Conducting Research in the CHC setting

MWCN RESEARCH COMMITTEE

CINDY SCHAEFER PHD, RN

Agenda

- Defining Research
- Why do Research?
- To provide information regarding the research process in the CHC setting
- Establishing a relationship with an academic investigator/partner
- Building infrastructure for research
- Getting started

Why do a research study?

- Answer questions you have regarding care of your patients
- Use your own data and evidence to integrate change into practice
- Lay groundwork for sustainable relationship with a researcher
- Real life setting provides a unique opportunity for the researcher

Why do a research study?

- Give health center staff an opportunity to pursue a research interest with an academic partner
- Provide funding to test out an innovative idea or implement a quality project that you wanted to try
- Organization can show innovation, leadership, quality, and evidence-based care to influence hiring, community partnerships, and marketing services to patients

Types of Research

- **Survey:** collect information from a certain group of people, obtain their opinions
- **Pilot:** the first step in answering a question, starts with a small sample size to see if the question is appropriate and feasible, provides foundation for larger study
- **Randomized controlled trial:** used to look at the effects of a treatment, procedure, medication where patients are randomly assigned to the experimental arm or the control or usual care arm of the study.
- **Interventional:** looking for what is the best treatment plan for a group of patients. What will improve patient outcomes. Testing cause and effect.

Interest in the Research Topic

- Everyday there are questions you ask regarding care
  - **Best practices**
    - Point of care projects
  - **Telehealth**
    - Virtual education
    - Text messaging
    - Continuous Glucose Monitoring
- **What questions do you have?**

Elements of A Research Plan

- Process of acquiring new knowledge
- Success is dependent on a well-designed study
- A diligent plan includes:
  - Aims: state the nature of the problem, specific objectives
  - Population: group of individuals that are the focus of the study
  - Conduct/technique: based on the intervention outcomes, comparison of groups
  - Support: Key staff/structure necessary to support the project
  - Outcome: specific, measurable, clinically relevant
  - Statistical considerations: sample size, based on objectives

- Garg, R. (2016). Indian J. of Anesthesia. Methodology for research I60(9): 640-645. doi: 10.4103/0019-5049.190619

Establishing a Relationship with a Researcher

- Identify academic investigator/partner
  - Nearby university
  - Partnership with another organization
  - Through MWCN/AHEAD CHC (**A**ccelerating **H**ealth **E**quity **a**nd **E**liminating **D**iabetes **D**isparities in CHCs)
    - Inform investigator of your interests and ideas to improve quality patient care/impact
- List-serve and newsletter will provide information about latest research projects.

Review the Protocol

- Information about the study will include:
  - Purpose/research question
  - Inclusion and exclusion criteria
  - Sample size
  - Financial information
  - Tentative timeline
  - Contact information

Start Up Administration Steps

- Things that may have to happen to get a study started:
- 1) Contract, agreement, or Memorandum of Understanding
- 2) Data use agreement
- 3) IRB approval for study
  - Process involves a little bit of paperwork (e.g., signed letter from CHC leadership, from with info about your study site) which the researcher's institution can guide you through.
- 4) IRB reliance agreement: provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution.

IRB Approval Process

- The purpose of the IRB is to review all clinical research for the protection and safety of the patient. It is mandated by the Federal Government.
- IRB approval must be obtained BEFORE any research activities begin
- Studies usually have one IRB of record, so typically the IRB at the researcher's institution to review the study.
- All research endorsed by the Research Committee has IRB approval
- Changes to the protocol MUST be IRB approval through amendments

“Important to follow the protocol”

Research Support

- The Principal Investigator and support staff are available for questions and support
  - Provide a start up meeting to go over the study, expectations, and anticipated time commitment
  - Put together worksheets, surveys, scripts, and support documents
  - Schedule webinars
  - Draft and submit papers/presentations to appropriate journals/organizations

Selection of Research Staff at the CHC

- Need to put together your team
- Be mindful of what the needs are of the study
- Who will be your best support staff?
- Communication is key, all the health center staff need to know about the study and what type of patients will be a fit for the study
- Expect/plan for turnover

Staff Involvement

- Staff who are engaged in CHC research activities:
  - will need to do a training about protection of human subjects in research
  - calling patients for recruitment,
  - obtaining consent from patients to participate in the study,
  - implementing an intervention that is not standard care,
  - collecting research data

Projects Involving Patients

- **Patient Recruitment**
  - Recruitment takes a lot of time and staff effort
  - Need to recruit more than you think because there will be dropouts

- **Protecting patient information**
  - The research staff will be asking you for information of those patients involved in the study
  - They will be asking you to make sure the information is de-identified (the patient's name must be removed from the data submitted)

Inclusion/exclusion criteria

- Inclusion and exclusion criteria are needed to conduct quality research and will be spelled out in the study protocol
- Inclusion criteria are the features that are needed to answer the research question. Need to be consistent, reliable, and uniform
- Exclusion criteria are features that could interfere with the success of the study or may increase the risk to the patient.
  - Include patients that are not likely to follow through with the study such as unmanaged serious mental illness, of plans to move in the near future.
  - Have comorbidities that could alter the results or increase the risk of severe adverse events.
    - Patino & Carvalho (2018) J Bras Pneumol 44(2):84 doi: 1590/S1806-37562018000000088

Data collection

- What data will be collected is directly related to the research questions.
- May need to collect data before the study begins as well as after to determine if there is a change in the outcomes.
- Information will be provided by the research team before the study starts.
- May need to designate a staff member to complete the data collection or work with others at your CHC, e.g. quality reporting or analytics person who can pull data from EHR.

Results

- Objective reporting of the findings
- Describes the analysis of the research question(s)
- Reports the results and what was statically significant
- Statements that clarify and support the questions asked

What are the expectations?

- Follow the protocol
- Communicate with the research staff regarding the project
  - If you run into problems with any aspect of the protocol
  - Needing to change the timeline
- If participating in a randomized trial the randomization should be performed by an independent person.
- Not favor one group of patients over another

Surveys

- Most researchers will want to ask the patients as well as the staff their opinion about the research being conducted
- Depends on the purpose of the research and the type of research question
- Example of surveys might include: Satisfaction/feedback, Procedural, and Opinion
- Some government sponsored research requires the completion of a specific data points (social determents of health, ACES, behavioral health sex, race, and ethnicity)

Sharing Results/ Dissemination

- Share your progress and results to senior leadership, board members, patients, staff, providers, funders, payors, local community members, and healthcare partners
- Consider the message are you trying to get across (may be different based on whom you are presenting to)
- When possible, consider including patient testimonials
- Keep stakeholders in the loop throughout the process of implementing your program and the results.
- If the results are not what you expected, how do you plan to use this opportunity to engage in quality improvement?

How to Get Started

- Identify a topic/question
- Partner with an academic investigator
- Secure leadership support
- Outline project

*At any time in the process you can reach out to MWCN Research Committee for input/guidance

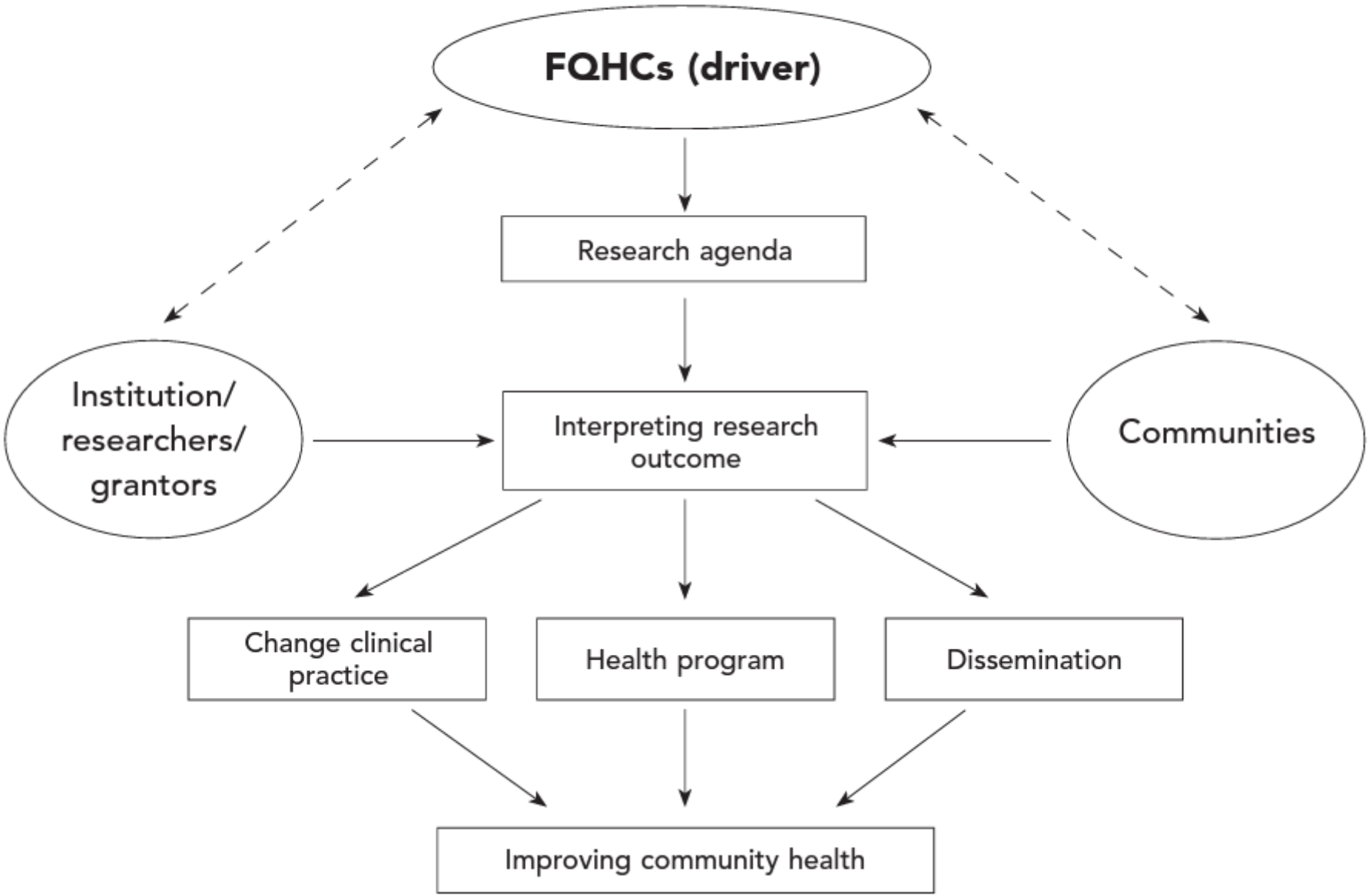
Get Team Excited

- Show data
- Explain potential impact
- Talk to community partners
- Realize you can make difference/fix problem

MWCN & U Chicago Diabetes Group Visits

- **Interest/Concept Development**
  - MWCN BOD expressed interest in shared medical appointments for patients with diabetes.
  - MWCN Research Committee worked with U Chicago.
- **Site visit study (2013-2014)**
  - Interviewed health center staff at 5 HCs in the Midwest to collect information on their experience running diabetes group visits.
- **Pilot study (2015-16)**
  - Trained 6 HCs in 5 states to conduct diabetes group visits.
  - Included text messaging at 1 health center.
- **Diabetes MESSAGES study (2017-22)**
  - Train 14 HC teams in Midwestern states to conduct diabetes group visit & text messaging program.
  - Cluster randomized controlled design.

Figure 1. Conceptual model of an FQHC research network



Past Research Collaborations

- Diabetes Standards of Care
- Health Disparities Collaborative
- Support of Diabetes Pilots
- Hypertension/Lipids
- Health Literacy
- Diabetes and Depression
- Combating Obesity
- Group Visits
- Virtual Group Visits (Chicago)

Resources

- Why do research? https://aapcho.org/wp/wpcontent/uploads/2012/11/WhyDoResearch.pdf
- List of potential projects?
  - Diabetes Distress (screening tool)
  - Continuous Glucose Monitoring
  - Telehealth

Questions

Contacts

Amanda Campbell, Executive Director
acampbell@midwestclinicians.org

Cindy Schaefer PhD, RN: Research Committee Chair

cschaeferPhD@gmail.com