ASSOCIATION OF COMMUNITY
CANCER CENTERS

USING BISPECIFIC ANTIBODIES IN COMMUNITY PRACTICE
Challenges and Opportunities

The Association of Community Cancer Centers (ACCC) education program, *Preparing Community Providers for Bispecific Antibodies*, seeks to identify and address barriers to the awareness, preparedness, adoption, and use of bispecific antibodies (BsAbs) for the treatment of cancer by the cancer care team. This publication provides an overview of bispecific antibodies and presents the results of an ACCC survey of multidisciplinary providers to assess their understanding of and readiness for using BsAbs in the treatment of patients with cancer.

BACKGROUND

BsAbs are an emerging class of novel immunotherapy agents that have led to major breakthroughs in the treatment of hematologic malignancies, and they have promising applications for treating solid tumors. Since the 1960s, researchers have been designing BsAbs by combining two different antigen-binding fragments into a single antibody construct.[1] By targeting two separate antigens at the same time, BsAbs can bridge tumor cells to cytotoxic immune cells. This construct can bypass several limitations of conventional monoclonal antibody (mAb) treatment, including low tumor penetration and drug resistance.[2]

During the past few decades, advances in genetic engineering have significantly accelerated the development of BsAbs, resulting in the invention of more than 100 different formats.[3] In general, BsAbs can be divided into two main categories: those with the Fc domain and those without.[4] In antibodies, the Fc region is responsible for mediating the immune response generated by an antibody by binding to various immune molecules and cell receptors.[5]

An Fc domain provides better stability, longer half-life, and the ability to stimulate secondary effector functions compared to BsAbs without Fc domains. However, using Fc domains presents its own disadvantages, such as the potential for generating mis-paired byproducts and purification challenges.[6] While BsAbs without Fc domains are easier to produce and have better penetration into tumor tissue, they require more frequent dosing due to their shorter half-lives.

While BsAbs have great therapeutic potential, they can also have unique and serious toxicities and practical considerations that can preclude their widespread use in the community practice setting. To provide optimal care to patients being treated with BsAbs, clinicians must understand the unique pharmacology and potential clinical and logistical challenges of these agents. Successful administration of BsAbs requires competence and effective collaboration among multidisciplinary providers on the cancer care team.

BLINATUMOMAB: THE FIRST FDA-APPROVED BsAb

In 2020, ACCC conducted a survey that it developed through an expert Advisory Committee and insights from interviews with clinicians at community cancer programs. The survey was built using Qualtrics online survey software and administered via eblast to ACCC members, specifically targeting oncologists, advanced practice providers, nurses, and pharmacists. The survey, to which 129 individuals responded, primarily assessed experiences with *blinatumomab*, the only FDA-approved BsAb for the treatment of malignancy at the time.[7]

Blinatumomab is a bispecific T-cell engager (BiTE®) that binds to CD19 receptors on B cells and CD3 receptors on T cells simultaneously. Upon binding, a synapse is formed between the tumor cell and the

T cell, and cytotoxic proteins are released from the T cell to induce apoptosis of the CD19+ B cell. Additionally, blinatumomab leads to T cell activation and proliferation and promotes the release of inflammatory cytokines and cytotoxic proteins, which can potentially target neoplastic B cells.[7]

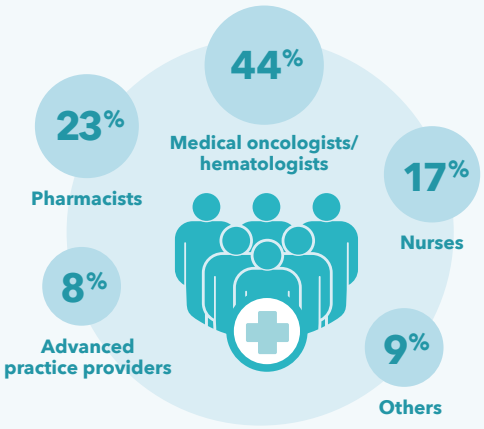
Blinatumomab consists of two single-chain fragment-variable antibodies tethered by a short peptide linker.[8] It has a brief half-life of 2 hours, and therefore must be administered by continuous intravenous infusion over 28 days. Pharmacodynamically, blinatumomab leads to a decline in peripheral B cell counts within 2 days, which lasts throughout the treatment period. An increase in T cells and cytokines, particularly IL-10, IL-6, and IFN-, also occurs to varying degrees in the weeks following blinatumomab treatment.

ACCC's survey attempted to gain an understanding of respondents' experiences with blinatumomab and emerging BsAbs. Of the 129 people who responded to the survey, 60% said they have prescribed, dispensed, or administered blinatumomab or have cared for patients being treated with blinatumomab. However, the provider experience with blinatumomab varies greatly, with 92% of the oncologists surveyed reporting that they have cared for patients on blinatumomab, and only 35% of nurses reporting having done so. Of those reporting experience with blinatumomab, 44% are medical oncologists or hematologists, 23% are pharmacists, 17% are nurses, 8% are advanced practice providers, and 9% are of various other disciplines. Forty-two percent of the respondents reporting experience with blinatumomab work at community cancer programs, 36% are from academic/NCI cancer programs, 18% are from private/physician practice, 3% are from other types of organizations, and 1% are from veterans' affairs cancer programs.

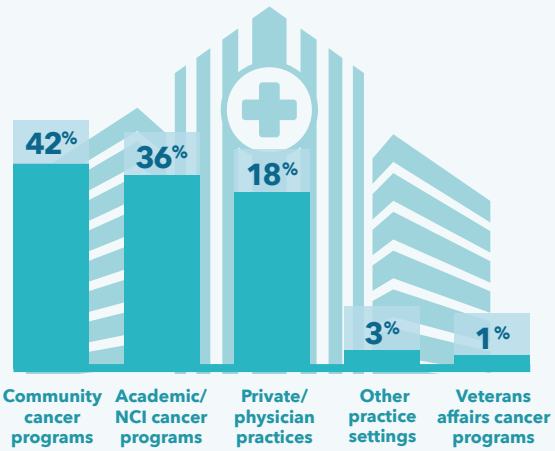
The clinical efficacy of blinatumomab has been demonstrated in measurable residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) and relapsed or refractory (R/R) B-cell precursor ALL in adult and pediatric patients.[9] In the BLAST study, patients 18 years or older who were in complete remission after three or more blocks of intensive chemotherapy with persistent MRD 0.1% received blinatumomab for up to four cycles. Following treatment, 78% of evaluable patients achieved a complete MRD response. The median overall survival was 36.5 months. The median relapse-free and overall survival were longer in complete MRD responders at 23.6 and 38.9 months, respectively, compared to 5.7 and 12.5 months in non-responders.[10]

Blinatumomab was compared to standard of care (SOC) chemotherapy in the phase 3, randomized, controlled TOWER study for relapsed/refractory (R/R) B-cell precursor ALL. A significant improvement in overall survival was observed in the blinatumomab treatment group compared to SOC chemotherapy (7.7 months vs. 4.0 months, hazard ratio 0.71). In the ALCANTARA study (with Philadelphia chromosome-positive B-cell precursor ALL), Study MT103-211, and Study MT103-205 (in pediatric patients), 36%, 41.6%, and 32.9% of R/R patients receiving blinatumomab achieved complete remission or complete remission with partial hematological recovery within two cycles of treatment. In addition to B-cell precursor ALL, blinatumomab has also shown promising results in early-phase studies of R/R Non-Hodgkin's Lymphoma, although this indication is not currently FDA approved.[11,12] Regarding its use in the community, ACCC survey results show that 59% of institutions use blinatumomab in the R/R setting, while 41% use it for MRD-positive B-cell precursor ALL. Seventy-four percent of oncologists use blinatumomab before CAR-T therapy for patients with B-cell precursor ALL.

Respondents Familiar with Blinatumomab



Survey Respondents' Practice Settings



BLINATUMOMAB SAFETY CONCERNS

The major safety concerns of blinatumomab are neurotoxicity and cytokine release syndrome (CRS). Neurotoxicity typically presents within the first seven days of treatment and can manifest as confusion, dizziness, somnolence, seizure, delirium, encephalopathy, speech disorders, or loss of consciousness. More than 50% of patients experience some type of neurotoxicity with blinatumomab, although most events are low-grade and resolve with interventions. Steroids are the primary treatment for this neurotoxicity, but drug interruption and potential discontinuation are recommended for grade 3 or higher neurotoxicity.[13] Older adult patients (>65) and patients who have had previous neurological events appear to be at higher risk for developing neurotoxicity with blinatumomab.[7,13]

CRS is a systemic inflammatory response that occurs because of the increase in cytokines triggered by blinatumomab. Symptoms range from fevers, malaise, and hypotension to signs of multi-organ dysfunction, including renal or hepatic dysfunction, pulmonary edema, capillary leak, and disseminated intravascular coagulopathy.[13] In clinical studies, CRS symptoms generally occurred at lower rates when compared to neurotoxicity and were more likely to occur at higher initial doses of blinatumomab and in patients with high disease burden. As patients with R/R disease have higher disease burden, CRS from blinatumomab is observed more commonly in the R/R population than in MRD-positive B-cell precursor ALL.[14]

To minimize CRS and neurotoxicity, the dose of blinatumomab for R/R B-cell precursor ALL starts at 9 mcg/day for those weighing 45 kg, or 5 mcg/m2/day for those weighing < 45 kg and is subsequently increased to 28 mcg/day (patients 45 kg) or 15 mcg/m2/day (patients < 45 kg) after the first seven days of cycle 1. For MRD-positive B-cell precursor ALL, the dose of blinatumomab is 28 mcg/day for patients weighing 45 kg and 15 mcg/m2/day for patients weighing < 45 kg. Additionally, dexamethasone premedication should be given at the time of treatment initiation, when the dose is increased, and after any treatment interruption of four hours.[9] For severe CRS, tocilizumab can be used to mitigate symptoms and potentially prevent fatal CRS.[15]

Blinatumomab can be prepared as a 24-hour, 48-hour, or 7-day infusion.[9] Clinicians should choose the appropriate infusion duration based on the patient's weight and the optimal frequency of bag changes for the patient. The reconstitution and administration of blinatumomab is complex and requires well-trained pharmacy and nursing staff to minimize medication errors. Considering the toxicities and the complex administration associated with blinatumomab, the FDA has established a REMS program to educate providers and monitor for toxicities and administration errors.[16] Besides neurotoxicity and CRS, blinatumomab can also lead to infections, tumor lysis syndrome, myelosuppression, and other less common side effects.

AMIVANTAMAB

Most recently, *amivantamab-vmjw* was approved in May 2021 as the first BsAb indicated for a solid tumor. Amivantamab interrupts EGFR and MET signaling in non-small cell lung cancer (NSCLC) and is specifically approved for patients with advanced NSCLC with exon 20 insertion mutations, a set of mutations that has not been the target of any approved treatments until now.[17] The efficacy of amivantamab was evaluated in the CHRYSALIS trial, which showed an overall response rate of 40% and a duration of response of 11.1 months in patients who were previously treated with platinum chemotherapy.[17] Unlike blinatumomab, amivantamab contains an Fc region, so its half-life is considerably longer at 11.3 days. This half-life allows for a more straightforward administration schedule that can be done in the outpatient setting, although there are still challenges for the first few infusions. Since there is a risk of infusion-related reactions with amivantamab, premedications are recommended. And since amivantamab is not a T cell engager, it does not come with the risk of CRS, although it is associated with rash, paronychia, musculoskeletal pain, nausea, stomatitis, interstitial lung disease, and ocular toxicity.

Aside from blinatumomab and amivantamab, *emicizumab* is the third FDA-approved BsAb on the market. Emicizumab is directed at activated Factor IX and Factor X to mimic activated Factor VIII, thereby restoring the coagulation cascade and promoting hemostasis, particularly in patients with Factor VIII deficiencies.[18] It is indicated for prophylactic use to prevent or reduce bleeding in patients with hemophilia A.

BsAbs IN CLINICAL TRIALS

The success of blinatumomab has inspired a global interest in the development of BsAbs, with more than 110 antibodies currently in clinical trials.[19] Most BsAbs in the pipeline are designed for cancer indications, although a small number are also being produced for non-oncology purposes. Within oncology, BsAbs are more often developed for hematological malignancies compared to solid tumors. Solid tumors tend to have antigens that are also expressed in low levels in normal tissues, making it challenging for a BsAb to direct an immune response at a tumor cell without subjecting normal cells to adverse effects.[3] Many BsAbs are currently being studied for a variety of solid tumors, including, but not limited to, NSCLC, SCLC, glioblastoma, gastric cancer, colorectal cancer, ovarian cancer, prostate cancer, and breast cancer.

The majority of BsAbs in development are known as obligate BsAbs, meaning that they induce a novel functionality that is dependent upon the connection of two entities by the BsAb. The primary example of this concept is T cell redirection, whereby a BsAb links effector T cells to tumor cells to induce cytotoxicity.[3] As with blinatumomab, most T cell-targeting BsAbs are designed to bind to CD3 with one arm and to a tumor antigen with the other arm, such as BCMA, CD20, CD33, CD38, FLT3, GPC3, HER2, MUC16, or PSMA. One promising example is *mosunetuzumab*, a CD20 and CD3 BiTE that has recently obtained breakthrough therapy designation for R/R follicular lymphoma.[20] One disadvantage of T cell redirection is that the BsAb activates all T cell lineages, leading to an increase in regulatory T cells that can nullify the tumor-killing effects. To circumvent this issue, researchers are also exploring using other immune effector cells such as NK cells.

Another mechanism of obligate BsAbs is the linking of cell surface receptors to inhibit or activate their downstream functions.[3] This mechanism is particularly useful for overcoming the drug resistance that arises due to upregulation of other receptor tyrosine kinases, allowing the cell to evade initial inhibition of the receptor. Aside from bridging receptors or bridging cells, BsAbs can also be designed to bind cofactors and elicit downstream actions, such as with emicizumab and its role in the coagulation cascade.

All of the aforementioned bridging mechanisms are spatial in nature, meaning that they require the BsAb to be in a position where it can simultaneously bind to the two different antigens to produce its therapeutic effect. There are also BsAbs that work by sequentially binding to one antigen after the other to enhance transportation of the antibody or other entity into restricted cellular compartments, known as piggybacking.[3] Some examples of the piggyback approach include using BsAbs to cross the blood-brain barrier to treat Alzheimer's disease or certain viral and bacterial infections by facilitating the internalization of toxins into restricted compartments.

Although only a few BsAbs have been approved by the FDA in the past few years, there will likely be more approvals in the coming years, as many BsAbs are now in late-phase studies. Due to the wide range of antigens these agents target, they can exhibit a variety of toxicities related to specific antigens. Moreover, the antibody construct itself as well as the disease area and tumor type can impact the safety profile of the BsAb. The medical community should be prepared to adopt these emerging therapies, as they provide novel mechanisms for the treatment of cancers and other disease states.

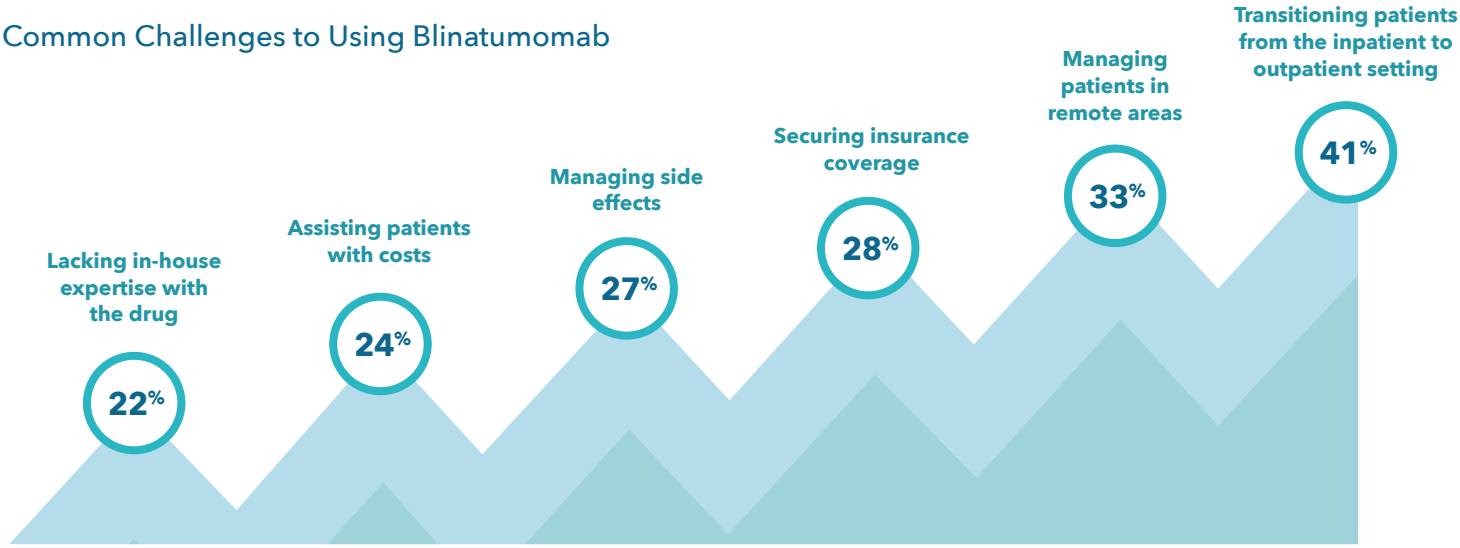
ACCC SURVEY REVEALS BARRIERS TO USING BLINATUMOMAB

As the role of bispecific antibodies continues to expand in the landscape of cancer treatment, these agents also continue to introduce an array of unique challenges for patients and providers. While 79% of the providers surveyed by ACCC said they feel comfortable caring for patients being treated with blinatumomab, 59% said they have experienced barriers when caring for such patients. Some of the common challenges survey respondents cited include transitioning patients from the inpatient to outpatient setting (41%), managing patients in remote areas (33%), securing insurance coverage (28%), managing side effects (27%), assisting patients with costs (24%), and lacking in-house expertise with the drug (22%).

In general, more oncologists described feeling comfortable with using blinatumomab compared to advanced practice providers (APPs) or nurses. Notably, 23% of the nurses surveyed said they do not feel that they have all the information they need to administer blinatumomab.

As mentioned above, a major obstacle with blinatumomab use is the transition from inpatient to outpatient administration. Hospitalization is recommended for

Common Challenges to Using Blinatumomab



at least the first three days of cycle 1 and the first two days of cycle 2 for the treatment of MRD-positive B-cell precursor ALL. For the treatment of R/R B-cell precursor ALL, hospitalization is recommended for the first nine days of cycle 1 and the first two days of cycle 2.[9] The patient can subsequently receive the remainder of the therapy at home with an ambulatory pump.

The transition to outpatient administration requires detailed coordination among physicians, APPs, care coordinators, nurses, pharmacists, home infusion agencies, and insurance companies to ensure that the patient can safely receive the drug at home. It can often be difficult to find a home infusion company that is sufficiently equipped with oncology nurses trained in administering blinatumomab. In addition to multidisciplinary coordination, diligent communication is critical among those working in the inpatient and outpatient settings to provide effective transfer of care.

Another substantial concern when using blinatumomab is managing its toxicities, particularly neurotoxicity and CRS. Less than half of the oncologists responding to ACCC's survey reported having experience managing CRS or neurotoxicity. Only 9% of APPs reported managing CRC, and only 6% of APPs reported managing neurotoxicity. Since these toxicities are so complex, it is recommended that institutions develop protocols and algorithms for addressing them.[21] Of the providers surveyed, 45% agree and 26% strongly agree that their organizations have standard procedures in place for managing adverse effects.

Eighty-two percent of the respondents to ACCC's survey felt that a resource on best practices for transitioning from inpatient to outpatient administration of blinatumomab would be helpful, along with information on how to address problems that may occur with outpatient administration. For example, should the infusion pump malfunction, the patient could be underdosed and need re-titration, or they could be overdosed and need evaluation for adverse effects. For rural areas, there is the added challenge of managing complications when the patient may live many miles from the nearest cancer center. In one of the key informant interviews ACCC conducted to develop the survey, a provider reported circumventing this issue by providing housing close to the hospital during the blinatumomab treatment period, although this solution may not always be an option, depending on funding.

Aside from the logistics of setting up the ambulatory pump in patients' homes or arranging infusion bag changes in an outpatient clinic, securing financial coverage for blinatumomab can also present a hindrance to an easy transition home. Although there are manufacturer resources to help cover medication costs, ancillary services—such as nursing care or home infusion—often introduce additional costs that can be problematic for patients, especially those who are uninsured.

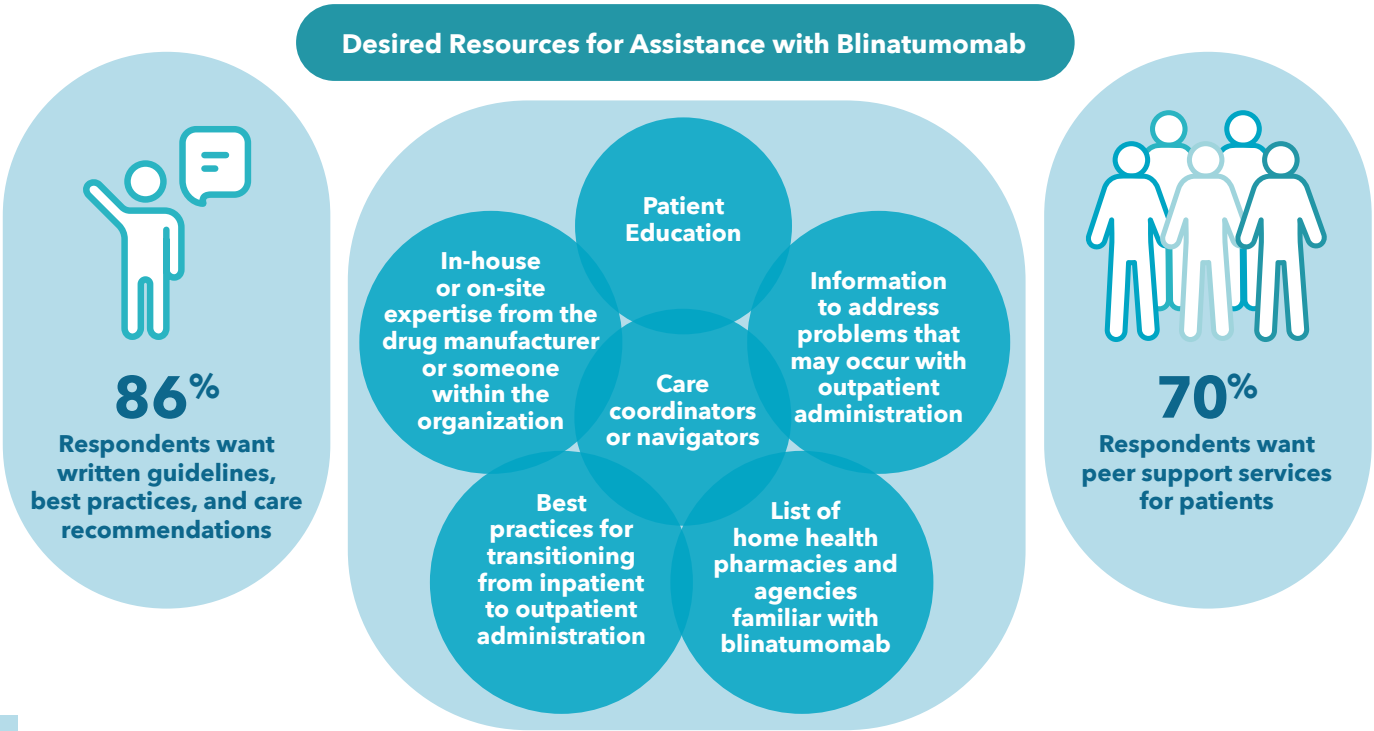
OVERCOMING BARRIERS

Now that blinatumomab has been on the market for more than six years, many institutions are familiar with the drug and its associated hurdles. It cannot be overstated that the administration of blinatumomab is a team effort, and cancer centers should have detailed algorithms in place to guide the management of toxicities and the transition from inpatient to outpatient administration.[21] Effective algorithms should include the use of Common Terminology Criteria for Adverse Events (CTCAE) to grade adverse effects and a synopsis of specific treatments based on the grade of toxicity. Institutional policies should also outline the appropriate compounding procedures for blinatumomab and how to change and discard infusion bags.

Crist et al. shared their institution's experience with managing blinatumomab toxicities in the R/R B-cell precursor ALL setting and found that their protocol for toxicity management was followed for 95% of the toxicities that occurred.[22] They set specific time restrictions for when blinatumomab could be administered in the inpatient setting to reduce loss of therapy in the transition from inpatient to outpatient. Although they did report a median of two hours of lost therapy for the 28-day cycle, this number could have been considerably higher had they not had specific guidelines in place to optimize timing.

In the ACCC survey, 86% of respondents indicated that written guidelines, best practices, and care recommendations would be helpful when caring for patients being treated with blinatumomab. Specific desired resources include a list of home health pharmacies and agencies familiar with blinatumomab, care coordinators or navigators, best practices on transitioning from inpatient to outpatient administration, information on how to address problems that may occur with outpatient administration, and in-house or on-site expertise from either the drug manufacturer or someone within the organization.

Respondents to the ACCC survey also indicated that another significant area of focus should be direct patient education. As these patients will be receiving a continuous infusion of blinatumomab for several weeks, it is imperative that they understand the logistics of the pump and their central line, as well as when and to whom to reach out about issues. With the risk of neurotoxicity, patients are advised not to drive, which means they need other means of transportation and support to go about their activities of daily living. The impact of blinatumomab on the quality of life of patients and caregivers is substantial, so proper education and counseling is crucial.



CONCLUSION

Blinatumomab has significantly enhanced the treatment of B-cell precursor ALL, but not without also introducing its own challenges. The logistics of administering a 28-day continuous IV infusion of blinatumomab, as well as its serious potential side effects (particularly CRS and neurotoxicity) can complicate its utilization. Although blinatumomab highlights some challenges of using BsAbs, there are various opportunities to overcome these obstacles, such as creating institutional protocols to guide the management of toxicities and the transition from inpatient to outpatient administration, having on-call experts to consult, and establishing comprehensive patient education practices. These strategies should be adopted and expanded as new BsAbs come onto the market for other indications.

Although B-cell precursor ALL is largely managed in the inpatient setting, it is likely that BsAbs use in the community will increase as indications expand to include more diseases routinely treated in the outpatient setting, such as myeloma and solid tumors. It will be an ongoing effort to evaluate the most appropriate outpatient settings for these complicated treatments, whether that be in community clinics or designated centers throughout the country. Nonetheless, with more and more BsAbs progressing through late-phase trials, providers should be prepared to welcome these agents into the community, as they have great potential to provide value to patients and change the landscape of cancer treatment.

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