

To stock or not to stock? Implementation of epinephrine autoinjectors in food establishments

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Clinical Implications

- More than 50% of anaphylaxis fatalities occur when food is consumed outside the home. Individuals forget to carry their epinephrine autoinjector (EAI) or do not have an EAI available at the time of a reaction. We identified factors to inform guidance recommendations for the use of stock epinephrine.

TO THE EDITOR:

The majority of first reactions to foods occur at home (37% to 46%).^{1,2} However, subsequent accidental reactions are more likely to occur outside of the home. In the United States, more than 50% of food-related anaphylaxis fatalities occur at restaurants or other food establishments such as ice cream shops, fast-food areas, and mall food courts.³ Optimizing anaphylaxis management in food establishments is a challenge. Food service personnel lack knowledge and training about food allergies; food-allergic individuals are often reluctant to disclose their allergies to restaurants, and either fail to carry or use their epinephrine autoinjector (EAI).^{4,5} We implemented a Stock Epinephrine Program (SEP) between September 2014 and March 2016 to better understand food allergy management in food service establishments at a food court in a mall in Hamilton, Ontario, Canada.

The SEP comprised a process whereby trained security guards carried 2 EAI doses (0.3 mg and 0.15 mg) in secured first-aid kit(s) located in the central administration office(s) within the mall. In 2 stand-alone, owner-operated restaurants at the mall, trained staff had access to 2 EAI doses in a central location (eg, behind the counter) with emergency backup in secured first-aid kit(s) located in a central office. Each site was required to identify a site leader(s), develop an anaphylaxis emergency response plan, participate in a 3-hour training session, and determine the most appropriate location for the EAI devices. Our study methods are described in this article's Online Repository at www.jaci-inpractice.org. Briefly, we administered surveys to evaluate the dining-out experiences of food-allergic individuals, qualitative interviews to understand the perceived benefits of the SEP, assessed circumstances in which stock epinephrine was used, and the SEP's costs and sustainability.

Our findings showed that food-allergic individuals, food service staff, and the general public were accepting the SEP (see Table 1 for participant characteristics). Participants reported feeling more comfortable dining out if stock EAI was available at food establishments, and if staff were trained to recognize

anaphylaxis symptoms and administer emergency epinephrine. However, even with an SEP, the onus is still on the allergic individual to carry an EAI, yet 26% of our respondents experienced an allergic reaction when dining out, and of those, 88% did not carry their EAI. We also observed a wide variability in EAI carriage among the participants (35% to 88%), consistent with the literature.⁶⁻⁸ Almost all food-allergic respondents (94%) indicated that they would continue to carry their EAI even if stock EAI was available, supporting the recommendation that SEP is meant to complement, not replace an individual's responsibility to self-manage. We also found that SEP's sustainability is dependent on numerous factors including municipal engagement and support from leadership, implementation of effective staff training and communication strategies, embedding program processes into existing policies and procedures, and minimizing resource requirements. Our study highlights the importance of integrating SEP with emergency medical services to establish emergency response processes (such as 9-1-1). The total average cost of the SEP was \$715/year for the sit-down restaurants and \$2155/year for the mall administration (see

TABLE 1. Characteristics of respondents of the online, national survey (N = 1072)

Characteristics	Respondents (%)
Who has food allergy? (n = 1072)	
Respondent	26.0
Child	71.4
Other family member	2.6
Who diagnosed? (n = 1072)	
Allergist	70.1
Emergency physician	14.4
Family physician	5.9
Pediatrician	5.3
Other	4.3
Food (n = 1072)	
Peanut	77.9
Tree nuts	62.2
Sesame	14.2
Milk	17.5
Eggs	19.8
Fish	10.9
Shellfish	18.9
Soy	9.8
Wheat	6.6
Mustard	2.7
Other	29.2
Prescribed EAI (n = 1064)	
Yes	98.2
No	1.8
Carry EAI when dining out (n = 1039)	
Always	91.6
Never	1.9
Sometimes	1.7
Usually	4.8

EAI, Epinephrine autoinjector.

TABLE II. Facilitators and barriers to applying stock epinephrine autoinjector (EAI) program to other settings

Facilitators	Description	
Leadership support	Support and leadership from City Council, specifically Council Lloyd Ferguson, to be a champion for the project Involving key stakeholders in the community who believe in the project Defining clear roles and responsibilities/accountabilities between project team and within their respective organizations	
Update policies and procedures	Incorporating the stock EAI implementation processes and emergency protocols into existing policies and procedures	
Staff training	Provide ongoing support and access to training for staff	
Effective communications	Establishing a clear communication process that allows all participants to be kept up to date with regard to media and perception by the general public that helps with onsite management decisions	
Not resource intensive	Program does not require equipment, space, or other capital costs to implement	
Barriers	Description	Recommendations
Recruitment	Recruitment challenges, reluctance of other sites to participate due to large corporate structures that involved multiple levels of decision making	Define the amount of resources required to sustain the program Increase public and business community awareness through municipal publications (flyers) and position the program as a public safety initiative Enable a municipal bylaw requiring the stock EAI program Involve food service organizations such as Restaurants Canada
Liability	Lack of understanding of liability and liability coverage caused reluctance of other establishments to participate	Obtain legal guidance early to better define liability for your organization in the context of existing legislation (ie, Good Samaritan Act)
Time-intensive development process	Slow project initiation and challenges working with multiple layers of different stakeholders (City of Hamilton, McMaster University, Food Allergy Canada, implementation sites) resulting in unclear project roles and responsibilities	Recommend a central staff lead to coordinate tasks required to implement the program and facilitate continued collaboration between businesses and municipal government; this should involve in-person meetings to expedite the decision-making process
Community services engagement	Lack of engagement with the Hamilton Fire Department and Hamilton Paramedic Service	Utilize municipal government leaders to encourage the paramedic service and the Hamilton Fire Department to actively participate
Staff training	Capacity of Food Allergy Canada to provide ongoing training High turnover rate of staff required more management time to ensure that new hires are knowledgeable and trained on the stock EAI program	Food Allergy Canada can provide free access to already developed training modules that can be accessed online. These have been medically reviewed. Note that managers would still need to review their own specific emergency response procedures with staff
Cost	No revenue stream identified to sustain the program Uncertain costs associated with the program	Cost analysis of project in order for key stakeholder to consider funding the program

this article's Online Repository at www.jaci-inpractice.org). The difference in cost between establishments was driven by the size of the food establishment (eg, the number of employees), and the maintenance costs associated with the SEP (eg, training time for new hires, trained staff's time to train new hires, and the time spent during daily EAI handover). The overall costs of implementing the SEP were relatively low compared with the cost of providing other life-saving devices such as automated external defibrillators.⁹

Our study has several strengths. First, to our knowledge, our study is the first to describe stock EAI implementation and use in public settings. Lessons learned from the use of stock EAI in public schools was our only reference for comparison. Studies of public schools have shown that anaphylaxis can occur even in those with no prior history of anaphylaxis.⁸ This highlights the benefits of an SEP that could protect all individuals at risk for anaphylaxis, not just those with a previous diagnosis. Second, the program is feasible to implement (ie, low cost and requiring few resources) and therefore sustainable. Third, the SEP was accepted

by food-allergic individuals as well as food service establishments, which have continued the SEP beyond our study. They have also integrated its processes into their emergency response procedures and new employee training policies. Fourth, our implementation study has had wide reach. Our findings have contributed to the provision of stock EAI to all City of Hamilton owned properties (recreation centers, arenas, Young Women's Christian Association (YWCA), senior centers, and community halls) in November 2016. In addition, a review of 99 anaphylaxis emergencies by the City of Hamilton found that firefighters arrived on the scene first, approximately 20% more often than paramedics, so now all Hamilton Fire Department trucks stock EAI. As of June 2017, the City of Hamilton has also expanded the SEP to 50 restaurants with the goal of spreading it to all 2000 restaurants in the city.

Our study also had limitations. First, we had only 1 critical incident that occurred over the study period (expected given the low prevalence of anaphylaxis), so it was difficult to show the full benefits of the program. Second, we had only 1 of 3 Hamilton

malls participating in our study, so our findings may not be generalizable to other mall settings. Low participation may be explained by fear of potential liability, and the multiple layers of bureaucracy to approve participation in the study. The lack of understanding of liability by mall and food service establishments, and how existing legislation could be applied in these settings may also be contributing factors. In Canada, there is no explicit legislation that addresses the provision of stock EAI by organizations. However, Good Samaritan Legislation exists in almost all provinces and territories in Canada to ensure that individuals acting in good faith are not held liable in the event that they administer stock EAI. Lastly, the SEP may be more implementable in Canada because EAIs are readily available (ie, they can be purchased without a prescription), thereby making it feasible for public places such as restaurants, community centers, and schools to stock EAIs.

To summarize, we identified the determinants of implementation of an SEP (Table II). Future SEP implementation options may include voluntary adoption by food service versus legislative action (ie, by-law), with varying degrees of government or private support. Although SEP provides enhanced access to emergency medication, it is meant to complement rather than replace an individual's responsibility to carry an EAI and self-manage their food allergy. SEP may also benefit those with no prior diagnosis of anaphylaxis and may prevent future fatalities resulting from failure or delayed administration of an EAI.

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Conflicts of interest: S. Wasserman reports grants from the City of Hamilton and The Allergy, Genes and Environmental Network; reports other from Pfizer Canada and Sanofi Canada during the conduct of the study. M. Allen reports personal fees from Food Allergy Canada, outside the submitted work. J. Perdrizet reports payment sent to St. Michael's Hospital to conduct the cost analysis for this study. The rest of the authors declare that they have no relevant conflicts of interest.

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REFERENCES

1. Grabenhenrich LB, Dolle S, Moneret-Vautrin A, Kohli A, Lange L, Spindler T, et al. Anaphylaxis in children and adolescents: The European Anaphylaxis Registry. *J Allergy Clin Immunol* 2016;137:1128-11237.e1.
2. Cherkaoui S, Ben-Shoshan B, Alizadehfar R, Asai Y, Chan E, Cheuk S, et al. Accidental exposures to peanut in a large cohort of Canadian children with peanut allergy. *Clin Transl Allergy* 2015;5:16.
3. Leftwich J, Barnett J, Muncer K, Shepherd R, Raats MM, Hazel Gowland M, et al. The challenges for nut-allergic consumers of eating out. *Clin Exp Allergy* 2011;41:243-9.
4. Ahuja R, Sicherer SH. Food-allergy management from the perspective of restaurant and food establishment personnel. *Ann Allergy Asthma Immunol* 2007;98:344-8.
5. Bailey S, Albardiaz R, Frew AJ, Smith H. Restaurant staff's knowledge of anaphylaxis and dietary care of people with allergies. *Clin Exp Allergy* 2011;41:713-7.
6. Greenhawt MJ, Singer AM, Baptist AP. Food allergy and food allergy attitudes among college students. *J Allergy Clin Immunol* 2009;124:323-7.
7. Sampson MA, Munoz-Furlong A, Sicherer SH. Risk-taking and coping strategies of adolescents and young adults with food allergy. *J Allergy Clin Immunol* 2006;117:1440-5.
8. White MV, Hogue SL, Bennett E, Goss D, Millar K, Hollis K, et al. EpiPen4-Schools pilot survey: occurrence of anaphylaxis, triggers, and epinephrine administration in a U.S. school setting. *Allergy Asthma Proc* 2015;36:306-12.
9. Moran PS, Teljeur C, Masterson S, O'Neill M, Harrington P, Ryan M. Cost-effectiveness of a national public access defibrillation programme. *Resuscitation* 2015;91:48-55.

ONLINE REPOSITORY

Assessment of the sustainability potential of the SEP

Sustainability is an important implementation outcome, so we administered a validated sustainability survey developed by the NHS in the UK, designed for teams to assess the sustainability of an innovation (Figure E1).

The National Health Service (NHS) sustainability survey was completed by 8 of the 10 members of the Stock Epinephrine Program (SEP) implementation team (security and food service personnel, mall administration, Food Allergy Canada, and City of Hamilton) (Table E1). The total mean sustainability score for SEP was 82.7 (range, 54.6-93.9), which was well above the threshold (>55) of what is considered a sustainable innovation (Figure E2).

We conducted a cost analysis from the perspective of four major stakeholder group settings (Table E2): (1) a mall; (2) a stand-alone fast-food restaurant establishment; (3) a stand-alone sit-down restaurant establishment; and (4) the City of Hamilton (Figure E3). Table E3 shows the description of cost estimates for the SEP. The startup costs, including (1) train-the-trainer program, (2) train-the-trainer materials (handouts, learning aids), (3) updating procedure and policy, and (4) current employee training, were one-time costs to the stakeholders over the 12-month time period. The recurring costs, including (1) training time for new hires, (2) trained-staff's time to train new hires, and (3) the time spent during daily EAI handover, were the costs that occurred at multiple time points throughout the 12-month time period. The costs of the EAIs themselves were factored in, and the cost analysis assumptions are presented in Table E4.

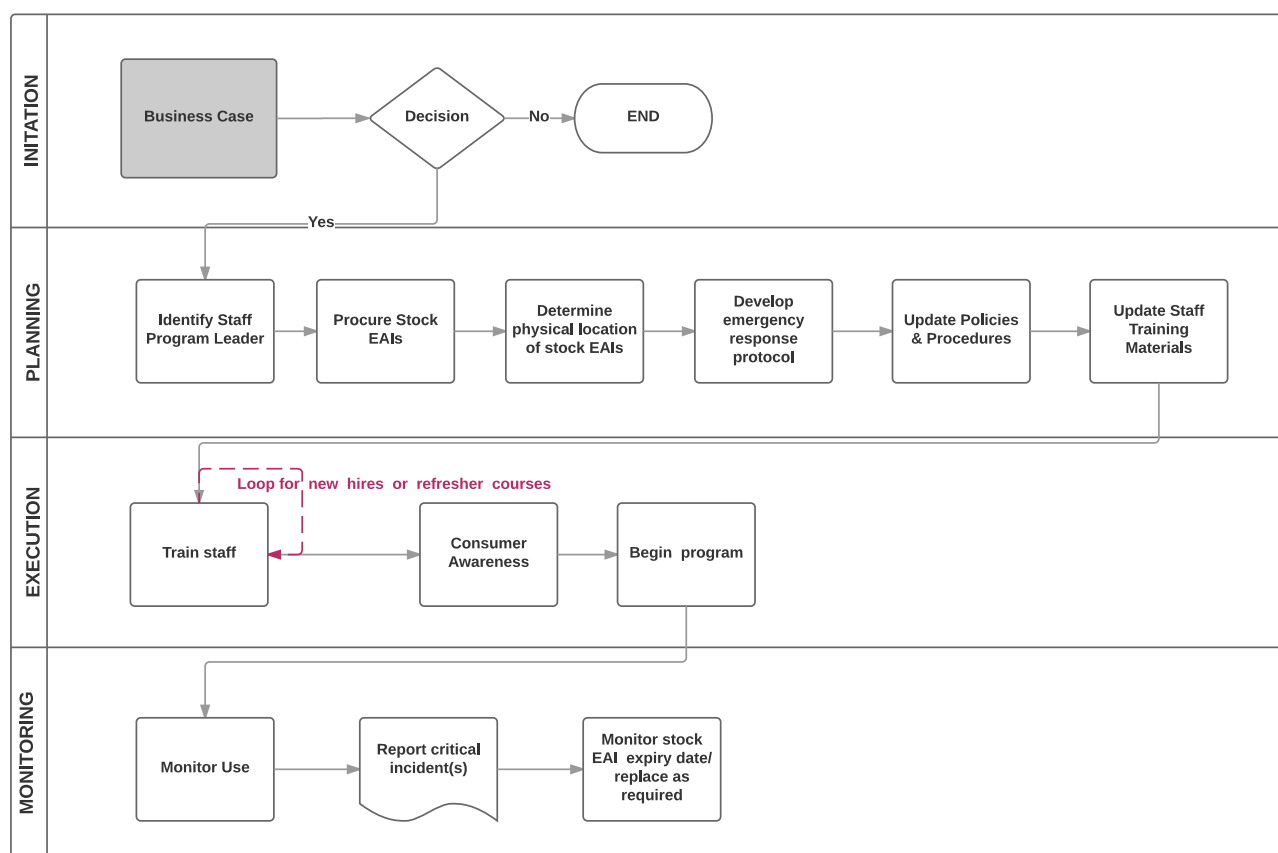


FIGURE E1. Stock EAI intervention flow chart. The figure outlines the development process of the SEP with our iKT team (initiation, planning, execution, and monitoring). Each site was required to identify a site leader(s), develop an anaphylaxis emergency response plan, participate in a 2-hour training session, and determine the most appropriate location for the EAIs. *EAI*, Epinephrine autoinjector; *SEP*, Stock Epinephrine Program.

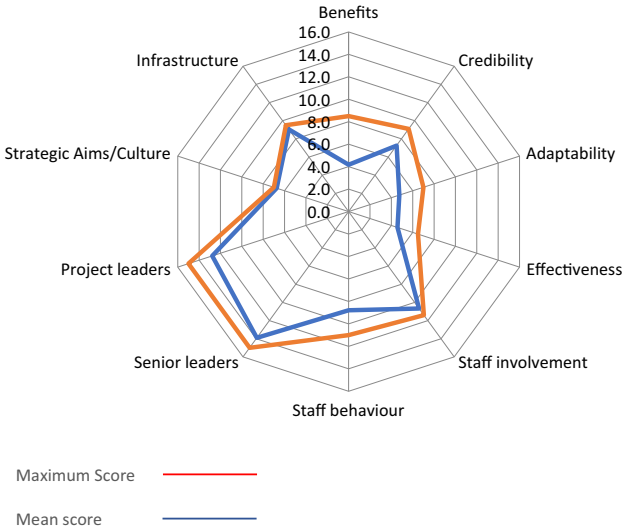


FIGURE E2. Sustainability portal diagram—assessment of the sustainability potential of the SEP. The figure shows the mean scores for each of the 10 sustainability factors highlighting the difference between the team mean score and maximum potential score. The best opportunities for improvement were in the “PROCESS” category (benefits beyond patients, credibility, and adaptability). [Table II](#) highlights the major sustainability facilitators (eg, leadership support) and barriers (eg, recruitment challenges, liability issues) that emerged from our qualitative analysis. Key informant interviews also identified recommendation(s) that were mapped to each key barrier identified. *SEP*, Stock Epinephrine Program.

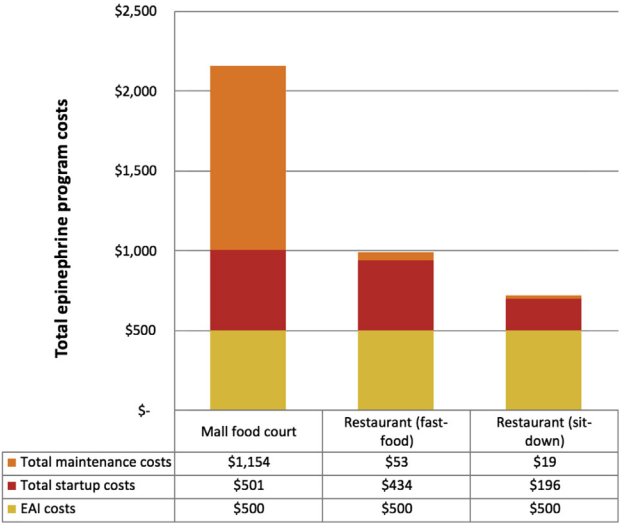


FIGURE E3. Total cost of the program for each stakeholder by cost type when each stakeholder is responsible for the cost of the epinephrine autoinjectors. The highest total cost was \$2,155/year for the mall stakeholder, followed by the fast-food restaurant establishment (\$987/year), and the sit-down restaurant establishment (\$715/year). The figure depicts the additional cost of the EAI that each stakeholder might bear if the City of Hamilton chose not to pay for the EAIs. When the cost of the EAI was the responsibility of the City of Hamilton, the total yearly cost was estimated to be \$1655 for the mall, \$487 for the fast-food restaurant, and \$215 for the sit-down restaurant. *EAI*, Epinephrine autoinjector.

TABLE E1. Implementation outcomes and measures

Implementation outcomes	Definition	Outcome measure	Implementation stage
A. Acceptability	The perception among implementation stakeholders that a given practice or service is agreeable, palatable, or satisfactory	Survey of food-allergic individuals	Early-mid implementation
		Survey of food-court consumers	During-late implementation
		Survey of food court behind the counter staff	During-late implementation
B. Adoption/uptake	The intention, initial decision, or action to try or employ the new SEP	Recruitment and participation rates	Early-mid implementation
C. Appropriateness	The perceived fit, relevance, or compatibility of the new SEP to address the issue or problem identified	Individual interviews with implementation team members	During-late implementation
D. Costs	Cost impact of the implementation effort	Cost analysis	Late implementation
E. Fidelity	The degree to which the new SEP was implemented	Site implementation survey Training program: pre-/post-test; evaluation	Early-mid-late implementation
F. Reach	The integration of the new SEP within a service setting	Number of individuals trained vs those eligible/not trained	Late implementation
	Level of institutionalization	Number of individuals who know about the program vs those who do not	
G. Sustainability	The extent to which new SEP is maintained within a service setting's ongoing, stable operations	NHS survey	Late implementation
		Individual interviews with implementation team members	Late implementation

Throughout this design, we applied the implementation framework from Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38:65-76.
SEP, Stock Epinephrine Program; NHS, National Health Service.

TABLE E2. Implementation site logistics

Site	Lead(s)	Location of devices	Policies and procedures updated
Mall administration	- Property manager - Assistant manager	1 set of backup epinephrine kept in a secure but accessible place at 3 separate security desks	Mall administration updated their policies and procedures to include a requirement for Intelligarde security to have all new employees trained before starting
Intelligarde security	Supervisor	- Each security staff person carried 1 of each adult and child EAI while on duty - EAI's returned to the security office and placed in the designated EAI unlocked/accessible storage container 2 sets of backup EAI's kept in a unlocked/accessible storage container in the security office	Site-specific emergency plan has been incorporated into security site instructions
Fast-food chain	Owner	4 doses (2 child and 2 adult) of EAI's in first-aid kits - Responsibility of 1 designated trained staff member per shift	- Official restaurant operating manuals have not been updated - Training materials used for new hire orientation
Restaurant chain	Manager	4 doses (2 child and 2 adult) of EAI's in first-aid kits - Responsibility of 1 designated trained staff member per shift	

This process led to the following SEP protocol: in public space settings operated by mall administration (including food courts), trained security guards carried 2 EAI doses (0.3 mg for patients weighing ≥ 30 kg; 0.15 mg for patients weighing 15-30 kg) with an emergency backup in secured first-aid kit(s) located in a central administration office(s) within the mall. In stand-alone, owner-operated restaurants (not connected to the food court), trained staff had access to 2 EAI doses in a central location (eg, behind the counter) with emergency backup in secured first-aid kit(s) located in a central office within the restaurant.
EAI, Epinephrine autoinjector; SEP, Stock Epinephrine Program.

TABLE E3. Unit cost variables and their estimates and descriptions

Unit cost	Estimate	Description
Security guard	\$12.46/h	2016 Canadian average security guard wage*
Fast-food restaurant employee	\$11.25/h	2016 Ontario general minimum wage†
Sit-down restaurant wait-staff	\$9.80/h	2016 Ontario liquor server minimum wage†
Two children and 2 adult EAIs	\$500.00/site	Price from pilot program (\$125 per EAI)
Train-the-trainer materials	\$20.00/person	Price taken from the expert opinion of the McMaster University research group

EAI, Epinephrine autoinjector.

*PayScale. Security Guard Salary (Canada). http://www.payscale.com/research/CA/Job=Security_Guard/Hourly_Rate. Accessed May 21, 2016.

†Ontario Ministry of Labour. Employment Standards, Publications, Guide, Minimum Wage. <http://www.labour.gov.on.ca/english/es/pubs/guide/minwage.php>. Accessed May 21, 2016.

TABLE E4. Epinephrine program assumptions for the cost analysis

Variable	Stakeholder	Assumption
Train-the-trainer program (2-h workshops per staff member)	Mall	7 security guards
	Sit-down restaurant	1 full-time staff
	Fast-food restaurant	4 full-time staff
Updating procedures (4 h per new stakeholder)	Mall	1 full-time staff
	Sit-down restaurant	1 full-time staff
	Fast-food restaurant	1 full-time staff
Current employee* (30-min training per current employee)	Mall	15 current security guards
	Sit-down restaurant	23 current employees
	Fast-food restaurant	35 current employees
New hire‡ (10-min training during orientation per new hire)	Mall	4 new security guards
	Sit-down restaurant	12 new employees
	Fast-food restaurant	24 new employees
Trainers for current employee and new hires (30 min for current employee or 10 min during orientation training for new hire)	Mall	7 security guards
	Sit-down restaurant	1 full-time staff
	Fast-food restaurant	4 full-time staff
Monitor and control EAI handover‡ (between 5 and 10 min per day)	Mall	2 security guards
	Sit-down restaurant	n/a
	Fast-food restaurant	n/a

EAI, Epinephrine autoinjector.

*Employees received training by a staff member who attended the train-the-trainer program.

†Staff training is part of the new hire training process. A 10-minute session including signs and symptoms, where the EAI is located and how it is used. Security staff completes first-aid certificate courses (offered by St. John's Ambulance and/or Red Cross) that cover EAI use and food allergy; reducing time required.

‡Mall security guards carry the EAI on their person; there is time spent each day for the handover. This is not the case for independent restaurant establishments, because the EAI is held in the office.

TABLE E5. Mall-administered, in-person food court consumers survey results (N = 120)

Characteristics	(N = 120) All respondents (%)	(N = 29) Food allergic (%)	(N = 89) Know someone with food allergies (%)
Male	35.8	62.1	61.8
Female	64.2	37.9	38.2
Age range			
<18	17.5	17.2	19.1
19-25	20.8	6.9	20.2
26-45	26.7	48.3	31.5
46-55	10.8	13.8	11.2
>55	24.2	13.8	18.0
Residency			
Hamilton resident	94.0	93.1	93.3
Visitor	6.0	6.9	5.6
Frequency at food court			
At least once per week	88.3	82.8	88.8
Once per month	8.3	13.8	9.0
Rarely	3.4	3.4	2.2
Food allergy*			
Peanut	—	14	—
Tree nuts	—	21	—
Milk/dairy	—	28	—
Fruits	—	21	—
Wheat	—	7	—
Fish	—	7	—
Shellfish	—	3	—
Egg	—	7	—
Pork	—	3	—

*Included responses from individuals with multiple food allergies.

TABLE E6. Implementation recommendations

1. Enlist the assistance of senior leaders to promote acceptance of SEP by members of your organization or community. Early endorsement of organizational leadership is critical to program success
2. Communicate with local public safety agencies, including police, fire, and EMS entities, to increase awareness of the program and inform them of your specific anaphylaxis emergency response plan
3. Establishing SEP site leads that work within your organization/community is key. The site leads are responsible for the daily activities of the program and serve as a communication link among key decision makers and the public
4. Target and train core staff about food allergy, how to recognize anaphylaxis, and how to provide emergency treatment with EAI. These individuals can train new employees
5. Develop detailed, site-specific anaphylaxis emergency response plans and a process for reporting critical incidents
6. Develop onsite stock epi maintenance plans and antitampering/theft prevention policies and procedures
7. Obtain legal advice about existing legislation and clarify how it applies to your organization. Legal concerns will impact owner-leader decision making with regard to SEP implementation. A lay person who administers epinephrine in an emergency situation would be protected from liability, unless he or she acted in gross negligence, according to Section 2 of the Ontario Good Samaritan Act

EAI, Epinephrine autoinjector; EMS, emergency medical services; SEP, Stock Epinephrine Program.