

5PSQ-138 BEST PRACTICE OF WARD-BASED RECONSTITUTION IN PAEDIATRIC HOSPITALS

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Objectives

This project investigates additional risk classification and best practice video instructions to each drug in the Swedish Formulary for Paediatric Medicines ePed [1], with ePed-ID 1417 (vancomycin intravenous infusion 5 mg/mL) as an example (Fig 1).

Method

This project is part of the Swedish National Pharmaceutical Strategy [2] and consists of four work-packages during 2017-2018,

- 1) Risk assessment developed by EDQM [3]
- 2) Usage of video recording to assess reconstitution in six different paediatric settings
- 3) Identification of best practice by a Delphi process
- 4) Recording of professional videos for instruction purposes.

Results

Six paediatric units contributed to the investigation of 100 of 630 ePed-IDs during four months in 2017. Using vancomycin as an example, two units order Ready To Use (RTU) to lower the residual risk. Four units use closed-systems, and three of the four units added risk reducing strategies such as a hood or forced ventilation. By observing the recorded videos (Fig 2), different strategies were present, e.g. additional protective clothing and processes in units with non-validated closed system. The risk assessment (Tab 1) will result in three videos for instruction purposes regarding vancomycin;

- 1) RTU
- 2) validated closed-system reconstitution
- 3) non-validated closed-system reconstitution with protective clothing and forced ventilation

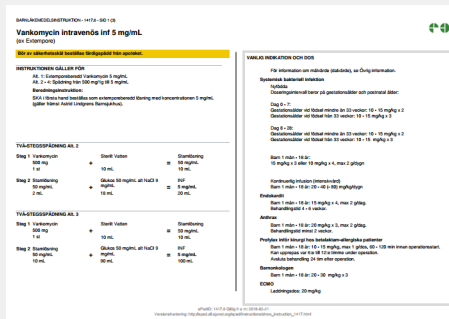


Figure 1. the Swedish Formulary for Paediatric Medicines with ePed-ID 1417 vancomycin intravenous infusion 5 mg/mL as an example, showing page 1 of 3.

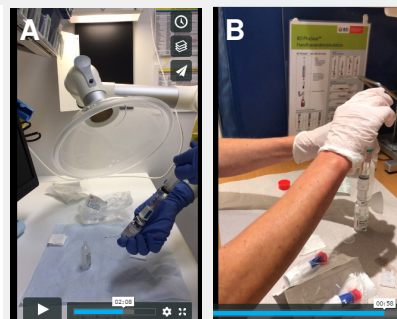


Figure 2. Video recording of ward-based reconstitution of antibiotics for A) non-validated closed-system reconstitution and B) validated closed-system reconstitution

Discussion

The use of the EDQM risk assessment by analyzing video recordings resulted in both major and minor findings. The major findings are carried through a Delphi process and the best practice identified will be processed into an educational video platform with a goal to achieve safer reconstitution.

References and acknowledgements

1. <http://www.eped.se> [In Swedish]
2. Financial support from The Swedish National Pharmaceutical Strategy
3. European Directorate for the Quality of Medicines and Healthcare, Resolution CM/Res (2016)2 On Good Reconstitution Practices in Health-Care Establishments

Risk assessment	1417	1417
ePedID	1417	1417
Product	Vancomycin iv inf 5 mg/mL	Vancomycin iv inf 5 mg/mL
Clinical Area	Prediluted from the pharmacy	Reconstitution at the ward
Hospital (type of unit)	Karolinska (Ward), Sahlgrenska (Ward)	Akademiska (Neo), Falun (Ward), Linköping (Neo), Lund (PICU)
Assessment by	Best Practice project	Best Practice project
A Risk microbiological contamination	Low	Medium
B Risk incorrect composition	Low	Medium
C Risks for the staff	Low/Medium	Medium
D Risks related to the pharmacological activity	Low (when monitored)	Low (when monitored)
E Any other risks not recorded above	Low	Low
Risk reducing strategies:	Ready To Use (RTU) product. Simplest range of concentrations. Most appropriate vials. Dose-Checking Software and calculating tools and local protocols (ePed).	Validated closed-system reconstitution or non-validated closed-system reconstitution with recommendation of protective clothing and forced ventilation. Simplest range of concentrations. Most appropriate vials. Dose-Checking Software and calculating tools and local protocols (ePed). Do not store the stock solution after dissolution.
Suitable for reconstitution in clinical area:	No, use RTU	Yes
Justification for the decision:	Use RTU due to previous adverse drug events caused by 10 fold dilution errors when not performing a two step dilution procedure.	Due to, a few orders of vancomycin it is not possible to store RTU. No storage of stock-solution (50 mg/mL) is allowed and proper use of closed systems is necessary.

Table 1: Risk assessment and risk reducing strategies for ePed-ID 1417 vancomycin intravenous infusion 5 mg/mL with or without the use of Ready To Use (RTU) products as a risk reducing strategy. This assessment have so far been carried out for 100 ePed-IDs out of 630.

Conclusions

- Hospitals act with different risk reducing strategies
- The residual risk of reconstitution can easily be captured by video imaging
- All instructions in the Swedish Formulary for Paediatric Medicines (ePed) are to be risk assessed
- Suggested risk reducing strategies are carried through a Delphi process
- The Delphi consensus of risk reducing strategies is used to produce video instructions for an educational video platform