Pediatric Blinatumomab Preparation: Risk Assessment and Compliance of Management Software

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DESCRIPTION

Blinatumomab is an anticancer drug used in the treatment of Acute Lymphoblastic Leukemia (ALL) in both adults and children, the preparation of which is unique and extremely complex. In pediatric field, unlike the adult world, blinatumomab must be prescribed according to unconventional rules: from EMA-SmPC, patients in a certain range of body surface area (e.g. 0.8-0.89 m2) should receive the same dose (e.g. 49.09 mcg for 96 hours). Even during the preparation phase, Technicians or Nurses must obtain the volume of the drug to be prepared corresponding with the specific body surface interval reported in the SmPC. To calculate the total dose into the infusion bag it is necessary to know three different parameters: Dose to be administered, dose lost in the "dead volume" of the infusion set used and dose needed to compensate for the average overfilling of industrial bags. Based on the Risk Assessment analysis, all these variables require management and computerized control of the entire process but at today no software manages so many variables. As working group we need to obtain all possible information to identify the critical issues related to the preparation of pediatric doses of this difficult drug.

The first step was to do an in-depth analysis of the SmPC looking for critical issues and unclear points; than we created a questionnaire to be submitted to the manufacturer to clarify all the possible problems. With the answers obtained, we realized a shared procedure between prescribers, staff of the centralized chemotherapy preparation laboratory and administering nurses, aimed at reducing the clinical risk related to the management of the drug blinatumomab: in this way we were able to obtain computerized prescriptions correct on the real dose to be prepared, secure worksheets with computerized processing of all variables (volumes to be added and corresponding drug dose) and complete labels containing all the information necessary for checking the preparation and its correct infusion.

The standard operating modes of the main oncology prescription software provide that the doctor only has to round or reduce a dose reported automatically by the computer system or calculated by the computer based on the body surface weight, or AUC, as per the setting of a previously shared protocol and validated by a doctor and pharmacist. The UFA technician or nurse prepares the drug according to the worksheet. The volume is automatically calculated based on the "drug" master data contained in the software and validated by a pharmacist. The drug blinatumomab, due to its particular dosage and infusion technique, overturns the traditional rules for setting up and administering antineoplastic drugs and in part also eludes the support of the UFA management software.

Computerization in the preparation process of antiblastic drugs is a necessary path for the safety of the patient and of all the operators involved; however, sometimes the specificity of the set-up is not compatible with the rigidity of the software. Not being able to have software already perfected on such a unique and recently released drug, a multidisciplinary team, made up of Physicians, Pharmacists, Nurses, Laboratory Technicians and Computer Scientists, shared their skills and knowledge, to design a system that was certainly not free from the risks, but which made handling blinatumomab much safer.

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