Anti-Phylax Pen

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Abstract

An EpiPen is a one-use, costly mechanism that still poses many flaws in the product. Our goal is to address these issues that EpiPen users are having while using the product, such as its accessibility, size, and costs. The specific complaint of bruising from EpiPen injection is resolved with the substitution of the auto-inject with a self injection mechanism that allows for those who suffer from anaphylactic allergies to inject epinephrine in a safe manner without unnecessary bruising. With our product, we will be able to compete with the unfair prices of the EpiPen, and bring awareness to the importance of having an affordable and accessible product for everyone.

Introduction/Background

Allergies affect common people every single day ranging from minor to severe. In fact, according to a recent study done by Food Allergy Research and Education, over 200,000 people go to the emergency room to seek medical help for allergic reactions to food. Allergies are so common in the U.S. that 15 million people were recorded to have food allergies with 5.9 million of those being children under the age of 18. These reactions include anaphylaxis, a life-threatening allergic reaction that occurs quickly and abruptly from a person being exposed to allergens. Over 300,000 people under the age of 18 are sent to the hospital for anaphylaxis without epinephrine every year. Using over the counter medicines such as Benadryl or Claritin do not work for people going into anaphylactic shock because they are not instant relief medications. Instead, people have been using an auto-injector device called the EpiPen. The EpiPen is a device filled with a 0.3mg shot of epinephrine intended to treat anaphylaxis.

Problem motivation

The EpiPen itself is a good idea with a few flaws, especially in the mechanism and how to use the device. In order to use the EpiPen one must exert a great amount of force jabbing the

needle into one's thigh. This is a huge problem with this device since it creates a lot of bruising on the thigh from such great force and the required force needed to correctly inject the EpiPen may be difficult to achieve while users are undergoing anaphylaxis. Most of the force is only used to set off the safety mechanism, which then sets off the auto injector mechanism. The amount of force needed for the needle to puncture through muscle is actually very minimal. Mylan, the company that produces EpiPen has faced multiple lawsuits from injured customers who attained bruising from the injection. Not only does the EpiPen cause injuries to users, users also complain about the device being too big. The device with casing is about 6 inches long and 1 inch thick in diameter, with an awkward shape too large to fit into anyone's pockets. This results in a lack thereof people carrying the device with them and ultimately risking a life-threatening allergic reaction with no treatment. 3.6 million people were prescribed EpiPens in 2015 for allergic reactions, yet 60% of people do not carry it due to its size and weight. Another issue with the EpiPen is that it is too expensive for its target customers. Currently, a two pack of 0.3mg EpiPen auto-injectors are on the market for a price around $4500. This is outrageous considering the device itself cost no more than $40 and is fairly cheap to make, while Mylan continues to claim to invest billions in the product. They are clearly profiting off their customers, because in May of 2017, they edged past their profit estimates, with their revenue rising to $2.69 billion from $2.18 billion (CNBC, 2017). Mylan is able to benefit from the strong demand, while users have no other alternative to the EpiPen. These pharmaceutical price hikes and high-deductible plans create a huge problem for people who need life-saving medications (Khazan, 2016). The World Allergy Organization determined that epinephrine autoinjectors were only available in about half of their surveyed countries, and that the cost of an autoinjector in some countries was equivalent to the monthly salary of an average citizen (Kemp, 2008). The biggest issues for the current EpiPen are that it is too expensive, too big, and causes injuries to users.

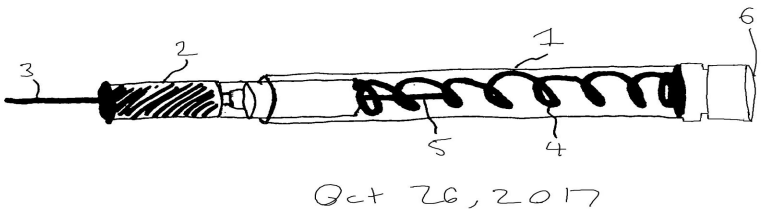
Solution description

In order to fix the problems with the EpiPen our goal was to create a more portable and affordable injector device that also injects epinephrine to treat patients with anaphylaxis. To

achieve our goal of making the device less harmful to patients, our group implemented a button-inject for the Anti-Phylax pen instead of EpiPen's auto injector. With this as our design, the pen uses less force than the EpiPen to inject into a person's thigh causing no bruising and minimal injuries. The button allows them to simply just place it against their thigh, and press the button, releasing the spring, and injecting the needle and epinephrine into the bloodstream. To fix the size problem of the EpiPen, our group designed our device to be smaller both lengthwise and in diameter with the final prototype being around the same size pepper spray. The pen we designed is significantly smaller, at 4.25 inches in length and 0.75 inches in diameter. It also includes an attachment that allows the user to make it a keychain. With the original cost of the EpiPen being around $4500 for a pack of two, but the cost to make the pen being minimal, we decided to make minimal profit off of our devices in order to make it easily affordable for everyone, catering to a much larger population.

Detailed methods with necessary figures, descriptions, etc.

In more detail of our solutions to making the Anti-Phylax pen safer, more affordable, and portable we went through multiple designs and mechanisms to find the best one. Our first step to figuring out our design for the pen was finding what materials we needed in order to recreate the EpiPen. We cut up an EpiPen to see how their mechanism worked and figured out how and why the auto-injector caused so much bruising. Based on the EpiPen mechanism, we decided to order syringes/needles, springs, hot glue, super glue, plastic tubes, and tools. We then constructed a casing and a button around the syringe with Solidworks once we decided to make our project a button injector. We then brainstormed how we should make a stopper for the needle. We cut apart screwable plastic tubes and tried to surround the casing with a 1-inch diameter tube without its bottom in an attempt to maintain the small size of the project. However, the plan to utilize the plastic tube as an additional casing and screw activated button ultimately fell through. We then rethought the design and came up with creating an extension for the casing we made. We again used Solidworks to forge a 2-inch long extension case and stopper which allowed us to arrive at our final injector, the Anti-Phylax. As our injector proved to be reliable, we constructed a safety cap that would go over the button to protect users from accidental injection.



(1) Plastic casing (2) syringe (3) needle (4) spring (5) plunge (6) button (7) safety cap

And to finish the product we added a touch sensor and a timed LED, configured with Arduino, that illuminates for 10 seconds and then turns off to indicate that the injection is complete. The Arduino reads the touch sensor as input, and outputs through the form of an LED. If the sensor detects a fingerprint, it will turn the LED on; otherwise, the LED will stay turned off. The overall purpose of the addition of the Arduino is to prevent any incorrect doses of epinephrine into one's system by early removal of the syringe.

Results

In order to test the reliability of the Anti-Phylax pen, we filled the syringe with water and dyed the water with food coloring so we could observe the spread of the injection. We then used 3 mediums of testing: beef, chicken, and gelatin. After some trial and error with adjustment of time of the injection, the Anti-Phylax proved reliable when injected in flesh (chicken and beef) so we then proceeded to inject it into the gelatin. The benefit of us using gelatin was to observe a transparent, non-liquid substance that allowed for us to view the spread of the dyed water. The Anti-Phylax was proven effective in 3 different mediums which then verified that the injector was reliable for an individual with anaphylaxis.

Discussion & Conclusion

It was important for us to test chicken and especially beef because the injection must be performed in a section of the body with a lot of muscle (typically the outer thigh). First and foremost, we needed to confirm how sturdy the needle was in order to verify that it wouldn't break or bend upon entry. Once that was confirmed, we would cut the meat on the site of injection to see if the injection was successful and complete. This is when we made our adjustments to the timer of the Anti-Phylax. Prior to the injections into meat, our timer was at 5 seconds because our trials had been done into clear, empty cups. But due to added pressure from the beef and chicken the final time needed for the full injection was 10 seconds. The trials helped us make necessary fixes and tweaks to our project to guarantee safe epinephrine injection in instances of anaphylaxis.

Implications and Future Work

The Anti-Phylax Pen will provide a more safe, affordable and portable method of epinephrine injection for individuals with anaphylactic allergies. We would like to provide an alternative to EpiPen users, or anyone who could not afford it or experienced flaws with the product. The button injector of the Anti-Phylax will solve the bruising problem of the auto-injector of the EpiPen and the timed LED gives an easy to follow instruction for proper injection. We intend to make our product much more affordable for consumers who have and don't have health insurance. Additionally, the size of the Anti-Phylax makes carrying the pen less intrusive and more convenient for people with anaphylaxis. With more professional tools and a large budget, we would like to continue to further reduce the size of the product by custom designing syringes. In the future, we would also like to make the Anti-Phylax reloadable (with doses of epinephrine) and replaceable sterile needles to minimize consumer costs. In addition, we would add safety labels and instruction guides, so that users would have no problem using our product during life-threatening situations. We would also like to receive FDA approval for the product to ensure the safety of users worldwide. Also, ideally, we'd like to attach the LED light to the pen with a more sophisticated system than Arduino so that it's portability is further guaranteed.

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