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New bulsulfan procedure to improve both preparation and administration

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Background

During the pharmacy days off, nurses had to prepare diluted busulfan solution from commercialized vials under a vertical laminar air flow hood, just before the administration because of its low stability (12h at 4°C). This protocol may induce occupational exposure to this cytotoxic drug.

Purpose

The aim of this work is to present a new preparation protocol and its preliminary evaluation.

Materials and Methods

✓Bibliographic and technical studies were performed to choose the best medical devices.

✓ Satisfaction of nurses and physicians was assessed by using a 5-items form.

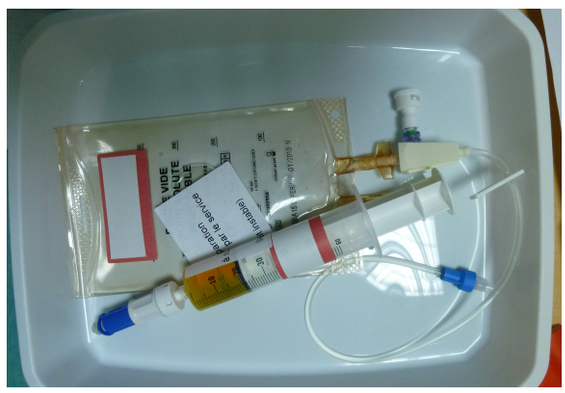
Results

Medical devices containing polycarbonate must be avoided because of the interaction with N'N-dimethylacetamide used as excipient in the formulation[1].

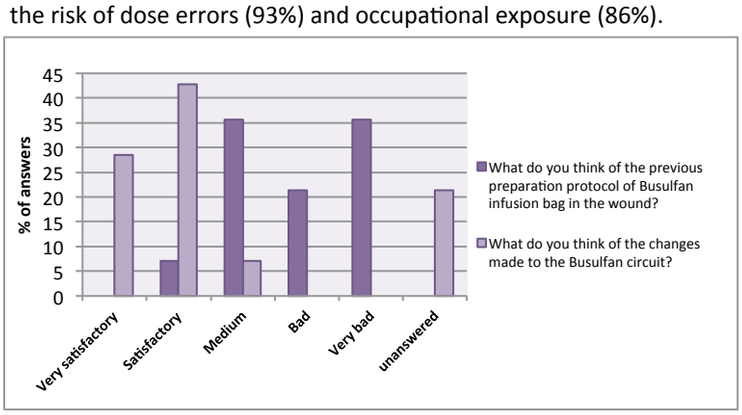
New kits/patient prepared by the pharmacy were proposed and then sent to the ward comprising:

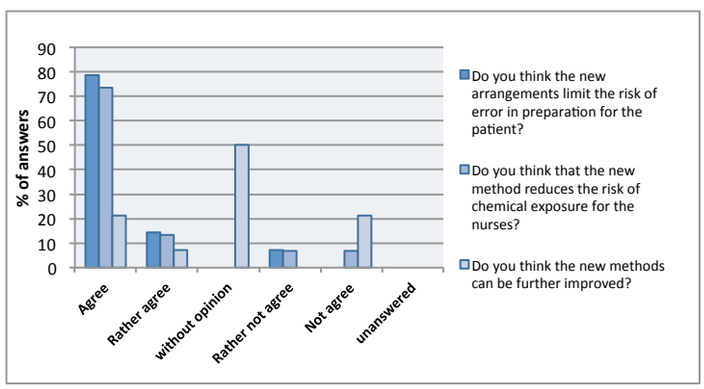
- Specific 3-parts syringes (reference 62.8426, Codan®) containing the right drug amount of commercial solution
- An infusion bag with the exact volume of diluent
- PhaSeal Injector® (BD - Becton Dickinson & Company) are used to close syringes and Connector-Luer® are connected to the infusion bag

Then, nurses just have to dilute the busulfan solution in the bag under a vertical laminar air-flow just before the administration.



Trough a period of 8 days off, 7 new kits were prepared. The results of the evaluation show that nurses and physicians (N=14) were overall unsatisfied by the previous protocol (mean: 35.7%, bad: 21.4% and very bad: 35.7%) while the majority preferred the new one (very satisfied: 28.6%, satisfied: 42.9%, mean 7.14%, no response: 21.4%). Overall nurses and physicians answer that new modalities limit the risk of dose errors (93%) and occupational exposure (86%).





Discussion

Despite the use of 2-parts syringes in the bibliography[2-3], 3-parts syringes with limited contact between elastomeric tip and busulfan solution were chosen because leaks were observed with the 2-parts syringes during the technical study. PhaSeal devices were specifically chosen as closed-system transfer device because they are polycarbonate-free.

The main limitation of this protocol is that a dilution step in a Biosafety Cabinet is still required to achieve the preparation
This protocol needs to be improved in the aim to deliver a ready-to-use preparation to the ward.

Conclusion

Implementing this procedure enhances improving good handling practices with good satisfaction of nurses and physicians.

References

1- Busilvex, Summary of Product Characteristics, available on the European Medicine Agency website: http://www.ema.europa.eu/
2- Senoo M, Tajika K, Shimizu H, Hamada M, Dobashi Y, Dobashi A, et al. Development of new mixing method of Busulfex injection for the purpose of improvement of medical safety method: the prefilled syringe method. Yakugaku Zasshi. 2009 juin;129(6):767-71.
3- Karstens A, Krämer I. Stability of busulfan injection solution (Busilvex, Busulfex) in B/Braun Injekt syringes. Pharmazie. 2006 oct;61(10):845-50.