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August 2014



BioMarketing Insight Newsletter

Creating Markets and Marketing
Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter. Last month I covered "How a Leaky Gut and Gut Microbiome Can Affect Our Immune System." If you missed last month's article, click [here](#) to read it. This month I will discuss how gluten increases glucose levels that can affect the brain and the heart.

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on September 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
[BioMarketing Insight](#)

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Save the Date: POC+mHealth Diagnostic Summit - November 5 - 7, 2014



Amidst a diminishing supply of providers and escalating costs of healthcare, the call for new point-of-care testing, direct-to-consumer diagnostics, patient-centered devices and apps to support mobile healthcare has never been greater. These technologies offer clinicians decision support capabilities, healthcare systems a real-time data stream for population health management and they offer providers, patients and payers the chance to improve the outcomes of care for less expense.

The conference will cover the topics technology developers, clinicians, researchers, payers and innovators should consider when developing, launching and integrating new point-of-care testing, patient-centered devices, direct-to-consumer diagnostics and apps/devices to support mobile healthcare.

I will be speaking on Friday, November 7th at 9:30 am on "eMedicine, eMonitoring, eHospital, and mHealth Apps: Seven Critical Factors that Need to Be Assessed in Determining Whether Your Product Will Be Commercially Successful." To learn more about Point-of-Care and Mobile Health Diagnostics Clinical-Consumer Interface presentations, click [here](#). To view the entire agenda, click [here](#). To register, click [here](#).

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How Gluten Increases Glucose Levels and Can Cause Neurological and Cardiac Diseases

Neurological Diseases

Last month, I discussed how gluten leads to a leaky gut and how one's unique physiology determines one's own immune system reactions. Unfortunately, gluten has another unfavorable effect, a glycemic index of 70 +, higher than any other natural food. This high glucose content causes glycation, where elevated blood sugar binds to protein. When this happens, free radical production increases and damages everything in sight (DNA, fat, protein etc.), according to Dr. David Perlmutter, neurologist and associate professor at the University of Miami School of Medicine. The resulting inflammation is devastating to the human brain.

Dr. Perlmutter mentioned that there is a direct relationship between blood sugar elevation and Alzheimer's (sometimes called Type 3 diabetes). Perlmutter stated that elevated



Bread contains gluten which has a

glucose correlated with dementia according to a study in the New England Journal of Medicine ([NEJM](#)). Even a mild elevation of glucose, slightly over 100 mg/dL, is an early warning sign.

glycemic index of 70+.

His recommendation is to eliminate carbohydrates from the diet, particularly wheat, rye and barley, because gliadin antibodies have been found in the spinal fluid and some have developed cerebellum ataxia that affects arms, legs and coordination due to gluten sensitivity. This relates back to the leaky gut and gluten. One can measure tissue transglutaminase 6 ([tTG6](#)) as an indicator for gluten ataxia. tTG6 is a component of the blood-brain barrier which protects the brain. If you produce antibodies against tTG6, large molecules can enter the brain, resulting in "leaky brain" that can cause cognitive symptoms. Once these patients were on a gluten - free diet, cognitive function improved. Dr. Perlmutter predicts that tTG6 could become a marker for schizophrenia.

Cardiac Disease

Cardiologist William Davis, MD, also spoke at the Gluten Summit, to explain how increased glucose levels can lead to coronary disease. Dr. Davis gave a couple of examples of his patients who were put on a gluten-free diet. Not only did his patients lose weight, but if they had reflux, their reflux was reduced; blood pressure and cholesterol decreased and their energy increased; moods were stabilized; they slept more deeply; and inflammation measurements signaled relief from arthritis symptoms.



Gluten has a higher glycemic index than sugar. Other foods with a high glycemic index-- 69 -- are dates; figs; gluten-free foods that use cornstarch, rice flour, tapioca starch, and potato starch; whole wheat flour; and white flour.

Pasta contains gluten which has a glycemic index of 70+.

Dr. Davis explained that eating gluten is like a vicious blood sugar cycle, with high blood sugar leading to low blood sugar. Low blood sugar causes hunger to kick in about 2 hours after onset. Peptides from gliadin act like opiates, further stimulating appetite and causing a craving for even more carbohydrates.

When we have high glucose levels, insulin is produced. But when there are very high insulin levels, this triggers resistance, or poor responsiveness to insulin. Type 2 diabetes is classified as insulin resistance. Type 2 diabetics can produce insulin, but it doesn't work in their cells. High blood sugar and insulin can cause inflammation in the body.

As mentioned previously, high glucose content causes glycation, where glucose binds to proteins and damages everything in sight. This can lead to cataracts, hypertension, rigid arteries, coronary atherosclerosis, arthritis and other maladies. "Glycation from high blood sugar is a fundamental process underlying multiple disease states and aging," said Dr. Davis.

When normal bowel flora is disrupted (gut microbiome), this leads to an increase in small low density lipoproteins (LDLs) in the blood stream, according to Davis. Excess small LDL particles are commonly abnormal in coronary disease. These small LDLs are of different shapes and conformations and they are more likely to adhere to connective tissue. They are also present in the bloodstream longer, at least a week more than normal LDLs. High blood sugar also leads to the formation of small LDLs.

When small LDLs become glycated, this leads to more oxidation or glycoxidated (glycated + oxidized) LDL particles, that can cause heart disease. Reducing grains, sugars and starchy legumes can reduce small LDL formation. Grains also contribute to an increase in triglycerides, due to de novo lipogenesis that occurs in the liver, according to Davis.

Davis puts his patients who have suffered a heart attack or have coronary disease, on a no grain, no sugar diet. He tries to raise their 25-hydroxy vitamin D to 60-70 ng/ml, and supplements with omega3 fatty acid, 3,000- 3,600 mg/day of EPA & DHA. He makes sure that their TSH is 1.5 or less and their free T4 and T3 are in the upper half of normal. Dr. Davis also does lipoprotein testing, [NMR LipoProfile](#), an FDA-cleared blood test that directly quantifies low density lipoprotein particles (LDL-P) circulating in the body.

Additionally, he does lipoprotein testing to determine whether his patients are ApoE 2, ApoE 3 or ApoE 4. He explains that we all have two ApoE genes. Most people are ApoE 3/3, some are ApoE 3/4 and a few are ApoE 4/4. Those that are ApoE 4/4 are hyper-absorbers of dietary fat (helps humans survive during periods of deprivation) and they need to be put on a low-fat diet, in contrast to the others, who do well on a low-carbohydrate diet.

A typical response for non-ApoE 4 patients who may start with a 1,800 nmol/L of small LDLs, when they eliminate wheat, grain and sugar, they lose 40 lbs and their small LDLs drops from 1,800 to 180 or sometimes zero. An ApoE 4 patient, starting at 2,500 nmol/L of small LDLs and eliminating the same foods will lose weight, but their small LDLs drop only from 2,500 to 1,400 nmol/L. These people need to reduce dietary fat to reduce their numbers.

In a meta-analysis of [ApoE](#), there was an association between those with ApoE 4 and an increased risk of coronary disease. Interestingly, in another study looking at coronary disease and Alzheimer's disease neuropathy, the authors found that those who had coronary disease and Alzheimer's were [ApoE 4 carriers](#).

A 2008 study in the [NEJM](#) looked at 3 types of diets: low carbohydrate diet vs. Mediterranean diet vs. low fat diet, to see which diet had the best weight loss results in obese people. The low carbohydrate diet had the greatest weight loss plus the additional benefits of increased HDL, decreased triglycerides and decreased LDL. Among the 36 diabetic subjects, changes in fasting plasma glucose and insulin levels were more favorable among those on the Mediterranean diet vs. the low-fat diet.

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Closing Thoughts

After learning about gluten and what it does to our body with respect to the leaky gut and glucose glycation, why are we eating foods that contain gluten? Gluten possesses modified properties to make it elastic for making bread, pasta and pizza, which is why most people don't want to give it up. Gluten is also in nearly every food that we eat, especially ready-made foods, or foods that have a long shelf life. This is yet another reason that it's hard to go gluten-free.

Those who have Celiac Disease or are gluten sensitive face a challenge when attempting to eat gluten-free. For those who want to go gluten-free to avoid the leaky gut or high glycemic levels, it is necessary to make sure that manufacturers aren't substituting gluten for another high glycemic ingredient such as cornstarch, rice flour, tapioca starch, or potato starch.

If we eliminate gluten from our diet, we usually need to add more fat to our diet, but we must add the good fat (monosaturated fat, olive oil, coconut oil, avocado, grass fed beef, wild fish, nuts and seeds). Fat is also needed for cell membrane structure.

I've decided to go gluten-free, almost, and reduce my gluten intake, even though I don't have Celiac Disease nor am I gluten-sensitive, for the reasons I detailed in this newsletter and the previous issue.



Reducing gluten intake is recommended for those who are not gluten-sensitive. Should I accidentally eat gluten, my immune system will have a stronger reaction to it than when I was eating gluten, because gluten will have been absent from my body for a period of time.

So far, I've eliminated bread, pizza, pasta, wheat cereals and crackers from my diet. In substitution I'm eating oatmeal for breakfast and rice --- brown rice is better --- instead of pasta or bread. Potato is a good substitute for rice, if you don't like rice. I've become a food label reader as I strive to eliminate as much gluten as possible in my diet.

I've also been eating more salads. Uncooked leafy greens help with the methylation process that makes and eliminates neurotransmitters that affect our thinking and our moods. But that is another topic for an expert to cover.

In 3-4 months, I will see whether I am feeling better and how much weight I've lost. So stay tuned and I will let you know.

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Developing a Product?



If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, email [me](#) for an appointment. For successful commercial adoption of your product, email [me](#) for an appointment.

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New Technology - "New mHealth Device Aims to Give Clinical Capability To Consumers"

The healthcare industry has been focusing on point-of-care for better healthcare delivery and homecare with the emphasis on monitoring or continuous monitoring with mobile apps. The industry is also moving toward a patient-centric focus in making the patient responsible for their own healthcare.

Cue, a San Diego startup, wants to take it one step further by allowing patients or consumers to have their own personal lab to monitor their health with a lab-grade mHealth consumer device.



The Cue device intends to allow

Cue, a lab-grade mHealth consumer device

patients/consumers to perform molecular diagnostics at home. The device has the following components - a base charger; the Cue testing unit; five separate cartridges labeled influenza, fertility, testosterone, inflammation, and Vitamin D; and sample wands to collect blood, saliva, or a nasal swab, to enable those results.

Source: *MDDI online*.

To read the full article in *Medical Device and Diagnostic Industry* online, click [here](#).

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About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

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