

# **RESEARCH IN HEALTH CENTERS: How to Get Started**

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a seminar presentation of the  
National Association of  
Community Health Centers, Inc.

## **NOTE TO SEMINAR LEADER:**

*This leader's guide contains duplicates of each slide in the NACHC all-day seminar. Each of the 4 sessions should run between 75 and 90 minutes. Allow a 15-minute break between Sessions 1 and 2 and between Sessions 3 and 4. The lunch break after Session 2 should be scheduled for 45-60 minutes.*

*Under each slide, you'll find suggestions for what you should say written in this type face. These are only suggestions. Look at the content of the slide, add your own knowledge, experience, and style, and put things in your own words. Instructions to you are written in this type face.*

*Good luck!*

□

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NACHC contracted with Ambulatory Innovations to develop this curriculum. AI is an Indianapolis-based firm that serves as a major resource for ambulatory care providers and organizations. While specializing in quality measurement and management, AI also provides expertise in a wide range of other issues facing health care professionals in today's rapidly changing environment.



NACHC acknowledges the support of the Bureau of Primary Health Care in the development of this curriculum.

# WELCOME!

- Introductions
- Logistics
- Schedule of the day
- Our obligation to you
- Getting the most out of this seminar

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Use this opportunity to introduce yourself and others in the room. Make sure that everyone can see the screen and hear your presentation. Review the schedule, including breaks and lunch. Explain that the handout contains copies of all the relevant slides; it omits an occasional slide used to mark a transition from one part of the day to another.

“Our obligation to you”: we want this seminar to stimulate your thinking about how you might begin or enhance a research program in your health center. We’ve focused on many of the key questions you must answer. Naturally, we think that health centers *should* do research; we think it’s good for health centers and good for patients.

How can you get the most out of this seminar? First, by approaching the day with an open mind. Don’t start off by assuming that research at your health center would be impossible. Second, consciously think about how the concepts and issues you’ll be dealing with might relate to your “back-home” situation. Finally and most important, be an *active* participant.



## **SESSION 1:**

What is Research,  
and Why Should Your Center  
Get Involved?

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## GOALS FOR THIS SESSION

- Provide rationale for health center involvement in research
- Highlight some noteworthy primary care research findings
- Discuss ethical issues in research

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In this first session we'll discuss some basics of research -- what it is and what it is not. We'll highlight *primary care research* -- studying the problems that most people have most of the time -- and why that's a useful arena for health centers wishing to start research programs. We'll also discuss the reasons why it makes sense for health centers to get into research, and we'll finish up with some discussion about an important aspect of research -- ethics.

# THE TRUTH ABOUT RESEARCH

- Sometimes considered a dirty word
- Research is...
  - Asking answerable questions
  - Systematically pursuing answers
  - Using methods that yield trustworthy results



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Research sometimes has a bad name. Many people associate it with an ivory-tower, purely academic perspective that's divorced from the real world. Others conjure up images of guinea pigs or worse.

But research is important. It's provided us with a better understanding of disease, better ways to treat patients, and better ways to organize our system of health care so that patients get the care they need and deserve.

The research process really involves 3 elements: asking questions in a way that can be answered; looking for the answers using a defined and systematic process; and assuring that the process is sound so that the results can be trusted. In that sense research resembles other organized problem-solving methods -- including the diagnostic method that clinicians use, and some organized forms of organizational problem-solving that managers employ.



## WHAT'S WRONG WITH TRADITIONAL RESEARCH?

- Need primary care, practice-based research to find out what works in real world
- Most university research is too selective and controlled to apply to primary care
- Most public health research is population-based, too broad to apply to primary care

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If one looks at much published research in prestigious medical journals, it's hard to see how the results apply to primary care in health centers. We live and work in the real world. Much medical school research is done in the context of tightly controlled, randomized trials. It's hard to know how the results apply in the messier world of real patients with real problems. Public health research is often population-based. Its results are difficult to translate into the language of the clinical encounter.

If, on the other hand, a given research study is conducted in a practice-based environment, it's more likely that its findings will apply to our work with our patients.

## PRIMARY CARE RESEARCH

- Most likely choice for health centers
- Questions about the common problems that affect most people most of the time
- The story of Dr. Will Pickles and Dr. Curtis Hames

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While health centers might get involved in, say, drug evaluation studies that are paid for by drug companies, most centers will want to do *primary care research*: studies about the patients and problems they deal with every day.

There is a rich tradition of practice-based research. It's generally low-tech, but its contributions have been significant. Consider the following country doctors who have influenced the way we practice medicine:

Dr. Will Pickles was a rural English general practitioner who was the first investigator to describe the difference between what we now call hepatitis A and hepatitis B. His research method was careful observation. His laboratory instruments were a pencil and a notebook.

Dr. Curtis Hames is a general practitioner from Claxton, Georgia. He's made numerous contributions over 30 years to the epidemiology of cardiovascular disease, again using observational methods and careful recording of those observations. He's received numerous awards for his work, all done within the confines of a busy solo general practice in the rural South.

## CONTRIBUTIONS: AN EXAMPLE

- Patients with new onset headache
  - Approach taken by primary care physicians did *not* increase risk that treatment for tumors or bleeds would be delayed
  - Would save \$2 billion per year if widely adopted

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Let's now discuss some other primary care research findings, so that you can get a sense of the impact that a robust primary care research program could make on the way we care for patients.

This study was conducted by the Ambulatory Sentinel Practice Network (ASPN, pronounced "aspen"). Standard neurology textbooks say that patients should have a CT scan if their new-onset headaches are "severe.." ASPN practitioners -- primary care doctors in the US and Canada -- kept track of the patients they saw with new-onset headaches, whether or not the patients had CT scans, and whether or not patients ultimately had serious intracranial pathology (bleeding or tumors).

Although 46% of patients said their headaches were severe, only 2% had CT scans. Serious intracranial pathology was extremely rare -- only 12 cases for every 100,000 patients with a new headache. *All* of those cases were diagnosed in a timely manner.

The study demonstrates that primary care clinicians have a safe and cost-effective approach to headache diagnosis, even though their approach differs from what the experts recommend.

## CONTRIBUTIONS: ANOTHER EXAMPLE

- Pelvic inflammatory disease
  - National guidelines advise hospitalization for many women
  - In primary care setting, vast majority of women do well without hospital care

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In another ASPN study, practitioners kept notes on how they managed patients presenting in their practices with pelvic inflammatory disease. Most women were managed as outpatients -- contrary to published guidelines. Outcomes were excellent.



## CONTRIBUTIONS: A THIRD EXAMPLE

- Carpal tunnel syndrome
  - Increasing incidence, probably because of widespread computer use and better awareness
  - Most cases can be treated by primary care physicians with simple measures
    - Splint
    - Drugs like ibuprofen
  - Referral to specialists infrequently needed

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Carpal tunnel syndrome has gained more attention in recent years. ASPN practitioners noted that non-occupational CTS was common in their practices. Simple measures appear to be helpful for most patients with CTS seen in primary care. Referral for complicated diagnostic procedures or for surgery is unusual.

These 3 studies may represent the tip of a very large iceberg. Imagine how medical practice might be different if we knew more about these and other problems that affect most people most of the time. Our treatment strategies surely would be more effective -- and more cost-effective. We might well be able to organize the *delivery of care* in ways that better met the needs of our patients.

# WHY GET INVOLVED WITH RESEARCH?

- Administrative reasons
- Clinical reasons



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There are numerous reasons for health centers to involve themselves with research. It's a somewhat arbitrary classification, but the reasons can be thought of as principally administrative or managerial on the one hand, and principally clinical on the other.



## PIGGY-BACKING

- Your center already doing research-like activities
  - CQI studies
  - Bureau of Primary Health Care reporting
  - Accreditation by Joint Commission or similar agencies
- Not much work to turn these into “formal” research studies

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Because research includes a lot of measurement, data analysis, and reporting, it's similar to activities already underway. CQI, for example, can be thought of as a kind of research program on quality. Bureau reporting and accreditation by outside agencies also involves collecting, reporting, and acting on data.

Therefore it's not impossible to think that some of these existing data-driven activities could be turned into research projects with a relatively small effort.

## REAL DOLLARS

- If existing research-like activities become funded research, then your required reporting is paid for
- Indirect costs or overhead

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If an existing activity is converted to a research study, then the budget that funds research also funds the existing activity.

Some research funding agencies pay indirect costs, or overhead, in addition to the direct line-item costs of a research budget. Overhead is typically calculated as a percentage of the direct costs. These dollars are used to pay for costs that cannot easily be assigned to a given cost center -- rent, utilities, and so on.

## BENEFITS OF A HIGH PROFILE



- Research raises your center's profile to insurers, state and local authorities, other providers, patients, broader community
- Higher profile itself can be leveraged to improve cash flow

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There is a more subtle and indirect benefit to doing research in your health center. Being known as a research center can increase the center's name recognition in the community. It may be possible to leverage this to improve cash flow.

# LINKAGES

- Horizontal
  - Other health centers
- Vertical
  - Universities
  - Hospitals
  - Other institutions

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A more intangible benefit of a health center research program concerns the linkages that are built as a result. Your center may create relationships with other centers in the course of doing research; those relationships may be helpful if the centers collectively wish to do problem-solving or advocacy work together.

## SKILL BUILDING

- Learn and use *quantitative skills* that are useful in satisfaction surveys, needs assessment, quality assurance
  - “In God we trust, all others bring data”
- Learn and use grant-writing skills
- Provides education and capacity building for health center staff

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Modern management emphasizes investing in people. Developing a research program is one good way to do that. Doing research allows your health center staff to develop their quantitative skills -- skills that will come in handy elsewhere. One of the “gurus” of continuous quality improvement, W. Edwards Deming, emphasized the importance of quantitative skills in his famous statement, “In God we trust, all others bring data.”

Research also allows your people to improve their grant-writing skills -- something that also can contribute in other ways to your center’s overall health.



## RECRUITMENT AND RETENTION

- High-quality clinicians (“best and brightest”) often want more professionally than seeing patients
- Research helps clinicians answer their own questions

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Make a comment that serves as a transition from what has been called administrative reasons for doing research to what we will call clinical reasons.

Recruitment and retention of high-quality clinicians is perhaps the number one problem that all health centers face. The “best and the brightest” need more than just patient care to keep them motivated. They need opportunities to develop all of their professional sides. Research appeals to the intellect, and showing that your center is involved in clinically relevant studies can help you recruit or retain the right sort of clinicians.

“Clinically relevant” is the key. Good clinicians naturally will have some questions as they see their patients. Is this the best way to diagnose such-and-such? How could we best serve patients with disease X so that they received optimal care from a team of clinicians? If your center operates a research program, your clinicians may have the chance to answer questions they themselves have asked.



## ACADEMIC CONNECTIONS

- Research can make health center more attractive to medical schools and residencies
  - Evidence of climate in which training programs can be comfortable sending their students



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Many health centers have pursued or are pursuing affiliations of some kind with academic centers. Certainly the presence of a research program can be comforting to those in the academic world.

## AND, OF COURSE, THE PATIENTS

- Patients who participate can enjoy
  - Improved access to care
  - Earlier access to new drugs and other therapies
- Center's clinical mission can be affected by information gleaned from research

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It's important to remember that patients can benefit from being part of research. We tend to focus on the downside for patients -- the "guinea pig" question and the need to protect patients. In fact, later in this session we'll discuss the idea of an institutional review board, perhaps the most powerful tool for protecting the subjects of research. But there is an upside, too. Patients who are part of clinical trials, for instance, can enjoy better access, newer therapies, and more thorough evaluations. Some researchers spend considerable time interviewing patients, and that can give patients something else important -- a voice, and someone who will listen.

Naturally the *results* of research can affect the way in which the health center carries out its mission. Your studies may lead you to new ways to deliver effective, cost-effective, and culturally sensitive care.

TIME FOR YOU  
TO DO SOME OF THE WORK!



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Tell the group something to the effect that you're through lecturing for awhile. Now they'll do a preliminary exercise that concerns the applicability of research to their own health centers.

## INDIVIDUAL ASSIGNMENT

- What interesting and useful research could your health center do?
  - Be as specific as possible
  - Refer to particular opportunities and people
- Be prepared to share your list with others in room
- Take 5-10 minutes

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The goal of this session is twofold: to get participants into a positive frame of mind about research, and to encourage them to speak with each other. This should make it easier for them to participate in other group tasks and role-playing later in the day.

Each participant should take a few private moments to answer the question listed on the slide, writing his or her answer on paper.

Frame this assignment with a lot of positive energy and enthusiasm. If someone asks whether a particular entry is appropriate, avoid commenting on the content and instead emphasize that *any* answer to the question, as long as it is specific and refers to particular opportunities and/or people, is okay. Try to avoid letting the participants censor themselves.

Keep an eye on the room and end the individual portion after 5-10 minutes or when it appears that most people are finished writing, whichever comes first.

## GROUP ASSIGNMENT

- Gather in groups of 2-3
- Share lists
- Look for common themes
- Don't focus yet on barriers to starting a research program

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Continue to show positive energy as you introduce the group portion of the exercise. You want to get people to share their lists. Instruct them to look for ideas that are common to more than one individual list. Acknowledged that all health centers face barriers to implementing research and that those barriers will be the focus of other sessions later in the day. You want to avoid letting this early group task become a “we-could-never-do-that-in-our-center” discussion.



## DEBRIEFING

- What did your group members have in common?
- What problems did you identify?



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Finally, have each group report briefly to the whole meeting. As groups report, listen carefully and make positive comments about the lists. If you see common themes that the participants don't notice, make a comment, but naturally it's best if the participants themselves notice and comment upon such themes.



## ETHICAL CONSIDERATIONS

- Is research in the health center environment ethical?
  - Tuskegee
  - Others
- What are the ethical safeguards that you must put in place?
  - Institutional review board

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The infamous Tuskegee Project was a study of untreated syphilis in poor Africa-American men in the American South that began in the 1930s and continued into the early 1970s. Researchers deliberately withheld penicillin from infected patients so they could learn about the disease. Public outrage forced the U.S. Public Health Service to rewrite its own rules about consent by research subjects.

Tuskegee is not the only recent case in which people were unwilling participants in research. Prisoners, patients with retardation or mental illness, and even ordinary citizens not normally thought of as “vulnerable” have been adversely affected by research studies.

The principal ethical safeguard now in place in the institutional review board or IRB.

# INSTITUTIONAL REVIEW BOARDS

- Medical schools, some health departments and hospitals, others
- Institutional and lay representatives
- Purpose:
  - Assure that rights of patients are respected and protected
- Unreviewed studies cannot be funded
- NIH approves and regulates IRBs

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A variety of institutions operate IRBs. Every medical school has one. Many large hospitals, especially those with active teaching programs, run their own. Some large health departments operate IRBs. While it would be impractical for one or more health centers to maintain institutional review boards, the Clinical Directors Network of Region II does have an IRB that is available to review and pass on health center studies.

A typical IRB has both institutional and lay representatives. Its sole purpose is to assure that patients' rights -- particularly in regard to confidentiality and informed consent -- are protected. As a practical matter, unreviewed studies cannot be funded; virtually every grant application asks for a copy of the IRB approval letter.

IRBs themselves do not operate in a vacuum. The National Institutes of Health must approve the creation of each IRB. NIH regulates how IRBs will go about their work.

## HOW DO IRBs PROTECT PATIENT RIGHTS?

- Review research designs
- Review informed consent forms
- Minimum requirements for informed consent:
  - Purpose of study
  - Benefits and risks of participation
  - Provide access to investigators

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Typically a researcher will submit to an IRB a plan for the study, including a draft consent form. IRBs pay particular attention to informed consent forms, which at a minimum must provide information to potential subjects about the purpose of the study, the benefits and risks of participation, and how to reach the investigators.

Naturally, the more invasive, intrusive, or experimental the study, the more requirements will be imposed on the consent form. The first patient who had an artificial heart implanted in his chest was asked to sign an *11-page* consent form! While no health center study realistically will need such elaborate consent, it's important to realize that the responsibility for securing *truly informed consent* rests with the researchers.

## EXEMPTIONS AND EXPEDITED REVIEWS

- Some studies are exempted
  - Record reviews *if* patient identifiers are removed
- Some studies can undergo expedited review
  - Observational, if potential for harm to patients (“subjects”) is minimal
- Only the IRB can decide if a study is exempt or eligible for expedited review

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If you believe your study has no or minimal potential to harm patients, you can try for an exemption or an expedited review. Usually the IRB chair can decide alone that a study has so little potential to harm patients that no review by the full committee is needed. An exemption granted by the chair still has weight -- that is, if the chair grants an exemption but tells you to change the informed consent in some way, you must make those changes or appeal to the chair for a revision in the ruling.

Other studies can undergo expedited review -- the full committee looks the study over but doesn't spend much time worrying about the details. Many studies done in health centers qualify for expedited review, which should be requested when the proposal is forwarded to the committee for review.

Obviously, you should never *assume* that your project is exempt or qualifies for expedited review. And you should save copies of *all* correspondence with the committee and its members.



## THEREFORE...

You *must* assure that *any* study performed in your center has been submitted to an appropriate institutional review board!



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## WHO'S RESPONSIBLE?

- Principal investigator  
(if your center is one  
of many sites)
- Your center (if study  
originates with you)



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If your center develops its own research proposal, IRB review should be complete before you submit grant requests to funding agencies.

If an investigator elsewhere has recruited your center to be part of a broader study, then securing the IRB approval is the investigator's responsibility.



# QUESTIONS, THEN A BREAK



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## **SESSION 2:**

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### Overcoming the Barriers to Getting Started

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## GOALS FOR THIS SESSION

- Discuss different research types and review impact of study design on health center operations
- Identify different “stakeholders” and their concerns
- Develop responses to stakeholder concerns

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In this session we'll talk about the various stakeholders in the C/MHC environment and how they are likely to view research. We'll discuss how an advocate for research -- which we hope you are or soon will be! -- can respond to common objections and concerns.

How stakeholders view research depends partly on how they think the study will affect them. One critical variable that determines the effect is the study design. We'll review the various study designs and their potential effect on health center operations.

# CLINICAL AND HEALTH SERVICES RESEARCH

## ■ Clinical:

- Natural history of disease
- Best routes to diagnosis
- Effectiveness of new treatments

## ■ Health services:

- Health care quality and effectiveness
- Patient outcomes
- Access to care
- Health care costs and financing
- Primary and managed care

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It's helpful at the outset to distinguish two broad types of research. Both are doable in health centers.

Clinical research probably adheres more closely to most people's view of what research is. Questions such as those listed on the slide most readily come to mind when people think of research. But health services research also plays an important role in health policy, and C/MHCs may find health services research both doable and interesting. After all, many health services research questions -- such as those listed -- are of critical importance to the at-risk populations served by most C/MHCs.

As you may know, an entire agency within the US Public Health Service is dedicated to health services research. Not surprisingly, it's called the Agency for Health Care Policy and Research.

## RESEARCH DESIGNS

- Why should you care?
  - Different types of studies can have different impacts on health center operations
- Types:
  - Record review
  - Observational
  - Interventional

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By way of repetition, we're not interested in turning you into an expert on research study design. But since different types of studies can have different impact on health center operations, it's important to have a feeling for the different designs.

At the risk of being overly simplistic and arbitrary, we've classified all study designs into three broad areas.



## RECORD REVIEW

- Resembles a quality management audit
- May involve
  - Looking at administrative data (computer print-outs) only
  - Clinical record review
    - Ethical considerations apply
- Affects medical records the most
- Intrusiveness depends on degree of computerization

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Much health services research will involve record reviews, and so will a lot of clinical research. This study design most closely resembles the quality audits you are now doing.

This study type usually has little impact on day-to-day operations, although medical records or your data processing people might disagree. If the study involves reviewing clinical records, then privacy questions must be answered. It's often possible to give the researchers copies of records with patient identifiers deleted. Of course, if the researcher is one of your own health center staff people, then the blanket confidentiality policy that you already have in place should cover the research activities, too. But it's a good idea to review and amend as necessary your confidentiality policy if research of this type is contemplated.

## OBSERVATIONAL STUDY

- Data collection at or near the time the patient is seen
- Often based on questionnaires
  - Completed by patient
    - Self at time of visit
    - Mail-out/mail-back
    - Interview
  - Completed by clinician

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As suggested by the title, in a study of this type the investigator observes something but does not try to influence or alter what's being observed. Often questionnaires are employed -- and as we'll discuss later, the mechanics of questionnaire completion should be carefully ironed out before the study is launched.

Patient questionnaires can be completed over the phone or at face-to-face interviews, at the time of the visit, or by a mail-out arrangement after the visit is over.

## OBSERVATIONAL STUDY (2)

- May involve actual observation of clinical encounter
  - Audiotape
  - Videotape
  - One-way window
  - Research assistant in examination room

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There may be actual observation in real time as part of an observational study. Most health centers don't have rooms with one-way windows, but it may be part of the study design to audiotape or videotape encounters with patients. Or a research assistant might be sitting -- hopefully unobtrusively -- in the examination room, taking notes. Obviously all of these designs have implications for patient consent, and must be addressed in the IRB presentation.

## INTERVENTIONAL STUDY

- Deliberate comparison of two treatments or diagnostic strategies
  - May involve use of placebos
- Random assignment of patients to study “arms”
- Likely to require most changes in routine operations
- Potentially most contentious

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This is the classical “drug A versus drug B” or “drug versus sugar pill” study. But even health services research can generate interventional studies -- for example, patients with heart failure might be randomly assigned to “usual care” versus “multidisciplinary team-centered care.” One key element of an interventional study is *random assignment of patients* to the various “arms” of the study. Expect the principal investigator to play the lead role in explaining how randomization works and why it meets ethical standards. As you might imagine, interventional studies potentially are the most contentious -- although that’s not necessarily so. (A detailed questionnaire covering, say, sexual behaviors can be perceived as much more intrusive than comparing 2 drugs for the treatment of high blood pressure.)

Because patients must be randomized and because, by design, the interventional study tests new ways of doing things, it is the design most likely to require changes in daily health center operations.

## WHAT ABOUT OUTCOME STUDIES?

- Outcome study is defined by *what* is studied, not *how* it is studied
- An outcome study could be interventional, observational, or record review

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Today's current health care buzzword is outcomes. Please remember that an outcome study is defined by what is studied, not how.



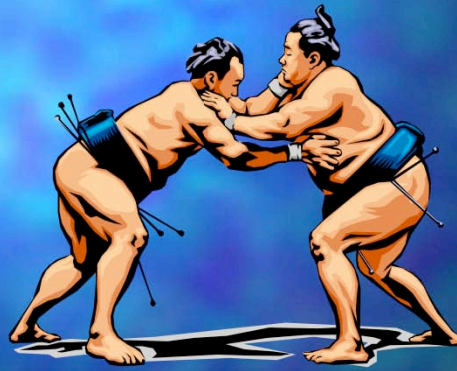
## WARNING!

Building support for *research in general*  
is **not** the same as securing support for  
any *particular study*!

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To create a research program at your center you'll first need to build support for the idea of research in general. But don't assume that, just because everyone has endorsed doing research, they've all agreed to the *particular* study that one of the clinicians at the center wants to do. Each study has its own special requirements, and it's *always* important to go through the particulars with all stakeholders.

## LET'S WRESTLE WITH SOME BARRIERS



You'll get a laugh when this slide goes up, so capitalize on it when you transition the discussion to another group exercise. You're going to ask participants to call out *stakeholders* -- groups (e.g., board members, senior management) who may have identifiable concerns about research.

## GROUP ASSIGNMENT: WHO ARE THE STAKEHOLDERS?

- Working together, let's list the key stakeholder groups
- What does each stakeholder group tend to be concerned about?

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Open it up. Using either a paper flipchart and marker (preferred) or an overhead projector with blank transparencies, encourage people to yell out the names of stakeholders. Don't edit the list yet -- there will be time enough to combine "check-out area clerks," "medical records," and "nursing assistants" into a single category called "support staff." For each stakeholder, have the participants try to list their probable concerns about research. (Don't try to distinguish general research concerns from concerns about any particular type of study.)

SING OUT!



You should get another chuckle with this slide. Use humor and positive energy to get people to call out answers.

Then go through the next series of slides (#46-61). As you review, say, slide #46 about clinicians, refer to points that the group has already made and listed on the flipcharts. (“Another issue for clinicians is that their job performance may be tied to productivity. Several of you raised that point in the ‘sing-out’ a minute ago.”) Move back and forth between the prepared slides and the flipchart lists.

Be sure that you lump together groups when appropriate. As suggested in the instructions for slide #44, “support staff” is an appropriately sized stakeholder group, while separately listing each individual support staff job description is not. If some participants object to, say, medical records being lumped together with receptionists, just indicate that their concerns about research studies probably are similar even though their jobs are not. If someone still gives you a hard time, ask him or her to hold onto the concern and bring it up again in the question-and-answer period at the end of the session.

## CLINICIANS

- “Research” = “academic” = “life I rejected already”
- How will patients react?
- I’m too busy already
  - My job is tied to productivity, not to research
- Subject matter doesn’t concern me or my patients

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These are generic concerns that health center clinicians have raised in the past when research programs were being considered at their centers. The last item obviously depends on what the particular study might be, while the first three are about research in general.

Participants may come up with more than these. That’s great!



## CLINICIANS: OVERCOMING RESISTANCE

- Research offers a creative outlet
- Facilitates recruitment and retention
- Results will help provide better patient care
- Some studies will allow underserved patients access to new treatments

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Naturally each clinician will respond to one or more of these arguments in a unique way. Not all of the above arguments will be persuasive for every clinician, and no doubt you will think of others that apply to particular clinicians in your setting.

## CLINICIANS: OVERCOMING RESISTANCE (2)

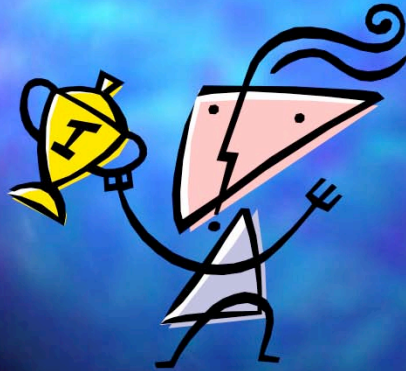
- Mechanics of all studies will be reviewed in advance with clinicians
- Administration will free up clinician time for research
- Revised pay formulas
  - More than just clinical productivity

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There has to be a “marriage” between clinicians and administrators if a health center is going to implement a research program. Both clinicians and administrators must be convinced of its value, and both must make changes that allow research to go forward.

Clinicians must be persuaded that administration is serious about a research program, whether the impetus for the program comes from clinicians or from administration. Clinicians will be wary of any program that adds responsibilities or hours to their already busy lives. It may require a negotiated agreement between administration and clinicians to get a research program going.

## CLINICAL CHAMPION



- Key to building support
- Respected clinician who can make the case with authority
- Not necessarily the medical director
- Can be clinical coordinator

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Without a champion for research among the clinical staff, there is little hope of launching a research program at a health center. This must be a respected clinician who can make the case persuasively for getting involved in research.

The clinical champion can be either a formal or informal leader, but he or she must be a leader. In some centers, the clinical coordinator could become the research champion.

## A "FINER" STUDY: GETTING CLINICIAN BUY-IN

- **Feasible**
  - Can get adequate numbers of patients
  - Available technical expertise
  - Manageable
- **Ethical**
  - No unacceptable patient risks
- **Interesting**
- **Novel**
  - Not just confirming someone else's work
- **Relevant**
  - Answer to research question could affect care delivered at center

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When trying to enroll clinician support for a particular study, this mnemonic can be helpful. Like other stakeholders, clinicians may support research in general while balking at a particular study. Research proposals that meet the "FINER" criteria have a higher chance of gaining clinician buy-in.

## SUPPORT STAFF

- How will this research impact
  - Patient flow?
  - My own work flow?
- Be sensitive when staff are evaluated in part based on productivity
- How will patients react?

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By “support staff” we mean nurses (in most centers) and nursing assistants, medical records staff, front desk people -- all those people who do not see patients independently, or in some cases do not see patients at all. Support staff tend to be keenly interested in how research studies will affect the day-to-day operation of the health center, and the impact of that on their own work flows.

If support staff are evaluated on the basis of productivity, whether in whole or in part, you must be extremely sensitive to the effect of a study on their productivity.

In most centers support staff view themselves as patient advocates. They will ask tough questions about how research may affect your patients.



## DO NOT UNDERESTIMATE THE IMPACT

- Researchers often fail to realize how disruptive their study requirements can be
- Sometimes design (do questionnaire during waiting-room downtime) conflicts with CQI goals (reducing waiting times)

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Many study designs have an impact on the day-to-day operations of health centers -- precisely the area of responsibility of support staff. Researchers can easily underestimate the impact of their proposed studies on patient flow, support staff workload, etc. This is true no matter whether the researcher is a health center outsider -- say, a medical school faculty member -- or one of your own clinicians. Clinicians frequently have an incomplete understanding of support staff work flows and routines in their own facilities.

It's important, when building staff support for research, to constantly check on hidden or implicit assumptions. For example, the researcher may decide that "waiting room time is dead time." The study may then include a waiting-room questionnaire that takes 15 minutes to complete. The implicit assumption naturally is that patients wait at least 15 minutes. At the same time you've got a CQI project going to reduce waiting times. You're trying to get the patients back quickly, the patients get confused because the questionnaire isn't completed by the time they're called, support staff tell patients not to worry about finishing the questionnaire, the investigator is furious because the data are incomplete...it's not a pretty picture.

## SUPPORT STAFF: OVERCOMING RESISTANCE

- Emphasize positive benefits of research for patients and center
- Make analogy to continuous quality improvement
- Map out workflows in detail
- Answer logistical questions in advance
- Insist on pilot study
- Appoint staff member as liaison to research project

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But it doesn't have to be that way. Careful planning is the route to enrolling support staff as, well, supporters of research. They will respond to things that benefit patients. The workflows should be mapped out in advance -- preferably using flowchart methods that many health centers learned in the context of continuous quality improvement. This exercise will allow everyone to identify the logistical issues before they become contentious.

Whether the researcher is from your own staff or from the outside, you should insist on a pilot study before jumping into a research project with both feet. No matter how well the project is planned, unanticipated glitches are more likely than not to show up. A pilot study can find the glitches, allowing them to be solved before the project goes into high gear.

It's very useful to appoint one support staff person as a liaison to the research project. That way, all support staff and administrative concerns can be funneled through one person, who in turn communicates with the researcher. Again, this makes sense even if the researcher is one of your own clinicians.