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## Proceedings of the AMCP Integrated Care Summit: Population Health and Quality Improvement in Anaphylaxis

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This report summarizes discussion, concepts, and ideas for solutions by participants at the AMCP Integrated Care Summit: Population Health and Quality Improvement in Anaphylaxis. It is not intended to be a consensus document, nor does it necessarily represent the positions and/or policies of the Academy of Managed Care Pharmacy. Although meeting participants provided constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they review the final draft of the proceedings before its release.

AMCP prepared this proceedings document. Jann B. Skelton, BSPharm, MBA, President, Silver Pennies Consulting, North Caldwell, New Jersey, facilitated the stakeholder meeting and coordinated the development of the proceedings as a paid consultant.

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# Proceedings of the AMCP Integrated Care Summit: Population Health and Quality Improvement in Anaphylaxis

Academy of Managed Care Pharmacy

## ABSTRACT

**BACKGROUND:** Anaphylaxis is a serious allergic reaction, often caused by food allergies, insect venom, medications, latex, or exercise. The condition is rapid in onset and may cause death. Because of the potential risk of death, it is critical to recognize anaphylaxis quickly and be prepared to treat it appropriately.

**OBJECTIVES:** To review the current trends and challenges related to anaphylaxis management, treatment, and prevention and explore strategies for how to improve access and awareness for patients who are at high risk for anaphylaxis.

**METHODS:** Fifteen stakeholders gathered on May 22, 2013, in Alexandria, Virginia, for a meeting to discuss population health and quality improvement in anaphylaxis convened by the Academy of Managed Care Pharmacy. Summit participants included managed care leaders, nurses, physicians, and organizations that advocate for consumers.

**SUMMARY:** Data on the clinical and financial impact of anaphylaxis are limited and are impacted by underdiagnoses, underreporting, and miscoding of anaphylaxis. There is a significant need to increase awareness of the symptoms of anaphylaxis and ensure that patients at risk have access to available treatments. Additional education and training for both patients and health care professionals are needed to recognize the signs and symptoms of anaphylaxis and ensure the appropriate use of epinephrine auto-injectors. Managed care companies have a need to better understand how to design and improve health benefits to support patients with anaphylaxis.

**CONCLUSIONS:** Summit participants determined that there are opportunities to improve care for patients with anaphylaxis. The availability of epinephrine auto-injectors is not and should not be highly controlled, and the education and training of patients and health care professionals on the appropriate use of these devices are priorities. Attendees discussed numerous strategies that can be implemented by providers, health plans, and hospitals to improve patient care in this disease state.

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The Academy of Managed Care Pharmacy's (AMCP) Integrated Care Summit on Population Health and Quality Improvement in Anaphylaxis brought together key stakeholders with an interest in discussing care improvements for patients at risk for anaphylaxis. Summit participants included managed care leaders, nurses, physicians, and organizations that advocate for consumers. The objectives of the meeting were as follows:

- Review current trends and challenges related to anaphylaxis management, treatment, and prevention
- Explore strategies for how to improve access and awareness for patients who are at high risk for anaphylaxis
- Discuss opportunities for enhancements in education and training for patients and health care professionals to ensure appropriate use of medications and auto-injector devices

- Understand key issues associated with the economic burden of anaphylaxis and the concerns around cost and coverage for epinephrine auto-injectors

Specifically, Summit participants discussed issues that impact the care and treatment of patients with anaphylaxis. The Summit engaged invited experts in discussions of access and awareness, education and training, and cost and coverage. These conversations resulted in a number of concepts and strategies to potentially improve health benefits for patients and family members and ensure that patients with anaphylaxis have access to needed medications and appropriate medical management for their condition.

## ■ An Overview of Anaphylaxis

Anaphylaxis is a serious allergic reaction that is rapid in onset and may cause death. It can be caused by food allergies, insect venom, medications, latex, and exercise, or it can be idiopathic. Although estimates of anaphylaxis prevalence vary, recently released data estimate the lifetime prevalence in the U.S. general population is at least 1.6% and probably higher. These prevalence numbers indicate that anaphylaxis is very common, occurring in at least 1 in 50 adults and more likely closer to 1 in 20 adults.<sup>1</sup> Food allergies are among the most common cause of anaphylaxis among children and adolescents.<sup>2,3</sup> According to Food Allergy Research and Education (FARE), 15 million Americans have food allergies.<sup>4,5</sup> This includes 5.9 million children, which translates to 1 in every 13 children.<sup>6</sup>

Ninety percent of all food allergies are caused by the following 8 foods: peanuts, tree nuts (e.g., walnuts, pecans, hazelnuts, almonds), milk, eggs, wheat, soy, fish, and shellfish.<sup>6</sup> More than 30% of children have multiple food allergies.<sup>4</sup> According to a study released in 2013 by the Centers for Disease Control and Prevention (CDC), the prevalence of food allergies increased approximately 50% between 1997 and 2011; however, the cause of this increase is unknown.<sup>7</sup> In particular, the prevalence of peanut allergy among children tripled between 1997 and 2008.<sup>8</sup>

Insect venom from honeybees, wasps, yellow jackets, hornets, and fire ants cause about 500,000 allergy-related emergency room visits and at least 40 U.S. deaths each year.<sup>9</sup> Medications most commonly associated with inducing anaphylaxis include antibiotics, aspirin, nonsteroidal anti-inflammatory drugs, opioid analgesics, intravenous anesthetics, and radiocontrast dyes. Latex is also a common allergen that can trigger anaphylaxis. Exercise-induced anaphylaxis is a rare disorder in which anaphylaxis can occur after physical activity.<sup>10</sup> When anaphylaxis cannot be associated with an identifiable trigger, it is often diagnosed as idiopathic anaphylaxis, which means "without known cause."<sup>11</sup>

Anaphylaxis can affect 1 or more areas of the body, the most serious being the cardiovascular and respiratory systems (see Table 1). Although skin or mucosal symptoms are present in approximately 80% of anaphylactic reactions, these reactions may not be seen in up to 20% of cases. In 2006, the *Journal of Allergy and Clinical Immunology* published 3 diagnostic criteria for the diagnosis of anaphylaxis.<sup>12</sup> These criteria are as follows:

**Criteria 1**—the acute onset of an illness involving skin, mucosal tissue, or both, with 1 of the following:

- Respiratory compromise
- Reduced blood pressure (BP)
- Associated symptoms of end-organ dysfunction

**Criteria 2**—two or more of the following that occur rapidly after exposure to a likely allergen for that patient:

- Involvement of the skin-mucosal tissue
- Respiratory compromise
- Reduced BP or associated symptoms of end-organ dysfunction
- Persistent gastrointestinal symptoms

**Criteria 3**—reduced BP after exposure to a known allergen for that patient. Reduced BP is defined in adults as a systolic BP of less than 90 mm Hg or greater than a 30% decrease from that person's baseline. In infants and children, it is a low systolic BP (age-specific) or greater than a 30% decrease in systolic BP from baseline.

Anaphylaxis can be life threatening, and death from anaphylaxis can happen quickly from the onset of initial symptoms. If medications cause anaphylaxis, death can occur within 5 minutes from initial symptom onset. If an insect bite or food allergy is the cause, death can occur within 15 to 30 minutes.<sup>13</sup> Because of the potential risk of death, it is critical to be able to recognize anaphylaxis quickly and be prepared to treat it appropriately.

Epinephrine is the only first-line treatment for anaphylaxis. Other medications, such as antihistamines and bronchodilators, will not stop an anaphylactic reaction. In general, epinephrine is safe and effective and can be lifesaving when available and administered to patients experiencing an anaphylactic reaction. There are 2 standard dose strengths of epinephrine approved in the United States: 0.3 milligrams (mg) for individuals over 55 pounds and 0.15 mg for those less than 55 pounds. Additional epinephrine doses can be given in as little as 5 minutes if symptoms worsen or if a biphasic reaction occurs. Biphasic reactions, where there are 2 phases to the symptoms, are common with anaphylaxis. It is estimated that a biphasic reaction can occur in up to 20% of anaphylaxis episodes.<sup>14</sup> These reactions are common enough that clinical practice guidelines have been revised to instruct patients to carry 2 doses of epinephrine.

**TABLE 1** Symptoms of Anaphylaxis<sup>24</sup>

Organ System	Symptom
Respiratory	Congestion
	Shortness of breath
	Wheezing
	Repetitive cough
	Throat itching
	Throat swelling
	Respiratory arrest
Cardiovascular	Chest pain
	Pale/blue color
	Weak pulse
	Dizziness
	Low blood pressure
	Shock
	Loss of consciousness
Skin	Hives
	Swelling
	Itchiness
	Rash
Digestive	Itchy mouth
	Nausea
	Pain
	Cramping
	Diarrhea
	Vomiting
Central nervous system	Lightheadedness
	Confusion
	Anxiety
	Headache
	Loss of consciousness
Other	Fear of impending doom
	Uterine contractions

**Economic Burden of Anaphylaxis: The Impact of Underdiagnosis and Undertreatment**

Although anaphylaxis is a severe and life-threatening reaction, data regarding the incidence, prevalence, and number of deaths caused by anaphylaxis are limited. It is estimated that tens of thousands of anaphylactic reactions occur each year, and the risk of death among those who experience anaphylaxis has been estimated to be 1%, with as many as 1,000 to 1,500 deaths per year.<sup>15</sup> These estimates are thought to be incomplete and/or underestimated because many true cases of anaphylaxis are not accurately identified in a patient's medical chart after an event or recorded on the death certificate following a fatal event. If anaphylaxis is not diagnosed and documented appropriately, it can lead to suboptimal treatment because epinephrine auto-injectors may not be prescribed for a patient if there is no diagnosis of anaphylaxis.

Epinephrine can be lifesaving, but it must be easily accessible to patients during the anaphylactic episode. Available data confirm that there are barriers that limit access to epinephrine.

According to the National Center for Health Statistics National Ambulatory Medical Care Survey, 77.9% of people with access to epinephrine were non-Hispanic white.<sup>16</sup> Despite the fact that it is a predominately Caucasian population that has access to epinephrine prescriptions, there is no evidence to suggest that anaphylaxis disproportionately affects the Caucasian population. This indicates a health disparity of great proportion and a potential opportunity to enhance outcomes for people of different racial or ethnic backgrounds by increasing awareness and improving access to epinephrine.

A 2011 study reported on the refill history of 14,677 patients in a large health maintenance organization who received an initial prescription for an epinephrine auto-injector between 2000 and 2006. Less than half (46%) of patients refilled the prescription at least once, despite the fact that the epinephrine auto-injectors expire and need to be refilled on a regular basis. Only 25% of the patients refilled the prescription multiple times, and only 11% refilled the prescription consistently at all expected refill times.<sup>17</sup> Even for patients who have a legitimate prescription for epinephrine auto-injectors, access to this life-saving medication is limited.

A recent study done in New York City found that administration of epinephrine before arrival at the emergency room was associated with a lower rate of hospitalization. If 2 doses of epinephrine were administered prior to the arrival at the emergency room, the patient was less likely to be hospitalized. Children with Medicaid were less likely than children with private health insurance to receive epinephrine before arriving at the emergency room.<sup>18</sup> This study suggests there is a disparity in access to epinephrine. If the medication is not accessible and used appropriately, patients may end up hospitalized with a more intense case of anaphylaxis, leading to more costs associated with their care.

## Discussion

Summit participants recognized that there are tremendous gaps in awareness of the symptoms of anaphylaxis by patients, caregivers, and physicians. Managed care companies also have a need to better understand how to design health benefits that support anaphylaxis patients and their families.

### Access and Awareness

Access to care and awareness of anaphylaxis is impacted by several factors. First and foremost, many patients do not have access to care simply because they do not realize they are at risk for an anaphylactic episode or have an undiagnosed allergy. Anaphylaxis is often unrecognized, underdiagnosed, and regularly misdiagnosed. There are reports of tremendous gaps in awareness of the symptoms of anaphylaxis by patients, caregivers, and physicians. Additional gaps in patient and caregiver knowledge that inhibit access include lack of information about how to respond in an emergency situation, medication information, and trigger risks.

In fact, a recent survey of 1,000 adults nationwide showed only 42% of respondents who had experienced an anaphylactic reaction sought treatment within 15 minutes of onset. Of those that sought treatment, 34% went to the hospital; 27% self-treated with antihistamines; 11% self-administered epinephrine; 10% called 911; and 6.4% received no treatment.<sup>1</sup> Even patients with multiple prior anaphylactic episodes are often unprepared to manage a future episode, with just one-third of patients reporting that they planned to use epinephrine for a future reaction. More than half of these patients had never even received a prescription for an epinephrine auto-injector or developed an emergency care plan.<sup>1</sup> These statistics are concerning and demonstrate the need to expand activities that improve awareness of and access to appropriate treatments for anaphylaxis.

A primary barrier to improving epinephrine use is the lack of emergency action plans for patients.<sup>19</sup> Every minute spent during an anaphylactic reaction influences the outcome of the episode. If patients and caregivers are not well educated about anaphylaxis and armed with an action plan they understand and can implement, the potential for hospitalization and death increases.

A significant part of the emergency action plan is how and when to use an epinephrine auto-injector. Patients and caregivers must understand the appropriate circumstances for using the medication, proper administration, the importance of immediate access to epinephrine, and the fact that auto-injectors expire and must be refilled in a timely manner to ensure continued access in the case of an anaphylactic emergency. Patients should also be re-instructed on how to use an auto-injector each time they refill their prescriptions.

Epinephrine auto-injector prescribing rose 69% from 2003 to 2010, with approximately 2.4 million prescriptions written in 2010.<sup>20</sup> In 2012, sales for epinephrine auto-injectors were estimated to be \$640 million.<sup>21</sup> Although prescribing has increased, disparities in access continue to be a barrier for appropriate care. Health disparities related to ethnicity exist; however, the reasons are not well understood. There is no evidence that food or other allergies that could potentiate an anaphylactic event are more prevalent or genetically linked to specific ethnicities. Nonetheless, data have shown that Caucasian patients are more likely to have access to epinephrine auto-injectors.

One study that focused on pediatric patients found that children from middle-, upper-, or high-income groups were 8.3 times more likely to be prescribed an auto-injector than those from lower income brackets. Families with lower incomes have also been shown to be less likely to fill and have regular access to epinephrine auto-injectors.<sup>22</sup> Medication cost presents a barrier to access for some patients. Patients without access to prescription benefits may have limited access to epinephrine auto-injectors due to cost. In order to improve morbidity and

mortality, and potentially decrease costly follow-up care for patients with anaphylaxis, it may be beneficial to design benefits that include an educational component for patients using auto-injectors.

Insufficient transitions of care can create unique barriers to access. Commonly, patients who have experienced an anaphylactic reaction requiring emergency room care or hospitalization are released without a discharge prescription for an epinephrine auto-injector. In a nationwide survey of over 1,000 patients, where the median respondent age was 45 years, 8.6% of respondents had visited the emergency room in the past 12 months for allergy-related reasons, and 5.6% of those were hospitalized for allergy-related reasons in the past 12 months. Among surveyed patients who had reported 2 or more prior episodes of anaphylaxis, 52% had never received a prescription for an epinephrine auto-injector, and 60% did not currently have epinephrine available.<sup>1</sup> Potential solutions for closing this gap include the use of standing orders, care plan templates, discharge summaries that include a prescription for epinephrine auto-injectors, education regarding administration and use, and individualized emergency action plans.

Because it is impossible to predict every anaphylactic reaction, improving public access to epinephrine auto-injectors has been explored. Much like the model of defibrillator equipment installed in public places, increasing consideration is being given to creating a similar model with “public use” epinephrine auto-injectors available in restaurants, schools, airports, malls, theme parks, and other venues where acute reactions to allergens in food or insect stings could stimulate anaphylaxis. Incredibly, many ambulances do not carry epinephrine in their vehicles and, therefore, may not have the equipment needed to provide assistance to patients experiencing anaphylaxis.<sup>23</sup>

Within the managed care companies present at this discussion, there did not appear to be issues with plan parameters, such as prior authorization or quantity limits, that would restrict patient access to epinephrine auto-injectors. Plans acknowledged that economic analyses may be needed when there are additional choices in epinephrine auto-injectors, which could result in tiering differences for certain products. While many plans are open to creating access for patients to obtain these devices, it was clear from the discussion that there are not active efforts to engage or educate patients at risk for anaphylaxis or to establish any drug utilization review, medication therapy management (MTM), or disease management efforts for this disease state. Additional data are needed to demonstrate how educational programs or utilization management efforts could impact improvements in outcomes and help prevent or minimize emergency care and treatment.

### Education and Training

There are numerous opportunities for enhancements in education and training for patients and health care professionals

to ensure appropriate use of medications and auto-injector devices in the treatment of anaphylaxis. Summit participants were clear that the most important issue concerning education and training is to improve recognition of the symptoms of anaphylaxis so that treatment can be initiated promptly. Meeting discussions illustrated that even trained professionals may not recognize an episode of acute anaphylaxis because it is observed in practice relatively infrequently. Providing education about the signs and symptoms of anaphylaxis to patients that have a known history of anaphylaxis, caregivers of patients with a known history of anaphylaxis, and groups that frequently encounter the lay public (e.g., community health workers, school personnel) would be valuable to raise awareness about anaphylaxis. Being able to quickly recognize the signs and symptoms of anaphylaxis could be lifesaving, and the ability of health care providers to quickly diagnose and treat anaphylaxis is a necessity.<sup>24</sup>

**Patient Education.** It is critical that patients at risk for anaphylaxis or with a known history of anaphylaxis are educated about its risks and understand that a previous episode is not a predictor for a future reaction. Patients should be educated and continually reminded to avoid any known allergens or triggers and to treat all episodes of anaphylaxis as serious and potentially life threatening. For this reason, it is crucial that patients are educated to carry appropriate medical identification, indicating their allergies and risk for anaphylaxis, as well as their epinephrine auto-injectors at all times. In addition, significant health care resources may be wasted on patients who do not follow a preventative regimen (i.e., avoidance of known triggers) or who do not have access to emergency auto-injectors, which results in more expensive emergency room treatments and/or hospitalization.

Patients at risk for anaphylaxis must have access to epinephrine auto-injectors. Education plays a role in making sure the patient understands and appreciates the need for access to multiple doses of epinephrine. All patients with an epinephrine auto-injector must also be properly trained on how to use the specific auto-injector that has been prescribed. Slight differences in the administration of different epinephrine auto-injectors exist, and it is important for the patient and the patient’s caregiver to clearly understand how to administer the type of epinephrine auto-injector prescribed to them. Patients should receive step-by-step education from a pharmacist each time the prescription is filled. Education about when, why, and how to use an epinephrine auto-injector should be included. Epinephrine products have short expiration dating and often expire within 18 months. Patients should be encouraged to monitor expiration dates and refill their prescriptions before the product expires. Ongoing education about the risks of anaphylaxis, how to reduce risk, and the appropriate way to manage and treat anaphylaxis if it occurs is vital to patient safety.

All patients with a known risk for anaphylaxis and/or a prescription for epinephrine require education on the importance of developing an emergency action plan and sharing this plan with key individuals and organizations (e.g., school personnel, coach, family member). Emergency action plans should be personalized and define when, why, and how epinephrine should be administered in the case of anaphylaxis. An emergency action plan should be written in lay language so anyone reading the plan can understand how to treat the patient if necessary. Patient specific information (e.g., name, known allergies, health conditions, medications), a list of the potential signs and symptoms of anaphylaxis, defined emergency action steps to be taken if anaphylaxis is suspected, and emergency contact information should all be included. An example of an emergency action plan is available from the American Academy of Allergy, Asthma, and Immunology at <http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/Anaphylaxis-Emergency-Action-Plan.pdf>.<sup>25</sup> Another example released by FARE focused on anaphylaxis associated with food allergies and can be found at <http://www.foodallergy.org/document.doc?id=234>.<sup>26</sup>

**Health Care Provider Education.** Health care providers should receive ongoing education and training in recognizing and diagnosing anaphylaxis. While health care providers are educated about anaphylaxis, some providers may go their entire career without seeing a case. Due to its infrequent occurrence, anaphylaxis can sometimes be difficult to differentiate from other common ailments (e.g., anxiety/panic attacks, neurological events, acute asthma attacks, cardiovascular events).<sup>27</sup> Early recognition of anaphylaxis ensures that appropriate treatment is initiated promptly. Having access to clear, concise guidelines and algorithms providing symptom identification and management tools would be a valuable asset for all health care providers.

First-line therapy for an acute episode of anaphylaxis involves the administration of epinephrine.<sup>24</sup> As soon as anaphylaxis is diagnosed or strongly suspected, epinephrine should be immediately administered. Health care providers should be educated on the safety of epinephrine and its vital role in the treatment of anaphylaxis. The risk for patient harm from the use of an epinephrine auto-injector, even if it is administered when anaphylaxis is not present, is low.<sup>28</sup> When in doubt about an anaphylactic reaction, epinephrine should be administered. Available epinephrine auto-injectors are listed in Table 2.

In many cases, patients may have self-administered epinephrine before arriving at the health care facility. Additional doses can be given in as little as 5 minutes if symptoms worsen or if the patient does not improve. It is vitally important for health care providers to recognize and understand that anti-histamines and bronchodilators will not stop an anaphylactic reaction. While these medications are valuable to treat other

**TABLE 2** Available Epinephrine Auto-Injectors

Product	Strength
Auvi-Q auto-injector	0.15 mg/0.15 ml 0.3 mg/0.3 ml
EpiPen auto-injector	0.3 mg/0.3 ml
EpiPen Jr. auto-injector	0.15 mg/0.15 ml
Epinephrine injection, USP auto-injector	0.15 mg/0.15 ml 0.3 mg/0.3 ml

*ml = milliliter; mg = milligram.*

acute conditions, they are not indicated for the first-line treatment of acute anaphylactic reactions.<sup>28</sup>

Health care provider involvement extends beyond the patient's acute reaction. Ongoing provider care includes appropriate monitoring and patient follow-up after an episode of anaphylaxis has occurred in a medically supervised setting. Ongoing monitoring is necessary due to the increased risk of biphasic anaphylaxis. Biphasic anaphylaxis is defined as the recurrence of symptoms without continued exposure to the allergen. Over 20% of patients who experience anaphylaxis have been reported to experience a biphasic reaction.<sup>29</sup> Because of the risk of a biphasic reaction, the National Institute of Allergies recommends repeated doses of epinephrine if a patient responds poorly to an initial dose or has progressive symptoms.<sup>30</sup> For this reason, epinephrine auto-injectors are now only available as dual packs.

After an appropriate period of monitoring, patients should be discharged with a prescription for epinephrine auto-injectors and educated about the risks of future episodes of anaphylaxis. Without appropriate aftercare and follow-up, patients may experience significant morbidity and mortality, and health plans may incur significant costs that could be avoided. Although this recommendation seems straightforward, many patients are discharged after treatment of an acute episode without a prescription for injectable epinephrine. Health care providers should recognize that most patients, especially pediatric patients, require multiple sets of auto-injectors—one for home use and another for school or work. This is clearly an area for improvement in education as providers may be overlooking an opportunity to ensure prompt and appropriate treatment of future anaphylactic events.

**Engaging Pharmacists.** Pharmacists remain the primary point of contact for patients filling prescribed injectable epinephrine, yet many may be unaware of how to administer the products that they dispense. Hands-on education programs for pharmacists and pharmacy students on how to administer epinephrine will better prepare them to adequately instruct patients. As has been seen with pharmacist immunization training programs, as pharmacists become more engaged in direct patient care, utilization and appropriate use increases.<sup>31</sup>

### Cost and Coverage

In 2012, the market for epinephrine auto-injectors was approximately \$640 million.<sup>22</sup> Summit participants discussed a number of managed care issues associated with cost and coverage for treatment of patients with anaphylaxis. These issues include lack of useful outcomes data on anaphylaxis, confusion around Orange Book ratings for epinephrine auto-injectors, potential product waste, and challenges with product expiration dating.

In 1999, the first *International Classification of Diseases (ICD)* codes were established for anaphylaxis. Table 3 provides an overview of ICD-9-CM (*Ninth Revision, Clinical Modification*) codes for anaphylaxis and the new ICD-10-CM codes that become effective on October 1, 2014. According to the discussion, these codes are often not appropriately utilized, leading to gaps in documentation. These gaps make it challenging for managed care companies to evaluate costs and determine the cost-saving benefits of planned educational or intervention programs.

Epinephrine auto-injectors are not considered interchangeable as generics by the U.S. Food and Drug Administration, and all commercially available products are rated BX. A BX rating indicates that the data are insufficient to determine therapeutic equivalence and therefore not substitutable.<sup>32</sup> Some states may allow therapeutic substitution as governed by their state pharmacy practice act. Pharmacists must be diligent in dispensing the prescribed treatment, maintaining product consistency to decrease the potential for misunderstanding or confusion on the part of the patient, and providing ongoing education and training on the use of the device. Similarly, when prescribing, providers must be aware of the variety of auto-injectors available and understand which products are covered by the patient's health plan to increase the likelihood that patients will fill their prescriptions.

In addition, not all episodes of anaphylaxis require a repeat dose of epinephrine, which raises concerns about the potential for wasted resources. Some patients have an anaphylactic episode and only use 1 auto-injector of epinephrine. Because all episodes are not alike, the patient would need to refill the full auto-injector prescription in order to have a dual dose kit available for a subsequent reaction. The second dose from the original dual pack is then wasted, since the patient is not likely to carry that auto-injector because they may need 2 doses next time. This scenario outlines the fine balance between access and waste, both of which impact cost. There are no studies that have evaluated the amount of epinephrine that is dispensed compared with what is actually used, so there is a data gap in understanding how best to support access to appropriate treatment. There are also challenges with the shelf life of epinephrine auto-injectors that have an expiration date of only 12-18 months. This short-dating may also result in waste of product.

It is important to note that none of the participants indicated that this category or disease state was a significant cost

**TABLE 3** Common ICD-9-CM and ICD-10-CM Codes for Anaphylaxis

ICD-9-CM Code	Description	ICD-10-CM Code (Effective October 14, 2014)	Description
995.00	Other anaphylactic reaction	T78.20	Anaphylactic shock, unspecified
995.60	Anaphylactic reaction due to unspecified food	T78.00	Anaphylactic reaction due to unspecified food
995.61	Anaphylactic reaction due to peanuts	T78.01	Anaphylactic reaction due to peanuts
995.62	Anaphylactic reaction due to crustaceans	T78.02	Anaphylactic reaction due to shellfish (crustaceans)
995.63	Anaphylactic reaction due to fruits and vegetables	T78.04	Anaphylactic reaction due to fruits and vegetables
995.64	Anaphylactic reaction due to tree nuts and seeds	T78.05	Anaphylactic reaction due to tree nuts and seeds
995.65	Anaphylactic reaction due to fish	T78.03	Anaphylactic reaction due to other fish
995.66	Anaphylactic reaction due to food additives	T78.06	Anaphylactic reaction due to food additives
995.67	Anaphylactic reaction due to milk products	T78.07	Anaphylactic reaction due to milk and dairy products
995.68	Anaphylactic reaction due to eggs	T78.08	Anaphylactic reaction due to eggs
995.69	Anaphylactic reaction due to other specified food	T78.09	Anaphylactic reaction due to other food products
		T80.50	Anaphylactic reaction due to serum
		T80.51	Anaphylactic reaction due to administration of blood and blood products
		T80.52	Anaphylactic reaction due to vaccination
		T80.59	Anaphylactic reaction due to other serum
		T88.60	Anaphylactic reaction due to adverse effect of correct drug or medication properly administered

ICD-9-CM = *International Classification of Diseases, Ninth Revision, Clinical Modification*; ICD-10-CM = *International Classification of Diseases, Tenth Revision, Clinical Modification*.

driver within their organizations. However, they did agree that unlike other disease categories, the severity of outcomes resulting from poorly managed or uneducated patients was unlike other chronic diseases that rarely have such immediate, life-threatening episodes.

### Opportunities to Enhance Care

Summit participants discussed a number of strategies that could be implemented by providers, health plans, and hospitals to better engage the public and health professionals, increase awareness about the risk factors for anaphylaxis, and support improved care for patients. Suggested strategies and resources to enhance care might include the following:

- Decision support tools that
  - facilitate and encourage patients who have experienced an anaphylactic reaction to complete an emergency action plan
  - develop innovative reminders to encourage patients to check the expiration dating on their epinephrine auto-injectors and to refill their prescriptions if necessary. Attendees felt that utilizing available technology, such as reminder applications on cell phones and Interactive Voice Response (IVR) technology, may be more effective and engage patients more directly
- MTM and patient emergency room discharge services for patients with anaphylaxis to ensure that appropriate education and training are provided and that the need to carry rescue equipment is clearly understood
- Utilize existing communication platforms (i.e., websites, newsletters, IVR technology) to reach both providers and patients and deliver information that improves awareness of the signs and symptoms of anaphylaxis
- Potential partnerships with community pharmacy organizations to develop adherence programs for epinephrine auto-injector users
- Educational programs for providers that focus on identified care gaps for patients with anaphylaxis to increase awareness and drive improvements in ensuring access to treatment and tools for self-management
- Information support tools (i.e., laminated lab-coat cards and access to counseling tools within the electronic medical record) targeted to providers that outline the key clinical decisions for treating patients with anaphylaxis
- Research to determine risk stratification among patient populations to understand actual treatment utilization and to measure both the care and the cost benefits of specific interventions

In order to facilitate quality of care, the following activities are recommended:

- Development of a quality metric for anaphylaxis
- Development of a simple algorithm for anaphylaxis treatment and management that could be easily programmed into clinical decision support systems within electronic medical records
- Development of ongoing education and training programs for health care providers on cost-effective mechanisms for the management and treatment of anaphylaxis

There are many exceptional resources available, but support is needed to ensure that providers are aware of, and have access to, these educational tools and resources.

### Conclusions

Summit participants discussed opportunities to improve care for patients with anaphylaxis and enhance plan benefits to support patients and caregivers. The availability of epinephrine auto-injectors is not and should not be highly controlled, and education and training of patients and health care professionals in the appropriate use of these devices is critical. Attendees discussed numerous strategies that can be implemented by providers, health plans, and hospitals to improve patient care in this disease state and help patients be successful in managing their risk.

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