The Soul of a New Pump: Surprising Educational Discoveries When Creating Medical Devices with Clinicians and Users

RMS Medical Products
24 Carpenter Rd. • Chester, NY 10918 • USA

Contributing authors:
B. Sealfon[1], C. Soderman[2,].
[1]Patient Programs, Chester, USA. [2]Clinical Programs, RMS Medical Products, Uppsala, Sweden.

Objective:
We sought to conduct a usability study to optimize design and development of a syringe infusion pump capable of using 20ml and 30ml syringes. The device is limited by design to a safe low pressure at .93 BAR, to retain the advantages of dynamic equilibrium and reduce local infusion side-effects.

Design:
A Clinical Advisory Panel, including prescribers, home infusion providers, a trade association representative, and a pharmaceutical manufacturer prioritized a simple-to-use 20ml syringe pump through qualitative discussion and a ranking rubric.

Method:
We tested prototypes through simulated home infusion use. Naive users were recruited in two 'challenge' populations: adults with limited dexterity or impaired upper extremity motor skill, and pediatric users. Study Protocol compared the smaller pump to the 60ml design which has for many years had an excellent safety and reliability record. Users were trained and then asked to demonstrate an infusion. The facilitator recorded ranking questions, pass or fail completion of administration steps, and qualitative feedback on user confidence.

Results:
Using the 20ml/30ml pump proved comparable to the 60ml device. Surprisingly, despite fewer device controls on the 20ml device, total steps to perform subcutaneous infusion remained similar. Minimizing operational steps proved to be a major factor in users' ability to complete an infusion successfully. Making the pump collapsible for transport led to confusion for some study participants. Teaching methods had enormous impact. Demonstration teaching is barely effective, even for simple processes. Engaging the user to actively explore, test out and learn independently, increased knowledge retention and confidence. Engaged pediatric users as young as 7 or 8 years old successfully followed both written and demonstrated instructions.

Conclusion:
The study reinforced the critical importance of training and education. The best investment in a device seems to be that which simplifies the user experience. We invest significantly in training-the-trainer programs, and graphical user guides and device labeling. We have simplified our instructions, with larger pictures, and key challenge areas recognized from user testing are highlighted in nurse education and patient training materials. To further minimize steps of operation, we are researching easier ways to prepare medication and eliminate the need to prime the infusion set. By applying emerging research on gamification and learner engagement we expect to significantly improve patient outcomes and satisfaction. Studying the effects of scientific training and behavioral intervention with existing resources, versus new drug and device product development, will profoundly impact global healthcare economics.

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Advisory Panel
- Prescribers
- Home Infusion Providers
- Trade Association Representative
- Pharmaceutical Manufacturer

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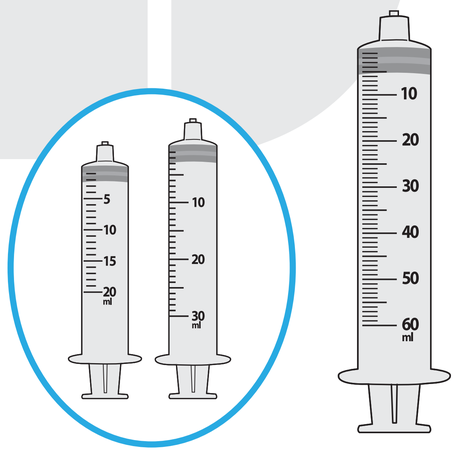
Ideas for New Pump
- Accommodate 20ml & 30ml syringes
- Employ safe, constant pressure
- Portable – no electric/batteries
- Easy to use & train



20ml & 30ml 60ml

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Testing of Prototype
- Adults with limited dexterity & children were recruited
- Compared smaller pump to the 60ml design
- Users were trained and then asked to demo an infusion
- Facilitator recorded results

Results
- 20ml/30ml pump was comparable to 60ml pump
- Total amount of steps remained similar to 60ml device
- Hands on, independent training proved more effective than a teaching method of demonstration

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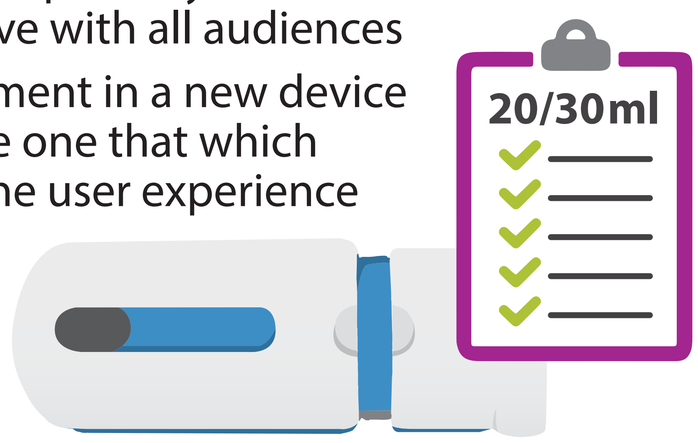
Conclusion
- Training & education are of critical importance
- 20/30ml pump is easy to learn & very effective with all audiences
- Best investment in a new device seems to be one that which simplifies the user experience



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Disclosure:
Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
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Chaterina Soderman: RN, MBA, Clinical Programs, RMS Medical Products
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