



The Canadian Society of Allergy and Clinical Immunology
La Société canadienne d'allergie et immunologie clinique

BSACI
Improving Allergy Care
through education, training and research

The Canadian Society of Allergy and Clinical Immunology (CSACI) and British Society of Allergy and Clinical Immunology (BSACI), along with members of the allergy community, are deeply saddened by news of the tragic death in May 2021 of a young girl with longstanding cow's milk allergy and asthma.

This statement is not meant to address what happened in that tragic situation, the details of which remain largely unknown. Rather, this statement is intended to address more broadly the subject of home dosing with food allergens, whether in the specific context of a food ladder or in the general context of food immunotherapy.

Food immunotherapy and milk/egg ladders are valid management options for food allergy as long as key considerations are met:

- They must be supervised and administered by a trained and experienced healthcare provider with the necessary expertise and experience in food allergy and anaphylaxis management, the performance of oral food challenges, and the careful selection of patients for food immunotherapy.
- A proper medical clinic set-up for food immunotherapy should mirror that which is required for oral challenges. This includes procedures for assessing whether patients are well enough on their appointment day to receive build-up doses, proper preparation and administration of the food item(s) by well-trained and experienced staff, layered close nursing and/or medical supervision for the patient, a management plan for reactions including having appropriate resuscitation equipment available, and an adequate post-feeding patient observation period.
- Informed consent must be obtained prior to initiation of food immunotherapy, and the documentation should set out in detail the risks and benefits of food immunotherapy, and confirm that these risks and benefits were clearly explained to and understood by the patient or caregiver. This practice should be extended to those on milk/egg ladders or taking regular full servings of baked milk/egg.
- A comprehensive plan should be established that includes protocols and procedures for home dosing between office visits and assessment of effectiveness of the therapy after a period of maintenance dosing (i.e. follow-up oral challenges).
- **With regards to careful patient selection, the following factors are paramount:**
 - asthma must be optimally controlled prior to and throughout the food immunotherapy process, with protocols in place when control deteriorates, such as during asthma exacerbations
 - coexisting atopic and other medical conditions must be well controlled
 - the family must be willing, able, and ready to recognize and treat allergic reactions, including using self-injectable epinephrine properly and in a timely manner
 - the family must understand conditions under which the food dose should not be taken, and when to contact the prescriber for further guidance related to dosing
 - adherence is essential, including ladder-based approaches to food immunotherapy
 - many are not appropriate candidates for food immunotherapy for reasons including, but not limited to:
 - extremely low threshold for reactions,
 - inadequately controlled asthma or other atopic conditions,
 - reluctance to using epinephrine promptly, and

- psychosocial factors, such as a history of poor adherence to prior therapy of one or more atopic conditions, unreliability for follow up, and language and other barriers to understanding the protocol and all other factors related to successful treatment
- Whether to choose milk/egg ladders or milk/egg oral immunotherapy (OIT) depends on the likelihood of resolution (“outgrowing”) versus persistence of milk/egg allergy. Specifically, baked milk/egg ladders are intended for use in low-risk cases with resolving food allergies. OIT, in contrast, is indicated where milk/egg allergy is more likely to persist, such as in older children (e.g. usually beyond 5 years old) and those with prior history of severe anaphylaxis to milk/egg or high milk/egg sIgE levels. As such, OIT is associated with a higher risk of allergic reactions, including potentially life-threatening anaphylaxis.
- The baked milk/egg ladder presupposes that in the early phases of reintroduction, the patient receives a low-dose of well-cooked milk or egg protein as a minor ingredient in baked goods. Caution should be exercised with certain types of baked goods (i.e. muffins, loaves, cakes) where cooking may be uneven in the centre, potentially exposing the patient to considerably higher doses of less well-cooked milk or egg than intended, thereby predisposing them to a higher risk of potentially life-threatening allergic reactions.

Milk/egg ladders and milk/egg OIT are to be contrasted with the approach of challenging a milk/egg allergic patient to full age-appropriate servings of baked milk/egg, followed by regular (e.g. daily) ingestion of full servings of baked milk/egg. With this approach, there is no “build-up” process as tolerance of a full serving of baked milk/egg is a prerequisite.

When patients are carefully selected by practitioners with the necessary experience in conducting oral challenges and food immunotherapy, the risks of food immunotherapy are not excessive, nor do they exceed the risks involved with providing other commonly available forms of non-food-allergen immunotherapy (i.e. subcutaneous immunotherapy injections for aeroallergens also carry a risk of severe and rarely fatal reaction). Also, the risk of a fatal reaction with food immunotherapy does not exceed the risk of a fatal reaction with avoidance. Knowing these risks as a provider and discussing these risks with every patient considering food immunotherapy, along with the potential benefits, is essential.

As clinicians, we must continually remind ourselves of the significance of proper patient selection, education, and supervision, and of putting sufficient office and home protocols in place to enable us to continue providing food immunotherapy to eligible patients in the safest and most effective manner possible.

References:

1. Pajno GB, Fernandez-Rivas M, Arasi S, et al. EAACI Guidelines on allergen immunotherapy: IgE mediated food allergy. *Allergy*. 2018;73(4):799-815. doi:10.1111/all.13319
2. Bégin P, Chan ES, Kim H, et al. CSACI guidelines for the ethical, evidence-based and patient-oriented clinical practice of oral immunotherapy in IgE-mediated food allergy. *Allergy Asthma Clin Immunol*. 2020;16(1):20. doi:10.1186/s13223-020-0413-7
3. Mehr S, Turner PJ, Joshi P, et al. Safety and clinical predictors of reacting to extensively heated cow's milk challenge in cow's milk-allergic children. *Ann Allergy Asthma Immunol*. 2014 Oct;113(4):425-9. doi:10.1016/j.anai.2014.06.023

4. Wasserman RL, Factor J, Windom HH, et al. An Approach to the Office-Based Practice of Food Oral Immunotherapy. *J Allergy Clin Immunol Pract*. 2021 May;9(5):1826-1838.e8. doi: 10.1016/j.jaip.2021.02.046
5. Chomyn A, Chan ES, Yeung J, et al. Canadian food ladders for dietary advancement in children with IgE-mediated allergy to milk and/or egg. *Allergy Asthma Clin Immunol*. 2021 Aug 5;17(1):83. doi: 10.1186/s13223-021-00583-w

Distributed by:

**The Canadian Society of Allergy and Clinical Immunology /
La Société canadienne d'allergie et immunologie clinique**

207 Bank St., Suite 406

Ottawa, ON K2P 2N2

CANADA

Tel: (613) 265-7571

E-mail: info@csaci.ca