ABSTRACT: **Purpose:** The purpose of this tutorial is to illustrate select research ethics issues that are relevant to speech-language pathology and audiology students who are involved in academic research and scholarship. **Method:** Graduate students participating in an advanced seminar reviewed the principles of the responsible conduct of research (RCR). They then each developed a realistic hypothetical case (dilemma) as a platform for analyzing standards of conduct as reflected in national and international guidelines and articulated by authoritative authors. Each case closes with a summary and conclusion as to an ethically appropriate course of conduct. **Results:** A range of RCR issues is addressed: resolving conflicting interests of clinicians and investigators; protecting the well-being of human participants while minimizing harm; respecting the voluntary and informed consent of participants; distinguishing the principles governing authorship, copyright, and data ownership; articulating the responsibilities of students and mentors when collaborating on works of scholarship; exploring the ethics of randomizing patients to experimental conditions in a clinical trial; and explaining why selective reporting of data is a form of research misconduct. **Conclusion:** The analytic, case-based approach is intended to engage speech-language pathology and audiology students in the topic of RCR and heighten their appreciation of why questions about ethically appropriate conduct in the academic research context can be both challenging and instructional. **KEY WORDS:** responsible conduct of research, research integrity, research ethics, case-based reasoning.
of ethical practices by all students and faculty involved in CSD research and scholarship.

In the spirit of raising students’ awareness and knowledge of RCR, the case studies in the present tutorial were prepared by graduate students at Ohio University as capstone projects for a special topics seminar. Each essay begins with a realistic hypothetical/fictional case, identifies the ethics issue(s), and analyzes the case from different points of view. This approach is intended to engage speech-language pathology and audiology students in the topic of RCR and heighten their appreciation of why questions about ethically appropriate conduct in the academic research context can be both challenging and instructional.

THE CLINICAL INVESTIGATOR: ETHICAL DECISION-MAKING

Individuals who serve as both clinicians and researchers/investigators play an important role in the advancement of knowledge in health-related fields. Clinical knowledge combined with real-world experience affords clinical investigators insights that investigators without these experiences may lack. Clinical investigators hold positions in the workplace that allow them to facilitate the coordination and flow of ideas between the clinical and research fields (Yanos & Ziedonis, 2006). However, they are often faced with conflicts between participants’ interests and research interests. Pellegrino (1992) acknowledged that clinical investigators are influenced by dominant values arising from their dual roles as clinicians (with a guiding value of beneficence toward clients) and scientists (with a guiding value of truth).

HYPOTHETICAL CASE

Karen is a speech-language pathologist (SLP) and the sole proprietor of a speech-language clinic with clientele consisting primarily of adults with chronic aphasia. Karen is approached by leaders in the field of aphasiology who are seeking research participants for an upcoming treatment study. These nationally recognized researchers invite Karen to participate in a large, multisite randomized treatment study examining the impact of constraint-induced (CI) language treatment for individuals with chronic aphasia.

According to Meinzer, Rodriguez, and Rothi (2012), the premise of CI therapy for aphasia is withdrawal from communication, change of communication strategies, and use of compensatory strategies adopted by many patients with poststroke aphasia could be viewed as a form of learned-nonuse in patients with aphasia. Thus, the original CI-based language treatment protocol encouraged patients with aphasia to focus specifically on communication channels they tend to avoid (ie, verbal communication). (p. 536)

The researchers inform Karen that at least five clinics have agreed to join the study. The study has received approval from the Institutional Review Board (IRB) of the host university, as well as from the IRB associated with each individual clinic that has agreed to participate. A commitment to join the study involves enrolling clients who qualify (i.e., diagnosed with moderate-to-severe aphasia, at least 12 months post-onset) into the study. Individuals with aphasia will only be enrolled after receiving informed consent and voluntarily agreeing to random assignment to one of two conditions: (a) an intensive CI treatment program, or (b) a standard treatment program, customized to the needs of each individual client, involving the same number of hours of treatment over a period of weeks. As a part of the study, Karen will receive training, free of charge, regarding administration of the CI treatment. In addition, her clinic will receive compensation in the amount of $100 per participant enrolled, which will be paid in a lump sum following completion of the study.

Ethics Issue

The research ethics question is whether or not it is ethically appropriate for a clinical investigator to recruit research participants from her proprietary clinic and administer CI language treatment in a multisite treatment study.

Discussion

Karen recognizes the need for evidence-based treatment protocols for individuals with chronic aphasia. Karen’s participation in this study with nationally recognized leaders in the field of aphasiology will give her an opportunity to become a recognized leader in the area of evidence-based practice; therefore, she begins to recruit research participants from her practice according to the IRB-approved plan.

Karen is contacted by Jim, an SLP and a friend. Jim works at a local hospital and refers clients with aphasia to Karen’s clinic. He has learned of the research protocol and has some concerns.

Scientific value. “Karen, CI therapy approaches have been studied for over a decade,” Jim begins. Jim is alluding to the requirement that clinical research should be socially and scientifically valuable in order to be ethical (Emanuel, Wendler, & Grady, 2000). If CI treatments have been studied for a decade, and the study in which Karen has been invited to participate has substantial overlap with other studies, it might not be considered scientifically or socially valuable.

“It is true that CI treatments have been studied,” Karen replies, “but there have been mixed results regarding the contribution of different aspects of the treatment protocol.” Karen also states that the small number of published studies, along with small sample sizes and a lack of control groups, limits the generalizability of reported findings (Meinzer et al., 2012). “The protocol that I have been given may provide new evidence about the intensity and duration of CI treatments. Therefore, the questions in this protocol do have value,” Karen responds.

Patient interests. “But Karen,” Jim persists, “your primary responsibility as a clinician is to your clients. Can
you really honor that commitment while participating in this study? What if a client doesn’t show improvement?” Jim is referencing ASHA’s Code of Ethics (2010), Principle of Ethics I: “Individuals shall honor their responsibility to hold paramount the welfare of persons … who are participants in research and scholarly activities.” Karen responds by referencing the Declaration of Helsinki (World Medical Association [WMA], 2008): “Physicians must immediately stop a study when the risks are found to outweigh the potential benefits” (B. Principles for all medical research, para. 20).

Karen adds, “I fully intend to objectively and subjectively measure my clients’ gains and/or losses in language abilities throughout the protocol, and I will offer them the opportunity to discontinue their participation in the CI arm of the study if absolutely necessary.”

**Risks and benefits.** Jim continues, introducing the concept of beneficence, which is a guiding principle in human subject research. Jim cites The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [National Commission], 1979), which states: “Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (a) do not harm and (b) maximize possible benefits and minimize possible harms” (Part B: Basic Ethical Principles, para. 7). Jim asks, “Are you sure that there is enough good in this protocol to balance the potential risks? These individuals have chronic aphasia. Restriction of any modality of communication may place them under psychological stress, not to mention encumber communication strategies that they have practiced for months.”

Karen responds by acknowledging that the concept of minimal risk, which involves weighing potential benefits against potential risks, is vitally important in any study involving human participants. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (Code of Federal Regulations, 45 C.F.R. pt. 46 §45.102(i), 2012).

“However,” Karen continues, “The Declaration of Helsinki (WMA, 2008) states that a primary purpose of research is to improve therapeutic interventions. Along with developing and testing new interventions, current ones must be continuously evaluated. There are several unanswered questions remaining regarding the efficacy, effectiveness, and efficiency of CI treatments. Therefore, it is our duty to continually evaluate CI protocols.”

**Protection of vulnerable participants.** Jim counters with another reference to the Declaration of Helsinki (WMA, 2008) regarding the protection of vulnerable patients: “Some research populations are particularly vulnerable and need special protection” (Part A: Introduction, para. 9). Jim notes that individuals with aphasia are likely to be characterized as a vulnerable population by the Office of Human Research Protections (U.S. Department of Health & Human Services, Office for Human Research Protections [U.S. DHHS, OHRP, n.d.]) due to their language comprehension and expression deficits. Because of this vulnerability, they are entitled to extra protection. Jim continues to cite The Belmont Report (National Commission, 1979):

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. (Part B: Basic Ethical Principles, para. 2)

Karen, also knowledgeable of The Belmont Report (National Commission, 1979) principles, responds with an additional reference:

Respect for persons requires that all subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. (Part C: Applications, para. 2)

Karen assures Jim, “I fully intend to complete the process of informed consent with each and every participant.”

**Decisional competency.** Jim remains concerned. He knows that there are potential obstacles that may arise in the informed consent process involving individuals with aphasia (Penn, Frankel, Watermeyer, & Müller, 2009). Comprehension, as elucidated in The Belmont Report (National Commission, 1979), is an integral part of informed consent, and Jim is worried that persons with chronic aphasia might not have the ability to fully comprehend the informed consent documents.

“First of all,” responds Karen, “this study has IRB approval, which means that the procedure for informed consent has been approved. Secondly, I will respect my clients’ autonomy by adhering to ethical guidelines from the Council for International Organizations of Medical Sciences (2002) involving the process, language, and comprehension of informed consent.” Karen thinks that her experience working with individuals with chronic aphasia gives her the insight necessary to ensure their comprehension and obtain fully informed consent. She is confident that her skills will enable her to present the documents, with appropriate supports (i.e., writing, pictures), at a level that each prospective participant can understand. She will use her clinical insight, judgment, and knowledge of people with aphasia to make sure each individual comprehends the information presented. She also assures Jim that she will continue the process of informed consent throughout the protocol.

**Therapeutic misconception of the participant.** “How can you ensure comprehension while protecting your clients against therapeutic misconception?” Jim asks. Therapeutic misconception “refers to the fact that many participants in clinical research overestimate the degree to which the study’s design is tailored to their own individual interests” (Larsen & McMillin, 2011, p. 340). “Your clients may consent simply because their therapist, whom they trust, is offering them the opportunity to participate,” Jim says.

Karen responds by assuring Jim that she will adhere to the guidelines in the Declaration of Helsinki (WMA, 2008), which state that “the physician must fully inform the patient which aspects of the care are related to the research” (C. Additional Principles for Medical Research Combined with Medical Care, para. 34). This concept is also reflected in ASHA’s RCR guidelines (2009), which highlight the...
importance of fully informed consent and the client’s right to withdraw without penalty.

**Therapeutic misconception of clinical investigators.**
“Therapeutic misconception has the potential to impact not only the participants, but the investigators as well,” Jim responds. Indeed, Miller, Rosenstein, and DeRenzo (1998) suggested that, in order to resolve the tension created by the client–clinician relationship, clinicians tend to adopt a therapeutic orientation. Clinicians may unknowingly increase the risk of therapeutic misconception by appearing excited and enthusiastic about the research, possibly leading to an overemphasis of the positive aspects of the research and an underemphasis of the potential negative aspects.

This is a direct threat to participants’ right to informed consent, making it a salient ethical issue.

“I didn’t think of it in that way,” Karen muses. “Perhaps I can hire an additional clinician to complete the informed consent process, or involve an individual who knows the client and can vouch that he or she comprehends the consent form. Also, a mandatory waiting period between the initial informed consent meeting and the first research session may provide additional safeguards against therapeutic misconception.”

**Conflict of interest.** “Regardless of those safeguards, Karen,” says Jim, “I still feel that you have a potential conflict of interest. I’m worried that the compensation that you will receive will compromise your professional judgment.” Both Jim and Karen are aware of ASHA’s Code of Ethics (2010), Principle III, Rule B, which states that “individuals shall not participate in professional activities that constitute a conflict of interest.” Karen assures Jim that she has absolutely no intention of spending the money in a personal manner. “I fully intend to use the compensation to buy new materials for my clinic, which will directly benefit current and future clients,” she says.

“Well Karen,” says Jim, “I appreciate you taking the time to have this conversation. I still think you have a lot to consider regarding your participation in this study. Please think it over carefully.”

**Summary and Conclusion**
In summary, Karen is faced with several ethics issues. These issues include (a) adherence to ASHA’s Code of Ethics (2010) regarding holding the interests of her clients paramount, (b) protection of vulnerable patients, (c) being true to the letter and spirit of informed consent, (d) protecting her clients from adopting therapeutic misconception, and (e) ensuring that her clients’ interests are held paramount to financial or reputational gain for the clinic or collaborator.

Karen must balance and weigh her values and responsibilities as an investigator and clinician. As an investigator, she is primarily concerned with enhancing the quality of evidence regarding the effect of CI treatment on the speaking abilities of individuals with aphasia, as compared to more customary or traditional treatment focusing on speech production ability. As a clinician, Karen must weigh the well-being of her clients more heavily than other competing interests. In order to make a morally and ethically appropriate decision, Karen must weigh within herself the pros and cons of each role.

As the sole proprietor of a speech-language clinic, Karen has a firm duty to hold paramount the well-being of her clients. Taking into account all of the ethical principles that were discussed between Karen and Jim, it might be appropriate for Karen to participate in the proposed research study as long as the following conditions are satisfied.

First, Karen must ensure that her clients are given the opportunity to be removed from their randomized group if they are not making any progress. Second, Karen must find a way to ensure the protection of vulnerable participants and the integrity of informed consent. Karen mentioned several ways she might achieve this, including hiring another individual to complete the informed consent process, having another person present who knows the research participant well to vouch for comprehension and voluntary consent, and imposing a mandatory waiting period between informed consent and the beginning of the research study to allow time to answer participants’ questions.

Third, Karen must protect her clients from therapeutic misconception. She must make it absolutely clear to her clients that “this is a research project,” not individualized treatment. Along with stating this fact several times throughout the informed consent process as well as during research sessions, it may be beneficial for Karen to conduct the research-related sessions in a different room from the traditional treatment sessions. Finally, Karen must guard against being swayed morally and ethically by the compensation she is being offered to participate in the study. Even if Karen uses the money for the clinic, she herself is still benefitting because she owns the business. To avoid the appearance of conflict of interest, Karen might choose to use the compensation to hire an independent clinician to administer the study in its entirety.

In conclusion, it is clear that Karen, as a clinical investigator, is faced with a myriad of challenges. Although it is certainly possible to conduct a morally and ethically appropriate treatment study, the clinical investigator will be faced with several ethical quandaries in the process, each of which has the potential to derail the study from its ethical tracks. Clinical investigators must have a strong moral character and good judgment. In addition, a solid education in the concepts governing RCR, along with a thorough knowledge of the literature, are essential to ensure the development and implementation of ethical research studies.

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**DATA OWNERSHIP, DATA CONTROL, COPYRIGHT, AND AUTHORSHIP**

In a research study involving a contract between a university scholar and a corporate publishing company, it is important to clarify issues related to ownership and use of original data (Mays, 2005), as well as authorship and copyright of the final product (Macrina, 2005b). In this case, issues of ownership and control of research data are

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*This case study was written by Fatimah Hani Hassan.*
based on the foundation of contracts; issues associated with reporting of research outcomes are based on the legal and moral foundations of copyright and authorship.

**HYPOTHETICAL CASE**

Dr. Reeves, a professor in CSD, is currently developing a preschool language assessment tool called the Preschool Language Battery (PLB). A publishing company, XYZ Diagnostics Inc., has expressed an interest in publishing the test. Dr. Reeves and XYZ agree to these terms: Upon completion of the PLB, Dr. Reeves will transfer the copyright of the PLB to XYZ, and XYZ will pay Dr. Reeves royalties in the form of monetary payment for each language assessment set that is sold.

Jo is a graduate student who is working as a research assistant in Dr. Reeves’ Child Language Disorders Laboratory. Among the many responsibilities of a research assistant, Jo is involved in data collection for development of the PLB that will be published by XYZ. Because of her plan to study at the doctoral level, Jo decides to write a master’s thesis with Dr. Reeves as her primary advisor. Without prior discussions or notification to XYZ, Dr. Reeves gives Jo permission to analyze data from her lab for Jo’s thesis (the same data used for development of the PLB). Dr. Reeves and Jo agree that Jo will use only the data that she has collected from 150 preschool children (out of a total of 700 participants) for her thesis.

Jo conducts a multiple regression analysis on the data to identify factors (e.g., total number of siblings, participants’ position among siblings, presence of language disorders among siblings, and gender of siblings) that might predict the level of receptive and expressive language skills among preschool children. After completing the master’s thesis, Jo submits the thesis to the graduate college for publication in both the university’s library database and a commercial distributor of theses and dissertations. The title page states “© 2012 Jo Brown.” A few months later, the PLB is published by XYZ, with Dr. Reeves as the sole author.

**Ethics Issues**

The research ethics questions are:

- Was it ethically appropriate for Dr. Reeves to give Jo permission to use data from an ongoing research study without notifying the commercial publisher with whom she had a relationship?
- Was it ethically appropriate for Dr. Reeves to include data reported in Jo’s thesis in the commercial publication?
- Was it ethically appropriate for Jo to be the sole author of the master’s thesis?
- Was it ethically appropriate for Dr. Reeves to be the sole author of the PLB?

These interweaving concerns about data ownership, data control, copyright, and authorship are relevant to graduate students, professors, and publishers, and deserve close examination.

**Discussion**

Three parties were involved in the ethical dilemma concerning the use of research data for multiple purposes—Dr. Reeves, XYZ Diagnostics, and Jo. The ethical issues that tie these three parties together are related to (a) the prerogative to use research data for more than one purpose, (b) the rights of a copyright owner, and (c) the right to be named as an author of a publication.

**Owning and using research data.** Legality is one of the fundamental values of science because legal behavior promotes the ethical conduct of research (Resnik, 1998). A frequently used legal tool is a contract, which is a bilateral agreement binding the involved parties based on the principles of honesty and promise-keeping. When an academic scholar and corporate sponsor sign a contract, clarity regarding data ownership and control is very important (Rowe et al., 2009).

*Owning and controlling research data.* A contract could include an agreement that (a) allows maximum freedom to a researcher to use research data for a secondary purpose, (b) restricts any use of data for a secondary purpose, or (c) agrees to “something in between” the foregoing alternatives.

In the hypothetical case, XYZ did not pay Dr. Reeves to collect the data and had no future need for the raw data (that were used in test development). As a result, Dr. Reeves owns the data and is free to use her original data in the future for other academic or scientific purposes. Therefore, it was ethically and legally appropriate for Dr. Reeves to share the data with Jo for the master’s thesis, even without sending prior notification to XYZ.

In contrast, if XYZ had paid Dr. Reeves to collect the data, XYZ could have asserted ownership of the raw data (if agreed in advance in the contract). If XYZ owns the data, neither Dr. Reeves nor Jo is free to use the data for different analyses or to answer different research questions, even though the subsequent analyses might not have any relationship to development of the assessment tool (Mays, 2005).

This example illustrates why it is important for researchers to comprehend the fine details of an agreement and understand the consequences of specific contractual promises. Researchers should make the effort to read the fine print in a contract before signing it. Breaching a contract could create legal liability, undermine the company’s trust, and jeopardize any potential collaboration in the future.

*Academic freedom.* If the freedom to share research data and analyses is restricted by the funding sponsor, the ability of researchers to expand scientific knowledge would be constrained. This undermines the value that the scientific enterprise places on researchers’ academic freedom to expand knowledge through scientific inquiry (Rowe et al., 2009; Shamoo & Resnik, 2003). Therefore, it is important that researchers enter contracts that allow them maximum freedom to control original data and to use these data for secondary purposes if they wish. It is also important that scientists avoid manipulating data or only reporting results that are favorable to the sponsoring company (Emanuel et al., 2000; Marco & Larkin, 2000). The home institution, such as the university or a research center, should play an active role during the formation of a contract. Ideally,
Copyright and data. According to the U.S. Copyright Act, copyright law does not protect research data:

In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work. (§102(b))

Although Jo’s thesis was published and copyrighted, data that were analyzed in the thesis are not protected by the copyright law. As such, Dr. Reeves was free to use the same data in development of the PLB.

Copyright and work for hire. Importantly, Jo collected the data as a research assistant when she was working in Dr. Reeves’ lab. Therefore, the data collected by Jo are considered a “work made for hire,” which is defined as

(1) a work prepared by an employee within the scope of his or her employment or (2) a work specially ordered or commissioned for use ... [such] as a test,... if the parties expressly agree in a written instrument signed by them that the work shall be considered as a work made for hire. (U.S. Copyright Act, §101)

Therefore, any data that Jo collected for the lab, including those that she gathered for her thesis, technically belong to Dr. Reeves and/or her university.

In contrast to the work involved in data collection, Jo’s work on her master’s thesis was creative. Writing the thesis was not Jo’s responsibility as a research assistant; it was not a work for hire. Because the thesis embodied Jo’s original work, Jo is the rightful copyright owner. Principal investigators such as Dr. Reeves should be sure to clarify the roles and responsibilities of their research assistants, especially when research assistants are also conducting research for academic purposes.

Analogously, in the development of the PLB, if XYZ had paid part of Dr. Reeves’ salary to collect data and create the PLB, her work product could have been considered a work for hire, in which case XYZ would own both the data and the copyright for the PLB. In the actual agreement with XYZ, however, Dr. Reeves had complete creative control; she was not commissioned to do the work. Therefore, during the creation of the PLB and before publication, Dr. Reeves is rightfully both the author and the owner of the copyright to her creative work. Upon completion and transfer of the PLB to XYZ, Dr. Reeves (per the contract) will transfer copyright of the PLB to XYZ; in turn, XYZ will publish the completed work and pay Dr. Reeves royalties.

At this point, Dr. Reeves remains the author of the PLB, but XYZ is now the copyright owner, and only XYZ may exercise the exclusive rights of ownership, such as duplication, dissemination, or modification of the test battery (U.S. Copyright Act, §106).

The right to claim authorship of a publication. The third question of our ethics analysis is whether it was ethical for Jo to be the sole author of the master’s thesis. Because Dr. Reeves was Jo’s advisor and she directed the methods by which the data were collected, she might wish to claim coauthorship of Jo’s master’s thesis. The appropriateness of her claim can be resolved by reference to guidelines promulgated by the International Committee of Medical Journal Editors (ICMJE, 2010):

Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3....

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship. (Authorship and Contributorship, para. 2)

Although recognizing that advisors offer guidance about study design, data analysis, and writing style, the academy expects thesis students to take control and responsibility for the creative ideas and forms of expression embedded in the thesis. Therefore, it was ethically appropriate for Jo to be sole author of her thesis.

The fourth research ethics question is also related to authorship claims. The question is whether it is ethical for Dr. Reeves to name herself as sole author of the PLB published by XYZ. Other individuals involved in the development of the test, such as technicians, statisticians, and research assistants, might claim coauthorship to this intellectual work. In this situation, it is necessary to weigh the intellectual contributions in the development of a publishable product by following ICMJE’s guidelines (2010). If no other individual was involved in making substantial intellectual contributions to the conception and design of the PLB, it was ethically appropriate for Dr. Reeves to claim herself as a sole author. Other individuals who assisted and supported the development of the test or were merely paid as employees to fulfill job responsibilities should be acknowledged in the publication for their contributions to the project but should not be authors of the scholarly work (ICMJE, 2010).

Summary and Conclusion

In summary, this hypothetical case elicited a discussion pertaining to three parties: Dr. Reeves (the primary investigator), Jo (the graduate research assistant and thesis candidate), and XYZ (the publishing company). The issues were related to data ownership, data control, copyright ownership, and authorship. Based on this case, it is crucial...
for all individuals and entities involved in an agreement to be honest and to keep their promises in order to maintain trustworthiness among all parties. It is also important that scientists realistically weigh their contributions in developing a product and avoid inappropriate claims to data, authorship, or copyright. Law (such as contracts and copyright) and authorship guidelines have been created to assist in fair and unbiased acknowledgment of involved parties in developing intellectual work. When making ethical decisions, researchers should uphold the fundamental bases of science, such as honesty, legality, respect for originality, and responsibility to acknowledge one’s contribution to science.

In conclusion, based on the principles governing ownership and control of research data, ownership of copyright, and the rights associated with authorship, (a) it was ethically appropriate and within the terms of the contract for Dr. Reeves to allow Jo to use some of the data for her thesis; (b) it was ethically appropriate for Jo to claim authorship of her thesis—her creative work—but not the data therein; (c) it was ethically appropriate for Dr. Reeves to include Jo’s data in the final publication of the PLB because Jo was a graduate employee; and (d) it was ethically appropriate for Dr. Reeves to be the sole author of the PLB, assuming she acknowledged Jo’s technical contribution to the final product.

AUTHORSHIP DISPUTES IN RESEARCH

Errors may occur while conducting research. Students are particularly susceptible to making errors during their early years as emerging researchers. These errors or mistakes may be learning opportunities for students to bring to light their lack of knowledge about research ethics. Errors committed in research may be truly unintentional or could be influenced by extraneous factors. Students may justify that these mistakes were made because they “were not educated about the ethical conduct of research,” or they “did not know any better,” or even that “they were not advised differently by their mentors.”

Does this mean that student researchers can be excused and not be held accountable for the ethical mistakes they commit? What are the principles that should guide a student researcher, and what guidelines should be followed when researchers conduct ethical misbehaviors? Will punishing students for honest ethical misbehaviors be detrimental to their maturation as researchers? Can the behaviors of students be overlooked, trusting that mentors will take responsibility for students’ mistakes?

HYPOTHETICAL CASE

Hannah’s master’s thesis at College X addressed a research question that extended Dr. Bright’s unique line of research (that has been funded by the National Institutes of Health for many years). Hannah had intended to do her PhD at College X with Dr. Bright as her mentor, but because College Y offered her a more attractive doctoral stipend (and tuition scholarship), she chose instead to do her doctoral work at College Y with Dr. Cash. Hannah’s thesis was approved, she attained her Master of Science in Communication Sciences and Disorders from College X, and now she is a doctoral student at College Y.

Hannah submitted a proposal about her master’s thesis research (from College X) to a national conference and it was accepted. The presentation listed her current mentor, Dr. Cash, as the second author because (a) Dr. Cash’s program at College Y encourages inclusion of all doctoral mentors on presentations by their doctoral students, and (b) College Y reimburses all travel for faculty and students presenting work at national conferences. Dr. Cash is very supportive of Hannah’s initiative, in part because she has not yet achieved tenure and is striving to build her academic resume—her curriculum vitae—by affiliating herself with the research activities of her doctoral students. Unfortunately, when Hannah presented her work at the national conference (with only Hannah and Dr. Cash in attendance to answer questions about the design and relevance to prior research), neither Hannah nor Dr. Cash was able to provide satisfactory answers to the audience.

Ethics Issue

The research ethics issue addressed in this case is whether it is ethically appropriate for a faculty member or a student to present ideas to the scientific community without attribution or coauthorship to the individual who originally directed and supported the line of research.

Discussion

Dr. Bright learned about this alleged “misbehavior” at the national conference through a professional colleague who was in attendance. To analyze the situation, Dr. Bright used authoritative materials such as ASHA’s RCR guidelines (2009), ICMJE’s Uniform Requirements for Manuscripts Submitted to Biomedical Journals (2010), Macrina (2005a), and Shamoo and Resnik (2009). These texts explain the principles that research investigators and students should follow when presenting or publishing collaborative work. These principles govern authorship, pressure to disseminate, plagiarism, and accountability.

To resolve the disagreement among the doctoral student Hannah, Dr. Bright (Hannah’s original mentor at College X), and Dr. Cash (Hannah’s new mentor at College Y), this essay will review some basic RCR principles, followed by a dialogue among the disputing parties.

Authorship guidelines. ICMJE’s manuscript requirements (2010) state that authorship credit should be given only to those who have made (1) “substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data,” (2) “drafting the article or revising it critically for important intellectual content,” and (3) “approval of the final version to be published.” The ICMJE mandates that authors must satisfy all three conditions.
According to ASHA’s RCR guidelines (2009), authorship should be granted to “all and only those who have contributed substantially to the research” (Ethical Issues for Authors, 2a). Granting authorship to someone who has not contributed to the work merely as an obligation is a misrepresentation of the original work by the primary author. In fact, “honorary authorship,” that is, assigning an author purely out of respect or gratitude, though endorsed by some mentors and research labs, is not permitted under ASHA’s publication policies (2009).

According to Shamoo and Resnik (2009) the order of the authors listed should reflect the relative importance of the contributions they made to the research project. Therefore, authorship should be granted only to those individuals who had an effect on the “direction, scope, or depth” of the research (Macrina, 2005a, p. 72). Although an individual may contribute to a project in important ways, he or she need not always be regarded as an author or contributor to the intellectual work (Shamoo & Resnik, 2009). Monetary contributions or reputational interests may be important but should not be the basis for granting authorship to any individual (in this particular scenario, a mentor).

**A mentor’s role.** Mentors provide “education and moral guidance” to their students (Shamoo & Resnik, 2009, p. 68), and mentoring is considered a prestigious role by faculty members. Mentors nurture and shape young researchers by providing them with the knowledge and expertise to perform professionally. However, the role of a mentor is not confined to these primary roles; the mentor also cultivates attitudes, habits of etiquette, and values important to the research enterprise that cannot be learned by a student as part of formal course instruction. A related observation is that students are likely to do what their mentors tell them to do. The mentor–student relationship has been described by Shamoo and Resnik (2009) as a fiduciary relationship—a relationship of trust, where an unequal balance of power rests in the hands of the mentor. A mentor has power over students due to superior knowledge, expertise, and finances (Macrina, 2005c; Shamoo & Resnik, 2009). This observation challenges all mentors to model good ethical practices conscientiously at all stages of students’ careers.

**Pillars of research.** The pillars that uphold the foundations of research are truth, trustworthiness, fairness, openness, and integrity (Shamoo & Resnik, 2009). Just as clients and patients trust their doctors or therapists to do no harm, a recipient of research trusts that investigators will conduct responsible, ethical research (Whitbeck, 1995). The integrity of the work depends not only on what one individual does, but also on what a profession as a whole represents. ASHA’s Code of Ethics (2010) states that professionals “shall honor their responsibility to the public” and shall not disseminate work that is misrepresentative of their contributions to research (Principles of Ethics III). By creating a culture of ethical research, we are claiming, as researchers, that we are honest and trustworthy.

Where authorship of original works is concerned, it is vital for authors of a paper to give credit where credit is due and separately acknowledge important contributions by individuals or financial organizations in the acknowledgments section (Horner & Minifie, 2011b). Authorship is granted to all significant contributors to honor their substantial intellectual contributions to the project. Acknowledgments, in turn, credit those who have contributed technical or editorial expertise.

**RCR education.** Formal education in the RCR might be overlooked or offered “optionally” in educational settings and in research laboratories, but all college students learn about academic integrity. In recent times, there has been an increased understanding by professional and scientific organizations that RCR education is needed (Horner & Minifie, 2011a). Below are questions Dr. Bright posed to Hannah and Dr. Cash, their responses, and finally, Dr. Bright’s evaluation of the situation.

**Hannah, why did you name Dr. Cash as your coauthor, rather than me?**

**Hannah.** Dr. Cash is my current mentor, and as a recipient of funds from her lab and College Y, I felt obliged to include her as an author on this work. I am no longer at College X or working with you, Dr. Bright.

**Dr. Cash.** Mentors are “scientific parents” who are assigned to monitor a student’s academic and research development. Being a mentor, I am entitled to receive credit for work produced by my students during their time in my lab. My students owe this to me in return for the mentorship I provide. In Hannah’s case, I recruited her to my university, she used resources from my lab, and she was supported financially to cover expenses that were incurred in reference to this particular conference. Hannah now represents my lab, and being my student means that she emulates the attitudes and beliefs I endorse. Therefore, it is appropriate for Hannah to return the favor by crediting me with an “honorary authorship.” Given the above reasoning, as a current mentor and provider of funds to Hannah’s cause, my being an author to the work presented at this conference is justified.

**Dr. Bright.** Hannah completed her thesis when she was at College X, so no major contributions to the study could have been made by you, Dr. Cash. The presentation of Hannah’s thesis at a national conference should be considered a derivative of my original work and not deserving of your coauthorship. Therefore, Dr. Cash, when you allowed your name to be listed as second author, you signified that you played a substantial role in Hannah’s paper, which is not true, and is misrepresentative.

**Was naming Dr. Cash as coauthor consistent with authoritative guidelines that determine authorship?**

**Hannah.** I am not aware of any such guidelines. I was not educated about this as part of my graduate academic orientation nor was this emphasized during orientation to research labs at College X or Y. Besides, Dr. Cash was aware that I was submitting an abstract to the conference and even proofed it for me; I did not have any reason to disbelieve her or question the accuracy of the work after it was approved by Dr. Cash.

**Dr. Cash.** College Y expects students to submit work to national platforms in collaboration with their mentors in order to receive travel funding. We were following the protocol set by our college by presenting this work together. I overlooked the ethics of authorship in this case, hoping
to do Hannah a favor and to provide her with an opportunity to present her work. In addition to this, I proofread Hannah’s work before she submitted the proposal to the conference (even though she needed only minor changes in terms of organization of ideas), and I offered her moral support during the presentation. These contributions should be sufficient to justify my coauthorship of her presentation.

Dr. Bright. Most research platforms, including publications and conferences, lay down guidelines and policies that individuals must adhere to when submitting research work. The individual submitting the proposal and all of those who are listed as authors must agree to these “terms and conditions” before submitting their work. If the individual does not abide by these guidelines and policies, the person can be held ethically responsible for breaching the agreement. Hannah’s justification that she was not educated about authorship criteria is not credible in this situation because she was the one who submitted the proposal to the conference.

As a professor, I will acknowledge that education in RCR is lacking and is not emphasized enough due to time constraints and academic responsibilities. In the future, I will make sure that my students in College X go through training in RCR as part of their lab orientation and will document that students have received this education. Consequently, in the future, a student from my lab will not be able to claim that he or she was never educated about the guidelines that exist for research practices.

Were there other motives behind this decision about authorship?

Hannah. I would not have been able to go to the conference or present this work if it were not for the support and financial contributions from College Y. Dr. Cash is on a tenure track and has to meet certain requirements, including scholarly presentations and peer-reviewed publications. For these reasons, including Dr. Cash on my paper provided benefits to both of us.

Dr. Cash. Hannah may have included me because I am presently the most accessible resource to her. I must also admit that because I am on a tenure track and have to meet certain requirements set by the college, Hannah’s offer to include me as an author was an attractive one. As a result, this was a “win-win” situation for both Hannah and me.

Dr. Bright. Research in the modern age has been viewed as a career and not simply as a hobby or passion one pursues. However, this should not allow researchers to violate the underlying principles of research ethics (Shamoo & Resnik, 2009). The ideals that are at the very essence of RCR should be held in priority by every academic scholar above the expectations to publish set forth by any institution (Macrina, 2005b). Hannah’s granting authorship to you, Dr. Cash, because it helps your professional dossier, led you to misrepresent the original line of research conducted by Hannah while she was working in my lab at College X.

As a student, Hannah is vulnerable to the advice of her mentor; she is in a situation where she is unlikely to question her mentor. You, Dr. Cash, should have advised Hannah to do the appropriate thing by including me (her primary thesis mentor) as the second author and disclaiming the privileges of authorship for yourself. Your claim to authorship based on the fact that you proofread Hannah’s proposal before submission is a weak justification. The services you provided (i.e., proofreading and “providing moral support”) are merely professional courtesies and do not support claims to coauthorship.

Looking back, was it ethically appropriate to name Dr. Cash as the second author?

Hannah. I did not discuss my intent to submit a proposal to the national conference with you, Dr. Bright, before submitting my abstract. This was an oversight; an honest mistake. I was in a “time crunch” and consulted only with Dr. Cash. I was not aware that it could have these implications. However, if my master’s thesis was my original idea and work, shouldn’t I have the right to decide who can share coauthorship with me on my work?

Dr. Cash. As a mentor, I will stand by Hannah and support her decision. It should be her decision who should be granted authorship, and it is not fair, Dr. Bright, to demand it from her.

Dr. Bright. The U.S. Public Health Service (2005) identifies research misconduct as fabrication, falsification, and plagiarism. Neither “honest error” nor “differences of opinion” are considered to be research misconduct (p. 28,386; 45 CFR §93.103). Ethical misbehaviors in research such as in Hannah’s case, where authorship is granted based on financial inducements and professional obligations, would not, by definition, constitute “research misconduct” as technically defined. However, these types of misbehaviors are recognized by Kopelman (1999) as related factors that can challenge a researcher’s integrity. Minor drifts from the path of “truth and justice,” especially in the early years of learning, may foster in the mind of a young researcher that subtle misbehaviors will go unnoticed or unpunished, and may even encourage research misconduct later on in life.

Young research investigators may also come to believe that they are exempt from such erroneous behaviors. Therefore, despite arguments you’ve presented, Hannah and Dr. Cash, students’ misbehaviors cannot be overlooked merely as “honest” mistakes. You both acknowledged that there may have been underlying motives or incentives for presenting the paper together. Even if your behavior was “unintentional,” I think it was unethical. Dr. Cash, by expecting your students to assign authorship to you simply as a reward or because the student is a member of your lab is not good mentoring. A critical aspect of mentorship is that students learn from their mentors as role models. If mentors show responsible ways of conducting research, their students are most likely to behave ethically in their future careers as professionals and researchers.

Could this ethical mistake impair reputations?

Hannah. I do not think this will impair your reputation, Dr. Bright, because this was my thesis. I am not familiar with the current work being done in your lab or the recent research available in the area because I am not currently working in your area of research. You are the expert in the field. I also have no reason to think that Dr. Cash’s reputation will be harmed.

Dr. Cash. At the conference, we were not able to answer questions because they were specific to the line of research in which you, Dr. Bright, are the expert. I was somewhat
embarrassed by not being able to answer audience participants’ questions, but this should not have lasting effects on my reputation. Dr. Bright, you weren’t even there, so I have no reason to think that your reputation will be harmed.

**Dr. Bright.** Being an author on a research work goes beyond the fame that surrounds it. By accepting to be an author, both the author and coauthor agree to be held accountable and responsible for the research work presented. You, Hannah and Dr. Cash, not only failed to credit my intellectual contribution, but also gave inaccurate information to the attendees at the conference (Shamoo & Resnik, 2009). On both counts, I believe you have misrepresented my work and potentially harmed my reputation.

Furthermore, by presenting yourselves as (co)authors without accountability or responsibility for the work presented is an imprudent practice (Shamoo & Resnik, 2009). When you, Hannah and Dr. Cash, coauthored the presentation, it is only fair that you should be held responsible for knowing the research in this unique line of work, even though it might not be your area of concentration. Your inability to answer questions at the conference is likely to undermine your credibility in the professional world.

Furthermore, regardless of what you think, Dr. Cash, misrepresenting my work damages my reputation as an established researcher. The attendees could have included acclaimed scientists or prospective research sponsors who might have been interested in collaborative efforts. By misrepresenting the work conducted in my lab, the mediocre presentation could have tainted my reputation and could raise concerns about the responsible conduct of research at both College X and College Y. In addition, this incident could affect not only the future collegial relations that I have with you, Dr. Cash, but also Hannah’s reputation as a budding scholar.

**Summary and Conclusion**

The research ethics issue addressed in this case is whether it is ethically appropriate for a faculty member or a student to present ideas to the scientific community without attribution or coauthorship to the individual who originally directed and supported the line of research.

In summary, the compelling arguments provided by Dr. Bright, based on ASHA’s Code of Ethics (2010) and other authoritative guidelines, show that it is inappropriate for a student or faculty member to disseminate ideas without attribution to the individual who made important contributions to the research. It is also dishonest for individuals to grant authorship merely as a token of appreciation or reward when significant contributions have not been made. Hannah should have named Dr. Bright as coauthor and should have listed Dr. Cash and College Y as contributors or supporters in an acknowledgment section. The contributions proclaimed by Dr. Cash do not warrant coauthorship.

In conclusion, at the heart of this ethics issue are the concepts of truth and honesty. Although an authorship dispute is not considered to be research misconduct, it cannot be ignored as unimportant. Fairness dictates that scholars grant authorship to those individuals who have made substantial intellectual contributions to the work and separately acknowledge other contributors based on the nature of their contributions (e.g., technical, editorial).

Education in RCR should be emphasized for both students and faculty members as part of orientation to a lab or employment protocol so that faculty, students, and employees can be expected to uphold the values of the science accordingly. A lack of knowledge or naivety on the part of a student should not be excused or ignored but rather should be used as an educational opportunity to impart knowledge of RCR.

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**EXPLORING THE ETHICS OF RANDOMIZED CLINICAL TRIALS (RCTs)**

RCTs are considered to be the “gold standard” in research designs in current biomedical research (Emanuel, Crouch, Arras, Moreno, & Grady, 2003). By adopting an RCT design where the participants are randomly assigned to one of the interventions, researchers aim to reduce selection bias and improve scientific validity (Emanuel et al., 2003). However, ethical principles and guidelines have limited the applicability of RCTs in the field of CSD (Larsen & McMillin, 2011), especially when experimental conditions curtail or suspend “standard treatments.” The following scenario involves a researcher adopting an RCT to compare the effects of two intervention strategies in stroke patients with dysphagia. This case will address ethical issues that arise when conducting RCTs, especially with regard to clinical equipoise and randomization.

**HYPOTHETICAL CASE**

Dr. A is a tenured faculty member of University Q. His primary research focuses on examining the relative effects of intervention strategies in populations with dysphagia. For this study, Dr. A aims to compare the relative effects of two interventions targeting delayed initiation of pharyngeal swallowing in two groups of stroke patients ($n = 120$) with pharyngeal dysphagia using an RCT.

Aiming to recruit a homogenous sample, Dr. A plans to include only stroke patients with pharyngeal dysphagia who exhibit delayed initiation of pharyngeal swallowing, as evidenced on a videofluoroscopic swallowing examination (VFSE). Study participants will be 12 to 15 months post stroke and will have been receiving individualized dysphagia treatment or a combination of treatments from a speech-language pathologist (SLP). For the research study, the stroke patients will have to discontinue receiving any other type of dysphagia treatment and consent to being

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1. This case study was written by Elizabeth Oommen.
2. Randomized placebo controlled trials are theoretically the best research design to determine the effectiveness of a treatment. When considering ethical principles and guidelines that emphasize promoting participant welfare in research, such research designs are ethically controversial, especially in medical research. The best alternative would be to randomize the participants into two experimental groups where the participants would be randomly assigned to one of the interventions being studied (Emanuel et al., 2003).
randomly assigned to one of two experimental interventions. After receiving informed consent from the participants, Dr. A will randomly assign the stroke patients to one of the two groups: Participants in Group A (n = 60) will receive neuromuscular electrical stimulation\(^7\) (NMES), and participants in Group B (n = 60) will receive thermal tactile stimulation\(^8\) (TTS). Both of the interventions are hypothesized to remediate delayed initiation of pharyngeal swallowing (Logemann, 1998) and are experimental.

Before receiving any intervention, all of the stroke patients will undergo a VFSE, from which objective baseline data will be recorded. Both groups will follow similar intervention protocols where each strategy will be performed three times a day, each trial lasting 10 min. The exercises will be repeated four times a week for 4 weeks. After 4 weeks, the stroke patients in both groups will undergo a second VFSE. Biomechanical and temporal measurements of oropharyngeal swallowing will be used to compare the effects of the two intervention strategies and to compare pre- and post-intervention changes.

Dr. A submitted the project proposal to the IRB at University Q. After reviewing the project application, the IRB asked Dr. A to respond to questions that were raised during the meeting regarding research ethics issues with the proposed study. Dr. A responded to these questions and comments and then incorporated the recommendations proposed by the IRB in the study design.

**Ethics Issue**

The primary research ethics question raised by the IRB of University Q for Dr. A’s proposed study is as follows: Is it ethical for Dr. A to randomly divide the stroke patients with pharyngeal dysphagia into two experimental groups, both with unproven effectiveness regarding delayed swallow?

Questions from IRB committee members are followed by Dr. A’s responses.

**Discussion**

*Can the researcher highlight some of the ethical principles that guide the proposed RCT?*

**IRB.** Before addressing the specific ethical issue with the research study, it is important to view the case from a broad perspective, taking into consideration doctrines and guidelines from governing bodies. The aim of performing clinical research is to answer specific scientific questions using objective and replicable methods so as to be able to generalize the results of the study to a specific population (Miller & Brody, 2003). However, the study design that is chosen by the researcher should be based on, and abide by, principles stated in founding ethical doctrines and those stated by credentialing organizations.

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\(^7\)NMES to the submental area targets delayed initiation of pharyngeal swallowing by stimulating the suprathyroid muscles, which contributes to the elevation and anterior excursion of the hyoid and larynx.

\(^8\)TTS targets delayed initiation of pharyngeal swallowing by stimulating the anterior faucial pillars vertically with a cold laryngeal mirror, which increases the oral awareness and sensitivity (Logemann, 1998).

For instance, the *Declaration of Helsinki* (WMA, 2008) clearly states that the well-being of the participants involved in medical research is of highest priority, and it is the duty of the researcher to protect the rights and information of the patients who consent to participate in research studies. Specifically, the *Declaration of Helsinki* states, “In medical research involving human subjects, the well-being of the individual research subject must take precedence over all interests” (WMA, 2008, para. A.6.).

Dr. A., the IRB requests that you elaborate on whether your protocol adheres not only to the Helsinki principles, but also to the balance of risks and benefits required by the beneficence and nonmaleficence principles explained in *The Belmont Report* (National Commission, 1979).

*Dr. A.* This RCT study has been designed in such a manner so as to abide by the principles stated in both the *Declaration of Helsinki* (WMA, 2008) and *The Belmont Report* (National Commission, 1979). These principles are also articulated in ASHA’s RCR guidelines (2009). I have taken the following steps to ensure the well-being of the participants in the RCT.

When conducting this RCT, the stroke patients who will be participating will be provided with an intervention strategy (either NMES or TTS), albeit experimental, that is designed to remediate the dysphagic sign exhibited (i.e., the delayed initiation of pharyngeal swallowing). Thus, the stroke patients who participate in the trial will receive some form of dysphagia “intervention,” even if it is unproven to be effective. All of the stroke patients who participate in the research study will be capable of participating in and providing informed consent. In accordance with the principle of autonomy and respect for the participants (National Commission, 1979), stroke patients in the RCT will also have the freedom to discontinue participation in the trial at any time during the course of the study.

When broadly assessing the risks and benefits associated with the research study, it can be stated that the risks associated with the research are greater than minimal. In patients with dysphagia, NMES has been associated with certain negative effects such as hyolaryngeal depression, discomfort, and pain at specific levels of stimulation (Lim, Lee, Lim, & Choi, 2009; Ludlow et al., 2007). TTS has also been known to result in discomfort and pain in patients with dysphagia (Lim et al., 2009).

The aim of this study is to assess the effectiveness of two interventions in dysphagia, and the results will add to the body of literature in this area, where currently a lack of research is acknowledged. When assessing the benefits associated with the study, it is reasonable to think that the stroke patients who participate potentially might benefit from the interventions on a personal basis (U.S. DHHS, OHRP, n.d.). Prospective benefits to others, especially similar poststroke patients with swallowing disorders, may also be identified from the results of this study (Raspe & Huppe, 2012). The value of the research lies in learning whether or not the “interventions” reduce swallowing delay or improve swallowing function.

*How do you justify randomization of the stroke patients into one of the two experimental groups?*
IRB. Freedman (1987) defined clinical equipoise as “an honest, professional disagreement among expert clinicians about the preferred treatment” (p. 4); equipoise represents an “honest null hypothesis.” Freedman also emphasized that an experiment must be designed in such a manner that the condition of clinical equipoise is satisfied at the beginning of the experiment, and the results of the study should aim at creating a condition where clinical equipoise is disturbed, meaning that data reveal there is reason to think that one intervention is superior to another. For an RCT involving unproven interventions to be considered ethical, many scientists/commentators believe that clinical equipoise should exist before participants are randomized (van der Graaf & van Delden, 2011).

For this RCT, can the researcher inform participants of the study that there exists an “honest disagreement” among the community of expert clinicians in the field of dysphagia regarding NMES and TTS?

Dr. A. One of the main criteria used to address whether randomization is ethical or not is the concept of clinical equipoise, often considered to be the “moral underpinning” of RCTs (Weijer, Shapiro, Cranley Glass, & Enkin, 2000). To ascertain the existence of clinical equipoise between the two arms of the study, it is important to base decisions on informal, semiformal, and formal information such as opinions of clinicians, evidence from literature, and specific measurements (Johnson, Lilford, & Brazier, 1991; Lilford & Jackson, 1995).

When examining the evidence from peer-reviewed published literature for NMES, varied viewpoints emerge regarding the effects of NMES on swallowing function (Clark, Lazarus, Arvedson, Schooling, & Frymark, 2009). Certain studies have considered NMES to be a superior treatment option when compared to traditional treatments. In particular, when compared to TTS, NMES was found to result in improved swallowing function in stroke patients (Freed, Freed, Chatburn, & Christian, 2001). In contrast, other studies have reported no differences in swallowing function when comparing NMES and other dysphagia interventions (Kiger, Brown, & Watkins, 2006). Importantly, some studies have reported negative effects of NMES on swallowing function (Lim et al., 2009; Ludlow et al., 2007). TTS, a dysphagia intervention strategy that has been adopted more frequently than NMES, has been found to reduce the delay in initiation of pharyngeal swallowing in stroke patients with dysphagia (Rosenbek, Roecker, Wood, & Robbins, 1996). Research in the field “has fueled cautious optimism about the method’s treatment potential” (Rosenbek et al., 1998, p. 1). In addition, the use of TTS has been found to be contraindicated in certain patients, secondary to pain and discomfort (Lim et al., 2009).

Based on the review of pertinent literature, a genuine uncertainty (equipoise) seems to exist among the clinical community regarding the relative usefulness of NMES and TTS, especially for remediating delayed initiation of pharyngeal swallowing. Few studies have directly compared the effects of both NMES and TTS on delayed initiation of pharyngeal swallowing in stroke patients, and the majority of experts do not prefer one intervention over the other for remediating delayed initiation of pharyngeal swallowing in stroke patients. Thus, evidence suggests that it is not possible to say that either intervention in this RCT is considered superior to the other.

This leads to the conclusion that clinical equipoise exists between the two experimental arms of the proposed RCT. Because the condition of clinical equipoise is satisfied, it is permissible to randomize the participants; only the results of the RCT will reveal the superiority of one arm of the RCT over the other.

Even though clinical equipoise exists, is an RCT the best study design to answer this research question? IRB. The research aim or question(s) addressed in this study can be addressed by adopting other research designs. Even when considering the many advantages of adopting an RCT to answer this research question, some arguments against using an RCT design include the following:

- The inclusionary and exclusionary criteria adopted in this study may make it difficult to generalize the findings to other stroke patients with pharyngeal dysphagia.
- The clinicians providing the interventions to the stroke patients might not be equally trained in both NMES and TTS (Logemann, 2006).
- The level of risk for harm using either of the experimental interventions is not well understood (Weijer et al., 2000).
- The clinical researcher is cognizant that “patients are entitled to the most appropriate treatment available” (Lilford & Jackson, 1995, p. 558) and is uncertain that either NMES or TTS will benefit the individual participants.

When considering these arguments, an RCT may not be the most appropriate option. The Declaration of Helsinki (WMA, 2008) states that “the benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best current proven intervention” (para. C. 32). In this RCT, the effects of NMES and TTS on delayed initiation of pharyngeal swallowing in stroke patients are being studied.

Does the researcher consider one of the two interventions in the study to be the “best current proven intervention” and the other to be the “new intervention” for remediating delayed initiation of pharyngeal swallowing in stroke patients? Dr. A. An RCT is an experimental design in which each participant is randomly assigned and has an equal chance of being assigned to any one of the arms of the study. Such designs are usually used to evaluate whether an intervention is efficacious or not (Ho, Peterson, & Masoudi, 2008). Therefore, the RCT is the best research design for determining the superiority of one intervention over another. Randomization of participants permits comparable experimental groups to be created, which also increases the study’s internal validity (Ho et al., 2008). The lack of such studies has been acknowledged widely by researchers in the field. I can also confirm that the clinicians providing the interventions to the stroke patients have had extensive training in both strategies.
Before randomization, I will not know whether NMES or TTS is potentially harmful for the stroke patient. Selection criteria dictate that the stroke patients who participate in the study are those who are 12 to 15 months post onset, medically stable, and who have been receiving individualized dysphagia treatment(s) over the past year. Although I do not expect negative effects from either intervention, I acknowledge that negative effects such as patient discomfort and pain might occur.

It is not possible for me to conclude that either NMES or TTS is the “best current proven intervention” (WMA, 2008, para. C. 32) for stroke patients with delayed initiation of pharyngeal swallowing because it is as yet unknown whether either one or both of the “interventions” will have a beneficial effect. Among other interventions that have been adopted clinically for patients with delayed initiation of pharyngeal swallowing, such as chin tuck and dietary modifications, TTS has been cited as being a frequently adopted intervention strategy (Logemann, 1998). On the other hand, NMES is a relatively newer intervention strategy in the field of dysphagia. Due to lack of evidence, it is difficult to conclude that TTS or NMES is the “best current proven intervention” (WMA, 2008, C. 32) for these stroke patients.

**Recommendations by the IRB**

On reviewing the responses of Dr. A, the IRB made the following conclusion and recommendations. The research question proposed by Dr. A aims to compare the effects of two intervention strategies, NMES and TTS, on remediating delayed initiation of pharyngeal swallowing in stroke patients using an RCT. Even though clinical equipoise exists between the arms of the RCT, it is difficult for Dr. A to justify that the stroke patients in this study should discontinue individualized treatment (i.e., the treatment currently offered by the SLP based on the symptoms of dysphagia exhibited) in order to enroll in the study to examine the effects of the experimental interventions (NMES or TTS).

When clinical research involves patients, the existence of clinical equipoise should not be considered as the sole criterion for ethically justifying randomization into experimental conditions. Decisions should also be based on founding doctrines and principles, such as the Declaration of Helsinki (WMA, 2008) and The Belmont Report (National Commission, 1979), as well as on ethics governing the helping professions.

Therefore, the IRB recommends that Dr. A adopt an alternate RCT design where the stroke patients will not have to discontinue receiving “standard therapy” (i.e., therapy recommended by the SLP based on evidence-based practices). The stroke patients can still be randomly divided into two groups: (a) Group A receiving NMES and standard dysphagia therapy and (b) Group B receiving TTS and standard dysphagia therapy. Using this alternate research design (known as an “add-on design”), the condition of clinical equipoise will still be satisfied, but the stroke patients will be assured of receiving the best available therapy option while participating in the RCT.

**Summary and Conclusion**

In summary, the research ethics issue discussed was whether it is ethical for a researcher to randomly assign stroke patients to different arms of an RCT designed to determine the relative effectiveness of two interventions aimed at remediating delayed initiation of pharyngeal swallowing.

Based on the existence of clinical equipoise, it can be argued that randomizing stroke patients in this RCT is ethical, and conducting an RCT would undoubtedly contribute to answering the research question with increased statistical power. On the other hand, considering guiding doctrines and principles from ASHA and WMA, it can be argued that establishing clinical equipoise should not be the sole criterion for randomization of patients in an RCT.

In this instance, it is not ethical for Dr. A to randomly assign stroke patients to one of the two experimental groups.

Finally, ethical justification regarding randomization should also be influenced by assessing whether one of the two interventions in the RCT is considered to be the “best current proven intervention” (WMA, 2008), and whether what is considered by the clinical community to be “standard therapy” is unnecessarily being withheld from the patients who agree to participate in the experimental arms of the RCT.

In conclusion, despite the fact that the clinical community has “honest uncertainty” (equipoise) about the two interventions, the vulnerability of the participants ultimately suggests that it is not ethical for Dr. A to randomly assign stroke patients with delayed initiation of pharyngeal swallowing to the two experimental groups. The better practice is to use an add-on design. Therefore, Dr. A decides to provide participants with “standard therapy” for delayed initiation of pharyngeal swallowing while randomly assigning them to NMES and TTS, respectively.

**ETHICAL USES OF DATA**

Research involves several steps: hypothesis formation, research design, literature review, data collection, data analysis, data interpretation, and publication (Shamoo & Resnik, 2003). The steps are related to achieving reliable results and maintaining the quality, objectivity, and integrity of research data. Most research data are collected from objective tasks and are approved by entities such as the IRB, and specific statistical analysis techniques are performed (Marco & Larkin, 2000). Although reliable results are ensured with these processes, data cannot be trusted if a researcher intentionally selects or omits data when reporting study results.

**HYPOTHETICAL CASE**

This hypothetical case involves Erica, a CSD student who works at the dysphagia research lab at her university. She

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9This case study was written by Taeok Park.
investigated the effectiveness of the Mendelsohn maneuver in stroke patients with aspiration. This investigation was required for completion of her master’s degree. Her research addressed an important clinical question, namely, whether aspiration occurs due to reduced closure of the airway entrance. Erica’s hypothesis was that the Mendelsohn maneuver, which is designed to improve the extent and duration of laryngeal elevation (Logemann, 1998), would improve oropharyngeal swallowing function in stroke patients with aspiration. Her research included stroke patients who exhibited aspiration during the VFSE. The patients signed a consent form to participate in the research and had 40-min therapy sessions twice a week for a month.

The research design involved capturing swallowing function using VFSE and analyzing swallowing physiological function using three measures related to the timing and movement of key oropharyngeal structures. The VFSEs were performed before and after treatment. Appropriate statistical analyses were used. Erica’s IRB application included the research design and experimental method. She obtained IRB approval before conducting the research.

Statistical analysis of the data showed that three temporal measurements—laryngeal closure duration (LCD), oral transit time (OTT), and pharyngeal transit time (PTT)—were statistically significantly different at \( p < 0.05 \) pre and post treatment. This result was different from Erica’s expectation: Erica had not expected the Mendelsohn maneuver to have a positive effect on the oral stage of swallowing (Lazarus & Logemann, 1993), only the pharyngeal stage of swallowing. Therefore, Erica reported only the two significant pharyngeal measurements, LCD and PTT, in her thesis, omitting the OTT data.

Discussion With Thesis Committee

Subsequently, members of Erica’s thesis committee had the following dialogue with Erica.

Committee. Erica, we remembered that you proposed to examine both oral and pharyngeal effects of the Mendelsohn maneuver. It appears that you did not report all of the data you collected. Is there any reason for this?

Erica. Based on my clinical experience and a review of the literature, I believe that the Mendelsohn maneuver has a positive effect on the pharyngeal phase of swallowing, not the oral phase.

Committee. Erica, it is not appropriate to report only those data that agree with previous research.

Erica. I would like to publish my research. I want to select data that seem to have high potential for acceptance in a publication.

Ethics Issue

The research ethics question is whether or not it is ethical to report research data selectively. To answer this question, I will discuss the importance of data integrity by reviewing ASHA’s Code of Ethics (2010), ASHA’s RCR guidelines (2009), and the federal research misconduct regulations (U.S. Public Health Service, 2005).

Discussion

Research integrity. Research involves “adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities” (Panel on Scientific Responsibility and the Conduct of Research, 1992, p. 17). Data integrity is critical for ethical research. Researchers should adhere to the methods that have been approved by the IRB, and researchers should report data accurately and honestly if they are to interpret the outcomes and apply the findings to real life (Fish, 1999; Gardner, Lidz, & Hartwig, 2005; Nylenna, Andersen, Dahlquist, Sarvas, & Aakvaag, 1999).

Research misconduct. ASHA’s RCR guidelines (2009) state that researchers shall “provide an honest description and analysis of their findings” (9.d). Also, ASHA’s (2010) Code of Ethics states that “individuals shall not … misrepresent … research and scholarly activities conducted” (Principle I, Rule O). In addition, the federal regulations state that intentional omission of data is “falsification.” The following definition of research misconduct was published by the U.S. Public Health Service in 2005:

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. (p. 28386, 42 CFR §93.103)

Cherry picking. In comparing LCD, OTT, and PTT measures before and after treatment, the statistical analysis yielded three statistically significant results. Underlying data were reliable and were gathered using a valid procedure. However, the problem is that Erica did not report the entire data set. Her conduct violates ASHA’s (2010) Code of Ethics and is considered research misconduct. She engaged in “cherry picking,” which is selectively reporting data that are favorable to the investigator’s bias or point of view (Marco & Larkin, 2000; Rudman, 2003).

Influencing factors. There are several internal or external factors that might compel an investigator to selectively report data. One of the internal factors is an investigator’s conscious or unconscious bias or point of view. Investigators like to present data that they think are more interesting or valuable. One of the external factors is the pressure to publish papers, which comes from departmental publishing requirements; requirements for promotion; competitive pressures; institutional, regional, and national recognition; financial support; and media publicity (Marco & Larkin, 2000). Erica’s main interest was to complete her thesis successfully so she could graduate. This could have prompted her to select favorable data.

Another potential factor leading to cherry picking might be a weak research design. For example, a weak research design might include inappropriate subject criteria or extraneous procedures that do not fit the purpose of the study. Researchers might cherry pick because the weak research design has yielded too much variation (Morse, 2010). In retrospect, Erica might have thought it inappropriate to have three (repeated) temporal measures in her research method, so she selectively omitted the one of less “value” to her.
Cherry picking is unethical. Despite possible explanations for why Erica engaged in cherry picking, none of them justify this practice. Cherry picking is unethical because it hides data from public view and can misguide investigators and clinicians who rely on the published results. Future investigators might be led to ask the wrong research questions or to develop inadequate research methods, and clinicians might choose the wrong techniques for certain types of patients, or might be led to think that certain patients are not candidates for the treatment.

Cherry picking can and should be avoided by designing a study well, by collecting data carefully, by using appropriate statistics, and by reporting all of the data, regardless of the outcomes (Marco & Larkin, 2000). In addition, recognition of potentially inaccurate data reporting methods is an important part of the peer review process. Good research needs to have peer reviewers in order to avoid the lure of picking certain data. Thesis committees, reviewers, editors, and publishers perform critical reviews, supervise the publication process, and share the burden of responsibility for the dissemination of accurate and relevant research data (Marco & Larkin, 2000). The fact that Erica’s thesis committee recognized her misconduct is a good example of ethical oversight and a necessary part of the scholarly process.

Summary and Conclusion

This discussion explains the case of Erica’s master’s thesis in terms of her decision to selectively report data in her thesis. Even though Erica executed an IRB-approved research protocol, when she obtained results that were different from her expectation, she engaged in data cherry picking. Based on ASHA’s research standards, cherry picking violates the ethical principle that investigators should report data completely and honestly (Fish, 1999); in turn, based on federal guidelines, selective reporting of data invites charges of research misconduct.

In conclusion, although researchers may be tempted to cherry pick data, it is important to keep in mind the negative impact it can have on the integrity of science. Because students are in the process of learning about research integrity, thesis committees have an important function to identify and remediate misconduct before the research is published. Cherry picking data is ethically inappropriate and should not be condoned, regardless of a researcher’s level of experience.

REFERENCES


Chapman et al.: Responsible Conduct of Research