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MAKING SELF-ADMINISTRATION POSSIBLE FOR ALL PATIENTS

Medication non-adherence is well recognised as a major cause of poor patient outcomes. To address this problem, manufacturers of delivery systems are becoming more proactive in gaining patient feedback during design and development phases. At West, extensive human factors studies were carried out to help create the SelfDose™ patient-controlled injector, designed for patients who have dexterity problems. Carl Dabruzzi, Director, Product Management, Self-Injections Systems explains more.

The market demand for integrated delivery systems – which combine an injectable drug, its container and the system used to administer it – continues to grow due, in large part, to the popularity of self-administered therapies for rheumatoid arthritis (RA), diabetes and other chronic conditions. This shift is part of an even larger trend towards a more patient-centric approach in the manufacturing of integrated delivery systems. Because of this renewed focus on the patient, drug delivery system manufacturers are continually re-evaluating the processes by which they improve existing systems and how they develop new ones. As a result, delivery system manufacturers have become an invaluable partner to pharmaceutical companies.

Often, those left behind by these trends are patients with conditions that leave them with dexterity challenges, such as RA and multiple sclerosis. Despite any desire they may have to self-administer their treatments, they often cannot do so effectively due to their limited ability to use their hands and fingers. To empower them, West wanted to design a self-administration delivery system with these patients in mind, so it conceived the SelfDose™ patient-controlled injector (Figure 1).

THE RISE OF PATIENT INPUT

Everybody involved in manufacturing, packaging and delivering medication to patients wants to achieve optimal patient outcomes. However, if patients are uncomfortable with an injectable drug's delivery system, they are less likely to use it. This can lead to a natural drop in adherence levels, which can then have a negative impact on patient outcomes.

In fact, medication non-adherence is a leading cause of poor clinical outcomes and increased healthcare costs. According to Capgemini, the pharmaceutical industry's global revenue loss due to non-adherence to medication for chronic conditions is estimated to be $564 billion.[1]

To address the adherence issue, manufacturers of integrated delivery systems have become proactive in seeking out patient feedback during design and development phases to ensure that the final product is something that patients are comfortable using.

> "Simply designing a delivery system that patients "can" use is no longer sufficient. Delivery systems should be designed for affinity, and encourage patients to "want" to use them."

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Because of the demand for self-administered injectable medicines, patient feedback on how they interact with delivery systems is more important than ever. Drug manufacturers have often relied upon patient focus groups for insight into end-user considerations for self-injection systems. However, the narrow focus group setting doesn't provide a full picture of how patients use injection systems in multiple environments: at home, work and other settings.

Integrated drug delivery system development must take into account the fact that patients interact with the system differently at each stage of their journey and in the various environments they encounter each day. Human factors analysis and engineering and usability testing can provide a detailed understanding of patient behaviours, motivations and needs and how they change over time. This process uses in-depth statistical analysis, data aggregation and synthesis techniques to produce actionable opportunities for innovations and enhancements to self-injection system technology.

UNDERSTANDING PATIENT NEEDS

Environmental research is key to human factors engineering; observation and interviews provide the critical context needed to make a qualitative assessment of a patient's abilities and challenges. Observing patients as they go about their day – and considering all of the surrounding environmental factors, such as temperature, noise and lighting – can help researchers better understand how the patient will use a self-administration system.

In-person surveys, questionnaires, user-based performance testing and heuristic analysis also add to the base of human factors knowledge.

One-on-one usability testing enables contextual inquiry that is essential in effective human factors analysis. It helps better evaluate a patient's physical and cognitive abilities, state of being, knowledge of the disease state and experience with delivery systems. This type of testing also allows researchers to explore new product concepts while closely evaluating whether a delivery system is appropriate and effective for patients. The resulting data is valuable in confirming patient needs, desires and preferences.

Once all of the environmental and usability data has been collected, human factors experts can perform detailed analysis of patient habits, human error triggers and risk scenarios. From there, designers are able to make objective recommendations on self-injection system design and develop a product-adoption roadmap based on real-life experiences.

Figure 1: The SelfDose patient-controlled injection system.

Working with human factors engineering and research professionals, drug delivery system companies can learn more about how an evolving disease state can impact the system use in real-life situations. By employing a flexible set of design tools that will help refine and enhance the delivery system they can then help reduce user-based error and control or reduce current and future risks associated with system use. Such refinements can help to create a system that not only aids in the effective delivery of an injectable drug product, but that enhances the patient journey and potentially earns brand loyalty for the pharmaceutical manufacturer during the entire course of treatment.

By applying human factors principles and conducting extensive usability testing early in the design process, drug manufacturers and their delivery system partners can maximise the likelihood that the self-injection system user interface is safe and effective for use by the intended users in various environments.

BUILDING PATIENT FEEDBACK INTO DESIGN

Extensive human factors studies were performed with the SelfDose patient-controlled injector. Patients with mobility and dexterity challenges received special consideration during the research, design and development processes. Formative testing provided validation of the platform's design and informed enhancements to improve the patient experience.

Through this process, West identified that, most commonly, patients seek the following traits in a drug delivery system:

- **Ease of use**: Perhaps the most essential consideration is how the patient will use the drug delivery system. Even the most innovative drug can only provide the appropriate therapeutic benefit if it can be delivered effectively and the patient adheres to the necessary treatment regimen. Most patients are not trained medical practitioners, therefore, they need delivery systems to be simple and intuitive to use. Ensuring a self-injection system is easy to hold and deploy, as well as limiting the number of steps that a patient has to manage through administration, will greatly increase their satisfaction with the injection system and can help promote greater adherence.

- **Affinity-based design:** Simply designing a delivery system that patients "can" use is no longer sufficient. Delivery systems should be designed for affinity, and encourage patients to "want" to use them. This starts from a thorough understanding of patient needs, including the fact that these needs may change during their treatment journey. These same inputs also ensure that risks from user-based errors are identified early in the design and development process and provide critical user information to the development team for risk mitigation measures. The full development process should consider the effectiveness of the integrated delivery system constantly, and adjust as needed.

THE SELFDOSE INJECTOR

With these points in mind, both the shape and size of the SelfDose injector serve multiple purposes. First, they allow for worst-case patients with limited dexterity to be able to self-inject their treatments at home easily and safely, saving them from what can be difficult trips to a clinical setting. The design also makes the device not immediately look like an injector, which is helpful in regard to traditional attitudes and impressions that injectors can be scary, intimidating and "medical looking".

A human factors study with 66 participants, 33 of whom suffer from rheumatoid arthritis, looked at whether SelfDose was intuitive to use and found:

- Without instructions, 56% of participants used the SelfDose injection system properly, whereas only 3% used a traditional autoinjector properly.
- With instructions, 85% used the SelfDose injector system properly, whereas 64% used a traditional autoinjector properly.

Additionally, summative human factors testing of 45 subjects specifically addressed the potential challenges faced by those with limited dexterity. The testing yielded a 100% dosage delivery success rate, validating the SelfDose injector system's ease-of-use.

Another concern addressed by the SelfDose injector system's design is safety, specifically preventing potential needlestick injury. Its passive needle safety system helps to ease that concern through the following features:

- The 1 mL needle rests inside the device when not in use and includes a safety cap.
- When the patient is ready to administer a dose, the safety cap is removed, and a shallow ring protects against accidental contact during injection.
- After injection, the needle automatically retracts back into the device.

The SelfDose injector incorporates additional features to help ensure successful adherence:

- A window confirming drug delivery
- A colour indicator of completed injection
- An audible click confirming completed injection
- Patient control of administration speed, which can reduce pain.

Designed to be Customer-Centric

There is a growing need for novel drug delivery systems that accommodate new modes of administering injectable drugs of varying dosage and viscosity. This is especially the case with the rise of biologics, which are often injectable and may require the delivery of large volumes of a drug over a longer period of time.

West designed the SelfDose injector to be a platform system for pharmaceutical partners. Whereas many self-injectors need to enter new development phases if the dose volume changes – engineers may need to change parts such as the plunger rod or spring and then go through a design verification programme – with the SelfDose injector, a wide range of dose volumes and viscosities can be used without modifying the product.

CONCLUSION

The top consideration when developing any new drug has always been the patient, but patient centricity in injectable drug delivery has not been as pressing a concern until recently. The combination of increased self-administration, patient input and the almost limitless possibilities of new technology has given rise to injectable drug delivery systems like the SelfDose injector that are easier to use and can directly facilitate positive patient outcomes.

More than ever, patient input is shaping this trend and leading system manufacturers to more proactively explore new ways to deliver these critically important injectable medicines for chronic conditions. Additionally, the partnership between packaging and delivery system and drug manufacturers has strengthened, as delivery systems are designed and developed with an expertise that gives both patient use and drug efficacy equal priority.

SelfDose™ is a trademark of West Pharmaceutical Services, Inc. or its subsidiaries, in the US and other jurisdictions. West seeks partners for its SelfDose™ injector technology platform. This platform is intended to be used as an integrated system with drug filling and final assembly completed by the pharmaceutical/ biotechnology company.

ABOUT THE COMPANY

West Pharmaceutical Services, Inc, is a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of its customers from concept to patient, West creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply. West is headquartered in Exton, PA, US, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2017 net sales of US$1.6 billion reflect the daily use of approximately 112 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world.

REFERENCE

1. *Forissier T, Firlik K, "Estimated Annual Pharmaceutical Revenue Loss Due to Medication Non-Adherence". November 2012, Capgemini Consulting.*

ABOUT THE AUTHOR

Carl Dabruzzi has over 20 years of experience in the pharmaceutical and drug delivery industries. He joined West in 2017 as a Senior Manager in the Product Management organisation. Carl's primary responsibilities are to manage the development and commercialisation of West's portfolio of self-injection systems. The portfolio includes the SmartDose® platform of wearable on-body infusers and the SelfDose™ injector. Prior to joining West, Carl worked in the Pharmaceutical and Drug Delivery Systems divisions of 3M. Carl holds a BS in chemistry from the University of Wisconsin in River Falls, WI, US.

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PRECISE. RELIABLE.
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FDA Approved

- The first combination product that incorporates the SmartDose platform technology was recently approved by the US Food and Drug Administration (FDA)
- Thousands of doses have been administered using the SmartDose platform
- Proven engineering, manufacturing and regulatory expertise to support your needs

Wearable Injector

- Subcutaneous self-administration
- Ability to deliver high volume and high viscosity drug products

Patient-Centric

- User-centered design
- Connectivity to a variety of software platforms
- Able to link with adherence solutions
- Onboarding and training solutions available

Flexible Technology

- Address a variety of delivery times through adaptable, pre-programmable technology
- Maximize patient comfort through pre-programmable delivery times

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For more information visit www.westpharma.com

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