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North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Position Paper: Plant-based Milks

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See ''GOT MILK-ish?'' by Rosen on page 149.

ABSTRACT

Parents and caretakers are increasingly feeding infants and young children plant-based ''milk'' (PBM) alternatives to cow milk (CM). The US Food and Drug Administration currently defines ''milk'' and related milk products by the product source and the inherent nutrients provided by bovine milk. Substitution of a milk that does not provide a similar nutritional profile to CM can be deleterious to a child's nutritional status, growth, and development. Milk's contribution to the protein intake of young children is especially important. For almond or rice milk, an 8 oz serving provides only about 2% or 8%, respectively, of the protein equivalent found in a serving of CM. Adverse effects from the misuse of certain plant-based beverages have been well-documented and include failure to gain weight, decreased stature, kwashiorkor, electrolyte disorders, kidney stones, and severe nutrient deficiencies including iron deficiency anemia, rickets, and scurvy. Such adverse nutritional outcomes are largely preventable. It is the position of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Nutrition Committee, on behalf of the society, that only appropriate commercial infant formulas be used as alternatives to human milk in the first year of life. In young children beyond the first year of life requiring a dairy-free diet, commercial formula may be a preferable alternative to cow's milk, when such formula constitutes a substantial source of otherwise absent or reduced nutrients (eg, protein, calcium, vitamin D) in the child's restricted diet. Consumer education is required to clarify that PBMs do not represent an equivalent source of such nutrients. In this position paper, we provide specific recommendations for clinical care, labelling, and needed research relative to PBMs.

Key Words: almond milk, cashew milk, childhood malnutrition, childhood nutrition, coconut milk, flax-seed milk, hemp milk, milk, oat milk, pea milk, plant-based milks, rice milk, soy milk

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Parents and caretakers are increasingly feeding infants and young children plant-based ''milk'' (PBM) alternatives to cow milk (CM) (1–5). In some cases, this is related to CM allergy or intolerance or the perception that these conditions are present. In addition, pediatricians and pediatric gastroenterologists are increasingly seeing families with health beliefs or religious or cultural values that either preclude CM intake or lead to a strong preference to avoid it (3). For some, this may be related in part to ecological concerns related to the environmental impact of extensive dairy farming (3,6,7). Such dietary choices may have unintended consequences. Published literature and confirmatory clinical experience of North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) members attest that when plant-based beverages are fed inappropriately to infants (especially) and young children in lieu of infant formula or standardized milk products, there is a potential for serious adverse effects (8).

This Position Paper has its origins in a NASPGHAN response to a September 18, 2018 FDA Federal Register Request for Comment regarding the ''Use of the Names of Dairy Foods in the Labeling of Plant-Based Products'' (Docket No. FDA-2018-N-3522). A working group from the Nutrition Committee, on behalf

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of NASPGHAN and The Council for Pediatric Nutritional Professionals (CPNP), submitted comments in response to that request on November 19, 2018. Our document noted that, historically, CM has played a key role in meeting the nutritional needs of most North American children. Adverse nutritional outcomes have been documented when young children have been inappropriately fed PBM substantially different from CM. In the FDA letter, the working group stated, ''We believe such adverse nutritional outcomes are preventable through FDA mandated labeling of non-standardized plant-based beverages, consumer nutrition education and efforts directed to heighten health care practitioners' awareness of these nutritional issues.'' The working group letter concluded, ''From a pediatric medical and nutritional standpoint, it is advisable that milk' be: 1) milk products as currently defined by FDA, or 2) provide comparable nutritional value to standard 'milk.' Such labeling, and education regarding this labeling, may reduce adverse nutritional effects from consuming nutritionally non-equivalent plant-based products labeled as 'milk.'''

On the basis of our understanding of the impact of milk elimination, it appears that in early childhood, cow's milk makes a significant contribution to linear growth (9,10), vitamin D status (11), and bone health (12–14). Herein, we provide information for practitioners regarding the composition, dietary uses, and nutritional limitations of PBM, and describe the substantial differences among PBM and how they differ from CM. This review does not include a comprehensive assessment of the benefits and any potential shortcomings of CM in the diet of children. It is rather an assessment of how PBM may have a similar or different nutritional impact relative to CM in young children. Although information concerning infants is included in aspects of this review, the intended focus is on feeding young children. The likelihood of harm for infants fed nutritionally inappropriate milks is recognized as much greater than that for young children, given the high percent of infant nutritional needs met by breast milk or formula. For infants, the milk source in the diet needs to be human milk or an iron-fortified infant formula (15). The specific needs of infants are not further discussed.

WHAT IS MILK?

The FDA currently defines ''milk'' and related milk products by the product source and the inherent nutrients provided by bovine milk (16). There appears to be limited consumer recognition of why some CM alternatives meet pediatric nutritional needs and others do not (17,18). The misguided substitution of a plant-based ''milk'' for CM, without adequate compensation for nutrients not supplied in such a product, can place a young child at risk.

Review of packages and labels of such products finds that many are packaged similarly to CM cartons, and most are labeled as ''milk'' or the plant milk as in ''ricemilk'' or ''almondmilk.'' Only a few are labeled as ''drinks'' or ''beverages'' rather than ''milk.'' The listed composition generally does not resemble CM, with the exception of some soy and pea products. Some PBM are free of sugar and others are as high as 17 g per serving. The calorie level varies from 30 to 550 calories per cup (eg, some coconut milks), among different plant milk sources, different products derived from the same plant, and even within each brand of a specific PBM. Serving size varies, especially for coconut milk. Many are supplemented with variable amounts of calcium and some with vitamins. Fortified PBM commonly contain stabilizers, such as gums or carrageenan. Table 1 highlights the nutritional differences between CM and nontraditional PBM.

THE ROLE OF MILK PRODUCTS IN THE DIET OF YOUNG CHILDREN

The universally preferred milk for infants is human milk (19) but many infants are fed infant formula because of maternal choice or other complex factors (3,5). Breast milk or infant formula (most commonly containing CM) should be an infant's sole food for the first 4 to 6 months of life. In infants not receiving breast milk, an iron-fortified infant formula should be the source of milk in the diet to 1 year of age (15). US infant formulas are regulated under the Infant Formula Act that requires that products labelled as infant formula support healthy growth. Since the introduction of the Infant Formula Act, reports of nutritional deficiencies related to US formulas have become exceedingly rare. By 1 year of age, most infants are weaned to some form of ''milk.'' USDA recommendations are to consume 2 to 3 servings of dairy products per day for a well-balanced, nutritionally complete diet; this amount provides approximately 25% to 30% of total energy needs of 1- to 3-year-olds. Despite lay concerns regarding adverse health impacts of CM, epidemiologic research has found that dairy product intake appears to reduce the risk for common chronic diseases in the population, increase population height (20–23), and supply key nutrients for growth and development (24). In USA, the Feeding Infants and Toddlers Study (FITS) and the National Health and Nutrition Examination Study (NHANES) have documented the key role that CM plays in the diets of toddlers for both macro- and micronutrients (25–27). Studies from multiple European countries, including the Identification and prevention of Dietary-and lifestyle-induced health EFects In Children and infantS study (IDEFICS), have similarly documented the important role of milk in the diets of young children (28–33).

Milk's contribution to the protein intake of young children is especially important. Considering both protein content per serving and protein quality is important in evaluating the protein adequacy of protein provided by PBM. In addition to the lower protein content per serving, the lower quality of plant proteins relative to CM protein further reduces the nutritional value of PBM. The current Food and Agriculture Organization/World Health Organization (FAO/WHO) standard for protein quality is the Digestible Indispensable Amino Acid Score (DIAAS) (34), whereas the FDA regulatory standard for

TABLE 1. Nutritional comparison of cow's milk and plant-based ''milks''

		Plant-based milk								
Per 1 cup (240 ml)	Cow's milk	Almond	Cashew	Coconut	Flax-seed	Hemp	Oat	Pea	Rice	Soy
Calories	150	30 to 100	25 to 80	45 to 90	55	70 to 170	130	115	110	90
Protein (g)	8	1 to 5	0 to 1	0 to 1	0	2 to 4	4	8	1	6
Fat (g)	8	3	2 to 3.5	5	2.5	5 to 6	2.5	5	2.5	3.5
Carbohydrates (g)	13	9 to 22	1 to 20	8 to 13	9	1 to 35	24	11	20	15
Sugar (g)	12	7 to 20	0 to 18	0 to 9	9	0 to 23	19	10	13	9
Calcium (mg)	300	300	100 to 450	100 to 450	300	400	350	450	300	400
Vitamin D (IU)	120	110	125	125	100	150	120	150	120	120

There are variations in plant-based milk nutrients because of different products available: averages or ranges are reported.

protein quality is the Protein Digestibility Corrected Amino Acid Score (PDCAAS) for most foods and, primarily, the Protein Efficiency Ratio (PER) (35), a rat growth rate bioassay, for infant formulas. On the basis of the available information, the approximate PER values relative to CM or its major protein are as follows: casein, are 80% for soy, 72% for oat, 66% for coconut and hemp, 60% for rice, 57% for pea, and 16% for almond protein (36–39). Values vary modestly with the starting material and food processing methods. By multiplying the protein content by the PER relative to milk, it is possible to estimate the protein equivalency of an 8 oz serving relative to CM. For soy or pea milk, a serving provides about 60%, and for oat milk, 36% of the equivalent of CM. For almond or rice milk, an 8 oz serving provides only about 2% or 8%, respectively, of the protein equivalent found in a serving of CM. In contrast to the rice-based hydrolysate infant formulas described below, rice PBM have low energy and protein content and are not fortified with multiple micronutrients and the limiting amino acids lysine and threonine. Although plant protein quality can be improved by adding limiting amino acids, it is at the expense of taste and aroma.

FEEDING MILK INTOLERANT INFANTS OR CHILDREN IN MILK-INTOLERANT FAMILIES

Most infants and young children tolerate CM-based formulas and milks with only 2% to 7.5% of infants and young children having true CM protein allergy or intolerance (40). These infants and children suffer adverse medical consequences, such as proctocolitis, poor feeding or poor weight gain from consuming CM-based infant formulas and milk products. Historically, in the late 20th century, the most common and available CM alternatives were soy-based beverages. Modern soy protein formulas have been produced that meet the nutritional needs of infants, comparable with CM formulas (41,42). Feeding soy products to infants and children has, however, led to what a toxicology review group technically defined as ''minimal'' concerns related to the composition of soybeans, including their phytoestrogen content. Historically, the phytate content was a concern for decreasing the bioavailability of minerals and trace elements of some products (43–48). Controversy surrounding the use of soy products in young children may have added to the attractiveness of other PBM to consumers. Commercial hydrolyzed rice protein concentrate-based infant formulas have also been developed and documented to support the normal or near growth of infants (49–52). In some cases, however, plant-based formula choices may not prove hypoallergenic and may not provide necessary nutrition (4,53,54). Financial considerations may also play an important role in substitution decisions, given the cost of expensive hypoallergenic infant formulas that are unlikely to be covered by health insurers, especially in orally fed children after the first year of life. Caretaker adaptation to such financial realities can lead to unintended health consequences (55). Aroma, taste, and texture differences may also influence choices between hypoallergenic formula versus plant-based alternatives (4).

CLINICAL ADVERSE EXPERIENCES WITH PLANT-BASED BEVERAGES

It is well known that some CM protein-intolerant infants and children can develop enterocolitis when fed soy formulas, but more recently, evidence now exists that this may also occur with other plant-based beverages (56–60). Due to such concerns, the European Society for Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) recommends the use of a protein hydrolysate or amino acid-based infant formula for the first year of life or longer in children with CM allergy (61).

Feeding PBM inappropriately to infants and young children has been reported to affect growth and nutritional status adversely. In 2017, Vitoria (8) cataloged more than 30 cases of infant (mostly) and early childhood malnutrition associated with the use of PBM in the American and international literature from the previous 30 years. Specific findings in the literature include slow linear growth (8,62), poor weight gain, and even overt protein calorie malnutrition, including with edema (kwashiorkor) (8,63) all of which may lead to compromise of future growth and development (64). Specific micronutrient concerns that have been documented include vitamin A deficiency (65), low vitamin D (53,66), rickets (8), scurvy (8), and iron deficiency anemia (8). In the Vitoria (8) report, soy milk was specifically associated with rickets, rice milk with kwashiorkor, and almond milk with rickets and scurvy. Most, but not all, reported clinical cases consumed such beverages in infants or young children where nutrient requirements were not being met, particularly for protein (63,67–70). A question about the possible risk of iodine deficiency (71,72) has been raised. In addition to nutritional deficiencies, almond milk has been associated with metabolic and electrolyte disorders including hematuria with kidney stones (73), metabolic alkalosis, and hyperoxaluria (8). Almond and soy milk could put children at risk for dental caries (depending on the specific composition and amount of added sucrose) (74).

Reports have not been, however, limited only to young children. Problems arise in older children where the plant-based beverage is used in excess of usual recommendations for ''milk'' intake, while at the same time, other dietary sources of protein and nutrients are significantly limited by multiple other dietary restrictions or displacement by ''milk'' (65,73). Furthermore, multiple food elimination is a higher risk situation for negative impact on growth and nutrient intake for children of all ages (24). A key for the practitioner in this scenario is to recognize that consultation with a nutritionist may be necessary in order to determine how best to meet nutrient requirements from multiple dietary sources, with consideration of supplementation with hypoallergenic formula or micronutrients, if also necessary. It should also be noted that even excess intake of CM in young children is not without risk, particularly being associated with iron deficiency (75–77).

Concern has also been expressed that consumption of some PBM could lead to excess intake of arsenic (rice milk, but perhaps not hydrolyzed rice milk formula) (78–81), and possibly manganese (soy and rice) (82,83), if intakes are very high.

FOOD-LABELING CHALLENGES

We believe most adverse nutritional outcomes related to PBM intake are preventable through FDA-mandated labeling, consumer education about the importance of a balanced diet for children (in which beverages are but 1 part of the diet) and nutrition education efforts directed to heighten health care practitioners' awareness of the nutritional limitations of these beverages. These challenges are not limited to the United States. The Codex Alimentarius (84) international food standards adopted by many countries of varying income levels as the basis for their food regulation similarly defines milk as coming from an animal lacteal source. Reported cases of children with nutritional compromise related to the inappropriate use of PBM come not just from America, but also from other high-income countries that use the Codex.

''Good nutrition'' has varying meanings to different segments of the population. To some, good nutrition means generally following dietary guidelines for the various age groups with foods that have long been part of the North American diet. To others, it may relate more to the avoidance of specific foods or food components (eg, animal-derived food products, CM or gluten) or the avoidance of toxins, food additives or genetically modified foods and ingredients. Food labeling needs to provide information to facilitate appropriate consumer food choices based on personal preferences as to ingredients and

ingredient sources, nutrient content and the role of specific foods in meeting daily dietary requirements, all in the small space of the label.

Based on our clinical experience and the available relevant medical literature, labelling a beverage as ''milk'' that: 1) does not come from CM, or 2) does not contribute the equivalent nutritional value of CM to the diet (18,85), is not in consumers' best interests. For plant-based products that require fortification to achieve a nutritional label value that approximates CM, (eg, with calcium), it is difficult to know to what extent this is actually achieved, in the absence of measurements of actual liquid nutrients content (86) and bioavailability studies (18). The biologic value of the protein source and its physical matrix relative to CM also need to be considered in this regard (4,87,88). There are documented physical stability issues with such products that require shaking (or may not be not fully corrected by extensive shaking (54) or special handling instructions (4)). Based on these considerations and the regulatory role of the FDA regarding the food supply and its labeling, new FDA labeling regulations and their enforcement are needed to help consumers avoid the risks of inappropriate use of plant-based beverages in infants and young children. Importantly and encouragingly, it appears that the food industry has the ability to produce improved PBM that achieve acceptable physical and nutritional properties that more closely approximate those of CM (41,49,50,52,89,90–93).

FOOD-LABELING RECOMMENDATIONS

As stated in the NASPGHAN/CPNP letter to the FDA, from a regulatory standpoint, it is advisable that products labeled as ''milk'' be: milk products as currently defined by the FDA, or provide comparable nutritional value to standard ''milk'' and CM products. Such labeling may reduce adverse nutritional effects resulting from consumption of nutritionally nonequivalent plant-based products, which should no longer be labeled as ''milk.'' Adding the RDA for children, as well as adults, PBM labels may also help consumers recognize the nutritional limitations of these products for children. Similarly, a label statement that a PBM that is not substantially equivalent to CM is ''Not a suitable CM alternative for children less than 2 years of age'' could serve as both a useful warning and provide important consumer information. Additional consumer education, as already initiated by some groups (46,94), and expansion of existing professional education regarding this labeling may also prevent PBM-associated malnutrition in infants and children.

CLINICAL RECOMMENDATIONS

From a clinical standpoint, clinicians should assess the ''milk'' a child is consuming whenever evaluating a child's diet. If the milk source is not breast milk, CM or a CM or soy formula, the clinician should explore family preferences and make a suitable recommendation in the context of the child's age and requirements. When counseling families with children for whom CM is medically contraindicated or an unacceptable feeding option, clinicians should advise families that in the absence of a balanced diet, nutritional reliance on an alternative PBM with composition substantially different from CM products may not meet the child's nutrient requirements and may compromise growth. Soy formula or soy milk may be suitable for a majority of infants or young children, respectively, with CM allergy, although not all. When CM allergy is present in young children, hypoallergenic formulas are safe and nutritious. NASPGHAN agrees with ESPGHAN in recommending an appropriate alternative infant formula for feeding for the first year of life or longer, when breast milk or a CM formula cannot be used because of allergy. Financial accessibility to such formulas, however, may preclude their use by many families, and suitable alternatives need to be identified.

As presently constituted, almond, rice, coconut, hemp, flax seed, and cashew ''milks'' are inappropriate replacements for CM in toddlers and young children for whom milk remains an important part of the diet. They have inadequate nutrient profiles to meet needs for protein, calcium, and vitamin D, in particular. Pea milk, and possibly oat milk, may be more reasonable PBM alternatives for young children requiring a CM and soy alternative, depending on the specific nutritional composition of the product, including the calorie, protein, vitamin and mineral contents, and the bioavailability of fortified nutrients. Families should be guided to these products and given support in reviewing the available information on nutrient composition. When a PBM is used as an occasional beverage, and not the primary milk source in a child's diet, the nutritional composition is likely not of concern [eg, as described by Steinman for allergic children (95)]. The use of PBM in a limited manner in the diet plan will be largely driven by the child and family's cultural and taste preferences and consideration of costs. In cases where PBM alternatives are used as the primary milk source in older children, the clinician should recommend adoption of a carefully planned diet that also includes alternative dietary sources of protein, calcium, iron, and vitamins B-12 and D (96,97). These may be from plant or animal sources and may include use of nutritional supplements to ensure a complete and well-balanced diet. Consultation with a registered dietitian can facilitate assessment of a CM-free diet, identify nutrients that are insufficient in the diet, and help a family find acceptable sources of those nutrients for a child. The Academy of Nutrition and Dietetics website (*www.eatright.org*) has a ''Find an Expert'' function to help healthcare professionals or consumers find an appropriate registered dietitian.

RESEARCH RECOMMENDATIONS

The bioavailability and nutritional quality of plant and plant hydrolysate-based milk products for children need to be further assessed. Growth studies and bone mineralization studies of young children fed PBM are needed, similar to those performed to assess the nutritional quality and tolerance of infant formulas. Data need to continue to be collected and reported regarding adverse medical and nutritional events associated with the use of PBM.

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