Usability of Drug Delivery Devices: Current Challenges and Innovative Methods

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SUMMARY

Healthcare human factors are ever evolving, driven by patient safety, technological advancement, and regulatory requirements. While this progress challenges current practices, it simultaneously serves as a driver for innovation. These current challenges are presented, alongside the innovative methods of force studies, injection and hold time measurements, and iterative instructions for use (IFU) design studies, which can be used to address these challenges.

KEYWORDS

Combination products, force studies, injection time measurement, hold time measurement, iterative IFU design

Introduction

In recent years, the landscape of human factors (HF) for drug delivery device development has been shaped by advancements in patient safety, evolving technological innovations, and increasingly stringent regulatory requirements. This development is exemplified by the U.S. Food and Drug Administration's stricter designation of critical tasks, as well as by the demand to record injection time measurements during validation studies. This regulatory rigor, while essential for safeguarding public health, introduces significant challenges not only during device development, but especially when validating device usability.

This paper focuses on three methods to address these challenges: injection force measurements, hold and injection time measurements, and iterative IFU studies. These methods enable precise, iterative, and comprehensive usability assessments, enhancing testing accuracy, efficiency, and effectiveness, ultimately leading to more reliable device performance and better patient outcomes.

Currently, formative usability testing is typically performed linearly, where the results of a study are analysed only after testing is completed, leading to longer durations between studies and fewer iterations and tests of design elements. Injection time measurement, which is used to validate complete dose administration, is often performed with a stopwatch or by analysing video recordings, causing inaccurate measurements as well as requiring extensive time to generate data through video analysis. Lastly, injection forces and other related factors such as injection angle and movement of the injection device or tremor are not typically assessed at all, despite their potential impact on usability and patient safety.

This paper presents these three methods that address challenges related to HF testing of the user interface of drug delivery devices.

Methods

This section outlines methods for evaluating user-applied injection forces, measuring injection and hold times to collect precise administration data, and using iterative approaches to optimise IFU

design. Specialised systems were developed to support these methods, facilitating data collection and analysis. The methods were adapted and refined to meet Design Science's specific requirements of usability studies, evolving through repeated application. Their use in proprietary studies provided supporting data on their effectiveness.

Force Studies

The growing number of biologic medications, often characterised by larger volumes, higher viscosities, and longer injection times, places greater physical demands on users of hand-held injection devices. This applies for example to the force necessary for depressing syringe plungers or holding autoinjectors in place on the injection site, as well as maintaining the respective device at a precise angle with little movement or tremor throughout the injection process.

To assess patient capabilities and determine design requirements for the device during formative studies, injection devices and injection pads were equipped with adapters containing load cells and accelerometers, respectively. These modifications were made with minimal impact on the device user interface, ensuring that the modified devices closely resembled the commercial versions. The underlying technology can be easily adapted to other devices, with only minor modifications, offering a versatile solution for a wide range of injection systems and other devices.

During usability testing, the modified devices and injection pads were used in the same manner as the original device, with the injection pad attached to the body. The combination of sensors recorded force data, e.g., plunger depression force or autoinjector depression force, as well as absolute device orientation data, i.e., device orientation and movement, at a sampling rate of 50 samples per second with a tolerance of 1%, ensuring accurate measurements. This level of accuracy ensures that even subtle variations in device use, such as slight changes in force or orientation, are captured with precision.

Injection and Hold Time Measurement

To accurately assess the completeness of injections in autoinjectors, an automated, sensor-based timing system was employed. This system utilised force sensors within specialised injection pads and auditory feedback mechanisms to precisely capture injection and hold times. The auditory feedback system used microphones to detect the click sounds produced by the device at the start and completion of the injection. Audio filtering was applied to block background noise, isolating the clicks generated by the autoinjector during the injection process for further timing analysis.

Additionally, a needle sensor integrated into the injection pad detected when the needle entered and exited the injection pad. These measurements were synchronised with the auditory feedback as well as force data from sensors in the injection pad, providing precise, real-time data for both injection time and autoinjector hold times. While the system used a specialised injection pad, the autoinjector itself remained unmodified, thus preserving its integrity. This makes the system particularly valuable for validation studies requiring commercial-equivalent devices. Overall, this approach provides significant advantages over manual injection timing methods across various research stages.

Iterative IFU Design

To expedite and refine the design of IFUs, several iterative methods were employed during usability studies. First, experts conducted heuristic evaluations prior to usability testing to identify potential issues based on established design principles, allowing for early-stage refinements. Next, designers observed participants from an observation room during study execution. With only small sample sizes most use errors were detected, allowing designers to identify trends and translate observations

into IFU design updates in real-time. These updates were then assessed during subsequent sessions of the same study, making the process both efficient and time effective.

By incorporating these strategies within a single formative study, iterative updates, and evaluations of the IFU could be completed within days or weeks, reducing time, and ensuring that design improvements directly addressed user needs and challenges.

Conclusion

Addressing the new developments and challenges in human factors testing requires innovative approaches to enhance both accuracy and efficiency of usability studies. The three methods presented - force studies, injection and hold time measurements, and iterative IFU design - offer benefits over traditional practices. They not only improve overall user experience but also ensure that device user interfaces are intuitive, safe, and effective for the intended users, while assuring regulatory compliance.