Am I Doing Research?

Nicole Villemarette-Pittman, PhD
Director, Clinical Research
Associate Professor (Hon), University of Queensland Medical School
Ochsner Health
Am I Doing Human Subjects Research?

• Human Subjects Research Defined
  • Human Subject: a LIVING individual about whom an investigator is conducting research
  • Human Subjects Research:
    • Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens
    OR
    • Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
Examples of Human Subjects Research may include:

- Collecting blood
- Conducting a survey
- Changing participants’ environments
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique
- Implanting a device
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Clinical Question
• I think my ALS patients should be assessed with the ALS Functional Rating Scale – will this help me determine the right support services for my patients?

Research Question
• Were ALS Clinic patients, who were assessed with the ALS Functional Scale, matched to support services in less time than those who were not assessed?

A Clinical Question helps me do my work better and directly impacts my individual patients.

A Research Question may offer no promise of benefit to my patients or my practice but may help others.
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Quality Improvement/Process Improvement/Quality Control/Quality Assurance

Safety: Avoid harming patients
Time: Reduce delays for patients and providers
Efficacy: Provide evidence-based care
Efficiency: Avoid waste (equipment, ideas, energy, etc.)
Equity: Provide care that does not vary in quality based on personal characteristics
Patient-Centered: Provide care that respects patient preferences, needs, and values

FOCUS: Process or System or Practice or Methods regardless of the individual characteristics of the members (patients, trainees, providers, etc.)
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Quality Improvement
If I give prophylactic antibiotics 5 days prior to non-traumatic knee replacement surgery, will that have a positive impact on my post-surgical infection rate?

- Target = process used to prevent infection in all patients having non-traumatic knee replacement surgery
- Intervention = prophylactic antibiotics
- Outcome = % of post-surgical infections during the 12 months prior to this process change versus the 12 months after this process change (group level data)

Research
Do my patients who had prophylactic antibiotics 5 days prior to non-traumatic knee replacement surgery have different rates of post-surgical infection compared to those who did not have prophylactic antibiotics?

- Target = individual patients
- Intervention = prophylactic antibiotics
- Outcome = % of post-surgical infections in prophylactically treated vs untreated in non-traumatic knee replacement surgical patients (patient level data – what is different about the patient groups? If outcomes differ, could it be attributed to antibiotic use prior to surgery?)
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Quality Improvement
If I train my fellow residents to use a behavioral plan with people who want to quit smoking, will we reduce the number of active smokers in the primary care clinic in 12 months?

• Target= **process** used in clinic to help people quit smoking
• Intervention= resident education
• Outcome= # of active smokers in clinic after the program (group level data)

Research
If I use this behavioral intervention with people who want to quit smoking, how many people who use my program will become nonsmokers compared to those who do not use my program over 12 months?

• Target= **individual** patients
• Intervention= behavioral plan vs standard of care
• Outcome= % nonsmokers after 12 months in the group that used program (patient level data – Who chose this plan? Who was successful?)
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- **Clinical Questions**
  - Affect patients
  - Affect medical practice

- **QI Projects**
  - Affect processes
  - Affect systems

- **Research Questions**
  - Inform others through generalizable knowledge
  - May have no effect on patients
  - May have no effect on processes
## Am I Doing Human Subjects Research?

<table>
<thead>
<tr>
<th>Clinical Question vs Research Question</th>
<th>Quality Improvement vs Research Question</th>
<th>Pre-research Activity vs Research Activity</th>
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| **Clinical**: I think my ALS patients should be assessed with the ALS Functional Rating Scale – will this help me determine the right support services for my patients?  
**Research**: Were ALS Clinic patients, who were assessed with the ALS Functional Scale, matched to support services in less time than those who were not assessed? | **QI**: If I train my fellow residents to use this behavioral intervention with people who want to quit smoking, will we reduce the number of active smokers in our clinic over the next 12 months?  
**Research**: If I use this behavioral intervention with people who want to quit smoking, how many people who use my program will become nonsmokers compared to those who do not use my program over 12 months? | **Pre-research**: I am interested in studying a behavioral intervention to help people quit smoking. Let me use SlicerDicer to see if I have enough smokers in my clinic to meet the target sample size.  
**Research**: How many people in my clinic using this behavioral intervention have been a nonsmoker for 12 months or longer versus those using nicotine gum? |
I’m Still Not Sure if I am Doing Human Subjects Research

• Ask the IRB for a determination
  • Not human subjects research
  • It is Quality Improvement/Process Improvement
  • It is pre-research activity

• If you submit a full application, they may also determine:
  • It is human subjects research, and it falls into the exempt category (most retro chart reviews)
  • It is human subjects research that requires continued oversight