Distinguishing the Ethics of Clinical Research and Clinical Care

Rashelle B. Hayes
University of Massachusetts Medical School

Follow this and additional works at: https://escholarship.umassmed.edu/prevbeh_pp

Part of the Behavioral Disciplines and Activities Commons, Behavior and Behavior Mechanisms Commons, Bioethics and Medical Ethics Commons, Community Health and Preventive Medicine Commons, and the Preventive Medicine Commons

Repository Citation
https://escholarship.umassmed.edu/prevbeh_pp/218

This material is brought to you by eScholarship@UMMS. It has been accepted for inclusion in Preventive and Behavioral Medicine Publications and Presentations by an authorized administrator of eScholarship@UMMS. For more information, please contact Lisa.Palmer@umassmed.edu.
The Legislative Committee is busy preparing for the upcoming legislative season. Here is what we are working on:

**Our State Licensing Law:** We have just completed the Department of Health Hearings on the revised regulations from the 2008 licensing revision. They will be soon implemented. We are now preparing a new licensing update to address several current issues. The current draft seeks to:

1. Allow the Board of Psychology to investigate and engage in disciplinary action anyone practicing psychology whether or not identified as a psychologist.
2. Add language to the discipline section that will enable psychologists to be assisted by a peer or psychology assistant appointed by the Board. The language would also allow the Board to refer a person who is the subject of a disciplinary complaint to the program for assessment and treatment. The Board would be able to enter into an agreement with a psychologist to participate in the program without having to come to a disciplinary finding. The Board would be able to dismiss or suspend a complaint if the psychologist complies and completes the program successfully. The Board would be able to reinstate the complaint if the psychologist was not compliant with the agreement.
3. Clarify the Temporary Permit section to allow post-docs to get permits before they take the EPPP (so they will have completed all requirements but the EPPP and the second year of supervision) and allow people in post-doctoral programs with temporary permits to use the title “psychology resident.”

When the bill is passed we will again update the regulations to be in compliance with the law. We hope the staffing situation at the Department of Health will enable us to do this promptly this time. In the regulations update we will also seek to clarify the requirements for supervision and training experiences.

**Mandated Insurance Benefits for Autistic Spectrum Disorders:** At the request of the psychologists at the Developmental Disabilities Services at Bradley Hospital, we are working with them on a bill that would mandate home based treatment services for kids with pervasive development disabilities from private insurance companies. Our consensus is that we are supportive of the basic intent of the bill. However, there is some aspect of the bill that the bill has been directed towards the patient by the sponsor by a national advocacy group, Autism Speaks. The current version would require the individual responsible for providing the service and supervising home workers to have a Certificate in Applied Behavioral Analysis or a certificate provided by an independent entity outside the scope of our licensing law. We hope we can resolve this issue with the sponsor.

**Marriage Equality:** The RIAP Board has reaffirmed support of Marriage Equality. RIAP will continue to advocate in support of the bill. Past-President James Campbell will lead our advocacy.

**Reimbursement Rates:** We continue to be concerned that despite the implementation of federal mental health parity, that some health insurance companies require the individual responsible for providing the service and supervising homeworkers to have a Certificate in Applied Behavioral Analysis. In our view this is inappropriate. By statute Rhode Island requires the provision of clinical services to be provided by a healthcare professional licensed by the Department of Health within their scope of practice, not through a certificate provided by an independent entity outside the scope of our licensing law. We hope we can resolve this issue with the sponsor.

**Ethics Corner**

Distinguishing the Ethics of Clinical Research and Clinical Care

Clinical research is vital to clinical care. These days, more research is conducted by clinicians in more organizations and across many disciplines. As a result, clinicians will undoubtedly work with researchers or may hold dual roles as both clinician and researcher. However, this can create enormous opportunities for advances in healthcare. Often this can potentially allow for ethical concerns to surface. These ethical concerns may stem from limited understanding of how clinical research differs from clinical care. Additionally, roles and obligations of a clinician versus clinician-researcher may unintentionally blur in research settings. Clarifying these differences for the clinician-researcher as well as for the patient may help to reduce ethical concerns when conducting research.

So, what are the differences? In clinical care, the primary goal is to promote the well-being of the individual patient. That is, treatment and assessment is tailored to the individual. Ethically, the potential benefits of therapeutic care prescribed to the patient must outweigh the risks posed to them. On the other hand, the goals of clinical research are to produce generalizable scientific knowledge that will improve clinical care for future patients and for society. Thus, in clinical research an individual patient receives treatment based on the scientific design of a research protocol and not on individualized care. The care is standardized and may not be the most optimal care that a patient could receive. In another procedure, the study is a part of a study protocol, may pose some risk to patients without providing individual benefits. However, federal regulations allow clinical trial sponsors to design a trial that minimizes risks, maximizes potential benefits, and presents the value of advanced knowledge for society that outweighs the minimal risks.

These separate goals suggest distinct roles for the clinician and clinical-researcher. Clinician-researchers duties are protective, not fiduciary. Clinician-researchers are obligated to protect patient confidentiality and exploitation of the patient's role as clinician and clinical-researcher, the research is unethical. These requirements are the following: value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review, informed consent, and respect for enrolled subjects.

Unfortunately, when clinician-researchers continue to blur their role as clinician and clinician-researcher the research participant is also affected. Often patients believe that their clinician will always act with their best interests in mind. They may fail to comprehend that the purpose of research requires them to promote their individual welfare. This tendency to view research as a form of medical care contributes to the therapeutic misconception. Appelbaum, P.S. (2002). Tendencies for clinician-researchers to single out any patient-participant further contributes to the therapeutic misconception which ultimately threatens informed consent and risks exploitation. Thus, clinician-researchers have an obligation to be honest with patient-participants about the risk of research that does not promote the patient-participant’s welfare. Altogether, an understanding of research ethics includes knowledge that the duties of the clinician and clinician-researcher intersect, but clearly are not identical.

Submitted by Rashelle H. Hayes, PhD RIAP Ethics Committee

**References**


Got a question about ethics in your professional work, whether clinical or research? Contact the RIAP Ethics Committee for assistance from a committee of your fellow psychologists. Contact the Ethics Committee Chair at (401) 736-2900 or jhutson@ripsych.org to find the Ethics on-call member.