



**Pharmacology  
Research  
Institute**

# The PRI Bulletin

**A Newsletter of Scientific Research  
for Quality Medical Care**

Since 1975: Convenient, Personal and Professional!

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## Research Studies: Who Volunteers and Why?

By: Charles S. Wilcox, Ph.D.

Since the tragedy of September 11<sup>th</sup>, volunteerism has been on the rise all across America; increasingly, people have shifted from the “me” mentality to the “we” line of thinking. Interestingly, well before the past six months we have received comments from numerous study participants reporting that they volunteered “to help others, and possibly myself as well.” Those of us who work here at PRI are always amazed by, and appreciative of, the many people who volunteer to participate in our research programs. When we think of *who* volunteers, we tend to think of study participants as co-researchers, working *with us*. We value your input in our scientific quest to identify new medications with the potential to improve the quality of life for you, the PRI study participants, as well as “others” whom so often benefit several years later.

In the late 1980’s, our patients reported that they volunteered for studies because of (#1) access to *new* research medications, (#2) our programs are *free* of charge and (#3) all of our research activities are conducted in a *confidential* environment. In the 1990s, we often heard that people volunteered because they liked the two-tiered (no-cost) opportunity to benefit from their participation: first, as a potential direct result of the research medication and/or secondly, as a result of PRI’s after-care program—during which they receive some of

the newest and most effective *currently marketed* medications.

While the reported primary reasons for volunteering to participate in our research programs have varied since we began conducting studies in 1975, there are several basic traits which have remained constant: study participants at PRI are honest, reliable and unselfish individuals! Did you know that the majority of patients who enroll in a study at PRI have alternative options? Consistently, we are told by study partici-

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pants that they volunteer for the opportunity to have access to the newest medications, in a confidential environment—with an unequalled opportunity to learn something about their condition, in a manner which is truly unique to the research experience—plus, there is a feeling of altruism which strengthens one’s feeling about “helping others, as well as myself.” Admittedly, in today’s world of “managed care,” it is exceedingly difficult for even the best and most experienced clinicians in private practice or working at a

Health Maintenance Organization [HMO] to offer the quality of care they would like to provide; nonetheless, we feel privileged to provide people with a level of care that makes them feel so pleased about their decision to volunteer.

For new study participants it is very natural to ask, “Why volunteer?” Thanks to the thousands of patients who have volunteered to participate in our programs over the years, we have learned that there are potentially many reasons *and* many benefits — both direct and indirect—from doing so. Regardless of one’s education, income, race or religion, we recognize, respect and appreciate the values which so many volunteers have in common. Furthermore, as we enter our 27<sup>th</sup> year of conducting research studies, we pledge to continue to do as much as possible to make *your* research experience as positive as possible, regardless of who you are or why you decided to volunteer!

**Thank You Volunteers!**

| <b>INSIDE THIS ISSUE:</b>            |   |
|--------------------------------------|---|
| Who Volunteers and Why .....         | 1 |
| Coming Back<br>from Depression ..... | 2 |
| Anxiety Dominates My Life ..         | 3 |
| The Professionals at PRI .....       | 3 |
| What’s New at PRI? .....             | 4 |

## Coming Back from Depression—The Glass is Half Full

By: Jon F. Heiser, M.D.

People recover from clinical depression in various ways. Some, the lucky ones, get well quickly and completely. More often, recovery is a complex, irregular, inconsistent, but ultimately complete process. There are many approaches to treating depression. The focus of this article is treatment through antidepressant medications. Most of these observations also accurately describe responses to non-pharmacological treatments of depression.

The term “antidepressant” is somewhat misleading. Antidepressant medications are not “happy pills.” They do not make anyone “feel good.” What they do is energize people while changing their attitude in a positive direction. This is perhaps best and most simply expressed by seeing “the glass” as half full rather than half empty. The renewed energy coupled with the positive outlook enables people to work far more effectively on many long-standing problems. Only when progress is made at solving these problems, however, does the person experience, very appropriately, happiness and contentment.

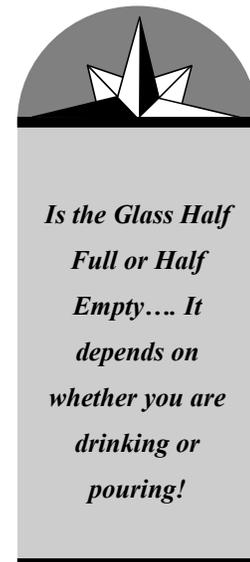
Most depressed patients have a combination of mental and physical suffering. Patients always have some combination of depressed mood, loss of interest in many (if not all) things, a belief that life is hopeless and that they are helpless as well. A patient might also develop physical difficulties, such as loss of appetite and weight, insomnia and a feeling of weakness or fatigue. The mental and physical symptoms may improve in perfect two-part harmony,

change independently of one another, or change in any other pattern. During recovery, the physical symptoms may abate first while the mental symptoms remain unchanged. Conversely, the mental symptoms may clear first, to be later followed by resolution of the physical symptoms. More commonly, there is a “back and forth” to the pattern of symptom resolution—improved sleep is often noted first, followed by increased interest in things, then increased appetite, and so on.

Equally important is the fact that improvement is never instantaneous, rarely rapid, and very seldom a smooth process. Typically recovery is a jagged or sawtooth experience with frequent spurts up and down. The spurts make it impossible for patients to know for sure whether or not they are improving. For example, taking a step back and looking at the pattern of change over the past, say, two weeks, might suggest that despite frequent relatively small jagged ups and downs, the general trend is towards improvement. Nevertheless, if the current “jag” is down, people may feel that there’s no end or bottom to it and that they are relapsing back to square one. Similarly, a current jag “up” may suggest that a complete remission is unfolding at that very moment, only to be invalidated by the next jag down, accompanied by feelings of discouragement and demoralization.

Smooth continuous improvement, if gradual enough, creates its own obstacles for patients. Our brains are not designed to detect and measure slow continuous change, instead this is typically

perceived as no change or no difference. Thus over a period of days and weeks someone often substantially recovers without recognizing it. They believe they are just as depressed as when the depression was the most severe. Sometimes the improvement is obvious to others while the patient experiences no change. The patient may appear: wearing new clothes, sporting a new hairstyle, walking with a bounce in their step, reflecting a gleam in their eye and report successful resolution of one or more long-standing problems and, yet, insist there is no change. The patient may further state that they are feeling just as badly as before and that nothing has changed. Eventually, these people experience the vast improvement so apparent to others.



*Is the Glass Half  
Full or Half  
Empty.... It  
depends on  
whether you are  
drinking or  
pouring!*

## Anxiety Dominates My Life!

By: Donna M. Adkins, R.N., M.S.N., N.P.

According to recent statistics, 20-30% of the population may be suffering from an anxiety disorder. Additionally, among the depressed 50-60% also have anxiety symptoms. Anxiety disorders are frequently and commonly presented to health care practitioner, yet it's often overlooked for the same reasons that patients may overlook them. The existence of mental worries and physical symptoms are often not a focus of complaint to the health care practitioner until they interfere with family, work or social life. The symptoms of anxiety and depression co-exist, which makes separating the two even more dubious.

Today there are eight recognized types of anxiety disorders, accompanied by an equally wide range of explanations for the cause. In many cases familial/genetic traits or alteration in neurotransmitter functioning appears to be the most likely cause. Medications, stress and an unhealthy medical condition can worsen symptoms of anxiety.

- Are you a worrier?
- Do you find yourself anticipating all the bad things that could happen?
- Do you feel restless, fatigued, distracted, tired from lack of sleep or physically tensed?
- Do you find that worrying dominates your mind, preventing you from doing things that you would like to do?

If you answered yes to these questions, you may be suffering from an anxiety disorder.

Regardless of the cause, anxiety is treatable. Although treatment with medication coupled with psycho-therapy or counseling is highly recommended, treatment with either medication only or psycho-therapy/counseling only is also a frequent

route taken by most people. There are three major groups of medications proven to be effective in relieving anxiety symptoms: benzodiazepines, tricyclic antidepressants and selective serotonin reuptake inhibitors (SSRIs). SSRI's are gaining recognition with the public as a safe and effective medication for treating anxiety.

Whether a patient is treated with medication only or in conjunction with psycho-therapy or counseling many people may have concerns about developing a lifelong dependence on one or both treatments. Therefore, the individual's major goal should be to reduce the disturbance anxiety creates in their personal sense of wellness and enjoyment of life.

It is important to understand that there are effective medications available to treat anxiety and depression. The task of the individual is to seek help and become a working partner with their health care practitioner in finding the medication that best works to treat their symptoms.



Arnelle I. Hardy, R.N., M.S.N., N.P.

### The Professionals at PRI

By: Francine E. Cho, M.A.

Our continuing series on the professionals at PRI focuses on Arnelle I. Hardy, R.N., M.S.N., N.P. Ms. Hardy is a member of our clinical staff at the Los Alamitos office. With 31 years of experience in nursing she is a veteran in the field, which includes varied work experience in clinical and research settings. She is a native Californian and has worked continuously in Southern California. Her 31 years of professional experience includes, among others, working at Long

Beach Memorial Medical Center and UCI Medical Center. She has also served on several committees on research and nursing.

Concurrent to her position as a clinical research nurse at the Los Alamitos office, Ms. Hardy is also an associate professor at California State University, Long Beach, where she teaches undergraduate nursing. We are indeed very fortunate to have Ms. Hardy as a PRI team member, she has contributed to the team's collective knowledge with her extensive work experience, presentation skills and research background.

## What's New at PRI?

### Migraine Headaches!

PRI continues to be recognized as one of the premier research centers involved in the "cutting-edge" research on migraine headaches. The average migraineur misses more than six full days of work per year, as a direct result of his/her migraine headaches. For many, the number of days at work, with diminished productivity, while enduring migraine headaches is even more significant. PRI is offering new programs to treat and prevent migraines.

### Anxiety/Nervousness

All too often patients with anxiety wait until they physically wear out before they reach out for help. Untreated anxiety can impact one's functioning as much as back pain, arthritis, diabetes and even heart disease. Also, patients

with anxiety are more likely to develop major depression when presented with stressful situations. Successful treatment of anxiety can lower one's health costs, possibly prevent or lessen the symptoms of depression and markedly improve one's quality of life!

### Depression

Did you know that almost 1 in 5 Americans will experience depression at some time? Today, more than 30 million Americans may suffer from some form of depression. Suffering in silence needlessly prolongs the pain and suffering. PRI has been awarded research grants for people suffering from moderate, severe, long-term and short-term depression. Only you can spot and do something about the warning signs of depression.

### Memory Loss?

#### Alzheimer's Disease?

We have studies for the treatment of mild, moderate and severe memory loss. It is often at the earliest and most mild stages of memory loss when treatment and intervention can be of most benefit to the patient as well as the family; however, between the fear and stigma associated with the diagnosis of Alzheimer's Disease, all too often denial prevails and persists for months and even years. Our team of physicians and research nurses have special skills and sensitivity with respect to the diagnosis and treatment of memory loss.

For a confidential and supportive [no cost] evaluation or information on any of these programs, please call the nearest office.

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