Pharmacology Research Institute

The PRI Bulletin

A Newsletter of Scientific Research for Quality Medical Care

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Fall 2000 **Volume 12, Number 2**

Clinical Research - Frequently Asked Questions and Answers[1]

By Alicia A. Puppione, RN, MSN

Over the last twenty-five years, Pharmacology Research Institute (PRI) has been conducting clinical trials on new medications and indications. Pharmaceutical companies, as part of the approval process, sponsor these trials for the Food and Drug Administration (FDA). Many of our prospective, current and returning patients frequently ask questions about this approval process and how their participation plays a role.

There are two basic types of research – basic and clinical. Basic research, also known as bench research, is usually conducted in a laboratory and examines the cellular and chemical aspects of a potential medication. Clinical research is conducted with patients in hospital and clinic settings. Clinical research is completed in phases.

- **Phase One**. These clinical trials are primarily evaluating a drug's safety and tolerability in humans. These studies use healthy volunteers to determine the medication's effect on the body and possible side effects.
- **Phase Two**. Studies in this phase provide information about a medication's efficacy and safety in patients who have the disease under diagnosis. Information about side effects and tolerability are also monitored closely. To evaluate if a potential medication is effective, it is compared to a placebo, or "sugar pill". These types of trials are known as a double-blind, because both the study subject and the researchers do not know if the subject is receiving the placebo or the "real thing."
- **Phase Three**. A phase three study is further evaluating the safety and efficacy of a drug by building on the information gathered in the first two phases. These studies also tend to be double-blind, but tend to include more subjects who have the diagnosis under investigation.

All phases of clinical research are overseen and evaluated by two independent bodies. Each site reports to an Institutional Review Board (IRB) in charge of making sure the research is being conducted safely at a particular site. Additionally, the IRB approves potential new studies and makes sure they are reasonable and safe. The FDA monitors both the company and individual research sites to insure that the studies are being conducted safely and properly. The FDA reviews all of the information gathered in each of the three phases and decides if the drug will be approved. A pharmaceutical company works an average of fifteen years on a single medication before it completes phase three and is presented to the FDA for approval.

Once the FDA approves a medication it can take a few more years to produce and market a new medication.

[1] Information adapted from Dunkin, M. A. (2000). Arthritis Research: Your top 10 questions answered. Arthritis Today, 14(4), 140-144. ©2000, the Arthritis Foundation, 1330 W. Peachtree St., Atlanta, GA 30309. Adapted with permission of Arthritis Today. For more information please call the Arthritis Foundation's Information Line at 800-283-7800 or log on to www.arthritis.org.

INSIDE THIS ISSUE:

The High Cost of Social Anxiety

By Jon F. Heiser, MD

Until recently, social anxiety, an intense discomfort, fear and even panic in routine social and professional situations, was considered an unfortunate but natural part of many people's lives. People were expected to either get over their fears or suffer through them. Unfortunately, most people do not spontaneously get over social anxiety. At best, they learn to endure the feared social and professional activities with intense pain and anxiety. During a social or performance situation people with social anxiety feel like they are constantly being watched and evaluated. After enduring an anxiety producing situation, people with social anxiety often feel sad, angry or remorseful because their fear and anxiety caused them to miss an important opportunity.

This dread before and the powerful anxiety during social activities continues until the person begins to avoid any situation that may cause anxiety. Avoidance may be partial; for example, a person may come late and leave early rather than skipping the entire event. Many people are unaware of their avoidance behaviors.

Unfortunately for people with social anxiety, the anxiety and the dread associated with it is a false alarm. There is no real threat in the majority of avoided situations. In the few situations where a person will be the focus of attention or closely evaluated, (e.g., tests, interviews,etc.) one is usually able to plan well in advance.

Whether aware or unaware, partial or complete, the worst feature of inappropriate social avoidance is that it works. People with social anxiety are positively reinforced each time they avoid a situation – their anxiety and discomfort goes away. This positive feedback that one receives comes at a cost. People with social anxiety disorder average several years less education, earn several thousand dollars less per year, and are more likely to self-medicate with drugs or alcohol. The good news is there are treatments available. Call your nearest PRI office for more information. You owe it to yourself.

Patient and Caregiver Resources for Depression and Dementia

By Nancy Farrell, RN MSN NP

The U.S. Department of Health and Human Services provides free informational guides on various health conditions, including depression and dementia. Several years ago Congress created the Agency for Health Care Policy and Research (AHCPR), a branch of the U.S. Department of Health and Human Services. AHCPR funds groups of health care providers (doctors, nurses, social workers) from across the United States to get together for the purpose of setting national standards for the diagnosis and treatment of common health problems. The health care providers chosen to be in the "think tank" groups are experts in the area being reviewed. These experts review current research and practice to develop research-based clinical practice guidelines for health care providers. Additionally, they create short, easy to read guides for patients and their families.

PRI patients and their families may find these guides apply to themselves or their loved ones. We think two may be especially useful to our patient population as a whole. The first is Patient and Family Guide: Early Alzheimer's Disease which talks about the effects Alzheimer's disease has on patients and their families. The booklet describes the early symptoms of Alzheimer's disease, and what you can expect during the evaluation process. It also outlines medical, social, and financial resources for those with Alzheimer's Disease. The second guide Depression Is a Treatable Illness: A Patient's Guide reviews the signs and symptoms of major depressive disorder, the most common form of depressive illness. This booklet gives helpful information about depression and getting treatment.

For more information on these or other guidelines, or to receive free copies of the booklets, call toll-free: 1-800-358-9295 or look on the World Wide Web at www.ahcpr.org.

Why I Enjoy Working At PRI

By Don DeFrancisco, M.D., Ph.D.

I began working in psychiatry about 30 years ago. From the beginning, I studied both psychodynamics, or "talk therapy", and biological psychiatry. Psychodynamics focuses on an exploration of a patient's emotional problems over many years of therapy. Biological psychiatry is based on clinical research and focuses on how medications effect a patient's mood. I was educated with a deep respect for both viewpoints. When I graduated, I pursued a private practice and simultaneously continued to involve myself in research. I have had a private practice and worked at PRI for the last 25 years in an attempt to continue to remain involved with both methods of treating patients.

My two jobs are both very interesting and only occasionally frustrating. At PRI, we get to see new drug treatments years before they hit the market. For example, we started researching the SSRI's (i.e. Prozac®, Paxil®, Zoloft®) in 1980. This was a very exciting time to be doing research at PRI because these medications were better drugs than what was available. However, it was frustrating because I had to wait nearly a decade before I could prescribe them to the patients in my private practice.

Another positive thing about PRI is we are able to treat many people who do not have the funds or insurance to get the most optimal treatment privately. While our research protocols have their own rigidities and reasons for excluding patients, I find the guidelines set-up by the pharmaceutical companies easier to work with than managed care.

When evaluating patients for PRI's studies, my role is quite different from my private practice. I cannot conduct psychotherapy during research because it would confuse the evaluation of the medication if you gave both. When doing research, we have to evaluate a person's symptoms, very carefully. A person is evaluated using very specific criteria to decide if they are eligible for the study. Those same criteria are used to monitor the effectiveness of a particular medication. The danger for the private practice psychiatrist doing research is that he can start bringing too much of the symptom focused research role into his private work where patients need to be encouraged to talk about their stories.

There are also some obvious frustrations in both types of practice and in trying to combine them. Research is rigidly regulated and is often placebo controlled. While a patient may have a chance of getting on a newer and possibly better drug, they also have the possibility of being on a placebo. At PRI we softened the potential impact of this decision a long time ago by offering all research subjects two months of aftercare. During our aftercare program, we work hard to get our patients on a marketed drug that works for them. Some of the pharmaceutical companies have seen the wisdom of aftercare and sometimes supplement PRI's aftercare program, which gives us a longer chance to work with our patients. Even with the free "aftercare" option at the end, deciding whether to put a very seriously depressed patient on a placebo controlled study can still be an agonizing decision for the researcher and potential patient. We exclude them if it is too dangerous, of course, and with the others we can only inform them again and again, until everybody is comfortable with the decision.

When the researcher returns to his private practice, there can be other frustrations and dangers. I've mentioned the danger of focusing too narrowly on a patient's symptoms and perhaps not encouraging them to talk about their stories. My private patients who do not respond particularly well to the standard medications on the market cannot try the new exciting drugs we're researching. If they went on a study, there would be no guarantee they would get better and they might have to give up other medications and even their psychotherapy. Very few private patients are willing to do this.

I enjoy working at PRI and I feel that doing research has made me a better private practice psychiatrist and an even better therapist.

What's New at PRI?

Depression

PRI has been awarded several new studies with new and quite novel potential antidepressant medicines. We have new depression programs for adults in each of our four offices. Plus, in Northridge we have a new depression study for children and adolescents, ages 7 to 17. For adults who suffer from recurrent depression, we have a new study specifically designed to evaluate the effectiveness of a new research medication in helping to prevent depression recurrence.

Alzheimer's Disease

The PRI team has been involved in the clinical evaluation of potential new medications for the treatment of memory loss since the 1970's. We are currently conducting a study with a new medicine that may delay the further progression of Alzheimer's Disease. Qualified participants must be at least 50 years of age and be suffering from mild-to-moderate memory loss.

Focus on Adolescents

The challenges associated with being an adolescent today are well known. These challenges are intensified by certain treatable conditions. PRI's Northridge site is conducting a number of studies specifically designed for adolescents. We currently have adolescent programs for depression, migraine headaches and social anxiety disorder. The potential benefits and improvements in quality of life that effective short-term treatment can produce for an adolescent are remarkable!

Anxiety: Generalized or Social?

Virtually all of us have times or events in our lives where we feel nervous. However, prolonged periods of nervousness steal away time, fulfillment, opportunities and enjoyment in one's life. PRI has been recognized as a leading research center in helping people with the symptoms of anxiety since 1975.

For more information on PRI's programs for Depression, Alzheimer's Disease, Adolescent Studies and Anxiety, please call the nearest office.

The PRI Bulletin is an official publication of the Pharmacology Research Institute and is intended for patients and friends of the Institute. Inquiries and changes of address may be directed to one of the site coordinators (listed below).

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