Human Factors Engineering for Medical Device Development

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Director, Devices Development & Technologies - IPSEN
PRESENTATION AGENDA

• Human Factors Engineering: overview & regulatory framework
• Patient-centricity in Device Design and Development
• Case study: Development of a New Delivery System for Somatuline® Autogel®
• Conclusion
DISCLOSURE

- I am currently employed by Ipsen
- This study was sponsored by Ipsen
Human Factors Engineering: overview & regulatory framework
Usability Engineering Process Objectives

“The aims of a usability engineering process are to deliver **products that are easy to use and safe in the intended context of use, and by intended users (whether by carers or patients themselves)**. Users should not have to read, understand and remember complex instructions for use and adapt to the requirements of the device, or use it in an uncomfortable, incorrect and possibly dangerous way: a well-designed product will be easy to use, and will have a user interface that is consistent with user experiences and expectations.

In addition to safety considerations, products designed with human factors principles are more pleasing to use, and are therefore likely to lead to better adherence to correct use, at the required frequency. Human factors principles are therefore employed by many companies in design for customer loyalty and marketing purposes.”*

  
  MHRA: Medicines and Healthcare products Regulatory Agency (UK)
### Regulatory Landscape Medical Device Development / Human Factor Studies

<table>
<thead>
<tr>
<th>EUROPE</th>
<th>USA</th>
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</thead>
<tbody>
<tr>
<td>2009 and repealing Council Directives 90/385/EEC and 93/42/EE</td>
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<tr>
<td>ISO 13485:2016 requirements for a quality management system specific</td>
<td>AAMI/ANSI HE75:2009 Human factors</td>
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<tr>
<td>to the medical devices industry</td>
<td>engineering - Design of medical devices</td>
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<tr>
<td>ANSI/AAMI/IEC 62366-1:2015 Medical devices - Part 1: Application of</td>
<td></td>
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<tr>
<td>usability engineering to medical devices</td>
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<tr>
<td>IEC/TR 62366-2:2016 Medical devices - Part 2: Guidance on the</td>
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<tr>
<td>application of usability engineering to medical devices</td>
<td></td>
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<tr>
<td>ANSI/AAMI/ISO 14971:2007/(R)2016 Medical devices - Application of</td>
<td></td>
</tr>
<tr>
<td>risk management to medical devices</td>
<td></td>
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# Key guidances for Human Factor Studies

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<tr>
<td><strong>MHRA Human Factors and Usability Engineering - Guidance for Medical Devices Including Drug-device Combination Products, v1.0 (2017)</strong></td>
<td><strong>FDA Applying Human Factors and Usability Engineering to Medical Devices (2016)</strong></td>
</tr>
<tr>
<td><strong>EC Guideline on the readability of the labelling and package leaflet of medicinal products for human use (2009)</strong></td>
<td><strong>FDA Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development (Draft, 2016)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>FDA Design Considerations for Devices Intended for Home Use (2014)</strong></td>
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* The Pharmacovigilance Risk Assessment Committee (PRAC) is the European Medicines Agency's (EMA) committee responsible for assessing and monitoring the safety of human medicines

Patient-centricity in Device Design and Development
User / Patient testing (Usability/Human Factor studies)

Verification (bench testing, mechanical stability, drug/device interactions …)

Prototyping (3D printing, soft & hard steel molds)

Define & Design (3D modelling)

DEVICES
PATIENT-CENTRIC DEVELOPMENT PROCESS

Development

Industrialization

Commerically ready

Early design

Users & Patients

* Human Factors
User Insights (→ User requirements)
Identification of use & environment (→ Use specifications)

Risk assessment of use and use error
Prioritise tasks and user interface characteristics related to safety
Develop user interface specification and HF validation plan
Formative testing and design iteration
Design fixed
Summative testing / design validation
Summary human factors report
Device Launch

Review of use error on comparable products
Post-market surveillance

New Use error identified

Adapted from MHRA Human Factors and Usability Engineering - Guidance for Medical Devices Including Drug-device Combination Products, v1.0, p.14 (2017)
**Life cycle management**

**Risk Management**

-e.g. Acromegaly patients
  - hand size & finger thickness
  - dexterity & vision

**User Insights**

- Identification of use & environment
  (- User specifications)

**Identification of use & environment**

-e.g. use by HCPs or patients in clinical and home environments, deep subcutaneous injection, administered to the upper, outer quadrant of the buttock, or the upper, outer thigh.

**Review of use error on comparable products**

**Post-market surveillance**

**New Use error identified**

-e.g. training effort, improvable ergonomics, etc.

**Human factors**

-e.g. use the product even if Pre-Filled Syringe dropped but does not look damaged, needlestick injury, do not inject the complete dose, do not inject in the right site, etc.

**USABILITY ENGINEERING PROCESS**

-Formative testing and design iteration

-Design fixed

-Summative testing / design validation

-Summary human factors report

-Device Launch

**Summary human factors report**

-e.g. training effort, improvable ergonomics, etc.
**User Insights**

(-> User requirements)

**Identification of use & environment**

(-> Use specifications)

**Risk assessment of use and use error**

**Post-market surveillance**

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<table>
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<tr>
<th>Potential Use Error (Failure mode) for the new injection system</th>
<th>Potential Use Error Effects (Failure effects) for the new injection system</th>
<th>Potential Harm</th>
<th>SEV</th>
<th>Failure effect occurrence</th>
<th>RPN*</th>
<th>Recommended actions</th>
<th>SEV</th>
<th>OCC</th>
<th>RPN*</th>
</tr>
</thead>
<tbody>
<tr>
<td>In what ways can a use error occur?</td>
<td>What is the impact of the use error?</td>
<td>NA</td>
<td>SEV</td>
<td>How often does effect error occur? (quoted here without taking account any labelling / intuitive use)</td>
<td>Before mitigation</td>
<td>What are the recommended actions for reducing the occurrence of the use error?</td>
<td>SEV</td>
<td>OCC</td>
<td>RPN*</td>
</tr>
</tbody>
</table>

**Risk Management**

**USABILITY ENGINEERING PROCESS**

- Formative testing and design iteration
- Design fixed
- Summative testing / design validation
- Summary human factors report
- Device Launch

* Risk Priority Number

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Potential Use Error (Failure mode) for the new injection system: In what ways can a use error occur?

Potential Use Error Effects (Failure effects) for the new injection system: What is the impact of the use error?

Potential Harm: NA

SEV: How severe is the effect to the patient?

Failure effect occurrence: How often does effect error occur? (quoted here without taking account any labelling / intuitive use)

RPN*: Before mitigation

Recommended actions: What are the recommended actions for reducing the occurrence of the use error? After mitigation

SEV: SEVERITY

OCC: OCCURRENCE

RPN*: RISK Priority Number
User Insights (-> User requirements)
Identification of use & environment (-> Use specifications)

Risk assessment of use and use error
Prioritise tasks and user interface characteristics related to safety
Develop user interface specification and HF validation plan

Review of use error on comparable products
Post-market surveillance

Risk Management ISO 14971

USABILITY ENGINEERING PROCESS

<table>
<thead>
<tr>
<th>N° risk</th>
<th>Task</th>
<th>Success Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>xx</td>
<td>Select injection site</td>
<td>Participant selects superior external quadrants of the buttock</td>
</tr>
<tr>
<td>xx</td>
<td>Push the plunger to inject</td>
<td>Participant depresses plunger completely</td>
</tr>
<tr>
<td>xx</td>
<td>Activates safety mechanism</td>
<td>Participant engages the needle safety mechanism without needlestick injury</td>
</tr>
</tbody>
</table>

New Use error identified

Device Launch

Summary human factors report
Case study: Development of a New Delivery System for Somatuline® Autogel®
Ipsen vision & commitment in Acromegaly & NET*

1995
Somatuline Long-Acting 30 mg;
(1/15 days)

1996
Somatuline autogel 60, 90, 120 mg, ready-to-use (1/28 days)

2000
Somatuline autogel ready-to-use + with safety system (1/28 days)

2001
Somatuline autogel 60, 90, 120 mg, ready-to-use (1/28 days)

2001
Somatuline autogel 60, 90, 120 mg, ready-to-use (1/28 days)

2010
Somatuline autogel ready-to-use + with safety system (1/28 days)

2017
Xermelo

2019
Somatuline autogel ready-to-use, + with safety system, new syringe (1/28 days)

*Neuroendocrine Tumors

References:
- Ruszniewski, Gut 1996; Ducroux, AMGastroenterology 2000;
- Caplin, NEJM 2014; Vinik Endoc Practice 2016; Kulke, JCO 2016;
- Pavel et al. Endocrine-Related Cancer 2018

(Updated: 13/09/2018)
(1) Treatment of acromegaly when circulating levels of growth hormone and/or IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who otherwise require medical treatment.

(2) Treatment of G1 and a subset of G2 (Ki67<10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin (where hindgut sites have been excluded) in adults with unresectable locally advanced or metastatic disease.

(3) Treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumours.

Source: [https://www.hpra.ie/img/uploaded/swedocuments/08c164f3-f344-4821-b9a7-3750eb2a0c60.pdf](https://www.hpra.ie/img/uploaded/swedocuments/08c164f3-f344-4821-b9a7-3750eb2a0c60.pdf)
Somatuline® Autogel®- Life cycle management

1 delivery system for 3 Somatuline® Autogel® doses
Addition of a passive safety system

Improved ergonomics & user-friendliness (market user feedback)
218 users gave their feedback to develop the new delivery system

→ 5 User studies for Regulatory submission in EU and US

<table>
<thead>
<tr>
<th>Study</th>
<th>Aim</th>
<th>Participants</th>
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</thead>
<tbody>
<tr>
<td>Jun-Sep 15</td>
<td>To understand users’ experience with the current on-the-market DS and rank preferred features of DS prototypes based on users’ expectations</td>
<td>71 participants: Acro&lt;sup&gt;(3)&lt;/sup&gt; + NET’s&lt;sup&gt;(4)&lt;/sup&gt; patients &amp; Endocrine nurses</td>
</tr>
<tr>
<td>Dec 15</td>
<td>To gather feedback on a prototype of the DS that had been developed using results from the first formative study</td>
<td>5 participants who participated to 1st study</td>
</tr>
<tr>
<td>Mar 16</td>
<td>To further test the new DS&lt;sup&gt;(1)&lt;/sup&gt; in order to finalise its design (e.g. rubber coating, colour), and test user’s understanding of the IFU&lt;sup&gt;(2)&lt;/sup&gt;</td>
<td>48 participants: Acro&lt;sup&gt;(3)&lt;/sup&gt; + NET’s&lt;sup&gt;(4)&lt;/sup&gt; patients &amp; Endocrine nurses</td>
</tr>
<tr>
<td>Sep 16</td>
<td>To maximise the likelihood that the product is used safely and effectively and assess the usability of various plunger protectors</td>
<td>8 (US) + 18 (EU) participants: 8 US HCPs&lt;sup&gt;(5)&lt;/sup&gt;, 2 Acro&lt;sup&gt;(3)&lt;/sup&gt; patients, 3 caregivers of NET&lt;sup&gt;(4)&lt;/sup&gt; patients, 13 rep. of patients &amp; caregivers</td>
</tr>
<tr>
<td>May-Jun 17</td>
<td>To validate that the product can be used safely and effectively by intended users, for intended uses, in the intended use environments</td>
<td>68 participants: 35 HCPs&lt;sup&gt;(5)&lt;/sup&gt;, 33 rep. of patients &amp; caregivers</td>
</tr>
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</table>

<sup>(1)</sup> Delivery system
<sup>(2)</sup> Instruction for Use
<sup>(3)</sup> Acromegaly
<sup>(4)</sup> Neuroendocrine Tumors
<sup>(5)</sup> Healthcare Professionals
**Somatuline® Autogel® - New Delivery System**

- A rigid plunger support with flat wide top to provide stability for depression with thumb
- Wider & curved wings to aid those with limited dexterity (hand size, wearing gloves...)
- Rigid, large and grippable syringe body to aid those with limited dexterity
- Easy grip and removal of the cap to aid those with limited dexterity

**What remains the same?**
- The formulation and primary container
- The low injection volume
- The syringe body transparency
- The needle size designed for deep sub-cut
- An automatic needle safety system
- Safety and effectiveness

Protective plastic tray to ensure no inadvertent depression of the plunger whilst within the packaging
CONCLUSION

Human Factors Engineering:

- Mandatory for device development. Detailed in US & UE regulations & guidance + international standards
- Patient-centric process by definition
- Essential for the development of a more ergonomic and user-friendly delivery system for Somatuline® Autogel®
For their support, advice & information presented here, I would like to thank:

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