

A Human Factors Validation of a Smart Autoinjector Accessory Designed to Improve Self-Injection Outcomes and User Confidence

Stephan Wegner¹, Jana Milenkovic¹, Anthony D Andre², Carson P Whitaker², Tobias Theiler¹

¹Ypsomed AG, Burgdorf, Switzerland; ²Interface Analysis Associates LLC, Saratoga, CA, USA

Correspondence: Stephan Wegner, Ypsomed AG, Brunnmattstrasse 6, Burgdorf, 3401, Switzerland, Email stephan.wegner@ypsomed.com

Purpose: Enhancing user guidance via visual and auditory real-time feedback during subcutaneous injections—combined with automated injection-data logging—has the potential to improve self-injection outcomes and increase user confidence. To meet these objectives, a Smart Autoinjector Accessory (SAA) was developed to help patients, caregivers, and healthcare practitioners (HCPs) manage the injection process more effectively. This human factors validation study assessed whether the SAA, together with its Instructions for Use (IFU), could be operated safely and effectively with an autoinjector by the intended user population.

Methods: Seventy-five untrained participants (patients, n=45; caregivers, n= 15; HCPs, n=15) were evaluated on completion of SAA use tasks and IFU knowledge tasks in a simulated use environment.

Results: All participants (75/75, 100%) successfully delivered the full dose with the associated autoinjector. A total of 1196 out of 1200 use tasks (99.7%) delivering a simulated injection with the SAA and 2772 out of 2775 knowledge tasks (99.9%) concerning content in the IFU were completed successfully. Therefore, the overall results show near perfect success rates. All observed errors were isolated to individual participants, and no patterns of recurring use- or knowledge-task errors were found. Root cause analysis attributed these errors to inattention rather than deficiencies in the IFU clarity or device design.

Conclusion: This study shows that the intended users can operate the SAA safely and effectively. Given the strong usability outcomes, the results warrant further investigation into the SAA's potential to improve treatment adherence and persistence in longer-term studies. In post-launch use, the SAA could play a key role in facilitating the onboarding of inexperienced patients or those undergoing more complex treatment regimens. Beyond individual therapy, the SAA also holds promise in digitalizing real-world evidence collection for post-market insights and clinical drug development, supporting decentralized clinical trial designs, where patients administer injections at home rather than in clinical environments.

Keywords: smart autoinjector accessory, human factors, validation, patients, automated data logging, digital health, usability, user guidance, subcutaneous injections

Introduction

For medication to be effective, it is crucial that patients adhere to their medication regimen.¹ However, studies suggest that over a third of therapies are not taken as recommended, regardless of the severity of disease or condition.² Consequently, medication adherence remains a significant challenge across various medical fields.³ This issue is particularly pronounced in the context of subcutaneous drug delivery using handheld autoinjectors,⁴ which are increasingly used as a preferred method of administration.^{5–22}

Providing users with enhanced guidance via visual and auditory real-time feedback during the injection process, combined with automatic injection-data logging, promises to increase patients' self-injection confidence and improve medication adherence.^{23–25} To meet these objectives, a novel Smart Autoinjector Accessory (SAA) was developed for use with compatible autoinjectors (Figure 1) and was thoroughly tested in several formative evaluations with a broad range of intended users in different countries.²⁶ The general design idea behind the SAA, when combined with the



Figure 1 Smart Autoinjector Accessory, exemplarily labeled, with a compatible autoinjector inserted.

compatible autoinjector, is providing step-by-step user guidance and capturing accurate injection data, thereby transforming an off-the-shelf autoinjector into a fully connected digital health solution. Before each injection the autoinjector is slid into the SAA and ejected after use. When attached, the SAA senses spring movements of the inserted autoinjector and translates them into step-by-step guidance through visual and auditory feedback. This also allows to detect potential use errors like partial injection or insufficient holding time and enables corrective actions in collaboration with healthcare practitioners (HCPs). This is a unique feature of the SAA in comparison to similar devices - most of which are still in the prototype or concept stage.^{27,28} The injection data is autonomously captured by the SAA and, as soon as a paired smartphone is connected, transmitted to a digital therapy management system to support remote adherence monitoring.

This validation study was designed to assess whether the intended user population—patients, their caregivers, and HCPs, who administer medication using an autoinjector—could safely and effectively use the SAA and its Instructions for Use (IFU). The primary study-endpoint was the successful completion of both critical²⁹ and non-critical use and knowledge tasks without patterns of preventable use errors, user harm, or compromised medical care.

Materials and Methods

Study Design and Participant Selection

Study evaluations were conducted in a simulated-use environment designed to simulate both home and clinical settings. The room was equipped with a table, chairs, and all necessary materials, including the SAA, compatible autoinjector, IFU, product packaging, alcohol wipes, manikin, skin simulation injection pad, gloves (for HCPs only), hand sanitizer, and a sharps disposal container. Each participant attended a single study session, lasting up to one hour. Each session was audio and video recorded.

Participants were recruited and screened to represent the intended user groups regarding sex, age, occupation, race, and highest education level. Eligible participants were patients with dexterity impairments aged 18–54 years, patients with other types of impairments caused by their diseases aged 18–54 years, elderly patients aged >55 years, caregivers and HCPs aged >18 years. To reflect real-world user familiarity, all participants were required to have experience using autoinjectors, but no prior training on the SAA was provided. Exclusion criteria included inability to read or speak English fluently, hearing loss, or severe visual or manual impairments that would prevent unaided use of the autoinjector or SAA.

Human Factors Validation Methods

Study participants were evaluated on their ability to successfully complete 16 SAA use tasks during simulated product use, and 37 knowledge tasks requiring identification of information related to proper device operation. Participant performance (ie, success, error, close calls, significant difficulties, and deviations from the IFU) and behaviour were observed and recorded.

Following task completion, participants were interviewed to provide subjective feedback on the SAA and its IFU. These interviews aimed to identify the root causes of any use errors, difficulties, or close calls, and to assess user confidence in using the SAA with an autoinjector when giving injections.

Participants were allowed to review the SAA and its IFU prior to task performance, simulating real-world conditions of first-time, untrained use.

Statistical Analysis

Participant task data was summarized using descriptive statistics, including the number and percentage of patients who successfully completed a task. Subjective feedback obtained during post-task interviews was analyzed qualitatively and reported in narrative form.

Results

Study Population

A total of 75 participants were enrolled and completed the study, including 45 patients, 15 caregivers, and 15 HCPs. To assess potential differences in usability outcomes, patients were divided into subgroups based on age and the presence of functional limitations. The patient subgroups included 15 patients with dexterity impairments, 15 patients with other types of impairments, and 15 elderly patients, thus allowing to find a minimum of 90% and an average of 97% of all use errors,³⁰ as recommended by the US FDA for a human factors validation study.²⁹ This grouping allowed the evaluation if different functional limitations or age affect the ability to use the device as intended. The median (range) age was 48 years (21–68) for patients, 49 years (28–64) for caregivers, and 39 years (31–61) for HCPs. The ratio of female participants was 33 of 45 (73%) for patients, 7 of 15 (47%) for caregivers, and 11 of 15 (73%) for HCPs. Overall, 53.3% of the patients had functional limitations, including dexterity, hearing and/or visual impairment. None of the caregivers or HCPs reported impairments, except for one caregiver participant with mild cataract.

Validation of SAA Use by the Intended User Population

Performance of SAA Use Tasks

All participants successfully delivered the full dose. In total, 99.7% (1196/1200) of the SAA use tasks were successfully completed (Table 1). In one critical task, a use error was observed, when an elderly patient failed to insert the autoinjector into the SAA. The root cause analysis showed, the error was linked to the participant's spontaneous action without consulting the IFU. After reviewing the IFU, the participant successfully inserted a new autoinjector without difficulty. In three non-critical tasks, one use error was observed in each case during use. One elderly patient attempted to pair the SAA with the companion app before inserting the autoinjector. Another elderly patient held the wrong end of the SAA against the smartphone for pairing, preventing successful pairing. One caregiver failed to dispose of the used autoinjector

Table 1 Evaluation Results of SAA Use Tasks. Table Entries Show the Number and Percentage of Participants Who Successfully Completed Each Use Task, Presented as Absolute Values (n/N) and Corresponding Percentages (%) Within Each Subgroup. Format: n/N (%)

Use Tasks	Dexterity Patient	Other Impairments Type Patient	Elderly Patient	Caregiver	Healthcare Provider	Overall
Select Compatible SAA-Autoinjector Combination ^b	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Remove SAA from Carton	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Safely Handle Autoinjector	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Check Devices for Damage ^{a,b}	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	150/150 (100.0)
Insert Autoinjector into SAA ^{a,b}	60/60 (100.0)	60/60 (100.0)	58/60 (96.7)	60/60 (100.0)	60/60 (100.0)	298/300 (99.3)
Pair SAA with Companion app ^a	45/45 (100.0)	45/45 (100.0)	44/45 (97.8)	45/45 (100.0)	45/45 (100.0)	224/225 (99.6)
Give the Injection ^{a,b}	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	150/150 (100.0)
Eject Used Autoinjector	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Dispose of Used Autoinjector	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	14/15 (93.3)	15/15 (100.0)	74/75 (98.7)

Notes: ^a Task included multiple sub-tasks, ^b Critical tasks.

Abbreviation: SAA, smart autoinjector accessory.

in the designated sharps disposal container. The root cause analysis attributed each non-critical error to either not carefully reading the IFU or to habitual behavior.

Neither critical nor non-critical use task errors were attributed to the design of the SAA or the IFU. All participants were able to successfully perform the use tasks when following the provided IFU.

Performance of Knowledge Tasks

In total, 99.9% (2772/2775) of the knowledge tasks were successfully completed (Table 2). In three cases, participants were unable to correctly answer to a knowledge task. One elderly patient misidentified the meaning of an indicator light signaling the need to eject the used autoinjector. One HCP misidentified the meaning of an indicator light intended to communicate that the SAA is not ready to record an injection. One caregiver was unsure how to respond when the SAA did not display any indicator lights or sound.

The root cause analysis attributed all three errors to the participants not carefully reading the IFU, as the information in the IFU was clearly presented in multiple locations.

Subjective Feedback

During the post-task interview, all 75 participants stated they can successfully use the SAA with an autoinjector when giving injections. One participant from the “other impairments type” subgroup reported initial difficulties understanding how to pair the SAA with the companion app without consulting the IFU but was successful when following the IFU. Another participant from the “other impairments type” subgroup reported to miss the instruction to re-insert the autoinjector in response to indicator lights signaling a device-error or empty battery. The participant later located the information and attributed the oversight to personal inattention.

Discussion

The near-perfect success rates in use (99.7%) and knowledge (99.9%) tasks demonstrate that the intended users can operate the SAA safely and effectively under expected conditions of use, without prior training and relying solely on the IFU. No patterns of preventable use errors were identified, and the few observed were attributed to participant distraction or forgetfulness. Subjective feedback further confirmed that the IFU clearly communicated the necessary information for correct and confident use.

These findings align with existing research demonstrating that connected injection systems with enhanced user guidance can improve self-injection confidence and contribute to better medication adherence. Lohmeyer et al supported the use of guided injection systems to reduce use errors and enhance user confidence, while Van den Bemt et al emphasized the importance of design that is informed by usability consideration for improving the overall treatment experience.^{24,26} Collectively, such factors have been directly linked to improved adherence and persistence in self-injected therapies.^{23–25}

The encouraging results of this study, together with supporting evidence from literature, provide a strong rationale for further evaluation of the SAA’s potential applications. In post-launch use, the SAA could play a key role in facilitating the onboarding of inexperienced patients and those on complex treatment regimens by offering a connected, feedback-enhanced injection experience. Beyond individual therapy, the SAA also holds promise in digitalizing real-world evidence collection for post-market insights and clinical drug development. Particularly in decentralized clinical trials, where patients administer injections at home rather than in clinical environments, the SAA could prove to enhance patient confidence, track adherence in real time, reduce data loss from use errors through corrective guidance, enable reliable automatic data capture, eliminate patient diaries and ultimately lower costs by improved operational efficiency.

A potential limitation of this study was the relatively small sample size. However, the enrollment of 75 participants met the US FDA recommendation of 15 per user group for a human factors validation study.²⁹ Additionally, the study was designed to reflect the diversity of the intended user population, including participants with a wide range of ages, educational backgrounds (from high school to professional degrees), and medical conditions. Another limitation was that the evaluation was limited to a one-time observation within a controlled, simulated home setting. However, the evaluation covered the most critical first-time use of the SAA and represented the highest use-related risk scenario

Table 2 Evaluation Results of Knowledge Tasks. Table Entries Show the Number and Percentage of Participants Who Successfully Completed Each Knowledge Task, Presented as Absolute Values (n/N) and Corresponding Percentages (%) Within Each Subgroup. Format: n/N (%)

Knowledge Tasks	Dexterity Patient	Other Impairments Type Patient	Elderly Patient	Caregiver	Healthcare Provider	Overall
Respond to Injection Indicator Light for Incomplete Injection ^{a,b}	45/45 (100.0)	45/45 (100.0)	45/45 (100)	45/45 (100.0)	45/45 (100.0)	225/225 (100)
How to Safely Use SAA ^{a,b}	75/75 (100.0)	75/75 (100.0)	75/75 (100.0)	75/75 (100.0)	75/75 (100.0)	375/375 (100.0)
Which Devices to Gather for Setup Process ^a	45/45 (100.0)	45/45 (100.0)	45/45 (100)	45/45 (100.0)	45/45 (100.0)	225/225 (100)
Check SAA for Damage ^a	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	30/30 (100.0)	150/150 (100.0)
Check the Autoinjector Before Use ^{a,b}	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	450/450 (100.0)
Respond to Indicator Lights for SAA Attempting to Pair	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Respond to Indicator Lights for Reminder to Eject and Dispose of the Used Autoinjector ^b	15/15 (100.0)	15/15 (100.0)	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	74/75 (98.7)
Respond to Indicator Lights for SAA is Not Ready to Record an Injection	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	14/15 (93.3)	74/75 (98.7)
Respond to Indicator Lights for Battery Low ^b	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Respond to Indicator Lights for Device Error or Empty Battery ^{a,b}	45/45 (100.0)	45/45 (100.0)	45/45 (100.0)	44/45 (97.8)	45/45 (100.0)	224/225 (99.6)
Storage ^{a,b}	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	90/90 (100.0)	450/450 (100.0)
Keep SAA out of Reach of Children ^b	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)
Cleaning the SAA ^a	45/45 (100.0)	45/45 (100.0)	45/45 (100.0)	45/45 (100.0)	45/45 (100.0)	225/225 (100.0)
Disposal of the SAA ^b	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	75/75 (100.0)

Notes: ^a Task included multiple sub-tasks, ^b Critical tasks.

Abbreviation: SAA, smart autoinjector accessory.

when no training is provided. Furthermore, the anticipated learning curve associated with the SAA is expected to further improve the user performance.

Conclusion

The SAA proved to be a safe, convenient and easy-to-use autoinjector accessory for a broad range of patients, their caregivers and HCPs. Enhanced injection guidance via real-time visual and auditory feedback and automatic data-logging support self-injection outcome and user confidence. The results warrant further investigation into the SAA's potential to improve treatment adherence and persistence in longer-term studies. In addition to individual self-injection therapy, the SAA may facilitate applications in decentralized clinical trials and help digitalizing real-world evidence collection for post-market insights.

Abbreviations

HCPs, healthcare practitioners; IFU, instructions for use; SAA, Smart Autoinjector Accessory; US FDA, United States Food and Drug Administration.

Ethics Approval and Informed Consent

The study protocol (IAA-2417) received institutional review board approval (Salus IRB, Austin, TX) before any procedures or assessments were initiated. As this was a simulated use environment study conducted using a skin simulation injection pad, it was determined to involve no more than minimal risk and qualified for expedited review in accordance with 21 CFR 56.110 and 45 CFR 46.110, under research Category 7.

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Disclosure

SW, JM and TT are employees of Ypsomed AG. ADA and CPW are employees of and shareholders in Interface Analysis Associates LLC. The authors report no conflicts of interest in this work.

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