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# From Basic Science to Dietary Guidance: Dietary Fiber as an Example

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## ABSTRACT

Although dietary fiber is a nonessential nutrient it has achieved the status of having nutrient intake values and dietary recommendations. How it achieved this may serve as a prototype for other nonessential functional food components. An important step was the development of a worldwide accepted definition and the analytical method consistent with that definition. A database of fiber values in foods facilitated important prospective cohort studies investigating the effect of fiber intake on decreased risk of key diseases. The strongest data relating dietary fiber to health involved its laxation effect, but due to high individual variability, laxation was not the endpoint upon which the intake value for fiber was established. Instead, the intake value for dietary fiber was based on decreased risk of coronary heart disease and calculated from three prospective cohort studies. Other physiological effects of fiber on health that are generally accepted are decreased risk of type2 diabetes and effect on weight maintenance. Since the 2009 final Codex definition for dietary fiber states that fibers that are extracted or synthesized (as opposed to endogenous to the food) need to prove a physiological benefit to health, there is strong interest in establishing health benefits for these functional fibers.

Key words: dietary fiber, dietary reference intakes, dietary guidance, nonessential nutrients, functional foods

## INTRODUCTION

One of the reasons most Dietary Guidelines around the world recommend meeting nutritional needs through foods, rather than through supplements, is that foods contain substances other than essential nutrients that are important to optimal health. Otherwise, the recommendation could be to take a supplement containing all of the essential vitamins, minerals, amino acids and lipids and not be concerned about foods. However, while these nonessential nutrients (NEN) are important to optimal health, most countries/agencies do not have processes in place to identify how a NEN could “earn” a recommended intake value based on its contribution to health or be a basis for dietary guidance recommendations as important to include in one’s diet.

Dietary fiber is a NEN but it has a Dietary Reference Intake value (DRI)<sup>(1)</sup> and is mentioned in most dietary guidance documents. Several key steps were necessary for dietary fiber to achieve this status and it may be helpful to describe those steps and how they facilitated advancing the recognition of the importance of this NEN.

### I. *Importance of Having an Accepted Universal Definition*

At the time the US Institute of Medicine DRI Committee for the Macronutrients (protein, amino acids,

carbohydrates, dietary fiber, lipids and energy) began its deliberations, it became apparent that it would not be possible to determine a DRI value for dietary fiber since there was no accepted *definition* for fiber<sup>(1)</sup>. A second Committee was formed to develop the definition and report back to the Macronutrient Committee which would then use that definition for determining the intake value<sup>(2)</sup>. The US Food and Drug Administration (FDA) at the time had a set of accepted AOAC approved assays that analyzed for fiber, and if one of those approved assays was used the end result was “dietary fiber”. The idea of the DRI Fiber Definition Committee was that the formal definition should determine the methods of analysis rather than the methods of analysis determining the definition. The rationale behind this was that currently there were some substances that analyzed as fiber but most experts would not consider to be fiber, and there were other substances that didn’t assay as dietary fiber but most would consider to be fiber<sup>(2)</sup>. The definition that was developed in 2001 and eventually adopted by the DRI Macronutrient Committee<sup>(1)</sup>, divided fiber into two categories, one that was endogenous to the food and did not have to prove a physiological benefit and a separate category called “functional fiber” that was synthesized or extracted and did have to prove a physiological benefit<sup>(2)</sup>. A definition very similar to this was adopted as the final Codex definition in 2009<sup>(3)</sup>. Having an accepted universal definition means that investigators can use the same

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definition in their studies and thus studies can be compared and used for documentation of physiological benefits. It is also helpful to consumers so that they know what is and isn't fiber and to research sponsors, including food manufacturers, so that they can be assured that when they are investigating physiological effects of fibers that what they consider to be fibers are actually accepted by regulatory agencies as fibers. A definition at Codex offers other benefits as a worldwide standard including as a basis for measurement, food labeling, setting reference nutrient values, and health claims<sup>(4)</sup>. Although it was a long and difficult process coming up with a universal definition for dietary fiber, it has advanced the science in this area. In applying this process to that of other NEN it is hoped that the differences in definitions that exist for many of the functional food components can be resolved in the interest of also advancing the science.

## II. *Importance of Having a Universal Accepted Methodology for Analyzing the NEN Which Is Compatible with the Definition*

Once the Codex definition of dietary fiber was accepted it was important to have a method that supported that definition. This took another year of work, and multi center trials and an AOAC method that analyzes fiber as defined by the Codex definition was approved in 2010<sup>(5)</sup>. Having an accepted method of analysis is also very important. Prior to the newly approved method there were a variety of different fiber analysis protocols some resulting in very different results. It was often difficult to compare experimental results among studies when how they analyzed fiber depended upon what they considered to be fiber. For example, fiber values in the UK were significantly different than elsewhere and resulted in knowledgeable interpreters of results of studies in assigning factors to use in interpreting results across studies. Again, it is hoped that proponents of various NEN may come to accept universal analytical methods rather than favoring their own methods so that the science can be advanced in their particular field.

## III. *Importance of Having a Database for Determining the Amount of the Substance in Food*

A database for the amount of the NEN in foods is needed for a variety of different reasons. Without this information it can't be argued that there is a need for fortification of foods with the NEN. Also, for dietary guidance it is critical to compare actual intake values to the standard (e.g. a DRI value). Only then do we know if individuals are consuming too little or too much of that NEN. If the NEN is considered a "shortfall" nutrient (i.e. falling well below the intake recommendation) then often there are government sponsored programs to increase consumption. Also, knowing the distribution of a NEN in foods will help to determine the amount that could be in food if foods were fortified to provide the efficacious amount. Further,

these data are critical for prospective epidemiological studies. And epidemiological studies are critical to establishing the benefits of the NEN. Finally, it is important for principal investigators of clinical trials designed to establish efficacy of a particular NEN to know the background consumption of the NEN. Without this information they could be adding a specified amount of NEN to an intervention but have very different "normal diets" as the background.

## IV. *Importance of Establishing an Efficacious Amount of the NEN*

Once the definition, the method of analysis, and the food database are established it is time to conduct the appropriate research to establish the efficacious amount of the NEN. Without this efficacious amount there will not be a DRI value as this requires a number.

### (I) *Determine the Most Important Health Endpoint*

Here the best idea is to concentrate on a particular endpoint (decreased risk of a specific disease or health related condition). Doing a few studies in multiple areas is not as productive as doing many studies in one area. There won't be a dietary guidance recommendation as this is based on the DRI value. The endpoint must be a significant disease or health related condition such as coronary heart disease, type 2 diabetes, or obesity.

### (II) *Use Established Surrogate Endpoints Rather than Championing New Ones*

Only established endpoints will be accepted by regulatory authorities. For example, in the US, FDA only accepts decreasing LDL cholesterol and decreasing blood pressure as surrogate markers for decreasing the risk of coronary heart disease. The only surrogate marker accepted for cancer is decreased polyp recurrence for colon cancer.

### (III) *Produce Dose-Response Data*

A DRI value requires a number, and a number is only generated from dose response data.

### (IV) *Consider an Upper Level (UL)*

There are different considerations for functional components vs NEN from foods. Functional components depend on intended use, and it is necessary to calculate this and determine what the 95% intake segment will be ingesting. For example, the IOM Macronutrient DRI Report states with reference to Upper Level estimates for dietary fiber that "overconsumption of dietary fiber may potentially have the following adverse effects: Decreased absorption of divalent cations (e.g. calcium, zinc) ; decreased absorption of fats, protein, energy; excess gas production"<sup>(1)</sup>. However, the rationale for

not having a UL for dietary fiber was that fiber from foods is unlikely to be overconsumed. And, high fiber foods are also rich in vitamins and minerals. However the following caution for the future was noted: "If more fiber supplements and "functional fiber" is incorporated into food this decision may need to be reconsidered"<sup>(1)</sup>.

The above discussion has centered on a potential process for establishing a DRI value which can then be used for dietary guidance, and how this was established for dietary fiber. The major issue with dietary fiber at this time is that the definition requires that fibers that are extracted or synthesized have to show a "physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities"<sup>(4)</sup>. Establishing what those physiological effects are, and how to demonstrate that presumptive fibers produce those effects is a current ongoing challenge for fiber researchers. There are two major issues regarding extracted and synthesized fiber having to prove a physiological beneficial effect to health, while endogenous fibers do not. First, one needs to agree on what the primary beneficial effects to health from fiber ingestion are, and then one also has to deal with the idea that only "functional" fibers have to prove that they are efficacious.

For the purposes of this paper I will put the physiological benefits to health from dietary fiber into a hierarchy from strongest evidence to less strong, but all effects mentioned are generally considered important benefits to health. But first, a brief explanation of the key attributes of dietary fiber that result in these physiological effects. There are two key attributes of different dietary fibers: viscosity and fermentability. Viscosity is important in the upper gastrointestinal tract, whereas fermentability is important in the colon. Viscous fibers can delay gastric emptying resulting in a feeling of fullness and satiety and also contributing to slower absorption in the small intestine. This slower absorption, in turn, can modulate blood glucose levels and a decreased absorption of cholesterol. The viscous fibers with the most research studies behind them are oat bran, pectin, guar, and psyllium. In contrast, the key attribute of fiber in the lower gastrointestinal tract is its fermentability. This is a combination of the structure of the fiber and the colonic microflora. Fermentable fibers are fermented to gases including CO<sub>2</sub>, H<sub>2</sub>, methane, and short chain fatty acids (including butyrate). Fermentable fibers are not good bulking agents as there is no more fiber left to contribute to fecal bulk after their fermentation. Fermentable fibers include oat bran, pectin, and guar. Poorly fermented fibers, which are good bulking agents and produce little gas or short chain fatty acids include cellulose and wheat bran.

### I. *Effect of Fiber on Laxation*

The greatest number of studies and the strongest science is on the effect of fiber on laxation. This involves the effect of fiber on transit time, and fecal

bulking. In a review of 150 studies on fecal bulking, Cummings summarized how much the weight of feces increased as a function of one gram of fiber to the diet<sup>(6)</sup>. He showed that the highly fermentable fiber pectin produced the lowest bulking response whereas wheat bran resulted in the greatest response with every g of wheat bran resulting in an additional 5.25 g of fecal material<sup>(6)</sup>. Wheat bran is considered to be the "gold standard" for a fecal bulking agent. Unfortunately, the individual variability in response of subjects to fiber ingestion is so great, that it was not possible to base a DRI value on the "bulking" effect of fiber despite the fact that it represents the strongest database for an important health effect of dietary fiber.

### II. *Effect of Fiber on Decreased Risk of Coronary Heart Disease*

The second strongest and most complete data set for a physiological benefit to health is for decreased risk of coronary heart disease (CHD). This database consists of a mixture of long term epidemiological studies and relatively short term clinical intervention trials. The clinical intervention trials focused on mechanisms by which fiber might decrease the risk of CHD, including lowering serum cholesterol, decreasing hypertension, and contributing to weight maintenance (all risk factors for CHD). The DRI value for dietary fiber was determined from three large scale prospective cohort studies. These included the Health Professionals Follow-up Study<sup>(7)</sup>, the Nurses' Health Study<sup>(8)</sup> and the Finnish Men's Study<sup>(9)</sup>. In each of these three studies the relative risk for CHD was much lower in the highest quintile for dietary fiber as compared with the lowest quintile. A calculation of the average amount of fiber that was required to be in the most protected group for CHD was divided by the amount of calories consumed on average in that group and expressed as g of fiber per 1,000 kcals. The number was 14 g/ 1000 calories. This then became the DRI value for dietary fiber when it was applied to both genders and all age groups as a function for the recommended amount of energy to consume by each of those groups<sup>(1)</sup>.

### III. *Dietary Fiber and Decreased Risk for Type 2 Diabetes*

Again, the strength of the relationship between dietary fiber and type2 diabetes was assessed with both small scale clinical trials and large scale epidemiological cohort studies. One review summarized the result of 50 studies on viscous fiber intake and glycemic response and found the viscous fibers reduced glycemic response in 33 of the 50 studies<sup>(9)</sup>. A position paper from the American Dietetic Association based on a systematic review, concluded that "limited evidence suggests that diets providing 30 to 50 g fiber per day from whole food sources consistently produce lower serum glucose levels compared to a low fiber diet."<sup>(10)</sup> A multiethnic cohort in Hawaii, with a 14 year follow up period determined that

participants in the top quintile of grain fiber intake had a 10% reduction in type2 diabetes and in the highest quintile of vegetable fiber intake the reduction was 22%<sup>(11)</sup>.

#### IV. Dietary Fiber and Decreased Risk of Obesity

Weight management information from epidemiological studies is supported by shorter term and smaller clinical studies addressing such issues as satiety, and result of fiber intake at one meal (e.g. breakfast) and effect of energy intake at the next meal. In a European Cohort study with men and women, a large cohort followed for 6.5 year, total fiber and cereal fiber were inversely associated with subsequent increases in weight and waist circumference<sup>(12)</sup>.

#### V. Summary of Major Physiological Effects of Dietary Fiber That Result in Benefits to Health and Next Steps

Based on the evidence summarized above, the 2010 Dietary Guidelines Advisory Committee completed an evidence-based review and concluded: "A moderate body of evidence suggests that dietary fiber from whole foods protects against cardiovascular disease, obesity, and type 2 diabetes and is essential for optimal digestive health."<sup>(13)</sup> Their recommendation was to increase consumption of naturally occurring plant-based foods that are high in dietary fiber, including whole grain foods, cooked dry beans and peas, vegetables, fruits, and nuts. In the future more areas of research will likely move into the "generally accepted" category. The most promising research area at this time appears to be the area of fiber as a prebiotic. This area is advancing rapidly and is now focusing more on functional rather than descriptive endpoints.

In summary, the new Codex Definition now place dietary fibers in three categories: endogenous to the food which do not have to prove a physiological benefit to health and extracted or synthesized fibers which do have to prove such a benefit. One might ask as to why the functional fibers have to prove a benefit whereas the endogenous high fiber diets do not. This is a question often asked about fiber. One major difference between high fiber diets and fibers added to foods involve the "vehicle" for the fiber. With obesity being a major health issue, the vehicle containing nutrients such as fiber becomes important as we can't afford to waste calories on non-nutritious substances. High fiber foods are almost a proxy for a good diet as they are whole grains, fruits, vegetables, and legumes. Supplementing other foods with fiber may not provide the same benefits as a high fiber diet.

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