**Module 5 Activity: Case-Based Questions**

**Excerpt 1: Outcomes from Orthopedic Implant Surgery**

Dr. X wrote a 5 page proposal for funding for a study to use a novel monitor with proprietary software to assess patient outcomes 2 years after orthopedic implant surgery. This prospective longitudinal study would determine the rate of sub-optimal outcomes based on specialized analysis using the proprietary software that accompanied the monitor. The study was funded and the research resident working with the PI prepared the IRB application that received approval. With a clearly defined research hypothesis, innovative monitor technology, and IRB application and consent form complete, the goal was to collect the same measures over 3 years.

The same patients were followed for three years so it required tracking them down to have them come in to allow for collection of data via multiple sources: patient surveys, accelerometer measurements, and surgeon notes from the physical exams. We had HIPAA authorization to use the patient’s name, Medical record #, and telephone/address to contact them for follow-up. However, the data base was organized by unique study ID assigned to each patient.

The study was complex due to the need to collect and integrate data from these three different sources:

1) Patient-generated data regarding their demographics and their symptoms, the amount of pain and disability. Patients filled out a hand-developed paper survey at baseline and annually for 3 years. Survey data were entered by various people into an excel spreadsheet and the source documents were stored in multiple locations. Eventually the patient surveys were moved onto a direct computer data entry system, and the data were captured in survey software that could be downloaded into a spreadsheet/data file for analysis.

2) The second source was measurements from an accelerometer that did 24 hour tracing of patients’ steps and walking rate annually. This novel monitor came with proprietary analytic software that was on a lab PC originally. It was a proprietary software package that could be loaded only on one computer and it had to be handed off as residents changed. We bought another monitor software license to get it off the original PC because the monitor analytic data were housed there and we then put it on a laptop.

3) The third source was a surgeon note in the EMR. Residents read the charts every month related to patients in the study to identify any follow-up MD office visits and to extract physical exam measures which were inserted into a structured database with data definitions for each measure.

The data from these multiple sources needed to be integrated for a biostatistician to apply longitudinal modeling software. ACCES was the final data base and was used to house the total data set and integrate data (through a flat file) from all the sources. Data sub-sets were imported to STATA software for particular analyses, as needed. Data were stored on a server solely for research that is password protected, backed up nightly, and protected by institutional firewalls, etc. (not on a computer). Security measures such as passwords, limited access, firewall, etc. were used to safeguard the data.

Data protection/privacy

* 1. What sorts of privacy conditions might a funder require for the data collected in this study?
  2. What ethical or privacy issues in this study relate to sharing data? How can they be resolved?
  3. What mechanisms were used to identify individual patients and maintain privacy? Would these need to be changed to preserve confidentiality during re-use?
  4. What issues might arise related to copyright or intellectual property rights to the data from each source or outcome data?
  5. How might the dataset be licensed or access fees charged to re-users if rights exist?

**Excerpt 2: Regeneration of Functional Heart Tissue in Rats**

The goal of the study is to try to regenerate functional heart tissue in a rat by delivering stem cells to the heart.

Two days before we operate on the rat, we take adult stem cells and incubate them for 24 hours with our marker for cells [fluorescent nanoparticles]. We then put them in a solution and inject them into a tube that has a biological suture in it, so the cells sit down on the outside of the biological suture. We incubate it for 24 hours, and then do the surgery. During the surgery, we open up the thoracic cavity of the rat and create a myocardial infarction by occluding the left anterior descending coronary artery. At this point it is ischemic; we keep it ischemic for 1 hour, not letting any blood flow go through, and then we reprefuse it and let the blood go back. About a minute after that, we put the biological suture with the cells on it through the infarcted region. We then close the rat up and put it back in the cage for a week. We go back a week later, open the rat up again, and use our camera system to acquire images of the heart. We take images with two cameras simultaneously and we’ll also have a pressure transducer which syncs automatically with the pictures inside the left ventricle cavity to measure left ventricle pressure. Then we reposition our cameras and take another data set and we usually do that about 4 or 5 times to look at different regions around that infarct. Then we euthanize the animal, cut sections of the heart, and put them onto slides. We stain some of them for specific markers in looking to find out exactly where the stem cells are in that cross section and take additional images of these.

In addition to stored images of the living heart and of heart sections after euthanization, we store measurements of the left ventricle pressure that syncs with images of the living heart. We look at the data we acquired and use our home-grown custom software to track particles on the surface of the heart to see how far and how fast those particles are moving.

The paper lab notebook basically performs the function of being an index into the actual datasets and it should record all the information the PI specifies. The content of a lab book relates to a particular experiment and is used by all staff working on that experiment. There could be on average 5-6 people using the notebook. We also have a paper surgical log that is kept with the animal and whatever project staff write down in that surgical log should be transferred into the lab notebook – so the data have to be in 2 places. They have to be kept with the animal in case there is a problem with the animal, but the PI also needs the data in the lab notebook to be able to write papers. Lab notebooks are just in the PI’s office or lab with no backup.

1. Data ownership, privacy and ethical issues

1. What are the ethical or privacy issues in this study and how are they being addressed? What are the implications do these issues have for re-use?
2. What are the issues related to the home-grown custom software used for analysis in terms of potential future re-use?
3. Who will own any copyright or intellectual property rights to the lab notebooks, data sets or custom software code?
4. How might the data sets or custom software be licensed or fees charged if rights exist?
5. If re-use requires sharing of lab notebooks, how might this be managed? What would make re-use of lab notebooks easier for re-use?

**Excerpt 3: Improving End-of-Life Care for African Americans**

An MD applied for grant funding to do a qualitative study focusing on how to improve physician communication with African Americans (AA) and their relatives when their patients were receiving end-of-life care. This qualitative study was conducted to expand knowledge about AA experiences and opinions about end-of-life care. Multiple-meeting focus groups were held to build trust and allow time for full participation. Following a review by a Community Advisory Board (CAB), protocols were approved by the University’s Institutional Review Board. Participants were AA adults who had experienced at least one death of a significant other or family member

*Data collection* All participants gave informed consent. An open-ended interview script stimulated discussion about (1) positive and negative experiences of participants related to end-of-life care in the hospital or at home, (2) preferences for treatment by health care providers, (3) communication issues, and (4) end-of-life decision making pertaining to living wills and advance directives. An AA member of the project staff moderated the focus groups.

Each session was audio-taped taped. Unlabeled tapes were mailed to a transcriptionist in their plastic cases which were labeled. During the mailing process the package was damaged and the plastic tape cases broke and were no longer associated with the tapes for which the cases had been labeled. The tapes, however, were not damaged. The transcriptionist transcribed the tapes and the transcripts were sent back to the project team for identification of which focus group and which session should be used to identify each transcript. Focus Group Participants’ comments were identified on the transcript by either Miss, Mrs. or Mr. plus the first initial of their first name. The transcripts were also reviewed for accuracy by the project team.

*Data analysis* Within-focus group multiple meeting set thematic analyses were performed, as well as cross-focus group set analyses to develop themes/recommendations for how end-of-life care communications might be conducted to improve the process for all concerned.

The tapes were eventually destroyed and the transcripts and other files generated during the analysis remained with the analyst who was not part of the project team and was affiliated with another medical school. The analyst was very involved with the drafting of the publication. Excerpts from the transcripts were later re-used as examples for a qualitative analysis class taught by the analyst at her medical school; however, for the reuse, all participant IDs were changed to P1, P2, etc.

1. Data protection/privacy
   1. What sorts of privacy conditions might a funder require for the data collected in this study?
   2. What ethical or privacy issues does this study present related to sharing or reusing data? How can they be resolved?
   3. What mechanisms were used to identify individual patients and maintain privacy? Would these need to be changed to preserve confidentiality during re-use?
   4. What issues might arise related to copyright or intellectual property rights to the data from each source or outcome data?
   5. How might the dataset be licensed or access fees charged to re-users if rights exist?

**Excerpt 4: Characterizing a Component of a Rocket Engine used to Control Satellites in Orbit**

Scenario:

A faculty researcher in Aerospace Engineering studies electric propulsion for spacecraft control, in other words a type of rocket engine that uses electricity to ionize and accelerate a gas to produce thrust. He is concerned about data security in his lab and is looking for a standard protocol that could be used by all and would comply with any security requirements imposed by his research sponsors.

The goal of one of his current projects is to study and characterize a component of an electric thruster being used by NASA, the Air Force, and private companies to control satellites in orbit. This work enables researchers to build more robust thrusters that will have a longer service life than current models, thus enabling longer and more ambitious space missions. The students in the lab have been experimenting on a particular engine component, called a “hollow cathode,” to characterize the plasma it generates. This data will help researchers understand where energetic ions are produced that erode surfaces and limit the cathode lifetime. They perform experiments using Langmuir and emissive probes to collect data from two different cathodes tested in a vacuum chamber.

The two cathodes used in the lab have different restrictions on their use. The first is from a private company, was developed with Air Force funding, and is the same model as a unit which has been used operationally in orbit. Because it is identical to flight hardware, work with this cathode must comply with International Traffic in Arms Regulations (ITAR) requiring that no foreign nationals have access to any aspect of the research. ITAR establishes strict controls on the use and dissemination of information related to defense articles. Some equipment and lab notebooks are kept locked up in order to comply. The second cathode is from NASA, is a laboratory use model (i.e. not “flight hardware”), and is not subject to the same ITAR restrictions.

Raw data is generated from the cathodes during experiments and is downloaded onto a laptop. For useful data, the students produce code using MATLAB and create appropriate graphs and charts displaying the data points. The MATLAB code is the intellectual property of the student and faculty advisor who create it. If code is written primarily by a student, then the advisor will usually try to contact the student (who may have graduated) for permission before distributing it to another research group. Permission is rarely granted for sharing this code outside the research group. When students graduate they are required to provide the researcher with a CD containing the MATLAB code used for any analysis they completed in the lab.

Laboratory notebooks which include any information on projects which are ITAR restricted are kept in a secure location, either in the researcher’s office or in a locked storage cabinet located in a lab. The archive CDs are stored in the researcher’s office and there is no backup plan for either the CDs or the notebooks.

1. Data Privacy/Restrictions

* + 1. What specific actions have been taken by the researcher in order to comply with ITAR restrictions?
    2. What concerns could arise related to privacy of research being conducted for a private company? How could these be addressed?
    3. Describe any intellectual property and ethical concerns that could arise related to the MATLAB code created by the researcher’s students.