

The Different Roles of Coordinating Research Versus Standard of Care

- ### Objectives
1. Understand the difference between research and standard of care.
 2. Explain how to balance the roles and responsibilities of research versus standard of care.
 3. Explain the importance of a coordinator's role in helping patients understand the difference in research versus standard of care.

What is research?

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

The Belmont Report

- Respect for persons- each person is autonomous individual with the right to self determination
- Beneficence- research design must provide benefit, protect from harm, limit risks
- Justice- there is equitable selection of subjects so that the risks and benefits of research are fairly distributed in the population

What is standard of care?

- In medicine, treatment that experts agree is appropriate, accepted, and widely used. Health care providers are obligated to provide patients with standard of care. Also called standard therapy or best practices. Treatment regimen or medical management based on state-of-the-art patient care.

What is standard of practice?

- Standard of practice and standard of care is sometimes interchangeable, but sometimes standard of practice can also mean that a physician may have certain tests or criteria that he/she wants done for all their patients. e.g. certain lab test.

What is the difference between research and standard of care?

- Line is sometimes blurry, but it is an important distinction.
- Important not to confuse research with standard of care.
- Departure from standard of care is not necessarily research.

What is the difference between research and standard of care?

- Practice refers to interventions designed solely to benefit an individual patient and have a reasonable expectation of success.
- Research is an activity designed to test a hypothesis and contribute to generalizable knowledge

Websites used for standard of care

- <http://www.cms.hhs.gov/Manuals/10M/ItemDetail.aspx?FilterType=none&FilterByDID=-99&sortByDID=1&sortOrder=ascending&ItemID=C145014961>
- http://www.wpsbc.com/medicare/policies/pol_home.shtm#tacts
- http://www.agsmedicare.com/providers/lmp/lmp_home.asp
- <http://www.aec.org/qualityandscience/clinical/statements.htm>
- http://www.scah.org/dlfrl.aspx?PAGE_ID=3303
- <http://www.nhlbi.nih.gov/index.htm>
- <http://www.ahrq.gov/>
- <http://www.guideline.gov/>
- <http://www.americanheart.org/presenter.jhtml?identifier=2158>
- <http://www.nice.org.uk/page.aspx?b=home>
- <http://www.nice.org.uk/page.aspx?b=cardiovascular&View=All&template=diseasetaxa391>
- <http://www.aan.com/go/practice-guidelines>
- <http://www.ishl.org/publications/guidelines.asp>

Websites continued

- <http://www.library.ubs.ac/Default.aspx>
- <http://www.icsl.org/index.aspx?catID=2>
- <http://ascelo.org/>
- <http://www.asaz.org/>
- <http://www.strokessociation.org/presenter.html?identification=1200037>
- <http://www.abimny.org/epg.html>
- http://www.esearchfo.org/knowledge/guidelines/Guidelines_list.htm
- <http://www.ipnotebook.com/RADCh3.htm>
- <http://hippo.findlaw.com/hippohome.html>
- <http://www.cdc.gov/ncidod/d/index.htm>
- <http://medicine.ucsf.edu/resources/guidelines/>
- http://gecommunity.gehealthcare.com/getCommunityUltrasound/best_practices_venous_evaluation_best_practices.js
- <http://www.medscape.com/nurses>
- <http://mdm.ca/cpgsnew/cpgs/index.asp>

Websites continued

- <http://gacguidelines.ca>
- <http://www.vascularweb.org/index.html>
- <http://www.bebis.com/betterknowledge/tee/>
- http://www.aetna.com/about/cov_detr_policies.html
- http://www.neurosurgerytoday.org/what/patient_ovcaroid.asp
- <http://www.thoracic.org/sections/publications/statements/index.html>
- <http://www2.interscience.wiley.com/cgi-bin/mrw/home/106568753/HOME?CRETRY=1&SRETRY=0>
- http://www.oap.med.va.gov/epg/SUD/SUD_Base.htm
- <http://www.tripdatabase.com/index.html>
- <http://www.cms.hhs.gov/center/coverage.asp>

What is clinical equipoise?

- Principle of clinical equipoise was defined by Dr. Benjamin Freedman as follows:
- Clinical equipoise is the ethical principle that in medical research involving randomly assigning patients to different treatment arms, the clinician should have no reason to prefer any one arm over the other. State of being balanced.

Objective

- Explain how to balance the roles and responsibilities of research versus standard of care.

Balancing Roles and Responsibilities

- Important to remember the three advocacies of a study coordinator;
- Patient advocacy
 - ◆ primary responsibility
 - ◆ commitment to the patient's welfare
 - ◆ our responsibility continues before, during, and/or after a patient/subject participates in research

Balancing R and R (cont'd)

- Example of balancing roles and responsibilities
- Coordinator recognizes the therapeutic value of patient's hope
- Coordinator hopes that patient will benefit from participation

Balancing R&R (cont'd)

- Subject advocacy
 - Promotes an informed decision to participate in research
 - To protect the rights of an individual and to remind investigators that subject's have the right to withdraw consent

Balancing R&R (cont'd)

- Example of balancing roles and responsibilities
- Primary responsibility here is the rights and welfare of an individual as research subject
- Duration of this responsibility lasts before and/or during a study

Balancing R&R (cont'd)

- ◆ Example of Balancing
 - Coordinator tries to hope-neutral, providing accurate information for decision making
 - Coordinator tries to be hope-neutral, focusing on voluntariness, no promise of benefit, and minimized risk

Balancing R&R (cont'd)

- Study Advocacy
 - ◆ Primary commitment here is advancing research goals; gathering valid, clean data via good recruitment and retention of subjects
 - ◆ A coordinators relationship with patient/subject is study specific

Balancing R&R (cont'd)

- Example of balancing
 - ◆ Coordinator recognizes that hope may encourage participation
 - ◆ Coordinator hopes that the study will be successful or that altruism will benefit the subject

Balancing the Roles

- Because the three advocacies have different objectives, they must be balanced
 - ◆ There are instances when the advocacies are synergistic but more commonly the result of balancing is one of potential conflict.

Scenario 1

- Pre-transplant patient being considered for research study.
- Standard of care versus research.
 - ◆ Patient pays for drug
 - ◆ Patient receives free drug

Scenario 2

- End-stage heart failure patient being considered for ventricular assist device (VAD).
- Standard of Care versus research
 - ◆ FDA approved VAD
 - ◆ Research VAD

Case presentation 1

- Comatose patient with massive MI needing VAD, possible future transplant. Coordinator reviewed chart, patient meets inclusion/exclusion criteria, but patient unable to hear or sign for VAD. No power of attorney for health care by any of the sisters. Note left in chart that patient can not be in study due to no power of attorney for health care.

Case Presentation 2

- A 49 year old gentleman flight for life in cardiogenic shock. Research called to evaluate for device study. Patient met inclusion/exclusion criteria when evaluated, but was sedated and unresponsive. LAR was not approved for this device study and wife did not have POA for health care. During chart review there was no indication that surgeon discussed research VAD with patient or family.
- IRB was consulted and recommended that coordinator talk with surgeon.

Case presentation con't

- During conversation with surgeon it was discovered that he had discussed with patient and family about research VAD prior to patient's sedation. Surgeon stated that a note was dictated, but during initial chart review document not found.

Objectives

- Explain the importance of a coordinator's role in helping patients to understand the difference in research and standard of care
- Therapeutic Misconceptions

Therapeutic Misconception

- Is the confusion experienced by some research subjects who may be under the false impression that their participation in a research study is the normal treatment for their medical condition.
- For example-

Perception of Clinical Research

- Peoples views on research benefits and risks shaped by research conduct.
- Media spin
- Word of mouth
- Personal experience as a participant, research professional.

Questions patients should ask before consenting to participate in a clinical trial:

1. What do researchers already know about the different experimental interventions in this study? Have they been tested before? What are the researchers trying to learn in the study?
2. Are drugs or devices already being used?
3. What interventions and tests will I get during this study?
4. Who will be in charge of my care during the study?
5. What are the differences between what I would get in this study and my current care? Are there different side effects? What are the risks and benefits?

Quote from the Monitor

- “Although PIs have historically assumed leadership roles in the research environment, CRCs contribute as much as or more in these areas, and are widely considered the “glue” that holds studies together.”
