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William R. Ware, PhD - Editor

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In this issue a further discussion of various aspects of the COVID pandemic will again be postponed due to the bizarre mix of politics and medical science in the US. Instead, two topics will be discussed. The first involves personalized diet. Recently, a remarkable observation has revealed huge variations in human metabolism of common foods and in particular the impact on glucose metabolism.

This discovery has profound implications for nutritional science based on observational studies which in turn influence guidelines, national food pyramids and the conduct of nutritional counselling. Fortunately, the researchers have developed a protocol for at home determination of the metabolic food response and how to identify unfavorable individual foods. This has important implications for selecting a healthy diet.

The second object involves medical misdiagnosis, either by missing the correct one or by making an incorrect judgment. Diagnosis is obviously at the heart of the practice of medicine, and much grief and suffering can result from following the guidance of an incorrect determination of the cause of a patient's problem. Unfortunately, it is not a rare event but fortunately the patient can play an important and frequently critical role in achieving a correct result.

Wishing you and your family good health,

William R. Ware, PhD, Editor

Highlights

HUMAN METABOLIC VARIABILITY AND THE PERSONALIZED DIET

INTRODUCTION

In the last few years there has been trail-breaking research from the Weizmann Institute by two professors, Eran Segal and Eran Elinav concerning the variability of human metabolism of food, what are the reasons and how can an individual determine their own profile, in other words a *personalized diet*. The Weizmann Institute of Science is a highly respected research institute with a university located in Rehovot near Tel Aviv.

Segal and Elinav, the latter a board certified physician, undertook to study personalized nutrition using the most advanced techniques available including determination of the impact of the microbiome. The results have been published in appropriate journals[1-3] and also those up to 2016-2017 in a fascinating book, *The Personalized Diet*. *The Pioneering Program to Lose Weight and Prevent Disease.*[4]

Their approach focused on fluctuations in blood glucose measured continuously which they hypothesized provided important food effects feedback instructions to the metabolic and biological control systems. For example in a thousand healthy subjects they found huge variations in the blood glucose response to eating a wide variety, 28 in all, of foods. The variations were so great that they rendered dietary recommendations based on averages and the one-size-fits-all useless. They found that commonly held beliefs were born out:

- The higher carbohydrate content of a meal, the higher the glucose response.
- The higher the fat content of a meal, the lower the glucose response.
- The higher the fiber content of a meal, the higher the glucose response. But the next day it was lower.

However, these three generalization are not true for all individuals by a wide margin with the opposite frequently seen. The above are simply averages concealing high levels of personal variation.

For example, consider their study of three popular artificial sweeteners, aspartame, sucralose, and saccharin. Artificial sweeteners are promoted for weight control and blood glucose control including for diabetics. This seemed to them quite reasonable until the examined the matter closely with a small study. Studies with mice found using doses equivalent to common human ones, that most of the mice became glucose intolerant, i.e. their ability to metabolize glucose was greatly reduced. This is of course the hallmark of diabetes. They were able to demonstrate that this result was due to changes in the microbiome. They even did microbiota transfer experiments between mice to confirm what was indeed going on. Human studies revealed that after only one week of artificial sweetener consumption at levels allowed by the FDA, subjects began to develop glucose intolerance, but there was a big variation. Only half showed this response. They found that in humans as in mice, the composition of the gut microbiota explained the variation and they mapped out the bacterial differences. They believe that

certain bacteria in the gut of those who developed glucose intolerance reacted to these artificial chemicals with an inflammatory response like what happens when someone ate a large amount of sugar. This promoted changes in the body's ability to utilize sugar even though the sweeteners were not sugar.

The studies from the Weizmann Institute call into question nutritional studies that use large databases and seek correlations between what people eat and what diseases they get. Some are based on only baseline data and changes over the duration of the study of participant diets and health has to be ignored even though ten or twenty years go by. Whatever the statistical experts pull out of the collected data the results amount to an average of a population with significant variation in their metabolic reaction to food. Thus averaging over large populations would appear to provide little guidance to a single individual looking for a healthy diet.

It is now recognized that the gut microbiome is key to many of the nutritional problems of humans.[5] Even knowing the details, the use of microbiome testing seems far from practical as a way to develop personalized nutrition. Since blood sugar response variations were highly indicative, they proposed a simple method to identify an individual's response to food and to identify those both good and bad. Poor glucose metabolism is related directly to diabetes risk and diabetes and its associated secondary health problems and diabetes is an epidemic worldwide.[3, 4] Segal ad Elinav list and document the following health conditions and risks as associated with fluctuation in post meal blood glucose levels that are too high for too long or regularly are too high after eating.[4] This justifies using a single easily measured parameter. The health conditions are:

- Wight gain and excess body fat
- Hunger, food craving and low energy levels
- Overall mortality
- Heart disease
- Cancer
- Dementia
- Damage to small nerve fibers.

THE PROTOCOL

The protocol is simple.[4] A reliable blood glucose meter and strips are required. The pain from finger pricking is trivial. Then the individual turns into a temporary researcher. Blood glucose is measured upon awakening (fasting), then before and after 30, 60 90, and 120 minutes for each meal and snack. The 120-minute measurement is what is used in the standard clinical glucose tolerance determination. These measurements allow one to identify the glucose response of each meal in a diet. Before a meal, the blood sugar should be within 10—20 mg/dL above the fasting level measured upon awakening. It will be found that in general some meals have a large effect on how high the glucose goes and how fast it comes down. Meals resulting in abnormally high glucose response are noted. Then the meals are repeated with removal of ingredients

to identify actual foodstuffs that are producing the large responses. When this is done for a variety of foods the result is a list of the best and worst foods by this metric. If one is like some of the 1000 in the above study of variability, it is quite likely that large variations in blood glucose and abnormal high responses are observed and a diet that instead provides only small fluctuations can easily be adopted. Thus diet is now being personalized at a cost of the strips.

Also, before starting some thought should be given to deciding if the meal components really represent healthy choices in general if that is what is desired. If during a week, junk food or highly processed items represent a significant component, changes should be considered since the whole exercise is aimed at increasing health. However, the guidelines that classify food from good to bad are again based on population averages. The notion that sugar in more than modest quantities is bad is backed by considerable evidence, but it is not the amount consumed that is important but the amount that ends up in the circulation to be offered to cells as fuel with the help of insulin.

INTERPRETING THE RESULTS

If blood sugar maximum after eating always goes up to about 120 mg/dL with most meals, generally in about an hour, then a maximum of 160 mg/dL would be judged abnormal and prompt a search for the responsible food. There is no consensus regarding what the healthy maximum should be. The 2-hour value is important. Thus a maximum which fails to come down to the normal value of < 140 mg/dL in two hours is cause for concern. Type 2 diabetics will have a higher maximum and a 2-hour value > 200 mg/dL, prediabetics 140-199 mg/dL. These numbers actually apply to the standard test for diabetes which measures blood glucose 2 hours after the subject drinks a liquid containing 75 grams of glucose. At two hours a value over 200 mg/dL is accepted as a diagnosis of diabetes. A frequent value over 200 mg/dL in the home study after a meal should be discussed with a doctor who will probably order a glucose tolerance test. The home study will also provide the fasting level which normally is 70-99 mg/dL, prediabetics 100—125 mg/dL, and diabetics > 200 mg/dL. When a red flag waves, it is a call according to the conventional wisdom for either altering the diet by reducing carbohydrates and generally calories or starting medication or both. In many cases, neither halts the progression to insulin dependence.

One theory of the advent of diabetes is that it generally follows a period of eating more calories than needed, becoming insulin resistant, storing fat and ending up with a fatty liver which exports toxic triglycerides to the pancreas disabling the beta cells. Note that this description is controversial. This is reversed by aggressive calorie restriction for eight weeks, the Newcastle Diet, and this is seen both with prediabetics and diabetics.[6-8] Mainstream medicine believes in drugs. Thus one of the merits of this determination of the personalized diet is that it will reveal the presence of prediabetes or diabetes, either initially or when the follow-up measurements are made periodically. It also offers the possibility that with the elimination of foods that strongly elevate blood glucose, over time this may also return glucose metabolism to normal. The Newcastle Diet does it by strongly reducing pancreatic and liver fat, as demonstrated by imaging.

Segal and Elinav have used the results of their 1000-person study to develop an algorithm that allows predictions via artificial intelligence. All the relevant information available for an individual plus a complete analysis of their gut microbiome is used. A company "*Day Two"* has been created to accomplish this and produce dietary recommendations. However, the company only operates in selected countries.

The tool used here for personalization is individual but based on minimizing blood glucose fluctuations. There is considerable evidence of the benefits of doing so associated with chronic diseases, including clinical study evidence, presented in the book. It remains to be shown in a long term trial, randomized or otherwise, the extent to which success translates into actual benefits for the individual.

CONCLUSIONS

The implications of this research are far reaching. Nutritional studies almost always study cohorts, sometimes large, and produce only results that represent averaging over the group. These results have a large influence on dietary guidelines issued by governments and professional societies. Governments then come up with a one-size-fits-all food guide claimed to offer optimum health. Diabetics are sent to nutritionists to get advice on diet. Given human variability, how can they tell if the proposed diet they are taught is beneficial or aggravates the problem? For example, drink diet soda. The glycemic index is a prime example of population average which would seem to have limited utility based on the results of Segal ad Elinav.

In the US, new healthy eating guidelines are due to come out soon and are presented as valid for 5 years and of course evidence based. Indications according to MedPage Today (August 12, 2020) are that sugar, salt, saturated fats, alcohol and red meat are the principal nutritional items for which government guidelines are deemed necessary for the health and happiness of the country. The coming battle will be between the Dietary Guidelines Advisory Committee and the food industry with academics taking sides. The first draft of the committee scientific report runs 834 pages! That should weigh in at about 33 lbs (equal to about 7 red bricks).

An example of variability. Why is a significant portion of obese people completely healthy while the rests have all sorts of problems? This is called the obesity paradox. Perhaps some with high BMIs have low post meal blood sugar responses and some have high ones.

In using blood sugar as a guide, one has avoided the trap of depending of averages over large populations to dictate an individual diet, which is clearly nonsense given the huge variations for each common food item found by Segal and Elinav studying 1000 healthy people and 28 food items.

In addition, we obviously mainly eat food combinations. Thus the popularity of using food patterns in search of a healthy diet through food pattern studies. Again the results average over a study population and cannot be personalized. One would not expect the Mediterranean diet to benefit everyone, even Mediterraneans.

Over the years we have seen a number of common beliefs backed by scientific studies demonstrated by scientific studies to be wrong.

- A calorie is a calorie.
- All fat is bad.
- Dietary cholesterol is bad.
- High-carbohydrate diets /low fat diets are bad.
- Going on a diet works.

These ideas are so firmly implanted that many chose to ignore the research that falsifies them. Some scientists have devoted whole careers to these notions. Segal and Elinav suggest that when solid science conflicts with solid science, it is because science seeks a one-size-fits-all approach, an approach which is not realistic because everyone reacts differently to different foods.[4] The explanation is probably much more complex but the message seems clear. The term “scientific” is being abused.

What is the big picture? Does human variability extend to other aspects of lifestyle? For example, risks or benefits of exercise, alcohol, sleep type, social interactions, family bonding, hectic and stressful daily life, etc.? These issues are also examined by studies of cohorts and conclusions based on benefit indicating risk ratios which are averages over the cohort. Furthermore, weights given to confounding factors used in statistical analysis go back to the same types of studies. The seemingly unanswerable question—where am I in the range indicated by the 95% confidence interval for these risk ratios? Incidentally that upper end is frequently very near the no-effect 1.00. If it is > 1.00 suggesting forget it.

MISDIAGNOSIS

THE FUNDAMENTAL PROBLEM

Medical errors are estimated to be the third leading cause of death in the U.S. However, estimates vary for incidence and annual mortality in the US. A recent paper from Johns Hopkins University provides the following:[9]

- Misdiagnosed-related hospital deaths roughly 40,000—80,000 annually.
- National malpractice data suggests roughly 80,000—160,000 deaths attributable to misdiagnosis.
- In the primary care setting, approximately 12 million Americans suffer a diagnostic error each year with 33% resulting in serious or permanent damage.

The researchers attempted to identify the diseases accounting for the majority of serious misdiagnosis-related harms (53% death). The top three accounting for 75% of high severity cases were vascular events, infections, and cancer. Around 85% were judged due to clinical judgement errors.

Furthermore, it is estimated that the occurrence of physicians failing to detect a disease occurs in 5% to 15% of attempts, i.e. failure to diagnose and false positives. The highest rate appears to be to be in emergency medicine.[10] Thus there is interest in what goes wrong and how it can be corrected, including changes in medical education.

These issues involve the physician. However, the patient has a frequently acknowledged role and sometimes can play a critical part both in the ER and in office encounters. The patents potential task is in the interaction where the presentation of what the patient considers important is ignored and where the interview appears to be dominated by a very early decision regarding the diagnosis. In the ER the triage typically endeavors to identify the so called principal complaint (chest pain, back pain, dizziness, severe and unusual headache, pain in the calf, etc., and this can dominate the working diagnosis and in some ER cultures, automatically launches the patient down a prescribed path of tests followed like a cookbook. If the hypothesis is wrong, time is lost and in some cases needless and dangerous diagnostic interventions take place to no avail. Sometimes the patient is sent home with the wrong diagnosis and wrong prescriptions and it will take some time before the next round is initiated.

The patient's potential role in their diagnosis is described in a book titled *When Doctors Don't Listen* by Leana Wen, MD and Joshua Kosowsky, MD. When this was written, Wen was a clinical fellow at Harvard and senior resident physician at Brigham & Women's Hospital and Massachusetts General Hospital. Dr. Kosowsky was a professor at Harvard Medical School and clinical director of the Brigham & Women's Emergency Department. This book covers the time when they worked either together or constantly discussed cases.

Wen was fortunate because Kosowsky is a remarkable diagnostician. The patient stories are not only fascinating but illustrate the necessity of patient participation in the interaction and how this can determine success or failure. A rigid question and answer format can prevent the patient from providing valuable information. This book is rather like a patient's handbook of how to navigate the ER or clinic episode and increase the probability of a correct diagnosis. Readers will come to appreciate the complexities of the challenge, how badly it can go wrong, and the remarkable skill of a top-notch diagnostician. They will even gain insight into the problem of hidden inherited diseases.

It is quite amazing how a single fact casually mentioned by the patient or by a family member can immediately turn the investigation down the right road in what otherwise might have been disaster. The authors are very critical of what they call cookbook medicine to describe how the principal complaint launches the patient down a fixed path of tests and scans while in fact the diagnosis is just a crude guess. The cookbook phenomenon may well be common only in some countries. The book addresses only the *modus operandi* in the US.

The same problem of course is critical in the office or clinic visit prompted by a concern. It is well known that in any large city there will almost always be patients that have been going from doctor to doctor and treated when the diagnosis is wrong. It is not

uncommon that the treatments cause temporary or permanent harm, physically and psychologically. Patients complain that in the examining room, the physician almost never looked at them and was entirely focused on entering details in a computer. The book makes a strong case by examples that the diagnostician needs to closely observe the patient and engage in a conversation that encourages the patient to give their whole rather than answer questions. It also makes it obvious that there should not be time constraints as are commonly dictated by administrators, where for some odd reason, 18 minutes seems the duration of choice for an office visits. This time constraint seems absent in the ER and the patient is seen by what might be described as mostly full time diagnostic specialists. Incidentally, 18 seconds is the commonly stated time for a snap diagnosis. Physicians are also notorious in interrupting the patient's story.

Why does the U.S. which spends twice as much per capita than other comparable countries, also produce remarkably inferior results, again judged by international standards? See Chapter 16 for insight into this remarkable anomaly. According to the authors, it has to do in part with vast number of uninformative tests ordered in the fog of uncertainty over what is really wrong with the patient. The authors also point out that the U.S. is pathologically litigious and physician behavior is strongly influence by fear of malpractice suits and are motivated to practice defensive medicine, sometimes in the extreme.

Finally, in many cases the diagnostic problem is first addressed by a family physician or internist. This may result in a referral to an appropriate specialist. In order to avoid the commonly reported situation where the patient goes from specialist to specialist, much time and grief can be avoided if the initial diagnosis leads to the correct referral. Specialists are not necessarily ideal diagnosticians when the problem presented is complex and actually outside their area of expertise. Referral to the wrong specialist may also result in wrong and useless treatment. However, for perspective it seems that it is totally unrealistic to expect anything near 100% success in meeting the diagnostic challenge. Human beings are too complex. Ask any biochemist knowledgeable with the many pathways with complex regulation processes, synergisms and cofactors which describe what goes on inside the black box sitting in the examination room or ER. Ask any geneticists about the vast number of epigenetic effects dependent on the multitude of cellular environments in the body.

The diagnostic problem arises because of the thousands of generally highly regulated processes and pathways going on all the time in the normal body and how hard it is to pinpoint what has happened when a symptom indicates that something has gone wrong. These are the problems for which Wen and Kosowsky's book provides perspective and offers insight into how to overcome a cultural malfunction and perhaps receive the correct diagnose and thus treatment. The book cited is highly recommended for providing patients with a handbook based on clinical examples that demonstrate techniques for gaining a role in the diagnosis process and how to organize one's thoughts to be effective. Also learn how to take control when necessary, even by stopping the termination of the interview before the patient is satisfied. This is a hard book to put down because of the gripping stories. The book will leave the reader with an

appreciation of how difficult diagnosis really is and should generate sympathy for those faced with the task.

NEAR DEATH OF THE WATCHDOG

The evolution of modern medicine began in the late 1880 with a rapid advance in the early 1990 when a scathing report on the quality of US medical education (The Flexner Report) was responsible for dramatic changes, essentially a revolution in medical education. Among other things, this report introduced a measure of hospital quality, the hospital autopsy as distinguished from being demanded by a medical examiner, the so-called legal autopsy, Read the biography of the famous North American physician William Osler (1849—1919). It makes clear that during the evolution of modern medicine, the autopsy was a major source of otherwise unavailable information. The patient was to a great extent a black box. The autopsy opened it and was a vital tool for learning about disease in an era where the microbiological and biochemical understanding was in its infancy and scanners had probably never been even imagined.

Disease was studied in the autopsy room or theater by physicians and medical students. As medical knowledge exploded, the autopsy became an essential tool for verifying diagnoses and for decades a hospital's autopsy rate (autopsies as a percentage of hospital deaths) was a significant indicator of quality and overall merit and used for ranking. With the advent of scanning techniques, some considered that the scrutiny of diagnostic accuracy afforded by the autopsy was becoming unnecessary. This was inconsistent with studies which demonstrated that even over many years into the scanning era, diagnostic errors were still distressingly prevalent.

Before 1970, 40% to 60% of all hospital deaths ended in autopsy. Recent studies indicate that rates are now becoming insignificant, even near 0%. Multiple factors appear to be driving this—financial (reimbursement), lack of interest, and the belief that the autopsy is now unnecessary. Lost is the traditional diagnostic watchdog, a source of feedback regarding treatment and tool in medical education and discovery.[11, 12]

PERSPECTIVE

It is very important to understand the true challenge and complexity of diagnosis such that it seems unreasonable under certain circumstances to lay blame when a failure occurs. There are a number of disorders and diseases that are rare enough that they will only be recognized by a limited number of specialists. In some cases there may be only a few in the whole state. The reader is referred to the *Washington Post* which has an excellent ongoing feature called Medical Mysteries where periodically they feature a baffling case, some with years of failed treatments. Resolution is described including disclosure of the patient's name as well as the successful physician's. In some of these case histories, the problem was a genetic mutation. In others, the symptoms suggested so many possibilities that many dead end paths were taken. Google *Medical Mysteries Washington Post* for their archives of many fascinating cases. Two excellent books on diagnostic mysteries by Lisa Sanders, M.D. are *Diagnosis* and *Every Patient Tells a Story.*

Seeking additional consultation, even by phone, is common when the attending physician and involved residents are mystified. Sometimes, the consultant comes up almost instantly with correct diagnosis simply because while it is a rare disease, he or she has seen it before. Sometimes a resident involved in a case realizes a clue is being ignored. In one case in *Every Person Tells a Story,* the internal medicine resident in charge of a patient in for observation for frequent severe and prolonged episodes of nausea and vomiting found the patient taking a shower. She recalled that the patient had commented during the diagnostic interview that this was the only thing that helped her. She went to a computer and Googled "persistent nausea improved by hot showers." Within seconds she had her answer. The patient was probably smoking marijuana frequently. This turned out to be true but had been concealed by the patient. Mystery solved. Discovered in 1996, the disorder was called C*annabinoid Hyperemesis* with a paper describing ten cases published in 2001.

CONCLUSIONS

Recognition of the role of diagnostic errors in patient mortality and morbidity is now increasing. Suggestions for more emphasis on teaching critical thinking by introducing into the medical curriculum instruction into intellectual errors and errors due to attitude that are implicated are being called for.[13] However, it might be said that it will be an uphill battle since there is merit in the notion that for the most part, excellent diagnosticians did not acquire their skill in a classroom.

The misdiagnosis problem highlights the importance of getting a second independent opinion when possible. The Mayo Clinic has a lot of experience in second opinions and reports that for those seeking such advice, 66% had their original diagnosis confirmed and for 21% it was changed. (Google Philanthropy in Action). Even in the ER, patients or their advocates can demand a second opinion which may bring a more senior physician into consultation. The book cited above gives a number of instances of this which produced the correct result.

Readers are encouraged to read Chapter 3 in Dr. Eric Topol's excellent recent book, *Deep Medicine. How Artificial Intelligence Can Make Healthcare Human Again.* Eric Topol, a cardiologist, is founder and director of the Scripps Research Translational Institute located in La Jolla California, and Professor of molecular medicine. He discusses misdiagnosis at length and explores the potential of artificial intelligence and algorithms based on big data and even crowd sourcing which may improve the accuracy of diagnosis but with many reservations. The whole book is well worth reading, especially by anyone who has visions of the future where a doctor's appointment starts with an interview by a robot asking questions and sending answers to a computer. Artificial intelligence appears to have great potential for reducing the risk of a missed disease or disorder in the list of possible diagnoses constructed during a patient interview and examination.

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