Evaluation of the safety and usability of FlexPro® 30 mg/3 mL for the delivery of Norditropin® in patients requiring growth hormone therapy

Disclosures: GF and MQ are employees of and stock/shareholders in Novo Nordisk. YW and RK are employees of Novo Nordisk. AMK is a consultant for, and shareholder in, Novo Nordisk.

Introduction
- FlexPro® 30 mg/3 mL (Novo Nordisk A/S, Denmark) is a pre-filled ready-to-use pen-injector intended as a delivery system for liquid Norditropin® (recombinant human growth hormone [GH], Novo Nordisk A/S, Denmark) for patients requiring GH therapy. FlexPro® 30 mg/3 mL is not yet approved for use by health authorities but has been submitted to the FDA and is currently under review.
- GH therapy has been proven effective in patients with GH deficiency (GHD), including adult GHD, Turner syndrome (TS), Noonan syndrome (NS), and short children born small for gestational age (SGA) (Harris et al. Paediatric Drugs 2004;6:93–106; Appelman-Dijkstra et al. Eur Endocrinol 2013;169:81–14).
- This summative usability test assessed the safety and usability of critical frequently used, and primary-operating functions of FlexPro® 30 mg/3 mL, and validated the instructions for use (IFU) and instructional video in the intended user groups.

Methods
- Children and adolescents aged 10–17 years with GHD, SGA, TS or NS, and specialist and inpatient nurses were enrolled in accordance with FDA Human Factors Engineering (HFE) guidelines.
- All participating children and adolescents were aged ≥18 years with GHD, caregivers of patients with GHD, SGA, TS or NS and specialist and inpatient nurses were enrolled.
- All enrolled participants were tested on normal use of (new pen-injector), end-of-content use (almost depleted pen-injector), and IFU comprehension.
- Use errors, close calls (nearly committing a use error), number of observations recorded and evaluated by trained observers based on IFU, instructional video and training materials.
- Use errors related to handling with no potential for harm. GHD, growth hormone deficiency; SGA, small for gestational age; TS, Turner syndrome; NS, Noonan syndrome.

Results
- Overall, 94 participants underwent evaluation, of which 74.5% were female.

Table 1 Baseline demographics and patient characteristics.

| Group                          | Gender   | Bill | Average length of diagnosis, months (range) | Average length of experience using FlexPro® 30 mg/3 mL, IFU excerpts, and provided positive responses for their overall experience with FlexPro® 30 mg/3 mL (mean ratings between 6 and 7). Mean (range) ratings of 6.7 (4–7) and 6.7 (5–7) were recorded for ‘FlexPro® was simple to use’, and ‘FlexPro® was easy to learn to use’, respectively. Ten participants did not interpret the ‘check flow’ excerpt (ensure GH can flow through pen and needle) correctly.
- Mean ratings between 6 and 7 were also recorded for the evaluation of the IFU and instructional video. The IFU and instructional video (mean range [6–7]) showed information clearly and effectively (6.7 [5–7] and 6.8 [5–7], respectively), and were easy to understand (6.7 [5–7] and 6.8 [6–7], respectively).
- This usability test was associated with some limitations: no blinding took place, the test was carried out in a controlled setting (not in the participant’s home or natural environment) and injections were performed into a foam cushion and not the participant’s own body, leading to different tactile feedback.

Figure 2 Use errors related to handling by group. Data are presented as number of errors (number of participants).

Conclusions
- Overall, participants reported positive experiences with FlexPro® 30 mg/3 mL, the IFU and instructional video.
- No task failures, potentially serious or non-serious use errors were observed.
- The majority (81%) of participants committed no errors in the handling scenarios or IFU interpretation scenarios. Untrained participants committed more handling use errors (no potential for harm) than trained participants.
- Positive experiences with GH injection devices may improve user adherence and clinical outcomes.

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