

Journal Pre-proof

Development and Acceptability of a Shared Decision-Making Tool for Commercial Peanut Allergy Therapies

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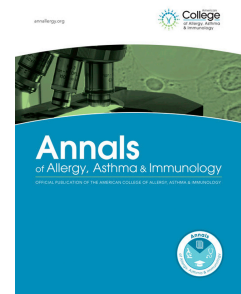
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Original Article: Development and Acceptability of a Shared Decision-Making Tool for Commercial Peanut Allergy Therapies

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Abbreviations: Shared Decision Making (SDM); International Patient Decision Aid Standards (IPDAS); Oral Immunotherapy (OIT); Epicutaneous immunotherapy (EPIT), quality of life (QoL), Food and Drug Administration (FDA); Decision Conflict Scale (DCS); Decisional Self-Efficacy Scale (DSE); Interquartile Range (IQR)

Keywords: Shared Decision Making; decision-aid; values clarification; decisional conflict; decisional acceptability; decisional self-efficacy; decisional needs; oral immunotherapy; epicutaneous immunotherapy; quality of life; peanut allergy; anaphylaxis; epinephrine; food allergy treatment; trade-off

Disclosures:

Matthew Greenhawt is supported by grant #5K08HS024599-02 from the Agency for Healthcare Research and Quality; is an expert panel and coordinating committee member of the NIAID-sponsored Guidelines for Peanut Allergy Prevention; has served as a consultant for the Canadian Transportation Agency, Thermo Fisher, Intromune, and Aimmune Therapeutics; is a member of physician/medical advisory boards for Aimmune Therapeutics, DBV Technologies, Sanofi/Genzyme, Genentech, Nutricia, Kaleo Pharmaceutical, Nestle, Aquestive, Allergy Therapeutics, Allergenics, Aravax, Protax, and Monsanto; is a member of the scientific advisory council for the National Peanut Board; has received honorarium for lectures from Thermo Fisher, Aimmune, DBV, Before Brands, multiple state allergy societies, the American College of Allergy Asthma and Immunology, 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.

Marcus Shaker: has a family member who is CEO of Altrix Medical and is a member of the Joint Taskforce on Allergy Practice Parameters.

Tonya Winders: is CEO of the Allergy and Asthma Network, which has received financial contributions from Aimmune & DBV Technologies for unbranded disease education & awareness activities.

John Oppenheimer:

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Edwin Kim: Consultant/honoraria: Aimmune, DBV, Allakos, AllerGenis, Ukko, Vibrant America

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Edmond Chan: has received research support from DBV Technologies, has been a member of advisory boards for Pfizer, Pediapharm, Leo Pharma, and Kaleo, is a member of the scientific advisory board for Food Allergy Canada, and was an expert panel and coordinating committee member of the National Institute of Allergy and Infectious Diseases (NIAID)-sponsored Guidelines for Peanut Allergy Prevention.

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David R. Stukus: Consultant for Aimmune Therapeutics, Before Brands, and Abbott Nutrition.

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Author Contributions: Drs. Greenhawt and Matlock were involved in the theme elucidation, incorporation, design and development of the initial version of the decision aid, the choice of validation instruments, and the interpretation of the data from the validation steps. They retained final authorization over any decisions for inclusion of changes to the decision aid. All other authors were involved in the iterative review of the subsequent drafts of the decision aid (1) made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafted the article or reviewed it critically for important intellectual content; (3) gave final approval of the version to be published; and (4) agree to be accountable for all aspects of the work related to its accuracy or integrity.

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Background: Shared decision making (SDM) is the process through which patients and their medical provider mutually explore therapy goals, risks/benefits, and treatment options regarding medical care. Decision-aids are tools to help with the values clarification process and assess decisional needs and potential decisional conflicts.

Objective: To develop and assess acceptability of a decision-aid for commercial peanut allergy therapies.

Methods: The creation of this decision-aid occurred in three stages, including a qualitative study to assess decisional needs, development of a draft decision-aid through multiple iterations in accordance with international guidelines and decision-aid experts, and assessment of decisional acceptability, decisional conflict, and decisional self-efficacy related to using the decision-aid.

Results: The decision-aid went through 9 iterations, resulting in a 4-page aid with 7 parts, explaining the therapies, the key risks and benefits of the therapy choices, the relative importance of key attributes of the therapies, and a self-check assessment regarding informational adequacy and how to take the next steps. Twenty-four subjects assessed the decision-aid, noting it had good acceptability, high decisional self-efficacy (mean score 91.9/100) and low decisional conflict (mean score 20.2/100). Respondents rated the information content as adequate and sufficient, and the information regarding the therapy choices as fair and balanced without a clear bias or presenting a “best choice”.

Conclusion: We have developed this decision-aid as a tool to help caregivers navigate the complexity of decision-making for peanut allergy treatment options. The decisionaid was noted to have good acceptability, with scores reflective of the instrument enhancing decisional self-efficacy and reducing decisional conflict.

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Table 1: Raw Item Scoring for the Decisional Self-Efficacy and Decisional Conflict Scales

Acceptability Index	Mean Raw Score (SD)	Median Raw Score (IQR)
Decisional Self-Efficacy (0 not confident at all to 4 very confident)^a		
Get the facts about the treatment choices available to me	3.8 (0.5)	4 (4)
Get the facts about the beliefs of each choice	3.5 (.98)	4 (3-4)
Get the facts about the risks and side effects of each choice	3.7 (0.63)	4 (4)
Understand the information enough to be able to make a choice	3.7 (0.69)	4 (4)
Ask questions without feeling dumb	3.7 (0.61)	4 (4)
Express my concerns about each choice	3.8 (0.51)	4 (4)
Ask for advice	3.7 (0.62)	4 (4)
Figure out the choice that best suits me	3.6 (0.77)	4 (3.5-4)
Handle unwanted pressure from others in making my choice	3.7 (0.92)	4 (4)
Let the clinic team know what's best for me	3.7 (0.71)	4 (3.5-4)
Delay my decision if I feel I need more time	3.7 (0.55)	4 (3.5-4)
Raw Total Decisional Self-Efficacy Score	3.7 (0.6)	3.9 (3.8-4)
Calculated Total Decisional Self-Efficacy Score	91.9 (14.1)	97.7 (93.2-100)
Decisional Conflict (0 strongly agree to 4 strongly disagree)^b		
I know which options are available to me	0.3 (0.48)	0 (0-1)
I know the benefits of each option	0.5 (0.83)	0 (0-1)
I know the risks and side effects of each option	0.6 (0.97)	0 (0-1)
I am clear about which benefits matter most to me	0.3 (0.7)	0 (0-0.5)
I am clear about which risks and side effects matter most to me	0.4 (0.78)	0 (0-1)
I am clear about which is more important to me (benefits vs. risks/side effects)	0.5 (0.83)	0 (0-1)
I have enough support from others to make a choice	0.7 (0.85)	0 (0-1)
I am choosing without pressure from others	0.7 (0.91)	0 (0-1)
I have enough advice to make a choice	0.6 (0.92)	0 (0-1)
I am clear about the best choice for me	0.8 (1.2)	0 (0-1)
I feel sure about what to choose	1.1 (1.3)	1 (0-2.5)
The decision is easy for me to make	1.8 (1.4)	1.5 (1-3)
I feel I have made an informed choice	0.7 (1.2)	0 (0-1.5)
My decision shows what is important to me	0.6 (0.92)	0 (0-1)
I expect to stick with my decision	0.8 (1.2)	0 (0-1)
I am satisfied with my decision	0.8 (1.1)	0 (1-1.5)
Raw Total Decisional Conflict Score	0.7 (0.8)	0.4 (0.19-1.2)
Calculated Total Decisional Conflict Score	20.2 (19.9)	10.9 (6.3-32.8)

^aTotal calculated score for the Decisional Self-Efficacy Scale is calculated by summing the raw score for all items, dividing by 11, then multiplying by 25 to arrive at a number between 0 (very poor decisional self-efficacy) and 100 (very high decisional self-efficacy).

^bTotal calculated score for the Decisional Conflict Scale is calculated by summing the raw score for all items, dividing by 16, then multiplying by 25 to arrive at a number between 0 (very low decisional conflict) and 100 (very high decisional conflict).

Table 2: Calculated Decisional Conflict Scale Subdomain Scoring

Decisional Conflict Item	Calculated Score ^a
I know which options are available to me	8.3
I know the benefits of each option	13.5
I know the risks and side effects of each option	15.6
Informed Sub-domain Score	12.5
I am clear about which benefits matter most to me	8.3
I am clear about which risks and side effects matter most to me	11.5
I am clear about which is more important to me (benefits vs. risks/side effects)	13.5
Values Clarity Subdomain Score	11.1
I have enough support from others to make a choice	18.8
I am choosing without pressure from others	16.7
I have enough advice to make a choice	14.6
Support Subdomain Score	16.7
I am clear about the best choice for me	19.8
I feel sure about what to choose	28.1
The decision is easy for me to make	45.8
Uncertainty Subdomain Score	31.3
I feel I have made an informed choice	18.8
My decision shows what is important to me	15.6
I expect to stick with my decision	20.8
I am satisfied with my decision	19.8
Effective Decision Subdomain Score	18.8

^aTotal score for the Decisional Conflict Scale is calculated by summing the raw score for all items, dividing by 16, then multiplying by 25 to arrive at a number between 0 (very low decisional conflict) and 100 (very high decisional conflict). Subdomain scores are formulated by summing the subdomain items, dividing by the number of items in the subdomain, and multiplying by 25.

Repository Text Material:

Figure E1: A Decision Aid for Patients and Caregivers for Considering Peanut Allergy Treatment Options

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Treatment Options for Peanut Allergy: A Decision Aid for Patients and Caregivers

Making a choice to start a therapy to treat your child's peanut allergy is an important decision. **There are no wrong choices you can make.** It may be helpful to discuss these options with family and friends and show them this shared decision making (SDM) aid to assist you in reaching a decision.

This decision-aid should help you to talk with your Allergist about treatment options that are best for you and your family. You should ask any and all questions you may have and express what your concerns are to your doctor.

When you are ready to make a decision, call or schedule an appointment with your Allergist. If you choose one of the therapy options, your Allergist will go over the planned schedule for starting and for monitoring your child's progress.

The best choice is going to be the choice you feel most comfortable with, and will be able to stick with, without regret. Not choosing to start a therapy at this time is also a choice—these therapies could be started in the future as well.

Do not attempt to try any type of desensitization therapy at home without talking to your Allergist.

This decision aid is for you if:

- Your child has been diagnosed with peanut allergy by your Allergist or Primary Care Provider.
- You are curious about possible treatment options for your child's peanut allergy.
- You are concerned your peanut-allergic child is at high risk for an accidental reaction to peanut.

What is Peanut Allergy?

- People with peanut allergy can have severe reactions if they eat any food with peanut in it.
- This is considered a potentially severe, lifelong allergy, often discovered in early childhood. Fatal reactions are rare.
- According to the latest research, only 23 out of 100 kids will outgrow peanut allergy on their own.

How can you treat peanut allergy?

- While in the past, advice recommended strict avoidance as the only option to manage peanut allergy when necessary, two treatments are now available with the potential to lower your risk of a peanut reaction – to “desensitize” someone to be able to tolerate a small amount of accidental peanut exposure.
- At present, these therapies do NOT cure peanut allergy or allow your child to eat peanut when you or they want.
- **IMPORTANT: Even during treatment, and possibly still after, everyone with peanut allergy must strictly avoid peanuts in the diet, and carry an epinephrine auto-injector in the event of a life-threatening reaction.**

What are your options:

Avoidance	Peanut oral immunotherapy (OIT)	Peanut epicutaneous immunotherapy (EPIT)
• You choose for your child to continue to strictly avoid peanut and carry emergency medication at all times. • Continued communication and avoidance strategies can help prevent accidental ingestion • Quality of life may be poor and anxiety around situations where your child is exposed to peanut high, potentially, in some. • Only 23 in 100 kids outgrow peanut allergy on their own.	• You choose for your child to eat small, increasing amounts of peanut up to a certain target level, under the direction of your doctor. • After reaching their target level of peanut in OIT, your child must continue to eat this amount every day (called a maintenance dose) to remain desensitized, or this protection will disappear. • Therapy is associated with 3-fold higher risk of a severe reaction than from just avoiding peanut naturally	• You choose for your child to wear a patch coated with peanut on their skin. The patch dose does not change. In the beginning, the number of hours your child wears the patch increases from a few hours a day to all day/night. • The patch must be worn every day or this protection will disappear.

What may affect your choice of treatment (check all that apply and what you wish to discuss with your Allergist):

- ☐ A preference for a way that my child will actually take the therapy (e.g., by mouth vs. worn on the skin)
- ☐ A preference for the number of allergist visits that are required during the updosing and maintenance phases
- ☐ A preference to avoid certain types of treatment-related side effects that may require epinephrine or other medications
- ☐ A preference for how quickly it will take the treatment to work
- ☐ A preference for how well the treatment will work and how much protection against peanut my child will have
- ☐ A preference for how often the treatment must be taken, and how long my child has to remain on treatment
- ☐ A preference for how much this treatment may cost me, out of pocket, beyond what my insurance will cover

Let's work through the key steps of making this decision.....

Step 1: What are the benefits and side effects of each treatment based on published research?**Benefits**

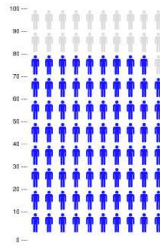
After a year of therapy how much peanut can my child tolerate



A peanut pod contains 2 peanuts.
Each peanut is 300mg of protein.
Peanuts are also called kernels.

OIT

79 in 100 can tolerate 1 peanut

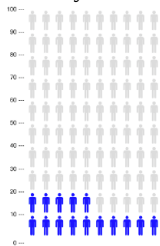
**EPIT**

51 in 100 improved from <1/3 of a peanut to 1 peanut before reacting

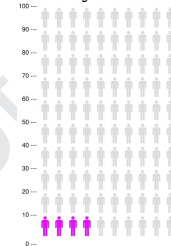
**Risks and Side Effects**

During the first year of therapy, how many children will have had a severe allergic reaction (a systemic reaction affecting multiple parts of the body) due to the therapy

15 in 100 will have a systemic allergic reaction

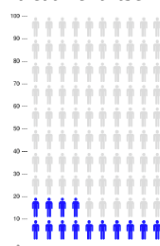


4 in 100 will have a systemic allergic reaction

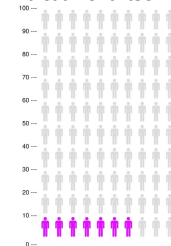


How many children will have to use epinephrine due to the treatment?

14 in 100 will need epinephrine due to the treatment itself

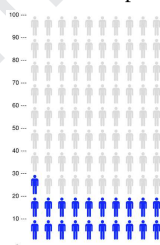


7 in 100 will need epinephrine due to the treatment itself

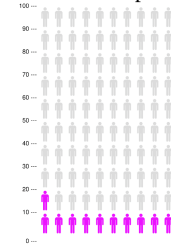


How many children will have to stop therapy before reaching their target goal where benefit begins

21 in 100 will stop therapy

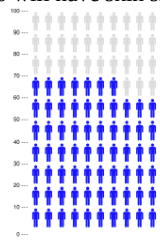


11 in 100 will stop therapy



How many children will have skin side effects (rash, itching, etc.) due to treatment (apart from patch site issues)?

67 in 100 will have skin side effects

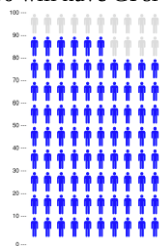


71 in 100 will have skin side effects



How many children will have Gastrointestinal (e.g. stomach) side effects (either a single or repeated episodes of stomach ache, nausea, vomiting) due to treatment?

86 in 100 will have GI side effects



0 in 100 will have GI side effects



Step 2: Clarifying what about treatment means the most to you:

Check ✓ how much each reason matters to you on a scale from 0 to 5. '0' means it is **not** important. '5' is **very** important.

Features of a particular treatment for your child	Not Important						Very Important					
How important is it to lower the risk of a severe reaction from eating peanut?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to have a high level of protection vs. just enough against small accidental exposures?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid having to take epinephrine because of a treatment-related reaction?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid treatment where you have to actually eat peanut (by mouth)?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it if you have to not have to take some form of therapy every day	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid frequent skin side effects (rash, hives, itching, eczema) due to treatment?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid frequent GI side effects (nausea, vomiting, pain) due to treatment?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid having frequent doctor visits to increase the daily dose of therapy?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to avoid having a severe allergic reaction caused by the treatment itself?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is it to have flexibility in when to take the treatment (not having to plan around meals, showering, exercise, illness, menstruation, or sleep schedule to prevent the risk of side effects)?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is the amount of out of pocket treatment costs beyond what is covered by insurance?	①	②	③	④	⑤		①	②	③	④	⑤	
How important is a therapy where after treatment you still have to avoid peanut and carry epinephrine?	①	②	③	④	⑤		①	②	③	④	⑤	

Step 3: Is there any additional information about the treatments to help you with your decision?**Comparison of Options**

	OIT (Paliforza)	EPIT (Viaskin Peanut)	Avoidance
What is this therapy and how is it taken	Every day, your child will eat small, increasing amounts of peanut up to a certain target level, under the direction of your doctor.	Every day, your child will wear a patch coated with peanut protein on the skin. The patch will be worn 24 hours per day every day.	Your child will continue to strictly avoid eating any amount of peanut
Time it takes for therapy to work	Around 6 months or less	Between 1-2 years	Indefinite
Target allergens	Peanut only	Peanut only	Avoid peanut
FDA Approved Ages	4-17y	4-11y	Any age
Number of Allergist visits on therapy	- Visits every 2 weeks to increase the dose until the top dose is reached (takes ~3-4 months) - Routine follow-up visits recommended to chart progress.	- No visits to increase the dose - Routine follow up visits recommended to chart progress.	Most see their allergist every year for routine follow up and testing
Risks	- Dose-related GI reactions such as stomach aches, nausea, and vomiting (~80%) - Eosinophilic esophagitis (~2.7%) - Systemic reactions from dose (~15%) - Increased risk of dose-related side effects if taken on empty stomach, when sick or menstruating, when tired, or too close to exercising or a hot shower (variable %)	- Skin rash and itching at patch site (71%) - Systemic reaction from patch (3.8%)	- Poor quality of life - Anxiety - Accidental reactions, which may or may not be severe 7% risk of anaphylaxis (baseline risk)
Benefits	Desensitization only, not a cure - May reduce reaction severity and prevent reactions from an accidental peanut ingestion - More people benefitted than EPIT - Because this is not a cure, still have to avoid peanut and carry epinephrine	Desensitization only, not a cure - May reduce reaction severity and prevent reactions from an accidental peanut ingestion - Fewer people benefitted vs OIT - Because this is not a cure, still have to avoid peanut and carry epinephrine	No risk of side effects related to a treatment Neither a cure nor a treatment
Duration of therapy	Unknown, but presumed indefinitely	Unknown, but presumed indefinitely	Unknown, but presumed indefinitely
Chances of mild side effects (which can be treated)	- High, but improves with time - Most can be treated and therapy continued	- High, but improves with time - Most can be treated and therapy continued	No direct side effects from avoidance
Chances of moderate side effects	- Moderate to high - May require epinephrine, and may cause family to stop therapy	- Low - These rarely required epinephrine or cause a family to stop therapy	No direct side effects from avoidance
Chances of severe side effects	- Low - If occur, likely require epinephrine and may cause family to stop therapy	- Very low - If occur, likely require epinephrine and may cause family to stop therapy	No direct side effects from avoidance
Side Effect Duration	Likely improves after first year	Likely improves after first year	No direct side effects from avoidance
Cost	Requires some out of pocket copay beyond what insurance covers. There may be copay assistance.	Requires some out of pocket copay beyond what insurance covers. There may be copay assistance.	No additional costs beyond cost of medications, doctor visit, and food that either therapy would also have
What happens if we stop treatment	- Missing a dose or two each week likely has no effect. - Probably lose protection after not taking a dose for 7-14 days in a row	- Missing a patch or two each week likely has no effect. - Probably lose protection after not wearing a patch for 7-14 days in a row	If strict avoidance is not followed, there is a risk of reaction every time any amount of peanut is eaten

Knowledge Check & “What Matters to Me?”

	OIT	EPIT	Avoidance	Can't Decide
Which option has the <u>lowest</u> chance of side effects?	☐	☐	☐	☐
Which option has the <u>highest</u> chance of working?	☐	☐	☐	☐
Which option is <u>most convenient</u> for your lifestyle?	☐	☐	☐	☐
Which option has the <u>highest chance</u> of better quality of life?	☐	☐	☐	☐
Do you know enough about the benefits and side effects of each option?			☐ Yes	☐ No
Values				
Are you clear about which benefits and side effects matter most to you?			☐ Yes	☐ No
Support				
Do you have enough support and advice from others to make a choice?			☐ Yes	☐ No
Certainty				
Do you feel sure about the best choice for you?			☐ Yes	☐ No

Step 4: What are the next steps?

After reading the information about your choices of therapy between OIT, EPIT, and choosing neither option (i.e., continuing your current practice of avoidance and not starting a therapy):

What goals are you seeking?

What benefits do you think your child will experience?

What risks do you think you are willing to take for your child?

How do you hope your child's life will change?

My questions and concerns:

My decision: Start OIT ☐

Start EPIT ☐

Do nothing at this time ☐

Repository Text Material:

Figure E1: A Decision Aid for Patients and Caregivers for Considering Peanut Allergy Treatment Options

Treatment Options for Peanut Allergy: A Decision Aid for Patients and Caregivers

Making a choice to start a therapy to treat your child's peanut allergy is an important decision. **There are no wrong choices you can make.** It may be helpful to discuss these options with family and friends and show them this shared decision making (SDM) aid to assist you in reaching a decision.

This decision-aid should help you to talk with your Allergist about treatment options that are best for you and your family. You should ask any and all questions you may have and express what your concerns are to your doctor.

When you are ready to make a decision, call or schedule an appointment with your Allergist. If you choose one of the therapy options, your Allergist will go over the planned schedule for starting and for monitoring your child's progress.

The best choice is going to be the choice you feel most comfortable with, and will be able to stick with, without regret. Not choosing to start a therapy at this time is also a choice—these therapies could be started in the future as well.

Do not attempt to try any type of desensitization therapy at home without talking to your Allergist.

This decision aid is for you if:

- Your child has been diagnosed with peanut allergy by your Allergist or Primary Care Provider.
- You are curious about possible treatment options for your child's peanut allergy.
- You are concerned your peanut-allergic child is at high risk for an accidental reaction to peanut.

What is Peanut Allergy?

- People with peanut allergy can have severe reactions if they eat any food with peanut in it.
- This is considered a potentially severe, lifelong allergy, often discovered in early childhood. Fatal reactions are rare.
- According to the latest research, only 23 out of 100 kids will outgrow peanut allergy on their own.

How can you treat peanut allergy?

- While in the past, advice recommended strict avoidance as the only option to manage peanut allergy when necessary, two treatments are now available with the potential to lower your risk of a peanut reaction – to “desensitize” someone to be able to tolerate a small amount of accidental peanut exposure.
- At present, these therapies do NOT cure peanut allergy or allow your child to eat peanut when you or they want.
- **IMPORTANT: Even during treatment, and possibly still after, everyone with peanut allergy must strictly avoid peanuts in the diet, and carry an epinephrine auto-injector in the event of a life-threatening reaction.**

What are your options:

Avoidance	Peanut oral immunotherapy (OIT)	Peanut epicutaneous immunotherapy (EPIT)
• You choose for your child to continue to strictly avoid peanut and carry emergency medication at all times. • Continued communication and avoidance strategies can help prevent accidental ingestion • Quality of life may be poor and anxiety around situations where your child is exposed to peanut high, potentially, in some. • Only 23 in 100 kids outgrow peanut allergy on their own.	• You choose for your child to eat small, increasing amounts of peanut up to a certain target level, under the direction of your doctor. • After reaching their target level of peanut in OIT, your child must continue to eat this amount every day (called a maintenance dose) to remain desensitized, or this protection will disappear. • Therapy is associated with 3-fold higher risk of a severe reaction than from just avoiding peanut naturally	• You choose for your child to wear a patch coated with peanut on their skin. The patch dose does not change. In the beginning, the number of hours your child wears the patch increases from a few hours a day to all day/night. • The patch must be worn every day or this protection will disappear.

What may affect your choice of treatment (check all that apply and what you wish to discuss with your Allergist):

- A preference for a way that my child will actually take the therapy (e.g., by mouth vs. worn on the skin)
- A preference for the number of allergist visits that are required during the up dosing and maintenance phases
- A preference to avoid certain types of treatment-related side effects that may require epinephrine or other medications
- A preference for how quickly it will take the treatment to work
- A preference for how well the treatment will work and how much protection against peanut my child will have
- A preference for how often the treatment must be taken, and how long my child has to remain on treatment
- A preference for how much this treatment may cost me, out of pocket, beyond what my insurance will cover

Let's work through the key steps of making this decision.....

Step 1: What are the benefits and side effects of each treatment based on published research?

Benefits

After a year of therapy how much peanut can my child tolerate



A peanut pod contains 2 peanuts.
Each peanut is 300mg of protein.
Peanuts are also called kernels.

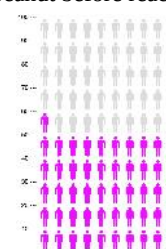
OIT

79 in 100 can tolerate 1 peanut



EPIT

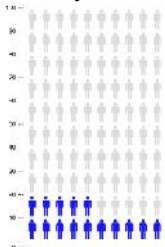
51 in 100 improved from <1/3 of a peanut to 1 peanut before reacting



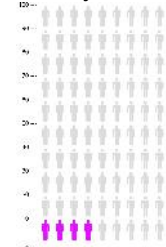
Risks and Side Effects

During the first year of therapy, how many children will have had a severe allergic reaction (a systemic reaction affecting multiple parts of the body) due to the therapy

15 in 100 will have a systemic allergic reaction

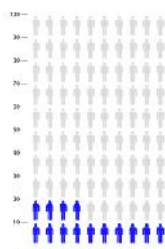


4 in 100 will have a systemic allergic reaction

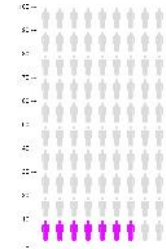


How many children will have to use epinephrine due to the treatment?

14 in 100 will need epinephrine due to the treatment itself

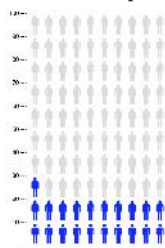


7 in 100 will need epinephrine due to the treatment itself

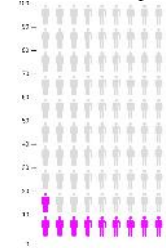


How many children will have to stop therapy before reaching their target goal where benefit begins

21 in 100 will stop therapy

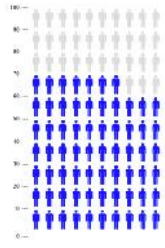


11 in 100 will stop therapy

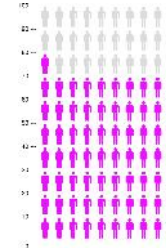


How many children will have skin side effects (rash, itching, etc.) due to treatment (apart from patch site issues)?

67 in 100 will have skin side effects

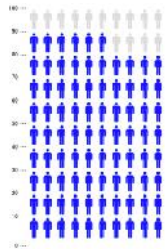


71 in 100 will have skin side effects

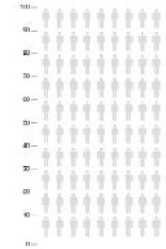


How many children will have Gastrointestinal (e.g. stomach) side effects (either a single or repeated episodes of stomach ache, nausea, vomiting) due to treatment?

86 in 100 will have GI side effects



0 in 100 will have GI side effects



Step 2: Clarifying what about treatment means the most to you:

Check ✓ how much each reason matters to you on a scale from 0 to 5. '0' means it is **not** important. '5' is **very** important.

Features of a particular treatment for your child	Not Important			Very Important		
How important is it to lower the risk of a severe reaction from eating peanut?	①	②	③	④	⑤	
How important is it to have a high level of protection vs. just enough against small accidental exposures?	①	②	③	④	⑤	
How important is it to avoid having to take epinephrine because of a treatment-related reaction?	①	②	③	④	⑤	
How important is it to avoid treatment where you have to actually eat peanut (by mouth)?	①	②	③	④	⑤	
How important is it if you have to not have to take some form of therapy every day	①	②	③	④	⑤	
How important is it to avoid frequent skin side effects (rash, hives, itching, eczema) due to treatment?	①	②	③	④	⑤	
How important is it to avoid frequent GI side effects (nausea, vomiting, pain) due to treatment?	①	②	③	④	⑤	
How important is it to avoid having frequent doctor visits to increase the daily dose of therapy?	①	②	③	④	⑤	
How important is it to avoid having a severe allergic reaction caused by the treatment itself?	①	②	③	④	⑤	
How important is it to have flexibility in when to take the treatment (not having to plan around meals, showering, exercise, illness, menstruation, or sleep schedule to prevent the risk of side effects)?	①	②	③	④	⑤	
How important is the amount of out of pocket treatment costs beyond what is covered by insurance?	①	②	③	④	⑤	
How important is a therapy where after treatment you still have to avoid peanut and carry epinephrine?	①	②	③	④	⑤	

Step 3: Is there any additional information about the treatments to help you with your decision?

Comparison of Options

	OIT (Paliforza)	EPIT (Viaskin Peanut)	Avoidance
What is this therapy and how is it taken	Every day, your child will eat small, increasing amounts of peanut up to a certain target level, under the direction of your doctor.	Every day, your child will wear a patch coated with peanut protein on the skin. The patch will be worn 24 hours per day every day.	Your child will continue to strictly avoid eating any amount of peanut
Time it takes for therapy to work	Around 6 months or less	Between 1-2 years	Indefinite
Target allergens	Peanut only	Peanut only	Avoid peanut
FDA Approved Ages	4-17y	4-11y	Any age
Number of Allergist visits on therapy	- Visits every 2 weeks to increase the dose until the top dose is reached (takes ~3-4 months) - Routine follow-up visits recommended to chart progress.	- No visits to increase the dose - Routine follow up visits recommended to chart progress.	Most see their allergist every year for routine follow up and testing
Risks	- Dose-related GI reactions such as stomach aches, nausea, and vomiting (~80%) - Eosinophilic esophagitis (~2.7%) - Systemic reactions from dose (~15%) - Increased risk of dose-related side effects if taken on empty stomach, when sick or menstruating, when tired, or too close to exercising or a hot shower (variable %)	- Skin rash and itching at patch site (71%) - Systemic reaction from patch (3.8%)	- Poor quality of life - Anxiety - Accidental reactions, which may or may not be severe 7% risk of anaphylaxis (baseline risk)
Benefits	Desensitization only, not a cure - May reduce reaction severity and prevent reactions from an accidental peanut ingestion - More people benefitted than EPIT - Because this is not a cure, still have to avoid peanut and carry epinephrine	Desensitization only, not a cure - May reduce reaction severity and prevent reactions from an accidental peanut ingestion - Fewer people benefitted vs OIT - Because this is not a cure, still have to avoid peanut and carry epinephrine	No risk of side effects related to a treatment Neither a cure nor a treatment
Duration of therapy	Unknown, but presumed indefinitely	Unknown, but presumed indefinitely	Unknown, but presumed indefinitely
Chances of mild side effects (which can be treated)	- High, but improves with time - Most can be treated and therapy continued	- High, but improves with time - Most can be treated and therapy continued	No direct side effects from avoidance
Chances of moderate side effects	- Moderate to high - May require epinephrine, and may cause family to stop therapy	- Low - These rarely required epinephrine or cause a family to stop therapy	No direct side effects from avoidance
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Side Effect Duration	Likely improves after first year	Likely improves after first year	No direct side effects from avoidance
Cost	Requires some out of pocket copay beyond what insurance covers. There may be copay assistance.	Requires some out of pocket copay beyond what insurance covers. There may be copay assistance.	No additional costs beyond cost of medications, doctor visit, and food that either therapy would also have
What happens if we stop treatment	- Missing a dose or two each week likely has no effect. - Probably lose protection after not taking a dose for 7-14 days in a row	- Missing a patch or two each week likely has no effect. - Probably lose protection after not wearing a patch for 7-14 days in a row	If strict avoidance is not followed, there is a risk of reaction every time any amount of peanut is eaten

Knowledge Check & “What Matters to Me?”

	OIT	EPIT	Avoidance	Can’t Decide
Which option has the <u>lowest</u> chance of side effects?	☐	☐	☐	☐
Which option has the <u>highest</u> chance of working?	☐	☐	☐	☐
Which option is <u>most convenient</u> for your lifestyle?	☐	☐	☐	☐
Which option has the <u>highest chance</u> of better quality of life?	☐	☐	☐	☐
Do you know enough about the benefits and side effects of each option?			☐ Yes	☐ No
Values Are you clear about which benefits and side effects matter most to you?			☐ Yes	☐ No
Support Do you have enough support and advice from others to make a choice?			☐ Yes	☐ No
Certainty Do you feel sure about the best choice for you?			☐ Yes	☐ No

Step 4: What are the next steps?

After reading the information about your choices of therapy between OIT, EPIT, and choosing neither option (i.e., continuing your current practice of avoidance and not starting a therapy):

What goals are you seeking?

What benefits do you think your child will experience?

What risks do you think you are willing to take for your child?

How do you hope your child’s life will change?

My questions and concerns:

My decision: Start OIT ☐ Start EPIT ☐ Do nothing at this time ☐

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