

# Current Management and Use of Oral Immunotherapy for Peanut Allergy Across Western Europe

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## Background

- Food allergies are a significant and growing health problem; peanut allergies affect 0.5-1.4% of children in high income countries; currently, there are no approved curative therapies for food allergies; in Europe, in particular, peanut allergy is a major health burden, affecting 4.4 million people
- Treatment of peanut allergy is largely limited to avoidance and management of acute reactions; peanut oral immunotherapy (OIT) remains experimental as there is no approved product available for use and most treatment guidelines do not support OIT as standard of care
- As a consequence, selection of patients for peanut OIT, OIT practices, and protocols are experimental, largely unproven, and vary significantly across western Europe

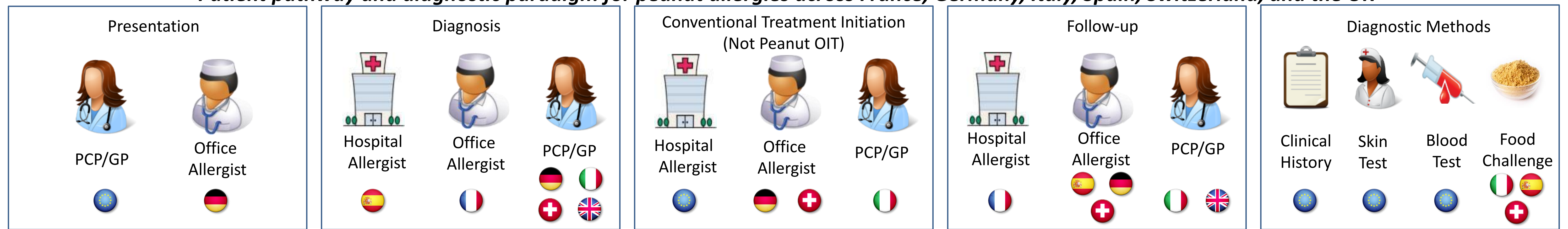
## Methods

- 90 in-depth, qualitative, one-hour interviews were conducted via telephone with physician allergists, physician GPs and paediatricians with an allergy specialty, and nurse food allergy specialists across six countries (France, Germany, Italy, Spain, Switzerland, and the UK) between September 2016 and February 2017
- Eligibility criteria included managing >100 unique peanut allergy patients per year and offering Immunotherapy (including subcutaneous, sublingual, or oral immunotherapy) to allergy patients
- Quotas were set to ensure that both food OIT-experienced and food OIT-naïve physicians and nurses were interviewed, as well as both academic-based and community-based respondents.
- In total, 39 of 75 interviewed physicians have offered peanut OIT to their patients at some point; the results pertaining to administration of peanut OIT and sample protocols are representative of these 39 physicians

		Physicians	Nurses
France		15	6
Germany		14	4
Italy		17	N/A
Spain		13	2
Switzerland		8	N/A
United Kingdom		8	3
<b>TOTAL</b>		<b>75</b>	<b>15</b>

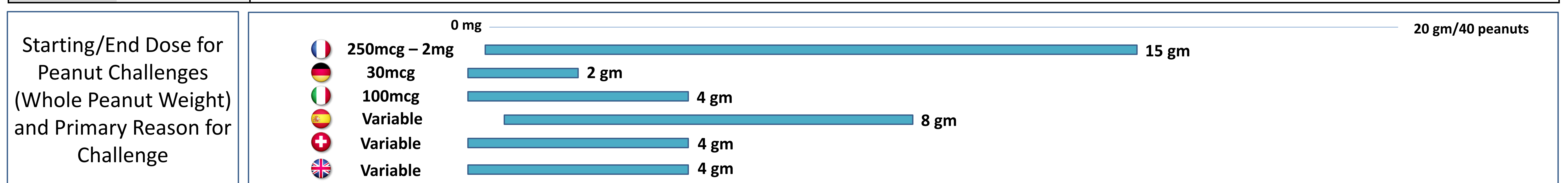
## Results

### Patient pathway and diagnostic paradigm for peanut allergies across France, Germany, Italy, Spain, Switzerland, and the UK



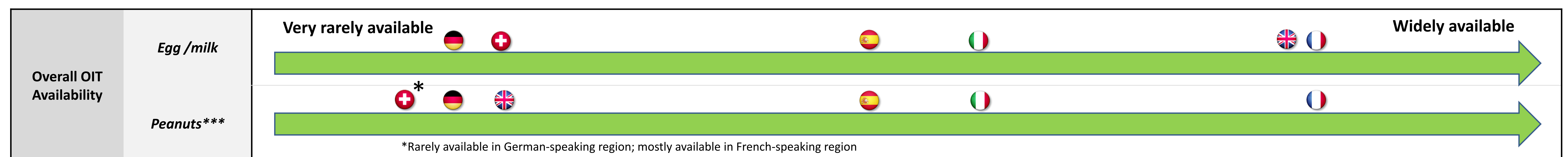
Note: Variations exist; flags represent the most common pathway

		France	Germany	Italy	Spain	Switzerland	UK
Peanut Challenge	Availability	Academic Hospitals	Academic Hospitals	Widespread	Widespread	Widespread	Widespread
	Utility	Prior to initiation of OIT	Clarify inconclusive diagnosis	Clarify inconclusive diagnosis	Clarify inconclusive diagnosis	Clarify inconclusive diagnosis	Confirmation of diagnosis
	Frequency	OIT patients only	1-5% of patients	20% of patients	~10-15% of patients	~5% of patients	2-5% of patients
	Observation Time	4-5 hours observation	4-5 hours observation	4-5 hours observation	3-4 hours observation	4-5 hours observation	2-4 hours observation



### Administration of Peanut OIT

- Inclusion and exclusion criteria for peanut OIT are fairly consistent across markets; inclusion criteria include highly motivated patients, impaired quality of life (defined by the burden associated with avoiding peanuts), and age >3-5 years old; exclusion criteria include uncontrolled asthma, near-fatal anaphylaxis, or suboptimal family circumstances which are likely to impact compliance
- However, stark differences exist regarding the administration of experimental peanut oral immunotherapy
  - Use of OIT for peanut allergies is not approved by the EMA or any national medicines agency; still, a few physicians have developed and use experimental peanut OIT protocols
  - These protocols vary substantially in terms of peanut material, start and end doses, up-dosing intervals, and clinician oversight during up-dosing



Country	Practice Type	OIT Material***	Start Dose (Whole Peanut Weight)	End Dose (Whole Peanut Weight)	Time Interval Between Up-doses	Total Time of Up-dosing	Maintenance Dose (Whole Peanut Weight)
	Hospital	Crushed peanuts or peanut candy	1/10 of dose reacted to in food challenge per day	600mg	1 month	6 months	600mg
	Hospital	Crushed peanuts or peanut candy	1/10 of dose reacted to in food challenge (once every 3 days)	200mg	1 month	6 months	200mg (once reaching maintenance dose, gradually move to daily dose)
	Office	Crushed peanuts in capsules provided by a pharmacist	0.5 mg/day	1 g	2 weeks (no maintenance at home)	Varies (up-dose ~15x)	None
	Office	Crushed peanuts in capsules	0.1 mg/day	800 mg	2 weeks	6 months	2 peanuts / day
	Office	Crushed peanuts provided by physician	Small crumbs each day	1-2 peanuts	2 weeks	6 weeks	None
	Hospital	Peanut flour in capsules	~ 2 mg/day	800 mg	2 weeks	Varies	None
	Hospital	Crushed peanuts, weighed and packed in capsules in-house	~10 mg/day	500 mg	2 weeks	6-7 months	1 peanut per day
	Office	Crushed peanuts in capsules	~10 mg/day	500 mg	Variable	~2 years	500 mg
	Hospital	Crushed peanuts	0.2-0.5mg/day (depending on patient age)	200mg	3 weeks	3 months	200mg
	Hospital	Peanut flour or crushed peanuts	30mg/day	3g	1 week	2-4 months	Equal to last visit dose
	Hospital	Crushed peanuts	0.625mg/day	12.5mg	2 days	37 days	10 peanuts
	Hospital	Peanut administered in liquid solution	1mg/day	800mg	2 weeks	6 months	800mg
	Hospital	Peanut flour in capsule	2mg/day	800mg/day	2 weeks	6 months	800mg/day

\*French-speaking region of Switzerland

\*\*All OIT in Germany is performed as part of clinical trials

\*\*\*Unless otherwise specified, peanut refers to whole peanuts rather than peanut protein

Note: with the exception of one protocol in Germany, OIT maintenance is done at home

## Conclusions

- Substantial variability in the approach to experimental peanut OIT exists within and across European countries
- Differing practices lead to uncertain and widely variable tolerability levels
- Amongst physicians not offering peanut OIT, major barriers include the lack of an EMA-approved therapy, standardized protocols, and national guidelines

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