Understanding Medical Devices: Simulating A Real-World Situation

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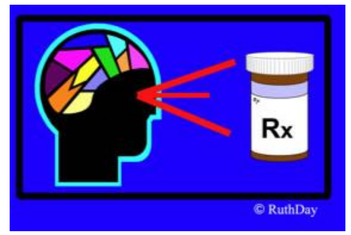


Basic Problem

Severe Allergies

--Many people have severe allergies to insect bites and can experience life-threatening anaphylaxis.

--Epinephrine is used as the first line of defense and must be injected immediately.

--Therefore it is provided in an autoinjector resembling a pen that patients carry with them and self-administer when needed.

Autoinjectors

--Millions of Americans are prescribed epinephrine autoinjectors every year.

--This medical device can save lives.

--However patients, parents, guardians, and even medical professionals often do not use it correctly.

--Therefore, patients may not get the drug needed
  --to reduce wheezing and swelling;
  --can lead to significant harm or even death.

Research Questions

Why do people fail to use the device correctly?

Previous Research

--Traditional focus on device design and quality of training.

--Recent research in the Medical Cognition Lab at Duke (Day & Ikner, 2019) found that the "cognitive accessibility" of the instruction leaflet plays an important role.

--They created an Enhanced version of the device instructions by using chunking, labeling, and spatial layout

--Participants who viewed the Enhanced version understood the instructions much better than those who saw the Original.

Current Research

--The Day & Ikner (2019) experiment focused on cognition, using comprehension and memory tasks.

--Will the same results occur in an action task?

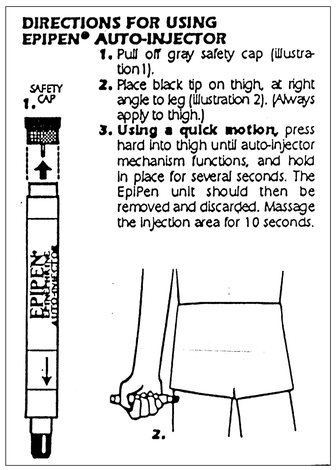
--The current study simulates a real-world situation.
--Participants
  --watch videos of someone using the device.
  --decide whether the actions were correct or incorrect.

Materials

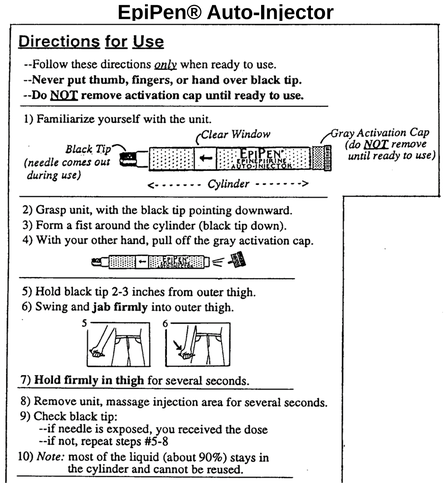
Instructions for Use

The manufacturer of a widely-used autoinjector (Epi-Pen®):
--learned about failures to use the pen correctly
--contacted the Medical Cognition Lab at Duke for assistance.

Day (2000) identified problems in the instructions packaged with the pen and created an Enhanced version.



Original
Packaged with the device



Enhanced
Created by Day (MedCog Lab)

Methods

Participants

--184 adults (wide range in age, education, geographic location)
--randomly assigned to the two leaflet conditions

Study Phase

--Participants read either the Original or Enhanced leaflet.

Inspection Task

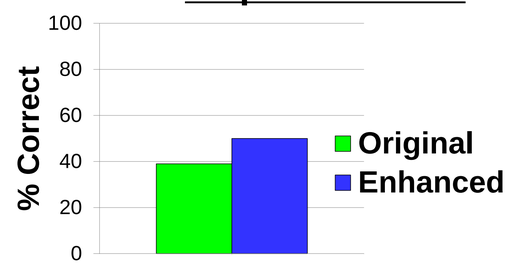
--Participants watched videos of someone inspecting the device.
--For each, they reported whether the person would be ready to use the device later.
--Some videos contained errors.

Use Task

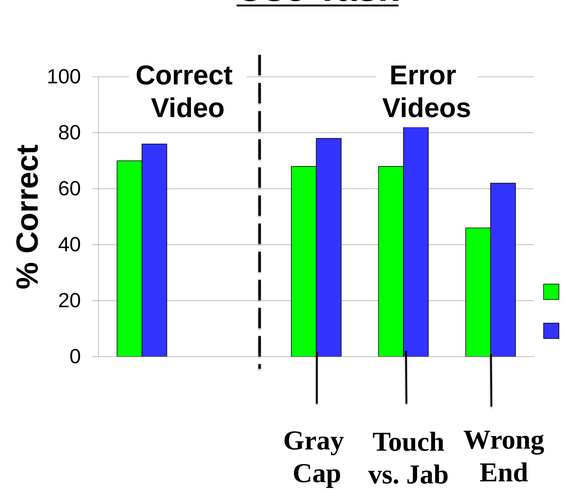
--Participants watched videos of someone demonstrating how to use the pen in an emergency situation.
--They reported whether the actions were correct or incorrect.
--Some of the videos contained errors.

Results

Inspection Task



Use Task



Discussion

Main Findings

--The Enhanced Group outperformed the Original Group in both the Inspection and Use Tasks.

--More in the Original Group would fail to recognize whether someone used the device correctly in a medical emergency.

--Improved cognition does translate to a real-world situation.

Next Steps

--Examine another, more critical, real-world situation.

--Participants study one of the leaflet versions, and then demonstrate how they would use it.

References

Day, R.S. (2018). Patient understanding of risks Cognition vs. metacognition. Invited Address, 10th Risk Evaluation and Mitigation Summit.

Day, R.S. and Ikner, T. (2019, in preparation). Cognitive accessibility of medical device instructions.

Umasunthar, T., Procktor, A., Hodes, M., Smith, J. G., Gore, C., Cox, H. E., Boyle, R. J. (2015). Patients' ability to treat anaphylaxis using adrenaline autoinjectors: A randomized controlled trial. *Allergy, 70*(7), 855-863. doi:10.1111/all.12628