

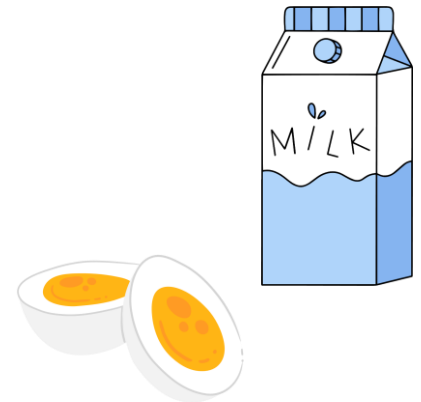
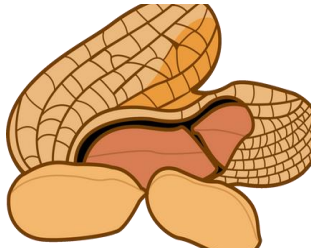
Oral Food Immunotherapy: What happens 5 and 10 years down the line?

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Learning objectives

Learning Objective 1:

The learner will be able to discuss long-term OIT options in terms of dose frequency and amount.

Learning Objective 2:

The learner will be able to describe alternative options to therapy.

Facts

- There are very limited data on long term OIT – both on outcomes and management approaches
- Many patients with food allergy have already entered the ‘long-term’ OIT phase
- Advice is very variable on long-term approach and no consensus currently exists

How do I advise my OIT patients on long-term management?

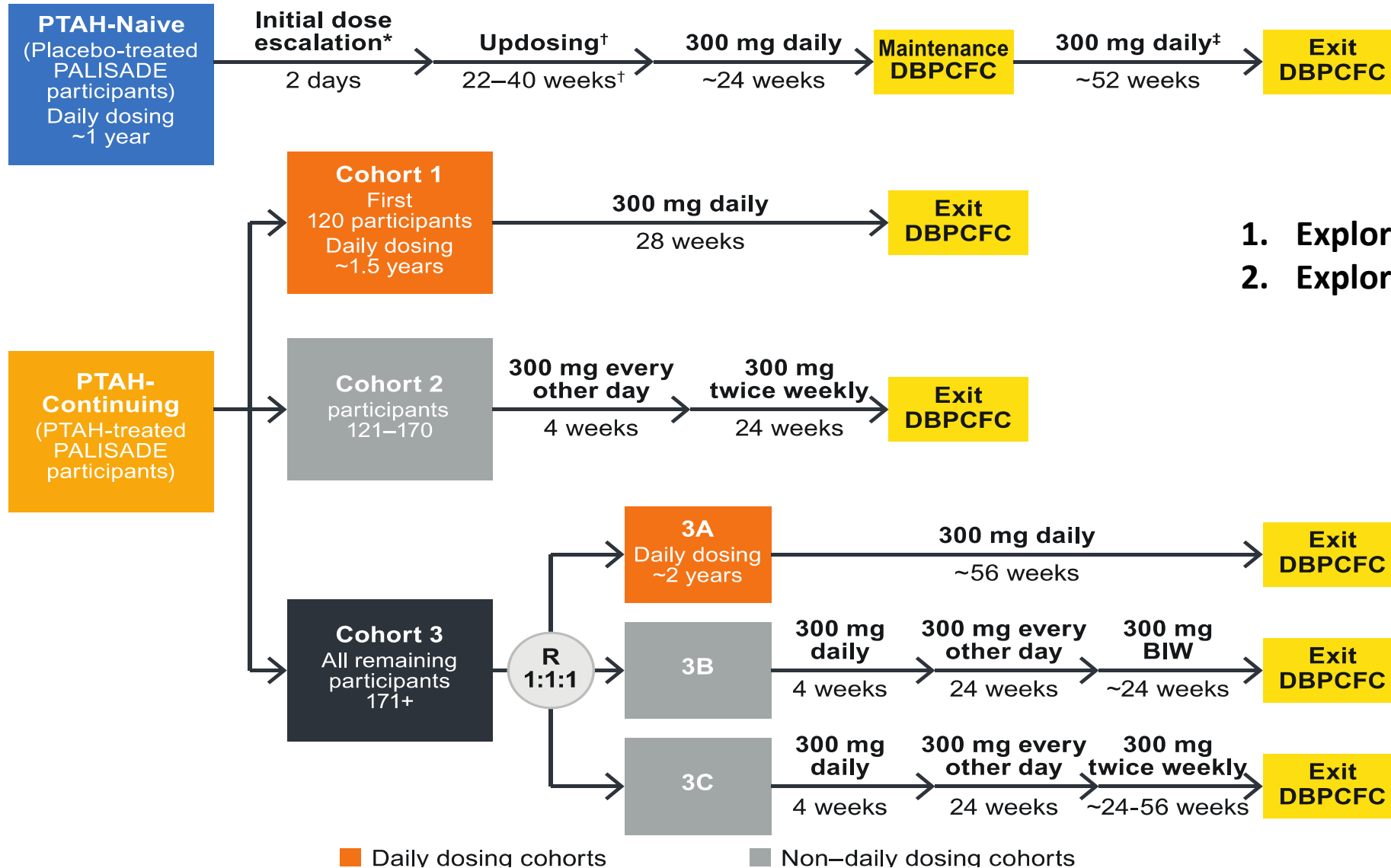
Dose

Frequency

Alternative therapies



Follow on open label study – ARC004



1. Explore treatment beyond 1st year
2. Explore alternative dosing regimens

Follow on open label study – ARC004

Characteristic	PTAH-Naive (n = 100) ~ 52 wk	Daily dosing cohorts		Non-daily dosing cohorts*		
		Cohort 1 (n = 109) ~ 28 wk	Cohort 3A (n = 31) ~ 56 wk	Cohort 2 (n = 46) ~ 28 wk	Cohort 3B* (n = 31) ~ 56 wk	Cohort 3C* (n = 34) ~ 56-84 wk
Median age (y) (range)	9.5 (5-17)	11 (5-17)	9 (5-17)	10 (4-17)	9 (5-16)	9 (5-16)
Sex: male, n (%)	65 (65.0)	57 (52.3)	17 (54.8)	25 (54.3)	19 (61.3)	18 (52.9)
No. of systemic allergic reactions due to peanut during lifetime, n (%)						
0	27 (27.0)	36 (33.0)	9 (29.0)	11 (23.9)	11 (35.5)	12 (35.3)
1	32 (32.0)	43 (39.4)	14 (45.2)	20 (43.5)	14 (45.2)	12 (35.3)
2	19 (19.0)	17 (15.6)	6 (19.4)	7 (15.2)	2 (6.5)	2 (5.9)
3	8 (8.0)	8 (7.3)	1 (3.2)	3 (6.5)	3 (9.7)	5 (14.7)
>3	13 (13.0)	5 (4.6)	1 (3.2)	5 (10.9)	1 (3.2)	3 (8.8)

Daily dosing was associated with lower rates of AEs and fewer severe systemic allergic reactions compared with non-daily dosing

Follow on open label study – ARC004

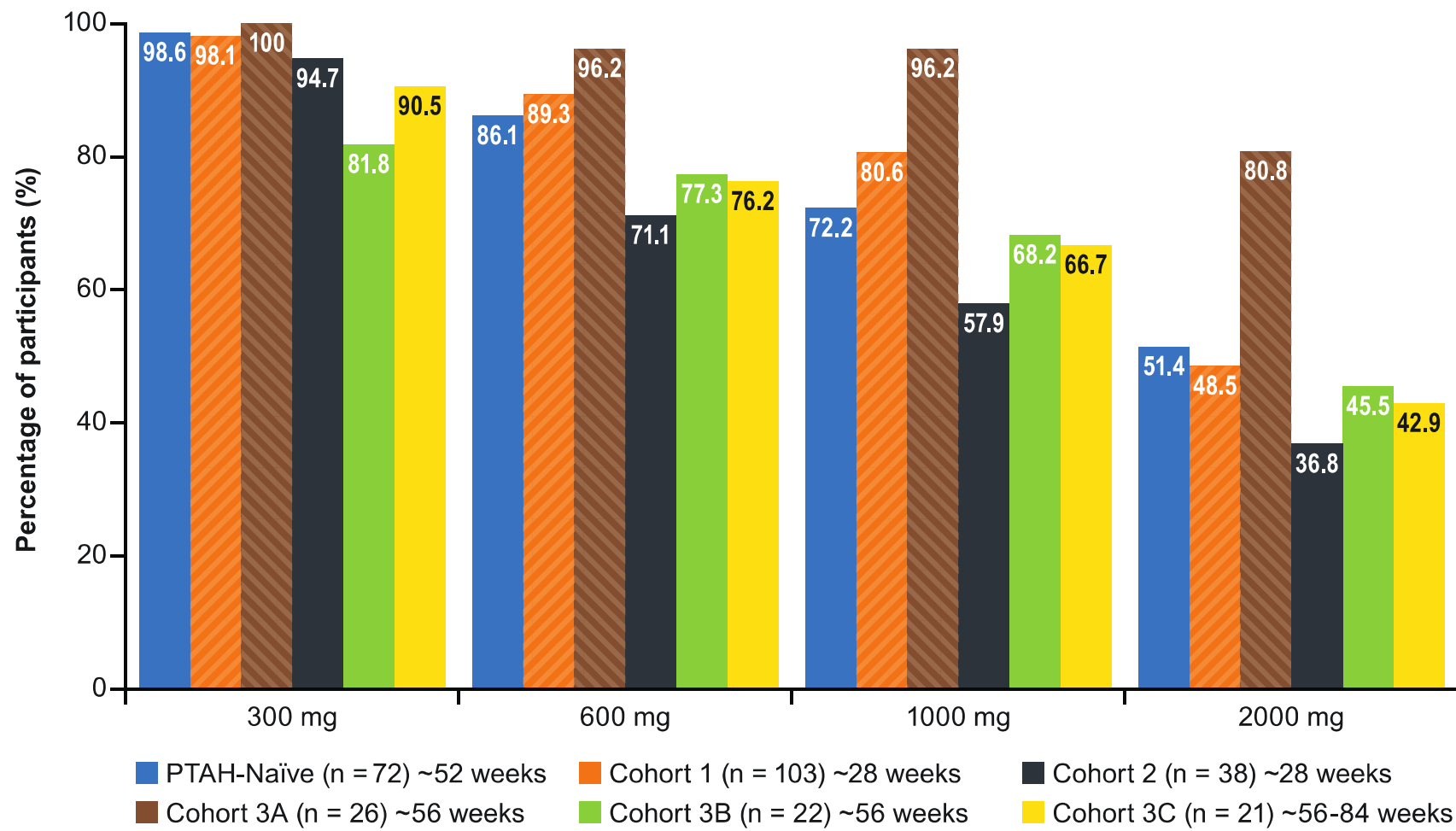


FIGURE 3. Desensitization rates based on the single highest tolerated dose at the exit DBPCFC (completer population; N = 282). Hatch marked bars indicate daily dosing cohorts.

Follow on open label study – ARC004

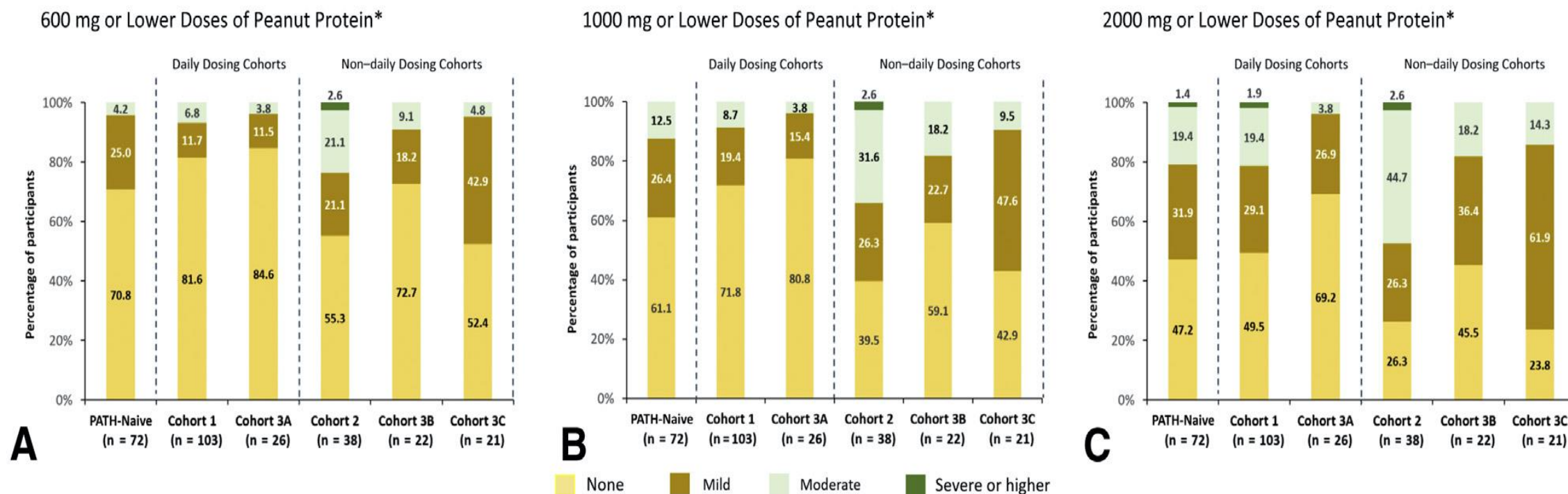


FIGURE E1. Maximum symptom severity at DBPCFC (completer population; N = 282) at peanut challenge doses of 600 mg or lower (**A**), 1000 mg or lower (**B**), and 2000 mg or lower (**C**). *The sum of the columns may be 99.9% or 100.1% due to rounding.

Peanut

145 peanut allergic patients
4 years old - >18 years old

77.9% were desensitized to 3000 mg.

Long-term maintenance: 3000mg vs 1200 mg

Followed up for 6 months or more.

100% vs 95.5% were successfully
re-challenged to 3000 mg.

**Adherence to treatment was
significantly higher in patients
consuming 1200 mg (96.1%) vs
those consuming 3000 mg (72.2%).**

**Low dose maintenance maintained
desensitization.**

PEANUT

Sustained outcomes in oral immunotherapy for peanut allergy (POISED study): a large, randomised, double-blind, placebo-controlled, phase 2 study

R Sharon Chinthrajah, Natasha Purington, Sandra Andorf, Andrew Long, Katherine L O'Laughlin, Shu Chen Lyu, Monali Manohar, Scott D Boyd, Robert Tibshirani, Holden Maecker, Marshall Plaut, Kaori Mukai, Mindy Tsai, Manisha Desai, Stephen J Galli*, Kari C Nadeau*

	Peanut-0 group (n=60)	Peanut-300 group (n=35)	OR (95% CI)	p value*
Passed DBPCFC to peanut				
Week 104 (desensitisation)	51/60 (85%)	29/35 (83%)	1.2 (0.3–4.1)	0.78
Week 117	21/60 (35%)	19/35 (54%)	0.5 (0.2–1.2)	0.086
Week 130	12/60 (20%)	15/35 (43%)	0.3 (0.1–0.9)	0.021
Week 143	9/60 (15%)	13/35 (37%)	0.3 (0.1–0.9)	0.022
Week 156	8/60 (13%)	13/35 (37%)	0.4 (0.1–0.8)	0.010
Complete build-up phase to 4000 mg peanut with only mild symptoms†	15/60 (25%)	12/35 (34%)	0.6 (0.3–1.6)	0.35
Complete build-up and maintenance phases (to peanut) with only mild symptoms†	13/60 (22%)	11/35 (31%)	0.6 (0.2–1.5)	0.33
Inability to tolerate at least 1000 mg peanut	9/60 (15%)	6/35 (17%)	1.2 (0.3–4.1)	0.78

Data are n/N (%). OR=odds ratio. DBPCFC=double-blind placebo-controlled food challenge. *Fisher's exact test. †Mild symptoms are adverse events with Common Terminology Criteria for Adverse Events grade 1.

Table 3: Efficacy outcomes for major secondary endpoints (peanut-0 versus peanut-300)

Peanut OIT can desensitize individuals with peanut allergy to 4000 mg peanut protein but discontinuation, or even reduction to 300 mg daily, could increase the likelihood of regaining clinical reactivity to peanut.

Case 1

- 7 year old boy with egg allergy
- Started OIT at age 9 months after 'failed early introduction'
- Currently eats egg ad lib (up to 1 egg daily), eats egg most days and enjoys the taste
- No reported allergic reactions
- Previously had eczema, which has now resolved
- SPT (egg white): 2 mm (was 14 mm before start of egg OIT)

Case 1

Parents want to know:

- Does he still need to carry epinephrine?
- Has the egg allergy gone away?

Consider discussing:

- Oral Food Challenge
- Assessment for Remission
 - Alternative therapies
- Alternative epinephrine routes

Case 2

- 16 year old girl with peanut allergy
- On year 6 of maintenance POIT
- Dislikes taste, but takes dose every day
- Complains about 2-hour activity limitation
- Excellent volleyball player - wants to play volleyball in college team
- Has had 2 previous episodes of anaphylaxis during maintenance year 1 and 3, when exercising soon after the dose
- Has no allergic co-morbidities
- SPT (peanut): 5 mm (was 36 mm before POIT start)

Case 2

Patient asks:

- How will I be consistent with my peanut dose taking during tournaments and frequent practice sessions?
- How likely is it I will have further episodes of anaphylaxis?
- How many days in a row can I skip my dose and still be safe?
- How much do I need to eat every day to stay safe?

Consider discussing:

- Dose frequency
- Low dose versus high dose OIT
- External factors and anaphylaxis
 - Alternative therapies
- Alternative epinephrine routes

Case 3

- 21 year old boy with cashew, peanut and milk allergy
- On maintenance multi-food OIT since 12 y.o.
- SPT: cashew 6mm, peanut 4mm, milk 5mm
- Adherence to daily dosing has been suboptimal
- Reports mild oral itching after missing doses and resuming OIT
- Dislikes taste of OIT doses
- Has moderate persistent asthma, well controlled

Case 3

Patient asks:

- How will I be consistent with my peanut dose taking during work shifts?
- How many days in a row can I skip my dose and still be safe?
- How much do I need to eat every day to stay safe?
- What happens if I stop?

Consider discussing:

- Dose frequency
 - Low dose versus high dose OIT
- What happens if OIT is discontinued
 - Alternative therapies
- Alternative epinephrine routes

Step 1: 'Let's discuss this together'

key points:

- Two-way communication between patient and physician
- Need to listen actively to patients



Step 2: 'Let's examine your options'

key points:

- Benefits and risks for different options
- Available choices and alternatives

Step 3: 'Time to make a decision if you are ready'

key point:

- Reaching the right decision for each individual patient, based on their goals, preferences and values



SUMMARY

- There is no consensus on long-term OIT approaches and management varies widely.
- Shared decision-making is key in finding the right approach for each individual patient
 - No 'one size fits all' approach

THANK YOU FOR LISTENING!

