies & catalyzes research partnerships among 13 CDRNs nationally

<table>
<thead>
<tr>
<th>Condition</th>
<th>PCORnet</th>
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<tr>
<td>Respiratory conditions</td>
<td>2,837,803</td>
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<td>Selected malignancies</td>
<td>1,294,158</td>
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<tr>
<td>Myocardial infarction</td>
<td>354,929</td>
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<tr>
<td>Stroke</td>
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<tr>
<td>Rheumatoid arthritis</td>
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<td>Ulcerative colitis</td>
<td>88,029</td>
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<td>Hypertension</td>
<td>5,902,641</td>
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<td>Renal disease</td>
<td>1,018,729</td>
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<tr>
<td>Influenza/pneumonia</td>
<td>869,306</td>
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OneFlorida Data Trust

- Statewide data repository for the OneFlorida CDRN

- Current inventory (1/2017)
  - 4.5 years of completed data
  - 10.6 million patients

- Utilizes a Common Data Model (CDM) to standardize the way patient health data is entered and retrieved
PCORnet CDM Domains

- Enrollment
- Demographics
- Conditions
- Diagnosis
- Encounters
- Vitals
- Procedures
- Lab Results
- Medications
- Dispensing Information
- Patient Reported Outcomes
- Death
- Death Condition
- PCORnet Trial
- Harvest

More information: [PCORnet Common Data Model](#)
Using the Data Trust

**Cohort Discovery**
- Available to “peek” at what you could do
- Identify trends

**Study Feasibility**
- View available data based on a variety of demographics

**Secondary Data Analysis**
- Diverse de-identified patient data
- Variety of health conditions
Future Research Workshop Topics
Potential Topics

• Study Methods and Design

• Human Subjects Research

• Grantsmanship

• Study Implementation and Data Analysis

• Dissemination of Findings
Feedback & Discussion

Questions?
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COLLEGE OF MEDICINE

Research Workshop Series #2
Introduction to Research
Outline

• Research Definitions
  • Human Subjects Research
  • Quality Improvement
  • Clinical Research
• Clinical Research Approaches
• Research Terminology
• Research Design & Methodology
• Questions & Discussion
HOW DO YOU DESCRIBE RESEARCH?
What is research?

As defined by the DHHS 45.CFR 46.102(d):

• A **systematic** investigation

• Designed to contribute to **generalizable knowledge**

• Must meet both conditions to be categorized as research
What is NOT research?

Examples:

• Surveys for evaluating the performance of faculty, staff, and students, or other studies for internal institutional use only
  ➢ NOT research – activity is for internal use, not generalizable

• Oral history of New Orleans jazz artists and memories of post-WWII era
  ➢ NOT research – not systematic or generalizable intent
Human Subjects Research

As defined by 45 CFR 46(f):

Human Subject:
• Living individual about whom an investigator (professional or student) conducts research

Human Subject Research Includes:
• Data through intervention or interaction with the individual, or
• Identifiable private information
Common Misconceptions: These ARE Human Subjects Research

• Case Studies (3+ subjects)

• Retrospective Chart Reviews

• Secondary analysis of publically available data or specimens
  – e.g., Medicaid claims data or publically available cell cultures
Human Subjects Research

Examples:

• Interviews with diverse patients with panic disorder to understand cultural differences in treatment preferences
• Questionnaires about cervical cancer prevention behaviors among minority women
• Surveys with patients and providers about their experiences and satisfaction with telehealth
• Pre and post tests to assess the impact of concussion management training on provider knowledge and treatment behaviors
Quality Improvement (QI) vs Research

Systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups (HRSA)

**Similarities**
- QI is systematic
- Leads to improvement in healthcare
- QI targets patient groups

**Differences**
- QI is not generalizable
- Institution-specific
Work with Your IRB

• Institution-specific requirements may vary

• Please check with your institution’s IRB and review policies for determining whether your project is considered to be human subjects research or QI

• Use your IRB’s tools and resources
Clinical Research

NIH defines clinical research as:

• Patient-oriented research
  • Research conducted with human subjects for which an investigator directly interacts with human subjects
• Epidemiologic and behavioral studies
• Outcomes research and health services research

NIH defines clinical trials as:

• A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (9/2016).
How can clinical research advance medicine?

• Provide information about disease trends and risk
• Improve knowledge of efficacy and adverse effects of medical interventions
• Can impact human health and longevity
• Can provide novel approaches to disease prevention
• Help translate basic research into new treatments and information to potentially benefit patients
Approaches to Conduct Clinical Research

• **Community-based participatory research (CBPR)** – A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings.

• **Comparative-effectiveness research (CER)** - compares effectiveness of different methods or practices on patient outcomes; designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options.
Approaches to Conduct Clinical Research

• **Implementation Science** – focuses on understanding how programs are implemented, translated, replicated, and disseminated in “real-world” settings. It expands the focus of traditional research from discovering what works to also discovering how the implementation works in specific contexts.

• **Translational research** - Research process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes; ‘translate’ findings bench to bedside.
Emerging Clinical Research Trends

• Precision/Personalized Medicine
• Biomedicine and bioengineering
• Technology and Health
  – Informatics
  – telemedicine
• Population health
• Minority health and health disparities
• Global health
INTRODUCTION TO RESEARCH

PART II
RESEARCH TERMINOLOGY

HANDOUT REVIEW
Research Designs

• Prospective
• Retrospective
• Observational
• Interventional
Retrospective vs. Prospective

Retrospective
• Uses existing records or information
  Looks backwards

Prospective
• Generates new information
  Looks forward

Adapted from:
Burge, S. K. All About Conducting Research. Department of Family & Community Medicine University of Texas Health Science Center at San Antonio.
Retrospective Design

Advantages
• Data “easy” to access
• Less time consuming
• Relatively inexpensive

Limitations
• Observational only
• Data may be incomplete
• Sample may not be representative of general population
Prospective Design

Advantages
• Data collection is targeted to study aims
• Control over data collection
• Can adapt study as needed

Limitations
• Expensive and resource heavy
• Time consuming
Observational Design

• Researcher observes ongoing behavior
  – The investigator *does not* alter or interfere (naturalistic)
  – Investigator may participate (participant observation)
Observational Design

Advantages
- Research in “real life” situations
- No change to subjects’ environment
- Validity of findings

Limitations
- Researcher participation may influence subject behavior
- Time consuming
Interventional Design

- Investigators manipulates or alters the research environment
- Investigator assigns participants to a specific intervention
- Types
  - Pre/Post intervention
  - Experimental vs. Control
    - Experimental vs. Placebo
    - Crossover
  - Examples: Clinical trials and community interventions
Interventional Design

**Advantages**
- Replicable
- Controlled environment yields better results
- Best way to draw causality

**Limitations**
- Controlled environment may not represent reality
- Cannot control all variables
- Subject attrition
- Expensive
Research Methods

Qualitative

• In-depth research
  • Exploration of experiences, opinions, perceptions

• Non-numerical data

• Benefits
  • Richer data
  • Insider perspectives
  • Hypothesis generating
Research Methods

Quantitative

• Systematic process of quantifying the problems and research questions
• Generates numerical data for statistical analysis
• Benefits
  • More likely to be generalizable to a larger population
  • Hypothesis testing
Mixed-Methods

• Combines the strengths of quantitative and qualitative research by utilizing both methods in the same study

• Benefits
  • Brings together benefits of both methods
  • Generates different kinds/levels of data
Training in the Protection of Human Subjects in Research:

CITI Instructions
Thank you!

Questions & Discussion
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Research Workshop Series #3
Research Design I
The Research Process

Steps of the Research Process

Find a Research Idea
Convert Idea into Hypothesis
Define Variables, Choose Measures
Identify Participants
Select a Research Design
Conduct the Study
Analyze the Data
Report the Results
Refine or Reformulate Your Idea

Florida State University
1851
Research Protocol

• A written plan of the study

• Documents the objectives, design, methodology, statistical considerations, and organization of the clinical study

• Addresses the protection of human subjects and integrity of the data collected
Protocol Components

• Research Topic & Question
• Background/ Literature Review
• Research Objectives
• Hypotheses
• Study Methods
• Independent & Dependent Variables
• Subject Selection/Inclusion & Exclusion Criteria
• Study Implementation Planning
• Data Management and Statistical Analysis
• References

*Additional components required for clinical drug trials
“Hourglass” Notion of Research

Begin with Broad Questions
Narrow Down & Focus
Operationalize
INVESTIGATE
Analyze Data
Draw Conclusions
Generalize & Disseminate
Research Topic & Question
Selecting a Research Topic

• Building your research portfolio

• Insert your own passion and goals

• Assess your own knowledge, skills, & abilities

• Consider collaborators with additional expertise
Formulating your research question

- Research topic should be an **answerable** question
- Should not be too broad or too narrow
- Evidence-based frameworks to assist in mapping question
- Organize the topic into a concept and assign terms to each concept to combine in a search strategy
- Essential characteristics: “FINER” **Feasible, Interesting, Novel, Ethical, and Relevant**
Formulating your research question

- Problem: disease
- Population: age
- Intervention: education
- Setting: school
- Service provider: health educator
- Methods/Theories of interest: study design (e.g., cohort study)
- Outcome(s) of interest: reduced risk
Formulating your research question


- Bragge, P. (2010). Asking good clinical research questions and choosing the right study design. *Injury, 41*, S3-S6

PICO Method

- Popular framework in medical research
- Used for clearly defined clinical questions

<table>
<thead>
<tr>
<th>P</th>
<th>Population, Patients</th>
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<tbody>
<tr>
<td>I</td>
<td>Intervention</td>
</tr>
<tr>
<td>C</td>
<td>Control</td>
</tr>
<tr>
<td>O</td>
<td>Outcome</td>
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PICO Exercise

• How would you frame this research question?
  • Does hand washing among healthcare workers reduce hospital acquired infections?

<table>
<thead>
<tr>
<th>P</th>
<th>patients with a hospital acquired infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>hand washing</td>
</tr>
<tr>
<td>C</td>
<td>no hand washing</td>
</tr>
<tr>
<td>O</td>
<td>reduced rates of hospital acquired infection</td>
</tr>
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</table>
Evaluating Research Questions

• What are the effects of childhood obesity in the U.S.?
  o Too broad

• How are schools addressing childhood obesity?
  o Difficult to operationalize

• What are the obesity rates among middle school students in Tallahassee, Florida?
  o Too narrow

• What are the effects of physical activity programs in middle schools on the rates of childhood obesity among 7th grade students?
  o Best question – requires an investigation & evaluation
Background & Literature Review
Background

• What is known about the topic at hand?

• Cites previous research that is relevant

• Indicates gaps with prior research & what uncertainties remain

• Specifies how study will help fill gaps & lead to new scientific knowledge
Why conduct a literature review?

• To evaluate existing research
• To describe other research
• To identify gaps in the literature
• To relate to your own research to existing research
• To identify ideas and information relevant to your own research
Literature Review Overview

The Literature Search Process:

1. Articulate topic to research
2. Select database/formulate search strategies
3. Run searches/manage citations
4. Review citations; if needed, modify search or topic
5. Conduct original research/write article/create poster/present findings, etc.
Health Sciences Databases

Subject-specific Databases

- PubMed
- Cochrane Library
- PsycINFO
- CINAHL Plus with Full Text

Interdisciplinary Databases on Multiple Subjects

- Web of Science
- Google Scholar
How to search effectively:

1. Determine your research question & main concepts
2. Choose databases (subject or type of information)
3. Search standard language in database (e.g., MeSH)
4. Identify keyword (synonyms) + MeSH terms
5. Create search strings of similar terms for each concept using **OR** combine search strings of each concept using **AND**
What is MeSH?

• Medical subject headings
• Standard terminology/descriptors
• Defines term + hierarchy in relation to other terms
• Refines the search to relevant records

MeSH Database

• Search term
• Select subheading
• Restrict to major topic
• Review entry terms for other keywords
• Add MeSH term to search builder
Running the Search

- Look at # of results
- Display Settings → Abstract
- Save citations to email, citation manager, Clipboard, My NCBI, etc.
- Use limits (filters)
- Review # of results as limiting search
Citation Management Tools

Advantages:

• Useful for managing & organizing several literature sources
• Allows you to build your own library for your research topic
• Simplifies creating a bibliography (auto-generate)
• Allows sharing references with peers
• Provides recommendations for sources
• Ability to change citation formats to fit journal submission requirements

Reference Managers:

• EndNote
• RefWorks
• Mendeley
• Zotero
• CiteULike
• JabRef
PubMed Exercise

How would you frame the research question we discussed earlier using MeSH terms in PubMed?

Example Research Question:
What are the effects of physical activity programs on childhood obesity among 7th grade students?
Research Objectives & Hypotheses
Research Objectives

Objectives

• Should answer these questions:
  o Why does this research need to be done?
  o What will this study accomplish?
  o What will be its relevance?

• Simple, specific, and stated in advance

*Example:

• To evaluate the effects of physical activity programs on middle school students
• To examine the rates of childhood obesity among 7th grade students
Hypotheses Development

• A prediction about the relationship between two or more variables
  o An expected answer to a study question
  o Establishes the basis for tests of statistical significance

• A study may have one or more hypotheses

• Qualitative research is often used for hypotheses generation
Hypothesis Examples

• Increased frequency of hand washing among health care workers is related to a reduction in hospital acquired infections

• Middle school students that participate in at least 3 hours of physical activity per week have lower rates of obesity compared to students that are less active

• Drug A combined with Drug B will increase the incidence of psychosis in elderly patients
Thank you!

Questions & Discussion