Visual Impairment Affordances Can Benefit All Users

Lisa Lacouette-Ward, M.S. & Anastasia Diamond, Ph.D.
West Pharmaceutical Services Inc., Scottsdale, Arizona, USA

PDA Universe of Prefilled Syringes and Injection Devices
Phoenix, AZ October 2024

Introduction

Increasing access to safe and effective devices is a top priority for global regulatory bodies, including the FDA[13]. Expanding access is multi-faceted approach that includes designing injection devices that can be used at home *and* by diverse patient populations. Interface designs of injection devices and accompanying materials such as labels and instructions for use (IFU) should aim to serve the most diverse user population allowable. When accommodations for impaired users do not impede use or increase risk for intended populations, efforts should include such affordances. Human factors should incorporate design principles that assist those with visual impairments. Inclusivity in design could facilitate patient device use at home, leading to increased adherence to treatment regimens, reduced need for hospital clinic visits, reduced exposure for immunocompromised patients, and increased patient and healthcare professional satisfaction. Human factors usability testing and validation of interfaces cultivated with inclusivity can have far reaching benefits for use.

Visual Terminology

Visual Acuity – A measure of the ability of the eye to resolve fine details[10].
Snellen Test – A measure of the observer's ability to resolve spatial patterns (i.e., letters)[10].
Normal Vision – Snellen results of 20/20 means you can resolve a pattern from 20 feet away that a normal observer can resolve from 20 feet away. Or in the case of 20/15 vision, you can resolve a pattern from 20 feet away that a normal observer can resolve from 15 feet away[10].
Vison Impairment – Vision that cannot be corrected to a "normal" level[2].
Mild Impairment – Vision in the better eye is correctible to 20/30 – 20/60[2].
Moderate Impairment – Vision in the better eye is correctible to 20/70 – 20/160[2].
Severe Impairment – Vision in the better eye is correctible to 20/200 or worse[2].
Legal Blindness (USA) – Visual acuity worse than 20/200 in the better seeing eye with best conventional correction[2].

Industry and Regulatory Considerations

ISO 11608-7: Needle-based injection systems for medical use-Requirements and test methods - Part 7: Accessibility for persons with visual impairment[6]

- ✓ This standard addresses the needs of those with low, moderate, or severe visual impairment; legal, functional, or total blindness; and color vision deficiencies regarding needle-based injection system (NIS).
- ✓ Though this standard is centered around designs that accommodate users with visual impairments, there are principles that **can be applied universally**. For example, using adjustability for text sizes or changing the contrast of displays or interfaces **can improve readability**.
- ✓ **Creating clear and simple designs with consistent labeling can reduce the potential for use errors for all users**. Additionally, using a multi-sensory approach, like tactile and auditory formats for communicating information, along with visual information.
- ✓ By using these device principles, it **can reduce the likelihood of errors** by using multiple approaches for feedback mechanisms and improve safety for all users.
- ✓ Consider providing training or materials to support use in multiple formats (e.g., written, video).
- ✓ NIS should indicate and distinguish the following states by visual *and* non-visual methods: unused, ready to deliver, delivery initiated, delivery completed, end of useful life.

The Principles of Universal Design – Universal design is a concept in which products and environments are designed to be useable by all people, to the greatest extent possible, without the need for adaptation or specialized design[4].

1. **EQUITABLE USE** – The design is useful and marketable to people with diverse abilities.
2. **FLEXIBILITY IN USE** – The design accommodates a wide range of individual preferences and abilities.
3. **SIMPLE AND INTUITIVE USE** – Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level.
4. **PERCEPTIBLE INFORMATION** – The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.
5. **TOLERANCE FOR ERROR** – The design minimizes hazards and the adverse consequences of accidental or unintended actions.
6. **LOW PHYSICAL EFFORT** – The design can be used efficiently and comfortably and with a minimum of fatigue.
7. **SIZE AND SPACE FOR APPROACH AND USE** – Appropriate size and space is provided for approach, reach manipulation, and use regardless of user's body size, posture, or mobility.

Characteristics Contributing to Visual Impairment (grouped by demographic)

AGE

- **Adults (18-65)**
  - **70% of adults wear glasses by their mid-40s**[7]
  - Acquired color perception deficiencies – color blindness (not inherited) related to exposure to solvents, heavy metals, medications, or disease comorbidities
  - Common medical conditions that affect vision[1]:

Medical condition	Effects
Diabetic retinopathy	Blindness
Macular degeneration (genetic)	Blurred vision, loss of central vision, distorted vision, faded colors
Retinal detachment	Flashes of light across the visual field, floaters
Optic neuritis	Inflammation of the optic nerve
Stroke	Dim vision, trouble seeing with one or both eyes
Brain tumor	Blindness
Migraine headaches	Spots of light, perception of zigzag patterns
Multiple sclerosis	Blindness in one eye
Vitamin A deficiency	Night blindness
HIV/AIDS	Vision loss

- **Seniors (65+)**
  - **80% of seniors have corrected vision after age 65**[7]
  - Visual acclimation – slowed light adaptation, reduced depth perception, increased sensitivity to glare
  - Eye lens degradation – color perception changes (i.e., blue/violet/green)[8]
  - Light perception changes – increased blurred vision potential, contrast perception reduction[14]
  - Processing ability changes – slower visual and cognitive processing potential
  - Age related color perception deficiencies – color blindness (not inherited) related to disease, exposure to harmful materials or aging tissues and blood vessels[1]
  - Common medical conditions that affect vision – the following are in addition to those listed above

Medical condition	Effects
Cataracts	Poor night vision, halos around lights, day vision eventually affected
Glaucoma	Poor night vision, blind spots, loss of vision to either side
Macular degeneration (age related)	Blurred vision, loss of central vision, distorted vision, faded colors
Stroke (increased chance with age)	Dim vision, trouble seeing with one or both eyes

GENDER (assigned at birth unless specified)

- **Males**
  - **Red-green inherited color blindness affects approximately 8.3% of males** – X chromosome linked recessive
  - Higher incidents of myopia (nearsightedness) based on genetic predisposition, occupational environment and toxic material exposure[1]
- **Females**
  - **Overall, females are 12% more likely to experience vision loss than males** – specifically 8% ↑ blindness, 15% ↑ moderate to severe impairment, 12% ↑ mild impairment, 11% ↑ near vision impairment, related to longer life expectancy, and socioeconomic factors[11]
  - Red-green color blindness (inherited) affects approximately 1 in 200[5]

LOCATION

- **USA**
  - 12.5 million adults aged 40+ currently living with a visual impairment are expected to increase by 118% by 2050[15]
- **Global**
  - 2.2 billion people have near or distance vision impairment[16]

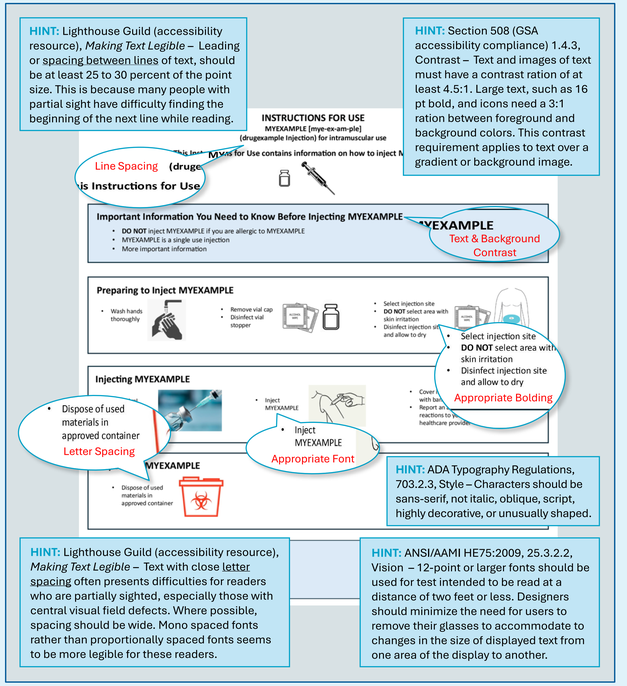
Designing IFUs for Users with Visual Impairments

When designing instructions for use for visually impaired users, it is important to consider those who may be helping to care for them or the environment in which they may be using the device and accompanying interfaces. So, making information easy to perceive, read and understand through simple language and clear graphics, as well as navigate, among others, are all factors to keep in mind when designing IFUs. To ensure accessibility and usability in instructional materials for visually impaired users, consider the following key factors:

Do's ✓	*Do Examples*	Dont's ✗	*Don't Examples*
Do use discernable colors. Consider the contrast of the font compared to the background. Similarly, use tactile graphics to communicate information through touch.	Hello.	Avoid using colors in the short-wavelength range (i.e., blue and violet if they must be discriminated).	Hello.
Do use 12-point or larger fonts for text intended to be read at distances of two feet or less. If possible, print font in size 16 to 18 points.	**Hello.**	Avoid causing users to adjust to differences in font size changes.	**Hello.**
Do use upper- and lower-case font styles.	**Hello fellow conference attendee!**	Avoid sole use of upper-case lettering, as well as italics, oblique or condensed font styles.	**HELLO FELLOW CONFERENCE ATTENDEE!**

Do's ✓	Dont's ✗
Consider paper quality to minimize glare.	Avoid printing on glossy paper for older adults.
Consider the size of the paper relative to the amount of information. Use a larger than normal font size and use enough spacing in between lines of text. Similarly, consider using whitespace to allow for information to spread out without feeling cramped or cluttered. This can help the user focus on the information needed to use the device.	Avoid forcing a lot of information onto a small piece of paper. Increasing the paper size will allow for the use of larger font sizes. Avoid packing a lot of information into a small section.
Do position important information in the center of the visual field. Follow an organized or hierarchical format for displaying information.	Avoid placing important information in the periphery.

Implementing these considerations makes instructions more accessible, enhancing the experience for visually impaired users, as well as those who are not. This can help to increase the ease of use for all. Additionally, consider using other forms of communication to present the instructions for use in various formats such as: E-text to allow the user to increase the size, auditorily to allow them to listen to the instructions, or Braille.



Conclusions

Of these affordance examples described above for IFUs to help increase the usability for those with visual impairments, all can help increase accessibility for them, as well as all other users. These design considerations can help in more ways than one. They can create less cluttered designs that are more organized to promote ease of navigation, and over all visually clearer IFUs that help patients, or their caregivers, have an easier time adhering to the treatment plan. All of this will play into the user's ability to adhere to and deliver successful treatments. Additionally, though a patient user population may not be clinically visually impaired, it may behoove the company to consider these affordances anyway as it could be a large demographic of older adults or a patient group with visual impairments as a side effect to their disease (e.g., diabetes).

Finally, as this quote states, "Professionals have a unique opportunity to provide important strategies to adults with vision loss, their families, and caregivers to enhance their health, safety, independence, and quality of life."[9]

References

1. American National Standards Institute, & Association for the Advancement of Medical Instrumentation. (2009). Human factors engineering—Design of medical devices (ANSI/AAMI HE75:2009). Arlington, VA: AAMI.
2. American Optometric Association. (nd). Low Vision and Vision Rehabilitation. https://www.aoa.org/healthy-eyes/caring-for-your-eyes/low-vision-and-vision-rehab?sso=y
3. Arditi, A. (n.d.). Making text legible: Designing for people with partial sight. Retrieved June 6, 2024, from http://www.lighthouse.org/accessibility/legible/
4. Burgstahler, S. (2009). Universal Design: Process, Principles, and Applications. *DO-IT*.
5. Cleveland Clinic. (2023, April 17). Color Blindness: *How common is color blindness*. https://my.clevelandclinic.org/health/diseases/11604-color-blindness
6. International Organization for Standardization. (2016). Needle-based injection systems for medical use—Requirements and test methods—Part 7: Accessibility for persons with visual impairment (ISO 11608-7:2016).
7. Johnson C. Peripheral visual fields and driving in an aging population. Paper presented at the Invitation Conference on Work, Aging and Vision, National Research Council, Washington (DC), February 1986.
8. Kashima K, Trus B, Unser M, Edwards P, and Datiles M. Aging studies on normal lens using the Scheimpflug slitlamp camera. Investigative Ophthalmology and Visual Science, 334:293–326, 1993.
9. Nasehi, L. (2023, December 18). National Council on Aging: How referring older adults to vision rehabilitation can strengthen their medical care relationships. National Council on Aging. https://www.ncoa.org/article/how-referring-older-adults-to-vision-rehabilitation-can-strengthen-their-medical-care-relationships
10. Stone, N. J., Chaparro, A., Keebler, J. R., Chaparro, B. S., & McConnell, D. S. (2017). Introduction to human factors: Applying psychology to design. CRC Press.
11. The International Agency for the Prevention of Blindness (2024). Inequality in Vision Loss: Gender. https://www.iapb.org/learn/vision-atlas/inequality-in-vision-loss/gender/
12. United States Federal Government. (n.d.). Fonts and typography. Section508.gov. Retrieved [date], from https://www.section508.gov/develop/fonts-typography/
13. United States Food and Drug Administration, Executive Summary for the Patient Engagement Advisory Committee Meeting, Advancing Health Equity in Medical Devices, September 6, 2023.
14. van den Berg T. Analysis of intraocular stray light, especially in relation to age. Optometry & Visual Science, 72:52–59, 1995.
15. Varma, R., et al. Visual Impairment and Blindness in Adults in the United States: Demographic and Geographic Variations From 2015 to 2050. *JAMA Ophthalmol*. 2016;134(7):802–809. doi:10.1001/jamaophthalmol.2016.1284
16. World Health Organization. (n.d.). *Blindness and visual impairment*. https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment

Lisa Lacouette-Ward
Lisa.Lacouette-Ward@westpharma.com
www.westpharma.com
Scan QR code for more information.