

Since 1975: Convenient, Personal & Professional



Pharmacology
Research
Institute

THE PRI BULLETIN

A NEWSLETTER OF SCIENTIFIC RESEARCH FOR QUALITY MEDICAL CARE

Quality of Life – It’s what *really* matters most!

by Charles S. Wilcox, Ph.D.



One of the most consistent evolutionary changes in the field of clinical research has been the ever-increasing number of rating scales and assessment tools to measure a drug’s effects, particularly in the areas of psychopharmacology/neuropharmacology.

Amongst the more important innovations has been the introduction of *Quality of Life [or QOL]* measures. While open to a wide array of definitions and interpretations, virtually everyone has feelings, thoughts and hopes about sustaining or improving their quality of life.

In addition to the traditional rating scales designed to evaluate a medicine’s effects on one’s mood, cognition and behavior, it is now routine to investigate genomic and economic measures or implications as well. While nearly all of these tools and indices have scientific, regulatory and commercial importance, from the study participant’s perspective, the key issue is usually *quality of life*. The World Health

Organization (WHO) identified three key components to one’s quality of life: physical, emotional and social well-being. For all of us, quality of life is something that has normal fluctuations over time. Importantly, QOL measures mandate a patient-centered approach to research and all of us here at PRI endorse that philosophy. Stated differently, QOL measures can help to identify the real “utility” of a new medicine. It’s another way of asking [and answering] the question: “What difference will this new medicine possibly make in my life?” We often hear that people are far more concerned about their long-term functionality [i.e. their strength, energy and ability to carry on normal activities of daily living] rather than the number of

continued on page 3

Methods for Smoking Cessation

by Jon F. Heiser, M.D.

What’s the best way to quit smoking? Whatever works best for you! Many different approaches to stopping smoking are available. All are effective for some. None is effective for all. Techniques range from education, organized group programs, hypnosis, acupuncture, medications, and even negative conditioning with electric shocks. Medicines to aid in smoking cessation include: 1) nicotine, 2) compounds designed to regulate central areas of the brain (including craving), and 3) compounds similar to nicotine.

It is important to note the difference between nicotine and the other compo-

nents of tobacco smoke. Nicotine is the only addictive component of tobacco smoke, while the other components of tobacco smoke, such as tar, are not addictive but are responsible for all the health problems related to smoking. Therefore, medicinal aids in smoking cessation are based upon nicotine systems (e.g. nicotine gum, nicotine patch, nicotine aerosols) as a stepping stone in the aid to stopping smoking. The idea of all nicotine systems is the same: stop smoking, substitute the safe and pure nicotine delivery system, then gradually (over a period of weeks) decrease the

continued on page 2

INSIDE THIS ISSUE

Quality of Life – It’s what really matters most! . . . 1

Methods for Smoking Cessation . . . 1

The Risks of Not Getting Treatment . . . 2

The Professionals at PRI . . . 3

What’s New at PRI? . . . 4

The Risks of Not Getting Treatment

by Nader Oskooilar, M.D., Ph.D.

People often say, “I hate taking medications... I am not a pill person... I only take things from natural sources... Medications are my last resort...” Unfortunately, these attitudes might place some people at a greater risk for illness and/or disability, by holding onto very strict biases and standards about the use of medications.

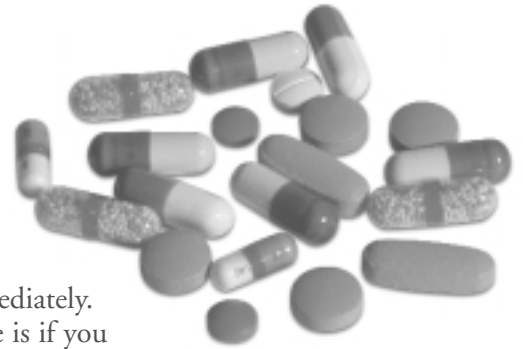
Resistance to taking medications may also be based upon one’s culture, religion, upbringing, or simply due to personal reasons. Whatever the underlying basis, one needs to separate fact from opinion. The fact is one can evaluate the need to take medication, like any other decision, based on benefits and risks. Does it usually cause more harm or good? If the benefits of taking medication far outweigh the risks, not taking medication is more harmful.

For example, if you are suffering from headaches and decide to “wait them out” until they go away, especially if they last more than a day, chances are your brain and body are going to sustain much more strain,

and possibly suffer damage, than if you treated the headaches with medication immediately.

Another example is if you had chronic insomnia and delayed getting medical treatment. It is very likely that the sleeplessness could get worse and you may develop additional problems, such as anxiety and depression. You may also resort to alcohol and/or illegal drugs and become dependent upon them. Furthermore, the pressures of insomnia itself could elevate the level of stress hormones in the body continuously over a period of time and weaken the body’s natural defenses, thus making an individual more vulnerable to illnesses.

A look into some of the personal reasons for not taking medications reveals that all reasons end up being personal in the final analysis. Some people may feel



continued on page 3

Continued from page 1. **Methods for Smoking Cessation**

intake of nicotine to nothing. One could achieve the same result by gradually cutting down on cigarette smoking except for one problem—it doesn’t work! This is due to the numerous social and psychological cues suggesting “it’s time to light up” that become second nature to smokers.

Compounds that regulate areas to the brain, thought to be critical to the process of addiction, are of interest because they may cure nicotine addiction; furthermore, there is evidence that many, possibly all addictions share a “final common pathway” or center in the brain. At PRI we are studying potential new medications that seem to regulate central areas of the brain. One of the research medications we’re evaluating at PRI may also regulate the center in the brain involved with other addictions, such as food addiction. It is possible that the new medication or a related compound may also assist in treating addiction to alcohol, various drugs and even behaviors such as compulsive gambling or compulsive stealing. An immediate payoff to participants in this new study may also be the prevention of weight gain while quitting smoking.

Analogues of nicotine (compounds similar to nicotine) have many of the properties of nicotine, but differ in important respects. It is these similarities and differences from nicotine which make such compounds



candidates for helping with smoking cessation. For example, a nicotine analogue might resemble nicotine enough to produce some aspects of nicotine satisfaction. At the same time, its effects may linger longer than nicotine in such a manner as to diminish or prevent withdrawal and craving for nicotine.

Tapering down to zero with a nicotine analogue could be easier than tapering pure nicotine. PRI is currently evaluating a nicotine analogue, in a comparison study against a marketed medication and placebo.

Finally, the old stand by of quitting “cold turkey” is easier and often more successful than tapering tobacco use. While nicotine itself is the ideal medicine to eliminate all withdrawal symptoms immediately and completely, nicotine cannot stop the withdrawal and craving that accompanies gradual reduction, whether it’s withdrawing from cigarettes or withdrawing from nicotine itself. This leaves you with two choices, the same two choices you have when removing adhesive bandage from your skin! Get it over with quickly (cold turkey) or make it less painful for much longer (gradual taper).

Participation in a study is a good way to get the two-pronged approach to smoking cessation. Both of PRI’s new smoking cessation studies provide patients with effective psychological-based smoking cessation counseling programs, plus the new research medication!

Continued from page 1. **Quality of Life — It's what really matters most!**

years they hope to live. For example, one study indicated that [on average] individuals would trade-off 14% of their full life expectancy to avoid a loss of their speech capabilities.

While QOL measures will not [at least yet] provide sufficient evidence for regulatory [FDA] approval of a medicine, they are gaining wide acceptance amongst researchers and patients alike. Interestingly, as we have worked in the area of Alzheimer's research since the 1970s, we now see the much-deserved attention and focus on how a potential new anti-Alzheimer's medicine will help the quality of life of both the patient *and* his or her caregiver. Similarly, when we evaluate medicines for anxiety, adult attention deficit disorder [ADD/ADHD], depression, migraine headaches, mild cognitive impairment, smoking cessation and social anxiety disorder [social phobia], as just a few examples, in addition to completing the conventional rating assessments, we now work with study participants to evaluate the potential new medicine's ability to significantly improve one's quality of life.

The ability of QOL assessments to identify real drug effects that are meaningful to an individual is the hallmark of their value. Ironically it was 55 years ago when the World Health Organization published a document encouraging scientists, physicians, sociologists and epidemiologists to define health in a more complete manner: "a state of complete physical, mental and social well-being—and not merely the absence of (an) infirmity." It is our sincere hope that today's research medications really will improve one's complete quality of life; in the end, it's what *really* matters most!

The Professionals at PRI

RoseMarie Lara, R.N., M.S.N., N.P. is a member of our clinical research team at the Northridge office. She brings to the position eight years of nursing experience and twelve years of academic (medical) preparation. Before completing her bachelor's degree in nursing from UCLA, RoseMarie had already completed four years of pre-med courses before changing to the nursing program. She continued with her education to obtain a master's degree in nursing with an emphasis on emergency medicine and cardiology. A California native, RoseMarie is originally from Oxnard in Ventura County and maintains an active, sports-oriented lifestyle. She enjoys snowboarding in the winter and surfing in the summer with basketball and softball in between with her family. Working in the medical field seemed like the obvious choice for RoseMarie since seven out of her eight siblings are in the medical field. She finds working with patients very rewarding and the medical research field equally gratifying.



*RoseMarie Lara,
R.N., M.S.N., N.P.*

Continued from page 2. **The Risks of Not Getting Treatment**

stronger and more proud of themselves if they can tolerate pain, depression, anxiety, etc. without medical treatment. The fact is, the person who seeks timely and appropriate medical treatment is the one who shows better judgment and is more likely to remain healthy and functional, as well as being strong and proud. Some people may feel weak if they take medications. These people are similar to those who take pride in tolerating pain. They are also pretending to be strong and proud, yet they may lack the insight and may be struggling with personal shame that could be explored sensitively and hopefully resolved. Another potential reason for resistance is what is called "secondary gain." In a nutshell, it may amount to a need for attention, respect, and social recognition by showing resistance to treatment; however, these supposed benefits are usually temporary and illusionary.

There are, of course, some individuals who take far too many medications, take them indiscriminately and develop a dependence on medications. These behaviors might be as detrimental, if not more, as resisting treatment when it is indicated. Dependence on medications might be from different convictions but it usually is a way of coping with internal conflict and insecurities. A little insight and education will often alleviate some, if not most, of these obstacles.

We should ideally approach the decision to take medications or accepting medical treatments like any other important decision, based upon benefits versus risks. Physicians and clinicians should also be very sensitive to patients' feelings and preferences, no matter how unrealistic they might appear. It is by understanding the individual client that we appreciate his/her unique mind and thus have a chance to influence them in a more healthy and stable direction.

The PRI Bulletin is an official publication of the Pharmacology Research Institute and is intended for patients and friends of the Institute. PRI does not rent, sell or trade its mailing list with any other organization or company. Your personal information is kept completely confidential. Inquiries and changes of address may be directed to any one of the sites below.

Medical Directors

Jon F. Heiser, M.D.
Daniel E. Grosz, M.D.
Robert D. Linden, M.D.
Alan L. Schneider, M.D.

Associate Medical Directors

Ronald L. Warnell, M.D.
Nader Oskooilar, M.D., Ph.D.
Don F. DeFrancisco, M.D., Ph.D.

Executive Director

Charles S. Wilcox, Ph.D.

PRI Bulletin Editor

Francine E. Cho, M.A.

Site Coordinators/Office Locations

My-Linh Tong, R.N., M.S.N., N.P.
4281 Katella Avenue, Suite 115
Los Alamitos, CA 90720-3589
714/827-3667

Barbara B. Katz, R.N., C.C.R.C.
1601 Dove Street, Suite 290
Newport Beach, CA 92660-2452
949/752-7910

Judy L. Morrissey,
R.N., M.S.N., C.C.R.C.
8435 Reseda Blvd.
Northridge, CA 91324-4625
818/349-4311

Donna M. Adkins,
R.N., M.S.N., N.P.
3576 Arlington Ave., Suite 301
Riverside, CA 92506-3988
909/778-9600

E-mail address: pri@priresearch.com

Web Site: <http://www.priresearch.com>

What's New at PRI?

Alzheimer's Disease

PRI has been involved in the clinical evaluation of anti-Alzheimer's medications since the 1970's. While there are several marketed medications for the treatment of Alzheimer's, they usually slow the rate of decline—rather than completely stop the progression of the disease. Today there are approximately 30 new compounds in clinical development for the treatment of Alzheimer's. We have new or ongoing studies for patients categorized as mildly, moderately and severely impaired.

Adult Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is a common disorder that affects up to 5% of children. ADHD often persists into adulthood, thereby indicating that Adult ADHD may be a relatively common disorder that is under-identified. PRI Northridge [@ 818.349.4311] is currently enrolling adult ADHD patients [ages 18 to 55] as part of a nationwide study with a potential new anti-ADHD compound. Quality of Life Enjoyment and Satisfaction Questionnaires are a key component of this new study.

Anxiety/Nervousness

Do you worry? Are you sometimes anxious, tense or nervous? Anxiety is an illness that affects millions of people; however, far too often people wait until they physically wear out [i.e. suffer from ulcers, high blood pressure, etc.] before they reach out for help. We have new and ongoing anti-anxiety research medication studies at all four offices.

Feeling Blue? More than Blue?

Whether it's called "Senior Sadness" or "Just the Blues," depression is not a personal weakness nor is it something that can be willed or wished away. Suffering in silence needlessly prolongs the pain and emptiness. If you are currently suffering from depression we encourage you to call the PRI office nearest to you.

Smoking Cessation

Did you know that California has the lowest rate of smokers [per capita] in the nation? It's true! However, there are still hundreds of thousands of smokers in California and for those who are *really* motivated to stop smoking, we have new or ongoing smoking cessation studies at our Riverside, Los Alamitos and Newport Beach offices. If you are *really* ready to quit – for good – please call us today!

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

THE PRI BULLETIN

Pharmacology Research Institute
Post Office Box 1645
Los Alamitos, California 90720-1645

Return Service Requested