

# Crossing the Line: Research versus Innovative Care and Quality Reporting

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# Agenda

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- Understanding the scope of clinical research and innovative care
- Explore examples of innovation vs. research and its impact on:
  - Quality of Care
  - Liability
  - Consent
  - Scientific Integrity
- Case Discussion

# Disclaimer

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- This presentation reflects the opinions of the presenter and does not necessarily reflect the views of the Regents of the University of California at Los Angeles. In addition, the examples set forth in this presentation are purely hypothetical.

# The Fundamentals

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- Research: an activity designed to test a hypothesis, permit conclusions to be drawn and thereby develop or contribute to generalizable knowledge
- Practice: interventions that are designed solely to enhance the well-being of a patient

The President's Commission of the Protection of Human Subjects

# The Fundamentals

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- Experimental
  - Somewhere between research and innovative therapy lies experimental care
  - For example, a procedure that has rarely been attempted, e.g., harvesting of vein for alternate blood supply to promote wound healing, may be viewed as “experimental” but does not meet the traditional definition of research
- Academic Medical Center Standard versus the Community Hospital Standard
  - The impact of resources
  - The intent in proposing the procedure or therapy

# Exploring Innovative Therapy and Care

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- By definition, when a provider proposes to use treatment, therapeutic interventions or procedures in a way that deviates from traditional or commonly accepted practice

# Exploring Innovative Therapy and Care

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- Characteristic of one or more of the following:
  - The modification of the commonly accepted practice is small or slight deviation of the norm
  - A change in common accepted practice that is based upon scientific observations and accepted in the medical community

# Exploring Innovative Therapy and Care

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- Characteristic of one or more of the following:
  - A non-standard approach to treatment or therapy that is only being proposed for a specific patient to enhance their well being
- If the therapy is such a deviation from the commonly accepted clinical practice, when does it become experimental or research?

# The Impact of Innovative Therapy and Care

- Does it create an increase in the risk to the patient?
- Has the patient been offered and/or informed of alternative treatment or therapy, e.g., Commonly accepted treatment?
  - Informed Consent Issues
  - Liability Issues
- Should the innovative therapy or procedure be reviewed by a medical staff committee?
- How does innovative care impact quality?
- Is “off label” use of a drug innovative care or research?

# Innovative Care and Quality Controls

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- Innovative Care
  - Quality Controls are governed by standard of practice definitions
  - Typically outcome determinant
  - Peer Review or Medical Staff Review Process encouraged but not required or regulated
  - Innovative therapy not widely published
  - Education on innovative care generally not established

# Exploring Research

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- Research is designed to translate discoveries into practice, or to verify a theory, or to apply existing knowledge to a new situation
- Research is characterized by one of the following:
  - An activity designed to prove or test a hypothesis that allows for conclusions to be drawn and contributes to generalized knowledge

# Exploring Research (cont.)

- The outcomes of the research increases the knowledge or scientific understanding
  - May not directly impact the participant
  - May be used to determine safety and efficacy of treatment or approach
- Investigation designed to develop, test and evaluate, for example, drug(s) or device, to contribute to generalized knowledge

The Purpose of Research and Corresponding Principles is Defined and Structured

# The Impact of Research

- The Role of the IRB, PI, Sponsor and Subject
- Impact of Good Clinical Practice, the Belmont Report, Federal Regulations and the National Coverage Decisions
- Education and Training on:
  - Protecting Human Study Volunteers
  - On Being a Scientist – the Responsible Conduct of Research
  - Practical Issues in the Conduct of Research
  - Ethical Issues and Research
- Development of Data and Safety Monitoring Plans

# Research and Quality

- Research and DSMP
  - Each investigator must specify the following items relevant to the DSMP:
    - Person responsible for conducting quality assurance;
    - Whether the DSMP has been approved by an NIH entity;
    - Information on the existence of an internal or external data and safety monitoring board and membership listing, including conflicts of interest;
    - Frequency of DSM reporting;
    - Whether or not an interim efficacy analysis will be performed;
    - What data will be reviewed by the DSM monitors;
    - A description of the DSM review process itself; and
    - Details of the DSM criteria to be used for decision-making regarding continuation, modification or termination of the study;

# Research and Quality

- Data Safety Monitoring Report may include:
  - *Date and type of report*
  - *Enrollment numbers (i.e. number enrolled, refused, withdrawals, terminations, deaths)*
  - Screening failure information (including reasons)
  - Reasons for withdrawals/dropouts/deaths
  - Protocol violations/deviations at enrollment or during the study
  - Changes/Amendments to protocol with IRB approval on file or in the process of being obtained
  - Frequency of Adverse Events (AEs) (i.e. listing of patients with no AEs, with 1 or more AEs, and those with missing AE information); Severity and attribution of the AEs
  - Overall aggregate analysis of AEs in the context of the monitoring plan
  - Protocol recommendations for modification, closure, or termination based upon the above data and the reasons for any major decisions (include scientific, clinical, biostatistical, or other reviews)
  - Investigator or key personnel changes
  - Communications to subjects regarding safety data and results of study determinations

# A Case Study – Research or Innovative Therapy

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- An ultrasound image and echo reveals a cardiac defect in an fetus that lacks maturity of the lungs
- 3-D images of the heart identify the defect
- Surgical intervention has been successful in babies born with this defect following delivery

# A Case Study – Research or Innovative Therapy

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- Issues to Consider:
  - Is this an incremental step in current therapy or activity designed to test a hypothesis?
  - Art of surgery is to adapt or apply a surgical procedure to a particular clinical situation to meet the needs of the patient
    - If so, is this a modification of an existing procedure or designed to advance the science of surgery

# A Case Study – Research or Innovative Therapy

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- Issues to Consider:
  - Ethical issues and possible consent issues raised by operating on an fetus
  - Liability impact created by innovation
  - Reimbursement impact of research versus innovation

# Conclusions

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- The spectrum of innovative care, experimental and research is blurry and turns on the facts of each case
- Consider developing a process for evaluating innovative therapy or procedures within the medical staff to create quality controls, guide the physicians and protect the patients

# Questions and Answers

