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Trevor Cates, ND
The Ins and Outs of Healthy Skin

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From the Publisher

How Do We Face the Growing Pandemic Risk of the Coronavirus?

Although it was initially believed that the coronavirus emerged from live and butchered animals sold in a market hall in Wuhan, China, it has rapidly transformed into an infection that is transmitted between humans typically seen in respiratory infection. Its appearance in December and rapidly increasing numbers in the past few months is typical of flu infection in the cold, dry air of winter. Efforts to control spread of the infection by essentially quarantining millions of individuals in central China and to a lesser degree throughout the country will likely slow transmission, but viruses easily pass through boundaries. Masks have limited effectiveness as does washing hands – it is unclear how effective the Hazmat suits are that health workers wear. As I write this in early February, it appears that the death rate in China has been hovering around 3%. Is that a reliable indicator of how lethal the coronavirus is? If the infection were to become a pandemic, that would represent a huge number of deaths.

Medical authorities are beginning to suggest possible medical treatments in the event of the infection spreading around the world. Drugs lopinavir and ritonavir used in HIV treatment are being considered as first-line treatment in combination with intravenous interferon. Some researchers are feverishly working

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Letter from the Publisher

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to develop a vaccine, a process that not only could take months to demonstrate effectiveness and safety but pose unknown risks (see denial of immunization risks article in this issue). Far less costly and risky would be implementation of nutraceutical support, including use of vitamin C, vitamin A (retinol), vitamin D, and calcium, magnesium, potassium, and zinc supplementation. Or supplementation with garlic, stinging nettles, cimicifuga, glycyrrhizin, and Sambucus. Administration of intravenous vitamin C has already demonstrated effectiveness in the hospital setting in support of sepsis. Hydrocortisone would be necessary for adrenal insufficiency. Naturopathic support employing hydrotherapy and homeopathy should be administered. Other modalities have shown effectiveness fighting viruses, including intravenous ozone. Sadly, public health authorities have positioned themselves to dispute efficacy of such treatment; it will remain "alternative medicine" that Google and Facebook will attempt to censor. Given the draconian measures that undoubtedly will be put forth if coronavirus becomes a pandemic, we should all put together our own "health emergency kit" at home including nutraceutical, herbal, and homeopathic support. (Refer to Dr. Peter D'Adamo's Datapunk summary of evidence-based treatment for coronavirus: https://datapunk.net/antivirals.pl.)

Fraudulent Studies and Ethical Clinical Practices

In this issue Alan Gaby, MD, our contributing medical editor, editorializes about putative fraudulent research curiously being conducted in Iran. These studies are not being published in "first-line" journals such as *NEJM, JAMA, Nature,* or *Science*. Still these papers are abstracted and are searchable on PubMed. The questionable writing is not about the use of drug agents for cancer or autoimmune disease. Instead the authors focus on the use of vitamins, essential fatty acids, amino acids, and related nutraceuticals that impact the course of symptomatic conditions generally not of a life-threatening or incapacitating nature. Many of the primary authors are university students, but clinical assessments are conducted at hospitals to which the students are not apparently affiliated. Gaby's evaluation of these reports done in the past two years shows inconsistencies one usually does not associate with medical research. More troubling is the pattern of irregularities in one paper is very similar to those in another paper. Could there be a cottage industry of individuals who generate fraudulent research articles for compensation? Students have always sought short-cuts to fulfill academic requirements, but why go through such elaborate charades to establish one's noteworthiness? Does this mean that every time we read a published study we need to do a "smell test" to see if something stinks about the research?

One of the smell tests that troubles me is when I read, or more often, listen to a practitioner who claims unassailable results in treating his/her patients. The condition is absolutely treatable but requires compliance to all the aspects of the doctor's protocol. Given the intricacy of many integrative and naturopathic regimens, it is not uncommon for a patient or referring clinician to not follow the treatment recipe exactly. If the condition improves or better yet resolves, all is good. However, if the condition deteriorates or worse eventuates in death, it is not uncommon

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Letter from the Publisher

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for the healer to claim that the patient was not compliant and did not follow instructions. This is the all-powerful doctor's mantra: "Follow my directions exactly or die." Closely following this thinking is remembering all the cures but curiously forgetting all the failures. Somehow there is a marvelous record of success with nary a loss. Of course, the failures do show up, sometimes quietly as a patient who cancels further appointments, sometimes noisily as a malpractice suit or medical board investigation. There is nothing wrong or bad with treatment failure; what is wrong is to dismiss it as though it did not happen. Worse, is to blame the patient for compliance failure. Even worse are the Monday-night quarterbacks who proclaim that if the individual had followed their treatment the individual would have been better, even alive.

When I hear such talk at conferences, I know that its score on the smell test is "stinking." And the practitioner is medically unethical.

Allergy Desensitization for Peanuts and Delayed Hypersensitivity

While waiting for the plane to take off, the announcement came over the P.A. system that passengers should desist from eating any food containing peanuts because an individual in row 12 had a severe peanut allergy. Peanut allergy is a life-threatening condition for the 2% of the population who deal with it on a daily basis – an exposure requiring, an immediate EpiPen injection to prevent anaphylaxis and death. Avoidance of all foods containing peanuts is a major challenge for patient and family not to mention classmates and co-workers. The nightmare of peanut avoidance may soon be changing with the recent FDA approval of Aimmune Therapeutics' pharmaceutical Palforzia as reported in the Feb 1-2 *WSJ*. The drug contains micro-quantities of peanut powder; the patient is instructed to use minimal dosing in apple sauce to begin with working up to a full capsule as tolerated. During its trial use, children demonstrated tolerance to peanut exposure by not reacting to what might be comparable to eating 14 peanuts. Of course, there were times when tolerance was exceeded and an EpiPen was necessary. The drug slated to cost $900/month won't eliminate peanut allergy, and individuals will still need to avoid peanuts – but life should be quite a bit less terrifying.

In this issue Diego Saporta, MD, who has written a series of articles for the *Townsend Letter* over the past decade, writes on delayed reaction after skin allergy testing. Most skin scratch testing at the allergist's office examines the immediate skin response: a positive reaction denotes an allergy that can be desensitized. However, the immediate skin response is largely dependent on an IgE allergy only. If the patient has a type III hypersensitivity reaction involving deposition of immune complexes, then the immediate skin reaction frequently is negative. If the allergist were to assess a late or delayed skin response, 24-48 hours after intradermal skin testing, the type 3 hypersensitivity reaction is positive and an allergic response is confirmed despite negative immediate skin response. In this issue's paper Dr. Saporta reviews clinical data from 400 of his patients for delayed skin response. Delayed hypersensitivity on intradermal dilutional testing is shown to develop in 11% of the tests. Saporta demonstrates

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Letter from the Publisher

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that safely determining delayed response requires testing the patient with individual allergens diluted serially with weaker and then stronger concentrations. As expected most positive delayed responses are shown with stronger concentrations; however, these doses pose greater risk for adverse response. Those patients demonstrating delayed hypersensitivity benefit from properly titrated desensitization treatment.

Denial of Adverse Effects Following Immunization

When I ventured into alternative medicine back in the '70s, I was exploring the possibility that healing was not solely based on surgery and drugs. Not only was the science of pathology lacking with most serious diseases having no known cause, but pharmacotherapy offered limited palliation of symptoms without any basis for cure. I did not expect that alternative therapies would necessarily provide answers or better outcomes, but I did think that I should examine what nutrition and functional medicine offered. Unfortunately, conventional medicine practice did not lend itself easily to exploring alternatives. Chiropractic was disdained by the medical profession, but not for reasons that made sense to me. One of the philosophies shared by most chiropractors was that nutritional supplements enhanced chiropractic adjustment – thinking that was denigrated by MDs. Another philosophy espoused by DCs was that vaccinations were not health promoting and could be seriously life threatening; of course, medicine absolutely assailed this. It would take a major lawsuit for chiropractors to ensure their autonomy to practice without MD harassment; however, medicine reviles any DC or other health practitioner who condemns vaccinations.

Chiropractors are no longer a lonely voice expressing concern about immunization. Naturopathic practitioners and alternative MDs, DDSs, DVMs and other health professionals have questioned the policy of mandated vaccination. Moreover, a burgeoning self-educated public has begun to challenge the requirement of an ever-increasing number of vaccines. Alarmed public health authorities have turned to draconian measures to force school-age children to get their shots or be expelled. Worse, a concerted effort has enjoined social media censors to remove "anti-vaxxer" postings and articles while promoting only pro-vaccination writing. The problem is that there are legitimate concerns about immunizations that deserve examination and review. Public health authorities would have one believe that vaccines are entirely safe and effectively control infectious disease and their complications. However, as Dr. Paul Stoller, MD, reviews in this issue adverse effects do take place following immunization. Their incidence is neither rare nor of minimal significance. Medicine and public health authorities deny adverse events take place, minimize risk, and do not warn the patient of such risk before vaccination. Medicine claims to be scientific, but their suppression of studies documenting adverse effects of vaccination is anti-scientific and unethical. Stoller examines the extent of the denial of immunization adverse effects and the consequent loss of informed consent.

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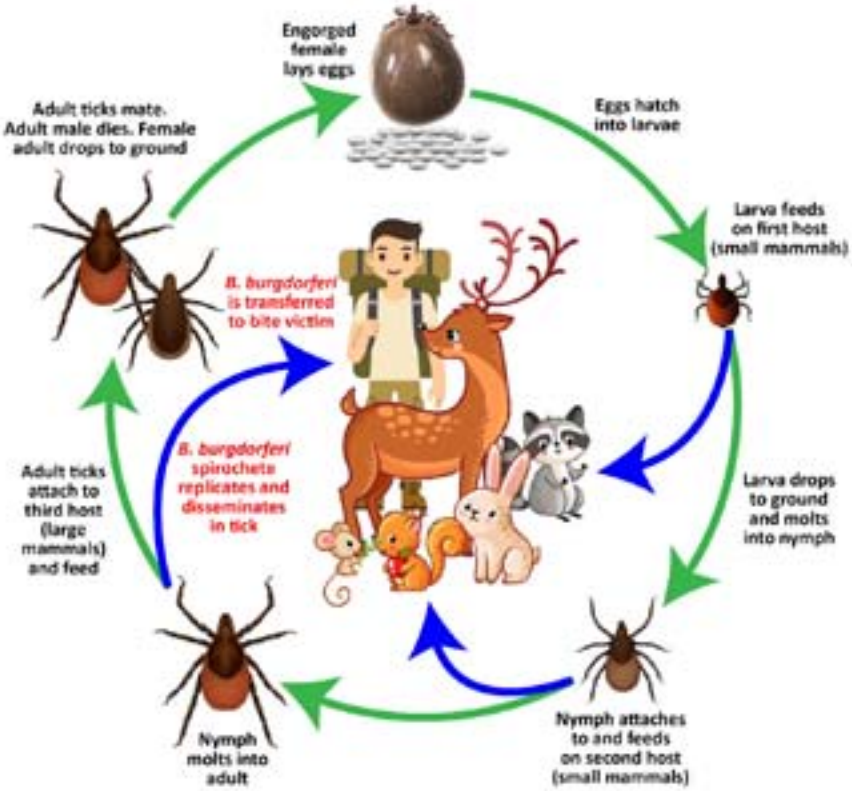

Untreated Lyme disease can turn into chronic Lyme disease, which in turn can lead to Lyme arthritis and neuroborreliosis.

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Letter from the Publisher

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Macular Degeneration – An Eye Condition That May Be Preventable

The news media loves to run fear-mongering articles claiming that vitamin supplementation is useless and, worse, is capable of making one's health deteriorate. There is almost palpable excitement when some study is announced that finds a nutrient or herbal is unhelpful in treating a condition. The medical profession holds forth that nutraceuticals do not deserve a place in an individual's daily regimen; everything one needs is available in three-square meals. If and when vitamins cause serious toxicity, the news shows really make hay of it; but a report in this issue reveals once again that there have been no deaths from vitamin use in 2019. However, ophthalmologists have not been toeing the line with the rest of medicine; they advise their patients to use antioxidant supplementation to prevent eye disease. Somehow the medical skeptics have largely ignored eye doctors' advising use of lutein and zeaxanthin.

In this issue Dr. Marc Grossman examines macular degeneration and its treatments but focuses on strategies to prevent the age-related process. In the same sense that nutrients, antioxidants and herbals can help to prevent macular degeneration, so can those same supplements mitigate the aging process associated with arthritis, heart disease, cognitive dysfunction, and potentially prevent neurologic disease and cancer. Functional medicine studies confirm that not only is there improvement in hormone physiology and oxygen physiology with nutrient support, but detoxification necessary to unload toxic metals and chemicals is accomplished. Grossman's two-part series on macular degeneration offers a blueprint to prevent macular degeneration and, overall, slow down the aging process.

Cover Story: Acne Fix – Beyond Benzoic and Retinoic Acid

At one time in my medical schooling, I thought about becoming a dermatologist. From an MD perspective, the specialty offered some definite benefits – a clinic-based practice, infrequent emergencies and hospital calls, less stress in working up patients, and long-term patient relationships based on skin conditions stabilizing but never resolving. While some dermatologic diseases are common and straight-forward like skin cancers, eczema, psoriasis, and acne, there are literally dozens of rarer conditions that are grotesque in appearance requiring skin pathology for diagnosis. Those patients experiencing pemphigus vulgaris, dermatitis herpetiformis, pemphigoid, and lichen planus are the basis for dermatology rounds where case histories, photographs, and pathology slides are viewed and discussed sometimes with quite varying diagnostic opinions. This academic aspect of dermatology was quite appealing to me. However, I chose a different road to travel, alternative and integrative medicine; still dermatology has remained a special interest. Now when a patient presents with a dermatitis, common or rare, I focus on underlying factors causing the inflammation and pathology.

In this issue Trevor Cates, ND, examines treatment strategies for acne. Dr. Cates states that there are six underlying causes for acne including "inflammation, microbiome disturbance, oxidative damage, blood sugar issues, nutritional deficiencies, and hormonal imbalances." From her perspective, skin disorders "mirror" the health of the body overall; hence acne treatment must focus not only on external skin treatments but internal support. She is particularly interested in the integrity of the microbiome not just in the gut but also in the skin. Cates agrees that the skin microbiome functions ideally when the pH is maintained between 4-5. Many cleansers and other skin treatments are less acidic with pH scores of 5.5 or higher. Surprisingly laundry detergents can contribute to disruption in the microbiome, and she will advise adding vinegar to the laundry being washed. Dr. Cates believes that prescriptions for the skin are more effective if they employ herbals, vitamins, and other nutraceuticals that can be compounded for easy topical application. Her approach to acne care requires nutritional management, naturopathic support, and PRP injections if cystic acne has caused scarring; and she has helped patients completely resolve their acne and overcome the emotional burden of having facial disfigurement. After reading her article in this issue, consider reading her book, *Clean Skin from Within*.

Jonathan Collin, MD

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Pathways to Healing

by Elaine Zablocki

Medical Intuition – Using the Sixth Sense in Integrative Health Practice

Our culture doesn't emphasize intuitive skills. We're aware that some people experience hunches or premonitions, but we don't pay much attention to that sort of thing. Some healthcare practitioners have an uncanny ability to reach a correct assessment, but we don't ask ourselves how they do that. There are studies published in medical literature on the use of intuition in healthcare, but misconceptions still exist.

Wendie Colter, CMIP, CEG, expects to change those attitudes, especially in healthcare. She has learned how to use medical intuition to help others heal, and ten years ago she set up The Practical Path® training program to help healthcare professionals access and develop their own medical intuition.

Colter was an intuitive child; and as she grew up, she studied many of the classics of metaphysical thought. She trained in a number of biofield-based wellness modalities such as Reiki and transcendental meditation. "I became an energy healer, and I noticed I was actually able to see into my client's body as I was doing my energy work," she recalls. "My colleagues began sending me their tough cases. Doctors began to call me for consultations, especially in atypical cases where standard lab tests were inconclusive."

Colter is a visually oriented person, and she "sees" what is happening inside the patient's body. But she thinks about medical intuition in terms of four different "meta-sensory skills."

- Claircognizance (clear knowing), the ability to know information without having prior knowledge – what we refer to as gut feelings or hunches;
- Clairsentience (clear feeling), the ability to feel someone else's emotional or physical information – what we call empathy;
- Clairaudience (clear hearing), the ability to hear information without using our physical ears – what we call the still small voice we hear in prayer or meditation.
- Clairvoyance (clear seeing), the ability to see information without the physical eyes – what we call visualization.

These abilities are innate, but our culture often does not recognize them. Colter is working to show people how to recognize and enhance their natural intuitive abilities. "Medical intuition is not a treatment, intervention or modality," she says. "It is a foundational energetic assessment and evaluation skill. It is designed to support all healthcare methods."

Wendie Colter, CMIP, CEG

As she trains healthcare professionals in her method, her students report it helps them save time, save money, and offers a 360-degree holistic view of the patient. "Most importantly, medical intuition helps provide insight when people aren't healing despite our best efforts," she says. "This is why doctors have called me over the years, because their patients weren't healing and they wanted to know what was going on. This is one of the places where medical intuition can really shine."

Exploring Our Own Intuitive Skills

I met Wendie Colter when I attended the 2019 Academy of Integrative Health & Medicine (AIHM) conference. She co-presented a 90-minute session on medical intuition together with Tiffany Barsotti, M.Th. C.Ht., and Paul J. Mills, PhD, Chief of Behavioral Medicine and Professor of Family Medicine and Public Health at the University of California San Diego (UCSD).

The room for this session held about 120 people and it was packed; people who arrived after the room was full had to be turned away. This is quite a change from five years ago, when a presentation on this subject would usually draw just a handful of people.

During her presentation, Colter invited us to explore our own intuitive abilities. She invited us to close our eyes, sit with straight spines and relaxed minds, and have a mental conversation with our own bodies. "We think of a part of our physical body and ask what it wants from us, what it wants to tell us," Colter says. "We can access all sorts of information we might not have had previously."

This is similar to the process she uses when she is working with a client. "The medical intuitive process views an 'intuitive MRI' of the client's body, along with images from a client's unique life experience," she says. "There is a correlation between past emotional trauma and physical imbalance. Awareness is the key that can help us to regain energetic balance in body, mind, and spirit."

Medical Intuitive Training Available

In 2009 Colter founded The Practical Path®, a training program in medical intuition for healthcare professionals. The certification program takes nine months, one weekend per month, with two levels of training. In Level 1, participants have an opportunity to learn the foundational skills of scanning into the biofield for a range of energetic blocks. Level II training includes intuitive scanning of the physical anatomy and in-depth evaluations designed to identify underlying causes of illness, imbalance, and disease.

The certification program is open to physicians, nurses, nurse practitioners, physician assistants, mental healthcare professionals, allied health professionals, naturopaths, acupuncturists, chiropractors, nutritionists, homeopaths, massage therapists, bodyworkers, hypnotherapists, certified biofield/energy therapy practitioners, certified health and wellness coaches, and more. "The training is open to people who have had a professional practice for at least one year and a certification in at least one modality," Colter says. "It is not open to laypeople because my goal is to help bring these skills into mainstream medicine."

A practitioner who completes the course is eligible for certification as a The Practical Path® Certified Medical Intuitive Practitioner, CMIP®. The programs are accredited by the California Board of Registered Nursing, the American Holistic Nurses Association (AHNA), and the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). The Practical Path® is working with other national boards to offer accreditation in other fields.

Formal Research Underway

Recently, some of the medical intuitives Colter has trained participated in a research pilot study. In blinded sessions, 67 participants were surveyed about their experience with the medical intuitive practitioner; 94% agreed that the practitioner had accurately evaluated their main health issue, and 98% agreed the practitioner accurately described life experiences that corresponded to their health issues. Ninety-nine percent were satisfied or extremely satisfied with the session, and 100% agreed that medical intuitives offered useful recommendations.

Today The Practical Path® is collaborating with the University of California San Diego (UCSD) School of Medicine on a larger research study into medical intuition. The study expects to advance the scientific study of medical intuition by having medical intuitives independently, blindly read individuals with documented illnesses, as well as a control group of healthy individuals. All study staff and medical intuitives will be blinded to the participants' illness categories and self-ratings on health and illness. The researchers anticipate this study will show that the medical intuitive will accurately classify each patient's primary illness, identify the primary underlying reason for the illness and assess emotional, mental, spiritual, and/or energetic reasons for imbalances.

Because this is an initial study, The Practical Path® and UCSD are seeking financial support from a broad range of private funding sources. To receive a copy of the UCSD research study proposal, please contact https://thepracticalpath.com/contact.

What comes next? Over the past few years Colter has offered presentations at the Prebys Cardiovascular Institute-Scripps Health, the Andrew Weil Center for Integrative Medicine IMER, the American Holistic Nurses Association, the Academy of Integrative Health & Medicine Fellowship, Canadian Association for Integrative and Energy Therapies, and many more. She is working on a book.

"Over the last few years I've seen the interest growing," she says. "When I speak to the medical students and residents at the Andrew Weil Center, for example, I'm always delighted by the interest from these young doctors. When I speak to seasoned doctors so many of them already understand that intuition is a big part of medicine. They just haven't been taught how to deliberately access their intuition. That's where I come in."

Resources

The Practical Path, https://thepracticalpath.com/
The website includes a list of classes and future events, newsletter sign up, and a blog.

For more information about The Practical Path/UCSD research study and to donate directly, go to https://thepracticalpath.com/ucsd-research-study

Practitioner Referral Service – to work with a CMIP® Certified Medical Intuitive Practitioner in your healthcare practice, go to https://thepracticalpath.com/practitioner-referral-service

To find out more about medical intuition go to https://thepracticalpath.com/what-is-medical-intuition

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Elaine Zablocki is the former editor of CHRF News Files.

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Does the Administration of Vaccines Require Informed Consent?

Public health authorities state that vaccines are entirely safe and effectively control disease. In this issue Dr. Paul Stoller counters this assertion citing that adverse effects do take place following immunization. For children to be vaccinated without first being fully informed about the serious risk incurred is a loss of informed consent.

See Stoller's article on page 62.

Remembering Berkley W. Bedell

FAIM Founder

Berkley Warren Bedell, age 98, passed away on December 7, 2019, three days after suffering a massive stroke in Naples, Florida. He spent his life focused on making the world a better place.

A third generation of Spirit Lake, Iowa, he was born on March 5, 1921. Growing up with two loving parents, Walter and Virginia Bedell and a younger brother, Jack, his life was filled with fishing, hunting, and hanging out with the South Side Gang – a harmless group of neighborhood friends who loved fishing, hunting, and the magical life in a small town surrounded by lakes and wildlife.

In 1937 when he was 15, he began tying fishing flies and selling them in a local tackle shop. With the encouragement of his family and his natural entrepreneurial instincts, he began developing fishing leaders and the beginning of what became Berkley & Co. He attended Iowa State University where he met the love of his life, Elinor Healy. He continued his fishing tackle business until World War II called, and he joined the Army Air Corps becoming a flight instructor. Elinor and Berkley were married August 29, 1943.

After the war, Berk and Elinor returned to Spirit Lake and restarted Berkley & Co, which grew rapidly. From Steelon leaders to Trilene fishing line, Berkley's inventiveness introduced new and better products into the fishing tackle market, enabling him to employ hundreds of local people and home workers. The company expanded into multiple locations, finally consolidating into a new factory building on Highway 71 where it remains today. In 1964 he was honored by President Lyndon Johnson as the country's first Small Businessman of the Year. Berk was inducted into the Fresh Water Fishing Hall of Fame, the Bass Fishing Hall of Fame, and the Iowa Business Hall of Fame.

Berkley was active in community affairs. He was a member of the Spirit Lake United Methodist Church, a founding member of the Spirit Lake Kiwanis Club, and a Mason. He served on the Spirit Lake School Board. Many people will recall his mentorship as a Boy Scout leader, the record number of Eagle Scouts, and the annual canoe trips to the Boundary Waters.

He served as the president of the American Fishing Tackle Manufacturing Association and the Iowa Manufacturing Association. He was active in the Young Presidents Organization. He served on the Boards of Trustees of Morningside College, American University, and Claremont School of Theology.

In 1974 he was elected to represent Iowa's 6th District in the US Congress. He served for twelve years until his retirement in 1987 because he contracted Lyme's disease. In Congress he served on the Agriculture Committee and chaired the Small Business Committee. He also represented the United States on the UN Convention on Law of the Seas.

When his health returned, due to alternative protocols, he lobbied Congress to establish an Office of Alternative Medicine (OAM) in the National Institutes of Health. He served on the advisory board. Becoming frustrated that OAM did not aggressively investigate alternate medical practices, he and his wife Elinor founded the Foundation for Alternative and Integrative Medicine (FAIM) in 1998, which continues today. FAIM is accomplishing Berkley's dream of searching the world for effective therapies, researching the protocols, and sharing the information on the FAIM website, www.faim.org. The foundation has become an umbrella for over 100 medical experts to share cutting edge information on alternative, integrative, and complementary approaches to health including new frontiers in medicine.

Berkley contributed in countless ways to the quality of life in the Iowa Great Lakes from co-leading the Save the Park funding drive for Arnolds Park to being a founding member of the Okoboji Foundation. He and Elinor contributed land to create Elinor Bedell State Park in Spirit Lake, Iowa.

In 1988 he and Elinor moved to Naples, Florida. He became active in North Naples United Methodist Church, Naples Council on World Affairs, and Great Decisions. He is known around Moorings Park as a hugger, dancer, and bridge player. He appreciated his many friends who joined him for dinner.

While being remembered for his achievements, most people think of Berk for his leadership, his kindness, his compassion, and his activeness to make a difference – not just in big causes, but in individual people's lives. He was alive with empathy and always ready to take on injustice.

In addition to his commitment to improving health care options, he was recently working to educate people on the perils of the unequal distribution of wealth, climate change and the impact on future generations, and the broken governmental system being controlled by large corporations. He often would explain how differently and more effectively the government operated in the 1970s and 1980s while he served in Congress.

With all that can be said about Berkley, he remained an avid fisherman to his last days. When his 5-year-old great-grandson was told about the stroke, he said it best saying, "Oh no, he was the greatest fisherman I ever knew."

Berkley was preceded in death by his wife of 73 years, Elinor Healy Bedell. He is survived by three children, Ken Bedell (Kathie) of Westminster, CO; Tom Bedell (Molly) of Bend, OR; and Joanne Quinn (Mike) of Loveland, CO; eight grandchildren and twelve great grandchildren.

Memorial gifts may be sent to the Foundation for Alternative and Integrative Medicine, PO Box 2860, Loveland, CO 80539 or via the online donation form (www.faim.org).

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Shorts

briefed by Jule Klotter
jule@townsendletter.com

Absorption of Sunscreen Chemicals

The skin's ability to absorb chemicals in personal care products is well documented, as Anne Marie Fine, NMD, discussed in her June 2019 *Townsend Letter* article "The Skin as Exposome: An Underappreciated Route of Entry for Toxicants." Recently, the FDA has turned its attention to the chemicals in sunscreen products. A 2020 clinical study confirms that active ingredients in commercial sunscreen products are absorbed through the skin, resulting in systemic exposure that exceeds the FDA guideline level of 0.5 ng/mL: "The 0.5 ng/mL threshold was selected because the approximated cancer risk associated with plasma concentrations below this threshold would be less than 1 in 100,000 after a single dose." The 2020 trial follows a 2019 pilot study that measured blood levels of four chemicals (avobenzone, oxybenzone, octocrylene, and ecamsule) after exposing four groups of healthy volunteers (n=6/group) to one of four commercial sunscreens. The blood levels of these chemicals also exceeded 0.5 ng/mL.

FDA issued a proposed rule for over-the-counter sunscreens in February 2019, which would update its recommendations for sunscreen use. As part of the update process, active ingredients are to be clinically tested for systemic absorption in people exposed to maximum recommended doses. Chemicals that produce blood levels above 0.5 ng/mL are required to be tested for developmental and reproductive effects and for carcinogenicity.

The 2020 study assessed six of the 12 active ingredients that FDA has questions about. Forty-eight participants, who stayed at a clinic and out of sunlight for seven days, were randomized into groups to test four sunscreen products (a lotion, an aerosol spray, a non-aerosol spray, and a pump spray). All four products contained avobenzone and at least two other active ingredients. The product was applied once on the first day, and four times on days 2-4 at two-hour intervals (following manufacturer guidelines). After a baseline blood sample, sunscreen was applied; and an additional 12 blood samples were taken on the first day. Further samples were taken on days 2, 3, 4, 5, 6, 7, 10, 14, and 21.

Twenty-three hours after the single application on day 1, all active ingredients measured above the 0.5 ng/mL level (using geometric mean maximum plasma concentrations) in over 75% of the participants. Each of the chemicals remained above the 0.5 ng/mL level for days after the final application (on day 4) in the majority of the participants: "day 7 for avobenzone (95%; n=42/44), octisalate (75%; n=24/32, octinoxate (90%); n=18/20; day 10 for oxtocrylene (67%; n =22/33); and day 21 for homosalate (55%; n=17/31) and oxybenzone (96%); n=22/23)."

In addition, skin samples (from tape stripping) showed that all of the chemicals were still present in the skin at day 7, despite daily showers taken in the morning (after blood sampling and before the first sunscreen application) while at the clinic.

In an editorial that accompanied the 2019 pilot study, Califf and Shinkai noted that evidence of systemic absorption in humans was first shown in 1997. Over the years, some sunscreen chemicals have been linked to cancer and adverse effects on endocrine, reproductive, and developmental functions and on the environment. An FDA public advisory panel determined in 2014 that there was insufficient evidence to confirm safety for many sunscreen ingredients and formulas – despite the large body of evidence that sunscreen use prevents sunburn, precancerous actinic keratosis, and squamous cell cancer. So far, two sunscreen ingredients, zinc oxide and titanium dioxide, are recognized as "generally regarded as safe and effective" (GRASE). Two are not: para-aminobenzoic acid (PABA) and trolamine salicylate.

Califf and Shinkai raise several unanswered questions that extend beyond these initial studies on absorption such as "the effects of different sunscreen formulations, clinical

characteristics (ie skin type, age, presence of skin diseases that disrupt the skin barrier), physical activity level, and exposure to sun and water on systemic sunscreen levels…." Moreover, absorption and effects may differ in infants and children compared to adults.

Califf and Shinkai say, "At a minimum, physicians should recommend use of sunscreen formulations containing GRASE ingredients such as titanium dioxide and zinc oxide as part of a larger program of photoprotection that includes seeking shade, and wearing protective clothing, hats, and sunglasses, until meaningful answers to these questions are available."

Lycopene supplementation and eating foods high in lycopene (red tomatoes, apricots, papaya, pink grapefruit, guava, watermelon) also protect from UV damage. Tomato paste is particularly high in lycopene as cooking increases lycopene's bioavailability.

Califf RM, Shinkai K. Filling in the Evidence About Sunscreen. *JAMA*. May 6, 2019.

Matta MK, et al. Effect of Sunscreen Application Under Maximal Use Conditions of Plasma Concentration of Sunscreen Active Ingredients. *JAMA.i May 6, 2019.*

Matta MK, et al. Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients. *JAMA*. 202;323(3):256-267.

Stahl W, et al. Lycopene-rich products and dietary photoprotection. *Photochem Photobiol Sci.* 2006;5:238-242.

Evidence-Based Healthcare and Corporate Interests

The December 2, 2019, issue of the *British Medical Journal* contains an analysis from an international team of researchers, clinicians, regulators, and citizen advocates that discusses the need to produce "trustworthy," corporate-free evidence for medical treatments. The problem of financial conflicts of interest is by no means a new problem. Over ten years ago in its 2009 report, the US Institute of Medicine pointed out the negative effects of accepting industry's largesse on "'the integrity of scientific investigations, the objectivity of medical education, and the quality of patient care, and the public's trust in medicine.'" Nearly 60% of US medical research is sponsored by the medical industry, and numerous studies have shown that such studies tend to emphasize positive results – may even be *designed* to produce positive results by using comparators that make the product seem safer and more effective than it actually is. Moreover, industry-sponsored research tends to ignore negative results or possible harms. In fact, unfavorable results may not be published at all. Independent studies, unencumbered by a company's profit-loss bottom line, tend to have more balanced views.

➤

Even more troubling than its influence on research is the way industry has infiltrated every level of a product's approval and recommendation process. Regulatory agencies, such as the European Medicines Agency and the US Food and Drug Administration, rely on pharmaceutical money to conduct their evaluation of new products. Many experts on panels and organizations that determine clinical guidelines and recommendations also receive funds from industry. Although these experts claim that such funding does not affect their decisions, a 2016 study shows otherwise; when conflict of interest policies are strengthened and enforced, recommendations for medical products become "less enthusiastic." Likewise, the excessive amount of money spent on direct-to-consumer advertising, pharmaceutical "education" seminars for practitioners, and pharmaceutical representative visits to clinics benefits the companies' bottom line more than patient health. The *BMJ* authors say, "Industry argues it provides valuable information that helps patients, yet a systematic review found exposure to drug company information is generally associated with prescribing more medicines, at higher costs and lower quality."

Some European nations are looking for ways to lessen or remove corporate influence from product evaluation, regulation, and use. "Many groups are already moving away from industry influence in education and practice, but the main priority and greatest challenge is to develop models for research and evaluation independent from companies with interests in the outcomes," say the authors. The Norwegian Medical Association no longer accepts industry-sponsored courses as accredited education. Medical journals such as *PLOS Medicine* and *Emergency Medicine Australasia* no longer take pharmaceutical advertising. For the past decade, the Italian government has taxed drug companies to obtain money that pays for public interest research. Last year, the UK Labour Party proposed a plan to use government funding for late-stage clinical trials and to set up state-owned pharmaceutical companies. US politicians proposed a system five decades ago in which public regulators would assign independent research teams to perform product testing that is funded by the product's company. Not surprisingly, industry lobbyists have blocked this idea – at least so far.

Corporate influence in medical care, however, is just the tip of the healthcare iceberg in my view. The regulation of environmental chemicals that have major impacts on health is subject to the same type of corporate influence. Many of these chemicals are known to adversely affect health, yet government agencies continue to whitewash the information to downplay the harms. Linda Birnbaum, former director of the National Institute of Environmental Health Sciences and the National Toxicology Program, recently stated that PRAS (per- and polyfluoroalkyl substances) *cause* immune dysfunction, elevated cholesterol levels, kidney cancer, weight gain, liver dysfunction, and reproductive problems. PFAS are used in stain- and water-repellant fabric, Teflon and non-stick materials, fire-fighting foam, and food packaging and widely contaminate drinking water and soil.

In an interview with Sharon Lerner at *The Intercept,* Birnbaum, now retired, said that she was told by the NIH deputy director to use "associated with" rather than "cause" – despite a body of over 800 studies, including longitudinal studies and studies with diverse populations, that all revealed the same adverse effects and despite laboratory studies that "show the mechanism through which PFAS chemicals cause harm in people." After co-authoring an editorial in *PLOS Biology* (December 18, 2017), Birnbaum was targeted by politicians and NIH superiors with more restrictions: "'Everything I did required clearance. Even in my lab,'" she told Lerner. She was denied a salary increase and threatened with the loss of her job. Her 2017 editorial concludes: "Closing the gap between evidence and policy will require that engaged citizens, both scientists and nonscientists, work to ensure our government officials pass health-protective policies based on the best available scientific evidence."

Gross L, Birnbaum LS. Regulating toxic chemicals for public and environmental health. *PLOS Biology.* December 18, 2017.

Lerner S. Top US Toxicologist Was Barred From Saying PFAS Cause Disease in Humans. She's Saying It Now. *The Intercept*. October 24, 2019.

Moynihan R, et al. Pathways to independence: towards producing and using trustworthy evidence. *BMJ*. 2019;367;16576.

Saffron and Macular Degeneration

Antioxidants, including vitamins C, E, lutein, and zeaxanthin, can slow the progression of age-related macular degeneration (AMD) by protecting against oxidative stress that damages retinal cells; but saffron works as an antioxidant and more. A 2019 Italian study reports that the spice saffron (derived from the *Crocus sativus* flower) is even more effective in protecting vision. The researchers conducted a study on Sprague-Dawley adult rats and a longitudinal open-label study with AMD patients. The human study compared saffron-treated patients to lutein/zeaxanthin-treated patients while the animal study looked at saffron's effects on morphology, immunohistochemistry, and enzyme activity in animals exposed to intense, vision-damaging light.

The rat study showed that saffron acts as an antioxidant but also regulates gene expression, modulating metalloproteinase expression and enzyme activity. Rats treated with saffron before light exposure had far less retinal damage than untreated rats, "in a range comparable to the [unexposed] healthy control."

In the human trial, the vision of AMD patients treated with saffron (n=23) was stable while the vision in the lutein/

zeaxanthin group (n=19) had declined after 29 months (±5) months. Patients were assessed with clinical exams and Focal (macular) electroretinogram to estimate flicker sensitivity. The authors conclude, "Patients treated with the AREDS protocol (lutein/zeaxanthin) present a deterioration of retinal function whereas saffron treated patients showed quite a stable response over time; altogether these results suggest that saffron is more powerful in slowing down the progression of the disease compared to the widely employed standard AREDS supplement." The authors say this study is preliminary and needs to be confirmed with larger trials.

DiMarco S, et al. Saffron: A Multitask Neuroprotective Agent for Retinal Degenerative Diseases. *Antioxidants.* 2019;8:224.

Relationship Between Atopic Dermatitis and Food Allergies

A 2016 British systematic review of 66 studies found "a strong and dose-dependent association" between atopic dermatitis (AD), food allergy (FA), and food sensitization. The studies were too diverse to perform a meta-analysis: 18 were population-based, eight had high-risk cohorts, and the remainder focused on patients with established AD or FA. Early onset, severity, and increased persistence of AD correlated to increased risk of food allergy in multiple studies. The authors report, "…in population-based studies, the likelihood of food sensitization was up to 6 times higher in patients with AD versus healthy control subjects at 3 months of age (odds ratio, 6.18;95% CI, 2.94-12.98; P<.001)."

Interestingly, the authors say clinical food allergy – particularly to egg and peanuts – can occur without a child ever eating the food. Evidence indicates that "it is likely that food sensitization occurs primarily across the inflamed skin barrier in eczematous skin." The authors refer to a study in which the presence of food protein in dust samples taken from a baby's home was associated with food sensitization, particularly if the baby had eczema. Also, in a lab experiment, mice were repeatedly given ovalbumin and cholera toxin orally over eight weeks or ovalbumin was repeatedly applied to tape-stripped skin over seven weeks: "Both…demonstrated sIgE antibody responses, and yet only those without oral immunization had signs in keeping with anaphylaxis on oral challenge."

If skin health is a major factor in the development of food allergies, the authors say, "environmental factors, such as water hardness, the use of soaps and detergents, and the frequency of washing, could further contribute to skin barrier permeability and thus food sensitization."

Tsakok T, et al.Does atopic dermatitis cause food allergy? A systematic review. I *J Allergy Clin Immunol.* April 2016.

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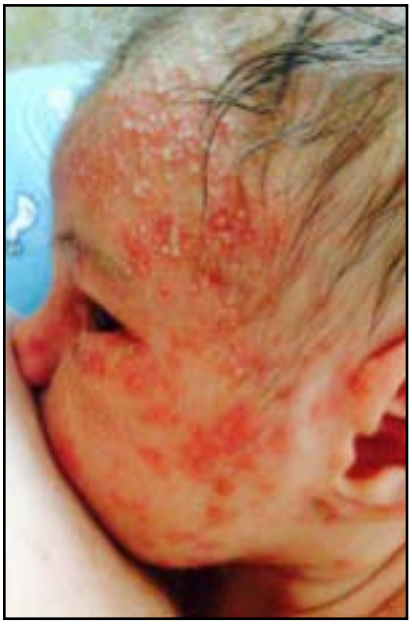
How FCT® Gets Under the Skin of Sick Skin

by Savely Yurkovsky, MD©

While skin is generally viewed in medicine as some wrapping paper for the body, it actually plays important health functions for the entire organism and can play an important diagnostic role in assessing health. It is the largest detoxifying organ in the body, thanks to its pores and sweat glands, as well as an assistant in regulating body temperature, through its blood vessels and perspiration, which impacts the entire body metabolism. Skin is also comprised of a connective tissue that runs through and connects virtually all organs and tissues, including DNA. Furthermore, being connected with blood and the main septic system of the body, lymph, it can reflect or speak volumes about someone's health, through its look and touch – even without any lab tests. Dry, oily, rough, pale, dark, sweaty, pimply, bumpy, rashy, cold, clammy, too hot, wrinkly or red, all reflect poor health, the causes of which must be addressed under the skin, internally.

From long FCT experience in identifying these causes through bio-resonance testing and clearing them with homeopathic-energetic drops, these causes usually are mercury and other toxic metals, residues of pesticides and antibiotics, environmental pollutants and infections, toxic liver, kidney, lymph and blood, poor thyroid, adrenal and ovarian functions, allergic reactions to foods, and chemicals. Some of these, and infections in the digestive organs, compromise absorption and assimilation of nutrients leaving skin malnourished. Common infections of the skin due to poor local and systemic immunity complete the picture. Likewise, common athlete's foot and toenail fungus are not just other isolated, wrapping paper conditions but internal systemic diseases too.



Case 1: Before FCT

Case 1: 10 Days After FCT

Not surprisingly, the centuries' long countless observations in homeopathy have abundantly confirmed this important body-skin connection by reporting serious internal diseases that followed skin conditions being treated from the wrong, external side through cutting, burning and rubbing something into it. In simple words, pimples, rashes, warts, and eczema with their toxins and infections were diverted to the brain, heart, ovaries, testicles, and you name it. That is why in the good old times, before the environmental, infectious, drug and electronic poisons reached the astronomical levels in the modern era, the serious internal diseases healed through classical homeopathy were followed by those "successfully" suppressed skin conditions, reemerging only to leave in a healthy way.

Unfortunately, classical homeopathy, due to this global poisoning of mankind, produces only rare miracles these days while reckless practices to make skin look better flourish more than ever because we are more concerned with our looks than health. As a result, instead of addressing external problems (skin disorders and toxic swollen faces) internally, these are just massaged, lasered or rubbed with something.

Keeping important observations of homeopathy and the body-skin connection in mind, FCT has followed it with more exact and reliable tools of bioresonance testing and energetic therapeutics based on modern medical knowledge. Quite often, the old suppressed skin conditions return as the body unloads toxic layers piled-up since birth healthily. In order to expedite the release of toxins and diminish an overall poisonous immunosuppressive carcinogenic effect of digital screens and EMF in general, the outstanding EMF protective Memon devices have been used. The following sample cases briefly reflect this approach.

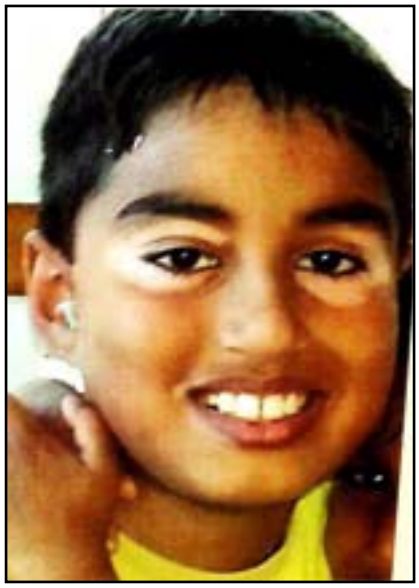
Case 1

It starts with birth or even before! This young man, only a second week into starting life, neither looked nor felt good. A heavy rash covered most of his body, likely causing severe itching and burning, as he was shutting down systematically by becoming lethargic and anorexic. After his wrapping paper treatments of steroid, antifungal and antibacterial ointments prescribed by a pediatrician and dermatologist failed, the mom brought him for FCT. Speaking of mom and the boy's rash, she and her husband had had infertility problems with the future boy's daddy having a very low sperm count, with his desire for procreating being in the same range. Fortunately, instead of following the "scientific" plan of his fertility specialists to get loaded with hormones up to his ears, with the real causes of the problem remaining a mystery, he turned to FCT. Following a few treatments of the established causes, his sperm count increased nine-fold, way into the normal range and so did his romantic drive.

Next, came the future mom, whose health and ovaries were found to be poisoned and infected. However, the treatment time that was necessary for gradual removal of her mercury fillings and clearing lifetime health problems seemed long to her; she rushed in vitro fertilization, in spite of my concerns over the health of her pregnancy and future baby. So, when I tested the baby, it became obvious that his topical skin treatments had failed because he was being re-poisoned and re-infected systemically, by mercury toxicity and candidiasis inherited from mom. These broke the skin's local immune barriers leading to a staph infection, on top. Progress commenced within the first 48 hours on homeopathic-energetic drops, which were addressing both systemic and skin problems and 10 days later, the young "fella" posed for a photo.

Case 2: Autoimmune Skin Disease

A nine-year-old boy presented with vitiligo on his face and parts of his body following one of those reckless reinventions of homeopathy, in this case, "sequential homeopathy," to cleanse toxins. But as usual, whenever any cleansing activities end up with problems, no one knows why and how to undo these. In his case too, it was left to FCT. Applying the aforementioned energetic diagnostic and therapeutic means, the causes were addressed and cleared his vitiligo entirely.



Case 2: Before FCT

Case 2: After FCT

Case 3

Case 3 provides an interesting observation from the body-skin connection. For many years, this 74-year old man believed his doctors that due to his past kidney surgery, its residual scar and his "old age," the muscles on that side of the spine, hip, and thigh had to be atrophied, weak, and hardly moving. However, once FCT addressed the discovered heavy metals buried in the muscles, he reported that they started suddenly to grow, increased in strength and mobility while at the very same time, some strange looking red flakes started pouring out of his skin.

Case 4

A red rash and peeling skin all over the body were completely cleared as the 40-year-old woman was treated with FCT for severe systemic toxicity of fluoroquinolone antibiotics, mercury, and candidiasis. At the same time, her external ailments: swollen face with dark, enfeebled skin were replaced with a healthy and much younger look, all owed to internal body FCT energetic cleansing. Her severe, multiple health problems have concurrently displayed good progress, too.

Case 5

One can only tell from the photos that both a swollen face and obesity are parts of the past. But, just as importantly there was a long list of this teen's serious health problems that vanished too. This is what the list looked like for years, which her pediatrician unsuccessfully treated with drugs:

- Anxiety, emotional, little things making her scared, over thinking, crying, negative thoughts, hurting self, feeling guilty a lot

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Case 5: Swollen, round face before and face after FCT

- Constipation/diarrhea/bloating. Bloating after meals, green BM sometimes
- Weakness of both hands/fingers, hard to hold a pencil
- "Pronates" when she walks – knees internally rotate
- Fatigue/lack of stamina – constant
- Hard to fall asleep, snores, groggy in the morning
- Uncoordinated – running awkward/ painful
- Sugar cravings – excessive and constant
- Sinus/postnasal drip– constant
- Neck and back muscle tightness
- Urine has strong odor

This case was reported by a dedicated FCT practitioner, Dr. Jason Pickel of Overland Park, Kansas. He shared this impression, "Amazing result! Another life changed with FCT! Thank you."

Case 6

When I saw Mrs. R last week in my office, the first thing out of my mouth was "Had I run into you today on the street, I would not have recognized you." But the best part of her good and much younger look was the complete turnaround from looking chronically sick to very healthy and vibrant. My office staff was stunned too, "You look fabulous!" "Yes," she said, "my bumps, dryness, puffiness and red spots on my face are gone." Her previous FCT protocol showed skin was not part of it.

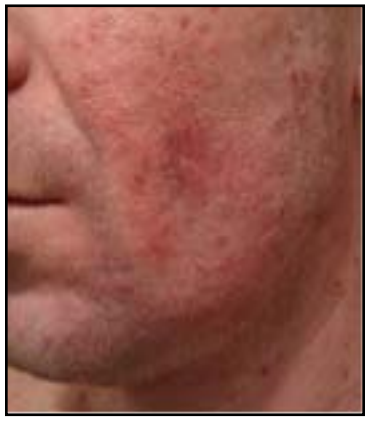
Case 7

Looking at Mrs. P a few days ago, I could not recognize her either, even though I had seen her only a few months prior when she accompanied her husband, a patient of mine. This time, she came as a patient in order to undo the "success" of her weight-loss program after she did lose weight. Yet, her usually glowing, full face and vibrant demeanor collapsed to the point of a hopeless-looking cancer patient, who has lost weight and not for a good reason. Her face looked haggard, dark, wrinkled, and as lifeless as her eyes and voice. "I went to see a nutritionist who placed me on a diet and gave me all these bottles. Initially, I felt better and started losing weight, but as I continued with the program, I became weak, constipated, and can hardly move, now. I have no desire to do anything, not even see my friends." Bioresonance testing indicated a flood of mercury and other heavy metals and toxins in her many organs, which are often released into the bloodstream from melting fat and toxic fluids on weight loss diets. Based on this, the corresponding treatment was issued, and she was reassured of recovery.

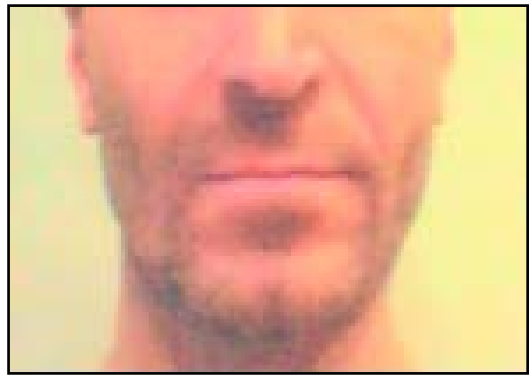
Case 8

Just the skin problem? This doctor wanted to kill himself. His photo reflects the product of multiple chemical sensitivities, where numerous chemicals found in his internal organs by bioresonance testing, had been turning his face and other skin areas into a bleeding, burning, itching, swollen sponges for years. The homeopathic-energetic drops to address these have led to such a massive release of these pollutants that he encountered plumbing problems, as they were literally clogging his shower drain. This photo and his testimony follow:

> I have been through hell, at the end of my rope and thinking of killing myself. FCT brought me back from the dead – and I mean that! I have my life back which I never thought I would have again – after 5 years I had forgotten how nice it can be just to be normal without 24 hours of burning, itching, and bleeding all over my sheets and waking up with my face stuck to my pillow. It was truly a nightmare that I never could wake up from. You saved me and I mean that in the true sense of the word. After all of my drastic efforts before finding you, I was helpless and TRULY, LITERALLY, dying – I don't know what it is but when you are dying suddenly you know it and your body and your mind changes. I am so glad I believed in you and your philosophy. It's some miracle. I did alternative therapies for five years and nothing even touched it. I wish other people knew this and it was available to the public.



Case 8: Before FCT



Case 8: Before FCT

Savely Yurkovsky, MD

About the author:

Savely Yurkovsky, MD, board-certified in internal medicine and board-eligible in cardiovascular medicine, undertook a particular interest in mercury toxicity as both its victim, and a clinician managing a busy private practice. Shortly after moving to the US from the former Soviet Union, he received several silver amalgam fillings, which he recognized later as the cause of his mounting health problems. These problems persisted despite removal of the fillings that prompted him to explore various mercury detoxifying approaches: oral, intravenous, homeopathic. After observing their corresponding partial benefits, limitations, and aggravations on himself and his patients, he resorted to bioresonance testing and causative homeopathy, based on relevant knowledge from physics and toxicology to optimize benefits and safety of the detoxification. The guidance of his physics consultant, Stanford University's materials science professor William A. Tiller, PhD, was instrumental in enhancing the diagnostic ability of bioresonance testing to address the known limitations of lab tests to detect the presence of toxicants in the internal organs. This testing also was used to draw a better comparative capacity between various mercury detoxifying treatments as well as to evolve a safer therapeutic strategy leading to minimize the reintoxication or dumping effect, which are common to these treatments. It also optimized an unlimited therapeutic potential of homeopathy that has a unique capacity to therapeutically connect with any organ and tissue, via specific signals, as no other treatment can.

His book, *Biological, Chemical, and Nuclear Warfare – Protecting Yourself and Your Loved Ones: The Power of Digital Medicine*, has been endorsed by Professor Emeritus William A. Tiller, PhD, of Stanford University and MIT physics professor George Pugh, PhD. He presented this system at the Combating Bioterrorism Conference in 2005, sponsored by the Office of Homeland Security.

Dr. Yurkovsky founded a teaching organization, "*SYY Integrated Health Systems, Ltd.*," in 1999, which is dedicated to training health practitioners in this biophysical system under the concept of FCT – Field Control Therapy®. He has lectured extensively in the US and Europe. ◆

Literature Review & Commentary

by Alan R. Gaby, MD
drgaby@earthlink.net

Vitamin D and COPD

A meta-analysis was conducted on three randomized controlled trials (in which individual participant data were available for a total of 469 patients) that examined the effect of vitamin D supplementation on acute exacerbations in patients with chronic obstructive pulmonary disease (COPD). Vitamin D did not have a significant influence on the overall rate of moderate or severe COPD exacerbations (adjusted rate ratio [RR] = 0.94; 95% confidence interval [CI], 78-1.13). In prespecified subgroup analysis, protective effects were seen in participants with baseline 25-hydroxyvitamin D levels below 10 ng/ml (RR = 0.55; 95% CI, 0.36-0.84), but not in those with baseline 25-hydroxyvitamin D levels of 10 ng/ml or higher (RR = 1.04; 95% CI, 0.85-1.27; p for interaction < 0.02).

Comment: In this meta-analysis, vitamin D supplementation prevented COPD exacerbations in patients who had severe vitamin D deficiency at baseline. However, vitamin D was not beneficial in patients who did not have severe vitamin D deficiency (25-hydroxyvitamin D level greater than 10 ng/ml). To the contrary, there was a nonsignificant trend toward worse outcomes in that subgroup. Two of the three studies in the meta-analysis used intermittent large bolus doses. Previous research has found that this method of vitamin D supplementation may decrease efficacy and increase adverse effects, when compared with more frequent, lower vitamin D doses. The third study in the meta-analysis, which used a moderate daily dose of vitamin D, had a relatively small sample size, so definitive conclusions cannot be made from that study. The results of this meta-analysis suggest that patients with COPD should not receive large bolus doses of vitamin D unless they have severe vitamin D deficiency. Further research is needed to determine the risks and benefits of using more moderate daily vitamin D doses in patients with COPD.

Of note, four randomized controlled trials met the inclusion criteria for the meta-analysis, but one of those studies[1] was excluded because individual participant data were not available. An author of that study told the meta-analysis research team that the data from their study had been lost. Not surprisingly, the "lost data" study was conducted in Iran. In an editorial in the July 2019 issue of the *Townsend Letter*, I argued that an enormous number of nutrition studies coming from Iran raise questions about possible research fraud. This point is discussed further in a follow-up editorial in the current issue of this magazine. The study with the "lost data" was registered with the Iranian Registry of Clinical Trials. The registration document makes contradictory statements: first, that the trial was registered while recruitment was in progress and, second, that recruitment was complete when the trial was registered. In addition, the study was not approved by the ethics committee until more than three months after the study began.

Jolliffe DA, et al. Vitamin D to prevent exacerbations of COPD: systematic review and meta-analysis of individual participant data from randomised controlled trials. *Thorax*. 2019;74:337-345.

Can Flavonoids Prevent Age-Related Macular Degeneration?

The association between flavonoid intake (assessed at baseline) and risk of age-related macular degeneration (AMD) was examined in a prospective cohort study of 2,856 Australian individuals aged 49 years or older. Follow-up data 15 years later were available for 2,037 participants. In cross-sectional analysis, after adjustment for age, smoking, fish consumption, intake of lutein and zeaxanthin, and other potential confounding variables, higher flavonoid intake was significantly associated

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The owner of a cancer clinic in San Diego just ordered two more Relax Saunas. She said she "***loves the Relax Saunas and frankly the wood infrared saunas just don't penetrate as much as the Relax Sauna***". The Relax Sauna generates about 98% FIR and other infrared saunas are usually about 50% at the most. The ones with the carbon panels can only do about 36% FIR. Those who cannot relate to this information can relate to the fact that the Relax Sauna raises core temperature FAR more than any other infrared saunas.

We recently saw an online review on reddit.com from a man who was fascinated with the research done on pubmed.com. So, he purchased a $250 sauna on amazon.com and was not able to replicate at all what the research that FIR saunas said they can do. He could not raise the core temp more than 0.5° in 25 minutes and the heart rate variability tests failed to do what the research indicated. He then purchased a $500 sauna on amazon.com that came very highly recommended and had the same results, no results.

He then got a Relax Sauna because he was impressed that it was 1500 watts and had advanced level technology. He was more than pleasantly surprised because he was able to raise core temperature 3.2° in 25 minutes, and all the heart rate variability tests not only replicated the research but exceeded them. The Relax Sauna in not an ordinary infrared sauna, and we know we are able to get better results, as evidenced by about 400 video testimonials from doctors and health professionals on youtube.com.

There is another cancer clinic in Washington state that uses the Relax Sauna while doing iv therapy. They use the sauna to increase core temperature 4.2° in one hour with many of their cancer patients. Other doctors use the Relax Sauna before doing iv therapy so that they can get veins to protrude for iv use.

"Gastra Girl: Saving America One Colon at a Time" by Rebecca Harder is a wonderful book we recommend you read. It is a compendium of holistic health information of topics such as hyperbaric oxygen, ozone, far infrared saunas, vaccines, etc.. Rebecca relates how she turned her nose at the Relax Sauna for 10 years (having wooden infrared saunas at her pristine clinic). After finally trying the Relax Sauna for 3 minutes she was sold on the instant relaxation and the difference. She now promotes the Relax Sauna and recommends it to her many clients. In her book she explains *"Why Infrared Sauna is an Absolute Necessity... For Everyone"*

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Gaby's Literature Review

➤ *continued from page 28*

with a lower incidence of AMD. There was a 24% lower risk of AMD for each 1-standard deviation increase in total flavonoid intake.

Comment: In this study, higher dietary flavonoid intake was associated with a lower risk of developing AMD. While observational studies cannot prove causation, there is some scientific support for the idea that certain flavonoids are beneficial for eye health. One class of flavonoids is known as anthocyanosides. These compounds are found in blueberries and some other fruits and vegetables, and are a main component of bilberry (European blueberry), an herbal supplement. Administration of anthocyanosides to rabbits caused a marked increase in the activity of certain enzymes in retinal tissue, indicating a direct effect of these compounds on retinal function.[2] Anthocyanosides also have antioxidant activity, and might therefore inhibit oxidative damage to retinal tissue, which is believed to play a role in the pathogenesis of AMD. Another potentially beneficial flavonoid is quercetin. This compound, which is present in apples, onions, black tea, and other plant foods, has been found in retinal tissue.[3] Quercetin protected retinal pigment epithelial cells from oxidative damage *in vitro* in a dose-dependent manner.[4] Clinical trials are warranted to determine whether anthocyanosides, quercetin, or other flavonoids can prevent or slow the progression of AMD.

Gopinath B, et al. Dietary flavonoids and the prevalence and 15-y incidence of age-related macular degeneration. *Am J Clin Nutr*. 2018;108:381-387.

N-Acetylcysteine for Bronchiectasis

One hundred sixty-one Chinese patients (mean age, 55 years) with bronchiectasis, who had had at least two exacerbations in the previous year, were randomly assigned to receive N-acetylcysteine (NAC; 600 mg twice a day for 12 months) or to a control group that did not receive NAC. An exacerbation was defined as a worsening of three or more key symptoms (including cough, sputum volume or consistency, sputum purulence, shortness of breath, fatigue or malaise, and hemoptysis). The mean number of exacerbations per patient per year was significantly lower by 34% in the NAC group than in the control group (1.31 vs. 1.98; $p = 0.001$). The proportion of patients who were free of exacerbations during the study was significantly higher in the NAC group than in the control group (24.7% vs. 11.3%; $p < 0.03$). Sputum volume was significantly lower in the NAC group than in the control group ($p = 0.002$). No severe adverse effects were reported.

Comment: Bronchiectasis is a chronic lung disorder characterized by irreversible dilatation of one or more bronchi. It frequently results from recurrent infection or inflammation and is seen in many patients with cystic fibrosis. Symptoms may include chronic cough with mucopurulent sputum production, impaired clearance of secretions, shortness of breath, and hemoptysis. Medical therapy includes antibiotics and regular drainage to remove bronchial secretions.

Orally administered NAC has been shown to enhance the clearance of mucus by the pulmonary cilia in healthy volunteers who had a slow baseline clearance rate.[5] Pulmonary mucociliary clearance is an important defense mechanism against bacteria and particulate matter, and patients with bronchiectasis have been found to have mucociliary dysfunction. Administration of NAC by aerosol produced clinical improvement in patients with bronchiectasis.[6] The present study is apparently the first to demonstrate that orally administered NAC is also of value for these patients.

Qi Q, et al. Effect of N-acetylcysteine on exacerbations of bronchiectasis (BENE): a randomized controlled trial. *Respir Res*. 2019;20:73.

Kanuka Honey for Herpes Simplex

Nine hundred fifty-two New Zealand adults presenting within 72 hours of an episode of herpes simplex labialis (cold sores) were randomly assigned to apply a medical grade kanuka honey preparation (Honevo; Honeylab Ltd, Tauranga, New Zealand; consisting of 90% kanuka honey and 10% glycerine cream) or 5% acyclovir cream five times per day until the lesions had healed completely or for 14 days, whichever occurred first. Kaplan-Meier-based estimates of the median time to complete healing were nine days for honey and eight days for acyclovir ($p = 0.56$). No serious adverse events were reported.

Comment: Kanuka honey is a type of honey native to New Zealand. It is produced by bees from the nectar of *Kunzea ericoides* (commonly known as kanuka), a small tree or shrub in the myrtle family. In this study, topically applied kanuka honey was nearly as effective as the antiviral drug acyclovir in the treatment of herpes simplex labialis. The study was funded by Honeylab Ltd (which sells the product being investigated), and one of the authors received grant money from the funding source. Confirmatory studies would therefore be worthwhile.

Semprini A, et al. Kanuka honey versus aciclovir for the topical treatment of herpes simplex labialis: a randomised controlled trial. *BMJ Open*. 2019;9:e026201.

An Epidemic of Low Magnesium Status in the United States

This review article discussed research related to magnesium nutritional status in the United States. Dietary magnesium intake among adults has decreased during the past 100 years by about 200 mg per day: from 400-500 mg per day in the early 20th century to 200-300 mg per day in the 21st century. In the National Health and Nutrition Examination Surveys from 2001-2002, 2005-2006, and 2007-1010, between 53% and 67% of adults consumed less than the Estimated Average Requirement for magnesium. The reduction in magnesium intake in modern times is due in part to decreased magnesium content of foods such as wheat and vegetables, decreased content of magnesium in cheese and meat (due to lower amounts of magnesium in animal feed), and increased use of processed foods.

Comment: Magnesium plays a key role in numerous physiological processes and is a cofactor for more than 300 different enzymes. Low or suboptimal magnesium status may contribute to a wide range of diseases and symptoms, including cardiovascular disease, fibromyalgia, osteoporosis, migraines, fatigue, anxiety, depression, asthma, premenstrual syndrome, and kidney stones. In my experience, magnesium supplementation is one of the most frequently beneficial nutritional interventions. Good food sources of magnesium include nuts, whole grains, legumes, leafy green vegetables, fish, meat, and dairy products. More than 80% of the

magnesium is lost in the refining of whole wheat flour to white flour and brown rice to white rice. Some 50-75% of the magnesium is lost in the water when vegetables are boiled.

Tarleton EK. Factors influencing magnesium consumption among adults in the United States. *Nutr Rev*. 2018;76:526-538.

Probiotic Beneficial for Acute Diverticulitis

Eighty-eight patients (mean age, 62 years) in Italy with acute uncomplicated diverticulitis were treated with ciprofloxacin (400 mg twice a day) and metronidazole (500 mg 3 times a day) for one week and were randomly assigned to receive, in double-blind fashion, *Lactobacillus reuteri* 4659 (5×10^8 colony-forming units twice a day, 30 minutes after meals) or placebo for 10 days, beginning at the start of antibiotic therapy. Mean severity of abdominal pain decreased to a significantly greater extent in the probiotic group than in the placebo group at each measured time point (days 3, 5, 7, and 10) ($p < 0.0001$ for each comparison). The mean decrease in the C-reactive protein concentration from baseline to 72 hours was significantly greater in the probiotic group than in the placebo group ($p < 0.0001$). The mean length of hospital stay was significantly less in the probiotic group than in the placebo group (93 vs. 113 hours; $p < 0.0001$).

Comment: In this study, a specific probiotic, when used as an adjunct to antibiotic therapy, decreased abdominal pain, inflammatory markers, and length of hospital stay in patients with acute uncomplicated diverticulitis. The mechanism of action is not clear, and it is not known whether other probiotic strains would have the same effect.

Petruzziello C, et al. Supplementation with Lactobacillus reuteri ATCC PTA 4659 in patients affected by acute uncomplicated diverticulitis: a randomized double-blind placebo controlled trial. *Int J Colorectal Dis*. 2019;34:1087-1094.

Adverse Effect of Red Yeast Rice

A 64-year-old woman developed acute hepatitis six weeks after starting a red yeast rice supplement. Infectious, toxic, and autoimmune causes of hepatitis were ruled out. After stopping the red yeast rice and starting treatment with methylprednisolone, the liver enzymes decreased. The Italian Surveillance System of Natural Health Products found 10 reports of liver injury associated with red yeast rice between April 2002 and September 2015.

Comment: Red yeast rice is fermented rice produced by growing red yeast (*Monascus purpureus*) on white rice. Some strains of red yeast rice contain compounds called monacolins, which are structurally similar to statin drugs such as pravastatin, simvastatin, and lovastatin. Indeed, lovastatin has been identified as the most predominant monacolin in red yeast rice, although up to 10 distinct monacolins have been found in some products. Like statin drugs, monacolins inhibit cholesterol synthesis by inhibiting HMG-CoA reductase. Like statin drugs, monacolins also lower C-reactive protein concentrations. For these reasons, red yeast rice is sometimes used as an alternative to statins.

The incidence of myopathy and hepatotoxicity is markedly lower with red yeast rice than with prescription statin drugs. However, the present report should serve as a reminder that red yeast rice is not entirely risk-free.

Loubser L, et al. Acute liver injury induced by red yeast rice supplement. *BMJ Case Rep*. 2019;12:e227961.

Does Fructose Cause Kidney Stones?

The authors of this study analyzed a previously published randomized controlled trial that included 33 healthy male adults (40-65 years of age) who ingested 200 g of fructose daily for two weeks. Fructose consumption was associated with a significant increase in serum uric acid, a significant decrease in urinary pH, a significant increase in 24-hour urinary oxalate excretion, and a significant decrease in 24-hour urinary magnesium excretion. Each of these changes would be expected to increase the risk of developing calcium oxalate kidney stones, and the higher uric acid excretion would be expected to increase the risk of uric acid stones.

Comment: Previous observational studies found that increasing fructose consumption is associated with an increased risk of developing kidney stones. The results of the present study suggest mechanisms by which fructose could increase kidney stone risk. Other dietary factors that may promote kidney stone formation include excessive consumption of sucrose, salt, or foods with a high oxalate content.

Johnson RJ, et al. Fructose increases risk for kidney stones: potential role in metabolic syndrome and heat stress. *BMC Nephrol*. 2018;19:315.

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How to Protect Against Glyphosate Toxicity

by Debby Hamilton, MD, MPH

In 1996 with the development of genetically engineered herbicide-tolerant soy, corn, and cotton, the use of the organophosphate pesticide glyphosate (n-phosphonomethylglycine) became more common. Since then there has been a dramatic 300-fold increase in application from its first introduction until 2014. Approximately 67% of this growth has been in the last 10 years. Glyphosate disrupts the shikimate pathway, which exists in plants, yeast, and bacteria but not in animals and therefore thought to be safe in humans. What was not considered is the large bacterial ecosystem in humans called the microbiome, which is critical for a healthy immune system. Lactobacillus, Bifidobacterium and soil-based organisms are decreased by glyphosate, causing an increase in Clostridium species and Salmonella-promoting dysbiosis.

The shikimate pathway through our gastrointestinal bacteria is involved in producing our aromatic amino acids, including tryptophan and tyrosine. These amino acids are important for the formation of neurotransmitters. This pathway also produces precursors for many critical compounds such as serotonin, melatonin, thyroid hormone, folate, CoQ10, and vitamins C and E. Methionine is another amino acid that is negatively impacted by glyphosate. Since methionine is a critical source of sulfur in the body, this can cause a sulfur depletion that impacts many critical biochemical and detoxification reactions.

Due to its ability to chelate, glyphosate can bind and cause a deficiency in minerals, including iron, cobalt, molybdenum, and manganese. Manganese is needed for the Mn superoxide dismutase enzyme that protects the mitochondria from oxidative stress. This can lead to mitochondrial dysfunction that is common in many chronic diseases. This deficiency also impairs the enzymes glutamine synthase and arginase, resulting in elevated glutamine and ammonia that can be toxic to the body.

Glyphosate interferes with our critical cytochrome P450 enzymes. These enzymes have multiple functions in the body ranging from detoxification, oxidation, and converting compounds such as pharmaceutical medicines, environmental chemicals, and endogenous molecules. By harming detoxification enzymes, glyphosate enhances the toxicity of other dangerous chemicals. It can also lead to damage of the liver and kidneys by interfering with natural detoxification mechanisms. CYP enzymes are involved in both cholesterol and vitamin D3 synthesis and breakdown. CYP enzymes are also involved in synthesis of steroids from cholesterol within the mitochondrial membrane, leading to potential mitochondrial dysfunction.

The rates of celiac and gluten intolerance have risen over the last few decades. Increasing use of glyphosate correlates with this increase. Several of the mechanisms that are harmed by glyphosate are involved in gluten and wheat reactions. Glyphosate is sprayed on wheat products before harvest, which increases the amount of glyphosate residues on wheat. It also contributes to dysbiosis, increasing the risk of food reactions and autoimmune reactions. Interference with detoxification enzymes leads to increases in toxic exposures in the intestine, contributing to damage in the intestine.

Concerns with glyphosate toxicity have led to research on natural substances that can counteract some of these harmful effects. Humic acid is derived from organic matter in humus and peat in the soil. It has been used safely in agricultural settings to remove glyphosate from the soil. Research has shown some positive results in humans and animals. Humic acid adsorbs glyphosate, decreasing its negative impact on the microbiome. Fulvic acid is another component of humus along with humic acid. It is a smaller molecule able to be absorbed into the blood stream to help bind glyphosate in the tissues while humic acid is larger and has more impact for binding glyphosate in the intestine.

Glyphosate damages the liver and kidneys by causing DNA damage. Because of this, research has looked for natural compounds to protect these organs. Research has shown both dandelion (*Taraxacum officinale*) and quercetin to be protective for the liver and kidneys. Dandelion is hepatoprotective partly through activation of the Nrf2-Keap1 pathway, leading to an antioxidant effect. It also helps restore the CWP enzymes that are harmed by glyphosate, therefore helping support detoxification. In a similar mechanism as dandelion, quercetin protects the detoxification CWP enzymes and has antioxidant and anti-inflammatory properties.

Another mechanism of detoxification is the binding of chemicals in the gastrointestinal tract. Adequate bile flow is important for binding of fat-

continued on page 34 ➤

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Glyphosate Toxicity

➤ *continued from page 32*

soluble molecules. Bile acids are bound to taurine or glycine to become bile salts to be secreted into the intestine. Glyphosate disrupts bile homeostasis interfering with this process. Taurine can promote bile flow to compensate for the harm from glyphosate. Taurine also is a source of sulfur in the body. Sulfur is a component of many amino acids and glutathione that are needed for detoxification.

Glyphosate exposure decreases the activity of several antioxidants, including superoxide dismutase, catalase, and glutathione-S- transferase, resulting in increased lipid peroxidation. Antioxidants such as vitamin C have been shown in research to decrease oxidative stress associated with glyphosate along with being protective from oxidative damage.

Glyphosate can also bind to toxic chemicals, such as aluminum, allowing them to bypass the normal intestinal barrier. By bypassing the intestinal barrier, glyphosate enhances the bioavailability of aluminum in the body and therefore its toxicity by increasing the amount entering the brain. Aluminum is a neurotoxin so increasing its exposure to the nervous system is dangerous. By having a different structure than other heavy metals, aluminum is also more difficult to remove from the body. The mineral silica has been shown to be an effective binder for aluminum in the intestine preventing its absorption into the body.

ToxinPul™ was designed as a multi-function detoxification supplement to support both glyphosate and heavy metal removal from the body. The ingredients were included based on research in supporting detoxification safely. It includes a combination of binders, supplements to facilitate tissue removal of toxins, and organ-specific protective ingredients. Cilantro helps bring toxins out of the tissues so they can be bound by the other binders including chlorella, humic acid, fulvic acid, and silica. The binders in ToxinPul™ are unique in being able to bind chemicals and metals both in the body and within the intestine. Quercetin, dandelion, and taurine help protect the liver and kidneys and support the detoxification system. Vitamin C is an antioxidant to decrease toxin-induced oxidative stress. Most detoxification supplements are targeted primarily for heavy metal removal. While heavy metal detoxification is important, we are learning more and more about the dangers of glyphosate and other pesticides. ToxinPul™ was designed to safely support removal of the multitude of chemicals, including the commonly used pesticide glyphosate.

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Hashimoto's Thyroiditis, A Common Disorder in Women: How to Treat It – Part 1

by Thierry Hertoghe, MD

Interest in Hashimoto's thyroiditis is high in the doctor's office as well as on the internet. Patients openly testify that they have Hashimoto's, and some attribute an endless list of complaints to this disorder. Most of these patients are women. What is true about this media hype? Is it merely media hype or does it reflect reality? What are the causes and what can be done about it?

Hashimoto's thyroiditis is an autoimmune disorder. In autoimmune disorders, antibodies are made against constituents of the body's tissues, and lymphocytes concentrate in the affected tissues. They are dysregulations of the immune system. The thyroid gland is the most common organ affected by autoimmune disease. Hashimoto's thyroiditis is the most frequent autoimmune disease of the thyroid gland.[1]

Two autoimmune disorders predominate in the thyroid gland: Hashimoto's thyroiditis and Graves' disease. Hashimoto's thyroiditis is also known as chronic lymphocytic thyroiditis or chronic autoimmune thyroiditis and involves the production of antibodies against thyroid peroxidase and/or thyroglobulin. Thyroid peroxidase is the enzyme that oxidizes iodide ions to form iodine atoms for incorporation into T3 and T4 hormones in the colloid. Thyroglobulin is the bigger protein that stores T3 and T4 in the colloid. [2-4]

Graves' disease, on the other hand, is also known as Basedow's disease and is characterized by the production of autoantibodies that target and stimulate the TSH (thyroid stimulating hormone) receptor on the thyroid follicular cells. It is the most common cause of hyperthyroidism.[2]

Table 1: Differences Between Hashimoto's Thyroiditis and Graves' Disease

Autoimmune disorder	Hashimoto's thyroiditis[2,4]		Graves' disease[2,5]	
Antibodies	• Antithyroid peroxidase antibodies • and/or Antithyroglobulin antibodies • (Normally no anti-TSH receptor antibodies)		• Anti-TSH receptor antibodies • (Antithyroid peroxidase antibodies (in 80% of patients)) • (Antithyroglobulin antibodies (in 50%))	
Thyroid state	Progresses into hypothyroidism		Hyperthyroidism	
Serum TSH	Variable	Progresses into hypothyroidism	Low	Hyperthyroidism
Free T3	Variable		High	
Free T4	Variable		High	
Clinical features	• Hypothyroid, • Euthyroid, • or (more rarely) Hyperthyroid		• Hyperthyroid signs and symptoms with sometimes pretibial myxedema, often thyroid eye disease	
Thyroid ophthalmopathy	• Rarely exophthalmos (<2%), • More frequently hypothyroid signs, such as suborbital edema		• Exophthalmos (in 25%), • Other signs: lid lag, eyelid edema, chemosis, extraocular muscle weakness	
Thyroid gland	• Thyroid atrophy and (micro) nodules are more common, • Occasionally goiter		• Goiter	
Histological findings	• Mononuclear cells, mostly lymphocytes (especially T cells)		• Activated follicular cells • Increased vascularization	
	• Destroyed thyroid follicles		• Hyperplastic follicles with colloidal absorption	
Thyroid ultrasound	• Reduced echogenicity (progresses to atrophic hypovascular thyroid)		• Increased echogenicity (diffusely enlarged hypervascular thyroid gland)	

Diagnosis of Hashimoto's Thyroiditis

The diagnosis of Hashimoto's thyroiditis relies on the presence of antibodies to thyroid peroxidase and/or thyroglobulin in the serum and reduced echogenicity on a thyroid ultrasound. On histological examination, the thyroid gland is infiltrated by mononuclear cells, mostly lymphocytes (especially T cells), and many thyroid follicles are destroyed. These pathological features of autoimmune thyroiditis lead to progressive atrophy and fibrosis of the thyroid gland. Clinically, the patient can present hypothyroid signs and symptoms, appear euthyroid, or (more rarely) hyperthyroid. Local symptoms such as thyroid tenderness and neck pain are only present in acute and subacute thyroiditis. As Hashimoto's disease is chronic, patients are generally devoid of local symptoms.[2,4]

Diagnosis of Graves' Disease

The diagnosis of Graves' disease is based on the presence of TSH-receptor antibodies, abnormally high T4 and T3 levels, suppressed TSH levels in the serum, and clinical features. Physical signs of Graves' disease include swelling of the anterior part of the calves (pretibial myxedema), thyroid eye disease, exophthalmos (prominence of eyes), lid lag (higher upper eyelid while the eye is directed down), eyelid edema, chemosis (conjunctival edema), extraocular muscle weakness, and possibly increased pigmentation and vitiligo. Thyroid ophthalmopathy is present in about 50% of Graves' patients, which includes exophthalmos in about 25% of cases.[2]

Table 1 reviews the differences between Hashimoto's thyroiditis and Graves' disease.

Hashimoto's thyroiditis is much more frequent in women. Thyroid autoimmune diseases affect up to 5-6% of the population, but in some age groups (30-50 years) its frequency may climb up to 10-15%, and are seen mostly in women.[3,6-7] Hashimoto's thyroiditis is the most frequent autoimmune thyroid disorder, affecting more than 10% of women and only 2% of men.[8] The higher frequency in women may be due to their lower androgen levels, particularly testosterone, which is 10 to 20 times lower than in men. Androgens are known to help prevent and treat autoimmune disorders of all types (for more information, refer to the treatment section).

Graves' disease affects eight times more women than men.[9]

Scientific data suggests that most cases of Hashimoto's thyroiditis are intermediate degrees of hypothyroidism. Most cases of Hashimoto's thyroiditis ultimately progress into hypothyroidism,[10-18] although initially patients can appear euthyroid or even hyperthyroid.[2] Indeed, Hashimoto's thyroiditis may trigger flare-ups of hyperthyroidism.-

Why do most patients with antithyroid antibodies suffer from some degree of thyroid deficiency? The reason lies in the repeated damage to the thyroid tissue from the accumulation of mononuclear cells and aggression of antithyroid antibodies, resulting in atrophy of the thyroid gland. Epidemiological studies often show that autoimmune thyroiditis is significantly associated with higher serum levels of TSH[19-27] and lower levels of free T3[28-29] and T4,[30-34] signs of decreased thyroid function. Research has also shown that patients with autoimmune antithyroid antibodies more often suffer from hypothyroid signs and symptoms[31] and are significantly more prone to psychological and somatic disorders, which are typically more frequent in hypothyroidism. Furthermore, thyroid therapy for autoimmune thyroiditis usually relieves the symptoms of thyroid deficiency and the risks and severity of hypothyroid-related disorders.[36-50] Thyroid therapy also reduces the levels of antithyroid antibodies (for more information see treatment section).

This explains why Hashimoto disease is considered the leading cause of hypothyroidism in iodine-sufficient areas of the world.[2]

Hashimoto thyroiditis is associated with other important disorders, for which the scientific evidence is abundant. Hashimoto's thyroiditis appears to facilitate many disorders that are serious and stressful.[51-265] It is accompanied by a lower quality of life, fatigue,[35,54-66] reduced brain perfusion,[51-53] reduced mental health,[67] cognitive impairment,[102] depression (up to 8-9x higher risk),[67,70-75] and anxiety[67,75,79-81,87] – with up to nine times a higher risk of panic disorder.[75,79]

Specifically, in women, fertility is lower, the pregnancy rate is lower[111-112] and the risk of miscarriages is also greater,[113] as is the risk of premature ovarian failure.[124-125] Nearly half of women with polycystic ovarian syndrome (PCOS) have antithyroid antibodies, which is 5-10 times higher than the normal rate![123]

In obese individuals, males and females, antithyroid antibodies are also frequently found.[149-152] Approximately one third of patients with autoimmune type 1 diabetes also have Hashimoto's thyroiditis.[127]

Patients with hair, skin, and mucosa disorders are also more likely to experience Hashimoto's. Hence, up to 25% of patients with alopecia totalis have been reported to present Hashimoto's thyroiditis,[180] 34% of patients with vitiligo,[190] and 20-30% of those with psoriasis have antithyroid antibodies.[186] Furthermore, four times more patients with Sjögren syndrome have Hashimoto's thyroiditis than in the general population.[171]

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What about the cardiovascular risk? In patients with Hashimoto's thyroiditis, cardiac function is lower,[68-69] the risk of mitral valve prolapse has been reported to be three-fold higher,[213] that of coronary vasospasm (main cause of heart attacks in women) is five times higher when antithyroid peroxidase antibodies are elevated,[214] and the incidence of coronary heart disease is about 40% higher.[219] The likelihood of myocardial infarction has been found to be two-fold higher.[225]

Autoimmune thyroiditis might also affect patients with inflammatory disease of the joints and muscles. The risk of rheumatoid arthritis, for instance, is 2.5 times higher in

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Table 2: Hashimoto's Thyroiditis: Associated Pathologies

TYPE OF DISORDER	RISK, SEVERITY*
Fitness deficits	
• Reduced brain perfusion[51-53]	*2.1x ↑ perfusion defects*[53]
• Low quality of life, fatigue[35,54-66]	*+66% greater fatigue*[55]
• Reduced physical functioning[67]	*-11% reduction*
• Low cardiac function[68-69]	*-29% reduction*[69]
Psychological disorders	
• Hypothyroid symptoms[35]	*+50% increase*
• Reduced mental health[67]	*-11% reduction*
• Depression[67,70-85]	**1.5-9x higher risk**[79]
• Suicide (death by)[86]	**1.4x higher risk**
• Anxiety[67,75,79-81,87]	**4x higher risk**[80]
• Panic disorder[75,79]	**9x higher risk**[79]
• Obsessive compulsive disorder[60-75]	**1.5x higher risk**[61]
• Neuroticism[88-89]	**1.3x higher risk**[88]
• Paranoia[90]	in 40% in Hashimoto's encephalopathy
• Psychosis[91-92]	in 25%[91] in Hashimoto's encephalopathy
Mental -Neurological disorders[90]	
• Neuropathy (peripheral)[93]	in 11% of HT patients
• Orbitopathy[94-96]	in 2% of HT patients[96]
• Encephalopathy[97-99]	Rare
• Attention deficit[100-101]	**2.9x higher risk**[101]
• Cognitive impairment[102]	in 28% of HT Patients
• Alzheimer's disease[103]	Rare
• Other dementias[104-107]	Rare
• Multiple sclerosis[108]	9% of men with MS have HT
Sleep disorders	
• Sleep apnea[109-110]	47% of patients have HT[109]
Sexual /reproductive disorders	
• Sexual dysfunction[35,72]	**1.4x higher risk**[72]
• Infertility[111-112]	HT women have
	-41% lower pregnancy rate[112]
• Miscarriages[113]	**1.2-2.5x higher risk**
Endocrine disorders	
• Prolactinomas[114-116]	30% of patients have HT[114]
• Thyroid nodules, goiter[117-121]	in 36% of HT patients[120]
• Hypothyroidism[10-18]	**10x higher risk**[10]
• Polycystic ovarian syndrome[122-123]	**11x higher risk**[123]
• Premature ovarian failure[124-125]	20-30% of patients have HT[125]
• Addison's disease[126]	**Higher risk**
• Type I diabetes[127-146]	35% of patients have HT[127]
• Type II diabetes[147]	19% of patients have HT
• High estradiol-low testosterone (men)[148]	Men with HT have +10% higher E2/T ratio
Metabolic disorders	
Overweight, obesity[149-152]	*4x higher ATPO and 10x higher ATG levels*[152]
Digestive disorders	
• Celiac disease[153-160]	**4x higher risk**[160]

TYPE OF DISORDER	RISK, SEVERITY*
General disorders	
• Reduced general health[67]	*-15%*
• Oxidative stress, low antioxidant capacity[161-165]	*↑ ROS, ↓ antioxidant potential, +18% ↑ AGEs*
• Other autoimmune diseases	in 20-40% of HT patients[126,166-177]
Hair, skin, mucosa disorders	
• Alopecia areata, totalis[178-180]	5-25% of patients have HT[178,180]
• Ichthyosis[43,181]	**Higher risk**
• Atopic dermatitis[182-183]	10% of patients have HT[182]
• Chronic urticaria[184-185]	18% of patients have HT[184-185]
• Psoriasis[186]	25-30% of patients have HT[184]
• Vitiligo[187-194]	34% have HT (vs 9% in the general population)[190]
• Hirsutism[43]	**Higher risk**
• Sjögren syndrome, reduced salivary output[170-174]	*4x more have HT (than the general population)*[171]
Cardiovascular disorders	
• Lipid disorders[195-200]	*High total-LDL cholesterol, triglycerides, low HDL*
• Hyperhomocysteinemia[201]	*+22% ↑ homocysteine*
• Arterial stiffness[202-204]	*+10% ↑ pulse wave velocity*[204]
• Atherosclerosis[205-208]	*Thicker intima media*
• Thrombosis[209-210]	*Fibrinolytic deficit*
• Pulmonary hypertension[211-212]	**3x higher risk**[211]
• Mitral valve prolapse[213]	**3x higher risk**
• Coronary vasospasm[214]	**5x higher risk (w/ ↑ ATPO)**
• Coronary heart disease[215-224]	**1.4x higher risk**[219]
• Myocardial infarction[225-226]	**2x higher risk**[225]
• Stroke[227]	**1.1-1.3x higher risk**
• Hepatitis C virus-related cryoglobulinemia[228-231]	**3-6x ↑ risk for high cytokines CXCL 9,10 & 11****[228]
Bone, joint, and tendon disorders	
• Temporomandibular arthritis (TMA)[232]	**100% risk** to have TMA symptoms
• Myopathy (proximal)[93,233]	in 13% of HT patients[93]
• Polymyalgia rheumatica[169,234]	**Higher risk**
• Body pains[235-236]	**Higher risk**
• Fibromyalgia[235,237-243]	in 31% of HT patients[241]
• Rheumatoid arthritis[235,244-248]	**2.5x higher risk**[247]
• Systemic lupus Erythematosus[169,175-177]	2.3x more patients have HT than controls[175]
• Systemic sclerosis[249]	20% of patients have HT
• Spinal disc degeneration[250]	**1.8x higher risk**
Cancer	
• Thyroid (papillary) cancer[117-118,251-261]	**3x higher risk**,[258] but more favorable outcome[262-264]
Premature death by	
• Suicide[86]	**1.4x higher risk**
• Unknown matters[86]	**1.4x higher risk**
• Cardiovascular causes[265]	**1.7x higher risk**

Notes: Symbols: * Approximate risks, severity found in various studies and compared to the general population or control subjects without Hashimoto's thyroiditis; **heart failure markers

Abbreviations: HT = Hashimoto's thyroiditis; ATPO = antithyroperoxidase antibodies; ATG = antithyroglobulin antibodies; x = times or -fold; ROS: reactive oxygen species = free radicals; AGE's = Advanced Glycation End Products; ↑= increased = higher

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patients with autoimmune thyroiditis.[247] Antithyroid antibodies are found in 13% of patients with proximal myopathy,[93] in 20% of patients with systemic sclerosis,[249] and in more than 30% of patients with fibromyalgia.[241] These figures are higher than the 5-6% found in the general population. Patients with systemic lupus erythematosus have 2.3-fold higher incidence of Hashimoto's thyroiditis.[175]

The gastrointestinal tract is also not spared by Hashimoto's thyroiditis with a risk of celiac disease that is approximately four times higher than in people without antithyroid antibodies.[160]

The incidence of thyroid cancer, particularly papillary cancer, has been found to be on the average three-fold as high in patients with autoimmune thyroiditis,[258] but with a more favorable outcome (less malignancy).[262-264]

Life expectancy also seems to be decreased in Hashimoto patients. Death by suicide and unknown matters, for example, has been reported to be 43% more frequent in these patients,[86] and death by cardiovascular disease 72%.[265]

Table 2 gives an overview of the most common psychological and physical disorders significantly associated with autoimmune thyroiditis. To provide an approximate idea of how much greater the risk of each disease is for patients with Hashimoto's, I have added some figures:

- **The severity of the disorder in patients with Hashimoto's thyroiditis**, which is presented in *italic characters*. For reduced brain perfusion, for example, patients with Hashimoto have *2.1x more perfusion defects* than controls without HT.[53]
- **How much higher antithyroid antibody** levels are in patients with the disorder (suggesting that higher antithyroid antibody levels promote the disease). These figures are presented in *italic characters*. In obesity, for example, *the levels of antithyroid peroxidase antibodies are 4 times higher and those of antithyroglobulin antibodies 10-fold higher.*[152]
- **The risk to have a disorder for patients with Hashimoto's thyroiditis**, which is presented in **bold characters**. A Hashimoto patient has, for example, a **2x higher risk** of suffering from an anxiety disorder.[80]
- **The percentage of patients with the disorder who have Hashimoto's thyroiditis**, a percentage that is generally higher than the 5-6% of the general population and which is presented in standard characters. For example, 34% of vitiligo patients have been reported to have HT (HT = abbreviation of Hashimoto's thyroiditis).[190]

Because Hashimoto's thyroiditis is often associated with hypothyroid symptoms and increased risks of many pathologies, even in its milder forms, it is not an innocent or safe condition. Hashimoto's thyroiditis is likely an intermediate degree of hypothyroidism. Patients suffer needlessly and need therapy. It is not to be considered as a silent condition that needs only surveillance.

Causes and Treatment of Hashimoto's Thyroiditis

To treat, find first the cause or causes of Hashimoto's thyroiditis. Because of all the adverse effects of Hashimoto's thyroiditis, it is important to test for antithyroid antibodies, and when antibodies are elevated to treat the autoimmune disorder. Indeed, autoimmune thyroiditis is treatable. Medical research has made substantial progress in this field, offering various solutions.

To treat it efficiently, it is essential to detect the cause or causes of abnormal productions of antithyroid antibodies. Treating the cause first is a principle in medicine for any chronic or recurrent pathology. When a patient suffers from recurrent headaches, for example, a doctor can transiently relieve the patient with pain medication, but the main focus should be put on finding the cause and eliminating it: a hormone deficiency, neck contracture due to emotional retention or poor posture, food intolerance, etc. In the case of autoimmune thyroiditis, the etiology is usually **multifactorial**. One factor is often not sufficient to trigger the production of autoimmune antibodies. For this reason, the treatment of autoimmune thyroiditis usually includes a combination of therapies, each one focused on one of the causes.

What are the causes of autoimmune thyroiditis? Basically, five categories of causes have been found:

1. Genetic predispositions,[266-269]
2. Dietary errors,
3. Nutritional deficiencies,
4. Hormone deficiencies,
5. Viral, bacterial, yeast, and parasitic infections,
6. Toxic products.

Combine various medical therapies to reduce antithyroid antibodies. Regarding causes other than genetics, physicians can act with efficacy to reduce the levels of antithyroid ➤

Table 3: Dietary Changes That Reduce Antithyroid Antibody Levels

DIETARY CHANGE	THE STUDIES; WHAT IT DOES	PRACTICAL TIPS
• Paleo diet[281-283]	This diet is easier to digest, as it consists of foods that our ancestors ate in the Paleolithic period before agriculture was discovered (the Neolithic) and humans started to consume foods less fit for their guts, such as cereal and milk products. A study showed that regular intake of fruit and berry juices increases the likelihood of autoimmune diabetes.	• Consume fresh vegetables, fruits, meat, fish, poultry, and eggs. • Consume organic foods. • Eat food raw, unprocessed[283] or steamed, boiled, or cooked at low temperature without oil. • Reducing fruit and fruit juice consumption to below-average levels might have value.[284]
• Protein-rich foods at breakfast	When protein-rich foods are eaten in the morning, there is time enough to digest them in the stomach and small intestine and absorb them as amino acids in the small intestine. At the end of the day, the gut can rest and recover better during sleep without undigested proteins remaining in the gut. A protein-rich breakfast also increases satiety.[285-286]	• Eat the main protein-rich meal (meat, poultry, fish, and eggs) in the morning. • Moderate protein intake at lunch. • Avoid consuming protein-rich foods in the evening.
• Small fatty fishes, rich in omega-3 polyunsaturated fatty acids	Regular intake of fatty (oily) fishes has been reported to reduce the incidence of postpartum thyroiditis by more than four times[287-288] and of autoimmune diabetes two-fold![289] When fish is eaten in the first part of the day, it also reduces food intake at supper, helping to not overload the gut during the night.[290]	• Increase the intake of small fatty fishes, such as sardines, mackerel, eels, and herring. • Limit the consumption of big fatty fishes, such as salmon, tuna, and trout, as they often contain too much mercury.
• Intermittent fasting • Supper: to skip or eat minimally	Intermittent fasting has been shown to reduce the production of autoimmune antibodies of a variety of diseases.[291-294] It provides a rest for the gut, allowing it to be temporarily free of new aggressors. It also permits the abdomen to get flat.	• In my experience, the best plan is to skip one meal daily, especially the evening meal, and eat proteins only in the morning. • Consuming boiled or steamed vegetables at supper is an acceptable alternative.
• Avoid soy milk	Soy milk intake is associated with a higher risk of autoimmune thyroiditis in children.[295]	
• Avoid cow-milk protein	Cow-milk protein is known to trigger autoimmune diabetes[296-299] and is suspected of triggering other autoimmune diseases.	• Avoid milk, yogurt, cheese, etc. • Clarified butter (also called ghee) is okay, as it has lost the white layer of allergenic proteins.
• Low-carbohydrate diet	• A low-carb diet alone has been reported to reduce thyroid antibody levels by 50%.[300]	Stop consumption of bread, porridge, and other cereals, particularly gluten-containing cereals, as well as high-sugar foods and drinks
	• Gluten-containing cereals can trigger autoimmune thyroiditis[301-303] and celiac disease. Celiac disease itself is often associated with autoimmune thyroiditis[153-160] and autoimmune diabetes.[304-306]	• No wheat. • Sprouted rice and other sprouted grains can be acceptable alternatives.
• Avoid artificial sweeteners	The consumption of artificial sweeteners is associated with a higher risk of autoimmune thyroiditis[307] and diabetes.[308]	Avoid aspartame, cyclamate, and other artificial sweeteners.
• Avoid sugar	The consumption of sugar and sweetened beverages is associated with a higher risk of autoimmune diabetes.[309-310]	Avoid sugar and soft drinks.
• Probiotics	Probiotic supplementation has been shown to reduce autoimmune antibody production in various autoimmune disorders, including autoimmune enteropathy, diabetes and multiple sclerosis.[311-314]	In the case of dysbiosis: • The addition of probiotics (with at least 10 billion germs of lactobacilli and bifidus bifidi strands per capsule) is recommended. • Take various types of probiotics in alternation to restore the variety in the strands better.

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antibodies. Therefore, let's focus on dietary adjustments and nutritional and hormone treatments complemented by avoiding toxic products as much as possible. The best results are obtained by combining these therapies, which should result in a 50 to 100% reduction of thyroid antibody levels within the next six to 12 months.

Changing the diet and improving the digestive system may decrease the levels of antithyroid antibodies by more than 50%.

What are the mechanisms? *Dietary maladjustments* cause *dysbiosis*[270-274] and a *leaky gut,*[275-279] which bring into the body foreign compounds and microorganisms that accumulate in the thyroid and trigger autoimmune thyroiditis.

Inappropriate foods may aggress the intestinal wall and break open the tight junctions that hold the intestinal wall cells together, causing leaks in the gut wall (leaky gut). Such foods may also cause some strands of gut flora to proliferate excessively while other strands are lacking. This *dysbiosis* can cause further harm and leaks in the intestinal wall. Through breaches of the gut wall, unusually large molecules (that form antigens), undesirable microorganisms, and toxic products may leak into the tissues surrounding the gut. From there, they penetrate the bloodstream and nest themselves in tissues and organs with high blood flow. The thyroid has some of the highest blood flow of any tissue in the human body. Brought by the bloodstream, these irritating compounds and microorganisms accumulate in the thyroid gland, where they trigger the production of antibodies against them and components of the thyroid gland that surround them.

The same mechanisms intervene when we consume good food at the wrong time of the day; protein-rich foods at supper, for example. Protein-rich foods, such as meat, poultry, fish, and eggs, provide essential amino acids to build the body but take much more time than carbohydrates and fats to be digested in the gut.[280] The stomach provides an initial (lengthy) digestion of these proteins, which takes about three to nine hours.

If this type of food is ingested in the morning, there is usually no problem. Proteins are fragmented by the stomach acid into smaller peptides and amino acids and leave the stomach in the afternoon, pushed by gravity and movements of daily living into the small intestine, where they are further digested and absorbed as amino acids. At the end of the day, the proteins have then been completely digested and absorbed. The abdomen appears flat and the gut empty of disturbing substances. If no food or light foods such as boiled vegetables are eaten in the evening, the stomach is empty during sleep and the gut can rest.

In most families, however, supper is the main meal and takes place in the evening. It contains plenty of proteins, making it impossible for the gut to digest everything before bedtime. This leaves the stomach overloaded and the abdomen bloated the whole night and next morning. The food overload overwhelms the gut with undigested foods that ferment and putrefy – "rotten" would be a better word – causing dysbiosis and damage to the intestinal wall and thus, a leaky gut during the nighttime.

How can the human immune system be stopped from producing autoimmune antibodies against its own thyroid gland because of a leaky gut and dysbiosis? Make the gut stop leaking by intermittent fasting and dietary improvements and recover good gut flora via probiotic supplementation.

So, what is the appropriate diet? Table 3 (page 41) gives an overview of the main dietary recommendations for patients.

◆

Born in Antwerp, Belgium, Dr. Hertoghe practices his medicine in his clinic in Brussels. With his sister, Dr. Thérèse Hertoghe, they proudly represent the fourth successive generation of physicians working with hormonal treatments – and this since 1892 (after Eugène Hertoghe, former vice president of the Royal Academy of Medicine in Belgium, and Luc and Jacques Hertoghe, endocrinologists). Dr. Thierry Hertoghe devotes his life to the promotion of a better, patient-oriented, and evidence-based medicine.

Author of numerous books, Dr. Thierry Hertoghe also travels a lot to take part in numerous conferences and congresses throughout the world. He co-organizes many of these specialized gatherings and holds important positions in several international and national medical organizations (which usually tend to fight against aging). He is the president of the International Hormone Society (over 2500 physicians), and of the World Society of Anti-Aging Medicine (over 7000 physicians), as well as the supervisor of two important postacademic trainings for doctors.

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An Integrative Medical Approach to Macular Degeneration: Part 1

by Marc Grossman, OD, LAc

Overview

Age-related macular degeneration (AMD) is the leading cause of irreversible blindness today and is the leading cause of vision loss of people over 60.[1] By the year 2020, an estimated 7.5 million Americans will suffer significant vision loss due to this disease. In 2010, 2.5 percent of white adults age 50 and older had AMD. By comparison, AMD affected 0.9 percent each of blacks, Hispanics, and people of other races. The risk of AMD increases with age. The disease is most common among older white Americans, affecting more than 14 percent of white Americans age 80 and older.[1] Although there is no effective conventional treatment yet, natural remedies can go a long way in helping to prevent this disorder from progressing to the point of vision loss.

What is macular degeneration? Macular degeneration is the slow deterioration of the cells in the macula, a tiny yellowish area near the center of the retina where vision is most acute. This deterioration affects central vision, the vision used for reading, writing, driving, and identifying faces. With macular degeneration, straight lines become crooked, distinct shapes are blurry, lines become wavy, and a fog forms in the center of vision. Peripheral vision however is not affected.

The two most common types of macular degeneration are the dry and wet type. Ninety per cent of people with macular degeneration have the dry type, in which small yellow spots called drusen form underneath the macula. The drusen slowly break down the cells in the macula, causing distorted vision. In approximately 10-15% of the cases, dry macular degeneration can progress to the second, more severe type called wet macular degeneration.

In the wet type of macular degeneration, abnormal blood vessels begin to grow toward the macula. These new vessels may leak blood and fluid that further deteriorate the macula, causing rapid and severe vision loss.

Parts of the Retina

The retina consists of four different layers, specifically:

1. Outer neural layer, which contains nerve cells and blood vessels;
2. Photoreceptor layer, which is a single layer containing the light sensing rods and cones;
3. Pigmented retinal epithelium (RPE), with the Bruch's membrane separating the RPE from the
4. Choroid layer, consisting of connective tissue and very fine capillaries known as choriocapillaries. They are responsible for carrying nutrients and oxygen to the cellular layers above them.

The choroid layer contains most of the eyeball's blood vessels. It is also the layer prone to bacterial and secondary infections. If not treated, the abnormal blood vessel growth can readily develop resulting in sight impairment or eventually total vision loss.

The macula (see illustration) contains two areas of unusually high concentrations of cones, which are the photoreceptors responsible for daytime and color vision, fine detail and central vision. There is a slightly depressed area in the center of the macula called the fovea where there is no retinal nerve fiber layer, only photoreceptors, approximately 199 to 300 thousand cones per square millimeter. At the center of the fovea is the foveola where there are no rods, only cones.

The gradual breakdown of these cells in the macula results in damage to or loss of your central vision. The macula provides focus in the center of vision where your vision sharpness is most acute. Such deterioration reduces the ability to read and recognize faces, two important tasks that use the central vision.

Types of Macular Degeneration (AMD)

The most common type (90%) is dry AMD, which results from the inability of the retina to reabsorb the natural waste created in the retina in the process of passing light from the photoreceptor cells to the optic nerve (and other normal physiological activity). The result is the slow deposit of this waste onto the retina (called "drusen"), which over time can result in loss in healthy vision. Drusen are thought to be comprised of waste proteins and lipids (oily material) that begin to accumulate due to poor circulation and waste-flushing in the eye. Antioxidants are important for the normal waste-clearing process and have the potential for even reducing drusen in the eyes. The drusen slowly crowd, distort, or break the visual cells in the macula, leading to deterioration and resulting in blurred vision. Because

drusen also include pro-inflammatory components, it is thought that they trigger the immune system. AMD has few symptoms in the early stages, so it is important to have your eyes examined regularly, and yearly, if you have a family history. For people who have early AMD in both eyes, about 10-15% percent will develop late AMD in at least one eye after 10 years.[2]

The second type (10%) of macular degeneration is the "wet" form, (also known as choroidal neovascularization) in which new blood vessels begin to develop near (underneath) the macula, causing fast and serious vision loss. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula. The damage may be rapid and severe, unlike the more gradual course of dry macular degeneration. It is possible to have both dry (geographic) atrophy and neovascular AMD in the same eye, and either condition can appear first. Wet macular degeneration is determined through a dilated retinal examination that can identify the presence of bleeding or leakage in the retina (wet AMD) versus only drusen, which are waste deposits underneath the retinal pigmented epithelium (dry AMD). Note that even if one has drusen in the retina, the diagnosis may not be dry AMD until the eye doctor determines the location and severity of the drusen.

If AMD is found first in one eye, the other eye tends to follow the same progression. This is because the nutrient deficiencies and other system-wide problems would exist in both eyes but manifest in one eye before the other. Research shows that a healthy diet and taking targeted supplements can significantly reduce the onset of neovascularization (new blood vessel growth that results in retinal bleeding).[3-8]

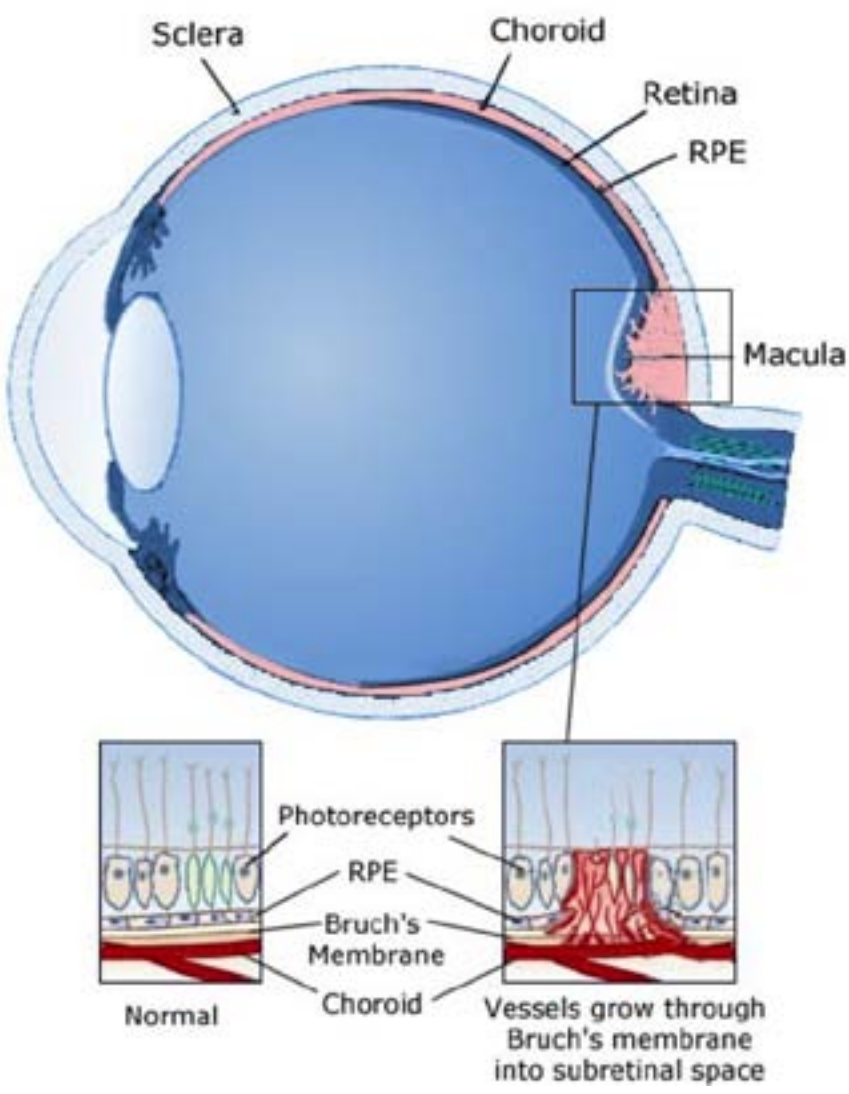
Stargardt's disease is the third type of macular degeneration. It affects about one in 10,000 children in the US. Although the disease starts before age 20, you may not notice vision loss until age 30 to 40. It is a genetic form of macular degeneration where patients need to avoid supplementing with vitamins that contain vitamin A and beta-carotene, along with foods high in certain carotenoids that can be converted to vitamin A in the body.[9]

Myopic macular degeneration, the fourth type, typically results in those people who are very nearsighted. In these cases, there is an extreme elongation of the eyeball, which causes the stretching of the retina and can result in tears in the macula and bleeding beneath the retina. Over time, this can cause cells in the center of the retina (the macula) to atrophy or die, causing a blind spot in the center of the visual field. In some cases, this form of macular degeneration can convert to the wet form. People who are very nearsighted, generally requiring glasses of -6 diopters or more, are at risk for myopic macular degeneration. The risk is higher as myopia becomes greater than -10 diopters.

Pathology of Macular Degeneration

The development and progression of macular degeneration rests upon the occurrence of the following pathological changes in the eye:

1. Oxidative stress is the imbalance between damage-causing free radicals and protective antioxidants. Because of its high metabolic activity, the retina is especially vulnerable to stress from free radicals. Inability of the retinal tissue to obtain adequate oxygen and nutrients leads to deterioration of the pigmented layer, which protects the retina from UV and blue light damage.[10,11] Antioxidants can significantly reduce the effects of oxidative stress.[12]
2. Angiogenesis is the growth of new, rapidly made blood vessels in response to a lack of oxygen. These ➤



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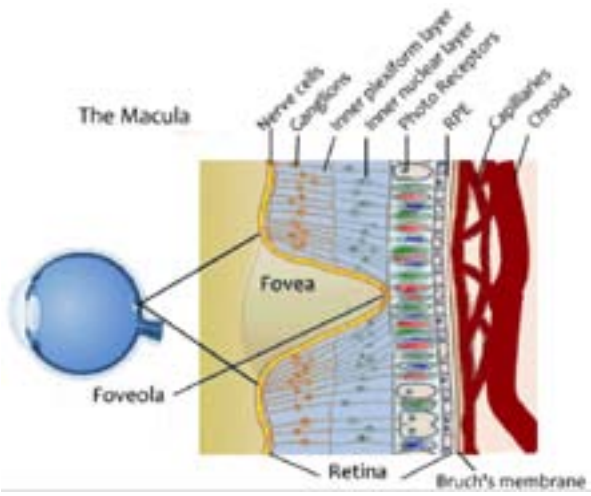
fragile blood vessels tend to easily break and leak fluid and blood onto and into the retina, which can distort vision in the retina. Targeted nutrients can inhibit new (unwanted) blood vessel growth.[3]

Apoptosis is the process of cell death that allows the body to replace worn and damaged tissue cells with new cells.



However, in the retina, oxidative stress is closely tied to excessive cell death. Antioxidants and enzymes can reduce excessive apoptosis.[12,13]

Inflammation response is the body's attempt to rescue tissue from cell injury but can also result in vision damage over time due to scar tissue and bleeding in the retina (growth of new, unwanted blood vessels).[14] Proteins that are responsible for the immune results are among the constituents of drusen deposits in the retina.

Signs and Symptoms

- Lines look distorted or wavy. Try the Amsler test for both dry and wet AMD. In more developed AMD, the Amsler grid can look quite distorted.
- Shapes look blurred, fuzzy, or hazy in central vision.
- Colors appear dimmer and less distinct.
- Words are hard to read because they are blurred.
- Blank or dark areas hide the center area of your vision.
- The center of vision looks foggy or cloudy.

Causes and Risk Factors

Macular degeneration in childhood and early adulthood is typically the result of genetics, versus seniors who develop age-related macular degeneration, which is more related to poor circulation, inadequate waste removal, and lack of availability of oxygen and essential nutrients getting to the eyes due to poor digestion, medications, less active lifestyle, etc. However, genetics does play a role in the age-related form of macular degeneration. One study determined that there was a 12-fold increase in the risk of getting macular degeneration if one had a sibling with AMD.[15] The risk factor was considered large with a parent with AMD.

The field of epigenetics shows that even though one may have a genetic disposition of getting AMD (or any other health condition), environmental factors including early childhood nurturing and lifelong lifestyle choices can play a significant role in whether these genes become active or not.[15]

There is a great deal of peer review research showing that the likelihood of onset of AMD can be significantly reduced through lifestyle choices such as eating a healthy diet,[16-18] exercising regularly,[19] not smoking,[3,20] avoiding heavy drinking[21] (moderate drinking of wine may have a beneficial effect[22]), managing chronic stress,[23] not being overweight,[24] controlling blood pressure,[25] and high cholesterol,[26] as well as supplementing with targeted supplements such as lutein, zeaxanthin and omega-3 fatty acids (such as fish oil or DHA from algae for those who are vegetarian).

Once a diagnosis of dry AMD is given, healthy lifestyle choices can both help maintain healthy vision and reduce the risk of the dry form of AMD turning to the wet form.

The more advanced the AMD has gotten, healthy lifestyle choices and targeted supplementation still can play a major role in slowing down and stabilizing the AMD; but lost vision due to the death of retinal cells cannot at this time be regenerated (though excellent research such as stem cells to regenerate lost retinal cells is underway). Keep in mind that patients can sometimes see improved vision if low functioning retinal cells can be stimulated and helped to become more active through diet, exercise, and targeted supplementation. Micro-stimulation can also be very useful to revitalize unhealthy retinal cells.

In addition to genetics and lifestyle factors, other risk factors include the following:

- Free radicals can damage the eyes. Free radicals are formed when the blue and ultraviolet sunlight passes through the crystalline lens of the eye. Free radicals are also byproducts of our bodies' natural metabolic processes. These chemicals are highly reactive and cause oxidation; the result is destabilization of healthy macula cells in the eyes. Blue light alone is not tied to macular degeneration; however, researchers have found that there is a consistent and significant connection between age-related macular degeneration and patients in the lowest quartile nutritional intake of vitamin C, vitamin E, zeaxanthin, and dietary zinc.[27]
- Hypertension. People with high blood pressure are more likely to develop AMD than those with normal blood pressure.[25]
- Smoking, chronic fatigue, and a weakened immune system hasten damage from free radicals. Smoking increases the risk of AMD by 200-300%.[3,20]
- Poor digestion and nutritional deficiencies: People with AMD are often deficient in a number of nutrients that are essential to eye health such as lutein and carotenoids,[17] essential fatty acids, zeaxanthin, taurine, antioxidants, zinc, bioflavonoids, selenium, and vitamin B-complex.[16-18, 28]

continued on page 48 ➤

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Macular Degeneration

➤ *continued from page 46*

- Systemic inflammation, indicated by high levels of C-reactive protein, has been tied to increased macular degeneration risk.[29]
- High homocysteine levels.[30,31]
- Women are more at risk at developing AMD.[32]
- People with diabetes are more at risk to develop AMD.[33]
- Phototoxicity is caused by exposure to blue and ultraviolet (UV) radiation, both of which adversely affect the functioning of retinal pigment epithelium (RPE) cells. The RPE's role is to nourish the fragile nerve tissue of the retina and maintain its health by transporting molecules in and out, getting rid of dead cells, secreting hormones, modulating immune factors, and more. All this has magnified the RPE's role in macular degeneration.[20] RPE cells are susceptible cell death induced by ultraviolet B (UVB) irradiation. Excessive exposure to sunlight without protective sunglasses is a risk factor for AMD. The retinal pigment epithelium (RPE) closely interacts with photoreceptors in the maintenance of visual function, responsible for providing blood and nutrients to reach the photoreceptor cells and supports the elimination of waste products.
- Drugs that can damage the retina:[34] Plaquenil® (hydroxychloroquine sulfate), often prescribed for rheumatoid arthritis, has been found to cause permanent damage to the retina; Catapres® (clonidine hydrochloride is the generic name), for high blood pressure; NSAIDs (non-steroidal, anti-inflammatory drugs). Side effects from regular use include retinal hemorrhages. This group includes ibuprofen, aspirin, ketoprofen, flurbiprofen, and naproxen sodium. In addition, acetaminophen (Tylenol), though not a NSAID, can harm vision.

Related Conditions

Poor circulation in the eye is a contributing factor to many eye conditions and is a side effect of diabetes and cardiovascular disease.[35]

Elevated homocysteine levels have been associated not only with macular degeneration but also glaucoma, diabetic retinopathy, optic neuropathy, and ocular complications from Behcet disease, as well as a macular pucker (epiretinal membrane), in which a thin layer of tissue grows over the retina.[36]

Retinitis pigmentosa is a degenerative disorder of the photoreceptor cells of the retina.

Conventional Treatment

No effective conventional treatment currently exists for dry macular degeneration.

Wet macular degeneration is typically treated with injections of Lucentis®, Avestin®, or Eylea®. These drugs have anti-antigiogenic properties, meaning they help prevent the growth of new blood vessels, while drying up existing blood vessels that are leaking. The injections are typically necessary on an ongoing basis, depending on the severity and history of bleeding. Over the long run, they do not necessarily prevent vision loss; however, they can be essential for helping to slow down the progression of the wet AMD. Moreover, these drugs are not designed to address the underlying problem, which in most cases, is the inability of the body to deliver essential nutrients to the retina and naturally eliminate waste materials generated in an ongoing process in the retina. Ultimately, the short-term goal is to stabilize the AMD, and the long-term goal is to maintain healthy vision and prevent additional vision loss. Drugs can have potentially serious side effects, so the benefits of using them should be evaluated with your eye doctor and your family doctor.

Laser surgery (photodynamic therapy) may be an alternative option to injections if the eye doctor determines that the injections may be ineffective or contraindicated for the patient. Your eye doctor will be able to provide guidance on the best therapy for you. Laser surgery accurately targets and seals leaking blood vessels, through the injection of a form of ink into the blood stream that gets absorbed at a much higher rate by leaking blood vessels than healthy ones.

Complementary Treatment

As always, prevention is the best medicine. Since less than one per cent of people with macular degeneration have progressed to the point of legal blindness, most are in a position to benefit greatly from preventive measures, particularly at the earlier stages of the disease.

Taking targeted supplements and establishing healthy lifestyle habits are still helpful at any stage of AMD, keeping in mind that the preservation of vision and potential level of vision improvement is based on the vision the patient has at the time of incorporating complementary approaches. Oxidative stress and inflammation play critical roles in the initiation and progression of a range of eye diseases, including age-related macular degeneration, glaucoma, cataract and diabetic retinopathy that lead to progressive loss of vision and blindness if untreated.[37-39] There is growing evidence that supplementing with targeted antioxidants, with their antioxidant and anti-inflammatory properties, may have a potential role in the prevention and treatment of these age-related eye diseases and disorder.[40]

Diet: We recommend following a strong alkaline diet to reduce overall inflammation in the body as chronic inflammation has been identified as a contributing factor in macular degeneration.[41] It has become more accepted that both local and systemic inflammatory processes contribute to the development and progression of AMD. Chronic inflammation for many may be related to leaky gut syndrome, so again an anti-inflammatory diet should be adopted as well if applicable.

Many research studies have shown that diet has a significant effect on health of the macula. Unfortunately, once a person has macular degeneration, a healthy diet is not enough to prevent this disease from worsening, so other

interventions are needed which may include conventional as well as targeted supplementation.

It is *very important* to make sure your diet includes plenty of fresh, preferably organic, dark leafy greens. These vegetables are rich in carotenoids, which are phytonutrients ("plant chemicals") that help plants absorb light energy for use in photosynthesis, and that deactivate free radicals, meaning they have antioxidant properties and are helpful for the entire body. Carotenoids are also responsible for the bright red, yellow, and orange color pigments in many fruits and vegetables; however, as evidenced by dark leafy greens, not all fruits and vegetables that contain carotenoids have these colorations. There are more than 600 carotenoids in the body, but two, lutein and zeathanthin, are of particular importance to eye health. So, even if you don't like vegetables such as collards, kale, Swiss chard, and spinach, you can add them to soups, puree them in green drinks, juice them with other fruits and vegetables, or add them to other greens in salads. Many studies report that the nutrients found in these healthy vegetables lower the risk of developing macular degeneration.

Numerous research studies have shown that diets high in antioxidants which includes a lot of fruits (particularly colored fruit such as berries that are lower in sugar, and leafy green or colorful vegetables) play two critical roles; they significantly reduce the risk of AMD onset, and they help to protect AMD patients from vision loss.[12,42]

It is also *very important* to reduce or eliminate all types of refined sugars (particularly white sugar, but also fructose, sucrose, fruit juice concentrates, maltose, dextrose, glucose, and refined carbohydrates). This includes "natural" drinks that contain a lot of sugar, including all fruit juices. Even milk sugar, lactose, found in all dairy products can contribute to macular degeneration as sugar contributes to overall body inflammation and the fluidity of circulation throughout the body and eyes. In one study those in the highest one-fifth of the dietary glycemic index (a system that ranks foods on a scale from 1 to 100 based on their effect on blood-sugar levels) had more than a 40 percent increased risk of significant macular degeneration than those in the lowest one-fifth.[18]

In addition to these dietary guidelines, it is very important to drink eight glasses of water per day (preferably filtered or purified). This is optimally taken as a four-ounce glass of water every half-hour, to equal 16 four-ounce glasses. Our bloodstream can only effectively handle about four ounces at any one time. When you drink more than four ounces at a time, this means more work for the kidneys to filter water that hasn't had a chance to travel through the lymph system and clean body tissues. Adequate water intake helps to maintain the flow of nutrients to the lens and to release wastes and toxins from tissues. Do not smoke (or quit smoking); smoking increases the risk of AMD onset by two-to-three times.[20]

It is important to limit or eliminate dairy products. For some people, regular consumption of dairy products can exacerbate eye problems by causing sinus congestion, which can impair lymph and blood drainage from the area around the eyes. When lymph and blood can't flow in and out of the eyes, nutrients don't reach the eyes, and toxins and metabolic wastes aren't eliminated as efficiently. Many people are lactose intolerant to some degree, so you may want to avoid dairy for at least one month to experience the effects of this, and to see the differences in your body and eyes. As a general rule, reducing or eliminating dairy from one's diet has many benefits. If you still choose to consume dairy, commit to organic products from A2 cows. A2 milk is just one amino acid different from the more common A1 milk products and the resulting proteins do not have the damaging effects that have come to be associated with milk products. Alternatively, you can switch to goat milk since milk from goats does not carry the A1 gene; or at the very least, obtain fresh, raw milk from local farmers for the freshest product. In general, changes in lifestyle related to healthier vision and taking targeted supplements will start making a difference right away; but it may take three-to-six months before maximum benefit starts to be seen.

Healthy lifestyle habits and a diet rich with phytonutrients will help preserve vision and slow AMD progression.

Drinking freshly made juice is also important. Our recommendation is six-to-eight ounces of fresh juice per day. Choose at least four-to-six items to combine; use mostly green leafy vegetables and do not use too many carrots because of their high natural sugar content (1 carrot per 12-16 oz. juice is preferred), as well as using organic products as much as possible. You can choose any combination of the recommended nutrients (in Part 2 to be published in *TL* May 2020) plus add any of your favorite fruits and vegetables: broccoli, green and red bell pepper, raspberries, apples, copious amounts of dark leafy greens.

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Since 1980 Dr. Marc Grossman has helped many people maintain healthy vision and even improve eyesight. He is best described as a holistic eye doctor, dedicated to helping people with such conditions ranging from myopia and dry eyes to potentially vision threatening diseases as macular degeneration and glaucoma. His combined multi-disciplinary approach using nutrition, eye exercises, lifestyle changes and Chinese medicine provides him with a wide array of tools and approaches to tackle difficult eye problems.

Dr. Grossman founded the Rye Learning Center in 1980, a multidisciplinary center for learning problems, in 1996 co-founded Integral Health Associates in New Paltz, New York, and in 1999 co-founded Natural Eye Care, Inc.

His background includes degrees in optometry, biology, physical education and learning disabilities, coupled with yoga, bioenergetics, nutrition, Chinese medicine and acupuncture, the Alexander technique and Feldenkrais. This orientation provides the foundation for an integrated approach to vision and its influence on the body, mind and spirit of each patient.

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On the cover

Skin Exposed: A Naturopathic Approach to Dermatology

by Dr. Trevor Cates

Skin is the body's largest organ; and although it is superficial, it is very revealing about overall health. We see that every day in our patients, such as dark under-eye circles (allergies), dry lips (dehydration), dry skin (hypothyroidism), yellow skin (jaundice), cold sores (herpes), butterfly rash (lupus), facial hair in women (PCOS), acne along the jawline (hormonal imbalance), keratosis pilaris (nutritional deficiencies), and those are just a few. As practitioners, the clues that show up on our patients' skin are valuable pieces for solving the mystery of their dis-eased state.

It is also a protective instinct for others to know the state of individuals' health by looking at their skin. People that are acutely sick have facial cues, including on the skin, that warn others of a potentially contagious illness. "Stay away!" the ill person's skin is telling others. This comes in handy when we want to avoid catching colds and the flu. But, with chronic skin issues, the patient with the skin problem suffers not only physically but often emotionally as well from rejection.

People with chronic dermatologic conditions, such as acne, eczema, rosacea, vitiligo, and psoriasis are often looked at differently; and it often impacts them emotionally. I have my own personal story of my childhood struggles with eczema, hives, and mysterious bumps that would appear on my face; kids would pick on me at school. I hid and stayed home as much as I could. Conventional approaches, including antihistamines, corticosteroids, and antibiotics only made me feel worse with allergic reactions and adverse reactions. Thankfully, in my case, what seemed like a curse at the time, turned into a blessing because holistic medicine is what turned my health around, eventually leading me to naturopathic medical school – and, later, to focus on naturopathic dermatology.

I share all this because, if you have not struggled with dermatologic issues, then you may not be aware of how emotionally upset your patients may be about their skin problems and how desperate they are to recover from them. While you are helping them physically, please also provide or refer for emotional support. And, know that they are likely to seek you out because they are distressed and looking for answers not to suppress but to address their skin.

You will continue to see more and more patients with chronic dermatologic conditions show up in your practice. Globally, the United States has the largest market for dermatology and GMR Data forecasts $12.3 billion in 2018, growing to $22.6 billion in 2028.[1] One of the reasons for this rise is due to an increase in dermatologic conditions such as acne, skin cancers, atopic dermatitis, and skin infections.

Atopic dermatitis affects one in ten people during their lifetime.[2] Rosacea affects 16 million Americans.[3] Around 7.5 million people in the United States have psoriasis.[4] But, the one we typically see the most in clinical practice is acne. After all, it is the most common skin condition in the United States, impacting over 50 million Americans annually.[5] Although the majority of people with acne (approximately 85%) are between the ages of 12 and 24,[6] adult acne is increasing, affecting around 15 percent of women.[7]

The American Academy of Dermatology states, "There is not enough data to recommend dietary changes for acne patients." Instead, the Academy says, the "recommended treatments include topical therapy, antibiotics, isotretinoin, and oral contraceptives." While that is currently their stance, there are many of us practicing a more integrative approach and finding excellent results.

In my book *Clean Skin from Within*, I discuss six main underlying causes that can lead to chronic skin issues: inflammation, microbiome disturbance, oxidative damage, blood sugar issues, nutritional deficiencies, and hormonal imbalances

These root causes probably do not surprise you because they are common to many chronic health problems. Performing a thorough history, lab testing, and physical exam helps unveil the root causes. When it comes to treating my patients with dermatologic conditions, I have seen certain patterns that have led me to focus on these six root causes with my patients.

While addressing root causes is no secret in the naturopathic and functional medicine world, the key is to address them *both* internally *and* externally. While dermatologists may rely heavily on topical treatments and estheticians focus on facials, naturopathic physicians and functional medicine practitioners often focus on the internal treatments (diet, supplements, BHT, etc.). However, greater success with dermatologic conditions comes when you come from both angles.

For the first fifteen years of my practice, I too focused on addressing the root causes internally. My patients would get sixty to eighty percent better, but then the improvements would stop. Around that time, my patients kept asking me why when they switched to natural skincare (which they were doing because I wanted them to avoid exposure to toxic ingredients) that their skin did not look as good. So, I asked my dermatologist and esthetician friends for recommendations on effective natural skincare products, but they replied that I had to choose between natural *or* effective and that the combination did not exist.

This answer was not sufficient for me because of my experience, personally and with my patients, with the healing powers of nature. So, I dug into the research to see what might be missing in the natural skincare products my patients were using. That is when I learned more about the skin microbiome and what helps it flourish not only internally but also externally.

Human skin is inhabited by approximately one million bacteria/cm,[8] and the microbiota varies around different areas of the body as well as amongst different individuals. Lifestyle, environment, hygiene, diet, age, and sex all greatly impact the makeup of the skin microbiome.[9] With unhealthy lifestyle choices, overuse of antibiotics, and overzealous hygiene practices over the years, it should not be a surprise that we are seeing these higher rates of acne, atopic dermatitis, and other inflammatory skin disorders.

Many of the microbiome studies to date have focused on describing the gut microbiota, but the skin microbiota has been gaining more attention over the past 10 years. The gut and skin are both densely vascularized and richly innervated organs. They have important immune and neuroendocrine roles and are significantly related. A healthy gut microbiome protects the gut lining, increases the body's ability to absorb nutrients, and protects against microorganisms that affect healthy skin. It is important to promote the skin microbiome from the inside out (via the gut) with diet.[10]

Achieving a well-balanced skin microbiota protects skin from harmful pathogens and promotes the natural lipid barrier and skin immune system. Ultimately, this function helps prevent acne, atopic dermatitis, and other skin eruptions. We can do that both internally through diet and supplements, such as probiotics, and also topically. Part of that ties into creating an ideal environment for skin microbiota diversity. Superficially, an important factor in supporting the skin microbiota involves the pH of the skin. The external pH of human skin has a natural pH level of about 4.5 pH.[11]

Many soaps, skincare products, and topical medications have a pH that disrupts the skin microbiota.

This mildly acidic environment helps keep the skin's microbiota in balance. On the other hand, a more alkaline pH (around 8 to 9), can disrupt the microbiota. Many common skincare products, including soaps, cleansers, masks, moisturizers, and OTC topical medications, have a pH of 5.5 and higher, which can make the skin more prone to infections and premature aging.[12] Ideally, skincare products and topical treatments should be in the 4.5-5.0 pH range to support healthy skin microbiota diversity.

When you create a healthy place for the skin microbiota to thrive, it also helps address other root causes externally, such as inflammation and oxidative damage. In addition to supporting the ideal pH for skin, it is important to protect the skin's barrier function by using topicals with natural humectants and emollients. And, use caution with occlusive ingredients since they may further disrupt the skin microbiota.

So, bringing it all together, we want to address root causes with a healthy diet, individualized supplements, and other key aspects of an integrative approach. To help demonstrate how to tie it together, here is a patient with acne and the course of her treatment.

Acne Case

This 24-year-old female came in to see me with acne vulgaris on her face and back, hypothyroidism, and dysmenorrhea. The onset of her acne started at 12 years old. At that time, she saw a dermatologist who prescribed topical retinoid and oral antibiotics. She also used a well-known MLM acne skincare line. This helped some; but, in high school, she developed cystic acne and then scarring.

At the time of her appointment, she was taking Armour Thyroid medication for hypothyroidism, her skin was oily, and she was still breaking out in acne on her face and back. For skincare, she was using a popular cleanser from the health food store plus a natural body scrub.

At this initial appointment, I ordered lab work and put her on an oral probiotic, chaste tree berry, EPO, and a supplement with skin, hair, and nails nutritional support (containing a blend of nutrients, including vitamin A, B vitamins, zinc, MSM, and green tea extract). I also counseled her on avoiding trigger foods, including sugar and dairy, and how to increase her intake of fiber, healthy fats, protein, and phytonutrients.

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After one month, looking at her lab results, I switched her thyroid medication to WP Thyroid and lowered the dosage, and added vitamin D3 (5000 IU) to her supplement regime. Topically, I recommended African Black Soap (liquid soap) for her back and recommended she remain on her supplements. (*Note:* African Black Soap is known for its pore cleansing and natural exfoliating effects. I prefer liquid soaps over bar soaps due to the fact that bar soaps, by the nature of how their made, have a higher pH that is not ideal for healthy skin.)

The following month, she mentioned her skin was less oily since starting the new thyroid prescription, but the cystic acne continued. Besides her skin, her menses were no longer painful, and her fatigue had diminished. At this appointment, she mentioned she was using a clarisonic skin brush for her face with a cleanser from her local health food store and a DIY mask made with apple cider vinegar and clay. Due to the fact that facial brushes can be too abrasive and over-exfoliating for compromised skin, I suggested she stop using the clarisonic brush. And, because I was concerned the DIY mask she was using was the wrong pH for her skin, I switched her skincare to a mildly acidic natural four-step skincare system; and I called in a topical prescription for her to the local compounding pharmacy for daily use on her face: azeloyl glycine with 5% niacinamide. (*Note:* Azeloyl glycine (also known as potassium azeloyl diglycinate or azeloglicina) is an azelaic acid derivative that resolves many of the issues azelaic acid carries with it. Azeloyl glycine is known for helping control the secretion of sebum and appears to have anti-inflammatory benefits when combined with niacinamide.[13] Even sensitive skin types have found azeloyl glycine easier to tolerate compared to azelaic acid. Nicotinamide gel applied twice daily for two months helps significantly reduce acne, appears to reduce excess sebum, decreases skin inflammation, and improves the skin barrier, according to a 2013 paper published in the *International Journal of Dermatology*.[14])

The next month, she shared she had a decrease in blackheads as well as cystic acne and that the topical treatment on her face had helped so much that she reduced its use to just three to four times per week. At that point, she reported that her skin was neither oily nor dry. The texture of her skin had improved. Even her esthetician said the skin on her face was the best it had ever looked, so she had stopped seeing her esthetician for regular facials. She mentioned that her back acne was still a problem even though her face had cleared up. At that point, I called in a topical prescription to apply daily to the skin on her back: Natapres (a blend of aspen bark, radish root, and honeysuckle) at 10% for antibacterial activity, with niacinamide at 4%, and glycolic acid at 3%. I also recommended using natural Konjac sponges for face and body with her mildly acidic plant oil-based natural cleanser; and, I recommended a series of PRP facials for acne scarring.

At the next appointment a month later, her back acne had reduced about 40%. When I inquired about her laundry soap, she said it was an eco-friendly detergent from the health food store. She tested (per my request) and found the pH to be 7. So, I had her add one-half to one cup vinegar to each laundry wash (50/50) to decrease the pH toward mild acidity. And, at her next appointment the acne on her back was an additional 40% better.

Three years later, I continue to see this patient a few times per year. She's received three PRP facials, which have decreased her acne scarring. Breakouts on her face and back only occur when she's eating sweets, traveling, and stressed, such as during the holidays. As with all my acne patients after they recover, she is thrilled to not only have her healthy skin back, but also her confidence.

As you can see from this case, we addressed the root causes of inflammation, nutritional deficiencies, hormonal imbalances, and microbiome disturbance internally with supplements and a healthy diet. And, while she had some improvement, there was greater recovery after adding in topical treatments with sebum-balancing, antibacterial and anti-inflammatory properties, plus the mildly acidic daily skin care system and topical support.

Hopefully, this inspires you to view your patients' skin as their magic mirror. What messages is the skin giving you that will direct their care, even if dermatologic conditions are only one of their concerns? You can also use skin as a guide for recovery since it is right on the surface and your patients can easily give you feedback. And, when they see the change right in the mirror, they will be forever grateful.

Dr. Trevor Cates graduated from the National University of Natural Medicine in 2000 and was the first woman licensed as a naturopathic doctor in the state of California. She was appointed by former Governor Arnold Schwarzenegger to California's Bureau of Naturopathic Medicine Advisory Council. She has worked with world-renowned spas and sees patients from around the world from her Park City, Utah base. She is author of the USA Today and Amazon #1 bestselling book *Clean Skin from Within*. She has her own PBS Special *Younger Skin from Within* and is host of *The Spa Dr. Podcast.* Dr. Cates' The Spa Dr. skincare line is formulated with the ideal pH and plant-based organic ingredients designed to help individuals achieve vibrantly healthy skin. www.TheSpaDr.com

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Prevalence and Role of the Delayed Reaction in the Management of the Allergic Patient

by Diego Saporta, MD

Introduction

There is a skin response that occurs hours to days after the injection of an allergen into the skin. In this article the information presently available about this delayed skin response will be discussed, followed by the author's experience. An analysis of the prevalence of these responses during skin allergy testing at the author's office will be presented, including information about the role of these delayed responses in the management of the allergic patient.

Background

Skin allergy testing has been in use since 1865 when Charles H. Blackley performed what later came to be known as the scratch test. He abraded his own skin and applied pollen over the abrasions, which resulted in intense itching and inflammation.[1] In 1926 the prick test was described by Lewis and Grant,[2] who also described the skin response that came to be known as the "wheal and flare" reaction, which is well known to all allergy practitioners.[3]

In 1930 French Hansel described an intradermal test using multiple 1:10 dilutions of the same extract. This provided a greater degree of information than the intradermal test with a single dilution used by the general allergists.[4] Herbert Rinkel modified this test in 1935 by using 1:5 dilutions. With this modification he observed that the skin response was now predictable through three or four dilutions in 72% of the patients. This increased the accuracy and safety of the test and also allowed for the diagnosis of skin reactivity to the allergen at very low and at very high allergenic concentration while minimizing the risk of a severe reaction.[4] Injecting a single dose of the allergen can be dangerous in a very sensitive (very reactive) patient.

The modified test as described by Rinkel became the Skin End Point Titration or SET, which at the present time is called Intradermal Dilutional Test or IDT. The IDT is used by ENT allergists and other practitioners usually trained at the PAAS or AAEM courses (see Sidebar 1).

The early workers also observed that introducing an allergen into the skin of an allergic patient could provoke not only an immediate skin response (ISR) but also a late skin response lasting from hours to days. This reaction could affect the skin and/or trigger constitutional symptoms also lasting from hours to days.[5]

The ISR develops rapidly after the injection of the allergen into the skin. The maximum size occurs 10-15 minutes after the injection and then disappears. After its resolution a second

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Abbreviation List
ISR: Immediate Skin Response
LSR: Late Skin Response
DSR: Delayed Skin Response
DR Delayed Reaction
LAR: Local Arm Reaction

Sidebar 1: Intradermal Dilutional Test (IDT)

For further information on how to perform the IDT or how to incorporate allergy management into the practice, consider a course in any of the following organizations:

American Academy of Otolaryngic Allergy (AAOA) offers courses on inhalant and food allergies for ENT practitioners. Visit aaoaf.org.

Pan American Allergy Society (PAAS) offers courses on inhalant and food allergies to any interested practitioner. Visit paas.org.

American Academy of Environmental Medicine offers courses on inhalant and food allergies to any interested practitioner. Visit aaemonline.org.

The following books offer in depth information on allergy and immunotherapy with the approach presented here:

- Krouse JH, et al (eds.). *Allergy and Immunology, an Otolaryngic Approach*. Philadelphia, PA: Lippincott Williams & Wilkins, 2002.
- King HC, Mabry RL, Mabry CS. *Allergy in ENT Practice*. New York: Thieme Medical Publishers, 1998.
- Mabry RL. *Skin End Point Titration,* AAOA Monograph Series. New York: Thieme Medical Publishers, 1994.

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skin reaction can develop. According to the time when this skin response develops, it is called Late Skin Response (LSR) – developing over 6 to 24 hours after the injection – or Delayed Skin Response (DSR) – developing 48 hours or later after the injection. These types of responses can develop even after negative tests (no ISR preceding the delayed response).[6,7]

It is suggested that the clinical relevance of the late skin response "is not yet fully established"[8]; but as stated, there is evidence that symptoms can develop when this LSR develops[5] and that it may be more important than the ISR when considering symptom development.[9]

The LSRs and the DSRs are described as well-identified and different skin responses:[10-12]

- LSR: skin reaction that develops after the ISR, plateaus between 6 and 12 hours, is present at 24 hours, and usually disappears by 48 hours after the skin challenge. It is characterized by edema, mixed cellular infiltrates including macrophages, eosinophils, neutrophils, tryptase positive mast cells, Langerhans cells, large numbers of basophils and T cells, and sometimes by fibrin deposition.[10]
- DSR: cell mediated delayed reaction, including lymphocytes and macrophages, that begins within hours, reaches maximum size in 48 hours but can persist for a week or longer and can even blister in some cases. [11]

However, the differences between both types of delayed skin reactivity may blur, not only clinically, but also histologically. It has been suggested that the clinical appearance of the LSR and the DSR may not be completely distinguishable.[12] The LSR could be the consequence of a Type III hypersensitivity reaction (with deposition of immune-complexes),[13] but a complex cellular infiltration of mononuclear cells is commonly described.[14-16] This cellular infiltrate starts to accumulate four-to-eight hours after the skin test, reaching maximal intensity at two-to-three days.[15] The infiltrate is composed of a variety of cells including T-cells, macrophages, eosinophils, neutrophils, Langerhans cells, and even mast cells and basophils.[15,17]

The concept that a delayed type of skin response can occur after a skin test (with or without development of an immediate reaction or positive test) is clear. As described above, differentiating between an LSR and a DSR is more elusive. It appears that after the initial skin challenge there is a complex immunological process. This process starts only a few hours after the allergen injection and continues to progress over many hours and even several days, with the possibility of triggering systemic clinical symptoms. These descriptions fit better the concept of a continuum that starts developing just hours after the injection of the allergen and continue to develop over a long time.

What is more difficult to understand is how a process that involves all cells of the immunological system (including both, the innate and the adaptative immune system) is even considered to be exclusively dependent on the presence of IgE.[5,18,19] These descriptions are more in agreement with the idea that a skin response after an allergen challenge is likely to involve several or all of the four mechanisms of hypersensitivity described by Gell and Coombs.[20]

A Clinical Significance for the Delayed Reaction?

Published literature suggests that the late skin responses should not be disregarded. The presence of delayed skin reactivity, "which does not include IgE" could be protective[21]and the size of the delayed reaction could be related to the health and immunocompetence of the individual.[22,23] It has been reported that immunotherapy administration significantly decreased the incidence of both the ISR and the LSR[24] and also decreased the incidence of both the immediate and late onset of asthma symptoms.[25]

Therefore, LSRs should be considered when managing a patient with allergic disease as allergens can cause significant immunological reactions without necessarily provoking

Sidebar 2: How We Manage the Delayed Reaction

This information is of interest for those practitioners that provide immunotherapy.

After the intradermal test is completed, the patient is asked to come to the office for a 24- and a 48-hour control. In these controls the tested area is examined for the presence of DRs. This is done visually and by palpation. The average of the 2 orthogonal diameters is obtained and recorded next to the immediate test results. Black color is used to record the immediate test results (either negative or positive), blue for DRs at 24 hours and red for DRs at 48 hours. To measure the wheal diameter, it sometimes helps to use a ball pen to slide over the normal skin until the tip of the pen "locks" in the periphery of the DR.

If no DR develops, a checkmark with the corresponding color is placed so that there is certainty that the control was done and there were no DRs.

Any DR with a diameter of 5 mm or larger is recorded. According to the DR-diameter, the concentration of the allergen to be mixed into the vaccine formula is selectively diluted as follows:

a. DR diameter of 5 mm or 7 mm: use allergen at 2 dilutions weaker
b. DR diameter of 9 mm: use allergen at 3 dilutions weaker
c. DR diameter of 11 mm or 13 mm: use allergen at 4 dilutions weaker
d. DR diameter >13 mm: use allergen at dilution #6

When the DR is present over several dilutions of the same tested allergen: choose the DR present at the weakest dilution for above calculations.

When the diameter of the DR in the same dilution is different at 24 and 48 hours: Choose the larger diameter DR for above calculations.

an immediate (Type I) hypersensitivity reaction.

Dr. Richard Jaekle observed that fungal allergens from the TCE mix (Trichophyton, Candida and Epidermophyton) triggered symptoms when tested on the skin of the allergy sufferer. He separated the TCE into its individual mold components and tested each mold separately. When DRs that triggered symptoms developed, he was able to use this information to formulate a vaccine with successful therapeutic effect.[26]

Dr. Alan McDaniel found that intradermal skin tests for molds showed greater prevalence of late and delayed skin reactions than other allergens.[27] He also observed that the wheal diameter for the delayed reaction grew by 3 mm when comparing progressively stronger concentrations of the same allergen.[27]

Author's Experience

Clinical observations are in agreement with what is described in the literature: Late-onset skin responses can develop after a skin test. They are frequently present at 24 hours. Less frequently they develop at 48 hours and rarely they can persist for days or even weeks. They can follow a positive skin test (ISR) or a negative skin test (no ISR).

Except for the timing when the measurement is done, it is not possible to differentiate from the clinical point of view, between a LSR and a DSR. Both appear to play a similar role in the clinical management of the allergic patient. For this reason, we decided to address the LSR and the DSR simply as "delayed reactions" (DRs) without differentiating when they develop. Published literature appears to support this decision as the delayed response is generally described as a reaction that starts a few hours after the injection and extends through a rather long period of 72 hours or more.[11,15]

The significance of the delayed reaction for the practicing allergist in the clinical context is two-fold:

1) When a DR develops the patient may complain of itching and dry skin (rarely blistering or long-standing discoloration) at the site of the skin test;
2) More importantly, vaccine formulas that contain allergens that triggered DRs will favor development of local arm reactions (LARs) at the site of the vaccine injection. These LARs are characterized by swelling, induration, and pain which can be significant. This pain is one of the most common causes for immunotherapy discontinuation. Severe cases of LARs after an immunotherapy injection can develop an eczematoid appearance of the skin and can even blister. Rarely they can leave a persistent discoloration of the skin lasting for a long time.

When a decision is made to treat a patient with immunotherapy, the test will provide information on how to formulate the allergy vaccine. For this formulation to be effective the type of test used is important.[28] Immunotherapy results are best when a strong dose of allergen is administered through a process of dose escalation over time.[29] It is not uncommon to develop a LAR[30] or just pain at the injection site when dose is advanced.

Since early in the author's practice, it was observed that when DRs were present, the incidence of LARs during dose escalation was more prevalent. As stated, these LARs make dose escalation difficult. While there are alternative ways to administer immunotherapy that do not involve weekly injections (SLIT[31] and LDA[32]), the majority of the patients elect to be treated with an insurance reimbursable service and this is only the subcutaneous injection immunotherapy ("allergy shots"). Therefore, learning to manage the DR is important to treat patients that develop LARs.

Dr. McDaniel's advice to selectively dilute the allergens that gave a delayed reaction forms the base for the management in the patient with DRs who is about to receive immunotherapy. The result of such intervention was a marked decrease in the number of LARs so that the quality of patient's management improved. (For further information see Sidebar 2: "How we manage the delayed reaction"). While LARs still occur, they are not nearly as frequent as early in the practice.

Delayed Reaction

The author strongly agrees with the concept that allergens that produce delayed skin responses can produce symptoms in the affected patient. The following observations appear to support such contention:

1) The author has treated a group of 10 patients, at no cost to the patients, who had an IDT with *only* delayed reactions; and he observed clinical improvement in all of them. (Obtaining a full IDT with only DRs is a rare occurrence).
2) The results of immunotherapy treatments clearly improved after the information provided by DRs that developed after a negative skin test (no ISR) was incorporated into the vaccine formula.
3) The author managed a patient who, 24 hours after a completely negative intradermal test, developed diffuse urticaria and an asthma attack. When this patient presented to the office the day after the IDT, she was noted to have DRs at the site of dust and dander tests.

These unpublished observations strongly suggest the role of the DR in symptom-provocation and support the decision to incorporate the information provided by the DR in the formula of the vaccine so that allergy vaccines include a) allergens with ISRs only, b) allergens with ISRs and DRs, c) allergens with DRs only.

Clinical Observations About the Delayed Reaction

The intradermal dilutional test uses six dilutions of each allergen. The number of the dilution expresses how many times the allergen extract was diluted, so the dilution #6 is the weakest. The dilutions #1; #2 and #3 then, carry a stronger concentration of allergen while the dilutions #4, #5 and #6 carry a weaker concentration of allergen. An allergen usually requires two-to-four injections to determine if that allergen is either reactive (positive) or non-reactive (negative). (See Sidebar 1 for more information on the IDT). The

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DR can occur after a positive test (ISR) or after a negative skin test (no ISR).

The majority of the DRs are observed with the three stronger dilutions (#1, #2 or #3) but sometimes DRs are observed with weaker dilutions (#4, #5 or even #6). When a DR develops after a positive test, it usually involves the confirmatory reaction or the first reactive wheal and the confirmatory reaction. Usually DRs are present at 24 and frequently at 24 and 48 hours. Finding DRs only at 48 hours is not common, and finding DRs lasting days to weeks or injuring the skin (discoloration or blistering) is rare. Frequently DRs can develop over two consecutive dilutions in the skin test (for example dilutions #2 and #1). It is uncommon to find DRs affecting three consecutive dilutions and extremely rare to find DRs over four consecutive dilutions.

Monitoring for the presence of DRs requires training. It is sometimes difficult to decide if a DR is present, as erythema may not develop so it may be difficult to see. In these cases, the DR is sometimes better evidenced by palpation. The "injury" of the needle stick is usually evident for several days, and it should not be confused with a DR. The measurement of the diameter of the DR is difficult as the border is not well formed. This is why it is difficult for patients to self-report the presence of DRs.

Table 1.
Non-Compliance with 24-Hour Check.

Panels	#	Ratio	(%)
DD	2	2/15	(13.3)
Mold	6	6/15	(40.0)
Pollen	7	7/15	(46.7)
Total	15	15/15	(100.0)

DD: Dust and dander panel.
Mold: Mold panel.
Pollen: Pollen group, including trees, grasses and weeds
#: Number of panels not compliant with a 24-hour check
Ratio (%): each panel /total of 15 non-complaint cases (Percentage)

Table 2. Incidence of Delayed Reactions.

Group	DD	M	P	Total
# Tests	588	1784	2705	5077
# DR (%)	122 (20.7)	149 (8.4)	300 (11.4)	571 (11.2)
No ISR (%)	36 (29.5)	77 (51.7)	71 (23.7)	184 (32.2)

Tests: Number of tests available for analysis.
DR (%): Number of Delayed Reactions (percentage)
No ISR (%): Delayed Reactions that developed after a negative skin test (Percentage)
DD: Dust and dander group.
M: Mold group.
P: Pollen group, including trees, grasses and weeds

Prevalence of Delayed Reactions After Intradermal Dilutional Test

Objective: To determine 1) the prevalence of DRs after intradermal testing with multiple dilutions (IDT) in a private practice setting. 2) which allergen groups (dust-dander, molds, pollens) are more likely to elicit a DR, 3) which of the dilutions used in the IDT are more likely to have a DR.

Methods: Charts containing the skin tests of patients receiving immunotherapy treatment were considered for inclusion regardless of sex, age, or presence of respiratory symptoms.

Two groups of charts were included because for many years our patients were encouraged to comply with a 24-hour and a 48-hour check after the intradermal test. Because of lack of compliance with the second check and time constraints at the office, in the last few years patients are only encouraged to come for the 24-hour check. The groups of charts included the following:

1. A group of 100 charts was randomly selected by pulling one out of every four charts from the active-patients cabinet. Charts were selected if they contained a complete test that included all panels routinely tested at our office and the patient had come to the office to determine the presence of delayed reactions for at least one of the panels. Patients are tested in four sessions. Each session tests for 1 panel: Dust and Dander; Mold; Tree-pollens; Grasses and Weed-pollens (see Sidebar 3 for a complete list of the allergens tested). This group of 100 charts was used to evaluate results of the 24-hour check. The two pollen-panels are considered separately to determine compliance but then they are combined in a "pollen group" to study prevalence of DRs.

2. The second group of charts was used for the 48-hour control. Charts were randomly pulled out and included for review if they contained at least one panel with a 48-hour control. A group of 71 panels was gathered from 38 different charts that met the criteria.

Information was anonymously charted in an Excel spreadsheet and data was then analyzed.

Results: 24 hour-check. There were 100 charts containing a *complete* intradermal dilutional test. There were 4 panels in each one, tested on separate days. The 400 panels contained a total of 5600 individual skin tests out of 5600. (See Sidebar 3 for complete information on all the allergens in each panel).

Of the 100 patients, there were 38 males and 62 females aged 8-72 years (average 36). There were 28 patients younger than 18 years of age.

Compliance: 15/400 panels lacked a 24-hour control leaving a total of 385 panels available for analysis. Overall compliance with the 24-hour check was 96.3% (385/400). The number of individual allergen tests available in the 385 remaining panels was 5077.

Table 1 shows distribution of the non-compliant cases. The panel for dust and dander shows the least number of non-compliant cases. This could be explained by the fact that this panel is the first one tested in the overwhelming majority of the cases. It is expected that compliance will be better with the first set of tests.

Delayed reactions: There were 571 delayed reactions (DRs) in the 5077 individual tests for an incidence of 11.2% DRs for any allergen tested with an IDT (Table 2). DRs were more prevalent with allergens of the Dust and Dander group and least prevalent with allergens from the mold group. (Table 2).

Delayed Reactions after a negative skin test: When the skin test is negative, there will be no growth of the wheal at the injection site (no ISR). Regardless, a DR can develop 24 hours later (or more). Table 2 shows that 184/571 or 32.2% of DRs occurred after a negative skin test. This is more likely to occur with mold allergens. In this series, while the occurrence of DRs in the mold group was 8.4%, more than 50% of these DRs followed a non-reactive (negative) mold test.

Delayed Reactions by Dilution: The IDT uses six dilutions. Dilution #6 (D6) is the weakest dilution (carrying the least amount of allergen) and Dilution #1 (D1) is the strongest one (carrying the most concentration of allergen). The majority of the positive results (ISRs) with the IDT are seen with the stronger dilutions (D3, D2, D1).[33] The prevalence of DRs follows a similar pattern (Table 3): Most of the DRs developed with dilutions #2 and #1 for all groups. This is more evident when the data in both dilutions was combined. The incidence of DRs markedly decreased in the weaker dilutions.

Dilution #5 is almost never used during testing. This explains why in this series no results were found with this dilution.

Molds appeared to have a higher percentage of DRs in the stronger dilutions (93.6% for D1+2). Pollens appeared to have a higher rate of DRs at Dilution #6 (16/18 DRs at dilution #6). A possible explanation for this is that pollens are usually the most reactive and molds are the least reactive of the allergens so it is common to stop the test for pollen (or for dust and dander) at a weaker dilution while mold testing usually progresses to very strong dilutions.

Diameter of the Delayed Reaction in reference to the immediate test result: When more than one DR for a tested allergen was encountered, the diameter of the DR was larger at the stronger dilution (the one containing more concentrated allergen). The diameter of the DR was compared to the diameter of the wheal at the time of the test. In the cases where more than one DR developed in a single allergen test, the DR with the largest diameter was chosen for this analysis. The diameter of the DR can be smaller, larger or the same as the wheal at the time of the test. As seen in Table 4, there was a tendency for the DR diameter to be smaller than the wheal at the time of the test. This was more evident for pollens.

Results: delayed reactions at 48-hour check. The 71 panels with 48-hour control information provided 853 individual allergen tests. All patients that came for the 48-hour control had previously come at 24 hours.

Table 5 shows there were 222 DRs present in the 853 individual allergen tests for a percentage of 26.0%. The majority of the DRs (87.4%) were present at 24 hours, 61.3% were also present at 48 hours. There is a subgroup of 28/222 DRs (12.6%) where the DRs were present only at 48 hours. From these, 12/28 (42.9%) occurred in a single pollen panel.

Delayed Reaction

Conclusions

Delayed reactions after an intradermal dilutional test are likely to develop in 11.2% of the tests.

They can develop not only with the perennial type of allergens (dust, dander or mold) but also with pollen allergens.

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Table 3. Delayed Reactions by Dilution

Group	#T	D6 (%)	D5 (%)	D4 (%)	D3 (%)	D2 (%)	D1 (%)	D1+D2 (%)
DD	141	2 (1.4)	0 (0)	13 (9.2)	4 (2.8)	66 (46.8)	46 (39.7)	122 (86.5)
Mold	155	0 (0)	0 (0)	9 (5.8)	1 (0.7)	35 (22.6)	110 (71.0)	145 (93.6)
Pollen	300	16 (5.3)	0 (0)	7 (2.3)	43 (14.3)	93 (31.0)	141 (47.0)	234 (78.0)
Total	596	18 (3.0)	0 (0)	29 (4.9)	48 (8.1)	194 (32.6)	307 (51.5)	501 (84.0)

Group: Tested group
DD: Dust and dander group.
Mold: Mold group.
Pollen: Pollen group, including trees, grasses and weeds
Total: all values together. The total in this table is higher than the total of DRs as some occurred in more than one dilution
#T: Number of tests available for analysis
D6 (%) - D1 (%): Number of delayed reactions in each dilution (percentage). 6 is the weakest dilution. 1 is the strongest dilution
D1 + D2 (%): Number of DRs in Dilutions #1 and #2 combined (percentage over #T)

Sidebar 3: List of Allergens Tested by IDT

DUST AND DANDER
Dermatophagoides Pteronyssinus
Dermatophagoides Farinae
Cat
Dog
American Roach
German Roach

MOLD
Alternaria
Aspergillus
Chaetomium
Cephalosporium
Cladosporium
Curvularia
Epiccocum
Fusarium
Helminthosporium
Mucor
Penicillium
Phoma
Pullularia
Rhodotorula
Rhizopus
Stemphyllium
Candida
Trichophyton
Epidermophyton

POLLENS-TREES
Ash
Birch
Cottonwood
Elm
Hickory
Mulberry
Oak
Pine
Privet
Red Cedar
Red Maple
Sycamore
Walnut

POLLENS-GRASS
Bahia
Bermuda
Johnson
Timothy

POLLENS-WEEDS
Cocklebur
English Plantain
Goldenrod
Kochia
Lambs Quarter
Marsh Elder
Nettle
Pigweed
Ragweed
Sheep Sorrel

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DRs are clearly more prevalent when a large amount of allergen is injected (Dilutions #1 and #2).

A large percentage of DRs develop after a negative skin test (184/571 or 32.9% of DRs of which 52.6% occurred in the mold panel). This is an important number that appears to be more significant for mold allergens.

When reactions are present at 48 hours, the majority are concomitant with the 24-hour event; but there is a subgroup of reactions that are present only at the 48-hour check. This happened in 12.6% of the DRs available for evaluation.

Discussion

Delayed reactions are not unusual. Not testing on dilutions #1 and #2 will prevent the practitioner from acquiring very important information. Many ENT allergists do not test for dilution #1. Not testing for dilution #1 will miss not only the immediate reactivity at this dilution but also approximately 50% of the information related to the presence of DRs. General allergists, when they perform an intradermal test, only test for a dilution weaker than the #2 of the IDT (an allergenic concentration between dilutions #2 and #3).[8] Not testing for dilutions #1 and #2, beyond missing the information pertaining to the immediate reactivity, will miss more than 80% of the DRs and this can account for a difference in treatment results.[28]

A proper evaluation for the development of DRs is complex and time consuming. In our experience it requires properly trained personnel. From this review it is clear that the 24-hour check is very important as it provides most of the information pertaining to DRs. A 48-hour check can provide additional information. In our series it amounted to 12.6%. Because almost half of the DRs at 48 hours were found in a single tested panel, which in our experience is not a frequent observation, potentially the value of a 48-hour check could be even smaller. In the author's opinion, the fact that DRs can develop at 48 but not at 24 hours should be considered to emphasize to the patient the need for a 48-hour check if the 24-hour check did not show any DRs. Otherwise the information obtained at 24 hours appears to be sufficient to handle the clinical aspects of immunotherapy administration.

The prevalence of DRs in the 100-chart group (5077 individual allergens tested), was 11.2%. In the group of tests used to evaluate the DR at 48 hours (only 853 individual tests) the prevalence of DRs was 26.0%. Probably 11.2% represents more accurately the rate of DRs after IDT.

When performing an IDT in the clinical setting, not all the available dilutions are necessarily used. When evaluating the number of DRs that occur with each dilution, obviously the results will be influenced by the number of times each dilution was used for testing. Ultimately a properly designed study should be planned using all the dilutions and having all participants comply with a 24- and a 48-hour check to gather complete information on the relationship between allergen concentration and prevalence and diameter of the DRs associated with each dilution and to completely assert the significance (or lack of) the 48-hour control after a 24-hour control. To validate the findings presented here, it should be important that these results be re-evaluated in a multi-office study. The caveat is that testing methods should be consistent using the intradermal dilutional test and testing for dilution #1 (the most concentrated of the allergen dilutions).[28]

Despite these shortcomings, it is clear that the DR is more prevalent with stronger (more concentrated) allergen. The study also suggests that when DRs occur with weaker concentrations, pollens probably are more prevalent.

In agreement with published data[5] we also observed that the diameter of the DR follows the diameter of the ISR. This is more evident when there are DRs on consecutive dilutions with increasingly stronger allergen concentration. As expected, the diameter of the ISR increases the more concentrated the injected allergen and the same happens with the diameter of the DR.

It has been suggested that DRs occur mainly with mold allergens[6,27] and some indoor allergens like roaches.[6] It is accepted that DRs can also occur with pollens[5] but this chart review clearly suggests that DRs after pollen tests is a common occurrence (Table 2). This analysis has not been done allergen by allergen, therefore it does not rule out the possibility that a single allergen is more likely to elicit a delayed reaction than others.

Beyond the controversy of the DR being related to IgE or not, there is clinical usefulness in checking for the development of DRs after a skin test. A patient that develops DRs is clearly more difficult to treat with immunotherapy. It is important to be aware that *all allergens* should be checked for the potential presence of a delayed reaction. The information provided by the DR helps attain better results with less problems and more tolerability by the patient. (For further information on this, see Sidebar 2: How we manage the delayed reaction).

Table 4. Diameter of Delayed Reaction in Comparison to Immediate Skin Reaction

Group (# DR)	DR< (%)	DR> (%)	DR= (%)
DD (122)	43 (35.2)	42 (34.4)	37 (30.3)
Mold (149)	70 (47.0)	37 (24.8)	42 (28.2)
Pollen (300)	164 (54.7)	60 (20.0)	76 (25.3)
Totals (571)	278 (48.7)	143 (25.0)	154 (27.0)

Group (# DR): Tested group (number of Delayed Reaction in that group)
DD: Dust and dander group.
Mold: Mold group.
Pollen: Pollen group, including trees, grasses and weeds
DR<: Number of cases when the diameter of the DR was smaller than the diameter of the wheal during skin test
DR>: Number of cases when the diameter of the DR was larger than the diameter of the wheal during skin test
DR=: Number of cases when the diameter of the DR was the same as the diameter of the wheal during skin test
NOTE: The wheal at the time of the skin test includes positive and negative skin tests.
When DRs occurred through more than one dilution, the one occurring at the strongest dilution was chosen.

Table 5. Delayed Reactions

Tests	853	100.0 %
Delayed reactions (DRs)	222	26.0%
24 Hours	194	87.4%
24 + 48 Hours	136	61.3%
Only at 48 hours	28	12.6%

Tests: individual tested allergens available for evaluation
DRs: Number of Delayed Reactions in the whole group
24 Hours: Number of delayed reactions present at 24 hours
24 + 48 Hours: Number of delayed reactions present at 48 hours
Only at 48 Hours: Number of delayed reactions present at 48 hours but not at 24 hours

The vast majority of the allergy-practitioners disregard the clinical usefulness of the DR as it does not conform to the idea that allergy is related exclusively to the presence of IgE.[20] While the answer to why this point of view is so strongly held is elusive, the discovery of IgE in 1965 may play a role.[34] This immunoglobulin was found only in patients with allergies. This may explain why it was assumed that allergy is exclusively an IgE-mediated phenomenon disregarding the fact that there are several types of hypersensitivity reactions as described by Gell and Coombs.[35] There are experiments where IgE triggers not only an ISR but also a LSR.[5] Concluding that the LSR is related *only* to the presence of IgE, excludes the concept that after an initial Type I hypersensitivity reaction, the other mechanisms of hypersensitivity can develop, following the complex cascade of substances liberated and produced after the initial stimulus. The view that allergy is exclusively an IgE-related phenomenon is widely accepted even though there is ample evidence in the literature of non-IgE immunological phenomena.[36-39]

Supporting the rationale that the allergic response is a complex one, probably involving multiple mechanisms at the same time, is the common observation that a patient with a clear history of allergic disease can have a negative "RAST"[40] test. The "RAST" test that is usually reimbursed by insurance carriers measures only for the presence of IgE. While this test is accurate for the measurement of IgE, finding a negative test is not uncommon. When a patient with clear clinical history of allergic disease and a negative IgE "RAST" is tested with an IDT, the patient will, in my experience, have a positive skin test. Obtaining a positive skin test (development of ISRs) in the face of a negative "RAST" test implies that at least some of the ISRs develop independently of an IgE-mediated mechanism.

The field of immunology is in constant evolution. It has been suggested that human immune responses may not adhere to classical Th1 or Th2 profiles. T cells from different subjects and even within the same individual may exhibit multiple specificities with Th1 and/or Th2 characteristics and the complexity of cytokine responses may reflect the genetic heterogeneity of humans compared with other animal systems that have been used to establish the Th1/Th2 paradigm.[41]

Different allergens were identified in a dermatophyte that are capable of eliciting either an ISR or a delayed type of reactivity.[42] The apparent difference between the LSR and DSR [10-12] may be related to the portion of the allergen interacting with the immunological system.

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Dr. Saporta completed his training in 1990 at Columbia Presbyterian Hospital in New York City. He is board certified in otolaryngology and has been a fellow of the American Academy of Otolaryngic Allergy (AAOA) since 2001. His private practice in Elizabeth, New Jersey, is heavily oriented to the management of allergic conditions. Interested in the use of oral vaccines since early in his practice, Dr. Saporta presented a protocol for sublingual immunotherapy at the 64th annual meeting of the AAOA that since then has been successfully used for the management of allergic rhinitis with or without asthma.

The Denial of Adverse Event Risk Following Immunization and the Loss of Informed Consent – A Perspective, Part 1

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"Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information...The interests and welfare of the individual should have priority over the sole interest of science or society."

2005 UNESCO Universal Declaration on Bioethics and Human Rights[1]

Introduction

Vaccines are public health measures that are not evidence-based as portrayed by authorities such as the United States Department of Health and Human Services (HHS) or the Centers for Disease Control (CDC). For example, despite political propaganda to the contrary, the scientific reality is vaccines are not subjected to the same kind of clinical trials as other drugs are. They are classified not as drugs but as biologics, which allows them to be routinely approved and mandated with little to no evidence of efficacy or safety while at the same time actual evidence of vaccine harm is systematically ignored by vaccine manufacturers and authorities who work together under multiple unethical conflicts of interest. Consequently, vaccines are a grave threat to public health and medical ethics. Furthermore, informed consent in vaccination is deeply endangered today both in medical practice and as an ethical principle in society. Natural immunity is similarly endangered today due to modern vaccination policy. Promoting categorically unsafe vaccines and discouraging the responsible development of natural immunity has become state-sponsored policy where the policy itself is what gets protected – not the public.

In the US, the Food and Drug Administration (FDA) has stated their policy on this issue clearly, "*any possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent consistent with the nation's public health objectives."* This was recorded in the Federal Register (vol 49, No. 107) and made specifically about the polio vaccine.

So, doubts about safety cannot be allowed to exist? An unambiguous policy that has nothing to do with science or public health. Considering how much of the world seems to blindly follow the lead of US health agencies or is coerced into following them, that FDA policy statement should be very alarming. The trust placed in US agencies ignores that they have been compromised and captured by industry[2]; furthermore, physicians and scientists who criticize this system of rampant corruption[3] will be increasingly pilloried and attacked as incompetent, dishonest, and a dangerous menace to the public's wellbeing.

In their 2014 policy paper, "Considerations regarding consent vaccinating children and adolescents between 6 and 17 years old," the World Health Organization (WHO) stated, *"the physical presence of the child or adolescent, with or without an accompanying parent at the vaccination session, is considered to imply consent."* A child sent to school on the day they are holding a vaccine clinic is now consenting by implication. A parent could refuse to send the child to school on vaccine day, but that assumes they knew about it. However, implied consent is Orwellian doublespeak inconsistent with the UNESCO declaration, and emblematic of an erosion of fundamental rights by the misinformed to protect marketing goals and policies that often have little to no public benefit.

Then in 2017, the WHO revised[4] what they would accept as an Adverse Event Following Immunization (AEFI). Only reactions that have been previously acknowledged in epidemiological studies would now be considered as vaccine related. Deaths seen in post-marketing surveillance would be identified as coincidental or unclassifiable. These deaths are not classified as vaccine-

Abbreviations: Department of Health and Human Services (HHS); Centers for Disease Control (CDC); Food and Drug Administration (FDA) ; The World Health Organization (WHO); Adverse Event Following Immunization (AEFI); American Academy of Pediatrics (AAP); diphtheria-tetanus-pertussis (DTP); oral polio vaccine (OPV); Physicians for Informed Consent (PIC); Vaccine Adverse Event Reporting System (VAERS); European Medicines Agency (the EMA); amorphous aluminum hydroxyphosphate sulfate (AAHS); National Association of County and Public Health Officials (NACCHO); GlaxoSmithKline (GSK); Simian Virus 40 (SV40) ; measles, mumps and rubella (MMR).

related if the vaccine had not caused a statistically significant increase in deaths in the Phase III trials. For example, Sri Lanka suspended the use of a pentavalent vaccine after five deaths within four months after its introduction in January 2008; and in 2013, Vietnam shelved the pentavalent vaccine because it had been associated with 12 deaths. However, in both cases, the WHO teams which investigated the deaths declared they were "unlikely" to be related to the vaccines used.

Puliyel, and Phadke wrote a letter to the editor of the *Indian Journal of Medical Ethics* expressing their dire concerns as there were 132 cases of children in India being hospitalized after the administration of a pentavalent vaccine between 2012 and 2016. Fifty-four of these children died. When these adverse events were analyzed using the new WHO criteria, not one of the deaths was classified as potentially vaccine related[5]: "AEFI reporting is said to be for vaccine safety. In view of the above, it is necessary that the AEFI manual be re-evaluated and revised urgently…. safety of children (child safety) rather that safety for vaccines (vaccine safety) needs to be the focus."[5]

In other words, Puliyel and Phadke are saying that reporting on AEFI's is supposed to be about identifying problems so that if there are safety issues children can be protected from a flawed vaccine. AEFI reporting is not meant to obfuscate safety issues to protect the vaccine from scrutiny. Apparently, Puliyel and Phadke are either naive ("*possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist")* or they are attempting to inform their colleagues in the most politically polite manner possible that protecting vaccine policy, terminating informed consent, and AEFI denialism has become the global vaccine agenda.

But Vaccines Save Lives, Right?

It is worth noting that the American Academy of Pediatrics (AAP) published a summary of vital statistics on the trends in the health of Americans during the 20th century: "Thus vaccination does not account for the impressive declines in mortality seen in the first half of the (20th) century."[6] Perhaps, it would be more prudent for the WHO to state that the physical presence of a child on this planet implies consent to clean water, sanitation, and a healthy diet, rather than eroding individual and parental rights for invasive medical interventions of questionable value.

The value of vaccines is called into question when unvaccinated and vaccinated populations are compared, which may be why so little is published in this area as the implication of such comparisons could destroy current global vaccine policies. In 2017, a rather unique study was published[7] that examined the introduction of the diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau (Africa) in the early 1980s. The conclusion of this study stated:

> DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the performance of national vaccination programs.
>
> It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.[7]

One might assume the intentions of most vaccine advocates is to help and protect children; however, by design (it seems) there is a pernicious lack of understanding about the risks involved. The indoctrination of today's medical community that "vaccines save lives" is so ingrained no room is left for the reality that many vaccines are flawed, or that there are serious safety concerns. The malevolent aspects of this level of indoctrination has its own risks that reach far beyond medical malfeasance.

The guiding principle that one simply does not expose a child to any unnecessary risk has apparently been abandoned if they are on the receiving end of a vaccine. Of course, many medical interventions have the risk to cause harm but the risk of that harm may be very small provided effective measures are in place, such as making sure, in the case of vaccines, the child does not have a known medical (physical, genetic or immune) problem that would amplify risk. It is often hard to judge the level of risk that can be tolerated because the science in this area is not complete. In the case of vaccines, without a previous vaccine reaction in the child in question or one in an immediate family member who shares a common genetic pattern, it really isn't possible to calculate accurate risk. This doesn't mean the risk is not there, it is just it can't be precisely calculated.

Today, with our current knowledge base, risk is balanced against the benefit and whether there is a better alternative to accepting the risk. It is reasonable to accept a level of risk if the risk from all the other alternatives, including doing nothing, is even greater. A risk is not acceptable if there is a reasonable alternative that offers the same or greater benefit but avoids the risk. Vaccine enthusiasts routinely assume the risk of the disease is greater than the risk of the vaccine. The reality is quite different. And this goes right to the heart of informed consent because it involves comparing relative risks of a medical intervention.

For example, it has not been proven that the MMR vaccine is safer than measles. The nonprofit organization Physicians for Informed Consent (PIC) recently reported in *The BMJ* that every year an estimated 5,700 U.S. children (approximately 1 in 640 children) suffer febrile seizures from the first dose of the MMR vaccine – which is five times more than the number of seizures expected from measles.[8] This amounts to 57,000 febrile seizures over the past 10 years due to the MMR vaccine alone. And, as five percent of children with febrile seizures progress to epilepsy, the estimated number of children developing epilepsy due to the MMR vaccine, in the past 10 years, is 2,850. In addition, PIC found that the Vaccine ➤

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Adverse Event Reporting System (VAERS) receives only about 90 annual reports of seizures following the first dose of MMR – that's only 1.6% of the 5,700 MMR-vaccine seizures that occur each year. PIC contends that VAERS, as a passive surveillance system, does not adequately capture vaccine side effects and that serious side effects, including permanent neurological harm and death from MMR and other vaccines, may similarly be underreported.

Moreover, there are multitudes of medical alternatives to vaccines, whereby patients prevent and heal infectious diseases and build their natural immunity. Another foundational premise is that good sanitation practices, coupled with well-balanced diet and sensible exercise, encourage a lifestyle conducive to strong natural immunity.

Public health authorities act callously and dismissively toward indicators that help identify children at risk of vaccine injury, either because the authorities care to do so in the first place or for lack of sufficient studies on how to use combined indicators of risk to predict injury, prior to vaccination; furthermore, the costs involved in screening children are not compatible with priorities or budgets of one-size-fits-all mass vaccination programs. Nevertheless, there are potential tools of science that could provide indicators (biomarkers such as pre-existing Th2/Th1 skew, certain genetic polymorphisms, family history or autoimmunity).

Vaccine mandate proponents (and those who would take away the rights to exemptions) use the tools of speculation and obfuscation to deny evidence of vaccine injury and deaths. This allows vaccine mandate proponents to propagandize the morality of the compulsory vaccine programs, and even to stifle the capability of the medical community to acknowledge and treat vaccine-injured children. If it is acknowledged that screening for risk is appropriate, then that risk itself is being acknowledged and that will increase the perception of risk with the public and obviously there will be those (vaccine mandate proponents) who would not want to take the risk, so risk-denialism has emerged as a part of compulsory vaccine programs.

The medical community has allowed a fixation on infectious disease entities alone to truncate our understanding of co-causations of several conditions, such as the role pesticides play, for example DDT, in acute flaccid paralysis/myelitis or in Burkett's lymphoma, just to name one environmental problem behind conditions that are considered solely the cause of an infectious agent.

The heart of informed consent involves comparing relative risks, based on actual data.

Ponder the huge increase in infant deaths in countries like India when polyvalent vaccines were introduced, but political and economic interests muddle decisions about safety. Indeed, safety is routinely and systematically ignored in the face of these interests. Safety concerns and finding out who might be more at risk from an adverse event does not sell vaccines; and in the US the only way a vaccine manufacturer becomes potentially liable is if they deliberately hide safety problems they learn about their product and were not transparent or forthcoming about those safety issues. Thus, functional safety research has almost completely ended. New vaccines are tested against false placebos (i.e., comparables to other vaccines) instead of using inert or saline placebos; then, children are only followed for a short time (sometimes 5 days, sometimes a matter of weeks). If the child doesn't immediately report adverse events (especially the predetermined adverse events on the list provided by the manufacturer) then the vaccine is considered safe. However, what is taking place goes beyond using "placebos" that contain the full complement of adjuvants.

Protocol V501-018 was the only controlled trial in the target age group of 9-to-15-year-olds for the Gardasil HPV vaccine and the FDA's June 2006 Clinical Review Table 210 shows that the vaccine formulation in Protocol 018 contained only **half** the amount of Merck's adjuvant amorphous aluminum hydroxyphosphate sulfate (AAHS) compared to marketed Gardasil. This failure to compare the marketed vaccine, containing 225 mcgs of AAHS, against the carrier solution control, suggests the intent to mislead. It also suggests reckless overexposure of children worldwide who received the marketed vaccine to double the AAHS amount in Protocol 018, helping to explain the high level of reported injuries and deaths worldwide.

In a 2017 commentary[9] Puliyel and Sathyamala describes a shocking dereliction of duty on the part of regulators who were presented with vaccine data carefully tailored to obscure serious risks. Tackling concerns about infant deaths that have occurred following vaccination in several European countries, the authors of the commentary show that GlaxoSmithKline (GSK) neglected to report to regulatory authorities that there was a statistically significant increased risk of sudden infant death in the four days after administration of its hexavalent vaccine – and the European Medicines Agency (the EMA) ignored the omission and accepted GSK's apparently whitewashed data at face value.

In the US, the FDA estimates that passive surveillance captures about one percent of vaccine-related adverse events. A study[10] in Africa that compared passive with active surveillance found that passive surveillance "failed to identify half of all AEFIs (adverse events following immunization) that were identified through active surveillance, including all of the serious AEFIs."

Reviewing and reanalyzing GSK's sudden death data, Puliyel and Sathyamala note a "clustering" of sudden deaths among infants (under age one) in the first three days following vaccination – with 72% of the deaths (42/58) taking place in that time frame and nearly all (93% or 54/58) occurring within 10 days of vaccination. The authors state:

> The fact that the rate of death decreases rapidly with the passage of time following immunization suggests that the deaths could be related to vaccination…. If one glosses over the deaths after vaccination, one can prevent/delay the evaluation of the vaccine's safety profile and this has the potential to result in more, unnecessary deaths, which is difficult to justify ethically.

The WHO and government health agencies are quick to dismiss as a "myth" any possible link between vaccines and sudden infant death syndrome (SIDS) or other unexplained infant deaths – despite a landmark ruling by the US Court of Federal Claims in 2017 (No. 13-611V) that vaccines "*caused or substantially contributed*" to a 2011 SIDS death. Nevertheless, following Hexavac's withdrawal from the European market, the EU has gone on to grant marketing approval to two other hexavalent vaccines manufactured by Sanofi Pasteur (Hexyon and Vaxelis, in 2013 and 2016, respectively). The EU also gave a scientific thumbs-up for rollout of Sanofi's Hexaxim vaccine in non-EU regions.

Vaccinologists at the CDC give lip-service for need to invest in vaccine safety infrastructure[11] "*at a level commensurate with investments in vaccine development*," particularly through post-licensure studies that compensate for the "*well-known limitations*" of prelicensure clinical trials. In what seemed like a lucid moment, these vaccine researchers also state there should be "increasing emphasis…on *proving*, rather than *assuming*, that no problems are associated with a vaccine." But actions speak louder than empty words. One action was to ignore CDC whistleblower, Dr. William Thompson, whose confession is hard to ignore:

> I have waited a long time to tell my story and I want to tell it truthfully. I have been involved in deceiving millions of taxpayers regarding the potential negative side effects of vaccines. We lied about the scientific findings. The CDC can no longer be trusted to do vaccine safety work. Can't be trusted to be transparent. The CDC can't be trusted to police itself.[12]

Puliyel and Sathyamala state that, as a result of the EMA's failure to perform due diligence on Infanrix hexa, "numerous children were unnecessarily exposed to the risk of death." They admonish that the "proof" offered by vaccine manufacturers cannot be accepted uncritically and that regulatory agencies must scrutinize pharma-authored/pharma-funded reports rather than simply rubber-stamping them. The problem is in not recognizing the extent to which regulatory agencies have been bled out from the inside by the vaccine industry. For example, in the US, the National Association of County and Public Health Officials (NACCHO) operates under a written policy to eliminate all exemptions to vaccines "to the greatest degree possible," other than medical exemptions, which they want to allow only on their terms. *The elimination of personal belief exemptions (PBEs) is code for eliminating informed consent.* Agencies in collusion with medical boards encourage attacks on those with opposing opinions be that to discredit, silence or discipline them.

Indoctrinated by the "vaccines are safe, and the science is settled" groupthink, all risks associated with vaccines are now considered acceptable risks; there is no room for discussion or debate ("*any possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist")*. However, even acceptable risk may become unacceptable over time or because circumstances change – such as the changing to a hexavalent vaccine or the health status or clinical condition of a child. Note that the schedule of vaccines for children has never been clinically evaluated for safety either prospectively or retrospectively. Having no science is not settled science; it is non-science, pseudo-science, and often fatally fraudulent.

What Is Unacceptable Risk?

Few would argue that having a life-threatening anaphylactic reaction to a previous vaccine might be an almost certain consequence of receiving another vaccine, but should that be held out as the standard that needs to be reached for unacceptable risk? Unacceptable risk is not limited to a history of already being injured by a previously given vaccine. You don't withhold a white cane from a blind person until they can demonstrate that they might be hit by a bus whilst walking down the street. The fact that they are blind calls for a white cane. In the same way, in the war against disease, you don't force the genetically infirm, for example, to be part of a public health army any more than you would send soldiers in wheelchairs to the front line.

Proponents of compulsory mass vaccine programs might argue that giving white canes to all the blind is too expensive or, if the blind actually found that walking down the street without a cane could cause them harm, they might not walk down the street at all. Should anyone question how inappropriate it is to withhold white canes from the blind, the authorities will insist it is just "coincidence" that the blind are injured walking around without white canes.

That might seem sadly humorous, but adverse events (AEs) are not to be trivialized[13]:

> AEs not only affect patients and their families but also may have devastating effects on health care providers, who may suffer emotional consequences both from preventable AEs and from subsequent malpractice litigation. Affected clinicians may feel guilt, shame, and isolation, and these feelings may be exacerbated by negative reactions from their colleagues. Anticipated or actual punitive consequences can add additional emotional and financial burdens on providers.

Alas, there is legal immunity for healthcare workers in the US for contributing to AEFI. Indeed, there are no punitive consequences. And given there is a lack of understanding about AEFI, there is no remorse either.

Who Is Responsible for Vaccine Safety?

A US law was passed in 1986, called the National Childhood Vaccine Injury Act. This was at a time when there was no coercion to get vaccines, and

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there were only 23 doses of vaccines required; but there were a lot of legal actions taking place against vaccine manufacturers, and they insisted on liability protection or they would no longer make vaccines. The law removed all liability from vaccine manufacturers and gave 100% responsibility for determining and evaluating vaccine safety to the Department of Health and Human Services (HHS). Not only was HHS responsible for safety, but it was legally required to report on same to the US Congress every two years. A recent court settlement had HHS admitting they have no reports – 30 years of no reports to Congress even though the law required same.[14]

Eventually, these HHS reports to Congress would likely have attracted a great deal of public attention, and open hearings would have been a likely outcome. The science (or lack thereof) of vaccinology would be center stage, and why would HHS want that? Better to ignore the law, hope no one notices, never study vaccine safety, and never try to improve on it ("*possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist").* Baum and Anello state:

> Vaccine safety is initially assessed in prelicensure clinical trials. However, such trials usually have sample sizes that are insufficient to detect rare adverse events. In addition, vaccine trials are usually carried out in well-defined, homogeneous populations with relatively short follow-up periods, which may limit their generalizability. Post-licensure drug evaluations have relied on passive surveillance systems to monitor adverse events. Such systems are more practical and less expensive than controlled trials; however, their data are usually inadequate to determine causality.[15]

Send in the Vaccines?

Where are the vaccines for some of the world's ongoing plagues? Is it just that there hasn't been enough money thrown at them, or are there just certain diseases that will never allow a vaccine to be efficacious? To facilitate protective immunity against malaria, TB and HIV requires the induction of humoral, antibody-dependent cellular inhibition (ADCI) and effector and memory cell responses that are sustained and vaccine efficacy at or above 75%. The genetic complexity of the pathogens in question exhibit genetic diversity and antigenic variation during the different stages of their life cycles that either exceed our current ability to create a vaccine or are not able to be addressed by any vaccine.

A risk is not acceptable if there is a reasonable alternative that offers the same or greater benefit but avoids the risk.

Even the vaccines used today don't necessarily provide protective immunity. The DTaP vaccine, for example, conveys no such protection, as that vaccine only mitigates the impact of the toxin made by the bacteria but is not capable of preventing colonization and transmission of *B. pertussis*. Those aP antibodies are also very ephemeral and may not last more than three years.[16] But there are other reasons for concern: "we conclude that aP vaccination interferes with the optimal clearance of *B. parapertussis* and enhances the performance of this pathogen. Our data raise the possibility that widespread aP vaccination can create hosts more susceptible to *B. parapertussis* infection."[17] Parapertussis does not produce a toxoid so the vaccine has no activity against a toxin that is not even present.

For the acellular pertussis vaccine to work, the *Bordetella pertussis* bacteria must have pertactin (PRN)–a key antigen component of the acellular pertussis vaccine. A study that screened *B. pertussis* strains isolated between 1935 and 2012 for gene insertions that prevent production of PRN found significant increases in PRN-deficient isolates throughout the US.[18] The earliest PRN-deficient strain was isolated in 1994; by 2012, the percentage of PRN-deficient isolates was more than 50%.

The CDC found the *B. pertussis* strains isolated in 2012 from six CDC sites:

> Enhanced Pertussis Surveillance Sites indicated that 85% of the isolates were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains**.** Moreover, when patients with up-to-date DTaP vaccinations were compared to unvaccinated patients, the odds of being infected with PRN-deficient strains increased, suggesting that PRN deficient- bacteria may have a selective advantage in infecting DTaP-vaccinated persons**.**[19]

In case the nuance of this report was missed, the CDC *did* do a vaccinated vs. unvaccinated comparison (at least for the DTaP). What they found was those children vaccinated with the DTaP were far more likely ("*a 2- to 4-fold greater odds*") of having PRN-deficient *B. pertussis* than the unvaccinated, to be infected by PRN-deficient pertussis, which seems to now comprise almost 90% of the circulating strains. It means not only does the current vaccine have little to no efficacy but increases the chance of coming down with the very illness it is meant to prevent. Gill et al. state:

> This disease is back because we didn't really understand how our immune defenses against whooping cough worked, and did not understand how the vaccines needed to work to prevent it….Instead we layered assumptions upon assumptions, and now find ourselves in the uncomfortable position of admitting that we made some crucial errors. This is definitely not where we thought we'd be in 2017.[20]

So, public health authorities are mandating a vaccine that doesn't work as advertised, and once vaccinated the child is more likely to get the infection. Is that a public health intervention you coerce people to take or destroy the right of informed consent over?

Is it even a vaccine that should be used at all?

Suspending the DTaP and explaining the reason for stopping its use could significantly shake the public's

confidence in all vaccines; having said that, to continue to use this harmful vaccine is clearly being done to protect the vaccine program, its policies and its profits. It is clearly not to protect children. Who is going to allow their child to get a vaccine that increases their chance of getting pertussis up to four times greater than if they had never been vaccinated – if the parents had that information? I suspect almost no one. It goes without saying that if the public knew the real science then virtually no one would consent; there would just be dissent, which is as it should be as that would be the catalyst for improved and safer vaccines, as well as encouraging modalities the enhance natural immunity.

What are a nation's public health objectives if they aren't about protecting children and the public? In the US, public health objectives seem to be to vaccinate as many children as possible with as many vaccines as possible, deny AEFI even exists, and terminate informed consent.

Are Safe Vaccines Even Possible?

When compromised government agencies, together with NGOs they control through funding, are the providers of vaccine safety information, that makes for a very unsafe situation. The *British Medical Journal* (*BMJ*) states these sources are not reliable.[21]

In the Fall of 2018, the *BMJ* published "Pandemrix vaccine: why was the public not told of early warning signs?"[22] This article discussed the unearthed GSK internal reports suggesting problems with the vaccine's safety. Editor Doshi asks what this means for the future of transparency during public health emergencies, because we are dealing with a situation where truth and safety are not part of operation. However, a public health emergency is taking place now because a virtually unregulated, well-financed industry colludes with the very agencies, organizations, and academic institutions the public relies on to help protect them from disease.

When Is a Poison Not a Poison?

Using aluminum as an example, in the US, children receive over 50 injections and over 200 antigens in those injections. If you count pregnancy vaccines of TDaP and flu, that would be four more doses. The total amount of aluminum injected is over 10,000 mcg, but how safe is this?

The American Academy of Pediatrics (AAP) published a policy in 1996 called *Aluminum Toxicity in Infants and Children,*[23] leaving little doubt that aluminum is a neurotoxin even at very small amounts.

Mold et al[24] looked at the brains of 10 donors who had autism and demonstrated they contain some of the highest levels of aluminum ever recorded in human brain, and the aluminum was found in the brain's immune cells, the microglia and the cells that provide support and protection for the neurons, the glia. How does a 15-year-old have as much aluminum in his brain as someone who is many decades older who has died of familial Alzheimer's disease? What does this mean for today's generation of children who receive 5,000 mcg of aluminum in vaccines by the age of 18 months and up to 5,250 additional mcg if all recommended boosters, HPV and meningitis vaccines are administered? Shaw would argue it is destroying their brains.[25] Gherardi et al state:

> Aluminum has long been identified as a neurotoxic metal, affecting memory, cognition and psychomotor control, altering neurotransmission and synaptic activity, damaging the blood–brain barrier (BBB), exerting pro-oxidant effects, activating microglia and neuroinflammation, depressing the cerebral glucose metabolism and mitochondrial functions, interfering with transcriptional activity, and promoting beta-amyloid and neurofilament aggregation.[26]

The danger of using aluminum-based adjuvants was further described by in Asin et al[27] in 2018: "Al-based adjuvants induce persistent, sterile, subcutaneous granulomas with macrophage-driven translocation of Al to regional lymph nodes. Local translocation of Al may induce further accumulation in distant tissues and be related to the appearance of system."

At the end of 2018, the same researchers published a study[28] describing behavioral changes in sheep after having received repetitive injections of Al-containing products, explaining some of the clinical signs observed in ovine ASIA syndrome (Autoimmune/Inflammatory syndrome induced by Adjuvants). Vaccinated lambs received the same aluminum adjuvant that is used in human vaccines and then began aggressively biting the wool from other sheep, pacing restlessly and overeating. The research effort was made to understand a new disease that had decimated the Spanish sheep industry between 2008 and 2010 following a government-mandated bluetongue vaccine campaign.

Obviously, if several toxins are in the mix together, the risk of a toxic synergy taking place is far greater than the additive effects of each toxin; but if no effort is made to study what that synergy is, there is no appreciation of how toxic a brew is created. It is pataphysics to believe the toxic metals in vaccines are safe.

Common sense alone should stop anyone from injecting the most toxic non-radioactive element into the human body. Nevertheless, in August of 2018, the CDC Immunization Safety Office posted a "fact" sheet that maintains that "Thimerosal in vaccines is not harmful to children," in spite of abundant evidence[29] to the contrary. The fact sheet parades their collection of CDC-controlled thimerosal-related studies ("conducted by CDC or with CDC's involvement") that it has used for years to hush-up thimerosal detractors.

Thimerosal is 49.55% percent ethylmercury by weight and is an organic mercury compound with toxicity comparable to methylmercury,[30] but ethylmercury is far more toxic to and persistent in the brain, where it has a propensity to accumulate as inorganic mercury,[31] with an estimated half-life of as long as twenty-seven years.[32]

All eight studies included in the CDC fact sheet involve lead or co-authors accused of fraud or known to have been involved in behind-closed-doors data manipulation or weighed down by serious conflicts of interest. Dr. Geier et all write: ➤

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> Thimerosal was not scrutinized as part of US pharmaceutical products until the 1980s, when the US Food and Drug Administration finally recognized its demonstrated ineffectiveness and toxicity in topical pharmaceutical products and began to eliminate it from these. Ironically, while Thimerosal was being eliminated from topicals, it was becoming more and more ubiquitous in the recommended immunization schedule for infants and pregnant women. Furthermore, Thimerosal continues to be administered, as part of mandated immunizations and other pharmaceutical products, in the United States and globally. The ubiquitous and largely unchecked place of Thimerosal in pharmaceuticals, therefore, represents a medical crisis.[33]

Manufacturers use thimerosal in some single-dose and multidose vaccines to impede bacterial growth during the manufacturing process even when it is not being used as a preservative. The CDC states that "when Thimerosal is used this way, it is removed later in the process" and only "trace amounts" remain (no more than one microgram per dose), which is extremely misleading given the known toxicity of mercury and some vaccines have as much as 25 mcg of mercury; but the FDA will obfuscate and state that is the same amount in a can of tuna fish, so nothing to be concerned about. Except this just brings to the fore the toxic load from eating fish, it does not placate concerns about mercury being injected into infants rather than orally ingested – indeed most of the mercury in fish is not bioavailable because it is ingested orally.[34] The FDA highlights the faux-science that will come out of compromised public health agencies.

Grandjean and Landrigan observed that the developing human brain is uniquely vulnerable to mercury and other neurotoxins, often "at much lower exposure levels than had previously been thought to be safe."[35] The authors also noted that developmental neurotoxicity occurs at far lower exposure levels than "the concentrations that affect adult brain function." Others have argued that there is no safe level of organic mercury.[36] One study showed that thimerosal diminished the viability of human cells in the lab at a concentration one-fiftieth that of methylmercury.[37] Vaccine injury deniers will state that ethylmercury disappears from the bloodstream more quickly than methylmercury – as if that means anything if you don't know where it goes after that. But we do know – it migrates quickly to organs and stays there.[38]

"No worries," the vaccine enthusiasts say, for the WHO's Global Advisory Committee on Vaccine Safety states that "no additional studies of the safety of [Thimerosal] in vaccines are warranted." Don't expect the WHO to state the reality: *"The ubiquitous and largely unchecked place of Thimerosal in pharmaceuticals, therefore, represents a medical crisis."*[33]

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Dr. Stoller is available remotely for medical consultations, including consults on addiction medicine. Website: www.hbotsf.org

Part 2 of Dr. Stoller's "The Denial of Adverse Event Risk Following Immunization" will be run only online with our April issue contents.

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Oxygen Metabolism

by Frank Shallenberger, MD, HMD

No one will argue that the most important substance by far that we take into our bodies is oxygen. And yet oxygen metabolism is completely ignored by our medical system. That's because it is still wrongly assumed that just because a person is breathing and his oxygen levels are normal, that all is well with oxygen metabolism. Nothing could be further from the truth.

The term "oxygen metabolism" refers to the process that occurs in our mitochondria in which oxygen is used to generate energy. Oxygen is just like every other nutrient we depend upon; *it's not just what we take in that is critical, it's what we utilize, i.e. metabolize.* Using a patented oxygen uptake assessment protocol that I will be describing later in this paper, I have been able to show that close to half of all men and women in their 30s already show a decrease in optimal oxygen metabolism.[1] And as they age, if nature is left to its course, this decrease will only get worse. So, let's talk about what oxygen metabolism is, how it is measured, what interferes with it, and most importantly, how it can be maximized.

All that oxygen you breathe in only does one thing: It finds its way into each cell. Once it is in the cell, it enters into one of the thousands of mitochondria in the cell. Mitochondria are tiny bubble-like structures in the cells. In the mitochondria, oxygen interacts with carbon molecules in glucose and fat to produce cellular energy. This is the energy that keeps us alive. If oxygen metabolism is efficient, we get optimal energy production. And, to the degree that it is less efficient, our cells are deprived of energy. And, that is critical.

Everything that goes on in our bodies is energy dependent. Think of oxygen metabolism as the accelerator pedal on your car. You can have a tank full of the best gas in the world, but if the engine is out of tune and cannot efficiently process the gas, you might as well get out and walk. Nothing works as well. So it is with oxygen metabolism. When it is inefficient, nothing works well. And, I mean nothing!

The nervous system, cardiovascular system, detoxification systems, musculoskeletal system, immune system, digestive system, hormonal system, regenerative system, reproductive system – every single one of these systems and the ones I did not list are 100% dependent on oxygen metabolism. That's why, when oxygen metabolism decreases these systems don't work as well, and the result is an ever-increasing vulnerability to disease, weakness, and the very process of aging itself.[2-6]

Think about it. Can you name one reaction in the human body that is not completely dependent on the availability of energy? Many reactions can occur in the absence of various vitamins and minerals and substrates, but nothing can happen without energy. Life itself and energy are synonymous. Couple this simple fact with the fact that oxygen metabolism declines commonly even in young persons, and you can begin to fully realize just how important it is for health and well-being.

There are two experimental studies that have been published that rather dramatically identify decreased oxygen metabolism as the primary cause of disease and aging.

In the first study mice were genetically manipulated to develop four times more mutations in their mitochondrial DNA than the control mice. This resulted in a greatly accelerated reduction in oxygen metabolism over their lifespan. The genetically altered mice had a significantly reduced lifespan compared to controls. Additionally, and perhaps even more importantly, they all aged prematurely. The authors concluded that the results provided a clear causative link between decreased oxygen metabolism and aging.[7]

In a second study, using NMR technology resting oxygen metabolism was determined in a cohort of mice, and the mice were followed over the course of their lifespan. Not surprisingly, there was significant genetic variation in their oxygen metabolisms.

And the researchers discovered that the mice with the most efficient resting oxygen metabolisms lived 36% longer than the mice with the least efficient metabolisms.[8]

Measuring Oxygen Metabolism

So, by now, I hope you are wondering what your oxygen metabolism is. Here's how you can find out.

Oxygen metabolism can be determined using VO2/VCO2 testing. This consists of wearing something like a scuba mask in which all the air you breathe in and out is measured for oxygen and carbon dioxide content. Optimal oxygen metabolism is characterized by a large amount of oxygen being consumed along with a small amount of carbon dioxide being produced. To the degree that less oxygen is consumed and more carbon

dioxide produced, oxygen metabolism is compromised.

The testing protocol takes about 40 minutes. During that time, a computer sorts out the breath by breath oxygen/carbon dioxide data; eliminates outliers caused by coughing, sighing, and irregular breathing; averages gas exchange pressures over 15 second intervals; and then inserts the data into algorithms that can determine the following: maximum oxygen metabolism (also known as aerobic capacity), resting oxygen metabolism, resting fat metabolism, and proper exercise zones. There are several other important measurements that are also determined, but in this paper I am only going to focus on these four most important measurements.[9,10] This method is the only way clinicians can evaluate oxygen metabolism in a reliable and consistent manner.

Maximum Oxygen Metabolism

The most important single measurement is maximum oxygen metabolism. Your ability to maximally metabolize oxygen, more than any other factor, is what is going to determine how long you live, how functional you are going to be in old age, and how resistant you are to disease. In essence, the primary goal of every practitioner interested in preventing disease and slowing down aging is to optimize maximum oxygen metabolism.

Telomeres last longer with optimal oxygen metabolism. Antioxidant systems work best with optimal oxygen metabolism. Senescent cells are decreased in the presence of optimal oxygen metabolism. The optimal function of every single aspect of health is completely dependent on optimal oxygen metabolism. And according to one review study, maximal oxygen metabolism, "is an independent risk factor for cardiovascular disease, cognitive dysfunction, and all cause mortality."[11]

When maximal oxygen metabolism is optimal, it indicates that given that person's genetics, their lifestyle and preventive medicine plan are working well, and no changes are needed. When it is sub-optimal, it indicates that something is missing.

Here is a list of the primary causes of decreased oxygen metabolism: decreased lipolysis (fatty acid breakdown), hypoglycemia, hypothyroidism, ischemia (impaired circulation), hypoxia (decreased oxygen levels), inflammation, toxicity, infections, stress, nutritional deficiencies, anabolic hormonal deficiencies, impaired methylation, decreased fitness, and medications. The practitioner must consider each of these factors to discover which ones are impairing oxygen metabolism. Only when those factors are treated and repeat testing indicates optimal oxygen metabolism is the job done.

Measuring and maximizing oxygen metabolism is the Holy Grail of preventive and anti-aging medicine.

Resting Oxygen Metabolism

Resting oxygen metabolism is the next most important measurement. It is a direct functional analysis of thyroid metabolism. This is particularly important because the diagnostic ability of thyroid hormone levels is limited. Many patients, particularly those over 50, have significantly depressed resting oxygen metabolisms in the face of completely normal thyroid testing.

Studies have repeatedly referred to the unreliability of thyroid testing.[12] When resting oxygen metabolism is below 90%, hypothyroidism is present even when thyroid testing is within normal limits. This makes resting oxygen metabolism the only reliable way to assess and monitor thyroid function. This is critical because thyroid is a major regulator of mitochondrial function. And an undiagnosed and untreated low thyroid status will impair and limit maximum oxygen utilization. This is why the study I quoted above found that the animals with the highest resting oxygen metabolisms lived 36% longer.

Resting Fat Metabolism

Resting fat metabolism is far more critical to overall metabolism than you would think. And although there are several factors that come to play in determining resting fat metabolism, the most common problem is excessive dietary carbohydrate. Carbohydrate intake completely shuts down fat metabolism due to its stimulating effect on insulin.

In 15% of the population this is not a problem because they are able to convert fat very efficiently into glucose in a process called gluconeogenesis. These people should be on a high complex carbohydrate diet. They are identified by having a high maximum oxygen metabolism in the face of a low resting fat metabolism.

However, in the remaining 85% of the population, eating carbohydrates not only suppresses resting fat metabolism, it also suppresses maximum oxygen metabolism. This group is identified by having a low maximum oxygen metabolism combined with a low resting fat metabolism. They should avoid carbohydrates. For a detailed explanation of the importance of resting fat metabolism and how it helps to determine who should and who should not eat carbohydrates please look at my YouTube video "Are You Eating Too Many Carbs?" (January 18, 2019; https://www.youtube.com/watch?v=WLYAS0ZVwAU).

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Cardiac Exercise Zones

The last measurement I want to discuss is cardiac exercise zones. I don't think that anyone will argue that high intensity interval training (HIIT) is one of the most important ways to optimize oxygen metabolism. But what is the best way to identify the most effective and safest cardiac exercise zones for a given individual? That's where VO2/VCO2 testing can be so helpful. It can also determine anaerobic threshold heart rate and recovery heart rate. This data can then be used to establish an effective and safe HIIT program for every person no matter how old or healthy.

And don't depend on formulas (220-age, etc.) to accurately determine your cardiac exercise zone. I published an experiment several years ago in which I was able to use VO2/VCO2 testing in 20 patients to show that the various formulas that are commonly used to establish proper exercise zones for HIIT are wholly inaccurate.[1]

So, what do you do when the maximum oxygen metabolism turns out to be less than desired? It's simple in theory, but it might require some time and investigation. In order to maximize oxygen metabolism, each of the various factors mentioned above that can impair oxygen metabolism must be evaluated. Thyroid, inflammation, toxicity, infections, stress, etc. must be addressed as is indicated in each case. The most influential factors in my experience are lack of aerobic fitness, undiagnosed hypothyroidism, excessive carbohydrate intake, heavy metal toxicity, deficient B-vitamins, and toxicity from pharmaceutical medications. Whether or not the interventions are successful can be determined with follow up VO2/VCO2 testing.

Conclusions

After analyzing the oxygen metabolism of thousands of patients, I can safely state that, except in rare cases, no one gets sick if they have optimal oxygen metabolism. There is good reason for this. A casual examination of the literature on mitochondrial function in various diseases and aging are undeniable; virtually every chronic disease is associated with decreased oxygen metabolism.[2-6] Measuring and maximizing oxygen metabolism is the Holy Grail of preventive and anti-aging medicine. Let me now conclude with a case study that illustrates this point.

The patient's name is Frank. I started measuring his oxygen metabolism back when he was 55. Each year was the same. He was in great shape. His oxygen metabolism was routinely 40-60% better than the average young man's. There was no way Frank was going to get sick with any disease with a metabolism that efficient.

But starting somewhere in his early 60s, Frank started to get over confident. He slacked off on his exercise schedule. His life became more complicated, and he became more stressed and less fit. Oh yes and by the way, he got five years older. Sound familiar?

Frank's oxygen metabolism started to drop. By the time he was 66 it had fallen 30%. It was still respectable for a 66-year-old, but nowhere close to his former glory. And then came the big tap on the shoulder.

When he was 67, it dropped another 50%. It was now, down to a level typical of a man his age – not good! Frank had lost his invulnerable status. If you haven't figured it out by now, Frank is me.

So, there I was at age 67, feeling and functioning great at every level, but knowing that unless I make some changes I might not be that way for long. Without that wakeup call I would never have guessed that I was going downhill. So, I started to clean up my lifestyle. I got more consistent with my supplements and exercise, I increased my thyroid dose enough to maximize my resting metabolism, and I decreased my stress load. Today, at 73 years old, I have an oxygen metabolism typical of a 35-year-old. I know my program is working, but I would not have known without the testing.

Readers can find practitioners who know how to analyze and treat oxygen metabolism on all of their patients at www.bioenergytesting.com. I look forward to the day when this procedure is routinely used in every anti-aging and preventive medicine clinic. My recommendation is that once your maximum oxygen metabolism is youthful, continue to monitor it every one-to-two years just so you don't become another Frank. Future adjustments are sure to be needed as you get older.

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Frank Shallenberger has been practicing medicine since 1973. He has developed and patented the first method using VO2/VCO2 analysis to measure mitochondrial function in a clinical setting known as Bio-Energy Testing® and has written two books on the importance of measuring and optimizing mitochondrial function. *Bursting With Energy* describes how decreased mitochondrial function causes aging. *The Type 2 Diabetes Breakthrough* describes how decreased mitochondrial function is the root cause of type 2 diabetes.

Dr. Shallenberger has been teaching ozone therapy to medical practitioners since 1991. He has authored two peer-reviewed papers on the use of ozone in clinical medicine. He has authored an instruction manual for doctors entitled, *The Principles and Applications of Ozone Therapy* and an instruction manual for lay people, *The Ozone Miracle*. He is the innovator of Prolozone® therapy, a method of eliminating pain and rejuvenating degenerated joints. He is the founder and president of The American Academy of Ozonotherapy. He is devoted to the prevention and treatment of aging and age-related diseases by improving mitochondrial function.

For more information visit www.antiagingmedicine.com.

Why Does Wikipedia Want to Deprive You of Acupuncture?

by Richard Gale and Gary Null

Progressive Radio Network

Although it is completely ignored by the mainstream media, all natural and alternative medical philosophies and therapies remain under constant attack in the United States, as well as in the UK, France, Canada, Australia and elsewhere. In addition to the pharmaceutical industry's profitable interests tied to our federal health agencies (FDA, CDC, etc.) to undermine natural healing, Wikipedia and an army of Skeptic healthcare mercenaries are also making every effort to deprive you of access to non-drug-based therapies, which lie outside their narrow paradigm of what qualifies as medicine.

As we have outlined in previous articles to counter Skepticism's, Science Based Medicine's (SBM) and Wikipedia's criticisms and assaults on complementary and alternative medicine (CAM), including homeopathy, naturopathy and energy medicine, sound science is clearly not on their side. The late astrophysicist Stephen Hawking noted, "The greatest enemy of knowledge is not ignorance, it is the illusion of knowledge." Hawking's statement accurately summarizes the dominant paradigm of medical materialism being promoted by Wikipedia. How often do we hear Skeptics and SBM advocates use repeatedly the ill-informed argument that natural healing modalities simply don't make sense or are implausible? And this is sufficient reason to discredit them? Such hypotheses, veiled in the fantasy of being valid conclusions, have no place in real science nor for substantiating any medical truth, especially to relegate all CAM therapies to the trash bin of "pseudo-science." In effect, non-scientific subjective opinions play an important role in SBM's gold-standard "scientific method."

Modern medicine's illusory self-perception about its reductionist view of the body, mind and health is largely due to the failure of today's conventional medical schools. Dr. David Sackett, the American-Canadian physician who pioneered evidence-based medicine (EBM) and founded its first departments at McMaster and Oxford universities, wrote: "Half of what you learn in medical school will be shown to be either dead wrong or out of date within five years of your graduation; the trouble is nobody can tell you which half. The most important thing to learn is how to learn on your own."[1]

As a result, speaking before a European Parliament conference convened to tackle the problem of rising disease epidemics and the failure of conventional medicine's response, British cardiologist Dr. Azeem Malhotra stated that "honest doctors can no longer practice medicine."[1] The epidemic of serious illnesses such as cancer, diabetes, obesity, Alzheimer's and dementia, autoimmune diseases, etc. is coupled with an equally dangerous epidemic of misinformed doctors and medical fundamentalists in the SBM community promoting questionable science and touting false accolades as the final voices of healthcare and the treatment of disease.

Wikipedia relies upon the Skeptics' treasure trove of biased medical research. Today this enormous body of literature, according to Dr. Malhotra, is plagued with biased funding of research for profit, biased reporting in medical journals, biased patient literature, biased media reporting, prevalent commercial conflicts of interests, and a gross failure to teach doctors how to understand health.[2] And now Wikipedia has become a contagion infecting its readership with these biases regarding patient health and safe, effective alternatives.

There is far more known about acupuncture than Science Based Medicine Skeptics want us to believe and that Wikipedia would permit us to know.

Traditional Chinese Medicine (TCM) has also come under Skepticism's brutal attacks on Wikipedia. TCM is a complete system, which includes distinct theories of human biology and disease, diagnostic methodologies, acupuncture and moxibustion, herbal medicine, dietary protocols, Qigong and other energy-based therapeutic techniques. Over the course of 5,000 years, it has developed and evolved into becoming the standard form of medicine practiced throughout Greater China, although in recent decades it has become increasingly interchangeable with and practiced alongside conventional Western medicine. Unlike modern Western medicine, TCM focuses primarily on identifying and treating the cause of an illness rather than relying upon a reactive treatment to relieve symptoms only. In this article, we will focus upon acupuncture, the most prevalent, controversial, and well-known form of TCM practiced in American clinics.

Wikipedia skepticism discredits TCM outright. "Scientific investigation," the encyclopedia states, "has not found histological or physiological evidence ➤

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for traditional Chinese concepts such as *qi*, meridians and acupuncture points. The TCM theory and practice are not based upon scientific knowledge." The entry also cites a flawed editorial in the respected journal *Nature* that accuses TCM as "fraught with pseudoscience" and that its treatments have "no logical mechanism of action."[3] Concerning acupuncture, Wikipedia relies upon the personal opinions of SBM's founder Stephen Novella, who calls it a "theatrical placebo."[4] Novella ignores positive outcomes from acupuncture clinical studies as nothing more than "false positives" or perhaps due to "biased study designs, poor blinding." This is an excellent example of the kind of psychological manipulation Wikipedia skepticism is best known for: suggesting ideas that are solely the subjective opinion of Wikipedia editors with no credible research to support it. It SEEMS to be the "placebo effect." Or there SEEMS to be "noise" within a study.[5]

Wikipedia doesn't offer an alternative theory or body of evidence to potentially substantiate acupuncture research's positive results. This is a common characteristic of Wikipedia skepticism and its efforts to promulgate a single reductionist model of medicine that denigrates and condemns natural and cheaper medical therapies that challenge its deceptive biases. When Wikipedia does acknowledge important medical research or studies confirming the effectiveness of CAM, it more often than not counters it with SBM's and Stephen Barrett's Quackwatch converse opinions. For example, citing a meta-analysis published in the *Journal of the American Medical Association* about acupuncture's effectiveness for treating certain kinds of pain, it is written off as having "negligible clinical significance." Or citing a Cochrane review noting the "high quality evidence" for acupuncture treating various conditions of pain, it is immediately countered with other cherry-picked studies promoting Skepticism's addiction to magically conjuring the "placebo effect" excuse.

As an aside, Skeptics and the SBM crowd convey little if any understanding about the more recent discoveries and theories for placebo and nocebo effects. Consequently their frequent misuse of the term. According to Dr. Fabrizo Benedetti, head of the Department of Neuroscience at the University of Turin in Italy and an internationally recognized expert in the placebo effect, "There is not a single placebo effect, but many, with different mechanisms in different diseases and in different systems." He also notes very recent experimental evidence that seems to indicate that certain genes are activated by certain placebo responses, such as "genetically controlled modulation of amygdala activity [in the brain] by the neurotransmitter serotonin, which is linked to placebo-induced anxiety relief."[6]

Wikipedia's entry for "Chinese Herbology" largely reproduces much of the same text, sometimes verbatim, found under "Traditional Chinese Medicine." Evidently, the same Skeptic editor or group of editors control the page. Chinese herbology is described as "fraught with pseudoscience" without a "logical mechanism of action." The page falsely argues that the research has "little or no rigorous evidence of efficacy."[8] Again, Skeptics are experts at sleight of hand and rational deception. And in the case of this past statement, an outright lie with respect to Chinese herbology. The actual study being cited from the *South African Medical Journal* only looked at African medicinal herbs and had nothing to do with Chinese botanicals. The South African study's abstract states, "We conducted systematic reviews of eight widely used African medicines and identified only one plant, *Pelargonium sidoides*, which has been extensively studied."[8] Hence the study's conclusion of "little or no rigorous evidence of efficacy." How this could have passed Wikipedia's editorial vetting process is astounding. Apparently, Wikipedia is perfectly fine with blatant distortion and misrepresentation of medical literature by whatever twist of the imagination necessary to advance Skepticism's SBM charade.

The South African study is an example of a common bait-and-switch ploy used by Wikipedia's Skeptic editors and is in direct violation of Wikipedia's own written editorial standards. Frequently research is cited or referenced that is unrelated or only distantly related to the subject in order to reinforce personal biases.

However, far more brutal than Wikipedia is the condemnation of acupuncture, Chinese medicine and practically everything that falls under the rubric of non-conventional medicine within the SBM community. What is immediately notable to people who visit SBM's primary website and read posts by its leading figures such as Stephen Novella, David Gorski, and Harriet Hall is a deep hatred and disdain for all health modalities that stand outside of their narrow belief system of what constitutes reliable medical practice. Typical of Skeptic writing, their words and circular logic are riddled with self-righteous indignation. For example, SBM outright denounces acupuncture as:

- A pre-scientific superstition
- Lacks a plausible mechanism (similar wording found in Wikipedia)
- Claims for efficacy are often based upon a bait-and-switch deception
- Clinical trials show that acupuncture doesn't work.[9]

Stephen Novella takes the Skeptics' illusion of medical knowledge and belligerent denialism regarding everything that can't be touched, heard or smelled to an even lower level:
Despite thousands of studies, there isn't a single indication for which real acupuncture has been shown to work to a high degree of confidence. At this point I would say that acupuncture should be abandoned as a scientific concept. It is a failed hypothesis that has added no real knowledge to our understanding of health and disease.[10]

Novella wishes us to assume he has thoroughly reviewed these "thousands of studies," which leaves us wondering when he has time to accomplish his university responsibilities at Yale. In fact, the National Institutes of Health PubMed database for peer-reviewed medical literature lists over 28,200 studies dealing with acupuncture, including many on the effectiveness of acupuncture in veterinary medicine. And in the words of Novella's SBM colleague David Gorski, "We write about acupuncture a lot here on SBM because it's a form of quackery that is arguably the most "respectable" and accepted among academic medical institutions and "conventional" doctors."[11]

Based on the latest available figures for acupuncture's use in the United States, a multi-institutional National

Health Interview Survey published in 2007 estimated that over 14 million Americans have or continue to receive acupuncture. Over a five-year period, its popularity has slowly increased by 2 percent.[12]

Acupuncture is based upon a whole systems model of human anatomy that is dependent upon the Chinese concept of *qi* or *chi* as a vital energy that pervades the cellular structure and is systemically interrelated with the body's bioactivity. It is complementary to the latest discoveries in systems theory, which lie outside the realm of SBM's competency. The theory of *qi* is not limited to Chinese medicine, but also found in various permutations and definitions across cultures, such as *prana* in Indian medicine and *elan vital* among the Stoic philosophers during the Classical Mediterranean period. Skeptics are correct in stating that without positing the existence of *qi*, acupuncture and other forms of Chinese medicine such as Tai Chi Chuan and Qigong have no foundation. The Skeptics argument is that *qi* simply doesn't exist. End of story.

One of the low points of SBM denial of real scientific endeavors, which goes to the heart of acupuncture, energy medicine, homeopathy and other therapeutic systems more closely aligned with quantum physics -- or what Paul Levy calls the "crown jewel" of the sciences -- is its unequivocal repudiation of the existence of a force outside of a mechanistic perspective of the human body.[13] Therefore Novella writes that "centuries of advancement in our understanding of biology has made the notion of life energy unnecessary....Within science, the vitalists lost the debate over a century ago. Without *chi*, there is no underlying basis for acupuncture as a medical intervention."[9] This fundamental fallacy in SBM Skepticism's gnarled reasoning and distorted reinterpretation of the history of biology goes well beyond the scope of this article because it takes us into a strange world where consciousness solely exists within the functions of neurobiology, neural synapses, and biomolecular activity. For this reason, we also find Skeptical culture entertaining the most hardened atheistic materialists. They share a cult-like mentality of exclusivity commonly found in extreme religious cults and fundamentalist sects. However, in the largely unconscious Skeptical worldview, life is utterly meaningless because every traditional medical system that has given meaning to human and cultural life for many millennia are deconstructed, mocked and tossed into the trashcan as mere superstition and foolishness. We are all in fact, according to the Skeptic catechism, nothing more than mechanical machines. You are analogous to the computer.

What Skeptics fail to comprehend, let alone consider, is the cornerstone of all quantum physics and science;

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that is, the world appears one way and exists in another. Consequently, Skeptics have remained stuck in the 18th century Cartesian universe that was later deconstructed by Einstein's law of relativity and quantum theories developed by Einstein, Max Planck, Niels Bohr, Werner Heisenberg among others. For Newton, a healthy human

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being was little more than a well-crafted clock. SBM's biomedical model is firmly grounded in Cartesian mechanistic thought, which remains a conceptual construct in modern medicine today. Consequently the current medical paradigm espoused by Skeptics should be properly labeled as mechanistic medicine. The Skeptics' definition of health is limited to the absence of disease. Although mechanistic medicine has much to offer, it nevertheless remains only a sliver of what can and should be known about health in relation to other scientific disciplines. And until conventional medicine can relate and benefit from physics and somatic psychology behind health and disease, it will continue to fail as epidemics worsen and new environmental illnesses increasingly appear.

"In every culture and in every medical tradition before ours, healing was accomplished by moving energy."

Dr. Albert Szent-Gyorgi

Scientific Evidence of Acupuncture Points and Meridians

Unquestionably, *qi* and its patterns of activity operating through meridians or channels and tubules traversing the body are perhaps the most mysterious concepts to support the validity of acupuncture; yet the general, conservative consensus is that *qi* and meridians mustn't exist because they cannot be observed or measured. Since Skeptics rely solely on the absence of direct proof for *qi* as the cause, or one cause, of an effect, they must also reject the existence of gravity since there is no solid proof of gravitation's existence as a "field" unto itself either. It is the same argument in both cases, although nobody can deny gravity's impact on our body.

Dr. Albert Szent-Gyorgyi, a biochemist and Nobel prize winner in medicine, is perhaps best known for his discovery of ascorbic acid. His work on cellular respiration and identifying the activity of fumaric acid later led to the important discovery of the Krebs cycle, the citric acid chemical reactions used by all aerobic organisms to release stored energy. Unlike today's conventional medical researchers and followers of SBM's reductionism, Gyorgyi delved into the world of quantum physics and biophysics, befriending Dr. Zoltan Bay, head of the US Department of Nuclear Physics in the 1950s. He noted that "In every culture and in every medical tradition before ours, healing was accomplished by moving energy." During the later years of his research, Gyorgyi focused on the role that free radicals played in the causes of cancer. His conclusion was that cancer is a problem at the biophysical level of molecular activity.[14] In short, he observed or intuited a non-measurable phenomenon that medical sages and healers have ascertained and known for thousands of years. However, with the enormous advances in modern technology to peek into the hidden worlds of the qualitative operations and causes underlying the quantitative effects of energy, there is no conclusive scientific evidence that *qi* and the meridians form the basis of acupuncture's movement of energy. This remains an area of biophysics still rich for future exploration and discovery. Nevertheless, there is far more known than SBM Skeptics want us to believe and that Wikipedia would permit us to know.

Biophysics continues to be a growing scientific endeavor revealing amazing discoveries in the body's energetic activities, yet it has yet to penetrate the walls of evidence-based medicine. Dr. Robert Becker, a pioneering researcher in electrophysiology and electromedicine at the State University of New York in Syracuse, was recognized as a leader in warning about the dangers of electromagnetic frequencies in high voltage power lines to human health. His research proved that our bodies hold direct currents of electrical charges that can be measured at the skin's surface.[15] This is analogous to what TCM contributes to the concept of *qi moving in the acupuncture meridians.*

In 2013, researchers at the Shanghai Institute of Applied Physics published their findings of clear visual images of acupuncture points with computerized tomography (CT) technology with synchroton radiation using state-of-the-art 3D imaging. Viewing both classical acupuncture points and other points outside the meridians, sharp anatomical distinctions were noticed. Acupuncture points showed "a higher density of micro-vessels and greater involuted microvascular structures," whereas non-acupuncture points did not show these properties.[16] Other technologies including magnetic resonance imaging (MRI), infrared, LCD thermal photography, and other CT imaging technologies have added further information about acupuncture points' and meridians' unique structures.

Another study coming out of China using an amperometric oxygen microsensor found and measured oxygen pressure variations at different locations on the wrist, which contains several critical acupuncture points in the TCM system. After looking at the photo images published in the study, the acupuncture points for the lung, pericardium and heart meridians are clearly recognizable.[17] Moreover, the measurements were taken without needles, therefore the points were observed in their natural inactive state absent of any stimulation.

In several later studies, the physical location of acupuncture points revealed "vessel-like structures made of calcitonin gene related peptide (CGRP) neuro-fibers at the acu-sites. CGRP accordingly plays a crucial role as a neurotransmitter and modulator in the central nervous system and as a vasodilator that is physically located at acupuncture points. The discovery was made using a laser confocal microscope. The importance of this finding is that not only did it locate certain acupoints, but it identified a biochemical mechanism that supports acupuncture's efficacy on human health.[18,19] This may biologically explain why acupuncture is so effective in the treatment of migraines.[20]

There are many other laboratory studies proving the existence of acupoints and some of their biological properties; however, another noteworthy body of research conducted by Dr. Morry Silberstein at Curtin University of Technology in Australia found that acupoints display a unique neuroanatomical structure containing both myelinated and unmyelinated afferent nerve fibers that are nowhere else found in the human body. Using confocal light microscopy, Silberstein concluded

that "acupuncture may incise afferent unmyelinated axonal branch points, disrupting both neural transmission to the spinal cord and crosstalk along meridians while simultaneously stimulating larger, myelinated afferents, thus explaining both the immediate and long-lasting effects of acupuncture."[21]

In a more recent 2017 study conducted by LA BioMed, one of world's foremost independent, non-profit research institutes on the UCLA Medical School campus, researchers discovered that acupuncture when accompanied by heat (the practice of moxibustion in TCM) elevated nitric oxide levels in the skin at the point sites. Nitric oxide is associated with the release of "analgesic or sensitizing substances" while increasing blood flow.[22]

Although TCM relies upon the idea of *qi*, which is not accurately translated into Western scientific terminology, the research is clear that acupressure points and meridian channels exist and are associated with biochemical activities. Moreover, underpinning our body's biochemical events are electrical changes along certain patterns/lines or meridians that can be detected with modern scanning and imaging technologies. Unlike conventional medicine, which holds no essential value for the prevention of disease, if a condition can be detected at an energetic level before developing into a full-blown illness, then reversing the cause of a potential pathology can start much sooner and promises to be far more effective in sustaining health than conventional drug protocols.

For over half a century, considerable laboratory research has been conducted to try to physically identify the meridian channels of *qi* that serve as the anatomical map in TCM's medical system. Back in 1991, Russian scientists led by physicist Dr. Kaznacheyew at the Institute for Clinical and Experimental Medicine in Novosibirsk in the former Soviet Union reported finding light conductivity traveling beneath the skin's surface layer and these light channels only corresponded to TCM's meridian lines. The study employed a photometric unit magnified by a photoluminescence microscope with a photomultiplier. It is worth noting that Soviet scientists customarily held an honest curiosity to explore biological phenomenon associated with medicine and health that laid outside the conventional medical model. Unlike the US, the integrity of Soviet medical research, regardless of how flawed some of its methodology may have been at times, was never jeopardized by private pharmaceutical commercial interests. In fact, the entire field known as "light medicine" largely originated in the USSR.[23]

Fourteen years later, using infrared technology to map the body's biophotonic spectral range after lightly stimulating acupoints, Dr. KP Schlesbusch at the International Institute of Biophysics in Neuss Germany identified "light channels" that appeared identical to the meridians in TCM medical theory. His conclusions stated that "it is likely that living matter is not in the ground state but permanently electronically ➤

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excited."[24] Years of research on mapping and measuring meridian functions at the bioengineering department at Tatung University and Taipei Medical University in Taiwan concluded that "meridians are open channels of interstitial fluid seems to be accepted based on evidence-based research." The hydrodynamic of waveform interstitial fluid flow of the meridians and acupuncture points could explain the electrical currents, acoustic and thermal responses, optical transmissions, and isotope passages in the meridians."[25]

Contrary to SBM screeds, according to the National Institutes of Health, acupuncture has been shown to be effective either alone or in combination with conventional medical practice for treating nausea caused by surgical anesthesia and chemotherapy, dental pain, addiction, headaches, menstrual cramps, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, asthma and may also help with rehabilitation after a stroke.[26] Johns Hopkins University School of Medicine additionally lists gastritis, anxiety and depression, insomnia, male and female infertility, sciatica, neurogenic bladder dysfunction and Parkinson's, bronchitis, prostatitis, and impotence.[27] In 2012, Memorial Sloan-Kettering Cancer Center conducted a meta-analysis involving almost 18,000 patients and concluded, "Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo."[28]

Another example. Dr. Richard Niemtzow, Editor-in-Chief of the peer-reviewed journal *Medical Acupuncture* developed "Battlefield Acupuncture" that started to be taught to physicians deployed to Afghanistan and Iraq in 2009. The quick insertion of tiny semi-permanent needles in specific acupoints provides immediate pain relief to wounded soldiers. According to Niemtzow, a consultant to the Surgeon General of the Air Force, "this is one of the fastest pain attenuators in existence.... The pain is gone in five minutes."[29] Unfortunately, Wikipedia and its experts in the SBM Skeptic community believe all of this is nonsense and proves TCM's motivation to scam patients. Gorski calls Niemtzow's battlefield acupuncture "a zombie that wouldn't die."[30]

The good news is that acupuncture is rapidly become more widely accepted in conventional clinical institutions and hospitals. "I think the benefit of acupuncture is clear, and the complications and potential adverse effects of acupuncture are low compared with medication," says Dr. Lucy Chen, a board-certified anesthesiologist, specialist in pain medicine, and practicing acupuncturist at Harvard University-affiliated Massachusetts General Hospital. In Western medical terms, Chen finds that acupuncture adjusts our neurotransmitters, hormone levels or our immune system.[31]

Conclusions

As we have noted repeatedly in this series, Wikipedia has aligned itself with today's far right of medical conservatism represented by SBM Skepticism. Psychologically, conservative thinking fails to deal with complexity thoughtfully and constructively; and therefore, it is limited to judging the world within a tight-knit spectrum of opposition, likes and dislikes, good and bad.

While working in the laboratories at Woods Hole, Dr. Szent-Gyorgyi witnessed a polarity and division within the larger scientific community he had worked in for over five decades. He realized that true scientific discovery "must be, by definition, at variance with existing knowledge." In an article written for the publication *Science* in 1972, he noted that the scientific status quo was diametrically at odds with this standard of science. He quotes an old saying that "a discovery is an accident finding a prepared mind."[32] Skeptics are far from having "prepared" minds and make every effort to claim that such a mind doesn't exist, only their linear rational thinking. Identifying with those Gyorgyi called "scientific dissenters" – those with the fortitude, curiosity and courage to reach out towards "the fringes of knowledge" and beyond the arameters of the dominant scientific culture – he directly challenged scientists who resist threats to their cherished beliefs. The latter group he called Apollonians, researchers who were only concerned with strengthening and perfecting their paradigm.

The followers of Apollonian medicine usually receive the most grants and funding, win the support of bureaucrats, and hence their undeserved influence and dominance over medical discourse. Scientific dissenters, on the other hand, those who Gyorgyi called Dionysians, relied upon "intuition and [were] more likely to open new, unexpected alleys of research." He also noted that the future of our species will depend upon scientific progress, and it will be the Dionysian scientists and practitioners, those who don't shudder in fear and dread over other medical disciplines that they erroneously perceive as enemies, including TCM, homeopathy, energy medicine, etc., who will assure the progress of science.[32]

Another example of SBM's Apollonian character is their sharp criticisms against medical schools introducing CAM therapies, including acupuncture, into their curriculum. However, what most frightens them is that the medical establishment's gradual acceptance of CAM will increase funding for further research into the mechanisms for how and why CAM is successful. Nevertheless, although SBM and Wikipedia are fighting a losing battle against the advancing tides of scientific and medical discovery and exploration, their influence should not be underestimated or taken for granted. Despite the wonderful advances in modern medicine, particularly in better understanding the body's biology, public satisfaction with conventional medical practice continues to erode rapidly. There are many reasons, but perhaps one of the most realistic ones is the enormous disparity between cost of healthcare and the lack of its effectiveness to actually cure diseases. Moreover, mechanistic

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medicine's adverse effects are frequently more life-threatening than the cure. Perhaps another failure at a more humanistic level is that SBM's mission is to turn medicine into a hard, cold science based upon biochemistry and completely absent of any philosophy of life, which has served as the underlying premise of traditional medicine, especially TCM and acupuncture, for thousands of years.

SBM has become the expression of a narrowly-defined scientific ideology claiming an authoritative, religious-like status that philosophers and renowned, pioneering scientists have warned about for over a century. And the greater danger is that SBM's leaders are not content with simply debating the evidence for or against CAM therapies. Rather, they hope to influence policy, and under an SBM regime, medicine and the future health of the public will rapidly descend into a Dark Age of totalitarian healthcare, more illness and iatrogenic deaths. And sadly, Wikipedia is all too willing to be SBM Skepticism's most popular mouthpiece.

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Healthy Lifestyle Trends for a New Decade: 2020

by Nooshin K. Darvish, ND, FICT, ABAAHP

As we enter a new decade, I'd like to share some thoughts about health and lifestyle trends that I believe will help us maintain our wellbeing and promote a thriving longevity. We live in an era where self-care and self-health knowledge is encouraged. Though social media and the internet provide a slew of self-health information, albeit inaccurate at times, an environment for independently investigating truths and a mindset to think out-of-the-box, both contributing to societal and individual advancement, have been created. During the last decade, through increased research on preventative and alternative health, we have begun to prove the efficacy and possibilities of nature cure and naturopathic medicine for wellbeing, longevity and regeneration. As we move into 2020, I believe we will continue to implement most of this knowledge for the betterment of our health, for stress reduction, and for keeping up with the demands of our modern-day high-tech society.

Back to the Basics

We live in a world of dualities, sometimes complementary and other times seemingly contradictory, with a variety of choices creating extraordinary complexity that impact our health; we yearn for simplicity in our health care and want good health. Most of us believe the more we lead and master our own healthcare through self-prescribing and prevention, the simpler our future health and the healthier we will be. And in many ways, this modern-day belief system is true, based on the recent research on epigenetics, which states that our environmental exposures and choices play a large role in switching a gene on or off. Perhaps, incorporating some of the basics of the period before the advent of modern-day prescription drugs may be just what we need to turn on the genes we want, turn off the ones we don't, and promote health, longevity, and simplicity. Therefore, my recommendations for re-establishing our health, reducing disease risks, and improving quality of our lives during the next decade means going back to the basics.

Plant-Based Diet

Our anatomy and its function, for instance, our teeth, mouth, tongue, and digestive tract, most efficiently conform to eating a plant-based whole foods diet. Our awareness of the damaging effects of the Standard American Diet (SAD) with its nutrient-poor and highly processed foods, and its impact on our environment, is forcing us to adopt new ways of growing, preparing, and eating foods.[1] As we become wiser and more knowledgeable, we are gradually turning to adopting an organic plant-based whole foods diet as the best way to regain not only the health of our planet but of our human species.[2,3] Research shows adoption of plant-based diet improves our health and increases longevity, reducing risks for heart disease, diabetes, cancer, and more.[4]

Current fads of the keto and paleo diets of the past decade have their benefits of temporarily shifting metabolism and physiology with short term usage of four-to-six weeks. However, their negative effects on insulin resistance, acidity, and inflammation with the use of such diets long-term (greater than 3 months) are beginning to prove to be devastating, increasing chronic disease risk.[5] We are learning that a whole foods plant-based diet provides the nourishment our bodies and brains require for healthy metabolism and optimum function in a world that is bombarded with chemical, electromagnetic, and emotional toxins.[6]

Fasting

Fasting, for centuries throughout most religious and cultural practices, has been a method of purification and cleansing for spiritual and physical wellbeing. During the last decade, research focusing on its physiological benefits, its role in metabolic modification, and its ability to extend longevity while reducing heart disease and diabetes risks, has helped us experiment further.[7-10] As we move through the next decade, I believe we will learn even more about the effects of fasting on wellbeing, disease prevention and treatment, as well as on our happiness – and, perhaps, implement it more aggressively into our daily routines.

Hydrotherapy

We are beginning to revisit the hot and cold therapies of the ancient cultures, where bathhouses and hot springs were prescribed for the treatment of many kinds of conditions. Hot and cold therapies – using various temperatures of water, infrared sauna, cryotherapy, exercise in cold rooms alternating with hot temperature rooms, and other forms of water therapies – are possibly making a comeback as we learn more about the physiological benefits of such therapies.[11-20]

Vitamin Infusions

With the complexity of our lives and the stress it poses on our bodies and gut, along with the recurrent use of pesticides in our foods, antibiotics, and chlorinated water, most of us have damaged guts with an altered microbiome. Such damage results in nutrient malabsorption and systemic inflammation, leading to nutrient-deprived cells, which promote disease. Intravenous vitamins, minerals, and amino acids bypass the gut, providing direct access of nutrients to our cells and organs. Direct nutrition to our cells helps calm the inflammation, improves cell function and energy production, and promotes cellular regeneration. Vitamin infusions to provide direct nutrient access to cells for recovery, cell regeneration, detoxification, immune system support, prevention and treatment of certain conditions will be key to helping us keep up with the multitude of information and stressors our environment continuously poses.[21-24] I believe we

will see more consumer direct access to such infusions in a spa-like setting, empowering consumers to take more control of their own health.

Oxygenation Therapies

Oxygenation and ozone therapies have been available in Europe for decades. In recent years, such therapies have been gradually making their way to North America. The initial European medical research focusing on understanding the effects of ozone therapy on healing the skin, resolving infections and chronic inflammation, improving memory, strengthening the immune system, stimulating stem cell regeneration, and reducing formation of diabetes, heart disease, and cancer is compelling and exciting.[25-30] As superbugs and their resistance to modern anti-microbial drugs become more prevalent, medicine must turn towards new methods of treatment. One of those methods, I believe, will be ozone and different forms of oxygen therapies. So keep an eye out for various ozone and oxygenation therapies, also known as bio-oxidative therapies.

Regenerative Medicine

During the past decade, a surge of research on a new field of medicine called regenerative medicine has been providing us with information about the healing potentialities of our own cells. We are just at the embryonic stage of learning more about the healing power of our cells – such as platelet-rich plasma, stem cells, and exosomes – to regenerate tissue and to fight disease and infections, as well as to slow aging and prevent disease while optimizing function. The possibility of such treatments used routinely by doctors and their availability as home kits, using cells from our saliva, urine, hair, and blood to self-treat, may not be too far away from our future reality.

Medical Oneness

For the past decades, our experiments with prescription medications and surgeries, on one hand, and with energy medicine, acupuncture, homeopathy, quantum physics and the role that the intangible and the unseen plays in healing, on the other hand, has created disunity and confusion. Perhaps, we have failed to recognize that none of the medical or healing systems by themselves have one hundred percent answers for every disease and condition. Each has a wisdom. Each has a role in helping heal as well as prevent disease and promote wellbeing. As a result of 25 years of practicing medicine, I have learned that the integration and balance of each system in a personalized manner for each patient, provides a better outcome than either one alone. I hypothesize that as medicine progresses, a new medical system will evolve, one that combines the best of each, into a "medical oneness."

Spirituality

Because in essence we are spiritual beings, our draw towards spiritual practices, which unite us, naturally is becoming stronger. Practices involving prayer, elevated and meaningful conversations enlightening our souls and minds, and meditation – which allow us to access the mysteries of the world and the source of innovation and advancement – help strengthen our bonds of friendship and unity, bringing us closer together and creating healing.[32-34] Acts of service and giving to others are another way to elevate our spirits while instilling wellbeing into our cells.

From ME to WE

Spiritual practices, as mentioned previously, help us move away from the ME era to the WE era as we begin to realize the benefits of working together in unity and acknowledging the beauty and sacredness of our diversity. With the increasing numbers of interracial marriages, the individual races are gradually dissolving, and a new one human race has begun to evolve. Ultimately, at an intuitive level, whether we like it or not, we are moving towards the oneness of our human race. Perhaps, sooner than later, we will recognize that the "world is but one country and humankind its citizens."

Our Human Destiny

For most of us, our ultimate human destiny is to live a fulfilling life of joyfulness through achieving our potential and feeling connected and at peace with others and ourselves. Perhaps, one approach to achieving such wellbeing is to become in alignment with nature, through daily practices of getting back to the basics of using plant-based foods, hot and cold waters, oxygen therapies, vitamins and minerals, regenerative therapies, and spirituality as we aim for unity and a simpler, more balanced lifestyle and optimum wellbeing.

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Nooshin K. Darvish, ND, FICT, is a licensed naturopathic physician, fellow in integrative cancer therapies, and Lyme-literate physician. She is one of the very few physicians who completed a two-year medical residency in naturopathic family medicine at Bastyr University. For over 20 years, she has specialized in diagnosing and treating chronic diseases including Lyme disease, cancer, and neurological disorders, using an integrative and noninvasive approach. Dr. Darvish blends the best of Western, Eastern, natural, bioenergy, functional, and anti-aging medicines to diagnose and create effective evidence-based individualized treatment plans. She trains medical and naturopathic doctors nationally and internationally in integrative and holistic medicine. She is the founder and medical director of Holistique Medical Center in Bellevue, Washington. For more info, please visit www.DrDarvish.com or e-mail info@DrDarvish.com.

Healing with Homeopathy

by Judyth Reichenberg-Ullman, ND, MSW
www.healthyhomeopathy.com

Why We Need Homeopathy More Than Ever Before

Homeopathy Then and Now

This is a critical time in the history of homeopathy in the US. Certainly not the first. Ten years short of century ago, homeopathy was virtually eliminated in this country when the Carnegie Foundation hired Abraham Flexner to "upgrade" the standard of medical education. At that time, one of every five-to-six MDs practiced homeopathy. The homeopathic medical colleges at that time did not meet Flexner's standards. This transformation emphasized scientific knowledge and established the "biomedical model" as the gold standard for medical training. The homeopathic medical colleges of the time lost their funding. From that time, a limited number of renegade physicians and dedicated mothers committed to homeopathic self-care for their children; and homeopathy went underground. There continued to be a relative handful of MDs and NDs in the US who carried on the tradition of homeopathy and nature cure, while it continued to flourish in Europe and India.

In the late 70s-early 80s, at the time I entered Bastyr University, George Vithoulkas, a Greek engineer, spearheaded a resurgence in homeopathic education, of which I and some of my colleagues were the lifeblood. The epicenter of this movement in the US was the Hahnemann Clinic in Berkeley and, subsequently, Hahnemann College (both names after Dr. Samuel Hahnemann, the brilliant founder of homeopathy). Dr. Hahnemann synthesized, in the late 1700s, various tenets of healing, dating back to Hippocrates (considered the founder of medicine) from 460 BC, and his own experience as a physician and medical translator of seven languages. The International Foundation for Homeopathy (IFH) in Seattle, of which I was ultimately the president, taught classical homeopathy to many licensed healthcare practitioners and sponsored the popular annual homeopathic case conference for professionals.

Homeopathy is a tough pill to swallow for many adherents of conventional medicine. Like acupuncture, it is a complex system of energy medicine. But it has proved very difficult to get funding and publication of homeopathic research, and there is much opposition to recognizing a form of medicine that, in many ways, flies in the face of conventional biomedicine. A recent film, *One Drop Homeopathy*, tells the story of how the deck is stacked against the funding and accurate reporting of homeopathic studies. The UK, which has been a bastion of homeopathy, including NHS funding and strong support from the Royal Family, is now at severe risk. Homeopathy was recently removed from the medical and veterinary curricula in Spain. The vibrant atmosphere of homeopathic study in Germany and the Netherlands has waned. Remedies continue to be available in pharmacies throughout France, but only in low potencies.

There was a threat to the continued availability of homeopathic remedies in the US in 2015, but all of the homeopathic medical, pharmaceutical, educational, and other institutions formed a united front to educate the FDA. The result was a continuation of the permissive stance for the availability of homeopathic remedies in the US. This is in significant danger at the moment. Sixteen homeopathic organizations in the US recently sent us a letter of alarm, which we and others have forwarded to as many people as possible. (This article will not be published in the *Townsend Letter* until April.) We are requesting, as a consortium of 16 homeopathic organizations in the US, a 180-day extension before any action is taken. The worst-case scenario would mean that all homeopathic remedies could potentially be eliminated from the marketplace, and possibly from prescribing physicians, as of January 1, 2020.*

Why is all of this happening now? I can only say that the pharmaceutical industry loses a fair amount of money to natural remedies in this country – pennies compared to competition from nutritional supplements, but apparently many injectables used by complementary medical docs are also on the chopping

*FDA extended its comment period until March 23, 3030, an extra 60 days instead of a hoped-for 180-day extension (InsideHealthPolicy.com; January 7, 2020).

block. Imagine our country with no natural healing products being available and the only alternative being conventional pharmaceuticals. This is not beyond the realm of possibility.

My intention in this article is, beyond sounding an alarm bell for the availability of homeopathic remedies, reminding you readers exactly how *homeopathy is unique, irreplaceable, and a one-of-a-kind healing art.*

There Is No Other Form of Healing Like It

How Dr. Samuel Hahnemann managed to synthesize the previous healing approaches into one unique healing art that would use any substance in nature for individualized healing is for me, a homeopath of nearly 40 years, nothing short of miraculous! There are many other remarkable healing modalities available, but *NONE* that has organized literally thousands of unique members of the animal, plant, and mineral kingdoms into a single system. The array of substances that, epitomizing Hippocrates, do no harm, in addition to the other features of homeopathy is simply unique. There is no other healing modality that could take its place if it were not available in the US. Tell me one other substance you could give to a desperate, screaming baby in excruciating teething pain, demanding to be carried constantly by the mom, that would work as well as *Chamomilla*. A lovely plant with white flowers and a bright yellow center that grows all over Europe and in much of the US. We are not talking about a tincture, but rather little white pills that taste good, are easy to administer, and – see the next point – have no side effects!

What Other Medical Intervention Does No Harm?

A couple of times over my nearly four decades of practice, I've gotten a call from an alarmed patient whose toddler had just swallowed a bottle of homeopathic pills. No problem! Unless it were the right remedy for that child, it simply wouldn't have an effect. And, if it *were* the right remedy, it could only help, not hurt. In this era of iatrogenic illness and death, where medications may be more harmful than the reason for which they are prescribed, a type of natural medicine that is not at all harmful is nearly inconceivable! Even herbal preparations come with their list of possible side effects or interactions with conventional drugs, though they are generally much safer than their pharmaceutical counterparts. How is it possible to claim that homeopathic remedies have *nothing in them* and, at the same time, claim that they are dangerous? Anyone who understands how homeopathic remedies are prepared by diluting the original substance dozens or hundreds or thousands of time, would find the accusation that they are dangerous impossible! Yes, remedies *can* be made from a substance that is dangerous or poisonous in its crude form, such as strychnine or arsenic. But, when diluted as described above, there is nothing material left to cause harm. We are talking about *energy medicine.* About the energetic pattern of the original substance that has been carefully studied and proved to have certain healing properties.

Homeopathic Care Is Highly Individualized

There are 100+ antibiotics, three FDA-approved antiviral flu drugs, a dozen or so types of antihistamines, five groups of immunosuppressive drugs, seven classes of antidepressants, and about 20+ antipsychotic drugs. There are over 5000 unique homeopathic remedies and many thousands of natural substances not yet prepared homeopathically. What does this mean? That there is likely a homeopathic remedy to fit each person, or nearly so, if the homeopath knows how to discover which remedy is needed. Of course, tens of thousands of substances are potential homeopathic remedies, but not yet proven. This is what makes homeopathy a lifelong study and why it makes sense to find a practitioner with a fair bit of experience under her belt! Doesn't it make sense that humans (and other sentient beings) are unique and would not benefit from the same medicine or drug as the next individual who is different in so many ways, despite a few shared symptoms?

With my patients, I find that the one well-chosen homeopathic remedy (*similimum*) for their particular cases often remains unchanged for years, This is possible, using the *Sensation Method* of Dr. Rajan Sankaran, because I am looking for the single remedy, out of over 4000, that matches all of that individual's symptoms. Not only the symptoms, physical, mental, emotional, but the *state*. It is too complex to explain in a few sentences, but basically, we are looking for the *thread* that runs through the case from birth, or childhood, to present time. We match that state to a mineral, plant, or animal substance prepared homeopathically. When the patient discovers what the remedy is, they may realize that they have had a curious affinity for it throughout their lives – consciously and in dreams. And the effects on the patient of being given that particular substance, repeatedly, in a homeopathic form, are often dramatic! Much more profound than what is possible from a conventional drug, an herb, or a supplement. When I explain to the patient what it is that I have prescribed and why, they are often amazed!

Homeopathy Can Be Used for First Aid and Acute Care with Little Training

We wrote *Homeopathic Self Care: The Quick and Easy Guide for the Whole Family* over 20 years ago for the public. It is filled with practical tips about how to use the most common remedies for about 70 first aid and acute conditions. We wrote it for those with no prior experience using homeopathy, but it is so useful that I still use it as a reference after nearly 40 years

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in practice. I invite, even challenge, anyone new to homeopathy to use this book and tell me the remedies don't work! Impossible! Nearly anyone who has ever used homeopathy has heard of *Arnica* for trauma and bruises. And most have a story of how it has worked for them or for someone they know. I could tell you dozens, hundreds, of success stories – not for chronic conditions prescribed by an experienced homeopathic practitioner but using a little kit just like ours, or any other, for conditions like insect bites, acute diarrhea (yes, including *Giardia*), ear infections, cold and flu, shock, hemorrhoids, acute grief, hay fever. I could go on and on. What other form of natural medicine or pharmaceuticals is this easy to use and as effective?

A Homeopathic Pharmacy Is Highly Portable

Our kit contains 50 of the most commonly used remedies. Some contain 30 or 100. As homeopathic doctors, we carry with us a compact, leather kit with over 300 tiny vials. Kits are lightweight, compact, and can be stuffed into a suitcase, backpack, purse. The pills and vials are tiny – much smaller than a bottle of prescription medication or even a nutritional supplement. We tell folks, "Don't Leave Home Without It" about our kits, but this is true no matter which kit (a virtual travelling pharmacy) you have on hand.

Homeopathy Is Affordable and Remedies Have No Expiration Date!

Healthcare in the US and elsewhere is unaffordable, plain and simple, for many. Scandinavia and some other countries have an enviable safety net for healthcare, at least for conventional treatment and medicine. Homeopathy is wildly popular in India, Why? Because there are homeopaths everywhere there, the remedies are practically free (or included in the visits), and it works! Homeopathic training programs in Haiti and Africa have grown in popularity and empower local practitioners to use the remedies virtually free of cost.

Over-the-counter homeopathic remedies, or kits, are very inexpensive. Kits generally cost $150 maximum and individual remedies cost under $10. Regarding constitutional care with a homeopathic professional, I have run across only a handful of professional homeopaths who I feel charge exorbitant rates. My fees, for example. are comparable with other homeopaths with my training and experience. The first year of appointments every six weeks, following the initial 90-minute appointment, costs less than $1500, and may be covered by insurance. The cost of the remedies is maximum $200/year. And this is for a homeopathic doctor practicing privately with nearly 40 years of experience!

Homeopathic remedies cost a fraction of nutritional supplements, over-the-counter herbal preparations, and, of course, prescription medications. And homeopathic remedies do not expire! Yes, you heard that right! Once you buy a kit, it will last a lifetime and you can simply replace the *Arnica* from the manufacturer!

Homeopathy Is an Effective Complement to Emergency, Hospital, and Conventional Care

In India, where we have studied homeopathy extensively, homeopathy is considered a vital and invaluable complement to pharmaceuticals, even in emergency medicine. Our Indian homeopathic mentors treat the most serious chronic and acute diseases, often with referrals from their allopathic colleagues. The results, which we watch by video in seminars, speak for themselves. I have, only on rare occasions, had the opportunity to give remedies to hospitalized patients. But, how amazingly effective homeopathy could be, as it is in India, for patients in urgent care or with drug-resistant conditions, along with the appropriate conventional care. This could not only reduce side effects and prescription drug mistakes, but it could reduce the cost of hospital stays and speed post-hospitalization recovery.

Illness and Death Due to Pharmaceutical Drugs and Medical Mistakes Is Enormous

I could cite countless statistics about the horrific effects of iatrogenic (illness caused by medical intervention). But you readers are sophisticated enough to find this information online, and there are more citations than I could possibly include. You are well aware that treatment for infections suppresses and can even lead to death. Antibiotics, in many cases, are no longer cost-effective even for the manufacturers, leading some pharmaceutical producers to go bankrupt, and leaving patients with antibiotic-resistant disease at risk of death. I have yet to hear of any death, ever, from homeopathy. It is not possible since they are so gentle due to serial dilution.

Homeopathy Works at the Level of the Vital Force and Can Reverse Symptom Suppression

I do not need to teach readers of this column that conventional pharmaceuticals and treatment can *suppress* disease rather than heal. For an incredible example, I refer readers to my previous *Townsend Letter* article: "Homeopathic Chelation of Methotrexate" (January 2018) . One of the brilliant effects of homeopathy is called the "return of old symptoms." This means that, after being given the *simillimum* (most exact) remedy, the patient may relive the exact symptoms (s)he experienced in the past, often in the reverse order of which they presented originally (*Herring's Law of Cure.)* What does this say? That the imbalance in the vital force was suppressed, driven deeper, rather than cured. Suppression results in a deeper level of imbalance or dis-ease, than the patient had in the first place. This is possible because there is a cellular memory which stores the pattern of the disease. How truly amazing that this memory can be triggered, and subsequently released, after being given the correct homeopathic remedy!

Homeopathy Removes Limitations to Freedom

One of my introductory books to the subject of homeopathy, which I read in 1979, during my first year at Bastyr, was *The Science of Homeopathy* by George Vithoulkas, my earliest teacher. Homeopathy, he explained, removes the limitations to freedom on the physical, mental, and emotional levels. This leads to increased energy and relief of pain and physical limitation, clarity of mind; and greater emotional balance and

happiness. Very few other forms of healing can claim such a far-reaching effect. Conventional drugs are prescribed to relieve physical pain and suffering, psychiatric medications to reduce depression and anxiety, but how many pharmaceuticals do you know that truly heal mind, body, and emotions?

Homeopathy Is an Effective Response for Refugees and Migrants Worldwide

At this time in history, when there is a migration of millions forced from their homes and homelands, with virtually no possessions and luck to escape alive, drastic healing measures are required. These individuals and families have no money and suffer terrible hardships on all levels, including homelessness and the grief of having lost those near and dear. This is where *Homeopaths Without Borders*, a group of heroic volunteers, steps in to assist in medical emergencies and close the most desperate health care gaps https://www.hwbna.org/ First-aid and acute homeopathic care is ideal for these homeless, penniless, traumatized individuals and families. With a bit of training, a small homeopathic first-aid kit, and an open heart, homeopathic miracles can and do occur regularly. I am not aware of homeopaths helping Latino refugees on the US/Mexican border, and I doubt, from what I have read, that it is permitted. But what a powerful healing gift it could provide to these families and children. There are wonderful remedies for shock and fright (*Aconite),* grief (*Ignatia),* and for the other conditions these traumatized folks are facing.

Homeopathy As an Intervention for the Environment

There is a little-known, but brilliant, book, *Homoeopathy for Farm and Garden* by Vaikunthanath Das Kaviraj, a bonified character, who found homeopathy in the 70s when no other form of healing could cure his serious illness; he eventually passed a couple of years ago. "He began his work with plants in Switzerland in 1986 when a friend suggested he try treating an apple cordon that had developed a virulent bright red rust. To everyone's surprise, *Belladonna* cleared the rust and left a much better-tasting apple than that tree had produced up until then! This experience inspired the years of research in Australia and Europe that form the basis for this book."

I have brought a few of his suggested remedies, including *Helix tosta* (slug), down to Southern Chile, where we have an organic farm. I wished I had brought *Bombyx* (caterpillar) for our recent invasion of *cuncunas*. I plan to make a homeopathic preparation of *pilme* (notorious and rampant potato blister beetles who decimate our garden). This is only the beginning of what might be possible with homeopathy to heal agriculture and the environment. If any readers know of any farmers using homeopathy agriculturally, please let me know!

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Healing with Homeopathy

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Homeopathy Can Be Gentle and Effective for End-of-Life Care

Now that we, the boomers, yours truly included, are entering our senior years, there is much talk and awareness about how we want to stay healthy and enjoy longevity, how to spend our final years and decades on this planet, and how to gracefully exit. One of our generational heroes, Baba Ram Dass, whose latest book, *Walking Each Other Home*, has served as a wonderful inspiration for me and my close friends, just died peacefully, at the age of 88. Many of my contemporaries have no desire to end their lives in a nursing home, on life support, or in an ICU or nursing home, drugged and dumbed down. Many of us know about the pharmaceuticals, mostly opiates, offered by hospice to relieve pain. But, do you know that homeopathic remedies can assist beautifully in the dying process?

Let me share with you what happened with Bob's mother, when she passed from lung cancer some years back. Madeline was surrounded, in her home in rural Pennsylvania, by loving family, including her sons and daughter-in-law. Hospice care was being provided to ease her suffering, and the family knew the end was near. Madeline was drifting in and out of consciousness, weak and intermittently aware of her surroundings. The most common homeopathic remedy for the final stage of life is *Arsenicum album* (arsenic). The symptom picture is of a very anxious person, restless, afraid of death, and panicky. This was quite the opposite of Madeline. She barely moved, her eyes were shut, her breathing was slow but steady. Bob had with him homeopathic *Opium*, which he thought, might ease her final transition and the effects of the opioids she had been given. He put the pellets under Madeline's tongue, she looked at him clearly and intensely, got up to go to the bathroom one last time, returned to her bed, and died peacefully with full awareness. Bob will never forget the clarity of her gaze…that one final, intense sharing. And the hospice nurse was speechless…in disbelief that Madeline had been able to get up and relieve herself while so weak and close to death. And to cross over in peace!

Homeopathy for Animals

I have sworn by homeopathy for three and a half decades for our pets. A raw meat diet with oatmeal, raw chicken wings, blended kale, carrots, and chard, and a few supplements have been a godsend for our six golden retrievers over the past 35 years – plus, our senior German shepherd who lived to about 15, and various of our kitties. *Rhus-tox*, in particular, has worked miracles for joint problems of aging. But their constitutional remedies have kept them largely pain-free and led to long, happy, healthy lives. It is far easier to administer tiny pellets or a couple of drops of a remedy to a cat than pills, believe me! I cannot begin to tell you the success stories I have heard from homeopathic veterinarians of their dramatic cures.

My dream, which I have not yet been able to realize in this lifetime, is to be a veterinary homeopath with wild animals. I read whatever I can get my hands on about animals in Africa, India, Thailand, and in zoos. What I would give to be able to treat a baby elephant who has lost his or her mom to murder for her tusks. These toddlers cry tears, just like humans, when they are abandoned. I would love to pop some *Ignatia* into their adorable, giant mouths! The closest I have come is to treat some of my human patients with remedies like elephant's milk (*Lac loxodonta*)! I can only imagine how effective it could be! Maybe I'll have a chance when we go on a wildlife viewing safari in Kenya next September!

Homeopathy Is Irreplaceable

In conclusion, there is no other form of healing that can take the place of homeopathy. A group of us has been meditating together once a week for the past month to visualize the continued flourishing of homeopathy and availability of homeopathic remedies in the US. We do so in "Circle of 8" with the intention of joining on the subtler planes to encourage FDA employees to act wisely in their decisions regarding homeopathy and of envisioning our remedies continuing to be widely available on shelves of health food stores, pharmacies, and as prescribed by homeopathic doctors and practitioners.

As a veteran homeopathic doctor, educator, and patient, I ask readers, from the bottom of my heart, to support us in this effort to keep homeopathy alive and well in the US, in whatever ways you can! ◆

Judyth Reichenberg-Ullman is a licensed naturopathic physician, board certified in homeopathy. She previously received her Master's in Psychiatric Social Work from the University of Washington. Dr. Reichenberg sees patients in person at Serene Natural Health in Edmonds, Washington, as well as by phone consultation internationally. Fluent in Spanish and French, Dr. Reichenberg is passionate about homeopathy and uses the Sensation Method of Dr. Rajan Sankaran. Drs. Reichenberg-Ullman and Dr. Robert Ullman have been together over 35 years and live on Whidbey Island, Washington, and in Pucón, Chile. Avid adventure travelers, they have visited nearly 50 countries, including hiking two Caminos in Spain and Portugal. Dr. Ullman retired from homeopathic practice as of April 1, 2020.

Dr. Reichenberg is the author of *Whole Woman Homeopathy* and co-author with Dr. Ullman of eight books on homeopathy: *Ritalin-Free Kids, Homeopathic Self Care* (with companion kit), *The Savvy Traveler's Guide to Homeopathy and Natural Medicine, Whole Woman Homeopathy, A Drug-Free Approach to Asperger Syndrome and Autism, The Homeopathic Treatment of Depression, Anxiety, and Bipolar Disorder,* and *Rage-Free Kids* as well as *Mystics, Masters, Saints and Sages – Stories of Enlightenment.* Pioneers in their field, they have been columnists for the *Townsend Letter* since the early 90s. They taught originally at Bastyr University, then offered seminars internationally, most recently in Prague in 2018.

Please visit their website at www.healthyhomeopathy.com (which contains a wealth of articles, blogs, and more) and Facebook at Healthy Homeopathy. She can be reached by phone at 425-774-5599 or through email at drreichenberg@gmail.com. Dr. Reichenberg-Ullman was recently honored by the American Holistic Health Association in their anniversary ebook: https://ahha.org/30th-anniversary .

CALENDAR

Please visit TownsendLetter.com for the complete calendar

APRIL 2-4: FREQUENCY SPECIFIC MICROCURRENT CORE MODULE 1 – PAIN/INJURY MODULE in Portland, Oregon. Also, **APRIL 24-26** in Denver, Colorado; **MAY 15-17** in Raleigh-Durham, North Carolina; **SEPTEMBER 18-20** in Chicago, Illinois; **OCTOBER 16-18** in Anaheim, California.; **DECEMBER 6-8** in San Francisco, California. CONTACT: 360-695-7500; https://frequencyspecific.com/

APRIL 2-4: 17th INTEGRATIVE MEDICAL CONFERENCE FOR CANCER AND CHRONIC DISEASE in Grapevine (Dallas), Texas. Pre-conference training. CONTACT: https://bestanswerforcancer.org/

APRIL 2-5: ENVIRONMENTAL HEALTH SYMPOSIUM 2020 - Immunotoxicity: The Intersection Between Toxic Exposure, Infectious Disease, and Autoimmunity in Scottsdale, Arizona. CMEs available. CONTACT: 855-347-4477; https://environmentalhealthsymposium.com/

APRIL 3-5: SIBOCON2020 – Clinical Applications in San Diego, California. CONTACT: https://www.synergycmegroup.com/sibocon2020

APRIL 3-6: MASTER OZONE CLASS in Palisades, New York. CONTACT: https://www.ozonemasterclasses.com/venue-schedule/

APRIL 5-7: FREQUENCY SPECIFIC MICROCURRENT CORE MODULE 2 – NEURO & VISCERAL in Portland, Oregon. Also, **APRIL 27-29** in Denver, Colorado; **JULY 10-12** in Philadelphia, Pennsylvania; **NOVEMBER 6-8** in Chicago, Illinois; **DECEMBER 3-5** in San Francisco, California. CONTACT: 360-695-7500; https://frequencyspecific.com/

APRIL 17-18: THE GREAT PLAINS LABORATORY, INC. presents GPL ACADEMY PRACTITIONER WORKSHOP in San Diego, California. Organic acids testing, toxic chemical testing, and mycotoxin testing, and more. CMEs available. CONTACT: http://www.gplworkshops.com/san-diego-2020

APRIL 23-26: ACUPUNCTURE MERIDIAN ASSESSMENT (AMA) TRAINING For Doctors, Dentists & Health Professionals: Detecting Parasites, Dental & Fungal in St. Louis, Missouri. Simon Yu, MD, CONTACT: www.preventionandhealing.com**.** 314-432-7802.

APRIL 25-27: AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS DC FLI – Leadership and Advocacy Training in Washington, DC. CONTACT: https://naturopathic.org/page/2020FLI

APRIL 28-MAY 1: INTEGRATIVE CONGRESS ON INTEGRATIVE MEDICINE AND HEALTH in Cleveland, Ohio. CONTACT: http://www.icimh.org/#home

MAY 1: LYME DISEASE, TICK-BORNE ILLNESS, & MENTAL ILLNESS with Robert Bransfield, MD, in Easton, Maryland. CONTACT: 410-726-4573; https://www.eventbrite.com/e/lyme-disease-tick-borne-illnesses-and-mental-health-tickets-69337717981

MAY 2-3: PRIMARY CARE UPDATE FOR NATUROPATHIC DOCTORS in Toronto, Ontario, Canada. Online & in person registration options. Earn up to 11 CEs. CONTACT: info@collaborativeeducation.ca ; http://www.collaborativeeducation.ca/toronto-naturopathic-conference/

MAY 14-16: 28th ANNUAL A4M/MMI SPRING CONFERENCE in Orlando, Florida. CONTACT: 561-997-0112; https://www.a4m.com/

MAY 15-17: 15th ANNUAL JOINT AMERICAN HOMEOPATHIC CONFERENCE – Homeopathy in Pain Management in Orlando, Florida. CONTACT: https://www.homeopathycenter.org/2020-joint-american-homeopathic-conference

MAY 20: LDN 2020 CONFERENCES in Cape Town, South Africa. CONTACT: https://www.ldnrtevents.com/

MAY 20-24: 12th INTERNATIONAL CONGRESS ON AUTOIMMUNITY in Athens, Greece. Special session on diet and autoimmunity, chaired by Dr. Aristo Vojdani. CONTACT: https://autoimmunity.kenes.com/

MAY 20-24: AUTISM-ONE CONFERENCE – Where Science, Hope, and Recovery Meet in Chicago, Illinois. CONTACT: https://autismoneconference.com/

MAY 28-30: INSTITUTE FOR FUNCTIONAL MEDICINE 2020 CONFERENCE – Advancements in Clinical Research and Innovative Practices in Functional Medicine in Phoenix, Arizona. CONTACT: 800-228-0622; info@ifm.org; www.ifm.org/aic

MAY 29-31: ADVANCED APPLICATIONS IN MEDICAL PRACTICES (AAMP) SPRING EVENT – Chronic Digestive Disorders in Scottsdale, Arizona. CMEs available. CONTACT: https://aampscottsdale.com/

MAY 29-JUNE 1: MEDICINES FROM THE EARTH HERB SYMPOSIUM in Black Mountain, North Carolina. CE credits for nurses, acupuncturists and naturopathic physicians. CONTACT: 541-482-3016; https://www.botanicalmedicine.org/.

JUNE 5-7: BIOLOGIC ALLOGRAFT SEMINAR (ADVANCED) in Parker, Colorado. CONTACT: https://www.brimhall.com/t-biologic%20allograft.aspx

JUNE 12-14: INTERNATIONAL CONGRESS OF REGENERATIVE MEDICINE on Captiva Island, Florida. CMEs available. CONTACT: https://www.icrmconference.com/

JUNE 12-14: THE GREAT PLAINS LABORATORY, INC. presents GPL ACADEMY MASTER PRACTITIONER WORKSHOP in Kansas City, Missouri. CONTACT: http://www.gplworkshops.com/kansas-city

JUNE 13-15: FIELD CONTROL THERAPY (FCT) INTENSIVE TRAINING in White Plains, New York. CONTACT: 914-861-9161; https://www.yurkovsky.com/

JUNE 15-19: FREQUENCY SPECIFIC MICROCURRENT SEMINAR (CORE) in Tuscany, Italy. Also, **OCTOBER 22-26** in Taiwan. CONTACT: 360-695-7500; https://frequencyspecific.com/

JUNE 20-21: FREQUENCY SPECIFIC MICROCURRENT ADVANCED SEMINAR in Tuscany, Italy. Also, **SEPTEMBER 9-11 (Master Class)** in London, United Kingdom; **OCTOBER 30-NOVEMBER 1 (Master Class)** in Taiwan; . CONTACT: 360-695-7500; https://frequencyspecific.com/

JUNE 20-27: CLINICAL AND COMPARATIVE MATERIA MEDICA @ Allen College of Homeopathy in the United Kingdom. On-site or interactive online course. CONTACT: https://homoeopathy-course.com/courses/england/7-day-summer-school

JULY 10-12: THE GREAT PLAINS LABORATORY, INC. presents **ENVIRONMENTAL TOXIN SUMMIT** in Portland, Oregon. CONTACT: http://www.gplworkshops.com/

AUGUST 20-23: 11th ANNUAL INTEGRATIVE MEDICINE FOR MENTAL HEALTH CONFERENCE in Chicago, Illinois. CONTACT: https://www.immh2020.com/

AUGUST 27-30: ACUPUNCTURE MERIDIAN ASSESSMENT (AMA) TRAINING For Doctors, Dentists & Health Professionals: Detecting Parasites, Dental & Fungal in St. Louis, Missouri. Simon Yu, MD, CONTACT: www.preventionandhealing.com. 314-432-7802**.**

OCTOBER 9-11: ADVANCED APPLICATIONS IN MEDICAL PRACTICE (AAMP) FALL EVENT – Immunology in Seattle, Washington. CMEs available. CONTACT: https://aampseattle.com/

OCTOBER 31-NOVEMBER 1: ARIZONA NATUROPATHIC MEDICAL ASSOCIATION CONFERENCE – Neurological and Musculoskeletal Issues in Scottsdale, Arizona. CONTACT: https://www.aznma.org/

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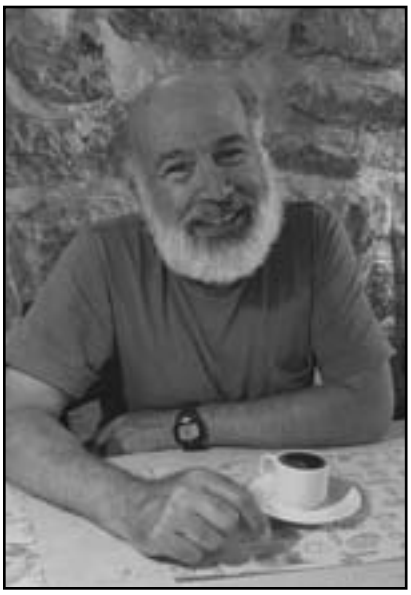

Curmudgeon's Corner

by Jacob Schor, ND, FABNO
drjacobschor1@msn.com

It's When You Eat, Not What You Eat

I've spent more time on the road traveling by car from one place to another in the past six months than perhaps the last twenty years. Though we've been lucky to spend an occasional night at the homes of friends, often we've resorted to roadside hotels.

Starting in the mid-1990s, America's medium-priced hotel chains started offering free breakfasts as a way to compete in the market place; apparently it is more profitable for them than lowering their room rates. In 2012, 79% of hotels offered complimentary breakfast, up from 55% in 2010, according to the American Hotel & Lodging Association.[1] Today more than 90% of midscale hotels offer this bait, not so much to draw guests in any longer but to keep up with the competition. Competition is incrementally improving the breakfast options. One server in Kansas bragged to me how she bakes the premade frozen omelets her hotel offers rather than merely microwaving them.

What one can't help but notice is how routine American breakfast choices are. Though they may brag about the wide selection of toppings one can choose from, the basic menu varies little. The most popular breakfast appears to be waffles. Almost every roadside hotel in America offers them (though a few let you make pancakes on a conveyor belt). Massive sections of the country also offer biscuits and gravy. Eggs, some form of pork meat (bacon, sausage, ham or imitation sausage made from turkey) and toasted bread, bagels, English muffins, pastries, doughnuts and so on, complete the list. To the side, there is usually a refrigerator stocked with yogurts, sometimes a crockpot of oatmeal, and of course Fruit Loops and other dried cereals to choose from.

Seeing this firsthand, and even occasionally succumbing to temptation, has left me thinking about what we should eat for breakfast. Thus, I was, shall we say, hungry for the information that has been reported in several recent papers that suggest that what we choose to eat for breakfast might not be as important as if and when we choose to eat breakfast.

In April 2019, Rong and colleagues reported that people who habitually skip breakfast were at higher risk of dying from any cause and in particular heart disease than people who regularly ate breakfast.[2] This prospective study followed a cohort of 6,550 US adults, 40 to 75 years of age, who participated in the National Health and Nutrition Examination Survey III 1988 to 1994. Frequency of breakfast eating was recorded during in-house interviews. Death and underlying causes of death were ascertained by linkage to death records through December 31, 2011. In following this cohort for 17 to 23 years, skipping breakfast was associated with a significantly increased risk of mortality from cardiovascular disease. Of the cohort, 59% consumed breakfast daily. The other 40% ate breakfast less frequently: 5% never ate breakfast; 11% rarely ate breakfast, 25% ate only on some days. The study recorded data of 112,148 person-years during which 2,318 deaths occurred, including 619 deaths from cardiovascular disease (CVD). That's a lot of data to draw from.

After all the adjustments were made for age, sex, race/ethnicity, socioeconomic status, dietary and lifestyle factors, body mass index, and cardiovascular risk factors, and so on, the researchers were left with what seem to be shocking conclusions. Study participants who never consumed breakfast compared with people who ate breakfast daily were almost twice as likely to die of heart disease and almost 20% more likely to die of any cause. (CVD hazard ratios 1.87 (95% confidence interval: 1.14 to 3.04) and 1.19 (95% confidence interval: 0.99 to 1.42) for all-cause mortality). The later upward trend did not reach statistical significance.

After adjustment for just age, sex, and race/ethnicity, participants who never consumed breakfast had a 75% higher risk of all-cause mortality (hazard ratio [HR]: 1.75; 95% confidence interval [CI]: 1.46 to 2.10) and 2.58-fold higher risk of cardiovascular mortality (HR: 2.58; 95% CI: 1.64 to 4.06) compared with those who consumed breakfast every day. The associations of eating breakfast with heart disease-specific and stroke-specific mortality were examined further.

Compared with those who consumed breakfast every day, participants who never consumed breakfast had a higher risk of stroke-specific mortality (HR: 3.53; 95% CI: 1.40 to 8.95) in models adjusted for just age, sex, race/ethnicity. In the fully adjusted model, the association between skipping breakfast and stroke-specific mortality remained significant (HR: 3.39; 95% CI: 1.40

to 8.24). Either way, skipping breakfast seemed to triple risk of dying of a stroke. Though these hotel breakfasts aren't always mouthwatering, they beat dying of a stroke.

According to this study regularly eating breakfast reduces risk of dying from cardiovascular disease and probably stroke…or put the other way around, not eating breakfast raises risk a whole lot. Thus, it seems like a no-brainer that we should make an effort to foster a habit of eating breakfast in our patients. Can you think of any other lifestyle habit that cuts risk of dying to such a degree?

More people die of cardiovascular disease than any other cause, not just in the United States but worldwide. Even small decreases in risk have the potential of having large impacts on disease and suffering. Could those free hotel breakfasts be cutting deaths to this degree? Personally, I wake up hungry in the morning and can't imagine not eating breakfast. Yet surveys suggest that almost a quarter of younger people now skip breakfast.[3,4]

Evidence from other papers suggests that skipping breakfast is associated with increased risk of obesity,[5] dyslipidemia,[6] hypertension,[7] type 2 diabetes,[8] metabolic syndrome,[9] coronary heart disease,[10] and cerebrovascular disease.[11]

This is not the first study to suggest bad associations with skipped breakfasts. Cahill et al reported in 2013 that they had assessed the eating habits of 26,902 American men from the Health Professionals Follow-up Study. During a 16-year period, 1527 cases of heart disease were diagnosed among these men. Men who skipped breakfast had a 27% higher risk of CHD compared with men who did not (relative risk, 1.27; 95% confidence interval, 1.06-1.53). Furthermore, we should note that men who ate late at night had a 55% higher CHD risk compared with men who did not eat late at night, (relative risk, 1.55; 95% confidence interval, 1.05-2.29).[12]

Kubota et al reported results in a 2016 paper from a large group of Japanese that included 82,772 participants (38,676 men and 44,096 women). Those people who skipped breakfast had a 14% greater risk of CVD, and 18% increased risk of stroke and a 36% greater risk of hemorrhagic stroke.[13]

Before we try to digest this information, I want to stir in the findings from another study, a small clinical trial conducted by Wilkinson et al that was published in December 2019. The authors recruited 25 people with diagnosed metabolic syndrome from hospital outpatient clinics at the University of California in San Diego medical school. They convinced these patients to follow a time restricted eating diet for 12 weeks.

Animal studies have pretty definitively shown that time-restricted feeding (TRF) prevents and reverses metabolic diseases. Human studies have suggested time-restricted eating (TRE) reduces risk of metabolic diseases in people as well. Thus, Wilkinson and colleagues conducted this single-arm, paired-sample trial.

Though they started with twenty-five participants in the trial only 19 (13 men and 6 women) made it to the final analysis. Not only did they all have metabolic disease, they were being treated with drugs to control their condition; the majority of the participants were on a statin and/or antihypertensive therapy. All met a minimum of three of the criteria for metabolic syndrome (MS). At baseline, the mean daily eating window of participants was ≥14 hours.

The participants followed a 10-hour time restricted eating (TRE) diet for 12 weeks. All foods consumed during the day had to be eaten in a 10-hour period.

The effects were striking. Nearly every marker of metabolic disease improved significantly. Participants experienced improved sleep as well as a 3-4 percent reduction in body weight, body mass index, abdominal fat and waist circumference. Major risk factors for heart disease were diminished as participants showed reduced blood pressure and total cholesterol. Blood sugar levels and insulin levels trended toward improvement.[14] Chew on that for a moment. All they did was change the eating schedule, not what the people ate.

Metabolic syndrome isn't as definitive an endpoint as dying of heart disease, but it does raise risk of diabetes by five-fold and doubles risk of heart disease. Thus, one must assume that lowering metabolic syndrome will eventually translate into lowering risk of dying from heart disease.

This Wilkinson study tested only "eating duration," that is the number of hours between the first and last time that one consumes any calories during the 24-hour day. We should ➤

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sidetrack and explain that when this dietary thing is done to animals it is referred to as time restricted feeding but in humans, who feed themselves, the name is changed to time restricted eating. Also note that TRE is the flip side of what is called night-time fasting. In Catherine Marinac's paper on night-time fasting and breast cancer risk, benefit was associated with night-time fasting for 13 hours or more per night as compared to 12 hours or less.[15]

In this Wilkinson study, the clock is flipped and the total daily interval when meals are consumed is counted instead of the time period spent not eating. Thus, a ten-hour time restricted eating intervention could also be described as a fourteen-hour night-time fast. It's that whole cup half full versus the cup half empty business. Both are describing the same thing. The only difference is that eating may sound more appealing to patients than fasting and this name change may increase patient compliance.

In recent years we have become aware that the health impact of food is not only a matter of what a person eats but also of when they eat, especially in relation to their sleep cycle. One current theory suggests this TRE effect is related to circadian cycles. The body is more efficient at digesting food and drink when a person is active and when light is present. Eating or drinking at night, when it is dark, appears to disrupt the body systems and impact metabolism negatively. A consistent daily cycle of eating and fasting nurtures the circadian clock to optimize metabolism. At least in rodents a regular schedule of eating and fasting keeps them healthier.[16]

Several theories have been floated to explain why skipping breakfast could be so harmful. Skipping breakfast might lead to overeating later in the day and impaired insulin sensitivity.[17] Eating breakfast helps regulate the appetite and improves the glycemic response at the next meal increasing insulin sensitivity.[18] Skipping breakfast is stressful and the longer period of fasting leads to elevated blood pressure in the morning because of a hypothalamic-pituitary adrenal triggered response.[19] It also may be a simple marker of general poor lifestyle choices.

The studies that tell us breakfast skipping is associated with DM-2, obesity, and CVD also associate breakfast skipping with late-night eating, variable eating patterns, increased high-fat/high-sugar snacking and reduced fruit and vegetable consumption.[20,21] So maybe it is not skipping breakfast that is the problem as much as what these breakfast-skippers choose to eat and how they live the rest of the day. Asking a patient if they skip breakfast could be just a screening question that reveals a full pattern of poor lifestyle choices. It could be similar to how intake forms once asked new patients whether they used a seatbelt while driving (automatic seatbelts and alarm buzzers that force compliance have made this query less useful).

At the same time, the standard American breakfast is far from perfect. Americans are perhaps unique in the world; we have a very specific and limited image of what we think breakfast foods are. People in the rest of the world select from a far wider range of food choices for their first meal of the day than Americans do. People might be far better off substituting what they eat for dinner for their breakfast. Yet to do so would require changing deeply ingrained beliefs that might not be easily amenable to change.[22] It's probably eating in the morning that provides the benefit of breakfast, not the foods Americans choose to eat for breakfast. We might see more benefit from better breakfast choices.

How does this time restricted eating thing fit in with the other eating strategies people are into these days? I'm thinking of caloric restriction (CR) or intermittent fasting (IF) in particular that emphasize calorie reduction. These strategies may change the daily eating duration even if not done so on purpose. Time-restricted feeding/eating is different from these caloric restriction strategies in that there is no requirement to reduce caloric intake. It just requires consistently limiting consumption to a specific time interval. The evidence to date suggests that this alone may improve metabolism and cardiovascular health by improving circadian clock function. The benefit on diabetes suggested by the Wilkinson study is consistent with data from research on mice. Benefits from TRE occur even without weight loss.

This is far from simple. Even Valter Longo, a major proponent of caloric-restricted diets, suggested in a 2016 paper that eating patterns such as this TRE diet may mimic the metabolic changes brought about by fasting and be useful in designing 'fasting mimicking diets.[23]

These recent additions to the medical literature give us some basis to what we might tell patients about meal timing. It is probably better to eat our largest meals, in particular our high fat meals, during our active, daytime period. Allowing mice to consume high fat meals during their rest period encourages metabolic disease. In humans eating close to when melatonin begins to rise leads to greater fat deposition. Eating earlier in the day leads to greater weight loss in women.

Insulin sensitivity is greater in the morning. Perhaps this is an argument in favor of those make-your-own hotel waffles? Larger meals are processed more effectively when eaten in the first half of the day. Melatonin does however reduce insulin release and so the body has a harder time processing glucose at night or early in the morning when melatonin is still elevated.[24] This might argue against those waffles, or perhaps, holding off eating breakfast until the last second before checking out of the hotel. Taking advantage of the ubiquitous workout rooms and pools the hotels seem to have might be a good idea. We should encourage patients to eat their large meals early in the day and to avoid eating for a few hours before bed, especially carb-loaded bedtime snacks.

Given the Wilkinson et al results, we clearly have a new strategy for treating metabolic syndrome and probably type-2 diabetes. Going too long in the morning without breakfast does not seem like a great idea even if we rationalize and discount the breakfast skipping studies. For sure, skipping breakfast 'may be a behavioral marker for unhealthy dietary and lifestyle habits.' Teenagers who skip breakfast tend to exhibit a list of other traits that may also put their health at risk, for example, eating more fast food and having more emotional problems.[25]

There remain good arguments to eat in the morning. Eating breakfast lowers blood pressure and reduces arterial stiffness. This is why measurements of these parameters are done in a fasting state.[26] Skipping breakfast may also trigger unwanted changes in blood lipids, in particular increased LDL cholesterol.[27] Whatever the reasons why, we need to assume skipping breakfast increases risk of cardiovascular disease. So, we should emphasize time restricted eating but not skipping breakfast. Of course, this is going to confuse many of our patients, especially if breakfast to them, looks like what America's hotels offer.

Ever since Carol Marinac's 2016 paper, we've been promoting the benefit of longer night-time fasting to lower risk of breast cancer recurrence. That data suggested that a night-time fast of greater than 13 hours benefited women with a history of breast cancer.[15]

The problem with encouraging this is that many women have fulfilled our suggestion by simply skipping breakfast. The resultant increase in CVD risk might outweigh any breast cancer risk reduction. We need an approach that will allow both a longer night-time fast and still encourage eating breakfast and the obvious solution would be to eat an earlier dinner. Such a meal pattern of eating an early dinner was encouraged by Kogevinas et al's 2018 study. In their results, compared to participants who went to sleep immediately or shortly after supper, those who delayed going to sleep for 2 or more hours after supper had a 20% reduction in risk for breast and prostate cancer combined (adjusted odds ratio [OR]: 0.80; 95% confidence interval [CI]: 0.67-0.96) and in each cancer individually (prostate cancer OR: 0.74; 95% CI: 0.55-0.99 and breast cancer OR: 0.84; 95% CI: 0.67-1.06).[28]

If we combine Kogevinas' findings with Marinac's, and add them to Wilkinson's and Rong's, then we should encourage an early dinner, two hours before bedtime, for example finish by 6 pm, stay awake to at least 8 pm and then eat breakfast 14 hours later, at 8 am. I think I got the math right. When laid out like that it doesn't sound that hard. Certainly not as hard as any protocol with the word fasting in it.

TRE: Eating interval of 10 hours: 8 AM (start breakfast) to 6 PM (end of dinner); Largest meal mid-day; Sleep, 8 PM or later.

Admittedly this is all rather strange, at least for those of us who have been so focused on this "You are what you eat" thing for so many years. When you eat may be as important or possibly more important than what you eat. Given all that, I still have not yet tried eating a hotel waffle.

The thing we haven't touched on here is the harm caused by ultra-processed foods, but let's save that for another day. That's my real reason for avoiding the waffles.

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Editorial

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4. Issues related to the study sites: All four authors listed in the paper were affiliated with Semnan University of Medical Sciences in Semnan, Iran. However, the study itself was conducted at 2 ICUs in Shiraz, Iran, which is more than a nine-hour drive from Semnan. None of the study authors listed an affiliation with any institution in Shiraz. In addition, the study was approved by the ethics committee of Semnan University of Medical Sciences. It is surprising that ICUs in Shiraz, which were treating critically ill patients, would have agreed to conduct a study without first running it by their own ethics committees.

5. Discrepancy related to the outcome measure: The stated outcome measure in the published paper was the incidence of stage 1 pressure injury, as defined by the National Pressure Ulcer Advisory Panel. In contrast, the IRCT registration document stated that the outcome measure was the incidence of pressure ulcer. Stage 1 pressure injury is defined as "intact skin with a localized area of nonblanchable erythema, which may appear differently in darkly pigmented skin." These lesions are not ulcers, although they may eventually progress to become ulcers.

6. Question related to funding: Because randomized controlled trials are expensive to conduct, such trials are generally reserved for treatments for which there is some evidence of efficacy (such as case reports or uncontrolled trials). Such was not the case with respect to peppermint gel for prevention of pressure injury.

7. Issue related to the assessment method: The paper stated that a pair of observers (nurse plus specialist) examined at-risk areas of the skin (hips, sacrum, back, elbows, knees, heels, and shoulders) once a day for evidence of pressure injuries. It was not stated what was meant by "specialist;" one might assume that referred to the neurologist or neurosurgeon involved in the case. It is difficult to believe that such a "specialist," who would be evaluating and treating a room full of seriously ill patients, would agree to spend extra time checking the hips, sacrum, back, elbows, knees, heels, and shoulders every day for early evidence of pressure injuries (such would likely be the job of the nurse), particularly when the request to perform such an examination was coming from a graduate student from a faraway university who was studying a treatment for which there was no prior evidence of efficacy.

Pomegranate Juice and Synbiotics for Polycystic Ovary Syndrome

A student in Shiraz, Iran, as part of a master's of science thesis, conducted a randomized controlled trial that examined the effect of pomegranate juice, a synbiotic beverage (probiotic plus inulin), a beverage containing both pomegranate juice and the synbiotic, or a placebo beverage on various laboratory parameters in women with polycystic ovary syndrome. Ninety-two women consumed their assigned beverage (300 ml per day) for eight weeks. Outcome measures included fasting blood glucose, insulin resistance, and serum levels of lipids, testosterone, luteinizing hormone, follicle stimulating hormone, C-reactive protein, malondialdehyde (a marker of oxidative stress), and serum total antioxidant capacity. Most of these parameters improved in the groups receiving synbiotics (with or without pomegranate juice), whereas there was no clear benefit of pomegranate juice alone. This research generated two papers in the medical literature, each of which presented a different portion of the data.[4,5] That both papers came from the same study is demonstrated by the fact that both listed the same registration document in the Iranian Registry of Clinical Trials (IRCT). These papers raise a number of concerns.

1. Issues related to the beverages: The papers stated that all four of the test drinks were identical in appearance, color, and taste. However, there are several reasons to believe that could not be true. First, the placebo consisted of water, pomegranate flavor, and red food coloring. Iran is the largest producer of pomegranates in the world, so it is likely that many of the study participants knew how pomegranate juice tastes and could distinguish it from artificially flavored, artificially colored water. Second, inulin was added to the synbiotic drinks at a concentration of 20 g/L. At high concentrations in water, inulin forms a gel, and at lower concentrations it has a white, creamy appearance. It seems unlikely that the drinks that contained inulin would look the same as those without inulin. Third, the papers stated that participants consumed 300 ml per day of their assigned beverage, and each person received a two-liter bottle once a week. At a dose of 300 ml per day, a two-liter bottle would leave everyone 100 ml short each week.

2. Discrepancy related to inclusion criteria: One of the inclusion criteria for the study was oligomenorrhea. In the published papers, oligomenorrhea was defined as at least 35 days between menstrual cycles. However, the IRCT registration document defined oligomenorrhea as less than six to nine menses per year.

3. Discrepancy related to recruitment dates: The published research stated that recruitment began in January 2017. However, the IRCT document stated that recruitment started on February 19, 2017.

4. Discrepancies related to outcome data: The IRCT document listed serum cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides as outcome measures. It did not mention fasting blood glucose, insulin sensitivity, malondialdehyde, total antioxidant capacity, C-reactive protein, testosterone, luteinizing hormone, or follicle stimulating hormone, even though the IRCT document was updated after the study was completed.

5. Questions related to logistics: Both papers stated that the study drinks were prepared fresh once a week and were delivered to participants immediately after they were prepared. However, one of the papers also stated that, in order to assess treatment compliance, participants were asked to return their empty bottles "when picking up their beverages for the following week." So, which was it? Did the researchers deliver the bottles, or did the patients have to come and pick them up each week? It seems like a daunting task for a graduate student to make 92 deliveries relatively "immediately" in a city of 1.6 million people where there are significant problems with traffic congestion. It is also difficult to believe that people would agree to participate in a study that required them to navigate city traffic each week to pick up a bottle of juice or placebo.

6. Discrepancy related to the probiotics used: One of the papers[4] stated that each liter of synbiotic beverage contained 2 x 10^8 colony-forming units (CFU)/g of lactobacillus. However, several paragraphs later, it stated that the synbiotic beverage contained 1 x 10^8 CFU/ml of each of 3 different strains: *Lactobacillus rhamnosus* GG, *Bacillus koagolans*, and *Bacillus indicous*. Bacilli are not the same as lactobacilli, so these statements are incompatible.

L-Carnitine for Pemphigus Vulgaris

A student in Tehran, Iran, as part of a master's of science thesis, conducted a double-blind trial that examined the effect of L-carnitine (2 g per day for 8 weeks) on various laboratory parameters in patients with pemphigus vulgaris. Outcome measures included serum levels of LDL cholesterol and triglycerides, total oxidant capacity, total antioxidant capacity, serum markers of bone turnover (osteopontin and bone morphogenic protein) and a serum marker of renal function (cystatin C). Most of these parameters improved significantly in the L-carnitine group compared with the placebo group. This research generated two papers in the medical literature, one in 2018[6] and one in 2019.[7] That both papers came from the same study is demonstrated by the fact that both listed the same registration document in the Iranian Registry of Clinical Trials (IRCT). Each paper presented a different portion of the data. Examination of these papers raises several issues.

1. Discrepancy in sample size: One paper stated that 52 patients were randomized, whereas the other paper stated that 48 were randomized. This difference was due to a difference in the number of eligible patients who refused to participate.

2. Discrepancies regarding inclusion criteria: The 2018 paper stated that patients had to have pemphigus vulgaris for at least one year. The 2019 paper stated that patients were eligible if they had the disease for "about 1 year." Considering that pemphigus vulgaris is a chronic disease, these different inclusion criteria would result in very different patient populations.

3. Discrepancy in compliance assessment: One paper stated that compliance was determined by measuring serum carnitine levels, whereas the other paper stated that compliance was assessed by the number of pills returned.

4. Discrepancy in the number of withdrawals: One paper stated that four patients withdrew in the L-carnitine group and six withdrew in the placebo group. The other paper stated that six patients withdrew in the L-carnitine group and no patient withdrew in the placebo group.

5. Discrepancy in the source of the study medication: Both papers stated that L-carnitine and placebo were manufactured by Asal Daroo Kish Pharmaceutical Company in Kish, Iran. The IRCT document stated that L-carnitine and placebo were manufactured by the KAREN Chemistry Company.

6. Issues related to outcome measures: Two of the outcome measures used in the 2019 paper (bone morphogenic protein and cystatin C) were added to the IRCT document more than two years after the trial was completed. It is possible that the researchers used stored frozen serum to measure these parameters. However, when researchers use stored samples from a previous study, they typically indicate so in the Materials and Methods section, which was not done in this case.

7. Question related to funding: Because randomized controlled trials that include multiple outcome measures are expensive to conduct, such trials are generally reserved for treatments for which there is some evidence of efficacy (such as case reports or uncontrolled trials). Such was not the case with respect to L-carnitine as a treatment for pemphigus vulgaris. One wonders why Tehran University of Medical Sciences, which almost certainly has limited financial resources, would have funded such a study.

8. The day before this editorial was completed, a third paper based on the same L-carnitine/pemphigus study appeared in the medical literature. In this paper, new lab tests were conducted, including serum levels of secreted frizzled-related protein-5 (SFRP5), omentin, and visfatin.[8] These outcome measures were added to the IRCT document more than two years after the trial was completed. Similar to point number 6 (above), no mention was made that stored frozen samples were being used for these additional lab tests. Even more baffling was the statement that the sample size for the study was calculated based on the standard deviation and difference in mean for serum SFRP5 (those values had been reported previously in the medical literature). There are two problems with that statement. First, one wonders why the Iranian researchers would have based their sample size on serum SFRP5 data, considering that they did not decide to measure that variable until two years after the study was completed. Second, the statement contradicts one of the other papers, which stated that the sample size was based on the standard deviation and mean difference of serum osteopontin (not SFRP5).

Vitamin E Vaginal Suppositories for Atrophic Vaginitis

In the November 2019 issue of the *Townsend Letter* I reviewed a 2019 paper that found vitamin E vaginal suppositories were as effective as conjugated estrogens vaginal cream for improving sexual function in postmenopausal Iranian women with vaginal atrophy.[9] I commented at the time that it is difficult to believe vitamin E would be as effective as conjugated estrogens, and that confirmatory studies are needed. I have since learned that another paper, from 2016, came from this same research (both papers listed the same IRCT document and the papers had many identical features). The 2016 paper reported that vitamin E vaginal suppositories improved histological signs of vaginal atrophy in postmenopausal women, although it was somewhat less effective than intravaginal estrogen.[10] Examination of these papers together raised several additional concerns.

1. Discrepancy in recruitment dates: One paper said the study was conducted in 2014, whereas the other paper said it was conducted from March 2013 to April 2014.

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2. The score on the Abbreviated Sexual Function Questionnaire was listed as the primary outcome measure in the 2019 paper. However, this questionnaire was not mentioned as one of the outcome measures in the IRCT document.

3. Discrepancies in the inclusion criteria: One paper listed an elevated serum FSH level as an inclusion criterion; the other paper did not. One paper listed a six-week interval since bilateral oophorectomy; the other paper did not. One paper listed symptoms of vaginal atrophy based on patient self-report; the other paper listed vaginal atrophy based on patient complaints and researcher's examination. One paper listed additional specific criteria for women aged 40-50 years; the other paper did not.

4. Study participants were required to submit to four Pap smears over a period of 12 weeks. It is difficult to believe that many women would agree to participate in such a study.

Vitamin C and Coronary Artery Bypass Grafting Surgery

Fifty patients in Shiraz, Iran, who were undergoing coronary artery bypass grafting surgery were randomly assigned to receive, in double-blind fashion, vitamin C or placebo. Patients in the vitamin C group received 5 g of vitamin C intravenously before induction of anesthesia and an additional 5 g of vitamin C in the cardioplegic solution. The placebo group received normal saline. Compared with placebo, vitamin C significantly improved left ventricular ejection fraction at 72 hours after surgery and significantly decreased the length of stay in the intensive care unit.[11] After reviewing this paper, I found it difficult to believe that such a study would have actually been conducted.

The main concern surrounding this study is that adding a large dose of vitamin C to a cardioplegic solution has not been demonstrated to be safe, and it has the theoretical potential to cause serious adverse effects. Cardioplegic solutions are used to stop the heart during open heart surgery. They typically consist of electrolytes such as sodium, potassium, magnesium, and calcium, and have an osmolarity similar to that of serum. Commercially available cardioplegic solutions are mildly acidic and must be adjusted to a pH of 7.4 to 7.8 before use, by adding 10 ml of 8.4% sodium bicarbonate to each liter of cardioplegic solution. The addition of vitamin C to a cardioplegic solution would increase its osmolarity, making it a hypertonic solution. It would also decrease the pH of the sodium bicarbonate-adjusted solution. The extent of that pH reduction would depend on the pH of the injectable vitamin C, which typically varies from 5.5 to 7.0 in commercial products. It would also depend on the volume of the cardioplegic solution to which the vitamin C was added, but that information was not provided in the paper. Nor was there a mention of any attempt to adjust the pH of the cardioplegic solution back to 7.4 to 7.8 after vitamin C was added. These changes in osmolarity and pH of the cardioplegic solution could conceivably interfere with the attempt to restart the heart.

A literature search revealed only one study that addressed the safety of adding vitamin C to a cardioplegic solution. That was a 1989 study that found no adverse effects of ascorbate in an animal model of cardiopulmonary bypass and ischemic cardiac arrest. It is not clear what the vitamin C concentration was in the cardioplegic solution used in the Iranian study, because the researchers did not state what volume of cardioplegic solution was mixed with 5 g of vitamin C. Let's assume the volume was 1 liter, because many commercial cardioplegic solutions come in 1-liter bags. If that is the case, then the concentration of vitamin C used in the Iranian study was around 2.8 times higher than the concentration that was investigated in the 1989 animal study.

No Deaths from Vitamins

Supplement Safety Confirmed by America's Largest Database

by Andrew W. Saul, Editor, Orthomolecular Medicine News Service

The 36th annual report from the American Association of Poison Control Centers shows **zero deaths from any vitamin**. Supporting data is in Table 22B, p 1412-1413, at the very end of the report published in *Clinical Toxicology*.[1] It is interesting that it is so quietly placed way back there, where nary a news reporter is likely to see it. But wait, there's more:

- The AAPCC report shows **no deaths from any dietary mineral** supplement.
- There were **no fatalities from amino acids**, creatine, blue-green algae, glucosamine, or chondroitin.
- There were **no deaths from herbs**. This means *no deaths at all* from blue cohosh, echinacea, ginkgo biloba, ginseng, kava kava, St. John's wort, valerian, yohimbe, ma huang/ephedra, guarana, kola nut, or yerba mate. And, there were no deaths from energy drinks. While the *Orthomolecular Medicine News Service* considers a number of these items to be improperly classified as dietary supplements, they are nonetheless specified by AAPCC as causing zero fatalities.
- There were **no deaths from any homeopathic remedy**, Asian medicine, Hispanic medicine, or Ayurvedic medicine. None.

On page 1407, a single death is attributed to an "Unknown Cultural Medicine" and five fatalities are alleged to have been caused by some "Unknown Dietary Supplements or Homeopathic Agents." The obvious uncertainly of such listings diminishes any claim of validity. Something caused those six deaths, but investigators simply have no idea what it was. So, they blame a supplement or natural remedy. It is a bit like a homicide detective telling a judge that murders were committed by either a man, or a woman, or an animal, using perhaps a knife, gun, or claws. Few magistrates would issue warrants accordingly.

Throughout the entire year, coast to coast across the entire USA, there was not one single death from a vitamin, mineral, or any other nutritional supplement. If supplements are allegedly so "dangerous," as the FDA, the news media, and even some physicians still claim, then *where are the bodies?*

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Andrew W. Saul is Editor-in-Chief of the Orthomolecular Medicine News Service, now in its 15th year of free publication. He is also a member of the Japanese College of Intravenous Therapy, the Orthomolecular Medicine Hall of Fame, and is author or coauthor of twelve books. He has no financial connection whatsoever to the supplement or health products industry. ◆

One can only imagine what was in the "informed consent" form that the patients signed. Perhaps it was something like, "We are going to stop your heart during your open-heart surgery by using a standard heart-stopping solution. There is a 50% chance we will add a large amount of vitamin C to the heart-stopping solution. We have no idea whether adding vitamin C will affect our ability to restart your heart, because that has never been studied in humans. But our study is in the interest of science, so please sign here."

Final Remarks

Honest scientists in Iran, in order to protect their own reputations, should help investigate questionable research and speak out against it. Journal editors and publishers also have an important role to play. First, they should insist on more rigorous peer review of submitted papers. It is astounding that peer reviewers failed to identify any of the red flags that I described in this editorial. Second, journal editors must overcome their resistance to investigating allegations of possible scientific misconduct. All too often, editors have seemed willing to accept a flimsy or factually incorrect response from the authors of questionable papers, rather than putting in the time and effort needed to investigate the allegations of "whistleblowers." The future of biomedical sciences depends on a major cleanup effort.

Alan R. Gaby, MD

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More on Apparent Fraudulent Nutrition Research from Iran

In the July 2019 issue of the *Townsend Letter*, I expressed concern that a large and growing number of nutrition studies, coming mostly from Iran, have left me wondering whether the research is fraudulent. That is, whether people were writing papers about research that had not actually been conducted. Fraudulent research is an affront to all who value integrity in science, and it has the potential to harm practitioners and patients who rely on its findings.

Since the July editorial was written, the problem seems to have gotten even worse. It has reached the point where, in my mind, the possibility of fraud should be considered in all nutrition research coming from Iran. My previous editorial listed nine characteristics of published papers that might suggest fabricated research. I now add another characteristic: that the research was conducted by a student as part of a graduate school thesis, and that the magnitude of the project seems to have been beyond the capabilities and resources of a student.

This tenth characteristic was added in part because of an article published in the journal *Science* in 2016. That article, which was titled, "In Iran, a shady market for papers flourishes," revealed that numerous companies in Iran will write theses and scientific papers for a fee.[1] According to one Iranian scientist, many politicians and diplomats obtain advanced degrees from universities, without actually earning them. Having an advanced degree allows them to compete better for scarce jobs in the science industry, and the law mandates that individuals with these degrees earn a higher salary for the same job. One company offers to have a paper placed in a journal published by Elsevier or Springer for a fee of $1,660. Many young scientists who are unable to find another job are involved in the paper-selling business.

In this editorial, I will review five recently published eyebrow-raising studies from Iran, three of which were conducted by graduate students. It is hoped that these examples will help illustrate the scope of the problem and will also provide the reader with tools to evaluate the credibility of suspect research papers.

Peppermint Oil Gel to Prevent Pressure Sores

A student in Semnan, Iran, as part of a Master of Science thesis, conducted a double-blind trial that examined the effect of topical peppermint oil on the incidence of stage 1 pressure injury (pressure sores) in critically ill patients. One hundred fifty patients admitted to a neurosurgical intensive care unit (ICU) because of head trauma, who required endotracheal intubation, were randomly assigned to have a gel containing peppermint oil or a placebo gel applied to at-risk areas of their skin three times per day.[2] The incidence of stage 1 pressure injury was significantly lower in the peppermint group than in the placebo group (23% vs. 77%). This study has numerous eyebrow-raising features.

1. Discrepancy related to the number of subjects: The sample size was listed as 150 in the paper and 70 in the document submitted to the Iranian Registry of Clinical Trials (IRCT).

2. Unusually low mortality rate: In most studies of patients with severe head trauma, the 30-day mortality rate was 20-50%. While the peppermint study only followed patients for 14 days, the mortality rate of 1.3% (2 of 150 patients) seems unusually low.

3. Weirdness related to preparing the peppermint gel: The paper stated that the peppermint gel was prepared "according to standard methods," as described in Appendix A. Briefly, peppermint oil was added to five different concentrations of carbopol 934 in water. Carbopol 934 is a polymer that is used as a thickening and gelling agent. The carbopol 934 concentration that produced the most desirable viscosity (not too runny, not too thick) was used to make the peppermint gel. The 190-word description of this "standard method" was taken verbatim (without attribution) from a 2007 paper on the use of peppermint gel to prevent nipple cracks in breastfeeding women.[3] This plagiarism including misspelling of the word "viscous" as "viscose." Putting aside the issue of plagiarism, one wonders why the researchers bothered to go through the process of testing five different carbopol 934 concentrations, when the 2007 study had already determined which concentration works best.

continued on page 92 ➤

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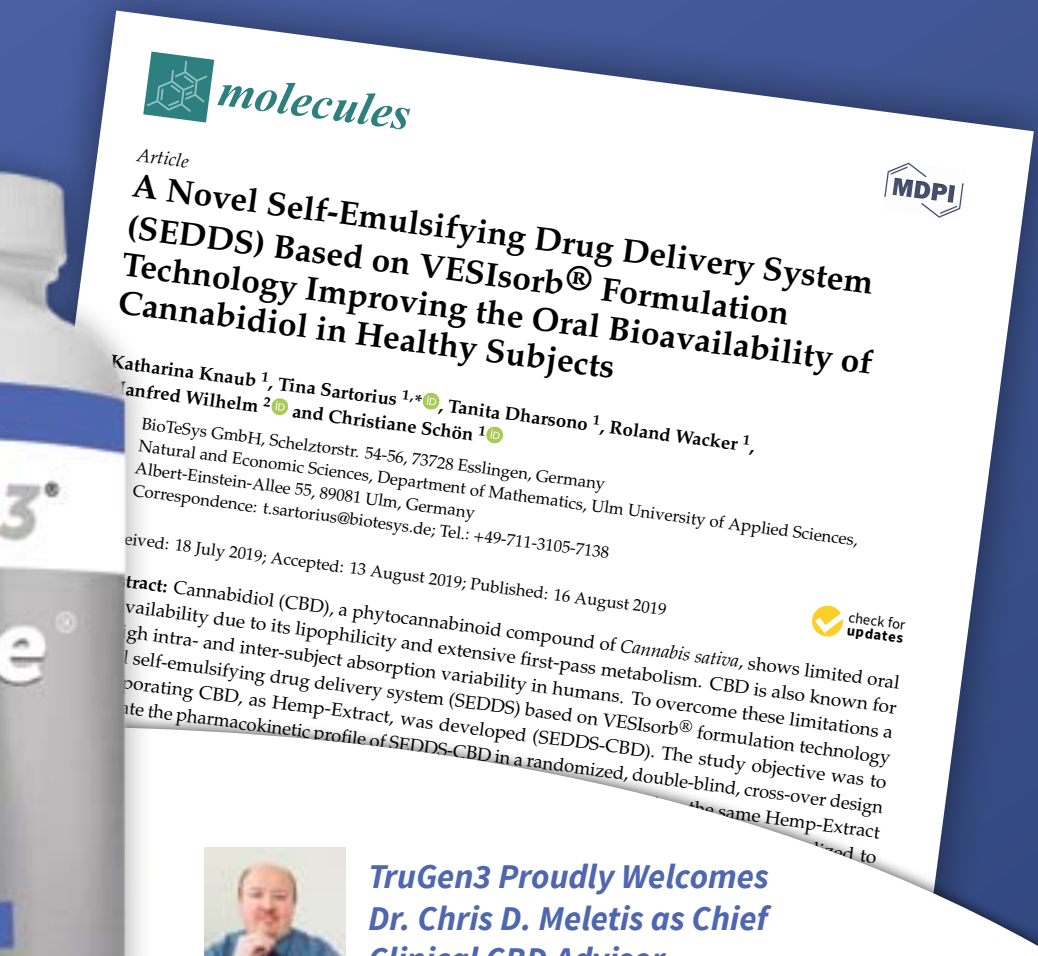

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Article

A Novel Self-Emulsifying Drug Delivery System (SEDDS) Based on VESIsorb® Formulation Technology Improving the Oral Bioavailability of Cannabidiol in Healthy Subjects

MDPI

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tract: Cannabidiol (CBD), a phytocannabinoid compound of *Cannabis sativa*, shows limited oral vailability due to its lipophilicity and extensive first-pass metabolism. CBD is also known for gh intra- and inter-subject absorption variability in humans. To overcome these limitations a l self-emulsifying drug delivery system (SEDDS) based on VESIsorb® formulation technology porating CBD, as Hemp-Extract, was developed (SEDDS-CBD). The study objective was to te the pharmacokinetic profile of SEDDS-CBD in a randomized, double-blind, cross-over design the same Hemp-Extract to

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