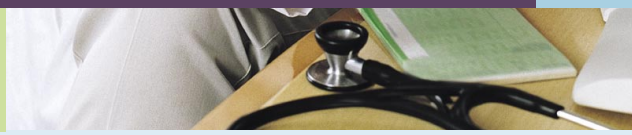
Pharmacology Research Institute

THE PRI BULLETIN

There's more than hope, there's PRI
SINCE 1975

■ VOLUME 23 ■ ISSUE 1 ■ WINTER/SPRING 2012



Is "65 The New 45," When it Comes to Our Memory Too?

By: Charles S. Wilcox, Ph.D.

We've all heard the ads about how, through healthier living and advances in medicine, people are now leading lifestyles almost 20 years younger than before – which is great! Most of us focus on the quality of our years as being even more valuable than the quantity of years we live...

In January of this year the British Medical Journal reported that, based on long-term study results involving more than 7,000 men and women, "mental decline can start at age 45"! Whereas many people have felt that age 65 and above was the average time point when memory loss was detectable, when men and women between the ages of 45 and 49 were tested-over-time for their memory, reasoning and vocabulary, there were measurable declines in cognitive performance of four and five percent, respectively. For those in the 65-to-70 age range, their cognitive skills declined by roughly ten percent.

The good news is that this heightened awareness (and additional scientific evidence) that our cognitive status is clearly at risk by age 45, can serve as extra motivation that changes in our lifestyle to improve our cardiovascular and overall physical health may also reduce the risk of declining cognitive health! These types of declines should not be interpreted to mean that all of these folks will develop Alzheimer's or any other type of dementia; nonetheless, they are one more call-to-action underscoring the need for all of us to work to prevent cognitive decline at younger ages.

As we age, knowing when cognitive decline has started and closely monitoring it can also be advantageous. The earlier treatment is initiated the more likely it is to be effective... Eventually, it is hoped that a biomarker will be reliably predictive about the forthcoming onset of Alzheimer's before the symptoms are noticeable. Currently, the Alzheimer's Association is working with organizations like PRI as part of the Alzheimer's Early Detection Alliance (AEDA™) to raise the awareness of people (especially people ages 65 and over) about the 10 Warning Signs (on pg. 2), along with the importance and benefits associated with early detection and early diagnosis. The benefits associated with an early diagnosis are extremely helpful to patients, as well as their families and friends.

AEDA CHAMPION
alzheimer's early detection alliance
alzheimer's association

If you and/or your loved one have "Memory Concerns," we encourage you to call the PRI office nearest you to learn about our latest medication research studies, as well as our Memory Tracking Program. Ideally, we would all like for "65 to be the new 45" both physically and mentally!

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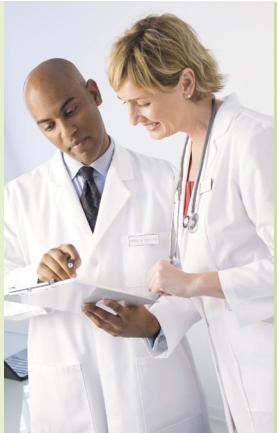

Spotlight on YOU!

By: Charles S. Wilcox, Ph.D.

As one of the recipients of The PRI Bulletin you have often read about our "Featured PRI Team Member," in several editions – including this one! Just as we are proud and grateful for our hard-working colleagues, we are equally proud and extremely grateful to you – the tens of thousands of YOU – who have participated in a PRI Study over the past 37 years! It has often been stated that the greatest gift is giving anonymously, when one has no idea if he or she will ever receive any direct personal benefit; this is the gift that many of you have given by taking part in clinical research!

In 2010 and 2011 we received so many thoughtful letters and e-mails telling us about the degree to which becoming involved in a PRI Research Program improved your lives. Already this year, I have met with a good number of prior study participants in order to learn first-hand about these positive research-related experiences. While confidentiality has been one of the key cornerstones of success for PRI since 1975, we have been very impressed by the number of you who have volunteered to "share your research experience story" with our readers. So, beginning with our next issue, you will see the "Spotlight on You" column as the first in a series of "Featured PRI Study Participant" brief articles, introducing you (our readers) to some of the people who have volunteered to share their stories as a means of encouraging others to join and participate in a clinical trial.

The investment in research that you, and others like you, have made has paved the pathway for the successful treatment of people all around the world! Medical advancements which improve the quality-of-life for these millions of people would never have happened without dedicated individuals like you; and, we Thank YOU!

Why Should I Participate in a Research Study?

By: Clifford Feldman, M.D., J.D., M.F.S.

Many people see advertisements on television or in the newspaper or hear them on the radio about pharmaceutical research studies. They wonder if a pharmaceutical research study is right for them. I often get asked questions about research studies and who would be appropriate for such a thing. Many are curious about study participants, methods and study medications. People also wonder about the types of new drugs being researched as some have been disappointed with their own medications or others currently on the market.

Studying new medications in a research protocol is an essential way to break new ground in treating such things as Major Depression, Memory Loss/Alzheimer's Disease, Anxiety and ADHD, just to name a few. Volunteers for a particular study are an essential element in the research process, sometimes helping uncover major breakthroughs in the treatment of an illness. There is a good chance that a patient will not only help alleviate his or her symptoms to a degree, but in doing so may help thousands of others as well.

People have their own reasons and motivations for entering a pharmaceutical research study. Some are frustrated with their current medications and seek something novel. Some enjoy the fact that they may be helping gain approval for a medication that can help many. Most feel assured that their health will be closely monitored and hope their symptoms improve during the study. Patients will often be compensated for their time and travel for participating in a research study, but this should not be the sole motivating factor to enter such a study.

The volunteer is a vital and essential element of any study. The volunteer has a chance to feel better and to possibly help many people in the future. Volunteers provide vital data on medications' side effects and clinical effectiveness. These things cannot be studied in a test tube or a vacuum. Patients are evaluated regularly by a highly trained, supportive treatment team often consisting of physicians and registered nurse practitioners, among others. Information from studies is ultimately published to disseminate the findings. Pharmaceutical companies can glean information from these published reports to develop more effective, potent medications with fewer side effects.

Volunteering for a pharmaceutical research study is a noble endeavor. The patient, while seeking help for him or herself, is potentially helping many others alleviate their symptoms as well; with the satisfaction of knowing this, comes complimentary medical follow-up. The next time you feel dissatisfied with your current medications and feel like trying something new and perhaps different, you should consider entering into a clinical trial. You may be happy that you did!

alzheimer's association®

KNOW the 10 SIGNS

EARLY DETECTION MATTERS

If you recognize any of these signs in yourself or a loved one, it is recommended to consult with a physician for further evaluation. **Early detection is important!**

- **Memory Loss that Disrupts Daily Life**
- **Challenges in Planning or Solving Problems**
- **Difficulty Completing Familiar Tasks, at Home, at Work or at Leisure**
- **Confusion with Time or Place**
- **Trouble Understanding Visual Images and Spatial Relationships**
- **New Problems with Words in Speaking or Writing**
- **Misplacing Things and Losing the Ability to Retrace Steps**
- **Decreased or Poor Judgment**
- **Withdrawal from Work or Social Activities**
- **Changes in Mood and Personality**

NEW AT PRI

What's New at PRI?

By: Charles S. Wilcox, Ph.D.

Alzheimer's Disease

The PRI Team has been on the leading edge of Alzheimer's-related research since the 1970s and today, in 2012, our commitment has been intensified! While currently marketed medications focus on symptomatic approaches that target synaptic function and cognitive enhancement, studies are now ongoing based on the "amyloid hypothesis" which suggests that an overproduction of Abeta and/or a failure to effectively clear this peptide leads to Alzheimer's disease. Newly initiated studies at PRI, which embrace the rationale of "modifying the progression of the disease," are now enrolling! One of the very positive aspects of these studies is that the research medication is added to one's ongoing treatment; so, your loved one can continue taking their Aricept® and/or Namenda™ – plus have the benefits associated with participation in a clinical trial! The latest information from the Alzheimer's Association indicates that for all Alzheimer's patients involved in clinical trials, independent of whether they received the active treatment or the placebo, their overall mental status declined more slowly when compared with patients at similar stages who were not participating. Please join us in this **'race-to-find-a-cure'!**

Depression

Depression is a serious illness and the **"side effects" of non-treatment** can become increasingly severe over time, taking a toll on patients, their families, co-workers and friends. The data showing the impacts and costs within the workplace are well into the billions of dollars. The lifetime prevalence of depression (or major depressive disorder – excluding bipolar disorder, etc.) affects literally millions and millions of people – each year. Sadly, in spite of the increased awareness, studies have shown that only 22% of people seeking treatment receive adequate treatment. As noted on our website, PRI has been involved in the evaluation and eventual commercial availability of numerous advancements in the treatment of depression! Together, with our current study participants, we are evaluating a promising array of potential advancements for the treatment of depression! If you are currently suffering from depression, we encourage you to call the PRI office closest to you – today!

Treatment Resistant Depression

Recently published estimates indicate that approximately 30-to-40% of people treated with an antidepressant do not achieve a completely satisfactory response. Furthermore, this shortfall on improvement is frequently associated with an increased risk of relapse, increasingly impaired levels of social, academic and/or vocational functioning, greater odds of other medical problems and a higher utilization of health care services in general. Treatment Resistant Depression [TRD] is often defined as **an inadequate response to an adequate dose** (and duration of treatment) with two different classes of antidepressant medications during the same depressive episode. If your antidepressant has not enabled you to reach the point of "being yourself again" – and fully enjoying life as you have in the past – please call us to learn about our newly initiated TRD studies. Even if you feel "somewhat improved" after an adequate period on your current antidepressant, enrollment in a TRD study may help you to achieve the full response that you are seeking!

Antidepressants and Sexual Dysfunction

We've all heard those commercials where the announcer speaks slowly, calm and cool for the majority of the time and then during the last ten seconds he speaks a-mile-a-minute about the "potential side effects" which may be 1 in 100, 1 in 1000, or even lower odds – but still (for legal reasons) need to be stated. One of the more common potential side effects from the antidepressants, Celexa® (citalopram), Paxil® (paroxetine) and Zoloft® (sertraline) is sexual dysfunction. In fact, while 14% of study participants spontaneously reported sexually related side effects, published reports indicate that the prevalence may be as high as 30% depending upon the medication – and in one published study 56% of the patients reported some level of **sexual dysfunction, including decreased interest.** At PRI's Encino and Newport Beach offices we are currently evaluating a new antidepressant for people (ages 18-to-55) who had relief from their depression (with one of the above-referenced antidepressants) but, also experienced decreased sexual interest (libido) and/or some other aspect of male or female sexual functioning.

PRI's Memory Tracking Program

Are you between 50 and 85 years of age and experiencing memory problems or concerns? Detectable declines in our memory begin at about 45 years of age. Our Memory Tracking Program is a no-cost opportunity that allows for semi-annual memory assessments for everyone with a memory complaint or concern. Although it is not a requirement, having someone to verify or corroborate that your memory has been 'slipping-a-bit' can be advantageous. These confidential (no-hassle and no insurance needed) assessments may not only help you, your involvement can be beneficial to millions of other people by **helping us to learn more about early-detection and (in some cases) early-intervention.**

The PRI Bulletin
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Los Alamitos, CA 90720

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Jennifer Pack, R.N., M.S.N., N.P.

By: Mellissa Henry, R.N., M.S.N., N.P.

Jennifer Pack, R.N., M.S.N., A.C.N.P.-B.C., is a valuable member of our clinical research team at the Los Alamitos office. Jennifer grew up in the Midwest and attended Valparaiso University in Indiana earning her Bachelor's degree in nursing. During her studies at Valparaiso University, Jennifer volunteered to go to Haiti on a nursing mission trip. While in Haiti, she worked very closely with a Nurse Practitioner in a Haitian Medical Clinic. This unique experience cultivated Jennifer's desire to become a Nurse Practitioner. Jennifer then moved to California and continued her nursing education at the University of California at Los Angeles, where she obtained her Master's degree in Nursing specializing in Acute Care.

Jennifer's work history includes Nurse Practitioner positions in the areas of Neurosurgery, Cardiology and Pain Management. With over 18 years of nursing experience, Jennifer quickly became a key member of the PRI Team. She decided to pursue work in the research field because of her desire to be a part of a team seeking out new therapies for many ailments needing more effective treatments.

When she is not working, Jennifer enjoys being outdoors. She has participated in marathons and ran one year with "Team in Training" to help raise money for the Leukemia and Lymphoma Society. Jennifer also enjoys bicycle riding, attending fitness classes and reading a good book.

Jennifer's flexible and adaptable style has made her very much appreciated by both co-workers and study participants alike. Given her many finely-tuned nursing skills and an abundance of extraordinary compassion, Jennifer makes study participants feel very well cared for here at PRI!

We are very fortunate to have such a compassionate and energetic individual as a member of the PRI Team.