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

Disclosures: WW, CNK and RK are employees of Novo Nordisk. AMK is a consultant for, and shareholder in, Novo Nordisk.

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).
- 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®.

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/adolecents 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.

Participants provided mean positive ratings (6.4–6.8) for PenMate® IFU (Figure 3). Five out of six IFU excerpts were correctly interpreted.

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/aphobia.
- 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 commits an error but corrects him/herself and 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.

Table 1 Participant demographics.

<table>
<thead>
<tr>
<th>Participant group</th>
<th>Mean age (range), years</th>
<th>Gender, male/female</th>
<th>Mean length of diagnosis, months (range)</th>
<th>Pen-experienced/pen-naive</th>
<th>Experience with pen injections, months (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children/adolecents with GHD/SGA/TS/NS (n=19)</td>
<td>14 (10–16)</td>
<td>142</td>
<td>59 (6–144)</td>
<td>105 (37–98)</td>
<td>9/6 (3–12)</td>
</tr>
<tr>
<td>Adult patients with GHD/SGA/TS/NS (n=19)</td>
<td>14 (11–17)</td>
<td>0/15</td>
<td>112 (12–204)</td>
<td>9/6 (3–12)</td>
<td>100 (8–156)</td>
</tr>
<tr>
<td>HCPS (n=15)</td>
<td>44 (25–59)</td>
<td>3/12</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Children/adolecents with GHD/SGA/TS/NS (n=19)</td>
<td>14 (10–16)</td>
<td>142</td>
<td>59 (6–144)</td>
<td>105 (37–98)</td>
<td>9/6 (3–12)</td>
</tr>
<tr>
<td>Adult patients with GHD/SGA/TS/NS (n=19)</td>
<td>14 (11–17)</td>
<td>0/15</td>
<td>112 (12–204)</td>
<td>9/6 (3–12)</td>
<td>100 (8–156)</td>
</tr>
<tr>
<td>HCPS (n=15)</td>
<td>44 (25–59)</td>
<td>3/12</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Conclusions

- PenMate® was considered easy to use, simple to use, easy to learn and 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®.

1. Yanhong Wen Nova Nordisk A/S, Hillerød, Denmark
2. Conny Nehr Korsholm Nova Nordisk A/S, Søborg, Denmark
3. Rasmus Klinck Nova Nordisk A/S, Hillerød, Denmark
4. Anne-Marie Kappelgaard Nova Nordisk International Operations AG, Zürich, Switzerland

This study was sponsored by Novo Nordisk A/S. The authors take full responsibility for the content of the poster but are grateful to Watermeadow Medical (supported by Novo Nordisk A/S) for writing assistance.