

A Survey Assessment of Epinephrine Injector Accessibility Within Pitt County, North Carolina Restaurants
in 2020

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Abstract

Background: Food allergies are relatively common in the United States. As the number of individuals with food allergies continues to grow, so does the concern for life-threatening anaphylactic reactions.

Methods: An online survey was disseminated to individuals with food allergies, and an in-person or phone survey was disseminated to restaurant managers within Pitt County, NC. Individuals with food allergies were surveyed about their comfort levels eating at restaurants and their attitudes towards having epinephrine injectors available at restaurants. Restaurant managers were surveyed about their preparedness to serve individuals with food allergies and their attitudes towards having epinephrine injectors in their restaurants.

Results: Results of this study indicate that restaurant managers (n=30) had concerns about individuals having allergic reactions and would be willing to pay for a reasonably priced epinephrine injector, preferably with audio instructions. Surveyed individuals with food allergies (n=25) expressed concern surrounding having an allergen in their food, and increased comfort eating when an epinephrine injector is present.

Conclusion: Frequent staff turnover within restaurants remains a barrier to adequate food safety training, however only one restaurant staff member is required to have training for epinephrine injectors. If kept on-site at restaurants, epinephrine injectors have the potential to save lives.

Introduction

A food allergy is defined as, “a medical condition in which exposure to a food triggers a harmful immune response” or allergic reaction (Food Allergy Research & Education, 2019). An immune response can be as simple as itchiness (on the mouth or skin is most common) and a rash that breaks out, or it can

be more severe such as causing one to vomit or have diarrhea. Additionally, severe swelling can cause throat closure and difficulty breathing, possibly leading to death. Anaphylaxis is a more severe type of reaction, thus not all allergic reactions are considered anaphylaxis. Anaphylaxis is “a serious allergic reaction that is sudden in onset and can cause death” (Food Allergy Research & Education, 2019).

Food allergies are one of the main causes of anaphylaxis. Over 170 different foods have been reported to cause allergic reactions, with most of the serious reactions in the United States (US) coming from milk, eggs, peanuts, tree nuts, wheat, soy, fish and crustacean shellfish. Approximately one in 13 children, and one in 10 adults have known food allergies (Food Allergy Research & Education, 2019). Food allergies are increasing each year within the US. The Centers for Disease Control & Prevention reported a 50% increase in food allergies between 1997 and 2011 (Food Allergy Research & Education, 2019). One known factor has not been pinpointed as the cause for this increase, however as food allergies have become more common there has been a growth in awareness and safety measures surrounding food preparation.

In addition to an increase in food allergies, hospitalizations and medical treatments for food allergies have increased. Between 2007 and 2016, the number of treatments for anaphylaxis from an allergic reaction increased 380 percent (Food Allergy Research & Education, 2019). It is common for an individual with a food allergy to have had a severe life-threatening reaction before they reach adulthood. Over 50 percent of adults and over 40 percent of children with food allergies have experienced a severe allergic reaction, such as anaphylaxis (Food Allergy Research & Education, 2019).

Every 3 minutes someone in the US goes to the emergency department for a food allergy reaction, totaling over 200,000 visits a year (Food Allergy Research & Education, 2019). The leading cause of anaphylaxis within emergency departments are food-induced anaphylaxis (Jarvinen, 2011). The US Food and Drug Administration estimates that food-related anaphylaxis causes approximately 30,000

emergency room visits, 2,000 hospitalizations, and 150-200 deaths every year (2017). Symptoms of food allergies can occur immediately or up to two hours after a person has come into contact with an allergen (US Food & Drug Administration, 2018). On average, the onset of symptoms include skin changes, respiratory issues, and circulatory issues. Symptoms can also include hives, swelling, itching, vomiting, diarrhea, dizziness, difficulty breathing, loss of consciousness, and more (US Food & Drug Administration, 2018).

Children diagnosed with asthma, atopic dermatitis and/or eczema, allergic rhinitis, insect sting allergy, medication allergy, urticaria, or latex allergy are more likely to have a food allergy compared to an individual without one of the listed diagnoses (Gupta et al., 2018). More specifically, children with food allergies are more than twice as likely to have asthma as those without food allergies (Branum & Lukacs, 2008). Children with food allergies are also three times more likely to have respiratory allergies or eczema compared to those without food allergies (Branum & Lukacs, 2008). Not only are individuals with food allergies more likely to have asthma, but they are also at increased risk for food allergy-related emergency department visits (Gupta et al., 2019). Compared to an individual who only has food allergies, an individual with food allergies and asthma is at an increased risk of an anaphylaxis reaction when coming into contact with the allergen (Smith et al., 2015).

Multiple studies also referenced racial disparities within food allergies (Jerschow et al., 2014; Gupta et al., 2018; Gupta et al., 2019; Keet et al., 2014). One study that reviewed death certificates of anaphylaxis-related deaths identified by the 10th clinical modification of the Internal Classification Disease (ICD-10) system from 1999-2010 within the US found that African Americans had higher food-related anaphylaxis rates compared to other races (Jerschow et al., 2014). African American children also have a significantly higher risk for developing a food allergy compared to non-Hispanic white children (Gupta et al., 2018). This difference was still evident after taking other covariance such as household income into account. In another study of 40,443 US adults, food allergy rates were

significantly higher among non-white adults even after adjusting for covariates such as income, education, and physician-diagnosed atopic conditions (Gupta et al., 2019). The number of food allergies each year are increasing, though the rate that food allergies are increasing is disproportionate among different races/ethnicities. Childhood food allergies are increasing at a rate of 2.1% per decade among African Americans, 1.2% per decade among Hispanics, and 1% per decade among non-Hispanic whites (Keet et al., 2014).

According to the North Carolina Food Code Manual, a restaurant is defined as a type of food establishment that prepares or serves food and provides seating (N.C. Department of Health and Human Services, 2012). A food establishment can be defined as an operation that relinquishes possession of food to a consumer directly, or indirectly through a delivery service (N.C. Department of Health and Human Services, 2012). For adults, most food allergy reactions occur in restaurants (Banerji et al., 2010). In fact, over a 13-year period nearly half of fatal food-related reactions were caused by food from a food service establishment (Weiss, Munoz-Furlong, 2008). Versluis et al. found that between 21-31% of unexpected allergic reactions occur in restaurants (2015). One in three people diagnosed with a food allergy reported having had a reaction in a restaurant (Environmental Health Services, 2019).

Within a meal at a restaurant, desserts were the most common culprit to cause an allergic reaction (Furlong et al., 2001). Asian food, ice-cream shops, bakeries, and doughnut shops were the most common establishments causing an allergic reaction (Furlong et al., 2001). About 55% of individuals that had a reaction at an establishment had not told the staff about their allergy, while 45% of individuals that had a reaction had told the staff about their allergy (Furlong et al., 2001). Allergen risks are still present with effective communication between the consumer and restaurant staff. The allergen can unintentionally cause a reaction if there is miscommunication between staff members or if there is cross contact of the allergen. Cross contact occurs when there is a mixture of proteins between two foods, such as when the proteins from one type of food comes into contact with another type of

food (Sheehan et al., 2018). If an allergen is unknowingly added to a plate that was not thought to have that particular allergen, then that can result in an allergic reaction in the individual that is allergic to that particular allergen. Cross contact can occur through reusing cooking utensils in the kitchen or reusing gloves when making two different dishes. During an anaphylactic or severe food allergy reaction, epinephrine should be administered as soon as possible (Smith et al., 2015). A major contributor to food allergy fatalities is delayed injection of epinephrine (Smith et al., 2015). Having epinephrine delivered minutes, or even seconds, earlier to someone in anaphylaxis could save a life. For food-induced anaphylaxis, a timeframe of approximately 30 minutes exists between the time symptoms begin until respiratory or cardiac arrest. (Pumphrey, 2000).

Not all food allergy reactions are caused by contact or consumption of the allergen. Inhalation of the allergen can result in allergic reactions of varying severity, and in some people can even cause anaphylactic reactions (James & Crespo, 2007; Stallings & Oria, 2017). Anaphylaxis due to inhaled food allergens have been reported when the cooked allergen forms vapors within the air the individual is breathing (James & Crespo, 2007; Roberts et al., 2002; Gonzalez-Mendiola et al., 2003; Martinez Alonso et al., 2005; Vitaliti et al., 2012). Cooking fish, shell-fish, seeds, soybeans, egg, and more are associated with anaphylaxis from inhalation allergens (James & Crespo, 2007). Furlong et al. reported that 7 out of 156 episodes of food reactions were from skin contact or inhalation (2001). Stallings & Oria hypothesize that allergic reactions from aerosolized food allergens come from water-soluble proteins in the cooking vapor (2017).

Not all individuals with food allergies choose to carry an epinephrine injector with them at all times. There can be many reasons for not wanting to carry an epinephrine injector, including inconvenience (due to space it takes up in a pocket or purse) and the cost to purchase one. Only about one fourth of adults with food allergies have a current epinephrine prescription (Gupta et al., 2019). Additionally, not all individuals are aware that their food allergies are fatal. A study by Brock et al.

retrospectively analyzing case fatalities caused by anaphylactic reactions to food, reported that many individuals who suffered a fatal reaction never had to use an epinephrine injector before, with some families claiming they did not know their allergy could be deadly (2007). While restaurants shouldn't be any less cautious regarding individuals that have a history of having severe reactions, restaurants and public health guidelines should be more cautious towards any individual with food allergies. A fatal anaphylactic reaction is impossible to predict ahead of time and can occur to those who have a history of less severe reactions. An allergic food reaction can occur with anyone, regardless of whether a diagnosis has been made. A review of medical records showed that over 15% of patients with food allergies were first diagnosed in adulthood (Kamdar et al., 2015). Even if a previous food allergy is known, a new food allergy can appear in adulthood. In a population-based survey study of 40,443 US adults, nearly half of participants experienced at least one adult-onset food allergy (Gupta et al., 2019).

Individuals with food allergies may be more cognizant of controlling food allergens in at-home settings when preparing food for themselves and their families. Furthermore, individuals with known food allergies may keep an epinephrine injector at home in case it is needed. As a result, most fatal food allergy reactions occur from consuming food outside of the home (Food Allergy Research & Education, 2019). Schools often keep epinephrine injectors in a nurse's office or given to a staff to have on hand for a child with severe food allergies. Thus, a survey was developed to focus on a location outside the home and school, specifically within restaurants. Over 15% of families with food allergies choose not to go to restaurants (Food Allergy Research & Education, 2019). Additionally, some families choose not to visit certain restaurants, and other families choose not to eat from certain dishes at restaurants if they do decide to go. Even if the food allergen can be removed, some individuals with food allergies still choose to not eat from that dish in fear of accidental cross contact with the allergen. Having an epinephrine injector on-site at restaurants will not prevent an allergic reaction, however it can prevent an

anaphylaxis reaction causing death. The sooner epinephrine can be administered, the less severe the cardiac and respiratory effects.

According to the 2009 North Carolina Food Code Manual, each restaurant is required to have at least one employee who has obtained a Food Protection Manager Certification (CFPM) through passing a standardized exam sponsored by the American National Standards Institute (ANSI) – Accredited Program (US Food & Drug Administration, 2019). Among other tasks, it is the responsibility of the CFPM to ensure all food employees are properly trained in food safety, including allergen training. Despite this requirement, multiple studies have indicated that restaurant staff and managers have misconceptions about food allergies. The Environmental Health Specialists Network collected data through restaurant staff interviews at 278 restaurants and found that more than 10% of managers and staff believe that a person with food allergies can safely consume a small amount of allergen in their food (Radke et al., 2016). Only 44.4% of restaurant managers reported receiving food allergy training (Radke et al., 2017). Approximately one out of four surveyed restaurant managers did not possess an ingredient list or recipe for menu items (Radke et al., 2017). Three out of four restaurant managers reported not having a dedicated set of utensils or equipment to use for those who communicate that they have a food allergy. Due to limited space within restaurants, it may be difficult to ensure food for individuals with allergies is separated from the other food being prepared in the kitchen. Only 7.6% of restaurant managers reported having a kitchen area designated for allergen-free food. Without designated space and utensils, food is susceptible to unintentionally receiving trace amounts of an allergen (Radke et al., 2017). Another study of surveying restaurant staff at 100 locations reported 35% of restaurant managers believed heat destroyed most allergens, 34% of restaurant managers thought providing water to an individual suffering from an allergic food reaction was an appropriate response, and 25% of restaurant managers thought that removing a nut from a finished meal was a safe practice for those with nut allergies (Ahuja & Sicherer, 2007).

Within the last decade, more states continue to adopt epinephrine entity stocking laws to allow establishments like restaurants to legally keep epinephrine injectors on-site (The Network for Public Health Law, 2016). Thirty-five out of fifty states have adopted an epinephrine entity stocking law as of June, 2019 (US Anaphylaxis Entity/Public Space Stock Epinephrine Legislation, 2019). Only recently were epinephrine injectors allowed for purchase by restaurants in North Carolina (NC). In 2015 a bill was passed in NC allowing healthcare providers to prescribe, and pharmacists to dispense, epinephrine auto-injectors to authorized child-serving entities other than schools for the emergency treatment of anaphylaxis (House Bill 647, 2015). House Bill 647 allows restaurants and other entities and organizations to obtain and maintain a supply of epinephrine injectors at their location. To obtain an epinephrine injector at a restaurant, at least one restaurant employee must complete the mandatory anaphylaxis training program, which can be completed online or in person.

A Stock Epinephrine Program (SEP) was implemented in Ontario, Canada between September 2014 and March 2016, which consisted of stocking participating food service establishments with epinephrine injectors (Waserman et al., 2019). Waserman et al. found that those with food allergies reported feeling more comfortable dining out if epinephrine injectors were stocked in the restaurant and the staff were trained to recognize a reaction (2019). Within the program it was found that in 20% of documented incidents firefighters arrived at the scene before paramedics, thus Waserman et al. recommended that fire departments also stock epinephrine injectors (2019). The implementation costs of the SEP program was less compared to the cost of other life-saving devices, such as automated external defibrillators (Moran et al., 2015; Waserman et al., 2019). In general, individuals with food allergies, food service staff, and the general public were accepting of the SEP program (Waserman et al., 2019).

The overall research questions that will be addressed in this study are: (1) What factors influence a restaurant manager's perspective on the importance of keeping epinephrine injectors at the

restaurant; and, (2) how does the presence or absence of epinephrine injectors influence decision making for customers with food allergies? The purpose of this study is to provide research to reference for future programs and interventions surrounding stocking epinephrine injectors in restaurants. Online surveys will be used to collect data from individuals with food allergies regarding their views on keeping epinephrine injectors on-site at restaurants. In-person surveys or phone surveys will be used to collect data from restaurant managers about their views on keeping epinephrine injectors on-site at their restaurants. The surveys will measure how the Health Belief Model variables (cues to action, perceived benefits, perceived barriers, perceived severity, and perceived susceptibility) influence the views of individuals with food allergies and restaurant managers on stocking epinephrine injectors. The survey consists of questions regarding the type of epinephrine injector (e.g. voice instructions vs traditional auto injectors), perceived susceptibility of customers to food allergies, and perceived severity of food allergies. The survey will also inquire about perceived benefits, barriers, and threats to keeping an epinephrine injector at the restaurant.

Questions in the survey to restaurant managers explore the acceptance of traditional epinephrine injectors compared to audio-prompt epinephrine injectors that give voice instructions. Audio-prompted epinephrine injectors are new to the market and may make staff more comfortable and confident in having to use it in the future. One study found that those that used an audio-prompted epinephrine injector correctly used the device 93% of the time, compared to those who only used it correctly 57% of the time with traditional epinephrine injectors (Umasunthar et al., 2015).

Multiple studies have been conducted to assess restaurant staff knowledge of safe food handling practices and food safety risk reduction steps and interventions. Limited research exists looking at if epinephrine injectors would be an efficient safety addition to restaurants. The goal of this survey study is to assess views of: (1) restaurant managers; and, (2) individuals with food allergies on stocking epinephrine injectors within restaurants. The objective of this study is to survey at least 25 restaurant

managers and at least 25 people with food allergies within the month of February 2020. The results of this study can be used to make future recommendations on safety precautions and safety procedures regarding epinephrine stocking within restaurants. Results can also be used to predict the impact of developing and applying an intervention to increase the number of restaurants that stock epinephrine injectors.

Methods

There are two populations within this study. The first target population is restaurant managers within Greenville and Winterville, NC in February of 2020. The study population will be a convenience sample of restaurant managers in Greenville and Winterville, NC. Participant inclusion criteria for the restaurant manager population includes: a) 18 years of age or older; b) English speaking; c) restaurant manager for a restaurant within Greenville or Winterville, NC. A study team member will recruit restaurant managers by one of two ways: 1) visit the restaurant in person and ask to speak with a manager regarding a survey, 2) call the restaurant and ask to speak to a manager regarding a survey. In either situation, if a manager is not available then the study team member will proceed to the next restaurant. If a study team member is able to speak to a manager, they will follow the recruitment statement to explain the study. A copy of the recruitment statement is in the appendix. The individual restaurant managers are the unit of analysis.

The second target population is individuals with food allergies associated with East Carolina University (ECU) in February of 2020. The study population will be a convenience sample of individuals with food allergies associated with ECU. Participant inclusion criteria for those with food allergies includes: a) 18 years of age or older; b) English speaking; c) have a food allergy; d) be associated with ECU via a listserv. Individuals with food allergies will be recruited to take the survey via undergraduate

and graduate ECU listservs. The individuals with food allergies will act as the unit of analysis. The sample size of 25 restaurant managers and 25 individuals with allergies is determined by what is convenient within the allotted time frame of a month.

The Health Belief Model was used when developing the survey. Questions on the survey were developed by creating questions centered around perceived benefits, barriers, and threats to keeping an epinephrine injector at the restaurant. The survey for individuals with food allergies and the survey for restaurant managers were created separately but have some questions that are similar. Similar questions between the two groups of surveys will allow for comparison of views between the two groups of participants.

Independent variables include Cost, Training, Plan, Allergies, and Voice. The dependent variables include Injectors, Concern, Pay, and Confidence. Definitions for each of these variables are listed in Figure 2. An arrow shows an interaction between two variables. Data analysis was done using SPSS to obtain frequencies and percentages of each of the answer choices for each question, as well as obtaining the mean, median, mode, standard deviation, and variance of relevant questions. SPSS was also used to conduct a t-test to compare the results of individuals who have needed an epinephrine injector to those who have not.

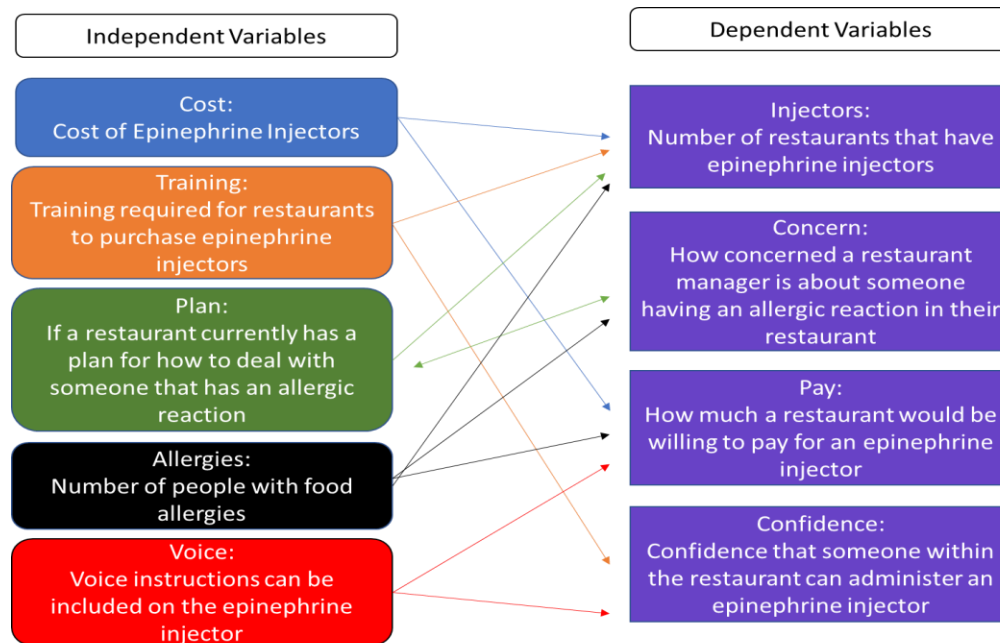


Figure 2: Independent And Dependent Variables That Factor Into A Restaurants Decision To Purchase An Epinephrine Injector

Results

This study surveyed 30 restaurant managers and 25 people with food allergies within the month of February 2020 with the hopes of making future recommendations on safety precautions and procedures regarding epinephrine stocking within restaurants.

Restaurant manager results: Of the 148 restaurants contacted, 30 (20.3%) restaurants had managers who agreed to participate. When asked about how concerned they were with someone having an allergic reaction in the restaurant, most responded with “to a great extent” (63.3%), while additional responses included “somewhat” (23.3%), “very little” (6.7%), or “not at all” (6.7%). Of the 30 surveyed managers, 33% of managers thought epinephrine injectors should be required to have at the restaurant; 70% of managers thought some type of food allergen training should be required; and 83% of managers

thought an ingredients list should be accessible to the customer. When restaurant managers were asked if they have a plan if an individual in the restaurant had a life-threatening food reaction, 83.3% said yes. Of those 83.3% that did have a plan, 68% said they would call 911 or for emergency services and 12% said they would get a first aid kit.

When asked how much restaurant managers were willing to pay for an epinephrine injector, prices ranged from \$0 to \$300. The most commonly answered prices were \$50 (14.8%), \$100 (14.8%), and \$200 (14.8%). The average price restaurant managers were willing to pay for an epinephrine injector was \$104. Over half (57.1%) of restaurant managers answered yes when asked if having an epinephrine injector with voice instructions would change the amount they were willing to pay. Additionally, 79.3% said that having voice instructions would increase their confidence in administering an epinephrine injector. Only 16.7% of restaurant managers had previously considered getting an epinephrine injector at the restaurant, and of those, 40% currently had one at the restaurant.

The top 3 barriers of restaurants possessing epinephrine injectors were lack of comfort (63%), cost to purchase (59%), and cost to train (56%). On a scale of 1 (no) to 5 (yes), 82.7% of restaurant managers answered 4 or 5 when asked if their restaurant would be willing to participate in a free epinephrine training program. If the restaurants did have epinephrine injectors in the future, 96.4% of restaurant managers said that they would utilize a sticker or sign to put on the window of their restaurant to show potential customers that epinephrine injectors were available. If insurance companies gave a discount on premiums when an epinephrine injector was kept at the restaurant, 96.4% of restaurant managers said they would participate in the program.

Individuals with food allergies results: For the surveys given to individuals with food allergies there were a total of 25 responses, one of which did not complete all questions on the survey. Of the respondents, 36% had previously had an anaphylactic reaction or needed an epinephrine injector. Additionally, 8.3%

had been diagnosed less than a year ago, 8.3% diagnosed 1-2 years ago, 12.5% diagnosed 3-4 years ago, 25% diagnosed 5-10 years ago, 25% diagnosed 10-20 years ago, and 20.8% were diagnosed more than 20 years ago. Within the last 10 years 83.3% had had a severe food allergic reaction, and 40% of those individuals had an allergic reaction within the last year.

An independent samples t-test was conducted to compare the answer choices of those who had previously needed an epinephrine injector and those who had not. There was no significant difference in the distribution of answer choices for any of the other questions when comparing those who had previously needed an epinephrine injector and those who had not. These results suggest that a previous experience of needing an epinephrine injector does have an effect on participants' answer choices for the following questions asked in the next paragraph.

When asked if they bring an epinephrine injector with them when they go out to eat, half (50%) of respondents said they did not, 20.8% said "rarely", 8.3% said "sometimes," 8.3% said "very often," and 12.5% said "always." Additionally, only 56% reported that they own an epinephrine injector. When asked if they restrict what they eat more heavily when they know that there is not an epinephrine injector around, respondents answers were distributed between "never" (24%), "rarely" (4%), "sometimes" (24%), "very often" (24%), and "always" (24%). When asked if they avoided certain restaurants due to their food allergy, respondents' answers were distributed between "never" (12%), "rarely" (28%), "sometimes" (8%), "very often" (12%), and "always" (16%). When asked how often they worry that their food might contain an allergen, respondents answers were distributed between "never" (12%), "rarely" (4%), "sometimes" (28%), "very often" (40%), and "always" (16%). When asked if having an epinephrine injector in the building makes them feel safer when eating, respondents answers were distributed between "never" (8.3%), "rarely" (4.2%), "sometimes" (16.7%), "very often" (33.3%), and "always" (37.5%). On a scale of 1 (no) to 5 (yes), 56% of individuals with food allergies answered 4 or 5

when asked if it would influence where they ate if restaurants publicized whether they had epinephrine injectors on site.

Discussion

This study was conducted with the intention of making future recommendations on safety precautions and procedures regarding epinephrine stocking within restaurants. Results will be used to submit an issue to the Conference for Food Protection, the body which utilizes a formal process to amend the FDA Model Food Code (Conference for Food Protection, 2020). The issue would call for a mandate for epinephrine injectors to be present on-site at all restaurant establishments. Results can also be used to predict the impact of developing and applying an intervention to increase the number of restaurants that stock epinephrine injectors.

The top two noted barriers for the adoption of on-site epinephrine injectors at restaurants were the lack of comfort using an epinephrine injector and the cost to purchase an epinephrine injector. These barriers can be addressed through interventions. Over half of restaurant managers were willing to pay \$60 or more for an epinephrine injector, with the average price being \$104. As of January 26th, 2020 the retail price of an Adrenaclick pack of 2 autoinjectors of 0.3 mg of epinephrine was \$109.99 on the GoodRx website (GoodRx, 2020). Thus, a single epinephrine auto-injector cost around \$55.00, much lower than the average price of \$104 that the restaurant managers were willing to pay.

Questions in the survey given to restaurant managers explored the acceptance of traditional epinephrine injectors compared to audio-prompt epinephrine injectors that give voice instructions. Over half of restaurant managers were willing to pay more for an epinephrine injector with voice instructions. The majority of restaurant managers indicated they would be more confident administering an epinephrine injector with voice instructions. Audio-prompted epinephrine injectors are new to the market and may make staff more comfortable and confident in having to use it in the future, but they're

also more expensive. An idea for an intervention that could be done is adding Quick Response (QR) codes to the epinephrine injectors. This would allow for audio-prompted directions, without increasing the price of making the injector.

Epinephrine injectors can be analogized to fire-extinguishers, both kept in the restaurant as a precaution. Each year about 100 injuries and fewer than five deaths occur from restaurant fires alone (US Fire Administration, 2017). If it were not for policies, procedures, and precautions put in place, the number may be higher. Fire trucks respond to fires, similar to ambulances responding to anaphylactic reactions. There are also fire extinguishers available to use before the firefighters arrive. Similarly, there are epinephrine injectors available to use for anaphylactic reactions before medical personnel arrive. Lives could be saved if precautions were taken for anaphylactic reactions, like precautions are taken for fires in restaurants.

One limitation of the study is the small sample size. Additionally, restaurant managers may have social desirability bias if they want to give the perception that they take food safety seriously. Online surveys may have response bias and be susceptible to having the questions misinterpreted without further explanation. Although multiple research studies have evaluated food allergen knowledge and education of restaurant staff, there is limited research regarding epinephrine injectors within restaurants to compare with this data. Nonresponse bias may have also occurred since individuals that feel strongly about the topic are more likely to respond to the survey.

There is limited accuracy with case fatalities due to allergic reactions to food. This is partly due to the incomplete history obtained from patients about the time directly before their death, as well as restricted specific pathological findings on postmortem examinations (Tanno et al., 2017). There can also be misclassification with the International Classification of Disease (ICD) coding. Due to misclassification, 71% of all studies based on ICD registries utilized secondary data to accurately capture anaphylaxis data (Tanno et al., 2018). An example of possible misclassification is with the ICD-10 code of

T78.3 which refers to angioedema, such as with giant urticaria. An individual who died after eating a food allergen could be coded incorrectly on their death certificate, resulting in them not being included in the total count of individuals that died from a severe or anaphylactic reaction to food. Additionally, anaphylactic symptoms can take up to hours to appear. Thus, even if the death is correctly coded as an anaphylactic reaction, it may be coded as an unspecified reaction instead of being coded as a food reaction. As a result, someone coded as suffering from an unspecified anaphylactic reaction would not be included in the total count of individuals that died from a severe or anaphylactic reaction due to food. An updated classification system in the ICD-11 may help to provide better records (Tanno et al., 2018). The ICD-11 will have most cases of anaphylaxis fatalities included in official mortality statistics, which can then serve as a standard for comparability to be referenced in the future (Tanno et al., 2017). With the ICD-11 coding the reported number of anaphylaxis deaths may increase (Tanno et al., 2016).

Conclusion

Food allergy education of restaurant staff has been shown throughout various studies to be an important factor in preventing allergic reactions to foods (Weiss, Munoz-Furlong, 2008; Furlong et al., 2001; Smith et al., 2015). Frequent staff turnover within restaurants remains a barrier to adequate food safety training, however only one restaurant staff member is required to have training. If kept on-site at restaurants, epinephrine injectors have the potential to save lives. Providing epinephrine injectors to restaurants, would not undermine food safety knowledge and training, but instead would show preparedness for life-threatening allergic reactions.

Competencies

Professional Paper Selected Competencies Achievement Table	
Professional Paper Title	A Survey Assessment of Epinephrine Injector Accessibility Within Pitt County, North Carolina Restaurants
Professional Paper Student	Holly Ingram
Competency	How Competency Was Met
<i>CEPH MPH Foundational Competency</i>	
2. Select quantitative and qualitative data collection methods appropriate for a given public health context	Data was collected via survey since that is what was determined this is convenient within the allotted time frame to complete the research.
3. Analyze quantitative and qualitative data using biostatistics, informatics, computer-based programming and software, as appropriate	Data analysis was done using SPSS to obtain frequencies and percentages of each of the answer choices for each question, as well as obtaining the mean, median, mode, standard deviation, and variance of relevant questions using SPSS. SPSS was also used to conduct a t-test to compare the results of individuals who have needed an epinephrine injector to those who have not.
4. Interpret results of data analysis for public health research, policy or practice	The results of this study were interpreted in a way to make future recommendations on safety precautions and procedures regarding epinephrine stocking within restaurants.
14. Advocate for political, social or economic policies and programs that will improve health in diverse populations	This study was conducted with the intention of making future recommendations on safety precautions and procedures regarding epinephrine stocking within restaurants. Results will be used to submit an issue to the Conference for Food Protection, the body which utilizes a formal process to amend the FDA Model Food Code. The issue would call for a mandate for epinephrine injectors to be present on-site at all restaurant establishments. Results can also be used to predict the impact of developing and applying an intervention to increase the number of restaurants that stock epinephrine injectors.
15. Evaluate policies for their impact on public health and health equity	House Bill 647 allows restaurants and other entities to obtain and maintain a supply of epinephrine injectors at their location. The impact of this bill on current stocking of epinephrine injectors in restaurants was evaluated in the study.
18. Select communication strategies for different audiences and sectors	The results of this study will be presented to audiences with related background (written paper and poster presentation), as well as to audiences with no scientific or public health background (oral PowerPoint Presentation).

19. Communicate audience-appropriate public health content, both in writing and through oral presentation	The results of this study will be presented in the form of a formal written research paper, a formal written and oral poster presentation, an informal oral presentation, and any other additional means of communication that can disseminate the findings.
21. Perform effectively on interprofessional teams	To complete this research, I worked with medical professionals, public health professionals, scientific (nutritional sciences) professionals, and received input from various other people about the topic.
<i>Community Health and Health Behavior Concentration Competency</i>	
1. Design a conceptual and/or logic model to guide intervention development and/or data collection for program evaluation	A conceptual model was created, separating the research into the following sections: Problem, Inputs, Activities, Outputs, and Outcomes.
3. Use qualitative and/or quantitative methods to analyze data regarding programmatic needs, evaluation, or other public health issue.	Data analysis was done using SPSS to obtain frequencies and percentages of each of the answer choices for each question, as well as obtaining the mean, median, mode, standard deviation, and variance of relevant questions using SPSS. SPSS was also used to conduct a t-test to compare the results of individuals who have needed an epinephrine injector to those who have not.
5. Demonstrate knowledge related to managing a project including budget preparation, managing timelines and deliverables, and training staff for data collection	Conducting this research involved operating on a minimal budget, creating to and adhering to a timeline, and training other team members how to collect surveys.

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Figures and Tables

Table 1. Distribution (Number and Percent) Of Epinephrine Injector Usage In Individuals With Food Allergies, Greenville, North Carolina, February 2020

Distribution (number and percent) of Epinephrine Injector Usage in Individuals with food Allergies, Greenville, North Carolina, February 2020		
	Number	Percent
Previous need of epinephrine injector		
Yes	9	36
No	16	64
Frequency of possession of epinephrine injector at restaurants		
Always	3	12.5
Very Often	2	8.3
Sometimes	2	8.3
Rarely	5	20.8
Never	12	50.0
Frequency of restriction of food at a restaurant		
Always	6	24

Very Often	6	24
Sometimes	6	24
Rarely	1	4
Never	6	24
Frequency of avoidance of certain restaurants		
Always	4	16
Very Often	3	12
Sometimes	8	32
Rarely	7	28
Never	3	12
Frequency of worry surrounding if restaurant food has allergen		
Always	4	16
Very Often	10	40
Sometimes	7	28
Rarely	1	4
Never	3	12
Knowing that there is an epinephrine injector at a restaurant influences where they eat out at		
1 (no)	5	20
2	2	4
3	5	20
4	7	28
5 (yes)	7	28

Frequency that an epinephrine injector increases the feeling of safety		
Always	9	37.5
Very Often	8	33.3
Sometimes	4	16.7
Rarely	1	4.2
Never	2	8.3
Frequency that an epinephrine injector with voice instructions increases the feeling of safety		
Always	7	29.2
Very Often	5	20.8
Sometimes	6	25
Rarely	4	16.7
Never	2	8.3
Believe that the following should be required for restaurants:		
Have set aside counter space to prepare food for customers with allergies	20	83.3
Have set aside utensils to prepare food for customers with allergies	19	79.2
An ingredient list somewhere accessible to customers: within menu or online	22	91.7
Yearly training for staff about food allergies	21	87.5

Any type of training offered or suggested to staff about food allergies	23	95.3
Onsite epinephrine injector for emergencies	21	87.5
Routinely ask customers if they have any allergies	19	79.2
Number of years since diagnosed with allergy		
Less than a year	2	8.3
1-2 years	2	8.3
3-4 years	3	12.5
5-10 years	6	25
11-20 years	6	25
More than 20 years	5	20.8
Number of years since had a severe allergic food reaction		
Less than a year	8	33.3
1-2 years	3	12.5
3-4 years	1	4.2
5-10 years	8	33.3
More than 10 years	4	16.7

Table 2. List of Safety Measures Categorized By Importance And If They Are A Recommended Requirement From The Perspective Of Individuals With Food Allergies, Greenville, North Carolina, February 2020

	Very Important	Moderately important	Unimportant	Recommended requirement
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Set aside counter space	17	5	3	20
Set aside utensils	17	5	3	19
Ingredient list	19	5	0	22
Yearly training	18	6	1	21
Any type of training	19	4	1	23
Onsite epinephrine injector	16	8	1	21
Routinely ask customers if they have any allergies	18	4	3	19

Table 3. Distribution (Number and Percent) Of Responses From Restaurant Managers Surrounding Views On Epinephrine Injectors Within A Restaurant, Greenville and Winterville, NC, February 2020

	Number	Percent
Extent concerned about an allergic reaction in restaurant		
To a great extent	19	63.3
Somewhat	7	23.3
Very little	2	6.7
Not at all	2	6.7
Plan in place if an individual has a life threatening reaction		
Yes	25	83.3
No	2	6.7
Unsure	3	10
Previous consideration of getting an epinephrine injector for restaurant		
Yes	5	16.7
No	14	46.7
Unsure	11	36.7

Currently stocking an epinephrine injector?		
Yes	2	6.7
No	27	90
Unsure	1	3.3
Epinephrine injector with voice instructions would change the amount willing to pay for the epinephrine injector		
Yes	16	57.1
No	12	42.9
Having voice instructions will increase confidence of administering an epinephrine injector		
Yes	23	79.3
No	6	20.7
If epinephrine injector training was available for free, will restaurant take advantage of that?		
1 (no)	1	3.4
2	1	3.4
3	3	10.3
4	11	37.9
5 (yes)	13	44.8
Would restaurants utilize a sticker/sign to communicate to customers that an epinephrine injector was there?		
Yes	27	96.4

No	1	3.6

Table 4. List of Safety Measures Categorized By Availability At Restaurant And If They Are A Recommended Requirement From The Perspective Of Restaurant Managers, Greenville, North Carolina, February 2020

	Available	Not Available	Recommended requirement
Set aside counter space	20	10	19
Set aside utensils	20	10	22
Ingredient list	24	6	25
Yearly training	15	15	21
Any type of training	19	11	21
Onsite epinephrine injector	2	28	10
Routinely ask customers if they have any allergies	13	17	13

Human subjects:

Within this project human subjects research is being proposed, and an IRB application was submitted on 1/27/2020. On 2/11/2020 this study was approved by the East Carolina University and Medical Center Institutional Review Board (UMCIRB): #20-000216.



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
 4N-64 Brody Medical Sciences Building · Mail Stop 682
 600 Moye Boulevard · Greenville, NC 27834
 Office 252-744-2914 · Fax 252-744-2284
rede.ecu.edu/umcirb/

Notification of Exempt Certification

From: Social/Behavioral IRB
 To: [Holly Pittard](#)
 CC: [Ronny Bell](#)
 Date: 2/11/2020
 Re: [UMCIRB 20-000216](#)
 Epinephrine Injector Interest Within Restaurants

I am pleased to inform you that your research submission has been certified as exempt on 2/11/2020. This study is eligible for Exempt Certification under category # 2ab.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

Document	Description
Anaphylaxis Survey .docx(0.02)	Surveys and Questionnaires
Epinephrine Consent(0.02)	Consent Forms
Proposal(0.01)	Study Protocol or Grant Application
Restaurant Survey(0.02)	Surveys and Questionnaires
Survey Recruitment(0.01)	Recruitment Documents/Scripts

For research studies where a waiver of HIPAA Authorization has been approved, each of the waiver criteria in 45 CFR 164.512(i)(2)(ii) has been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) 10/26/00-04/18
 IRB00000781 East Carolina U IRB #2 (Behavioral) 10/26/00-04/18