Usability and safety of FlexPro® PenMate® in patients, caregivers and healthcare professionals

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Introduction

- FlexPro® PenMate® (PenMate®) (Novo Nordisk A/S, Denmark) is an automatic needle insertion system for the administration of a recombinant growth hormone (GH), Norditropin® (Novo Nordisk A/S, Denmark).
- PenMate® aims to reduce needle anxiety by hiding the needle during injection.
- The ability to hide the needle during injection is a valuable feature of a GH injection device (Meinhardt U *et al. Expert Rev Med Devices* 2014;11:31–8) and patients prefer automatic needle insertion to manual needle insertion (Kappelgaard AM *et al. J Pediatr Endocrinol Metab* 2012;25:285–94).
- This summative usability test validated the safe and effective use of PenMate® and the instructions for use (IFU) in patients with GH deficiency (GHD), Turner syndrome (TS), Noonan syndrome (NS) and short children born small for gestational age (SGA).

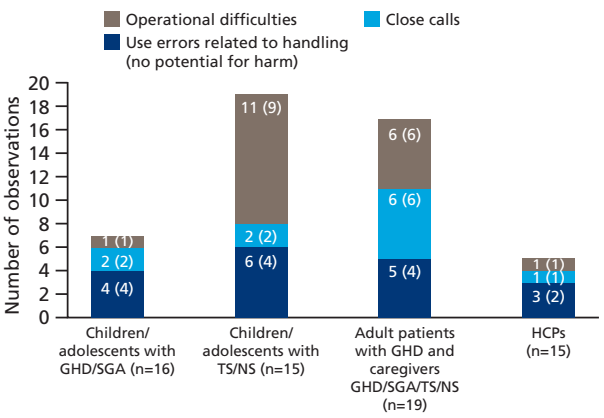
Methods

- This study was conducted across 5 cities in the USA: Encino, Irvine and Marina Del Rey, California; Chicago, Illinois; and New York, New York.
- Children/adolescents aged 10–17 years with GHD, SGA, TS or NS (Norditropin® is approved for the indication NS in the USA, Switzerland, Israel, South Korea and the Philippines), adult patients aged ≥18 years with GHD, caregivers of patients with GHD, SGA, TS or NS, and healthcare professionals (HCPs) with ≥2 years of experience managing patients with GHD, SGA, TS or NS were enrolled according to FDA Human Factors Engineering (HFE) guidelines.
- All participants were trained in the use of PenMate®, using the IFU as the basis for training.
- All participants performed four test scenarios: 1) first time use of PenMate®, performing the injection into a foam cushion, 2) remove a depleted FlexPro® pen from PenMate® and replace with a new pen (50% participants: 'wet hands'; 50% participants: 'dimmed light'), 3) check the GH is clear and colourless, and wipe the front stopper on the needle thread of FlexPro® with an alcohol swab ('distracted user' conditions), and 4) IFU comprehension.
- Participants completed post-test questionnaires on PenMate® use, training and IFU (18-item; 7-point scoring scale: 1=strongly disagree, 7=strongly agree).
- Task failures, use errors, close calls (a participant almost commits an error but corrects him/herself) and operational difficulties were recorded by observers, and root causes were evaluated by subjective feedback from participants.

Results

- Overall, 65 participants underwent evaluation (Table 1). HCPs had a mean (range) of: 9 (2–24) years training patients requiring GH; 15 (6–84) patients instructed in the use of GH devices per month; 65 (10–120) minutes per GH device training session and 49% (5–100%) of patients with needle anxiety/phobia.
- A total of 18 use errors related to handling (no potential for harm), 11 close calls and 19 observational difficulties were made by 14 (22%), 11 (17%) and 17 (26%) participants, respectively (Figure 1).
  - Forgetting to check GH before injection (5/18 observations), almost forgetting to select the dose (4/11 observations) and unintentionally preparing PenMate® while removing the depleted pen (12/19 observations) were the predominant observations for handling-use errors, close calls and observational errors, respectively.
- 78% of participants completed the test scenarios without committing any use errors.
- No task failures, potentially serious or non-serious errors were recorded.

Figure 1 Total number of observations by participant group during scenarios 1–3. Data are number of observations (number of participants).



GHD, growth hormone deficiency; HCP, healthcare professional; SGA, small for gestational age; TS, Turner syndrome; NS, Noonan syndrome.

- Participants gave near maximum mean positive ratings (6.0–6.6) for PenMate® use (Figure 2).
- PenMate® training received mean positive ratings (6.7–6.9) and participants considered PenMate® training to have: all required information; clear and effective materials; an easy-to-follow flow; and thoroughly prepared them to use PenMate®.
- Participants provided mean positive ratings (6.4–6.8) for PenMate® IFU (Figure 3).
- Five out of six IFU excerpts were correctly interpreted.
  - 'Mount a new needle', 'Wipe the front stopper', 'Insert the needle', 'Inject your dose' and 'Remove needle' were correctly interpreted by all participants.
  - Five (8%) participants did not correctly interpret 'Test the Norditropin® flow' due to difficulty associating the Norditropin® flow test dose described in milligrams (0.025, 0.05, 0.1 mg) for each size FlexPro® pen (5, 10, 15 mg) with the description of 'one tick mark' to set the test dose.
- Study limitations included performing test scenarios in a controlled setting versus a real-world setting and injecting into a foam cushion versus a subcutaneous injection.

Figure 3 Evaluation ratings for PenMate® instructions for use (IFU) (1=strongly disagree, 7=strongly agree). Data are mean (range).

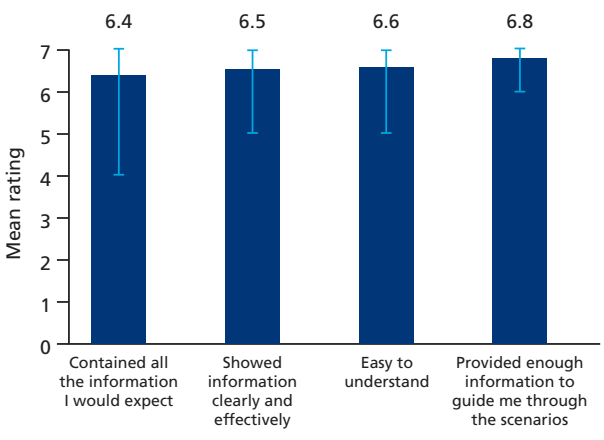


Figure 2 Evaluation ratings for PenMate® use (1=strongly disagree, 7=strongly agree). Data are mean (range).

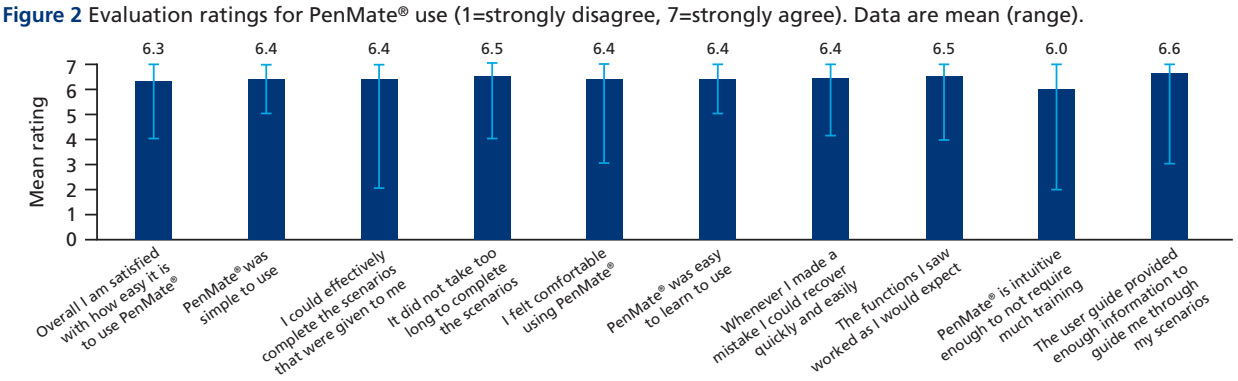


Table 1 Participant demographics.

Participant group	Mean age, years (range)	Gender, male/female	Mean length of diagnosis, months (range)	Pen-experienced/ pen-naïve	Experience with pen injectors, months (range)*
Children and adolescents (GHD/SGA) (n=16)	14 (10–16)	14/2	59 (6–144)	10/6	37 (9–84)
Children and adolescents (TS/NS) (n=15)	14 (11–17)	0/15	112 (12–204)	9/6	100 (8–156)
Adult patients with GHD and caregivers (GHD/SGA/TS/NS) (n=19)	44 (18–71)	8/11	87 (5–336)	11/8	59 (12–120)
HCPs (n=15)	44 (25–59)	3/12	N/A	N/A	N/A

*Excluding pen-naïve participants and HCPs. GHD, growth hormone deficiency; HCP, healthcare professional; N/A, not applicable; NS, Noonan syndrome; SGA, small for gestational age; TS, Turner syndrome.

Conclusions

- PenMate® was considered easy to use, simple to use, easy to learn to use and patients felt comfortable using PenMate®.
- The IFU was considered helpful and easy to understand.
- No potentially serious or non-serious user errors were recorded.
- Use errors related to handling were not related to PenMate®.

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