

REMS survey 20210065 Abstract May23 2022

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Title: Healthcare Providers' Awareness of the Risks and Safety Associated With BLINCYTO® use: A 2021 REMS Assessment Survey

Rationale and Background

BLINCYTO® (Blinatumomab) is a bispecific T-cell engager indicated for the treatment of relapsed or refractory (R/R) CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL). A Risk Evaluation and Mitigation Strategy (REMS) with goals to mitigate the risks of cytokine release syndrome (CRS), neurologic toxicities, and preparation and administration errors, was identified at the time of approval of the biological license application (BLA). Previous REMS assessment surveys have studied three populations: prescribers such as medical doctors, physician assistants, and nurse practitioners; nurses; and pharmacists. Results from the 5-year REMS assessment (submitted December 2019) indicated that surveyed physicians, pharmacists, and nurses demonstrated adequate knowledge of the risks of cytokine release syndrome and neurological toxicity associated with BLINCYTO. Surveyed pharmacists and nurses, however, had lower understanding of the risk of preparation and administration errors associated with the use of BLINCYTO. This REMS assessment conducted 7 years after the launch of BLINCYTO in the US assessed awareness and knowledge of preparation and administration errors associated with BLINCYTO use among pharmacists and nurses.

Research question and objectives

The broad objective of this study was to determine the level of awareness of the risks and safety associated with BLINCYTO therapy and certain aspects of the BLINCYTO REMS Program among pharmacists and nurses who have used BLINCYTO for patients in the treatment of R/R ALL.

The specific objective was to evaluate the awareness and understanding of the preparation and administration errors associated with BLINCYTO use among pharmacists who have prepared BLINCYTO, and nurses who have administered BLINCYTO.

Study design

An online cross-sectional survey was conducted among pharmacists and nurses who have dispensed, prepared and/or administered BLINCYTO in the US in the past 12 months outside the clinical trial setting. Previous similar surveys were conducted at 18 months, 3 years, and 5 years after the launch of BLINCYTO. This cross-sectional survey was conducted 7-years after the launch of BLINCYTO in the US.

Setting

This 7-year assessment was administered by NAXION Research Consulting, an independent research group. Invitations for participation in the survey were sent to all nurses and pharmacists with a matched specialty who were on professional panels maintained by the recruiting agency. Both online and computer-assisted telephone interviewing surveys were offered; however, all respondents elected to complete the survey online.

Subjects and Study Size, Including Dropouts

Pharmacists and registered nurses were included in the current round of the REMS assessment. Eligible participants were those who had dispensed, prepared, and/or administered BLINCYTO within the past 12 months outside the clinical trial setting. There were 101 registered nurses and 101 pharmacists studied.

Variables and Data Sources

The main endpoint of interest in this assessment is the awareness of the risk of preparation and administration errors associated with use of BLINCYTO®; including frequency of errors, medication errors such as underdosing and overdosing, adherence to instructions and guidelines for change of infusion bags, and reconstitution of BLINCYTO. Other variables include knowledge about preparation

instructions, access to checklists and Product Information/Package Insert (PI) in the workplace setting of pharmacists and nurses, and awareness and utilization of REMS materials.

Results

- Overall, 69% (95% CI = 60% - 78%) of nurses and 61% (95% CI = 52% - 71%) of pharmacists correctly identified $\geq 75\%$ of the items in their respective preparation and administration error questions, and thereby were considered to have knowledge of the risk of preparation and administration errors associated with BLINCYTO, which was below the prespecified 80% threshold. Greater than 85% of nurses and pharmacists reported that they should follow the preparation instructions provided in the Full Prescribing Information when preparing BLINCYTO, although they cannot recall full details in the foil questions.
- Most nurses and pharmacists indicated that reference materials (eg, checklists or step-by-step instructions) and/or colleague support (eg, colleague recheck of actions) were available in their practice setting when preparing or administering BLINCYTO. Specifically, 88% of pharmacists indicated that step-by-step instructions for preparing BLINCYTO, either the Prescribing Information/Package Insert or instructions developed by the facility, are kept open for reference when BLINCYTO is prepared, and 77% of pharmacists reported that preparation of BLINCYTO is checked by 2 pharmacists. Similarly, 91% of nurses stated that the dose on the bag is checked by 2 nurses before BLINCYTO is administered and 89% of nurses indicated that a reference material (eg, checklist) for proper BLINCYTO administration is available, whether in the electronic medical record, on the floor, or delivered alongside the drug.
- Most nurses (84%) indicated that the tubing is primed by pharmacy staff before BLINCYTO is delivered for administration. Of the subset of nurses who have personally prepared BLINCYTO for infusion, 86% were aware that when preparing BLINCYTO, the preparation instructions provided in the Full Prescribing Information should be followed. Thirty-eight percent (38%) of nurses who have personally prepared BLINCYTO for infusion recognized the benzyl alcohol preservative foil statement
- HCPs were most aware of the Full Prescribing Information for BLINCYTO (87% nurses and 90% pharmacists). Additionally, most nurses and pharmacists cited other HCPs/colleagues, drug, and prescribing databases, and the BLINCYTO product website as the sources they used to learn about the risk of preparation and administration errors associated with BLINCYTO. Most nurses

and pharmacists were aware of the BLINCYTO REMS Fact Sheet and website; awareness and use of the BLINCYTO REMS letters were relatively low.

Discussion

The knowledge rates achieved for the key risk of preparation and administration errors associated with BLINCYTO have been generally consistent across the 3-, 5-, and 7-year surveys, with the knowledge rates for nurses and pharmacists ranging from 69% to 74% and 56% to 70%, respectively, over the past 3 reporting periods. Overall, the results of the 7-year survey indicate that HCPs are aware of the risk of preparation and administration errors associated with BLINCYTO treatment. Although the composite passing scores for nurses and pharmacists were below the desired 80% knowledge threshold, $\geq 89\%$ of nurses and $\geq 93\%$ of pharmacists were consistently aware that the Full Prescribing Information contains the most complete BLINCYTO preparation and administration instructions across the surveys.

Results from the previous BLINCYTO REMS Assessments indicated that surveyed physicians, pharmacists, and nurses demonstrated adequate knowledge of the risks of CRS and neurological toxicity associated with BLINCYTO. The goal of the BLINCYTO REMS, to inform HCPs about these specific risks of BLINCYTO treatment, is being met and, from cumulative experience, the Communication Plan and Prescribing Information have been effective in communicating these risks to HCPs.