# Toward a National Food Allergy Strategy
# "The Gaps Story"

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# Disclosures

**Name: Dr Susan Waserman**

**I have the following financial relationship to disclose:**

- **Consultant for:** AZ, GSK, Merck, Takeda Canada, Pfizer Canada, Novartis, CSL Behring, Paladin, Sanofi, Shire
- **Honoraria from:** All of the above
- **Employee of:** McMaster University

**- AND -**

- **I will not discuss off label use and/or investigational use of any pharmaceutical in my presentation.**

# Canadian Milestones

- Sabrina's Law first of its kind legislation for schools worldwide
- Increased public support
- Improvements to food labelling (2012)
- Wider array of food choices for allergic consumers
- Greater collaboration within allergy community
- Allergy-aware travel policy (e.g. WestJet/EpiPen)
- Increased investment in allergy research
  - AllerGen (Allergy, Genes and Environment Network)

# Challenges in the Management of Food Allergy and Anaphylaxis

# Challenges

- There has been a definition of anaphylaxis only recently (2006)
- Food allergy is a main cause, however:
  - The diagnosis is not always straightforward
    - Many are sensitized to foods-who is truly allergic?
  - Many food allergies are lifelong
    - Do we always identify those who have outgrown?

# Challenges

- We don't know how to prevent food allergy
  - Avoidance does not generally work
  - Learning Early About Peanut (LEAP) study: Early exposure to peanut(PN) in high risk infants (4-11 months of age) is associated with less PN allergy
  - Still no informed advice on when and how to introduce other allergenic foods

# Challenges

**Only known treatments are:**

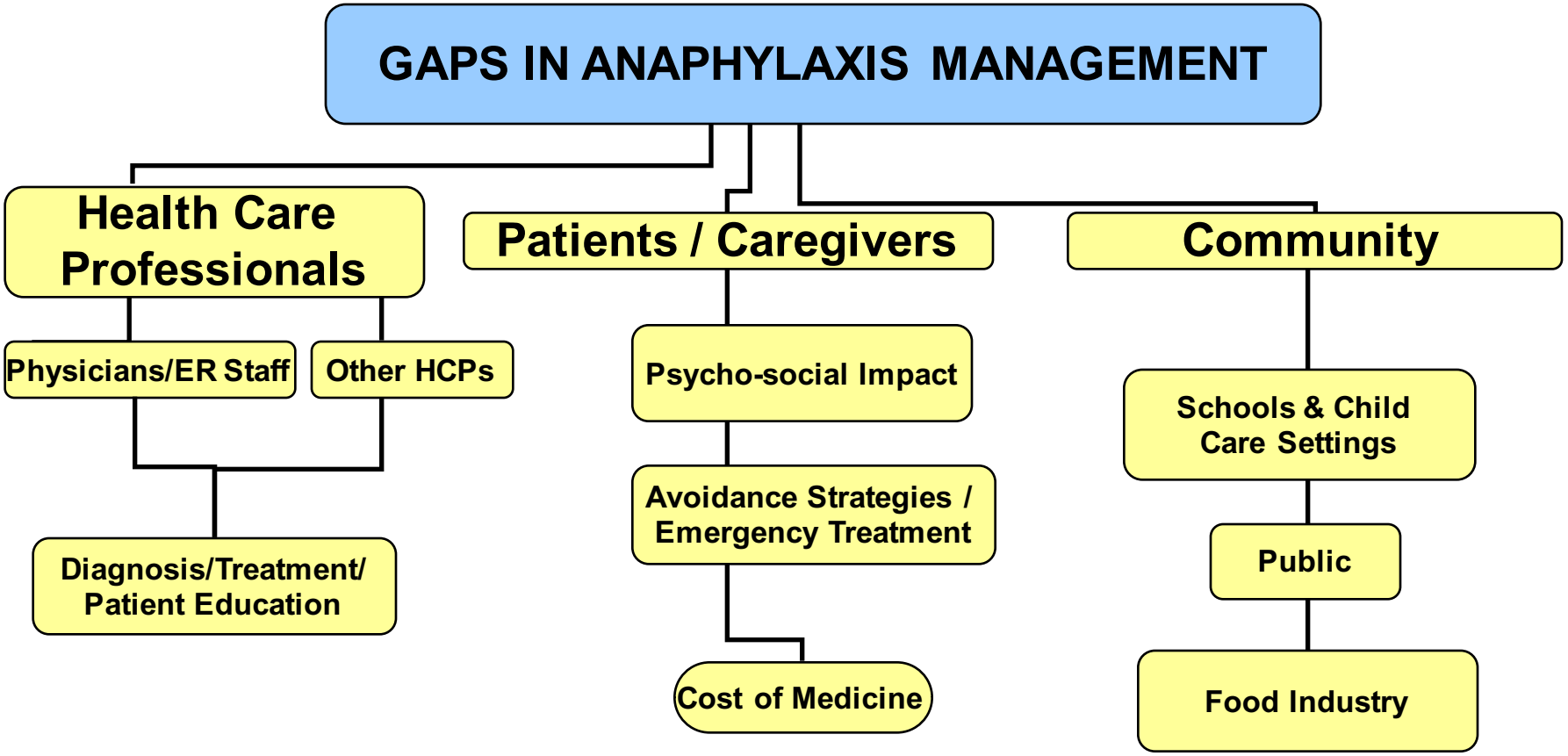
- Avoidance:
  - patients do not receive correct/sufficient information
  - health care professionals lack time/information
  - high rate of accidental exposure
- Epinephrine Auto injectors (EAI):
  - Under-prescribed
  - Underutilized
- Pathophysiology not completely understood, hence there are no treatments which are ready for prime time

# Challenges

**QOL issues:**

- High rate of anxiety in patient, families, caregivers and community
- Patients attempts at coping (control of the environment, food bans) have led to significant backlash in the media/ community
- Encroachment on the practice of Allergy
  - Approval by the BC government for an increased scope of allergy practice for naturopaths

# Where are the gaps?



# Systematic review
# Gaps in anaphylaxis management

**Methods**

•Studies were identified (up to August 2008)

**Results**

•Of 5014 potentially relevant articles, 59 studies were included

•Gaps in anaphylaxis management were organized according to 3 major outcome categories

- Physicians
- Patients
- Schools/Communities

Kastner et al. *Allergy* 2010

# Systematic Review Physicians

**Results:**

**3 main themes:**

- Insufficient **Knowledge** to:
  - Identify signs and symptoms or correctly diagnose
  - Use EAI correctly (dose and route of administration)
  - Provide EAI training to patient
- **Treatment** with epinephrine and diagnostic coding of anaphylaxis in ED
  - Infrequent or delayed use of epinephrine in acute allergic reactions
- **Follow-up** care:
  - Low prescription of EAI (antihistamines and steroids more often)
  - Lack of referral to an allergy specialist
  - No action plan, or food avoidance education

Kastner et al. *Allergy* 2010

# Systematic Review
# Patients

**Results:**

- Don't fill EAI prescription from ED (affordability, need)
- If they fill, don't carry it
- Many don't know how to use EAI correctly
- Are unaware of allergen avoidance
- Have trouble coping-public misunderstanding, inconsistent medical information, mislabeled foods

Kastner et al. *Allergy* 2010

# Systematic Review Schools/Communities

**Results:**

- EAI are insufficiently available at schools and child care centers
- Lack of organized training on EAI use and no anaphylaxis action plans

Kastner et al. *Allergy* 2010

# Addressing the GAPS

# Physicians

# The Referral and Epinephrine Auto-injector prescribing Clinical Tool (REACT) study

# Objectives

- To determine if the REACT tool can facilitate:
  - Appropriate referral to an Allergist
  - Prescription of EAI
- To investigate the usability of the REACT tool

# Methods

- **STEP 1:** Allergy experts developed REACT prototype
- **STEP 2:** Focus Groups (3) conducted with Family physicians and feedback incorporated
- **STEP 3: Usability Study**
  - 100 Family Physicians
  - REACT Tool APP applied to 18 evidence-based clinical vignettes (online)

- **Monitor**
- **Collect data**
- **Analysis**

**Primary Outcomes:**

- Appropriate use of the REACT tool applied to vignettes to arrive at answer which conforms to clinical practice guidelines

**Secondary Outcomes:**

- Ease of use
- Feasibility of using REACT in practice
- Intention to use REACT in practice
- Satisfaction with the design

| **Persons at-risk for anaphylaxis are those who have any of the following:** | **Refer to Allergist** | **Prescribe Epinephrine Auto-injector** | **Symptoms & Risk factors** | |
|---|---|---|---|---|
| | | | **Rapid onset of Systemic Symptoms** | **Additional High Risk Factors** |
| ☐ **Any** rapid onset systemic allergic reaction or diffuse hives to **ANY Food or Stings** | ✓ | ✓ | ☐ Mouth: Itching, swelling of lips/tongue<br>☐ Throat: Itching, tightness, closure, hoarseness<br>☐ Skin: Itching, hives, eczema, swelling, flushing<br>☐ Gut: Vomiting, diarrhea, abdominal pain<br>☐ Lung: Shortness of breath, cough, wheeze<br>☐ Heart: Hypotension, dizziness, syncope, tachycardia<br>☐ Neuro (or head): Lightheadedness<br>☐ Other: Feeling of impending doom, anxiety | ☐ Previous need for epinephrine or hospitalization<br>☐ Repeated reactions to the suspected food<br>☐ Symptoms caused by minute quantities of allergenic foods<br>☐ Age (teens and young adults)<br>☐ Allergic reaction with exercise<br>☐ Significant medical conditions (e.g., asthma, cardiovascular disease) |
| **OR…** | | | | |
| ☐ **Any** rapid onset reaction *(minutes to hours)* of any severity *(even if mild)* to the **HIGHEST RISK Foods**:<br>• Milk<br>• Peanut<br>• Tree nuts<br>• Fish<br>• Shellfish<br>• Sesame<br>• Egg | ✓ | ✓ | | |
| ☐ None of the above | | | | |

***Are you uncertain?***

☐ ***No***

☐ ***Yes, then***

1. Refer patient to an allergist for evaluation, and prescribe epinephrine auto-injector
2. Read the **Symptoms & Risks** *(see Table to the right)*

# ED Care Plan

# Improving anaphylaxis management in ED

## Objective:

- To assess the efficiency of an updated protocol to improve medical performance in a PED in a tertiary hospital

## Methods:

- Before/after comparative study of children aged < 14 years diagnosed with anaphylaxis in the PED

*Arroabarren, Pediatric Allergy Immunol 2011*

# Improving anaphylaxis management in ED

**Results:**

•With the protocol, significant increases were observed pre protocol and post protocol in:

- Epinephrine administration (27% vs 58%)
- Prescription of EAI (6.7% vs 55%)
- The number of admissions

•Reductions were observed:

- The use of corticosteroid monotherapy (29% vs 3%)
- In patients D/C with no follow-up instructions (69% vs 22%)

**Conclusion:**

•The anaphylaxis protocol improved physicians' skills to manage this emergency in the PEU

# TWH/McMaster

- Care plan instituted at TWH ED in June 2014
- Any patient who presented to ED with a presumed allergic reaction/anaphylaxis was referred to Allergy (facilitated by AAISO)
- 26 patients seen over this time
  - Medications
  - Idiopathic
  - Food
- McMaster Children's Hospital

# Patients

# Newly Diagnosed (within12 mos) Study - Patient Concerns

- Long wait time for allergist referral
- Lack of / limited post-diagnosis information, e.g. avoidance strategies, EAI, dealing with anxiety
- Lack of / limited knowledge of anaphylaxis by first response MD and the ED
- Most made lifestyle accommodations (restaurants, work, travel) in response
- 85% indicated they would participate in education program after a first reaction

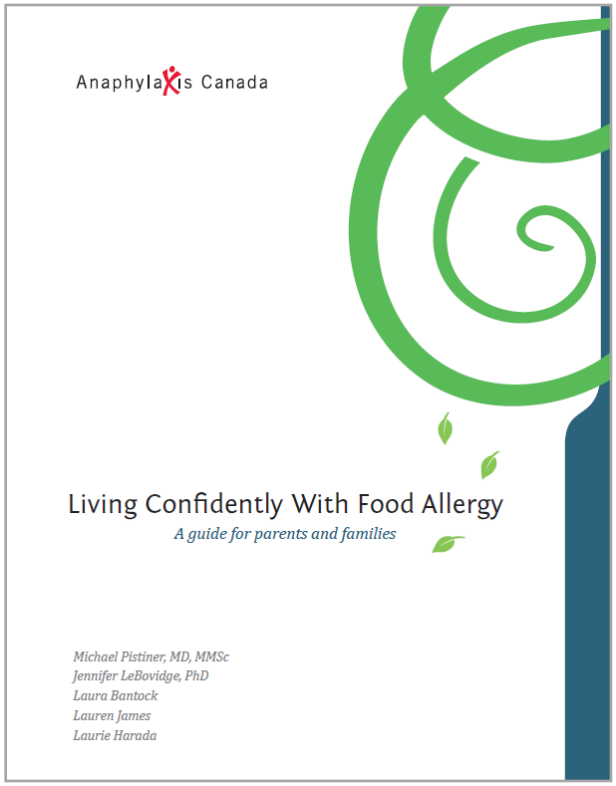
Abdurrahman et al. Allergy, Asthma & Clinical Immunology 2013

# Handbook Developed For Parents of the Newly Diagnosed

- To provide information/support
- Free webinars and resources
- Workshops

**Parents wait 6 months and longer for their child to see an allergist. Without proper information, support and guidance from time of diagnosis, their child is at risk of an allergic reaction. Anxiety for both parent and child often increases.**

# *Living Confidently* Handbook

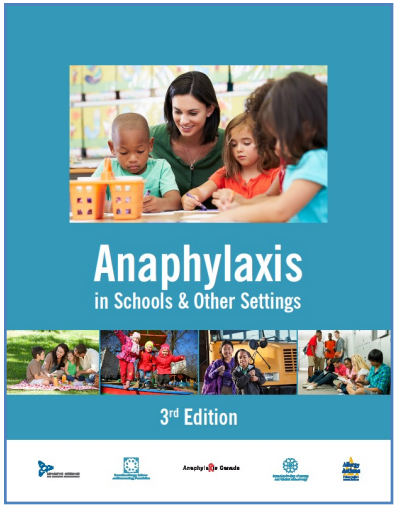



- A **free**, reliable resource to supplement physician management of food allergy
  - Information to improve food allergy knowledge and QOL
  - Evidence based content
  - Simple language
- Written by Anaphylaxis Canada staff in collaboration with Boston pediatric allergist, psychologist, and reviewed by Canadian allergists
- Study shows parental improvement in knowledge, QOL, and confidence levels
- Manuscript submitted

# Schools

# Community Guidelines

- Third update on Anaphylaxis in Schools and Other settings
- Anaphylaxis Canada was the original project lead:
  - Worked with CSACI and other allergy groups
- Guidelines used by schools and others as foundation for anaphylaxis education
- Reviewed by 19 national and provincial associations





**Available for free on www.anaphylaxis.ca / other websites**

# Policy at School

- The OHRC is updating its policy and guidelines on disability and the duty to accommodate
- Anaphylaxis is a “non evident disability”
- Roundtable June 22 2015 with the OHRC, allergists, and Anaphylaxis Canada to gather information
- Meetings with key stakeholders (educators, parents etc) to follow

# Communities

# Stock Epinephrine/Food Service

# Objectives

- To understand how “stock” EAI can be best implemented in food service outlets/restaurants/malls

- To implement a pilot study that will provide EAI access to trained security guards and senior restaurant management staff in Hamilton, Ontario

# Accidental Reactions More Likely to Occur Outside the Home

**Dining Experience:**

- Data from US reveals that over 50% deaths were associated with eating in restaurants or other food establishments
- In Ontario, 30% experienced an allergic reaction while dining out (Anaphylaxis Canada)
- Death of a 12 year old in a Burlington food court in 2013

# PHASE 1:
# Surveys

- **Restaurant Personnel/ Mall personnel/Security guards**
  - Knowledge of food allergy and anaphylaxis, level of comfort with providing meals to food-allergic consumers
  - **In-progress**
- **Food-allergic Consumers:**
  - Frequency of accidental ingestion, dining practices/challenges
  - **1581 survey responses**

# PHASE 2: Development/Planning

- Education and Training of security and food service
  - In-person training: (Food Allergen Training Program)
    - Food allergy/anaphylaxis
    - Treatment
      - EAI
      - Emergency response plan
- Clear roles and responsibilities for mall administration, security guards and stand-alone restaurants
- Procedure for critical incident reporting

# PHASE 3:
# Use of Stock Epi

*Food-consumer:*

- Demographic characteristics
- Did consumers get information they needed?
- Were consumers more willing to eat out?

*EAIs:*

- How many times was the EAI taken out of its emergency toolkit?
- How many times was EAI used?
- Description of critical incidents
- Patient outcomes

***KT Implications***

# GLOBAL EPINEPHRINE STUDY

# Rationale

- Rising prevalence of life-threatening allergy
- Delay or failure to give epinephrine is a factor in anaphylaxis fatalities
- Wide variations in reported access to EAIs reported by patients, and now emerging economies

# Global Epi Study Phases

- **1a. Allergy Association Survey**
  Understand Allergy Associations' perspective on the availability/use of epinephrine
  - Pilot project: June 2015

- **1b. Anaphylaxis Emergency Plans**
  Review plans from different countries

- **2. Consumer Survey**

# Impact of Socioeconomics on Access

- Families with lower incomes:
  - Less likely to fill prescriptions
  - Tend to carry expired product

- In Ontario, Canada:
  - Children at schools with >20% low-income households were less likely to have EAI at school than those with <20% low income (7.5% vs 16.3%)

Dunn et al. American Journal of Medicine. 2014; 127:S45-S50.

# Global review of epinephrine availability and anaphylaxis management practices as reported by patient organization countries

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**Ruchi Gupta MD MPH, Northwestern University, US**
**Antonella Muraro, MD PhD, University Hospital of Padua, Italy**
**Mary Jane Marchisotto (US)**
**Laurie Harada (Canada)**
**Frans Timmermans (Netherlands)**
**Patricia Carmelo (Chile)**
**Monika Kastner, PhD (Health Research Methodologist, University of Toronto)**
**Elizabeth Yeboah, MD (Research Fellow, McMaster)**
**Ernie Avilla, (Health Care Analyst, McMaster)**

**"Global Epi Study"**

# Phase 1

- 12 countries participated in Allergy Association Pilot Survey

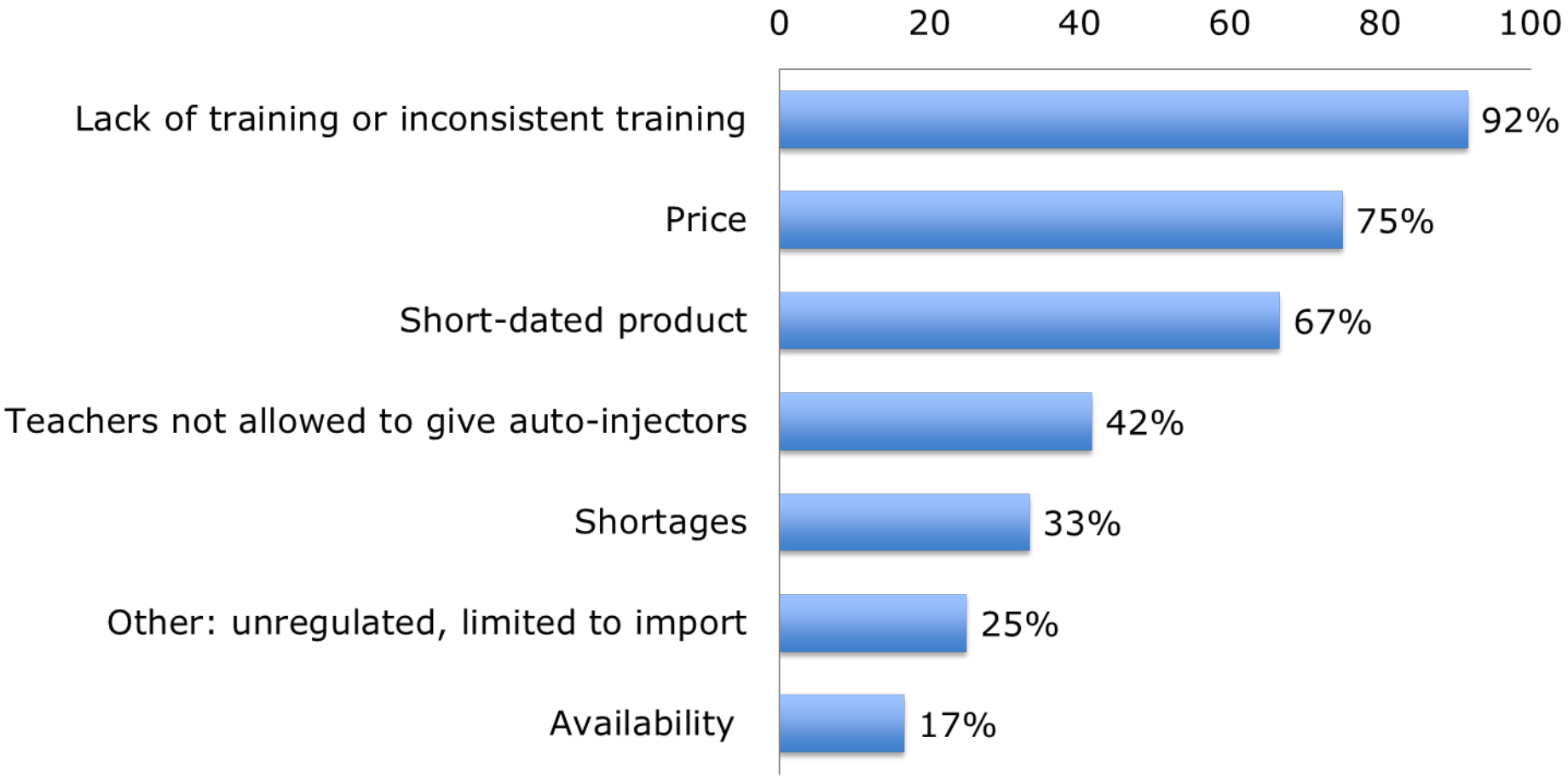
# EAI availability/cost

| Auto-injector | | Countries w/ access to both doses (Unsubsidized Cost reported $USD) | |
|---|---|---|---|
| **Allerject** |  | Canada ($96) | |
| **Auvi-Q** |  | United States ($475) | |
| **Emerade** |  | Germany ($133) / United Kingdom ($43) | |
| **EpiPen** |  | Australia ($90)<br>Canada ($96)<br>Hong Kong ($117)<br>Netherlands ($54)<br>New Zealand ($107) | South Africa ($73)<br>Qatar ($45)<br>United Kingdom ($40)<br>United States ($475) |
| **Fastjekt (i.e. EpiPen)** |  | Germany ($109) / Italy ($88) | |
| **Jext** |  | Germany ($109)<br>Italy ($83) | Netherlands ($54)<br>United Kingdom ($36) |

# Who pays for the EAI?

| | |
|---|---|
| **Government** | Qatar |
| **Patient** | New Zealand |
| **Patient & Government** | Italy, UK |
| **Patient & Private** | Chile, Hong Kong |
| **Patient, Private & Government** | Australia, Canada, Germany USA, South Africa, Netherlands |

# Major challenges



# Comments

Australia: Prescribing guidelines:

- The first EAI must be prescribed by an allergist, pediatrician, or emergency physician after seeing patient in ER
- Family physicians can only do first prescription if allergy referral pending
- Standard anaphylaxis action plan in all schools

# Prevention/Treatment

# LEAP Trial

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 26, 2015 VOL. 372 NO. 9

## Randomized Trial of Peanut Consumption in Infants at Risk for Peanut Allergy

George Du Toit, M.B., B.Ch., Graham Roberts, D.M., Peter H. Sayre, M.D., Ph.D., Henry T. Bahnson, M.P.H., Suzana Radulovic, M.D., Alexandra F. Santos, M.D., Helen A. Brough, M.B., B.S., Deborah Phippard, Ph.D., Monica Basting, M.A., Mary Feeney, M.Sc., R.D., Victor Turcanu, M.D., Ph.D., Michelle L. Sever, M.S.P.H., Ph.D., Margarita Gomez Lorenzo, M.D., Marshall Plaut, M.D., and Gideon Lack, M.B., B.Ch., for the LEAP Study Team*

# Treatment

- Peanut oral immunotherapy (OIT)
  - PN OIT for children 5-10 yrs
- Canadian Peanut Threshold Study
  - To define amount of PN at which people start to experience allergic symptoms
- Peanut patch-3 Canadian sites
- Any food allergy strategy needs to advocate for food allergy dollars!

# Conclusions

- There are many gaps at all levels in food allergy and anaphylaxis management
- There are few fatalities so we must be doing something right, but there is still significant morbidity and effects on quality of life
- Informed, consistent, messaging, a *strategy* is needed, with the understanding that
- *This is a complex issue, and one size may not fit all!*

# QUESTIONS?