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SELFCARE SOLUTIONS

HOW USERS DISTINGUISH BETWEEN SELF-INJECTION DEVICE PLATFORM VARIANTS

Ever-increasing interest in device platforms raises concerns around the broad availability of lookalike autoinjectors that may result in inappropriate medication usage and potentially put patients at risk. Here, Andreas Schneider, PhD, Innovation & Business Development Manager, Ypsomed Delivery Systems, summarises a recent empirical study¹ detailing how effectively various user groups distinguished platform device variants. The article highlights how patients, healthcare professionals and non-professional caregivers distinguished between device versions, provides insights into which device attributes drive device distinguishability, and then relates these attributes to user group-specific characteristics.

Self-injection device platforms have come a long way in disrupting the traditional device development process. In fact, they resolve long-standing industry challenges. Not only do platforms provide attractive cost structures and proven handling concepts across user groups but they also reduce technical risks and speed up time to market. A platform is referred to as a user-tested drug delivery system that, by design, enables the efficient development and manufacturing of drug-specific product variants. It comes as no surprise that most of the recently approved handheld autoinjectors are derived from device platforms (Table 1).

The significant interest in self-injection device platforms, however, conceals certain reservations. One concern raised by industry experts is that the increasing adoption of platforms may heighten the risk of medication errors. Much is at stake. The emergence of lookalike devices might, experts worry, provoke preventable events causing inappropriate medication usage, potentially putting patients at risk.

On the one hand, patients with multimorbidity increasingly self-manage complex medication plans that could include more than one version of an injection device platform. On the other hand, the complexity of dosing regimens continues to increase and, for instance, may involve the

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same drug delivery device platform across dose strengths, often distinguished by label information and colouring only.

Unfortunately, we know very little about how users distinguish between self-injection devices. Although research has repeatedly put labelling and packaging of solid oral dosage forms under the microscope to avoid inappropriate medication use, there is limited empirical evidence on what drug delivery device attributes drive users' ability to distinguish between platform device versions.

We also lack understanding of how various user characteristics – such as professional background, age, dexterity or visual impairments – shape their perceptions and similarity ratings. This matters because platform devices are increasingly used across chronic disease states where device differentiation should be carefully adjusted to specific patient needs and characteristics.



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							Xyosted® Antares	

Table 1: Non-exhaustive list of approved platform-based disposable single-use autoinjectors (compiled in December 2019).

“We undertook a non-interventional simulated usage study¹ where participants assessed the similarity of autoinjectors.”

THE STUDY DESIGN SEARCHING FOR ANSWERS

In searching for answers, we undertook a non-interventional simulated usage study¹ where participants assessed the similarity of autoinjectors. 74 participants among patients across chronic disease states, non-professional caregivers and healthcare professionals rated the similarity of eight autoinjector platform variants.

These device variants differed across four design dimensions that are typically adjusted during customisation work between device manufacturers and pharmaceutical firms: the colour of the label (grey, yellow, orange), the colour of the needle shield (grey, orange, yellow), the overall size (1.0 mL and 2.25 mL prefilled syringe formats) and the device shape (round or square). Eight different autoinjector configurations were included.

Each participant thus assessed the similarity of 28 device pairs.

Multidimensional scaling analysis then transformed these individual ratings in solution spaces to empirically derive the attributes driving how participants distinguish platform device variants. Fuelled by a powerful computational algorithm, this statistical technique allows determination of the underlying dimensions on the basis of individual similarity perceptions – without the need for participants to articulate the rationale for their rating.

Much like drawing a map using the distances between pairs of cities, the algorithm produced solution spaces where the distance between devices corresponds



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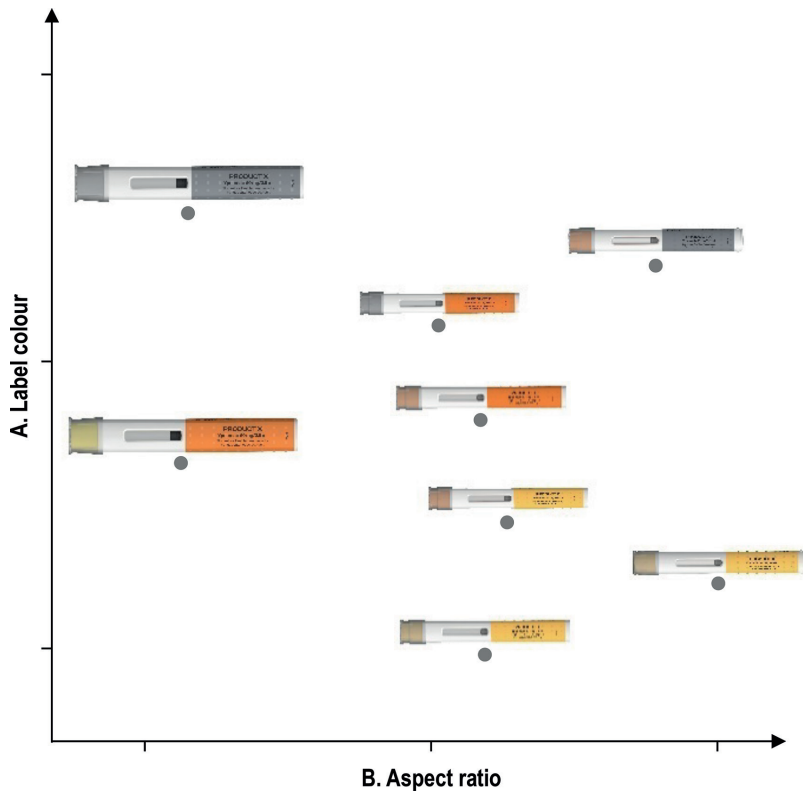


Figure 1: Typical solution space where the distance between autoinjectors reflects participants perceived device similarity. The two dimensions correspond to two design attributes – label colour and aspect ratio – empirically identified to drive device similarity (total sample, n=74).

to their perceived similarity: the closer the devices were positioned, the higher their perceived similarity. Figure 1 shows a typical solution space generated by the study. Using a systematic multi-step coding procedure, we then assigned a specific device attribute, or a combination thereof, to each of the emerging dimensions for each resultant solution space.

FIVE DEVICE ATTRIBUTES DRIVE AUTOINJECTOR DISTINGUISHABILITY

First and foremost, the results show that, regardless of their apparent similarity, users are still moderately-to-well able to distinguish between platform device variants. More than half of the similarity ratings (50.3%) were above four on the nine-point Likert scale. Moreover, the simulated use study empirically derived five attributes driving device distinguishability across user groups: the label colour, the size and shape of the device, its aspect ratio and chromaticity.

Device attribute	Description	Illustration	Does the attribute drive device distinguishability?					
			G1. Healthcare professionals	G2. Non-professional caregivers	G3. Adolescent patients	G4. Adult patients	G5. Elder patients	G6. Visually impaired patients
Label colour	Plain colouring of the label	 grey yellow orange	No	Yes	Yes	Yes	Yes	[weak]
Size	Small versus large size of the device	 large (square) small (round) small (square)	Yes	Yes	Yes	Yes	Yes	Yes
Shape	Square versus round shape of the device	 round (small) square (large)	[weak]	No	Yes	No	Yes	Yes
Aspect ratio	Compound device shape and size	 small / round large / square	Yes	Yes	Yes	Yes	No	No
Chromaticity	Compound label and needle shield colour (overall hue)	 grey / grey yellow / yellow	[weak]	Yes	No	Yes	No	[weak]

Table 2: Empirically derived device attributes driving platform device distinguishability.

Although label colour, size and shape were anticipated to drive users' similarity ratings, aspect ratio and chromaticity did not correspond to single design features but highlighted interaction effects between them. First, aspect ratio was the combination of the autoinjector size and shape. Second, chromaticity represented the overall device hue or brightness along the continuum, with the configurations "grey label and needle shield" and "yellow label and needle shield" as its two ends.

These findings hold important implications for device development. The participants did not necessarily distinguish user interface elements but used the overall device appearance, such as its chromaticity, as a basis for similarity ratings. Future device design development thus should integrate different units of analysis, considering potential interaction effects between distinct user interface elements.

The results also show that colouring of the needle shield did not emerge as a single device attribute driving device distinguishability. Although needle shield colour is typically modified as part of the routine customisation work, participants did not use this element in isolation to distinguish platform device variants.

Overall, the study suggests geometric features take precedence over tested colour schemes of a specific attribute driving distinguishability. Future device development programmes thus may not only differentiate through colouring a single user interface element, such as the needle shield, but also more holistically adjust colour schemes – including colouring of the label, housing and needle shield – or even pursue individual industrial design options. For instance, YpsoMate Design offers fully customised autoinjectors with specific individual outer shapes produced

"YpsoMate Design offers fully customised autoinjectors with specific individual outer shapes produced on the standard platform manufacturing line."

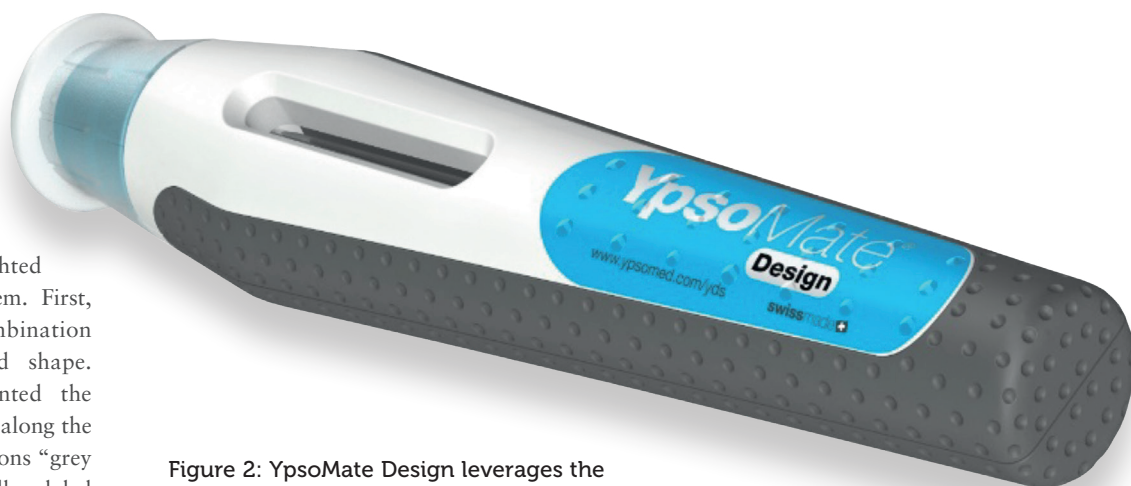


Figure 2: YpsoMate Design leverages the autoinjector platform advantages while offering high industrial design flexibility on the basis of product-specific design shells.

on the standard platform manufacturing line. From a device development perspective, YpsoMate Design offers the best of both worlds: leveraging the proven platform while enabling full differentiation with the help of unique design shells (Figure 2).

USER CHARACTERISTICS AND USE CONTEXT MATTER

The study provided insights into user group-specific patterns and how device similarity was perceived. Table 2 summarises which design attributes were found to drive similarity ratings per user group. Interestingly, some patterns were linked to user group characteristics (e.g. age, professional education, dexterity and visual impairments) and device usage context.

Elderly patients, for instance, did not use aspect ratio – an attribute linked with the user's sense of touch and perceived ease of holding the device – as the basis for recognising the device. Their emphasis on visual instead of tactile attributes may be linked to decreasing dexterity with age. Elderly patients may well be aware of, and thus compensate for, decreasing dexterity, thereby prioritising visual over tactile attributes. Similarly, visually impaired patients largely excluded device attributes related to colour (i.e. chromaticity) as the basis for device distinguishability.

The results also detail how educational backgrounds and situational factors influence how users distinguish autoinjector variants. Unlike non-professional caregivers, healthcare professionals primarily used geometric features to assess device similarity. Neither label colour nor chromaticity was relevant for healthcare professionals. These findings re-emphasise prior work where this user group raised concerns over limited time to become familiar with

label colouring schemes to identify drug products correctly.

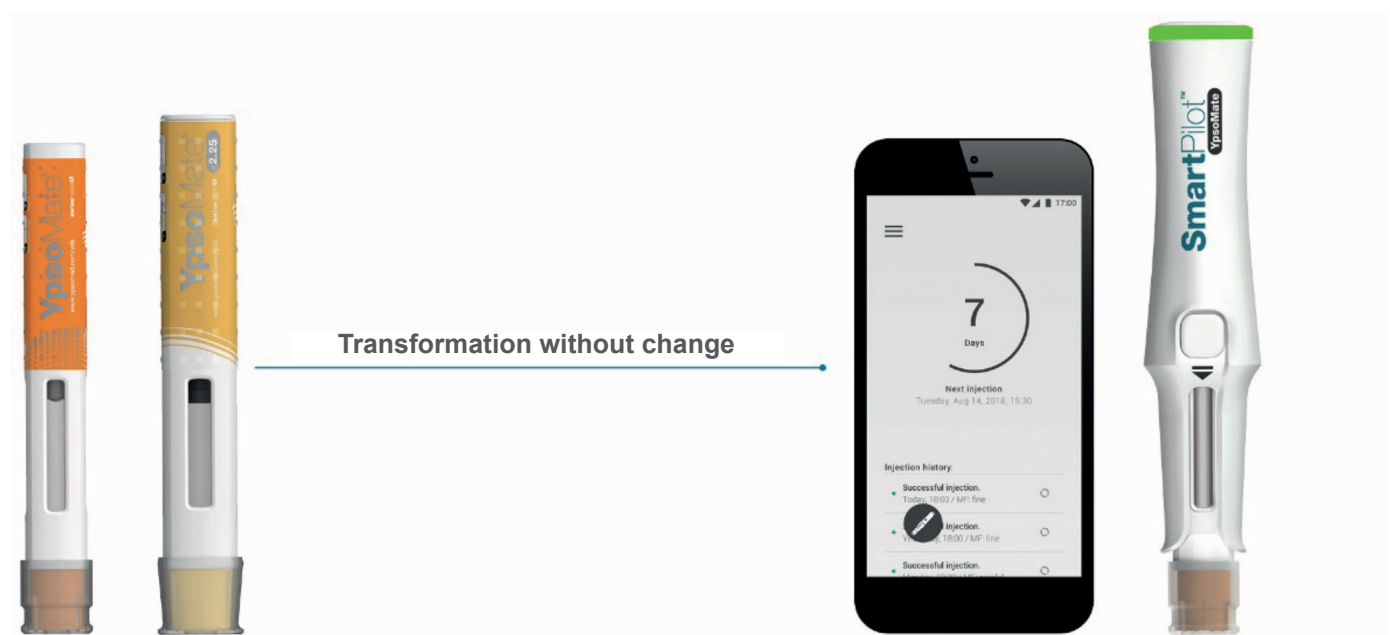
These challenges are particularly pronounced in the context of complex clinical trials where label colouring may be used to convey information about investigational drug type or dosage strength. Here, innovative auxiliary technologies may foster not only effective but also efficient device identification at the point of use.

For example, the reusable cloud-connected sensor module SmartPilot for YpsoMate (Figure 3, next page) automatically identifies the drug product using near-field communication (NFC) tags embedded in the autoinjector label. Using both visual and acoustic feedback, the connected system then notifies users about the correctness of the drug product at hand, thereby reducing the administrative burden at clinical trial sites and confirming allocation of the correct investigational drug to the correct treatment arms.

CONCLUSION

The study summarised here offers much-needed insights into how user groups distinguish potentially lookalike platform-derived autoinjectors. The results guide future device development toward device attributes that support device distinguishability – namely device size, shape, label colour, aspect ratio and chromaticity. The methodology provides the pharmaceutical industry with a novel toolbox which helps to avoid medication errors through effective device differentiation.

Revealing user group-specific patterns to device distinguishability, the study also suggests it is worth adjusting device differentiation to the intended user population, bearing in mind their characteristics (e.g. age, educational background, dexterity or vision



YpsoMate® suitable for standard
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Figure 3: SmartPilot for YpsoMate is a reusable monitoring add-on to transform the marketed disposable two-step autoinjector into a cloud-connected system. It not only tracks injection events and provides real-time guidance to patients but also authenticates the drug product at the point of use.

impairments) and the context of device usage. In so doing, it provides the basis for more informed decision making to improve platform device distinguishability and mitigate inappropriate medication use.

The empirical study summarised here was funded by Ypsomed and conducted in collaboration with HFC Human-Factors-Consult (Berlin, Germany).

As a leading developer and manufacturer of mechanical and cloud-connected autoinjectors and pen systems for self-administration, Ypsomed has established the *Scientific Research & Communications* programme. Its objective is to advance new insights into self-injection devices relevant to industry and academia. The results regularly appear in peer-reviewed scientific forums such as *Expert Opinion on Drug Delivery* and *Medical Devices: Evidence and Research* and are presented at leading medical device and drug delivery conferences.

ABOUT THE COMPANY

Ypsomed's comprehensive drug delivery device platforms comprise autoinjectors for prefilled syringes in 1 mL and 2.25 mL format, disposable pens for 3 mL and 1.5 mL cartridges, re-usable pen injectors, ready-to-use prefilled wearable patch injectors, and injection devices for drugs in dual-chamber cartridges. Unique click-on needles and infusion sets complement the broad self-injection systems product portfolio.

With more than 30 years of experience and pioneering spirit in the development and manufacturing of innovative injection systems, Ypsomed is well equipped to tackle digital healthcare challenges and has strategically invested into the development of connected solutions and therapy-agnostic digital device management services.

Anticipating future needs of patients, pharmaceutical customers, payers, and healthcare professionals, Ypsomed moves beyond manufacturing connected sensors. Ypsomed's smart device solutions strive to transform patients' lives by capturing therapy-relevant parameters, processing them to facilitate self-management of chronic diseases, and integrating these insights with third-party digital ecosystems. Ypsomed leverages unique in-house capabilities in electronics, software and connectivity for the development of new devices and digital product systems.

Ypsomed is ISO 13485 certified and all processes comply with design control and cGMP guidelines with operational QA/QC experts on-site at each of its locations.

Ypsomed's US FDA-registered manufacturing facilities are regularly inspected by both pharma customers and regulatory agencies to supply devices for global markets including the US, Europe, Japan, China and India.

REFERENCES

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ABOUT THE AUTHOR

Andreas Schneider is Innovation & Business Development Manager with Ypsomed Delivery Systems. His responsibilities include the definition and development of new platform devices with a particular emphasis on connected and smart device systems. As such, he has been actively involved in the design and development of SmartPilot for YpsoMate, a reusable connected add-on that transforms the proven two-step autoinjector into a connected system. Dr Schneider has published various articles and held presentations in the areas of innovation management and drug delivery. He received his PhD in Innovation Management and Organisation Sciences from ETH Zurich, Switzerland.



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