What Makes a Pre-filled Syringe Usable and Ergonomic?

Critical Human Factors Design Attributes and Interacting Factors

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Welcome to Interface Analysis Associates (IAA), where the user experience comes first. IAA has been a leading human factors, usability and ergonomics consultancy since 1993. Starting in 2010, IAA is now co-branded with Usernomics.

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Interface Analysis / Usernomics has been a leading human factors, usability and ergonomics consulting firm since 1993. Interface Analysis / Usernomics helps make technology approachable, intuitive and fun! We can research, design, evaluate or test your product or work environment to be more useful, usable, safe, satisfying and desirable.

IAA applies a business-centered approach to user-centered design, evaluation and testing by focusing on user experiences that have marketability and economic impact. Our dedicated staff has experience in a variety of domains and contexts, including: Medical/Healthcare, Aerospace, Web, Desktop Software, Business and Enterprise Applications, IT/Security, Computer Input Devices, Gaming, Networks, Mobile Devices, and more.

IAA is led by Dr. Anthony D. Andre, CPE, an internationally recognized expert in human factors, usability, user experience research and ergonomics. Dr. Andre has been both a practitioner and educator of human factors and ergonomics for the past 20 years. Dr. Andre is the 2010 incoming President of the Human Factors & Ergonomics Society.

Consulting Services
You have arrived at the right place if you need expert assistance with your:

- User Interface Design
- Usability
- User Experience
- Human Factors
- Ergonomics
- Internet Searches
- Online Forums
- Organizations
- Journals
- Standards
- Academic Programs
- Usability in the News
How We Can Assist You With Medical Device Design...

IAA provides guidance throughout the medical device development process, to include design, evaluation, usability testing, instructional design, FDA approval and regulatory issues.

Our Role

Dr. Andre and his staff have designed, evaluated and usability tested numerous medical device and drug delivery products over the past 18 years, to include syringes, autoinjectors, insulin pumps, glucose meters, drug reconstitution kits, Automated External Defibrillators (AED), patient record applications and more. We have performed research and testing for a variety of patient populations and health care provider populations.

IAA can help your team develop a user experience that is safe, comfortable, easy to learn, simple to use and satisfying. We address both cognitive-usability and physical ergonomics issues to help ensure that your device has beneficial usability and ergonomics properties from the start. Identifying potential HF/E issues early in the development process is key to designing a successful product.

IAA is well versed in the FDA's Human Factors process, having conducted many studies for a range of medical products and drug delivery systems. Our testing process satisfies the FDA's requirements, from study design to execution to reporting. We have developed a unique approach that couches the study findings in the context of known use-based risks and the potential consequences of errors.
# Portfolio (over 500 clients)

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What Makes a Pre-filled Syringe Usable and Ergonomic?

Drug Delivery Systems: Services & Experience

- User Experience Research
- Device Design
- Instructional Design
- Labeling Design
- Device Evaluation
- Usability Testing
- Regulatory Consulting

- Pre-filled syringes
- Reconstitution Kits
- Safety Syringes-Manual
- Safety Syringes-Automatic
- Fixed Dose Pens
- Variable Dose Pens
- Auto Injectors
- Micro Infusers
- Infusion Pumps

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What Makes a Pre-filled Syringe Usable and Ergonomic?

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Disclaimer

- The syringe images I show were found on the web and are not intended to represent, promote or critique any given product or manufacturer. They are merely used to represent the content topic in a visual manner.
Presentation Overview

- Why Human Factors?
- Ergonomic Design
- Usable Design of Safety Mechanisms
- Human-Centered Design
- Robust Design Needs
- Common User Problems
Why Human Factors?

- After all, it’s only a syringe!

- The FDA considers syringes and drug delivery combination products as “devices”. As such, a syringe falls under the same scrutiny as a heart monitor or insulin pump or other, more complicated, “device”.

- The FDA is looking for —intentional design” — proof that your syringe is designed to satisfy the specific intended audience and use cases.

- The FDA is looking for —design validation” — proof that the intended user audience can safely and effectively use the syringe and delivery the proper dose.

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Two Main Dimensions of Human Factors

Cognitive
Usability

Physical
Ergonomics

What Makes a Pre-filled Syringe Usable and Ergonomic?
What does the FDA really want from you?

- Design with intent for the target population
- Design with intent for known use errors
- Prioritized risk analysis
- Design optimization and assessment aimed at risks
- Validation in a realistic context
- A strong argument about the safety and effectiveness of your device in the context of the intended users
- Use of human factors professionals
- Acknowledgement and incorporation of known human factors guidelines and resources
Error/Hazard Mitigation

Failure points and hazards should be identified before you design a product.

- Design to mitigate the predicted hazards, rather than trying to mitigate the hazards at a point where it is either costly or impossible.

- Keep in mind the FDA is asking you to study your own flaws, so the fewer you have, the better off you are.
  - For example, don’t design a drug kit that requires precise dosing using a difficult-to-read syringe, then later (or before), identify a risk of precise dosing. Identify the risk beforehand, and use a syringe with clear and readable markings.
Common Syringe Tasks

- Drug and Label Inspection
- Cap Removal (from needle or PFS)
- Needle install (PFS)
- Needle Insertion (site, angle, technique)
- Aspiration (?)
- Delivery
- Confirm delivery
- Deployment of safety mechanism
- Disposal
Syringe Design
“Touch Points”

- Thumb pad design
- Flange design
- Plunger rod design (stiffness, color)
- Barrel shape/grip/size
- Needle cap/shield
- PFS cap
- Drug visibility
- Label visibility
- Safety mechanism intuitiveness, design and feedback
- End of dose feedback
- Packaging
- IFU
What Makes a Pre-filled Syringe Usable and Ergonomic?

What are the attributes of a good syringe design?

- Intuitive and transparent mechanism
- Needle stick safety
- Provides added leverage to the user
- Affords multiple plunging postures
- Affords multiple injection postures/sites
- Requires few steps, no learning or memory or things to “figure out”
- Provides good visibility to label and drug
- Provides clear feedforward and feedback
- Is comfortable to use
- It packaged intelligently to avoid inadvertent activation

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Ergonomic Design
Drug and Label Visibility

The drug and label visibility, an important attribute of all syringes, is increasingly compromised by the mechanisms and additional materials required of many needle safety syringes.
Cap Removal

- Cap removal can be a source of frustration and injury.

- Small/thin caps are difficult for patients with diminished hand dexterity/strength.

- As cap removal force increases, associated "recoil" effects are more likely, whereby the patient’s hand snaps back towards the needle and results in a needle prick.

- Help users with this task!
Plunger Head

- Most prominent and constant user touch point on the syringe.
- The size, shape, bevel, texture, thickness and material, either aid or hinder the user’s comfort, administration force, and ability to express the full dose.
- Many plunger heads are too small, have sharp edges, are uncomfortable, or lack conformity to the digit being used (thumb vs. index finger).
Plunger Head Design Guide

✓ Slip resistant
✓ Concave
✓ No sharp edges
✓ Usable with index finger and thumb
✓ Larger is generally better (average thumb pad size)
✓ Should feel stable and increase leverage
Plunger Rod

- The plunger rod is an important element in the design equation.
- Must be stiff enough to provide support with higher viscosity drugs.
- Must provide the user with a sense of stability and direct linear motion during the drug expression.
Finger Flanges

Are the basis for the stability and counter-force required to administer the injection.

Too often these are too small, uncomfortable, and in conflict with non-conventional injection postures (index dart, palm).
Finger Flange Design Guide

- Large (length and width) enough to accommodate at least one full finger on each side
- Grooved to provide additional leverage and comfort
- Avoid sharp edges
- Does not interfere with index finger "push" posture
Syringe Barrel

- The size and shape of the syringe barrel influences the ease with which the user can handle, grasp and stabilize the syringe.

- Size and shape are particularly important in the context of the index finger “push” posture.

- The device should not roll when placed on a flat surface.
Syringe Barrel Design Guide

✓ Use the correct barrel diameter.
  ✗ Too large will reduce grip strength.
  ✗ Too small will result in high pinch grip forces.

✓ Round barrel shape.
  ✓ More conventional.
  ✓ Allows for high variance of grip postures.
  ✗ May roll on a table and/or slip in the hand.

✓ Square barrel shape.
  ✓ Won’t roll and provides a better grip for some postures.
  ✗ May be viewed as unconventional.
Safety Syringes

- Exist in a variety of styles.
- Are becoming the syringe of choice in many environments.
- Needle safety mechanisms vary greatly in their approach to activation, deployment, feedback and design affordances.
- Wide range of reactions and interaction behaviors across the various needles safety syringes on the market today.
Safety Syringe Design Guide

- Mechanisms with internal retraction may reduce the incidence of contact with the injection site.
- The mechanism should be obvious to the user.
- The mechanism should be deployed without any overt action required of the user.
- The needle safety mechanism should not interfere with the plunger movement, require more precise alignment of the plunger head, or affect the user’s ability to express the full dose.
- The safety mechanism should be intuitive, easy to identify, learn, remember and control.
- It should not surprise the user.
Human-Centered Design
Human-Centered Design

A human-centered approach integrates the specific needs, capabilities and limitations of the intended user population.
User Type

Performance and acceptability can vary widely depending on the user population (healthcare providers vs. patients self-injecting).
User Behavior

- Each population has different needs, habits, constraints and contexts.

- Even within a population there can be large variances in usage behaviors. Note the 3 different injection postures shown in these images.

- How do HCP needs differ from patients?

- What varies within each population?
Patient Population

- Some patients have limited hand dexterity and strength that should be accounted for in syringe design.
- These patients need greater stability, grip and leverage than other patient populations.

Different diseases produce unique needs.
Patient Profile

- What is relevant about your user audience?
- What degradations do they have?
  - Physical
  - Cognitive
  - Memory
  - Visual
  - Tactile

You must describe why and how your product is specifically designed for your audience.
Patient Population

Some patients have cognitive and memory deficits that could make it difficult for them to learn and remember any "procedure" or manipulations required of a needle safety syringe.
What Makes a Pre-filled Syringe Usable and Ergonomic?

Patient Age

- Age-related factors play a large role in device interaction.
- Younger (under 10) and older (above 65) patients alike may lack motor coordination, hand strength, and procedural understanding that could undermine their safe and effective use of a syringe.
Your design must have a large success range. Don’t require users to be perfect in order to succeed.
Robust Design

- A syringe design may be appropriate for one user type but not for another, or for one self-injection site but not another.

- Large finger flanges may not be needed, and may even be detrimental, to a pediatric nurse using a dart-like injection posture with a single hand, while they are essential for an RA patient.
Drug Viscosity

- Drug viscosity not only affects the required plunger force, but also influences the overall injection posture and specific syringe interaction behaviors of HCPs and patients alike.

- Syringes used to deliver highly viscous drugs may have to include unique design attributes that increase the leverage and comfort for the user.
Effects of High Viscosity Drugs on Users

Awkward postures

Extreme contact pressure
Effects of High Viscosity Drugs on Users

Discomfort and pain

Changes in body posture and facial expressions.
What Makes a Pre-filled Syringe Usable and Ergonomic?

Feedback: Explicit vs. Implicit Design

Drug delivery devices are all about feedback.

- Users need explicit positive feedback for all steps and states.
- The more sensory channels you use, the better: visual + auditory + tactile.
- When and how does the safety mechanism activate?
- How does one know they’ve properly attached a needle onto a Luer syringe tip?
Explicit vs. Implicit Design

Take the interpretation out of the hands of the user. Do as much for them as possible, and give unambiguous cues, feedback and forcing functions.
Common User Problems

- Inadvertent activation of safety mechanism during removal packaging
- Patient assumes needle guard body is protective packaging
- Can’t see label or drug clearly
- Difficulty removing cap to syringe
- Inadvertent activation of safety mechanism
- Not sure what to do about air bubble in pre-filled syringe
- Not sure how safety mechanism works or when it activates
  - Does not activate
  - Activates too late
  - Activates into site
- Difficult to hold and manipulate due to flange or barrel design
- Difficult to plunge due to plunger head or viscosity
- Difficult to inject on side or rear of body
- Difficult to inject with index or palm plunging posture
Packaging Errors

- Inadvertent activation of safety mechanism during removal from packaging is not uncommon.
- Make sure that the packaging is designed so that users can lift out the syringe from the barrel—NOT the safety triggers or the plunger rod!
- Packaging design must be considered early on to reinforce how/where users should handle the syringe.
Safety Mechanism Design Errors

- Many users will play with a device, or not use it correctly, if they are not sure how the safety mechanism works or when it activates
  - Does not activate
  - Activates too late
  - Activates into site
  - Inadvertent activation of safety mechanism (some users think they extra plastic is a protective package)
- A good design would be obvious to the user that: a) it exists, and b) how it works, and c) when to deploy it.
- We call this design —“transparency”
What Makes a Pre-filled Syringe Usable and Ergonomic?

Alternative Site Injections

- Good syringe designs would provide leverage for injections into hard to reach areas.
- Some users are forced to utilize caregivers for injections in these areas. Others might use “vices” to manipulate the device.
- Your design should have some feature to help users when they have to reach or inject blindly.
Keys to Success
Instructions for Use

- For some of the issues described earlier, the IFU is the best way to address user perceptions and behavior.

- The IFU, if designed correctly, can help users understand how to handle the device, how to deploy the safety mechanism and what NOT to touch. It might make the difference between successful validation or failure to validate.
What are the attributes of a good syringe design?

- Intuitive and transparent mechanism
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Final Thoughts

- Developing pre-filled syringe designs that are ergonomic, usable, human-centered and robust requires consideration of many different factors and contexts. By maintaining a focus on human factors and ergonomics issues, and the unique needs of the target user audience, we can greatly increase HCP and patient safety, performance and satisfaction.

- We’ve come a long way, but we are not there yet!
The Human Factors and Ergonomics Society invites you to attend the 2012 Symposium on Human Factors and Ergonomics in Health Care, to be held March 12–14 at the Marriott Baltimore Waterfront Hotel in Baltimore, Maryland. Mark your calendars!

Please bookmark this page and return often for updates about

- Booking your hotel room
- Submitting a proposal
- Registering for the symposium
- Viewing the complete program

The objective of the symposium is to bring together professionals and other stakeholders in both the scientific and practice realms of the health-care community and to bridge knowledge gaps among them. HF/E professionals will present the latest research, best practices, and case histories.

**Lucien L. Leape, MD**, kicks off the symposium with the opening plenary address on Monday, March 14. Leape is Adjunct Professor of Health Policy in the Department of Health Policy and Management at the Harvard School of Public Health. A health policy analyst whose research has focused on patient safety and quality of care, Leape was one of the founders of the National Patient Safety Foundation.

Unique to this symposium is the inclusion of manufacturers, health-care providers (physicians, nurses, administrators, etc.), and policy makers, who will discuss their experiences in using HF/E processes and principles. The symposium will also enable them to communicate their need for additional collaboration with the HF/E community.

The symposium will address a variety of topics and perspectives in health-care improvement, including the following:

Welcome to MedicalDeviceHumanFactors.org, your source for resources (standards, guidelines, science, best practices, books, journals, etc.), consultants, organizations and events related to medical device human factors and ergonomics (HF/E). Companies that make devices which must meet FDA standards and approval should make use of this site to become knowledgeable of HF/E requirements and resources and the consultants that can help them meet these requirements.

This site was jointly developed by the Human Factors and Ergonomics Society (HFES) and the Association for the Advancement of Medical Instrumentation (AAMI). We hope that you find it a useful resource for guiding your efforts towards developing a new or revised medical device with HF/E principles in mind.

Inquiries about this site should be directed to the staff of the Human Factors and Ergonomics Society, who maintains the site.

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