Anaphylaxis Treatment: Ergonomics of Epinephrine Autoinjector Design

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ABSTRACT

Epinephrine administration is a critical component of individualized emergency action plans for patients at risk for anaphylaxis. Fundamental ergonomic principles can be used to facilitate rapid and effective use of an epinephrine autoinjector when appropriate. Specific patient characteristics, including age and strength, that impact physical and cognitive capabilities, should be considered when choosing an epinephrine autoinjector. Considerations in the optimal functioning of an autoinjector include the device being portable, identifiable, safe, and effective. Size, shape, coloring, and labeling of the device all contribute to the device being portable and identifiable. Trigger-lock features, designs resistant to physical perturbations, and safety technology to prevent injury after use contribute to reliability. Optimal grip designs, tailored in size and/or shape to specific patient types, contribute to reliability and effectiveness. After selection of the most appropriate autoinjector, hands-on training, practice, and drills should be implemented. © 2014 Elsevier Inc. All rights reserved. • The American Journal of Medicine (2014) 127, S12-S16

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Anaphylactic reactions, as described in the earlier article in this supplement by Dr Phillip Lieberman,¹ tend to be unexpected and are life threatening.^{2,3} Prompt administration of epinephrine is necessary to reduce the incidence of fatal reactions, which can occur rapidly.²⁻⁵ Therefore, each patient at risk for anaphylaxis should have an individualized

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emergency action plan and should have epinephrine autoinjectors readily available.

The design of the autoinjector and its resulting physical form affects the effective delivery of epinephrine as a firstline treatment and therefore needs to be considered in the development of an individualized emergency action plan. As part of the action plan, the autoinjector needs to be used quickly and effectively by individuals vulnerable to unanticipated anaphylactic shock. The populations at risk include children, adults, and the aging population, all with varying physical capabilities. Because ergonomics examines the balance of an individual's capabilities with task demands, ergonomic approaches that incorporate cognitive and physical factors within the design and use of an autoinjector could prove helpful in increasing the success of any individual emergency action plan.

INCORPORATING ERGONOMIC PRINCIPLES INTO ACTION PLANS

Four considerations regarding the physical functions of an autoinjector were identified by utilizing a cognitive analysis method, which is a common process in product design.⁶ The physical form must lend itself to being *portable* through the

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individual's activities of daily living, *identifiable* among other items carried by the individual (the patient and also their caregivers and peers), *safe* so as to avoid inadvertent preinjection triggers and postinjection sharps injuries, and finally and most importantly, *effective* in delivering the dose of epinephrine to a given individual (Table).

For the portable and identifiable functional factors, the device's size, shape, coloring, and labeling—all classic modes of communicating functionality to users—are the major physical form factors to consider in device design. Portability is an important factor in getting individuals to consistently carry the autoinjector,⁷ yet portability design criteria can conflict with functional and task performance capability, as has been demonstrated in the design of computer technology.⁸

To be safe and reliable, the physical form should prevent unintentional activation before and after the injection (eg, trigger lock feature). Trigger locks also provide security so that the device remains functional and is not rendered useless by inadvertent activation. Moreover, the design needs to be robust to perturbations, such as being dropped or crushed.⁹ To prevent injury after use, the autoinjector should incorporate safety technology available for most needles within general health care practice.¹⁰

For the autoinjector to be effective in delivering the full dose of epinephrine, 2 aspects of the physical form of the device are essential: the design of the injection mechanisms and the human factors associated with activating, positioning, and holding the device while self-injection occurs. In terms of effective autoinjector mechanisms, the device should deliver the drug into the thigh of the patient such that it penetrates into muscle tissue. The depth to which the drug penetrates is dependent on the needle length,¹¹ the pressure at which the drug is injected,¹² and the external force applied to the needle to overcome the resistance of the patient's clothes and tissue.^{9,13,14} The forces described should result in the drug being deposited at a depth greater than the length of the needle,^{11,12} surpassing the subcutaneous tissue.

While the automatic mechanisms of the autoinjector are important for drug delivery, the device requires a human to prepare and activate these mechanisms. Preparation by the user necessitates removing the trigger lock. This process requires important design features such as effective labeling, colors, position, and shapes of the unlocking devices, which should increase successful preparation by untrained users, as shown in simulated usage scenarios.¹⁵

Once prepared, the user must position the device and apply the minimum force needed to overcome the recoil force of the autoinjection. In addition, the user has to apply enough force to overcome the mechanical activation trigger that then releases the needle and administers the drug, typically in the range of 5-10 lbs.¹⁴ Finally, the user needs to hold and maintain a minimum force as the drug is delivered from under pressure in the autoinjector, which usually takes 3 seconds, well within the 10-second hold period instructed.¹⁶ The way that users apply these forces is through gripping the device and pressing or pushing the needle end of the injector into the skin (often covered by clothing).

OPTIMIZING DESIGN OF THE GRIP

To optimize force delivery as the needle enters the skin, the autoinjector should incorporate a classic handle design to optimize grip force. Research studies optimizing tool design to maximize grip performance offer varying approaches depending on the function of the grip and the resulting type of grip.¹⁷ For example, key-pinch and tip-pinch grips are associated with manipulation of objects, while power and hook grips are used to transmit forces between the body and the environment.^{18,19} The 3 fundamental design factors associated with power grip performance (ie, maximum force production and transmission) in the literature are handle size, shape, and surface friction.

Optimal handle size varies for the 2 types of power grips (**Figure 1**), with cylindrical grips having smaller diameters than the widths of prismatic grips. For cylindrical grips, maximum gripping force in adult populations occurs between 35 and 40 mm.^{20,21} For prismatic grips (eg, pliers, typical hand strength exerciser), the optimal width is between 50 and 60 mm for young adults. When the diameter or width increases or decreases from these optimal

The mystat function and the Associated mystat form factors for Enective Design of an Automjector				
Physical Function	Portable: Easy to Carry	Identifiable: Know When Seen or Touched	Safe and Reliable: Prevent Unintentional Triggering and Self-injection	Effective Injection: Get Drug into Correct Tissue
Physical form	SizeShapeAppearance	Unique Use multiple approaches • Shape • Color • Labeling	 Preuse Trigger locks Robust after typical drop, static load Postuse Needle safety device 	Device • Length of needle • Force of needle • Pressure of drug User • Easily activate • Needed applied force via grip • Position and orientation of needle

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