Designing an Adrenaline Auto-Injector: The Perception of Shape as an Affordance of Use

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Abstract
Adrenaline auto-injectors are considered an effective and immediate emergency treatment for severe allergic reactions that may result in potentially fatal anaphylaxis if not treated on time. These auto-injectors are designed to be self-administered intramuscularly by the patient or the carer, who are generally instructed on how to apply them; however, studies indicate that these are often used incorrectly, causing accidental injuries and failed administration of the dose. A significant number of such failed deliveries can be attributed to the shape of the injecting device which according to conducted surveys is un-intuitive, especially in situations of stress and emergency, and when the person administering has no previous knowledge or experience of using the device. In conjunction, this paper argues that the shape of the auto-injector is crucial towards communicating how to use the device correctly and describes a research project that aims to develop an intuitive, accessible, and user-friendly auto-injector that can be used without previous training, and wherein the shape can promote natural associations towards ensuring correct usage. The paper also discusses key design considerations, such as common usage errors, and the patients' perceptions of, and relation with, auto-injectors. It emphasizes how by focusing on use-case affordances, the device can foment a functional rather than arbitrary relation with the user, restricting the way the device can be used and, thus, allowing it to be properly administered in emergency situations.

Keywords: Product Design, Adrenaline Auto-Injector, Affordance, Common Usage Errors, Emergency Device

Background

"Anaphylaxis is serious allergic reaction that is rapid onset and may cause death" (Sampson et al., 2006, p.392). This is the definition encountered to define anaphylaxis, purposely universal and broad, given the complexity and variability of the condition. It can be characterized as a serious systemic allergic reaction, which happens suddenly after contact with an allergen which, by the activation of mast cells and basophils, leads to the release of active chemical mediators, that originates this acute response. Anaphylaxis may present a wide variety of symptoms, differing from patient to patient and can affect one or multiple organ systems. Reactions may be categorized as mild, moderate, or severe, depending on the degree of allergy and the dose of allergen present in the body (Suzanne C. & Smeltzer, 1999), which results in a lack of harmonization in its epidemiological data (Tanno et al., 2018).

Due to its quick response, Epinephrine, commonly known as Adrenaline, is the preferred medication for treating anaphylaxis' symptoms. This drug can be given via an Adrenaline Auto-Injector (AAI), which is currently considered the best first-line treatment for anaphylaxis, since these devices are simple to use in an emergency and deliver a constant and fixed dose of adrenaline (Hill et al., 2016). The injection must be given intramuscularly, ideally into the outer mid-thigh muscle, in order to ensure a fast absorption of the drug and to lower the risk of hitting a bone, which can result in further complications. The dosage depends on the weight of the patient: children weighting less than 30kg are advised to receive a dose of 150mg of adrenaline, while children or adults weighting more than 30kg are advised to take either 300 or 500mg of adrenaline, depending on what AAIs dosages are available in the patient's country (MHRA, 2014). In order to ensure proper administration, AAIs must be able to be administered by anybody, with no margin for error – which usually does not happen – as there are several reports on improper administration of these devices (Knibb and Morton, 2014) (Kessler et al., 2019). These failures are frequently attributed to the device's shape, which is commonly described in an emergency and stressful situation as perplexing and unintuitive (Money et al., 2013). In addition to taking into account patients' perceptions of AAIs and common use errors, designers of new AAIs should concentrate on developing affordances that foster a functional rather than arbitrary relationship with the user, restricting the way the device can be used, and enabling it to be administered correctly.

Methodology

This article follows the current state of work developed at the University of Aveiro with the aim of designing a new Adrenaline Auto-Injector that is accessible, intuitive and that can be used by anyone, whether the user has had previous training or contact with such devices.

Firstly, literature research was conducted using PubMed and ResearchGate databases to understand: a) what is anaphylaxis and its symptoms; b) currently available adrenaline auto-injectors (AAI) and its technologies; c) common use-errors and patients' perception of, and relation with, their devices; d) the concept of affordances and their importance in Design. An analysis of emergency devices was also conducted to better understand how these devices communicate with the user and ensure a rapid and correct use of the object in a stressful situation.

Interviews were conducted to understand patient's perceptions on EpiPen® and Anapen® and later compared with current research. Patients who had previously been prescribed an AAI were interviewed after their routine vaccine appointment at the Centro Hospitalar

Universitário de São João, in Portugal. Seven patients were interviewed between April and May 2022 (ages between 14 and 56 years old) and consent was obtained to record the interview with a digital voice recorder. Patients were asked to discuss their allergy history, experience as an AAI carrier and/or user, aspects of the device design they would change and whether they consider that anyone would be able to use the device if needed.

Lastly, several shapes were designed, and foam mock-ups were tested in six subjects, with ages between 23-65 years old, that had no previous contact with an AAI, to understand: 1) which shape best identifies the needle-end of the device, to prevent accidental injections and 2) which shape best restricts the way the device can be used, to ensure a correct administration of the dose of adrenaline.

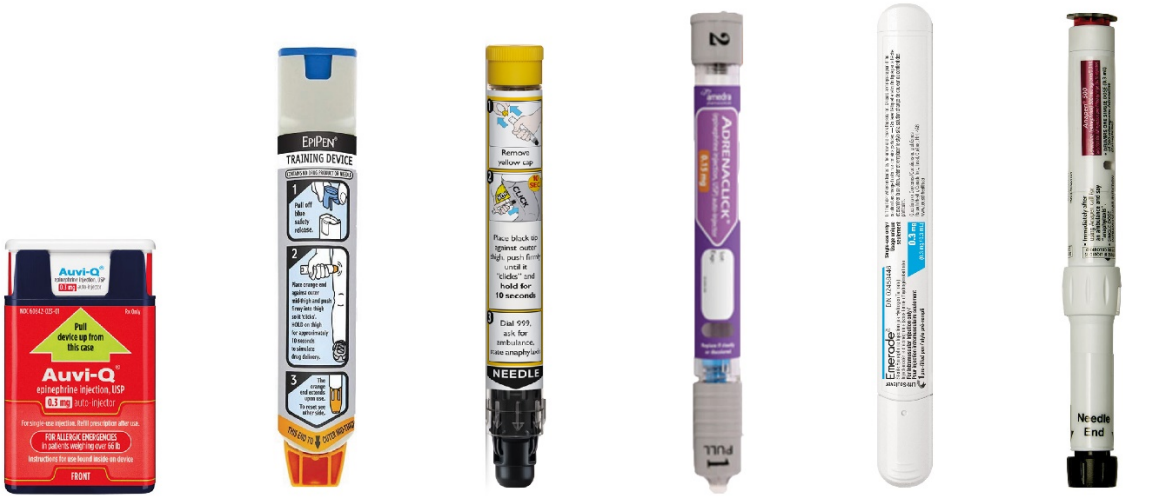
Emergency Device's Analysis

James Gibson (1979) introduced the term *affordance* in his book "The Ecological Approach to Visual Perception". Donald Norman later used and adapted the term in Design to describe "… the relationship between the properties of an object and the capabilities of the agent that determine just how the object could possibly be used" (Norman, 2013, p. 11), which is in charge of assisting the user in handling the object without the need for labels or instructions (Norman, 2013). Norman (2013) defends that affordances play an important role in understanding how an object must be handled: it is the relationship between the properties of an object and the capabilities of the agent that determine how the object might be used. The affordances of an object may or may not be visible, but they always exist. The more visible the affordance is, the more likely the user will understand how the object works. This is especially important when designing an AAI or any medical emergency device, given the stressful situation the user is facing and/or the lack of knowledge on operating these devices.

An analysis of different emergency devices was conducted to understand how these communicate with the user and what cues they give so the user understands how they can be handled. These were analyzed in terms of colour, shape, material, labeling and then related to the way they should be handled in order to function. An emergency hammer is a safety feature used to break through window glass that may be found in vehicles and some buildings to aid in the emergency extrication of its occupants. This is an excellent example of good design for an emergency as its shape restricts the way the user can handle the device, making sure that it is always handled correctly. Its handle's size as well has the bumps present in the handle give an obvious affordance that that is where the person should grab the object, leaving a very small margin for the user to grab it in any other way. A fire extinguisher is an object known by many to combat small fires and it is mandatory in many buildings and vehicles. It is also a good example of a well-designed emergency device, since it is intuitive enough so every user is able to use it and its shape restricts the way it can be used. Just like the emergency hammer, its handle has bumps to guide the user's hand, which then naturally grabs the handle of the device correctly. Besides its shape, simple illustrations instructing how it should be handled are also present in the body of the device. Emergency buttons are a universal object often used in emergencies. When pressed, the user expects it to be followed by some kind of action, either to begin or stop it. All devices have in common the use of the colour red, usually a colour associated with danger and to grab the user's attention, which is a must-have in an emergency situation.

Adrenaline Auto-Injectors

AAIs are considered the best first-line treatment for anaphylaxis and users are advised to carry with them two AAIs, in case there is a need of a second dose of adrenaline to subside the symptoms. Adrenaline does not cure anaphylaxis, instead, it lessens its symptoms, so even after receiving the adrenaline dose, the patient must be rushed to the hospital to receive further examination and treatment, as anaphylaxis may reoccur up to 24 hours after the first symptoms. They allow the user to self-administer the drug when in an anaphylactic episode, which is beneficial when working with anaphylaxis as it is a condition that has a very rapid onset where the symptoms can get worse in a matter of seconds or minutes, so waiting of emergency services might be a problem. These devices are mainly used by the patients, but there are cases where the patient is unable to self-administer the dose of adrenaline, either due to extreme symptoms or even panic generated by the situation, so the device will have to administered by a family member or even by a third-party person, who may have never received any type of training on how to work with these devices and may not even know anything about them. It is therefore important that these devices be intuitive enough to be used by anyone.



Auvi-Q®[1] EpiPen®[2] Jext®[3] Adrenaclick®[4] Emerade®[5] Anapen®[6]

Figure 1: Currently available AAIs

There are currently six available AAIs globally (figure 1): Auvi-Q®[1], EpiPen®[2], Jext®[3], Adrenaclick®[4], Emerade®[5] and Anapen®[6]. To note that authorized generic versions of EpiPen® and Adrenaclick® are marketed in some countries, without the brands' name, and are usually cheaper than the original devices (U.S. Food and Drug Administration, 2018). These devices are available in different dosages of adrenaline (table 1), depending on the country where they are sold: Adrenaclick®, Anapen®, Auvi-Q®, Emerade®, EpiPen® and Jext® all have versions with 150mg or 300mg of adrenaline solution; Auvi-Q® also sells a version with 100mg of adrenaline for toddlers, and Emerade® and Anapen® a version with 500mg of

[1] Source: www.auvi-q.com/about-auvi-q
[2] Source: www.epipen.co.uk/en-gb/patients/your-epipen/how-to-use-your-epipen
[3] Source: www.adults.jext.co.uk/about-jext/how-to-use
[4] Source: www.adrenaclick.com/convenient_packaging_options.php
[5] Source: www.emerade.ca/
[6] Source: www.anapen.com.au/anapen

adrenaline, which is only available in some countries. The ideal dose of adrenaline is prescribed by the patient's doctor depending on the patient's weight.

	100mg	150mg	300mg	500mg
Adrenaclick®		×	×	
Anapen®		×	×	×
Auvi-Q®	×	×	×	×
Emerade®		×	×	×
EpiPen®		×	×	
Jext®		×	×	

Table 1: currently available doses of adrenaline in each AAI

These devices all have their own method of administration. To use an EpiPen®, the user must remove the safety cap and swing it in the direction of the thigh. Emerade®, Auvi-Q® and Jext® are activated by removing the safety cover, positioning the needle end on the outer thigh, and pushing the auto-injector against it. For Adrenaclick®, one must remove the needle and safety cap, position the needle end on the outer tight, and press the auto-injector to activate it. Anapen® is activated by pulling the black needle shield, taking off the grey safety cover, putting it on the outer thigh, and pressing the red button. Whereas the majority of the AAIs rely on images and/or text to instruct the user, Auvi-Q® is the only device that gives sound cues to guide the patient to ensure its correct administration. The majority of the devices have a pen-like shape, which in some cases prove to be problematic. To understand if users could correctly use their AAIs, different authors conducted usability tests. Carneiro-Leão et al. (2016) evaluated the patients' capacity to use AAIs, the effect of switching devices, and the patients' preferences by comparing Anapen®, EpiPen® and Emerade®. Out of 32 patients, 11 (34%) (5 with an Anapen® and 6 with an EpiPen®) were unable to show effective delivery of adrenaline. When switched devices, 11 out of 17 patients who had been prescribed EpiPen® where unable to administer Anapen®, whereas 9 out of 15 patients who had been prescribed Anapen® were unable to administer EpiPen®. The Emerade® auto-injector, which was chosen as the most favoured auto-injector by the majority of the participants, was only improperly used by 2 participants. In a study by Kessler et al. (2019), the usage of Auvi-Q® and EpiPen® Jr. in 96 inexperienced adults was compared. The results show that a larger number of participants were able to correctly administer Auvi-Q® (85.4%) than EpiPen® Jr. (19.8%). Auvi-Q® did not cause any accidental thumb-injections, whereas 14 participants would accidentally be hurt when using EpiPen® Jr. Participants explained that given the design of the EpiPen®, which resembles a pen, this mistake may happen and that the bright orange tip might have suggested that the end needed to be interacted with. With 90 participants, (Knibb and Morton, 2014) compared Jext®, EpiPen®, and Emerade® to evaluate the devices' accuracy and intuitiveness of usage, both with and without instructions. Results indicated that, without instructions, none of the volunteers could successfully administer EpiPen® and Jext®, however when utilising Emerade®, there was an 82 percent success rate. All subjects were successful in administering the dosage of adrenaline using Emerade® after reading the instructions, as opposed to Jext® (64%) and EpiPen® (33%). On average, patients took less time using Emerade® than Jext® or an EpiPen®. With or without instructions, participants considered Emerade® to be simpler and more intuitive since pictures were easier to follow.

Interviews were conducted at the Centro Hospitalar Universitário de São João on 7 patients to understand their opinions on their AAI (6 use or have used EpiPen® and 1 once used Anapen®). Results show that most patients feel that the size of these devices should be smaller, as it is a hindrance to carry around:

> *#4: "It's big, I think it's big. To carry around a bag: yes. Because we also have to carry other medication with us, right? So, I had a case where I stored (...) everything. Especially the length, as it is difficult to find cases for it."*

Patients also revealed a certain fear on whether they were able to administer the AAI, if it reached the muscle, if it was activated, if it passed through clothes. The feedback the device gives back seems to worry patients.

> *#3: "I find it quite violent. It's not about courage, but about the self-administration part of it. The first times must be quite stressful: (...) there's a specific place, fear if it went through clothing or not, if it delivered everything or not."*

The instruction images present on the EpiPen® are considered important and necessary to be able to understand how the device must be administered.

> *#6: "(...) but if I ever need to use one, I will have to look at the images to understand how to do it, because the doctor did teach me, but a person tends to forget it".*

A study conducted by (Money et al., 2015) to understand patients' perceptions of the EpiPen® revealed that participants believed that: there was a lack of public awareness on what AAIs are and their purpose; there is uncertainty as to when is the right time to deliver the dose of adrenaline and whether it works or not; and the size of the device and lack of a clear transportation feature prevents them from carrying it.

Product Development

Frew (2011) outlined five requirements to design the "ideal" adrenaline auto-injector: a) it must have a sufficient needle length to deliver adrenaline intramuscularly, across a variety of body types; b) it must deliver adrenaline within the correct timeframe, the quicker the better, given the unpredictability of anaphylaxis; c) it must deliver the correct dose of adrenaline and offer a range of concentration; d) it must be reliable to withstand real-life use, meaning it must operate without failure, given any circumstances and e) it must be easy to use and safe for the user. This study focuses on this last requirement outlined by Frew (2011) in the development of this new AAI.

Considering previous investigation, the authors identified a need to design a more intuitive AAI. Currently available AAIs' shapes do not ensure that the user handles the device correctly, hence the accidental injuries or administration failures that occur with these devices. The pen-like shape is often associated with a normal pen so the movable piece of the device, which is usually the needle-end, can be understood as a button that should be pressed to activate the device, resulting in accidental thumb injections and further complications.

This new AAI should be designed keeping in mind that it should be universal and intuitive enough that, just by itself, it is able to communicate how it should be handled. This way, it is guaranteed that every user can use this device, whether they have had previous contact or

training with said device or not. It should also restrict the way the device can be handled, in order to prevent any accidental injuries and/or administration failure, which can be solved by designing an AAI that can only be administered when the user is handling it correctly. Any other way of handling the device must not be allow to activate it. The shape of the device is one of the major factors in charge of communicating with the user how it should be handled. If it is not immediate, the user will not be able to understand how to handle it and fail to use the device.

Emergency devices that involve an injection, which is the case of most auto-injectors, must guarantee the safety of the user. This can be done by:

a) having the needle-end of the device clearly identified.

b) restricting the way the device can be used.

The authors defend the shape of the device is capable of giving the clues necessary so the user understands correctly how the device must be handled.

Five different shapes were designed (figure 2) to test how the shape can dictate how the device must be used. All shapes were designed keeping in mind the ergonomics of the hand, in order to make this device as comfortable on the hand as possible. Mock-ups of all five shapes were built using foam and tested by six subjects, to analyse if it was possible to identify the needle-end of the device and whether there were other options for handling the device beyond the defined one.

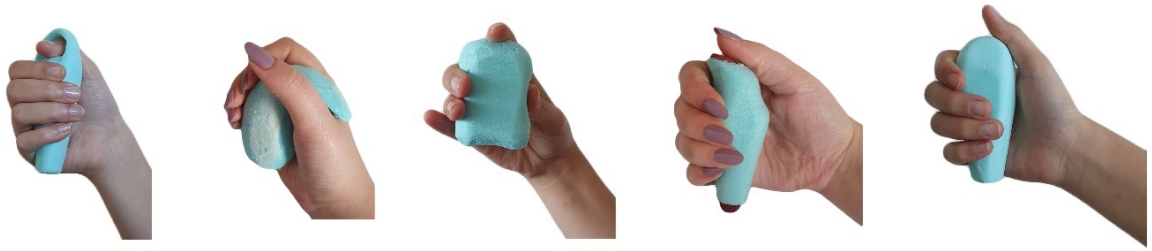


Figure 2: Mock-ups of different shapes

	Was the needle-end identified?	**Was it grabbed correctly?**
A	yes	yes
B	no	no
C	no	no
D	yes	no
E	yes	yes

Table 2: Test results

With the tests results, it can be concluded that some shapes work better than others. With mock-up A, all six subjects were able to identify the needle-end and how the device should be handled, by placing one or two fingers inside the loop. This shape has many benefits since, besides helping in identifying the needle-end of the device, this loop can act as a protection of an activation button, preventing accidental presses and accidental thumb injections, in case the device is handled upside down, which was not verified in the tests. One problem

identified was that the finger placed inside the loop changes between the thumb and the index-finger, which may reveal a problem since depending on it, the way the device is grabbed and the angle of injection changes. If not injected perpendicularly to the leg, it can result in the needle not reaching the muscle, raising the time of absorption of adrenaline. With mock-up B, the needle-end could not be identified, with two subjects saying the needle would come out from the smallest extremity. With more rectangular shapes like mock-up C, the needle-end could not be identified and the tests showed two possible ways of handling and using the device, since it could be interpreted in different ways: five subjects said the device resembled an arrow, thus placing the rounded end against the body, while one subject said the curvature of the device resembled the curvature of the thigh, hence placing the other end against the thigh. With mock-up D, all subjects were able to successfully identify the needle-end of the device, placing it against the body. Even with both ends painted red (one to symbolise a button and other the needle-end), it was still possible to identify which side should go against the leg. With mock-up E, the needle-end and how it should be handled were successfully identified by the subjects.

With shapes with a tapered end (mock-ups A, D and E) the needle-end of the device seems to be easily identified. All subjects were able to correctly point that the needle would come out of that extremity and placed that side of the device against a part of their body. The subjects then explained that by having this tapered shape, it was obvious that the needle would come out from that side. Ergonomic shapes like mock-up B and D prove not to be enough to restrict the way the device must be handled. As shown with mock-ups A and E, vertical symmetry seems to work best to prevent wrongful ways of handling the device. It also allows the devices to be grabbed from both sides.

Conclusion

In emergency devices, the affordances must be visible and clear to the user, to ensure that it is handled correctly. Currently available AAIs fail to communicate to the user how they should be handled, mainly given their shape which can be confusing in emergency situations. Some are too confusing, or have too many steps, which makes the user doubt whether someone without previous training with such devices would be able to correctly administer it if needed. Users complained that most of these devices are too big, and would prefer something smaller, so it is easier to carry. To prevent accidental injuries, the affordances created in these kinds of devices must be clearer and restrict the way the device can be handled with its shape itself.

Testing showed that shapes with a tapered end seem to be a better option to identify the needle-end of the device. Each participant successfully pointed to the extremity from where the needle would emerge and placed that against a region of their body. The subjects went on to say that it was evident that the needle would emerge from that side due to its tapering design. Even so, the shape of the device itself is not enough to instruct that the device must be place in the outer-third part of the leg, since most of the subjects placed the devices against either the arm or belly. The presence of a button seems to be the most intuitive way of activating the device, as most subjects looked for a button or simulated the pressing of one.

This is an ongoing research and further developments are underway. These shapes give good foundations for the development of the project, and they should be improved.

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