DESIGNING CORE CLINICAL BIOETHICS TRAINING FOR MASTER'S LEVEL STUDENTS AND PROFESSIONAL FACULTY IN AN AMERICAN CHIROPRACTIC COLLEGE

Dana J. Lawrence, DC, MMedEd

Palmer College of Chiropractic

Background

- There is no history within the chiropractic profession of training students, faculty and clinicians in bioethics.
- Currently, there is a growing emphasis on training both students and faculty in the practice of evidence-based medicine, a growing importance in faculty development and the expectation that faculty must be involved in scholarship.
- Studies in the profession have shown that few in the faculty are actively involved in conducting their own research.

Objective

- To develop a core curriculum for teaching biomedical ethics to master's level students involved in a clinical research training program at a chiropractic institution and research center as well as for the postgraduate training of DC faculty as part of a larger effort by academic administration to enhance research infrastructure.

Methods

- This was a two-part, mixed-methods study.
- In the first part, qualitative research was conducted using interviews with semi-structured questions.
- In the second part, a survey assessing faculty knowledge of institutional policies regarding use of institutional review boards was sent to all full-time faculty members at a chiropractic college.

Methods- Part 1

- Four leaders with experience in ethics teaching or administration were interviewed.
- The interviews asked each interviewee to consider a set of topics for bioethics, add to, alter or delete topics, and then to provide one key learning objective for each final topic.

Methods- Part 1

- Interviewees were then asked to comment on best teaching methodologies for these topics, as well as best assessment models (for both students and institutional assessment).
- Answers were coded thematically, with responses used to revise and derive a curriculum for a course in clinical bioethics.

Methods- Part 2

- The survey provided four separate scenarios involving educational research and asked respondents to select from one of three actions: submit to IRB, consult with Human Protection Administrator or IRB chair, or submit a conference abstract without prior approval.
- The survey also asked respondents to select those they discussed ethical issues with from a list of college positions.

Methods- Part 2

- The survey gathered data on area of assignment and years of service, and left one area blank for open-ended comments if a respondent wished to explain an answer.
- Categorical data was collected on an Excel spreadsheet for analysis of frequency counts and percentages, and the open-ended question was coded for theme and subject.

Results

- Part 1: Interviews
  - Responses from participants provided guidance for the development of a course in clinical bioethics that relies heavily upon the use of case scenarios and combined teaching and learning methodologies.
  - The curriculum for the program includes, for each topic of a course that meets one hour per week for 14 weeks, a “driving scenario” around which classroom discussion will take place.

Results

- Part 1: Interviews
  - It also provides a list of learning objectives, both cognitive and affective in nature.
  - There are suggested readings, and an assignment for each section of the course.

Curriculum Example

- **Unit 4: Informed Consent**
  - **Aim:** The graduate fellow will understand the required elements of a properly developed and legal informed consent form

Curriculum Example

- Driving Scenario
  - You have developed a survey which you intend to use in your class to provide you information about how the students in your class perceive your teaching style and your teaching methods. You conduct the survey with your class of 50 students, and from your interpretation of the results, you alter the manner in which you teach. The next term you conduct the study again, leading you to make further change. After the third survey is completed a term later, your department chair suggests you may wish to prepare an abstract for an upcoming chiropractic educational conference. Please discuss the nature of informed consent throughout the conduct of all the surveys as well as into the development of the conference abstract submission.

Curriculum Example

- Learning Objectives
  - On completion of this Unit the participant should be able to:
    - Define the elements of proper informed consent: information, understanding, voluntariness and decision-making capacity.
    - Describe the circumstances under which informed consent is not needed, i.e.; when research is exempt from IRB consideration.
    - Compare and contrast the professional standard, the reasonable person standard and the subjective standard with regard to providing patients information.

Curriculum Example

- Learning Objectives
  - On completion of this Unit the participant should be able to
    - Determine the level of understanding of a potential participant and be able to present information to the patient at his or her ability to understand that information.
    - Describe circumstances where patients do not have the ability to appropriate make decisions, and know how to seek consent from surrogates.
    - Describe the concept of *clinical equipoise* and how it applies to the entry of human subjects into research projects.
    - Demonstrate the ability to conduct an informed consent interview with a research subject.

Curriculum Example

- Learning Materials
  - **Learning Materials**
  - 1. NCI guide to informed consent: http://www.cancer.gov/clinicaltrials/AGuidetoUnderstandingInformedConsent/Page2
  - 2. Ethics in Medicine: http://depts.washington.edu/bioethx/topics/consent.html
  - 3. Pedroni JA, Pimple KD. A brief introduction to informed consent in research with human subjects. Bloomington, IN: Indiana University, 2001
  - 4. Lenrow DA, Chou LH. Interventional spine research: evolution of informed consent. Pain physician 2002;5:8-17

Curriculum Example

- Assignment:
  - Please read the following paper: *Childs JD, Fritz JM, Flynn TW, Irrgang JJ, Johnson KK, Majkowski GR, Delitto A. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: A validation study. Ann Intern Med 2004;141:920-928.* Using the paper by Childs et al as a sample research protocol, please prepare an informed consent document specific for that research project. (No word count required)

Results

- Part 2: Survey
  - In the survey, results indicated that faculty have a relatively poor understanding of the use of institutional review boards in educational research and are unfamiliar with or unaware of institutional policies regarding educational research.
  - For the four scenarios, the highest correct response for any questions was 41%; many faculty members automatically assume that they are to submit to the IRB, while college policy requires them to seek consult with the Human Protections Administrator to determine whether the research is exempt from IRB consideration; only then would the project have to undergo IRB review.

Results

- Part 2: Survey
  - Few people actually discuss ethical issues with anyone, and when they do it is with departmental colleagues or with administrators.
  - Most of the faculty are simply unaware of the college policy. The highest percentage of respondents in the survey had more than 10 years service, and 56 responses were received (54.4% response rate).

Conclusion

- This work allowed me to apply knowledge gained through my course of study in the MMedEd program at the University of Dundee to the development of a new curriculum for teaching bioethics to master's students in clinical research.
- The work became more important when it coordinated with institutional need to enhance faculty scholarship while providing faculty training in the necessary ethical, methodological, and design issues required for modern day scientific and educational research.

Conclusion

- The program of study has application not just to master's student, but is adaptable for use in various settings within the institution (clinical teaching faculty, clinicians, academic administration, etc.) and without (continuing education at the state or local level).
- The need to understand the ethical underpinnings of research has never been greater.

Conclusion

- There are both legal and moral needs to be met when using human subjects in research settings, and no institution can afford to violate an ethical standard, as witness recent news releases where notable research universities have had hundreds of millions of federally-funded research halted while investigations are made.
- While chiropractic education cannot compete at that level, there is no doubt that the standards must be the same and equally high.
- It is my hope that this work will contribute creating an environment that fosters such high standards.

Acknowledgements

- Thanks to Dr. Maria A. Hondras, co-investigator for the survey.
- This project was conducted in a facility constructed with support from Research Facilities Improvement Grant C06 RR15433 from the National Center for Research Resources, National Institutes of Health

- Thank you so very much!