Publishable Summary for 15SIP03 InfusionUptake

Standards and e-learning course to maximise the uptake of infusion and calibration best practices

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.

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.

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.

Results

This project undertook two activities:

1. Training course & workshops on the risks and best practices of infusion technology:

   The e-learning on the risks and best practices of infusion technology was successfully launched during the 2017 ESICM LIVES conference. It was developed to provide appropriate training to users of multi-infusion technology (nurses and hospital technicians) on the safe use of infusion pumps by creating awareness and understanding of the physics and metrology involved. 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. The course is comprised of a theory section followed by actual clinical and metrology cases from the field developed in cooperation with healthcare professionals. The ESICM academy was further rolled out in 2018 which brings strong exposure to the e-learning on the risks and best practices of infusion technology to the relevant community, i.e., users of infusion technology. The e-learning was promoted in various ways, such as announcements in trade journals such as Medicoteknik and Tecnohospital promotion on international conferences such as the 2017 ESICM LIVES, and an online link on the website http://www.drugmetrology.com/ of the research project EMRP JRP HLT07 MeDD. 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. This number exceeded the initial target at the project start which was to train 100 users of infusion technology. Several live workshops and events were organised in Denmark, France, Portugal, and The Netherlands. Many course participants have provided feedback at events, workshops, or online. The feedback was collected right after the workshop either from statements made by the course participants or through the questionnaire which is part of the e-learning. To follow-up on the feedback, sessions were held amongst partners and an ESICM Academy representative to implement the improvements. An extra metrology case was included and improvements in the course accessibility, readability and navigation through the e-learning were made. In general, positive feedback was received. The course participants that completed the entire e-learning course were positive about the quality of the information provided. 76% of the course

participants gave the e-learning a rating of at least 4 out of 5. Furthmore, the awareness and understanding of multi-infusion issues and risks therefore, was increased in more than 10 European hospitals and/or events due to this e-learning. 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. The wider impact of the e-learning is a reduced number of adverse patient incidents related to infusion technology.

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.

2. Incorporating best metrology practices relating to calibration of infusion devices into 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 calibration of infusion devices. Results from the EMRP JRP HLT-07 MeDD research project was presented to the ISO TC84/WG11 working group and IEC 62D/MT23 subcommittee at the start of the project.

Amendments to ISO 7886-2 were submitted to the corresponding work group. Most metrological amendments for ISO 7886-2 were included into a new working draft. The working draft ISO 7886-2 and additional comments from the working group TC84/WG11 were discussed in November 2018. Since many Participating-members in the ISO committee were involved in composing the new working draft ISO 7886-2, positive feedback was received during the ISO-meetings. The working draft was transformed into a committee draft draft ISO standard and the new revised standard, with inclusion of the best metrology practices, will be published in September 2019.

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 which resulted in the IEC 62D/MT23 convenor resigning. A new convenor of IEC 62D/MT23 was appointed in 2019. The project’s input on best metrology practices was shared with the IEC 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.

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.

Further standardisation activities to disseminate best metrology practices were undertaken:

- A new work item “Manually operated precision laboratory syringes” 8655-9 was developed in ISO TC 48/WG4 using several inputs from the EMPR JRP HLT-07 MeDD project. This new standard will be available in 2020, it is now in CD stage in ISO.
- Input to draft ISO TR24971 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 best practice guide on infusion pumps developed by IPQ based on the EMRP JRP HLT-07 MeDD project and results was translated to English and was made available to the public in August 2018: http://www.drugmetrology.com/good-practices-guide-for-infusion-pumps/. During the workshop participants expressed very good feedback.

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 organised 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.

Project start date and duration:	01 May 2016; 36M	
Coordinator: Dr. Menne Schakel, VSL, Tel: +31 15 2691681 E-mail: mschakel@vsl.nl Project website address: www.drugmetrology.com		
Primary Supporter: Alice Carter, *ESICM*		
Internal Funded Partners: 1. VSL, Netherlands 2. DTI, Denmark 3. IPQ, Portugal	External Funded Partners: 4. UMCU, Netherlands	Unfunded Partners: 5. ESICM, Switzerland