Adrenaline auto-injector pens: Recommendations and updates

ALK

British Journal of SCHOOL NURSING

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What is anaphylaxis and how common is it?

Anaphylaxis is a life-threatening medical emergency, which requires immediate treatment with adrenaline. It is time critical. While fatal anaphylaxis is rare and unpredictable, it does occur. Over the last few years we have seen a number of high-profile and tragic cases of fatal, food-triggered anaphylaxis where coroners have made a number of recommendations around its emergency management. There are other common causes of anaphylaxis, such as wasp venom or medication, where people may be at risk.

An adrenaline auto-injector (AAI) is a medical device which can inject a therapeutic dose without having to draw up the adrenaline using syringe and needle. The AAI has become a popular way of delivering adrenaline in the community for patients who have been assessed as being at risk of anaphylaxis. This has become their lifeline, as the fear of dying from anaphylaxis can cause anxiety and impair quality of life. Imagine their concerns when they learn about shortages of AAIs!

There has been a 355% increase in children prescribed AAIs over a 12-year period, with a 506% increase in the proportion of AAI devices prescribed in the community.[1] In total, 75% of AAIs prescribed are repeat prescriptions. This means that often the only person the patient sees is the pharmacist, so their training on 'how to use' the device can become more distant in their minds. This is a concern for many patients.

MHRA advice is to always carry two AAIs. This is particularly important for people who also have allergic asthma, as they are at increased risk of a fatal anaphylactic reaction.

There are three brands of AAIs currently licensed in the UK, with only two currently available for prescribing—EpiPen® and Jext®. All the industry suppliers have experienced strain on supply so that when one brand cannot supply, there is pressure on the others to fill the gap.

Problems can arise for patients when clinicians, or indeed CCGs, make decisions to 'script switch' to another brand without considering the training that is required to familiarise patients with how the new device works. There are differences between each brand. There are videos on manufacturers' websites with resources for health professionals to easily access and enable them to train the patient. There are also website areas for patients on how to learn to do this themselves and for recommended annual refresher training. Some even have areas specific to teenagers or younger children, as well as adults.

It is also important to teach and train each person when first prescribed an AAI, as they will need some key guidance on matters such as recognition of symptoms; how to use their AAI; when to use it; and where the expiry date is displayed. It is advisable to tell your patient to register their AAI expiry date with the manufacturer, as then they will receive an expiry alert to remind them to renew their prescription. This is important because many patients forget this key detail and adrenaline that is well out of date may not be effective—there have been fatalities because of this. Storage of the device is also important, especially when travelling to very hot countries. Translation of a patient's allergy into different languages when travelling can be challenging. Allergy UK has translation cards available in over 30 languages which can be ordered from the Allergy UK Helpline.

Allergy UK is the leading patient organisation for people living with allergic disease, providing a wide range of support and information. The website (www.allergyuk.org) also includes a dedicated area for health professionals. As part of our patient information commitment, we also post statements on our website about shortages and other key information about AAIs. Our Helpline frequently takes calls from people who are anxious and want more information, so this is an additional resource for you and your patients (01322 619898).

These are difficult times for patients who carry adrenaline as they find themselves with a device they are not familiar with. As health professionals it is important that we understand those patients' anxiety and pro-actively provide them with the information and guidance they need to feel confident about their AAI use, storage and expiry.

I do hope you enjoy reading this supplement on anaphylaxis and are able to take away some key messages to best support those who may be at risk.

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1. Diwakar L, Cummins C, Ryan R et al. Prescription rates of adrenaline auto-injectors for children in UK general practice: a retrospective cohort study. Br J Gen Pract. 2017;67(657):e300-e305. https://doi.org/10.3399/bjgp17X689917

Anaphylaxis and the use of adrenaline auto-injector pens

ABSTRACT

Anaphylaxis is a medical emergency that may occur in any setting, including both community and healthcare settings. Key triggers include foods; stinging insects, medications and latex—with the most frequent foods implicated in anaphylaxis being peanuts and tree nuts; sesame; hen's egg and cow's milk. All health professionals need to be competent in the recognition and management of anaphylaxis. The first-line treatment for anaphylaxis is intramuscular adrenaline (epinephrine). Adrenaline is the only medication to reduce hospitalisation and death in anaphylaxis and therefore patients identified as high-risk must be prescribed an adrenaline auto-injector. It is imperative that any patient prescribed an adrenaline auto-injector is given comprehensive education on how it should be used.

Key words | Anaphylaxis | Epinephrine | Allergy

Anaphylaxis is a severe, life-threatening, generalised or systemic hypersensitivity reaction characterised by rapidly developing airway and/or breathing and/or circulatory problems usually associated with skin and mucosal changes.[1] This is a medical emergency that may occur in any setting including both community and healthcare settings.

Key triggers include foods, stinging insects, medications and latex, with the most frequent foods implicated in anaphylaxis being peanuts and tree nuts, sesame, hen's egg and cow's milk. The presence of co-morbidities such as asthma and atopic dermatitis are important and are associated with an increased risk of anaphylaxis.[2,3]

Reactions may be exacerbated by alcohol and non-steroidal anti-inflammatory drugs (NSAIDs).[4] Exercise-induced anaphylaxis (EIA) or food-dependent exercise-induced anaphylaxis (FDEIA) may also occur, the latter being dependent on the presence of two factors—both the triggering food and exercise. The risk of recurrence is high, and it is therefore imperative to identify those most at risk of anaphylaxis to reduce morbidity and mortality in this group.

All health professionals need to be competent in the recognition and management of anaphylaxis.[5] The European Academy of Allergy and Clinical Immunology (EAACI) Taskforce on Anaphylaxis has provided evidence-based recommendations for recognising patients at risk. The population-based incidence of anaphylaxis in Europe is 1.5–7.9 per 100 000 person years, although this appears to be rising. The number of adults and children being admitted to hospital in England with a severe allergic reaction has risen every year for the past 5 years between 2013 and 2019, rising from 4107 cases to 5497 over 5 years. Approximately 20 deaths per year in the UK occur due to anaphylaxis, but this could be an underestimate as anaphylaxis may be miscoded as asthma.

Allergic reactions generally occur within 2 hours of exposure, and frequently within 30 minutes. The most commonly occurring manifestations are the development of cutaneous symptoms (present in 84% of individuals and particularly common in children), followed by cardiovascular and then respiratory symptoms, although anaphylaxis can occur in the absence of cutaneous symptoms.[3] Respiratory compromise predominates in children, with cardiovascular symptoms occurring most frequently in adults.[6] Up to 20% of anaphylactic reactions may be biphasic and may be more severe than initial symptoms.[7]

Treatment of anaphylaxis

First-line treatment for anaphylaxis is intramuscular (IM) adrenaline (epinephrine). Guidelines include further second-line interventions for controlling allergic symptoms, including antihistamines, corticosteroids and bronchodilators. These should only be given after IM adrenaline has been administered. IM adrenaline should be injected into the lateral aspect of the thigh as this allows for a quicker absorption than injection in the arm. The intravenous route should not be used in a community setting.[8]

People who have experienced anaphylaxis, or who have been identified as being at potential risk of future anaphylaxis, should be issued with and taught to use an adrenaline auto-injector (AAI) while in the emergency department or GP surgery, and a referral made to a recognised specialist allergy clinic.[9] The British Society of

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Table 1. Recommended doses for adrenaline auto-injectors in the community*	
Children under 25–30 kg from 6 months of age	0.15 mg
Children and adults over 30 kg	0.3 mg
The 0.5 mg dose is essentially for the use of health professionals according to the Resuscitation Council Guidelines	0.5 mg+

*Doses of adrenaline recommended by the Resuscitation Council for use by health professionals in children vary from those recommended for use in the community. For example, a child over 6 years of age weighing 20 kg would be given a 0.3 mg dose in hospital but would be prescribed a 0.15 mg dose to carry[8]
+There is no strict guidance on which patients should be prescribed the 0.5 mg dose which at the time of going to print is only available as Emerade

Allergy and Clinical Immunology (BSACI) has a list of suitable UK clinics.[10]

In the UK, there are three different AAI devices available via prescription: Emerade, EpiPen and Jext. EpiPen and Jext operate on the same principle of containing pre-filled cartridges, while Emerade uses a pre-filled syringe. At the time of going to print, Emerade is under recall and not currently being prescribed, but is still carried by a large number of patients. Cartridges may confer some benefit as the adrenaline is only released once the tip of the needle is fully extended into the tissue, whereas there is a risk that the pre-filled syringe may deliver some adrenaline in the needle track, potentially reducing the amount of drug reaching the target site of the muscle.[11]

The safety of IM adrenaline is good and there are no absolute contraindications for treatment with adrenaline, given that the benefits outweigh the risks in acute anaphylaxis. However, individuals may experience tremor, palpitations and headache. It is important to consider the use of beta-blockers as these may reduce the efficacy of adrenaline.[12] Parenteral administration of glucagon may be useful in patients failing to respond to adrenaline.

Adrenaline is the only medication to reduce hospitalisation and death in anaphylaxis; therefore, patients identified as high risk must be prescribed an AAI, as immediate administration constitutes first-line treatment. As the onset of anaphylaxis can be rapid, the individual should use an AAI at the first signs of a severe reaction, and then call for emergency medical help.[13] Signs of a severe reaction include:

- Swelling in the throat (altered voice, difficulty swallowing or breathing)
- Wheezing
- Dizziness, feeling faint, tiredness (symptoms of low blood pressure).

If in doubt about severity, or if previous reactions have been severe, the individual should use an AAI. If the individual does not feel better after the first injection, the second auto-injector should be used 5–15 minutes after the first.[11]

Table 2. Absolute indications for prescribing an adrenaline auto-injector
Previous anaphylaxis
Exercise-induced anaphylaxis
Previous idiopathic anaphylaxis
Co-existent unstable or moderate-to-severe persistent asthma
Venom allergy with a previous systemic reaction
Underlying mast cell disorder and any previous severe reaction

Responsibilities when prescribing an AAI

Prescribing practices vary, but the Medicines and Healthcare products Regulatory Agency (MHRA) has released the following guidance for health professionals after a Europe-wide review of AAIs:[14]

- It is recommended that two AAIs are prescribed, which patients should carry at all times
- Ensure that people with allergies and their carers have been trained to use the particular auto-injector that they have been prescribed—technique varies between injectors
- Encourage people with allergies and their carers to obtain and practise using a trainer device (available for free from the manufacturers' websites).

Each device has different educational requirements when dispensing. The European Medicines Agency (EMA) requires each manufacturer to provide adequate packages of training for patients via leaflets, web pages or other means.[14] It is important therefore that the health professional is familiar with these so as to direct them to the correct material. The quality and extensiveness of the education packages varies depending on what the manufacturer has developed. The Jext device has a phone app, videos and an online training package for health professionals with certification, while EpiPen and Emerade have websites, leaflets and videos.[15]

Ensuring patients know how to use AAIs

It is imperative that any patient prescribed an AAI is given comprehensive instructions on how it should be used. They should also be provided with written information, which includes advice on allergen avoidance, instructions on how to use their AAI and an emergency action plan. Emergency plans[20] for children can be downloaded for free from the BSACI website and work on adult BSACI action plans is ongoing.

These plans include avoidance advice, contact details for further information and guidance on likely presenting symptoms and how these should be responded to. It has been demonstrated that accidental allergic reactions are reduced following provision of an action plan.[18] Adolescents are a recognised high-risk group and require particular attention given the challenges in this age group.

Children should be advised to take their action plan to school and to have devices available to be kept in school. Considerable work has been done to enable schools to purchase generic AAIs available for use with any child experiencing anaphylaxis in school whose parent or carer has given written consent for their use. Further information on this is accessible at: www.sparepensinschools.uk. Older children, young people and adults should be encouraged to set up their Medical Emergency information on their mobile phones and may need to be shown how to do this.

Training must include the recognition of symptoms, and when and how to administer their device. All patients, and, if appropriate, their families and/or carers, should be given the opportunity to practise using a demo device and signposted to information on obtaining their own. Contact information for patient support resources such as Allergy UK or the Anaphylaxis Campaign should be provided as a resource for further information. It is imperative that patients and families are advised that their medication must be carried at all times, as adrenaline cannot help them if they do not have it with them. It has been demonstrated that approximately one-third of both adults and children do not always have their devices available.[20]

Patients and families should be taught to always call for emergency help in the event of their device being used, as they may require additional medical intervention and will require a period of observation. Advice should also be given on the positioning of patients suffering from anaphylaxis. Individuals experiencing anaphylaxis should be kept calm. In the event of respiratory distress, they should be positioned sitting up. If experiencing circulatory problems, they should be positioned lying on their back with their legs raised. All patients and families should be informed of the need to avoid any sudden change to a more upright posture and should wait for emergency help to arrive. Any unconscious patient must be placed in the recovery position and monitored closely.

Conclusion

There are several factors to consider when ensuring the best chance that patients who are being prescribed adrenaline carry their AAIs and use them effectively during an emergency. Above is an overview of anaphylaxis and a recommendation to visit the manufacturers' websites to train yourself and other practice staff. The following steps are critical:

- During the conversation with the patient, focus on establishing the patient's responsibility to sign up to the device's appropriate web-based expiry date reminder service. Some clinicians do this with their patients on site (Guy's Hospital Adult Allergy Service). Advise the patient to act as soon as the first text/email alert arrives so as to obtain a further prescription for two replacement devices, as this will reduce the chance of delays in pharmacy stock
- Demonstrate the correct use of the device. Watch the patient practise themselves with a trainer version of the device (obtainable from the manufacturer) and correct where appropriate
- The devices usually come in a hard, protective tube for safe carriage. Additional 'bags' that have room for the AAI, as well as other allergy medications and the action plan, can be purchased from independent retailers. Further details can be obtained from the AAI websites and the BSACI. Trustworthy, helpful advice and support can be obtained from The Anaphylaxis Campaign (www.anaphylaxis.org.uk) and Allergy UK (www.allergyuk.org).

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Practical ways to empower patients at risk of anaphylaxis

ABSTRACT

Hospital admissions due to anaphylaxis have risen in recent years. As well as practising allergen avoidance, patients at risk of anaphylaxis should be issued with adrenaline auto-injectors and trained in their use, in order to self-manage anaphylaxis. Young people are at particular risk of anaphylaxis and health professionals have a key role to play in educating this group in the importance of carrying their prescribed adrenaline auto-injectors.

Key words | Anaphylaxis | Epinephrine | Allergy

Health professionals are becoming more aware of allergic disease, including anaphylaxis. A review of anaphylaxis hospitalisations and fatalities in the UK from 1992 to 2012 revealed an increase of over 600% for hospital admissions due to anaphylaxis, but fatalities of 0.047 cases per 100 000 population remained stable. Food triggers were common causes for anaphylaxis in children and adults aged under 24 years; and 78% also had asthma.

Fatal food-induced anaphylaxis was most common among those aged 10–29 years. Anaphylaxis due to drug and venom had the highest prevalence but mostly affected adults aged 60 years and over.[1] Delayed administration of adrenaline is a risk factor for fatal food-induced anaphylaxis.[2]

As well as practising allergen avoidance, patients at risk of anaphylaxis should be issued with adrenaline auto-injectors (AAIs) and trained in their use, in order to self-manage anaphylaxis. There are clear national guidelines for indications of prescribing AAI devices.[3]

In the UK, AAI devices are prescribed by primary care clinicians under the advice of specialist centres. Between 2000 and 2012, there was a reported increase of 355% in the proportion of children in the community issued with AAI devices, and a 506% increase in the number of devices issued per high-risk child.[4] Fatal food-induced anaphylaxis has occurred at home, in restaurants and in educational environments.

Patient adherence to medical advice and treatment can be variable, but tends to be poorest among adolescents. In a Danish prospective dataset, it was found that only 3 out of 4 patients prescribed an AAI device from an allergy specialist centre actually collected their prescription from the pharmacy.[5] Young adults aged 18–35 years had the poorest adherence—only 45% collected their adrenaline prescription. In an Australian study, it was found that 59% of adolescents aged 10–14 years did not carry their AAI device with them to at least one location, including when attending a school sports activity.[6] This period of transition, when children become more independent and are away from parental supervision, creates anxiety for most parents. It is vital that as health professionals, we take every opportunity to empower young people to minimise their risk of anaphylaxis.

Patient education in primary care

Dissemination of anaphylaxis education would be seamless if every health professional were equipped to do so. GPs, practice nurses and school nurses should ensure all patients recognise signs and symptoms of anaphylaxis and can demonstrate the correct techniques to AAIs. There are three available devices in the UK. Ideally, patients should be trained to use all three due to recent problems with availability for patients. At the time of publishing this article, only two devices are available on the UK market—Jext and EpiPen.

One way to improve patient adherence is by ensuring all health professionals are competent to recognise anaphylaxis and to use AAIs. The British Society for Allergy and Clinical Immunology hosts regional primary care training days (events and venues can be accessed on the website: www.bsaci.org/meetings-and-events/regional-meetings).

Anaphylaxis training is usually offered as a practical workshop, and is part of the training day. Alternatively, online resources can be found on the Anaphylaxis Campaign website as well as manufacturers' websites:

- www.anaphylaxis.org.uk/information-trainingallergywise-training/
- https://jext.co.uk
- http://www.epipen.co.uk.

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Everyone working in primary care can provide useful input in reducing the risk of anaphylaxis in patients.

Practice managers

An audit of adrenaline prescription is useful as it identifies patients issued with a device, the type of device issued and when they are due to expire. In addition, a rich database can identify patients who require training on AAI device use.

Practice nurses

The majority of patients identified as at risk of anaphylaxis have been seen in secondary or tertiary care settings. They will have received a host of information, including allergen avoidance advice, an emergency treatment plan and training to use the AAI. Due to capacity issues, most centres will see patients at specific time points—not nearly often enough to ensure optimal adherence.

AAI training in primary care would help improve adherence. Practice nurses should be competent at educating patients to recognise anaphylaxis and providing AAI device training, in order to help build patients' confidence at self-treatment in an emergency at home. Opportunities to become skilled have been listed above. In addition, optimising patients' asthma control should be standard practice. Patients with food allergy are at higher risk of anaphylaxis if asthma control is poor. The UK anaphylaxis review found that 78% of young people with food-induced anaphylaxis had a physician's diagnosis of asthma.[1]

School nurses

In 2017, the Human Medicines (Amendment) Regulations were amended to allow schools to obtain, without a prescription, spare AAI devices for use in emergencies. These spare devices are in addition to devices pupils have been prescribed and bring to school. It would be wonderful if opportunities for anaphylaxis training could be created in school—the review of anaphylaxis in the UK revealed that 17% of cases of fatal anaphylaxis occurred at educational environments, including school.[1] Raising awareness of anaphylaxis in a wider context keeps high-risk children safer against the consequences of anaphylaxis.

Conclusion

GPs, practice nurses and school nurses all have a role to play in empowering patients at risk of anaphylaxis. Dissemination of anaphylaxis education would be seamless if every health professional were equipped to do so. This article has provided some key ways that health professionals can help to improve adherence to advice and provide better education to people at risk of anaphylaxis.

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Please refer to the Summary of Product Characteristics before prescribing. **Name** Jext® 150 micrograms solution for injection in pre-filled pen Jext® 300 micrograms solution for injection in pre-filled pen **Active Ingredients** Jext® 150 micrograms: One pre-filled pen delivers one dose of 0.15ml solution for injection containing 150 micrograms of adrenaline (as tartrate). Jext® 300 micrograms: One pre-filled pen delivers one dose of 0.30ml solution for injection containing 300 micrograms of adrenaline (as tartrate). **Indication** Jext® is indicated in the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis. **Dose** Patients between 15 kg and 30 kg in weight – The usual dose is 150 micrograms. Patients over 30 kg in weight – The usual dose is 300 micrograms. **Administration** For single use. Jext® is for intramuscular administration into the anterolateral thigh. It is designed to inject through clothing or directly through the skin. Massage around the injection area is advised to accelerate absorption. Please refer to the Summary of Product Characteristics for detailed instructions for use. In the absence of clinical improvement or if deterioration occurs, a second injection with an additional Jext® may be administered 5 – 15 minutes after the first injection. It is recommended that patients should carry two Jext® pens which they should carry at all times The patient should seek emergency medical assistance immediately after administering Jext® for monitoring of the anaphylactic episode and further treatment as required. **Contraindications** There are no absolute contraindications to the use of Jext® during an allergic emergency **Undesirable Effects** The alpha and beta receptor activity of adrenaline may cause undesirable effects on the cardiovascular system, central nervous system and other organ systems including hyperglycaemia, hypokalaemia, metabolic acidosis, anxiety, hallucination, headache, dizziness, tremor, syncope, tachycardia, arrhythmia, palpitations, angina pectoris, stress cardiomyopathy, hypertension, vasoconstriction, peripheral ischaemia, bronchospasm, nausea, vomiting, hyperhidrosis or asthenia. Please consult the Summary of Product Characteristics in relation to side-effects. **Warnings** Do not inject Jext® into the buttocks. Accidental injection into hands or feet may cause peripheral ischaemia due to vasoconstriction. In patients with thick subcutaneous fat layer, there is a risk of the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. **Precautions** Special caution should be taken in patients with cardiovascular diseases, hyperthyroidism, phaeochromocytoma, narrow angle glaucoma, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia, hypokalaemia and diabetes. Caution is indicated in patients receiving drugs that may sensitise the heart to arrhythmias, including digitalis and quinidine. The effects of adrenaline may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors (MAO-inhibitors) and catechol-O-methyl transferase inhibitors (COMT inhibitors), thyroid hormones, theophylline, oxytocin, parasympatholytics, certain antihistamines (diphenhydramine, chlorpheniramine), levodopa and alcohol. Caution should also be taken in elderly and pregnant patients. Jext® contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions in susceptible people. Susceptible people must be carefully instructed in regard to the circumstances under which Jext® should be used. All patients who are prescribed Jext® should be thoroughly instructed to understand the indications for use and the correct method of administration. It is strongly advised also to educate the patient's immediate associates (e.g. parents, caregivers, and teachers) for the correct usage of Jext® in case support is needed in the emergency situation. Patients should be advised to regularly check Jext® and ensure it is replaced within the expiry period. **Legal Category:** POM **Basic NHS Cost:** Jext® 150 and Jext® 300 are available as single unit doses at £23.99 each or as a twin pack of two injectors at £47.98. **Marketing Authorisation Numbers:** PL 10085/0052, PL 10085/0053 **Marketing Authorisation holder:** ALK Abelló A/S, Bøge Alle 6-8, DK-2970 Hørsholm. **Date of last revision:** June 2018 1238AD

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to ALK-Abelló Ltd.

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Date of preparation: April 2020
Code: 1448AD

Jext®
Adrenaline Tartrate