October 11, 2016

Dear Colleagues,

As many of you may be aware, the Commission on Dietetic Registration (CDR) sent an e-mail on September 30, 2016 regarding the discontinuance of Continuing Professional Education (CPE) credit for MRT/LEAP related activities. As a longtime member of the Academy of Nutrition and Dietetics (AND) and a dietitian in private practice who uses MRT, I feel it is my duty to inform all AND members that the CDR e-mail was not factually accurate and could have potentially misled those that read it.

The purpose of this communication is not to proselytize, but to provide you with the facts as to what MRT/LEAP is and what MRT/LEAP is not. I will then discuss why the e-mail from CDR deserves a response.

What is MRT and What is LEAP? Are They Interchangeable?

Food allergies, sensitivities and intolerances are not an area of nutrition that many dietitians are deeply exposed to in school. For the dietitian who does not specialize in this area, the topic can be confusing.

MRT stands for Mediator Release Test, a blood test Oxford Biomedical Technologies (OBT) patented that identifies *non-IgE (non-allergic) food sensitivity pathways*. MRT tests 120 foods and 30 food chemicals and has successfully been used by dietitians for over 15 years in individuals who are non-responsive to conventional treatment. MRT is used to identify reactive foods in people with conditions ranging from Irritable Bowel Syndrome (IBS) to fibromyalgia to migraines and arthritis and more. MRT can provide a useful structure to investigating possible food sensitivities when a patient has failed to respond to other dietary and lifestyle changes and when medication has not helped.

LEAP is the dietary protocol implemented based on the patient's MRT results. When designing the LEAP protocol for each patient, the trained dietitian takes into account several factors: the test results, the patient's current medical condition and diagnosis, previous interventions, known and/or suspected trigger foods, known food allergies, chemical sensitivities, current medications (both prescription and over-the-counter), current supplements, lifestyle, motivation and most importantly, food preferences. All of these must be taken into account to design a LEAP protocol that may yield symptom relief. The LEAP protocol is meaningless if the patient isn't willing to follow it, so we work with them to ensure we set them up for success.

Are Food Allergies and Food Sensitivities the Same Thing?

No. They are two different, distinct pathways that occur in the body and are not interchangeable. Food allergies are type I hypersensitivities mediated by *Immunoglobulin E (IgE)* whereas food sensitivities are types III and IV hypersensitivities and are *strictly non-IgE pathways*. Think of one as I-95 in the east and the other as I-5 in the west; two different north/south interstates that never intersect.

Does MRT Identify Food Allergies?

No. It never has and it never will. As discussed, allergies and sensitivities are two distinct pathways and therefore, the "plan-of-attack" in identifying them is different. Skin prick tests and/or an ImmunoCAP blood test are typically ordered for food allergies because these tests measure whether or not IgE antibodies are present in the body. However, even though these tests are used, they have a high false-positive rate. Since MRT *does not and cannot measure IgE*, *it is not used for this purpose*.

Rather, MRT is used to identify *non-IgE food sensitivities only*. LEAP dietitians do not use MRT to identify or treat food allergies. If anyone has proof to the contrary, I recommend you bring it to my attention.

Premise of CDR Email Is False

In their e-mail, the CDR cites the recently released practice paper, the Role of the Registered Dietitian Nutritionist in the Diagnosis and Management of Food Allergies, published by the Academy of Nutrition and Dietetics (AND), as their rationale for establishing the MRT/LEAP moratorium.

On the first page of the practice paper, the author writes, "This paper will explore the role of the RDN in working with patients and clients with immunoglobulin E (IgE) mediated food allergy; therefore, all references to food allergy in this paper will specifically refer to IgE-mediated food allergy" (Collins, 2016).

Further in the paper, Collins (2016) writes, "According to the NIAID, there are a variety of non-evidence-based tests that should not be used for diagnosing a food allergy. Namely, basophil histamine release/activation…and mediator release assay (LEAP diet)." However, Collins fails to report that MRT is not used by dietitians to identify food allergies. Failing to state this basic fact misleads the reader into believing that MRT has been and is currently being used to diagnose food allergies.

Now let's turn our attention to the CDR e-mail. The e-mail states, "While there are many evidence-based methods for diagnosing food allergies, current evidence does not support use of the mediator release assay (MRT test) for diagnosing a food allergy, as noted in the recent Food Allergies practice paper." It is bad enough the practice paper did not mention that MRT is not used for food allergies, but it's even worse the CDR didn't mention it either. Either both the author of the practice paper and the CDR are unaware of this basic fact or they intentionally hid it from readers. In the first scenario, neither did their research. In the second scenario, they misled by omission.

When the Academy was seeking reviewers for said practice paper, several Certified LEAP Therapists (CLT), dietitians who are trained in the LEAP protocol, applied for these positions. One in particular, who has served on the "Adverse Reactions to Food Committee" in the American Academy of Allergy, Asthma and Immunology for the past 19 years, was not considered when she applied. This is extremely puzzling and leaves the impression the outcome had been decided before the paper had even been drafted.

Interestingly enough, ALCAT, another food sensitivity test that some dietitians use, was not mentioned in the practice paper or the CDR's e-mail. LEAP dietitians bad, ALCAT dietitians good? Why so?

Respecting the Evidence Base

The CDR e-mail goes on to state, "We encourage any CDR credentialed dietetics practitioner working with clients with potential food allergies to utilize evidence-based practices as they implement the Nutrition Care Process…CDR credentialed practitioners who use MRT must weigh the risks and benefits of this strategy, for which there are no evidence-based guidelines."

According to the Academy, "Evidence-based practice uses the best available evidence, the results of peer-reviewed scientific studies, whenever possible, and, when the science is lacking, expert opinion and experience" (Laramee, 2005). By this definition, dietitians that use MRT/LEAP are practicing evidence-based guidelines.

All LEAP dietitians are anxiously awaiting peer-reviewed research that shows the benefits of MRT/LEAP in treating *food sensitivities*. In the meantime, we continue to work, with much success, with clients that other practitioners have not been able to help. If MRT/LEAP were not effective, OBT would not be in business for this long; word of mouth is powerful and unforgiving. Dietitians like myself would not continue to use it if we didn't have success. I'd also be demanding my money back from OBT for what I paid to become trained and certified.

I was once a skeptic. All dietitians that use MRT/LEAP were before getting their feet wet. Skepticism is healthy but cynicism is not. For those that criticize what we do, they have failed to prove harm has been done with the LEAP protocol. If we were harming individuals, we wouldn't offer it and patients wouldn't be asking for it. To the contrary, interest is only growing.

Studies from OBT are forthcoming but are costly and take time. When the studies come out, I predict they will be critiqued as biased since the funding came from OBT. Fair enough. Private practice dietitians like myself do not have the resources or time to conduct studies; even case studies can be difficult to organize and are often criticized as not being generalizable to the overall population.

Pharmaceutical companies will not fund relevant studies since the results will not bring about medications they can patent. In fact, they may lose out since people tend to come off their medications when on LEAP. Unless there is a team of independently wealthy, unbiased, third party researchers eager to study food sensitivities, who will lead the charge?

You may have recently been made aware that flossing is not an evidence-based practice. Should floss be removed from store shelves because there aren't numerous studies to back up its efficacy? This revelation has not changed the way I feel about flossing. I will continue to floss despite the lack of evidence.

How Does MRT/LEAP Fit into EB Practice?

When used properly, MRT is an extremely useful tool. Like any lab test, it has its limitations.

Is MRT for everyone? No. People with conditions associated with inflammatory cytokines are often good candidates if they are willing to participate in the process. Those that are unable or unwilling to read labels and cook from scratch may not be good candidates. Those that travel frequently and/or who always eat out, or have symptoms not impacting their quality of life may not be good candidates. Those who are not willing to give up their reactive foods and/or try new foods may be less likely to benefit. People with a history of eating disorders would not be good candidates for more than one reason. Though many people can benefit, it's not for everyone. We are trained to screen for best candidates.

Our profession is founded on the principles of enhancing the health of all Americans, yet ideas as to how to accomplish this remain narrow. Neither the Academy nor the CDR have provided evidence of harm with LEAP, yet they've dismissed our clinical usefulness and the thousands of clients that have been helped over the years, with the push of a button.

"CRITICAL ACTIONS FOR DIETETICS PRACTITIONERS

For dietitians to remain competitive within the health care, education, and business arenas, they must incorporate evidence-based practice into their day-to-day activities and decisions. In doing so, dietitians must accept change as inevitable and must not be unduly resistant to new ideas or opinions...While evaluating the current literature, practitioners need to assess, without bias, both sides of controversial issues and remain open to new approaches."

Vaughan LA[1], Manning CK. ***Meeting the challenges of dietetics practice with evidence-based decisions.*** *J Am Diet Assoc. 2004 Feb;104(2):282-4.*

In this, the 21st century, there should be room for more than one way of thinking. If practitioners didn't step out of their comfort zone, FODMAPS wouldn't exist. Neither would fecal transplants to treat *C.diff*. If it weren't for practitioners thinking outside the box, we'd never know *H. pylori* was responsible for the vast majority of ulcers instead of stress. If we only went by what appears on PubMed, we wouldn't be very far as a nation health-wise.

Those who seek us out have been ill for a long time and have not received relief anywhere else. Medications may compound their situation with side effects. What's wrong with removing a few foods from their diet to seek relief? Why is a short-term, low risk, food-based approach so controversial?

Patient-Centered Dietetics is the Future

While it is disheartening that some members of our profession rejoice in bashing MRT on social media, we feel we are contributing to the evidence base in a positive way.

Those who want to be more informed about the MRT/LEAP process need only ask one of us and we will share what we know. To clear up a factual errors:

-Myth: MRT is used to diagnose food allergies

MRT has never been used or marketed as a tool to diagnose food allergies.

-**Myth: OBT is handing out fake credentials**

This is also false. The CLT is not a credential; it's a certification, similar to the certifications the CDR awards to those who meet certain competencies like the CSSD, CSR, CSP, etc.

-**Myth: LEAP RDs diagnose their patients**

This is also false. Like all dietitians, inpatient and outpatient, we interpret lab results to create an individualized oligoantigenic diet for each patient. The test is a tool; appropriate dietary care is the intervention.

Thank you.

If you've made it this far, I thank you for hearing me out. Feel free to contact me should you have any questions. I can be reached at ryan@gutrxn.com.

Sincerely,

Ryan Whitcomb, RD, CDN, CLT

GUT RXN Nutrition, LLC

P: 631-600-3340

F: 888-506-7860

www.gutrxn.com

References:

Collins, S. C. (2016). From the Academy: Practice Paper of the Academy of Nutrition and Dietetics: Role of the Registered Dietitian Nutritionist in the Diagnosis and Management of Food Allergies. Journal Of The Academy Of Nutrition And Dietetics, 1161621-1631. doi:10.1016/j.jand.2016.07.018

Laramee, S. H. (2005). Evidence-based practice: a core competency for dietetics. Journal Of The American Dietetic Association, 105(3), 333.

Vaughan LA, Manning CK. Meeting the challenges of dietetics practice with evidence-based decisions. J Am Diet Assoc. 2004 Feb;104(2):282-4.