Ethical Decision Making in Clinical Research: Application of CELIBATE

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The need for high-quality evidence to support practice is an ongoing issue in occupational therapy. As a consequence, growing numbers of occupational therapists are engaged in both clinical practice and research activities. Therapists who find themselves in these dual roles are sometimes faced with ethical conflicts when the responsibilities of being a researcher appear, on the surface, to diverge with the responsibilities of being an occupational therapist. This article applies one clinical tool, CELIBATE, to problem solve through an ethical dilemma experienced by a clinician involved in research. Based on the experience of using the tool, recommendations are presented to make CELIBATE more useful in research situations.


Introduction

As Kornblau and Starling (2000) described in Ethics in Rehabilitation: A Clinical Perspective, a dilemma arises when “one’s response or actions can cause negative consequences or nullify the benefits of good consequences” (p. 5). An ethical dilemma forces a clinician to decide between “the lesser of two evils” and requires him or her to make a choice between options that have consequences, often both positive and negative. One such example is deciding to report cases of apparent abuse in nonmandatory reporting situations, particularly when they arise through a research interaction.

To support and guide occupational therapists in ethical conduct, the American Occupational Therapy Association (AOTA) has prepared the Occupational Therapy Code of Ethics (2005). This document describes seven principles for ethical practice: beneficence, nonmaleficence, autonomy and confidentiality, duty, procedural justice, veracity, and fidelity. To assist occupational therapists in applying this code, textbooks in the field offer problem-solving tools for therapists to identify and analyze ethical dilemmas. One such tool commonly introduced in occupational therapy curricula is CELIBATE (Clinical Ethics and Legal Issues Bait All Therapists Equally) (Jonsen, Seigler, & Winslade, 1998, as cited in Kornblau & Starling, 2000).

CELIBATE guides a therapist through a series of 10 steps (see first column of Table 1), including (1) identifying the problem, (2) identifying the facts, (3) identifying the interested parties, (4) identifying the nature of their interest, (5) examining the potential ethical dilemmas, (6) examining the potential legal dilemmas, (7) asking whether more information is needed, (8) brainstorming possible action steps, (9) analyzing the steps, and (10) then choosing a course of action. Through each of the steps, CELIBATE provides a series of prompting questions to assist the occupational therapist to think through the issue at hand.

CELIBATE was designed for clinical work and not for research applications (Jonsen, Seigler, & Winslade, 1998, as cited in Kornblau & Starling, 2000). Nevertheless, persons involved in research face ethical challenges as well and often must choose between two less-than-desirable options. The Belmont Report outlines
three basic ethical principles—respect for persons, beneficence, and justice—and provides guidelines for the protection of research participants (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). This document, which is the foundational guiding document for research on human subjects in the United States, provides principles for ethical conduct but offers no specific structure to guide a clinician involved in research through a decision-making process in a challenging situation. The overarching messages of the report are to treat individuals autonomously and do no harm (National Commission for the Protection of Human Subjects, 1979).

As occupational therapists experience increased roles in research, they need skills and strategies to address ethical challenges. The objectives of this article are to explore an ethical dilemma experienced during a research interview by an occupational therapist, examine the issue using CELIBATE, and evaluate the applicability of CELIBATE in a research situation.

Case and Context
The ethical dilemma that will be explored in this article occurred during a telephone interview being conducted for a large multistate epidemiological study of people aging with a chronic condition. The participant in the study, who will be called Michelle (pseudonym), disclosed information during the interview that suggested elder abuse. The details of the situation are described here and summarized according to CELIBATE in Table 1.

Michelle was a 64-year-old woman with a chronic and disabling health condition, living alone in the community. During the interview, Michelle described a lack of available social support and previous experiences with physical and mental abuse in a nursing home. At the time of the interview, Michelle expressed concern over the management of her trust fund by an employee of a local community services agency. Michelle reported that a case manager, Ms. Kass (pseudonym), had attempted to take control of her finances. Michelle reported that she had been declared mentally incompetent to control her own finances. Michelle was asked two times during the interview whether she was mentally competent to control her own finances. Michelle reported that she had been declared incompetent by a court proceeding. This court proceeding was done to protect the trust fund, which was owned by Michelle and funded by her mother.

After gathering this information, the principal investigator discussed the situation and determined that additional information was required to make a decision about what actions to take, particularly because Michelle did not live in the same state in which the investigative team was based. Both the principal investigator and interviewer wanted to do no harm to Michelle and respect her autonomy and confidentiality but also to ensure that she was protected, if in fact she was being abused.

To begin, the principal investigator contacted the Human Subject Protection Board (HSPB) office of record for the study for consultation. As advised by the HSPB, an Adverse Event/Unanticipated Problem Report was completed and filed. In addition, the staff at the HSPB office noted the importance of complying with the state mandatory reporting laws regarding abuse. Second, the principal investigator and interviewer contacted the Adult Protective Services (APS) in Michelle’s state to further clarify that state’s mandatory reporting laws. It was learned that in Michelle’s state, reporting elder abuse was “required” rather than “mandatory.” In comparison, in the state in which the research was based, reporting elder abuse is mandatory if an older adult is unable to seek assistance because of dysfunction. A conflict arose between being a mandatory reporter in one state and a recommended reporter in another.

After gathering this information, the principal investigator and interviewer decided that the interviewer would contact Michelle again to confirm or deny the concerns over the potential financial abuse. During this call, the interviewer reiterated the fact that she was concerned about Michelle and tried to encourage Michelle to self-report the incident. Michelle, however, continued to express distrust of the APS. Because of the “recommended reporting” status in Michelle’s state, the interviewer was concerned about reporting the incident without Michelle’s knowledge and consent because of issues of confidentiality, respect, and autonomy. This information was conveyed to Michelle, who remained hesitant about calling APS.

Given the potential risk to Michelle if her allegations of financial abuse were true, the principal investigator and provided a step-by-step guide for probing to confirm or deny beliefs, expressing concern about the situation, offering the abuse hotline telephone number, and taking notes of the incident. When the interviewer expressed concern to Michelle over the situation and provided her with the abuse hotline number, Michelle refused it because “they wouldn’t believe me anyway.” Michelle was fearful the hotline agency would have some contact with Ms. Kass, stating that “[I] will suffer horribly for telling you [i.e., the interviewer] this.” The interviewer became increasingly concerned about Michelle’s welfare.

Upon conclusion of the interview, the interviewer and principal investigator discussed the situation and determined that additional information was required to make a decision about what actions to take, particularly because Michelle did not live in the same state in which the investigative team was based. Both the principal investigator and interviewer wanted to do no harm to Michelle and respect her autonomy and confidentiality but also to ensure that she was protected, if in fact she was being abused.

Given the potential risk to Michelle if her allegations of financial abuse were true, the principal investigator and
interviewer decided to report the incident to the APS. Upon doing so, they were referred to Michelle’s county and spoke with an intake worker. The intake worker reported that she had known Michelle for many years and had had other experiences with her. The interviewer’s report, as reviewed and approved by the principal investigator, was faxed to the intake worker, who agreed to follow up. A month later, the interviewer received a letter indicating that a case of abuse had not been opened because Michelle did not meet the definition of “vulnerable elder.” This conclusion felt very unsatisfactory and raised questions about whether the decision to report had been the appropriate one.

Discussion and Examination of CELIBATE for Research

Using a single case, this article explored an ethical dilemma experienced during a research interview. Despite the unsatisfactory resolution of the situation, CELIBATE was a useful, logical approach to carefully consider aspects of the case.
(Table 1) and provided some comfort in the decision-making process. Nevertheless, based on the experience, a few suggestions are made to modify CELIBATE and facilitate its use in clinical research and in practice more generally.

First, rather than addressing ethical issues in Step 5, it would have been more helpful to address them upfront in Step 1. This order would have made it easier to quickly recognize that the real conflict was not between being a researcher and being a clinician in this situation but instead that it was between the principles of beneficence and respect for the individual (i.e., autonomy and confidentiality). The principles are identified in both the Occupational Therapy Code of Ethics (AOTA, 2005) and the Belmont Report (National Commission for the Protection of Human Subjects, 1979). If CELIBATE is supposed to guide ethical decision making, then identifying ethical issues and describing how they apply to the situation should be the first step in the process. In the situation described, addressing the ethical issues upfront would have made it easier to get to the heart of the issue more quickly. In the current format of CELIBATE, it is possible that the conflict between these two ethical principles may not even have been identified.

Directing users of the tool to list relevant ethical principles from both professional and research perspectives would be particularly valuable.

At this point in the process, it would then make sense to identify whether additional information is needed and from whom it could be obtained. In other words, Step 7 of CELIBATE also needs to be moved up in the process. With the conflict identified and the information gathered, it would then be possible to outline the facts, identify challenges of the situation, brainstorm potential actions and their consequences (both from clinical and research perspectives), and make an informed decision. Finally, a new and final step is needed in CELIBATE and that is reflection and evaluation. The user of the tool needs to be directed to ask, What did I learn from this case? Why did I make the choices I did? What could I have done differently? Addressing these questions would facilitate the development of the user’s self-efficacy and skill for handling other cases in the future.

As a final reflection on this case, it is apparent that ongoing dialogue is needed within occupational therapy about the dual role of researcher and clinician and about the challenges of dealing with situations in which two ethical principles conflict with one another. The most challenging point in this case was deciding which action was truly upholding the ultimate good of the client. From the research perspective, if the case was not reported, confidentiality and autonomy would be respected and upheld, and the participant’s identity would be protected. The interviewer, however, would walk away with concerns about the participant’s financial well-being and safety. From the clinician perspective, if the case was reported, confidentiality would be breached, but the interviewer would ensure that assistance would be given to a potentially vulnerable adult and the recommendation to report would be satisfied. Reflective questions or guidelines for thinking through these situations would facilitate therapists’ decision-making processes in these situations.

Conclusion

One of the goals of this article was to further the discussion of ethics in clinical research to assist in preparing and equipping evidence-based clinicians. Hopefully this case will encourage discussion in the field. CELIBATE was useful, but requires adjustments, not only for use in clinical research but also to emphasize ethical principles more generally. Slight modifications to the tool would help occupational therapists, regardless of their role, to sort out multiple aspects of the ethical issues they face. Like any other tool, CELIBATE has both strengths and limitations. As such, additional considerations about the dual role of clinician and researcher, and how to balance these roles, need to be addressed to make this tool truly valuable to occupational therapists working in research situations.

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References

