FINAL PUBLISHABLE REPORT

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Project short name	InfusionUptake
Project full title	Standards and e-learning course to maximise the uptake of infusion and calibration best practices

Project start date and duration:	01 May 2016, 36M	
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Internal Funded Partners: 1 VSL, Netherlands 2 DTI, Denmark 3 IPQ, Portugal	External Funded Partners: 4 UMCU, Netherlands	Unfunded Partners: 5 ESICM, Switzerland

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1 Overview

For more than 25 years, multiple drug infusions through one injection point (multi-infusion) have been known to cause severe dosing errors. A large percentage of these errors can be avoided if the users of infusion technology have a better understanding of the equipment. Therefore, it is very important to create awareness and understanding of the physics and metrology involved to the users of infusion technology.

The primary supporter ESICM, as well as other institutes such as the European Society of Pediatric and Neonatal Intensive Care (ESPNIC), the Dutch Society for Intensive Care (NVIC), the Dutch Pediatric Association and the Danish National Society of Anesthesia and Intensive Care Medicine (DASAIM), recognize the challenges in multi-infusion and agree that a wide dissemination of the key outputs of EMRP JRP HLT07 MeDD will facilitate to reduce the number of dosing errors.

2 Need

A key output of EMRP JRP HLT07 MeDD was the development of a best practice guide and a (preliminary) e-learning training course on infusion technology, which discusses the challenges and pitfalls, as well as potential solutions, related to this technology. While these items were presented at the final conference of EMRP JRP HLT07 MeDD and are available from the EMRP JRP HLT07 MeDD website http://www.drugmetrology.com/, the uptake so far has been limited. Hence, there is great need for further dissemination of these materials and for the e-learning course to be more interactive to enhance its quality.

A second key output of EMRP JRP HLT07 MeDD was the realisation of calibration services for infusion devices. These services followed the construction and validation of several calibration facilities in the (very) low flow range < 1 ml/min. Following the showcases of calibration of infusion systems, EMRP JRP HLT07 MeDD has generated a vast experience on how to calibrate infusion devices with the lowest possible uncertainty. While this knowledge has been presented at various scientific conferences, it has not yet been formalised via amendments to written standards.

The current available standards dealing with calibration of infusion devices (and accessories), e.g. ISO 7886-2 (Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps), IEC 60601-2-24 (Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers), ISO 28620 (Medical devices – Non-electrically driven portable infusion devices) and IEC 62353 (Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment), have room for improvement, especially for low flow rate calibrations.

The European Society of Intensive Care Medicine (ESICM) is the primary supporter of the project. The ESICM educational division is responsible for developing and promoting the educational training program of the ESICM in Europe and has started harmonising this training with the launch of the ESICM Academy in 2017. One of the main outputs of this project is the freely available e-learning (https://academy.esicm.org/course/view.php?id=210) on the risks and best practices of infusion technology which is fully integrated into the ESICM Academy, and which will remain available until after the end of the project. Infusion is the most used technology in hospitals. Because of its widespread application, often in critical situations and by many users, many infusion errors are made, with some having severe effects. Not all users of infusion devices are aware of the errors that can be made when using multiple drug infusions through one injection point. Increased awareness and understanding will diminish preventable errors; and hence users need to be aware of the best practices to help them to optimise patient care. By the end of the project more than 100 people involved in infusion technology were trained on the risks and best practices of this technology.

For critical infusion applications to vulnerable patients, well-controlled medication care is needed. If infusion pumps deliver drugs inaccurately, this can have large adverse effects on the effective administration of the medication. The availability of intravenous (directly into a vein) administration devices that can guarantee accurate drug dosage is of paramount importance to fulfil this need. Therefore, all available knowledge on the actual infusion system used for patient care should be incorporated in relevant written standards on the calibration of infusion devices. During this project the input to incorporate best metrology practices into IEC 60601-2-24 “Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and

essential performance of infusion pumps and controllers" was given while best metrology practices were incorporated into the new ISO 7886-2 "Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps" standard just after the lifetime of the project.

3 Objectives

The overall objective of this project was to realise the uptake of the key outputs of EMRP JRP HLT07 MeDD, thereby aiming to reduce the number of adverse patient incidents caused by multi-infusions.

The objectives of this project are:

1. To broadly disseminate the risks and best practices related to infusion technology by upgrading and disseminating the e-learning training course on infusion technology from the outputs of EMRP JRP HLT07 MeDD. The aim is to create awareness and understanding of multi-infusion risks and thereby reduce dosing errors, thus decreasing adverse patient incidents and increasing the quality of medical treatment.
2. To incorporate the best metrology practices relating to calibration of infusion devices (developed in EMRP JRP HLT07 MeDD) in ISO standards ISO 7886-2 and IEC 60601-2-24.

4 Results

This project undertook two activities: e-learning course and incorporating best metrology practices into standards.

Publicly available e-learning & workshops on the risks and best practices of infusion technology

In order to broadly disseminate the risks and best practices related to infusion technology obtained from the outputs of EMRP JRP HLT07 MeDD an e-learning course was developed in this project. The aim was to create awareness and understanding of multi-infusion risks and thereby reduce dosing errors, thus decreasing adverse patient incidents and increasing the quality of medical treatment.

e-learning launch

The first version of the e-learning "Infusion Pumps" on the risks and best practices of infusion technology was launched at the ESICM LIVES 2017 annual conference which constituted a trial run. Laptops on which the course was installed were accessible in the exhibition hall of the conference so that conference participants could try it out. Some representatives of infusion pump manufacturers took the course and positive feedback was received from this trial run. The course is comprised of a theory section followed by actual, interactive clinical and metrology cases from the field. The cases were developed in close cooperation with healthcare and metrology professionals (see the "Contributors" list in the link below). The course is part of the ESICM Academy. The academy was further rolled out in 2018 bringing strong exposure to this e-learning.

The e-learning is, and will remain, freely available to the public through this link on the ESICM academy: https://academy.esicm.org/course/view.php?id=210.

Workshops and e-learning feedback

Workshops and trainings using the e-learning were given at the ESICM LIVES 2018 in Paris, in three different hospitals in Portugal, and in two different hospitals in The Netherlands. Figure 1 shows a typical announcement which was used at the ESICM LIVES 2018. Presentations about the e-learning were given in five different countries on conferences and in hospitals. The objectives of these workshops and trainings were: (I) to train users of infusion pumps on the risks and best practices of infusion technology and encourage other infusion technology users to also be trained, and (II) to receive feedback on the course from users of infusion pump technology in order to improve it. The collection of feedback was necessary to check if these cases are indeed day-to-day practice in other hospitals (and countries) as well. At the end of 2018 the feedback received through the workshops and the online feedback form embedded with the course was used to make improvements to

the e-learning content. Improvements were in accessibility, in readability, and in navigation through the e-learning.

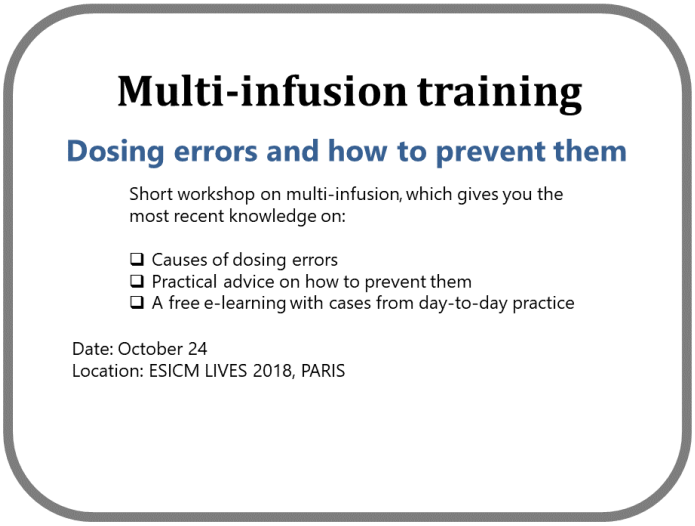

Figure 1: workshop announcement using the e-learning at the ESICM LIVES 2018

The feedback of the workshops and presentations showed that users of (multi-)infusion across a variety of countries recognize the issues that are presented in the e-learning course. This is an important result, as day-to-day clinical practice can vary between different European countries, and it was thus confirmed that the cases presented in the course are directly relevant to the users of infusion technology. Further feedback given was that the course participants feel that they have a better understanding of the causes of the issues presented in the course cases. The participants of the e-learning course that finished the entire e-learning are positive about the quality of the information provided evidenced by 76% of them giving the e-learning a rating of 4 out of 5 or higher.

Some reactions from course participants

- Participants stated that they recognized several situations of time delays, accuracy of devices and compliance effects of which they were not aware of before.
- Some suboptimal hospital practices were identified with the knowledge gained from the e-learning, and course participants have improved those practices.
- The information obtained regarding the importance of the calibration and verification of infusion pumps and infusion device analysers was also considered valuable by the participants who indicated that they were not aware of the need and impact of having traceable and calibrated instruments in the hospital.
- Generally, we were informed that the content of the course will be very helpful for the daily work improvement as course participants indicated to be more aware of the risks and identified risks of infusion pump technology.

Promotion

The e-learning was promoted in various ways, such as announcements in trade journals, promotion on international conferences, and an online link on the website http://www.drugmetrology.com/.

Key outputs

- At project end more than 100 people involved in infusion technology (nurses, doctors, maintenance officers) were trained on the risks and best practices of this technology. This number exceeds the initial target at project start which was to train 100 users of infusion technology.
- With the aid of the feedback the e-learning course was further improved, making the knowledge more readily available to health care professionals.

- The workshops and trainings were a good formula to improve user awareness on multi-infusion best practices and the impact and need of having traceable and calibrated instruments in the hospital. The help of experts in the field of metrology and multi-infusion during the workshop was crucial to create optimal awareness and impact.
- The lessons learned during the sessions helped participants to improve on suboptimal practices in their own hospital, which were not recognized before as a possible negative impact on the patient safety.
- The e-learning course is, and will remain, freely available to the public through this link on the ESICM academy: https://academy.esicm.org/course/view.php?id=210. As the publicity of the e-learning and the ESICM platform increases, so will the awareness of the risks of multi infusion. And because the e-learning is, and will be, an open-access e-learning the information and cases will be available for every healthcare professional that wants to test and increase his or her knowledge on multi-infusion.

By training more than 100 users of infusion technology and making the e-learning publicly available, the objective of creating awareness and understanding of multi-infusion risks to increase the quality of medical treatment using this technology was met.

The wider impact of the e-learning is a reduced number of adverse patient incidents related to infusion technology.

Incorporating best metrology practices relating to calibration of infusion devices into standards

In the parent research project EMRP JRP HLT07 MeDD traceable calibration facilities were developed and validated for the low flow range (< 2 ml/h). At project start standards ISO 7886-2 “Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps” and IEC 60601-2-24 “Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers” were identified to benefit from incorporation of best metrology practices relating to the calibration of infusion devices. These standards are employed by manufacturers to develop drug delivery devices and by laboratories and maintenance departments of hospitals to verify and calibrate infusion devices. By incorporating the metrology practices into these standards, which is the second objective of the project, a lower calibration uncertainty is achieved corresponding to reduced risk of dosing errors.

ISO 7886-2 “Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps”

Results from the parent research project EMRP JRP HLT07 MeDD was presented to the ISO TC84/WG11 working group at the start of the project. Subsequently metrological content to ISO 7886-2 was submitted to the corresponding work group. Most metrological content for ISO 7886-2 was included into a new working draft. This working draft and additional comments from the working group TC84/WG11 were discussed in November 2018. Since many Participant-members were involved in composing the new working draft, positive feedback was received. The working draft was transformed into a committee draft ISO standard and the new revised standard, with inclusion of the best metrology practices, will be published in September 2019. It will have incorporated many of the EMRP JRP HLT07 MeDD results such as:

- The EURAMET guide 19 was added as reference for uncertainty calculation; there were no uncertainty calculation instructions in the standard before.
- The water density is now calculated, not a fixed number.
- The ambient conditions are established along with the thermo-stabilisation time.
- The type of water and thermometer characteristics are now established.
- The evaporation and buoyancy effects are now included in the calculations.
- The specification of the balance is established.

IEC 60601-2-24 “Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers”

Results from the parent research project EMRP JRP HLT07 MeDD was presented to the IEC 62D/MT23 subcommittee at project start. Suggestions for amendments to IEC 60601-2-24 including best metrology practice suggestions were submitted to the corresponding subcommittee IEC 62D/MT23 during the first months of the project. The planned revision of IEC 60601-2-24 was postponed several times and the IEC 62D/MT23 convenor resigned about halfway through the project. Before that, input on the degree to which the

comments of national committees agree was given, and the metrological comments were further detailed in a proposed “Metrology Annex“ to the standard. A new convenor of IEC 62D/MT23 was appointed around the beginning of 2019. The project’s input on best metrology practices was shared with the 62D/MT23 subcommittee in March 2019 with the intent to make the results of the project available for the further development of IEC 60601-2-24. Due to the revision of IEC 60601-1 - *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, the IEC goal is to have the IEC 60601-2-24 updated by 2020/2021. It is expected that the metrological amendments will be incorporated in this revised IEC 60601-2-24 by that time.

Further standardisation activities to disseminate best metrology practices

- A new work item “Manually operated precision laboratory syringes” 8655-9 was developed in ISO TC 48/WG4 using several inputs from the parent research project EMRP JRP HLT07 MeDD. This new standard will be available in 2020, and it is now in the ISO committee draft stage.
- Input to draft ISOTR24971 within TC210/JWG01 was provided by providing infusion pumps as an example that can help in identifying hazards and sequences of events that can lead to a hazardous situation.
- A good practices guide on infusion pumps was made available to the public in August 2018: http://www.drugmetrology.com/good-practices-guide-for-infusion-pumps/. Very good feedback was received. Figure 2 shows excerpts from this guide.

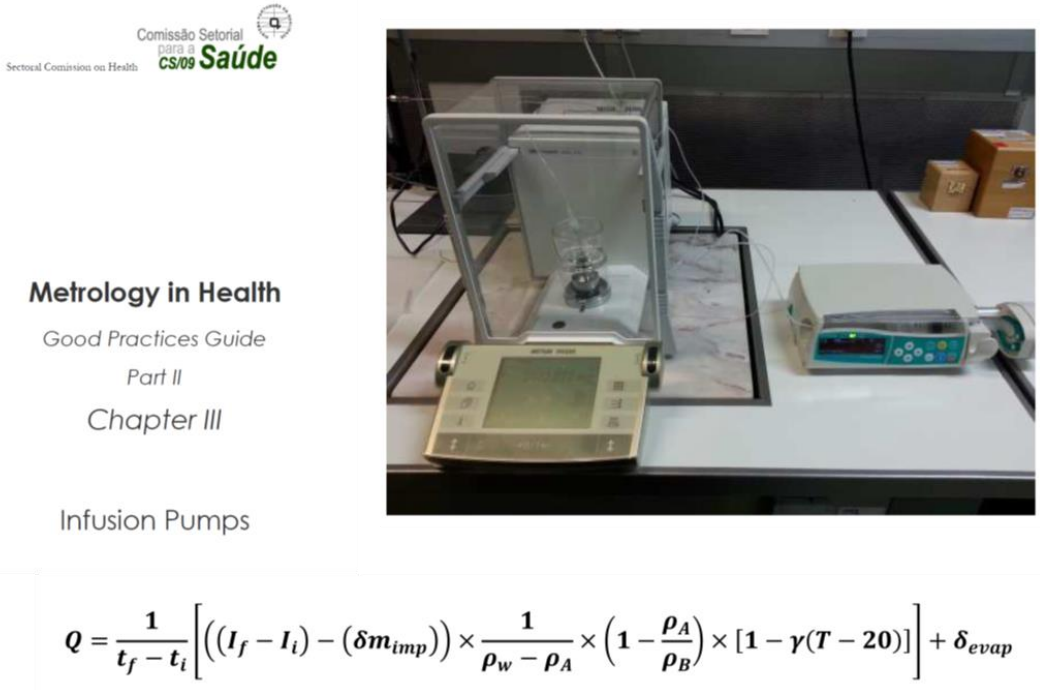

Figure 2: Excerpts from the good practices guide on infusion pumps showing cover page (top left), gravimetric calibration standard of a syringe pump (top right), and the equation to compute volumetric flow using a gravimetric standard (bottom).

Key outputs

Best metrology practices relating to calibration of infusion devices were incorporated into relevant ISO/IEC standards and a good practices guide:

- ISO TC84 WG11. ISO 7886-2 - "Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps". This standard was revised using the project consortium inputs on metrology and a new standard will be published in September 2019.
- IEC TC62D MT23. IEC 60601-2-24 - "Particular requirements for the basic safety and essential performance of infusion pumps and controllers". The project consortium inputs on metrology were incorporated into the report of comments for the proposed revision of the standard.

- ISO TC48 WG4. ISO 8655-9 - "Manually operated precision laboratory syringes". The project consortium inputs on metrology were incorporated into this new work item.
- ISO TC210 JWG01 ISO TR24971 - "Medical devices – Guidance on the application of ISO 14971". The project consortium inputs were incorporated into this draft standard.
- A publicly available good practices guide for infusion pumps was made which you can download from here: http://www.drugmetrology.com/good-practices-guide-for-infusion-pumps/

The input to incorporate best metrology practices into IEC 60601-2-24 was given while best metrology practices were incorporated into the new ISO 7886-2 standard just after the lifetime of the project meeting the second project objective for ISO 7886-2 in full.

5 Impact

Summary of dissemination activities

During the project partners have participated into conferences, standardisation committee meetings, and have written publications and articles to promote the e-learning and disseminate best metrology practices relating to calibration of infusion devices. Metrological input was given to IEC 60601-2-24, ISO 7886-2, ISO TC 48/WG4 and ISO TR24971. The primary supporter ESICM, has incorporated the revised e-learning into the ESICM Academy such that the users of infusion technology are made aware of the risks and best practices when using this technology. The ESICM and partners within the project organized live workshops to train users of infusion technology (clinician and technicians) where the e-learning material was disseminated.

The wider impact of the project is a reduced number of adverse patient incidents related to infusion technology, especially in neonatology where multiple pump infusion is typically combined with low flow rates. The route to impact is two-fold. First, the risks and best practices of infusion technology are disseminated through the e-learning amongst those involved in infusion technology. This will realise a better understanding of the importance of metrology and physics of infusion devices, thereby reducing the risks related to human interaction with multiple infusion pumps. Trainings were given that are based on the best practices developed in the EMPR JRP HLT-07 MeDD research project. Second, the outcomes of the project ensure that the best metrology practices related to the calibration of infusion devices are incorporated into revised ISO 7886-2 and IEC 60601-2-24 standards. This will ensure suitable calibrations to be performed by those relying on these standards. Following these two routes, the knowledge generated from the EMRP JRP HLT-07 MeDD project will be more widely disseminated to those involved in infusion technology and calibration.

The “Infusion Pumps” e-learning on the risks and best practices of infusion technology is freely available to the public: https://academy.esicm.org/course/view.php?id=210. It was launched in 2017 during the European Society of Intensive Care Medicine annual conference and is now part of the ESICM Academy, making it directly available for the relevant community. The e-learning will remain freely available to the public ensuring its further impact after completion of the project. The e-learning was successfully used in several workshops organised at European hospitals in which users of infusion technology were trained on the risks and best practices of infusion technology. At project end more than 100 people involved in infusion technology were trained on the risks and best practices of this technology. This number exceeds the initial target at project start. Furthermore, with the e-learning available to the public, there is no limit on the number of users of infusion technology that can be trained. Moreover, most of the feedback given following the live workshops and feedback given through the questionnaire was incorporated into an improved e-learning to further improve the learning experience of users of infusion technology.

The ISO 7886-2 standard “Sterile hypodermic syringes for single use – Part 2: Syringes for use with power-driven syringe pumps” was revised to include many of the metrology comments. The working draft was transformed into a CD draft ISO standard and the new revised standard, with inclusion of the best metrology practices, will be published in September 2019.

Metrology recommendations following from the EMRP JRP HLT-07 MeDD project results were made within the IEC 62D/MT23 subcommittee to improve the IEC 60601-2-24 standard “Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers”. These comments are expected to be included in future revisions of the standard. The IEC goal is to have the IEC 60601-2-24 updated by 2020/2021.

The standardisation activities will, in the longer run, have lasting impact, as manufacturers and hospitals relying on these standards will perform calibrations following these standards. Given the impact that standardisation can have further activities were undertaken such as the creation of a new work item “Manually operated precision laboratory syringes” 8655-9 within ISO TC48/WG4 and input to draft ISO TR24971 within TC210/JWG01.

Further effort was taken to disseminate best metrology practices by releasing a best practice guide on infusion pumps based on the EMRP JRP HLT-07 MeDD project results. This guide is freely available to the public: http://www.drugmetrology.com/good-practices-guide-for-infusion-pumps/.

The ultimate goal of the above disseminating activities is to make the health care community, especially the users of infusion pumps (nurses and hospital technicians), more aware of the potential risks with infusion devices. Ultimately this should facilitate an even better and safer health care.

6 List of publications

n/a

7 Contact details

n/a