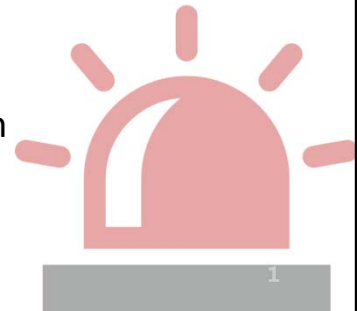


Simulating Stressful, Emergency Use Scenarios During Usability Tests of Injection Devices

Allison Y. Stochlic
Research Director – Human Factors Research & Design
UL LLC / UL-Wiklund



Introduction



- Applies HFE to myriad combination products
- Leads HFE strategy, research, testing, & analyses
- Advises clients on regulators' HFE expectations
- Develops HFE documents for design history files
- Certified Human Factors Professional
- Author of *Usability Testing of Medical Devices*



Simulating Stressful, Emergency Use Scenarios During Usability Tests of Injection Devices

Usability testing basics

Representative ...
users
use scenarios
use environments
product/system
training



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Simulating Stressful, Emergency Use Scenarios During Usability Tests of Injection Devices

Simulation factors

- Sound
- Light
- Space
- Temperature
- Air quality / smell
- Distractions
- Supplies
- Personnel
- Context
- Presentation

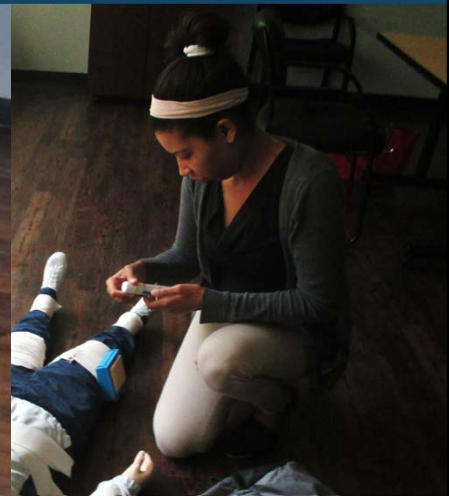


An important caveat

Consider human subjects protections and seek IRB approval of test protocols.



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Case study 1: Epinephrine injection



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Case study 2: Naloxone injection



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Case study 3: Atropine/2-PAM injection



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Case study 3: Atropine/2-AM injection



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Key takeaways

- Consider all environmental characteristics
- Increase simulation fidelity as design matures
- Implement several simulation factors
- Seek feedback on simulation realism
- Seek IRB review of simulation approach

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Questions?

Contact information:

Allison Y. Strochlic
Research Director, Human Factors Research & Design
UL LLC / UL-Wiklund
300 Baker Avenue, Suite 200
Concord, MA 01742 / USA

Email: allison.strochlic@ul.com
Telephone: +1 978 371 2700



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