USABILITY EVALUATION OF A NOVEL, USER-INDEPENDENT UNIT DOSE NASAL SPRAY VIA HUMAN FACTORS STUDIES

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INTRODUCTION

- Single dose nasal drug delivery devices are intended for use by a wide range of people, of different backgrounds, abilities, and in various use scenarios. With conventional device designs, the force, maximum displacement and associated velocity, applied by the user – as well as formulation viscosity and other factors – determine dispersion parameters and delivered dose.[1-3]
- The application of human factors engineering throughout the design process is a prerequisite to ensure the correct use of a device, with minimal effort required from the user. The aim of the work reported here, was to enable further device development through understanding of user interaction.

EXPERIMENTAL METHODS

- In a formative usability study of four variants of Recipharm's water-filled proprietary development device (PD) (see figure 1 and table 1), 23 participants (aged 12-61 years) were asked to hold, position and actuate them, with minimal instructions.

Figure 1. Example of PD samples used in the formative evaluation and hand actuation study (left), and reference device (RD) samples (right); all PDs were externally identical, except for the button, for which there were two designs.

*Table 1. Practical differences between device samples and use instructions. Actuation force was measured separately on a NSx actuator. (*Patient mannequin.)*

	PD sample 1	PD sample 2	PD sample 3	PD sample 4
Actuation Force	Optimal (mean 23 N)	Optimal (mean 23 N)	Optimal (mean 36 N)	Optimal (mean 36 N)
Button Design				
Gloves	Yes	No	No	Yes
Administered to	Self	Third party*	Third party*	Self (close to ear)
Position	Participant chooses	Sitting	Supine	Sitting

- A hand actuation study was also conducted, recording stroke length, actuation velocity and acceleration. These data were used to set up lab-based measurements of actuation force, replicating human use with: 76 PDs; 18 RDs (currently marketed, single dose nasal spray pumps) for benchmarking.
- The effect on PD actuation force, of changing the spring and orifice, was investigated. Metered shot weight (MSW) was also measured to assess variability in device performance when actuated by hand, using samples filled with sumatriptan (n=13, five adult participants), nalmefene (n=19) or water (n=25). This was repeated using the NSx actuator.

RESULTS & DISCUSSION

- In the formative usability study, participants provided useful feedback on their interactions with the PD, as shown in table 2 and figure 2. Rating scores from two participants were excluded from the data presented due to technical difficulties with the audio recording for the session.

Table 2. Participant feedback from formative usability study.

Positive findings	Negative findings
100% correctly used device, identifying and pressing button → therefore concluded to be intuitive for use by design	28% found edges of finger pad too "sharp" → device design was updated (blend radius increased to 2 mm from 0.2 mm) and retested in follow-up session, showing discomfort reduced to <5%
100% were able to actuate device at forces tested (25 N & 35 N on average)	
100% understood when device had been used, based on auditory feedback and retracted button	Excessive flexion and radial deviation of wrist caused discomfort when administering dose to supine 3rd party → not a device design-related issue
Wearing gloves did not hinder, or substantially alter, device use	

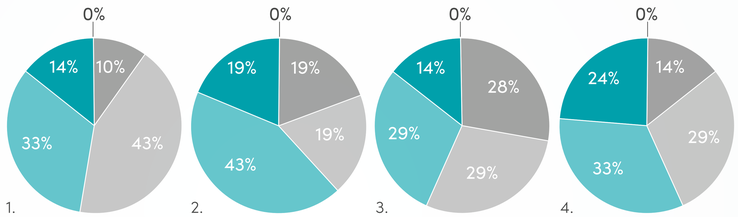

Figure 2. Feedback on actuation pressure from PD samples 1 (far left) to 4 (far right). Participant ratings: dark green = Very Comfortable; pale green = Comfortable; pale grey = Neutral; dark grey = Uncomfortable; black = Very Uncomfortable.

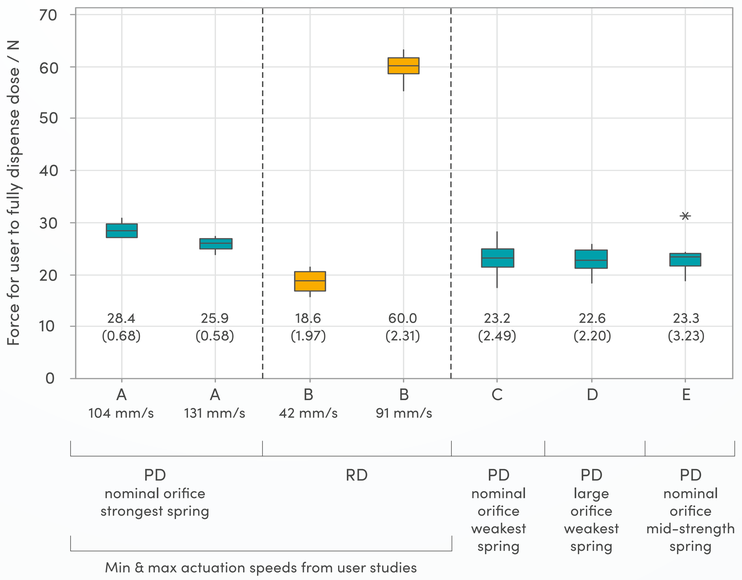

Figure 3. Peak force applied by a device user as required to dispense a full dose. Mean and (SD) values shown underneath boxplots.

- The expected range of forces experienced by the device user, which would be required to dispense a full dose of drug formulation, were repeatable for the PD (figure 3).
- Data for the RD (figure 3) show that a broad range of forces can be experienced by users of approved, marketed user-driven products, depending on their interaction with them.
- The MSW data (figure 4) demonstrate that the PD performed consistently for all formulations and remained within FDA limits, whether actuated by hand or lab apparatus.

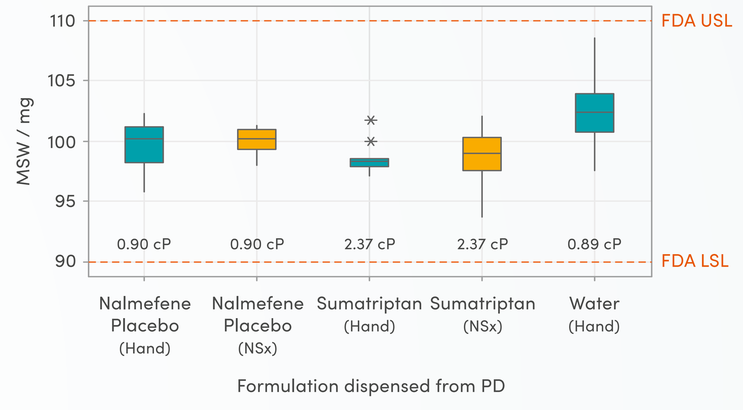

Figure 4. MSW for PD actuated by hand (green plots) and by the NSx actuator (orange plots). Mean dynamic viscosity values (at 25°C) for each formulation are shown below their respective boxplots; water[4].

CONCLUSIONS

- Findings from the human factors evaluation highlighted the ergonomic and intuitive use elements of the proprietary device, while informing further design improvements.
- Consistent MSW delivery and actuation forces experienced by the user, contributed to ease of use, with no prior device experience or training required. All devices were successfully actuated by hand.

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