The Research Question
Part II: Research Ideas

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Welcome this video is entitled The Research Question Part II: Research Ideas. I will remind you to please refrain from distributing or copying this video lecture.

Outline

- Research Ideas
- Clinical Inquiries Process
- FINER
- Clinical equipoise

This module will cover research ideas, ClinIQ, the clinical inquiries process, FINER, and clinical equipoise

Foundation of Clinical Research

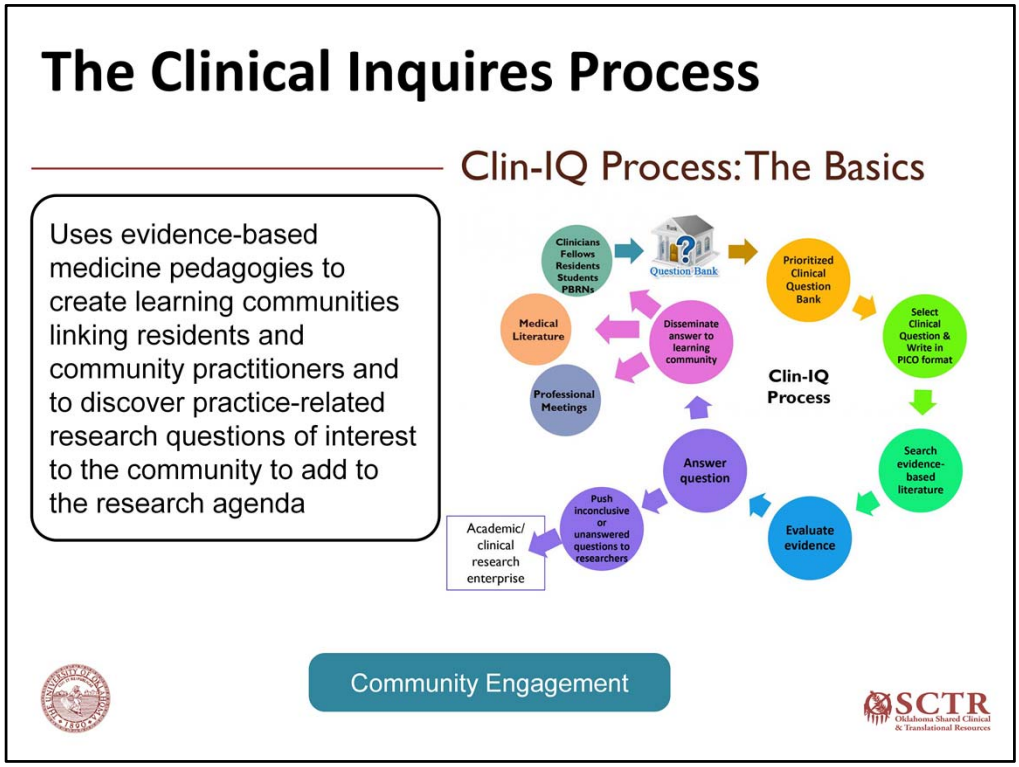
- Well designed research question

Most IMPORTANT part of the study

In this module we will continue to talk about clinical research and your research question. The foundation of clinical research is your well-designed research question. This question is actually the most important part of your study.

When investigators have new research ideas were do the ideas actually come from. These ideas come from several different sources. They may come from the literature, for example you may be reading an article and the article may either cause you to think about a new research idea or the discussion section may highlight further research that needs to be done in the area. Another source of research ideas are scientific conferences or meetings. When you are at a conference and you hear about currently conducted research that is completed or ongoing this may prompt you to think of a new research idea or you might hear colleagues discussing gaps in the knowledge that need to be filled. This can also occur in conversations with colleagues when you are discussing issues or problems that exist in your field that need to be resolved.

Other methods of ascertaining research ideas are new technologies. When you learn about new techniques or technologies that have been developed this may naturally lead to a new research idea. For example, when digital mammography became available, a resulting research idea is trying to determine if the digital mammogram is superior in detecting malignant breast tumors as compared to screen mammography. Another source of research ideas or observations is clinical practice. When you are in the clinic you may identify a case or issue that you are unsure how to solve. After searching the literature you still may not know the answer and this too may lead to research idea for you to discover how to solve this problem. This is the translating practice into research piece. Research ideas also come from teaching. In the process of explaining to students or trainees why something is done you may realize that the evidence for this procedure is weak and perhaps there is a way to determine through research if this is the best way to accomplish this task. Research ideas also come from mentorship. Your mentor may be able to help you find the gaps in knowledge and also help you determine which ideas are most important and answerable in your field.

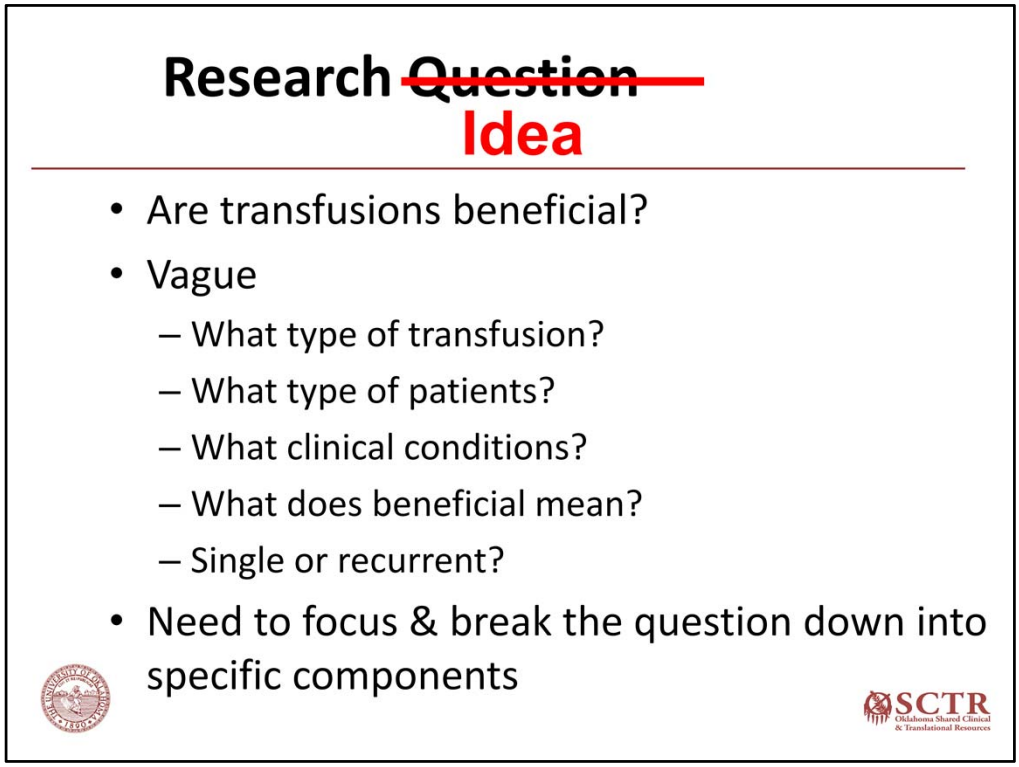


So I mentioned that one source of ideas is clinical practice. Within Oklahoma Shared Clinical and Translational Sciences Resources the Community Engagement core has refined a process called the Clinical Inquiries Process or the Clin-IQ process. This is a method to formalize the process of taking research ideas from the clinic through a process to determine if they are potential research project questions. In the diagram the process starts by the building. Clinicians, residents, students as well as practice-based research networks have the ability to contribute questions to a question bank. Within the question bank there's a prioritization of the clinical questions. Then certain questions are selected and written in PICO format. We will describe what the PICO format is in module four of this session. Then a search for evidence-based literature occurs and that evidence is evaluated. Then there is a determination of whether or not the question is answered. If the question is answered then dissemination occurs back to learning community. This includes dissemination back to the people that contribute to the question bank but also dissemination to the medical literature and to professional meeting, potentially national as well as local meeting. On the other hand, if the question is inconclusive or not answered then these questions are passed on to the academic clinical research enterprise. So this is a more formalized process of translating practice into research.

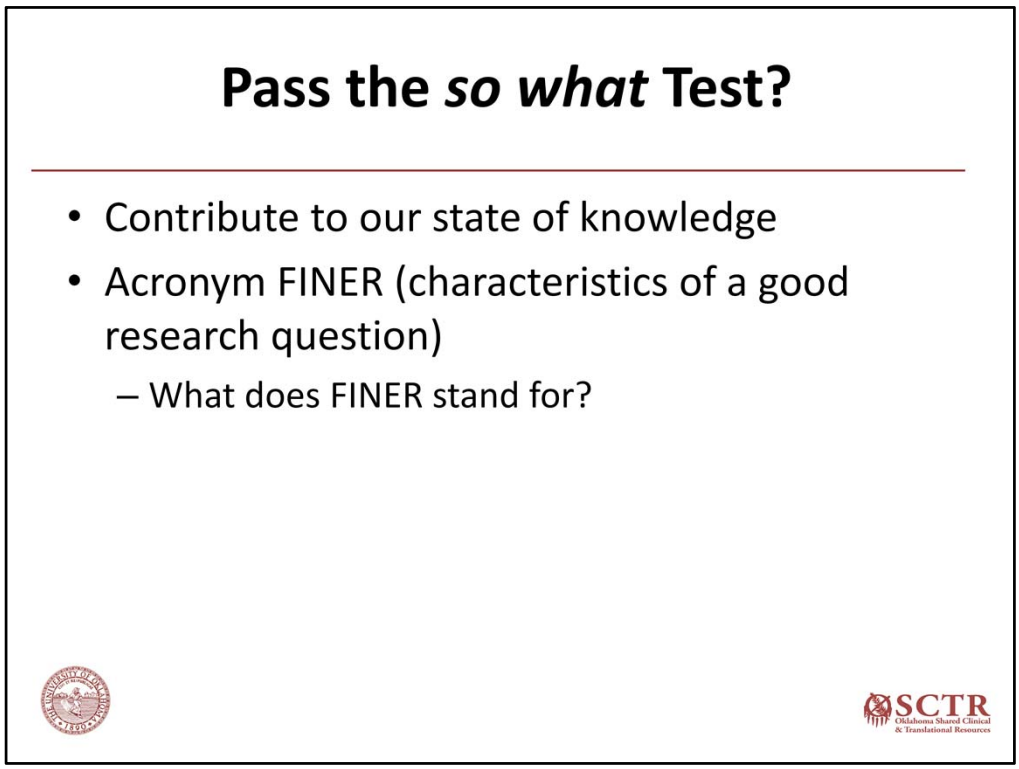
Research Question

- Are transfusions beneficial?

So here is an example of a research question, are transfusions beneficial?



Is this actually a research question? No, in reality this is more of a research idea. So why isn't this a research question? The question is too vague. The question does not contain information about what type of transfusion? What type of patient? Patients receiving chemotherapy or trauma patients? What are the clinical conditions where we are administering transfusions? What does beneficial actually mean? Are we talking about single or recurrent transfusions? So to make this research idea into a question you need to focus and break the question down into specific components.



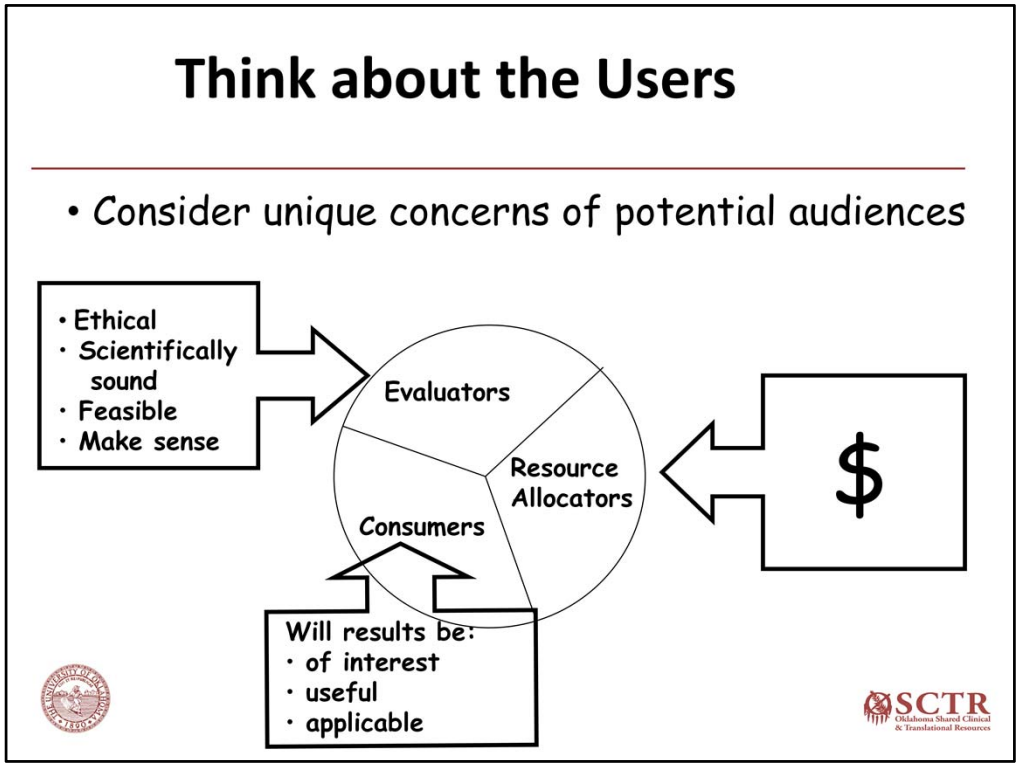
Another thing our research idea needs to become a research question is to pass this so what test. If we are able to answer this question does it contribute to our state of knowledge? One way to determine if this question is actually important is the acronym FINER. FINER describes the characteristics of a good study and then we can use this to determine if our question is reasonable. What does FINER stand for?

FINER

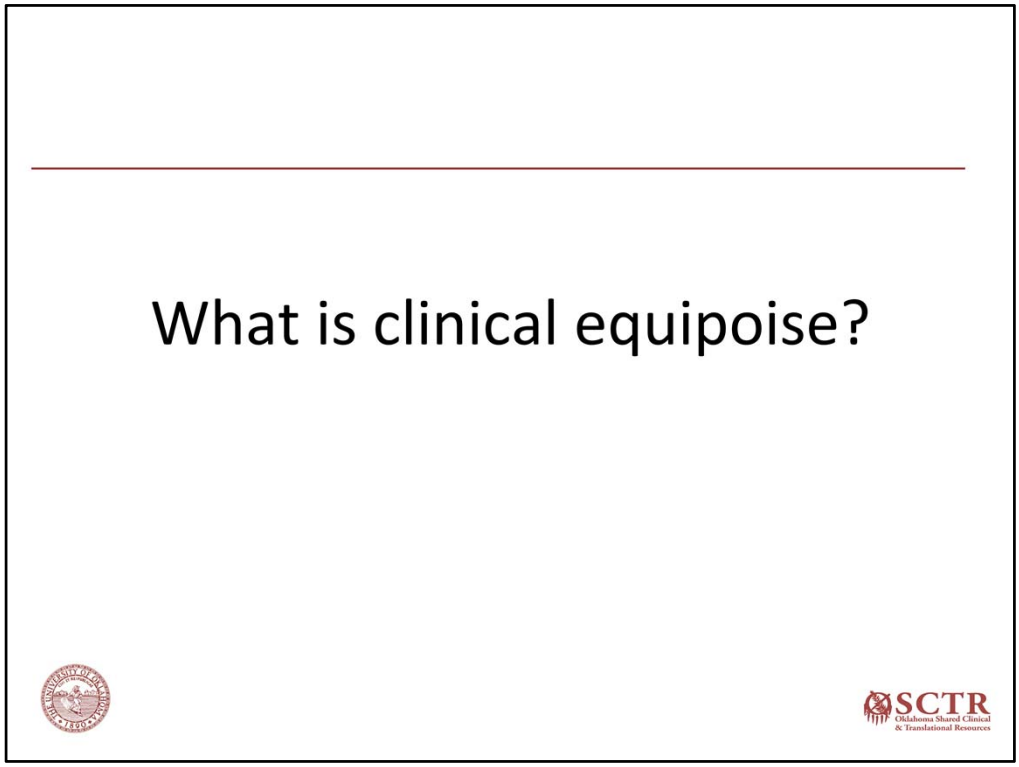
FINER	Explanation
Feasible	Adequate # of patients Adequate expertise Affordable (time and $) Manageable in Scope
Interesting	Getting the answer intrigues the investigator, colleagues, patients
Novel	Confirms, refutes or extends previous findings Provides something new
Ethical	Able to obtain IRB approval
Relevant	To scientific knowledge To clinical practice and health policy To future research

Modified from Hulley & Cummings, Designing Clinical Research, 3rd ed., 2007

FINER is an acronym for feasible, interesting, novel, ethical and relevant. Feasible means can we actually do the study? Can we find an adequate number of patients, do we have adequate expertise to conduct the trial, is the trial affordable in terms of money and time, is the project manageable in its scope? You may have several related questions but one trial may be to extensive to answer all components. By interesting we want to know if this answer is intriguing to investigators colleagues and patients. Is this something that your community is interested in knowing? Is the question novel, will this provide an new information? Will you be able to confirm or refute or extend the previous findings? Is this an ethical project? Ultimately all projects in human subjects will need IRB approval. If the IRB does not approve your study, then your study will not happen. The last characteristics is relevance. Is this question relevant? Will the study contribute to scientific knowledge, to clinical practice and healthcare policy, or to future research?



Next you need to think about your users. You need to consider unique concerns of potential audiences. Let's start with the evaluators. The evaluators of the study will ask: is this study ethical, is it scientifically sound, is it feasible and does it make sense? Think about the consumers. Consumers want to know if the results will be interesting, if they will be useful, if they will be applicable. The resource allocators are most concerned with the cost. How much your study will cost, will impacts whether or not you're able to obtain funding. As you can see, these three potential stakeholders: evaluators, consumers and resource allocators, have concerns that overlap with the characteristics raised with the FINER acronym.



We also need to be concerned about clinical equipoise. What is clinical equipoise?

Clinical Equipoise

Definition:

- True state of uncertainty
- Careful literature search

- Best example of research without equipoise
  - Meta-Analysis Aprotinin in Cardiac Surgery
    - Fergusson et al., Clinical Trials, 2005
  - 64 RCTs identified (1987-2002)
  - Performed a cumulative meta-analysis

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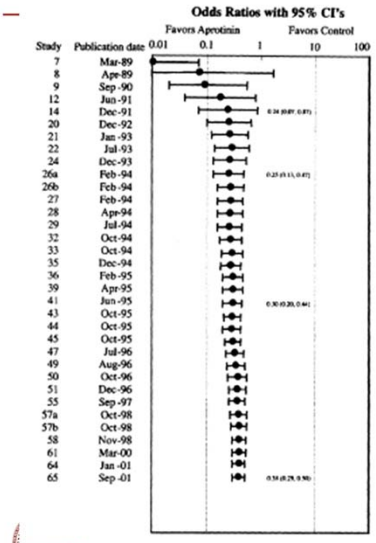
One concept to be considered when thinking about the design of a clinical study is the issue of equipoise. Clinical equipoise exists when there is a true state of uncertainty about the effectiveness of an intervention. If the answer is already known then you should not be thinking of doing yet another study. The best example of research performed in the absence of clinical equipoise is illustrated by the cumulative meta-analysis by Fergusson and colleagues that included 64 RCTs that have been done to address the efficacy of aprotinin to decrease blood loss in cardiac surgery

Meta-Analysis Aprotinin in Cardiac Surgery

Fergusson et al., Clinical Trials, 2005



High Quality Studies

RESULTS

- By the 3rd study (Sept 1990) efficacy was demonstrated
- By Dec 1992 the point estimate was stable & CI was narrow
- 47 additional studies were done
- Failure to cite previous literature
- Conclusion:
  - Equipoise did not exist
  - The answer was known

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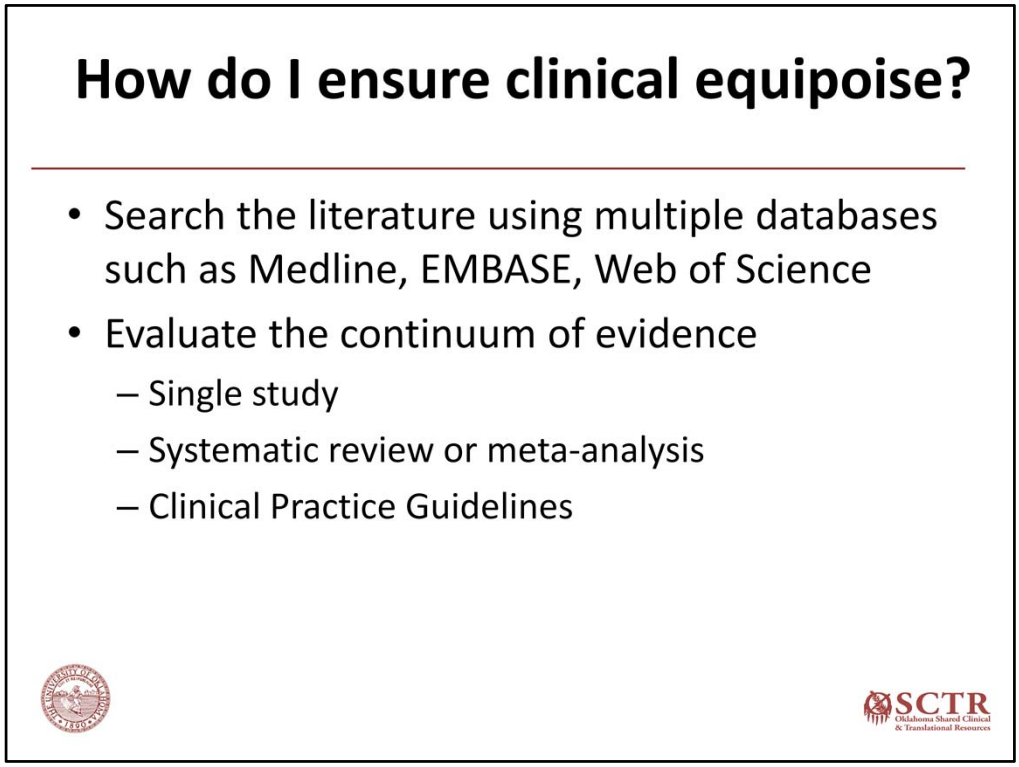
On the left side of this slide the results of this cumulative meta-analysis are summarized. By the 3rd study efficacy was demonstrated; the 95% CI for the OR does not include one. By the 6th study the point estimate was stable and the CI narrow. And yet 47 additional RCTs were performed. Most having small numbers and most failing to cite the literature published before. All 47 studies were conducted after the efficacy of aprotinin had already been demonstrated – in other word they were conducted in the absence of equipoise.



How can you ensure there is clinical equipoise? You need to conduct an extensive literature search using multiple databases such as Medline, EMBASE, web of science. These database can be accessed through PubMed, OVID, and other library resources. You also need to evaluate the continuum of evidence. There are single studies, syntheses of single studies such as systematic reviews and meta-analyses, and system documents such as clinical practice guidelines. There is another module from the TPIR program that will discuss in more detail searching the literature as well as critical appraisal of the literature and conducting systematic reviews and meta-analysis. This concludes part II: Research Ideas of the Research Question module. I would like to acknowledge and thank Professor of Medicine, Nancy Heddle, from McMaster University in Hamilton Canada for sharing her slides with me and allowing me to modify them to fit the needs of this portion of the presentation.

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