

Clinical Commentary Review

Practical Challenges and Considerations for Early Introduction of Potential Food Allergens for Prevention of Food Allergy

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Recent randomized controlled trials aimed at the prevention of food allergy have led to sweeping changes in food allergy prevention guidelines. Emphasis is now on the introduction of potential food allergens, particularly peanut and egg, rather than avoidance. Although guidelines recommend against delaying the introduction of other potential allergens, there remains little or no evidence of the benefit of their early introduction. Parents and physicians alike report a need for greater guidance and resources on early potential allergen introduction in the complementary feeding period. A thorough understanding of early introduction literature, current prevention guidelines, and infant nutrition will empower physicians to address patient

needs and concerns both when advice is established as effective and where uncertainty remains. We discuss the state of the science, compare recommendations between guidelines, and provide practical options to introduce allergenic foods, alongside other complementary foods, within the first year of life. We include a review of the available literature, including review and suggestions of potential doses of food allergens, and the first published comparison of commercially available products and homemade early introduction foods to help clinicians support their patients. We address the nutritional, dietary, and practical considerations of introducing food allergens in the first year of life while adhering to infant feeding guidelines. Finally, given the limitations of existing guidelines, we review the need for shared decision-making between physicians and parents regarding early allergen introduction. © 2020 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2020; ■: ■-■)

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Evidence that the introduction of peanut in the first year of life prevents peanut allergy has shifted prevention guidelines and clinical practice both in primary care and allergy clinics. Although there are many recommendations about the introduction of peanut, less guidance has been provided about the introduction of other allergenic foods such as egg despite randomized controlled trials (RCTs) demonstrating benefit of early egg introduction. Furthermore, there are few or no studies to guide the introduction of other potential food allergens. Barriers to early introduction of peanut still exist, with patients and physicians reporting discomfort with feeding peanut-containing foods to infants, despite reported awareness of updated guidelines.^{1,2} Although gaps exist in our knowledge base, understanding specific ways to introduce potentially allergenic foods as a part of infant complementary feeding may assist clinicians and parents to optimize the early introduction of potentially allergenic foods. The time-sensitive nature of food allergy prevention necessitates that the practical aspects early food introduction be addressed.

In this article, we address the real-world aspects of introducing allergenic foods for allergy prevention. We discuss the state of the science, compare recommendations between guidelines, and provide practical options to introduce allergenic foods, alongside other complementary foods (CF), within the first year of life. We include the first published comparison of commercially available products and homemade foods for the timely introduction of food allergens to help clinicians educate their patients. We

Abbreviations used

BSACI- British Society of Allergy and Clinical Immunology
 CF- Complementary foods
 CI- Confidence interval
 CM- Cow milk
 CMA- CM allergy
 DGAC- Dietary Guidelines Advisory Committee
 EAT- Enquiring About Tolerance
 FDA- Food and Drug Administration
 LEAP- Learning Early About Peanut
 NIAID- National Institute of Allergy and Infectious Disease
 RCT- Randomized controlled trial
 SDM- Shared decision-making
 SPADE- Strategy for Prevention of Milk Allergy by Daily Ingestion of Infant Formula in Early Infancy

address the nutritional and dietary considerations of introducing allergens while adhering to infant feeding guidelines. Finally, given the limitations of existing guidelines, we review the need for shared decision-making (SDM) between physicians and parents regarding early allergen introduction.

WHAT WE KNOW: FOOD ALLERGY PREVENTION LITERATURE

Multiple prospective RCTs provide evidence that the early introduction of peanut and hen's egg decreases the incidence of peanut and egg allergy in infants who are at high risk of developing food allergy.³⁻⁸ Studies on the prevention of other food allergens have been less robust and have shown evidence of safety, but not necessarily efficacy. The Enquiring About Tolerance (EAT) trial randomized infants from the general population to an intervention of the early introduction of milk, egg, peanut, sesame, fish, and wheat beginning at 3 months of age.⁸ Adherence to the protocol was moderate (42.8%), and the intention to treat (ITT) analysis indicated a nonstatistically significant trend toward the prevention of peanut and egg allergy. There was no increased risk of allergy to any of the foods when compared with the "standard" introduction group even with moderate protocol adherence.

The Strategy for Prevention of Milk Allergy by Daily Ingestion of Infant Formula in Early Infancy (SPADE) study is an RCT by Sakihara et al⁹ that investigate the effect of daily ingestion of ≥ 10 mL of cow milk (CM) formula plus breastfeeding (N = 242) versus use of avoidance of CM while breastfeeding using soy formula as needed (N = 249) from the ages of 1 to 2 months old in a general population on the rate of CM allergy (CMA) at 6 months old. Participants were able to ingest CM before randomization, and the median intake before the study was 80 mL per day. CM ingestion challenges done at 6 months found CMA in 2 of 242 (0.8%) in the CM ingestion group and 17 of 249 (6.8%) in the CM avoidance group (risk ratio, 0.12; confidence interval [CI], 0.01-0.5; $P < .001$) in the ITT analysis. This is the first RCT to demonstrate that early and frequent CM ingestion may be associated with lower rates of CMA with no significant effect on breastfeeding. However, high rates of CMA in the control group and a relatively homogeneous population limit the generalizability of this study. Other prospective observational studies provide a mixed message about

whether to introduce CM to prevent CMA.¹⁰⁻¹² Katz et al¹¹ showed that the introduction of CM between 0 and 14 days old was associated with a rate of milk anaphylaxis of 0.05%, and milk introduction between 105 and 194 days old had a rate of 1.75% of anaphylaxis to milk. With further supportive research, frequent ingestion of low volumes of CM in early infancy could potentially be recommended as a strategy to prevent CMA.⁹

In terms of other allergens, the HealthNuts study reported that ingestion of cashew under age 1 (n = 140) was associated with no cases of cashew allergy at age 6 years (adjusted odds ratio, 0.19; 95% CI, 0.00-1.09; $P = .07$).¹³ There are no available studies on the safety or efficacy of the early introduction of other tree nuts, soy, or shellfish.

WHAT IS ADVISED? NATIONAL AND INTERNATIONAL PREVENTION GUIDELINES

Guidelines regarding the introduction of food allergens have evolved over the last 2 decades, though differing approaches remain. Initial guidance from the United Kingdom and the United States recommended avoidance of peanut (United Kingdom) and other allergens (United States) until 3 years of life in children with familial risk for allergy as a means to prevent allergic disease.^{14,15} In 2008, the revised UK and US recommendations on peanut avoidance¹⁶ rescinded previous recommendations to delay the introduction of peanut in high-risk children because the advice was being broadly applied by families that even if they had no familial risk of allergy, there was no apparent decrease in the incidence of peanut allergy in the United Kingdom from 1998 to 2008, and they suggested that there was little evidence to delay food allergen introduction beyond 4 to 6 months.¹⁷⁻²⁰ The 2013 American Academy of Asthma, Allergy and Immunology guidance recommended that in all infants, potentially allergenic foods can be given once a few CF have been tolerated, consistent with the Canadian Society of Allergy and Clinical Immunology.^{21,22} The European Academy of Allergy and Clinical Immunology guidelines (2014) made a neutral statement, not recommending to delay or introduce potential food allergens in the first year of life for all infants.²³ One commonality among the various current early introduction guidelines is that they suggest that 4 months old is an acceptable age for CF introduction reflecting historical norms despite current World Health Organization guidance on age of solid food introduction, suggesting the introduction of solid foods at 6 months.²⁴

Following the publication of the Learning Early About Peanut (LEAP) study in 2015⁷ and a number of RCTs on egg and multiple allergen introductions,^{3,4,6,8,25} guidelines around the world adapted. The Australian Society of Clinical Immunology and Allergy guidelines suggested that peanut, cooked egg, wheat, and dairy foods be introduced into the diets of all infants in the first year of life without screening.²⁶ The National Institute of Allergy and Infectious Disease (NIAID) guidelines (2017) are more prescriptive and suggest different peanut introduction schedules depending on the degree of risk.²⁷ The NIAID guidelines are the only guidelines that recommend allergy testing before the introduction of peanut. The 2017 UK Committee on Toxicity report suggests that peanut and egg should be treated no differently than other CF.²⁸ The British Society of Allergy and Clinical Immunology (BSACI) guidelines suggest that in the

general population, egg and then peanut can be introduced as part of the family diet, but in high-risk infants, introduction between 4 and 6 months is recommended.²⁹ BSACI is the only current guideline to recommend egg introduction before peanut introduction because egg sensitization seems to occur before peanut.²⁹ The American Academy of Pediatrics Committee on Nutrition and others actively recommend the early introduction of peanut in infant-safe forms and do not recommend delaying the introduction of any specific food after 4 to 6 months of age.³⁰

Unfortunately, this significant recommendation variability can be confusing for families and clinicians alike. With the increasing evidence that early food allergen introduction may induce tolerance, and recommendations by most guidelines not to delay food allergen introduction, physicians and patients desire guidance on how to introduce potentially allergenic foods as a healthy component in the early infant complementary feeding period.³⁰

Therefore, when implementing the early introduction of potentially allergenic foods in clinical practice, we suggest that clinicians place first priority on supporting the introduction of peanut and egg, which have evidence of benefit. The order of egg and peanut introduction should be determined based on national guidelines, cultural practices, and individual SDM between patients and clinicians. Foods that have been evaluated and have been shown not to increase the risk for allergy (milk, wheat, sesame, fish) could be a second priority. Finally, even in the absence of evidence, the early introduction of foods such as tree nuts, soy, and shellfish in high-risk children should be addressed with families (Table I).^{8,31} This discussion is even more important now that commercial products containing various amounts of proteins from these foods are marketed for allergy prevention (Table II).

BARRIERS TO EARLY INTRODUCTION

Barriers to the introduction of food allergens may impede opportunities for food allergy prevention. Greenhawt et al² surveyed new and expectant parents and found reluctance to feed peanut around 6 months of age. A survey by Lai and Sicherer¹ reported parental fear of reaction (36%), choking (11%), and lack of infant-safe forms of peanut (6%). Parents also requested additional physician advice (44%), written information (24%), and allergist access (18%). Despite parental awareness of guidelines, peanut-feeding rate was only 37% in infants >6 months of age. In this same survey, only 60% of physicians provided recommendations consistent with guidelines at the time of the study.¹ Encouragingly, follow-up studies from EarlyNuts showed that the rate of peanut introduction in an unselected Australian population increased from 28.4% during 2007-2011 to 88.6% in 2018.³² Even when enrolled in clinical trials, continued adherence to protocols remains a challenge and adherence is different based on the food. In the largest early introduction trial to date, PreventADALL found that adherence at 26 weeks to the introduction of potentially allergenic foods between 13 and 18 weeks old was 35% for peanut (44% of those who started peanut), 43% for CM (63% of those who started milk), 44% for wheat (66% of those who started wheat), and 24% for egg (43% of those who started egg).³³ Altogether, data suggest that physicians and families require reassurance and guidance on the practical aspects of early peanut introduction and that written materials may assist implementation (Table I).

The EAT study group also evaluated barriers to early food allergen introduction; nonadherence was associated with 3 enrollment factors: older maternal age (≥ 33 years old), non-white ethnicity, and lower maternal quality of life at enrollment.³⁴ After enrollment, parent reporting of infant feeding difficulties by 4 months of age was associated with nonadherence. However, feeding difficulty was reported more frequently in the early introduction group. Because the reported rate of feeding difficulty was similar from 4 months through 12 months of age, the feeding difficulty is likely to have been conflated with the stringent target of allergen consumption, rather than representing developmental issues with consumption.

A qualitative analysis of the parental reporting of problems feeding their infant the allergenic foods identified 3 main themes: infant refusal (swallowing issues, dislike of the taste, and infant illness), concerns about reactions (digestive or skin issues and actual allergy), and practical problems (lifestyle convenience and food preparation issues).³⁵ Sesame and egg predominated in the parent reporting of feeding problems.

Although noted barriers exist, there is patient and clinician interest in safe and practical early introduction of a variety of potential food allergens. In the absence of evidence, food manufacturers are marketing early feeding products containing various potential allergens (Table II). The interest in early feeding of multiple potential allergens is outpacing the ability for RCTs to provide evidence for the efficacy, safety, timing, dose, and forms of these allergenic foods. This evidence gap leaves many practical questions unanswered for allergists, pediatricians, and families.

WHAT FORM AND HOW MUCH TO FEED? CLUES FROM THE LITERATURE

Reviewing previous early introduction studies gives clinicians options for specific recommendations on safe forms and dosing of a food that can be used during early infant feeding. The LEAP study recommended peanut puff snack or smooth diluted peanut butter for younger children and supplied peanut recipes for older children. The participants in LEAP consumed a median peanut protein intake of 7.5 g/week (goal dose was 6 g/week, approximately 6 teaspoons) beginning between 4 and 10 months of age and continuing until 60 months old.⁷ In addition, early introduction in this form or amount did not affect growth, nutrition, or breastfeeding duration.³⁶ To prevent choking in infants thinning of peanut butter with water, milk, or pureed fruit has been recommended. This dilution may be necessary until children are able to safely eat foods with the consistency of peanut butter spread thin that can be after 12 months of age or based on individual developmental abilities.³⁷

The EAT trial attempted the introduction of multiple foods in the early complementary feeding period including boiled egg, peanut butter, sesame paste, cow's milk yogurt, white fish, and wheat-based cereal.⁸ EAT aimed to introduce at least 2 g of protein from multiple foods, eaten twice per week. Together, the LEAP and EAT studies provide information on effective dosing of peanut for allergy prevention. Infant-safe forms of peanut, in the amount of 2 teaspoons, 3 times per week (6 g of peanut protein), are the dose recommended by the NIAID based on the LEAP protocol. A smaller weekly dose is likely effective (4 g of peanut protein per week was used in the EAT trial). Some guidelines simply recommend regular intake.³⁸

TABLE I. Including potential allergens for allergy prevention and/or healthy infant feeding during the first year of life

| Food | Choose healthy infant foods* | How much/how often As part of the infant's complementary diet |
|---|--|---|
| BENEFICIAL for prevention | | |
| When developmentally ready† around 6 mo of age or between 4 and 6 mo of age if advised by your doctor due to high risk of allergy (severe eczema or egg allergy)‡ | | |
| Peanut§ | Choose peanut flour or thinned peanut butter that has no added ingredients (salt, sugar, oils) for healthier options Peanut butter should be thinned with breast milk, water, or formula or mixed into a pureed food, eg, 2 teaspoons of peanut butter mixed with 2-3 teaspoons of liquid | Approximately 1-2 teaspoons of peanut butter/powder per serving, served 2-3 times per week as tolerated |
| BENEFICIAL for prevention but effective dose requires further research | | |
| When developmentally ready after 4-6 mo of age† | | |
| Egg | Serve <i>well-cooked</i> egg mashed with pureed foods or chopped and served as finger food | Approximately 1/3 of a well-cooked egg, 2-3 times per week |
| HAVE NOT BEEN STUDIED SUFFICIENTLY to know if early introduction decreases the risk of allergy; therefore, doses are based on healthy feeding | | |
| There is currently no evidence of benefit to delay the introduction of highly allergenic foods after 4-6 mo of age and developmentally ready† | | |
| Wheat | Infant wheat cereals (iron-fortified for the breastfed infant); whole-wheat toast, pasta, or crackers for older infants | 1/2 to 1 ounce total grains per day. 1/2 ounce wheat serving includes 1/4 cup fortified infant wheat cereal, 1/4 cup pasta, 1/2 slice bread |
| Milk | Plain, full-fat yogurt can be mixed into pureed fruit or vegetable; cow's milk should not substitute for breast milk or infant formula | 2-4 fluid ounces per day |
| Sesame§ | Tahini is sesame paste typically served as an ingredient in hummus or as tahini dipping sauce for finger foods like vegetables (blended with water, lemon juice, olive oil, and herbs for flavoring) | ≥1/2 ounce seeds/any nuts per week (or 3 teaspoons) |
| Seafood | Low mercury finfish https://www.fda.gov/media/102331/download | 1 ounce per serving, 3 times per week (see FDA link for frequency and type of fish) |
| HAVE NOT BEEN STUDIED to know if early introduction decreases allergy risk; therefore, doses are based on healthy feeding | | |
| There is currently no evidence of benefit to delay the introduction of highly allergenic foods after 4-6 mo of age and developmentally ready† | | |

| | | |
|------------|---|--|
| Tree nuts§ | Smooth, thinned nut butters, eg, almond, cashew, hazelnut, pistachio, walnut, and pecan | ≥1/2 ounce seeds/any nut per week (or 3 teaspoons) |
| Soy | Soft tofu | 2 tablespoons per serving |

FDA, Food and Drug Administration.

Goal doses of food protein per week from the Enquiring About Tolerance study: 2 g of each allergenic food protein twice each week (4 g of allergen protein per food per week). The full weekly amount for the allergenic foods consisted of 2 small 40 to 60 g portions of cow's milk yogurt, 3 rounded teaspoons of peanut butter, 1 small hard-boiled egg (<53 g), 3 rounded teaspoons of sesame paste, 25 g of whitefish, and 2 wheat-based cereal biscuits (eg, Weetabix).⁸

*When beginning complementary feeding, offer single ingredient foods one at a time initially to determine tolerance. There is no prescribed number of days or feedings required to determine tolerance, but we recommend only 1 new food per meal.

†How do I know if my infant is developmentally ready? Here are some signs:

- Holds head upright.
- Closes mouth around a spoon can open mouth and lean forward to accept a spoon.
- Can sit with some assistance. Offer your baby 1 to 2 foods before offering potentially allergenic foods to ensure that they are developmentally ready to eat complementary foods.

‡For most infants with severe eczema and/or egg allergy who are already eating solid foods, introducing foods containing ground peanuts between 4 and 10 months of age and continuing consumption may reduce the risk of developing peanut allergy by 5 years of age. The FDA has determined, however, that the evidence supporting this claim is limited to 1 study. If your infant has severe eczema and/or egg allergy, check with your infant's health care provider before feeding foods containing ground peanuts.³¹

§Peanut and tree nuts and sesame

- Peanut, tree nuts, and sesame are protein foods with higher fat and calorie content; therefore, a smaller serving size is more appropriate.
- Balance these higher fat/protein foods with lower fat foods such as fish, soy, and other proteins not considered highly allergenic such as lean meats, poultry, and legumes.
- Doses for tree nut prevention are not known.
- It may not fit within healthy infant feeding regimens to aim for 1 to 2 teaspoons of each tree nut per week.
- See mixed nut butter recipe in Table E2 in this article's Online Repository at www.jaci-inpractice.org.

||Infant feeding

- Protein foods, modified for texture, such as peanut, tree nuts, egg, sesame, fish, and soy, can be fed as healthy additions in the infant diet within this recommended framework.
- We recommend introducing potential allergenic foods early and feeding them regularly rather than a prescribed amount as long, as it is within the context of healthy infant feeding.
- See Table E1 in this article's Online Repository at www.jaci-inpractice.org for further infant feeding guidance.

TABLE II. Early allergen introduction: commercial products

| Product | Recommended weekly dose (maintenance) | Allergens: type and protein dose | Form | Ingredients | Instructions | Cost per 4 weeks (USD) | Nutrition/serving peanut products |
|----------------|--|---|----------------------|---|---|--|--|
| Hello, Peanut! | Up to 3 g of peanut protein | Peanut: <i>Introduction</i> packets: gradually increasing dose <i>Maintenance</i> packets: 1 g/ packet | Powder | Organic blend of peanut and sprouted oat flakes | <i>Day 1-7</i> Introduction: mix 1 packet into baby food daily <i>Days 8+</i> Maintenance: mix 1 packet into baby food up to 3 times per week | Introduction kit: \$25 Maintenance kit: \$20 28 d cost 3 times/ wk = \$30 Combination kit: \$40 | 10 calories 1 g of protein 2 g of carbohydrate 0 g of fat 0 mg of sodium 0 g of added sugar |
| Lil Mixins | 4-6 g of egg white protein (2 g of egg white protein, 2-3 times) 6 g of peanut protein (2 g of peanut protein, 3 times) 6 g of tree nut protein, mixed (2 g of mixed tree nut powder, 3 times) | Egg white: 2 g in 2 scoops (5 g) Peanut: 2 g in 2 scoops (5 g) Tree nut: (almond, pistachio, hazelnut, walnut): 2 g of mixed tree nut protein in 2 scoops (5 g) | Powder | Egg: baked egg whites and tapioca starch Peanut: organic ground peanuts Tree nut: almonds, walnuts, hazelnuts, and pistachios | Add 2 scoops (5 g) of peanut powder and mix into any baby food. Mix well to blend into food | Egg: single serve 1 mo = \$16.66 240 g jar 1 mo = \$8.74 Peanut: single serve 1 m = \$16.66 240 g jar 1 mo = \$8.74 Tree nut: single serve 1 mo = \$16.66 240 g jar 1 mo = \$8.74 | Egg: 20 calories 2 g of protein Fat content not available 30 mg of sodium 0 g of added sugar Peanut: 20 kcal 2 g of protein 0.5 g of fat Sodium content not available 2 g of carbohydrate 0 g of added sugar Tree nuts: 20 calories 2 g of protein Fat content not available 30 mg of sodium 3 g of carbohydrate 0 g of added sugar |
| MightyMe | 6 g of peanut protein (1 full pouch) | Peanut: 1 g per serving | Puff: meltable solid | Organic rice flour, organic ground peanuts, organic peanut oil, sea salt, and calcium carbonate | 1 pouch per week | \$17.60 per month | 30 calories 1 g of protein 1.5 g of fat 20 mg of sodium 3 g of carbohydrate 0 g of added sugar |

| | | | | | | | |
|-------------------|---|--|--|---|---|---|---|
| Ready, Set, Food! | 3 g of milk protein 0.88 g of egg protein 3 g of peanut protein | Milk: 0.43 g per maintenance packet Egg white: 0.125 g per maintenance packet Peanut: 0.43 g per maintenance packet | Powder | Organic cow's milk, organic peanut, and organic cooked egg white | Add a daily packet to the child's breast milk, formula, or food. Start with stage 1 packets (days 1-11), and then offer daily stage 2 (maintenance) packets | Individual intro box from Amazon: \$18 1 mo supply: \$49/ mo 3 mo supply: \$39/ mo 6 mo supply: \$29/ mo | 10 calories 1 g of protein Fat content not available 10 mg of sodium 1 g of carbohydrate 0 g of added sugar |
| SpoonfulOne | 210 mg of each allergen protein | 30 mg per day of each of the following: milk, egg, wheat, soy, sesame, peanut, tree nuts (almond, cashew, pistachio, hazelnut, walnut, and pecan), fish (salmon and cod), and shellfish (shrimp) | Mix-in powder Puffs Oat crackers | All products contain a blend of the following ingredients: peanuts, milk, shellfish (shrimp), tree nuts (almond, cashew, hazelnut, pecan, pistachio, and walnut), pasteurized egg white, fish (cod and salmon), grains (wheat and oat), soy, and sesame Mix-Ins: rosemary extract, salt, organic cane sugar, natural flavors Puffs: organic white rice flour, salt, rosemary extract, organic invert sugar syrup, organic strawberry powder (organic strawberry, organic maltodextrin, organic corn starch), natural flavors, calcium carbonate, and mixed tocopherols Oat crackers: organic whole oat flour, organic sugar, organic palm oil, salt, rosemary extract, organic invert sugar syrup, organic vanilla extract, natural flavors, organic dried blueberries, baking soda, organic sunflower lecithin, salt, cinnamon, and mixed tocopherols | Mix 1 packet into your baby's food daily | 1 time purchase: 7 pack: \$19.00 14 pack: \$34.95 28 pack = \$67.95 Subscription: 14 pack: \$33.20 28 pack: \$59.50/ mo | Mix-Ins 10 calories <1 g of protein 0 g of fat 0 mg of sodium 1 g of carbohydrate <1 g of sugar Puffs: 30 calories 1 g of protein 0 g of fat 0 mg of sodium 6 g of carbohydrate 1 g of sugar Oat crackers: 50 calories 1 g of protein 1.5 g of fat 35 mg of sodium 7 g of carbohydrate 2 g of sugar |

(continued)

TABLE II. (Continued)

| Product | Recommended weekly dose (maintenance) | Allergens: type and protein dose | Form | Ingredients | Instructions | Cost per 4 weeks (USD) | Nutrition/serving peanut products |
|----------------------------------|--|---|---------------------------------------|--|--|---|---|
| Gerber Organic BabyPops Peanut | No dose recommended | Peanut protein content unknown. 1 g of total protein per serving (18 pieces or 1/3 cup) Also available in tomato flavor and banana flavor with 0 g of protein per serving (peanut listed as last ingredient) | Puffs | Organic corn flour, organic de-fatted peanut flour, organic whole grain oat flour (contains wheat), organic high oleic sunflower oil, calcium carbonate, mixed tocopherols (to maintain freshness), vitamin B1 (thiamin mononitrate) | No instruction on how much or frequency to feed for allergy prevention | \$2.29/5 servings Cost per month for 3 servings per week: \$5.50 | 30 calories 1 g of protein 1 g of fat 5 mg of sodium 5 g of carbohydrate 0 g of added sugar |
| Happy Baby Organics Nutty Blends | 3 g of walnut protein 3 g of peanut protein 3 g of cashew protein 3 g of almond protein | Apple-walnut with 1 teaspoon of walnut butter = 1 g of walnut protein Banana-peanut with 1/2 teaspoon of peanut butter = 1 g of peanut protein Pear-cashew with 1 teaspoon of cashew butter = 1 g of cashew protein Banana-almond with 1/2 teaspoon of almond butter = 1 g of almond protein | Fruit pouches (each 3 ounces or 85 g) | Apple-walnut: organic apple puree, organic walnuts, organic lemon juice concentrate, mixed tocopherols (vitamin E), and ascorbic acid (vitamin C) to preserve freshness Banana-almond: organic banana puree, organic almonds, organic lemon juice concentrate, mixed tocopherols (vitamin E), and ascorbic acid (vitamin C) to preserve freshness Banana-peanut: organic banana puree, organic peanuts, organic lemon juice concentrate, mixed tocopherols (vitamin E), and ascorbic acid (vitamin C) to preserve freshness Pear-cashew: organic pear puree, organic cashews, organic lemon juice concentrate, mixed tocopherols (vitamin E), and ascorbic acid (vitamin C) to preserve freshness | Feed "several times per week" for allergy prevention | \$1.99 per pouch 23.88/mo per allergen | Apple-walnut: 100 calories 1 g of protein 4.5 g of fat 0 mg of sodium 13 g of carbohydrate 0 g of added sugar Banana-almond: 100 calories 2 g of protein 3 g of fat 0 mg of sodium 19 g of carbohydrate 0 g of added sugar Banana-peanut: 90 calories 2 g of protein 1 g of fat 0 mg of sodium 19 g of carbohydrate 0 g of added sugar Pear-cashew: 80 calories 1 g of protein 2.5 g of fat 0 mg of sodium 13 g of carbohydrate 0 g of added sugar |

TABLE III. Early allergen introduction foods

| Food | Serving | Calories | Protein (g) | Fat (g) | Added sugar (g) | Sodium (mg) | Cost per 4 weeks (USD) |
|---|--------------------------------------|----------|-------------|---------|-----------------|-------------|--|
| Egg—hard-boiled, well-cooked scrambled | 1/3 egg | 24.8 | 2.08 | 1.67 | 0 | 21.6 | Large organic eggs: \$3.49 Conventional eggs: \$1.18 Based on using portions of 3 eggs/wk/4 wk |
| Peanut butter national brand | 1 teaspoon | 32 | 1.17 | 2.67 | 0.5 | 23 | \$0.44 Based on 3 teaspoons/wk/4 wk |
| Peanut butter “healthy” brand (just ground peanuts) | 1 teaspoon | 33 | 1.33 | 2.67 | 0 | 15 | \$0.52 Based on 3 teaspoons/wk/4 wk |
| Powdered peanut butters (eg, PB2) | 1 teaspoon | 10 | 1.0 | <0.5 | <0.5 | 15 | \$0.86 Based on 3 teaspoons/wk/4 wk |
| Bamba | 0.35 ounce (approximately 10 sticks) | 55 | 1.0 | 3.5 | 0.5 | 40 | \$5.25 Based on 3 servings/wk/4 wk |

Based on: Organic eggs dozen: \$3.49; conventional eggs dozen: \$1.18; peanut butter, 16 ounces: \$3.49; peanut butter “healthy,” 16 ounces: \$4.19; PB2, 6.5 ounces: \$5.99; Bamba 8 packs of 0.7 ounce: \$6.99.

TABLE IV. Commercial products for early introduction of food allergens compared with conventional foods*

| Features | Commercial | Conventional |
|-------------------------|--|---|
| Cost | More expensive | Less expensive |
| Convenience | More convenient for families spending little time preparing foods | Can be convenient to families, cooking and preparing most of their meals |
| Additional ingredients | These foods can act as food allergens too | Ability to use a pure source of the food allergen only |
| Nutritional composition | Generally low in calories and lacking a wider nutritional profile | Rich sources of other nutrients: see Table E1 in this article’s Online Repository at www.jaci-inpractice.org |
| Dose of food allergen | Some products contain far less food allergen compared with doses used in research and those recommended by international guidelines | A desired dose can be chosen from allergen-containing foods |
| Degree of heating | Degree of heating/cooking of the allergen may be not similar to those used in research and those recommended by international guidelines | A desired degree of cooking/heating can be chosen from allergen-containing foods |

*There are a range of commercial products currently available for early food allergen introduction. These products differ by the allergen they contain, the dose of the allergen, and the degree of heating of the product. The cost of commercial products is significantly higher than that of conventional foods, and the nutrient content of the products differs among each other and also when compared with conventional foods. It is a complex decision to make about whether to use the commercial products versus conventional foods. As always, the families’ needs and preferences need to be a part of the decision-making process. However, to collaborate with families in decision-making, we suggest that the allergist/dietitian take the features listed in the table into account.

Many forms of egg have been studied for early introduction. EAT is the only trial that used regular unprocessed boiled egg at a dose of 1 small (<53 g) egg per week. All other early egg introduction trials used various forms of egg such as egg white versus whole egg and boiled versus pasteurized raw.^{3,4,39} These trials used a wide range of doses per serving and frequencies of ingestion. The Prevention of Egg Allergy with Tiny Amount Intake Trial study evaluated a dual intervention of aggressive management of eczema and introduction of tiny doses of egg.⁴ The highest daily dose was 0.075 g of egg white protein powder, equivalent to 2% of a 50 g egg and reported the greatest reduction of egg allergy in their ITT analysis (9% early egg-group versus 38% placebo-group) (risk ratio, 0.22; 95% CI, 0.081-0.61; $P = .0012$) at 12 months.⁴ It is possible that both interventions contributed to the prevention of egg allergy. In contrast, the Hen’s Egg Allergy Prevention trial, which used 2.5

g of powdered pasteurized raw egg white protein (approximately 2/3 of a large egg white) eaten 3 times per week, did not show evidence of allergy prevention and found high rates of reactions on first exposure to the pasteurized raw egg.³ The EAT study found that 2 g of whole egg protein (1.2 g of egg white protein) eaten once per week had a protective effect in the group that followed the early introduction advice (standard 5.5%, early 1.4%, $P = .009$).⁸ Using predictive probability plots in this study, it was estimated that 4 g of well-cooked egg protein (equivalent to 2 g of egg white protein) was associated with the prevention of egg allergy. These trials also found that pasteurized raw whole egg appears to be less well tolerated with more allergic reactions.³⁹ The exact dose and type of egg to prevent egg allergy requires more research. It is clear that raw egg and large doses of egg inconsistent with infant nutrition needs are not required.

The early introduction of other foods in the EAT trial included a 40 to 60 g dose of CM yogurt, 3 teaspoons of sesame paste (1 tablespoon), 25 g of white fish, and 2 wheat-based cereal biscuits eaten once per week, all equivalent to approximately 2 g of protein to be eaten twice per week.⁸

The SPADE study used ≥ 10 mL of CM formula daily for 2 months starting at 1 month old and found decreased rates of CMA at 6 months.⁹

It is not possible to say if the early introduction of fish, sesame, or wheat prevents the development of allergy to these foods although in most instances it does not appear to increase the risk.

COMPLEMENTARY FEEDING—POTENTIAL ALLERGENS FIT!

During the initial complementary feeding period, serving single ingredient foods, one at a time, is recommended to observe for symptoms of allergy. Once foods are tolerated, they can be combined. There is no evidence guiding how long a food must be fed before moving on to the next “new” food; however, 1 new food per day is likely reasonable, especially in terms of the food allergens.⁴⁰ Prolonging time between new foods may negatively affect diet diversity, which has been shown to affect food allergy outcomes.^{41,42} Roduit et al⁴¹ indicated that children with a more diverse early diet had a lower prevalence of food allergy. This finding was supported by Venter et al,⁴² who demonstrated that increased diversity of both food and food allergen intake in the first year of life was associated with a lower prevalence of food allergy up to 10 years of age. For each additional food given by 6 months, the odds of food allergy over 10 years was reduced by 11%. For each additional allergen consumed by 12 months, the odds of food allergy over 10 years was reduced by 33%.

From 6 months of age, it is difficult for infants to meet nutritional needs from breast milk alone, and breastfeeding should continue alongside the introduction of nutrient-dense CF. Based on the 2020 Dietary Guidelines Advisory Committee (DGAC) report, fortified infant cereal is an important contribution to meet iron and zinc needs, and 0.5 ounces (15 g) should be included in the breastfed infant diet.⁴³ The DGAC recommends caloric intake ranges from CF based on a percentage of total energy intake. Consumption from CF at 6 to 9 months of age is 120–280 kcal/day (20%–35% of total energy intake), 56 kcal of which comes from a fortified grain for breastfed infants; the remaining CF “budget” is 64–224 calories/day. Therefore, after the introduction of infant grain, other CF in this age group should come from a variety of nutrient-rich foods to help meet the nutritional needs for iron, zinc, potassium, and choline, all of which are nutrients with gaps in the breastfed infant diet. Formula-fed infants taking sufficient formula do not benefit from fortified infant cereal to meet iron and zinc requirements, and a whole grain is recommended instead to avoid excess dietary iron and zinc intake.⁴⁴

Food group patterns have not been established in the 6- to 12-month age group; however, recommended infant serving sizes of food groups to meet nutritional goals are listed in Table E1 in this article’s Online Repository at www.jaci-inpractice.org.⁴³ Likewise, there are no recommended food group patterns for 4- to 6-month infant feeding, but foods in the amounts found to prevent food allergy (particularly in a high-risk population) are listed in Table I. The DGAC did not calculate energy levels from

CF for 4 to 6 months because it targeted 6 months as the starting age for CF. Total energy requirements are lower at 4 to 6 months than at 6 to 9 months. If one assumes an average energy need for infants of approximately 600 kcal at 4 to 6 months, then up to 100 kcal (<20%) from CF is reasonable leaving ample opportunity for early introductions of allergenic foods, for example, 60 kcal from peanut butter or alternatively 20 kcal from peanut flour or powder (2 g of protein/2 teaspoons), 26 kcal egg (2 g of egg protein/1/3 egg), 2 to 3 times per week. There is no specific need to add a fortified grain to the diet before 6 months of age.⁴³

The goals of early infant feeding are to introduce foods of varying flavors and textures to encourage future food preference,⁴⁵ and to provide nutrition in a balanced and proportional manner for growth and development (Table E1, available in this article’s Online Repository at www.jaci-inpractice.org). The goal and challenge of early complementary feeding of foods thought to be allergenic is to offer these foods without exceeding the needs for calories in the CF period and without displacing other nutrient-dense foods such as fruits, vegetables, meats, and whole grain-based foods.

There are a range of commercial products currently available for early allergen introduction (Table II). These products differ by the allergen they contain, the dose of the allergen, and the degree of heating of the product. A blinded RCT suggested the tolerability and acceptability of a commercial product containing 13 allergens, although efficacy was not evaluated.⁴⁶ Furthermore, the product protein levels were significantly smaller than doses currently recommended (<1 g of total protein), and patients were excluded if they had parent-reported severe eczema or pre-existing food allergy. The nutrient content of the products differs among each other and when compared with conventional foods (Table II). Conventional foods (peanut butter, eggs, and yogurt) can be purchased at lower cost in the local market and prepared for infant-safe feeding (Tables III and IV). A homemade recipe for mixed tree nut butter is available in Table E2 in this article’s Online Repository at www.jaci-inpractice.org.

Timing of early introduction plays a role in the choice between conventional and commercially available early introduction products. The average age of peanut introduction in LEAP was 6 months, and most children above 6 months old are developmentally ready to introduce various conventionally available forms of peanut, egg, and other potentially allergenic foods.⁷ Therefore after 6 months, there may be limited benefit for most commercially available early introduction products.

Once early introduction has been initiated, it then requires maintenance. Most studies of early introduction employed intensive monitoring and encouragement. For example, parents (mostly mothers) were contacted over 100 times over the 5 years of early peanut introduction.⁷ Continuation rates and frequency of ingestion of these foods in the real world are unknown and likely require more support from clinicians than is typically offered or is even available. Specialized dietitians were heavily used during food-prevention studies and may complement efforts supporting early introduction.

As cited, risk factors for lower adherence to early introduction protocols from the EAT or LEAP studies include non-white ethnicity, older maternal age, and lower maternal quality of life.^{34,35} Food allergy rates are significantly higher in non-white infants making the challenges of early introduction even more relevant in this population.⁴⁷ Patients with these risk factors

should be identified and offered support for initiation and continuation of early food introduction. This can involve more frequent monitoring and advice from their primary care specialists and/or dietitians. It also requires identifying affordable sources of potential allergens. Egg and peanut will generally be cheaper than sesame, fish, and tree nuts. This also makes the cost of commercially available products an important factor when implementing early introduction of food.

The decision to introduce allergenic foods is complex, and families must consider the pros and cons of commercial products versus conventional food. As always, the family's needs and preferences need to be a part of the decision-making process. There are a range of commercial products currently available for early food allergen introduction. To collaborate with families in SDM, we suggest that the allergist/dietitian take the following features into account: cost, convenience, additional ingredients, nutritional composition, dose of allergen, and degree of heating (Table IV). Clinicians should be comfortable guiding the patient through this decision-making process.

SHARED DECISION-MAKING

SDM involves a collaborative dialogue between clinicians and patients to reach decisions based on evidence and personal values. Optimization of early food introduction can only be possible if and when a family is willing and able to introduce these foods. As part of the therapeutic relationship with patients and parents, clinicians must ensure that the values and the preferences of patients are incorporated with current scientific understanding to guide the medical decision-making process.⁴⁸ This alignment is especially important when clinical guidelines change or differ substantially between countries; when there may be significant anxiety surrounding the available approaches; when there is some degree of uncertainty or disagreement regarding the best approach; or when there is a lack of practical guidance. Early introduction of foods encompasses all these barriers. Decision aids have been used to help guide decisions about therapies when there is no easy answer. A decision aid for early introduction could be a useful tool; however, there are currently none available. Therefore, an allied approach using SDM yields the optimal outcome by ensuring that the needs of the patient remain a priority and that therapeutic decisions incorporate both medical understanding and patient expectations.⁴⁹

Understanding that many food-introduction guideline recommendations have drastically changed from full avoidance to early introduction and that guidelines will continue to adapt allows clinicians to empathize with patients who distrust new recommendations. Normalizing the initial reluctance of clinicians and patients to incorporate new changes can start an effective conversation about options. Discussion may include addressing mixed messages received from primary care clinicians (or other sources), which may differ from specialist suggestions.⁵⁰ The ability to have an open and honest dialogue about this variability in guidance and lack of certainty is crucial in the SDM model.

The early introduction of foods is further complicated when a patient has already developed a food allergy. Although the probability of coexistence of other food allergies may be low at a young age, the question of how best to support families with the introduction of similar allergens has not yet been formally addressed.⁵¹ As a result, families are left with few evidence-based choices: avoid other allergenic foods; introduce at home without

testing; test and then introduce or avoid; or introduce in office with medical supervision. If families elect to test before introduction, the potential for false-positive (and false-negative) testing must be carefully discussed. In addition, planning how to introduce foods based on testing results should be reviewed before any diagnostic evaluation.

Because the efficacy of early food introduction is time sensitive, these challenging conversations may be most effective before CF is introduced. The dialogue involved in SDM can take significant time to understand families' perspectives, to discuss limitations of available diagnostic testing and the potential need for oral challenges.⁵¹⁻⁵³ A significant and practical barrier to early food introduction is the lack of timely access to clinicians who are knowledgeable and capable of having these detailed conversations, and there is limited access to clinicians who are willing and able to perform food challenges when needed.⁵² Unfortunately, a recent Canadian survey suggested significant inconsistency in advice regarding the introduction of allergenic foods among allergists, pediatricians, and family practitioners.⁵⁰ Ensuring that primary care clinicians are suitably trained and able to have these evidence-based SDM discussions remains the responsibility of allergists and policymakers through education and practical, user-friendly guidelines. The allocation of clinician and allied health experts such as allergy trained dietitians, and the establishment of a triage priority for patients who may benefit from early introduction may help to direct resources more efficiently.

As clinicians, we should encourage at-risk infants to be exposed to potentially allergenic foods in a safe manner. To prevent various food allergies in as many patients as possible, clinicians should use an SDM approach to incorporate patient desires when creating specific early introduction approaches with families.

CONCLUSION

As guidelines continue to adapt to developing literature, it is prudent for clinicians to understand that eating certain potential food allergens should be a part of early complementary feeding, and other potential food allergens can be part of complementary feeding. Neglecting to engage in discussions around feeding potentially allergenic foods may risk missing the window of opportunity of early introduction. As we venture into a new era of "let the babies eat," clinicians should be able to discuss available options for introducing homemade or commercially available products containing potential allergens and how these foods might fit in the infant diet. Educational materials will aid clinicians in SDM and provide families with written guidance as they navigate complementary feeding. A thorough understanding of the early introduction literature, current prevention guidelines, and complementary infant nutrition will empower physicians to address patient needs and concerns both when advice is established as effective and where uncertainty remains.

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ONLINE REPOSITORY

TABLE E1. Recommended daily infant portions, 6 to 12 months⁴³

| | Smaller portions for younger infants | Sample infant-safe forms |
|--|--|--|
| Fruits | 2-8 tablespoons | Smooth puree or soft cooked and chopped |
| Vegetables: include red, orange, and dark green vegetables | 2-8 tablespoons | Smooth puree or soft cooked and chopped |
| Grains:* choose a variety of whole grains including wheat grains | 1/2 to 1 ounce (this includes 1/2 ounce per day or fortified grains for the breast-fed infant) | Whole wheat or fortified infant cereal (or farina or cream of wheat), whole grain pasta or pastina, toast, or crackers |
| Protein foods:† meat, fish, poultry, eggs, nuts, and seeds | 3/4 to 3 ounces | Smooth diluted peanut or tree nut butters or powders or butters/powders mixed into pureed foods Hard-boiled, well-scrambled eggs blended into pureed foods or chopped for finger foods Tahini (sesame) |
| Dairy | 1/4 to 1/2 cup | Yogurt and cheese |
| Breast milk or formula | 3-5 feedings 24-32 ounces/d (and as low as 16-20 ounces as infant approaches 12 mo of age) | |

*One ounce protein foods = 50 g egg; 28.35 g lean meat or seafood; 1/4 cup tofu; 1 tablespoon of peanut butter, tree nut butter, or seed butter (diluted for infant-safe feeding); for vegetarian diets, the recommendation for protein foods increases to 4 ounces per day of nuts, seeds, and legumes.

†One ounce grain = 1/2 cup pasta, 1 slice bread, or 4 tablespoons for infant cereal.

TABLE E2. Mixed nut butter recipe*

| Nut (total g wt per nut) | Gram of protein per nut | 2 g of protein per serving |
|--------------------------------|-------------------------|--------------------------------|
| Almond (1.2 g) | 0.254 | 8 nuts (2.032 g) |
| Peanut (0.9 g) | 0.219 | 9 kernels (1.917 g) |
| Cashew (approximately 1.5 g) | 0.273 | 8 (whole nuts 2.1 g) |
| Pistachio (0.7 g) | 0.141 | 14 nuts (1.974 g) |
| Macadamia (2.6 g) | 0.202 | 10 nuts (2.02 g) |
| Brazil (5 g) | 0.716 | 3 nuts (2.139 g) |
| Walnut (4 g whole = 2 halves) | 0.609 | 3.5 whole or 7 halves (2.13 g) |
| Pecan (4 g whole = 2 halves) | 0.348 | 6 whole or 7 halves (2.088 g) |
| Hazelnut (approximately 1.4 g) | 0.234 | 9 nuts (2.11 g) |

<https://fdc.nal.usda.gov>.

Four types of nuts (approximately 1/3 cup) plus 2 tablespoons of oil—grind and mix with a blender.

Nine types of nuts (almost 1 cup) plus 4 tablespoons of oil—grind and mix with a blender.

Keep in the fridge and eat as is or mix with any preferred food such as apple sauce or yogurt.

Oil will separate from nut butter during storage. Mix well before using.

*Mixed nut butter recipe: place all ingredients in a food processor and process until completely smooth (including any added nuts). Serve spread on whole-wheat toast or as a dip for soft cooked.