



An update on international practice variation in peanut introduction: conundrums, controversies, and a new direction

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Purpose of review

Introduction of peanut during the first year of life is associated with an 81% relative risk reduction of developing peanut allergy in infants with severe eczema, egg allergy, or both. However, significant international variation exists in risk stratification prior to peanut introduction.

Recent findings

A policy-level screening approach, such as the one in the United States, is not practical and is associated with higher costs and more cases of peanut allergy over time, in contrast to international models that recommend universal early introduction without prescreening. In Australia, population-level efforts to introduce peanut early without screening have demonstrated high rates of peanut introduction before 12 months of age and low rates of severe allergic reactions. In contrast, screening prior to peanut introduction in the United States is associated with 'screening creep' – the tendency of clinicians to test populations where screening is not recommended.

Summary

Early peanut introduction can reduce the risk of developing food allergy and is more effective without a risk-based screening approach. In some circumstances, shared clinical decision-making can facilitate food allergy prevention in a manner consistent with family values and preferences.

Keywords

cost-effectiveness, early introduction of peanuts, guidelines, peanut allergy, practice variation, screening, shared decision-making

INTRODUCTION

Peanut allergy is a common childhood allergy that has been steadily increasing in prevalence over the past 20 years [1,2[•]]. It affects between 1 and 4.5% of children in the United States [1,2[•]] and has significant health and economic impact on children, families and societies [2[•],3^{••},4]. Peanut allergy is lifelong in 65–80% of those diagnosed, in contrast with milk and egg allergies, which are more commonly outgrown by mid-childhood [5–7,8[•]]. Fatal food anaphylaxis is rare (on the order of 1 fatality per million person-years in those diagnosed, and 1 fatality per 10 million person-years in the general population) and the risk is lower than that of accidental death in the general population [9,10,11^{••},12^{••}]. However, the concomitant anxiety regarding this risk and efforts made to avoid peanuts contribute to poor quality of life and significant psychosocial burdens of illness [2[•],13–17,18[•]].

Prior guidelines recommended delaying introduction of allergenic foods in children at high risk

for developing food allergy [19–21]. In 2000, the American Academy of Pediatrics (AAP) suggested delaying cow milk protein to 1 year of age, egg until 2 years of age, and peanut and seafood until 3 years of age [20]. However, it was subsequently noted that delayed food introduction was paradoxically

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KEY POINTS

- The 2017 NIAID guidelines, which recommend screening infants with severe eczema and/or egg allergy prior to introducing peanuts, risk inadvertently over-diagnosing peanut allergy, with excessive costs and poor adherence at a population level.
- Multiple international guidelines recommend early introduction of peanuts without screening as a well tolerated and effective practice.
- In select cases, shared clinical decision-making may be an effective tool to facilitate early introduction of peanuts to all children in their first year of life.

associated with an increasing prevalence of food allergies [22–24]. The perception on how to best prevent food allergy changed with an observational study comparing peanut allergy prevalence in Jewish children living in Israel versus those living in the United Kingdom (UK). This study documented significantly decreased peanut allergy in Israel compared with the United Kingdom (0.17% versus 1.85%). Notably, in Israel, peanuts are routinely eaten in the first year of life, unlike in the UK, where peanuts were avoided until after age 3 years of age [22]. After controlling for other factors, the timing of introduction was found to be significant, and this study directly influenced the Learning Early About Peanut (LEAP study) [23].

EARLY INTRODUCTION PREVENTS PEANUT ALLERGY

The 2015 LEAP study evaluated infants at high-risk for peanut allergy, defined by severe eczema, egg allergy, or both. The findings of the LEAP study revolutionized the world of food allergy prevention. This landmark trial demonstrated that the early peanut introduction to high-risk children (compared with delayed introduction) reduced the relative risk of developing peanut allergy at 5 years of age by 81% [23,25]. The study included infants with and without low-positive skin prick test (SPT) responses to peanut. Although a higher overall percentage of infants with a positive SPT developed peanut allergy [26], the absolute risk reduction of early versus delayed introduction was significantly greater in the infants with positive SPT. Notably, eating peanut products within the first year of life was associated with a decreased risk of peanut allergy across the board [27,28]. Of note, the high-risk criteria used in the LEAP study focused exclusively on egg allergy and/or severe eczema, and did not take into account other high-risk factors

previously considered in studies, such as parental atopic history or other food allergy [19,20].

Shortly after LEAP was published, clinical practice guidelines quickly evolved to implement the study findings, though distinct approaches to balance risk of early infant peanut introduction with benefit of peanut allergy prevention were taken across multiple countries [29,30]. In formulating a United States approach concerns that many high-risk infants would already be peanut-allergic, and that home introduction might result in a severe reaction, contributed to the sentiment that some level of screening was necessary to protect against this risk [30,31]. The LEAP study, wary of similar concerns, had used peanut skin testing in the trial subjects prior to peanut introduction to minimize such risk; all patients underwent skin testing, and those with ‘large’ skin tests were excluded from randomization as they were considered likely to be already allergic. However, the threshold for what was considered a ‘large enough’ test was low. The theory, which was not entirely proven, was that preexisting ‘large’ skin tests in persons who have never previously eaten the food were true indicators of food allergy. However, the LEAP team did not randomize the use of skin testing to assess if this was truly necessary or predictive of outcomes. Subsequently, the 2017 National Institute of Allergy and Infectious Diseases (NIAID) approach broadened (from 4 to 8 mm) the size of the peanut skin test used in screening that would indicate a high likelihood of preexisting allergy. Although this approach was different from what was used in the LEAP study, screening tests for infants with severe eczema, egg allergy, or both were still strongly recommended.

PROBLEM: CONUNDRUMS AND CONTROVERSIES REGARDING UNITED STATES GUIDELINES TO SCREEN

Currently, there is widespread acceptance that eating peanuts early in life prevents peanut allergy [30,32,33,34,35] and early peanut introduction is strongly supported by evidence of efficacy from an extensive 2016 meta-analysis [36]. The issue with this widespread belief was less that early introduction actually worked, but more how best to implement it. Addendum 1 of the 2017 NIAID guidelines recommends screening high-risk infants (i.e. those with severe eczema and/or egg allergy) between 4 and 6 months of age using peanut SPT. For infants who may not have been initially seen by an allergy specialist, a peanut serum-specific immunoglobulin E (sIgE) test could be measured instead. A child screened by a peanut sIgE test should then be

referred to an allergy specialist for any result elevated above 0.35 kUa/l, the threshold of reporting a 'positive' test, in order to be skin tested. If the SPT is positive but below a predetermined cut-off value of 8 mm, a level that was 95% predictive for peanut allergy in a 2010 Australian population study of children 12–18 months, then it is strongly recommended to introduce peanuts as a food challenge in the specialist's office [37,38]. If the level is greater than or equal to 8 mm, the guidelines state the child is 'probably allergic to peanut', which effectively means peanuts will not be introduced. No screening or in-office introduction is recommended for the remainder of children not considered high-risk – those with less severe or no eczema and without egg allergy (regardless of family or personal history of other food allergy), and home introduction is encouraged [30].

In contrast to the United States, other countries do not recommend screening prior to peanut introduction. Both the Australian Society for Clinical Immunology and Allergy (ASCIA) and the British Society for Allergy and Clinical Immunology (BSACI) guidelines do not include any provision for routine screening [30,32,33]. ASCIA's policy recognized the importance of breast-feeding in child health, is broad, and has language to accommodate exclusive breast-feeding for the first 6 months of life ('when your infant is ready, at around 6 months, but not before 4 months, start to introduce a variety of solid foods, starting with iron rich foods, while continuing breastfeeding...'). ASCIA also specifies a more prescriptive introduction of multiple foods in the first year of life without any screening. The United Kingdom found a middle ground; while screening was not routinely recommended, the BSACI noted that some families 'may wish' to have preevaluation before introduction in a patient or family-preference context [32]. The Canadian Pediatrics Society adopted an approach more consistent with the ASCIA policy in 2019 [34²²]. The 2020 European Academy of Allergy and Clinical Immunology Food Allergy Prevention Guideline Task Force public comment draft guidelines also advise early peanut introduction without any mention of prescreening [39]. In 2020, the United States Department of Agriculture also issued guidance concordant with these international bodies – early peanut and egg introduction with no prescreening advised [40²²,41].

With the notable international variation that exists, arguments for and against screening have recently been summarized by Abrams *et al.* [42²²]. Although current guidelines are well intentioned to prevent life-threatening reactions, fatal anaphylaxis from first peanut introduction is highly unlikely and

has never been reported [43]. Ironically, calculations show that the likelihood of having a fatal motor vehicle accident driving to and from clinic for screening is higher than the risk of fatal anaphylaxis from simply introducing peanuts at home [42²²,44²²,45²²]. Furthermore, when applied at a population level, screening can miss a significant percentage of infants with peanut allergy [22,43,46]. In summary, screening may do more harm than good, and is therefore, intentionally more permissive of the presumably false-positive tests that become diagnostic in order to protect against this very small risk of a severe reaction [35²²,42²²,44²²,45²²,46].

There are strong health economic arguments against screening. In a simulation and Markov model comparing a screening approach (modeled after the NIAID strategy) with a universal home introduction strategy without screening (similar to the ASCIA and BSACI approaches), Shaker *et al.* found that the no-screen approach was both considerably more cost-effective and prevented more cases of peanut allergy. The no-screen approach was associated with higher quality-adjusted life years (QALY), a metric that measures a year of perfect health relative to the condition of interest that an intervention may add [44²²,47²²,48²²]. Shaker *et al.* demonstrated that over a 20-year time horizon, the screening approach resulted in ~3200 more cases of peanut allergy at an additional cost of ~\$650 million dollars, with only a minimal difference in the rate of reactions. So what is the difference? In the screening model, fewer children are offered introduction, so fewer reactions occur initially. However, more peanut allergy diagnoses accrue over time because of delayed peanut introduction. With no screening, there obviously are no false-positive diagnoses as all infants are essentially challenged by being given peanuts [44²²]. Additional exploration comparing the two approaches has shown that screening is only cost-effective if a family has a very high aversion (e.g. health disutility) of having their potential initial reaction from early peanut introduction occurring at home versus at an allergy clinic. The threshold disutility equivalent to justify screening would need to equal a time-trade off of ~20% of a year of life [45²²].

Screening feasibility and acceptance are also concerning. Indeed, a significant barrier may be clinician and family buy-in [49²²,50²²,51²²]. In a 2020 survey of 1700 United States pediatricians, Gupta *et al.* [49²²] found that despite high pediatrician guideline awareness, less than 30% actually adopted the recommendations in full. Similarly, in a survey of 1000 new and expectant parents, Greenhawt *et al.* [50²²] found that only about half

would allow in-office allergy risk assessment before 1 year of age (49% for SPT and 43% for oral challenge). The hesitancy shown by families coupled with the clinician lack of enthusiasm to screen cast doubt on the feasibility of implementing a policy that employs peanut allergy screening at a population level [35²²,44²²,46,49²²,50²²,51²²].

The failure to fully implement screening is problematic and even harmful, as partial implementation may result in more peanut allergy over time. Performing the first step of screening with serum IgE or skin-prick testing without confirmation with a supervised oral food challenge leads to over-diagnosis and may cause children to miss a critical window in which to develop immune tolerance [37,38,52²²]. As an example, Volertas *et al.* [53²²] studied 84 infants screened prior to peanut introduction at a large academic allergy referral center documented only half of infants with a positive skin test less than 8 mm were offered a supervised food challenge, which subsequently was associated with a 57% pass rate.

In the United States, there has also been confusion about who actually needs to be screened, as it can be difficult distinguishing between ‘severe eczema’ and ‘moderate eczema’ [23,30,31,46]. The NIAID guidelines intended for ‘severe eczema’ to be progressive and treatment refractory but this could be widely interpreted. This confusion in defining ‘high-risk’ may lead to a concept known as ‘screening creep’, where children are deemed at risk when they in fact do not meet the NIAID guidelines criteria (e.g. infants with mild eczema). In the aforementioned Volertas study, only 48% of those screened actually met United States screening criteria [53²²]. In addition, using egg allergy as a decision point is problematic as many infants have not yet consumed egg at the time peanut introduction occurs, and using egg skin or blood testing as a screening instrument is no less problematic than using peanut testing [54].

SOLUTION: AVOID TESTING PITFALLS AND CONSIDER USE OF SHARED CLINICAL DECISION-MAKING

Screening is not recommended prior to peanut introduction outside of the United States [32,33,34²²]. Studies are starting to confirm the feasibility and safety of implementing this no-screen approach at the population level. In 2019, Soriano and colleagues published the Australian experience of early introduction without screening in Early-Nuts, a population-based, cross-sectional survey of 860 12-month old infants in Melbourne, Australia. Most infants [88.6%, 95% confidence interval (CI),

86.1–90.7%] had peanut introduced by 12 months of age (median age, 6 months) after the new Australian guidelines were adopted [43]. This is a significant increase, because data from 2007 to 2011 indicated a much lower rate of early peanut introduction (28.4%; 95% CI, 27.2–29.7%) [43]. Possible IgE-mediated reactions occurred in only 4.0% (95% CI, 2.7–5.8%) of infants [43]. Skin reactions (including hives, rash, and/or swelling of the lips, eyes, or face) and/or gut reactions (including vomiting, diarrhea, or both) occurred in 3.7% (95% CI, 2.5–5.5%) of patients, with wheezing occurring in 0.3% (95% CI, 0.1–1.3%) [43]. No reports of life-threatening anaphylaxis with initial home ingestion of peanut were reported in this or any other study [43].

It is time for the United States to strongly consider moving towards the no-screen model currently implemented in other countries, including the United Kingdom, Australasia, and Canada [32,33,34²²,39,55²²]. Indeed, the recent USDA scientific report of the 2020 dietary guidance advisory committee highlights the importance of early food introduction and omits any discussion of risk-based screening tests [40²²,41²²]. However, while unlikely, the risk of an allergic reaction to a first peanut exposure is not trivial. It also is understandable that some families with high-risk children may prefer introduction in a supervised allergy clinic [56²²]. This is where shared clinical decision-making helps recognize a situation that is clearly preference-sensitive. Although made somewhat more complicated in the setting of a global pandemic [57²²], shared clinical decision-making remains a strategy that encourages the practitioner and patients to make joint decisions based on values-clarifying discussions [56²²,58²²,59²²]. It has been shown to improve patient knowledge, produce better health outcomes, and lower healthcare costs [48²²,56²²,58²²,60²²]. Clinicians could incorporate shared clinical decision-making into conversations with parents who are reluctant to introduce peanuts early, to better define what the family prefers and values, and to discuss the full scope of risks and benefits for each approach. When appropriate decision-making discussions have occurred, it is a reasonable care option to then refer high-risk infants on a case-by-case basis to board-certified allergists for further counseling, testing, facilitated introduction, or supervised oral food challenge [35²²,42²²,44²²,45²²,61²²]. There still remains an acute need to develop validated decision-support tools to assist healthcare providers and families alike in the important conversations about early food introduction [35²²].

CONCLUSION

Early peanut introduction is a well tolerated and effective measure to decrease the risk of developing

peanut allergy. However, implementation in the United States has been complicated by risk-stratification and a screening paradigm that increases peanut allergy over-diagnosis, at an excessive cost, compared with alternative approaches employed by other countries [44[■],45[■]]. Changing current guidelines to a no-screen approach would allow greater flexibility and likely result in wider adoption, with consequently less children being diagnosed with peanut allergy. While encouraging all infants to eat peanut-containing products by 6 months of age is good practice, parents with a strong preference should have the ability to choose a screening option through shared clinical decision-making [35[■]]. This key feature would be an evolution of the 2017 NIAID guidelines, in order to improve implementation and reduce 'screening creep'. For families introducing peanut at home, it is important to emphasize that products should be in a form that is not a choking hazard, such as peanut butter mixed in other soft foods, and that they should be introduced slowly and gradually. If symptoms occur, families should stop, immediately contact their clinician, and seek care as appropriate.

Communicating and understanding risk of peanut allergy is complex but central to providing patient-centered care [56[■],60[■]]. Clinicians are key in educating families on the safety of at-home peanut introduction for all children, even in those traditionally considered high-risk for peanut allergy. By optimizing simple strategies, we can begin to move towards more universal adoption of early peanut introduction, in a field where truly 'an ounce of prevention is worth a pound of cure'.

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member who is CEO of Altrix Medical; serves on the Editorial Board of the Annals of Allergy, Asthma, and Immunology, the Journal of Allergy and Clinical Immunology In Practice, and the Journal of Food Allergy.

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