A Cost-Effective and User-Centered Approach to Adapting the EpiPen Auto-Injector for Safer Use

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SUMMARY

This work focuses on the steps we took in adapting the commonly misused EpiPen Auto-Injector for safer use. Here, we present the process by which we determined which modifications needed to be made, the literature-backed reasons for those modifications, and a medium fidelity prototype of our resulting product. Utilizing iterative 3-D printing, we executed a physical representation of our design prototype, while applying human factors principles and incorporating misuse results reported in the literature. We plan to expand this project in the future by conducting a formal usability study, however only the process by which we arrived at a prototype and the prototype itself will be presented at this time.

It is difficult to underestimate the lifesaving value of the EpiPen, but this value can only be realized when the device is properly used. Error patterns have been explored previously in the literature through a wide range of methods and populations (Arkwright & Farragher, 2006; Mehr et al., 2007). A central population in this line of work is health care providers who prescribe these devices. In a study by Mehr et al. (2007) with 100 Australian physicians, 37% of the doctors' demonstrations of their use of the EpiPen would not have resulted in the delivery of medication. This highlights the need to not only construct a device more resistant to error, as we have done in our prototype, but the need also for training in the use of the existing device. Common errors revealed in this study include: "not holding the pen in place for >5 seconds (57%), failure to apply pressure to activate (21%), and self-injection into the thumb (16%)" (Mehr et al., 2007, p. 1). This pattern of errors motivated the design updates we incorporated into the existing EpiPen. These adaptations included an aural feedback mechanism, motivated by its use in other EpiPen redesigns (Camargo et al., 2013; Guerlain et al., 2010), which helps facilitate the necessary pressure needed to deliver epinephrine, as well as, the length at which the pressure should be maintained, and an ergonomic grip to prevent needle injection into the thumb.

Our process in considering the redesign of the device was centered on basic human factors and ergonomics principles that were omitted in the design of the original EpiPen Auto-Injector. We started our analysis with a hierarchical task analysis (HTA) of the unaltered EpiPen Auto-Injector in order to visualize the necessary steps to execute the task successfully. We then used the task structure revealed in the HTA to help us assess the physical design of the instrument. Our analysis began with the obvious issue of the device's symmetry, which allows for self-injection into the thumb. We sought out a resource-effective solution to this problem by way of a 3-D printed ergonomic grip, which accommodates the anatomy of the hand. The placement of the grip on the device was also considered: placing the grip away from the needle (towards the top of the device) would prevent the operator's thumb from reaching to the needle-delivery side of the EpiPen.

In recent years, there have been advancements in the medical device community with regard to designing different types of epinephrine delivery devices. However, the affordability of the generic option available (similar in design to the EpiPen Auto-Injector we worked with) makes it the more commonly purchased device (Skinner, 2016). While the current prototype requires access to the innards of the EpiPen, we believe a noninvasive 2.0 version will meet affordability concerns by allowing the user to simply attach the inexpensive addition to the exterior of the EpiPen without losing functionality. We predict the addition of the ergonomic grip will shrink the observed error rate of the EpiPen Auto-Injector by reducing the operator's ability to place their thumb on the epinephrine-delivery end of the device. Additionally, we predict those who are prescribed the EpiPen may find the grip preferable, as it could be customized to fit the expressive desires of children and others who require the device.

A second principle that was omitted in the original EpiPen design was any source of feedback for the operator to know medicine had been deployed. To address this, we implemented an aural alert that will only deploy when necessary pressure has been applied and will remain sounding for the seconds required to deliver medicine. This also led us to consider the ecological implications of working with this device. The stressful environment surrounding the operator would likely reduce their tendency to attend to, interpret, and appropriately apply the instructions that are printed on the original EpiPen Auto-Injector. Our design modifications effectively reduce the reliance on these printed instructions through the use of aural feedback. Specifically, step two on the printed instructions, a crucial step that ensures medicine is indeed delivered, is addressed with the application of feedback. Step two states, "Swing and push the auto-injector firmly into the thigh until it 'clicks.' Hold firmly in place for 10 seconds – count slowly, '1, 2, 3...'" With the installation of a small alarm in our updated design, the operator will now be able to rely on an intentional sound to know both when enough pressure has been applied and when the device has been held in place long enough for epinephrine to be deployed. Though the installation of the alarm mechanism is intrusive to the mechanics of the EpiPen, it has been easily and cheaply incorporated into the EpiPen Auto-Injector

training device, which was presented, alongside the poster, as a component of our medium fidelity prototype.

As mentioned, future work will focus on formal usability testing of our updated design. This work will focus on three separate components intended to intervene in EpiPen Auto-Injector misuse. The three factors we will assess include our two design updates (an ergonomic grip and aural feedback), as well as, the effect of training on the device's use. The results of this study will be reported in future submissions and are not included here. Instead, in this work, we focus on the value of applying human factors principles to ameliorating the design of familiar medical devices in a way that eliminates the need for retraining on a new device. We believe this process could be applied to other existing medical technologies, and provides a good example of how the application of human factors and ergonomic principles can save lives.

The authors acknowledge the assistance they received from fellow Engineering Psychology student Matthew Scalia in rendering the 3-D printed grip.

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