THE WHOLE PACKAGE: CONDUCTING EFFECTIVE AND INFORMATIVE EVALUATIONS OF INJECTION DEVICE PACKAGING

Here, Allison Strochlic, Research Director, and Andrea Dwyer, Associate Research Director, both of Emergo by UL's Human Factors Research & Design team, discuss the often overlooked aspect of a combination product user interface: the packaging. With a specific look at injection devices, the authors cover how to perform proper human factors testing of a combination product's packaging, and the advantages doing so can confer to a project.

INTRODUCTION

When you hear about an injectable product, you might immediately envision some type of drug injection device, such as a prefilled syringe, autoinjector or pen injector. Such a product could be based on an existing device platform or it might reflect a novel design developed to accommodate specific drug characteristics or enable a company to differentiate its offering from others in the competitive commercial landscape. Although the injection device itself is often "the star of the show", a product's packaging, labelling and instructions are also integral components of a product's user interface.

Designing, evaluating and validating a medical device's packaging is essential to produce a safe and effective product. In fact, there is an explicit regulatory imperative from the US FDA to carefully consider the design and evaluation of packaging throughout the device development process. Packaging often serves as a key risk mitigation factor for critical tasks, such as selecting the proper dose strength of a given injectable drug. Despite this important role, packaging is too frequently neglected from a human factors (HF) engineering and design perspective compared with other user interface elements and user touchpoints, such as the injection device hardware, companion software applications and accessories.

In this article we put the spotlight on packaging and present methods for conducting effective and informative evaluations of product packaging.

Packaging for medical and drug delivery products can come in many shapes and sizes.

> "Packaging can support or hinder proper device use by the way it provides critical information – such as storage, usage or disposal instructions."

Common types of medical packaging include cartons, pill bottles, peel packs, sterile kits, vials and blister packs. Considering this issue of ONdrugDELIVERY's focus on prefilled syringes and injectables, we will focus on cartons, vials and medication kits as the most relevant types of packaging.

WHY EVALUATE PRODUCT PACKAGING?

There are several reasons it is important to evaluate product packaging. As previously mentioned, packaging is part of a product's "user interface". As such, even though packaging is not the direct means by which a given drug is administered, packaging can affect users' ability to interact with a given injection device safely and effectively. Specifically, packaging can support or hinder proper device use by the way it provides critical information – such as storage, usage or disposal instructions. A product's packaging is responsible for communicating key drug information to the user, including the brand and generic names and dose strength. And, almost always, packaging is a user's first point of interaction with a given product.

Allison Strochlic
Research Director
T: +1 978 371 2700
E: allison.strochlic@ul.com

Andrea Dwyer
Associate Research Director
T: +1 978 371 2700
E: andrea.dwyer@ul.com

Emergo by UL
300 Baker Avenue, Suite 200
Concord
Massachusetts 01742
United States

www.emergobyul.com

Packaging is often much more than a protective or convenient container in which to distribute a product. Rather, packaging presents or contains information that often serves as a risk mitigation factor for critical tasks, for example presenting information intended to help someone distinguish their prescribed insulin pen injector from that of their partner when both are stored in the same place. Packaging-based risk control measures need to be designed initially based on users' needs and regulatory requirements. They should then be evaluated throughout the product development cycle, from formative evaluations to HF validation testing, just like the injection device itself.

Finally, FDA and other regulators expect manufacturers to evaluate packaging design during product development, along with software, hardware and labelling. Despite this expectation, packaging is sometimes relegated to an afterthought.

Going forward, this article will focus on two primary reasons to evaluate product packaging:

1. Product differentiability
2. How packaging guides proper use.

But first, we'll provide a quick primer on key methods that can be employed to evaluate any aspect of a product in development, including, of course, product packaging.

USABILITY TESTING – A BEST PRACTICE PRODUCT EVALUATION METHOD

There are a number of HF engineering methods that can be employed to evaluate a product in development. Such methods include one-on-one and group interviews, cognitive walkthroughs, design or heuristic reviews, and formative usability tests. Each method has its place in the development process and yields key insights when leveraged at the right time with the right stimuli (e.g. early-stage prototype versus representative product samples). Moreover, each method can be designed to evaluate every aspect of a product's user interface or to test just a select few.

This article focuses on evaluating product packaging during usability testing, an activity that involves representative users interacting with, and providing feedback on, a product in development to evaluate the product's interactive qualities (Figure 1). In the case of an injection device, the representative users – or test participants – would likely be lay users who might self-administer medication for a certain medical condition, non-professional caregivers who might support medication administration for others, or healthcare professionals who typically prescribe and/or train end users on a product. Researchers present participants with a product in its packaging, along with any labelling and accessories, and ask the participants to simulate using the product, for example by administering a simulated injection into an injection cushion. The researchers then seek feedback regarding various product attributes. Such attributes often include usability (whether something is easy or difficult to use), clarity, learnability and perceived use safety, depending on the test objectives.

Figure 1: Scene from a usability test evaluating a pen injector and its packaging.

There are several types of usability tests, but the most common ones conducted during injection device development are formative and HF validation tests.

> "One of the most common objectives of drug delivery device packaging evaluations is to assess representative users' ability to differentiate between various drug products and/or dose strengths."

A formative test is one conducted iteratively and frequently as the design is being formed, whereas an HF validation test is one conducted to validate that the device can be used safely and effectively. Sometimes, usability tests focus exclusively on product packaging but, more often, packaging is one component included in the usability test alongside the device and potentially other accessories.

KEY OBJECTIVE 1: EVALUATING PRODUCT DIFFERENTIABILITY

One of the most common objectives of drug delivery device packaging evaluations is to assess representative users' ability to differentiate between various drug products and/or dose strengths. We state this objective in terms of the users' ability, but the true test is directed at the product packaging: whether or not it has been designed in a thoughtful and error-resistant manner.

The following is an outline of the key steps to take when planning and conducting an evaluation of a product's differentiability. The steps are described in the context of a usability test although, as noted earlier, other types of evaluations can be conducted to serve the same objective.

Simulate a Representative Product Storage Area

In a pharmacy, injection device packages (usually, cartons) are typically lined up on standard shelving units or stored in a refrigerator if necessary for the drug contained within (Figure 2). Products are

likely to be sorted according to a logical scheme, such as alphabetically by generic name, but any given facility will have its own, possibly idiosyncratic, method. Automated medication dispensing systems are common sights in hospitals. At home, injection devices are stored in perhaps the widest range of places – including, but not limited to, household refrigerators, medicine cabinets and storage closets. For an effective usability test, you don't need to rent out a pharmacy or visit tens of patients' homes to evaluate product packaging in their actual storage conditions. However, you should simulate a reasonably representative set-up rather than simply present a given product's packaging on a table or in another isolated manner. For example, a refrigerator can be a good choice to represent a typical storage set-up.

Present the Target Product in Various Strengths and Among Representative Comparators

In addition to presenting the product within a representative setting, it's best to present the product being evaluated in its available dose strengths and among realistic "comparators." The goal is to add the context of realistic use to your evaluation. By presenting a product in multiple dose strengths, you can evaluate a participant's ability (read: the packaging's ability to enable the participant) to select a specific prescribed dose strength from among other dose strengths. By presenting the target product alongside different products that might be stored or used in the same environment, you can evaluate whether the packaging is distinct enough from that of other comparator products with which it could commonly be found. At certain stages in development, the most productive evaluation is one that presents an opportunity for a high-risk or worst-case mix-up to occur. Presenting such mix-up opportunities gives injection device manufacturers the best chance of detecting any potentially harmful differentiation errors during development, rather than after launch.

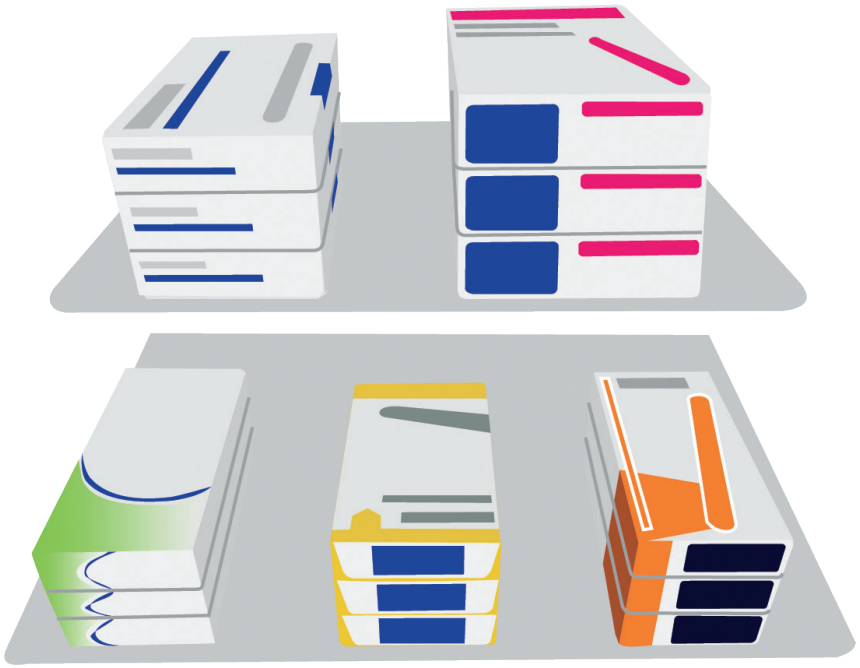

Figure 2: Insulin pen injector cartons as they might be arranged in a pharmacy refrigerator. *(Illustration by Jacqueline Edwards, User Interface Design Associate at Emergo by UL)*

Have Each Participant Perform Representative Selection Tasks

Once you've set up a representative use environment and context, it's time to bring in your test participants and put your product packaging to the test. With a focus on packaging differentiation, the primary task is one of product selection or retrieval. You want to see if the participant can select the target product – the one you're evaluating – from among the various comparators and other items in the storage environment. Be sure to present selection tasks in a representative manner. You might present the task information to a pharmacist participant via a sample, printed prescription and give a layperson participant a verbal prompt asking the participant to retrieve "your medication," medication which the participant would have previously seen.

Present the Target Product in Packaging Representative for That User

The fundamental task of selecting a product might be the same for different types of users, but not all users will interact with a given product in the same packaging. For example, pharmacists handle injection devices most often within their outer cartons, and lay users at home interact with the product first in its outer carton, and then might also need to differentiate unpacked products – for example, a single pen injector that is in use and stored among other, often similar, pen injectors without their cartons. Be sure that you consider and evaluate each of these packaging variations during usability testing and other evaluation activities.

> "In some cases, packaging is simply an outer enclosure intended to protect an injection device and other items contained within the packaging. However, in other cases, packaging serves a dual, and arguably equally important, purpose of helping users understand how to prepare, use and/or store a product."

KEY OBJECTIVE 2: EVALUATING HOW PACKAGING GUIDES PROPER USE

In some cases, packaging is simply an outer enclosure intended to protect an injection device and other items contained within the packaging. However, in other cases, packaging serves a dual, and arguably equally important, purpose of helping users understand how to prepare, use and/or store a product. During development, it's important to evaluate whether the packaging does in practice help users as intended, and confirm that the packaging effectively complements a well-designed product and other labelling.

There's no doubt that having informative and instructive packaging is beneficial for all products. That said, evaluating how packaging guides proper use is particularly valuable for more complex products, such as injection systems comprised of multiple components (e.g. an injection device packaged with lyophilised drug and diluent vials and a transfer device) or other "kits" that require users to assemble components or otherwise prepare the product before injecting.

The following is an outline of the key steps to take when evaluating packaging's effectiveness in guiding proper use. Again, the steps are described in the context of a usability test.

Present the Product and Labelling in Representative Packaging

This might be self-evident but, to conduct an effective evaluation of product packaging, you want to be sure the packaging is representative. Early on in development, you might want to collect users' feedback on a few different design concepts you are considering – ideally, all options that reflect any known technical, production or financial constraints (for example, in terms of packaging size and materials). Towards the end of your development efforts, you want to provide all product components and labelling in production-equivalent, or commercial-equivalent, packaging. For example, use representative cardboard thickness and opening/closing mechanisms, and place the products, accessories and labelling in the exact planned locations a user would see them when opening the commercialised product for the first time (Figure 3). Presenting the real-world solution will enable participants to interact fully with your proposed packaging and provide valid, context-appropriate feedback.

Have Participants Perform Naturalistic, Hands-On Tasks

Similar to presenting representative selection tasks to evaluate product differentiability, you should present representative tasks that require test participants to interact with the packaging and items contained within it in a realistic manner. Such tasks might include asking someone to use the product for the first time (to simulate injecting a drug), or asking someone to do anything they might need to before injecting later in the day or week (which can help evaluate someone's ability to properly unpack and store a product). You want to confirm a user can open a package properly to access the items within, and then see how packaging elements – such as integrated instructions, trays with dedicated spaces for different components, and the placement of various documents – help enable someone to prepare, use and, ultimately, discard a product as intended.

Include Untrained Users in Your Evaluation

Some injection devices might not be dispensed to a patient until the patient receives training on proper device use from a clinician or company representative. If your goal is to evaluate how packaging can guide proper use, you should "stress test" the packaging by including untrained users, at least in your early-stage evaluation activities. Users who do not receive training are more likely to rely on other product user interface elements – namely, packaging and labelling – to determine proper product use.

> "Injection device packaging deserves attention – perhaps more than you've given it in the past – from a design and evaluation perspective; it is often tested to evaluate product differentiability and how packaging guides proper use, but there are other objectives served by evaluating packaging as well."

In these packaging-centric evaluations, you want to put the onus on the packaging and what's contained within to lead users down the right path.

CONCLUSION

Injection device packaging deserves attention – perhaps more than you've given it in the past – from a design and evaluation perspective; it is often tested to evaluate product differentiability and how packaging guides proper use, but there are other

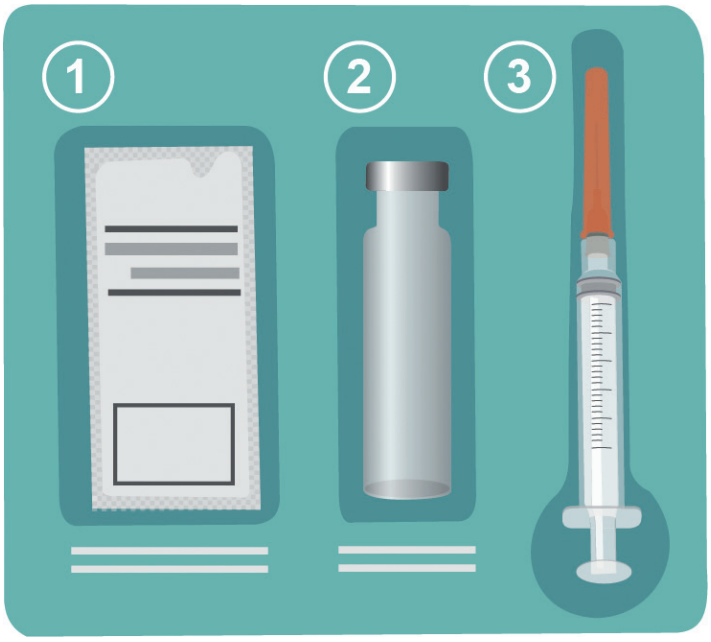

Figure 3: Medication kit with moulded inlays that create designated sections for specific components, thereby grouping related items and guiding sequential use. *(Illustration by Jacqueline Edwards, User Interface Design Associate at Emergo by UL)*

objectives served by evaluating packaging as well. For example, packaging can be evaluated to confirm legibility of printed or graphical information, sometimes from an expected viewing distance, for example, considering oral medication bottles in a pharmacy.

Furthermore, while this article focuses on evaluating packaging, it's worth noting that the design of packaging also warrants careful consideration. Don't spend the development process only focusing on an injection device's design; ensure you also give due attention to the packaging and labelling. A well-designed product package is a strong start to a user's safe and effective interaction with an injection device and an overall positive user experience.

ABOUT THE COMPANY

Emergo by UL's Human Factors Research & Design (HFR&D) team is a an experienced global team that specialises in early-stage user research, product design, usability testing and user interface design. With a primary focus on medical devices and combination products, the team has over 15 years' experience helping clients bring safe and effective products to market and ensuring best-in-class user experiences. The team's injectable device experience includes novel and platform-level prefilled syringes, needle safety devices, autoinjectors and on-body injectors, among others. The team includes over 70 specialists and has offices in the US, the UK, the Netherlands and Japan.

ABOUT THE AUTHORS

Allison Strochlic is a Research Director in Emergo by UL's Human Factors Research & Design team, and was one of the team's co-founders in 2005. She contributes to a wide range of activities that serve to identify user needs and evaluate and validate combination products and other medical technology. Ms Strochlic also advises clients on meeting FDA and other regulators' expectations, is co-author of "Usability Testing of Medical Devices" and several technical articles, and speaks frequently on applying human factors to medical technology development. She is a board-certified human factors professional, and has undergraduate and graduate degrees in human factors.

Andrea Dwyer is an Associate Research Director with Emergo by UL's Human Factors Research & Design team, and has been with the team for 10 years. A board-certified human factors professional, Ms Dwyer leads research activities required to meet regulators' expectations for applying human factors engineering during medical device development. She frequently conducts workshops, speaks at industry events and advises clients on how to implement human factors engineering in the medical device development process. Ms Dwyer is co-author of "Medical Device Use Error – Root Cause Analysis." She holds a BS in human factors and an MS in engineering management, both from Tufts University (Medford and Somerville, MA, US).