



Parkinson's

Companion

Voices of Parkinson's

The Yellow Jacket—A Look at a Clinical Trial by Ralph Schwarz

My three children gave it to me. It was a yellow windbreaker, and I looked cool in it—my children told me so. I was wearing it the day my son-in-law called 14 years ago to tell me my daughter had been 'life-flighted' to The Cleveland Clinic. Her pregnancy had gone horribly wrong. I was still wearing the jacket 12 hours later when I arrived at intensive care. My daughter relates that, although barely conscious, she saw the yellow jacket, knew that her Daddy was there and that she and my wonderful granddaughter would be all right.

It was also 14 years ago that I was diagnosed with Parkinson's. My neurologist said that a cure was at most ten years away, so hang in there and be optimistic.

Two years ago, my son came across a Phase II clinical trial that had shown encouraging Phase I results. Twelve PD patients had received a procedure involving attachment of a steel frame to the skull, MRI brain mapping and precision surgery to inject genetic material. A year later, all showed 30-50 percent reversal of symptoms and arrest of PD progression. It sounded absolutely too good to be true! The surgeon was guardedly exuberant and The Michael J. Fox Foundation enthusiastically contributed over \$1 million toward Phase II funding.

After exhaustive research and with consensus approval from my family, I notified The Cleveland Clinic of my interest. Thirty-four of 51 participants would randomly receive the full surgery while 17 underwent all but the injections in this "double-blind" procedure. The surgeon would be instructed only after anesthetizing the patient. If we were in the placebo group, we would be offered the real surgery the following year.

Accepted into the trial, evaluated on two

occasions and flown to Vancouver with my wife for a PET scan, I was operated on three weeks later. I awoke to see the faces of my concerned wife and mother. Then the nurse pulled the curtain back to reveal my three children, all wearing yellow jackets. I cried.

For the next 18 months, I was physically and psychologically tested on and off medication every three months: blood and urine tests, MRIs, another Vancouver PET scan and three-day diaries of my progress in 30-minute increments. I received no feedback for 20 months, and repeatedly imagined I was making progress—and the lack of it as well.

In December I got the word. I had been 'placeboed' and, despite the exciting Phase I results, the conclusion was that there was no appreciable difference between the real and sham surgery groups. The study was declared a stunning disappointment. The manufacturer apologized to the patients, doctors, and medical staff. All data, procedures and results are being reevaluated. I have many questions to ask all parties.

That was two months ago. What a lift to PD sufferers and caregivers it might have been to have the spark relit in their eyes at the prospect of a cure. As it is, the disappointment is tangible. I think I may have that jacket dry-cleaned.

Ralph Schwarz had a 37-year career designing and building commercial and institutional kitchens. In 2004, he moved to New Hampshire with his wife, Lynne, to own and operate The North Gallery in Peterborough, which they recently closed. He leads a life of hope, optimism, courage, humor and, above all, great love for his children, grandchildren and mother. You may contact Ralph at ralphschwarz@hotmail.com.



IN THIS ISSUE

- Voices of Parkinson's..... 1
- A Note from the Coordinator 1
- Parkinson's Wellness Program 2
- Faces of PD Professionals 2
- Ask the Doc 3
- Symposium Summary 4
- Announcements, Events and Support Groups 4
- Lending Library..... 4



National Office:
135 Parkinson Avenue
Staten Island, NY 10305
www.apdaparkinson.org
(800) 223-2732



A Note from the Coordinator Diane L. Church, PhD

It was a tough winter for many in the Northeast: icy roads and long power outages often diverted attention from beautiful snowy vistas and a spot by the warm fireplace. In this issue, we move into spring with another look at research in our cover story by a research trial participant and a Q&A by a DHMC neurologist/ethicist. And, we discuss ways to man-

age Parkinson's with a report on the PD Wellness Program adopted by DHMC in the fall of 2008 and an interview with a DHMC Occupational Therapist. Please note upcoming activities, including the April Parkinson's Awareness Month events in Concord and Lebanon. Be sure to contact me if you would like to borrow materials from our Lending Library.

Parkinson's Wellness Program A "Toolkit for Wellness"

People with Parkinson's often report difficulties with movement and communication, limiting their ability to perform tasks and participate in favorite activities. In the fall of 2008, the Parkinson's Center and Department of Rehabilitation Medicine at DHMC teamed up to offer an innovative wellness program to address these problems. Developed at The Center for Neurorehabilitation at Boston University, the program is based on research indicating that those with PD can improve their quality of life and ability to do everyday tasks through exercise and functional, task-oriented training.

In our pilot program, six participants gathered twice weekly for six weeks with rehabilitation specialists. Physical therapists Dawna Pidgeon, David Edson, and Maggie Stone taught exercises designed to improve motion, flexibility, and strength, coached participants on proper technique, and modified exercises according to individual needs. Participants received manuals and exercise books, and were encouraged to practice at home to further improve their outcomes.

Each meeting included discussion of three approaches to solving a given problem: change something about yourself, the strategy you use, and/or something about the envi-

ronment. For example, has your handwriting become small and illegible? Occupational therapist Dennis Tobin demonstrated exercising to improve hand coordination; changing strategies by using different types of pens or a computer; and changing the writing environment by using a cardboard template to cue larger writing. Perhaps you have had difficulty with communication due to reduced speech volume, intonation, and facial expressivity? Speech language pathologist Cheryl Lundgren introduced voice exercises that increase vocal cord and facial muscle flexibility; used strategies such as exaggerating facial expressions and practicing functional phrases; and suggested moving social interaction to a quiet environment with few distractions (Ms. Lundgren is a certified provider of Lee-Silver Voice Treatment, "LSVT®/LOUD," which is scientifically documented to help people with Parkinson's).

Most sessions ended with gait training to music. Participants were encouraged to focus on their "heel strike" and swinging arms evenly. As the tempo gradually increased, so did walking speed, stride length, and rhythmicity, and some broke into impromptu dance!

Participants enjoyed the social aspects of helping, encouraging, and laughing with



each other while soaking up the professional expertise offered by our Rehabilitation Medicine staff. Pre- and post-assessments suggested improvements in balance and in speed and ease of standing up/sitting down and walking. Participants reported improved posture, flexibility, and voice volume. The program will be offered at least twice annually at DHMC, and we hope to introduce the program at other sites across New Hampshire.

Faces of PD Professionals Dennis G. Tobin, OT

What is occupational therapy?

Occupational therapy (OT) helps individuals to be independent in performing daily tasks—such as personal hygiene, dressing, and feeding—and work, play, and leisure activities. Life challenges could be physical, behavioral, psychological, and/or developmental. OT focuses on improving function (rehabilitation) or helping individuals to live and cope with their limitations (habilitation).

How could someone with Parkinson's disease benefit from OT?

The therapist assesses one's limitations, helps

sort out which to address, and helps set goals depending on the individual's situation and support system. For example, many are challenged with dressing themselves. For some, independence in this task is a goal, while others will choose to rely on assistance from family members or caregivers. Together, the therapist and individual develop strategies to address personalized goals.

What are some OT strategies?

Adaptive equipment is frequently associated with OT and might prove beneficial. However, the OT first works with the individual to see if "rehabilitation" can accom-

plish his or her goals. Rehabilitative strategies include exercise (to improve strength and coordination), stress reduction, energy conservation, environmental modification and/or training to perform a task. Adaptive equipment is considered once other alternatives have been explored.

Is there anything else you'd like to add?

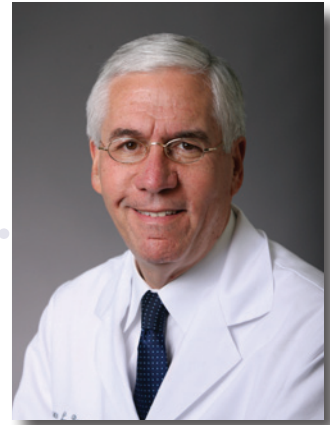
Each person with PD needs to determine what is important to them in their daily lives and to set realistic goals. Challenges can be great, but my advice is to stay focused and open to alternative strategies.

Dennis G. Tobin, OT, FACHE, received his bachelor's degree in occupational therapy from Boston University, MEd from the University of Massachusetts-Lowell, and MBA from Plymouth State University. He retired from the US Army Reserves with 28 years of service and is a Fellow of the American College of Healthcare Executives (FACHE). He has worked as an Administrative Director at DHMC since 1986.



Dennis Tobin, wife Patricia, and granddaughter Addison

Ask the Doc



James L. Bernat, MD
Professor of Neurology and Medicine,
Chairman, Ethics Committee,
Dartmouth-Hitchcock Medical Center

Q Is it ethical for an investigator to administer a placebo medication to a research subject in a clinical trial of a new drug for PD?

A Medications prescribed by physicians may be effective as a result of the therapeutic bond between patient and physician and not merely from the physical effect of the drug. This response is called the “placebo effect” because it can be produced by totally inactive ingredients (placebos). In Latin, placebo means “I will please.” The placebo effect is principally, but not solely, a psychological response. In the case of prescribing medications for pain relief, placebos stimulate the release of endorphins, powerful chemicals secreted within the nervous system that suppress pain.

The placebo effect is an important element of the beneficial response of many prescribed medications. When pharmaceutical companies develop new medications, the FDA requires the manufacturer to show that they are safe and effective. Because the placebo effect is powerful, newly developed drugs must exceed the benefit from a placebo to prove they are effective. Placebos also can produce side effects, so the manufacturer compares the side effects of the newly developed drug against those from a placebo.

Placebo use in clinical trials of new PD drugs is ethical if the subjects volunteering for the trial understand that they might receive a placebo instead of the tested new drug during part or all of the trial. Research subjects need to provide voluntary informed consent

to make their participation in the clinical trial ethical. An important element of consent is understanding the general study design, their role, what types of drugs they might receive, and anticipated benefits and side effects. Many clinical trials have a “double blind” design in which neither the subject nor the investigator knows whether the subject is receiving the new drug or a placebo until the trial ends. Subjects volunteering for these trials usually are “randomized” into each of the study groups to eliminate a bias resulting from physician or patient selection. Many trials have a “crossover” design in which midway through the trial, the placebo group is switched to the test drug and the test group to the placebo.

Q Is it ethical for “sham surgery” to be performed in PD research for innovative operations?

A Medications are not the only therapies that produce a placebo effect. Surgical operations induce a profound placebo effect. The strength of this effect is only now being fully appreciated by physicians and researchers. Although there is a scientific tradition in the development of new drugs (and an FDA requirement) to test them against placebo, there is less of a tradition for new surgical procedures to be tested in this way. Proving the benefit of appendectomy for acute appendicitis does not require a surgical trial but measuring the more subtle effect of some new operations requires assessing the surgical placebo effect

and showing that the operation’s benefit exceeds it. To measure placebo effect in surgery, a “sham” operation must be performed in which the subject is anesthetized, an incision is made, no further surgery is conducted, and the incision is closed.

The most famous trial including sham surgery in PD patients studied the effect of transplanting fetal dopamine neurons into the brain. Half of the subjects underwent sham surgery because it was clear that the benefit, if any, would be so slight that the study design required a surgical placebo group to detect it. Some physicians and ethicists criticized the performance of sham surgery as exposing subjects to too much risk for too little benefit, and stating that the degree of risk to subjects would not be tolerated in a study of medication effect. Others defended the study design claiming that without it, no knowledge could be gained that could help future patients, and that all subjects understood in advance that they might be randomized to receive sham surgery and consented freely. Although this debate continues, sham surgery remains a permissible study design to test the effectiveness of some innovative surgical procedures.

To submit a question to our Parkinson’s medical team, please contact our Information & Referral Center Coordinator at apda@hitchcock.org or call (603) 650-5280.

PARKINSON’S COMPANION IS A PUBLICATION OF THE PARKINSON’S CENTER AT DHMC

Department of Neurology,
an Information & Referral
Center of the American
Parkinson Disease
Association, Inc.

One Medical Center Drive
Lebanon, NH 03756
(603) 650-5280
apda@hitchcock.org
dhmc.org/goto/parkinson

Diane L. Church, PhD,
Coordinator/Editor
Medical Directors
David J. Coffey, MD
Stephen L. Lee, MD, PhD

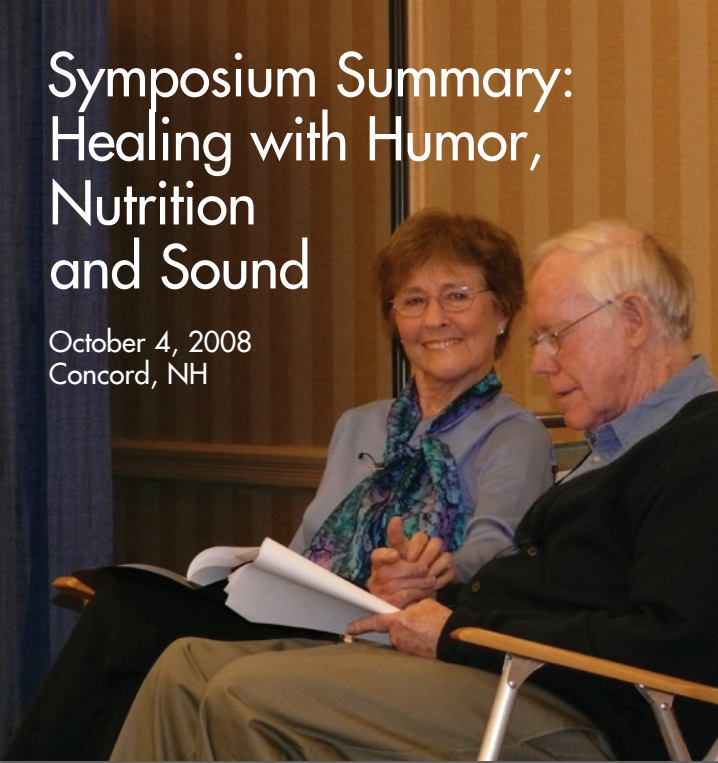
National Affiliation
American Parkinson
Disease Association, Inc.
135 Parkinson Ave.
Staten Island, NY 10305
(800) 223-2732
www.apdaparkinson.org

This newsletter is intended solely to provide you with information on Parkinson’s disease. You should not make any changes in your treatment without first discussing them with your healthcare provider.

200902-09

Symposium Summary: Healing with Humor, Nutrition and Sound

October 4, 2008
Concord, NH



Jo and Terry Ortwein had the audience laughing throughout their presentation of "I'm Herbert," a one-act play by Robert Anderson. Terry retired from teaching English and theater in 1997, a year after being diagnosed with PD. He underwent DBS surgery in 2007. Jo retired from a career that spanned virtually all aspects of nursing, from hospital nursing to teaching to case management for elders.



Paula Nash, RD, LD, provided an excellent overview of nutritional needs as we age. Paula has served as Nutrition Service Manager at Havenwood-Heritage Heights Retirement Community in Concord, NH for 15 years, providing nutrition assessments, education and the in-house TV segment "Nourishing News."

Stefany Shaheen, an advocate for stem cell research, likened embryonic stem cells to "wild cards" that, with expanded research, might be designated "dopamine-producing neurons" or "insulin-producing pancreatic cells." Stefany delivered a passionate plea for the support of political candidates dedicated to funding and expanding research into chronic illnesses such as PD and diabetes mellitus, which affects her young daughter.



Zacciah Blackburn demonstrated the use of music as a therapeutic tool for healing and transformation. Zacciah practices in Vermont at the Center of Light Institute of Sound Healing, teaches internationally, and directs sound-healing networks.



Photos by
Maureen M. Chamberlain

Announcements and Events

Thursday, April 16, 2009,
6:30–7:30 pm

Candlelight Vigil outside the State

House in Concord, NH: Governor's Proclamation of April as Parkinson's Disease Awareness Month. For more information on this and other APDA-NH Chapter fundraiser and awareness events, contact Maureen Chamberlain, President, at (603) 434-6252 or by email at MaureenMargaretC@aol.com.

Saturday, April 25, 2009
9:30 am–2:30 pm

Living with Parkinson's Disease: Communication, Exercise, and Dance Movement.

Fee of \$12 per person includes continental breakfast and box lunch at Dartmouth-Hitchcock Medical Center in Lebanon, NH. Space is limited. Pre-registration must be received by April 17. For more information, please call (603) 650-5280, send an email to apda@hitchcock.org or visit us on the Web at dhmc.org/goto/parkinson.

Saturday, June 20, 2009, 7:05 pm
Baseball Night: NH Fisher Cats vs.

Erie SeaWolves. Merchantsauto.com Stadium, Manchester, NH. Fireworks after the game! Fee of \$10 per person benefits APDA-NH. Purchase tickets from Maureen Chamberlain, (603) 434-6252 or by email at maureenmargaretc@aol.com. Ask about the Curt Schilling autographed baseball raffle!

Saturday, June 27, 2009
9:00 am–12:00 pm

Discover Treatment Options for People with Parkinson's.

Speakers include DHMC specialists David J. Coffey, MD, Neurology, and David W. Roberts, MD, Neurosurgery. Event held at Dartmouth-Hitchcock Medical Center in Auditoria E-F, Lebanon, NH. The event is free, but space is limited. Mid-morning refreshments will be provided. Register by calling (603) 650-5280 or email us at apda@hitchcock.org.

Ongoing

Powerful Tools for Caregivers.

Six weekly sessions, offered at least twice a year, each about 1½ hours, at the Health Education Center at Dartmouth-Hitchcock Medical Center, Lebanon, NH. For information or to sign up for the next session, call (603) 653-0868, email HealthyAging@hitchcock.org or visit us online at dhmc.org/goto/healthyaging.

Thank You to Our Donors

Our condolences to the family and friends of Bruce "Peter" Tuttle. We received many donations in his memory.

Support Groups

Parkinson's Support Groups

Concord, Keene, Lebanon, Manchester, Nashua, New London, Peterborough, Rochester, and Wolfeboro, NH. We are happy to announce a new support group in Exeter, NH!

Caregiver Support Groups

For caregivers and care partners of those with PD and other chronic illnesses: Bristol, Charlestown, Concord, Keene, Laconia, Lebanon, Meredith, Nashua, New London, Northfield, Portsmouth, and Wolfeboro, NH plus online possibilities.

To connect with or start a Parkinson's or Caregiver Support Group in your area, contact Diane L. Church at (603) 650-5280 or apda@hitchcock.org.

Lending Library

We have many books and DVDs. Selected titles, recently published and available for one month loan:

- **Carley** *Surviving Adversity: Living with Parkinson's Disease*
- **Christensen** *The First Year—PD: An Essential Guide for the Newly Diagnosed*
- **Friedman MD** *Making the Connection Between Brain & Behavior: Coping with PD*
- **Graboyes MD** *Life in the Balance: A Physician's Memoir of Life, Love, and Loss with Parkinson's Disease and Dementia*
- **Marie** *Various Ebook Printouts of Practical Tips Gathered from People with PD*
- **Meyer, Derr, Imke** *The Comfort of Home for PD: A Guide for Caregivers*
- **Stark** *Silence of the Bunnies: Tales of Life, Love and Survival*
- **Zid** *Delay the Disease: Exercise & Parkinson's Disease*

Please help us keep our shelves stocked! Return materials to:

Diane L. Church
DHMC Parkinson's Center 3C
One Medical Center Dr
Lebanon, NH 03756

To request a title, suggest materials that you have found interesting, update your mailing address or request an electronic version of this newsletter instead of a hard copy, please contact Diane L. Church at (603) 650-5280 or apda@hitchcock.org.