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ORIGINAL RESEARCH

Operationalization and Use of Bispecific T-Cell–Engaging Antibodies in Community Practices: Multidisciplinary Perspectives on Developing Logistics and Workflow for Cytokine Release Syndrome Management

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Abstract

Objectives: Operationalizing workflows to manage cytokine release syndrome (CRS) in community practices presents challenges for multidisciplinary teams. Real-world experience was gathered from OneOncology community health-care professionals to establish best-practice workflows for CRS management. **Methods:** Qualitative data were gathered via focus groups from hematology-oncology MDs, PharmDs, and nurse providers (*N* = 13) with experience treating patients with bispecific T-cell–engaging antibodies (BsAbs). Theme matrix techniques facilitated analysis. **Results:** Three themes were identified: (1) creating a coordinated workflow plan, (2) building network partnerships, and (3) understanding patient support. Workflow decisions were driven by community practices managing patients treated with BsAbs or partnering with sites for initial dosing and maintenance. Catalysts for developing CRS workflows included: FDA approval of BsAbs; BsAbs clinical trial experience; BsAbs on formulary; having patients receiving BsAbs; and practice champion(s) for protocol development. Key steps included defining communication during and after practice hours,

designating training leads, and creating practice-specific plans for interdisciplinary team coordination. Inpatient admission processes developed with hospital staff and hospital staff training were fundamental for successful patient management. Communication processes among practice, pharmacy, and hospital staff throughout BsAbs treatment were established, along with methods to ensure the availability of CRS treatment if needed. Continuous patient/caregiver education on BsAbs treatment, monitoring for adverse events (particularly CRS), and how/when to access care were described. **Conclusions:** BsAb use in community settings requires multidisciplinary coordination between practices and hospitals. Actions included identifying practice champions, establishing clear workflows for transitioning patients between inpatient and outpatient settings, and ensuring continuous training of staff, patients, and caregivers.

For patients with hematologic malignancies, bispecific T-cell–engaging antibodies (BsAbs) are new treatment options, and these therapies are becoming available for patients with solid tumors (Baeuerle & Wesche, 2022; van de Donk & Zweegman, 2023; Ahn et al., 2023). To date, seven BsAbs have been approved by the US Food and Drug Administration (FDA) for the treatment of patients with hematologic malignancies, including relapsed or refractory forms of acute lymphoblastic leukemia, multiple myeloma, and large B-cell and follicular lymphomas (FDA, 2024). Cytokine release syndrome (CRS) is a systemic inflammatory response that may follow BsAb treatment and other immunotherapies such as chimeric antigen receptor (CAR) T-cell therapy. Cytokine release syndrome is characterized by the activation of immune and non-immune cells, resulting in the mild to massive release of inflammatory cytokines. The frequency of any grade of CRS in patients receiving BsAb therapy can vary widely, occurring in approximately 38% to 81% of patients depending on cancer type and BsAb therapy used, and most often occurs during the first week of treatment (Noori et al., 2023).

Common symptoms of CRS include fever (temperature ≥ 38° C), chills, fatigue, headache, and arthralgia; serious cases are potentially fatal, and patients may experience hypotension, hypoxia, atrial fibrillation, renal insufficiency, and possible cardiac failure (Adkins, 2019; Shimabukuro-Vornhagen et al., 2018). Cytokine release syndrome severity is classified into grades 1 to 4, as defined by the American Society for Transplantation and Cellular Therapy criteria (Lee et al., 2019). Patients with grade 1/2 CRS experience fever with or without hypotension that does not require a vasopressor or hypoxia that can be managed by low-flow nasal cannula; these patients can be monitored and managed in an outpatient setting. Grade 3/4 cases are considered severe and require hospitalization and the use of one or more vasopressors and/or supplemental oxygen, with the potential need for mechanical ventilation.

In order to decrease the risk of developing CRS following BsAb therapy, step-up dosing is applied to incrementally increase the dose during the initial 3-to-4-week dosing cycle until target steady-state concentrations are reached (Salvaris et al., 2021). Anti-cytokine therapy, most commonly the interleukin-6 receptor antagonist tocilizumab, as well as steroids may be used as additional CRS treatments for grade 3/4 cases and some grade 2 cases and must be readily available before initiating BsAb treatment (Crombie et al., 2024). Therefore, patients who initiate BsAbs are monitored closely during the first weeks of treatment to ensure early intervention and reduce the risk of CRS escalation (Crombie et al., 2024).

Patients with lymphomas are commonly treated in community-based health-care settings (Feldman et al., 2017). As BsAb therapies become increasingly available in these settings, there is a great need for systems and protocols that optimize patient monitoring and ensure that patients with CRS are efficiently transitioned between inpatient and outpatient care. One key factor impacting the ability of a community practice to offer BsAbs is the capacity and workflows to manage adverse events (AEs), including CRS, that may occur during BsAbs treatment. Creating coordinated practices for health-care staff, establishing practice network partnerships, and

understanding patient support systems are essential to managing CRS associated with BsAbs in community settings. The objective of this qualitative study was to gather real-world experience from community health-care professionals in order to understand key steps, challenges, and best practices for establishing workflows to manage patients with CRS.

METHODS

Participants

Qualitative data were gathered via a 90-minute physician focus group (n = 5), a separate physician phone interview (n = 1), and an advanced practice provider (APP) focus group (n = 7). Participants were hematology-oncology physicians as well as APPs, including hematology-oncology–focused nurse practitioners, as well as pharmacists and nurses. All participants worked in community-based practices as part of the OneOncology cancer care network. As of January 2024, participants had treated over 30 patients with commercially available BsAbs. All participants consented to being included in the discussion.

Data Collection

Theme matrix techniques were used to facilitate data analysis. Themes were grouped into three categories: (1) creating a coordinated workflow plan, (2) building network partnerships, and (3) understanding patient support. Discussion topics surrounding workflow plan coordination included specific triggers that initiated the development of a CRS management plan, current roles and responsibilities of those involved with CRS monitoring and management, and challenges of coordinating patients with CRS (Table 1). Questions posed when discussing practice network partnerships included how to determine where patients are admitted, who the appropriate points of contact in the hospital or emergency department are, and how hospital staff are trained to recognize and manage patients with CRS. Regarding strategies for patient support, participants were asked about specific forms of education that have been most successful, resources used to track symptoms and vital signs at home, and considerations for outpatient and/or inpatient monitoring (i.e., caregiver support and social services).

RESULTS

Creating a Coordinated Workflow Plan

Participant insights indicated that a consensus first step for managing CRS in community settings is developing a coordinated, site-specific workflow plan (Table 2). Catalysts that triggered the initiation of a BsAbs program included FDA approval of BsAbs for hematologic malignancies, previous participation in related BsAbs clinical trials, the addition of BsAbs to the practice formulary, and the identification and scheduling of a first patient to receive BsAbs. Depending on the resources and experience of the practice, it is important for practices to decide whether they will partner with another site to administer the initial BsAb step-up dosing or instead offer complete management, from initiation through treatment completion. Practices with prior clinical trial experience with CAR T-cell therapies or BsAbs can more easily operationalize commercial BsAb use, while sites without that experience will likely have additional hurdles to overcome.

An important initial step when building a CRS workflow infrastructure is to identify a practice champion whose role is to initiate and drive efforts primarily through education but also includes coordination among different stakeholders and overcoming barriers. The practice champion is often an experienced hematology-focused oncologist, but other health-care professionals can also take the lead. Providers with experience managing CRS along with connections to external health-care teams can build support among their own team members and work with local hospitals to help strengthen relationships. For practices with multiple locations, it is helpful to pick one or two main locations to treat patients.

A multidisciplinary team composed of physicians, APPs, pharmacists, nursing staff, formulary decision-makers, and financial managers should collaborate to develop site-specific standard operating procedures (SOPs) for managing patients with CRS. Extended members of the clinical care team, including front-office personnel, infusion nurses, and pharmacy staff can also play key roles in education and care coordination.

Key themes to consider when developing a site-specific workflow are flexibility (to account for different patient populations and resources),

Table 1. Example Interview and Focus Group Discussion Prompts for Community-Based Heme-Oncology Health-Care Professionals on Creating a CRS Management Program

Workflow and logistics themes	Discussion prompts
Creating a coordinated workflow plan	• Who was the point person that led the setup of logistics/workflow for CRS monitoring and management at your practice site? » What was the trigger to initiate this process? » What were this person's roles/responsibilities, and how did they engage others at the site (consider responsibility, skills, decision-making role, etc.)? • Within your practice » How does your practice keep site staff continuously educated about CRS management? » Who is the point person? What kind of materials are used? » How did your practice go about creating or obtaining an algorithm/protocol to monitor/manage patients? » What is the role of each member of the care staff in monitoring and assessing patients who might be exhibiting symptoms of CRS? » How did you set up a communication plan among the multidisciplinary team? Was there a lead person? » How do you coordinate communication with inpatient and outpatient teams? » How do you coordinate/communicate after-hours? • What were the challenges you faced/are facing? What is working well?
Building network partnerships	• How do you determine where patients would be admitted, if needed? » If you didn't have a designated hospital before starting treatment with bispecific antibodies, how did you establish a connection/network with the local hospital? » Who was the contact person at the hospital or ED? • How did you educate hospital staff (ICU and ED) to ensure they were trained to recognize and manage patients with CRS? • What were the challenges you faced/are facing? What is working well?
Understanding patient support	• What forms of patient education have been most successful in your experience? » How do you educate patients on who and when they should call (including after hours) to report symptoms? • What is your experience with monitoring patients after the administration of bispecific antibody treatment? » What resources or tools are useful for patients to track their symptoms and vital signs at home? » For your practice, what are the considerations for outpatient and/or inpatient monitoring? - Caregiver support - Social services • What are the potential roles of digital tools in the future? • What were the challenges you faced/are facing? What is working well?

Note. CRS = cytokine release syndrome; ED = emergency department; ICU = intensive care unit.

lines of communication, adequate training, and consistent procedures. Practice sites may have different patient populations with varying resources; although guidelines and frameworks from other sites may be useful, a site-specific "playbook" of SOPs should be created as part of the coordinated workflow plan. Prepared communication plans that include specific information, recipients, and methods of communication can ensure effective communication when management of patients with CRS is needed. Drug information or onsite training provided by the pharmaceutical manufacturers of BsAbs, including medical science liaisons and certified nurse educators, can be a useful resource for practice staff. One implemented strategy was to designate a lead BsAb nurse who can educate additional staff, streamline training, and ensure consistency through periods of staff turnover. Practice-specific SOPs can be standardized through automated prompts in electronic medical records (EMRs). One practice implemented a pop-up in the EMR that identified any patient receiving a BsAb; on the day of the patients' first dose, all staff were informed, from the front office to infusion nurses. In another practice, a process for inpatient admission for patients with moderate to severe CRS was developed in coordination with hospital

Table 2. Theme Matrix Summary of Challenges and Best Practices for CRS Management

Workflow and logistics themes	Challenges	Best practices
Creating a coordinated workflow plan	• Community practices unfamiliar with CRS need education • After-hours call schedules can include non-hematology physicians unfamiliar with CRS	• Coordinate cross-functional committee of physicians, pharmacists, nurses, and financial team members to develop practice-specific CRS management protocols • Continuously educate front-office staff/schedulers and nursing staff to coordinate via a patient care/treatment plan • Recruit APPs to fill gaps in off-hours hematology coverage, and provide non-hematology physicians with written care plans for CRS
Building network partnerships	• Community oncology practice needs to develop close partnership with local hospital system • Inpatient care staff can have high turnover and require more frequent training	• Provide protocols, guidebooks, and training resources as well as risk assessment tools to inpatient care partners • Use EMR systems to highlight patients at risk of CRS, which triggers calls to treating physicians • Coordinate scheduling and reports between clinic and hospital to ensure seamless transition of patient • APPs employed by the clinic may work in the hospital to coordinate inpatient care
Understanding patient support	• Patients' and caregivers' capacity to monitor vital signs can vary	• Continuously leverage existing education processes for patients and caregivers who are generally already familiar with post-treatment protocols • Provide education and assessment tools in languages other than English • If possible, ensure reasonable proximity to a hospital and access to transportation during step-up dosing

Note. APP = advanced practice provider; CRS = cytokine release syndrome; EMR = electronic medical record.

staff and was fundamental for successful patient management and ensuring hospital staff training. In addition to the playbook of SOPs, site-specific educational tools may include patient-care plans, pamphlets, CRS assessment tools, immune cell-associated neurotoxicity syndrome (ICANS) grading scales, pharmaceutical manufacturer–created materials, and pharmacy educators.

Teams must also be prepared for after-hours needs of patients with suspected CRS. A call or triage system should be implemented to ensure a hematology specialist is available outside of working hours. Advanced practice providers can fill gaps in after-hours hematology coverage for triaging patients while providing non-hematology physicians with written plans for management of patients with CRS.

Building Network Partnerships

Community practices considering a BsAb program must have adequate staffing to implement necessary procedures for the management of patients throughout their treatment, including access to a hospital. By establishing a network, practices offer potential benefits for patients, including expanded treatment options and potentially fewer travel requirements to receive care.

Support of hospital leadership and a commitment to training their staff are essential for successful implementation of a BsAbs program. Ideally, a partnership should be established by the hematology practice champion and the hospital's chief executive officer or chief medical officer. Hospitals with or without an existing T-cell–engaging therapy program but with adequate resources and motivation to expand into this therapeutic arena would be favorable partners to community practices.

Once processes and workflows are established, emergency department, pharmacy, and intensive care unit staff can be included in training and implementation for a successful BsAb program between the practice and hospital. Community practices can share their own protocols, playbooks, screening tools for CRS and ICANS, guidebooks, training resources, and risk

assessment tools with their network partner hospitals. Short educational presentations were found to be useful for continuing education, particularly because hospital staff tend to experience more turnover than clinic staff. In particular, nursing team education should focus on patient management, while pharmacy team education would focus on product dosing, safety information, and product-specific risk evaluation and mitigation strategies (REMS), if applicable.

Challenges arose with training network hospital staff who may not have prior experience with CRS and with high rates of turnover of emergency department staff. Solutions included assigning practice APPs to manage inpatient care at the partner hospital and creating a system of hand-off reports as patients transitioned from outpatient to inpatient and on to release; nursing leadership also represented an important partnership at local hospitals.

When hospital staff have received training, several communication best practices can be implemented to ensure that the practice-network partnership operates effectively across all aspects of BsAb administration and CRS management. Practices can create care checklists to disseminate to network partners. For example, the emergency department, the intensive care unit, and other stakeholders were provided with slide decks and a CRS management playbook. When a patient initiates a BsAb therapy, front-office staff and chemotherapy schedulers should be notified when a new patient enters the program as well as when a patient begins to receive step-up doses. For newly approved agents, if hospitalization was indicated or suggested in the prescribing information, inpatient care was preferred. Practices can then coordinate with hospital staff to pre-register patients to ensure the availability of a bed at the end of infusion, as well as using EMR systems to highlight patients at risk of CRS and to provide guidance on when to inform a hematology specialist. In order to accurately assess patients with suspected CRS, shared assessment tools for CRS should be agreed upon between the practice and hospital to ensure consistency between locations. In addition, reimbursement practices may be impacted by whether the hospital has an independent tax identification number or shares one with the clinical practice.

Understanding Patient Support

Patients who are ideal candidates to receive outpatient BsAb therapy are those who can monitor vital signs and other symptoms of CRS, have social support, and can access emergency care if needed. While not required for BsAb administration, caregivers are considered important, particularly during step-up dosing, and are encouraged to attend appointments. In the absence of a caregiver, patients may be admitted to the hospital for step-up dosing.

Continuous patient and/or caregiver education on pre- and post-BsAb treatment, particularly around CRS symptoms and how and when to access care, is integral to patient success during and following BsAb therapy. Patient and caregiver education is an ongoing process that should continuously leverage existing tools for patients and caregivers who are already familiar with post-treatment protocols. Because patients who are candidates for BsAb treatment have typically undergone multiple lines of cancer therapies, direct communication is often an effective approach to educating these patients about a new treatment. In many practices, a registered nurse, nurse navigator, pharmacist, or APP educates patients on their treatment regimens, potential side effects, and when to contact their provider. Nursing staff were key to educating patients on what CRS signs and symptoms to be aware of after therapy. Importantly, patient education resources should be provided in languages other than English to account for racial and ethnic diversity of patient populations.

The degree of at-home CRS monitoring varied by patient and was influenced by the capability of the patient and the availability of a caregiver. The benefit of at-home monitoring is earlier identification of CRS symptoms, enabling patients to be treated sooner. However, information gathered is highly dependent on correct use of the equipment; moreover, monitoring their own symptoms can create anxiety in some patients. At-home monitoring tools that are regularly provided include a thermometer, directions for when and whom to call, and a handwritten diary, which most patients are familiar with using. Digital monitoring devices such as wearable sensors can facilitate continuous symptom monitoring and provide increased convenience; however, feasibility among patients

may vary, especially among older patients who are less familiar with such technologies, and carries a risk of false positives and resources diverted to address concerns later found to be irrelevant. Additional simple tools, such as written scripts and wallet cards with treatment details, can prepare patients to communicate with the emergency department and hospital providers if necessary. Proximity to a hospital and support for patient transportation is an important consideration, but requirements would need to be established on a per-practice basis.

CONCLUSIONS

This qualitative study leveraged real-world experience of multidisciplinary community oncology specialists and described best practices and tactics for managing patients with CRS in community health settings. Use of BsAbs in the community setting requires thoughtful care coordination within and between the practice and hospitals. Keys to success include identifying practice champions to develop flexible, practice-specific workflows for managing CRS, transitioning patients efficiently between the outpatient and inpatient settings if needed, and continuous training of staff, patients, and caregivers.

The recent emergence of BsAbs has ushered in a promising new therapeutic avenue for patients with hematologic malignancies. As more BsAb therapies become available to treat patients with a wider range of cancer types, especially those with solid tumors, community-based practices have the opportunity to address the needs of these growing patient populations by offering these patients convenient and comprehensive BsAb administration and monitoring. Furthermore, community-based availability of BsAb therapy could help narrow treatment disparities among patients who are older, less educated, and reside in rural areas, since these patients are generally unaware of BsAb therapy (Adu et al., 2023). This shift in striving for more equitable care for patients is critical to the advancement of patient-centered care in oncology and should be recognized by health-care professionals in community settings and traditional academic treatment centers alike. Establishing workflows to allow for the continuum of at-home care and monitoring with resources available across demographic backgrounds and languages are essential for the wide-ranging success of community BsAb therapy programs and partnerships.

Guidelines for toxicity management of patients receiving CD3 × CD20 BsAbs have recently been established by the Lymphoma Research Foundation, representing a pivotal first step in providing a foundation for community practices to adopt or optimize their own existing BsAb AE management programs (Crombie et al., 2024). Additional recommendations for expanding cellular and BsAb therapies to community settings have been outlined by the Association of Community Care Centers and the Society for Immunotherapy of Cancer (ACCC & SITC, 2023). These recommendations align with the findings of our study, particularly with respect to identifying the most appropriate patients to initiate BsAb therapy, adequate training of clinical staff involved with patients receiving BsAbs, and emphasizing the importance of patient education on symptom monitoring. Based on these recommendations for treating CRS in patients receiving CAR T-cell or BsAb therapy, community practices may consider establishing similar frameworks of patient monitoring and management for those who experience post-treatment bacterial, viral, and/or fungal infections, as well as less common but more serious neurologic toxicities such as ICANS (Braun et al., 2024).

This study comes with several limitations. The relatively small sample size of the interview and focus group respondents may limit the generalizability of these findings and the variety of ideas that could be attained with a larger cohort of participants from a survey-based approach. Likewise, the qualitative nature of the results restricts quantitative data presentation and the use of comparisons. Nonetheless, the breadth of information and level of detail that was acquired from the interview and focus group sessions of this study provided valuable experience-based insights that likely could not have been captured by a survey-based approach. Although physician assistants (PAs) were not included in the APP focus group, PAs should be considered for a separate study to understand their perspectives on CRS management. The participants of this study were community-based oncology health-care

professionals, but future studies could include health-care providers who work in hospital settings, as well as hospital administrative executives, all of whom would be involved in CRS management workflow decision-making.

The burgeoning field of cancer immunotherapy, and specifically the increasing use and availability of BsAbs in community practices, holds great promise for the advancement of cancer treatment but carries a myriad of logistical intricacies for widespread implementation. Integrating BsAb therapy in community settings requires a multidisciplinary approach that will involve significant investment of time and resources into collaborative frameworks by community healthcare providers, hospital staff, and patients. The proactive strategies described in this study will better prepare community oncology professionals to adopt BsAb therapies into their therapeutic repertoire amid the ever-changing landscape of cancer treatment.

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