INNOVATIVE MEDICAL DEVICE FOR INTRAVENOUS THERAPEUTICS AND FLUSHING: PRE-CLINICAL STUDIES IN SIMULATION CONTEXT

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CLINICAL BACKGROUND

Peripheral intravenous catheterization

Enables the intravenous administration of fluids and medications in the bloodstream

High number of complications
(mechanical, chemical, infectious)

Frequent procedure performed in nursing clinical practice

FLUSHING
Brief report on double-chamber syringes patents and implications for infusion therapy safety and efficiency

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Health Technology Assessment
EUnetHTA Joint Action (2015)

MEDDEV
Consensus statements

Portuguese legal framework:
✓ Lei n°21/2014 (Clinical research)
✓ Decreto-lei n°145/2009 (MDs)

INFARMED
(Portuguese National Authority of Medicines and Health Products)
**Human-centered Design**

ISO 13407: 1999  
ISO 14155: 2011  
ISO 14971: 2012

- Iterative methodology;
- Increase the usability of the MD;
- Involvement of users throughout design and development process;
- Increase the safety, satisfaction, effectiveness and efficiency;
- Minimizing product recalls and modifications;

**Design solutions meet user requirements**

- Understand and specify the context of use
- Specify the user requirements
- Produce design solutions to meet user requirements
- Evaluate the designs against requirements
Describe the initial steps on the development of this new MD. Through this, we intended to accomplish with the stages 1 to 3 of the Technology Readiness Level, covering basic principles (TRL 1), technology concept formulated (TRL 2), and experimental proof of concept (TRL 3).

- explore the conceptual idea about this new device, establishing the user and user requirements, as well as the contexts of use;
- obtain enough data regarding such aspects in order to produce design solutions;
- assess those design solutions against the initial requirements;
- select the better design solution and determine any necessary modification in order to improve the MD.
**Plunger**  
- Course: Without annotations
- Dimension: Higher support base
- Colour: Different colours for the plungers

**Syringe body**  
- Increase of the support flaps
- Mechanical trauma by the luer lock system

**Chambers**  
- Identification: The chamber for flushing solution and the chamber for medicines
- Scale: Lack of consensus regarding the scale of both chambers
- Filling: First the flushing solution and then the medicine

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**QUALITATIVE DATA**

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**QUANTITATIVE DATA**

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<td>126.6</td>
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Concept 2 was excluded because it did not enable the pre-flushing. Likert scale for concept assessment: 0-terrible; 1-very weak; 2-weak; 3-sufficient; 4-good; 5-excellent; (in parenthesis are presented the corrected values according to ponderation values achieved for each evaluation criteria).
Study Protocol

Study protocol for two-steps parallel randomized controlled trial: Pre-clinical usability tests for a new double-chamber syringe

Pedro Parreira¹, Liliana B. Sousa¹, Inês A. Marques¹, Paulo Santos-Costa¹, Sara Cortez³, Filipa Carneiro¹, Arménio Cruz¹ and Anabela Salgueiro-Oliveira¹

Usability validation protocol for a double-chamber syringe supported in the User-Centered Design (UCD) method:

✓ describe the pre-clinical validation steps that will be used during the assessment of the functional prototype, to accomplish the requirements established by the regulatory entities

✓ under the SPIRIT 2013 Guidelines, with some adjustments according to pre-clinical trials in healthcare simulation research specificities.
**Phase I. Intra-subject analysis**

- **Assessment for eligibility**
  - Nursing professionals

- **Randomized**
  - (n=20)

- **Arm A** (n=10)
  - 1<sup>st</sup> Double-chamber syringe
  - 2<sup>nd</sup> Standard syringes

- **Arm B** (n=10)
  - 1<sup>st</sup> Standard syringes
  - 2<sup>nd</sup> Double-chamber syringe

- **Excluded**
  - Not meeting inclusion criteria
  - Decline to participate
  - Other reasons

**Phase II. Inter-subject analysis**

- **Assessment for eligibility**
  - Nursing professionals

- **Randomized**
  - (n=20)

- **Arm A** (n=10)
  - Double-chamber syringe

- **Arm B** (n=10)
  - Standard syringes

- **Follow-up**
  - Quantitative (usability questionnaire) and qualitative assessment (interview, focus group) of outcomes.

- **Analysis**
  - Analysed
Simulation environment in nursing laboratory for usability tests, with

(a) the material available for the participants, and

(b) the simulator with an inserted PIVC for mimeticize the intravenous drug administration and flushing.
Assess the usability of an innovative double-chamber syringe, by their end users (nurses), through a mix-method of quantitative and qualitative data, considering the development stages

- concept
- semi-functional
- functional prototype
QUANTITATIVE DATA

(Usability scores)

<table>
<thead>
<tr>
<th>Concept</th>
<th>Concept (n = 16)</th>
<th>Semi-functional prototype (n = 22)</th>
<th>Functional prototype (n = 30)</th>
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<td>M ± SD</td>
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<td>Min - Max</td>
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<td>Satisfaction/</td>
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<td>Use intention</td>
<td>Min - Max</td>
<td>4.71 - 7.00</td>
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</table>

- Mean; SD - Standard Deviation; Min. - Minimum; Max. - Maximum; r - correlation coefficients with professional experience (months).

QUALITATIVE DATA

+ usefulness of this innovative device
+ potential of the syringe “to assess the patency” and “to prevent drug interaction or contamination”
+ “reduces the amount of material wasted” and “reduces the number of catheter manipulations”
+ “improving safety for patients and professionals” and “also lowers the risk of infection”
+ syringe body dimensions are “as close as possible to the syringes on the market”
+ simplicity in preparation and administration phases (“easier”, “reduce errors in the chambers charging”)

- “a bit more hand strength than usual is required”
- “you feel slight pressure, making it harder to aspirate”
- “having two plungers makes it harder to aspirate the solutions and remove aspirated air from the chamber”
- “hand coordination is slightly harder with two plungers”
CONCLUSION

Refinement of Duo Syringe main characteristics:
✓ Plunger
✓ Syringe body
✓ Chambers

HCD in development of MDs

Users involvement in earlier stages of product development

Necessary to obtain successful products

✓ Define user requirements and contexts of use;
✓ Evaluate design solutions and prototypes.
Double-chamber syringe versus classic syringes for peripheral intravenous drug administration and catheter flushing: a study protocol for a randomised controlled trial

Pedro Parreira, Liliana B. Sousa, Inês A. Marques, Paulo Santos-Costa, Luciene M. Braga, Arménio Cruz and Anabela Salgueiro-Oliveira
DUO Syringe | An innovative device for intravenous administration

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