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Participatory Study to Explore Healthcare Professionals' Perceptions of a Connected Digital Solution for Adherence Monitoring of Recombinant Human Growth Hormone Treatment: Study Protocol and First Findings

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Abstract. Adherence to recombinant human growth hormone (r-hGH; somatropin, [Saizen®], Merck Healthcare KGaA, Darmstadt, Germany) treatment is fundamental to achieve positive growth outcomes in children with growth disorders and to improve quality of life and cardiometabolic risk in adult patients affected by GH deficiency. Pen injector devices are commonly used to deliver r-hGH but, to the authors' knowledge, none is currently digitally connected. Since digital health solutions are rapidly becoming valuable tools to support patients to adhere to treatment, the combination of a pen injector connected to a digital ecosystem to monitor treatment adherence is an important advance. Here, we present the methodology and first results of a participatory workshop that assessed clinicians' perceptions on such a digital solution – the aluetta™ smartdot™ (Merck Healthcare KGaA, Darmstadt, Germany) – combining the aluetta™ pen injector and a connected device, components of a comprehensive digital health ecosystem to support pediatric patients receiving r-hGH treatment. The aim being to highlight the importance of collecting clinically meaningful and accurate real-world adherence data to support data-driven healthcare.

Keywords. Adherence, connected device, digital ecosystem, recombinant human growth hormone, participatory research, pen injector

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1. Introduction

Adherence to medication is an important factor in the management of long-term conditions, including growth disorders such as growth hormone (GH) deficiency. Clinicians need to have an objective overview of their patient's adherence to treatment, allowing them to personalize treatment to achieve positive clinical outcomes [1]. Technology-based medication adherence monitoring is widely used [2], enabling the provision of clinically meaningful patient support based on the analysis of objective data. GH treatment is an example of a pharmacologic therapy for which adherence to daily injections is a key factor in achieving positive clinical outcomes [3].

The use of smartphones with Bluetooth-enabled adherence monitoring devices complementing medication injectors present an important opportunity for scalable adherence monitoring.[4, 5] Simple pen injectors are the most commonly used devices to deliver GH therapy; however, to the authors' knowledge, none is digitally-connected. The combination of the convenience of a pen injector and the benefits of a connected digital ecosystem will allow healthcare professionals (HCPs) to support patients to optimize treatment and clinical outcomes. One such example is the aluetta™ smartdot™ (Merck Healthcare KGaA, Darmstadt, Germany; Figure 1), combining the aluetta™ pen injector and a connected device. These are part of a large and comprehensive digital health ecosystem to support treatment with recombinant human GH (r-hGH; somatropin [Saizen®], Merck Healthcare KGaA, Darmstadt, Germany) and facilitate collaboration between patients/caregivers and HCPs to generate real-world data to support clinical decision making.[6]

Figure 1. aluetta™ smartdot™ connected device.

A typical approach to evaluate the usability of connected devices such as aluetta™ smartdot™ is to perform usability testing with a strong focus on maximizing safety. However, this approach has important limitations since it does not address other human factors such as intention to use, integration into a more comprehensive digital ecosystem, or trust in data capture.

As such, participatory health informatics research methods [7] are increasingly used to capture insights into the barriers to and opportunities for the integration of digital health solutions into clinical practice.[8, 9] Here, we present the methodology used in a workshop that explored clinicians' opinions and expectations concerning the aluetta™ smartdot™ to monitor adherence to r-hGH treatment in pediatric patients with growth disorders and adults affected by GH deficiency.

2. Methods

A pilot study following the workshop protocol was conducted in November 2022. Eight HCPs (five pediatric endocrinologists and three endocrinologists) from hospitals and universities from across Italy participated as members of the expert panel.

2.1. Workshop structure, activities, and materials

The workshop was co-moderated by two researchers with experience in participatory methods. Following an approach used in focus groups, participants were split into two teams with each team performing the activities in separate rooms. During the workshop (which was conducted in Italian and lasted 4 hours), participants were asked to provide their opinions of the aluetta™ smartdot™ prompted by a variety of predefined topics, based on their clinical experience.

The workshop consisted of five phases. *Phase 1* briefly outlined the project, introduced the moderators, described the Saizen® digital health ecosystem as an example, and outlined the general structure of the workshop. The objective of *Phase 2* was to understand the current healthcare context in Italy. Five topics were discussed independently by each team: the perceived importance of treatment adherence and potential factors impacting on it; the perceived usefulness of collecting adherence data; the current methods used to collect adherence data; HCPs' attitudes toward the use of digital health solutions for adherence monitoring; and the use of digital health solutions to support GH deficiency self-management. Participants identified relevant factors regarding each topic, and considered HCPs, patients/caregivers, and healthcare institutions/healthcare systems. Predefined templates were used to facilitate the activity (Figure 2).
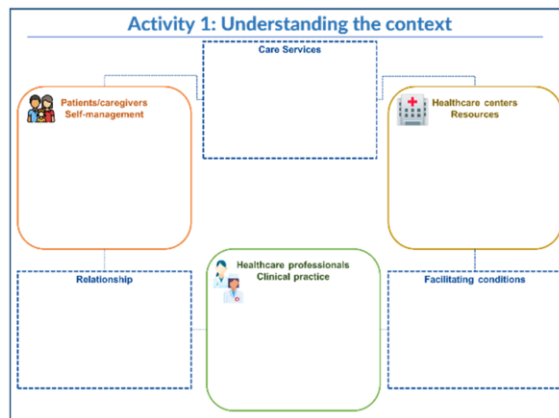

Figure 2. An example of the predefined templates.

The Saizen® digital health ecosystem was preselected and presented as a case study using an introductory video at the beginning of *Phase 3*. A prototype of aluetta™ smartdot™, which had the same look and feel, dimensions, weight, and ability to inject and store injection data as the final commercial product, but not enabled with complete functionality (e.g., the colors of the LED), was provided to each team. The aluetta™ pen injector was also provided. Participants assessed the physical characteristics of aluetta™ smartdot™, attempted to attach it to and detach it from aluetta™, assessed the perceived robustness of the attachment, and attempted to simulate an injection. Participants then

discussed several predefined topics focused on ergonomics, ease of use, perceived usefulness, and potential barriers and facilitators, in the context of GH deficiency management in Italy. Thereafter, the three most relevant topics from the given set were selected from the HCP's perspective, having identified relevant factors from their clinical experience.

Phase 4 aimed to explore HCPs' perceptions on how the technologic evolution of the device could impact on the adherence data collection process, HCPs' daily clinical practice, and patients' self-management. Several topics were predefined for each of these themes, and three scenarios were predefined: 1) Non-digital alternative (patients using a pen device to administer treatment and a paper diary to record their adherence; 2) Partially digital alternative (patients using a pen device to administer treatment and a digital diary integrated into a mobile app/website to record their adherence; and 3) Fully digital alternative (patients using aluetta™ smartdot™ and the growzen™ ecosystem that automatically registers their adherence data and transmits it to a secure internet-based cloud, as part of an adherence decision support system. Thus, enabling HCPs to monitor individual patients' adherence based on information retrieved from their aluetta™ pen injector).

In *Phase 5*, the relevant opinions raised during the previous activities were summarized and discussed by the participants. Members of each team selected the most relevant barriers to (and facilitators for) the use of aluetta™ smartdot™ in the current healthcare context in Italy. Thereafter, the participants discussed the level of agreement on their perceptions of aluetta™ smartdot™ according to the predefined topics.

2.2. Data collection and analysis

Data were collected via audio-recordings of the sessions, completion of the predefined templates, and facilitators' notes. Audio recordings were transcribed and translated into English for thematic analysis. Data from the templates and notes were combined and used to support the thematic analysis.

3. Discussion

The method employed to conduct the participatory workshop enabled collection of clinically valuable and understandable technology acceptancy information with regard to potential barriers to and facilitators for the use of aluetta™ smartdot™ to monitor treatment adherence in patients receiving r-hGH treatment in Italy. The workshop facilitated discussions about the perceived advantages of using aluetta™ smartdot™ to support data-driven health care, including the importance of unbiased data to support clinical decision making and personalized care. Our work reinforces emerging efforts to ensure comprehensive user involvement in the design and implementation of data-driven healthcare solutions.[10] While some topics required no explanation, others required clarification due to technical terminology (e.g., technologic and psychologic terms). This shows the importance of having an interdisciplinary support team during the participatory workshops. The predefined templates were understood and appropriately used by participants, allowing them to engage in the activities; this is aligned with previous experience on template-driven brainstorming (e.g., model business template).[11] Preliminary findings from the thematic analysis report that participants perceived aluetta™ smartdot™ to be highly useful and easy to use; the former driven by

the importance of automated collection of adherence data to improve data quality (more accurate, less risk of bias) and supporting clinical decision making.

4. Conclusions

We captured clinically meaningful insights on the usefulness of a new connected device – aluetta™ smartdot™ – to support adherence to r-hGH treatment. It is hoped that the outputs of this workshop will highlight the importance of collecting clinically meaningful, comprehensive, and accurate adherence data via a connected device to support clinical use and promote patient empowerment.

Acknowledgments and Conflicts of interest

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