Distinguishing the Ethics of Clinical Research and Clinical Care

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The Legislative Committee is busy preparing for the upcoming legislative season. Here is what we are working on:

**State and Federal Advocacy Issues**

#### 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 implemented. We are now preparing a new licensing update to address some 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 colleague assistance program approved by the Board. The language would 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 completes 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 see 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 developmental disabilities from private insurance companies. Our consensus is that we are supportive of the basic intent of the bill. However, there is one aspect of the bill that we have not been able to move until post-mortem. This is the sponsor by a national advocacy group, Autism Speaks. The current version would 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.

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

**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. Some clinicians may seek out research to benefit the clinician who undoubtedly works with researchers or may hold dual roles as both clinician and research investigator. While this can create enormous opportunities for advancements in healthcare, often this can potentially allow for ethical concerns to surface. These ethical concerns may stem from a 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 provided 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 fact, nontherapeutic procedures that are part of a study protocol, may pose some risk to patients without providing individual benefits. However, federal regulations allow institutions to report a high bill that we find inappropriate. The bill has been introduced in Rhode Island that minimizes risks, maximizes potential benefits, and presents the value of advanced knowledge for society that outweighs the risks for the individual patient.

These separate goals suggest distinct ethical 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 patient risks in the course of conducting research. They must protect patient participants from facing unnecessary risks to answering the research question and protect them from any exploitation of any vulnerabilities due to health, age, income, or other factors. Further, clinician-researchers must protect the autonomy of patient-participants by providing accurate and clear information about the research aims, procedures, risks and benefits, and treatment alternatives.

Ethical concerns surface when the clinician-researcher believes he/she can stop investigational harm and exploitation of patient-participant, thereby changing their role and relationship with the patient-participant. For example, they may not recruit particular patients to a study if they believe that the individual patient would not benefit from the research, or they may change an aspect of the research protocol (e.g., reduce the number of assessment follow-ups) to benefit an individual patient. Although it can be argued that these behaviors were done for the patient-participant’s best interests, they still violate research ethics. Emanuel and colleagues (2000) offer an in-depth discussion of the requirements that are necessary and sufficient to make clinical research ethical. These requirements are the following: value, autonomy, beneficence, non-maleficence, risk/benefit ratio, dependent 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 is not to promote their individual welfare. This tendency to view research as a form of medical care contributes to the therapeutic misconception (Appelbaum, 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 risks of research that do 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 B. Hayes, Ph.D.
RIPA Ethics Committee