Preparing Families for OIT: Components of Consent

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Disclosures

- No relevant disclosures

Learning Objectives

- Be able to discuss the components of informed consent
- Be able to describe the process by which an approach to informed onsent for oral immunotherapy for food allergy was developed using a Delphi process
- Be able to apply the information in the article *"Preparing Patients for Oral Immunotherapy (PPOINT): International Delphi Consensus for Procedural Preparation and Consent" Mack DP, et al. J Allergy Clin Immunol. 2024 Jun;153:1621-1633. doi: 10.1016/j.jaci.2024.02.019. PMID: 38597862.*

Consent Is a Process, Not a Form

- Patients (families) must be fully educated about the procedure or treatment
  - Problem to be solved
  - Definition of success
  - Likelihood of achieving success
  - Risk of adverse events, immediate and long term
  - Burden of care
  - Alternatives
- There must be an opportunity to digest the information and ask questions

Shared Decision-Making

- Healthcare team educates the patient (family)
- The patient (family) explains relevant issues to the healthcare team
  - Their understanding of the clinical problem
  - Their view of the therapeutic options
  - Relevant clinical information about the patient
    - Co-morbid conditions
    - Concerns (fears/anxieties) about the clinical problem and the potential therapies
    - Relevant financial, social, cultural information
- The healthcare team leader makes a recommendation
- The patient (family) makes an informed decision

Preparing Patients for Oral Immunotherapy (PPOINT): International Delphi consensus for procedural preparation and consent

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Mack DP, et al. J Allergy Clin Immunol. 2024 Jun;153:1621-1633. doi: 10.1016/j.jaci.2024.02.019. PMID: 38597862.

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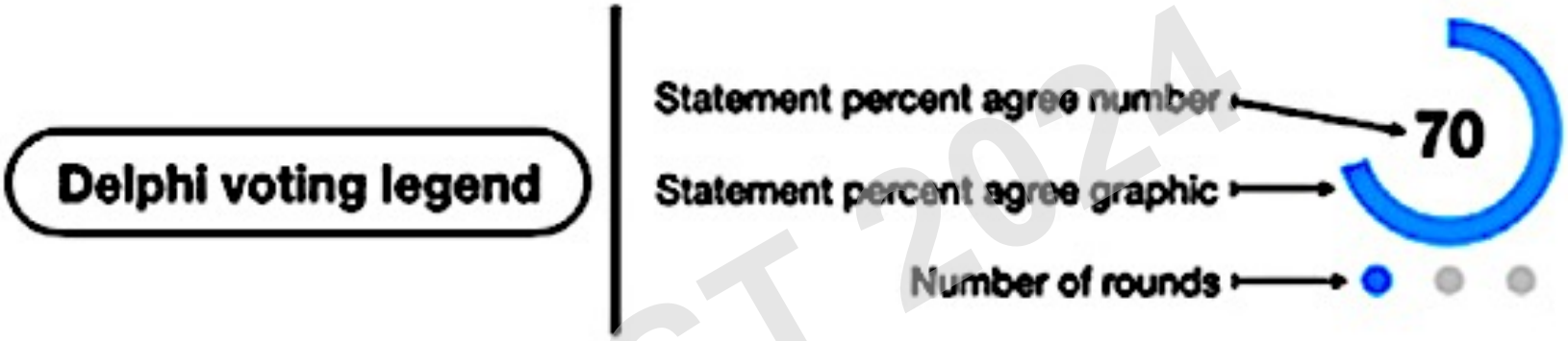
Methodology – Statement Development

- A panel of 36 allergy experts from 10 countries was convened between October 2021 and July 2023
  - Panelists were selected based on clinical experience and publication history
- OIT-related statements were solicited from the panel yielding 322 statements
- Statements were sorted into four procedural themes and nine consent themes
- A writing group edited, compiled, and sorted the statements into themes
- The statements and themes were iteratively refined by the panel
  - Similar statements were combined
  - Ambiguous statements were split to improve clarity
  - Irrelevant statements were deleted
- The statements were then subject to a modified Delphi process

The Delphi Process

- Anonymous REDcap survey
- Panelists voted on each statement
  - 1 strongly disagree, 2 disagree, 3 neutral, 4 agree, 5 strongly agree, or not applicable
  - Strongly disagree and disagree were grouped
  - Strongly agree and agree were grouped
  - Anonymous free text comments were encouraged
- Consensus was defined as 75% agreement
- Statements that did not achieve consensus were reworded
- Total of three rounds of voting
  - 265 statements achieved consensus for inclusion
  - 9 statements reached consensus for exclusion
  - 49 did not meet consensus
- Contraindications were then subject to another round of voting on absolute or relative contraindication

Reporting the Results



Example

General Considerations for Counseling

ISSUE	AGREEMENT
Discuss natural history of food allergy without OIT	100%
Detailed discussion of the steps involved in OIT	97.2%
OFC for diagnosis prior to OIT should be prioritized	88.9%
Patient/caregivers' goals should be prioritized	97.2%
Robust education of patient and all caregivers	100%
All caregivers must understand the process/precautions	100%
OIT is not a cure	88.9%
OIT may be disease modifying	91.7%
OIT dosing may be lifelong	94.4%

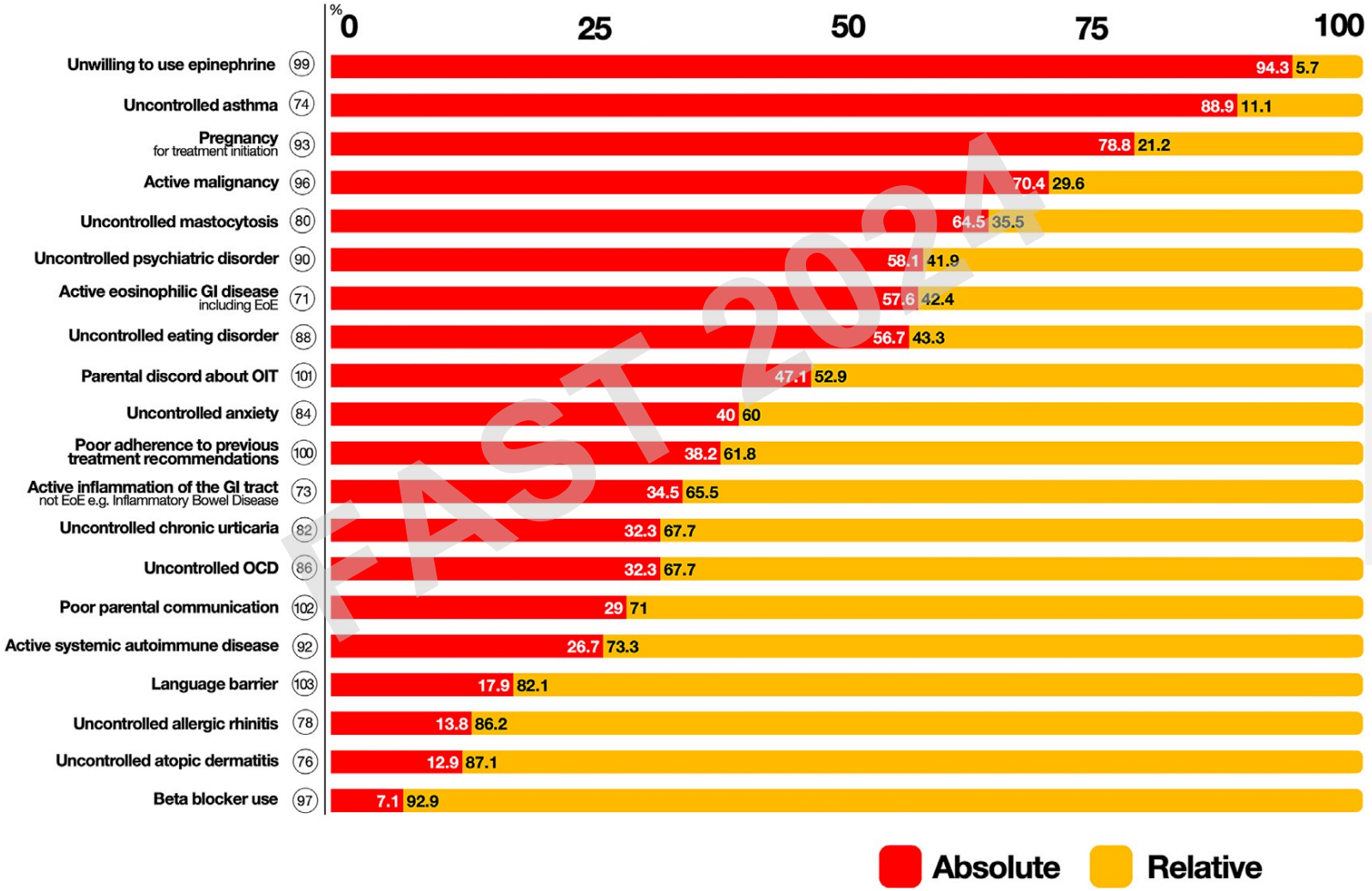
Patient and Family Specific Factors

ISSUE	AGREEMENT
Co-morbid atopic diatheses should be well controlled	
Asthma	100%
Allergic rhinitis	86.1
Atopic dermatitis	91.7
Chronic urticaria	94.4
Baseline GI symptoms should be evaluated and treated	91.7
Address OIT-related anxiety and provide counseling, if appropriate	94.4%
Availability of adult supervision for home dosing	100%
Ability to comply with safe dosing rules, especially activity restriction	100%
Separated or divorced parents must agree on the therapy	86.1%

Indications for Initiating OIT

ISSUE	AGREEMENT
Age <18 years	77.1%
Age 1-4 years	83.3%
Age 4-17 years	88.9%
Age >18 years	No consensus
Multiple food allergies	77.1%
Food allergies unlikely to be outgrown spontaneously	91.7%
Food allergies likely to be outgrown spontaneously	No consensus
Impaired QoL because of reaction anxiety	80.0%
Impaired nutrition	80.6%
Previous anaphylaxis	80.6%
Unsuccessful food avoidance	75%

Absolute and Relative Contraindications for OIT



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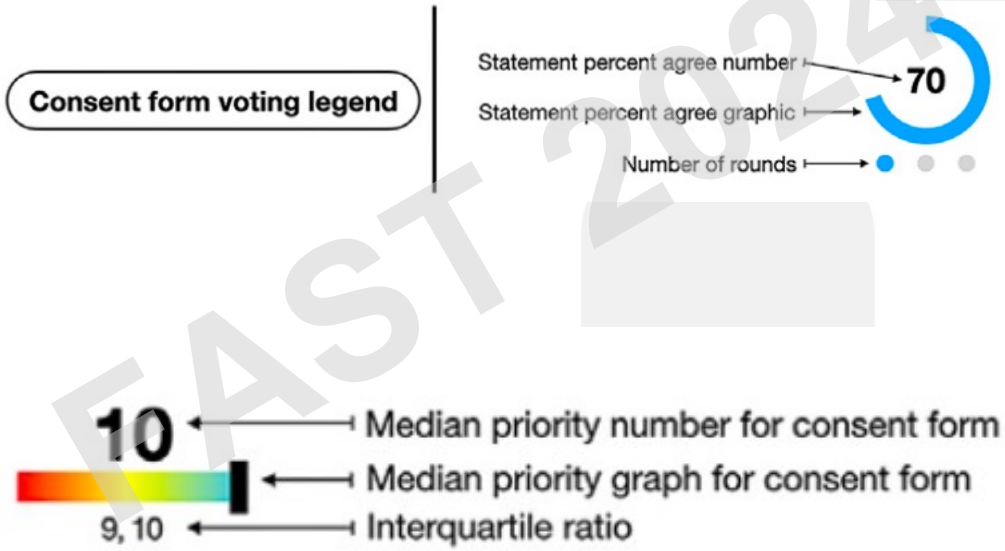
Inclusion in a Consent Form

- Statements that reached consensus were subject to an additional round of voting on inclusion in a written consent form
- Statements were scored on a 10-point scale
  - 0 not important, 5 neutral, 10 very important, not applicable
  - Results reported as the median plus interquartile range
- Statements achieving a median greater than 9 were included in a customizable sample consent form

Voting on Inclusion in the Written Consent Form



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Consent Form Elements: Potential Benefits

- Lower risks of reaction on accidental exposure
- Less severe reaction on accidental exposure
- Increase threshold required to elicit a reaction
- Ingestion of foods despite precautionary allergen label

Consent Form Elements: Potential Risks

- Oral itch
- Abdominal pain
- Mild allergic reaction such as rash or hives
- Anaphylaxis
- Rarely, fatal allergic reactions
- Reactions in clinic or at home
- Reactions may occur at any time although they are less likely on maintenance
- Epinephrine may be needed for an allergic reaction
- Eosinophilic GI disorders may occur
- EoE responsive to dose reduction may occur

Risk Mitigation Strategies to Include in Consent

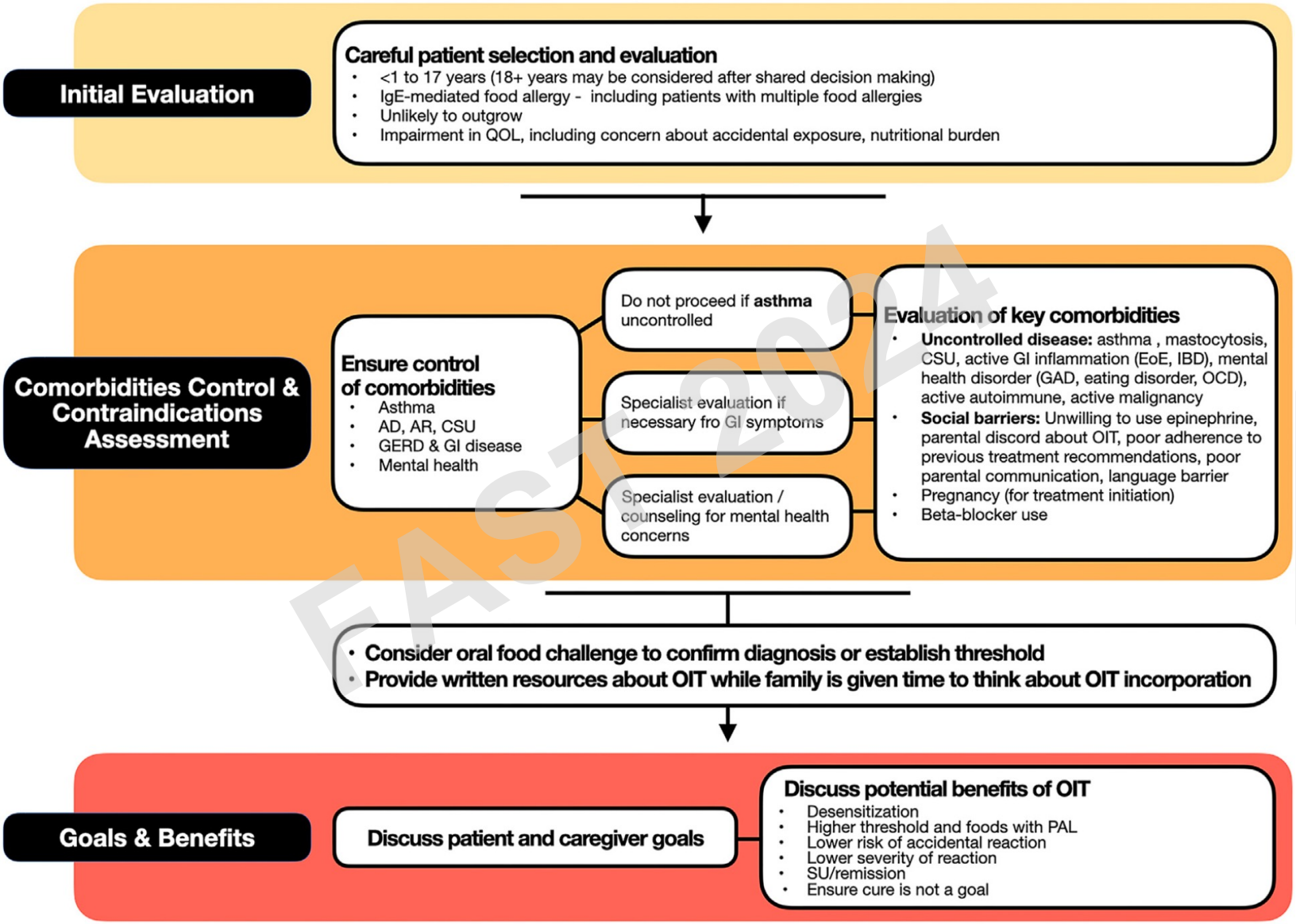
- Dosing errors may cause reactions so care must be taken to administer the correct dose
- An adult should supervise dosing administration
- There should be no active infection or signs of illness at the time of dosing
- Doses should be reduced or deferred if the patient is febrile, during an asthma exacerbation, during a vomiting illness, or for dental work
- Avoid exercise before and soon after dosing
- Avoid alcohol, NSAIDs, and hot showers or baths before or soon after dosing
- Avoid dosing while sleep deprived
- Female patients might be at increased risk for reaction during menses

Medical Reasons to Discontinue OIT Listed in the Consent

- Recurrent systemic reactions despite adherence to precautions
- Medical team judges the balance of reactions is too high
- Recurrent abdominal symptoms
- Confirmed eosinophilic esophagitis
- Eosinophilic GI symptoms that do not resolve with management
- Uncontrolled asthma
- Development of another medical condition that is a contraindication for OIT

Social/Behavioral Reasons to Discontinue OIT Listed in the Consent

- Failure to adhere to the protocol
- Failure to adhere to the safety precautions
- Epinephrine not administered when indicated despite appropriate training and education
- Side effects not reported
- Family refuses to treat asthma despite physician recommendation
- Patient requests to stop treatment
- Medical team feels it is in the best interest of the patient to stop treatment



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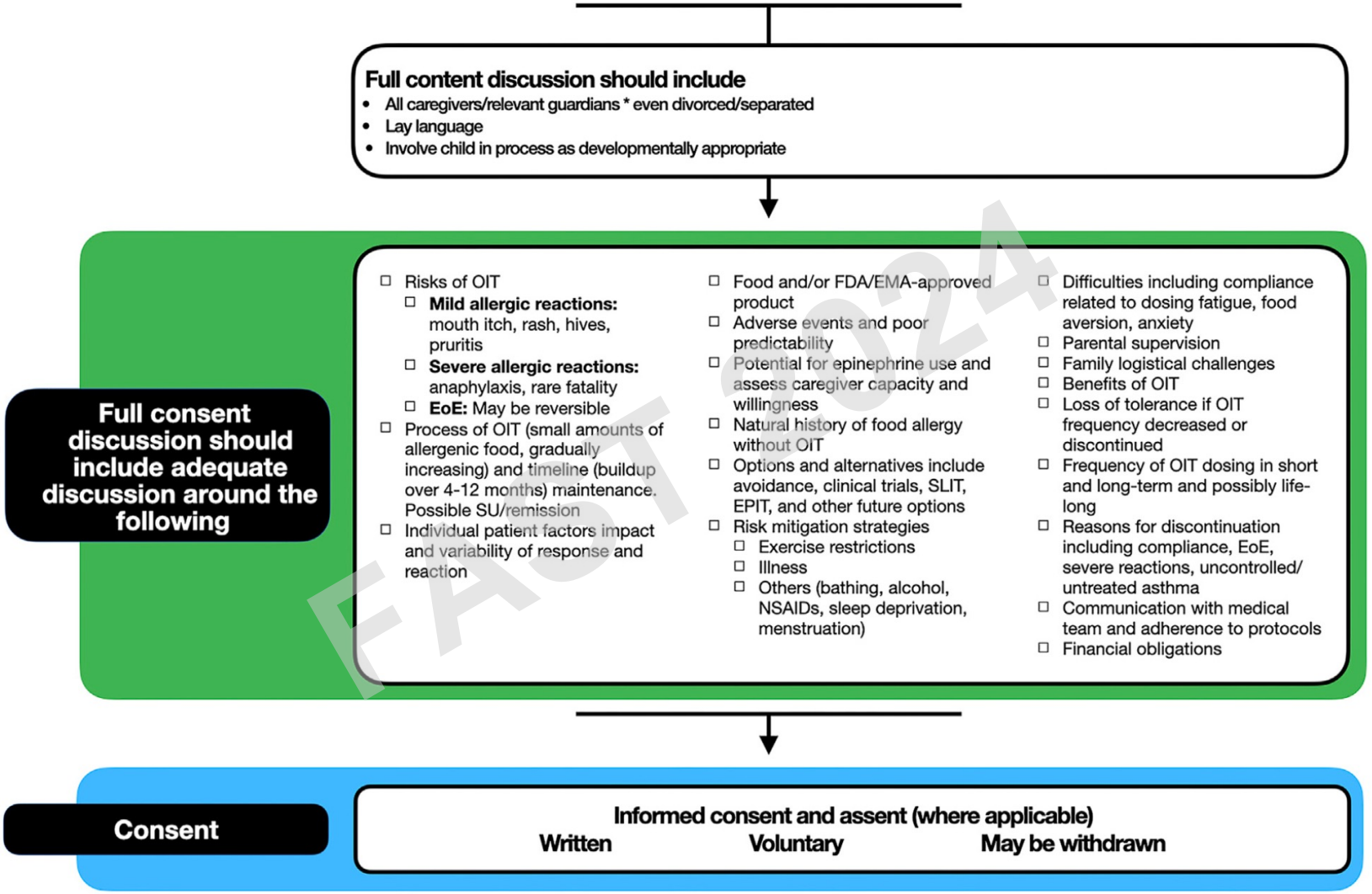

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17. Do you think that risk mitigation strategies belong in the consent form?

ⓘ Start presenting to display the poll results on this slide.

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18. Do you agree that refusal to use epinephrine when indicated is a reason to discontinue OIT?

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19. Do you agree that the risk of death should be included in the consent form?

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