

Clinical Commentary Review

The Role of Shared Decision Making in Pediatric Food Allergy Management

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Shared decision making was first highlighted in a report by the Institute of Medicine in 2001. The primary aim of this initiative was to improve the quality of care provided to patients in the United States by creating a health care system that is safe, effective, efficient, and equitable. Currently, medical decision making is based on a patient-centered approach, with the individual's preferences, needs, and values guiding optimal care. Patients are frequently faced with various treatment choices with no absolute guarantee of any desired outcome and no clear indication of the "best or least worse" option. In fact, in healthcare, each of these options usually has potential trade-offs and outcomes. The process of how to choose a particular option becomes a discussion where the clinician and the patient have to jointly review the medical evidence, but also the patient's openness and preference for balancing particular attributes of the treatment (both positive and negative). Shared decision making is important for chronic diseases that require long-term management, such as most allergic conditions, including food allergies. The landscape of food allergies has changed considerably in recent years with multiple and significant scientific advances in both diagnostics and treatment, providing an ideal field for the use of shared decision making. For the purposes of this review, we will discuss different areas of food allergy management within a single complex case, focusing on the role of shared decision making. © 2019 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2019;■:■-■)

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immunotherapy; Skin prick testing; Oral food challenge; Early introduction

INTRODUCTION

During the 20th century, medical decision making gradually shifted from a paternalistic approach to a patient-guided process,¹ with the term "patient-centered care" coined in 1988.² Shared decision making was first highlighted in a report by the Institute of Medicine in 2001. The primary aim of this initiative was to improve the quality of care provided to patients in the United States by creating a health care system that is safe, effective, efficient, and equitable.³ The report also promoted patient-centered care, defined as "providing care that is respectful of and responsive to individual patient preferences, needs and values" and "ensuring that patient values guide all clinical decisions." In addition, it stated that decisions should be based on current scientific knowledge, while communication between patients and health care providers should be effective, with information and knowledge shared freely.³ Specifically for pediatric medicine, the American Academy of Pediatrics issued a revised policy statement on informed consent in 2016, stating that "shared decision-making is a central tenet of the family-centered medical home."⁴

In health care, management decisions are not always straightforward—often, the patient is faced with various treatment options with no absolute guarantee of any desired outcome and no clear indication of the "best or least worse" choice. In fact, on a lot of occasions they are merely presented not as a "best choice," just as a number of different options. This is the essence of what is best

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Aimmune Therapeutics, DBV Technologies, Sanofi/Genzyme, Genentech, Nutricia, Kaleo Pharmaceutical, Nestle, Acquestive, Allergy Therapeutics, Allergenis, Aravax, and Monsanto; is a member of the scientific advisory council for the National Peanut Board; has received honoraria for lectures from Thermo Fisher, Aimmune Therapeutics, DBV Technologies, Before Brands, multiple state allergy societies, the American College of Allergy Asthma and Immunology, and the European Academy of Allergy and Clinical Immunology; is an associate editor for the *Annals of Allergy, Asthma, and Immunology*; and is a member of the Joint Taskforce on Allergy Practice Parameters.

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*Abbreviations used**EPIT- Epicutaneous immunotherapy**OFC- Oral food challenge**OIT- Oral immunotherapy*

described as preference-sensitive care, situations in which there are multiple treatment options, each with potential trade-offs and outcomes where the decision to choose 1 option is largely dependent on the values and personal preferences of the patient,^{5,6} with which their clinician can help. In these instances, the process of how to choose a particular option becomes a discussion where the clinician and the patient have to jointly review the medical evidence, but also the patient's openness and preference for balancing particular attributes of the treatment (both good and bad). Thus, in true shared decision making, both the patient and the health care provider contribute equally by bringing important, albeit different, perspectives to the decision-making process. By working together, patients and physicians ensure achievement of the best possible outcome. In pediatrics, while shared decision making includes the parent or legal guardian, because minors lack legal authority to provide informed consent for treatment, as the child gets older and more mature, they may assume a more primary role and autonomy as decision makers in their own care, and in some cases express different values and goals from their parents' choices.⁷

Shared decision making can be reviewed in detail elsewhere, but briefly, this is an iterative process involving motivated patients and well-informed clinicians.⁸⁻¹¹ The key components of approaching this process with the patient are highlighted in [Figure 1](#). Upon quick review, this may appear quite intuitive, and most clinicians likely already involve multiple aspects of this framework in their daily patient encounters. Each encounter is a building block in an ongoing partnership with a patient to manage his or her disease. As clinicians familiarize themselves with patients, they can assess and understand their receptive capacity for information and how they clarify their level of understanding regarding their condition, as well as their goals and health beliefs. This capacity is very variable between individuals and between consultations, so 1 clinical approach will not fit all cases. This learned clinical assessment behavior influences how we provide choices of care that are consistent with a patient's values (defined as the extent to which decisional attributes matter to an individual) and preferences (defined as an individual's inclination toward or away for a particular decisional option).

In our role for caring and managing the patient's condition, we either present or direct a patient toward evidence that can help them understand their condition and the choices in how this can be managed. At that point, this becomes a basic negotiation of options—clinicians offer a few options on how to address their health problems, taking into account their likes/dislikes and concerns (eg, steroid phobia, aversion to certain forms of medicine, and concerns over cost or access), and if all goes right, a point of mutual agreement is reached on an option where all parties feel comfortable with the decision. [Figure 1](#) also displays a framework on how to coach this approach, so that decisional needs are identified (eg, through tools that allow for values clarification), the process of considering options is

supported (through tools such as decision aids), key stakeholders in the patient decision-making process are involved, and any decisional conflict the patient has can be resolved. The framework intends to make sure that the quality of the underlying decision is improved by providing the requisite support.

Shared decision making is important for chronic diseases that require long-term management, such as most allergic conditions, including food allergies, though there is no research footprint in this area in most of allergy, outside of asthma.^{13,14} Food allergy may be an ideal area where shared decision making is of key value—there are many potential management paths, each having trade-offs, and parents (and patients) often have very particular preferences for care. The landscape of food allergies has changed considerably in recent years with multiple and significant scientific advances in both diagnostics and treatment. From the use of component-resolved diagnostics and *in vitro* testing, to the emergence of biologics and food immunotherapy, food allergy management has moved from a previously static and passive approach to a continuously developing and advancing field, where multiple management paths may exist. The issue is now one of ensuring that all parties involved in the decision-making process have assessed and processed the potential outcomes and trade-offs, and can enter into an open discussion of all available or emerging options and their consequences. With the advent of treatment on the near horizon, this will become an essential facet of food allergy management.

Children should also be involved in decision making, and both parents and health care providers play a crucial role in supporting young patients as they learn to make decisions on their own. This process can be facilitated by the physician during an office visit by asking for the child's opinions, concerns, and preferences and checking for their understanding on what has been said, so that the child is given opportunity to clarify their values, though this must be approached in the context consistent with the child's developmental capabilities to understand the medical care being discussed.¹⁵ Parents may choose to engage their children in specific decisions, involve them in the management of their condition, and prepare them for the transition to greater independence when they reach adulthood.¹⁵

For the purposes of this review, we will discuss different areas of food allergy management within a single complex case, focusing on the role of shared decision making. We have framed this discussion to provide a practical approach for clinicians facing similar decisions in their everyday practice, and highlight how common these situations may be.

PATIENT CASE

A 5-month-old infant with moderate eczema since he was 2 months old (under adequate control by the primary care physician) and a recent episode of anaphylaxis to egg (hives, vomiting, and wheeze) presents to the Allergy Clinic. He tolerates cow's milk, wheat, oat, rice, chicken, fruits, and vegetables, but his parents have now stopped introducing any new foods and want him "tested for all foods he has not tried yet." They are angry (with their primary care physician and themselves), scared, and feel pressured by new recommendations to introduce potentially dangerous allergens. They recount only being informed of the benefits of early introduction, and not the potential risks.

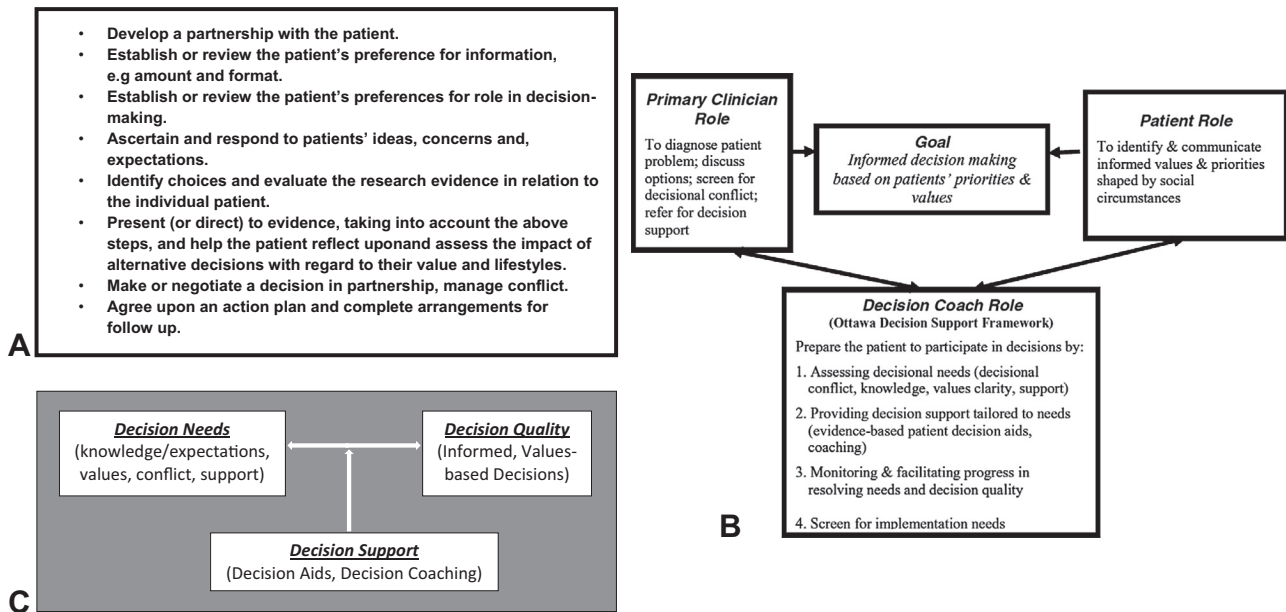


FIGURE 1. Key features and approaches in shared decision making. (A) Key features of the approach to shared decision making. (B) A model of roles and responsibilities to foster a shared decision-making approach. (C) A framework for decisional support to facilitate shared decision making. Source: The Ottawa Hospital Research Institute.¹²

Initial approach

The family has been particularly expressive of their concerns—they were not comfortable with early introduction recommendations, there is decisional regret, and there is fear of further food allergies developing. A more informed approach is needed to map out how this child's diet will progress. The family needs to be asked what their concerns are and what their comfort level is with recommendations, in particular new recommendations for the looming issue of early peanut introduction, that are diametrically unlike what the family had heard about before from friends with older children. Allowing time for families to express their feelings not only shows respect for their concerns but also creates an environment of mutual trust and allows for emotional support, as needed; these are all crucial elements in the shared decision-making process. Time for patient care is precious, and unhurried clinical encounters are much appreciated by parents/guardians.¹⁶ However, in this scenario—about peanut introduction—the clock is ticking. The main issue to confront is their desire for wide-ranging panel testing and their fear of early peanut introduction. This is an at-risk child, and evidence suggests that the sooner peanut is introduced, the risk of peanut allergy may be reduced significantly. However, this health benefit is balanced by their having already witnessed anaphylaxis (to egg), and very understandable fear of future similar reactions, which is already delaying his weaning of other solid foods not “known to be safe.” Both parents want testing for “all foods” that had not yet been introduced.

The above is a common scenario in the allergy clinic. Although an easy procedure, is widespread allergy testing really a preference-sensitive care option? Likely no, but it may be, to selected allergens, most particularly peanut, in certain contexts. The low specificity of allergy testing in a child naive to that food risks a false-positive interpretation of what detectable peanut sensitization may mean clinically, and is not an easy concept to

explain to families. In this particular case, the benefits and pitfalls of skin prick testing and specific IgE should be explained in detail, in particular that positive test results are not uncommon in tolerant individuals and are not diagnostic of food allergy in isolation. One approach is to highlight the most pressing risk, and take advantage of the situation where the National Institute of Allergy and Infectious Diseases recommendations do indicate that testing to peanut is warranted, but at the same time explain the lack of established risk with other foods, and that positive test results would necessitate an oral food challenge (OFC) to determine whether the child is allergic.

You empathize with the parents' concerns, and agree that although some testing is necessary, testing to “all foods” is impractical and has potential risks that may outweigh the benefits. However, you ask the parents what food(s) they are most afraid of trying but desire in his diet—they indicate peanut. The parents understand how expanded testing is not practical and may not help, but remain afraid of a future reaction, especially to peanut. Considering the patient's history of recent anaphylaxis to egg, you have a lengthy discussion about the risk of peanut allergy and the potential value of testing before introduction, according to new guidelines.¹⁷ The option is offered that irrespective of what the test shows, that to ensure their comfort, peanut can be introduced in your office under supervision if indicated. The parents are very happy, reemphasize that this was their overwhelming fear, and that they were unlikely to introduce peanut outside of your office. Skin testing to just peanut was performed, the result of which was positive with a 6-mm wheal. You explain the risks and benefits of an oral challenge to the parents, who while afraid, agree to the procedure.

The value of shared decision making

Identifying their underlying values and decisional conflicts helped elicit their preference for supervised peanut introduction, after limited testing. This dialogue was important for

shared decision making and potential future adherence to regular peanut consumption. What about a family that had these risk factors but was determined to forego testing and just introduce peanut at home, or a family with a less clear-cut case of risk, for instance, someone with moderate but not severe eczema and no egg allergy, but insistent on screening before introduction? These situations highlight the preference-sensitive care nature of this situation, even the high-risk family that does not desire screening (which may not align with our values as a clinician, but may align with patient values so long as the risks and benefits are understood). To assist with these decisions, clinical decision support tools such as a decision aid would likely be helpful. However, none exists for food allergy (and only 4 exist for any allergy topic). A recent Cochrane Systematic Review concluded that compared with usual care across various decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values.¹⁸ There is also growing evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.¹⁸ In this example, a decision aid would provide details on the evidence from the Learning Early About Peanut Allergy (LEAP) study, which helped inform the guidelines and explain the risks and benefits of testing (including when it is not indicated and why) and the risks and benefits of where to introduce peanut (as well as why the guidelines recommend that certain children with very high skin prick test value or specific IgE level be counseled to avoid peanut introduction, and explore reasons why parents may wish to not have this done at all). It would also allow the parents to clarify what is and is not important to them in terms of these relative trade-offs, and help walk them through the critical pieces of information needed for them to reach a decision. As the clinician, to truly embrace shared decision making, one must consciously relinquish judgments over what is “right” or “best” or what our personal values/beliefs may be, given that a patient will reach a decision in this process consistent with what is right for them after considering the evidence and our recommendations. However, because parents are proxy decision makers for the actual patient (their child), the clinician can sometimes encounter tension when parents have introduction-hesitancy or fears, akin to vaccine hesitancy as the guidelines and the allergists’ focus on early introduction are based on basically 1 study and are counter to the dogma and professional and community culture that prevailed before the LEAP study.

In the course of the in-office challenge, the child reacted on the second dose with generalized hives and was treated easily with antihistamine. The parents are now more concerned, and despite previous discussion over testing limitations demand testing to all other nuts before introduction, citing a recent case, which they found on the Internet, of fatal anaphylaxis due to tree nuts. They also reported that on the social media site of a large national advocacy group, multiple other online members recommended further investigations for tree nut allergy.

Incorporating shared decision making into additional problems

“Plus ça change, plus c’est mème chose.” Or does it? It was already established that this is a family wary of new early introduction guidelines, and frightened by the prospect of food allergy development. They have now just experienced their second

reaction to a food that their clinician had seemed willing for them to offer their child at home without testing, until they insisted otherwise. Their values and preferences have actually not changed when confronted with the next potentially high-risk allergen. However, there are additional stakeholders leveraging the decision in this context, in particular nonmedical and online information sources. Internet use continues to increase exponentially and is now an integral part of life for many patients, in all fields of medicine, including food allergy. The Internet is an accessible source of health information, but this is often of variable quality.¹⁹ In 2011, a survey of more than 22,000 Americans found that 1 in 5 use social media sites to find health information.²⁰ One in 4 Americans reported that social media’s influence would “very likely” or “likely” impact their future health care decisions, and 32% had “very high” or “high” trust in social media.²⁰ A 2016 survey noted that the food allergy online community is highly health-literate but was overtrusting of online sources of information, with worse quality of life noted among those who belonged to online advocacy groups versus those who did not and worse quality of life among those with high trust in online information sources.²¹ In this case study, the increased parental anxiety and desire for wide-ranging testing is understandable, as is how their decision may be supported by particular stakeholders that they may value more highly than their allergist, informing them of the ambient utility of additional testing in this context. There is poor understanding of the precise nature of the risk of developing tree nut allergy in a peanut-allergic individual. Early studies have suggested a prevalence of 30% to 50%, but these studies are dependent on rather literal interpretation of strong cross-sensitization on skin and serologic tests as likely indicative of allergy, and possibly confounded by delayed introduction and high rates of copositivity on tests.^{22,23} Few challenge-based studies exist. A 2016 study noted that among peanut-allergic/tree nut-naïve children, 96% passed an OFC to tree nut, and an estimated 50% had negative predictive values for tree nut skin test (wheal diameter of 9 mm) and serologic IgE to tree nut (of 11.5 KU/A), emphasizing the high utility of offering OFC to such individuals if they are tested, and to caution against literal interpretation of even plausibly elevated sensitization.²⁴

You discuss the difficulty in interpreting potentially positive tree nut test results in a peanut-allergic infant who has not eaten any tree nuts. While acknowledging some potential for elevated risk of tree nut allergy versus the general population on the basis of challenge-proven peanut allergy and having another food allergy (egg, which caused anaphylaxis), this still may not be a high enough risk to reduce the need for an OFC to clarify a positive result. After further discussion of the risks and benefits of testing, the parents agree to limited skin testing to walnut, pecan, cashew, and pistachio and agree to follow up positive results with an OFC. Skin testing results to these tree nuts were negative, and the family is happy to introduce these at home, as well as the “untested” nuts: almond and Brazil. An action plan was created, avoidance management emphasized, and dietary support with a registered dietician offered. In their follow-up visit to the allergy clinic a year later (which was scheduled with parents who wanted some time away from allergy care to “get on with being a normal family”), you are pleased to learn they have advanced the diet and the child is avoiding only egg and peanut. The parents request treatment for their child’s egg and peanut allergy, specifically food immunotherapy.

Back to the future

With food immunotherapy emerging as potential treatment for food allergies (in particular commercially available peanut therapies), families will certainly start inquiring about this potential option. Commercial therapies for egg and other allergens are in the developmental pipeline, but not at the stage of clinical trials at present. Different options for food immunotherapy exist currently under the research umbrella, including oral immunotherapy (OIT), epicutaneous immunotherapy (EPIT), and sublingual immunotherapy.

Shared decision making here is highly important, and parental goals and expectations of treatment as well as their values and preferences need to be addressed from the beginning. Work surrounding how parents approach this process is just beginning, but there is suggestion that parent and clinician expectations may not necessarily align. A recent qualitative study, which included both EPIT and OIT research trial participants, reported that families may have more modest treatment goals of desensitization than their doctors, seeking confidence that their children can develop a buffer against accidental peanut exposure, which would increase their confidence in engaging socially outside the home but would not lessen their overall allergen-associated vigilance and avoidance practices.²⁵ Although this is 1 study, it highlights the potential for goal misalignment—many clinicians may automatically presume long-term tolerance as the most valuable outcome in seeking therapy. Moreover, because anxiety may motivate particular goals of participating in a therapy or trial, it is important to identify these before initiating any therapy or making a decision about a particular type of therapy.²⁶ However, no studies have been done to directly elicit preferences on therapy and few that have discussed what families goals may be, creating a void in terms of understanding the values clarification process for families considering therapy.

What may this values clarification process involve for food immunotherapy? Two possible key attributes may be safety and efficacy. Phase 3 trial data for the 2 commercial peanut products have been published, suggesting a higher rate of efficacy versus placebo at a 1-year end point for OIT versus EPIT, though EPIT had far fewer adverse events, including severe reactions, treatment-related dropout, and lower use of epinephrine than OIT in the same time frame. This differential may lend itself to a preference-sensitive decision for parents to consider—higher efficacy with lower safety versus lower efficacy with higher safety. Other key attributes around value clarification with treatment may be convenience of daily dosing and activity restrictions, duration of therapy, costs, long-term data (lacking for both products), clinic visits, and the issue of an oral versus nonoral product. Long-term peanut OIT data from Israel have suggested that taste aversion develops in a significant proportion of individuals, leading to either dose reduction or discontinuation.²⁷ The larger point is that there are many attributes for a parent to consider, each individualized for their child and their family life. Success in any therapy will be dependent on maximizing safety, treatment adherence, and understanding the risks and benefits associated with the decision—all key elements that must be emphasized during the shared decision-making process. Some families may wish to involve older children in this decision from the start, especially considering the risk of the child experiencing potential adverse events, the importance of long-term

adherence to the treatment, and the need to incorporate the therapy into daily life for the foreseeable future.¹⁵ Younger children may also be involved in an age-appropriate way, but parental input for them is more central because parents typically are their young child's best advocates and in the best position to understand the child's values and goals.^{7,15}

Food OIT is a long-term commitment, not a “quick-fix” solution, and requires dedication, effort, and a high level of compliance. Patient decision aids are not currently available for use in food OIT, but would potentially be beneficial in this area of practice. Any tool needs to carefully balance presentation of the available options including benefits and risks, and incorporate that for some patients the right decision may be no therapy.^{28,29} For other allergic conditions such as asthma, use of a shared decision-making patient asthma portal was feasible and acceptable to families and improved clinically meaningful outcomes.¹³ Parents of children with moderate to severe persistent asthma using the portal reported that this improved their communication with the office, ability to manage asthma, and awareness of the importance of ongoing attention to treatment. Parents in the intervention group also reported that children had a lower frequency of asthma flares and parents missed fewer days of work because of their child's asthma.¹³ The time a family needs to make a decision is also a key element that must be considered—discussions cannot be rushed, and time has been reported as a barrier in effective shared decision making for both patients and physicians.¹⁶ Although little evidence exists on when physicians and patients perceive that “time has run out,” allocating ample time for questions and an unhurried discussion will likely allow physicians to better understand their patient's preferences and values.¹⁶ Consideration for providing decision-making materials in advance of an appointment versus after will require study to determine which leads to more optimal decision making. It is also important to note that the patient's needs and preferences may evolve or depend on the patient age. This is known as the “shared decision-making continuum” and reinforces the fact that patient preferences should guide decision making and physicians must appreciate that these preferences may change over time.¹

CONCLUSIONS

There is a clear trend to enhance the voice of the patient in their clinical care, and shared decision making is one such vehicle to accomplish this aim. Shared decision making is a vital part of patient care, in particular care of complex conditions where multiple therapeutic approaches may exist, each with distinct risks and benefits that may differentially appeal to a particular individual. Although this process may seem intuitive, it is a coachable skill that clinicians need to learn how to incorporate into routine patient care. Few food allergy care decisions are clear-cut, even when to use epinephrine, for example, where trade-offs and preferences should not be under consideration. Within food allergy, multiple aspects of clinical care do lend to processes of decision sharing, including the use of diagnostic testing, application of new clinical guidelines on early potentially allergenic solid food introduction, the use of formal OFC or less formal supervised feeds, and other emerging treatment options. We are their allergists, not their priests or parents, and we must remember that our role is that of best medical advocate, with the

information, training, and empathy they need to make decisions about their food-allergic child.

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