METROLOGY for DRUG DELIVERY



COVID-19 Crisis & Emergency Practices with Drug Infusion Pumps in ICU The Role of Metrology

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Challenges



The unprecedented conditions Public Health Institutions experience due to COVID-19 pandemic crisis have forced the hospital administrations to use procedures *outside the usual work practices* in order to mitigate several challenges:

Reduction of health care staff exposure to COVID-19
Conservation of personal protective equipment (PPE)
Manage shortages of equipment



COVID-19: adapted pratice for Drug Delivery Devices

The procedures taken by some Hospitals *outside the usual work practices* include:

- 1. To use the drug delivery devices outside the patient's room
- 2. Use of drug delivery devices outside of manufacturer specifications
- 3. Delayed maintenance and calibration of equipment for patient-critical use

These practices can cause large dosing errors resulting in adverse incidents, morbidity and mortality

Can Metrology help in decision making?



1. Use the drug delivery devices outside the patients' room

Use of drug delivery devices outside the patients' room: Questions....

- 1. Is delivery through long extension tubing appropriate for the specific patients medication administration?
- 2. Are there limitations in the performance of the infusion pump stated by the manufacturer?
- 3. Are there risks for infection?
- 4. Is this setup going to lead to significant conservation of PPE?
- 5. Are there other / better solutions for saving PPE use, *e.g.* remote control, robots, reusable PPE?
- 6. Is the accuracy of the device affected by the setup?

Which factors affect the decision ?





Non-Conventional Practice: Putting the Pump in the Hallways



1. Set up of the infusion pump *a. Extension tubing*

- Priming volume increases with extensions
- Increased fluid flow resistance
- Accuracy may be affected, specially at low flow rates
- ✓ Risk of under infusion
- More bubbles in the system due to the incorrect priming and the extra connections
- ✓ Fluid viscosity effects can be found with long extensions
- Several problems with occlusion alarms may occur depending on the type of line.

Critical Concerns



Non-Conventional Practice: Putting the Pump in the Hallways



- 1. Set up of the infusion pump
- b. Position of the devices outside the room
 - Availability of sufficient power outlets in the hallways
 - Accessible rooms & corridors (distance & fire regulations cannot be adhered to)
 - Labeling the tubing inside and outside the room
 - ✓ Secure tubing to avoid disconnection
 - Route the tubing into the patient room without keeping the door open
 - Adhere to regulations when tubing is routed into negative pressure rooms

Critical Concerns





In case of FIRE??

Metrology Recommendations



It is recommended to *test the flow rate* and *volume* delivered when using extension lines, especially at low flow rates, as the accuracy of the device may change due to setup modification and the *pump will not perform* according to the specifications of the manufacturer.



2. Use of drug delivery devices outside of manufacturer specifications

Use of drug delivery devices outside of manufacturer specifications



1- Replacement of syringe infusion pumps by volumetric infusion pumps

- Volumetric infusion pumps can produce, due to their mechanical design, a continuously oscillating dosing error in the flow rate of approximately 1.5 ml/h.
- To minimize the impact of this error, the oscillation of 1.5 ml/h should always be less than 10% of the setpoint flow rate, hence a flow rate of greater than 15 ml/h is required.



Syringe pump

Volumetric pump



Use of drug delivery devices outside of manufacturer specifications - Guidelines



- 1) Replacement of a syringe pump by a volumetric pump if the flow rate of the volumetric pump is greater than 15 ml/h
- 2) Infusion bag : To be connected to a separate lumen within the catheter
- 3) Highly active or short $t_{1/2}$ substances: Always use a syringe pump
- 4) Noradrenaline : Do NOT use a volumetric pump. Always use a syringe pump

Use of drug delivery devices outside of manufacturer specifications - Guidelines



5) If syringe pump is connected together with a volumetric pump on the same lumen. Then flow rate of each pump must be great than 15 ml/h

6) IMPORTANT

If multiple pumps have been connected to the same lumen :

Make sure to always close ALL infusion taps and stop cocks (connected to that single lumen) directly PRIOR to a syringe exchange, and to open them ALL again ONLY AFTER all pumps have been re-activated Use of drug delivery devices outside of manufacturer specifications



2- Other variations to the manufacturer specifications

• Any other variation to manufacturer specification should be validated by performance tests done by qualified laboratories in order to assure accuracy of the results.



3. Delayed maintenance and calibration of equipment for patient-critical use



Delaying maintenance and calibration of equipment

Normally the verification of the pumps is performed using a pump device analyzer or using the gravimetric calibration method.



Calibration of a syringe pump using the gravimetric method





Delaying maintenance and calibration of equipment

It is possible to perform a *quick check* of the pumps dosing error using a measuring cylinder and a stop clock.

- 2% uncertainty
- ✓ Done in 10 minutes
- Simple check for the metrological performance of the pump
- Evidence to justify extending verification deadline

Measuring cylinder

Stop clock



Syringe pump

Conclusions



To overcome some hospital challenges using drug delivery devices during the COVID-19 situation *procedures outside the normal work practices* can be taken under controlled conditions in order to avoid large dosing errors that may result in adverse incidents, morbidity and mortality. **Metrology** is a key factor in decision making.

Metrology can advance the understanding of how drug delivery devices perform in non-ideal conditions of use through testing to mimic the setups used in hospitals. Testing with the actual fluids used for patient infusions can identify errors and quantify uncertainties. This type of testing enables the development of best practice and methodology for using drug delivery devices in challenging conditions of use.

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THANK YOU

Further info:

DrugMetrology.com