Show Notes - Episode #16
Best Business Practices in Aphasia Care:
In conversation with Dr. Myrna Schwartz

Have you ever asked yourself, “What do you mean I need a consent form? We are just presenting on a project we did with our community aphasia group.” Dr. Myrna Schwartz speaks with Dr. Janet Patterson about the important role of ethics and institutional review in clinical research activities in which community aphasia groups may wish to participate. It’s an important and often confusing topic that all people who are interested in either research or program evaluation should understand.

Dr. Schwartz is co-founder of the Moss Rehabilitation Research Institute (MRRI). Before coming to Moss, she earned a PhD in experimental psychology from the University of Pennsylvania, completed a fellowship in behavioral neurology at Johns Hopkins School of Medicine, and held faculty appointments at Hopkins Medical School, Swarthmore College, and University of Pennsylvania. At MRRI, Dr. Schwartz headed the Language and Aphasia Laboratory, which conducts basic and applied research on language processing impairments in stroke. She pioneered the use of convergent behavioral, computational, and neuroimaging methods to investigate how the mind and brain access the names of things. Dr. Schwartz’s research program has received continuous NIH funding for more than 30 years. She has served on many NIH scientific review committees and frequently reviews for journals in psychology, neuroscience, and speech-language pathology.

In today’s episode, you will:

- Hear Dr. Schwartz describe the human face of research and the importance of institutional review board activities and informed consent to clinical research happening in community aphasia groups;
- Learn how to differentiate inward focused research examining Quality Assurance and Quality Improvement of a community aphasia group from outward focused research designed to answer a clinical question;
- Learn strategies and techniques for your community aphasia group to develop an institutional review board or to partner with a university or hospital for clinical research activities.

Note: These show notes has been edited and condensed.

Janet Patterson
Let me start by asking you what is probably a deceptively simple question: Why is the concept of research ethics important to community-based aphasia groups and to persons with aphasia?

Dr. Myrna Schwartz
I think the reason to start there is because many of us have an approach where we think, “We need to be concerned about research ethics when we're dealing with biomedical science where there are interventions that put people at risk. But, that's not the case with what I do. So, I don't understand why I need to be concerned with those kinds of issues in clinical research studies. What I do is small, behavioral, and non-invasive.” That's a very common place for these conversations to start.

When we think of research ethics we often think about minimizing risk to participants, or about risk-benefit ratio. These are important issues but they’re not the sole issue of concern. When we're dealing with research ethics, we're also dealing with very basic human values that we all share - things like respect for personhood and respect for the autonomy of individuals. That respect means that everyone should be able to make informed decisions about how they spend their time, what activities they engage in, and so on. That's fundamental to the notion of research ethics and the issue of informed consent to participate. There are other issues as well, including issues of justice because we want to make sure that vulnerable populations aren’t excluded from participating in research or overly burdened in participation of research.

There are also concerns about types of vulnerabilities that some participant populations might bring with them. In the case of aphasia, this is a group that’s vulnerable to what's called “cognitive incapacity”. That is to say that questions get raised about whether this individual, because of the language and communication impairment, is in fact able to fully comprehend the benefits and risks involved in participation. Do special procedures need to be in place (large print, simplified language, visual and pictorial aids, for example)? All of these are questions that arise for any research project where the participants are human beings and the work that we do is not excluded from that.

What is an institutional review board or research ethics board and why are they important both in research and to the individual aphasia community groups?

We'll start with some definitions. An institutional review board is a type of research ethics board. We don't need to worry here about the distinctions between them. Other names can be used: some are called research committees and so on.

Historically, because of the kinds of abuses in the ethical treatment of human subjects in research that have become notorious in our world (like the Tuskegee incident), federal governments in the United States and elsewhere became concerned about ensuring that such abuses didn't happen again. They drew up guidelines about how these things can be prevented and the result was the requirements that any institution that receives grants from the government would have to conform to a review process. This led to the formation of oversight bodies that came to be called Institutional Review Boards (IRBs) or Research Ethics Boards in Canada. In short, these are oversight bodies that are put in place to ensure that the ethical principles that we talked about are done properly - respect for persons, minimization of risks, and the informed consent process to name a few

Although this process began with a mandate from the federal government for institutions that apply for federal grants, it's become accepted now that these same sorts of procedures should apply to all research conducted with human subjects regardless of whether they are in grant supported institutions or not. So, a freestanding aphasia center or an aphasia group within a hospital that doesn't have access to its own IRB, needs to then think about how to become associated with an IRB or research ethics board so that it can have this kind of necessary oversight, irrespective of whether there are grants involved. I want to make that clear because some people also think that this is really about grants and it's not.

In the freestanding aphasia groups, we are asking a lot of questions such as: How do we implement book groups in a better, more efficient manner? How do we best implement supportive communication? These questions may not seem like research at the beginning, but they are. I've heard you use the terms “quality assessment” and “quality improvement”. How do the ideas of quality improvement and quality assessment (of the activities that happen inside our groups) differ from the impairment-based research we might usually think of? And, how do we involve quality assessment and quality-based improvement in the IRB and the research ethics enterprise?

Wonderful question! *Very complicated answer.* This is one of the hardest questions and it's one that comes up again and again in clinical settings. The reason it comes up is that the expectation is that we will continuously be assessing and improving what it is that we do. That's just built into every healthcare group program institution - data gathering for the purpose of providing better care. This process has gone by a lot of different names, but I use QAQI for “Quality Assessment Quality Improvement”. The idea is that the kinds of assessments, data collection, and analysis that we often do for QAQI is very similar to research and the goals can overlap enormously.

Let’s talk about goals, because it is the goals and intentions of the individuals collecting the data that really makes a difference. Research is the collection of systematic data to answer a question that's of general interest to the field. Clinical research has to answer issues related to replication - because the field wants to know whether particular findings in the literature are reliable. We do clinical trials to see whether a new treatment is better than a standard treatment. We do outcomes-based research to see whether the outcomes from our interventions are as we expect them to be and better than some other interventions. Those are examples of clinical research and they're addressing questions that are important to the outside world. These interventions are evaluated through publication and presentation.

On the other hand, QAQI addresses inward questions related to a particular program or activity. In QAQI, what we want to know is: Does our particular way of doing things work the way we think it should work? So, you collect whatever data you need to answer that particular question, make the changes, see how that works, then make more changes and see how *that* works. It's an ongoing process of data collection and program modification with an eye towards improving the situation in our local setting. So, it's really a matter of research being data collection in an outward focused way and QAQI being data collection in an inward focused way.

Because research is outwardly focused, it needs to conform to certain expectations of the scientific and clinical community: How do you do an experiment? How do you assign people to groups? How do you prove your hypothesis? There are standards for what an adequate research design is that don't necessarily apply in the case of QAQI. Inward assessment can be simpler, but in all cases, there’s a minimum amount that you need to do in order to answer a particular question.

It's very important that QAQI happen quickly and that the approval process happen quickly. Quick oversight and approval is *not* what we get with IRBs. They’re concerned with the questions of human subject ethics and don’t care about the viability of a particular program and whether it’s achieving its local goals - they only care about human subjects participation. The people who *do* care about your local success is *you*, right? QAQI is usually left to the stakeholders for that reason - it can be done quickly with an understanding of the local context.

As you alluded to in your question, there's a very grey area between research and QAQI and, very often, what starts out as a local evaluation turns into something that we think will be of importance to the field. So, when we gather data for ourselves and then have a retrospective desire to take that inward focused activity and turn it outward to the world by deciding that there might be value for others in the field, that’s where we get into very murky areas.

You've anticipated my question about navigating that grey area because you've articulated the issue so well. That distinction between "inward" and "outward" is helpful, and the idea of taking an inward focused question and applying it in an outward focused manner, making the question one that must be attended to from an IRB perspective. So, for an aphasia group that is not affiliated with a university or medical center or doesn't have a relationship with an IRB, how might they consider incorporating participant protective action? What are the initial steps that they could take so that they're not operating out there in a vacuum?

The important thing to do is to begin by asking a couple of questions. First, is it practical for us, in our aphasia group or aphasia center context, to think about forming our own oversight research ethics committee? If the expertise is available to you, I think that would be the ideal step to take because individuals would know you're local setting the best and could best navigate this difficult territory between the inward and outward focus. This does require a considerable amount of expertise, however. There is extensive knowledge about the ethical principles involved that have to be safeguarded. There's also lots of regulatory issues - there are local, state, and federal laws that deal with things like proxy consent. Those kinds of issues are the sorts of things that people who serve on IRBs have have become experts in and have acquired expertise.

So, when you consider the practicalities of forming an IRB, you must consider if you have those kinds of resources to draw on. You don't need many individuals to constitute such a committee. Ideally, you could start with one individual on your staff, on your board, or a consultant who can guide you in forming a research ethics committee?. So, the first question is, "Do I have the resources to do this?"

The second question is: Is it necessary for me to do this? Will you be undertaking research with the resources at hand or will you be doing it in collaboration with a researcher who's based at a university or a medical center that has its own IRB? Do you want to engage in research through affiliation with a consortium such as the Aphasia Bank? There are ways of participating in research and having your members participate in research without having the lead for that research based in your own establishment. If you have those kinds of research collaborations, then oversight can be done through their institutions.

Once you have access to that kind of expertise, you can engage in a dialogue with them about the gray area between QAQI, research, and how best to collect data. They'll be able to tell you if you need a formal IRB review or if your intended research falls into the QAQI area.

We could talk about this topic with you for days and I would never get bored - there's just so much to think about. Your answer also got me thinking that maybe it's time for Aphasia Access to develop a research mentoring group. This could help people navigate the process of getting their inward focused questions answered.

I'm a member of the research and education committee of Aphasia Access and the research priorities working group. We are currently thinking of ways to facilitate research. I'll suggest that on my end. Thank you for that suggestion!