Human Factors Engineering

Nuts! I Can't Figure Out How to Use My Life-Saving Epinephrine Auto-Injector!

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Scenario 1. Becky, a college student, is out with her friends, enjoying a midnight coffee at a café. As she sips her coffee, she begins to feel a tingling sensation in her mouth. Becky has a food allergy to peanuts and tree nuts. Apparently, the coffee was brewed in the same carafe as a nut-roasted coffee. She begins to feel her throat close. She slips into unconsciousness, and her friends immediately look for the epinephrine auto-injector in her purse. The auto-injector is used to administer intramuscular (IM) epinephrine during anaphylactic reactions. Because Becky had educated her friends about her food allergy, they knew just what to do. After taking out the auto-injector, one friend puts it against Becky's thigh and pushes the top with his thumb to activate it. Nothing happens. The needle doesn't come out. He tries again and again, pushing the top harder each time. Still nothing.

Scenario 2. A 5-year-old named Adam is playing at a neighbor's house with his father. They are about to sit down to have lunch. The hostess brings out some peanut butter and bread. Adam's father reminds her of his son's peanut allergy. The hostess asks if strawberry jam is okay. Adam's father agrees that it is fine. The hostess makes a peanut butter sandwich for her son and then proceeds to make a jam sandwich for Adam. After one bite, Adam complains to his father that his tongue feels tingly, and his face begins to swell. The butter knife used to spread the peanut butter was also used to make Adam's jam sandwich! The father, noticing the urticaria around his child's face, immediately recognizes it to be the beginnings of an anaphylactic reaction. The father is horrified as he realizes that he did not bring an auto-injector.

Article-at-a-Glance

Background: Epinephrine auto-injectors for food allergy emergency treatment is used as a case study to illustrate how human factors in device design has an impact on proper management of anaphylaxis. Because timely injection is so crucial, epinephrine comes in preloaded syringes or auto-injectors that patients can carry with them. However, many factors influence whether treatment is carried out properly.

Human Factors Engineering (HFE) Analysis: The incidence of incorrectly using auto-injectors is not isolated; studies have shown that a significant proportion of patients, and even physicians, do not know how to correctly use the devices. Some auto-injectors appear to be modeled with a metaphor in mind (a pen), but they do not appear and operate consistently with the metaphor. In addition, the device is difficult to transport. The portability issue creates a challenge that cannot be adequately addressed with traditional intervention measures—reminders or more education. They are all human factors issues and require human factors-based interventions.

Summary: Although education and training in how to use an auto-injector are important for effective management of anaphylaxis, a poorly designed device can lead to incorrect operation of such a device. HFE can improve device design so that it is reliably and correctly used even with minimal training. Manufacturers, allergists/immunologists, and pharmacists all have critical roles to play to ensure the correct use of this life-saving device.

Peanut-induced anaphylaxis affects an estimated 1.5 million people.[1] It is estimated that anaphylactic food reactions are responsible for 30,000 emergency department visits and cause 150–200 deaths per year in the United States.[2] Because death may occur within minutes if not treated, it is an urgent immunologic event. Treatment includes the administration of epinephrine. Because timely injection is so crucial, epinephrine comes in preloaded syringes or auto-injectors that patients can carry with them. However, as the two scenarios (page 220) demonstrate, many factors influence whether treatment is carried out properly.[3] This article illustrates how human factors engineering (HFE) can play a role in "controlling" these factors.

HFE is a discipline concerned with designing systems that fit known human capabilities and limitations.[4] The two scenarios described (page 220) are fictional. However, they illustrate the challenges facing anyone dealing with a severe food allergy. They represent my own worst nightmares in raising a peanut-allergic child. Even with daily diligence, things can still go wrong.[5,6] When accidental exposure occurs, the next line of defense is having an epinephrine auto-injector at hand and knowing how to use it. Patient education and training are an important aspect of managing anaphylaxis.[3,7,8] However, even when these are provided, challenges still remain.[9] This article discusses the HFE issues that are associated with auto-injector design—specifically its storage and operation—and how such a life-saving device can be redesigned to be more effective.

HFE Analysis

The Operability Issue

Scenario 1. *"…one friend puts it against Becky's thigh and pushes the top with his thumb to activate it. Nothing happens. The needle doesn't come out…"* I often provide friends and family with "refresher training" on how to use an auto-injector. Each time, their tendency is to push the top end of the auto-injector as if they were activating a ballpoint pen. They instinctively do it, even with previous training. I have to remind them: "It does not work like a pen."

This incident of incorrect use of an auto-injector is not isolated. Studies have shown that a significant proportion of patients do not know how to correctly use these devices.[8,10] Similarly, two studies have reported that physicians have also had similar difficulties.[11,12] This is a human factors design issue. The design of a device (whether or not intended by the designer) provides cues to the user on how it operates. In this case, the device appears to be modeled with a metaphor in mind (a pen). For a metaphor to be effective, the device should appear and operate consistently with that metaphor. If it doesn't, it goes against intuition and makes the device "opaque," or difficult to figure out how to use. The auto-injector is just one of many examples where the primary user/operator of the medical device is a layperson. This fact makes it imperative for the design of the device to be as intuitive as possible, even if the user has little or no training.

The first step in using an auto-injector is to remove the cap at the top. This is an inadvertent or poorly designed cue to the user because it may plant the expectation that the cap is covering an activation button, which is not the case. As in my family's own experience, even with refresher training, the tendency to put a thumb over this button is overwhelming. This cap may give users the false expectation that there is a button to activate. This cue is further reinforced by the fact that once the cap is removed, what appears underneath could be easily mistaken for a button, when in fact it is a nonoperable part of the device. Also, because the buttonlike feature is different in color than the rest of the device, it may also inappropriately draw a user's attention.

An additional problem created by using this pen metaphor is that it may have an "anchoring" effect, limiting the exploration of how one tries to use the device to ways that one might expect of a pen. This might be characterized as "cognitive tunnel vision."[13] In the absence of helpful cues, most users rely on expectations and familiar routines to form a mental model of how a device works. This metaphor creates a bias toward erroneous expectations. Because humans are susceptible to confirmation bias—that is, people tend to seek information that confirms a chosen hypothesis and ignore information that disconfirms it—the cues such as the buttonlike feature only serve to confirm any incorrect notions of how this device may operate. This tendency appears to be enhanced under conditions of high stress.[14]

Another cue that may lead users to incorrectly operate this device is the notion that a cap often acts as a

protective cover for something. This may be a source of confusion for a user who believes that the cap is protecting the end where the needle comes out, potentially leading the user to accidentally inject it into his or her finger. This notion may be further reinforced by a small hole that appears at the "wrong" end, easily leading the user to believe that it is where the needle comes out.

These misleading cues are compounded by the time-critical nature of anaphylaxis. There is little time to pull out the instruction sheet to figure it out. Therefore, relying on instructions is simply not dependable. Furthermore, patients are not often correctly instructed in its use when it is prescribed.[8] This makes it more critical that the device be as transparent as possible—that is, a user should be able to tell immediately, just by looking at it, how to operate it.

The Portability Issue

Scenario 2. *"…The father is horrified as he realizes that he did not bring an auto-injector."* As a parent of a nut-allergic child, this is one of my greatest fears. Yet, excursions with my nut-allergic child are sometimes taken without an auto-injector, as is often the case.[5,15] Why are patients and their families so forgetful? The more appropriate question is What makes this device so difficult to transport? This is a human factors issue. The size and shape of this device determine its portability. This issue has a greater impact on the male population because many women can compensate by transporting the auto-injector in a purse. However, men carry wallets, and auto-injectors on the market today are not wallet sized. Nor do they neatly fit in most pockets without risk of constantly falling out or imposing their bulkiness.

The portability issue creates a challenge that cannot be adequately addressed with traditional intervention measures. Using reminders seems to be an inherently weak method of dealing with it (as my family has concluded after a year of futile reminders). Also, we, like many patients, are well aware of the seriousness of anaphylaxis, so it is unlikely that further education is going to have significant impact. What is needed is an intervention that addresses the human factors issue behind the problem. Designing a device that is convenient to carry will likely have a greater impact on patients conforming to the rule to bring it with them at all times. Redesigning it to be small enough to fit on a key chain or in a wallet or pocket would (1) provide immediate options for carrying and (2) minimize the reliance on memory if it is already attached to something (for example, keys) that one customarily takes along when leaving the house.

Because remanufacturing an auto-injector is in the hands of device makers, an interim solution that addresses the human factors issues is necessary. One such solution is to purchase a carrier that clips to one's key chain or belt. After a six-month trial period, we have found that while reminders are still necessary, this solution has had a greater influence on behavior than any other measure.

Look to Design, Not to Training

The two scenarios described have a common underlying theme: Device design may have greater influence on correct use of this life-saving device than more training. The problem of incorrect auto-injector use can be easily and unjustly attributed to bad training or forgetfulness. Yet the actual culprits in this problem are latent errors that happened well before the user even picked up the medication from the pharmacy. (A *latent error* is something that predisposes a device to improper use.[16]) In this case, the latent error is the design of the device that does not take human factors principles into consideration.

Recommendations

Allergist/Immunologist, Primary Care, and Emergency Medicine Physicians

Physicians can influence the design of a device by contacting the manufacturer and requesting usability data on future products to ensure that users can easily use prospective devices. For an existing device, they should provide manufacturers with input regarding patients' ability or inability to correctly use a device. This is crucial data that may encourage the manufacturer to incorporate human factors considerations into device design. In the mean time, provide high-impact training (hands-on training, video demonstrations) to patients. Physicians should support this with materials the patient can take home (brochures, auto-injector trainer, posters, videos) or provide information on where to obtain such materials. They should allow patients to view and/or purchase video training material in their offices, or they should provide information on where to obtain materials to train others, such as school personnel, babysitters, and family members.

Pharmacists

When patients are filling or refilling their prescription, pharmacists should offer "refresher" training—hands-on or video demonstration. They should offer trainers and provide data (more research is needed to generate such data) on the effectiveness of auto-injectors when used with the aid of support products (carriers, insulated carrying cases, posters that show how to use the devices).

Manufacturers/Researchers/Engineers

Manufacturers, researchers, and engineers have the most leverage in ensuring correct use of auto-injectors. They should design devices that can be easily used without training (change the design or discard the concept of the pen, alter the use of the cap at the end), and can be more easily transported (smaller, thinner). They can incorporate HFE in product development from early stages of conceptual development to usability testing. They should adopt a user-centered design approach that includes iterative design and testing.[16] The cost benefit of doing so is clear.

Summary

It is widely recognized that education and training of how to use an auto-injector is important for effective management of anaphylaxis. Yet it is often not recognized that a poorly designed device can lead to incorrect operation of such a device. HFE can improve device design so that it is reliably and correctly used even with minimal training. To reach this goal, manufacturers, allergists/immunologists, and pharmacists all have critical roles to play to ensure the correct use of this life-saving device.

Key Points

- Incorrect use of auto-injectors can be traced back to device design.
- HFE analysis can identify deficiencies in design that may predispose devices to use errors.
- Improving their ease of use may reduce injury and mortality associated with incorrect use of auto-injectors.
- The goal of improving device usability requires awareness and adoption of a new frame of mind from manufacturers, allergists/immunologists, and pharmacists. J

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