ABSTRACT

Transfer of Responsibility for Auto-Injectable Epinephrine Devices from Parents to Children and Adolescents with Food Allergies

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Epinephrine auto-injectors are routinely prescribed for patients at risk of anaphylaxis, including children and adolescents with food allergies. This study sought to identify factors that impact the age at which parents transfer responsibility for carrying auto-injectable epinephrine devices to their children. In addition, this study sought to determine whether various stages of shared responsibility for carrying auto-injectable epinephrine devices are associated with adverse outcomes like anaphylaxis, emergency room visits, parental anxiety, and patient anxiety. Data was collected using a 32-question Qualtrics survey and participants were recruited via Amazon Mechanical Turk. Demographic variables like income, stock epinephrine availability, and a self-reported diagnosis of a developmental delay, anxiety disorder, or depressive disorder were found to correlate with the expected ages at which children would assume greater levels of responsibility. The lowest reported rates of anaphylaxis and ER visits due to allergic reactions occurred among children who shared responsibility with their parents.

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TRANSFER OF RESPONSIBILITY FOR AUTO-INJECTABLE EPINEPHRINE DEVICES FROM PARENTS TO CHILDREN AND ADOLESCENTS WITH FOOD ALLERGIES

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

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CHAPTER ONE

Introduction

Food Allergies

A food allergy (FA) is an adverse reaction produced by an immune response to a particular food (Sicherer et al., 2020). FA may be more generally categorized as a food hypersensitivity (FH), a term that includes both FA and various other adverse reactions to food (Begen et al., 2017). The 2014 National Health Interview Survey (NHIS) reported that 5.4% of American children under 18 years of age suffered from FA (National Center for Health Statistics, 2014). In general, Parrish reports that FA prevalence is increasing (Parrish & Kim, 2018). In 2018, Gupta estimated the FA prevalence to be around 8% in the same population (Gupta et al., 2018).

Anaphylaxis

FA can sometimes induce anaphylaxis, "a more serious allergic condition characterized by a systemic reaction involving at least 2 organ systems" (Pier & Bingemann, 2020). Food is not the only trigger that can induce anaphylaxis, but it is the most common trigger (Gupta et al., 2011). Like FA prevalence estimates, food-induced anaphylaxis (FIA) prevalence has been shown to be increasing (Parrish & Kim, 2018). FIA fatality prevalence, however, remains static (Parrish & Kim, 2018). Notably, adolescents and young adults are overrepresented among fatal FIA cases (Parrish & Kim, 2018).

Epinephrine

Current standards of care regarding anaphylaxis identify epinephrine as the only medication that prevents FA-related hospitalizations and fatalities (Tanno et al., 2019). Acute anaphylaxis management is thus focused on epinephrine administration (Sacco & Gonzalez-Estrada, 2018). The importance of epinephrine cannot be overstated. Delayed epinephrine administration has been identified as a risk factor for fatal anaphylaxis (Turner et al., 2017). Similarly, a lack of epinephrine availability at the time of an anaphylactic reaction has been correlated with fatal anaphylaxis (Bock et al., 2001). FA management plans thus involve carrying epinephrine auto-injectors, or auto-injectable epinephrine (AIE) devices (Simons et al., 2013).

Gallagher defined ideal use of an AIE device as a patient's ability to undergo training in auto-injector technique, carry and store the auto-injector appropriately, identify an anaphylactic reaction when it occurs, know at what point in the reaction to use the device, make the decision to administer it, and actually administer epinephrine using the correct technique (Gallagher et al., 2011). The steps involved in administering epinephrine vary slightly by brand. Today, patients may choose between Adrenaclick, Auvi-Q, EpiPen, Symjepi, and generic Epinephrine. Previous studies have examined patient preferences and found that significant differences exist between AIE brands. In 2013, Camargo found that differences in patient preferences exist between Auvi-Q and Epi-Pen brands of AIE; namely, surveyed parents and patients preferred Auvi-Q (Camargo et al., 2013). Portnoy examined differences in carriage among 2,000 patients that filled a prescription for either Auvi-Q or Epi-Pen and found that patients carried their

device for a greater portion of the day when prescribed Auvi-Q in comparison with an Epi-Pen (Portnoy et al., 2019).

Personal allergy management plans may vary depending on the patient's school policy. In 2016, Hogue reported that "schools differed substantially in their preparedness to manage anaphylaxis, with significant disparities in staff training and permission to treat" (Hogue et al., 2016). Greenhawt reports that some schools now maintain a supply of non-student specific stock epinephrine, although such school policies are not nationally uniform (Greenhawt et al., 2018).

CHAPTER TWO

Literature Review

Epinephrine Compliance and Carriage Studies

AIE misuse is a well-documented issue among patients with a FA. In 2015, Bonds found that only 16% of patients or parents of minors with a previous prescription for an AIE device could demonstrate the proper technique for AIE administration (Bonds et al., 2015). A meta-analysis of 61 reports regarding "pitfalls in the use of epinephrine" identified the most common problem as a lack of AIE availability at the time of anaphylaxis, followed by inadequate education, uncertainty about when or how to administer epinephrine, concern for systemic effects, failure to administer, and accidental administration (Cohen, 2016).

Reasons for noncompliance are varied, and pitfalls in food allergy maintenance can be attributed to parents as well as children and providers. Kim found that parental empowerment was "directly correlated with increased comfort with EpiPen use, but knowledge [was] not" (Kim et al., 2005). Prince found that cost, availability, failure to use even when it is available, and incorrect technique also presented barriers (Prince et al., 2018). Bonds found that younger patients and those with prior medical experience were more likely to demonstrate correct technique (Bonds et al., 2015).

Adolescents with FA do not carry AIE consistently due, in part, to a desire to blend in and the perceived cumbersome nature of an AIE (Leach et al., 2018, Gallagher et al., 2011, Frew, 2011). Additionally, inadequate training, poor motivation or self-

discipline to carry the medication, inability to recognize or identify a reaction, and inadequate emotional preparation for managing the stressors that accompany emergencies like anaphylaxis have been identified as additional issues (Gallagher et al., 2011). Emotional preparedness matters because patients must be able to use their auto-injectors correctly while under the high stress level that may accompany an anaphylactic attack (Frew, 2011).

Adolescent patients, in particular, assume several risks. They do not always carry their AIE device, eat foods labelled with "may contain" allergen warnings, and withhold information regarding their food allergy from people around them, for instance (Macadam et al., 2012). Absence of an auto-injector was found to be a common factor in anaphylactic fatalities in the United States (Macadam et al., 2012). Risky behavior was found to decrease in correlation with peanut allergy, supportive female friends, overprotective mothers, and teachers who were aware of their food allergy (Warren et al., 2017). In 2012, Macadam offered an optimistic interpretation to such risk-taking behaviors. Their team found that among food allergy patients between the ages of 12 and 18 with an AIE prescription, “most teenagers made complex risk assessments to determine whether to carry the auto-injector. Most but not all decisions were rational and were at least partially informed by knowledge. Factors affecting carriage included location, who else would be present, the attitudes of others and physical features of the auto-injector” (Macadam et al., 2012). This article qualifies claims that adolescents with food allergies are willing to assume risky behaviors.

Parents may gauge their child’s level of risk according to a number of factors. Ogg surveyed 202 parents of food-allergic children at an allergy clinic (Ogg et al., 2017).

The authors write that "a lack of a university education, higher anxiety score, and, particularly, possession of an epinephrine auto-injector… were key factors associated with heightened risk perception" (Ogg et al., 2017).

Several interventions have attempted to increase AIE carriage rates. Anderson applied the behavioral intervention technology model to anaphylaxis management plans, texting participants to promote compliance (Anderson & Wallace, 2015). Davidson designed a mobile app to increase adherence to anaphylaxis management plans among 10 to 19 year old participants (Davidson et al., 2017).

Transition of Responsibility

One potential method to increase carriage involves a smooth transition of responsibility from parents to their child. Members of the American Academy of Pediatrics Section on Allergy and Immunology (AAP-SOAI) were surveyed about when they typically begin to transfer these responsibilities from adults to children and teenagers. Most allergists involved reported beginning the process between the ages of 9 and 11 years old. A child's ability to recognize symptoms was one factor pediatric allergists used to determine if the patient was ready to self-carry (Simons et al., 2012). DunnGalvin writes that "the transfer of responsibility from parents also denotes, to a certain extent, the transfer of the burden and concerns [which] are greater when adolescents are away from their parents" (DunnGalvin et al., 2016).

Another noteworthy published study regarding transfer of responsibility for children with FA is the Simons 2013 study titled "Perspectives of Parents and Caregivers Regarding Timing the Transfer of Responsibilities for Anaphylaxis Recognition and Use of an Epinephrine Auto-Injector From Adults to Children and Teenagers." This study

surveyed caregivers regarding the age at which their children first assumed responsibility for carrying AIE devices and the factors the caregivers considered when determining the timing of this shift in responsibility. The study found that while children usually agreed with their parents regarding who was responsible for care, adolescent answers did not always agree with parental answers. The authors conclude that additional studies are necessary to determine how transition of care can occur smoothly such that both the patient and the caretaker understand their respective responsibilities. This study also correlates a history of severe reactions with better self-management among children, and anxiety with better self-management among adolescents (Simons et al., 2013).

Food Allergies and Quality of Life

DunnGalvin reports that food allergies have an overall negative impact on quality of life among children that increases in severity with age (DunnGalvin et al., 2016). One study of Dutch food-allergic adolescents found a greater burden on quality of life in food-allergic adolescents prescribed an AIE device who reported not carrying the AIE device at all times in comparison with adolescents who reported they did, suggesting that patterns of carriage affect overall quality of life (Saleh-Langenberg et al., 2016).

Another study, a qualitative interview of five families of children with peanut allergies, found that peanut allergies impact all family members (Stensgaard et al., 2017). Siblings took responsibility for the patient with the allergy (Stensgaard et al., 2017). The authors add that additional research is needed in order to investigate if these trends are generalizable to all food-allergic patients, and how this impacts timing of transfer of responsibility. Their work implies that because FA impacts the whole family, additional

surveys should ask about family structure and parental marital status (Stensgaard et al., 2017).

Gaps in Literature

Annunziato examined the distribution of responsibility for food allergy management skills between caregivers to children in "Allocation of food allergy responsibilities and its correlates for children and adolescents." The authors reported that "In this study, carrying/using self-injectable epinephrine was not included due to the wide age range of participants, differences in local school regulations, and rarity of need to use the medication; we included behaviors that could apply to all patients" (Annunziato et al., 2015). The following study thus makes a meaningful contribution to existing research as it examines an aspect of FA management skills that the Annunziato study did not.

The Simons 2013 study titled "Caregivers' perspectives on timing the transfer of responsibilities for anaphylaxis recognition and treatment from adults to children and teenagers" surveyed caregivers regarding the age at which their children first assumed responsibility for carrying auto-injectable epinephrine devices and the factors the caregivers considered when determining the timing of this shift in responsibility (Simons et al., 2013). They found that most caregivers reported beginning transferring responsibility for anaphylaxis recognition by the time the child reached 8 years of age. Most caregivers reported planning to transfer responsibility for AIE administration between the ages of 6 and 11 years old (Simons et al., 2013). The following study was meant to build on their work by also examining the associated outcomes that might be

correlated with a particular stage of shared responsibility, like anaphylaxis, emergency room visits, parental anxiety, and patient anxiety.

CHAPTER THREE

Methods

Research Questions

The primary objective is to identify factors that impact the age at which parents transfer responsibility for carrying auto-injectable epinephrine devices to their food allergic children. The secondary objective is to determine whether the stage of shared responsibility is associated with emergency room visits related to food-induced anaphylaxis, parental anxiety levels, and patient anxiety levels. The three stages of responsibility examined in this study were: 1) the parent is fully responsible for carrying the AIE device, 2) responsibility for carrying the AIE device is shared between the parent and child, and 3) the child is fully responsible for carrying their own AIE device.

Institutional Review

The project was submitted to the Baylor University Institutional Review Board and granted an "Exempt" status.

Recruitment

Participants were recruited through Amazon Mechanical Turk. Amazon Mechanical Turk, or MTurk, is a crowdsourcing marketplace where requesters can post tasks and workers can complete surveys in exchange for a monetary reward. Qualifiers were applied such that the survey was only visible and accessible to individuals who had

previously identified themselves as parents. Potential participants were invited to "Answer a survey about shared responsibilities with your child." Further instructions stated that "This survey asks about how you share responsibilities with your child, and takes about 15 minutes to complete." Participants were given a maximum of two hours to complete the survey. At the conclusion of the survey, Qualtrics was used to generate a random six digit survey ID. Participants could then add this code to their MTurk account as proof of completion. The survey code was used to confirm that workers had completed the survey fully, and participants were compensated between $1.15 and $1.50 for complete responses. Data was collected between 3/29/2021 and 4/8/2021.

Three questions were developed to assess participant eligibility. First, participants were asked "Are you at least 18 years old?" Next, they were asked "Are you the parent or primary caregiver of a child with a food allergy?" and "Has your child been prescribed an auto-injectable epinephrine device, like an EpiPen or Auvi-Q?" If participants answered "no" to any of the above, no further data was collected and their answers were not included in the final analysis.

Survey Development

Next, demographic data was collected regarding both parents and children (Appendix). The first question, "Where are you taking this survey?" was used as an attention checker among MTurk participants. Demographic questions 4 through 6 were drawn directly from previously validated questions, namely the 2019 National Survey on Drug Use and Health distributed by the Substance Abuse and Mental Health Services Administration (Center for Behavioral Health Statistics and Quality, 2018). The original NSDUH questions are shown below.

Q4 Are you of Hispanic, Latino, or Spanish origin or descent?
1 YES
2 NO

Q5 Which of these groups describes you?
1 WHITE
2 BLACK OR AFRICAN AMERICAN
3 AMERICAN INDIAN OR ALASKA NATIVE (AMERICAN INDIAN INCLUDES NORTH AMERICAN, CENTRAL AMERICAN, AND SOUTH AMERICAN INDIANS)
4 NATIVE HAWAIIAN
5 GUAMANIAN OR CHAMORRO
6 SAMOAN
7 OTHER PACIFIC ISLANDER
8 ASIAN (INCLUDING: ASIAN INDIAN, CHINESE, FILIPINO, JAPANESE, KOREAN, AND VIETNAMESE) 9 OTHER (SPECIFY)

Q6 *Are you now married, widowed, divorced or separated, or have you never married?*
1 MARRIED
2 WIDOWED
3 DIVORCED OR SEPARATED
4 HAVE NEVER MARRIED

Depression and the developmental delays referenced in question 11 have previously been identified among the factors pediatric allergists consider "very important" when assessing patient readiness to begin transferring responsibility for epinephrine auto-injector carriage (Simons, 2012). Question 12 includes both depressive and anxiety disorders because food allergy has previously been correlated with anxiety among pediatric patients (Ferro, 2016). Age categories for children were drawn from the Simons 2013 study such that results would be easily comparable to previous findings. Questions 13 - 17 ask questions regarding food allergy. The list of common allergens listed in question 13 was drawn from Begen's 2017 study. The Simons 2013 study found that 50% of parents ranked institutional policy like school rules regarding epinephrine auto-injector carriage as "very important," so question 16 seeks to determine how a

specific school policy, namely stock epinephrine availability, might influence the transfer of responsibility (Simons, 2013). Question 17 presents participants with a list of factors that have previously been identified as "very important" or "somewhat important" by the majority of surveyed caregivers, including level of anxiety regarding needles, ability to recognize anaphylaxis symptoms, and ability to self-inject epinephrine (Simons, 2013). Frew's literature review suggests that "ability to make decisions in stressful circumstances" ought to be considered when assessing ideal features of an epinephrine auto-injector, and this question is designed to see if this factor also impacts transfer of responsibility (Frew, 2011).

Questions 18 - 22 are designed to assess how caregivers and children currently distribute responsibility for auto-injectable epinephrine carriage. The stages of shared responsibility listed in question 18 were adapted from a 2017 FA study (Shemesh, 2017). Their study identifies the following stages: 1) Adult/s (parent/caregiver/someone else at home) is fully responsible, 2) youth and adult share responsibility, 3) youth is fully responsible, 4) someone else in the home, and 5) nobody really does this (Shemesh, 2017). Questions 19 - 22 are designed to assess the age at which patients moved from one stage to another, or the age at which parents anticipate that their child will progress from one stage to the next.

Questions 23-31 were designed to assess food allergy-related outcomes at each stage of shared responsibility, including instances of anaphylaxis, emergency room visits, and both the caregiver and child's anxiety levels. The Qualtrics survey includes display logic that skips sections that are not applicable to given participants. For example,

participants that selected “Parent or primary caregiver is fully responsible” for question 18 would not see questions 26 through 31.

Finally, question 32 was designed to weigh the impact of COVID-19 on children with food allergies and their parents.

Statistical Analysis

Frequencies and percentages were used to describe demographic and psychosocial characteristics of the sample. For the primary study objective, we created a binary variable of age at which parents and/or primary caregivers transfer responsibility for carrying auto-injectable epinephrine devices to their children as 1=<9 years of age and 2=9+ years of age. After data collection, the distribution of responses were assessed and these two categories were selected in order to ensure that a significant number of responses fell into each category. A chi square analysis was conducted to determine factors associated with age at which parents and/or primary caregivers transfer responsibility for carrying auto-injectable epinephrine devices to their children with food allergies. For the secondary objective of the study, the average reported value and standard deviation for variables listed in question 16 were calculated according to the stage of shared responsibility. These variables include the child’s current level of anxiety regarding needles, ability to recognize symptoms of anaphylaxis, ability to self-inject epinephrine, ability to make decisions in stressful circumstances, and level of risk taking behavior. The three stages of shared responsibility were 1) the parent is fully responsible for carrying the AIE device, 2) responsibility for carrying the AIE device is shared between the parent and child, and 3) the child is fully responsible for carrying their own AIE device. The survey also includes options which state that: 4) someone else in the

home does this, or 5) nobody does this. All data was analyzed by the IBM Statistical Package for Social Sciences (SPSS) version 25.0.

CHAPTER FOUR

Results

One hundred and ninety individuals started the survey. One hundred and four responses were excluded from analysis because the potential participant answered "no" to a screening question, left questions blank, submitted illogical answers (e.g. indicating that their child was simultaneously in two different age categories), or indicated that they were completing the survey from a clinic location rather than through MTurk. The final parameter served as an attention checker. The following results thus reflect the data collected from 86 complete surveys.

Table 1 outlines the demographics of the sample, and Table 2 details the demographic characteristics of the children in the study sample.

Table 1. Characteristics of the study sample (N=86)

Characteristics	**n (%)**
Age	
18-34	64 (74.4)
35+	22 (25.6)
Relationship to child	
Mother	50 (58.1)
Father	36 (41.9)
Hispanic, Latino, or Spanish origin or descent	
Yes	24 (27.9)
No	62 (72.1)
Race	

White	49 (57.0)
Asian	23 (26.7)
Other	14 (16.3)
Marital Status	
Married	81 (94.2)
Divorced, separated, or have never married	5 (5.8)
Education	
Completed college or less	61 (70.9)
Graduate degree or higher	25 (29.1)
Income	
Up to $49,999	46 (53.5)
$50,000 and above	40 (46.5)
Age of Child	
Under 9	66 (76.7)
9 and older	20 (23.3)
Sex of Child	
Male	50 (58.1)
Female	36 (41.9)

Table 2. Demographics of children in study sample (N=86)

Characteristics	**n (%)**
Food allergy	
Milk	39 (45.3)
Egg	38 (44.2)
Soy	20 (23.3)
Peanut	36 (41.9)

Tree nut	18 (20.9)
Seafood	41 (47.7)
Other	1 (1.2)
Type of Epinephrine Auto-Injector	
Auvi-Q	28 (23.3)
EpiPen	24 (27.9)
EpiPen Jr.	17 (19.8)
Generic Epinephrine	10 (11.6)
Other	7 (8.14)
Diagnosis of developmental delay, attention deficit hyperactivity disorder, or autism spectrum disorder	
Yes	45 (52.3)
No	41 (47.7)
Diagnosis of an anxiety or depressive disorder	
Yes	48 (55.8)
No	38 (44.2)
Do other members of the household have a prescription for auto-injectable epinephrine?	
Yes	63 (73.3)
No	23 (26.7)
Stock epinephrine available at school?	
Yes	48 (55.8)

No	21 (24.4)
Unsure	17 (19.8)

As seen in Figure 1, most participants (76.7%, n=66) indicated that the parent was fully responsible for carrying the auto-injectable epinephrine device. Options four and five, which state that "someone else in the home does this" and "nobody does this," were excluded from further analysis because only one participant selected each option. As seen in Table 3, 72.2% (n = 13) of parents who had already started sharing responsibility with their child indicated that the child had started this step younger than 9 years old. In contrast, 47.1% (n=32) of parents who had not yet started sharing responsibility reported that their child would start this step younger than 9 years old. Next, 87.5% (n=7) of parents who have already transferred full responsibility to their child reported that this step took place younger than 9 years of age, while 37.2% (n=29) of parents with children who have not yet taken this step expected that their child would take this step by 9 years old.

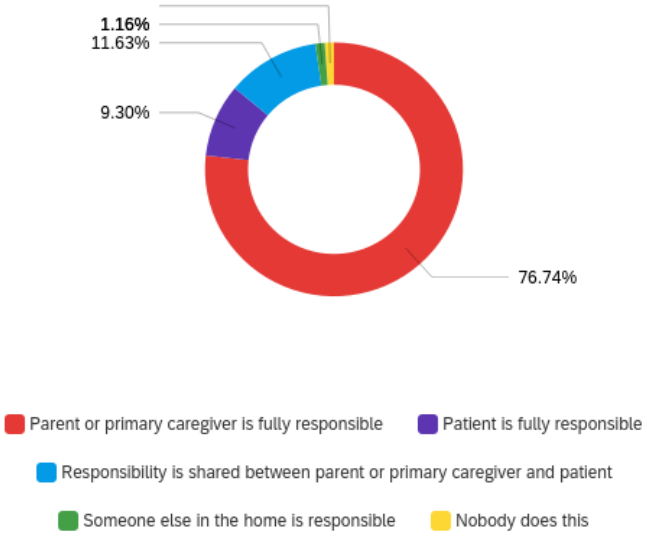

Figure 1: Who is responsible for carrying the auto-injectable epinephrine device?

Table 3. Age of transfer or expected age of transfer

Characteristics	n (%)
Age of transfer from "Parent is fully responsible" to "Responsibility is shared" among children who already completed this step	
Under 9	13 (72.2)
9+	5 (28.8)
Expected age of transfer from "Parent is fully responsible" to "Responsibility is shared" among children who have not yet completed this step	
Under 9	32 (47.1)
9+	36 (52.9)
Age of transfer from "Responsibility is shared" to "Child is fully responsible" among children who already completed this step	
Under 9	7 (87.5)
9+	1 (12.5)
Expected age of transfer from "Responsibility is shared" to "Child is fully responsible" among children who have not yet completed this step	
Under 9	29 (37.2)
9+	49 (62.8)

In Table 4, the average reported values for needle fear, the child's ability to recognize symptoms of anaphylaxis, ability to self-inject, ability to make decisions in stressful circumstances, and level of risk taking behavior are shown. Results were sorted according to the stage of shared responsibility. While the highest values for the first four variables were reported for the second stage of shared responsibility, the difference

between these values and the values reported in the first two stages was not statistically significant, as seen by the level of standard deviation reported. The highest values for level of risk taking behavior were reported among parents who stated that their child was fully responsible for carrying their AIE. Once again, however, the difference between these values and the values reported in the first two stages was not statistically significant.

Table 4: Average variables during each stage of shared responsibility

Stage 1: Parent is fully responsible (n = 66)	**Mean (SD)**
Needle fear	3.2 (1.0)
Ability to recognize symptoms	3.3 (1.1)
Ability to self-inject	3.1 (1.2)
Ability to make decisions in stressful situations	3.2 (0.96)
Level of risk taking behavior	3.1 (1.1)
Stage 2: Responsibility is shared (n=10)	**Mean (SD)**
Needle fear	3.6 (0.70)
Ability to recognize symptoms	3.7 (0.82)
Ability to self-inject	4.2 (0.92)
Ability to make decisions in stressful situations	4.1 (0.93)
Level of risk taking behavior	3.2 (1.1)
Stage 3: Child is fully responsible (n=8)	**Mean (SD)**
Needle fear	3.4 (0.92)
Ability to recognize symptoms	3.3 (0.75)
Ability to self-inject	3.1 (0.35)
Ability to make decisions in stressful situations	3.5 (0.76)
Level of risk taking behavior	3.8 (0.88)

Table 5 outlines the rates at which adverse outcomes like anaphylaxis and emergency room visits caused by allergic reactions occur at each stage of shared

responsibility. The lowest reported rates of each occurred among children who shared responsibility with their parents, and the highest rates were reported among pediatric and adolescent patients who were fully responsible for carrying their own auto-injectable epinephrine device. Figure 2 visualizes these trends.

Table 5: Adverse outcomes at each stage of shared responsibility

Stage 1: Parent is fully responsible (n = 86)	**n (%)**	**Mean (SD)**
Child experienced anaphylaxis		
Yes	49 (57.0)	
No	26 (30.2)	
Unsure	11 (12.8)	
Child experienced ER visit due to allergic reaction		
Yes	52 (60.5)	
No	28 (32.6)	
Unsure	6 (7.0)	
Parent anxiety level		3.7 (0.81)
Child's anxiety level		3.4 (1.1)
Stage 2: Responsibility is shared (n=18)		
Child experienced anaphylaxis		
Yes	9 (50.0)	
No	7 (38.9)	
Unsure	2 (11.1)	

Child experienced ER visit due to allergic reaction		
Yes	10 (55.6)	
No	6 (33.3)	
Unsure	2 (11.1)	
Parent anxiety level		3.1 (0.74)
Child's anxiety level		3.4 (0.90)
Stage 3: Child is fully responsible (n=8)		
Child experienced anaphylaxis		
Yes	5 (62.5)	
No	3 (37.5)	
Unsure	0 (0)	
Child experienced ER visit due to allergic reaction		
Yes	6 (75.0)	
No	2 (25.0)	
Unsure	0 (0)	
Parent anxiety level		2.9 (0.93)
Child's anxiety level		3.3 (1.1)

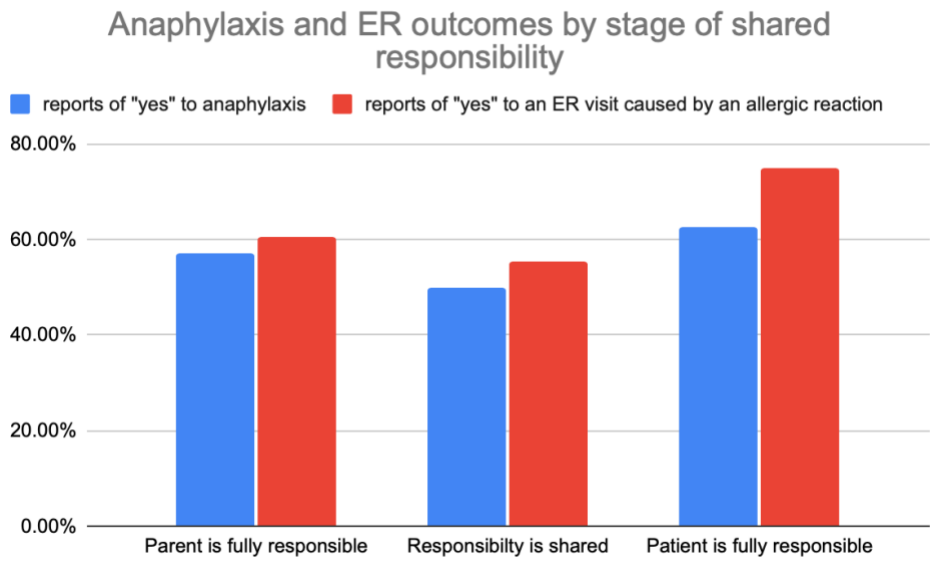

Figure 2: Percentage of participants who replied "yes" to a given adverse outcome at each stage of shared responsibility.

The mean reported parent anxiety level at each stage was 3.7 (SD 0.81), 3.1 (SD 0.74), and 2.9 (standard deviation of 0.93), respectively. This downward trend was also seen in patient anxiety levels. The mean reported patient anxiety level at each stage was 3.4 (SD 1.1), 3.4 (SD 0.90), and 3.3 (SD 1.1). Figure 3 summarizes these trends.

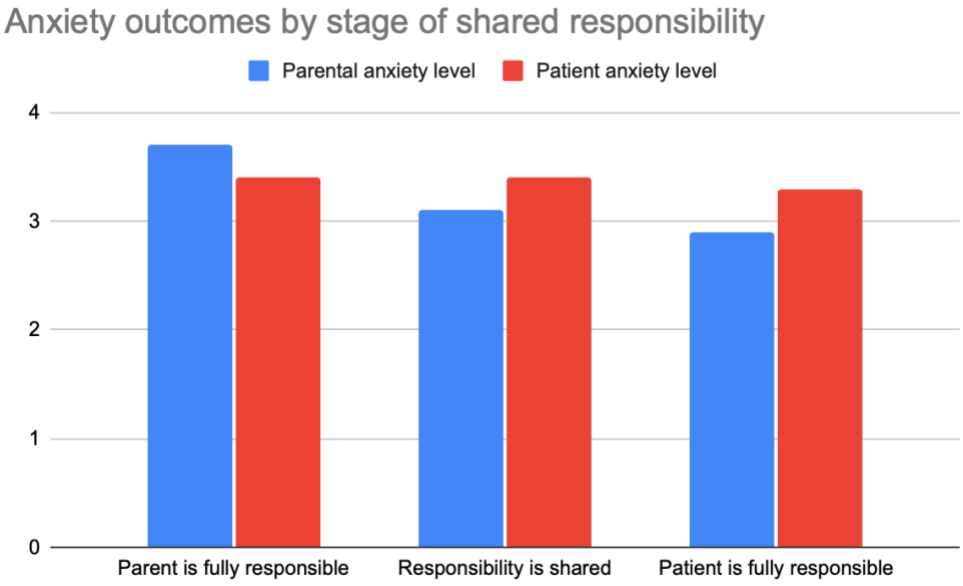

Figure 3: Mean reported anxiety levels at each level of shared responsibility.

Next, multiple chi-square tests were conducted in order to determine if demographic factors were correlated with the age at which parents transferred responsibility to their children with food allergies. Because most participants have not yet started sharing responsibility or transferred full responsibility to their child, most available data pertains to the age at which parents expect to take these steps. The child's sex was not found to correlate with the expected age of shared (X^2 (1, N = 68) = 1.336, p = .248) or expected age of full responsibility (X^2 (1, N = 78) = .120, p = .729). An advanced degree was not found to correlate with the expected age of shared responsibility (X^2 (1, N = 68) = .022, p = .881) or the expected age of full responsibility for the child (X^2 (1, N = 78) = .220, p = .639). Parents with incomes greater or equal to $50,000 were more likely to report that their children would start sharing responsibility by age 9 than their counterparts with incomes under $50,000 (62.9% vs. 30.3%, p=0.007). Parents with incomes greater than or equal to $50,000 were also more likely to report that their children would assume sole responsibility by age 9 than their counterparts with incomes under $50,000 (51.4% vs. 24.4%, p = .014). Income was thus negatively correlated with the expected ages at which children moved to the next step of shared responsibility.

Parents who self-reported that their child had a history of a diagnosis of a developmental delay were more likely to report anticipating shared responsibility under 9 years old in comparison with parents who did not self-report a diagnosis of a developmental delay (60.6% vs 34.3%, p = .030). A self-reported diagnosis of a developmental delay in the child did not have a statistically relevant impact on expected age of sole responsibility ((X^2 (1, N = 78) = 2.690, p = .101). A self-reported diagnosis of an anxiety or depressive disorder in the child was correlated with a younger expected age

of shared responsibility; parents who self-reported this diagnosis in their child were more likely to anticipate sharing responsibility under age 9 than their counterparts who did not report this diagnosis (63.9% vs. 28.1%, p = .003). A self-reported diagnosis of an anxiety or depressive disorder in the child was also correlated with a younger expected age of sole patient responsibility; parents who self-reported anxiety or depressive disorders in their children were more likely to expect transferring responsibility prior to 9 years old than their counterparts who did not self-report this diagnosis (47.6% vs. 25.0%, p = .039).

Whether or not additional members of the household had an epinephrine auto-injector was not correlated with the anticipated age of shared responsibility ((X^2 (1, N = 68) = 3.653, p = .056) or the expected age of patient sole responsibility ((X^2 (1, N = 78) =2.740, p = .098). Stock epinephrine availability was not correlated with expected age of shared responsibility ((X^2 (1, N = 54) =3.382, p = .066). It was, however, correlated with the expected age at which children would assume full responsibility; parents who reported that stock epinephrine was available were more likely to anticipate transferring sole responsibility to their child before 9 years of age in comparison with parent who reported that stock epinephrine was not available (52.4% vs. 21.1%, p = .033).

Finally, 54.1% (n=46) of participants reported that they either "Agreed" or "Strongly Agreed" that their child had experienced an increase in anaphylactic reactions since the beginning of the COVID-19 pandemic. A majority of participants, 65.1% (n=56), reported that they either "Agreed" or "Strongly Agreed" that they had experienced difficulty refilling a prescription for their child's AIE device.

CHAPTER FIVE

Discussion and Conclusion

This study found that 72.2% (n = 13) of parents who had already started sharing responsibility with their child indicated that the child had started this step younger than 9 years old, while 47.1% (n=32) of parents who had not yet started sharing responsibility reported that their child would start this step younger than 9 years old. These findings suggest that in reality, parents begin sharing responsibility with their children at younger ages than parents might anticipate. Similar trends are evident in the ages at which parents report giving their children full responsibility for carrying AIE devices. In comparison with the data collected by Simons et al., where most physicians reported beginning the transfer of responsibility from parents and caregivers to children with food allergies between ages 9-11(Simons et al., 2012), this study found that parents reported beginning the process at younger ages. Consistent with Greenhawt's findings that school stock epinephrine policies vary, only 55.8% of participants reported that stock epinephrine was available at their child's school (Greenhawt, 2018).

This study also found that parental anxiety levels were lower when patients assumed more responsibility for carrying their own AIE devices compared to when parents assumed full or shared responsibility. These findings are consistent with DunnGalvin's findings that as parents transfer responsibility for carrying AIE devices, they also transfer a degree of the concerns and mental burden associated with a food allergy to their child (DunnGalvin et al., 2016). In this study, the average reported child

anxiety levels decreased between the first two stages of shared responsibility, but increased when children assumed sole responsibility. These findings are inconsistent with the trends observed by DunnGalvin.

A diagnosis of a developmental delay, anxiety disorder, or depressive disorder in the child was correlated with an expectation of transferred responsibility at a younger age. It is possible that parents who have a child with a developmental delay play a larger or more active role in their child's development, fostering early independence by anticipating early transfer of responsibility. With regards to the anxiety finding, a history of severe reactions may be a confounding variable, such that children with more severe food allergies experience more anxiety, and parents are thus willing to transfer responsibility at earlier stages in order to help with the associated symptoms. Each of these possible explanations ought to be pursued in future investigations.

Limitations

The primary limitation to this study involves the relatively small sample size. Because most participants were still fully responsible for carrying their child's AIE, limited data was available on the actual ages at which parents began to share or transferred full responsibility to their child. Further studies ought to target this population. The small sample size also limited our ability to conduct multivariable analysis.

In addition, it is possible that some participants through Amazon Mechanical Turk misrepresented themselves in order to pass screening questions and earn the survey reward. In order to combat this, full details regarding eligibility were not available to

Amazon Mechanical Turk workers at the time they accepted the assignment. In addition, the qualifiers were applied such that the survey was only visible to individuals who had previously identified themselves as parents.

Finally, this study did not ask about the age at which children were diagnosed with their food allergy, and thus did not distinguish between children who had been prescribed an AIE device in early childhood and those who had been prescribed an AIE device later in childhood. Further studies ought to examine this variable.

Conclusion

This study found that the average reported values for needle fear, a child's ability to recognize symptoms of anaphylaxis, ability to self-inject, and ability to make decisions in stressful circumstances were highest among parents who shared responsibility for carrying an AIE device with their food-allergic child. The average reported values for a child's level of risk-taking behavior were highest among parents who reported that their child was fully responsible for carrying their own AIE device. The lowest reported rates of adverse outcomes like anaphylaxis and emergency room visits caused by a food allergy occurred among children who shared responsibility with their parents, and the highest rates were reported among pediatric and adolescent patients who were fully responsible for carrying their own auto-injectable epinephrine device.

Factors like parental income and a self-reported diagnosis of a developmental delay, anxiety, or depressive disorder in the child were found to positively correlate with an expected age of shared responsibility of less than 9 years old. Factors like parental income, stock epinephrine availability, and a self-reported diagnosis of a developmental

delay were found to positively correlate with an expected age of transferring full responsibility to the child younger than 9 years old.

APPENDIX

Survey

Eligibility
Are you at least 18 years old?

- o Yes
- o No

Are you the parent or primary caregiver of a child with a food allergy?

- o Yes
- o No

Has your child been prescribed an auto-injectable epinephrine device, like an EpiPen or Auvi-Q?

- o Yes
- o No

Q1 Where are you taking this survey?

- o Oklahoma City, OK
- o Waco, TX
- o Through Amazon MTurk

Q2 What is your relationship to the patient?

- o Mother, biological
- o Mother, other (including foster, step, or adoptive)
- o Father, biological
- o Father, other (including foster, step, or adoptive)
- o Other primary caregiver (please specify)

Q3 What is your age?

- o 18-24
- o 25-34
- o 35-44

- o 45-54
- o 55-64
- o 65+

Q4 Are you of Hispanic, Latino, or Spanish origin or descent?

- o Yes
- o No

Q5 Which of these groups describes you?

- o White
- o Black or African American
- o American Indian or Alaska Native (American Indian includes North American, Central American, and South American Indians)
- o Native Hawaiian
- o Guamanian or Chamorro
- o Samoan
- o Other Pacific Islander
- o Asian (including Asian Indian, Chines, Filipino, Japanese, Korean, and Vietnamese)
- o Other (please specify) _____

Q6 Are you now married, widowed, divorced or separated, or have you never married?

- o Married
- o Widowed
- o Divorced or separated
- o Have never married

Q7 What is the highest level of education you have completed?

- o Completed high school or less
- o Completed college
- o Completed graduate school

Q8 What is your annual household income?

- o Less than $10,000
- o $10,000 to $14,999
- o $15,000 to $24,999
- o $25,000 to $34,999
- o $35,000 to $49,999
- o $50,000 to $74,999

- o $75,000 and above

Q9 What is the patient's age?

- o Under 6
- o 6-8
- o 9-11
- o 12-14
- o 15-18

Q10 What is the patient's sex?

- o Male
- o Female

Q11 Has your child been diagnosed with a developmental delay, attention deficit hyperactivity disorder, or autism spectrum disorder?

- o Yes
- o No

Q12 Has a doctor, nurse or other health professional ever diagnosed your child with an anxiety or depressive disorder?

- o Yes
- o No

Q13 To which of the following foods is the patient allergic? Select all that apply.

- ☐ Milk
- ☐ Egg
- ☐ Soy
- ☐ Peanut
- ☐ Tree nut
- ☐ Seafood
- ☐ Other (please specify) _____

Q14 Which kind of auto-injectable epinephrine was the patient prescribed?

- o Adrenaclick
- o Auvi-Q
- o EpiPen
- o EpiPen Jr.
- o Symjepi
- o Generic Epinephrine
- o Other (please specify) _____

Q15 In addition to the patient described, do other members of your household have a prescription for auto-injectable epinephrine?

- o Yes, the patient's parent or primary caregiver
- o Yes, the patient's sibling
- o Yes, another member of the household
- o No

Q16 Does the patient's school have stock epinephrine available?

- o Yes
- o No
- o Unsure

Q17 On a scale from 1-5, how would you rate your child's current

	1 (low)	2	3	4	5 (high)
Level of anxiety regarding needles	o	o	o	o	o
Ability to recognize symptoms of anaphylaxis	o	o	o	o	o
Ability to self-inject epinephrine	o	o	o	o	o
Ability to make decisions in stressful circumstances	o	o	o	o	o
Level of risk-taking behavior (ie knowingly eating foods with an allergen, choosing not to carry their auto-injectable epinephrine device, etc.)	o	o	o	o	o

Q18 Who is responsible for carrying the auto-injectable epinephrine device?

- o Parent or primary caregiver is fully responsible
- o Patient is fully responsible
- o Responsibility is shared between parent or primary caregiver and patient
- o Someone else in the home is responsible
- o Nobody does this

Q19 If the patient shares responsibility for carrying the auto-injectable epinephrine device, at what age did he or she start?

- o 6-8
- o 9-11
- o 12-14
- o 15-18

Q20 If the patient does not yet share responsibility for carrying the auto-injectable epinephrine device, at what age do you anticipate that he or she will start?

- o 6-8
- o 9-11
- o 12-14
- o 15-18
- o 19+

Q21 If the patient is fully responsible for carrying the auto-injectable epinephrine device, at what age did he or she start?

- o 6-8
- o 9-11
- o 12-14
- o 15-18

Q22 If the patient is not yet fully responsible for carrying the auto-injectable epinephrine device, at what age do you anticipate that he or she will start?

- o 6-8
- o 9-11
- o 12-14
- o 15-18
- o 19+

The following questions ask about the time *before* your child started sharing responsibility to self-carry an auto-injectable epinephrine device

Q23 Did your child ever experience an anaphylactic reaction?

- o Yes
- o No
- o Unsure

Q24 Did your child ever go to the emergency room for an allergic reaction?

- o Yes
- o No
- o Unsure

Q25 How would you rate (or have rated) the following:

	1 (low)				5 (high)
your level of anxiety regarding your child's food allergy	o	o	o	o	o
your child's level of anxiety regarding his or her food allergy	o	o	o	o	o

The following questions ask about the time *after* your child assumed a shared responsibility to self-carry an auto-injectable epinephrine device but *before* the child assumed sole responsibility.

Q26 Did your child ever experience an anaphylactic reaction?

- o Yes
- o No
- o Unsure

Q27 Did your child ever go to the emergency room for an allergic reaction?

- o Yes
- o No
- o Unsure

Q28 How would you rate (or have rated) the following:

	1 (low)				5 (high)
your level of anxiety regarding your child's food allergy	o	o	o	o	o
your child's level of anxiety regarding his or her food allergy	o	o	o	o	o

The following questions ask about the time *after* your child assumed sole responsibility to self-carry an auto-injectable epinephrine device.

Q29 Has your child ever experienced an anaphylactic reaction?

- o Yes
- o No
- o Unsure

Q30 Has your child ever been to the emergency room for an allergic reaction?

- o Yes
- o No
- o Unsure

Q31 How would you rate:

	1 (low)				5 (high)
your level of anxiety regarding your child's food allergy	o	o	o	o	o
your child's level of anxiety regarding his or her food allergy	o		o	o	o

Q32 Please indicate the extent to which you agree or disagree with the following statements Since the breakout of the COVID-19 pandemic:	Strongly disagree	Disagree	Neither disagree / agree	Agree	Strongly Agree
Your child has experienced an **increase** in anaphylactic reactions	o	o	o	o	o
You have had trouble getting prescription refill for auto-injectable epinephrine	o	o	o	o	o

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