

I.G. LIVING!

IMMUNE GLOBULIN COMMUNITY

www.igliving.com

April-May 2008

Evidence-Based Medicine:

Defining Evidence



**Electronic Health Records:
In Theaters Everywhere
by 2014**

**Specialty Pharmacies:
Here Today,
What Tomorrow?**

A community service from FFF Enterprises and NuFACTOR Specialty Pharmacy Newsstand Price \$2.00

Our mission is to support the IG community through education, communication and advocacy

A community service from FFF Enterprises and NuFACTOR Specialty Pharmacy

Advisory Board

Erika Lawrence, PhD

Assistant Professor, Department of Psychology
University of Iowa

Todd Levine, MD

Director, Department of Neurophysiology
at Good Samaritan Hospital, Phoenix
Assistant Professor of Clinical Neurology,
University of Arizona

Fred Modell

Co-founder of the
Jeffrey Modell Foundation

Patricia A. Morrison, RPh

NuFACTOR Specialty Pharmacy

Marc Riedl, MD, MS

Assistant Professor, Department of Medicine
Clinical Immunology and Allergy
UCLA, David Geffen School of Medicine

Publisher **Patrick M. Schmidt**

Editor **Kit-Bacon Gressitt**

Assistant Editor **Cheryl Brooks**

Copy Editor and Proofreader **Jackie Logue**

Creative Director **Allan Bean**

Graphic Artists **Allan Bean**

Caroline Carlson

Kim Kinman

Contributing Writers

Ever Fecske

Amy Fuller

Lauren Gerstmann, MPH

Kit-Bacon Gressitt

Chris Ground

Cheryl L. Haggard

Mark T. Haggard

Zachary Pugh

Jessica Schulman, PhD, MPH, RD

Richard Robinson

Jeff Siegel

Shirley German Vulpe, EDD

©2008 FFF Enterprises Inc. All rights reserved.

Please direct editorial, advertising and marketing communications to
41093 County Center Drive
Temecula, CA 92591
Ph: 800-843-7477
Email: editor@igliving.com
www.igliving.com

Features

17 Electronic Health Records: In Theaters Everywhere by 2014

By Lauren Gerstmann, MPH

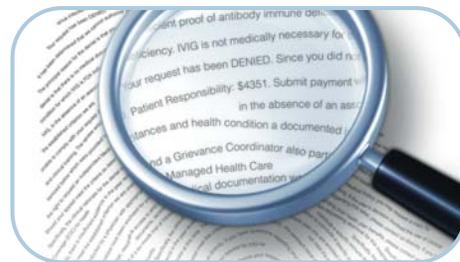


24 Specialty Pharmacies: Here Today, What Tomorrow?

By Jeff Siegel

26 Evidence-Based Medicine: Defining Evidence

By Kit-Bacon Gressitt and Amy Fuller



About IG Living

IG Living is the only magazine dedicated to bringing comprehensive healthcare information, immune globulin information, community and reimbursement news, and resources for successful living directly to immune globulin consumers and their healthcare providers.

IG Living, published bimonthly, is a community service provided by FFF Enterprises and NuFACTOR, 41093 County Center Drive, Temecula, CA 92591, 800-843-7477 x1143, fax 951-699-9655.

Subscriptions to *IG Living* are free, and readers may subscribe at www.igliving.com or by calling 800-843-7477 x1143.

The opinions expressed in *IG Living* are those of the authors alone and do not represent the opinions, policies or positions of FFF Enterprises, NuFACTOR, the Board of Directors, the *IG Living* Advisory Board or editorial staff. This material is provided for general information only. FFF Enterprises and NuFACTOR do not give medical advice or engage in the practice of medicine. FFF Enterprises and NuFACTOR under no circumstances recommend any particular treatment for any individual and in all cases recommend that individuals consult with a physician before pursuing any course of treatment.

All manuscripts should be submitted in MS Word, in Arial font. Manuscripts should be between 650 and 1,300 words in length, with unjustified margins and without any other formatting. Submission guidelines are available for download from the Contact Us page on www.igliving.com. Email manuscripts to editor@igliving.com. *IG Living* retains the right to edit submissions. The contents of each submission and their accuracy are the responsibility of the author(s) and must be original work that has not been, nor will be, published elsewhere, without the written permission of *IG Living*. A copyright agreement attesting to this and transferring copyright to FFF Enterprises will be required. Acceptance of advertising for products and services in *IG Living* in no way constitutes endorsement by FFF Enterprises or NuFACTOR. ©2008 FFF Enterprises Inc.

Departments

- 4** **IGL Editorial**
By Kit-Bacon Gressitt
- 8** **Lifestyle Celebration**
By Ever Fecske
- 22** **IG and Jet Fuel**
- 29** **Let's Talk**
By Shirley German Vulpe, EdD
- 36** **The Secret's in the Sauce**
By Cheryl L. Haggard
- 12** **Inquiring Minds Ask Kris**
- 14** **Parenting The Metamorphosis**
By Mark T. Haggard
- 35** **Community News From the Neuropathy Action Foundation**
- 10** **Medical News A New Molecular Mechanism Is Implicated in Sporadic Inclusion Body Myositis**
By Richard Robinson
- 13** **Where Does My IVIG Come From? IVIG Supply Consistency**
By Chris Ground
- 30** **Managing SCIG Expectations**
By Kit-Bacon Gressitt
- 32** **Hope Is In the Blood: IVIG and Alzheimer's Disease**
By Zachary Pugh
- 38** **Nutrition Troubled Waters: Preventing Waterborne Illnesses**
By Jessica Schulman, PhD, MPH, RD
- 43** **Resource Directory**



Join an IGL Readers Group!

We hear from many, many patient and family member readers who would like to connect with others in their geographic areas—to share their experiences living with chronic diseases or maybe just to have a cup of coffee with folks who understand.

We can help you determine if there's a patient organization support group in your area or help you start an IG Living Readers Group.

To join a group or start one in your own area, visit www.igliving.com and click on IGL Readers Groups.



Old Friend, New Advisor

We are very pleased to introduce Dr. Todd Levine, our new *IG Living* Advisory Board member. Dr. Levine is board certified in psychiatry and neurology and he is co-director of the Samaritan Peripheral Neuropathy Center; director of the Samaritan Stroke Clinic and the Samaritan ALS Clinic; director of the Department of Neurophysiology at Good Samaritan Hospital; assistant professor of Clinical Neurology at the University of Arizona; and a member of the Medical Board of Directors of the Neuropathy Action Foundation. He has a private practice in Arizona, Phoenix Neurological Associates, and he is well-regarded by his peers and well-loved by his patients.

Although new to the board, Dr. Levine is not new to *IG Living*. He is a regular consultant to our “Ask Kris” column, providing thoughtful answers to many of the great questions sent in by our readers. We are grateful for the wisdom and heart he brings to the magazine. Welcome, Dr. Levine!

Seeking Interns With Smarts and Hearts

The Alliance for Plasma Therapies is offering internships for college students in its Washington, D.C. office. Responsibilities include educating members of Congress and federal officials about the diseases treated with immune globulin and the importance of access to IVIG for all patients in all sites of care. Additional work includes research projects and interaction with members of the immune globulin community. There is a small stipend, and the Alliance will coordinate with colleges to qualify the internship for credits.

To apply, submit a 500-word essay on the following topic: “Why I am interested in the Alliance for Plasma Therapies internship,” and be sure to describe any knowledge you have about IVIG and the diseases treated with it. Send the essay with your resume and any other information you would like the Alliance to consider to: Alliance for Plasma Therapies, P.O. Box 65200, Washington, D.C. 20035-5200 or email your application materials to info@plasmaalliance.org.

How About a Hug?

We received an interesting “Ask Kris” question that one of our consulting physicians, Dr. Richard Schiff, suggested might warrant some special attention—and we agree!

A reader asked if people with immune deficiencies should avoid physical contact with others. This raises the prospect of losing out on the wonderful and often healing benefits of human touch, whether a patient experiences a warm handshake or a comforting hug—a sad prospect indeed.

According to Dr. Schiff, “Everything has a risk-benefit ratio. The more susceptible you are to infection, the more important it is to keep more to yourself. A SCID patient before and during transplant must be kept isolated because infections could be fatal. A CVID patient may get more colds, but with proper treatment will avoid more serious complications such as pneumonia. A large justification for IVIG treatment is to allow patients to lead more normal lives. I don't think anyone says patients shouldn't hug. I hugged my patients all the time. However, it is important to practice good hand washing or use disinfectant gels after contact (e.g., after shaking hands, before eating, touching your nose, etc.), and avoid people who are actively sick. There are a lot of practical ways to reduce risk without becoming a hermit.”

Dr. Schiff wonders how others would respond to this question. Send your answers to editor@igliving.com.

A Fond Farewell

This is my last issue as editor of *IG Living*. I am sad to be moving on, but I will take with me countless “IGL” moments that are precious to me—and plenty that made me laugh just a bit too much. I am grateful to have come to know our writers, Advisory Board members, the team that creates each magazine, our advertisers and so many of our readers. The generosity of time, talent and heart that you all bring to *IG Living*, the willingness to share poignant sorrows and successes with the hope of helping others, the courage and creativity repeated in so many of our readers lives; these are the stuff that makes parting such sweet sorrow. Thank you! 📌



RIM Study

Rituximab in the Treatment of Refractory Adult and Juvenile Dermatomyositis (DM)
and Adult Polymyositis (PM)

Building strength for the future...

The RIM Study is a NIAMS sponsored multi-center clinical trial being conducted at 34 locations in the United States, Canada and Europe. This study will be directed and coordinated by Chester V. Oddis, MD, Professor of Medicine, University of Pittsburgh Division of Rheumatology and Ann M. Reed, MD, Professor of Pediatrics and Medicine, Chair Pediatric Rheumatology, Mayo Foundation and School of Medicine at the Mayo Clinic.

The goal of this study is to examine the effectiveness of rituximab, a biological agent that has been studied in adult and pediatric autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosus. The result of this study will help determine the drug's potential benefit in the management of individuals diagnosed with myositis.

DURATION OF STUDY:

Eligible participants will be asked to participate for up to 45 weeks for a total of 14 study visits. The study doctor will be measuring muscle strength and evaluating the symptoms of the disease. Other study tests include an electrocardiogram (ECG), physical examination, and blood testing for muscle enzymes, general chemistry and immunological tests. Study subjects may be asked to voluntarily consent to participate in a sub-study in which a muscle biopsy will be performed from a weakened muscle at study entry and again at four months. All study participants will receive the investigational study drug while participating in the study.

YOU MAY QUALIFY IF:

- You are an adult with a diagnosis of polymyositis or dermatomyositis or are five years of age or older with a diagnosis of juvenile dermatomyositis
- You have had an inadequate response to prior immunosuppressant treatment(s)

For a complete list of inclusion/exclusion criteria, please visit the RIM Study website at www.rimstudy.org

Please visit the following websites to obtain more information or find a center near you. ►►►

Study Website
www.rimstudy.org

Clinical Trials Website
<http://www.clinicaltrials.gov/ct/show/NCT00106184?order=4>



**RIM Study
Coordinating Center
(412) 647-3241
(412) 647-3105**



By Ever Fecske

The highs and lows of a chronic illness can drain one's morale, and, while it may be beneficial to stay on an even keel, the need for happiness and celebration is still prominent. Life and illness have their ups and downs, so when is it time to celebrate? With every word of good news comes relief and hope, but riding the emotional roller coaster perhaps isn't the healthiest response. So, I believe in having a little party

on the inside when I get some significantly good news. The challenge is to keep a balance in a world that is so unbalanced.

I have found my physical health directly affects my mental health. The mind is such a powerful tool. But seeking out other tools to cope is sometimes necessary.

About a year and a half ago, I started to notice I was feeling down all the time. I was overwhelmed with all

that was going on in my life, from procedures to medications—and no promising news. I was stuck in a rut and my doctors didn't even know what to do or where to go with my confusing diagnosis.

I decided it would be beneficial for me to see a therapist. I needed to be able to speak openly about the way I was feeling—with someone who wasn't involved in my situation, so I could say anything without hesitation. For too long, I had sugarcoated my words because I was more concerned with protecting those around me from the pain I was feeling. Therapy gave me the opportunity to share my hopes and fears and all the injustices I felt. It was such a relief to have someone objectively listen and question thoughts that may have been irrational, but, most of all, it was the best to have someone there to encourage me and tell me what a good job I was doing.

My therapist, Karen, told me how strong I was and how I was experiencing things that most people would never have to experience. That alone makes me a better, more understanding person. She also helped me cope with many challenging events, and she was there when I had something to celebrate. Before, when I got good news, I was so hesitant to enjoy the relief that came with the news, because some other bit of information might cancel it out. Karen told me that feeling happy about good news is normal and healthy. She said I should celebrate and reward myself for making it this far and still being strong. She is right.

Living in the moment is important. So, when I get a bit of good news, I celebrate the news and the journey I have been on by doing something small for myself. I treat myself to a pedicure or something pretty to wear in my hair, anything that will make feeling good last a little longer.

I feel the real challenge is sharing that party with those around me. There is no question that, when I get some good news, I run right to my family to share it with them. They get more pleasure out of the good news than I. The way I think of it is, my family is immune deficient by association and, though they don't have COVID, they go

through the ups and downs with me. My family feels the heartbreak and helplessness I feel at times when my doctors don't know what to do. It is normal for me to be optimistic because that's just my nature. But, at times, I feel my family has doubts. I also know, more than anything, they want the old Ever back. When I am feeling well, that is my gift to them—I dance around the room and sing in the shower the way I used to. I know they look for those small hints to let them know I am feeling good.

Perhaps we can learn from each other's experiences. When we live in the moment, it eliminates the very stress that complicates our conditions. When we live in the moment, we love and laugh and cry and share in that moment. We don't need to think about the last moment or the moments to come—just the here and now.

My dad is the one person who truly helps me stay in the moment. He always knows how to bring me back to the present when I get off-track. I was talking to him the other day and he asked me when was the last time I truly laughed to the point that it hurt. I told him it was when I was decorating cookies with my boyfriend's mom, Elaine. The cookies looked just awful, covered in sprinkles and frosting everywhere. You could hardly tell what they were. We were laughing and rolling all over the floor!

My dad then asked if I remembered what it felt like. I said, "Of course," and he said I remembered because I was living in the moment. When you have laughed once, you have laughed for a lifetime. Having experienced that first laugh inspires the desire to laugh again. When you live in the moment, you are experiencing that moment for the first and last time. And that is special. Those moments are the ones that will stay with you.

My dad sparked something in me; he helped me gain the perspective I needed. Life is exciting and challenging. It's the challenges that mold us and the excitement that keeps us wanting more—and celebration is a way to acknowledge those exciting moments as something special.

So let yourself celebrate. You deserve a party. You are worth it. 🍷

A New Molecular Mechanism Is Implicated in Sporadic Inclusion Body Myositis

Article in Brief:

Investigators contend that a lipid-related transcription factor, peroxisome proliferator-activated receptor gamma, might be affected in sporadic inclusion body myositis.

By Richard Robinson

WASHINGTON—Sporadic inclusion body myositis is a mysterious disease of unknown cause. It has some characteristics of an autoimmune disorder, but some authorities view it instead as a degenerative disorder of aging muscle with a strong inflammatory component.

The inclusion bodies that give the disease its name contain large amounts of amyloid-beta (A-beta), the same protein found in Alzheimer disease plaques, along with a variety of other proteins.

Now a new study shows that A-beta appears to trap an important lipid-related transcription factor, peroxisome proliferator-activated receptor gamma (PPAR-gamma), inhibiting its entry into the nucleus.

Anna Nogalska, PhD, described the new findings here at the annual meeting of the American Neurological Association in October. Dr. Nogalska and colleagues conducted the research in the laboratory of Valerie Askanas, MD, PhD, at the University of Southern California (USC) Keck School of Medicine Neuromuscular Center in Los Angeles.

But some experts question whether this newly identified prisoner of the inclusions actually holds the key to unlocking the mystery of the disease, or whether it is instead one more bystander in the long and growing list of molecules that are found in the inclusions.

Why Explore PPAR-gamma?

PPAR-gamma is a transcription factor that is held in its inactive form within the cytoplasm. It is activated when it binds a prostaglandin, becomes dephosphorylated, and links up with a co-transcription factor called retinoid X receptor. When this occurs, the complex moves from the cytoplasm to the nucleus, where it binds DNA and regulates lipid metabolism.

The PPAR family of transcription factors, including PPAR-gamma, has aroused interest among researchers in diabetes and Alzheimer disease. Rosiglitazone (Avandia), for example, is a PPAR-gamma activator, which increases insulin sensitivity and is used to treat type 2 diabetes. PPAR-gamma promotes breakdown of amyloid-beta



Dr. Anna Nogalska: “Our studies demonstrate for the first time PPAR-gamma abnormalities in s-IBM muscle fibers. It suggests that PPAR-gamma cannot function properly in these muscles. It is possible that because PPAR-gamma is bound to amyloid-beta, it can’t get properly dephosphorylated and therefore cannot get to the nucleus.”

precursor protein, and in transgenic Alzheimer disease animals, PPAR-gamma-activating drugs (called thiazolidinediones) have slowed disease progression and reduced the accumulation of A-beta plaques. In a small study of AD patients, rosiglitazone improved memory.

Study Findings

All these connections led Dr. Nogalska and colleagues to ask whether PPAR-gamma might be affected in sporadic inclusion body myositis (s-IBM). They studied muscle biopsies from 15 s-IBM patients and 20 controls. Among findings, PPAR-gamma messenger RNA was increased threefold in s-IBM muscle compared to controls. The inactive protein was also elevated threefold in the cytoplasm, and co-localized with A-beta in inclusions. In contrast, active nuclear PPAR-gamma was decreased by 50 percent compared to normal controls. The cytoplasmic kinases that phosphorylate—and thereby inactivate PPAR-gamma—were also increased.

“Our studies demonstrate for the first time PPAR-gamma abnormalities in s-IBM muscle fibers,” Dr. Nogalska said. “It suggests that PPAR-gamma cannot function properly in these muscles. It is possible that because PPAR-gamma is bound to amyloid-beta, it can’t get properly dephosphorylated and therefore cannot get to the nucleus.” The investigators previously reported that an increase in kinases in s-IBM muscle may indicate an excess of phosphorylation, which may also play a role.

Some experts question whether this newly identified prisoner of the inclusions actually holds the key to unlocking the mystery of the disease, or whether it is instead one more bystander in the long and growing list of molecules that are found in the inclusions.

There is currently no effective treatment for s-IBM. “A drug to increase the activity of PPAR-gamma might be a potential new strategy for sporadic IBM,” Dr. Nogalska said. Rosiglitazone is one such possible drug. “We are looking further into the molecular mechanisms, and are hoping this will suggest treatment.”

Experts Comment

But neuromuscular disease experts, who were not involved in the current study, expressed skepticism about the role of PPAR-gamma in the pathogenesis of s-IBM.

“Overexpression of ‘alien’ proteins in muscle fibers, such as A-beta, is a tantalizing aspect of this disease,” George Karpati, MD, professor of neurology at McGill University, told *Neurology Today*, “and A-beta may be a neo-antigen [an antigen present in tumors induced by certain types of adenoviruses and papovaviruses or in



Dr. George Karpati acknowledged that “overexpression of ‘alien’ proteins in muscle fibers, such as A-beta, is a tantalizing aspect of this disease,” but he added that other investigators “have shown upregulation or downregulation of so many diverse molecules in sporadic IBM muscle fibers that, now, to single out PPAR-gamma as the target for a ‘magic bullet’ is more like wishful thinking than a realistic expectation.”

cells transformed in vitro by those viruses] that provokes an immune response.” But, he added, researchers, including those who conducted this study, “have shown upregulation or downregulation of so many diverse molecules in sporadic IBM muscle fibers that, now, to single out PPAR-gamma as the target for a ‘magic bullet’ is more like wishful thinking than a realistic expectation. Why this one, and not alpha-chymotrypsin or presenilin?”

Dr. Karpati, who was not involved in the current study, said he also does not hold much hope for rosiglitazone as a potential treatment. “To try to make a case for a drug that is supposed to be therapeutic in Alzheimer disease, and weakly at that, is stretching it,” he said.

Richard Moxley, MD, director of the Neuromuscular Disease Center at the University of Rochester, said that from his perspective, there is a “morass” of information about possible causes of s-IBM. He said these results, while intriguing, do not make an especially stronger hypothesis than some of the others. “The bottom line is that for me personally, it is still a morass.” ■

Reprinted from *Neurology Today*, Nov. 20, 2007; Volume 7, Page 7, with permission of the American Academy of Neurology.

ASK KRIS



Kris McFalls has two adult sons with chronic diseases treated with IG and is also receiving IG therapy. Formerly a physical therapist assistant, Kris is *IG Living's* full-time patient advocate, and she is eager to find answers to your questions. Email them to editor@igliving.com. Your confidential information will not be used for any purpose but communicating with you about your questions.

Betty: The clinic where I get my infusions can no longer get Gamunex. What should I do?

Kris: Changing products can be worrisome. My sons seem to tolerate one particular product better than others we have tried, and this is a common experience for many patients. Nonetheless, because of many problems in the marketplace, they were indeed forced to switch products a number of times. It is important to communicate with your doctor and your pharmacist about your concerns and your product preferences. Do not be afraid to inquire about your pharmacy's current supply of IVIG. You might also ask which product is less likely to be in tight supply in the future, so you can try to avoid having to change products again in the near future. A pharmacist specializing in immune globulin products and an immunologist responded to your question.

Pharmacist response: It is important for patients to remain on the same brand of IVIG that is successful for them whenever possible. While some patients tolerate all brands of IVIG, more often patients may tolerate one brand over another or may even find that one brand seems to work better for them than another. Anytime a patient has to switch from one brand to another, there is an increased potential for side effects. Why this is, we do not really know. The best practice when switching from one brand to another is to double the infusion time. In other words, if a patient normally has a two-hour infusion, when he or she is switched to the new product, it should be infused over four hours. If the patient tolerates the first infusion, then the infusion time can be shortened with each subsequent infusion, as long as the product is tolerated. Some infusion centers will pre-medicate patients with an antihistamine such as diphenhydramine

for the first several infusions of a new product while others do not.

Dr. Melvin Berger, director of allergy-immunology at Rainbow Babies and Children's Hospital in Cleveland: Start at a low infusion rate and allow longer intervals between rate changes, and/or pre-medicate the first time the patient uses a different product. The treating doctor should review the choice of available products, and/or the infusion provider must ask the doctor if the product they propose to use is acceptable for that patient. Gamunex is free from sugar, so patients at risk from sucrose or maltose should be sure they are not switched to a product containing them. Patients who tolerate the IgA in Gamunex should not have problems with the IgA in other products.

Cherry: We are having a lot of problems getting approval for IVIG therapy using the selective antibody deficiency code (273.0). What are others doing to get this diagnosis approved?

Kris: We ran your question by Michelle Vogel, a reimbursement advocate, and she provided the following answer:

Michelle Vogel: I recommend using two paragraphs from an article published on the AAAAI website as part of the "IVIG Toolkit." The article, "Use of intravenous immunoglobulin in human disease: A review of evidence by members of the primary immunodeficiency committee of the American Academy of Allergy Asthma & Immunology," was originally published as a supplement to *The Journal of Allergy and Clinical Immunology* in April 2006, and you can link to it at www.aaaai.org/members/resources/initiatives/ivig_toolkit/2006_ivig_evidence_review.pdf. To support the diagnosis, use the two paragraphs regarding normal immunoglobulin levels on Page S528. They refer specifically to polysaccharide antibody and other selective antibody deficiencies.

Unfortunately, I don't think there is a better code to use, and you may have to provide the medical documentation in support of IVIG use. ■



Where Does My IVIG Come From?

IVIG Supply Consistency

By Chris Ground

Patients and healthcare providers often wonder why we do not have a consistent supply of intravenous immune globulin products (IVIG), and, like most issues surrounding plasma products, the answer is not simple. In fact, IVIG supply consistency is a very complex issue. One easy way to think about this is to break it down into the four basic elements of the IVIG supply channel.

- ① Human plasma supply
- ② Manufacturer supply
- ③ Distribution supply
- ④ Demand for IVIG

Human Plasma Supply

Human plasma is the raw material for IVIG production, and its availability determines how much overall output of IVIG can be manufactured to supply the market. The supply of human plasma is not consistent; it varies, based on the number of plasma collection centers that are operational at any given time and on the success of each center to recruit donors.

Manufacturer Supply

The supply of IVIG at the manufacturer level also varies. As each lot of IVIG is filled and finished, it is subject to an FDA release process. At any given time, a lot can be held or denied release by the FDA for myriad reasons, most often to protect patients from potential contaminants or other concerns that may put a patient at risk. This can then create a “dip” or “hole” in the supply chain for that particular brand of IVIG. In addition, sometimes shipping challenges hamper getting product into the distribution chain by a week or more, creating a short-term disruption in supply. However, patient needs cannot be postponed for a week or more. This leads to the third link of the supply process.

Distribution Supply

Manufacturers typically use a network of specialty distributors to move IVIG to healthcare providers throughout the United States. During periods of short supply of IVIG, when demand outpaces manufacturers’ ability to supply enough IVIG, distributors will employ various methods of allocating product to each provider in an effort to maintain as consistent a supply to patients as possible. However, when a certain brand of IVIG is not available from a manufacturer at the time the provider needs it, due to one or more of the various reasons mentioned above, the distributor may offer another brand of IVIG to ensure that the patient is infused within the time frame necessary to maintain efficacy of the treatment.

Demand for IVIG

Demand for IVIG continues to grow. New areas of use for IVIG outside the currently approved FDA indications continue to be explored and identified by the clinical community. And, although these new indications appear to translate into a beneficial clinical response for patients, they also result in increasing demand, exacerbating an already thin supply of IVIG.

So, all four of these factors work together to define the “consistency factor” for IVIG. When the four elements are balanced consistently, the supply is consistent, but this is rarely the case. More often, one element is out of balance, inevitably resulting in an inconsistent supply of IVIG.

One of the most helpful things *IG Living* readers can do to improve IVIG supply consistency is encourage every healthy person you know to become a regular plasma donor. As so many of you are aware, each donation contributes to the making of a miraculous lifesaver! ■

THE META

By Mark T. Haggard

"Dad," I heard a deep voice bellow from the room behind me.

Holyoke, Massachusetts, I thought, *who is in my kitchen?*

"Where's the sugar?" the voice boomed, rocking the furniture like a Southern California earthquake.

I looked over my shoulder in time to catch my 8-year-old son climbing on the shelves of the pantry, reaching for the Rice Krispies.

"Caleb!" I yelled.

"I'm hungry, Dad."

"You had Lucky Charms 30 minutes ago."

"Dad," he bellowed again with the voice of a 57-year-old bass in a barbershop quartet. "I'm hungry."

It was like I was trying to communicate with Linda Blair in "The Exorcist." All I needed was the split-pea soup. Or I was Rocky Balboa, entering the ring against Ivan Drago. Or the Ghostbusters, facing off against a 10-story Stay-Puft Marshmallow Man.

Only one thing accounted for my son's metamorphosis into Mr. Hyde: steroids. And they were scaring me to death.

Our three kids already eat me out of house and home. The steroids prescribed to Caleb for hives only made matters worse. As a former athlete, current high school football coach, and frequent viewer of ESPN's SportsCenter, I am familiar with the dangers of steroids.

Now it was my son's turn. The side effects of this particular steroid were an insatiable appetite and moon face. What would he look like after a week of BALCO's best stuff? An 8-year-old with man-breasts and facial hair? Would his head be too big for his baseball cap? Would his name show up in the Sen. George Mitchell Report? And, when his sister started bugging him next time, would he throw the SUV at her in a fit of rage? Would I have to pull his older brother out of the DVD player after

one of their many spats over the GameCube? Oh, what kind of future did we face?

One afternoon at a high school football practice I looked at one of my adolescent players, and I had to look a second time, thinking the student was my own son. "Crimony," I muttered, "my 8-year-old son could start at left tackle on Friday night."

I figured the steroids had already added 10 years to Caleb's life. How much more would they age him by the end of the week? How much shorter would his life be by the time he had finished his prescription? These questions troubled me!

As it turns out, by the end of the week, Caleb did not age at all. He did not stuff his brother into the DVD player, nor did he throw the SUV at his sister. The steroids did the job that they were supposed to do: His moon face waned and his appetite returned to a normal, healthy 8-year-old level.

My worries were for nothing, but they were legitimate, nonetheless. As parents, we must worry when foreign substances are being infused into our children's bodies. We have a heightened level of trust with our doctors, but that trust must also allow us to ask hard questions concerning the well-being of our own flesh and blood. My experience is that the doctors, the good doctors as we have in the immune deficient community, are more than gracious enough to answer our concerns and actually appreciate the fact that we have concerns. It makes our jobs advocating for our children's healthcare a little easier.

The other day I heard, "Dad, where's the sugar?"

"Get off of the shelves," I called.

"I'm hungry."

"Wait until dinner."

This time there was no debate. "OK," he sighed.

Good deal, I thought. *I won't need him at left tackle for another eight years.* ■

MORPHOSIS



IG Therapy In Your Home

with Care



NuFACTOR Provides:

- Patient Care Coordinators who truly care

"I not only appreciate the efficient and prompt service, but especially the kindness and caring by each member of the NuFACTOR staff."

- Training in all forms of immune globulin administration
- Reliable home delivery of immune globulin
- Individualized services to meet your lifestyle

"Your company and personnel are a pleasure to work with. Thank you for all you do!"

- Peer Support Program™
- 24/7/365 Pharmacist availability for you and your physician
- Arrangement of home infusion nursing services
- Expert claims and reimbursement assistance

"Service is high quality and the best I have dealt with since I started taking IVIG 13 years ago."

- Coordination with your healthcare provider and case manager



Subscribe to IG Living—
your community magazine
at www.igliving.com

Call us to find out more about NuFACTOR's services: 800-323-6832 • www.nufactor.com

NuFACTOR
Specialty Pharmacy

NuFACTOR is the Specialty Pharmacy Division of FFF Enterprises





ELECTRONIC HEALTH RECORDS: IN THEATERS EVERYWHERE BY 2014

By Lauren Gerstmann, MPH

When I was a kid, you could tell I had assorted ailments by my thick medical chart. Every time I visited the doctor, he would ruffle through a tattered, overstuffed file with pages falling out. Of course the best doctors didn't rely too much on charts. They held their patients' medical histories in their heads. This worked well when people developed lifelong relationships with one primary doctor.

But the model is very different now. Doctors see more patients each day, and the patients often move from doctor to doctor as their insurance coverage dictates. Patients also see more and more specialists to individually treat our hearts, our backs, our immune systems—each distinct part of our bodies. We have no way of developing the kind of intimate relationship that I had as a child with my family doctor, but doctors still need a reliable way to access our medical histories, our prescriptions and our previous treatments.

Going Digital

Today, the patient chart is critical, and ideally it would be accessible to every doctor who treats an individual patient. As a result, there is a halting, uneasy movement to make our medical records electronic, standardized and available. But available to whom and to what standard?

Right now, many medical practices and hospitals have their own electronic health records systems. The electronic chart is accessible to all of the doctors within the practice or hospital, for instance, but not beyond. This helps within the given organization, but it is not a huge leap beyond the old system of paper charts.

Despite years of effort to improve this, there are many reasons electronic health records have not evolved further, the most significant of which is patient privacy. Doctors and hospitals will release protected health information (PHI) only with the explicit consent of the patient. But, in recent years, the federal government has been advocating for a national healthcare information infrastructure. ➤

Linked, Interoperable and Protected

On July 21, 2004, at the direction of President Bush, the Department of Health and Human Services (HHS) released a 10-year plan to build a national electronic health information infrastructure in the United States.¹ HHS Secretary Mike Leavitt announced the goal to create an infrastructure that will “link all health records through an interoperable system that protects privacy as it connects patients, providers and payers, resulting in fewer medical mistakes, less hassle, lower costs and better health.”²

At the president’s order, HHS designated a national coordinator³ for Health Information Technology (HIT) within the Office of the HHS Secretary. The coordinator’s job is to facilitate access of most Americans to an integrated electronic health information system by 2014.

What form would a national healthcare information infrastructure take—how would it be different from a database?

“A database is a place where you store information, and it can be gathered from lots of different places,” Dr. Robert



Robert Kolodner, MD, HIT national coordinator

Kolodner, the HIT national coordinator, said. “And yet, it is by itself not an infrastructure. It is just one piece of an infrastructure. You can also have a structure that does not store data centrally, but accesses it when it is needed.

“If you think about the Internet, there are lots of web pages out there, but it isn’t as though they are pulled into a single machine or database. But you can get to all of those

things when you need to.”

But several pieces need to be in place before such an infrastructure becomes feasible.

“We need to have standards, so that the data can be understood when we retrieve it,” Dr. Kolodner explained. “And we need to have policies and rules for how that information is used, and when that information is used, and

who it is used by, and we need to have a network or a way of connecting over a network. [W]e are not creating something new, we are essentially creating a secure channel—a secure way of communicating information over the Internet.”

The logistics of creating such an infrastructure are hard to fathom. But, according to Dr. Kolodner, many of the pieces are already in place. “[T]here is a lot of information that is already electronic. All of your medications are available electronically,” he explained. “If you went to a pharmacy... all of them have computers and I think something like 70 percent can receive ePrescribing or something at a distance if your doctor places an order. But, all of your medicines, essentially, are entered into a computer database at the pharmacy. And much of your laboratory [data] is already automated.”⁴

Dr. Kolodner emphasized that we are not going to be able to coordinate all the different databases currently used by individual healthcare providers. Instead, the plan is to standardize the data. He used the example of telephone service. “If you think about your...phone system, you [could] be on a land line or a cell phone or you could be [making a call from a] computer. You don’t have to have the same brand, but as long as they use the standard going back and forth, we can all talk to one another.

“And, so by standardizing on the information and not the software, we can move that information around, and it is up to the software (some are more capable than others) to take that information and do something that would be beneficial to your health and well-being.”

Despite the fact that there is a lot of data already available, Dr. Kolodner believes the emphasis will be on building a new record, not on uploading existing data. This type of forward thinking, he explained, would involve standardizing new data entry to make it more easily utilized by the infrastructure.

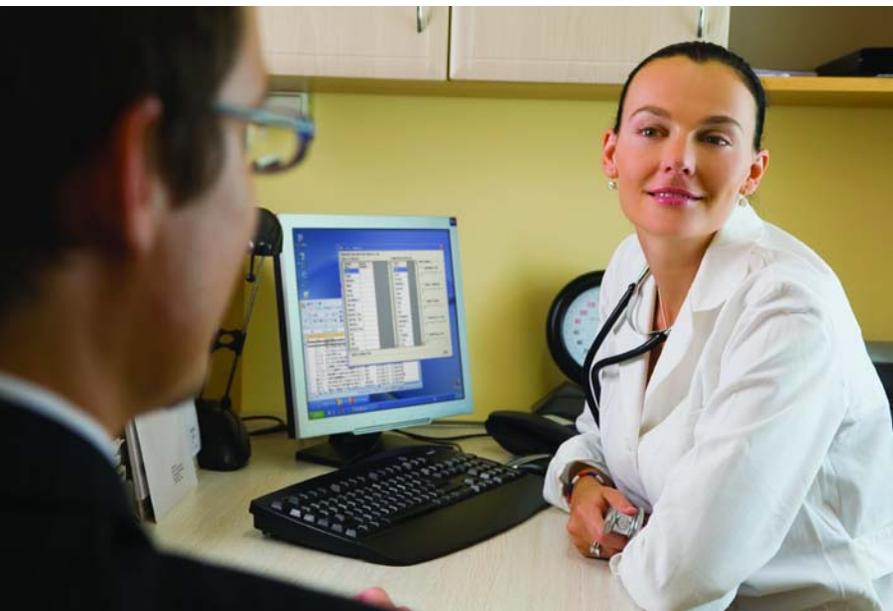
“What we are really doing is building and going forward,” Dr. Kolodner said. “And what we want to do is really standardize that data. So if I want to know that a penicillin allergy is really to penicillin or a spelling artifact (error)...

¹ www.hhs.gov/news/press/2004pres/20040721.html.

² www.hhs.gov/healthit/onc/mission.

³ For more information on the Office of the National Coordinator, please see www.hhs.gov/healthit/onc/mission.

⁴ For more on ECLINCs (a detailed specification for the formatting and coding of lab results messages from laboratory information systems to ambulatory electronic health records) see the California HealthCare Foundation’s website at www.chcf.org/topics/chronicdisease/index.cfm?itemID=114774. For more on ePrescribing (software that allows healthcare practitioners to send electronic prescriptions to pharmacies) see www.rxnt.com.



Improved Care, Decreased Costs and— Again—Protected

Why is there such a widespread interest in a health information infrastructure?

“Potentially, a health infrastructure could improve safety and quality of care delivery while reducing costs,” Dr. Kolodner said. “Many of us consult with multiple health practitioners...and if one of them knows about an allergy, and the others don’t know about it, and they write a prescription for that other medication, that could cause a problem for you.

“My mother is 95 years old. She is seeing four or five doctors, and, one of them wrote a medication that aggravated a condition that another doctor was treating. And, if I had not worked with her, we would not have figured out why she deteriorated.”

According to Dr. Kolodner, electronic records can improve the quality of healthcare delivery. “Because no matter how much doctors want to do the right thing, we can’t remember all the things we want to do for all the patients. And so, having a computer that reminds us, ‘Hey, this person is at risk for pneumonia, they should get an influenza vaccine—they have not had one yet,’ then I’ll get closer to having 100 percent of people who should get that shot, get it.”

Electronic health records can also decrease costs to consumers and insurance companies. “Turns out that 20 percent of the lab tests that are ordered in this country are ordered because an existing result cannot be accessed by that doctor. So we are paying more for healthcare,” Dr. Kolodner explained.

Dr. Kolodner pointed out that the database can be configured so that our healthcare providers have access to just the necessary information they need to keep us safe, but not enough to impinge on our privacy rights. He also mentioned that a health data infrastructure might allow people greater access to view and edit their own health information than is currently possible.

“[We need] to make sure that the infrastructure we put in place is one that respects the individual’s privacy and honors their preferences,” Dr. Kolodner said. “And it is ➤

[we need to] use codes and standards. We have standards that have been out there a while, but unfortunately everyone has different standards. So we started a process in 2006 with the Healthcare Information Standards Technology panel, a way of harmonizing the standards. It does not create them, but it harmonizes them so that we can decide for a given purpose, what is the right set of standards to use? And then we take those standards and write additional specifications.”

Medicare is also invested in making health data electronic and has taken steps that may mean there is more data available to the national infrastructure once it goes live. Until recently, the software that doctors and hospitals would need in order to keep comprehensive health records electronically was so expensive that many balked at the cost. Now, however, there is software available in the public domain: the VistA electronic health record system, which was developed by the Department of Veterans Affairs to serve military veterans.⁵ Medicare is distributing this software in a form that can be installed and used by individual users, but those users will still need to pay installation costs. According to an article in *The New York Times*, the cost of installing VistA is “\$10,000 to \$12,000 for an entire medical practice.” That means that a practice of five doctors might pay \$100,000 to computerize, but if the doctors used the Medicare system they might pay only \$10,000 for the whole office.”⁶

⁵ www.vistasoftware.org/what/index.html.

⁶ Kolata, G U.S. Will Offer Doctors Free Electronic Records System, *The New York Times*, 7/21/2005 www.nytimes.com/2005/07/21/health/21records.html?ex=1279598400&en=65d75ef0b6ef2340&ei=5090&partner=rssuserland&emc=rss.

possible to do that. In fact, it's more possible [than it is to do with paper charts]. Right now we have security by obscurity... We can't get to the data, so that is how we keep it secure. Unfortunately, if you are in a hospital and [you have a paper chart], anybody can walk up and pick up your chart. And, by the way, that happens more often than it should. And, you have no record of that."

While paper files may be difficult to secure, the difference between one person picking up a chart erroneously—or even illicitly—and a hacker compromising the privacy of the records of the entire American public is dramatic. Dr. Kolodner said that, while we need to take privacy threats and breaches very seriously, "people with chronic illness want their information available to their docs, and right now, that is not possible. So we have to ensure that they have that right as well."

Who Is Allowed Access?

While many people may want their information available to their doctors, no *one* entity can make that decision unilaterally. Consumers need to be the ultimate decision makers about who can see their health information.

"There are rules set out by HIPAA.⁷ Insurance companies pay for your care, and they get to see enough of your information to let them know that you received care and that you received appropriate care. But they don't get to see all of your record," Dr. Kolodner said. "They don't have that right. Now, if you are worried that they are getting too much information, I do think that it is reasonable to have that fear. I think that we need to find rules that people will be comfortable with, and [ways] that they know their privacy is being honored.

"The issue of not being discriminated against because of their health information, the issue of not having their job affected because somebody inappropriate has their health information—I think are very important, whether it is paper or whether it is electronic. And, what we are working to do is to develop a system, an electronic system, an infrastructure that is actually more secure, and that gives you more control [over] who has access to your information than you could ever possibly get from paper."

Online banking is a comparable example. Many consumers

use online banking now, but, when online banking first became available, identity theft was a tremendous concern. Credit card companies have put protections in place to protect against identity theft, but consumers still need to beware a lost credit card or a sophisticated email phishing scheme. It is the coordinated effort of the software designers and programmers, combined with consumer vigilance, that have made online banking a success.

Despite the data security concerns, there is a large demand for a more efficient way to store health data, and for patients to be able to access and interact with that stored data. Last October, Microsoft unveiled HealthVault, a free website⁸ that allows patients to store any or all of their health records electronically. It also incorporates the ability for consumers to download health information from their participating providers (e.g., participating doctors, hospitals and pharmacies), and it allows them to selectively upload or share data with healthcare providers who opt into the system. The service is free to the public. Microsoft makes its money from advertisers when users perform searches for health-related information.

HealthVault is a more fully voluntary process than the government's planned system, but there are some drawbacks. HealthVault is a private, for-profit service. When you use the service, Microsoft has access to (and control of) your health records. Although HealthVault puts the patient in the driver's seat, if you are not comfortable with computers, if not all of your providers use the system or if you become unable to enter new information, your record may be missing key pieces.

How would the government's planned system protect against these concerns?

"Right now, you sign a consent form when you go to your doctor, and so they have to keep a record of it, and they have to be able to pull that record if you have released information," Dr. Kolodner said. "In the same way, you may say, 'I don't want my information revealed, and I don't even touch a computer.' Just don't let it go. And, the system and the accreditation need to make sure that [your request] is honored. You should not have to be a computer geek to protect your information."

⁷ HIPAA (the Health Insurance Portability and Accountability Act) has provisions for personal health information privacy. For more information about HIPAA, visit the HHS HIPAA website at www.hhs.gov/ocr/hipaa.

⁸ www.healthvault.com.

Approaching the 2014 Target

Given all that needs to fall into place, a 2014 deadline seems like a true challenge, but Dr. Kolodner is optimistic. “I think we are on target, because you need to understand that, if you look at any new technology, there is a repeating pattern. The repeating pattern is that there is a period of time where the foundation is being laid where it looks as though there isn’t much happening. And then, the right factors all come together, and things start to really take off.

“We think about technologies like the Internet, and how quickly it took off in the mid-1990s. The Internet was there for 20 years before that. What we are doing right now is laying a solid foundation for things to move forward. Our delivery standards are in place, we will be having dialogues about privacy and security next year, we’re getting governance into place, we’re getting standards into products... and we’re aligning a variety of conditions that can act as incentives. We’re removing barriers to adoption. So, I think we are very much on target.”

Although Dr. Kolodner sees the target within reach, he is also realistic about the need to be patient with those expected to adopt the new infrastructure. “I don’t expect to see a huge jump in terms of the key mark—that is, the adoption of electronic health records in the next few years—probably not until 2009 or 2010. But, somewhere in the 2010, 2011 time frame, I expect there to be all of these pieces that have matured, so that they come together and communicate their value and there is a very rapid time frame of adoption. I really do think that we are going to hit that 2014 target that President Bush set out.”

The Final Product

The national health information infrastructure is well on its way, and it will surely affect patients, as intended or not. A good system will integrate all patient health data, secure that data, improve care and reduce medical bills. But everyone agrees the finished product must respect patient privacy and protect against identity theft, insurance discrimination, job discrimination or other privacy abuses. HHS clearly articulates these goals. In fact, a working group devoted to consumer empowerment released a paper in June 2007, discussing all of the ways consumers will be able to interact with the final product.⁹

But, right now, the planning process has been a bit opaque for consumers, despite four public forums held in 2007 and at least two more planned for 2008.¹⁰ There are also plans to involve the community more regularly in the planning stages, although it is not yet entirely clear how this will be accomplished.¹¹ Whatever the methods, healthcare consumers would ideally be actively involved to help ensure the system is realized in its most perfect form—for all its potential users.

Personally, this is one party at which I want to get out on the dance floor. It could be a great thing for all of us, but it could be a real disaster if we stand shyly by the door. ■



To learn more about specific electronic systems mentioned in this article, see the following websites:

VistA (template for electronic medical records database that is available in the public domain and that is being freely distributed by Medicare)—www.vistasoftware.org

ePrescribing (allows healthcare practitioners to send prescriptions to, and receive feedback from, pharmacies): www.rxnt.com

ELINCS
Standardizes laboratory data:
www.chcf.org/topics/chronicdisease/index.cfm?itemID=114774

HealthVault
Microsoft’s free electronic health record database for consumers: www.healthvault.com

To learn more about the U.S. government’s efforts to develop a national health information infrastructure, visit the Department of Health and Human Services Health Information Technology website at www.hhs.gov/healthit

⁹ www.hhs.gov/healthit/documents/UseCaseCACI.pdf.

¹⁰ See the DHHS website at www.hhs.gov/healthit/healthnetwork/forums/ for more information on dates.

¹¹ The transition plan is available on the HHS website at www.hhs.gov/healthit/community/background/AHICsuccessor.html.



IG and Jet Fuel



Immune globulin (IG) and jet fuel might not normally be considered in the same breath, but for one *IG Living* family and the “Gunfighters” of the U.S. Air Force 366th Fighter Wing, the two went hand-in-hand—at least for a day.

On Dec. 13, Caleb Haggard, 8, and a diehard Air Force fan, and his siblings, Molly, 6, and Calvin, 10, became honorary Gunfighters at the Mountain Home Air Force Base in their home state of Idaho. Because Caleb and Molly have primary immune deficiency disease and are treated with the plasma-derived product IG, their visit to the base was almost a homecoming of sorts: It allowed donors to the base American Red Cross (ARC) blood drive to meet face-to-face with people their donations can help. It was a very special moment for all involved.

Upon the Haggards’ arrival at the base, the three children and their parents, Cheryl and Mark (writers for *IG Living*), were met by Mountain Home ARC Director Jim Koseki, Boise ARC Director Ann Callanan, Chief Master Sgt. Allen



Niksich and Maj. Damien Pickart. Then the kids began a dream of a base tour.

First, Chief Master Sgt. Niksich gave the children patches bearing the 366th insignia, T-shirts, hats and specially minted coins that no serviceman is supposed to be without.

Next stop: the base fire department. Tech. Sgt. Ryan Glosson led the family through the station, showing off the trucks, hoses, Jaws of Life, and the PXX Jaguar advanced firefighting vehicle.

Then the family went on a guided tour of the canine kennel of the 366th Security Forces Squadron, led by the kennel master, Tech. Sgt. William Gaulke. Senior Airman Michael Marks and his dog, Dasty, demonstrated his skills, chasing, taking down and immobilizing a "bad guy."

After the canine connection, the family moved on to the highlight of their visit: Chief Master Sgt. William Patterson and 2nd Lt. David Rhodes escorted the troop into the hangar of the 390th Fighter Squadron, the Wild Boars, and their F-15 Eagle aircraft. The children climbed into the cockpit,

while pilots Capt. Rich Ward and Scott Prom pointed out the highlights of the jet.

"When I look across this hangar, I am reminded of how privileged we are to live in this country," Mark Haggard said. "I can't imagine living in another country, with my kids having the illness that they do. And it is the servicemen here that protect our way of life that gives my kids an opportunity at life."

Chief Master Sgt. Koseki underscored the importance of blood and plasma donations to families such as the Haggards. "The impact of donating blood was one thing I wanted airmen to see during the visit," he said. "The second thing I wanted to emphasize was the selflessness of the men and women of this wing."

Mission accomplished: Mountain Home personnel are now more aware of the effect they have on the lives of those who depend on plasma products. And the Haggards will never forget the gallantry of the Gunfighters of Mountain Home Air Force Base. ■

Specialty Pharmacies: Here Today, What Tomorrow?

By Jeff Siegel

If you don't know what a specialty pharmacy is, you'd better learn. And if you do know, be prepared for some changes in what specialty pharmacies do for patients and how they do it.

That's the conclusion of a report called "Specialty Pharmacy Management Insights," which details significant transformation in the specialty pharmacy business that has taken place in the past several years.

Specialty pharmacies have for years provided the important service of dispensing specialty, often expensive, pharmaceuticals, such as immune globulin (IG) products and other injectables, directly to patients and physicians. The report indicates that specialty pharmacies are becoming even more important for new reasons, as insurance companies, managed care providers and other payers seek ways to streamline specialty pharmaceutical dispensing and cut costs.

The report, compiled by consulting firm The Zitter Group for Wyeth Healthcare Systems, indicates there will be more specialty pharmacies acquired by larger companies and offering more services. What is not expected to change, though, is the role of those specialty pharmacies that provide consumer services. These companies will continue to fill a niche, much as they have for several years, which is especially important given the IG products they dispense.

"The results are more or less what we expected to see," says Jeff Christensen, a senior marketing manager for Wyeth HealthCare Systems Marketing. "The study supports the trends that we saw going on—specialty pharmacies are more prevalent, they're trying to become efficient, and, so, we want them to have more of our products."

What Is a Specialty Pharmacy?

Specialty pharmacies developed over the past couple of decades, as science and technology delivered an increasing number of expensive, difficult-to-administer drugs that require special handling for patients suffering from chronic diseases. It's one thing to stop at your neighborhood retail pharmacy, be it independent, one of a chain or part of a national retailer, and pick up some pills. It's another thing entirely to obtain a specialty pharmaceutical such as IG. Can the retail pharmacy store it correctly? Can it afford

to keep an adequate supply on hand? Probably not, hence, the need for specialty pharmacies.

As specialty pharmacies developed, they became adept at providing the special needs of patients that are peripheral to the actual administration of their medicine. In addition, specialty products became a bigger piece of the pharmacy pie, growing from 18 percent in 2004 to an estimated 26 percent in 2008, according to the report. Other types of companies saw these marketplace developments and figured they could adapt what specialty pharmacies do to meet their own needs and business goals.

Today, all sorts of companies own specialty pharmacies, including large drug store chains, such as Walgreens and CVS; insurance companies such as Cigna, Aetna and WellPoint, which sells Blue Cross policies in 14 states; companies that serve niche markets within the specialty pharmacy field such as NuFACTOR, which focuses on IVIG and antihemophilic factor (NuFACTOR is an *IG Living* sponsor, along with owner FFF Enterprises, the nation's largest IVIG distributor); home health firms, which combine specialty pharmacy with home health services, including infusion nursing services; and the country's three biggest drug distributors.

Another significant newcomer to the specialty pharmacy realm is pharmacy benefit managers (PBMs). PBMs manage pharmacy benefit services, acting as a middleman for employers and insurance companies. This group is becoming increasingly more important, says the report.

The reason PBMs and specialty pharmacies are such a good fit, says Melinda Haren, director of business content for Zitter, is that PBMs are able to deliver savings to insurers and



plan owners. In fact, PBMs are the most common provider of specialty pharmacy services, according to the report, by almost two-to-one over retailer-based specialty pharmacies.

PBMs are seen as big enough to have substantial clout in the marketplace, allowing them to buy drugs in greater volumes for less and cut other costs by using other economies of scale. The report found they were seen as much as 10 times more able to deliver lower prices than their competitors.

Why Is This Important to Patients and Physicians?

Because, says Haren, as drug costs continue to increase, insurers and plan owners will want to find ways to contain costs.

Yet some of the cost-cutting changes are disturbing to some patients and physicians, particularly the trend by many insurers toward sole-source specialty pharmacy agreements, which eliminate patient and physician choice.

No one is certain how the specialty pharmacy market will continue to evolve, although Haren and Christensen are sure that it will continue to change. One of those changes will likely be that more insurers and plan providers will consider using PBM-based specialty pharmacies, although Haren and Christensen do not think all insurers will do so.

Not surprisingly, the report indicates that PBMs are not seen as especially effective in delivering consumer services. They rated in the middle of the pack when it came to patient and physician satisfaction, trailing smaller or specialized specialty pharmacies. "That's why the smaller companies will continue to have a role in the marketplace, especially in the IVIG market," says Haren. "Health plans like a lot of things the PBMs do, but when it comes to rare conditions, they're not always comfortable with fragile patients and companies as large as PBMs. They feel comfortable with smaller companies who are more familiar with the conditions."

The smaller specialized pharmacies, she says, are better with one-on-one patient contact. And, given the nature of the diseases, that individual attention is crucial.

Among the Report's Other Findings

- Intriguingly, two-thirds of insurers and plan operators believe they need to manage immune disorders better, but only one-quarter think that current management by specialty pharmacies is effective. This may be because, like cancer therapies, IG products are often difficult to administer and are expensive.

- Most insurers and plan operators prefer to use a one-stop shop that covers most disease category products. They find the one-stop shops easier to work with, and think they are less confusing for patients and doctors.
- About one-third of payers mandate which specialty pharmacy is used. This number, says Christensen, is expected to increase, as insurers and plan operators look for more savings and determine they can find it by cutting the number of specialty pharmacies members can use. But, he says, that number will never become 100 percent. "[Payers] understand a lot is about patient choice, and what the patient feels comfortable with."
- Some payers may institute discount and disincentive programs—more claims paperwork, added fees—to encourage patients and physicians to use the preferred specialty pharmacy.
- Insurance companies and plan operators would really like to find a specialty pharmacy that can offer PBM-style cost savings and the more effective consumer services of smaller specialty pharmacies. That's one reason why Haren and Christensen expect to see more consolidation in the industry, as medium-sized specialty pharmacies try to find a format to satisfy payers' dual goal. This consolidation may not affect specialized, smaller companies as much, because they concentrate on consumer service. It also won't likely mean as much to the larger PBM-style companies, because their asset is cost savings.

That conclusion really isn't surprising, says Christensen. The one thing noted again and again is that specialty pharmacy patients need the so-called "high touch services." That's why, he says, "there will always be an incentive for payers to stick with smaller specialized pharmacies, and that's something we hear not just one time, but multiple times. In that scenario, in any industry segment, if you can capture the hearts of the customers, you're going to succeed."

What that success and the ongoing industry changes look like in the next year or two or more will affect many patients with chronic diseases who require specialty pharmaceutical therapy. And, ultimately, it is the quality of care and its outcomes that will define success for patients. ■

Evidence-Based Medicine: Defining Evidence

By Kit-Bacon Gressitt and Amy Fuller

A woman in California, diagnosed with multiple sclerosis (MS), was shocked to learn her insurance company would no longer cover her intravenous immune globulin (IVIG) therapy because of a lack of medical evidence supporting the treatment of MS with IVIG. After approving the IVIG infusions for three and a half years, at the recommendation of her physician and MS specialists, the insurance company suddenly denied coverage on the basis that IVIG is an experimental treatment for MS.

This was devastating news to the patient, who believes IVIG is her lifesaver, enabling her to once again do things, such as walking, that most people take for granted. The patient also reported that IVIG therapy had relieved her debilitating headaches, severe muscle weakness and cognitive dysfunction. She was convinced her quality of life would be dramatically diminished without the IVIG infusions prescribed by her physician and supported by her MS experts. So, the patient paid more than \$4,000 per treatment out of pocket for her monthly infusions, while she appealed her insurance company's coverage denial. But, when she could no longer afford the expense, she had to follow her insurance company's treatment recommendation to try those therapies considered standard treatment for MS: steroids and interferon.

At first glance, the insurer's recommendation seemed sound, claiming a basis in medical evidence-based decision-making. However, in this particular case, the insurance company's recommendation failed to include consideration of three other factors that had been considered by the patient's physician and experts:

1. The patient's experience with IVIG, that it was demonstrably effective in reducing her MS symptoms during the previous three and a half years, improving her physical and mental functioning and, thereby, enhancing her quality of life;

2. The patient's additional diagnosis of osteoporosis, a condition that is exacerbated by the use of steroids; and
3. The patient's history of treatment for depression, which is a side effect of interferon.

In fact, the insurance company's treatment recommendation increased the risks of serious side effects for the patient. Still, the company insisted that she first fail the standard MS treatments before they would reconsider IVIG.

Stories such as the California patient's are not rare. Over the past year, Michelle Vogel, director of the Alliance for Plasma Therapies, knows of more than 250 patients who have lost access to IVIG based on insurance company determinations that their IVIG treatment is not supported by evidence-based medicine.

What Is Evidence-Based Medicine?

"Evidence-based medicine is not what payers are claiming it is," said Dominick Spatafora, president of the Neuropathy Action Foundation (NAF) and CEO of the Los Angeles County Medical Association. He is concerned about "the growing misuse of so-called evidence-based medicine" (EBM) in payer decisions about IVIG reimbursement. "Evidence-based medicine is a great tool when it is used as it was intended—for medically based diagnosis and treatment decisions—but it can put patient care at risk when it is misused to achieve cost containment or cost reduction by government and commercial health insurance companies."



EBM was developed in the mid-1990s to help physicians avoid wide variations between clinical practices, unproven medical interventions and inconsistent application of practice guidelines, with the ultimate goal of improving the physician-patient relationship, patient care and outcomes. The early proponents of EBM claimed it would help ensure healthcare funds would be spent more efficiently,¹ while improving outcomes. They believed doctors who consistently used evidence in planning a course of treatment for their patients would be more likely to use new, more effective treatments and abandon treatments that failed to show results.

Spatafora explained that EBM was defined in the mid-1990s by David Sackett, MD, and others as the “conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” Sackett and his colleagues stressed that doctors would be encouraged to keep up with the latest medical innovation and still have the ability to draw on their accumulated practical knowledge.²

As defined by Sackett and his colleagues, EBM essentially has three key elements:

1. **A physician’s clinical expertise**—the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice;
2. **The best available external clinical evidence**—the clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative and preventive regimens; and
3. **The patient’s situation and preferences**—the thoughtful identification and compassionate use of the individual patient’s predicaments, rights and preferences in making clinical decisions about his or her care.

The EBM model dictates that the first element, a doctor’s clinical expertise, is integrated with the second, the best available external clinical evidence, to result in treatment decisions that match the patient’s clinical state, predicament and preferences.

“When all three of these components are combined, the best evidence-based medical decisions can be made,” Spatafora said to attendees at a September 2007 Alliance for Plasma Therapies meeting with the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS). “But,” Spatafora clarified recently, “the cost of clinical research prevents the body of scientific evidence EBM suggests and payers are now demanding for less common and rare diseases.”

At the same meeting, Lisa Christopher-Stine, MD, of Johns Hopkins University Department of Rheumatology, said that many patients who benefit from IVIG, such as some myositis patients, are unlikely to become the subjects of clinical trials because the number of these patients is too small to motivate drug companies to invest in the research necessary to meet U.S. Food and Drug Administration (FDA) guidelines. She said, however, that in informal clinical settings, when a person who had been dependent on a wheelchair for mobility stands up and walks, it’s obvious that IVIG has improved the quality of the patient’s life tremendously.

“Were EBM applied as intended in this instance, the treating physician’s clinical expertise and the patient’s situation and preferences could serve as proof that IVIG treatment is appropriate,” said Spatafora, “despite the off-label indication and lack of external clinical evidence. And this would be reasonable within the EBM model.”

However, some public and private insurers appear to be making use of EBM primarily as a cost containment or cost reduction tool. “This is evidenced in the increasing reference to EBM in coverage denials for expensive therapies,” said Vogel, “even if the patient has used the therapy with good results for years. And now CMS has proposed making EBM the bedrock for deciding which treatments, devices and services Medicare will cover. Government and private payers must assure physicians and patients that they will use EBM, not a cost-cutting spin that emphasizes only one of the three elements over the other two.”

The director of CMS’ Coverage and Analysis Group, Dr. Steve Phurrough, offered an interpretation of EBM that appears to represent a policy shift from the EBM founders’ concept to an emphasis on clinical research: “Evidence-based medicine de-emphasizes intuition, unsystematic ➤

¹ “Some fear that evidence based medicine will be hijacked by purchasers and managers to cut the costs of health care. This would not only be a misuse of evidence based medicine but suggests a fundamental misunderstanding of its financial consequences. Doctors practising evidence based medicine will identify and apply the most efficacious interventions to maximise the quality and quantity of life for individual patients; this may raise rather than lower the cost of their care.” Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn’t. *BMJ*. 1996;312:71-77.

² Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence-based medicine: what it is and what it isn’t. *BMJ*. 1996;312:71-77.

clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and *stresses the examination of evidence from clinical research.*"^{3,4}

This interpretation of EBM would likely deny IVIG access to many patients with rare diseases and complicating diagnoses, despite previously observed beneficial outcomes, as was the case with the MS patient. Because the numbers of these patients are, again, small and clinical research is expensive, manufacturers would likely need some financial incentive to invest in the clinical trials necessary to scientifically prove IVIG's efficacy to FDA standards. But the incentives do not exist, the research is not being done, and such indications for IVIG treatment are inevitably failing the external clinical evidence litmus test payers are mistakenly representing as EBM.

According to several critics of the CMS proposal to adopt EBM, the potential human cost of misuse of EBM would be great. The Alliance's Vogel said, "In short, misuse of EBM by payers to make coverage determinations threatens to weaken the doctor-patient relationship, to dismiss the importance of clinical experience and to de-emphasize the observable efficacy of a treatment for a single patient by focusing solely on the statistical outcomes for a group. If this is the intent, it is a dangerous course that could leave damaged patients in its wake," she concluded.

Pfizer's Health Reform Policies posted on the company's website clearly states the pharmaceutical manufacturer's position that EBM is a tool for practitioners: "Evidence-based medicine should be used by the medical provider—not the payer—as a factor in determining the most appropriate treatment for individual patients."

Indeed, as Spatafora indicated, the originally conceived EBM is a tool for experienced healthcare practitioners to plan a rational course of treatment with their patients: Physicians review external clinical evidence, draw on their experience, and make a judgment to match the treatment to the individual patient's situation and preferences.

Spatafora believes that if EBM is implemented with these principles in mind, quality of care can improve and healthcare dollars can be spent efficiently. However, said Spatafora, "when EBM is applied with an emphasis only on clinical research evidence, it results in predominantly a cost-cutting tool, diminishing or even rejecting the relevance of physicians' clinical expertise and judgment

and the patient's individual needs. Without consideration of all three elements, it is not EBM."

In the MS patient's case, Vogel said, "her doctor's opinion was not given adequate consideration compared to the medical evidence. Neither was the medical expertise of the MS specialists who concurred with her doctor's recommendation. Additionally, the patient's other diagnoses and positive clinical experience with IVIG were not considered relevant, and, instead, her insurer rejected her appeal for IVIG. She has been forced off a therapy that was proven to be effective for her and shifted onto interferon, a therapy that puts her health and well-being at risk."

Since starting interferon, the patient reports that her muscle weakness and cognitive dysfunction have increased, and her quality of life has decreased. She said she will continue to appeal to restore her access to the one therapy that has proved effective for her, IVIG. But, as she struggles through the complexities and frustrations of her current appeal process, she is afraid she will not regain access to IVIG before her MS has progressed to the point that the IVIG treatment will no longer be effective.

This situation leaves the patient and those who care for her seriously questioning the insurer's decision-making. "This does not appear to be true evidence-based medicine," Spatafora said. "The insurer's disregard of the treating physician's expertise, along with the patient's situation and preferences, is a perversion of EBM—apparently with the sole purpose of cutting costs. And it appears to be a trend in this country, one with potentially devastating human cost."⁵

One day, a patient, a physician, a manufacturer, a politician or perhaps a payer will manage to elevate the bottom-line question to the public ear: What human cost will we tolerate to achieve cost containment? ■

For More Information

Read the British Medical Journal editorial, "Evidence based medicine: what it is and what it isn't" BMJ 1996;312:71-72 www.bmj.com/cgi/content/full/312/7023/71.

Pfizer's Health Reform Policies www.pfizer.com/about/public_policy/pfizer_health_reform_principles.jsp
Copyright © 2002-2008 Pfizer Inc., Last Updated September 2007.

³ Evidence-Based Medicine Working Group, JAMA 1992.

⁴ Emphasis is the editor's.

⁵ Pfizer's Pharmaceutical's Health Reform Policies. Copyright © 2002-2008 Pfizer Inc. Last Updated September 2007. www.pfizer.com/about/public_policy/pfizer_health_reform_principles.jsp.



Let's Talk!

By Shirley German Vulpe, EdD

If your life depends on immune globulin, this column is for you! It is an opportunity to network and share our experiences, because it behooves us to learn as much as possible about all of the ramifications of our illnesses. This column allows us to learn from one another. If you have a story you'd like to share, please email us at editor@igliving.com.

For this column, I interviewed 76-year-old Roslyn Roberts. Roz has chronic inflammatory demyelinating polyneuropathy (CIDP), an autoimmune disease. The first symptoms are tingling and numbness in the fingers and toes, with progressive weakness in the arms and legs. Antibodies attack and damage the myelin sheaths that cover nerves, interfering with the conduction of electrical impulses and resulting in impairment of muscle movement and sensation.

Shirley: Tell me about your illnesses.

Roz: Well, it is a type of peripheral neuropathy that affects my legs, toes, arms and fingertips.

Shirley: Was the diagnostic process difficult?

Roz: It took some time. About four years ago, I developed tingling in my fingers and severe pain in my thumbs, followed by tingling and numbness in my toes. My doctor referred me to a neurologist. My situation is complicated because I have arthritis as well as spinal stenosis in my neck and lower spine. I also had breast cancer and have alopecia, causing complete hair loss—another immunological condition. Did these symptoms come from a new illness or were they from those I already had? The neurologist ordered many tests, including an MRI and a nerve conduction test called an EMG. He said he thought I had a neuropathy. He advised a second opinion at

University of Southern California medical school. They did a battery of nerve tests. The diagnosis of CIDP was confirmed almost a year later. I was put on Neurontin and Ultram for pain control. I was also seeing an oncologist and specialist in rare diseases, because I had breast cancer. When I told him about the neuropathy and my treatment, he suggested I look into getting IVIG. My neurologists agreed. I was referred to a clinic for IVIG. I receive 40 grams of IVIG once a week.

Shirley: Have you had any difficulty receiving it?

Roz: Yes, when the hospital clinic where I was receiving my IVIG notified me that they would no longer be giving IVIG.

Shirley: How was that resolved?

Roz: Luckily, there was a nurse who worked there who saw the problem as it emerged. She was very concerned for all the patients and recognized a community need. She started a company specializing in giving infusions.

Shirley: Do you know why the hospital clinic stopped giving IVIG?

Roz: Well, I'm not 100 percent sure, but we understand it was a financial decision.

Shirley: Has the medication helped you?

Roz: Yes. I think the Neurontin and Ultram help control the pain. I still have breakthrough burning pain in my toes and legs, which is very bad. But I am managing much better. I credit IVIG

with slowing the progress of the disease and maintaining my quality of life. My legs are no weaker, and I can still walk without a cane most of the time. I say this because I have a friend with a neuropathy whose HMO will not give her IVIG. Her disease has been progressing, and she now wears braces and uses a cane.

Shirley: Have you had any problems paying for the IVIG?

Roz: No problems, fortunately. I have Medicare with Blue Cross supplement. IG is delivered to our house and I give it to the nurse when she comes. The nurse is also paid by our insurance.

Shirley: Have you suggestions for our readers?

Roz: Yes. Attitude! Attitude! Attitude! Keep it positive. Know that there is always someone with a bigger rock in their shoes than the one you are walking on. Keep smiling. ■

Resources

- CIDP USA Foundation is committed to raising awareness of immune mediated diseases and supporting research into the cure of autoimmune disorders. www.cidpusa.org
- The GBS/CIDP Foundation International focuses on providing information and support for patients, family members and healthcare professionals. www.gbsfi.com
- The National Institute of Neurological Disorders and Stroke. www.ninds.nih.gov/disorders/cidp/cidp.htm

Managing SCIG Expectations

By Kit-Bacon Gressitt

Subcutaneous immune globulin (SCIG) is the treatment of choice for many patients, often for lifestyle reasons. Three of the most commonly cited benefits of SCIG are the flexibility of self-administration at the location and time of the patient's choice, greater mobility during treatment and a sense of freedom and control over one's care. But there are more than lifestyle factors to evaluate when deciding whether to shift from intravenous immune globulin (IVIG) to SCIG, and recognizing all the considerations can help patients make the most successful decision.

The first steps are for the patient and physician to discuss SCIG and review the available SCIG literature and other materials. "We bring it up to every patient," said Ralph Shapiro, MD, from the Midwest Immunology Clinic in Minnesota, an independent treatment center for patients with immune deficiencies and autoimmune disorders. "We offer all our patients all the choices they have for immunoglobulin replacement," including the full range of administration methods and sites of care. "We talk about the pros and cons of each, because for each patient the right choice may be different. A patient may wish to start with one method and as they get more comfortable, they move to the next. Or they'll see someone doing [SCIG], and they want to give it a try."

Although IVIG products have long been used in the United States for subcutaneous administration, since the 2006 Food and Drug Administration approval of Vivaglobin, the first U.S.-licensed SCIG for treating primary immune deficiency diseases, SCIG information has become more readily available (see SCIG Information Sources below) and more patients are pursuing SCIG.

"We have about 140 patients on subcutaneous," Dr. Shapiro said. "Maybe 10 to 15 have either tried it and decided it wasn't right for them or were on it for a while and then decided to go back to IVIG for one reason or another."

To assure the best experience with SCIG, it is important to understand how it works, how it is administered, potential side effects and what will be required of the patient and/or caregiver in comparison to IVIG treatment.

SCIG is, in action, similar to IVIG in that they both replace immunoglobulin (Ig). However, because SCIG is infused into subcutaneous or fatty tissue (see illustration), rather than into a vein, it is absorbed more gradually and does not

result in the dramatic shifts in Ig levels seen with IVIG infusions. Regular SCIG treatment—usually weekly infusions of smaller volumes than IVIG infusions—typically results in relatively stable serum Ig levels and consistently high trough levels.

Some patients who have successfully shifted from IVIG to SCIG anecdotally report fewer side effects, such as headaches, and less frequent infections. Anecdotes aside, however, there are some concrete issues to consider: The medical reasons for making the change—or not—should be thoroughly discussed with your physician. The chart below reviews deciding factors for and against SCIG.

Medical reasons for considering SCIG

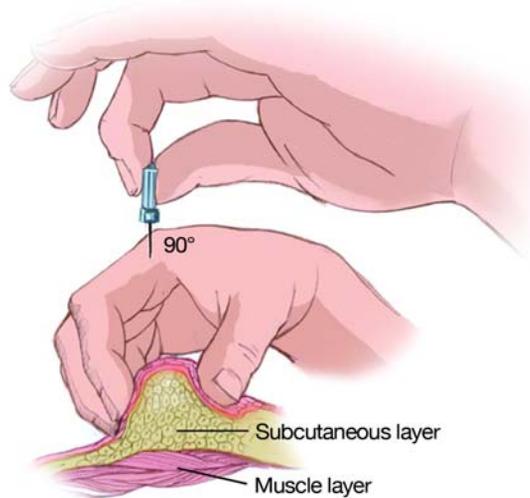
1. Feeling fatigued or listless between IVIG infusions, as serum Ig levels decline between visits
2. Developing infections between IVIG infusions, as Ig levels drop
3. Having difficulty accessing a vein or starting an IV
4. Experiencing severe reactions during or shortly after IVIG infusions, i.e., migraine, aseptic meningitis, severe nausea and vomiting
5. Requiring pre- or post-medication to avoid systemic reactions with IVIG

Medical reasons for rejecting SCIG

1. History of anaphylaxis or severe systemic response to IVIG
2. Having selective IgA deficiency
3. Having known antibodies to IgA
4. Having severe eczema or poor skin integrity
5. Having limited subcutaneous tissue
6. Being a patient or caregiver who is concerned about the ability to follow through on treatment at home
7. Physical inability of the patient or caregiver to administer SCIG therapy

In addition to the medical issues relevant to SCIG treatment, there are also personal issues to consider. Living with a chronic illness is challenging in many ways, and a therapy that, for instance, reduces logistical burdens can have a significantly positive effect on a family. Patients have found the following personal issues relevant to their decisions to shift to SCIG:

- Desire for more freedom and flexibility in scheduling treatments



"Pinch an inch" needle insertion

- Family, school, work or travel requirements that make regular IVIG infusion appointments problematic
- Ability to continue with work or household tasks while infusing
- Frequent visits to a healthcare facility for treatment have negatively affected the patient's self-image
- Desire for the sense of control and independence that self-administration provides
- Long distance to an infusion clinic or lack of in-home IVIG infusion services
- Presence of a caregiver in the home who can assist with SCIG treatment

In contrast, patients who have opted to stay on IVIG therapy have found the following personal issues affected their decisions:

- Desire for the social interaction and camaraderie at IVIG infusion appointments
- Discomfort with increased frequency of treatments
- Greater comfort with a traditional healthcare setting rather than homecare
- Desire for healthcare professional involvement rather than relying on self-administered treatment
- Having extreme discomfort with needles

Another increasingly important consideration is reimbursement. Medicare reimbursement for SCIG is currently higher than for IVIG, and, after the initial training, nursing services are not required for SCIG administration, but there may be a higher copay for the patient.

"We've had a couple of issues with insurance," Dr. Shapiro explained. "One of the insurance companies would not authorize subcutaneous for a patient under 2. I find SCIG is a lot less risky than a port-a-cath or an indwelling line. We've had a couple insurance companies have no idea what subcutaneous is. It's getting better with our local

insurers, but the ones who don't do a lot of it still have a learning curve." SCIG reimbursement is a topic you should explore with your physician's office and your insurer.

Perhaps the greatest challenge patients have had in transitioning to SCIG is training, a topic we have previously addressed in *IG Living* (see "SCIG Administration: Learning to Do It Yourself," Dec-Jan 2007-08). Vivaglobin's manufacturer, CSL Behring, recommends four to six training sessions prior to independent self-administration. The training sessions provide patients the opportunity to explore reactions (such as the red lumps some patients initially experience at infusion sites), get past that first needle "stick," learn to use the infusion pumps and develop an adequate level of comfort to continue treatment independently.

Dr. Shapiro described his center's training program: "Our process is that we have the patient come into the infusion center for the first dose. Then they go through the training program, and we encourage our patients to give it to themselves (some want a parent or spouse to administer it). It usually takes a couple weeks to get used to it. Most of the time we hear patients will never go back to IV because of the ease of subcutaneous and they don't have to go into a center."

Whatever method of immune globulin treatment is ultimately determined to be most appropriate for the individual patient, the best way to make that determination is to ask questions, evaluate the options and ask even more questions. A patient should never feel pressured into a treatment decision. Collaborative, well-informed decision-making with one's healthcare provider is the most likely path to a successful treatment decision. ■

SCIG Information Sources

American Academy of Allergy, Asthma and Immunology:
www.aaaai.org

FDA: www.fda.gov/bbs/topics/news/2006/NEW01294.html

Manufacturer: www.vivaglobin.com

"Subcutaneous IgG Replacement Therapy" by Melvin Berger MD, PhD, and Kim Duff, RN: www.uhhospitals.org/Portals/0/Docs/OurServices/Rainbow_Sub-Cu.pdf

Also visit the various online patient-oriented bulletin boards and chat rooms for personal anecdotal information (try searching by "subq ig" and "subcutaneous immune globulin") and any of the self-help medical information websites.



Hope Is In the Blood: IVIG and Alzheimer's Disease

By Zachary Pugh

In 1906, a German physician by the name of Dr. Alois Alzheimer examined the body of a woman who had died of a mysterious mental illness. He detected a peculiar and unexplained change in her brain tissue: abnormal clumps and tangled bundles of fibers. Often called *amyloid plaques*, because they are formed due to high levels of amyloid peptides, these clumps are actually harmful deposits of plaque found between neurons. The fibers are called neurofibrillary tangles. And the plaque and fibers are now known to be signs of Alzheimer's disease, but achieving a diagnosis does not produce a treatment, and that pursuit has become more serious as the population of the United States is aging.

Recently, hope has arisen that an effective treatment for Alzheimer's disease may become a reality, and the hope quite literally is in the blood. More specifically, in the antibodies found in human immunoglobulin, the essence of intravenous immune globulin (IVIG).

Currently completing a Phase II clinical trial, researchers and scientists at NewYork-Presbyterian Hospital/Weill Cornell Medical Center have discovered that antibodies found in IVIG could protect the brain from Alzheimer's disease. These antibodies could essentially preserve the

brain by reducing the harmful levels of amyloid peptides, thus inhibiting formation of the amyloid plaque.

The research is essentially directed toward patients with mild to moderate cases of Alzheimer's disease. "Mild is really the earliest categorization that we currently have available. When you first get diagnosed, it's very slight discreet memory difficulties, and you've ruled out everything else," said Dr. Maria Carrillo, director of medical and scientific relations at the Alzheimer's Association. "And you have a 90 percent certainty that this is Alzheimer's disease, we classify those folks as mild."

Alzheimer's disease progresses over a period of time, and the rate of progression varies from person to person. For people with moderate Alzheimer's disease, there are more than just mild, slight memory problems. "They start experiencing confusion, they start to not recognize their family members, they'll start to have difficulties performing everyday tasks such as dressing themselves," Dr. Carrillo explained.

What Causes Alzheimer's Disease?

Although the complete understanding of what causes Alzheimer's disease is relatively unclear, research has targeted a particular protein called beta amyloid, which naturally

occurs in the human body. "Beta amyloid is a kind of lynchpin in a cascade of events that we think eventually lead to the disease," said lead researcher Norman Relkin, MD, associate professor of clinical neurology and neuroscience at Weill Cornell and director of the Memory Disorders Program at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. "Amyloid is produced in our body, in particular, in our brain, in a natural form, which is fairly benign and which we live with for a good portion of our lifespan without having any difficulty.

"We recognized that this protein was the center of the plaque that accumulates in an Alzheimer's disease brain, and in the brains of many elderly people without Alzheimer's," Dr. Relkin continued. "In recent years, it's come to light that, in the process of going from the single molecule of amyloid to the insoluble clumps that accumulate in the brain, there are some intermediates. And these intermediates are soluble aggregates. They're small clumps of molecules that stay in solution and which are highly toxic to brain cells."

These aggregates, commonly known as oligomers, "bind to the membranes of brain cells and can actually punch holes in them," Dr. Relkin explained. "They can bind to the connections between brain cells and block the transmission of impulses between them and thereby interfere with memory and other thinking ability. So, we set out to find a way to get rid of amyloid, but discovered even more in the process."

The Trials

The first attempt of using anti-amyloid therapy occurred in 1999 when scientists at Elan Pharmaceuticals, using animal models, developed a vaccine targeting the single molecules. "The vaccine causes the body to produce antibodies against amyloid, which in animal models cleared the plaques out of the brain—quite a remarkable result," Dr. Relkin said.

However, in 2002, when the vaccine method was used on humans, there were some severe side effects including "brain inflammation in about 6 percent of people who were vaccinated, and two out of the 300 people who got the initial treatment died as a result," Dr. Relkin explained.

Because of these adverse reactions, the trials for this vaccine method were stopped. "It was really in that context that we turned to IVIG, because now we have some evi-

dence that antibodies could exert some therapeutic benefit, but we were concerned, of course, about safety," Dr. Relkin said. "Here's where IVIG offered some very clear advantages because there was a 25-year record of use and an established record. We knew what we had to watch out for.

"In 2004, we started a small trial. And the basic reason for that trial—it was only eight patients—it was to examine whether, if we gave IVIG to Alzheimer patients, it would be tolerated and it would raise levels of antibodies against amyloid and, as a consequence, change the levels of amyloid in the blood and the spinal fluid. The study was a success in terms of showing all of those things."¹

With the success of the 2004 trial, Dr. Relkin and his team began to further research the advantages of IVIG therapy for the treatment of Alzheimer's disease. "In 2006, we started a Phase II trial. Now we were much more interested in seeing what the clinical effects were," Dr. Relkin explained. "We did a full placebo-controlled double-blind study with biological markers and brain imaging. And we're still in the process of completing that study, but we did the preliminary interim analysis from six months of double-blind placebo-controlled work, and they were positive again. So, we replicated our results from the first study."²

Dr. Relkin's work did not go unnoticed. "In 2007, the National Institutes of Health awarded us a grant close to \$8 million for initiation of a Phase III study," he said. "This past summer, Baxter committed additional funds to permit us to do a much bigger and better Phase III study that is now getting under way in 2008."

Supply: A Delicate Balance

With this exciting new discovery comes the topic of IVIG supply. Will there be enough IVIG to meet the demand when, and if, it is approved for the treatment of Alzheimer's disease? This is a topic familiar to Dr. Relkin, one that he and his team have considered.

"Alzheimer's disease represents a very new direction for intravenous immune globulin therapy and one which kind of has an inherent problem," Dr. Relkin explained. "There is a relative shortage of IVIG for its approved indications. There's a lot of off-label use, and there have been shortages where people who have diseases for which IVIG is clearly life-preserving had their supply threatened. ➤

¹ "18-Month study of intravenous immunoglobulin for treatment of mild Alzheimer disease," *Neurobiology of Aging*, 21 February 2008, Norman R. Relkin, Paul Szabo, Basia Adamiak, Tuna Burgut, Carmen Monthe, Richard W. Lent, Steven Younkin, Linda Younkin, Richard Schiff and Marc E. Weksler.

² Phase II interim results will be presented for the first time at the American Academy of Neurology meeting in Chicago, April 17, 2008.

“One of the things that we’re very aware of ... is that there’s some anxiety on the part of IVIG users with other diseases about this particular indication,” Dr. Relkin said. “If this is approved as a treatment for Alzheimer’s, the concern is that it would basically bankrupt the supply of IVIG and potentially deprive other people of that supply.”

Although the issue of supply is a factor that troubles many, Dr. Relkin is optimistic and believes it is not going to become an “either-or proposition—that people either get it for Alzheimer’s or get it for these other indications. He elaborated. “We’re working both on understanding how IVIG works on Alzheimer’s disease and taking from that ways of either increasing supply or coming up with alternatives based upon the mechanism.

“We’re not doing this blind to the other side of the coin, which is that IVIG is an effective treatment for many other diseases, and we have no intention of bankrupting the supply.” Dr. Relkin suggested there would likely be a gradual transition to IVIG, if approved, and the supply would be “controlled and the supplies will be increased and there will be other steps taken to prevent it from toppling the balance of distribution of IVIG.”

New Findings

In their research, Dr. Relkin and his team have found some new and unexpectedly positive results regarding the effects of IVIG in Alzheimer’s disease patients. “We’ve discovered that the antibodies that we originally measured in IVIG could not account for the effects that we were seeing. There were too few to cause such large changes in the amyloid levels and the spinal fluid,” Dr. Relkin explained. “We went back, and we and another group have found new antibodies that were not previously known to exist present in much higher quantities.

“And what’s extremely interesting about these antibodies in IVIG, and in our blood, is that they bind not to the single molecules of amyloid but the clumps. So, they don’t recognize the chemical structure of amyloid; instead they recognize the folded shape and aggregated form that the amyloid assumes when it becomes toxic. And this has led us to question whether this, in fact, might be part of a natural body defense against diseases like Alzheimer’s.”

This surprising discovery has enabled the researchers to reduce the doses of IVIG and could, Dr. Relkin said, potentially lead to the development of a synthetic antibody, which would provide the same treatment and relieve the dependency on IVIG. “We’re now using one-tenth the amount of IVIG that we initially started studying, because we recognized that we had more antibodies

present than we initially appreciated,” Dr. Relkin explained. “It’s intriguing that we have antibodies at all against a protein that we produce from birth because most of the time the body does not do that, it’s tolerant of its own proteins. But it appears that the body differentiates between amyloid in its native form and amyloid in its toxic, age-related form. And these antibodies are produced and bind to the amyloid protein, and we’re showing now it reduces its toxicity and fosters its clearance from the body.”

Moving Forward

Dr. Relkin expects the Phase III trial to be completed in 2010 or 2011. “It’s a pivotal trial, so the intention is to submit it to the FDA for potential regulatory approval of an indication.”

With their long-term trials showing sustained benefits, Dr. Relkin and his team will continue to treat their Phase II patients out to two years and beyond. “So far, it has been an extremely enlightening experience,” Dr. Relkin said. “And happily, it’s also led to some patients getting better, which is something that we ultimately, of course, want to see happen. We have patients from our regional study who are now in their third to fourth year of treatment and have enjoyed sustained benefits. We are really, really happy about that.”

Although these new developments are extremely promising, Dr. Relkin is cautious. “I certainly would not refer to this [IVIG] as a cure. I think that this is an important step forward in treating a disease ... which is reaching epidemic proportions and increasing very rapidly. And I think it’s a window into how we’re going to treat Alzheimer’s disease in the future. But it’s not the final answer to the problem.”

Dr. Relkin said that Alzheimer’s is the result of increased human longevity. “And, because of that, we are now facing a situation where it really is desperate, almost, that we find a way of at least halting the progression of the disease. If we can do that, if we can delay the start of the illness, people will die of better causes and of old age before they develop dementia from Alzheimer’s.”

And there are millions of families around the globe who share Dr. Relkin’s vision. ■



From the Neuropathy Action Foundation

Mark your calendar now for the largest neuropathy patient event of 2008!

The Neuropathy Action Foundation's (NAF) second annual meeting coincides this year with the State of California's Neuropathy Action Awareness Day on June 26, 2008. NAF will host the information-filled event at the University of California San Francisco.

NAF expects nearly 300 patients, physicians and others from around the country to attend the free daytime educational sessions, exhibits and lunch, and the evening reception, silent auction and dinner. The dinner will feature California state Sen. Leland Yee; California state Assemblymember Mary Hayashi; the 17th surgeon general of the United States, Richard H. Carmona; and a special celebrity guest!

Educational session topics include patient advocacy, neuropathy basics, pain management, diabetic neuropathy and nerve decompression surgery, Medicare, IMG and the importance of plasma, complementary and alternative approaches to pain management and more.

From the 2007 NAF Meeting



Dominick Spatafora



California State Assemblymember Mary Hayashi



Melissa Schweitzer, Michelle Vogel and Dominick Spatafora

The speakers confirmed to date include:

- Scott M. Fishman, MD, University of California Davis
- Eric Hassis, MD, Institute for Restorative Health
- Jonathan Katz, MD, California Pacific Medical Center
- Todd Levine, MD, Banner Good Samaritan Medical Center and Clinical Assistant Professor, University of Arizona
- Ziv M. Peled, MD, Dellon Institute for Peripheral Nerve and Plastic Surgery
- Jeffrey W. Ralph, MD, University of California San Francisco
- David Saperstein, MD, Banner Good Samaritan Medical Center and Clinical Assistant Professor, University of Arizona
- Patrick M. Schmidt, President and CEO of FFF Enterprises
- Marco Vespignani, ND, Institute for Restorative Health
- Michelle Vogel, Alliance for Plasma Therapies

The NAF is dedicated to ensuring neuropathy patients obtain the necessary resources, information and tools to access individualized treatment and improve their quality of life. The NAF increases awareness among physicians, appropriate institutions, the general public and public policy officials that neuropathy can potentially be a serious, widespread and disabling condition, which may be treatable when appropriate medical care is accessible.

For more information, please visit the NAF website at www.neuropathyaction.org or email the NAF at info@neuropathyaction.org. ■

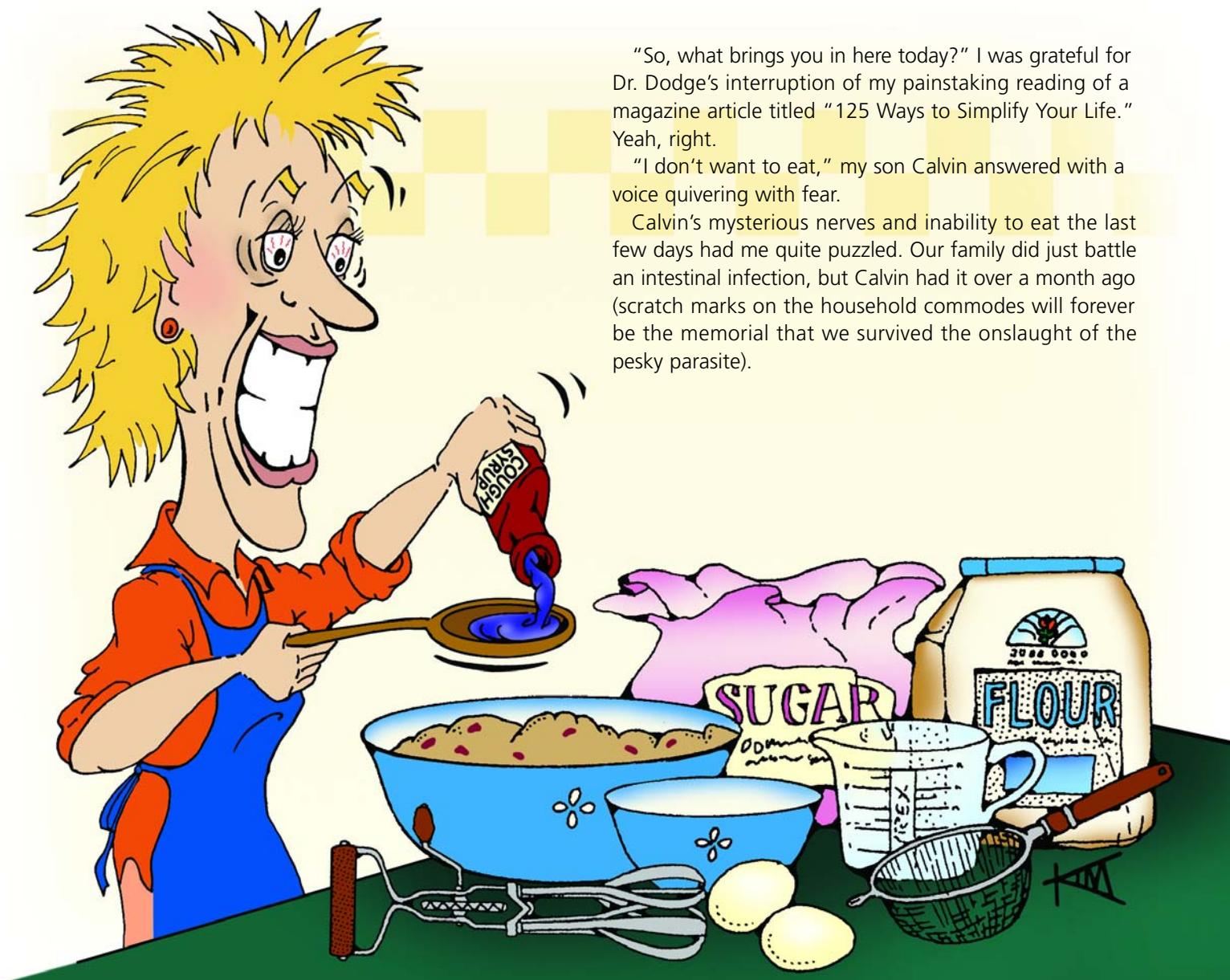
The Secret's in the Sauce

By Cheryl L. Haggard

"So, what brings you in here today?" I was grateful for Dr. Dodge's interruption of my painstaking reading of a magazine article titled "125 Ways to Simplify Your Life." Yeah, right.

"I don't want to eat," my son Calvin answered with a voice quivering with fear.

Calvin's mysterious nerves and inability to eat the last few days had me quite puzzled. Our family did just battle an intestinal infection, but Calvin had it over a month ago (scratch marks on the household commodes will forever be the memorial that we survived the onslaught of the pesky parasite).



Calvin had seen his fair share of doctor and hospital offices, as his younger siblings, Caleb and Molly, live with an immune deficiency. By age 10, I thought he had the office visit routine mastered: Stand here to be weighed, put your arm out like this for the blood pressure cuff, and place your finger in here to measure oxygen levels.

In fact, our kids are quite versed in soothing themselves during office visits. Calvin usually relaxes in a corner, manipulating "Mario and Luigi" on his handheld video game. Molly likes to draw princesses on the "sterile" paper exam table liners. And Caleb usually finds something brilliant to do with examination gloves (mostly blowing them up into balloons or putting them over his head, bending at the waist and clucking like a chicken). Recent clinic notes have become entertaining: Patients are not interested in examiner; spent most of their time giving a petrified cockroach a ride on examination table.

But now, Calvin just wasn't himself, and it was driving me batty. His uncommon behavior reminded me of a golf ball unraveling as I became increasingly frustrated with him.

"Calvin, sit still!" I pleaded as Dr. Dodge guided his stethoscope over his chest.

"Yeah, Calvin," Dr. Dodge jumped in. "If you don't chill, I may misdiagnose you and prescribe the wrong medicine!"

"Maybe that's what the doctor should order," I joked. "Chill pills for Calvin and an extra dose for Momma!"

The momentary giggling turned serious as Dr. Dodge turned to me and said, "I don't find one thing wrong with him."

"Really?" I questioned.

"Just growling in his stomach from lack of food," Dr. Dodge assured.

"Tell me, Calvin," Dr. Dodge asked, "what was the last thing you ate?"

A contemplative look came over my melancholy young man. He placed an index finger on the side of his nose as if he was engaging in some meaty conversation with Plato himself.

Deep in thought, Calvin mumbled something, and Dr. Dodge and I labored to understand Calvin's breathy answer.

"Did you just say cinnamon rolls?" I asked.

"Yeah, cinnamon rolls from IVIG day," Calvin responded.

Infusion day for Caleb and Molly usually includes doses of Benadryl and Tylenol, chased down with freshly baked cinnamon rolls, a pleasant family tradition that comforts the other, rather unpleasant tradition of needle sticks.

"But why haven't you eaten since then, Calvin?" I asked with a hint of concern.

A defeated look took over Calvin's countenance as he hung his head and smacked his dangling feet together in nervous rhythm. I knew he wanted to fess up to whatever was bothering him, but Calvin's 10-year-old moral code (and innate fear of being grounded) kept his secret deep within.

"If I tell you, will you promise not to punish them?" Calvin asked.

"Them?" I asked, while Dr. Dodge muffled his laughter.

As a protective big brother, Calvin has become accustomed to shielding his chronically ill siblings from unnecessary pain. But this was ridiculous.

Calvin turned a guarded eye and muttered, "You know you're the best cooker in the world, Mom."

"Yes?"

"Well, Caleb and Molly told me you were using numbing cream to frost the cinnamon rolls and cough syrup for vanilla when you were baking cookies the other day."

I know normal families tease each other. Whoopee cushions and joy buzzers come to mind.

But families with PIDD? Oh, we'd rather torture one another with threats of drug-tainted cookies and infusion-site numbing cream frosting! That's brilliant!

After explaining that I did not mess with Calvin's favorite bedtime snack or our family's traditional IVIG day cinnamon rolls, my son and I enjoyed a hearty laugh over hot chocolate. I was relieved that we were not in for another round of rotavirus.

And just last Thursday, IVIG day, Calvin shot me a curious smirk as I was frosting the cinnamon rolls and whispered, "Hey mom, the icing looks real gooooood today."

"Yes, Calvin," I teased. "The secret's in the sauce." ■

Troubled Waters:

Preventing Waterborne Illnesses

By Jessica Schulman, PhD, MPH, RD



Dr. Hardcastle had so many sick patients that he could not take care of them all. It was the summer of 1831, and residents of Newcastle, England, were contracting cholera, a serious infection that causes cramps, vomiting and diarrhea severe enough to cause dehydration and death if left untreated. Overwhelmed, Hardcastle sent his apprentice, 18-year-old John Snow, to treat those who had fallen ill. After 50,000 people had perished from the disease, Snow grew to believe that the infection was at least partly spread through contaminated water. By mapping the incidence of new cases, he was able to identify the public water pump on Broad Street as a source of new infections, and he recommended that the handle on the pump be removed so that local residents would no longer be exposed. In September 1854, after a new outbreak of cholera, authorities finally removed the handle on the contaminated pump, but this came too late for many. Snow eventually became a medical doctor.

Although the risks today may not be as grave as they once were, the U.S. Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) warn that we still have far to go before we can drink water without worrying about the threat of waterborne diseases.¹ In a 2006 review of household drinking water, scientists estimated there are 16.4 million cases of acute gastrointestinal illness (AGI) due to consumption of waterborne pathogens each year.² As staggering as this estimate is, it does not account for illnesses associated with commercially bottled water or recreational water. Moreover, this estimate addresses only AGI, not other chronic conditions such as autoimmune phenomena (see Table 1) that are also associated with waterborne infections.

The purpose of this article is to increase awareness of waterborne illness and describe how individuals with weakened immune systems or other vulnerabilities can become better consumers of water—and have a safe summer!

¹ EPA, Health and Environmental Effects Research Lab. Waterborne disease research summaries. July/August 2006. URL: www.epa.gov/nheerl/articles/2006/waterborne_disease.html.

² Messner M, Shaw S, Regli S, Rotert K, Blank V, Soller J. An approach for developing a national estimate of waterborne disease due to drinking water and a national estimate model application. *Journal of Water and Health* 2006;4(Suppl 2):201-240.

Do You Know Your Water?

Do you know what you are drinking? Dive in and test your knowledge with this True or False quiz about the safety of your drinking water.

True or False? Do not drink water directly from lakes, rivers, streams, springs or swimming pools.

True. That was an easy one. If you said, “true,” good work!

True or False? Tap water is safe for everyone.

False. Do not assume that drinking water in the United States is safe for everyone. The safety of tap water depends on an individual's health status or vulnerability. Both tap and bottled water may contain at least small amounts of some contaminants, because drinking water

comes from rivers, lakes, streams, ponds, reservoirs, springs and wells. As water travels, sometimes thousands of miles, it picks up naturally occurring minerals and, in some cases, radioactive materials or waste from human or animal activity. The EPA and state governments enforce regulations so that water is considered reasonably safe for human consumption. However, people with weakened immune systems, such as older adults, pregnant women and infants, and those who have undergone medical treatments or live with immune system disorders should also seek advice from their physicians about drinking water. Annual consumer confidence reports are available in most water districts so that the public can read about the level of residual disinfectants or contaminants (i.e., microbes, inorganic contaminants, pesticides, herbicides and radioactive elements) that might land in

their drinking glasses. Because public water quality and treatment standards vary throughout the United States, always check with the local health department and water utility company to see if they have issued any advisories about the use of tap water for those living with weakened immune systems or chronic conditions.

True or False? Anyone who lives with a weakened immune system should avoid exposure to ice or drinking water from a public water or soda fountain.

True. Ice is typically prepared with tap water. If public water or soda fountains are not well maintained, the drinking water used to make ice can easily be contaminated with infectious agents. Additionally, popsicles and flavored ices that may have been made with contaminated water should be avoided. ➤

Table 1. Waterborne contaminants with selected examples and associated complications.

Contaminant	Selected Examples	Associated Complications
*Bacteria	<i>E. coli</i> O157:H7	Hemolytic uremic syndrome (destruction of red blood cells) and kidney failure
	<i>Shigella</i>	Reactive arthritis, or Reiter's syndrome
	<i>Campylobacter jejuni</i>	Infections of the blood, liver, and pancreas; Guillain-Barré or Miller Fisher syndrome (a polio-like paralysis)
	<i>Legionella</i>	Pneumonia, sepsis, kidney failure
	<i>Salmonella</i>	Reactive arthritis, sepsis
	<i>Vibrio cholera</i>	Dehydration and shock
	<i>Yersinia enterocolitica</i>	Colitis, rheumatic disease, ankylosing spondylitis, and extraintestinal infections
*Parasites	<i>Plesiomonas shigelloides</i>	Sepsis and blood poisoning
	<i>Cryptosporidium</i>	Hepatitis, pancreatitis, bile duct infections
	<i>Giardia</i>	Malabsorption of nutrients
	<i>Naegleria fowleri</i>	Inflammation and destruction of the brain
*Virus	Norovirus	Rare cases of encephalopathy
	Hepatitis A	Liver disease
Inorganics	Lead	Cognitive deficits, kidney damage, high blood pressure
	Nitrate	Methemoglobinemia or “blue baby syndrome”
	Arsenic	Various cancers, cardiac disease, diabetes
	Disinfection byproducts	Bladder and GI cancer, poor reproductive and developmental end points
Organics	Methyl tert-butyl ether (MTBE)	Cancers, neurological and reproductive health effects
	Pesticides	Cancers, birth defects, neurologic and endocrine abnormalities
Radionuclides	Ionizing radiation (alpha/beta particles, photon emitters, radium 226/228, uranium) and radon	Various cancers

*Denotes pathogen that causes acute gastrointestinal issues and was documented by the CDC, 1991-2002.³ Total outbreaks reported = 207; confirmed cases of the waterborne illness = 433,947.

³ Craun MF, Craun GF, Calderon RL, Beach MJ. Waterborne outbreaks reported in the United States. *Journal of Water and Health* 2006;(Suppl 2):19-30.

True or False? Ornamental and splash fountains can transmit harmful bacteria.

True. It is sensible to avoid ornamental water fountains in public spaces, especially for those with weakened immune systems. *E. coli*, salmonella and other bacteria have been identified in ornamental fountains. When geysers from contaminated fountains are projected several meters high, their mist helps to transport pathogens to your eyes, nose and mouth. In 2005, for example, an outbreak of cryptosporidium (also called crypto) that infected nearly 4,000 people was traced to Seneca Lake State Park, a state-of-the-art spray park facility in upstate New York.⁴

True or False? I should be concerned about foods that may have come in contact with contaminated water.

True. Waterborne infections can be contracted by eating food that has been exposed to contaminated water. For example, the cholera bacteria can spread disease rapidly in areas with polluted rivers, coastal water or contaminated drinking water. Even people with robust immune systems have contracted cholera from consuming undercooked or raw shellfish. Due to increased travel from the United States to other countries, where cholera epidemics still occur, travelers may be exposed to cholera and bring contaminated seafood back to the United States.

Moreover, there have been cases of produce, such as salads and fruit, that have been contaminated at the source. Produce that is not peeled, such as lettuce, is easily contaminated and difficult to wash well. For example, hepatitis A has been found in lettuce, frozen strawberries, raspberries, diced tomatoes and watercress; Norwalk virus has been found in raspberries, basil and lettuce; crypto has been found in unpasteurized apple cider; and giardia has been found in lettuce and onions. In general, it is advised that individuals with weakened immune systems avoid raw vegetables and fruits that cannot be peeled or boiled.

True or False? Boiling your water will kill most microorganisms.

True. Boiling is the best additional measure to ensure that your water is free of germs. A rolling boil for more than one minute will kill pathogens such as crypto. After the water cools, put it in a clean container with a lid



and store it in the refrigerator. It is advisable to use this water for drinking, cooking and making ice. There is a down side to boiling water, however. In certain cases, boiling water may concentrate chemicals such as nitrate and lead by 20 percent. This is particularly dangerous for infants and young children. Thus, before relying on boiled water, contact your local water provider and find out if your water is high in certain contaminants. If there is a concern about these contaminants, obtain water from another source.

True or False? Bottled waters have had all pathogens removed.

False. There is no way to ensure that all contaminants have been removed without testing the water. NSF International is an independent certification company that tests bottled water to determine whether or not the manufacturer is in compliance with federal guidelines. There are two questions to ask when evaluating the safety of bottled water: (1) What is the source? and (2) What is the method used to disinfect the water?

Bottled water from a protected well or spring is less likely to contain pathogens than bottled water that contains municipal water from a river, stream or lake. Still, selecting a protected source is just the first step in assessing drinking water safety.

The CDC explains that bottled water labels reading "well water," "artesian well water," "spring water" or "mineral water" do not guarantee that the water does

⁴ Clark BT. Cryptosporidiosis: A Recreational Water Threat That Hasn't Gone Away. *Journal of Environmental Health*. 2007;69(10):65-67.

not contain pathogens. In general, water that comes from some of these protected sources is less likely to contain microbes than water that comes from rivers or lakes. A more cautious approach is to look at how the water was treated or disinfected. The CDC considers most water sources that have been treated by one or more of these methods to be considered safe for removing pathogens: (a) reverse-osmosis treated, (b) distilled, or (c) filtered through an “absolute” 1 micron or smaller filter. This method will filter out other contaminants but not all types.

True or False? Any home filter will remove pathogens.

False. Not all home water filters remove pathogens. Filters that have the words “reverse osmosis” will protect against crypto. The filter should say, “absolute 1 micron” because some “1 micron” and most “nominal 1 micron” filters will not guard against crypto. Also, look for the terms, “Standard 53” and “cyst reduction” or “cyst removal” for an NSF-tested filter. Check the model number on the filter you intend to buy to make sure it is exactly the same as the number on the NSF list (search for NSF certified products at www.nsf.org/consumer). The NSF mark provides some assurance that the product has been tested by an independent certification company.

However, it is important to remember that NSF tests filters for many different purposes. A filter that is “effective against giardia” may not guard against crypto—a smaller parasite. According to the CDC, terms such as carbon filter, water purifiers, EPA approved or registered (beware—EPA does neither!), removes chlorine, activated carbon, ultraviolet light, pentiodide resins and water softeners do not guard against crypto.

Be sure to maintain and replace filter cartridges as suggested by the manufacturer or the filter may fail. Ask someone who has a robust immune system to change the filter. Wear gloves and wash your hands afterward. Still, no single filter can remove everything. Consider having your drinking water tested by a certified laboratory—do not rely on salespeople—so you can choose the filter that best suits your needs. Have the test results explained to you.

True or False? Soft drinks in cans or bottles are a better choice for avoiding microbes than drinks made at a fountain.

True. Carbonated drinks and other beverages may or

may not contain disease-causing germs, depending on how they are prepared. Beverages that are steaming hot (more than 175 degrees Fahrenheit) are a good choice. Also, pasteurized dairy or juice drinks and canned or bottled soda are good choices. In contrast, ice tea, fountain drinks and smoothies that are mixed with ice from tap water are not always safe. When traveling, carbonated drinks that are canned or bottled are a better choice than flat drinks.

True or False? A waterborne infection can be transmitted from water to a person, person to person and animal to person.

True. Waterborne diseases can be spread in different ways including: (1) drinking liquids or eating foods that are infected, (2) touching surfaces or objects that are contaminated and (3) having direct contact with another person who is infected or showing symptoms. When an individual is exposed to the pathogen, it can thrive in, or pass through, the host and become infectious to others.

For example, in 1993, there was an outbreak of cryptosporidiosis in Milwaukee, Wis. Approximately 400,000 people were affected, and many cases of crypto were contracted from secondary sources, including food, recreational water, infected people and animals and contaminated surfaces (including toys). Although the actual incidence of primary and secondary waterborne disease is not well studied, Dr. Snow warned about this phenomenon more than 150 years ago:

“Cholera ... spreads more readily from person to person in the crowded dwellings. ...Even when the malady is propagated through the water supply, it causes a higher mortality among the poor than among the well-to-do, because, in addition to the cases caused directly by the water, others arise from the disease passing from one member of a family to another.”⁵

Is there a way to reduce the chances of acquiring a secondary infection? Use good hand hygiene and clean surfaces with a diluted solution of chlorine-containing bleach (mix about one-fourth of a cup of bleach with one gallon of water). This will not destroy all microorganisms but will reduce your chances of becoming infected.

True or False? The chlorine in swimming pools, hot tubs and water parks kills all pathogens. ➤

⁵ Snow J. Further remarks on the Mode of Communication of Cholera; including some comments on the recent reports on cholera by the General Board of Health. MTG 11 (14 July 1855): 31-35; (28 July 1855): 84-88. Published in *Medical Times and Gazette*, 1851, Vol. I.

False. Certain pathogens may be present in chlorinated water, fresh water or salt water. Crypto, for example, is not killed by the amount of chlorine used in swimming pools, hot tubs and at water parks. E. coli bacterium and hepatitis A virus die fairly quickly when a pool is properly disinfected, but parasites are more unruly. Giardia may take one hour to die, whereas crypto may take seven days to die. Over the past five years, there has been a steady increase in the number of cases of crypto as it has become more resistant to chlorine.

In 2006, about 18 cryptosporidiosis outbreaks were reported to the CDC, compared with five outbreaks reported for 2003.⁶ Nearly 50 percent of all pool infections are a result from crypto.⁷ People who live with weakened immune systems should avoid swallowing water when using a pool or hot tub.

The Bottom Line: Drinking Water Safely

Although we follow strict methods of water protection and treatment to guard against waterborne diseases, these methods can break down in a variety of ways. Scientists at the EPA and CDC warn that we should not be complacent about current water sanitation processes. If we ignore the potential for water contamination as it travels through the distribution system, we place our health at risk. This is particularly true for those who live with immune deficiencies.

How Can We Be Good Consumers of Water and Prevent Waterborne Illness?

- Follow guidelines: Track the CDC and EPA guidelines for water safety and hygiene—and consult with your doctor.
- Order confidence reports: Request an annual confidence report to learn what contaminants may be in your water, and read about advisories in your area.
- Make inquiries: Contact the CDC, EPA, and/or NSF International for more information about drinking water safety, filters and bottled water.
- Call and report: Take action! Contact the CDC to find out how to report suspicious symptoms or concerns about waterborne illness.
- Document the incidents: Make sure your healthcare provider is documenting evidence of any suspected waterborne illness.

The water industry and government can only correct drinking water problems if they know what is occurring in our communities. So, it is crucial that patients and the medical community report and document cases of waterborne disease. In the end, protecting an individual's health might depend on being an informed consumer of water—and physicians being able to guide their patients to make sensible health choices.

Ultimately, we need to be aware of the handle on our own “Broad Street pumps.” ■

Resources

Centers for Disease Control and Prevention
CDC-INFO at 800-CDC-INFO (800-232-4636)
TTY: 888-232-6348

Consumer Confidence Reports
www.epa.gov/safewater/dwinfo/index.html

Clean Water Lead Testing Inc. (CWLTl)
Visit www.leadtesting.org for useful information

EPA's Safe Drinking Water Hotline:
800-426-4791 www.epa.gov
Visit www.epa.gov/safewater/labs to find a lab in your area

NSF International
800-NSF-MARK (800-673-6275)
Visit www.nsf.org for information about filters and bottled water

Recreational Water Illness Prevention Week
May 19–25, 2008
www.cdc.gov/healthyswimming/index.htm

This article is for informational purposes only and is not meant to be used as a substitute for consultation with a physician. Individuals with chronic conditions should consult their physicians to determine what is appropriate for them. The author is a credentialed dietitian, holds a doctorate in health behavior, and is a visiting scholar in the Department of Psychology at the University of California, Los Angeles.

⁶ Morbidity and Mortality Weekly Report (MMWR), Cryptosporidiosis outbreaks associated with recreational water use—five states, 2006. July 27, 2007;56(29):729-732.

⁷ CDC, MMWR, Your health, swimming, and waterborne illnesses. Podcast released: 5-18-07. Series Name: A cup of health with CDC. URL: www.cdc.gov/healthyswimming.

Resource Directory

Ataxia Telangiectasia (A-T)

Websites

- A-T Children's Project: www.atcp.org
- NINDS A-T Information Page: www.ninds.nih.gov/disorders/a_t/a-t.htm

Chronic Inflammatory Demyelinating Polyneuropathy (CIPD)

Websites

- GBS/CIDP Foundation International: www.gbsfi.com
- National Institute of Neurological Disorders and Stroke (NINDS) Chronic Inflammatory Demyelinating Polyneuropathy (CIPD) Information Page www.ninds.nih.gov/disorders/cidp
- Neurology Muscular Dystrophy and Neuropathy Institute Illustration of a damaged myelin sheath on a nerve: www.beverlyhillsneurology.com/cidp

Online Peer Support Links

- The Neuropathy Association: www.neuropathy.org
- Barbara's CIDP/GBS Site (This is a personal website) www.geocities.com/HotSprings/Falls/3420

Evans syndrome

Websites

- Evans Syndrome Research and Support Group: www.evanssyndrome.org
- Office of Rare Diseases (catalog of online resources) <http://rarediseases.info.nih.gov/asp/diseases/diseaseinfo.asp?ID=6389>

Guillain-Barré Syndrome (GBS)

Websites and Chat Rooms

- The GBS/CIDP Foundation International, www.gbsfi.com, has 23,000 members in 160 chapters on five continents. 610-667-0131
- The GBS Foundation Discussion Forums provide the opportunity to talk to other GBS patients and learn more about ways to manage the illness: www.guillain-barre.com/forums.
- Miller Fisher syndrome, considered to be a variant of GBS, is explained on the National Institute of Neurological Disorders and Stroke, NINDS Miller Fisher Syndrome Information Page: www.ninds.nih.gov/disorders/miller_fisher/miller_fisher.htm.

Online Pamphlets

- The National Institute of Neurological Disorders and Stroke has a GBS Fact Sheet at www.ninds.nih.gov/disorders/gbs/detail_gbs.htm.
- The Mayo Clinic has an overview of Guillain-Barré syndrome at www.mayoclinic.com/health/guillain-barre-syndrome/DS00413.
- The National Institute of Neurological Disorders and Stroke has an information page about CIDP: www.ninds.nih.gov/disorders/cidp/cidp.htm.

Online Peer Support

- GBS & CIDP Discussion Forum – UK Bulletin Board – For Ireland and England www.gbs.org.uk/cgi-bin/ikonboard3/ikonboard.cgi
- GBS Support Group and Chat Room, UK www.jsmarcussen.com/gbs/uk/chat.htm

- GBS Foundation Discussion Forums: www.guillain-barre.com/forums
- Yahoo Support Group Discussion Board http://health.groups.yahoo.com/group/GBS_CIDP

Books and Articles

- "A Handbook for Care Givers," by Helen Rummelsburg, gives an account of caring for her husband and offers helpful hints for patients and caregivers. Available at the GBS website bookstore at www.gbsfi.com.
- "Bed Number Ten," by Sue Baier, provides a view of long-term care through the eyes of a patient totally paralyzed with GBS.
- "Caring for a Child With GBS," by Patricia Schardt, is a short guide written by a mother of a child with CIDP. Available at the GBS website bookstore at www.gbsfi.com.
- "No Laughing Matter," by Joseph Heller (the best-selling author of Catch-22), who teamed up with Speed Vogel, his best friend, to describe Heller's battle with and triumph over GBS.

ITP (Idiopathic Thrombocytopenic Purpura)

Websites

- ITP Support Association, UK: www.itpsupport.org.uk
- Platelet Disorder Support Association: www.pdsa.org
- National Heart, Lung and Blood Institute www.nlm.nih.gov/health/dci/Diseases/itp/ITP_Whats.html

Online References

- Idiopathic thrombocytopenic purpura http://en.wikipedia.org/wiki/Idiopathic_thrombocytopenic_purpura
- Idiopathic Thrombocytopenic Purpura: Michael A. Silverman, MD www.emedicine.com/EMERG/topic282.htm
- Immune Thrombocytopenia: Current Understanding and Future Research, Robert S. Mocharnuk, MD www.medscape.com/viewarticle/459249
- ITP: Idiopathic Thrombocytopenic Purpura: <http://familydoctor.org/113.xml>

Kawasaki Disease

Websites

- Kawasaki Disease Foundation: www.kdfoundation.org
PO Box 45 • Boxford, MA 01921
Tel: 978-356-2070 • Fax: 978-356-2079 • Email: info@kdfoundation.org
- Kids Health discusses Kawasaki disease at www.kidshealth.org/parent/medical/heart/kawasaki.html.
- Overview from the American Heart Association focuses on how the disease affects the heart. www.americanheart.org/presenter.jhtml?identifier=4634

Mitochondrial Disease

Websites

- United Mitochondrial Disease Foundation promotes research and education for the diagnosis, treatment and cure of mitochondrial disorders and provides support to affected individuals and families. www.umdf.org

- The Cleveland Clinic website provides many articles when searched by the topic, "mitochondrial disease." www.clevelandclinic.org/health
- The National Institute of Neurological Disorders and Stroke provides an informative Mitochondrial Myopathies Information Page. www.ninds.nih.gov/disorders/mitochondrial_myopathy/mitochondrial_myopathy.htm

Multifocal Motor Neuropathy (MMN)

Websites

- National Institute of Neurological Disorders and Strokes (NINDS) provides a Multifocal Motor Neuropathy Information Page: www.ninds.nih.gov/disorders/multifocal_neuropathy/multifocal_neuropathy.htm
- Multifocal Motor Neuropathy Center at Johns Hopkins Department of Neurology www.neuro.jhmi.edu/MMN/index.html
- The Neuromuscular Center at Washington University in St. Louis, Mo. Neuromuscular Home Page www.neuro.wustl.edu/neuromuscular
- The Neuropathy Association is dedicated to helping those with conditions affecting peripheral nerves. www.neuropathy.org

Multiple Sclerosis (MS)

Websites and Chat Rooms

- The mission of the National Multiple Sclerosis Society is to end the devastating effects of MS. www.nationalmssociety.org/
- All About Multiple Sclerosis provides accurate and comprehensive medical information about MS written in plain English by people living with the disease and its symptoms. www.mult-sclerosis.org/index.html
- Multiple Sclerosis Foundation works for a brighter tomorrow for those affected by MS. www.msfacts.org
- Multiple Sclerosis Association of America seeks to enrich the quality of life for individuals with multiple sclerosis. www.msaa.com
- MSWorld's Chat and Message Board features patients helping patients. www.msworld.org

Online Peer Support

- Friends with MS: <http://friendswithms.com>
Forum: <http://health.groups.yahoo.com/group/FriendsWithMS>
- My MSViews: www.mysviews.org
Forum: http://health.groups.yahoo.com/group/MSViews_Multiple_Sclerosis
- MS Support Group: <http://health.groups.yahoo.com/group/mscured>
- The MS Carousel—A Place to Meet With People Who Understand MS!
<http://health.groups.yahoo.com/group/themscarousel>

Myasthenia Gravis (MG)

Websites and Chat Rooms

- The Myasthenia Gravis Foundation of America (MGFA) is the only national volunteer health agency dedicated solely to the fight against (MG). www.myasthenia.org
- Myasthenia Gravis Fact Sheet prepared by National Institute of Neurological Disorders and Strokes. www.ninds.nih.gov/disorders/myasthenia_gravis/myasthenia_gravis.htm
- Mayo Clinic's overview of myasthenia gravis: www.mayoclinic.com/health/myasthenia-gravis/DS00375

Online Peer Support

- MGFA's Forum: <http://health.groups.yahoo.com/group/MGnet>
- Bette's Myasthenia Gravis Support: <http://health.groups.yahoo.com/group/bettesmyastheniagravisupport>
- Maddy's MG Support: <http://health.groups.yahoo.com/group/maddysmgsupport>
- Autoimmune Information Network Inc.: www.aininc.org
PO Box 4121 • Brick, NJ 08723 • 877-246-4900
Email: autoimmunehelp@aol.com

Myositis

Websites

 <p>THE MYOSITIS ASSOCIATION</p>	<p>The mission of The Myositis Association, www.myositis.org, is to find a cure for inflammatory and other related myopathies, while serving those affected by these diseases. 202-887-0088</p>
--	---

- International Myositis Assessment and Clinical Studies Group is a coalition of healthcare providers and researchers with global approaches to improved treatments and understanding of myositis: <https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=home.main>
- The Cure JM Foundation was created specifically to find a cure for Juvenile Myositis (JM), while also providing support and information for families affected by JM. <http://curejm.com>
- Johns Hopkins Myositis Center is a new patient treatment center that brings the expertise of rheumatologists and neurologists into a single clinic for patients with inflammatory (autoimmune) and toxic (drug induced) muscle conditions. www.hopkinsmedicine.org/rheumatology/clinics/myositis_center.html

Online Peer Support

- Juvenile Myositis Family Support Network: www.curejm.com/family_support/index.htm
- Myositis Association Community Forum: www.myositis.org
- Myositis Support Group: www.myositissupportgroup.org
- Myositis Support Group UK: www.myositis.org.uk
- Yahoo Myositis Support Group Discussion Board: <http://health.groups.yahoo.com/group/OurMyositis>
- The California Myositis Symposium held in 2005 was captured on DVD. It contains information about polymyositis, dermatomyositis and inclusion body myositis, including doctors' discussions and detailed slides and explanations of muscle biopsies, skin rash, and tools used to diagnose these diseases. Other presentations offer valuable lessons in maintaining a positive attitude, exercises for physical therapy and innovative tools to aid in everyday activities. The DVD is available at no charge by sending an email to Richard Gay at rgay@socal.rr.com.

Books and Articles

- "Coping With a Myositis Disease," by James R. Kilpatrick, is written by myositis patients telling their personal stories.
- "Inclusion-Body Myositis and Myopathies," by Valerie Askanas (Editor), Georges Serratrice (Editor) and W. King Engel (Editor), is devoted to discussing the two forms of inclusion-body myositis.
- "Living With Myositis," edited by Jenny Fenton, is an accessible, realistic and sympathetic guide to facts, feelings and future hopes.
- "Myositis—A Medical Dictionary, Bibliography, and Annotated Research Guide to Internet References," by ICON Health Publications, is a three-in-one

reference book: a complete dictionary of terms relating to myositis, a list of bibliographic citations about the disorder and a guide to Internet resources.

- “Myositis and You: A Guide to Juvenile Dermatomyositis for Patients, Families, and Healthcare Providers,” an indispensable resource for families of children with myositis and their healthcare teams, is available at www.myositis.org.
- “The Official Patient’s Sourcebook on Inclusion Body Myositis,” by James N. Parker (Editor) and Philip M. Parker (Editor), is a reference manual for self-directed patient research.

Pemphigus and Pemphigoid

Websites

- The International Pemphigus and Pemphigoid Foundation provides information and support to people living with the autoimmune diseases. www.pemphigus.org
- Information from the National Institutes of Health: www.niams.nih.gov/hi/topics/pemphigus/pemphigus.htm
www.nlm.nih.gov/medlineplus/ency/article/000882.htm
- Rare disease report: <http://rarediseases.about.com/od/rarediseases/p/ pemphigus05.htm>

Peripheral Neuropathy (PN)

Websites



The Neuropathy Association, www.neuropathy.org, is devoted exclusively to all types of neuropathy, which affects upwards of 20 million Americans. The Association’s mission is to increase public awareness of the nature and extent of PN, facilitate information exchanges about the disease, advocate the need for early intervention and support research into the causes and treatment of neuropathies. 212-692-0662

- To learn about PN, how it is classified, the symptoms, causes and treatments, see the Peripheral Neuropathy Fact Sheet available at www.ninds.nih.gov/disorders/peripheralneuropathy/peripheralneuropathy.htm.
- The Neuropathy Action Foundation, at www.neuropathyaction.org, educates, empowers and informs patients and physicians about neuropathy.

Support Groups

- Click on the Member Services tab of the website, www.neuropathy.org, for listings of support groups across the nation.

Online Peer Support

- Calgary Neuropathy Support Group: www.calgarypnrs.org/index.htm
- MSN Support Group Discussion Board: <http://groups.msn.com/PNPARTNERS>
- The Neuropathy Association Bulletin Board: www.neuropathy.org
- Yahoo Neuropathy Support Group Discussion Board: <http://health.groups.yahoo.com/group/neuropathy>
- Yahoo Support Group – Australia Discussion Board: <http://au.groups.yahoo.com/group/LifeWithPN>

Books and Articles

- “If You’re Having a Crummy Day, Brush Off the Crumbs!,” by Mims Cushing, is a how-to book that offers more than 75 ways to help people get through the days when neuropathy (or other ailments) is particularly difficult.
- “Medifocus Guide to Peripheral Neuropathy,” is a guide to current and relevant PN research, organized into categories for easy reading.

- “Numb Toes and Aching Soles,” by John Senneff, discusses the symptoms, causes, tests, treatments and coping strategies for peripheral neuropathy.
- “Numb Toes and Other Woes,” by John Senneff, is the second in a series of three books. It focuses on clinical findings and treatment strategies for PN.
- “Nutrients for Neuropathy,” by John Senneff, the third in the Numb Toes series, is focused exclusively on nutrient supplementation as a means for managing PN.
- “Peripheral Neuropathy: When the Numbness, Weakness, and Pain Won’t Stop” by Dr. Norman Latov, MD, PhD, published 2007, Weill Medical College, Cornell University, provides practical information on all the neuropathies, causes and treatments.

Primary Immune Deficiency Disease (PID)

Websites and Chat Rooms

 <small>IMMUNE DEFICIENCY FOUNDATION</small>	<p>The Immune Deficiency Foundation (IDF), www.primaryimmune.org, is dedicated to improving the diagnosis and treatment of PID through research and education. 800-296-4433</p>
---	--

Jeffrey Modell Foundation

The Jeffrey Modell Foundation, www.info4pi.org, is dedicated to early and precise diagnosis, meaningful treatments and, ultimately, cures for primary immunodeficiency. 212-819-0200

- The National Institute of Child Health and Human Development (NICHD), www.nichd.nih.gov, is part of the National Institutes of Health. Go to the “Health Information and Media” tab on the website and do a search under “primary immunodeficiency.”
- The American Academy of Allergy, Asthma & Immunology, www.aaaai.org, has a helpful Q&A section on its website, with resources and tips for those with various immune deficiencies.
- The Michigan Immunodeficiency Foundation, www.midf.org, seeks to improve the quality of life for Michigan residents affected by PID.
- The International Patient Organization for Primary Immunodeficiencies (IPOPI), www.ipopi.org, promotes the worldwide improvement in the care and treatment of PID patients.
- To connect to a PID message board, go to www.info4pi.org.
- To chat with peers on IDF’s Forum, go to www.primaryimmune.org/forums/forum_intro.htm.
- Chat with parents of children affected by primary immune deficiency at <http://health.groups.yahoo.com/group/PedPID>.
- Chat with peers with PID at <http://health.groups.yahoo.com/group/PIDsupport>.
- A group of family and friends of patients with primary immune deficiencies maintains a nonprofit network in the New England area: www.nepin.org
- Baxter’s website, www.immunedisease.com, offers in-depth information on immunology, PID and treatment with intravenous immune globulin. Click on “European” to see SCIG information.

Online Pamphlets and Education

- Go to the National Institute of Allergy and Infectious Diseases site at www.niaid.nih.gov and search for “primary immune deficiency.”
- “Understanding the Immune System: How It Works,” by the U.S. Department of Health and Human Services, is found at www.niaid.nih.gov/publications/immune/the_immune_system.pdf

- "NIAID Initiative Addresses Primary Immune Deficiency Diseases by National Institute of Allergy and Infectious Diseases" is located at <http://www3.niaid.nih.gov/news/newsreleases/2003/pirc.htm>
- The "Immunodeficiency in Pediatrics" program (PREP®) audio series is a new pediatrician education program that can be obtained by contacting the American Academy of Pediatrics at 866-843-2271 or visiting www.prepaudio.org.

Online Peer Support

- Chat with parents of children affected by PIDD <http://health.groups.yahoo.com/group/PedPID/>
- Chat with peers with PIDD: <http://health.groups.yahoo.com/group/PIDsupport/>
- Immune Deficiency Foundation Forum www.primaryimmune.org/forums/forum_intro.htm
- Jeffrey Modell Foundation Message Board: www.info4pi.org

Books and Articles

- "21st Century Complete Medical Guide to Primary Immune Deficiency, Severe Combined Immunodeficiency (SCID), Chronic Granulomatous Disease (CGD), for Patients and Physicians," by PM Medical Health News, contains federal government clinical data and practical information for patients and physicians.

Scleroderma

Websites

- Johns Hopkins Medicine Scleroderma Center: scleroderma.jhmi.edu
- Scleroderma Research Foundation: www.srfcure.org
- Scleroderma Foundation: www.scleroderma.org

Online Peer Support

- Educating instead of medicating CureZone.com <http://curezone.com/forums/f.asp?f=404>
- International Scleroderma Network www.sclero.org/support/forums/a-to-z.html

Stiff-Person Syndrome (SPS)

Websites

- American Autoimmune Related Diseases Association Inc., www.aarda.org, is the only national organization dedicated to addressing the problem of autoimmunity. 800-598-4668 aarda@aarda.org
- Autoimmune Information Network Inc., www.aininc.org, helps patients and family cope with the disabling effects of autoimmune diseases. 732-262-0450 autoimmunehelp@aol.com
- National Association for Rare Disorders (NORD), www.rarediseases.org, promote awareness of rare diseases and the need for research. 800-999-6673 orphan@rarediseases.org
- National Institute of Neurological Disorders and Stroke (NINDS), www.ninds.nih.gov, offers treatment, diagnosis and research information for rare diseases. 800-352-9424 braininfo@ninds.nih.gov
- Mayo Clinic
Stiff person syndrome: Can it be treated?
www.mayoclinic.com/health/stiff-person-syndrome/AN01377
- Diagnosed with SPS in 1994, Debra Kemery recounts her experience and offers practical information about coping with the disease at www.stiffman.org.

General Resources

Product Information

- Influenza and the influenza vaccine www.cdc.gov/flu or call 800-CDC-INFO (800-232-4636)
- IVIG Carimune NF www.carimune.com
- IVIG Flebogamma www.grifolsusa.com/flebogamma.htm
- IVIG Gammagard Liquid www.gammagardliquid.com
- IVIG Gammagard S/D www.immunedisease.com/US/therapies/gammagard/index.html
- IVIG Gamunex www.gamunex.com
- IVIG Octagam www.octapharma.com/corporate/03_products_and_therapeutic_areas/01_immunoglobulin_product_line/03_octagam.php
- SCIG (subcutaneous immune globulin) Vivaglobin www.vivaglobin.com

Other Organizations

- Alliance for Plasma Therapies is a unified, powerful voice of patient organizations, healthcare providers and industry to advocate for fair access to plasma therapies. www.plasmaalliance.org
- For suggestions on how to deal with the medical and emotional impact of caring for an ill child, go to www.kidshealth.org/parent/system/ill/seriously_ill.html.
- The National Committee for Quality Assurance provides free access to detailed report cards on health plans, clinical performance, member satisfaction, access to care and overall quality on its Health Plan Report Cards Online at www.ncqa.org.
- The nonprofit Patient Advocate Foundation, www.patientadvocate.org, seeks to assure patient access to care, maintenance of employment and financial stability. 800-532-5274

	<p>The nonprofit Patient Services Incorporated, www.uneedpsi.org, specializes in health insurance premium, pharmacy co-payment and co-payment waiver assistance for people with chronic illnesses. 800-366-7741</p>
--	---

- WebMD, www.webmd.com, is a handy medical reference that helps consumers take an active role in managing their health by providing objective healthcare and lifestyle information.
- For a pediatrician's guide to your child's health and safety, visit www.keepkidshealthy.com.
- The National Organization for Rare Diseases, at www.rarediseases.org, provides links to numerous other organizations that have disease-specific support groups and virtual communities for patients and caregivers.
- American Autoimmune Related Diseases Association (AARDA) www.aarda.org brings national focus to autoimmunity through research, education and patient services. 800-598-4668
- Band-Aides and Blackboards, www.lehman.cuny.edu/faculty/jfleitas/bandaides, started by a nurse working on her dissertation, focuses on children with chronic illness.
- American Chronic Pain Association (ACPA) was founded in 1980 to provide resources for people coping with chronic pain. www.theacpa.org

Education and Disability Resources

- Continuation of Health Coverage—Consolidated Omnibus Budget Reconciliation Act (COBRA): www.dol.gov/dol/topic/health-plans/cobra.htm
- Social Security: www.ssa.gov/disability
- California State Disability Insurance (SDI): www.edd.ca.gov (Please note that each state has a different disability program.)

- IDEA 2004 Resources: www.ed.gov/policy/speced/guid/idea/idea2004.html
News and information on the Individuals with Disabilities Education Improvement Act of 2004 (IDEA), the nation's law that works to improve results for infants, toddlers, children and youth with disabilities.
- The National Disabilities Rights Network: www.ndrn.org. This website offers a search tool to find resources in your state to assist with school rights and advocacy.
- U.S. Department of Education Website: www.ed.gov.
This website, a U.S. federal government website, offers a parents section that has a subsection titled "My Child's Special Needs" that can be most helpful.
- U.S. Department of Health and Human Services, Office of Civil Rights, www.hhs.gov/ocr/504.html, spells out your rights under Section 504 of the Rehabilitation Act.
- Wrightslaw: www.wrightslaw.com. Parents, educators, advocates, and attorneys come to Wrightslaw for accurate, reliable information about special education law and advocacy for children with disabilities.
- The Americans with Disabilities Act of 1990
Provides protection for people with disabilities from certain types of discrimination and requires employers to provide some accommodations of the disability. For more information, visit www.usdoj.gov/crt/ada/adahom1.htm.

Additional Reading

- "Anatomy of an Illness," by Norman Cousins, is a best-seller about overcoming illness and the triumph of the human spirit. The premise is that the human mind is capable of promoting the body's capacity for combating illness and healing itself even when faced with a seemingly hopeless medical predicament.
- "A Parent's Guide to Special Education: Insider Advice on How to Navigate the System and Help Your Child Succeed," by Linda Wilmschurst and Alan W. Brue, is available on Amazon.com.
- "The Confused Consumer's Guide to Choosing a Health Care Plan: Everything You Need to Know," by Martin Gottlieb, helps consumers through the confusing maze of choosing a healthcare plan.
- "The Everyday Guide to Special Education Law," by Randy Chapman, Esq., makes the law accessible to parents so they can be more effective advocates for their children. Available at www.thelegalcenter.org/thelegalcenter-cgi-bin/shop?item=15.
- "Living Creatively With Chronic Illness: Developing Skills for Transcending the Loss, Pain and Frustration," by Eugenia G. Wheeler, is a self-help book specifically designed to help the chronically ill, their families, friends, counselors, medical personnel and the clergy.
- "Managing Pain Before It Manages You," by Dr. Margaret A. Caudill, is a wellspring of wisdom and practical approaches that can help transform your life and your pain.
- "Not Dead Yet: A Long Strange Trip From Doctor to Patient and Back Again," by Dr. Robert Buckman, an oncologist and comic writer, is a witty account of his life as a doctor and autoimmune disease survivor.
- "Pride and the Daily Marathon," by Jonathan Cole, describes how Ian Waterman was suddenly struck down at work by a rare neurological illness that deprived him of all sensation below the neck, and how he reclaimed a life of full mobility.
- "Pronoia Is the Antidote for Paranoia," by Rob Brezsny, explores the best way to attract the blessings that the world is conspiring to give us.
- "When You're Ill or Incapacitated" comprises one-half the booklet it shares with "When You're the Caregiver," both written by James E. Miller, suggesting 12 things to remember or do in each role.
- "YOU the Smart Patient: An Insider's Handbook for Getting the Best Treatment," by Michael F. Roizen, MD, and Mehmet C. Oz, MD, with the Joint Commission on Accreditation of Healthcare Organizations, shows you how to tackle such healthcare decisions as picking the best doctors and hospitals for you, knowing when to get a second opinion, and more.

IG Manufacturer Websites

- Baxter: www.baxter.com
- CSL Behring: www.cslbehring.com
- Grifols: www.grifolsusa.com
- Octapharma: www.octapharma.com
- Talecris: www.talecris.com

Pump and Infusion Sets Websites

- EMED Corporation: www.safetymedicalproducts.com
- Graseby Marcal Medical: www.marcalmedical.com
- Intra Pump Infusion Systems: www.intrapump.com
- Repro Med Systems, Inc: www.repro-med.com
- Norfolk Medical: www.norfolkmedical.com

Medical Research Studies

- Check out the official website for the National Institutes of Health patient recruitment program. This site provides summaries and criteria for studies as well as the ability to search for studies being conducted for a specific disease or disorder. <http://clinicalstudies.info.nih.gov>
- This website provides a wealth of information about clinical trials and volunteer participation. It gives you the ability to specify the disorder you are interested in, the location of the study, and the medication names or research protocols. www.centerwatch.com
- This site has a registration form to request that you be notified about recruitment for future studies. www.clinicaltrials.com
- WebMD has a service that matches volunteers with trials. There is an online questionnaire to complete and you will be notified via email of upcoming studies that match the criteria of your questionnaire. You can also search for specific studies. www.webmd.com

Food Allergies

- Allergic Disorders: Promoting Best Practice www.theallergyreport.com/reportindex.html
- American Partnership for Eosinophilic Disorders: www.apfed.org
- National Institutes of Health, National Institute of Allergy and Infectious Diseases (2004). Food Allergy: An Overview (NIH Publication No. 04-5518). www.niaid.nih.gov/publications/pdf/foodallergy.pdf
- Food Allergy and Anaphylaxis Network: 800-929-4040 www.foodallergy.org
- World Allergy Organization: www.worldallergy.org
- Sicherer, S.H. (2006). "The Complete Peanut Allergy Handbook: Understanding and Managing Your Child's Food Allergies," Johns Hopkins Press.

Reading Just for Kids

- "Germs Make Me Sick," by Melvin Berger, explains with colorful illustrations how your body fights germs.
- "Little Tree: A Story for Children With Serious Medical Illness," by Joyce C. Mills, is a comforting fable for young children facing serious life challenges.
- "My IVIG Book," written from a 3-year-old's perspective about his infusions, comes with a kit for other children to create their own personalized book. Free from Baxter at www.immunedisease.com/US.
- "Our Immune System," enables children who are immune deficient and their families to explore together the immune system. Available from the Immune Deficiency Foundation at www.primaryimmune.org.

Have something to add to these pages? Please send your suggestions for additions to the IG Living Resource Directory to editor@igliving.com. In this case, more is indeed better!

When it comes to flu vaccine,
timing is everything!



April – Time to place your order
on MyFluVaccine.com

- Now, no prepayment required!
- Order online, by phone or by fax.



From FFF Enterprises, the nation's leading flu vaccine distributor | **800-843-7477** | www.fffenterprises.com

IG Living
41093 County Center Drive
Temecula, CA 92591-9815

PRSR STD
US POSTAGE PAID
ESCONDIDO, CA
PERMIT NO. 390