Making Clinical Sense of the Microbiome

By Erik Goldman
Editor in Chief

It’s “the greatest turnaround in science and medicine in the last 150 years,” says Raphael Kellman, MD, of the current microbiome revolution.

The recent shift from a view that bacteria are our worst enemies to one that sees microbes as our most important allies in health “is opening a new chapter in medicine,” says Dr. Kellman, an internist and functional medicine practitioner in New York City.

Of course, the core concepts in this “new” chapter are not really all that new.

Hearken back to 1907, when Benedict Lust—widely recognized as the father of naturopathic medicine—said the following: “We believe that germs and microbes should be looked upon as beneficent workers instead of enemies to human health.”

But what is new is our ability to plumb the mysteries of the microbiome with sophisticated scientific tools, and to discover the myriad ways in which probiotic organisms influence and regulate (dare we say control?) human physiology and behavior.

The microbiome is no longer a fringe concept. It’s gone mainstream. Last year, an article in the Mayo Clinic Proceedings predicted that “in a short time understanding the basic concepts about the interactions between humans and their microbiomes will be as important to clinicians as understanding concepts of genetics or germ theory.”

When Zeal Overtakes Reason

New microbiome information is emerging at such a rapid clip that few can keep up. Ninety percent of the roughly 4,000 microbiome articles now on PubMed were only published within the last 5 years!

As in all revolutions, zeal sometimes overtakes reason. Over-simplification of the complex relationships between man and microbes is leading many clinicians and patients to intervene in ways that far exceed our actual scientific understanding.

Wanton use of probiotics is one example. Many people are using probiotic supplements indiscriminately. That, says Dr. Kellman, isn’t such a good idea.

He stressed that probiotics are an important piece of the gut health equation. But in the absence of a comprehensive approach aimed at eliminating unfriendly organisms, improving diet and lifestyle, rebuilding damaged GI mucosa, and eliminating food triggers, they are unlikely to be effective.

The challenge for clinicians today is how to synthesize the wealth of new microbiome information into truly effective therapeutic strategies.

NIH Center to Confront Fears of Herb–Drug Interactions

By Janet Gulland
Editor in Chief

Mislaid fear about herb–drug interactions is keeping many practitioners from recommending potentially beneficial botanical medications, said Josephine Briggs, MD, director of the NIH’s National Center for Complementary and Integrative Health (NCCIH).

Speaking at the annual meeting of the American Herbal Products Association earlier this year, Dr. Briggs said NCCIH (formerly known as the National Center for Complementary & Alternative Medicine) is launching a major initiative to re-evaluate herb–drug interactions. The new center will develop “rigorous standards for herb–drug interaction testing.”

Clinicians’ apprehensions are largely unfounded, she said. “Most interactions identified in current resources are hypothetical, inferred from animal studies, cellular assays or other indirect means. Concern is often poorly founded, not based on rigorous studies.”

The new project will begin by studying test cases of five widely used herbal products and their interaction with five common meds, and then to begin to establish clinically validated criteria for identifying and quantifying interactions.

Dr. Briggs, a nephrologist, believes clinical judgment about herbs is clouded by significant, unexamined biases.

Unexamined Biases

“There are 11 major drug interactions with coffee, yet doctors don’t tell patients not to drink coffee based on possible interactions! A lot of the fears about herbs are not founded.
Scrutiny

On reaching the agreement, the AG’s office permitted GNC to resume selling the products held back by the initial cease-and-desist—a move indicating that there was never anything fraudulent about these products in the first place.

14 State AGs Call on Congress to Fix FDA Oversight

On April 2, AGs in 12 other states (CT, DC, HI, ID, IN, IA, KY, MA, MS, NH, PA, RI) plus the Mariana Islands joined the New York AG in signing a joint letter to 4 US Congressional committees urging legislators to give the FDA oversight authority over herbs, and by extension, all supplements.

The AGs called on Congress to review the adequacy of existing quality assurance measures, the measures used for verifying identity and purity, the degree to which marketers are using terms like ‘natural’ and ‘herbal’ in a misleading way, the need for further federal mandates on dietary supplement quality, and the need to develop new raw materials management requirements.

Senate Democrats Urge FTC to Investi-
gate ‘Piramal PEAP’

In April, Senators Richard Blumenthal (D-CT) and Dick Durbin (D-IL) pushed the Federal Trade Commis-
sion to investigate Piramal Pharmaceuticals for using herbal supplements for weight loss that contain β-Methylphenylethylamine (BMPEA), a synthetic stimulant. According to a recent FDA report, 52% of natural health products labeled as containing Acacia rigidula (an adrenergic herb) are spiked with BMPEA. Sens. Durbin and Blumenthal claim that some supplement manufacturers are deliberately mislabeling these products and using deceptive advertising to sell them.

Class Action Attorneys Meet to Develop Strategies

At the end of April, FDA’s Center for Drug Evaluation & Research held a two-day “information-seeking” hearing on the use of homeopathic products, in preparation for a re-think of the regulatory framework governing the manufacture and marketing of these increasingly popular remedies. Though officials have been mum on what potential revisions may be considered, this is the first time the agency has looked at homeopathy in nearly 30 years.

Top FDA Official Nods Consent to AG Actions

“GMP standards are minimal standards. Anything over and above what industry might want to set, or the states might want to undertake: it strengthens the industry we are all for,” said Carla Welch, director of the FDA’s Division of Dietary Supplemental Petitions. Speaking at the recent International Conference on the Science of Botanicals, Welch indicated that FDA does not see Schneiderman’s actions as an overstep of authority or a breach of FDA jurisdiction.

So far, all of the regulatory and negative media have been trained on botanical supplements sold in retail channels, though the language of both the consumer protection and the state and federal demands for greater regulation are clearly inclusive of supplements in general.

Some practitioner-focused brands have not been implicated so far, there’s no reason to believe practitioner lines will avoid scrutiny, according to AGs.

A Chaotic Patchwork

Jeff Bland, PhD, a founder of the Institute for Functional Medicine, as well as one of the original founders of nutraceutical giant Natural Factors, said he was particularly concerned about precedents set by Schneiderman’s actions.

Though scientific questions about DNA barcoding in the context of herbal medicine remain wide open, and though the AGs ultimately agreed that GNC’s products were not fraudulent, Dr. Bland says the allegations could create greater potential issues for future agreements in de facto standard for all types of class action suits for hungry lawyers to bring all kinds of lawsuits against the industry.

Other industry-watchers say the individual actions of various state AGs could result in a patchwork of state-by-state regulations and analytic standards that would make it difficult for supplement makers to comply.

According to Mark Blumenthal, of the American Botanical Council, the potential danger in allowing state attorneys general to set standards for something like analytical methodology. These are scientific questions, not political or legal ones.

“Is the AG trying to dictate authentica-
tion? A single state stipulating a single issue that could lead to a patchwork quilt of regulatory standards … is not in the interest of having a consistent national standard for all types of class action suits for hungry lawyers to bring all kinds of lawsuits against the industry.”

Loren Israelson, President of the United Natural Products Alliance, an industry group, agrees.

“AGs are the ranking law enforcement officer of the respective states. Their jobs are to protect the law. They are now getting into the policy business. This letter (to Congress) is directly related to policy considerations.”

They discuss and agree among themselves what the policy should be, and then they go out and implement it. Instead of having federally mandated policy coming from Congress to FDA or USDA or FTC, this is a completely new and different mandate coming from law enforcement agencies in the states.

In the context of raw materials analysis, DNA barcoding is a valid method for confirming plant identity.

An attorney who worked closely with GNC on the agreement, stressed that the agreement on using DNA barcoding applies only to botanical raw materials and not to final extracts. In the context of raw materials analysis, DNA barcoding is one among a number of valid methods of identifying plant material.

He also stressed that the terms of the agreement are narrower than they might seem on first glance. The agreement recognizes that some barcodes may not exist. If you ran the test in its full context you would see there’s no way to implement DNA barcoding unless there’s a valid scientific method for doing it. There is no question.

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eted very differently, than the three other distributional structures. This is the first time the agency has looked at homeopathy in nearly 30 years. The laws of public health are to be based on science. DNA barcoding as a valid method for confirming plant identity.

A Contentious Agreement

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Testing Takes Guesswork Out of Omega-3 Supplementation

By Janet Gulland
Contributing Writer

For many practitioners, omega-3 fatty acids are a standard part of patient care, especially when working with people at high risk of heart disease or inflammatory conditions like arthritis or chronic pain.

Holistic Primary Care’s 2015 practitioner survey, which drew responses from over 650 clinicians, showed that 81% of those who routinely recommend supplements are recommending omega-3s.

Yet the vast majority takes a very broad-stroke approach. Most practitioners base recommendations on general population guidelines like those laid out by the Dietary Reference Intakes or by organizations like the American Heart Association (AHA).

Others simply tell people to take omega-3s, and leave patients on their own to follow “serving size” recommendations on the product labels.

Either way, both practitioner and patient are flying blindly, and patients may not be getting the actual benefits of omega-3 supplementation simply because they’re not taking enough.

That’s unfortunate because it is easy and relatively inexpensive to test omega-3 levels in blood and tissue, and to then tailor supplementation to each patient’s actual needs, based on objective measurements.

“Standard” Doesn’t Mean Adequate

One could argue that there’s no such thing as a “standard” dose of omega-3s guaranteed to be effective for all people. People show variability in how they digest, absorb, transport and integrate fatty acids. A number of studies have shown that the same daily dose of combined EPA and DHA results in widely divergent blood and tissue levels.

In one such study of 30 cardiac patients, a 1,000 mg daily dose of EPA/DHA (the AHA’s recommended level for people with coronary artery disease) resulted in Omega-3 Index measures ranging from 4.3% to 11.2%.

The Omega-3 Index, developed by William Harris, PhD, indicates the amount of DHA and EPA incorporated into red blood cell membranes, expressed as percentage of total membrane fatty acids. It tells a lot about tissue uptake of omega-3s, correlates strongly with CVD risk, and is an important factor in considering risk reduction.

According to Harris’ research, the Omega-3 Index target value is around 8%. Measurements up over 10% are highly cardioprotective; levels below 8% correlate with increased risk.

To put it in perspective, the “typical” American eating a diet low in fish and plant-based foods but high in saturated fats, refined carbs, and processed foods has an Omega-3 Index of around 4–5%.

In Harris’ studies, 60% of the CVD patients on 1,000 mg of EPA/DHA failed to reach 8%. Only about 20% got up over the 8% threshold and into the really healthy zone.

Tissue Is the Issue

“The tissue is the issue,” says Doug Bibus, PhD, paraphrasing Bill Lands, the pioneering biochemist who first discovered the relationship between omega-3s and omega-6s, and the role of omega-3s in improving human health.

“It’s not what you put into your mouth that really matters. It’s what gets into the blood, and ultimately into the tissue, that matters,” Dr. Bibus told Holistic Primary Care.

Without testing and interpreting the trials. Without baseline and post-intervention fatty acid measures, there’s no way of knowing whether the dose under test was adequate or continued long enough to bring blood and tissue levels up to the point where actual clinical benefit could be expected.

Testing in the Clinical Setting

In patients with clear cardiovascular risk, or signs of other inflammation-related disease, it makes a lot of clinical sense to test, said Dr. Bibus, who worked closely for many years with Dr. Ralph Holman, the University of Minnesota biochemist who coined the term “Omega-3” and who laid the groundwork for subsequent research in this field.

Dr. Bibus now heads a company called Lipid Technologies (www.lipidlab.com) that has been running 60 years of analytical chemistry experience for clinical as well as research applications.

Lipid Technologies has translated Dr. Holman’s decades of work in fatty acid analysis into a simple finger-stick bloodspot test that can provide clinicians with information about a patient’s actual fatty acid profile. The Holman Bloodspot Test provides:

- Total omega-3 score based on circulating blood levels
- Omega-3 levels
- Omega-3 as percentage of total highly unsaturated fatty acids (HUFAs)—the so-called “Lands Test”
- Omega-3 Index
- Arachidonic acid to EPA ratio (indicator of inflammation)

Dr. Bibus explained that each of these tests, while useful, has limitations on its own.

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For example, the Omega-3 Index tells you about incorporation of omega-3s into cell membranes, but does not give any indication about omega-6 or arachidonic acid—two key players in chronic inflammation.

Likewise, it does not tell anything about docosahexaenoic acid (DPA), an important predictor for CVD risk.

DPA: The Unknown Omega

The importance of DPA was underscored in a nested case control study of 6,438 adults. Among them, there were 94 heart attacks within a 7-year period. DPA was highly predictive of heart attack risk (low levels confer greatest risk). In fact, it was actually more predictive than EPA and ALA (Simon JA, et al. Am J Epidemiol. 1995; 142(5): 469–476).

DPA may serve as a reservoir of EPA and DHA. It is structurally similar to both, and may be present in human blood at twice the level of EPA and half the level of DHA in non-supplemented individuals. DPA inhibits platelet aggregation more efficiently than EPA or DHA, and stimulates endothelial cell migration more efficiently than EPA. Available research suggests DPA is both anti-inflammatory and neuroprotective.

Though the story on DPA is still in an early stage, it appears to be an important piece of the essential fatty acid puzzle, one worthy of greater clinical attention.

Eliminating Guesswork

Without testing, omega-3 supplementation is largely a game of guesswork: you make a recommendation, then hope that the patient will comply and that the recommended dose will confer the expected benefit.

Testing enables you to give much more intelligent and personalized guidance. Plus, it’s inexpensive! The comprehensive omega-3 test costs under $100, usually as low as $70. There is even a CPT code for it (82544—EPA testing). Insurers’ willingness to pay varies widely, but this is technically a billable service.

Years ago, Dr. Lands worked out a series of equations to guide supplementation based on baseline omega-3 percentages.

- If someone scores below 30% (of total HUFA as omega-3), the suggested daily dose is 2–3 g/day of EPA/DHA.
- If someone’s in the 30–40% range, 1–2 g usually suffices.
- If they’re in the 40–50% range, a 0.5–1.0 g dose is fine.

Without knowing someone’s baseline values, you really don’t know how much to recommend.

“The reality is, for many people at the low end of the omega-3 spectrum, 300 mg per day isn’t going to cut it. Even 1,000 mg is going to be too low. You need 2,000–3,000, or even more, to get levels up to where you want them,” said Dr. Bibus.

He added that even at the topmost end of Lands’ dosing guidelines, one is still well within recommended safety ranges. For example, according to the European Food Safety Authority’s most recent guidelines (2012):

“Long-term supplemental intakes of EPA and DHA combined up to about 5 g/day do not appear to increase the risk of spontaneous bleeding episodes or bleeding complications, or affect glucose homeostasis, immune function, or lipid peroxida
tion, provided oxidative stability… is guaranteed.”

Is it possible to obtain a truly healthy omega profile without supplementation? Yes, says Dr. Bibus, provided you love to eat fish.

He noted that his mentor, Dr. Holman, religiously ate two cans of sardines with two cups worth of mixed green vegetables every day. He lived to be 94 years of age, in good health, and at last measurement he had more omega-3 in his blood than omega-6.

Lipid Technologies has partnered with Nordic Naturals to familiarize more clinicians with the value of omega-3 testing by providing two free Holman Bloodspot Tests per year for practitioners and staff. To learn more, visit: lipidlab.com/get-test.
NIH Confronts Fears
cont’d from page 1

on good meaningful accurate data. The aim of our new center is to help determine which interactions are really significant and require attention and which are not.

Many physicians wring their hands when patients mention that they’re taking—or even considering—a botanical in conjunction with drug therapies. Yet, many patients “are on 10 active pharmaceuticals and the potential for drug–drug interactions is so enormous that the minor agents in dietary supplements are unlikely to change that.”

Dr. Briggs voiced irony that many in the medical community are quick to vilify herbal medicine, while turning a blind eye to what she sees as two of the most pressing public health issues: prescription opioid addiction and antibiotic overuse. For one physician’s answer to the overuse issue, visit: www.holisticprimarycare.net and read “What to Do When Patients Demand Unnecessary Antibiotics.”

Clear Need for Alternatives
“Every time I open the paper, I see stories on overuse of psychoactive drugs . . . for pain, for sleep, for common colds.” According to CDC data, recorded death rates from cocaine and heroin have been more or less stable over the last decade, while deaths from prescription opioids have soared, from 4,000 in 1999 to over 16,000 in 2010. Newer data are consistent with this, she said.

“I am ashamed of the medical profession in this regard. The overuse and inappropriate use of opioids is incredibly shocking. In certain communities drug-related deaths are exceeding motor vehicle fatalities.”

She and her colleagues at NCCIH have been active in developing a framework for researching non-pharmaceutical alternatives for treating pain syndromes. She has also been working jointly with the Office of the Army Surgeon General on a Pain Management Task Force to implement non-drug pain treatments throughout the Department of Defense and the Veterans Health Administration.

While oxycodone and other opioids are a big culprit in the overuse epidemic, benzodiazepines and other psychoactive meds are also causing their share of problems.

“There are 50 million prescriptions for Xanax per year. In 2008, 12% of women at age 80 had a benzodiazepine, and for men it’s about 6%, even though guidelines call for great caution in using these drugs for elders.” Citing major sleep disturbances as a common and dangerous side effect, Dr. Briggs said that the need for safe and effective non-pharmaceutical sleep remedies is clear.

“We all have to learn together about alternatives to these drugs.” To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs. “To that end, NCCIH is working on an initiative on natural products natives to these drugs.

The antibacterial overuse problem is another one for which the natural medicine world might have good solutions. Currently, there are about 16 million Z-Pak prescriptions per year, mostly for colds and other conditions for which they are inappropriate.

Citing the book Missing Microbes: How Overuse of Antibiotics Is Fueling Our Modern Plagues, by Martin J. Blaser, MD, Dr. Briggs stressed that overuse carries massive risks not only because it promotes drug resistance and the evolution of superbugs, but also because it decimates the microbial diversity which is essential for good health.

“This is enormously relevant to natural products research,” Dr. Briggs said. “It is a reasonable hypothesis that a lot of the variability we see in peoples’ responses to various natural products has to do with variations in their microbiomes, and in concurrent use of antibiotics.”

For further information on non-drug alternatives visit: www.HolisticPrimaryCare.net
- “Lavender: An Effective, Non-Pharm Alternative for Anxiety & Depression”
- “Nutritional Treatments for Insomnia”
- “To Sleep, Perchance to Heal: Managing Sleep Disorders Without Meds”

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The Alkaline Way: Ten Tips for Reversing Metabolic Acidosis

BY RUSSELL JAFFE, MD
Contributing Writer

There’s a lot of talk these days about following an “alkaline” diet as a way of restoring health and prolonging life. In principle a lot of the core ideas behind this approach make good physiological sense.

Yet many people who try to follow an “alkaline lifestyle” are doing so based on observations that may be true in test tubes yet fail in physiology, in life, in reality.

To make sensible lifestyle choices on this matter, it is important to understand a little bit about the chemistry and physiology of acid-base balance.

All metabolic, neurohumoral, and immune system processes produce a net excess of acids. When foods induce immune reactions, additional acids are produced that lead to mineral loss in the urine, sweat and stool.

Adaptive, acquired immune responses directly and indirectly generate substantial amounts of acidic products (Jaffe R. Townsend Letter for Doctors and Patients; 2009; 316: 90–98). This isn’t just limited to B cells and/or T cell immune reactions and impaired buffering capacity. It is important to identify the causes of immune reactions by avoidance provocation or ex vivo lymphocyte response assays (LRA).

Simply put, when cells are more alkaline, they are more tolerant, better able to detoxify, and more able to maintain a high energy metabolism. This is mission-critical for cellular health.

Metabolic acidosis results when potassium and magnesium levels are too low to neutralize the normal production of acidic byproducts of metabolism. This impairs the body’s protective physiologic mechanisms so toxins are more likely to harm and less likely to be effectively removed.

Another consequence is that metabolic acidosis burdens the cell battery that depends upon a proton gradient to eliminate excess acid and export ATP.

**Latent Mg Deficiency**

Many people are walking around in states of “chronic latent magnesium deficiency” or CLMD (Bin RJ. Magnesium Research. 2011; 24(4): 225–227). This is defined as being in the lower half of the usual serum magnesium range. It won’t show up with red sines as a frank deficiency, but it does indicate reduced capacity to neutralize ordinary metabolic acids.

It is important to understand that blood (plasma) pH is highly conservative: it is one of the most tightly controlled of physiological parameters. The body has numerous mechanisms for keeping the plasma pH within a very tight range.

Inside cells, however, the situation is different. There can be significant mineral starvation and substantial net acid excess long before it would ever show up as a critical illness and significant changes in blood pH.

**Assessing Acid Status**

In a previous issue of Holistic Primary Care (Spring 2009), we covered the value of first morning urine pH as a simple method to assess metabolic status and need for minerals.

While some question the value of this test, we continue to find that after six or more hours of rest the high contrast Hydron pH paper (with at test range of 5.5–7.8) provides a useful measure of net acid status.

A healthy after-restore urine pH is in the range of 6.5–7.5. The body routinely uses the overnight rest time to concentrate excess acids in the urine, and this capacity varies widely. It is possible for an individual ability to make energy, detoxify toxins, and actively excrete them.

Too much acid in the urine after rest indicates mineral deficits in the cells.

The clinical challenge, of course, is how to get magnesium and other minerals into the cells. The key is by mouth and as close to the cells, all in the interest of reversing or preventing CLMD and its downstream consequences.

I’ve described this approach in depth in a new book called The Joy of Eating: The Alkaline Way. It is available online at www.peregue.com, www.elhsact.com or by calling 1.800.525.7372 or emailing clientservices@peregue.com.

One key to this is to combine balanced, soluble magnesium salts with concurrent choline citrate in a nano-droplet form that is readily taken up by the cell and absorbed (Jaffe R. Enhancement of Magnesium Uptake in Mammals. US Patent #8017160). The choline citrate terns each beneficiary in primary cell metabolism.

**Acid or Alkaline: It’s a Choice!**

A metabolically alkaline diet includes foods that have a buffering, alkalinizing effect on cell chemistry (Budde RA, Crenshaw TD. J Am Coll Nutr. 1999; 18(6): 421–430). This is different from the food’s ash residue or physical chemistry. For example, citrus fruits are alkalinizing by mouth and alkalinizing efforts. Warm, hot or room temperature beverages are better than cold ones. Iced beverages slow down and upset the digestive system rather than bottle of cained sodas helps with weight management and restorative sleep.

**Breakfast** is important! Listen to your body. Find which breakfast your body prefers. Some people do better with a large protein-rich breakfast; some do better with a smaller breakfast higher in complex carbs. Either way, breakfast is a very important meal.

• Fruit and fruit smoothies
• Eggs baked in a whole-grain- rich foods
• Granola or steel cut oatmeal as sources of complex carbs

3. Lunch: If your big breakfast works bet- ten. For example, citrus fruits are alkalinizing for keeping the plasma pH within a very tight range. (plasma) pH is highly conservative: it is one of the most tightly controlled of physiological parameters. The body has numerous mechanisms for keeping the plasma pH within a very tight range.

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One key to this is to combine balanced, soluble magnesium salts with concurrent choline citrate in a nano-droplet form that is readily taken up by the cell and absorbed (Jaffe R. Enhancement of Magnesium Uptake in Mammals. US Patent #8017160). The choline citrate terns each beneficiary in primary cell metabolism.

**Acid or Alkaline: It’s a Choice!**

A metabolically alkaline diet includes foods that have a buffering, alkalinizing effect on cell chemistry (Budde RA, Crenshaw TD. J Am Coll Nutr. 1999; 18(6): 421–430). This is different from the food’s ash residue or physical chemistry. For example, citrus fruits are alkalinizing by mouth and alkalinizing efforts. Warm, hot or room temperature beverages are better than cold ones. Iced beverages slow down and upset the digestive system rather than bottle of cained sodas helps with weight management and restorative sleep.

**Breakfast** is important! Listen to your body. Find which breakfast your body prefers. Some people do better with a large protein-rich breakfast; some do better with a smaller breakfast higher in complex carbs. Either way, breakfast is a very important meal.

• Fruit and fruit smoothies
• Eggs baked in a whole-grain- rich foods
• Granola or steel cut oatmeal as sources of complex carbs

3. Lunch: If your big breakfast works bet-
Got Fractures? Milk Raises Risk

By Kristen Schepker
Assistant Editor

From a young age, Americans are taught that milk is an essential component of a healthy, well-rounded diet. But new research on the long-term health effects of drinking dairy questions some age-old assumptions about milk’s protective benefits.

A study published last fall in the British Medical Journal found a positive association between high milk intake and increased fracture incidence among women, contradicting the commonly held understanding that dairy consumption reduces the risk of osteoporotic fractures. The study also revealed a correlation between high milk consumption and higher mortality among both men and women.

Conducted by researchers at Uppsala University in Sweden, the study examined milk intake in two large cohorts of Sweden across three counties. One cohort included 61,433 women between the ages of 39–74 years at baseline; the second included 45,339 men aged 45–79 years at baseline. Both groups completed food frequency questionnaires regarding their average consumption of common foods, including milk, fermented milk, yogurt, and cheese (Michaelsson et al. Brit Med J. 2014; 349:7981).

Within the female cohort, the researchers found that during a mean follow up of 20.1 years, 15,541 women had died and 17,252 had experienced a fracture, 4,259 of which were hip fractures. In the male cohort, a mean follow up of 11.2 years revealed 10,112 deaths and 5,066 fractures, with 1,166 hip fracture cases.

Women who drank three or more glasses of milk per day were found to die at nearly twice the rate of those who drank less than one glass a day, with an adjusted mortality hazard ratio of 1.93 (95% confidence interval 1.84 to 2.06).

The authors also concluded that higher milk consumption did not appear to reduce fracture risk among either women or men.

Increased Oxidative Stress

Significantly, they observed an additional positive association between high milk intake and increased levels of oxidative stress and inflammatory biomarkers. In subsamples of two additional cohorts, one male and the other female, urine 8-iso-PGF2α, a biomarker of oxidative stress, and interleukin 6, an inflammatory biomarker, increased with milk consumption.

They attribute this finding to the presence of the monosaccharide sugar D-galactose in dairy products. Milk is the primary dietary source of galactose, and consuming it either by injection or in the diet, the study notes, is an “established animal model of aging by induction of oxidative stress and inflammation.”

Pros & Cons

The Swedish study is just one recent example of the conflicting data on milk’s purported health benefits. Milk is praised for its broad nutrient profile, which includes protein, carbohydrates, and—in some milk types—fat. It’s also a convenient source of essential vitamins and minerals, including phosphorus, potassium, calcium, and vitamin D.

Adequate calcium and vitamin D intake play key roles in bone growth and strength throughout all stages of development. Some researchers have argued that a focus on bone disease prevention should begin prenatally, promoting the maintenance of healthy calcium and vitamin D levels during early childhood in order to “maximize peak bone mass and to prevent osteoporosis-related bone disease in adulthood” (Sopher et al. Cur Op Endo, Diaib & Ob. 2015; 22(1): 35–40).

While a significant body of research supports the notion that milk helps to promote bone growth and prevent osteoporotic fractures, it’s also been shown that fracture rates among the elderly are significantly higher in countries with high calcium intake and high mean bone mineral density (BMD) than in countries with lower calcium intake and a low mean BMD (Klompmaker TR. Med Hyp. 2005; 65(3): 552–558).

In the US, the USDA recommends consuming two to three cups of dairy products per day, depending on one’s age.

Milk and other dairy items have become many Americans’ primary source of calcium. From ubiquitous school cafeteria milk cartons to the FDA’s former food pyramid and newer My Plate nutrition models, children and adults alike learn that milk is a necessary component of a well-balanced diet.

But what’s often left out of the dominant conversation about milk is the fact that it’s simply not good for everyone. At birth, most people can readily digest lactose, the primary carbohydrate found in breast milk and an important source of nutrition during infancy. However, in most mammals, including humans, the natural production of lactase—the enzyme responsible for lactose digestion—decreases after weaning.

A Rare Trait

Some humans do continue to produce lactase into adulthood, a trait known as lactase persistence. But we haven’t always possessed the ability to digest lactose as adults either; it’s an adaptation we’ve developed in response to our ongoing consumption of non-human milk beyond infancy (Genbault et al. Philos Trans R Soc Lond B Biol Sci. 2011; 366(1566): 863–877).

Lactase persistence is a relatively rare trait. An estimated 75% of the world’s population eventually loses the ability to digest milk sugar and becomes lactose intolerant at some point in life (Mattar et al. Clin Exp Gastro. 2012, 5: 113–121). Rates of lactose intolerance are even higher in countries with minimal milk intake.

Notably, humans are the only species that routinely consumes milk produced by other animals. This curious fact, alongside the striking number of lactose intolerant adults, raises important questions about why we eat and drink so much dairy.

Calcium intake is certainly one motivating factor. But a long list of non-dairy calcium-rich foods reveals many other sources of this essential nutrient. Among them are green peas, chickpeas, quinoa, sesame seeds, oranges and fortified orange juice, and soybeans and other soy products such as tofu.

Additionally, leafy green vegetables like kale, spinach, and collard, mustard, and beet greens are high in calcium. One cup of raw kale contains approximately 90 mg of calcium; a 3.5 cup kale salad exceeds the amount of calcium—300 mg—found in one cup of milk.

If dairy is required to achieve adequate nutrition, some food items may offer better choices than others. The Swedish milk study found that a high intake of fermented milk products—such as yogurt, strained milk and cheese—was actually associated with lower rates of bone fracture and mortality. Beyond dietary considerations, many forms of exercise and healthy activity are known to support healthy bone growth and fracture prevention.

Those at risk of osteoporosis should have their bone mineral density tested regularly and take efforts to reduce the risk of falls in the home. Physical activity, especially weight-bearing activity, also helps to build and strengthen bones. Additionally, exposure to natural sunlight promotes vitamin D production and calcium absorption. Drinking milk may not be the most healthful approach to osteoporosis prevention.
Disturbance of the gut microbiome, also known as dysbiosis, has a major detrimental effect on human health. As microbiome research continues to explode worldwide, we are learning that microbial dysregulation within the gut is an important contributing factor in a wide range of common disorders. Those 70 trillion to 100 trillion beneficial bacteria living in our digestive tract are responsible for multiple physiological functions including:

- **Immunity:** Our digestive tract is base camp for 70% of our immune system: a good relationship between the body and its beneficial bacteria is important to fight off colds and common infections.
- **Neurotransmitter Production:** Every class of brain neurotransmitter has been found in the gut, including about 80% to 90% of our serotonin.
- **Enzyme Harvesting:** Gut microbes extract energy from undigested food products as they pass through the digestive system.
- **Bacterial Regulation:** The microbiome plays a role in regulating everything from appetite and fat storage to sleep cycles.
- **Production of Key Vitamins and Co-factors:** A number of things can adversely affect microbiome composition, such as chronic stress, age, environmental toxins, food sensitivities, antibiotics, malnutrition, smoking, genetics, and others, and most importantly, diet.

Some bacterial strains once present in the upper GI tract can cause gas, bloating, fat malabsorption, diarrhea, and constipation (or both). Ultimately, they damage the lining of the small intestine, the body from absorbing essential nutrients.

### Eluding the Radar

Dysbiosis is most prominent in the digestive tract and the skin, but really, it can be found on any exposed surface or mucus membrane, such as the vagina, lungs, mouth, nose, sinuses, ears, nails or eyes.

The only way to properly test dysbiosis is to remove bad bacteria, yeast and parasites, all of which can be considered infections that elude the radar of conventional medical tests (Am Dutta, et al. *Gastroenterology & Endoscopy News*, 2015: 65–6).

But that doesn’t mean we as clinicians must be completely blind or rely only on guesswork. There are a number of testing methods—some of which have been around for decades, others of which are very new—to identify dysbiotic states. Some of these methods have been around for 15 years ago: there’s a huge number of people who are not getting well. What should we look for? Likely to be related to gluten sensitivities, and who are desperate for meaningful solutions.

### A Basic Approach

There are a number of effective ways to test for dysbiosis, and a number of different labs that test for it: Genova Diagnostics; Metametrix Laboratories; Doctors Data Laboratory; Essential Diagnostics; and QuinTron.

These laboratories and cell science centers are among the top labs providing tests to evaluate potential dysbiotic states.

It is also possible for patients to get genetic testing of their gut microbiome for $89, from a company called uBiome.

Here’s the basic outline for how to approach patients whose symptoms fit the picture of dysbiosis.

**1. History:** It’s important to listen to patients and ask about symptoms, diet and supplements, medical, family, and social history. This wealth of information can often give you a lot of information for your next clincial visit.

**2. Comprehensive Stool Test:** This non-invasive test evaluates the 300 different bacteria that are found in the stool. It is a good place to start with many patients.

**3. Urine Test:** This method looks for unique products of microbial metabolism in the urine. It can indicate presence of small bowel yeast, bacterial overgrowth, and unknown intestinal microorganisms that manufacture large quantities of compounds produced by human cells, such as D-arabinotol.

These compounds are absorbed into the blood from the intestines and will appear in the urine. The virtue of urine testing is that it is very easy to do.

**4. Intestinal Permeability Assessment or Mannitol-Lactulose Intestinal Permeability Test:** This involves having the patient drink a premeasured amount of two sugars: lactulose and mannitol. The relative presence of these sugar in the urine will show how well the patient’s bowel is colonized by the beneficial bacteria is important to protect the mucosa, such as the vagina, lungs, mouth, nose, sinuses, ears, nails or eyes.

**5. Hydrogen or Methane Breath Test:** This is the gold standard for assessing dysbiosis. Though fairly simple in principle, it can be cumbersome and time-consuming. It tests for the presence of breath hydrogen or methane. Small Intestinal Bacterial Overgrowth (SIBO), and other digestive disturbances related to increased sugar fermentation. As a baseline breath gas measure, the patient ingests a standardized solution of lactulose or another substrate of which is normally indigestible by humans but highly digestible by bacteria. The measurement of hydrogen or methane in the breath at regular intervals—typically every 20 minutes—will indicate the degree of microbial fermentation of the lactulose within the upper GI tract. Rapid and steady rises in hydrogen and methane are proof-of-positive dysbiosis. These tests can help guide progress with treatment of leaky gut and dominate. It’s important to note that dysbiosis cannot be found through an endoscopy or colonoscopy, nor does it show up definitively on a test for bad blood work, so many practitioners miss it.

**6. Watch the B Vitamins**

That said, according to Raphael Kellman, MD, a functional medicine physician in New York City, there are a few major clues to be found among measurements of basic blood test levels.

*If B vitamins are low, and zinc is low, the patient's microbiome is unhealthy,* says Dr. Kellman.

The following are some B vitamins to watch:

- **B1** (Thiamine): Helps with conversion of proteins to energy and supports the immune system.
- **B2** (Riboflavin): Helps support energy metabolism in the body and may help decrease inflammation.
- **B3** (Niacin): Helps convert food into energy and supports brain, heart, and liver health.
- **B6** (Pyridoxine): Helps with protein and fat metabolism and supports healthy skin.
- **B7** (Biotin): Helps with energy production and supports healthy skin.
- **B9** (Folic Acid): Helps with red blood cell production and supports brain health.
- **B12** (Cobalamin): Helps with energy production and supports brain health.

**7. Other Bacteria:**

There are additional tests that can be useful in evaluating a patient's gut health.

- **Food Sensitivity Tests:** These tests involve measuring allergies to various food antigens, along with cellular panels.
- **Genetic Tests:** It's now possible to measure how effectively patients' enzymes are functioning. This can help identify the enzymes involved in liver detoxification pathways and those that regulate brain neurotransmitters.
- **Toxins:** Measuring levels of acetate that blocks gluten from slipping through the tight junctions between epithelial cells. In other words, it purports to treat one of the key symptoms of celiac disease: leaky gut syndrome. Alba was recently acquired by global drug giant Teva Pharmaceuticals.

*It's exciting to see new research showing that gluten and "psychosomatic" seem to be contributing to the symptom patterns.*

### Vitamin D May Improve Colon Cancer Survival

Among its many other known benefits, vitamin D may improve survival rates in patients with gastrointestinal malignancies. According to new research presented at the American Society for Clinical Oncology's 2015 GI Cancers Symposium, Kimmie Ng, MD, PhD, of the Dana-Farber Cancer Institute, studied patients with metastasized gastrointestinal metastatic colorectal cancer and found that those with higher blood levels of vitamin D lived longer and experienced greater disease-free survival following conventional treatment than those with lower vitamin D levels. The study also identified a correlation between higher levels of plasma 25(OH)D and treatment response. Patients with higher vitamin D levels lived a median of 8 months longer than those with lower levels. Those in the highest vitamin D quintile had a median overall survival of 51.5 months, versus 36.3 months in the lowest quintile (HR 0.67, 95% CI, 0.53–0.86; p trend 0.002).

The study also identified a correlation between vitamin D levels and improved progression-free survival. Patients with high vitamin D levels experienced a median 12.2-month period before disease progression, versus a median 10.1 months in the lowest quintile (HR 0.64, p = 0.01; trend 0.002).

Interestingly, there were no significant differences in progression-free survival based on the stage of disease.

Ng and colleagues concluded that higher concentrations of plasma 25(OH)D are associated with improved survival outcomes in metastatic CRC patients treated with chemotherapy and other anti-cancer drugs. In addition to its key role in maintaining bone health, vitamin D is a natural anti-inflammatory agent that possesses numerous anti-cancer properties, including the capacity to suppress tumor growth and promote cell death, while inhibiting angiogenesis.

*It's a natural holistic family medicine physician in Aurora, Ill. She received her MD, from the National College of Natural Medicine and completed her residency in 2010 at St. Joseph Regional Medical Center. She is currently board certified in Family Medicine and is board certified in Integrative Holistic Medicine. The Society of Teachers of Family Medicine awarded her the Resident Teacher Award in June 2010. Dr. Sadow also has a diploma in clinical homeopathy.*

**Big Pharma Discovers a Gluten Goldmine**

Alvine Pharmaceuticals, a small, privately-held drug company based in San Carlos, CA, has finalized a deal on a formula known as ALV003 that contains two enzymes that—at least in principle—break down gluten into non-allergenic fractions before it ever reaches the intestine.

*ABV1, a Chicago-based pharmaceutical development company with revenues of $118.8 billion in 2013, recently paid $70 million to Alvine for an option on the global rights to ALV003 that contains two enzymes that—at least in principle—break down gluten into non-allergenic fractions before it ever reaches the intestine.*

**Vitamin D May Improve Colon Cancer Survival**

By Kristen Schepker

Contributing Writer

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Microbiome

cont’d from page 1

What we do know is that bacterial cells out-number human cells in the body by a factor of 9:1, "We are basically bacteria dressed up in a suit," quipped Dr. Kellman at the Functional Forum, a monthly NYC-area practitioner meet-up.

The microbiome has tentacles into every aspect of our physiology. It is involved in production of vitamins, amino acids, bile acids, and fermentation of non-digestible substances. It plays a key role in glucose and fat metabolism, caloric consumption, cell proliferation, cancer signaling, and weight regulation.

When healthy, the microbiome is the "good guy." Bacteria from colonization by pathogens, regulates immune function, and modulates inflammatory reactions.

Some authors have referred to the microbiome as the "forgotten organ. " Others see it as the "software of the body.

Microbiome changes have been linked to a host of common disorders including:

- Type 2 Diabetes: Diabetics show reduced production of Bifidobacteria.
- Obesity: Obese people show low ratios of Bacteroides to Firmicutes.
- Atherosclerosis: Linked to low levels of Bacteroides and high levels of Ruminococcus.
- Irritable Bowel Syndrome: Patients typically show low levels of Bifidobacteria.
- Inflammatory Bowel Disease: Patients typically show high levels of Enterobacter, but low levels of E. coli.
- Colorectal Cancer: Associated with low levels of Bacteroides.

Microbiome & Autoimmune Conditions

"If you treat autoimmune diseases, you must treat the microbiome, because that’s part of the deep causes," stressed Dr. Kellman. "I almost always find microbiome abnormalities in autoimmune diseases. Improve that and you see overall improvement of the disease."

IBS, IBD and ulcerative colitis are all closely associated with dysbiosis and poor microbiome diversity. Protocols aimed at restoring microbiome health often confer significant improvements in these patients.

In a double-blind, placebo controlled study published a decade ago, Elizabeth Furrie and colleagues at the University of Dundee, Scotland, treated 35 patients with ulcerative colitis with either placebo or a "synbiotic" combination of probiotics (Bifidobacterium longum derived from healthy nasal epithelium) and a prebiotic (inulin-oligofructose derived from chicory). After one month, patients underwent sigmoidoscopy. The researchers saw major reductions in visible inflammation and reductions in the number of active ulcerative colitis. They found no such changes among the patients on placebo.

"Microbiome disturbances are a key player in the development of autoimmunity. The key is to get the microbiome back in balance. The microbiome is the "forgotten organ,"" Dr. Kellman said. But the microbiome is only part of the puzzle. There are many other factors that contribute to "autoimmune" conditions, such as genetics, lifestyle, and environmental exposures.

"The microbiome is a key player in the development of autoimmunity. But there are many other factors that contribute to "autoimmune" conditions, such as genetics, lifestyle, and environmental exposures.

Assessing the Microbiome

Microbiome research is fueling a surge of clinical testing methods for characterizing the flora in and on the human organism. There are dozens of labs offering tests for assessing the health of the microbiome.

How many of these tests prove to be practical clinically speaking remains to be seen. It is important to remember that the "ideal" microbiome appears to be efficacious in IBS, but the magnitude of benefit and the most effective species and strain are uncertain! Keep in mind that the microbiome can change rapidly and the effects of treatment can vary widely. It is important to assess the microbiome in conjunction with other clinical factors and to tailor treatment plans accordingly.

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Breaking the Mold: How to Get a Grip On Household Mycotoxin Exposure

By Jill Carnahan, MD  Contributing Writer

Indoor air pollutants, including mold and mycotoxins, may be contributing to more than 50% of many illnesses. The environmental movement has rightly focused our attention on smog, smoke, and outdoor pollution as disease drivers, but to some extent it has caused us to be a bit myopic to the fact that for many people, poor indoor air quality may be an even bigger threat to health.

Many patients are unaware that a toxic home or workplace—especially one contaminated by mold—is contributing to their symptoms. Exposure to chronically water-damaged indoor environments is associated with exposure to molds. The most common types found indoors include Cladosporium, Penicillium, Alternaria, and Aspergillus.

**Stachybotrys chartarum** (sometimes referred to as “toxic black mold”) is a greenish-black mold, which grows on household surfaces that have high cellulose content, such as wood, fiberboard, gyspum board, paper, dust, and lint. The unwelcome—and all-too-common—presence of Stachybotrys is usually an indicator that there has been elevated moisture present or previous water damage. Some molds secrete mycotoxins that can be measured in the urine, such as ochratoxin, aflatoxin, and trichothecenes.

**Inflammatory Triggers**

Exposure to mold and mold components is well known to trigger inflammation, allergies and asthma, oxidative stress, and immune dysfunction in both human and animal models.

Mold spores, fungal fragments, and mycotoxins can be measured in the indoor environments of moldy buildings and in humans who are exposed to these environments.

Most of the time, we are exposed to molds like *Stachybotrys* via skin contact, through ingestion, and by inhalation. Sites of exposure typically include water-damaged and poorly ventilated homes, offices, buildings, court houses, hospitals, and hotels. It is estimated that as many as 25% of buildings in the US have had some sort of water damage.

Molds have the ability to trigger a wide range of symptoms, such as skin rashes, respiratory distress, various types of inflammation, cognitive issues, neurological symptoms, and immune system suppression. In day-to-day clinical practice, the most common symptoms associated with mold exposure that we’re likely to see are allergic rhinitis and new onset asthma.

**When in Doubt, Ask**

I believe we need to raise our index of suspicion about mold exposure among our patients with chronic inflammatory conditions, especially when those conditions do not resolve with typically effective treatments.

I start to think about mold exposure whenever I see patients with the following:

1. Fatigue and weakness
2. Headache, light sensitivity
3. Poor memory, difficulty finding words
4. Difficulty concentrating
5. Morning stiffness, joint pain
6. Unusual skin sensations, tingling and numbness
7. Shortness of breath, sinus congestion, or chronic cough
8. Appetite swings, body temperature dysregulation
9. Increased urinary frequency or increased thirst
10. Red eyes, blurred vision, sweats, mood swings, sharp pains

**How to Treat Mycotoxin Exposure?**

Dealing with the sources of exposure is obviously the first step. The patient needs to find the mold and to the best extent possible, eliminate it from their homes or workspaces. There are a number of companies across the country that specialize in household mold detection, elimination and remediation. It is essential for patients to remove themselves from the contaminated environment or to reduce the contamination from their midst. Don’t even think about going on to other treatment modalities until they’re able to minimize their exposure by avoiding or cleaning up the contaminated environment.

Here are a few other steps for mitigating the potential health damage caused by chronic mold exposure:

- Use clay, charcoal, cholesteramine or other binders to bind internal mycotoxins. My favorites are Upgraded Coconut Charcoal or GI Detox and Glutathione Force!
- While using binders, the patient must maintain normal bowel function and avoid constipation. If needed, magnesium citrate, buffered C powder, or even gentle laxatives can be a big help. Make sure your patients understand that constipation is the enemy of detoxification.
- Look for and treat colonizing molds/fungal infections in the body. Common locations of colonization include sinuses, gut, bladder, vaginal, and lung.
- Test and treat for candida overgrowth. Living in an environment with mold leads to immune suppression. One study showed that aflatoxins are liposomal glutathione, milk thistle, n-acetylcysteine, alpha lipic acid, glycine, glutamine, and other vitamins.
- Methylation support is also key and involves optimal levels of methylcobalamin (B12), methyl-folate, B6, riboflavin, and minerals.
- Encourage patients to invest in a high quality air filter and home and at work. Some examples include Austin Air or E. L. Faust. When detoxing from mold exposure, it’s a good idea to avoid common mycotoxin containing foods. These include: corn, wheat, barley, rye, peanuts, sorghum, cottonseed, some cheeses, and alcoholic beverages such as wine and beer.
- Other foods to avoid include: oats, rice, fruit, nuts, chili powder, oil seeds, spices, black pepper, dried fruits, figs, coffee, cocoa, beans, and bread.

**Other Treatment Options**

- Follow Dr. Jill’s Low Mold Diet. Many of my patients do well on a paleo, grain-free diet, like the one I’ve developed. Grains are often contaminated with mycotoxins and molds, which can exacerbate the effects of airborne or cutaneous exposure to molds in the environment.
- Sublingual immunotherapy (SLIT)
- Anti-fungal herbs and medications
- Infrared saunas
- Detoxification support — oral and intravenous
- Create a “safe” place, with little potential for mold/allergens and great filtration systems. This could be a bedroom or other room that is mold and chemical free.
- Some patients with severe symptoms may benefit from IV immunoglobulin therapy (IVg).

Jill Carnahan, MD, ABFM, ABIHM, practices functional medicine with her medical practice partner Dr. Robert Rountree, at Boulder Wellness and Functional Medicine, in Boulder, CO. Dr. Carnahan is board certified in both Family Medicine and Integrative Holistic Medicine. She founded the Methodist Center for Integrative Medicine in 2009 and worked there as Integrative Medical Director until October 2010. She completed her residency at the University of Illinois Program in Family Medicine at Methodist Medical Center and received her medical degree from Loyola University Stritch School of Medicine in Chicago.

Dr. Carnahan will be a featured presenter at the 2015 Heal Thy Practice conference, October 16–18, at the Coronado Island Marriott, San Diego, CA.

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- Decker Weiss, NMD: New Perspectives on Inflammation. Among the nation’s only naturopathic cardiologists, Dr. Weiss brings his unique view on the realm of inflammation in heart disease, as well as practical approaches for ameliorating chronic inflammation.
- Miriam Zacharias: Making PEACE with Market ing. HTP veteran Miriam Zacharias returns with strategies to maintain new clients. The PEACE Process. This 5-step program (Purpose, Establish, Attract, Connect, Engage) will sharpen your conscience and consciousness to the marketing process.
- Jacques Simon, Esq: Medical/legal Perspectives for Holistic Practitioners. Jacques has a healthy dose of preventive lawyer-ing from one of the nation’s top attorneys in the field of integrative medicine.
- Mark Menolascino, MD: Selecting & Integrating Ancillary Services. Ancillary services can make or break your practice. But with so many different options available, how do you pick the winner? Dr. Menolascino offers his top choices… and a few lessons learned along the way.

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Aluminum, Alzheimer’s & Autism: Understanding the Connection

By Erik Goldman
Editor in Chief

Back in the late 1980s, James Tyler Kent, a forefather of American homeopathy, described the nature of someone suffering from aluminum toxicity as follows: “...a confusion of mind, confusion of ideas and thoughts. ... The consciousness of his personal identity is confused ... he is in a dazed condition of mind. ... Confusion and obscuration of the intellect.”

Kent might very well have been describing an elderly person in the throes of Alzheimer’s disease—or an adolescent who, today, would receive a diagnosis of autism or one of the related “spectrum” disorders.

There’s a reason those high-enough concentrations, aluminum becomes neurotoxic. Next to bauxite miners, factory workers, and people who live in highly polluted industrial areas, children and elderly people are the populations at greatest risk of exposure to potentially harmful levels, says Jared Skowron, ND, a naturopathic physician in Wallingford, CT.

“Aluminum is the 3rd most abundant mineral on earth. It is literally all over the place, in small amounts. It is in the soil, in the air, in the water, in the foods we eat. Our bodies have adjusted to it in natural forms and its natural distribution. But when you extract it from the earth, concentrate it, and make it into things to which we have constant daily exposure, it can create problems,” he said at the 10th annual meeting of the New York Association of Naturopathic Physicians.

Oral intake of 330 mg/kg/day or more results in decreased myelination of nerves in experimental animals, and even 230 mg/kg/day is enough to cause neurological damage, said Dr. Skowron. Bearing in mind the caveats that go along with drawing human conclusions from animal toxicity studies, the point here is that humans living a modern lifestyle can very easily reach these daily dose levels.

Antacids & Other Aluminum Sources

In modern industrialized countries, aluminum is found in a very wide range of consumer products: processed foods, baked goods, grains, and dairy products as well as deodorants and antiperspirants, cosmetics, personal care products and over the counter medications like antacids and buffered aspirin.

The latter two are among the main reasons that elderly people are at elevated risk of accumulated neurotoxic aluminum levels. Many elders are taking aluminum-containing aspirin tablets every day to help reduce cardiovascular risk. Many also take antacids, which typically contain 300–600 mg of aluminum hydroxide.

To put it into perspective, a typical sample of pond or lake water in the U.S. will contain less than 0.1 mg/l of naturally occurring aluminum. The average adult not taking any aluminum-containing drugs ingests between 10 mg per day from food and water.

Someone who is taking a buffered aspirin and an antacid is getting between 600 and 3,000 mg of aluminum-containing compounds per day.

“Who’s doing that? Elderly people” said Dr. Skowron.

The rate of absorption of aluminum via the GI tract is relatively low, and true symptomatic aluminum poisoning is rare. Absorption ranges from around 0.01% for aluminum hydroxide to roughly 5% for aluminum citrate. Most aluminum ingested from food, water and drugs is excreted out in feces and urine.

Aluminum Sponges

The problem is that neurons are very good at absorbing whatever aluminum does make it into the bloodstream. Essentially, they’re aluminum sponges. And unlike other types of cells that absorb aluminum, which die quickly and get replaced, aluminum-damaged neurons are not. The result over time is a gradual destruction of neural tissue.

Dr. Skowron noted that people on kidney dialysis who regularly take aluminum-containing antacids develop Alzheimer’s very quickly. Why? Because they can’t excrete the aluminum via the kidneys. This is a known phenomenon among renal specialists—they’ve named it “dialysis encephalopathy” or some other euphemism, but essentially it is aluminum-induced dementia.

Bone also absorbs aluminum fairly easily. This blocks the incorporation of other minerals into the bone matrix contributing to osteoporosis, a double-whammy for elders, and one that’s compounded by the fact that generally, as people age, the ability to eliminate toxins like aluminum tends to decline.

Aluminum & Children

The so-called vaccine wars, which flared up once again this year, represent one of the most contentious issues in primary care, one that typically defaults to heated emotions on both sides.

Lost in much of the rhetoric are some subtle but important facts that have bearing on the question of why most children tolerate vaccines without problems while in others the same vaccines trigger unexpected problems.

Dr. Skowron, who is author of Fundamentals of Naturopathic Pediatrics and 100 Natural Remedies for Your Child, is a long-time veteran of the vaccine debates. He says it’s important to recognize that a big question about vaccines is not so much the principle behind immunization as the fact that most vaccines contain aluminum.

The amounts are small, typically less than 0.85 mg of aluminum per dose. But he stressed that while they are well below “safe” levels for adult weights, they approach potentially toxic doses for babies. It’s also important to keep in mind that babies and small children are metabolically very different from adults. They’re not just small versions of grownups.

Following a typical injection, 59% of the aluminum content is excreted within the first five days, but 25% may be retained long term. In some children, the aluminum may have a 10-year half-life.

Why do manufacturers put aluminum in vaccines? It “glues” the antigens together so the bolus will stay in the skin or muscle for longer periods and therefore generate greater immune responses as the B-cells keep hitting the vaccine material to create more and more antibodies, Dr. Skowron explained.

Assuming that each shot contains between 0.2 and 1.0 mg/kg of aluminum, a 12-pound baby getting the typical array of “required” vaccines, is getting up to 5 mg/kg directly injected. Not every infant can handle that.

Some children with compromised excretory function may build up toxic levels of aluminum fairly quickly. Dr. Skowron referred to the case of a two year old boy in whom aluminum was by far the most prevalent mineral in the blood.

Keep in mind that in infants, the blood-brain barrier is not fully developed, and that the aluminum an infant gets from vaccines is on top of that which she ingests from breast milk (there is evidence that aluminum does pass into mother’s milk), soy or dairy formulas, and various food sources. In some cases, the cumulative amounts can reach neurotoxic levels fairly quickly.

The situation may be worsened if parents choose to treat common childhood ailments like headaches with aspirin or colic with antacids. Prolonged use of aluminum-containing drugs in young children has been associated with growth reduction, hypotonia, muscle weakness, and premature ossification of the skull.

Minimizing Exposure

The good news is that it is fairly easy for all people, regardless of age, to reduce exposure to aluminum. Given what we do know about its neurotoxic potential, it certainly makes sense to do so.

Dr. Skowron recommended:

• Avoiding processed foods.
• Avoiding aluminum pots & pans.
• Installing a home water filtration system.
• Minimizing or eliminating use of antacids and buffered aspirin.
• Avoiding aluminum-containing vaccines.

In some extreme cases, it may make sense to consider detoxification interventions such as chelation with deferoxamine (DFO) or EDTA. The toxic effects of aluminum can be mitigated with Vitamin E, Vitamin C, selenium, and herbs like Bacopa moniera or curcumin. (Visit www.holisticprimarycare.net for more information use of curcumin and herbs.)
"People are so hungry for this. We were fully booked and profitable after the first six months!" 

In an era when so many clinicians are convinced private practice is a relic of the past, and corporate control of medicine is inevitable, Dr. Lundquist’s clinic, located roughly an hour north of San Diego, is a radiant example of what can happen when a group of practitioners is responsive to what their community really needs. 

To be sure, building the Temecula Center for Integrative Medicine (TCIM) from the ground up had its challenges. But Dr. Lundquist told Holistic Primary Care that it was not nearly as difficult as many practitioners imagine it would be. 

The practice, which is largely insurance-based, is founded on a team approach that includes naturopathic medicine, chiropractic, nutrition counseling, massage and bodywork, lifestyle education, and oriental medicine. Extended, unhurried office visits are the norm, and the center sees patients with a wide range of complex chronic disorders. 

As a keynote speaker at HPC’s upcoming 2016 Heal Thy Practice conference, (www.HTPConference.com) Dr. Lundquist will share key insights on how to plan, develop, and manage an integrative clinic—particularly one that takes insurance. 

Erik Lundquist is no stranger to challenges. Prior to his private practice life, he completed 8 years of active duty with the US Navy, including a stint in Afghanistan shortly after Sept. 11, and a subsequent deployment as a battalion surgeon with the Marines in Iraq. 

After leaving the military, he joined a family practice in Southern California—one with a definite “wellness” focus. Dr. Lundquist, who had a strong leaning toward nutrition and natural medicine, was thrilled to be working alongside a PhD nutritionist with whom he could develop meaningful dietary interventions. 

“People are so hungry for this. We were really ready to help you.” One such patient had been a battalion surgeon with the Marines in Iraq, who realized, in 2012, that it was not nearly as difficult as many practitioners imagine it would be. 

He found some initial clues in the recordings from the 2012 Heal Thy Practice conference. “It was really inspiring. That’s when I made the decision that I was going to do this.” Attendance at Heal Thy Practice the following year solidified the commitment. 

Today, not quite a year after opening its doors, TCIM is thriving beyond its founder’s wildest expectations. 

“We started out with five practitioners: myself, a chiropractor, a naturopath, another MD, and a lifestyle educator. Today we’ve got 10 practitioners, and another 10 employees. We’re seeing close to 200 patients per week, and we’ve got a three-month waiting list.” He noted that he personally sees about 45–60 patients per week. “It’s not crazy volume. We keep the numbers down and we give extended visits.” 

Even before TCIM opened, there were 150 patients ready to join the new practice. Dr. Lundquist estimated that roughly half of his previous patient panel followed him to the new clinic. 

While many stars aligned to make the launch so prosperous, Dr. Lundquist said it was not entirely due to luck. A few core principles laid the foundation for success:

- Teamwork: From the get-go, TCIM was built around an interdisciplinary employee model in which each type of practitioner could shine at what s/he does best, and that true collaboration would be the norm.
- Learning How to Bill Insurance: Though TCIM does have a small cash-payer segment, the vast majority of patients use insurance. Partnership with coding experts has enabled the clinic to obtain reimbursement levels seldom seen for integrative medical services.
- Listening & Responding to Patient Needs: Dr. Lundquist recognized that he was not the only one frustrated by the limitations of conventional settings. His patients were equally dissatisfied. He was able to learn what they really wanted, and then to channel their enthusiasm into the new practice. Some of his strongest allies in creating TCIM have been the patients themselves. 

“A few of my patients said, ‘When are you going to open up your own practice? We want to help you.’” One such patient had been the director of a hospice, who then went on to train as a Reiki practitioner. She had time to spare, and worked with Dr. Lundquist to set up the new clinic.

The practice grew almost exclusively by word-of-mouth within Dr. Lundquist’s patient base, and among people in the broader Temecula community who were excited about integrative care. 

While there are a handful of other holistic or functional medicine practices around Temecula, they are all single-practitioner solo offices. “There was no true multidisciplinary center here until we came along.” That unique offering, plus the fact that TCIM was willing to take insurance made it highly appealing to patients in this 100,000-person community.
Temecula

**Careful Coding, Ample Returns**

Ms. Fox, a former sales rep for Metagenics, was able to connect Dr. Lundquist with billing and coding experts who understand the nuances of functional medicine as well as the details of the coding system—a rare combination that has functional medicine as well as the details of the coding experts who understand the nuances of coding system.

**Eliminating Fear & Uncertainty**

“Everything goes through an MD gatekeeper, and is billed under medical services,” he explained.

“All patients must first see me or Dr. Narayan for an initial visit, and then they are referred to other practitioners within the center based on what they need. If they’re seeing the practitioners within our center, we can bill insurance for these services as incidental to the initial MD visit. Of course, patients do have the option to see chiropractors or coaches or any other practitioners outside our center, and we honor those choices.”

TCIM has a small number of direct-pay patients, but the vast majority does use insurance to cover at least part, if not all services.

The practice also has several ancillary cash revenue streams including an onsite supplement dispensary, and a series of classes focused on specific conditions such as chronic fatigue and autoimmune disease. Attendees pay $30 per 90-minute class. Ms. Fox noted that these classes, though not formal group visits, are a step in that direction.

TCIM practitioners also do teleconsults with patients on a cash basis, charging for increments of online time. So far, they have not sought insurance reimbursement for online visits, though that may change at some point.

Dr. Lundquist and Dr. Lee Hazen, the group’s chiropractor, are co-owners of TCIM, along with a third business partner. All the other practitioners are salaried employees. The group currently includes a naturopath, a nurse practitioner, a behavioral health specialist, two lifestyle educators, a licensed acupuncturist, and two certified massage therapists.

“To have all the resources for complete patient care right at my fingertips is fantastic. I used to do all the nutrition consults myself, but now I have people working with me who are dedicated just to that. Having all the services integrated under one roof, and then to be able to bill insurance is just remarkable, and very rewarding. The camaraderie and collaboration are phenomena.”

He stressed that cultivating a spirit of teamwork has been essential to TCIM’s success.

“One of the big challenges we face as physicians is that we tend to be very independent. We want to control everything. We’re not so good at playing in the sandbox with others. To make a thing like this work, you really need to recognize the value of other types of practitioners and other healing disciplines, and to realize that what they bring to the table can help your patients just as much as you can.”

**Cultivating Teamwork**

Staffing is one of the biggest challenges facing any practice, and Dr. Lundquist says he was initially concerned about how he was going to attract the right team.

“I was fortunate because a lot of the right people just came to me. With every one of our practitioners, when there was a need, a door opened and someone really good showed up. We actually did very little recruiting.”

While there may be an element of kismet at work, Dr. Lundquist says attitude also plays a role. “I think it happened the way it did because I was really open. I did not need this to be ‘Erik Lundquist’s Clinic.’ From the start, I was open to advice, to letting others take over certain aspects of the practice. That really helped me attract the right people.”

**A Touch of Tech**

The care at TCIM is high-touch, but Dr. Lundquist and his team are firm believers in utilizing digital technology when appropriate.

New patient questionnaires and several other key forms are available electronically and provided to patients with the expectation that they will complete these prior to the actual office visits. This saves time and also helps engage patients before they ever set foot in the Center.

Dr. Lundquist has found Google Glass to be a valuable tool. He uses the head-mounted optical display system to connect to the Internet via Skype, so he can interact with an offsite medical scribe. The system allows him to securely live-stream each encounter to the scribe, who records all key details in the patient’s medical record.

He says he prefers this approach because he found it difficult to truly pay attention to patients while simultaneously trying to enter case notes. “This allows me to communicate that info to the scribe, who will then document what’s going on in real time. I can be more focused on the patient and be thinking about why he or she is experiencing what they’re experiencing.”

Finding the right EHR system was definitely a challenge for TCIM. Ms. Fox said the group tried three different systems before finally settling on HealthFusion. Though far from perfect, she says the team is generally happy with it.

Is the TCIM model replicable by other doctors in other communities? Dr. Lundquist definitely thinks so.

He hopes his presentation at Heal Thy Practice, and the Integrative Medicine Consulting Group’s ongoing efforts will help physicians across the nation develop new clinic models that truly deliver on the promise of holistic and functional medicine.
The FDA currently recognizes the US Homeopathic Pharmacopoeia, maintained by a non-government organization—the Homeopathic Pharmacopoeia Convention of the United States (HPCUS)—as the primary governing framework for homeopathics. The pharmacopoeia includes 1,200 monographed homeopathic remedies in use since 1897, and it defines how these remedies are to be manufactured.

Evaluation & Research held a two-day preparation for a reevaluation of the regulatory framework governing the manufacture and marketing of these increasingly popular remedies.

A panel of nine FDA officials, including lawyers, a pediatric ethicist, and the director of the agency’s OTC drugs division, heard testimony from 45 people, including some of the nation’s leading advocates of homeopathy, such as Alison Teitelbaum, director of the National Center for Homeopathy, Bruce Shelton, MD, PhD, of the Arizona Homeopathic & Integrative Medical Association, and J. P. Borneman, of the Homeopathic Pharmacopoeia Convention of the US. Some of the discipline’s most vehement detractors—including Yale neurologist Dr. Steven Novella—see the current hearings as a welcome first step toward curtailment of what they view as a worthless and pseudoscientific practice.

Under the Spotlight
Since the late 1930s, when the FDA was initially formed, the agency has viewed homeopathic drugs as a category distinct from both pharmaceutical drugs and dietary supplements.

For the first time in nearly 30 years, the Food & Drug Administration is considering revision of how homeopathic medications are regulated.}

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The FDA does not currently require safety reviews for the manufacture or sale of homeopathic medicines. Since 1988, any “drug products” labeled as homeopathic have been able to be sold and manufactured without FDA approval, based on manufacturer adherence to the Compliance Policy Guide (CPG) published in the Federal Record that year.

Homeopathy’s critics say these standards are lax to ensure public safety, and even some people who are sympathetic to homeopathy in principle are in agreement that existing standards leave room for questionable manufacturing practices. Some homeopaths cite the fact under the existing regulatory framework, unethical companies can market “homeopathics” not produced in accordance with the principles of homeopathy and containing potentially dangerous, undisclosed pharmaceutical or synthetic ingredients.

Ambiguous Signals, Veiled Motivations
FDA has been deliberately vague about what sort of regulatory revisions might be under consideration, other than to say that the agency is “Seeking to obtain information and comments from stakeholders about the current use of human drug and biological products labeled as homeopathic, as well as the Agency’s regulatory framework for such products.”

In an article on Bloomberg.com titled “FDA Might Finally Crack Down on Homeopathy,” FDA’s Cynthia Schnedar, who chaired the hearings, is quoted as saying, “We’ve seen a huge expansion of the market and we’ve also seen some emerging safety and quality issues.”

Schnedar noted the agency was trying to determine whether consumers have “adequate information to make informed decisions” about homeopathic remedies. The FDA says the hearings were not intended as a forum on the efficacy of homeopathy, or the right of practitioners to utilize the modality. Likewise the hearings were not intended as prelude to categorical prohibition of retail sale of homeopathic remedies.

Some reassurances are of little comfort to some homeopaths, including Dr. Shelton, whose own personal and clinical experience made him a strong advocate.

“This could reverse a 75 year history that has helped make homeopathy as respected and as popular as it has become,” Shelton notes on a post to the Arizona Naturopathic Medical Association’s website. He is concerned that if the FDA opts to apply pharmaceutical-style regulations, it would all but eliminate free public access to OTC homeopathic remedies.

Though these initial hearings in and of themselves may be insignificant, they are taking place in the context of increased scrutiny—some would say overt hostility—toward all non-pharma products, as exemplified by the recent actions against botanicals by the New York Attorney General, and the letter from 14 state AGs calling on Congress to increase regulatory stringency on supplements.

It remains to be seen what will come out of the FDA’s homeopathy review. Holistic Primary Care will be following the developments closely.
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