AN EXPLORATION OF INNOVATIONS IN PATIENT COMPLIANCE & ADHERENCE

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Laurie Reed | Senior Director, Human Factors Engineering

- Manages the Human Factors group at Farm Design, a Flex Company
- Has 18 years of experience in the research and usability industry
- Laurie has worked for many large OEM, pharmaceutical, and startup clients
- Holds a BA in human factors engineering from Tufts University. Prior to her current position, she was a research scientist at the American Institutes for Research. She also owned and operated her own research recruiting company for nine years.

Lisa Gunther, PhD. | Principal Human Factors Engineer

- Has over 25 years of experience conducting both basic and applied psychological research
- Is a well-published author in behavioral psychology
- Prior to joining Farm, worked in higher education for 19 years and established both the Human Factors Psychology Program and User-Experience Research Lab (UXLab) at Greensboro College.
- Earned her PhD in Psychology from Binghamton University, specializing in Behavioral-Cognitive Psychology with an emphasis in Statistics.

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WEBINAR OVERVIEW

Today we will:

1. Key Definitions
2. Explore the most common root causes of patient compliance and adherence issues across a set of drug delivery devices
3. Review compliance and adherence issues and present some smart technologies that provide potential solutions to the issues
4. Summarize what user needs remain largely unsolved and may be ripe for opportunity and innovation

KEY DEFINITIONS (FOR TODAY'S PURPOSES)

Compliance

The degree to which a patient utilizes the prescribed medical treatment correctly (i.e. performing the steps correctly)

Adherence

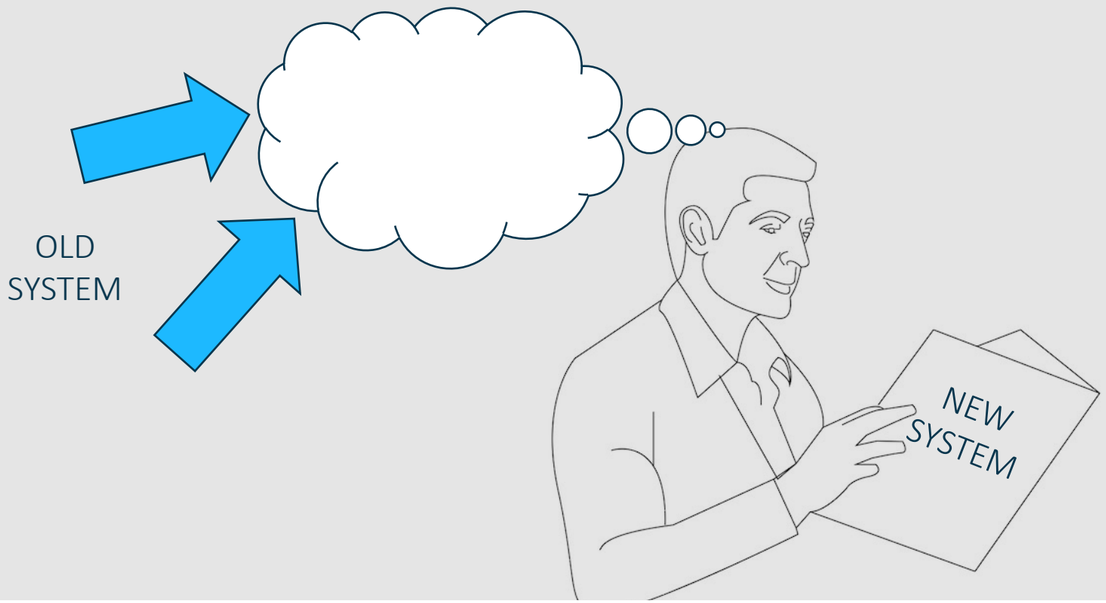
The degree to which a patient follows the prescribed treatment regimen (i.e. taking them regularly as directed)

A REVIEW OF COMMON ROOT CAUSES

COMMON ROOT CAUSES

1 Device Design

Failure in compliance and adherence may be caused by transferring prior mental models of the user's current and frequently-used system may impact the ability use a new system. This is known as negative transfer.



2 Packaging & Labeling Design

Packaging design can either hinder or enhance patient adherence to a medication regimen.

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COMMON ROOT CAUSES

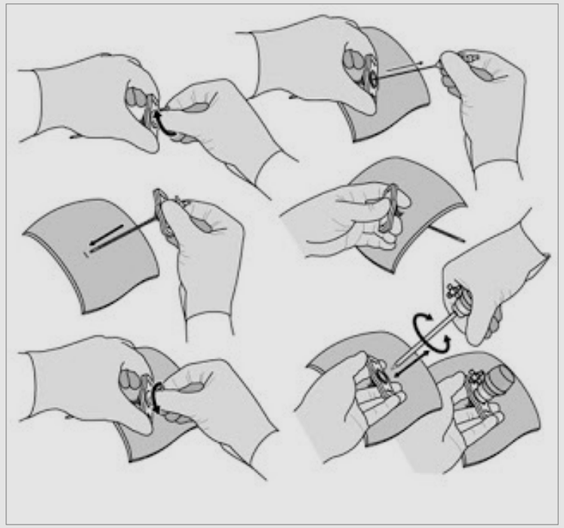
3 Training

For some products, training may be required in order to mitigate against compliance and adherence issues.

HCP training parent and child to use EpiPen

4 Instructions for Use

Ease of access (e.g., folding/unfolding), layout, word choice, and use of images all impact users' utilization and understanding of user documentation.



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COMMON ROOT CAUSES

5 Human Capabilities and Limitations

In designing for compliance and adherence, engineers need to consider the capabilities and limitations of the user.

Cognitive Overload

Sensory Impairment

Physical Impairment

ISSUES AND SOLUTIONS FOR PATIENT COMPLIANCE

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COMPLIANCE ISSUES

- Loading the device
- Measuring a dose
- Orienting the device
- Determining where to inject
- Angle of injection
- Priming the device
- Using aseptic practices
- Dose actuation
- Force of actuation
- Determining when a dose is complete
- Determining when medication is out/empty
- Knowing when to change transdermal patches
- Cleaning the device
- Taking note of the expiration date
- Storage and disposal

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ISSUE: HOW DO I LOAD THE DEVICE?

For non-prefilled medications, there is an added step requiring the user to get the drug into the device. This can sometimes lead to use difficulty and/or use error because:

- It is not always obvious how to correctly load the cartridge/syringe/medication
- Some end users even forget they need to load the drug
- Even users who are aware they need to load the drug sometimes do not correctly seat the cartridge/syringe/medication
- Even users who are aware they need to load the drug and understand how the loading works can experience physical difficulty executing the action

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SAMPLE SOLUTIONS: DEVICE LOADING

Most of the drug loading difficulties described on the previous slide can be mitigated through design.

The following device features are expected to alleviate device loading errors to some extent:

- Devices that come with the drug prefilled, therefore eliminating this use step completely
- Physical features and affordances that prevent the user from incorrectly loading the medication
- Labeling, markings, color coding, and other visual cues on the device itself that communicate the correct loading direction
- Step by step visual and/or auditory loading instructions portrayed by the device itself

The AutoTouch only enables the user to close the door if the cartridge is loaded correctly

The Elcam Flexi-Q eMU-C utilizes a digital display to instruct users on how to load the cartridge

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ISSUE: HOW MUCH DO I DOSE?

Users sometimes experience difficulty measuring out the desired dose with drug delivery devices.

The use issues center primarily around:

- Misinterpreting how the dose numbers match up to the gradient markings
- Misinterpreting dosages in between gradient markings
- Measuring a dose by the beveled curve of a stopper or plunger vs. by the actual medication level
- Not accounting for air in the syringe

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SAMPLE SOLUTIONS: DOSE AMOUNT

Most of the drug loading difficulties described on the previous slide can be mitigated through design.

The following device features are expected to alleviate dosing errors to some extent:

- Syringes that provide sufficient contrast between it gradient markings, the plunger, stopper, and expected color of the liquid drug
- Pre-set dials that eliminate the need to measure a liquid up against a gradient marking
- Devices that do not leave any gradient markings unlabeled
- Pen injectors that only present the relevant dose numbers near the dose viewing window
- Pen injectors that prevent dialing a dose that is larger than the available drug left in the cartridge

Ypsomed UnoPen

BD Enteral Syringe

AcuLife True Easy Syringe

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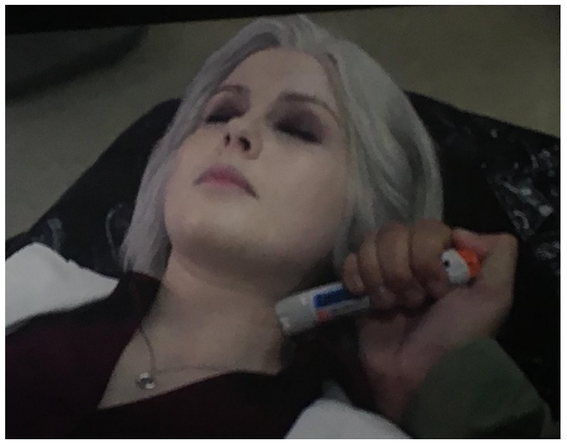
ISSUE: HOW DO I ORIENT THE DEVICE?

Users often experience confusion over how to correctly orient drug delivery devices for administration, especially if they do not refer to the Instructions for Use and try to rely solely on device design cues.

This type of use error can have a number of negative impacts, including:

- Skipped doses
- Ineffective dosing
- Needlestick injury
- Wasted drug
- Delay of treatment



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SAMPLE SOLUTIONS: ORIENTATION

Devices that are designed with obvious ergonomic affordances and visual cues that communicate to users where to grip the device and how to position it in relation to their body are likely to be more successful in mitigating the orientation use error.

- Packaging, labeling, and IFU designs that are ‘in the user’s face, or strongly encourage the user to take note of instruction will also reduce the likelihood of orientation errors.
- Multi-modal instructions have a higher chance of being encoded in the brain, so some new packaging designs are supplementing visuals with auditory scripts.

Inhey ergonomic inhaler for kids

BD Libteras On-body injector

K-haler packaging design

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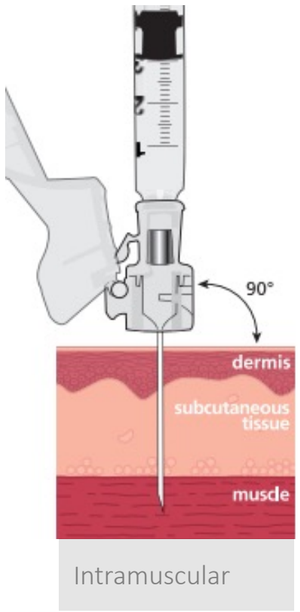
ISSUE: WHERE DO I INJECT AND AT WHAT ANGLE?

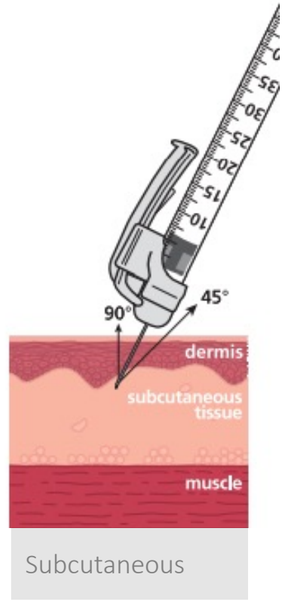
The difference between intra-muscular, subcutaneous, and intradermal injections is not widely understood by the general patient population.

For this reason, users often do not have an inherent mental model of where on their body to inject a subQ or IM device.

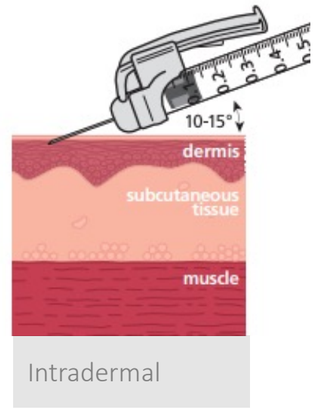
- Users are not aware that each injection type typically has a different indicated injection angle.
- Users make assumptions about acceptable injection sites based on a number of factors including what they have seen on TV and in the movies, negative transfer from past device use, and their understanding of how the drug will travel through their system to the affected area.
- Even when patients read an instruction to inject “in the outer thigh” (for example), or at “45 degrees” they have varying interpretations of what actually constitutes the outer part of the thigh or what 45 degrees looks like.



Intramuscular



Subcutaneous



Intradermal

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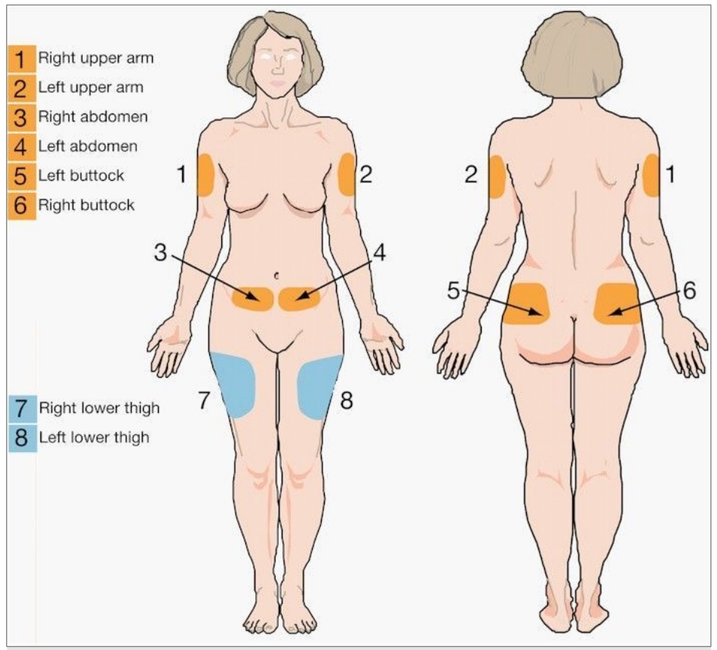
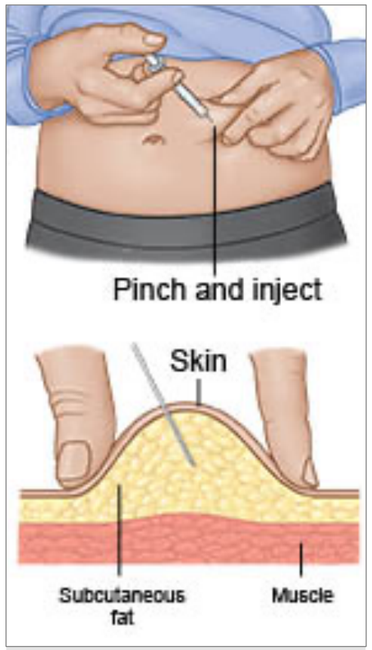
SAMPLE SOLUTIONS: INJECTION SITE

Communicating the correct injection site is not something easily done through design.

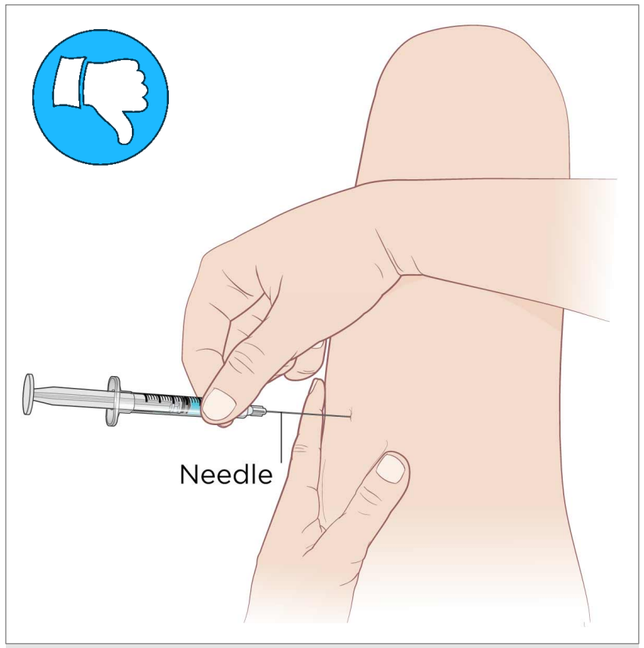
For this reason, it is more appropriate to try to mitigate this use error through the Instructions for Use and training.



This IFU promotes correct interpretation of injection sites like “lower thigh”



This IFU promotes an understanding of the intention of a subQ injection



This IFU could be misinterpreted because there is no clear indication of the body part

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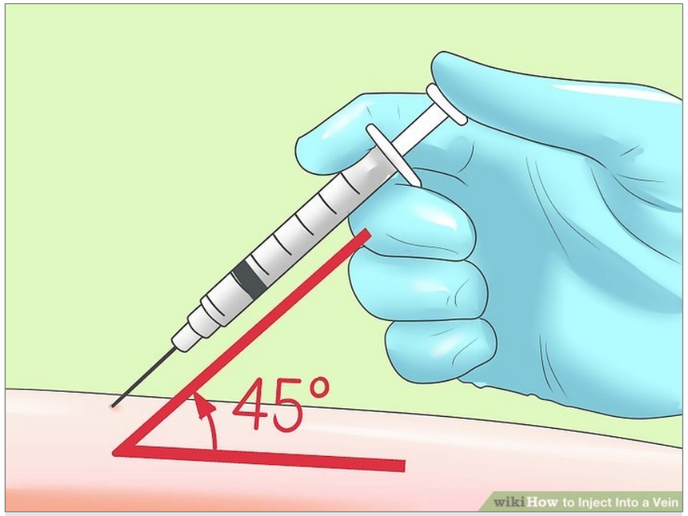
SAMPLE SOLUTIONS: INJECTION ANGLE

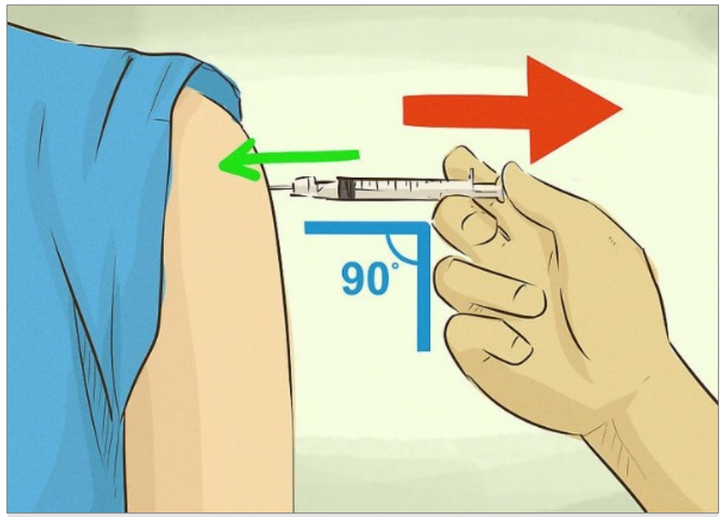
Communicating the correct injection angle is not something easily done through design.

For this reason, it is more appropriate to try to mitigate this use error through the Instructions for Use and training.

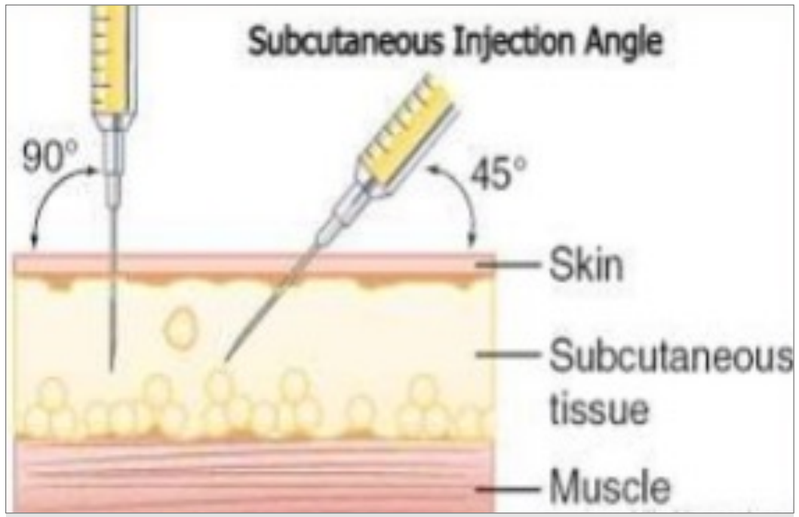
- Design mitigations should focus on enabling users to effectively and comfortably hold the device in the desired angled position.



This IFU supports an understanding of how to measure the injection angle



This IFU supports an understanding of how to measure the injection angle AND shows the device in the wider context of the external body part



This IFU supports an understanding of how to measure the injection angle AND shows the device in the context of the internal body

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ISSUE: HOW DO I ACTIVATE A DOSE?

Users sometimes experience confusion over how to actuate drug delivery devices.

Common factors that contribute to this use difficulty include:

- Negative transfer from using other types of devices
- Mental model
- Device design (actuation feature is not easily discoverable)
- Imperfect technique
  - For example, they locate the actuation feature but do not realize the button/lever needs to be held down for a set period time.
  - For inhalers, there is the added complication of how and when to exhale and inhale in relation to pressing the button/lever.

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SAMPLE SOLUTIONS: DEVICE ACTUATION

In cases where user activation is required or desired, it is important that devices are designed with obvious interaction points, ergonomic affordances and visual cues that communicate to users where the actuation feature is and how to successfully utilize it.

- One way to mitigate activation confusion through design is to develop a product that removes this burden from the user; i.e. a device that automatically actuates the injection when it senses the skin, for example. In the case of inhalers, this could mean only registering a dose when it is performed correctly.

The West SmartDose has a very obvious actuation feature

ISSUE: HOW MUCH FORCE DO I NEED?

Users frequently experience difficulty pushing and/or holding the injection device against the skin to actuate the dose. Sometimes this is compounded by fear of pushing too hard.

Common factors that contribute to this use difficulty include:

- Device design - ergonomics
- How the user opts to grip and hold the injector
- The angle of injection the user is trying to achieve
- The relationship between drug viscosity, drug flow rate, and needle specifications (length and diameter)
- Compromised manual dexterity

SAMPLE SOLUTIONS: ACTUATION FORCE

In order to effectively understand whether users will be able to physically actuate a device, it is important for developers to test their device with the target population of end users having the relevant comorbidities with a liquid having similar viscosity to the indicated drug.

- Where challenges are present, developers can sometimes re-work device ergonomics (for example, to encourage a certain grip), flow rate, needle specifications, viscosity, and force requirements to mitigate this use difficulty.
- Alternatively, there are designs that remove the need to exert physical force to activate a dose; for example, an autoinjector fitted with a power source or a wearable injector with mechanism that generates the high forces needed to deliver a highly viscous drug.

Bespak is innovating the delivery of difficult-to-administer formulations, such as biologics, with its VapourSoft compact energy source.

ISSUE: HOW DO I KNOW THE DOSE IS DONE?

Users may prematurely assume their dose is complete, especially when they are learning to use a new device for the first time.

They sometimes:

- Fail to hold an autoinjector or pen injector in the skin for the prescribed period of time
- Remove an inhaler from their mouth before inhaling a full dose
- Detaching a patch pump before it has injected the full volume of drug

This use error can lead to:

- Missing doses or ineffective dosing
- Over-dosing or injury if and when users realize their mistake and try to recover by re-dosing with the same device

SAMPLE SOLUTIONS: DOSE COMPLETION

Mitigating a premature dose delivery use error can be accomplished through a number of design considerations.

Including:

- Implementing multi-modal feedback cues, including auditory, visual, and tactile feedback to confirm the start of the dose, progression of the dose, and dose completion
- Automatically timing the dose rather than placing the burden on users to count down a certain amount of time
- [In cases where the measure of a successful dose is not time-based] Identifying other parameters that can be measured and communicated to users

3M Intelligent Control Inhaler

AUVI-Q Epinephrine Autoinjector

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ISSUES AND SOLUTIONS FOR PATIENT ADHERENCE

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ADHERENCE ISSUES

Fear of needles / pain

Memory issues: Remembering how to dose (e.g., complex sequences)

Comorbidities: Tactile limitations

Unapproachability of the device

Comorbidities: Visual limitations

Portability and privacy

Comorbidities: Auditory limitations

Cost / insurance coverage

Memory issues: Remembering to dose / if already dosed

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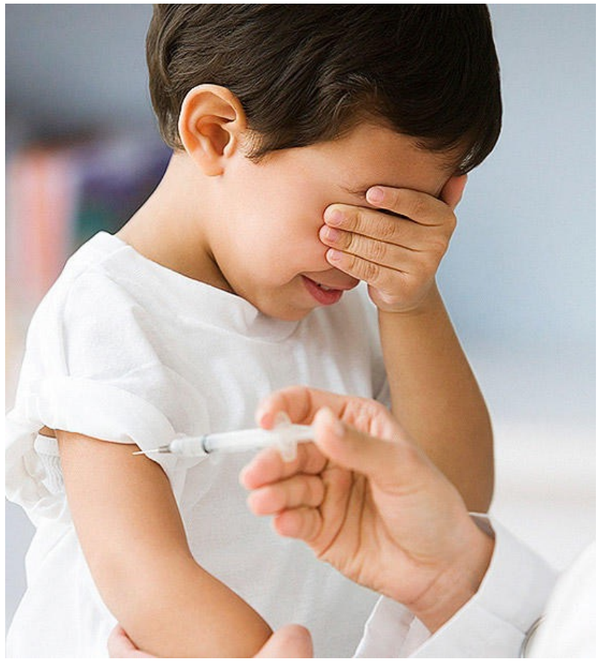
ISSUE: FEAR OF NEEDLES / PAIN

Fear of needles / pain is a common reason for not wanting to self-dose.

This can negatively impact patient adherence by delaying treatment, skipping doses, and dosing incorrectly.

- Those fearful of self-injecting may be more likely to rely on a caregiver (partner, neighbor) to administer medication



Fear of needles
Affected roughly 21% of Americans (Gallop, 2001)

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SAMPLE SOLUTIONS: FEAR OF NEEDLES / PAIN

Mitigating adherence issues surrounding not wanting to self dose, particularly due to pain or needle fear can be done through a number of design considerations.

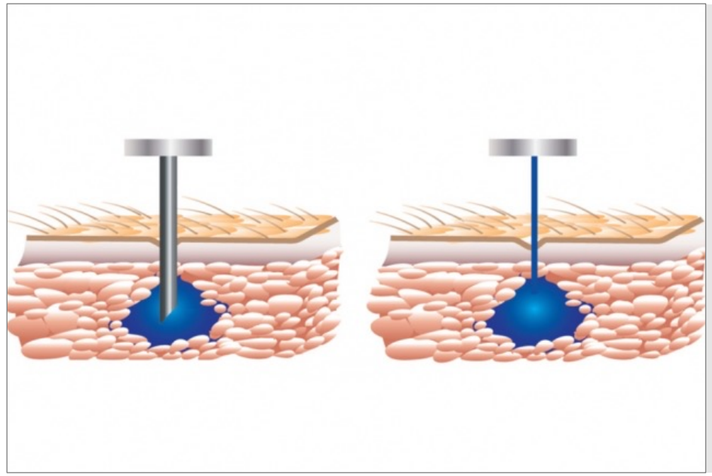
Including:

- [Novel Innovation] Designing drug delivery device with needle-free mechanism to ensure consistent adherence to self-dosing

Taken from MIT News Office
Dec 7, 2017

MIT spinout Portal Instruments has landed a commercialization deal for a smart, needle-free injection device that could reduce the pain and anxiety associated with needle injections, shorten administration time, and improve patient adherence.

Courtesy of Portal Instruments



Based on research by Ian Hunter, the George N. Hatsopoulos Professor in Thermodynamics at MIT, Portal Instruments developed a jet-injection device that delivers a rapid, high-pressure stream of medicine, as thin as a strand of hair, through the skin in adjustable dosages, causing little to no pain.

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SAMPLE SOLUTIONS: FEAR OF NEEDLES / PAIN

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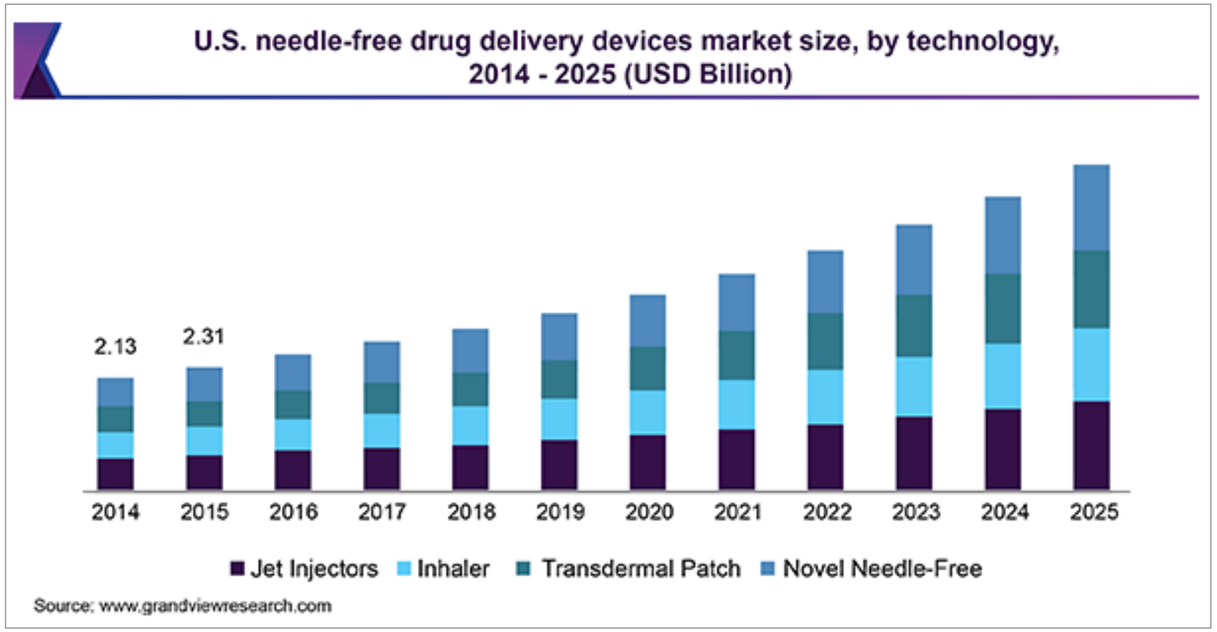

Development of needle-free injectors is increasing, and this growth is predicted to continue.

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SAMPLE SOLUTIONS: FEAR OF NEEDLES / PAIN

Mitigating adherence issues surrounding not wanting to self dose, particularly due to pain or needle fear can be done through a number of design considerations.

Including:

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- Designing devices where the needle isn't visible to reduce fear of needles

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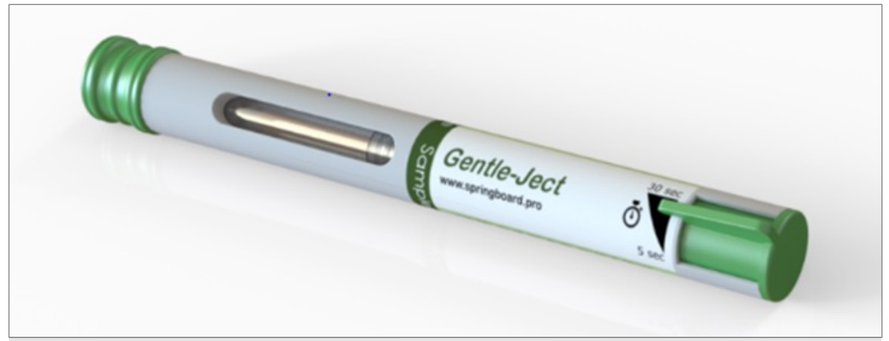
SAMPLE SOLUTIONS: FEAR OF NEEDLES / PAIN

Mitigating adherence issues surrounding not wanting to self dose, particularly due to pain or needle fear can be done through a number of design considerations.

Including:

- [Novel Innovation] Designing drug delivery device with needle-free mechanism to ensure consistent adherence to self-dosing
- Designing devices where the needle isn't visible to reduce fear of needles
- Implementing packaging and labeling design that doesn't encourage or suggest pain (i.e., avoid using red color, or putting large images of the syringe on device packaging)

Amgen, Novartis. Aimovig, injection for migraine. Use of "cool" colors, and no image of the needle provides a calming experience.



Gentle-Ject. Name of injector implies minimal pain.

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ISSUE: COMORBIDITIES RESULTING IN TACTILE LIMITATIONS

Tactile limitations may include:

- Hand tremors
  - Concern about instability/slipping during injection
- Limited dexterity / hand strength
  - Concern about lack of strength required for injection
  - Fear of pain during actuation

SAMPLE SOLUTIONS: TACTILE LIMITATIONS

CIMZIA ® Pre-filled Syringe. The design of the syringe's plunger reportedly helps a user to exert 48% more force than on a typical syringe. Button-free delivery system with a wide nonslip grip.

CIMZIA AutoClicks ® Prefilled Pen. A button-free delivery system, wide non-slip grip.

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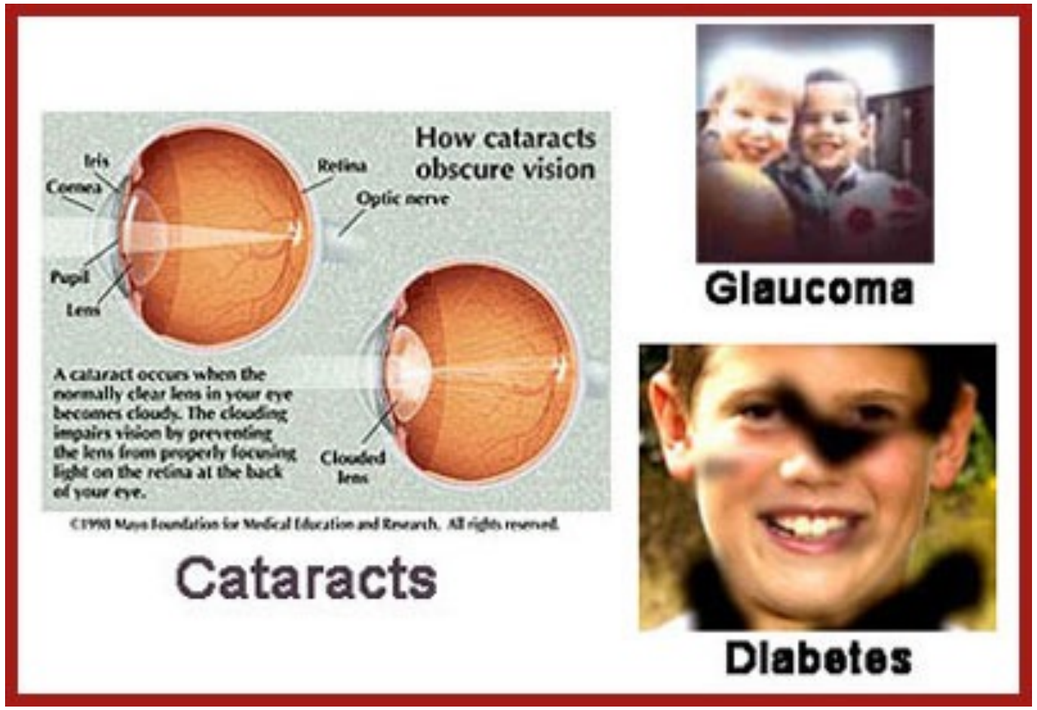
ISSUE: COMORBIDITIES RESULTING IN VISUAL LIMITATIONS

Visual limitations may include:

- Difficulty focusing/reading small font
  - Could be related to a specific comorbidity (e.g., diabetes) or due to aging
- Color-blindness



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SAMPLE SOLUTIONS: VISUAL LIMITATIONS

Font Size:

- Ensure that text is large enough to read
- HE75:2009 (R)2016 provides suggested character heigh for various reading distances. Consider the “upper size limit” when designing for those with visual limitations.

Use of Color:

- While the use of color can draw attention to important information, be sure that color is not the only cue

Table 6.2—Recommended character height and corresponding font sizes for various reading distances[1]

Character height (inches)[2]	Reading distance (inches)	Visual angle (minutes of arc)		Font size (points)[3]
0.112	16	24	Upper size limit	8
0.168	24	24		12
0.251	36	24		18
0.838	120	24		60.5
1.257	180	24		91
0.102	16	22	Preferred (upper bound)	7.5
0.154	24	22		11
0.230	36	22		16.5
0.768	120	22		55.5
1.152	180	22		83

SAMPLE SOLUTIONS: VISUAL LIMITATIONS

Lantus, large dose display

Soliqua, large dose display, no glare

Freestyle Libre, large digital readout

On-body Injector for Neulasta

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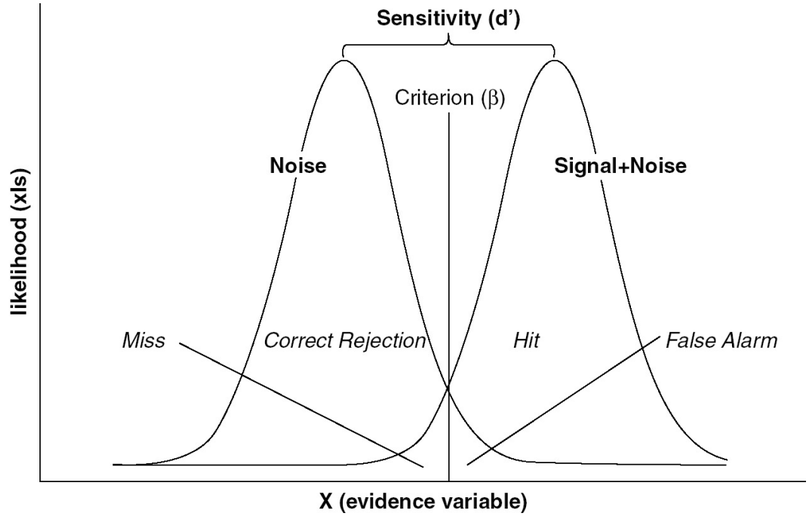
ISSUE: AUDITORY LIMITATIONS

Auditory limitations may include:

- Difficulty hearing a cue emitted by a device due to a specific hearing impairment
- Difficulty hearing a cue against background noise
- Note: Should also take into consideration participant concerns regarding devices that are too loud (i.e., are embarrassing)



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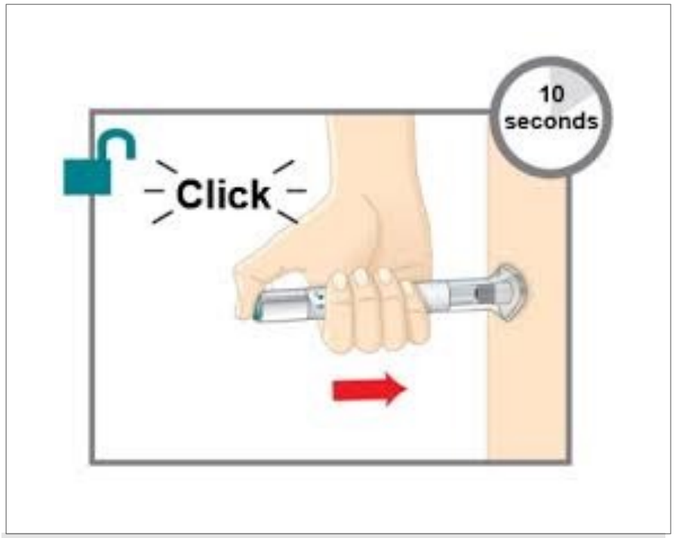
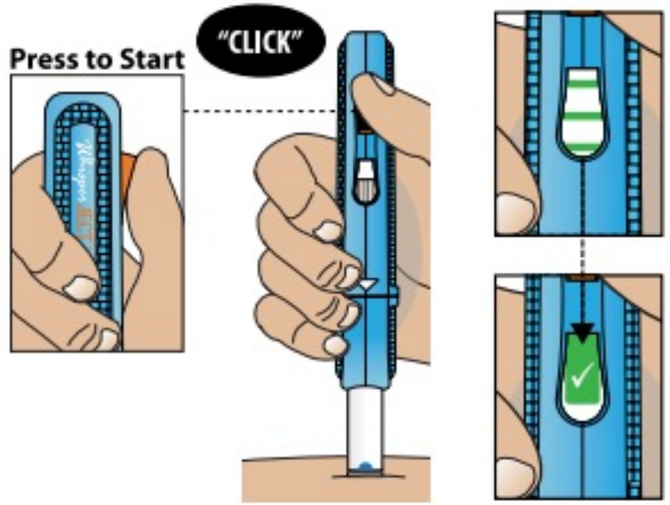
SAMPLE SOLUTIONS: AUDITORY LIMITATIONS

Auvi-Q, provides loud, clear, auditory instructions for injections



Ensure instructions clearly convey the actual sound the user will hear



Mylan WhisperJECT autoinjector incorporates both visual and auditory cues for. Injection progress.

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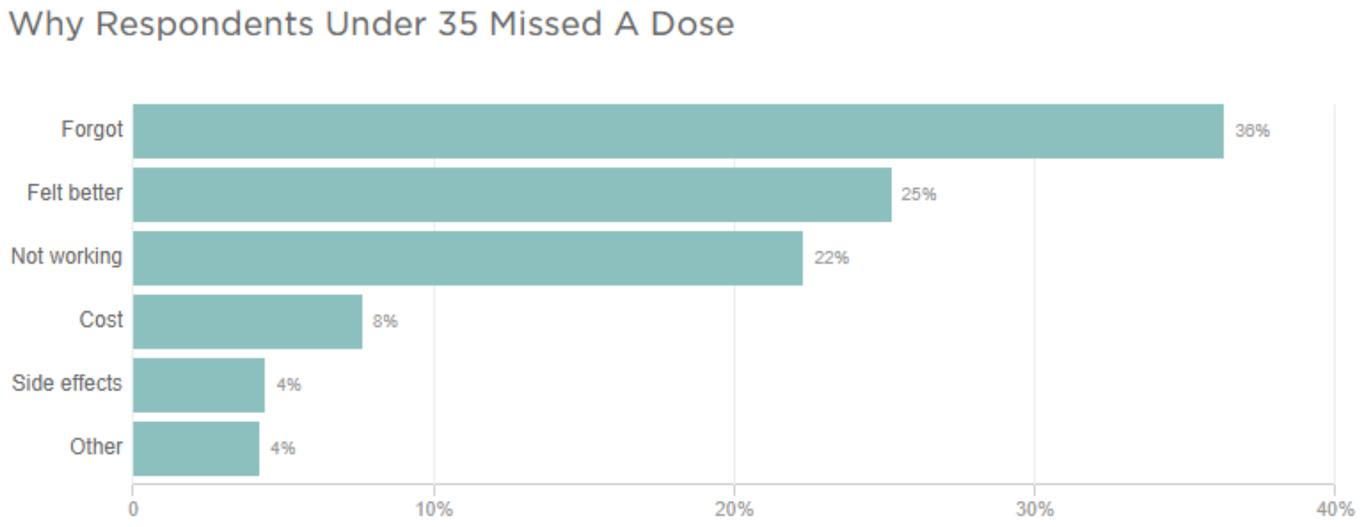
ISSUE: MEMORY LOSS

Another common adherence issue is when patients either forget to take their medicine or forget to reorder them in time.

- In a study done by NPR- Health Poll with over 3,000 U.S respondents, 52% percent suggest that forgetting is the main reason why they missed a dose of prescribed drug.
- The study also found that this is true for respondents under 35 years old (see graph below).



Source: Truven Health Analytics-NPR Health Poll; numbers do not add up to 100 percent because of rounding

Credit: Katie Park/NPR

SAMPLE SOLUTIONS: REMEMBERING TO DOSE

Devices or packaging that are designed with smart user interface and affordances that communicate to users when to take their medicine or even better, when to order their medicine.

- There are several novel innovations that are currently on the market such as smart pill bottles, and smart pills packaging.
- Manufacturers are also starting to introduce the use of mobile applications to assist users and improve adherence.

Adhere Tech Smart Pills Bottle

Abbvie - Viekira pak Pills

SmartPilot App for YpsoMate autoinjector

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SAMPLE SOLUTIONS: REMEMBERING TO DOSE

Clipsulin™. Clips onto existing insulin pens and record. DIABNEXT™ (app) tracks insulin doses and blood glucose levels.

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SAMPLE SOLUTIONS: FORGETTING THE LAST DOSE

Propeller Health's smartphone app and inhaler add-on allow users to track doses. The dose is recorded in the app, allowing users to see the last time they dosed.

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ISSUE: REMEMBERING HOW TO DOSE

Users with cognitive / memory impairments may forget specific steps.

In order to combat this:

- Design devices with the minimal number of steps possible
- Create Instructions for Use with clear, concise language and corresponding images
- Provide quick reference guides for more complex devices (e.g., insulin pumps)
- Provide in-app instructions/helps
- Include instructions for critical steps on the actual device

**We will discuss sample solutions in the next section on Unapproachability.*

ISSUE: UNAPPROACHABILITY

Users may be not adhere to a medication regimen over concerns regarding device approachability.

This may be due to:

- Fear of technology, or the initial impression that the device appears to complex or daunting
- Users may verbalize this as “technophobia”
- Many of the solutions that increase approachability also mitigate against memory impairment

SAMPLE SOLUTIONS: UNAPPROACHABILITY

- Designing devices with minimal number of steps helps users to feel more comfortable (and reduce cognitive load for those who have memory issues).
- Adding on-label instructions increase users' confidence (and address memory issues)
- Use of color may also increase the approachability of the device.

YpsoMate™. 2-step auto-injector. Shown here, is the large-volume version of the auto-injector.

On-label instructions instill confidence in the user

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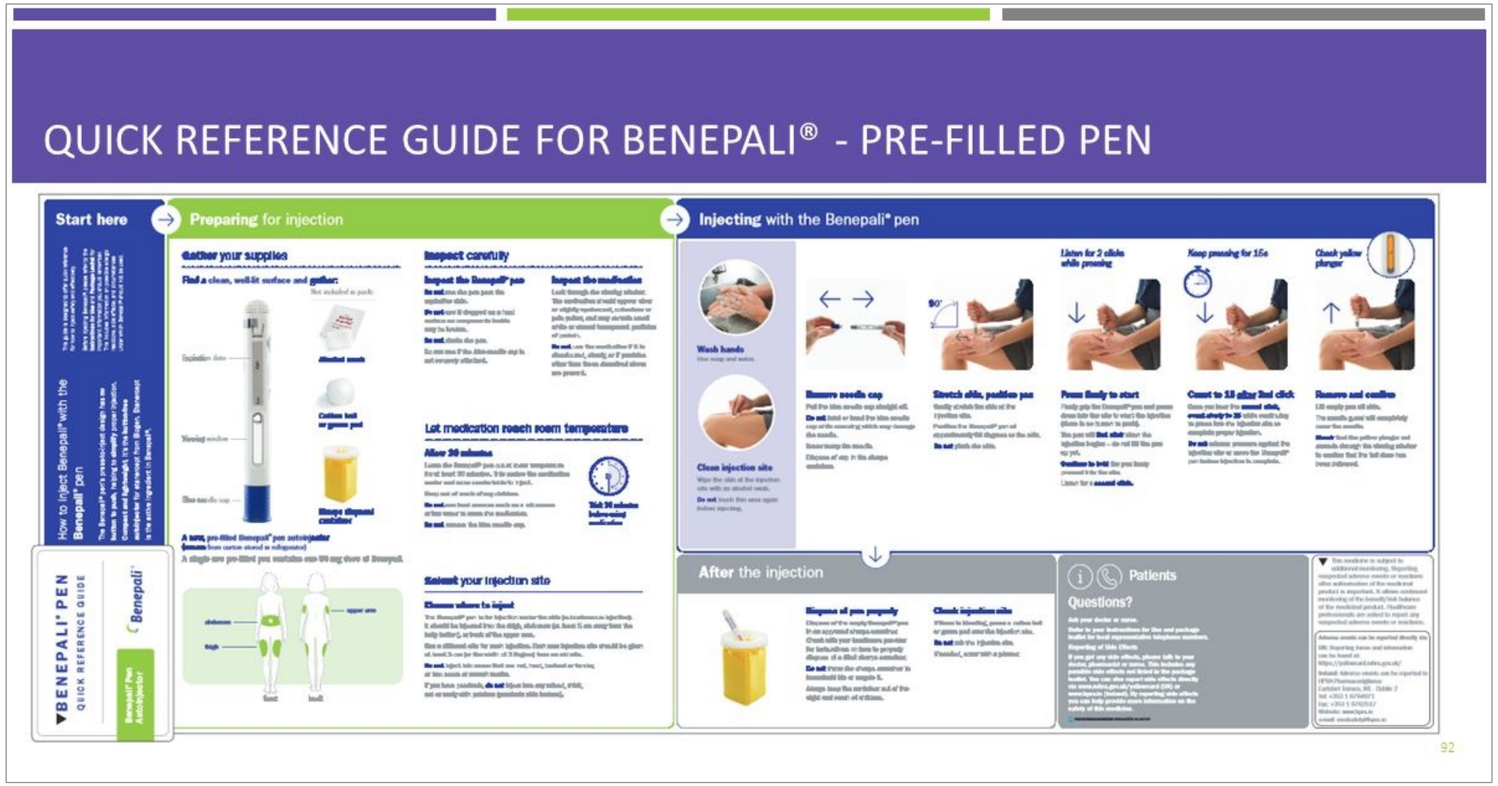
SAMPLE SOLUTIONS: UNAPPROACHABILITY

- Quick reference guides with images help users feel more confident about using a device (and may assist users who have difficulty remembering all steps).



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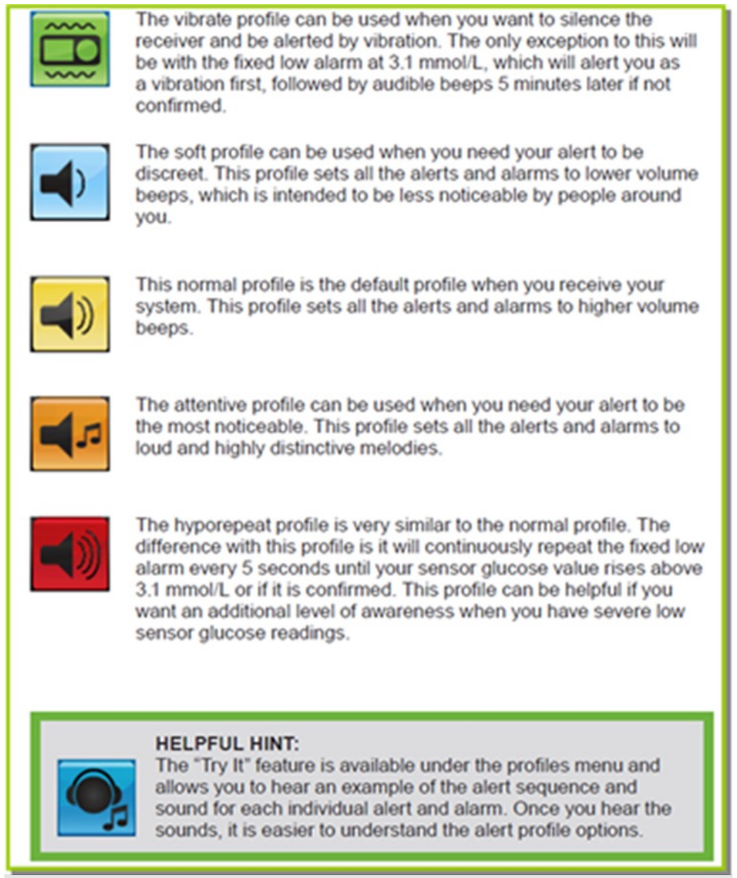
ISSUE: PORTABILITY & PRIVACY

Possible concerns:

- Being able to carry when traveling
- Dosing in public

SAMPLE SOLUTIONS: PORTABILITY & PRIVACY

T1D Daily Kit. Packages all diabetes supplies in a travel case.



Dexcom, allows user to set volume control for “low” alerts based on need for privacy versus in noisy environments

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OPPORTUNITIES FOR FURTHER INNOVATION

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OPPORTUNITIES FOR INNOVATION

Although there has been much advancement in the drug delivery industry to promote patient adherence and compliance through thoughtful design, there are still areas that could benefit from further innovation. And of course there are a number of common use issues that remain largely unmitigated.

Here are some potential opportunities for further innovation.

OPPORTUNITIES FOR INNOVATION

Alleviating the negative transfer that occurs within a set of profile of drug delivery devices. For example, striving for consistency in how and when auditory feedback is provided to the end user to signify the start, progression, and completion of an injection.

Avoiding the need for users to measure out doses according to gradient markers (for example, the incorporation of digital displays)

Developing devices that eliminate or automate the need for users to prime

Solving the burden of aseptic technique

Determining if there are ways to promote correct injection angle through design (or prevent incorrect injection angle)

Exploring whether re-usable devices can automatically self-clean

Brainstorming smart transdermal patch solutions that alert patients when the product needs changing

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OPPORTUNITIES FOR INNOVATION

Delving deeper into smart packaging and labeling designs that can help mitigate some of the more knowledge-based use errors

Developing devices that alert the patient when the expiration date is impending or when the medication has gone off

Exploring the best way to signal that a dose is has started, is in progress, and has been delivered; ensure that there is not only one cue

Considering all the ways in which comorbidities may impact the use of the device and designing appropriate mitigations

Designing devices that are simple and approachable, putting users at ease

Considering ways that users can easily transport devices, and feel comfortable dosing in public

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KEY TAKEAWAYS

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1. Conduct early generative studies to explore possible compliance and adherence issues.
2. Conduct human factors expert reviews early in the product development cycle to fully consider relevant human capabilities and limitations.
3. Develop user documentation (e.g., paper and electronic IFUs, in-app instructions, training protocols) aimed at reducing participant anxiety, thereby enhancing compliance and adherence.
4. Evaluate packaging and labeling for opportunities for improving compliance and adherence.

QUESTION & COMMENTS?

Didn’t get to ask your question? Email us at: laurier@farmpd.com; lisag@farmpd.com

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